IEC 60601-2-16

Edition 6.0 2025-01
REDLINE VERSION

INTERNATIONAL STANDARD

colour inside

Medical electrical equipment –
Part 2-16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment

IEC 60601-2-16:2025-01 RLV(en)

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment

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This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition IEC 60601-2-16:2018. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

IEC 60601-2-16 has been prepared by subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

This sixth edition cancels and replaces the fifth edition published in 2018. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) update of references to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, of references to IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, of references to IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, of references to IEC 60601-1-9:2007, IEC 60601-1-9:2007/AMD1:2013 and IEC 60601-1-9:2007/AMD2:2020, of references to IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020 and of references to IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020;
b) consideration of ESSENTIAL PERFORMANCE in SINGLE FAULT CONDITION regarding IEC 60601-1:2005/AMD1:2012/ISH1:2021;
c) including the information given in the document 62D/1771A/INF regarding 201.11.8;
d) including withdrawn IEC PAS 63023[17] as Annex CC;
e) including SECURITY (CYBERSECURITY) requirements;
f) consideration of HAEMODIALYSIS EQUIPMENT using pre-manufactured DIALYSIS FLUID bags;
g) improvements for labelling;
h) other minor technical improvements;
i) editorial improvements.

The text of this International Standard is based on the following documents:

Draft	Report on voting
62D/2163/FDIS	62D/2184/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

In this document, the following print types are used:

– requirements and definitions: roman type;
– *test specifications: italic type;*
– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;
– TERMS DEFINED IN CLAUSE 3 OF IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 AND IEC 60601-1:2005/AMD2:2020, IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

– "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes Subclauses 7.1, 7.2, etc.);

– "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this document are preceded by the term "Clause" followed by the clause number. References to subclauses within this document are by number only.

In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 and IEC 80601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

NOTE The attention of the users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committees that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

IMPORTANT – The "colour inside" logo on the cover page of this document indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

The minimum safety requirements specified in this document are considered to provide for a practical degree of safety in the operation of HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION EQUIPMENT.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment

201.1 Scope, object and related standards

Clause 1 of ~~the general standard~~[1] IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/ AMD2:2020 applies, except as follows:

201.1.1 * Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION EQUIPMENT, hereafter referred to as HAEMODIALYSIS EQUIPMENT. It applies to HAEMODIALYSIS EQUIPMENT intended for use either by medical staff or under the supervision of medical experts, including HAEMODIALYSIS EQUIPMENT operated by the PATIENT, regardless of whether the HAEMODIALYSIS EQUIPMENT is used in a hospital or domestic environment.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

This document does not take into consideration specific safety details of the DIALYSIS FLUID control system of HAEMODIALYSIS EQUIPMENT using regeneration of DIALYSIS FLUID or CENTRAL DELIVERY SYSTEMS for DIALYSIS FLUID. It does, however, take into consideration the specific safety requirements of such HAEMODIALYSIS EQUIPMENT concerning electrical safety and PATIENT safety.

This document specifies the minimum safety requirements for HAEMODIALYSIS EQUIPMENT. These HAEMODIALYSIS EQUIPMENT are intended for use either by medical staff or for use by the PATIENT or other trained personnel under medical supervision.

This document includes all ME EQUIPMENT that is intended to deliver a HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION treatment to a PATIENT, independent of the treatment duration and location.

If applicable, this document applies to the relevant parts of ME EQUIPMENT intended for other extracorporeal blood purification treatments.

The particular requirements in this document do not apply to:

– EXTRACORPOREAL CIRCUITS (see ISO 8637-2 [1][2]),

– DIALYSERS (see ISO 8637-1 [2]),

– DIALYSIS FLUID CONCENTRATES (see ISO 23500-4 [3]),

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[1] ~~The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*~~

[2] Numbers in square brackets refer to the Bibliography.

– pre-manufactured DIALYSIS FLUID bags,
– DIALYSIS WATER supply systems (see ISO 23500-2 [4]),
– CENTRAL DELIVERY SYSTEMS for DIALYSIS FLUID CONCENTRATES (see ISO 23500-4 [3]), described as systems for bulk mixing concentrate at a dialysis facility,
– equipment used to perform PERITONEAL DIALYSIS (see IEC 60601-2-39 [5]).

201.1.2 Object

Replacement:

The object of this document is to establish BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for HAEMODIALYSIS EQUIPMENT.

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and Clause 201.2 of this document.

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020, IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020 apply as modified in Clauses 202, 208, 210 and 211.

IEC 60601-1-3 ~~and IEC 60601-1-12~~ does not apply. IEC 60601-1-9:2007, IEC 60601-1-9:2007/AMD1:2013 and IEC 60601-1-9:2007/AMD2:2020 does not apply as noted in Clause 209.

All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

~~For brevity, IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 are referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.~~

The numbering of clauses and subclauses of this document corresponds to that of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this document addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are specified by the use of the following words:

"*Replacement*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is replaced completely by the text of this document.

"*Addition*" means that the text of this document is additional to the requirements of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard.

"*Amendment*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables which are additional to those of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered starting from 201.101. However, due to the fact that definitions in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered 3.1 through 3.~~147~~154, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, for example 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this document" is used to make reference to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this document, the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 Normative references

NOTE Informative references are listed in the Bibliography.

Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

~~*Replacement:*~~

~~*IEC 60601-1-2:2014, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*~~

~~*IEC 60601-1-6:2010, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*~~
~~*IEC 60601-1-6:2010/AMD1:2013*~~

~~*IEC 60601-1-8:2006, Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*~~
~~*IEC 60601-1-8:2006/AMD1:2012*~~

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60601-1-10:2007, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*
IEC 60601-1-10:2007/AMD1:2013
IEC 60601-1-10:2007/AMD2:2020

IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*
IEC 60601-1-11:2015/AMD1:2020

IEC 61672-1:2013, *Electroacoustics – Sound level meters – Part 1: Specifications*

ISO 3744:2010, *Acoustics – Determination of sound power levels and sound energy levels of noise sources using sound pressure – Engineering methods for an essentially free field over a reflecting plane*

ISO 23500-3:2024, *Preparation and quality management of fluids for haemodialysis and related therapies – Part 3: Water for haemodialysis and related therapies*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020, IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020, and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at https://www.electropedia.org/
- ISO Online browsing platform: available at https://www.iso.org/obp

NOTE Refer to section "Index of defined terms used in this particular standard" for the index of defined terms.

201.3.8
*** APPLIED PART**

Replacement:

EXTRACORPOREAL CIRCUIT and all parts permanently and conductively connected to it (e.g. DIALYSIS FLUID circuit)

Note 1 to entry: See Figure AA.8 in Informative Annex AA Subclause 201.16 and see 201.16.6.3.

Note 2 to entry: One example of an APPLIED PART is the EXTRACORPOREAL CIRCUIT including any pre-manufactured DIALYSIS FLUID bags, extension lines, and drain bags in a stand-alone system connected during treatment.

Note 3 to entry: Another example of an APPLIED PART is the EXTRACORPOREAL CIRCUIT including connected DIALYSIS FLUID bags, that are online prepared before treatment without the patient connected and drain bags. During treatment the online preparation part of the HAEMODIALYSIS EQUIPMENT is conductively disconnected.

Note 4 to entry: Another example of an APPLIED PART is the EXTRACORPOREAL CIRCUIT including all connected fluid paths of the HAEMODIALYSIS EQUIPMENT and the connection to a drain during the treatment.

201.3.78
PATIENT CONNECTION

Addition:

Note 1 to entry: The PATIENT blood lines connectors are the individual points on the APPLIED PART through which a current can flow between the PATIENT and the HAEMODIALYSIS EQUIPMENT in NORMAL CONDITION or SINGLE FAULT CONDITION.

Additional terms and definitions:

201.3.201
ARTERIAL PRESSURE
pressure measured in the blood withdrawal line of the EXTRACORPOREAL CIRCUIT between the PATIENT CONNECTION and DIALYSER connection

Note 1 to entry: A difference can be made between the pre-pump pressure, which is upstream of the blood pump, and post-pump pressure, which is downstream of the blood pump.

201.3.202
*** BLOOD LEAK**
leakage of blood from the blood compartment to the DIALYSIS FLUID compartment of the DIALYSER

Note 1 to entry: When performing an HF PROCESS, this involves the filtration fluid section.

201.3.203
CENTRAL DELIVERY SYSTEM
part of a ME SYSTEM which proportions DIALYSIS FLUID CONCENTRATE and DIALYSIS WATER for distribution as DIALYSIS FLUID to the HAEMODIALYSIS EQUIPMENT or distributes DIALYSIS FLUID CONCENTRATE

201.3.204
DIALYSER
device containing a semi-permeable membrane that is used to perform HD, HDF or HF

201.3.205
DIALYSIS FLUID
DIALYSATE
DIALYSIS SOLUTION
DIALYSING FLUID
aqueous fluid containing electrolytes and, usually, buffer and glucose, which is intended to exchange solutes with blood during HAEMODIALYSIS

Note 1 to entry: The DIALYSIS FLUID could be pre-manufactured in bags as pharmaceuticals according to the relevant pharmacopoeia monograph or be prepared by the HAEMODIALYSIS EQUIPMENT or be influenced in composition by the HAEMODIALYSIS EQUIPMENT.

[SOURCE: ~~ISO 23500-1:— [15], 3.15, modified – The word "dialysing fluid" has been added as synonym, and the notes have been deleted~~ ISO 23500-1:2024 [6], 3.15, modified – The notes have been deleted and a new Note 1 to entry was added.]

201.3.206
DIALYSIS FLUID CONCENTRATE
substances which, when appropriately diluted or dissolved with DIALYSIS WATER, produce the DIALYSIS FLUID

201.3.~~220~~207
DIALYSIS WATER
water that has been treated to meet the requirements of ISO 23500-3:2024 and which is suitable for use in HAEMODIALYSIS applications, including the preparation of DIALYSIS FLUID, reprocessing of DIALYSERS, preparation of ~~concentrates~~ DIALYSIS FLUID CONCENTRATE and preparation of SUBSTITUTION FLUID for online convective therapies

Note 1 to entry: The words "water for dialysis", "permeate" and "reverse osmosis water" ~~and "purified water"~~ are commonly used as synonyms of DIALYSIS WATER.

[SOURCE: ~~ISO 23500-1: [15], 3.17, modified – The reference number "[17]" has been added in the definition, as well as the note.~~ ISO 23500-1:2024 [6], 3.17, modified – The note was reworded.]

201.3.208
EXTRACORPOREAL CIRCUIT
blood lines, DIALYSER and any integral ACCESSORY

Note 1 to entry: An alternative for DIALYSER could be a HF-filter, adsorber or other device.

201.3.~~208~~209
HAEMODIAFILTRATION
HDF
PROCESS whereby concentrations of water-soluble substances in a PATIENT'S blood and an excess of fluid of a PATIENT are corrected by a simultaneous combination of HD and HF

201.3.~~209~~210
HAEMODIALYSIS
HD
PROCESS whereby concentrations of water-soluble substances in a PATIENT'S blood and an excess of fluid of a PATIENT are corrected by bidirectional diffusive transport and ULTRAFILTRATION across a semi-permeable membrane separating the blood from the DIALYSIS FLUID

Note 1 to entry: This PROCESS typically includes fluid removal by filtration. This PROCESS is usually also accompanied by diffusion of substances from the DIALYSIS FLUID into the blood.

201.3.~~210~~211
*** HAEMODIALYSIS EQUIPMENT**
ME EQUIPMENT or ME SYSTEM used to perform at least one of the following: HAEMODIALYSIS, HAEMODIAFILTRATION ~~and/or~~, HAEMOFILTRATION

Note 1 to entry: When the term ME EQUIPMENT is used in headings, it is equivalent to HAEMODIALYSIS EQUIPMENT. When the term ME EQUIPMENT is used in the text, it is referring to a general ME EQUIPMENT.

201.3.~~211~~212
HAEMOFILTRATION
HF
PROCESS whereby concentrations of water-soluble substances in a PATIENT'S blood and an excess of fluid of a PATIENT are corrected by convective transport via ULTRAFILTRATION and partial replacement by a SUBSTITUTION FLUID resulting in the required NET FLUID REMOVAL

201.3.~~212~~213
NET FLUID REMOVAL
fluid loss from the PATIENT

Note 1 to entry: Historically, this term was "weight loss".

201.3.~~213~~214
*** ONLINE HDF**
HAEMODIAFILTRATION PROCEDURE where the HAEMODIALYSIS EQUIPMENT produces SUBSTITUTION FLUID for infusion from DIALYSIS FLUID for the HAEMODIAFILTRATION treatment

201.3.~~214~~215
*** ONLINE HF**
HAEMOFILTRATION PROCEDURE where the HAEMODIALYSIS EQUIPMENT produces the SUBSTITUTION FLUID for infusion from DIALYSIS FLUID for the HAEMOFILTRATION treatment

201.3.~~215~~216
*** PROTECTIVE SYSTEM**
automatic system, or a constructional feature, specifically designed to protect the PATIENT against HAZARDOUS SITUATIONS

201.3.~~216~~217
SUBSTITUTION FLUID
fluid used in HF and HDF treatments which is directly infused into the EXTRACORPOREAL CIRCUIT as a replacement for the fluid that is removed from the blood by filtration

[SOURCE: ISO 23500-1:2024 [6], 3.~~40~~42, modified – The words "patient's blood" and "ultrafiltration" have been replaced respectively by "EXTRACORPOREAL CIRCUIT" and "filtration" in the definition, and the note~~s have~~ has been deleted.]

201.3.~~217~~218
TRANSMEMBRANE PRESSURE
TMP
fluid pressure difference exerted across the semi-permeable membrane of the DIALYSER

Note 1 to entry: Generally, the mean TMP is used. In practice, the displayed TRANSMEMBRANE PRESSURE is usually estimated from the measured EXTRACORPOREAL CIRCUIT pressure minus the measured DIALYSIS FLUID pressure, each obtained at a single point.

~~Note 2 to entry: This note applies to the French language only.~~

201.3.~~218~~219
*** ULTRAFILTRATION**
PROCESS of fluid removal from the PATIENT'S blood across the semi-permeable membrane of the DIALYSER

201.3.~~219~~220
VENOUS PRESSURE
pressure measured in the blood return line of the EXTRACORPOREAL CIRCUIT between the DIALYSER connection and PATIENT CONNECTION

201.4 General requirements

Clause 4 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.4.3 * Essential performance

Additional subclauses:

201.4.3.101 * Additional ESSENTIAL PERFORMANCE requirements

If applicable, the ESSENTIAL PERFORMANCE of HAEMODIALYSIS EQUIPMENT includes, but is not limited to, the functions found in the subclauses listed in Table 201.101, which shall be met within the tolerances specified by the MANUFACTURER under NORMAL CONDITION.

The behaviour of the HAEMODIALYSIS EQUIPMENT for ESSENTIAL PERFORMANCE in SINGLE FAULT CONDITION shall be determined by the MANUFACTURER'S RISK MANAGEMENT.

Table 201.101 – ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Blood flow rate	201.4.3.102
DIALYSIS FLUID flow rate	201.4.3.103
NET FLUID REMOVAL	201.4.3.104
SUBSTITUTION FLUID flow rate	201.4.3.105
Dialysis time	201.4.3.106
DIALYSIS FLUID composition	201.4.3.107
DIALYSIS FLUID temperature	201.4.3.108
SUBSTITUTION FLUID temperature	201.4.3.109

NOTE 1 Some ESSENTIAL PERFORMANCE requirements listed in Table 201.101 are dependent on the characteristics of the disposables used (e.g. blood flow rate is dependent upon the pump segment tube diameter in rotary peristaltic pumps).

NOTE 2 Subclause 7.9.2.5 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 describes requirements giving the specifications for the ESSENTIAL PERFORMANCE in the instruction for use.

201.4.3.102 Blood flow rate

The blood flow rate of the HAEMODIALYSIS EQUIPMENT shall be delivered as specified by the MANUFACTURER. The specification shall take into account the pump segment fatigue for the maximum specified usage life of the EXTRACORPOREAL CIRCUIT.

* NOTE 1 A blood flow rate lower than the set value is considered detrimental for a typical treatment. Therefore, the goal of testing is to find the highest negative blood flow rate error.

Compliance is checked under the following test conditions for typical peristaltic pumps:

– *apply an unused pump segment to the HAEMODIALYSIS EQUIPMENT according to the instructions for use ~~and let it run for at least 30 min~~;*

– *apply a fluid source (e.g. water) with a temperature of 37 °C ± 1 °C to the EXTRACORPOREAL CIRCUIT;*

– *either set the NET FLUID REMOVAL rate to 0 ml/h or bypass the DIALYZER, or both;*

– *set the blood flow rate of the HAEMODIALYSIS EQUIPMENT to 400 ml/min or – if not possible – to the highest possible blood flow rate;*

~~– *set the pre-pump ARTERIAL PRESSURE to –200 mmHg;*~~

– *create a pre-pump average ARTERIAL PRESSURE of –200 mmHg (± 10 mmHg);*

– *let the pump run for 30 min to 45 min at maximum blood flow rate;*

– *after this preconditioning measure the blood flow rate.*

The value of the measured blood flow rate shall be within the tolerances specified by the MANUFACTURER in the instructions for use.

NOTE 2 Pump segment fatigue can reduce the blood flow rate.

NOTE 3 The blood flow rate in peristaltic pumps can ~~be affected by negative input pressures~~ considerably decrease in case of high negative pressures on the suction side.

201.4.3.103 DIALYSIS FLUID flow rate

The DIALYSIS FLUID flow rate of the HAEMODIALYSIS EQUIPMENT shall be delivered as specified by the MANUFACTURER.

NOTE A DIALYSIS FLUID flow rate lower than the set value is considered detrimental for a typical treatment.

Compliance is checked under the following test conditions:

– *set the HAEMODIALYSIS EQUIPMENT to the HAEMODIALYSIS mode as specified by the MANUFACTURER;*
– *set the HAEMODIALYSIS EQUIPMENT to maximum DIALYSIS FLUID flow rate;*
– *measure the DIALYSIS FLUID flow rate over a period of 30 min ± 2 min;*
– *set the HAEMODIALYSIS EQUIPMENT to minimum DIALYSIS FLUID flow rate;*
– *measure the DIALYSIS FLUID flow rate over a period of 30 min ± 2 min.*

The values of the DIALYSIS FLUID flow rate shall be within the tolerances specified by the MANUFACTURER in the instructions for use.

201.4.3.104 NET FLUID REMOVAL

The NET FLUID REMOVAL of the HAEMODIALYSIS EQUIPMENT shall be achieved as specified by the MANUFACTURER.

Compliance is checked under the following test conditions.

Test 1 for the balancing part of the HAEMODIALYSIS EQUIPMENT only:

– *set the HAEMODIALYSIS EQUIPMENT in the HAEMODIALYSIS mode, if applicable, with a DIALYSER according to the MANUFACTURER's recommendation;*
– *apply fluid (e.g. water) in the EXTRACORPOREAL CIRCUIT. If the temperature can have an impact on the NET FLUID REMOVAL measurement, the fluid shall have a temperature of 37 °C ± 1 °C at the arterial patient connection;*
– *set the highest DIALYSIS FLUID flow rate, if applicable;*
– *set the DIALYSIS FLUID temperature to 37 °C, if applicable;*
– *set the NET FLUID REMOVAL rate to 0 ml/h or the lowest adjustable value;*
– *create a DIALYSER blood outlet pressure of 50 mmHg (± 10 mmHg) below the highest operating pressure specified by the MANUFACTURER;*
– *measure the NET FLUID REMOVAL during an appropriate time interval.*

Continue with test 2:

– *set the NET FLUID REMOVAL rate to the maximum value;*
– *measure the NET FLUID REMOVAL during an appropriate time interval.*

Continue with test 3:

– *create a DIALYSER blood outlet pressure of 20 mmHg (± 10 mmHg) above the lowest operating pressure specified by the MANUFACTURER;*
– *measure the NET FLUID REMOVAL during an appropriate time interval.*

The values of the NET FLUID REMOVAL shall be within the tolerances specified by the MANUFACTURER in the instructions for use.

201.4.3.105 SUBSTITUTION FLUID flow rate

For HAEMOFILTRATION and HAEMODIAFILTRATION EQUIPMENT only.

The SUBSTITUTION FLUID flow rate of the HAEMODIALYSIS EQUIPMENT shall be delivered as specified by the MANUFACTURER.

NOTE A SUBSTITUTION FLUID flow rate lower than the set value is considered detrimental for a typical treatment.

Compliance is checked under the following test conditions.

Test 1 for the balancing part of the HAEMODIALYSIS EQUIPMENT and of the therapeutic relevant SUBSTITUTION FLUID flow rate:

- *set the HAEMODIALYSIS EQUIPMENT to the HDF or HF mode with a DIALYSER according to the MANUFACTURER's recommendation;*
- *apply fluid (e.g. water) in the EXTRACORPOREAL CIRCUIT;*
- *set the NET FLUID REMOVAL flow rate to 0 ml/h, or – if not possible – to the minimum;*
- *set the maximum SUBSTITUTION FLUID flow rate;*
- *set the temperature of the SUBSTITUTION FLUID to 37 °C, if applicable;*
- *measure the substitution fluid flow rate and the net fluid removal.*

Continue with test 2:

- *set the minimum SUBSTITUTION FLUID flow rate;*
- *measure the SUBSTITUTION FLUID flow rate and the NET FLUID REMOVAL.*

The values of SUBSTITUTION FLUID flow rate and NET FLUID REMOVAL shall be within the tolerances specified by the MANUFACTURER in the instructions for use.

201.4.3.106 Dialysis time

The accuracy of the dialysis treatment time for the HAEMODIALYSIS EQUIPMENT shall be as specified by the MANUFACTURER.

Compliance is checked by functional tests relevant for the definition of dialysis treatment time specified by the MANUFACTURER.

201.4.3.107 * DIALYSIS FLUID composition

~~*The test method for accuracy of the composition of the DIALYSIS FLUID shall be specified by the MANUFACTURER and compliance checked accordingly.*~~

The accuracy of the composition of the DIALYSIS FLUID shall be specified by the MANUFACTURER.

The test method shall be specified by the MANUFACTURER.

Compliance is checked by inspection and by appropriate functional test(s) that demonstrate the MANUFACTURER's limits specified in the instructions for use are maintained.

201.4.3.108 Dialysis fluid temperature

The temperature of the DIALYSIS FLUID shall be achieved as specified by the MANUFACTURER.

NOTE This test applies only to HAEMODIALYSIS EQUIPMENT having a heater for the DIALYSIS FLUID.

Compliance is checked under the following test conditions:

- *let the HAEMODIALYSIS EQUIPMENT run until it is thermally stable at environmental conditions within 20 °C to 25 °C;*
- *set the DIALYSIS FLUID temperature to 37 °C, if applicable;*

– *set the highest DIALYSIS FLUID flow rate;*
– *measure the temperature at the DIALYSER inlet;*
– *record the temperature during a period of 30 min ± 2 min;*
– *set the lowest DIALYSIS FLUID flow rate;*
– *measure the temperature at the DIALYSER inlet;*
– *record the temperature during a period of 30 min ± 2 min.*

The values of the DIALYSIS FLUID temperature shall be within the tolerances specified by the MANUFACTURER in the instructions for use.

201.4.3.109 SUBSTITUTION FLUID temperature

The SUBSTITUTION FLUID temperature of the HAEMODIALYSIS EQUIPMENT shall be achieved as specified by the MANUFACTURER.

NOTE This test applies only to HAEMODIALYSIS EQUIPMENT having a heater for the SUBSTITUTION FLUID.

Compliance is checked under the following test conditions.

– *let the HAEMODIALYSIS EQUIPMENT run until it is in a thermally stable condition within the environment;*
– *the environmental temperature is within 20 °C to 25 °C;*
– *set the SUBSTITUTION FLUID temperature to 37 °C, if applicable;*
– *set the highest SUBSTITUTION FLUID flow rate;*
– *measure the temperature of the SUBSTITUTION FLUID at the connection point of the SUBSTITUTION FLUID line to the blood line;*
– *record the temperature over a period of 30 min ± 2 min;*
– *set the lowest SUBSTITUTION FLUID flow rate;*
– *measure the temperature of the SUBSTITUTION FLUID at the connection point of the SUBSTITUTION FLUID line to the blood line;*
– *record the temperature over a period of 30 min ± 2 min.*

The values of the SUBSTITUTION FLUID temperature shall be within the tolerances specified by the MANUFACTURER in the instructions for use.

201.4.7 SINGLE FAULT CONDITION for ME EQUIPMENT

Addition:

An example of SINGLE FAULT CONDITION is a failure of a PROTECTIVE SYSTEM (see 201.12.4.4.101, 201.12.4.4.102, 201.12.4.4.103, 201.12.4.4.104, 201.12.4.4.105);

NOTE 101 If air is permanently present in the EXTRACORPOREAL CIRCUIT when the HAEMODIALYSIS EQUIPMENT is used as intended by the MANUFACTURER, air is not regarded as a SINGLE FAULT CONDITION, but as a NORMAL CONDITION.

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.5.4 Other conditions

Addition:

aa) When the outcome of a test can be affected by the initial temperature of the pre-manufactured DIALYSIS FLUID bags, the temperature of the DIALYSIS FLUID at the start of the test shall be equal to or less than 4 °C, or the minimum DIALYSIS FLUID temperature specified by the MANUFACTURER of the ME EQUIPMENT.

bb) If the conditions (e.g., temperature, humidity) during either storage or transport, or both, influence NORMAL USE, this shall be addressed by the RISK MANAGEMENT PROCESS.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.7.4.3 Units of measurement

Addition:

mmHg may be used for measurement of pressures in any part of the HAEMODIALYSIS EQUIPMENT.

201.7.8.2 * Colours of controls

Replacement:

The colour red may be used for a control of the blood pump function or for a control by which a function is interrupted in case of emergency.

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.2 Instructions for use

201.7.9.2.1 General

Addition:

The instructions for use shall additionally include the following:

– * minimum weight values of the intended PATIENT population including applicable limitations for specific PATIENTS' groups;

Compliance is checked by inspection of the instructions for use in the ACCOMPANYING DOCUMENTS.

201.7.9.2.2 Warning and safety notices

Addition:

The instructions for use shall additionally include the following, if applicable:

– a warning statement which draws the OPERATOR'S attention to the precautions necessary to prevent any cross-infection between PATIENTS;

– a warning statement which draws the OPERATOR'S attention to the HAZARDOUS SITUATION associated with connection and disconnection of the PATIENT;

– a warning statement that draws the OPERATOR'S attention to the actions required to respond to ALARM SIGNALS from any PROTECTIVE SYSTEM;

– a warning statement that draws the OPERATOR's attention to potential HAZARDS relating to inappropriate selection of the pre-manufactured DIALYSIS FLUID bags;

– a warning statement which draws the OPERATOR'S attention to the HAZARDS, including any HAZARDOUS SITUATIONS, arising from improper installation and improper connections of the EXTRACORPOREAL CIRCUIT;

– a warning statement on the HAZARDS related to incorrect choice of DIALYSIS FLUID CONCENTRATE(S);

– a quantitative description of the possible deviation of each component of the DIALYSIS FLUID in SINGLE FAULT CONDITION depending on the ALARM LIMITS of the PROTECTIVE SYSTEM;

– * a warning statement on the HAZARDS and underlying causes related to a possible transport of undesired substances from the DIALYSIS FLUID compartment to the blood compartment of the DIALYSER;

– for the PROTECTIVE SYSTEM employed according to 201.12.4.4.104.1 a):

  • a warning statement that this PROTECTIVE SYSTEM reduces the RISK in part only and an explanation of the remaining RISK;

  • a description of OPERATOR responsibility for further mitigation of residual RISK;

– a warning statement of the adequate OPERATOR action upon an ALARM CONDITION and associated HAZARD(S), if the ALARM ~~CONDITION~~ SIGNAL is repeatedly ~~cleared~~ confirmed without solving the underlying problem;

– * a warning statement specifying that any narrow passages in the EXTRACORPOREAL CIRCUIT (such as arising from kinks in the blood line or ~~cannula that are too thin~~ using needles not suitable for the selected blood flow rates) ~~may~~ can cause haemolysis and that this HAZARDOUS SITUATION ~~may~~ is possibly not ~~be~~ detected by the PROTECTIVE SYSTEM;

– if a PROTECTIVE SYSTEM, according to 201.12.4.4.105, Note 1, is applied: a warning statement that improper functioning of an ultrasonic air detector ~~may~~ can be caused by a coagulum or the application of ultrasound gel;

– * a warning statement that air ~~may~~ can enter into the EXTRACORPOREAL CIRCUIT downstream of the air detector, at for example insufficiently tightened connection points, if pressures are negative; this can occur in cases such as single needle applications or central venous catheter applications;

– ~~for ONLINE HDF and ONLINE HF~~ regarding the microbiological quality of fluids:

  • a warning statement that only the disinfection PROCEDURES defined and validated by the MANUFACTURER shall be used ~~for ONLINE HDF and ONLINE HF~~;

  • information on the required quality of the incoming DIALYSIS WATER and of the DIALYSIS FLUID CONCENTRATES used;

  • information about the microbiological quality of the DIALYSIS FLUID and the SUBSTITUTION FLUID, prepared by the HAEMODIALYSIS EQUIPMENT;

  • intervals at which wearing parts (e.g. ENDOTOXIN-RETENTIVE FILTER – ETRF) should be exchanged;

– a warning statement that the blood flow rate, and thus the treatment efficacy, ~~may~~ can be reduced when the pre-pump ARTERIAL PRESSURE is extremely negative; and the range and accuracy of the blood flow rate of such pump(s) and the inlet and outlet pressure ranges over which this accuracy is maintained;

– for HAEMODIALYSIS EQUIPMENT with APPLIED PARTS other than TYPE CF APPLIED PARTS, a warning statement, addressed to both the OPERATOR and the RESPONSIBLE ORGANIZATION, to ensure that no electrical equipment (non-ME EQUIPMENT and ME EQUIPMENT) with TOUCH CURRENTS and PATIENT LEAKAGE CURRENTS above the respective limits for type CF APPLIED PARTS is used in the PATIENT ENVIRONMENT in combination with a central venous catheter whose tip is in the right atrium;

NOTE 101 For information, see 201.8.3 in Annex AA.

– ~~if applicable,~~ a warning statement that the use of low delivery rates of ~~device~~ HAEMODIALYSIS EQUIPMENT-integrated anticoagulation means (e.g. use of undiluted anticoagulation solution) could lead to delayed and non-continuous delivery due to mechanical compliance in the delivery means including the disposables or output pressure changes in the EXTRACORPOREAL CIRCUIT.

– a warning statement that protective measures should be taken to prevent back siphonage from the drain.

NOTE 102 The term "warning statement" is used in a generic way and it is under the MANUFACTURERS' responsibility to identify how to provide the related information to the user in accordance with the MANUFACTURERS' RISK MANAGEMENT PROCESS.

Compliance is checked by inspection of the instructions for use in the ACCOMPANYING DOCUMENTS.

201.7.9.2.5 ME EQUIPMENT description

Addition:

The instructions for use shall additionally include the following, if applicable:

– a definition of TRANSMEMBRANE PRESSURE if the MANUFACTURER makes use of one different from that stated in 201.3.~~217~~208;

– an explanation of the coloured markings on the DIALYSIS FLUID CONCENTRATE connectors;

– information on the effective delivered blood flow rate in single-needle treatments;

– information on the recirculation of blood in the EXTRACORPOREAL CIRCUIT in single-needle treatments;

– the delay time after which an auditory ALARM SIGNAL is activated after interruption of the power supply;

– for PHYSIOLOGIC CLOSED-LOOP CONTROLLER functions (see also the collateral standard IEC 60601-1-10):

  a) the technical working principle;

  b) the PATIENT parameters which are measured and the physiological parameters which are controlled;

  c) the methods by which these PHYSIOLOGIC CLOSED-LOOP CONTROLLER modes have been evaluated, including beneficial and adverse effects recorded during clinical evaluation;

– for any data that is displayed or indicated by the HAEMODIALYSIS EQUIPMENT and that ~~may~~ can be used for adjusting the treatment or measuring or confirming the treatment efficacy:

  a) a description of the technical working principle;

  b) if the measurement is indirect: information about the accuracy and possible influencing factors;

  c) * the method by which the technical working principle has been evaluated relative to standard medical care;

– for HAEMODIALYSIS EQUIPMENT with APPLIED PARTS other than TYPE CF APPLIED PARTS information, whether this HAEMODIALYSIS EQUIPMENT can be used together with a central venous catheter whose tip is in the right atrium. If the HAEMODIALYSIS EQUIPMENT is not suitable for a central venous catheter whose tip is in the right atrium, associated HAZARDs shall be listed.

Compliance is checked by inspection of the instructions for use in the ACCOMPANYING DOCUMENTS.

201.7.9.2.6 Installation

Addition:

The instructions for use shall additionally include the following, if applicable:

– information that it is essential for the HAEMODIALYSIS EQUIPMENT to be installed and used in compliance with appropriate regulations/recommendations on quality of DIALYSIS WATER and other relevant fluids;

– for CLASS I HAEMODIALYSIS EQUIPMENT, information of the importance of the quality of the protective earth in the electrical installation;

– information of the applications in which a POTENTIAL EQUALIZATION CONDUCTOR should be used;

– the acceptable range of temperature, flow rate and pressure for inlet DIALYSIS WATER and any CENTRAL DELIVERY SYSTEM;

– a note emphasizing the importance of compliance with all local regulations regarding the separation of the HAEMODIALYSIS EQUIPMENT from the water supply, the prevention of back flow to the potable water source, and prevention of contamination via the drain connection of the HAEMODIALYSIS EQUIPMENT from any sewer connection;

– if different schemes for colour coding of visual ALARM SIGNALS can be configured, information that the RESPONSIBLE ORGANIZATION should select the colour coding scheme which minimizes the RISK of ALARM SIGNAL misunderstanding in their environment;

– if settings of operating parameters or PROTECTIVE SYSTEMS can be configured, information that the RESPONSIBLE ORGANIZATION should select the configuration(s) or explicitly confirm the default configuration.

Compliance is checked by inspection of the instructions for use in the ACCOMPANYING DOCUMENTS.

201.7.9.2.12 Cleaning, disinfection and sterilization

Addition:

The instructions for use shall additionally include the following, if applicable:

– * a description of the method(s) by which sanitization or disinfection of the non-single use fluid path inside the HAEMODIALYSIS EQUIPMENT and either the ENCLOSURE surface cleaning or disinfection, or both, is achieved;

– information on how to handle an extended time between sanitization or disinfection, so as to return the system to a state of microbial control;

– * information that the test PROCEDURE by which the effectiveness of sanitization or disinfection of the fluid path inside the HAEMODIALYSIS EQUIPMENT has been validated is available upon request from the MANUFACTURER, including information on how the testing represented the microbial controls risks throughout the EXPECTED SERVICE LIFE;

– a warning statement to follow the MANUFACTURER's instructions to disinfect the HAEMODIALYSIS EQUIPMENT; if other PROCEDURES are used it is the responsibility of the RESPONSIBLE ORGANIZATION to validate the disinfection procedure for efficacy and safety; this

warning shall specifically list HAZARDS, including the failure mode that ~~may~~ can result from other PROCEDURES;

– a warning statement that the RESPONSIBLE ORGANIZATION is responsible for the hygienic quality of any delivery system(s), for example central DIALYSIS WATER supply system, CENTRAL DELIVERY SYSTEMS, HAEMODIALYSIS EQUIPMENT connecting devices, including the fluid lines from connection points to the HAEMODIALYSIS EQUIPMENT.

NOTE The term "warning statement" is used in a generic way and it is under the MANUFACTURERS' responsibility to identify how to provide the related information to the user in accordance with the MANUFACTURERS' RISK MANAGEMENT PROCESS.

Compliance is checked by inspection of the instructions for use in the ACCOMPANYING DOCUMENTS.

201.7.9.2.14 ACCESSORIES, supplementary equipment, used material

Addition:

The instructions for use shall additionally include the following, if applicable:

– information on pre-manufactured DIALYSIS FLUID bags, DIALYSIS FLUID CONCENTRATES, DIALYSERS and ~~blood lines~~ EXTRACORPOREAL CIRCUITS intended to be used together with the HAEMODIALYSIS EQUIPMENT.

Compliance is checked by inspection of the instructions for use in the ACCOMPANYING DOCUMENTS.

201.7.9.3 Technical description

201.7.9.3.1 General

Addition:

The technical description shall additionally include the following, if applicable:

- installation:
  - a description of the particular measures or conditions to be observed when installing, deinstalling and transporting the HAEMODIALYSIS EQUIPMENT or bringing it into use. These shall include guidance on the type and number of tests to be carried out;
  - information about the maximum temperature which can occur at the drain of the HAEMODIALYSIS EQUIPMENT:
  - * information about energy consumption, energy delivery to the environment and energy delivery to the drain under typical operating conditions and as a function of inlet water temperature;
  - * information about consumption of water and DIALYSIS FLUID CONCENTRATE(S) or (pre-manufactured) DIALYSIS FLUID under typical operating conditions;
- HAEMODIALYSIS EQUIPMENT specification:
  - for HAEMODIALYSIS EQUIPMENT that includes integral anticoagulant delivery means: the type of the pump(s), the range and the accuracy of the flow rate for such pump(s) and the pressures against which this accuracy is maintained;
  - any additional measures foreseen by the MANUFACTURER in case of the interruption of the power supply;
  - the type, the measurement accuracy and the value(s) ~~or~~/ range(s) of the ALARM LIMIT(S) of the PROTECTIVE SYSTEM required by 201.12.4.4.101 (DIALYSIS FLUID composition);
  - the type, the measurement accuracy and the value(s) ~~or~~/ range(s) of the ALARM LIMIT(S) of the PROTECTIVE SYSTEM required by 201.12.4.4.102 (DIALYSIS FLUID and SUBSTITUTION FLUID temperature);

- the type, the measurement accuracy and the value(s) ~~or~~/ range(s) of the ALARM LIMIT(s) of the PROTECTIVE SYSTEM required by 201.12.4.4.103 (NET FLUID REMOVAL);
- the type, the measurement accuracy and the value(s) ~~or~~/ range(s) of the ALARM LIMIT(s) of the PROTECTIVE SYSTEM required by 201.12.4.4.104.1 (extracorporeal blood loss to the environment), and if applicable the delays introduced by an INTELLIGENT ALARM SYSTEM;
- * the type and the measurement accuracy of the PROTECTIVE SYSTEM required by 201.12.4.4.104.2 (BLOOD LEAK to the DIALYSIS FLUID) and the ALARM LIMIT of the PROTECTIVE SYSTEM at the minimum and maximum flow rate through the BLOOD LEAK detector;
- the type and the ALARM LIMIT(s) of the PROTECTIVE SYSTEM required by 201.12.4.4.104.3 (extracorporeal blood loss due to coagulation);
- the method employed and the sensitivity under test conditions specified by the MANUFACTURER for the PROTECTIVE SYSTEM required by 201.12.4.4.105 (air infusion);
- the override time(s) for any PROTECTIVE SYSTEM;
- the auditory ALARM SIGNAL AUDIO PAUSED period;
- the range of sound pressure levels of any adjustable auditory ALARM SIGNAL source;
- a disclosure of all materials intended to come into contact with the DIALYSIS WATER, DIALYSIS FLUID and DIALYSIS FLUID CONCENTRATE;
- for ONLINE HDF and ONLINE HF: the method of preparation of the SUBSTITUTION FLUID, if applicable the method of the integrity test of the SUBSTITUTION FLUID filters (e.g. ENDOTOXIN-RETENTIVE FILTER – ETRF) and the accuracy of these tests.

Compliance is checked by inspection of the technical description in the ACCOMPANYING DOCUMENTS.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.8.3 * Classification of APPLIED PARTS

Addition:

HAEMODIALYSIS EQUIPMENT with LEAKAGE CURRENTS complying with TYPE CF APPLIED PARTS requirements are considered to be suitable for being used with a central venous catheter whose tip is in the right atrium.

If HAEMODIALYSIS EQUIPMENT having an APPLIED PART other than a TYPE CF APPLIED PART is intended to be used for treatment of PATIENTS with a central venous catheter whose tip is in the right atrium, the following shall apply:

aa) under NORMAL CONDITION, the PATIENT LEAKAGE CURRENTS and the TOUCH CURRENTS shall be within the limits for TYPE CF APPLIED PARTS;

bb) under SINGLE FAULT CONDITION, the PATIENT LEAKAGE CURRENTS, TOUCH CURRENTS and EARTH LEAKAGE CURRENTS shall be within the limits for TYPE CF APPLIED PARTS.

Compliance is checked by inspection.

If the HAEMODIALYSIS EQUIPMENT does not comply with bb), external means shall be provided and justified by the MANUFACTURER'S RISK MANAGEMENT PROCESS to keep the PATIENT LEAKAGE CURRENTS within the limits for TYPE CF APPLIED PARTS under SINGLE FAULT CONDITION.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

201.8.7.4.7 Measurement of the PATIENT LEAKAGE CURRENT

Addition:

aa) * The measuring device shall be connected where both extracorporeal blood lines are connected to the PATIENT. For the duration of the test, a test solution with the highest selectable conductivity, referenced to a temperature of 25 °C, and to the highest selectable DIALYSIS FLUID temperature in the application, shall be flowing in the DIALYSIS FLUID circuit and in the EXTRACORPOREAL CIRCUIT. The HAEMODIALYSIS EQUIPMENT shall be operated in typical treatment mode with highest possible blood flow rate and no ALARM CONDITIONS activated. For practical reasons the measuring device ~~may~~ can be connected to the DIALYSIS FLUID connectors.

NOTE 101 The measurement of PATIENT LEAKAGE CURRENTS described above does not include the measurement according to 8.7.4.7 b) ~~(voltage applied to the APPLIED PART)~~ (external voltage on the PATIENT CONNECTION(S)) of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 for HAEMODIALYSIS EQUIPMENT with TYPE B APPLIED PARTS.

NOTE 102 The highest possible blood flow rate leads to the lowest resistance of the air gap in the venous drip chamber.

201.8.11.2 * MULTIPLE SOCKET-OUTLETS

Addition:

If a MULTIPLE SOCKET-OUTLET is provided and a mutual interchange or interchange with other MULTIPLE SOCKET-OUTLETS of the HAEMODIALYSIS EQUIPMENT could create a HAZARDOUS SITUATION, the MULTIPLE SOCKET-OUTLET shall be of a type which prevents such an interchange.

Compliance is checked by inspection and functional tests.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.11.6 * Overflow, spillage, leakage, ingress of water or particular matter, cleaning, disinfection, sterilization, and compatibility with substances used with the ME EQUIPMENT

201.11.6.1 General

Addition:

All the provisions of 11.6.2 to 11.6.4 shall be applied using appropriate liquid.

NOTE Examples for appropriate liquid are saline solution, DIALYSIS FLUID, other as identified by the MANUFACTURER.

~~**201.11.6.3 Spillage on ME EQUIPMENT and ME SYSTEMS**~~

~~*Addition:*~~

~~*Compliance is checked by test according to code IPX1 of IEC 60529.*~~

201.11.6.5 Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

Addition:

The subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies and IPX1 of IEC 60529 is required as minimum.

201.11.6.6 * Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS

Addition:

For HAEMODIALYSIS EQUIPMENT employing non-disposable (e.g. non-single-use) fluid paths and fluid contacting components where the fluid comes into contact with the PATIENT directly or indirectly, means shall be provided for their ~~disinfection~~ hygienic maintenance.

~~The operating conditions and~~ The microbial control PROCESS for HAEMODIALYSIS EQUIPMENT shall be developed and validated by the MANUFACTURER for HAEMODIALYSIS EQUIPMENT using a RISK based approach considering EXPECTED SERVICE LIFE, disposability, filtration, cleaning/disinfection, system maintenance, storage and ~~/or~~ relevant DIALYSIS FLUID quality standards.

Compliance is checked by inspection of the validation documentation, of the RISK MANAGEMENT FILE, of the ACCOMPANYING DOCUMENTS and of the HAEMODIALYSIS EQUIPMENT.

The disinfection PROCEDURES shall not deteriorate internal components, external surfaces or external ACCESSORIES (e.g. ENDOTOXIN-RETENTIVE FILTER – ETRF) that could lead to a HAZARDOUS SITUATION.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and ~~by functional tests of the HAEMODIALYSIS EQUIPMENT~~ the validation documentation.

201.11.8 * Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

Addition:

a) HAEMODIALYSIS EQUIPMENT powered only by SUPPLY MAINS without INTERNAL ELECTRICAL POWER SOURCE ~~for backup, or with INTERNAL ELECTRICAL POWER SOURCE for operation~~:

In the event of an interruption of the power supply / SUPPLY MAINS to the HAEMODIALYSIS EQUIPMENT, the following safe conditions shall be achieved:

- activation of an auditory ALARM SIGNAL ~~, lasting~~ for at least 1 min;
- additional measures ~~may~~ can be needed as determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS;
- the HAEMODIALYSIS EQUIPMENT may restart automatically on restoration of the power supply only if this does not cause any HAZARDOUS SITUATION to the PATIENT as determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS.

NOTE 101 Power sources for the 1 min auditory ALARM SIGNAL are not regarded as INTERNAL ELECTRICAL POWER SOURCE.

NOTE 102 For the 1 min auditory ALARM SIGNAL IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 allow in Subclause 6.3.3.1 deviations from the full requirements thereof. See also 208.6.3.3.2 and 208.6.3.3.101.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and by functional tests.

b) HAEMODIALYSIS EQUIPMENT powered by SUPPLY MAINS with an INTERNAL ELECTRICAL POWER SOURCE for ~~backup~~ limited functionality in case of interruption of the power supply / SUPPLY MAINS:

In the event of an interruption of the power supply / SUPPLY MAINS to the HAEMODIALYSIS EQUIPMENT, the following safe conditions shall be achieved:

– directly after the loss of SUPPLY MAINS an activation of a visual ALARM SIGNAL;

– activation of an auditory ALARM SIGNAL after a time interval specified by the MANUFACTURER;

While the INTERNAL ELECTRICAL POWER SOURCE is active:

– The limited functionality shall always fulfil the requirements from 201.12.4.4.104.3;

– If applicable, all other requirements from 201.12.4.4 shall be fulfilled.

In the event of starting depletion or loss of the INTERNAL ELECTRICAL POWER SOURCE the following safe condition shall be achieved:

– no more than 30 min before depletion of the INTERNAL ELECTRICAL POWER SOURCE activation of a visual and auditory ALARM SIGNAL. If applicable, the ALARM SIGNAL activation should give the OPERATOR the time usually needed for returning the blood to the PATIENT. The ALARM SIGNAL shall last for at least 1 min.

Or, as an alternative option, after loss of the INTERNAL ELECTRICAL POWER SOURCE:

– activation of an auditory ALARM SIGNAL for at least 1 min.

In both options:

– additional measures ~~may~~ can be needed, as determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS;

– If functions of the HAEMODIALYSIS EQUIPMENT were stopped in the event of an interruption of the power supply / SUPPLY MAINS they may restart automatically on restoration of the power supply / SUPPLY MAINS only if this does not cause any HAZARDOUS SITUATION to the PATIENT, as determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS;

NOTE 103 In the second option (i.e. ALARM SIGNAL at the loss of the INTERNAL ELECTRICAL POWER SOURCE), the INTERNAL ELECTRICAL POWER SOURCE does not need to be tested for functionality, if it is not being used to generate the 1 min auditory ALARM SIGNAL.

NOTE 104 In the second option (i.e. ALARM SIGNAL at the loss of the INTERNAL ELECTRICAL POWER SOURCE), power sources for the 1 min auditory ALARM SIGNAL are not regarded as INTERNAL ELECTRICAL POWER SOURCE.

NOTE 105 For the auditory ALARM SIGNAL in the event of interruption of the POWER SUPPLY and for the 1 min auditory ALARM SIGNAL in the event of the loss of the INTERNAL ELECTRICAL POWER SOURCE, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 allow in Subclause 6.3.3.1 deviations from the full requirements thereof. See also 208.6.3.3.2 and 208.6.3.3.101. If possible, the auditory ALARM SIGNAL in the event of interruption of the POWER SUPPLY and the 1 min auditory ALARM SIGNAL generated before depletion of the INTERNAL ELECTRICAL POWER SOURCE are preferred to be compliant with Clause 208.

NOTE 106 Regarding the first option (i.e. ALARM SIGNAL no more than 30 min before the expected loss of the INTERNAL ELECTRICAL POWER SOURCE), an ALARM SIGNAL generated more than 30 min before the expected loss of the INTERNAL ELECTRICAL POWER SOURCE, would not serve the purpose of reminding the OPERATOR to start the blood restitution before the INTERNAL ELECTRICAL POWER SOURCE gets depleted. If the limited functionality is specified for 30 min or less, the SUPPLY MAINS loss ALARM SIGNAL and the INTERNAL ELECTRICAL POWER SOURCE loss ALARM SIGNAL could be combined in one ALARM SIGNAL.

~~– if the INTERNAL ELECTRICAL POWER SOURCE is interrupted or discharged, the HAEMODIALYSIS EQUIPMENT shall meet the requirements described in 201.11.8 a).~~

Compliance is checked by inspection of the RISK MANAGEMENT FILE and by functional tests.

c) HAEMODIALYSIS EQUIPMENT that is INTERNALLY POWERED:

In the event of starting depletion or loss of the INTERNAL ELECTRICAL POWER SOURCE the following safe condition shall be achieved:

– no more than 30 min before expected depletion of the INTERNAL ELECTRICAL POWER SOURCE activation of a visual and auditory ALARM SIGNAL. If applicable, the ALARM SIGNAL activation should give the OPERATOR the time usually needed for returning the blood to the PATIENT. The ALARM SIGNAL shall last for at least 1 min and shall be compliant with Clause 208 (with an allowed exception on duration of AUDIO PAUSE, regarding 208.6.3.1 and 208.6.3.3.101).

Or, as an alternative option, after loss of the INTERNAL ELECTRICAL POWER SOURCE:

– activation of an auditory ALARM SIGNAL for at least 1 min.

In both options:

– additional measures can be needed, as determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS.

– The HAEMODIALYSIS EQUIPMENT may restart automatically on restoration of the power supply only if this does not cause any HAZARDOUS SITUATION to the PATIENT, as determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS.

NOTE 107 Case c) applies to HAEMODIALYSIS EQUIPMENT where the INTENDED USE is achieved by INTERNAL ELECTRICAL POWER SOURCE, e.g. wearable HAEMODIALYSIS EQUIPMENT.

NOTE 108 Case c) also applies to HAEMODIALYSIS EQUIPMENT that can provide the INTENDED USE by the INTERNAL ELECTRICAL POWER SOURCE or alternatively by the SUPPLY MAINS or in combination with the SUPPLY MAINS (e.g. for charging the INTERNAL ELECTRICAL POWER SOURCE while in use). See the additional requirement regarding charging mode indication in 15.4.4 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

NOTE 109 Power sources for the 1 min auditory ALARM SIGNAL are not regarded as INTERNAL ELECTRICAL POWER SOURCE.

NOTE 110 For the 1 min auditory ALARM SIGNAL in the event of the loss of the INTERNAL ELECTRICAL POWER SOURCE, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 allow in 6.3.3.1 deviations from the full requirements thereof. See also 208.6.3.3.2 and 208.6.3.3.101.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and by functional tests.

201.12 * Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

See Annex BB for examples of HAZARDS, foreseeable sequences of events, and HAZARDOUS SITUATIONS in HAEMODIALYSIS EQUIPMENT.

201.12.4.4 Incorrect output

Addition:

The test PROCEDURES in 12.4.4.101 to 12.4.4.105 give an overview of the minimum requirements for the validation of a HAEMODIALYSIS EQUIPMENT. All details are not included for each test PROCEDURE and it is incumbent upon the test laboratory to address these details based on the specific HAEMODIALYSIS EQUIPMENT and the MANUFACTURER'S RISK MANAGEMENT PROCESS.

Additional subclauses:

201.12.4.4.101 * DIALYSIS FLUID composition

A) The HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM, independent of any fluid preparation control system, which prevents DIALYSIS FLUID from reaching the DIALYSER that, due to its composition, ~~may~~ can cause a HAZARDOUS SITUATION.

NOTE 1 A PROTECTIVE SYSTEM is not necessary for HAEMODIALYSIS EQUIPMENT using only pre-manufactured DIALYSIS FLUID, which is quality controlled for the DIALYSIS FLUID composition, and is not changed in composition by the HAEMODIALYSIS EQUIPMENT, for example using pre-manufactured DIALYSIS FLUID bags.

The design of the PROTECTIVE SYSTEM to prevent a hazardous composition of the DIALYSIS FLUID shall consider a potential failure in any phase of preparation or regeneration of the DIALYSIS FLUID.

Activation of the PROTECTIVE SYSTEM shall achieve the following safe conditions:

– activation of auditory and visual ALARM SIGNALS (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101). The auditory ALARM SIGNAL may be delayed as specified in 208.6.3.3.101 b);
– stopping of the DIALYSIS FLUID flow to the DIALYSER;
– in ONLINE HDF or ONLINE HF mode, stopping of the SUBSTITUTION FLUID flow to the EXTRACORPOREAL CIRCUIT.

b) Conductivity profiles and PHYSIOLOGIC CLOSED-LOOP CONTROLLERS:

In case of pre-programmed time-dependent variation of the DIALYSIS FLUID composition or in case of feedback control of the DIALYSIS FLUID composition by measuring a physiologic relevant parameter of the PATIENT, the HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM, independent of the control system, which prevents any unintentional changes in the control system that could cause a HAZARDOUS SITUATION.

Activation of the PROTECTIVE SYSTEM shall achieve the following safe conditions:

– activation of auditory and visual ALARM SIGNALS (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);
– other measures, if defined by MANUFACTURER'S RISK MANAGEMENT PROCESS.

c) If the HAEMODIALYSIS EQUIPMENT is equipped with a bolus administration feature for temporarily changing the DIALYSIS FLUID composition, the HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM, independent of the control system, which prevents the bolus administration function to result in a HAZARDOUS SITUATION to the PATIENT.

Activation of the PROTECTIVE SYSTEM shall achieve the following safe conditions:

– activation of auditory and visual ALARM SIGNALS (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);
– interruption of the DIALYSIS FLUID composition bolus administration.

Compliance is checked by functional tests and by the following tests in treatment mode.

Test 1 for determining the ALARM SIGNAL activation, beginning with step 1:

~~– Set the unit under test to the lowest and the highest compositions of the DIALYSIS FLUID respectively without generating an ALARM SIGNAL.~~

~~– Slowly change the DIALYSIS FLUID composition until the PROTECTIVE SYSTEM activates an ALARM SIGNAL.~~

~~– Take samples at the DIALYSER inlet under NORMAL CONDITION and immediately after the ALARM CONDITION is detected.~~

~~– Determine and evaluate (e.g. by flame photometry) the DIALYSIS FLUID composition of the samples taken in NORMAL CONDITION and after the ALARM CONDITION is detected.~~

– Select one typical concentrate formulation
– Set the treatment parameters of the unit under test to the lowest settable DIALYSIS FLUID composition and wait for stabilization.
– Slowly manipulate the DIALYSIS FLUID composition to a lower DIALYSIS FLUID composition until the PROTECTIVE SYSTEM activates the ALARM SIGNAL according to the specified ALARM CONDITION.
– Take sample at the DIALYSER inlet immediately after the ALARM CONDITION is detected.
– Determine the DIALYSIS FLUID composition of the sample taken after the ALARM CONDITION is detected.

– The measured value shall be within the limits specified by the MANUFACTURER.

– *For step 2, set the treatment parameters to the lowest settable DIALYSIS FLUID composition, wait for stabilization and slowly manipulate the DIALYSIS FLUID composition to a higher DIALYSIS FLUID composition until the PROTECTIVE SYSTEM activates the ALARM SIGNAL according to the specified ALARM CONDITION.*

– *For step 3, set the treatment parameters to the highest settable DIALYSIS FLUID composition, wait for stabilization and slowly manipulate the DIALYSIS FLUID composition to a higher DIALYSIS FLUID composition until the PROTECTIVE SYSTEM activates the ALARM SIGNAL according to the specified ALARM CONDITION.*

– *For step 4, set the treatment parameters to the highest settable DIALYSIS FLUID composition, wait for stabilization and slowly manipulate the DIALYSIS FLUID composition to a lower DIALYSIS FLUID composition until the PROTECTIVE SYSTEM activates the ALARM SIGNAL according to the specified ALARM CONDITION.*

Test 2 for in-time alarm reaction:

– *Set the unit under test to the highest possible DIALYSIS FLUID flow rate*

– *Simulate complete interruption of each DIALYSIS FLUID CONCENTRATE supply, one at a time (for examples see Annex AA, 201.15.4.1.101).*

– *Take sample at the DIALYSER inlet ~~under NORMAL CONDITION and~~ immediately after the ALARM CONDITION is detected.*

– *Determine ~~and evaluate (e.g. by flame photometry)~~ the DIALYSIS FLUID composition of the samples taken ~~under NORMAL CONDITION and~~ after the ALARM CONDITION is detected.*

– *The measured value shall be within the limits specified by the MANUFACTURER.*

Test 3 for foreseeable misuse:

~~– Exchange DIALYSIS FLUID CONCENTRATES, if possible.~~

~~– Determine the ALARM CONDITION activation.~~

~~– Take samples at the DIALYSER inlet under NORMAL CONDITION and immediately after the ALARM CONDITION is detected.~~

~~– Determine and evaluate (e.g. by flame photometry) the DIALYSIS FLUID composition of the samples taken under NORMAL CONDITION and after the ALARM CONDITION is detected.~~

– *Select one typical correct concentrate connection.*

– *Interchange the connection of the different DIALYSIS FLUID CONCENTRATES components, if possible.*

– *Wait until the PROTECTIVE SYSTEM activates the ALARM SIGNAL according to the specified ALARM CONDITION.*

– *Take sample at the DIALYSER inlet immediately after the ALARM CONDITION is detected.*

– *Determine the DIALYSIS FLUID composition of the sample taken after the ALARM CONDITION is detected.*

– *The measured value shall be within the limits specified by the MANUFACTURER.*

NOTE 2 See 201.4.3.107 for methods for determining DIALYSIS FLUID composition.

201.12.4.4.102 * DIALYSIS FLUID and SUBSTITUTION FLUID temperature

a) It shall not be possible to set the temperature of the DIALYSIS FLUID and SUBSTITUTION FLUIDS outside a range of 33 °C to 42 °C unless justified by the MANUFACTURER'S RISK MANAGEMENT PROCESS.

b) The HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM, independent of any temperature control system, which prevents DIALYSIS FLUID reaching the DIALYSER and SUBSTITUTION FLUID reaching the EXTRACORPOREAL CIRCUIT at a temperature below 33 °C or above 42 °C, measured at the HAEMODIALYSIS EQUIPMENT DIALYSIS FLUID outlet and~~/or~~, if applicable, at the SUBSTITUTION FLUID outlet.

c) Temperatures below 33 °C and for a short time up to 46 °C are acceptable, but time and temperature ~~have to~~ shall be justified in the MANUFACTURER'S RISK MANAGEMENT PROCESS.

d) Activation of the PROTECTIVE SYSTEM shall achieve the following safe conditions:

– activation of auditory and visual ALARM SIGNALS (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101). The auditory ALARM SIGNAL may be delayed as specified in 208.6.3.3.101 b);

– stopping of the DIALYSIS FLUID flow to the DIALYSER and~~/or~~, if applicable, the SUBSTITUTION FLUID flow to the EXTRACORPOREAL CIRCUIT.

Compliance is checked by functional tests and by the following tests.

Test 1 for DIALYSIS FLUID:

– *Set the unit under test to the highest DIALYSIS FLUID flow rate, if this setting is possible.*

– *Set the highest ~~/~~and in a second test run the lowest DIALYSIS FLUID temperature.*

– *Wait for stable temperatures at the DIALYSER inlet.*

– *Slowly increase ~~/~~and in a second test run decrease the temperature of the DIALYSIS FLUID until the PROTECTIVE SYSTEM activates an ALARM SIGNAL.*

– *Measure the temperature continuously at the DIALYSER inlet and determine the maximum ~~/~~and in a second test run the minimum value.*

– *The measured maximum and in a second test run the minimum value shall be within the values specified at point b) or if applicable c).*

Test 2 for SUBSTITUTION FLUID:

– *Set the unit under test to the highest SUBSTITUTION FLUID flow rate, if this setting is possible.*

– *Set the highest ~~/~~and in a second test run the lowest DIALYSIS FLUID / SUBSTITUTION FLUID temperature.*

– *Wait for a stable temperature at the inlet to the EXTRACORPOREAL CIRCUIT.*

– *Slowly increase ~~/~~and in a second test run decrease the temperature of the DIALYSIS FLUID / SUBSTITUTION FLUID until the PROTECTIVE SYSTEM activates an ALARM SIGNAL.*

– *Measure the temperature of the SUBSTITUTION FLUID continuously at the inlet to the EXTRACORPOREAL CIRCUIT and determine the maximum ~~/~~and in a second test run the minimum value.*

– *The measured maximum and in a second test run the minimum value shall be within the values specified at point b) or if applicable c).*

201.12.4.4.103 * NET FLUID REMOVAL

a) The HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM, independent of any ULTRAFILTRATION control system, which prevents a deviation in the NET FLUID REMOVAL of the HAEMODIALYSIS EQUIPMENT from the set value of the controlling parameters that ~~may~~ can cause a HAZARDOUS SITUATION.

In case of HDF and HF the HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM, independent of any SUBSTITUTION FLUID control system, which prevents an incorrect administration of the SUBSTITUTION FLUID that ~~may~~ can cause a HAZARDOUS SITUATION.

Activation of the PROTECTIVE SYSTEM shall achieve the following safe conditions:

– activation of auditory and visual ALARM SIGNALS (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);

– prevention of the continuation of the hazardous fluid balancing error.

b) Ultrafiltration profiles and physiologic closed-loop controllers:

In case of pre-programmed time-dependent variation of ULTRAFILTRATION or in case of feedback control of ULTRAFILTRATION by a monitor measuring a physiologic relevant parameter of the PATIENT, the HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM,

independent of the control system, which prevents any unintentional changes in the control system that could cause a HAZARDOUS SITUATION.

Activation of the PROTECTIVE SYSTEM shall achieve the following safe conditions:

– activation of auditory and visual ALARM SIGNALS (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);

– other measures, if defined by MANUFACTURER'S RISK MANAGEMENT PROCESS.

c) If the HAEMODIALYSIS EQUIPMENT is equipped with a fluid bolus administration feature, the HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM, independent of the control system, which prevents the fluid bolus administration function to cause a HAZARDOUS SITUATION to the PATIENT.

Activation of the PROTECTIVE SYSTEM shall achieve the following safe conditions:

– activation of auditory and visual ALARM SIGNALS (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);

– interruption of the fluid bolus administration.

Compliance is checked by functional tests and failure simulations, including the following test.

Test for deviations of the NET FLUID REMOVAL ~~rate~~:

– *Use a reservoir to simulate the PATIENT and place it on a scale.*

– *Set the unit under test to the highest DIALYSIS FLUID flow rate.*

– *Set the highest SUBSTITUTION FLUID flow rate, if this is adjustable.*

– *Set the DIALYSIS FLUID temperature to 37 °C, if applicable.*

– *Set the highest and the lowest ~~ULTRAFILTRATION rates~~ NET FLUID REMOVAL RATE (one at a time).*

– *Simulate an error with a negative and a positive deviation in each of the fluid removal control components (one at a time) which influence the NET FLUID REMOVAL ~~rate~~ until the PROTECTIVE SYSTEM activates an ALARM SIGNAL.*

~~– Determine the difference between the set target volume and the measured NET FLUID REMOVAL At the activation of the ALARM SIGNAL.~~

– *Monitor the simulated PATIENT's weight by the scale.*

– *At the activation of the ALARM SIGNAL, the NET FLUID REMOVAL value or rate measured by the scale shall be within the NET FLUID REMOVAL limits specified by the MANUFACTURER.*

201.12.4.4.104 Extracorporeal blood loss

201.12.4.4.104.1 Extracorporeal blood loss to the environment

a) * The HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM to protect the PATIENT from extracorporeal blood loss to the environment that ~~may~~ can cause a HAZARDOUS SITUATION.

NOTE 1 At the time this document was written, no system that can totally be relied upon to detect blood loss to the environment had been developed.

If a PROTECTIVE SYSTEM is utilizing measurement of the VENOUS PRESSURE, the OPERATOR should have at least a means to adjust the lower ALARM LIMIT manually as closely as possible to the current measurement value. The single-needle treatment mode needs additional or other measures.

b) The HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM to protect the PATIENT from extracorporeal blood loss to the environment caused by a rupture or separation in the EXTRACORPOREAL CIRCUIT due to excessive pressure, unless this is prevented by inherently safe design.

NOTE 2 This is not related to separation of the PATIENT CONNECTION or access needle but related to the potential pressure that can be generated by the pump which could cause tubing rupture or joint separation in the EXTRACORPOREAL CIRCUIT.

c) * Activation of the PROTECTIVE SYSTEM shall achieve the following safe condition:

- activation of auditory and visual ALARM SIGNALS (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);
- stoppage of the blood flow to the environment caused by the HAEMODIALYSIS EQUIPMENT, even under SINGLE FAULT CONDITION;
- In the case of haemofiltration or haemodiafiltration, stoppage of the substitution fluid flow.

Compliance is checked by functional tests and by the following test in treatment mode.

Test for PROTECTIVE SYSTEMS utilizing the VENOUS PRESSURE measurement:

- *Set the unit under test to the medium blood flow rate.*
- ~~*Adjust the VENOUS PRESSURE to a medium value.*~~
- *Create a typical treatment value for the VENOUS PRESSURE.*
- *Set the low ALARM LIMIT as close as possible to the venous pressure.*
- *~~Lower~~Reduce the VENOUS PRESSURE until an ALARM SIGNAL is activated.*
- *Determine the difference of the measured VENOUS PRESSURE against the set limit when the ALARM SIGNAL is activated.*
- *The calculated difference shall not exceed the accuracy declared by the MANUFACTURER for the ALARM LIMIT(s) of the PROTECTIVE SYSTEM (see 201.7.9.3.1 hyphen 10).*
- *If applicable, the delay introduced by an INTELLIGENT ALARM SYSTEM shall not exceed the value declared by the MANUFACTURER (see 201.7.9.3.1 hyphen 10).*

201.12.4.4.104.2 * BLOOD LEAK to the DIALYSIS FLUID

a) The HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM to protect the PATIENT from a BLOOD LEAK that ~~may~~ can cause a HAZARDOUS SITUATION.

b) Activation of the PROTECTIVE SYSTEM shall achieve the following safe condition:

- activation of auditory and visual ALARM SIGNALS (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);
- prevention of further blood loss to the DIALYSIS FLUID.

c) Override of the PROTECTIVE SYSTEM for the blood leak:

- Override time shall not exceed 3 min;
- Under certain clinical conditions it may be accepted by RISK MANAGEMENT to override the BLOOD LEAK detector for more than 3 min with the maximum duration of a single treatment;
- Override activation shall maintain at least a visual indication of the overridden PROTECTIVE SYSTEM for BLOOD LEAK.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS, by functional tests and by the following test.

Test for determining the ALARM LIMITS:

- *Set the maximum flow rate through the BLOOD LEAK detector (highest DIALYSIS FLUID flow rate, highest ULTRAFILTRATION rate, if relevant also highest SUBSTITUTION FLUID flow rate).*
- *Add bovine blood, human blood or porcine blood (Haematocrit Hct 32 % ± 2 %) to the DIALYSIS FLUID ~~so that the flow through the BLOOD LEAK detector exceeds the BLOOD LEAK ALARM LIMIT as specified by the MANUFACTURER~~ until an ALARM SIGNAL is activated.*
- *Determine the difference of the applied BLOOD LEAK against the ALARM LIMIT specified by the MANUFACTURER.*
- *The calculated difference shall not exceed the accuracy declared by the MANUFACTURER for the ALARM LIMIT(s) of the PROTECTIVE SYSTEM (see 201.7.9.3.1 hyphen 11).*

201.12.4.4.104.3 * Extracorporeal blood loss due to coagulation

a) The HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM to protect the PATIENT from blood loss due to coagulation as a consequence of the interruption of the blood flow that ~~may~~ can cause a HAZARDOUS SITUATION.

NOTE An acceptable method of complying with this requirement is, for example, a PROTECTIVE SYSTEM operating if the blood pump(s) advertently or inadvertently stop(s) for a longer period of time.

b) Activation of the PROTECTIVE SYSTEM shall activate an auditory and visual ALARM SIGNAL (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101).

c) Other effects, not covered by 201.12.4.4.106, which ~~may~~ can result in a blood loss due to coagulation~~, for example stopping or missing start of any anticoagulant delivery means, or excessive SUBSTITUTION FLUID flow rate in case of HDF or HF with post-dilution~~, shall be addressed in the MANUFACTURER'S RISK MANAGEMENT PROCESS, e.g. excessive SUBSTITUTION FLUID flow rates in HDF or HF post-dilution can result in coagulation by haemoconcentration at the blood outlet of the DIALYSER.

Compliance is checked by functional test and failure simulation.

201.12.4.4.105 * Air infusion

a) The HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM to protect the PATIENT from air infusion, under NORMAL CONDITION and SINGLE FAULT CONDITION, that ~~may~~ can cause a HAZARDOUS SITUATION.

NOTE 1 An acceptable method of complying with this requirement is, for example, a PROTECTIVE SYSTEM utilizing an air detector (e. g. ultrasonic) capable of detecting non-dissolved air.

b) Activation of the PROTECTIVE SYSTEM shall achieve the following safe condition:

– activation of auditory and visual ALARM SIGNALS (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);

– prevention of further hazardous air infusion via the arterial and venous bloodlines, even under SINGLE FAULT CONDITION.

NOTE 2 The prevention of further air infusion can typically be accomplished by stopping the blood pump and clamping the venous bloodline.

Compliance is checked by functional tests ~~taking into account the principles of the test described below~~ following the principles of the test below and by inspection of the RISK MANAGEMENT FILE.

NOTE 3 ~~Given numbers in the tests are examples. The MANUFACTURER has to define the values by his RISK MANAGEMENT PROCESS.~~ Values given in the tests are examples and are defined by the MANUFACTURER.

NOTE 4 ~~As a matter of principle,~~ There are two methods for monitoring air infusion:

a) at an air trap (e.g. at the venous drip chamber) where buoyancy forces act on the air bubbles so that bubbles are prevented from exiting the air trap with a correctly set level; the air bubble monitoring method used here is the method of monitoring the level;

b) directly at the bloodline (air bubbles are delivered in the fluid stream), where the air volume can be determined by means of the flow velocity.

There are two different test PROCEDURES independent of the air monitoring methods in Note 4.

Continuous air infusion test:

– *Set up the HAEMODIALYSIS EQUIPMENT with a ~~standard~~ typical capillary DIALYSER (e.g. surface area between 1 m^2 and 1,5 m^2), the recommended EXTRACORPOREAL CIRCUIT and cannulas (e.g. 16 gauge).*

~~– Clamp or close the DIALYSIS FLUID lines after priming.~~

~~NOTE 5 This is a worst-case condition. If degassed DIALYSIS FLUID is running, gas will be removed by the DIALYSER.~~

– *Stop the DIALYSIS FLUID flow to and from the DIALYSER.*

NOTE 5 If degassed DIALYSIS FLUID is running, gas will be removed by the DIALYSER. Stopping the flow could be achieved by full bypass of the DIALYSIS FLUID flow, clamping the DIALYSIS FLUID lines or interconnecting the dialyzer inlet and outlet.

– *Operate the EXTRACORPOREAL CIRCUIT with heparinized blood (human, bovine or porcine) with a defined Hct (e.g. Hct between 0,25 and 0,35) or with an appropriate test fluid.*

~~NOTE 6 An appropriate test fluid has a viscosity of 3,5 mPa·s at 37 °C and contains a surfactant causing spallation of gas bubbles.~~

NOTE 6 If a fluid other than blood is selected, its equivalence with blood is demonstrated and documented in the RISK MANAGEMENT FILE, both in term of viscosity and in term of spallation of gas bubbles.

– *Position a storage container for the test fluid at a level of, for example, 100 cm (±20 cm) from the ground.*

– *Position a collection container for the test fluid at a level of, for example, 100 cm (±20 cm) from the ground or recirculate the fluid into the storage container.*

– *Position at least one vertically positioned test tube with diameter of, for example, 8 mm and a length of, for example, 2,0 m in line with a second tube with smaller diameter of, for example, 4,3 mm and a length of, for example, 20 cm directly at the venous PATIENT connector in the venous path between the PATIENT connector and collection container (see as an example the setup in Figure 201.101).* ~~*More than one test tube in parallel configuration can be used to monitor continuously the infused air before the ALARM CONDITION occurs.*~~ *The test tubes shall be completely primed.*

NOTE 7 The volume of the second tube with a smaller diameter allows to collect all of the air expected.

NOTE 8 With regards to the measurement of the air volume collected in the tube with the smaller diameter (hereby referred as air measurement tube), an additional tube can be inserted in order to ensure equalization of the trapped pressure to atmosphere by opening the corresponding clamp before measuring the air volume. If present, the equalization line is positioned below the air measurement tube as well as to prime it before starting the air injection. Regarding the recommended equalization line position, refer to Atmosphere Equalization line in Figure 201.101.

– *Insert a primed cannula (e.g. 22 gauge) into the arterial blood tubing in the section of negative pressures close to the connection to the arterial (blood withdrawal) cannula and connect it to a syringe pump capable of controlling air injection under negative pressure condition.*

NOTE 9 Another possible method is the use of a small reversible peristaltic pump. This pump is initially primed with test fluid by operating it in reverse mode to avoid uncontrolled injection of air when the blood pump is started. A check valve between the needle and the pump could be used.

– *Adjust the blood pump speed with a defined pre-pump negative pressure (e.g., between −200 mmHg and −250 mmHg).*

~~– *Inject air at slowly increasing rates specified by the MANUFACTURER until an air detector ALARM CONDITION occurs which prevents further hazardous infusion of air.*~~

– *Inject air at increasing rates until the PROTECTIVE SYSTEM activates an ALARM SIGNAL.*

NOTE 10 The rationale of this test is based on the assumption that, with the DIALYSIS FLUID line closed, air cannot escape from the EXTRACORPOREAL CIRCUIT ~~and will eventually be pumped to the fluid collection vessel at the same rate as pumped in~~.

– *Clamp the test tube according to Figure 201.101 at both ends immediately after the air detector ALARM SIGNAL.*

– *Open the clamp on the Equalization line, if present; measure the air volume that develops at the vertical top of the small diameter test tube after 15 min when the air bubbles have combined to a solid air volume.* ~~*Equalization of trapped pressure to atmosphere in the fluid part of the measurement tube by opening a pressure equalization clamp before measuring the volumes can improve the repeatability of the measurement results.*~~

– *Calculate the air flow rate by blood flow rate, test tube volume and measured air volume as follows:*

$$Q_{air} = Q_b \times V_{air}/V_{tube}$$

where:

Q_{air} *is the air flow rate;*

Q_b *is the blood flow rate; direct measurement of the blood flow rate in the venous bloodline is recommended;*

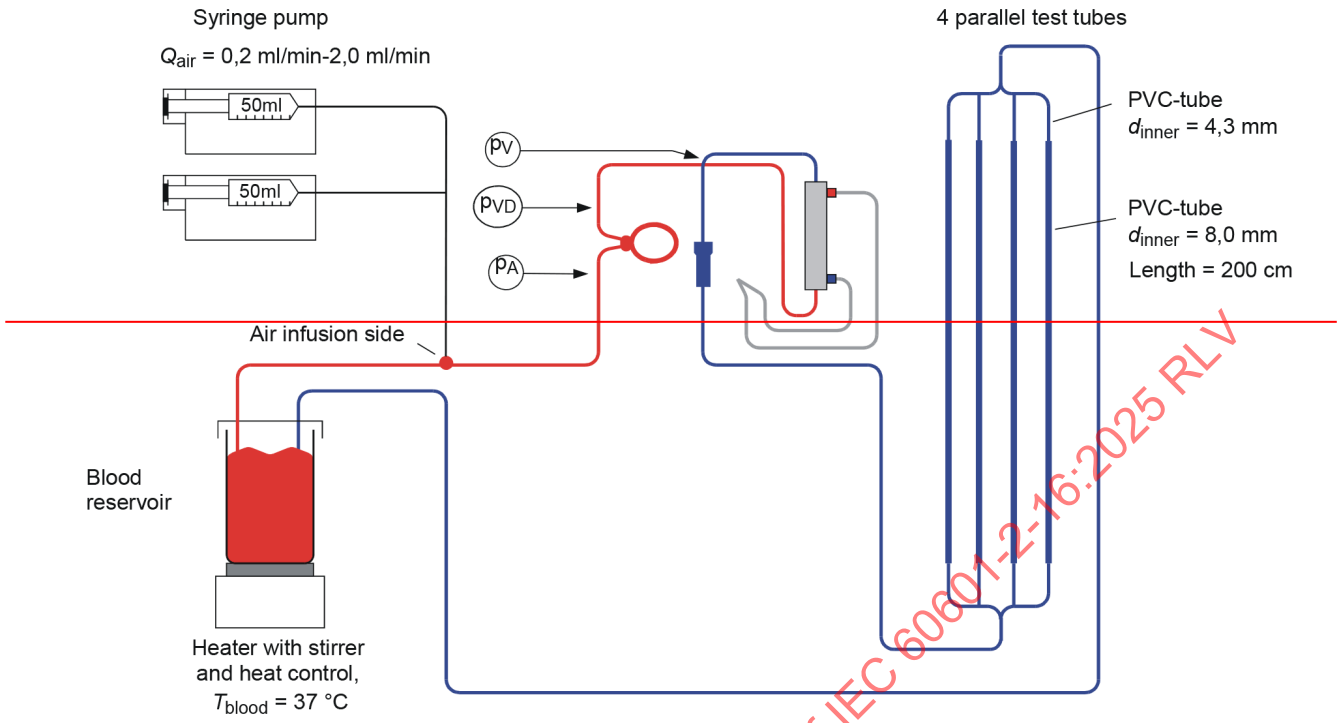
V_{air} *is the volume of air collected in the test tube;*

V_{tube} *is the volume of the test tube.*

– *The calculated air flow rate shall be less than the continuous air infusion rate limit identified by RISK MANAGEMENT.*

– *If the HAEMODIALYSIS EQUIPMENT allows the DIALYSER to be operated with blood flowing upwards through the DIALYSER ~~and~~or, alternatively with blood flowing downwards through the DIALYSER, separate continuous air infusion tests shall be done with both flow directions.*

– *If RISK ANALYSIS reveals pathways for injecting air downstream of the blood pump leading to continuous air infusion that ~~may~~ can cause a HAZARDOUS SITUATION (e.g., by a level adjust pump) the continuous air infusion test shall be repeated by pumping air at the specified rate into the EXTRACORPOREAL CIRCUIT at this point.*



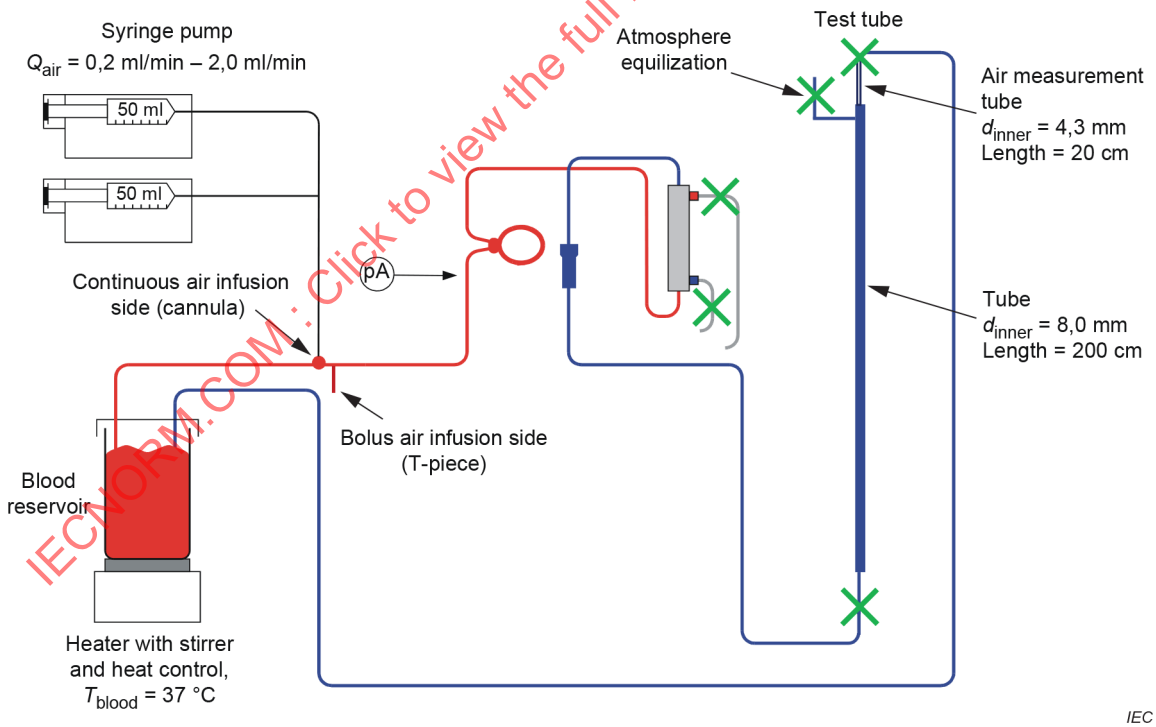


Figure 201.101 – ~~Continuous~~ Air infusion test setup with example dimensions

- *Bolus air infusion test:*
  - *Set up the HAEMODIALYSIS EQUIPMENT with a ~~standard~~ typical capillary DIALYSER (e.g. surface area between 1 m^2 and 1,5 m^2), the recommended EXTRACORPOREAL CIRCUIT and cannulas (e.g. 16 gauge).*
  - *Clamp or close the DIALYSIS FLUID lines after priming.*

    NOTE 11 This is a worst-case condition. If degassed DIALYSIS FLUID is running, gas is removed by the DIALYSER.
  - *Operate the EXTRACORPOREAL CIRCUIT with heparinized blood with a defined Hct (e.g. Hct between 0,25 and 0,35, human blood, bovine blood, porcine blood) or an appropriate test fluid.*

    NOTE 12 ~~An appropriate test fluid has a viscosity of 3,5 mPa·s at 37 °C and contains a surfactant causing spallation of gas bubbles.~~ If a fluid other than blood is selected, its equivalence with blood is demonstrated and documented in the RISK MANAGEMENT FILE, both in term of viscosity and in term of spallation of gas bubbles.
  - *Position a storage container for the test fluid at a level of, for example, 100 cm (±20 cm) from the ground.*
  - *Position a collection container for the test fluid at a level of, for example, 100 cm (±20 cm) from the ground or recirculate the fluid into the storage container.*
  - *Position a graduated measuring cylinder or the same test tubes as in the ~~previous~~ continuous air infusion test ~~case~~ setup such that any air that ~~may be~~ is pumped through the return (venous) cannula is collected.*

    NOTE 13 With regards to the measurement of the air volume collected in the small tube, an additional tube can be inserted in order to ensure equalization of the trapped pressure to atmosphere by opening the corresponding clamp before measuring the air volume. If present, the equalization line is positioned above the expected level reachable by air as well as completely primed before starting the air injection. See Atmosphere Equalization line in Figure 201.101.
  - *~~Insert~~ Connect a T-piece with Luer connectors ~~between~~ at the arterial blood tubing ~~and~~ in the section of negative pressures close to the connection to the arterial (blood withdrawal) cannula.*
  - *Connect a piece of tubing (e.g. 5 cm long) with a Luer connector to the T-piece.*
  - *Prime the EXTRACORPOREAL CIRCUIT and said piece of tubing. Clamp the piece of tubing.*
  - *Adjust the blood pump speed with a defined pre-pump negative pressure (e.g. between 0 mmHg and –250 mmHg) so that no pressure ALARM CONDITION arises in the EXTRACORPOREAL CIRCUIT with the opening of the clamp.*
  - *Open the clamp at the piece of tubing and wait until an ~~ALARM SIGNAL is activated~~ ALARM CONDITION occurs which prevents further hazardous infusion of air.*
  - ~~*Check the amount of air collected in the graduated measuring cylinder or in the test tube.*~~
  - *Open the clamp on the Equalization line, if present; measure the amount of air collected in the graduated measuring cylinder or in the test tube.*
  - *The collected air volume shall be less than the bolus air infusion limit identified by RISK MANAGEMENT.*
  - *If the HAEMODIALYSIS EQUIPMENT allows the DIALYSER to be operated with blood flowing upwards through the DIALYSER ~~and~~ or, alternatively with blood flowing downwards through the DIALYSER, separate bolus air infusion tests shall be done with both flow directions.*
  - *If RISK ANALYSIS reveals pathways for injecting air downstream of the blood pump and leading to bolus air infusion that ~~may~~ can cause a HAZARDOUS SITUATION (e.g., by a level adjust pump) the bolus air infusion test shall be repeated by pumping air at the maximum rate into the EXTRACORPOREAL CIRCUIT at this point.*

~~**201.12.4.4.106 * ALARM CONDITION override modes**~~

~~Within the meaning of 201.12.4.4.106, override is a means to allow the HAEMODIALYSIS EQUIPMENT to function under ALARM CONDITIONS if the OPERATOR consciously selects to temporarily disable the PROTECTIVE SYSTEM.~~

~~a) All PROTECTIVE SYSTEMS shall be active throughout treatment. A delayed activation of PROTECTIVE SYSTEMS following the start or restart of the treatment is not regarded as an override mode of the HAEMODIALYSIS EQUIPMENT if it does not cause a HAZARDOUS SITUATION.~~

~~NOTE 1 For exceptions, see item b) below.~~

~~NOTE 2 Within the meaning of 201.12.4.4.106, treatment is considered to have started when the PATIENT'S blood is returned to the PATIENT through the EXTRACORPOREAL CIRCUIT. Treatment is considered to be finished when the venous needle is disconnected.~~

~~b) The PROTECTIVE SYSTEMS for DIALYSIS FLUID composition and temperature shall be activated before the first contact of DIALYSIS FLUID with blood in the DIALYSER.~~

~~c) During an ALARM CONDITION of any PROTECTIVE SYSTEM of 201.12.4.4, a temporary override mode may apply only to the following PROTECTIVE SYSTEM:~~

~~– utilizing the BLOOD LEAK monitoring (see 201.12.4.4.104.2) the override time shall not exceed 3 min, but under certain clinical conditions it may be necessary to override the BLOOD LEAK detector completely or partially for the maximum duration of a single treatment.~~

~~d) Activation of an override mode shall maintain a visual indication that a pertaining PROTECTIVE SYSTEM is being overridden.~~

~~e) Overriding a particular PROTECTIVE SYSTEM (see item c) shall have no effect on any other subsequent ALARM CONDITIONS. Subsequent ALARM CONDITIONS shall achieve the safe condition specified. A remaining ALARM CONDITION shall, after the elapsed override period, re-achieve the safe condition specified.~~

~~*Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and by functional tests.*~~

201.12.4.4.~~112~~106 * Anticoagulation

If the HAEMODIALYSIS EQUIPMENT is intended to include anticoagulant delivery means and a non-automated stop/start of the anticoagulant delivery means ~~may~~ can cause a HAZARDOUS SITUATION, the control system shall stop a running anticoagulant delivery with the stopping of the blood pump during the treatment due to an OPERATOR control input or due to a PROTECTIVE SYSTEM stopping the blood pump, and shall restart ongoing anticoagulant delivery on ALARM CONDITION recovery or resumption of treatment.

~~NOTE 1 The user can be able to start or stop the anticoagulation means independently of the blood pump.~~

NOTE 1 If the blood pump is running, it would be helpful for the user to be able to stop or start the anticoagulation means manually.

NOTE 2 ~~In some treatment situations, it can be desirable~~ The HAEMODIALYSIS EQUIPMENT can provide an automated function to stop anticoagulation for a specified time period prior to ending the treatment.

The MANUFACTURER'S RISK MANAGEMENT PROCESS shall take into consideration at least the following HAZARDOUS SITUATIONS, if applicable.

– Stopping or missing start of any anticoagulant delivery means.
– Improper dosing of the anticoagulant solution(s) by first fault of the anticoagulant delivery means, for example delivery rate(s), delivery rate(s) ratio, delivery rate(s) ratio versus blood flow rate.
– Improper dosing of the anticoagulant solution under negative pressure conditions in the EXTRACORPOREAL CIRCUIT in the case an anticoagulant delivery means doses upstream of the blood pump.
– ~~Interconnecting~~Interchanging of solutions by mistake, if more than one anticoagulant solution is used for anticoagulation within one treatment.

– Air infusion or unintended anticoagulant solution fluid flow via the arterial PATIENT CONNECTION because of wrong delivery rate or delivery while the blood pump is not running, especially in the case an anticoagulant delivery means doses upstream of the blood pump.

– Air infusion or unintended anticoagulant solution fluid flow via the venous PATIENT CONNECTION because of wrong delivery rate or delivery while the blood pump is not running, especially in the case an anticoagulant delivery means doses downstream the air detector.

– Blood loss by reversal of anticoagulant solution fluid flow(s) by first fault of the anticoagulant delivery means or by improper fixture of the syringe plunger(s).

– Improper setting of anticoagulation parameters against prescription values.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and by functional tests.

201.12.4.4.107 PROTECTIVE SYSTEMS

All PROTECTIVE SYSTEMS shall be active throughout treatment, when the blood from the EXTRACORPOREAL CIRCUIT reaches the PATIENT until when the venous needle is disconnected. Additionally, the PROTECTIVE SYSTEMS for DIALYSIS FLUID composition and temperature shall be activated before the first contact of DIALYSIS FLUID with blood in the DIALYSER.

A delayed activation of PROTECTIVE SYSTEMS following the start or restart of the treatment is possible if it does not cause a HAZARDOUS SITUATION.

A failure of the PROTECTIVE SYSTEMS required by 201.12.4.4.101 to 201.12.4.4.105 shall become obvious to the OPERATOR within the following time limits:

a) for all PROTECTIVE SYSTEMS except 201.12.4.4.105 (air infusion):

   – at least once per day or, if this is not possible, as determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS;

     NOTE For example, acceptable methods of complying with this requirement are:

     • periodic functional check of the PROTECTIVE SYSTEMS, requested by the HAEMODIALYSIS EQUIPMENT, initiated and controlled by the OPERATOR;

     • periodic functional check of the PROTECTIVE SYSTEMS, requested by the HAEMODIALYSIS EQUIPMENT, initiated by the OPERATOR and controlled by the HAEMODIALYSIS EQUIPMENT;

     • redundancy of the PROTECTIVE SYSTEMS with self-checking by the HAEMODIALYSIS EQUIPMENT;

     • periodic functional check of the PROTECTIVE SYSTEMS initiated by the HAEMODIALYSIS EQUIPMENT and controlled by the HAEMODIALYSIS EQUIPMENT, if the control function ~~of the PROTECTIVE SYSTEM~~ is designed such that it cannot fail simultaneously with the corresponding PROTECTIVE SYSTEM by a single failure.

b) for the PROTECTIVE SYSTEM required by 201.12.4.4.105 (air infusion):

   – if an amount of air can be infused to the PATIENT which ~~may~~ can cause a HAZARDOUS SITUATION as a result of a first fault of the air detector, the maximum detection time for this fault is calculated as the fault tolerance time;

   – the minimum volume of the EXTRACORPOREAL CIRCUIT between the position of the air detector and the venous cannula, divided by the highest blood flow rate;

   – in all other cases, a) applies.

Every failure of a PROTECTIVE SYSTEM required by 201.12.4.4 shall inhibit the corresponding function supervised by the pertaining PROTECTIVE SYSTEM. This shall be indicated to the OPERATOR.

Compliance is checked by functional tests and failure simulations.

201.12.4.4.108 * Prevention of contamination by chemicals

a) It shall not be possible to treat the PATIENT while the HAEMODIALYSIS EQUIPMENT is in the cleaning, sterilization or disinfection mode. Subclauses 4.7 and 11.8 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 apply.

B) Chemicals (e.g. water, DIALYSIS FLUID, disinfectant or DIALYSIS FLUID CONCENTRATE) shall not flow from the HAEMODIALYSIS EQUIPMENT reverse to any supply line, even under SINGLE FAULT CONDITION.

c) Erroneous connection of disinfectant, specified by the MANUFACTURER for use with the HAEMODIALYSIS EQUIPMENT, instead of DIALYSIS FLUID CONCENTRATE shall not cause a HAZARDOUS SITUATION.

Compliance is checked by functional tests, failure simulations and inspection of the RISK MANAGEMENT FILE.

201.12.4.4.109 * Blood pump(s) and~~/or~~, if applicable, SUBSTITUTION FLUID pump(s) reversal

A method shall be included to prevent inadvertent reversal of the blood and~~/or~~, if applicable, SUBSTITUTION FLUID pump(s) during the treatment that ~~may~~ can cause a HAZARDOUS SITUATION.

The applicable HAZARDOUS SITUATIONS (e.g. air infusion via the arterial bloodline) ~~have to~~ shall be determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS. USE ERRORS as well as technical failures ~~have to~~ shall be taken into account.

Compliance is checked by inspection and by functional tests.

201.12.4.4.110 Selection and change of operation modes

Inadvertent selection and change of operation modes shall be prevented. USE ERRORS, as well as technical failures, ~~have to~~ shall be taken into account.

Compliance is checked by inspection and by functional tests.

201.12.4.4.111 ONLINE HDF and ONLINE HF

If the HAEMODIALYSIS EQUIPMENT is intended for ONLINE HAEMOFILTRATION (ONLINE HF), ONLINE HAEMODIAFILTRATION (ONLINE HDF) or online preparation of other infusion or rinsing fluids (e.g. online bolus application or online priming the EXTRACORPOREAL CIRCUIT), the MANUFACTURER shall ensure that the HAEMODIALYSIS EQUIPMENT shall be capable of producing SUBSTITUTION FLUID that complies with the requirements (e.g. microbiological, see ISO 23500-5 [7], and ISO 23500-1 [6]) for a solution intended ~~for intravenous applications~~ to be infused directly in the patients' blood when the MANUFACTURER'S instructions are followed. This requirement shall also be complied with under SINGLE FAULT CONDITION according to the MANUFACTURER'S RISK MANAGEMENT PROCESS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and by functional tests.

201.13 Hazardous situations and fault conditions for ME EQUIPMENT

Clause 13 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.13.2.6 * Leakage of liquid

Addition:

The liquid-carrying parts of the HAEMODIALYSIS EQUIPMENT shall be ~~so shielded against the electrical parts~~ constructed such that liquid which ~~may~~ can leak under normal working pressure does not lead to the PATIENT being exposed to HAZARDS caused by contact with electrical parts, for example due to short-circuiting of CREEPAGE DISTANCES.

Compliance is checked by the following test:

a) by means of a pipette, drops of potable water are applied to couplings, to seals and to tubings which might rupture, moving parts being in operation or at rest, whichever is least favourable;

and in case of doubt in test a):

b) by means of a syringe, a jet of an appropriate liquid for the part of the HAEMODIALYSIS EQUIPMENT is directed from couplings, from seals and from tubings which might rupture, moving parts being in operation or at rest, whichever is the least favourable.

After these PROCEDURES, the HAEMODIALYSIS EQUIPMENT shall show no signs of wetting of uninsulated electrical parts or of electrical insulation which is liable to be adversely affected by potable water or the selected liquid. In case of doubt, the HAEMODIALYSIS EQUIPMENT shall be subjected to the dielectric strength test specified in 8.8.3 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

The determination of other HAZARDS and HAZARDOUS SITUATIONS is checked by inspection of the HAEMODIALYSIS EQUIPMENT.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.14.13 * PEMS intended to be incorporated into an IT-NETWORK

Addition:

Data transfer between an IT-NETWORK and the HAEMODIALYSIS EQUIPMENT shall not cause a HAZARDOUS SITUATION to the PATIENT under SINGLE FAULT CONDITION.

NOTE 101 Independent of this document, IEC 80001-1:2021 [8] includes requirements, that every MEDICAL DEVICE MANUFACTURER to make available ACCOMPANYING DOCUMENTS to the RESPONSIBLE ORGANIZATION with information about the IT-NETWORK capabilities of the MEDICAL DEVICE.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

Additional subclause:

201.14.13.101 * Specific security features for HAEMODIALYSIS EQUIPMENT used in MEDICAL IT-NETWORKS

HAEMODIALYSIS EQUIPMENT used in MEDICAL IT-NETWORKS shall contribute to safe operation related to SECURITY (CYBERSECURITY).

This can be fulfilled beside other alternative ways by following the recommendations in the technical report IEC TR 60601-4-5:2021 [9], which gives a guidance in establishing safety-related technical SECURITY (CYBERSECURITY) specifications. This document also encourages the particular standard writers to include basic guidance for determining specific SECURITY (CYBERSECURITY) features for MEDICAL DEVICES by the MANUFACTURERS (Subclause 4.6.3) regarding the specific intended use environments of the MEDICAL DEVICES covered by the particular standard.

If IEC TR 60601-4-5:2021 is used, SECURITY COUNTERMEASURES as specified in Clauses 4 to 7 should be implemented as appropriate, with following specific additions to Subclause 4.6.3 regarding the dialysis specific intended use environments:

– IEC TR 60601-4-5:2021, 4.6.3: "*beside BASIC SAFETY and ESSENTIAL PERFORMANCE, the required product group appropriate ESSENTIAL FUNCTION (e.g. AVAILABILITY in case of ongoing SECURITY attacks on the MEDICAL IT-NETWORK and the connected devices) even with temporarily reduced IT functionality of the MEDICAL DEVICE*"

  Normally, dialysis treatments are performed in an access controlled clinical or home environment under continuous supervision during treatments, where the risk of physical attacks is limited. Regarding this, during or after attacks via the MEDICAL IT-NETWORK or wireless connections to the HAEMODIALYSIS EQUIPMENT, it is recommended, that the operator is able to restart the treatment without IT/wireless connection including disabling of IT/wireless functionality to perform basic treatments with the possibility to set or recall the patient individual ESSENTIAL PERFORMANCE parameters of this document (201.4.3.101) in an offline scenario on the HAEMODIALYSIS EQUIPMENT.

– IEC TR 60601-4-5:2021, 4.6.3: *"specific appropriate FIRECALL functions for emergency access to have the possibility to override SECURITY measures and how they are managed (e.g. by logging, information signalling, alarming) in cases of intentional overriding a SECURITY measure due to higher priority SAFETY needs*"

  Due to the access controlled clinical or home environments with continuous supervision during treatments, HAEMODIALYSIS EQUIPMENT normally do not require authentication or authorization procedures for standard treatment access. Therefore, no additional FIRECALL functions beside the option to disconnect the attacked network access (including wireless connections) are needed.

  If authentication for operators to operator accessible treatment settings is in place for the user interface, a FIRECALL function should be able to overrule that operator authentication combined with a log entry protected against modifications by the operator. IT-NETWORKS interfaces including those for remote access typically require authentication but should not include FIRECALL functions as an operator is always close to the HAEMODIALYSIS EQUIPMENT and to the patient.

– IEC TR 60601-4-5:2021, 4.6.3: *"appropriate minimum target SECURITY LEVEL SL-T for all INTENDED USE environments including the network integrations normally existing in these use environments in which the ME EQUIPMENT is typically used. If SECURITY LEVELS for the use environments are defined by other documents, they should be taken into account and referenced*"

  Based on the intended use environments and designs OF HAEMODIALYSIS EQUIPMENT, the following target SECURITY LEVEL SL-T can be assumed as appropriate:

  - Not connected home HAEMODIALYSIS EQUIPMENT: SL1 – Protection against casual or coincidental violation;
  - HAEMODIALYSIS EQUIPMENT in a dialysis station or clinical environment not connected or connected in a clinic network separated from the public network: SL2 – Protection against intentional violation using simple means with low resources, generic skills and low motivation;
  - HAEMODIALYSIS EQUIPMENT in a dialysis station or clinical environment connected in a clinic network not separated from the public network/internet or contain wireless communication: SL3 – Protection against intentional violation using sophisticated means with moderate resources, IACS specific skills and moderate motivation;
  - Internet connected home HAEMODIALYSIS EQUIPMENT: SL4 – Protection against intentional violation using sophisticated means with extended resources, IACS specific skills and high motivation.

  NOTE Authentication of operators is normally not needed for the physical user interface, only for remote access via data interfaces.

A SL-T of SL2 or better for secure updates or restorage of software, remotely or locally, is recommended.

Compliance is checked by inspection and functional testing.

NOTE For further information how to use above information to implement adequate MEDICAL DEVICE SECURITY COUNTERMEASURES, refer to the IEC TR 60601-4-5:2021[9] itself.

201.15 Construction of ME EQUIPMENT

Clause 15 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.15.4 ME EQUIPMENT components and general assembly

Additional subclauses:

201.15.4.101 EXTRACORPOREAL CIRCUIT or other single-use components

If an incorrect installation of the EXTRACORPOREAL CIRCUIT (or of other single-use components) can cause a HAZARDOUS SITUATION to the PATIENT, means shall be provided to ensure the correct installation of the EXTRACORPOREAL CIRCUIT (or of other single-use components) to the HAEMODIALYSIS EQUIPMENT.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and of the HAEMODIALYSIS EQUIPMENT.

NOTE To assess non-interconnectable characteristics of small-bore connectors based on their inherent design and dimensions in order to reduce the RISK of misconnections between HAEMODIALYSIS EQUIPMENT and ACCESSORIES, see ISO 80369-1:2018 [10].

201.15.4.1 Construction of connectors

Additional subclauses:

201.15.4.1.101 * DIALYSIS FLUID CONCENTRATE connectors

The various DIALYSIS FLUID CONCENTRATE supply containers and cleaning solutions should be differentiated by mechanical connections to the DIALYSIS FLUID CONCENTRATE connectors of the HAEMODIALYSIS EQUIPMENT or shall be permanently colour marked (see ISO 23500-4 [3]).

The HAEMODIALYSIS EQUIPMENT shall additionally prevent a mix-up of the various DIALYSIS FLUID CONCENTRATES and cleaning solutions which ~~may~~ can cause a HAZARDOUS SITUATION for the PATIENT, by mechanical differentiation of the connectors or by colour coding of the connectors.

NOTE 1 The use of various DIALYSIS FLUID CONCENTRATES presents a problem in that connection of the wrong DIALYSIS FLUID CONCENTRATE can cause a HAZARDOUS SITUATION to the PATIENT. The design of connectors and colour coding were recognized as methods to minimize this RISK. There is always a residual RISK that the OPERATOR will cause a HAZARDOUS SITUATION by not following the MANUFACTURER's instructions for use.

The MANUFACTURER should make every effort to minimize the possible mix-up in the connection of DIALYSIS FLUID CONCENTRATES.

The following colours shall be used for DIALYSIS FLUID CONCENTRATE connectors:

– the connector for acetate shall be white;
– the connector for acidic component in bicarbonate dialysis shall be red;
– the connector for bicarbonate component in bicarbonate dialysis shall be blue;
– for common usage of one connector for different DIALYSIS FLUID CONCENTRATES, on the HAEMODIALYSIS EQUIPMENT the respective coloured markings shall be affixed on that connector. For example, a common connector for acetate and acidic DIALYSIS FLUID CONCENTRATE shall be marked white/red.

Compliance is checked by inspection.

NOTE 2 ISO 23500-4 [3], gives requirements for the colour coding of DIALYSIS FLUID CONCENTRATE containers.

201.15.4.1.102 * Connectors for blood pressure transducers

Any HAZARDS to the PATIENT, such as blood loss, air infusion or cross contamination, shall be taken into account in the MANUFACTURER'S RISK MANAGEMENT PROCESS.

Compliance is checked by functional tests and inspection of the RISK MANAGEMENT FILE.

201.16 * ME SYSTEMS

Clause 16 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.16.1 General requirements for the ME SYSTEMS

Addition:

ME SYSTEMS have not yet been examined comprehensively with regard to the whole field of dialysis in this particular standard. Application of RISK MANAGEMENT with consideration of ME SYSTEMS is therefore also recommended for MANUFACTURERS of HAEMODIALYSIS EQUIPMENT, since definite identification of a particular MANUFACTURER of the complete ME SYSTEM is often not possible in a dialysis clinic (see Informative Annex Subclause A.4, 4.2 and 16.1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020).

201.16.2 ACCOMPANYING DOCUMENTS of an ME SYSTEM

d) advice to the RESPONSIBLE ORGANIZATION

Addition:

– a listing of HAZARDOUS SITUATIONS (e.g. increased LEAKAGE CURRENTS) and possible protective measures when HAEMODIALYSIS EQUIPMENT is connected to CENTRAL DELIVERY SYSTEMS, DIALYSIS WATER supply systems or other fluid-carrying central systems.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.16.6.3 PATIENT LEAKAGE CURRENT

Addition:

NOTE Possible methods for reducing PATIENT LEAKAGE CURRENTS are the utilization of conductive rings in CENTRAL DELIVERY SYSTEMS and central DIALYSIS WATER supply systems or ensuring that all connection points of the dialysis unit have the same potential and are PROTECTIVELY EARTHED (see ISO 11197 [11]).

201.16.9.1 * Connection terminals and connectors

Addition:

– The connectors on the CENTRAL DELIVERY SYSTEMS for DIALYSIS FLUID CONCENTRATES shall be permanently colour marked. See 201.15.4.1.101.

– Additional markings shall be affixed such that the OPERATOR can easily assign the DIALYSIS FLUID CONCENTRATE to the appropriately marked DIALYSIS FLUID CONCENTRATE connectors of the CENTRAL DELIVERY SYSTEMS for DIALYSIS FLUID CONCENTRATES.

Compliance is checked by inspection.

201.17 ELECTROMAGNETIC COMPATIBILITY of ME EQUIPMENT and ME SYSTEMS

Clause 17 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

202 Electromagnetic disturbances – Requirements and tests

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply except as follows:

202.8 Electromagnetic IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS

202.8.1 * General

Addition:

The following IMMUNITY pass/fail criteria for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to EM DISTURBANCES shall be met by HAEMODIALYSIS EQUIPMENT:

– BASIC SAFETY functions listed in 201.12: The ME EQUIPMENT or ME SYSTEM BASIC SAFETY shall continue to operate as intended without OPERATOR intervention. No degradation of BASIC SAFETY function is allowed below a performance level specified by the MANUFACTURER when the ME EQUIPMENT or ME SYSTEM is used as intended. Alternatively, the ME EQUIPMENT or ME SYSTEM shall reach and remain in the safe state ~~of the device~~.

– ESSENTIAL PERFORMANCE functions: After the test, the ME EQUIPMENT or ME SYSTEM shall continue to operate as intended without OPERATOR intervention. During the test, degradation of performance is allowed, but no degradation of performance is allowed below a performance level specified by the MANUFACTURER, when the ME EQUIPMENT or ME SYSTEM is used as intended.

– Other functions: Loss of function is allowed, provided the function is self-recoverable, or can be restored by the operation of the controls by the OPERATOR in accordance with the MANUFACTURER'S instructions.

NOTE 101 A HAEMODIALYSIS EQUIPMENT is not considered to be a life-supporting equipment or system, since a premature termination of the dialysis treatment is not likely to lead to serious injury or death of a PATIENT.

202.8.9 IMMUNITY TEST LEVELS

Addition:

NOTE 101 HAEMODIALYSIS EQUIPMENT is normally used in the following EMC environments:

- professional healthcare facility environment (e.g. dialysis centres, intensive care units or dialysis departments in hospitals or self-care environments);
- HOME HEALTHCARE ENVIRONMENT (e.g. home or portable dialysis).

208 General requirements, tests and guidance for ALARM SYSTEMS in MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS

IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 apply except as follows:

208.4 * General requirements

Addition:

If the INTENDED USE of the HAEMODIALYSIS EQUIPMENT includes the intensive care or surgery environment, it is acceptable to implement additional ALARM SYSTEMS deviating from

IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 in the following subclauses:

- 6.1.2 Determination of ALARM CONDITIONS and assignment of priority;
- 6.3.2.2 Characteristics of visual ALARM SIGNALS;
- 6.3.3.1 Characteristics of auditory ALARM SIGNALS.

If the INTENDED USE of the HAEMODIALYSIS EQUIPMENT includes the intensive care or surgery environment and additional ALARM SYSTEMS deviating from IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 are implemented, then

a) the ALARM SYSTEM according to IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020should be the MANUFACTURER default setting. If the ALARM SYSTEM according to IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 is not the MANUFACTURER default setting, the ACCOMPANYING DOCUMENTS shall include a statement about these MANUFACTURER default settings;

b) only the RESPONSIBLE ORGANIZATION shall be able to change the ALARM SYSTEM.

The paragraph d) 1) i) in Subclause 6.3.3.1 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD2:2020 is not applicable in the context of this document.

Compliance is checked by functional tests.

NOTE 1 Table AA.1 shows an example of ALARM CONDITION priorities according to IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, 6.1.2, adapted for HAEMODIALYSIS EQUIPMENT needs.

If the INTENDED USE of the HAEMODIALYSIS EQUIPMENT does not include the intensive care or surgery environment, the following subclauses of IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 are not mandatory:

- 6.1.2 Determination of ALARM CONDITIONS and assignment of priority;
- 6.3.2.2 Characteristics of visual ALARM SIGNALS;
- 6.3.3.1 Characteristics of auditory ALARM SIGNALS.

NOTE 2 Subclause 7.8.1 Colours of indicator lights of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, but the urgency of the response of the OPERATOR can have other than PATIENT-centric causes. The changes introduced by this addition are transferable to Subclause 7.8.1.

NOTE 3 If a COMMUNICATOR is equipped with additional set of auditory ALARM SIGNALS to comply with this subclause, it is optional to implement auditory ALARM SIGNALS compliant to Annex G of IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020.

208.5.2.1 Instructions for use

Addition:

NOTE 101 In the listing and description of every possible ALARM CONDITION only the conditions ~~need to be written~~ with a remaining HAZARDOUS SITUATION beside the safe state of the HAEMODIALYSIS EQUIPMENT are sufficient.

208.6.3 Generation of ALARM SIGNALS

208.6.3.1 * General

Addition:

Unless otherwise specified by this particular standard, both auditory and visual ALARM SIGNALS shall be activated. The visual ALARM SIGNAL shall remain activated for the entire duration of the ALARM CONDITION, whereas AUDIO PAUSING the auditory ALARM SIGNAL for the amount of time specified in 208.6.3.3.101 ~~b~~a) is allowed.

Compliance is checked by functional tests.

208.6.3.3 Auditory ALARM SIGNALS

208.6.3.3.2 * Volume and characteristics of auditory ALARM SIGNALS and INFORMATION SIGNALS

Replacement:

~~In the initial setting by the MANUFACTURER, the HAEMODIALYSIS EQUIPMENT shall generate a sound pressure level of at least 65 dB(A) at a distance of 1 m at the position of maximum sound pressure level in the horizontal plane passing through the geometric centre of the front of the part of the HAEMODIALYIS EQUIPMENT that contains the auditory ALARM SIGNAL generating device.~~

In the out of factory setting by the MANUFACTURER, for all the auditory ALARM SIGNALS, the HAEMODIALYSIS EQUIPMENT shall generate a sound pressure level of at least 65 dB(A) at a distance of 1 m from the HAEMODIALYSIS EQUIPMENT and at a position specified by the MANUFACTURER.

Compliance is checked by measuring the A-rated sound pressure level and the time weighting F of the sound level meter (i.e. LAF_{max}) with instruments meeting the requirements for measuring instruments of class 1 according to IEC 61672-1:2013 and free field conditions as specified in ISO 3744:2010, but only in above specified position.

208.6.3.3.3 OPERATOR-adjustable sound pressure level

Addition:

If the RESPONSIBLE ORGANIZATION can reduce the auditory ALARM SIGNAL volume to zero, there shall be an alternative means, for example a DISTRIBUTED ALARM SYSTEM, to notify the OPERATOR in an ALARM CONDITION even under SINGLE FAULT CONDITION.

Additional subclause:

208.6.3.3.101 * Special characteristics of auditory ALARM SIGNALS for HAEMODIALYSIS EQUIPMENT

Auditory ALARM SIGNALS shall meet the following requirements.

a) ~~If it is possible to pause the auditory ALARM SIGNAL,~~ It shall only be possible to inactivate ALARM SIGNALS by using AUDIO PAUSED. The AUDIO PAUSED period shall not exceed 3 min.

   ~~Exception:~~ For ALARM SIGNALS as described in 201.12.4.4.101 (DIALYSIS FLUID composition) or 201.12.4.4.102 (DIALYSIS FLUID and SUBSTITUTION FLUID temperature), the AUDIO PAUSED period shall not exceed 10 min.

   NOTE 1 During the preparation phase or during an intended interruption of treatment, when no patient is connected, audible ALARM SIGNALS can be inactivated.

   NOTE 2 For other ALARM SIGNALS, not addressed within the Subclauses 201.12.4.4, the requirement of IEC 60601-1-8 applies, unless differently specified by the subclause itself (e.g., 201.11.8).

b) If, during an AUDIO PAUSED period, another ALARM CONDITION occurs requiring the immediate response by the OPERATOR to prevent any HAZARDOUS SITUATION, then the AUDIO PAUSED period shall be interrupted.

Compliance is checked by functional tests.

208.6.8.4 Termination of inactivation of ALARM SIGNALS

Delete the first paragraph / sentence.

209 Requirements for environmentally conscious design

IEC 60601-1-9:2007, IEC 60601-1-9:2007/AMD1:2013 and IEC 60601-1-9:2007/AMD2:2020 do not apply.

NOTE IEC 60601-1-9 does not include significant content relating to BASIC SAFETY and ESSENTIAL PERFORMANCE for PATIENTS and OPERATORS in the field of HAEMODIALYSIS.

210 Requirements for the development of PHYSIOLOGIC CLOSED-LOOP CONTROLLERS

IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020 apply, with the following addition:

Annex A – General guidance and rationale

A.2 Rationale for particular clauses and subclauses

Definition 3.20 – PHYSIOLOGIC CLOSED-LOOP CONTROLLER

Addition:

Physiological parameters are, for example, blood temperature, blood pressure, pulse and haematocrit. The controller in the control circuit compares the physiological parameter with a reference value and, using the resulting difference, varies a control signal that affects the variable quantities, such as ULTRAFILTRATION rate, DIALYSIS FLUID composition and temperature.

211 * Requirements for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS used in the HOME HEALTHCARE ENVIRONMENT

IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020 apply, with the following addition:

211.6 Classification of ME EQUIPMENT and ME SYSTEMS

Addition:

NOTE 1 IEC 60601-1-11 allows CLASS I ME EQUIPMENT in the HOME HEALTHCARE ENVIRONMENT only when specific additional measures are implemented.

Instead of a PERMANENTLY INSTALLED connection to SUPPLY MAINS, the same level of safety may be achieved by a unique MAINS PLUG connector with a corresponding unique MAINS PLUG outlet that is not normally available in the HOME HEALTHCARE ENVIRONMENT.

NOTE 2 This principle can also be applied to other electrical components of the HAEMODIALYSIS ME SYSTEM, for example the water treatment system.

Annexes

The annexes of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 apply, except as follows:

Annex G
(normative)

Protection against hazards of ignition of flammable anaesthetic mixtures

Annex G of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 does not apply.

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

Clause A.1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclauses in this document, with clause and subclause numbers parallel to those in the body of the document.

Subclause 201.1.1 – Scope

The relevant parts of this document ~~may~~ can be applied to other ME EQUIPMENT intended for extracorporeal blood purification treatments beside HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION ~~treatment to a PATIENT, for example suffering from kidney failure~~, if no other specific particular standard exists. Examples of such blood purification treatments are plasmafiltration, hemoperfusion, apheresis, adsorption or liver dialysis. Relevant are for example all contents about the safety of the blood processing system and the EXTRACORPOREAL CIRCUIT.

Safety details of dialysis fluid control systems of haemodialysis equipment using regeneration of dialysis fluid or central delivery systems for dialysis fluid should be part of the manufacturer's risk management process.

The AAMI Renal Disease and Detoxification committee has developed a technical information report on sorbent-based regenerative HAEMODIALYSIS EQUIPMENT. (AAMI TIR 77 [12]).

Subclause 201.3.8 – APPLIED PART

The PATIENT is in direct contact with the HAEMODIALYSIS EQUIPMENT and could be in contact with the ME SYSTEM via fluids or electrical connections. In order to determine the PATIENT LEAKAGE CURRENTS, it is also important to consider the parts of the ME SYSTEM or non-ME SYSTEM coming into direct or indirect contact with the PATIENT e.g. via the OPERATOR.

Refer also to Figure AA.8 in the rationale of Subclause 201.16 for a graphical representation of APPLIED PARTS.

For HAEMODIALYSIS EQUIPMENT, the blood lines of the EXTRACORPOREAL CIRCUIT are not considered to be insulating, indeed, it should be assumed that conducting solutions in and around the tubing establish an electrical contact with the patient.

An EXTRACORPOREAL CIRCUIT or DIALYSIS FLUID circuit is considered isolating if:

a) the material is electrically isolating, and

b) the circuit is built such that a rupture is sufficiently unlikely.

Point a) is tested by applying 1 500 V AC to the relevant segments of the circuit, filled with 0,9 % NaCl. A conductive foil is wrapped over the tube over a length of 10 cm. No breakthrough between foil and fluid should occur over 1 min.

Point b) is demonstrated by the RISK MANAGEMENT of the MANUFACTURER of the EXTRACORPOREAL CIRCUIT, which should include the interface between the HAEMODIALYSIS EQUIPMENT and the circuit and the manufacturing PROCESS (e.g. see requirements of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Subclause 4.9).

Subclause 201.3.202 – BLOOD LEAK

Blood appears in the DIALYSIS FLUID compartment only if there is a pressure gradient from the blood compartment to the DIALYSIS FLUID compartment and a rupture in the semi-permeable membrane in the DIALYSER.

The BLOOD LEAK detector detects a rupture of the semi-permeable membrane only if the blood volume entering the DIALYSIS FLUID exceeds the threshold value of the BLOOD LEAK detector. This threshold depends on the flow rate in the DIALYSIS FLUID circuit because the leaked blood volume dilutes into the DIALYSIS FLUID stream.

Subclause 201.3.~~210~~211 – HAEMODIALYSIS EQUIPMENT

~~The type of HD, HDF and HF equipment can be classified as HAEMODIALYSIS EQUIPMENT with or without preparation of DIALYSIS FLUID.~~

HD, HDF and HF equipment can be designed as HAEMODIALYSIS EQUIPMENT with integrated preparation of DIALYSIS FLUID or without integrated preparation of DIALYSIS FLUID.

HAEMODIALYSIS EQUIPMENT with integrated preparation of DIALYSIS FLUID usually requires a water treatment system (RO system) and ~~may~~ can also be connected to a CENTRAL DELIVERY SYSTEM for DIALYSIS FLUID CONCENTRATE.

HAEMODIALYSIS EQUIPMENT without integrated preparation of DIALYSIS FLUID can use pre-manufactured DIALYSIS FLUID bags.

HAEMODIALYSIS EQUIPMENT can consist of a CENTRAL DELIVERY SYSTEM DIALYSIS FLUID delivery together with the corresponding individual dialysis console(s).

HAEMODIALYSIS EQUIPMENT can consist of a batch treatment HAEMODIALYSIS EQUIPMENT filled with the entire DIALYSIS FLUID prior to the treatment and the corresponding DIALYSIS FLUID preparation unit, which can be a separate device or integrated with the treatment HAEMODIALYSIS EQUIPMENT.

HDF HAEMODIALYSIS EQUIPMENT can also be used for performing the HD or HF treatment PROCEDURES. The treatment PROCEDURE is then defined by the ACCESSORIES and the setting parameters.

Subclause 201.3.~~213~~214 and 201.3.~~214~~215 – ONLINE HDF and ONLINE HF

According to the state of the art, the SUBSTITUTION FLUID is produced from the DIALYSIS FLUID produced by the HAEMODIALYSIS EQUIPMENT. The PROCESS comprises microbiological filtering and delivery into the EXTRACORPOREAL CIRCUIT.

Subclause 201.3.~~215~~216 – PROTECTIVE SYSTEM

See reference [28]. The authors point out that HAEMODIALYSIS EQUIPMENT comprises redundancy or PROTECTIVE SYSTEMS in addition to control systems. A ~~HAZARD (editors comment: HARM)~~ to the PATIENT is only possible if the control system and the PROTECTIVE SYSTEM both fail. The likelihood for any of these systems to fail is less than 10^{-4} per hour resulting in a combined likelihood of less than 10^{-8} per hour. This observation was made by the first author in the mid-1980s based on quality feedback data from ~ 3 000 HAEMODIALYSIS EQUIPMENT and is

corroborated by the low number of serious accidents caused by HAEMODIALYSIS EQUIPMENT malfunction in the US where accident reports are published by the FDA.

Subclause 201.3.~~218~~219 – ULTRAFILTRATION

In HF or HDF treatment, ULTRAFILTRATION should not be confused with the reduction in the PATIENT'S weight (NET FLUID REMOVAL), because in this PROCEDURE, the volume equivalent to the SUBSTITUTION FLUID flow also flows across the DIALYSER membrane.

ULTRAFILTRATION rate = NET FLUID REMOVAL rate + SUBSTITUTION FLUID flow rate.

Subclause 201.4.3 – Essential performance

The following general philosophy for the definition of test PROCEDURES for ESSENTIAL PERFORMANCE items was applied.

When defining the test PROCEDURES, it was the opinion of the committee that a safety standard for HAEMODIALYSIS EQUIPMENT should not duplicate what is common knowledge in test laboratories with good laboratory practice, for example:

– selection of a suitable method of measurement (e.g. flow measurement by flow meter or by volume and time);
– the use of instruments with sufficient accuracy;
– the use of calibrated instruments.

Therefore, the test PROCEDURES contain only the basic information needed for testing HAEMODIALYSIS EQUIPMENT.

When ESSENTIAL PERFORMANCE deviates from its expected NORMAL CONDITION tolerance due to a SINGLE FAULT CONDITION, risk mitigations for example can be:

– Description in the instruction for use of possible deviations from the ESSENTIAL PERFORMANCE specification due to a SINGLE FAULT CONDITION not reaching the PROTECTIVE SYSTEM ALARM LIMITS (for example, blood flow rate lower than the tolerance due to unexpected pump segment degradation);
– Information messaging on the user interface of possible deviations from the ESSENTIAL PERFORMANCE specification due to a SINGLE FAULT CONDITION not reaching the PROTECTIVE SYSTEM ALARM LIMITS (for example, temperature deviating from the set value);
– Alarming by activation of a PROTECTIVE SYSTEM (for example, conductivity deviating from the expected value).

With respect to the Subclauses 4.3 and 4.7 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 including the IEC 60601-1:2005/AMD1:2012/ISH1:2021, the specified performance limits can be different in NORMAL CONDITION and SINGLE FAULT CONDITION.

Regarding ESSENTIAL PERFORMANCE in NORMAL CONDITION tests according to IEC 60601-1:2005/AMD1:2012//ISH1:2021 items 4.3 dd), representative functional tests are given in Subclauses 201.4.3.

Regarding ESSENTIAL PERFORMANCE in SINGLE FAULT CONDITION tests according to IEC 60601-1:2005/AMD1:2012/ISH1:2021 items 4.7 dd), representative tests are given in Subclauses 201.12.4.4.101 to 201.12.4.4.105.

If different modes can impact the tests (e.g. double needle, single needle, low weight patients), the tests shall be repeated for each mode or the worst case shall be identified by the MANUFACTURER.

Subclause 201.4.3.101 – Additional ESSENTIAL PERFORMANCE requirements

The ESSENTIAL PERFORMANCE for HAEMODIALYSIS EQUIPMENT was determined with the following aspects taken into account: on one hand, all parameters required for the therapeutic effectiveness of the PROCEDURE should be included; on the other hand, definition of more parameters than necessary should be avoided, because the ESSENTIAL PERFORMANCE ~~has to~~ shall be complied even under the irradiation conditions of the ELECTROMAGNETIC COMPATIBILITY – (EMC) IMMUNITY test. The observation and documentation of a great number of ESSENTIAL PERFORMANCE features would cause impractically high time and cost expenditures during the EMC test. The list of ESSENTIAL PERFORMANCE features defined here is a compromise between these two contrary aspects (see IEC 60601-1-2).

Since a standard cannot describe all possible special PROCEDURES modifying or expanding the classical dialysis PROCEDURE, this subclause involves merely a standard HAEMODIALYSIS EQUIPMENT. If special PROCEDURES require further parameters for therapeutic effectiveness or if parameters that are defined as ESSENTIAL PERFORMANCE in this document are not required, the list of ESSENTIAL PERFORMANCE features should be adjusted to the HAEMODIALYSIS EQUIPMENT concerned by the MANUFACTURER. The MANUFACTURER should list ESSENTIAL PERFORMANCES and appropriate rationales.

The MANUFACTURER can specify, beside the accuracy, the averaging period of the specific values, to cover small fluctuations that do not result in an unacceptable RISK.

Subclause 201.4.3.102, Note 1 – Blood flow rate

~~If peristaltic pumps are used, the blood flow rate may considerably decrease in case of high negative pressures on the suction side.~~

If the blood flow rate is measured collecting the blood fluid from the venous return line, an ongoing ultrafiltration can influence the measurement results. It is therefore advisable to set either the ultrafiltration to zero or to bypass the dialyzer (clamping the DIALYSIS FLUID lines or interconnecting the dialyzer inlet and outlet), or both.

Subclause 201.4.3.107 – DIALYSIS FLUID composition

Due to the complexity of determining the DIALYSIS FLUID composition, a simple solution practical for all kind of HAEMODIALYSIS EQUIPMENT has not been found to date.

~~The standard laboratory methods used for blood analysis may not be accurate enough for measurement of absolute values in DIALYSIS FLUID.~~

~~Ideas for determining the DIALYSIS FLUID composition are:~~

- ~~measurement by ion selective sensors;~~

~~NOTE The readings of blood gas analyzers (that use ion selective electrodes) calibrated for blood or plasma show systematic differences measuring ions in dialysate due to the different matrices. The bicarbonate readings are typically 3 mmol/l too low.~~

- ~~measurement of the dilution by adding a dye to the DIALYSIS FLUID CONCENTRATE. The optical absorption is measured before and after mixing;~~
- ~~theoretical calculation of conductivity, based on the known composition of the DIALYSIS FLUID CONCENTRATE. Create a systematic matrix of different dialysate compositions, for example:~~
  - ~~highest sodium with lowest bicarbonate;~~
  - ~~lowest sodium with highest bicarbonate;~~
  - ~~highest sodium with highest bicarbonate;~~
  - ~~lowest sodium with lowest bicarbonate;~~

~~measure the conductivities of the different dialysate compositions and compare the difference or the ratio of the measured and the theoretically derived conductivity values of each dialysate composition;~~

~~– measurement of conductivity and pH in order to distinguish the sodium from the bicarbonate.~~

Bicarbonate DIALYSIS FLUID is typically produced by the mixing of three components: the acid concentrate (sometimes referred to as acidified concentrate), the bicarbonate concentrate and the DIALYSIS WATER. Depending on the type of acidified concentrate in use, the acid component can be in the form of acetic acid, sodium di-acetate, citric acid or lactate.

It should also be noted that in the DIALYSIS FLUID the bicarbonate reacts with the acid and this results into a reduction of the bicarbonate.

Therefore, when specifying the DIALYSIS FLUID composition regarding bicarbonate, it is recommended that the MANUFACTURER indicates if the bicarbonate concentration refers to concentration pre or post reaction with the acid. See also ISO 23500-1:2024 [6], Clause B.6 Dialysis fluid proportioning.

In case the post-reaction values are specified, it should be noted that they can differ from that measured in the patients due to the metabolism of the acid component by the body: indeed, acetate and lactate are metabolized to bicarbonate in a 1:1 ratio, while citric acid generates bicarbonate in a 3:1 molar ratio. Therefore, the range for settable values should take this into account.

Moreover, during bicarbonate DIALYSIS, the patient's plasma bicarbonate concentration can never exceed the DIALYSIS FLUID concentration due to the dialysis process since excessive bicarbonate is dialyzed out.

Possible methods for the determination of the DIALYSIS FLUID composition include, but are not necessarily limited to:

– measurement by ion selective electrodes or sensors;
– measurement of electrolyte concentrations by flame photometry;
– measurement of the dilution following the addition of a dye to the DIALYSIS FLUID CONCENTRATE, by optical absorption before and after dilution;
– theoretical calculation of the conductivity based on the known composition of the DIALYSIS FLUID CONCENTRATE, using a systematic matrix of different DIALYSIS FLUID compositions, and comparing the difference or the ratio of the measured and the theoretically derived conductivity values of each dialysate composition. Example of a systematic matrix of different DIALYSIS FLUID compositions:
    - highest sodium with lowest bicarbonate;
    - lowest sodium with highest bicarbonate;
    - highest sodium with highest bicarbonate;
    - lowest sodium with lowest bicarbonate.

It should be noted that ion selective electrodes method and standard laboratory methods used for blood analysis could be not accurate enough for measurement of absolute values in DIALYSIS FLUID.

Accepted tolerances in respect of electrolytes and other chemical constituents of the DIALYSIS FLUID CONCENTRATE are given in ISO 23500-4:2019 [3], 4.1.1.2.

Depending on e.g. the mixing system of the DIALYSIS FLUID, additional tolerances shall be taken into account for a final accuracy specification of the DIALYSIS FLUID composition.

Subclause 201.7.8.2 – Colour of controls

Extracorporeal systems use red and blue indicators, symbols, and nomenclature to identify blood pump function and blood lines to and from the PATIENT. USABILITY improvements can be enabled with red blood pump controls.

Subclause 201.7.9.2.1, 1st hyphen – General

Each MANUFACTURER should define intended PATIENTs' weight limit values and their associated limitations: indeed, certain ESSENTIAL PERFORMANCE functions, such as NET FLUID REMOVAL, and PROTECTIVE SYSTEM limits are dependent on the PATIENT's weight (e.g., smaller values are intended for the paediatric population, such as neonate baby and infants, than for the adult population). The PATIENT's weight should also be considered for e.g. the SUBSTITUTION FLUID non-pyrogenicity, the BLOOD LEAK and the air infusion limits.

The definition of the minimum weight could lead to possible different approaches since the weight normally changes during the treatment.

Subclause 201.7.9.2.2, ~~6~~8th hyphen – Warning and safety notices

Because of counter current flow in the DIALYSER, backfiltration of DIALYSIS FLUID takes place in at least one part of the DIALYSER even in low-flux DIALYSERS (ULTRAFILTRATION coefficient < 10 ml/(h*mmHg)). If high-flux DIALYSERs are used, backfiltration cannot be avoided even by high ULTRAFILTRATION rates acceptable for fluid removal from the PATIENT.

The effect of backfiltration through an intact DIALYSER membrane is limited to the increased backtransport of larger molecules from the DIALYSIS FLUID to the blood. DIALYSIS FLUID does not contain such substances intentionally. In case of bacterial contamination, the DIALYSIS FLUID contains endotoxins and other bacterial cell debris. Intact endotoxin molecules are too large to pass through the membrane but they can split into smaller components. The molecular weight of lipid A, the active component causing pyrogenic reactions, has a molecular weight of ~ 2 000 mass units and will readily diffuse even through low-flux membranes. Other molecules causing adverse cell reactions in blood have even lower molecular weights.

Backfiltration only contributes less than 50 % to backtransport even for high-flux membranes under unfavourable conditions. Considering that bacterial and endotoxin contamination is scaled by orders of magnitudes, a factor of 2 is not relevant. "Avoiding" backfiltration by increasing TMP or ULTRAFILTRATION cannot be regarded as a sufficient measure to prevent backtransport. It is therefore necessary to avoid contamination of DIALYSIS FLUID by bacteria by using appropriate means.

The effect of backfiltration through structural leaks in the DIALYSER is usually limited to an amount not detected by the BLOOD LEAK detector. Because of the pulsating flow produced by a peristaltic blood pump, back and forward ULTRAFILTRATION will alternate in the DIALYSER. During the backfiltration phase, bacteria ~~may~~ can enter into the blood stream undetected. Assuming that the back-flow rate is 1 ml/min (three times larger than the typical sensitivity of a BLOOD LEAK detector), the hypothetical contamination of blood is 100 CFU/min (CFU means "colony-forming units"), if DIALYSIS WATER or DIALYSIS FLUID is according to ISO guidelines. It is extremely unlikely that such a small leak below the detection limit of the BLOOD LEAK detector will persist in a DIALYSER. Usually, small leaks close by clotting within a few minutes.

Subclause 201.7.9.2.2, ~~9~~11th hyphen – Warnings and safety notices

Haemolysis ~~may~~ can be caused by excessive shear which is the result of high blood flow rate through a narrow passage, especially when the flow becomes turbulent. Static pressure (–600 mmHg to +1 000 mmHg) does not cause haemolysis. Elevated pressures measured in the EXTRACORPOREAL CIRCUIT indicate increased flow resistance which ~~may~~ can cause subclinical haemolysis. Acute haemolysis has been reported to be caused by obstructions in the blood

tubing system downstream of the blood pump but upstream of the VENOUS PRESSURE monitor. Such obstructions are not detected by the VENOUS PRESSURE monitor. For a review of accident reports see reference [28], p. 328-332.

Subclause 201.7.9.2.2, 13th hyphen – Warnings and safety notices

In single-needle applications, depending on the applied connecting configuration, air can enter via the needle luer connector during the arterial phase and be infused back to patient in the venous phase without passing the air detector.

In central venous catheter applications, the respiration-induced intra-venous patient's pressure could lead to negative pressure at the catheter's inlet thus causing air infusion in case of not well tightened connection and this can happen without passing through the air detector.

Subclause 201.7.9.2.5, 7th hyphen, item c) – ME EQUIPMENT description

For Kt/V, applicable recommendations are, for example, KDOQI guidelines [15] and the European best practice guidelines for haemodialysis [31].

Subclause 201.7.9.2.12, 1st hyphen – Cleaning, disinfection and sterilization

ISO 17664 family ([16] and [33]) relates to the information to be provided by the medical device's manufacturer for the processing of the medical devices and the validation of the correctness of the information.

These standards include definitions of cleaning vs. disinfection.

In the HAEMODIALYSIS EQUIPMENT context, the term "processing" in the title of the ISO 17664 family standards ([16] and [33]) implies to consider:

1) the internal hydraulic disinfection;
2) the surface cleaning/disinfection.

The pertaining subclause in the particular standard is 201.7.9.2.12 Cleaning, disinfection and sterilization, including information to be given to the OPERATOR to disinfect/clean the internal non-single use fluid path and the ENCLOSURE of the HAEMODIALYSIS EQUIPMENT. This subclause, like the ISO 17664 family ([16] and [33]), is intended for the content of the instructions for use.

At the time of writing this document there was not enough clarity how to apply the ISO 17664 family ([16] and [33]) to HAEMODIALYSIS EQUIPMENT. The following sections are providing considerations about how to address the ISO 17664 family standards ([16] and [33]) to HAEMODIALYSIS EQUIPMENT.

Internal hydraulic disinfection:

– HAEMODIALYSIS EQUIPMENT (including online HAEMODIALYSIS EQUIPMENT) non disposable (e.g. non-single-use) fluid paths cannot be classified according to the Spaulding scheme of ISO 17664 family ([16] and [33]), since there is no intended direct contact of the device with the patient (tissues).
– The internal fluid path disinfection/cleaning of the HAEMODIALYSIS EQUIPMENT is typically fully automated (i.e. activated by a user's action with no further need for user's intervention during the process).

  ISO 17664-1:2021[16] covers in 6.7.2.2 information for automated disinfection, but the needed information mentioned there is actually covered by 201.7.9.2.12 – 1st hyphen, 3rd hyphen and 4th hyphen and the corresponding informative annex.

– Online HAEMODIALYSIS EQUIPMENT can include a path that carries SUBSTITUTION FLUID that complies with the requirements (e.g. microbiological, see ISO 23500-5 [7], and ISO 23500-1 [6]) for a solution intended to be infused directly in the patients blood. This is covered in 201.12.4.4.111.
– The validation of such disinfection means for non-disposable (e.g. non-single-use) fluid paths is covered in Subclause 201.11.6.6 Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS.
– In case of not fully automatic processing of the hydraulic fluid path, the ISO 17664 family can give additional advice for the information needed regarding 201.7.9.2.12 – 1st hyphen.

Additional information to processing of "Dialysate Delivery Systems" can be found in [16].

Surface cleaning/disinfection:

– The external surfaces of the HAEMODIALYSIS EQUIPMENT should be classified as non-critical in the context of surface disinfection, see also examples in Appendix Table E.1 of ISO 17664-2 [33].
– The ISO 17664-2 [33] can give additional advice for the information needed regarding 201.7.9.2.12 – 1st hyphen.

Subclause 201.7.9.2.12, ~~2nd~~3rd hyphen – Cleaning, disinfection and sterilization

This description of the test PROCEDURE should include at least the following:

– the recommended type of disinfectant;
– the required concentration of disinfectant in the container;
– the resulting concentration of disinfectant in the HAEMODIALYSIS EQUIPMENT;
– the required minimum time of the disinfection phase (if not automatically set by the HAEMODIALYSIS EQUIPMENT);
– the required minimum rinse phase (if not automatically set by the HAEMODIALYSIS EQUIPMENT).

Subclause 201.7.9.3.1, 3rd and 4th hyphens – General

Proposal for typical operating conditions of chronic HD treatments with HAEMODIALYSIS EQUIPMENT to compare different features:

– HAEMODIALYSIS time: 4 h, plus preparation time and post treatment operation;
– DIALYSIS FLUID flow rate: 500 ml/min;
– blood flow rate: 300 ml/min;
– ULTRAFILTRATION rate: 0,5 l/h;
– DIALYSIS FLUID temperature: 37 °C;
– either chemical ~~and/~~or heat disinfection according to the MANUFACTURER'S specification.

Subclause 201.7.9.3.1, 11th hyphen – General

The flow rate through the BLOOD LEAK detector can depend on the treatment type and~~/or~~ position of the BLOOD LEAK detector.

Subclause 201.8.3 – Classification of APPLIED PARTS

Compliance with TYPE CF APPLIED PART requirements for HAEMODIALYSIS EQUIPMENT that are provided with a permanent DIALYSIS WATER connection ~~and/~~or connection to a CENTRAL DELIVERY SYSTEM can be achieved with high technical expenditures only. For that reason, an exception

rule has been established for the use of HAEMODIALYSIS EQUIPMENT with TYPE B APPLIED PARTS for PATIENTS with a central venous catheter whose tip is in the right atrium.

In addition to the rationale of IEC 60601-1-11:2015, Clause 6, Classification of ME EQUIPMENT and ME SYSTEMS: For HAEMODIALYSIS EQUIPMENT without any installed connections to an external water supply system, central dialysate supply system or drainage line, compliance with TYPE CF APPLIED PART requirements can be obtained much easier. The goal of the exception rule is to protect the PATIENT under NORMAL CONDITION and under SINGLE FAULT CONDITION from LEAKAGE CURRENTS with the same effectiveness as HAEMODIALYSIS EQUIPMENT with TYPE CF APPLIED PART. Two sources of LEAKAGE CURRENTS ~~have to~~ shall be distinguished.

1) LEAKAGE CURRENTS originating from the HAEMODIALYSIS EQUIPMENT.

   These LEAKAGE CURRENTS could flow through the central venous catheter, whose tip is in the right atrium, via the heart of the PATIENT to the grounded PATIENT bed, chair or other means. Under NORMAL CONDITION, these LEAKAGE CURRENTS flow to earth via the PROTECTIVE EARTH CONDUCTOR of the HAEMODIALYSIS EQUIPMENT. Under SINGLE FAULT CONDITION (PROTECTIVE EARTH CONDUCTOR of the HAEMODIALYSIS EQUIPMENT is interrupted), the LEAKAGE CURRENTS ~~needs to~~ shall be minimized by other means.

   If ME EQUIPMENT complies with these special LEAKAGE CURRENT limits in NORMAL CONDITION, but does not comply in SINGLE FAULT CONDITION (i.e. with the PROTECTIVE EARTH CONDUCTOR interrupted), an external POTENTIAL EQUALIZATION CONDUCTOR ~~may~~ can be used for reducing the LEAKAGE CURRENTS to the necessary lower levels.

   The external POTENTIAL EQUALIZATION CONDUCTOR has to be protected against unintentional disconnection (unintentional disconnection of the plug). Intentional disconnection of the plug without the use of TOOLS ~~may~~ can be possible.

2) LEAKAGE CURRENTS originating from other electrical equipment and ME EQUIPMENT set up in the PATIENT ENVIRONMENT.

   These LEAKAGE CURRENTS could flow through the body of the PATIENT via the heart and the central venous catheter, whose tip is in the right atrium, to the earth via the HAEMODIALYSIS EQUIPMENT. Under NORMAL CONDITION, these LEAKAGE CURRENTS flows to earth via the PROTECTIVE EARTH CONDUCTOR of the external equipment.

   Under SINGLE FAULT CONDITION (PROTECTIVE EARTH CONDUCTOR of the external equipment is interrupted) and if the HAEMODIALYSIS EQUIPMENT has a TYPE CF APPLIED PART, the isolation barrier between the APPLIED PART and the rest of the HAEMODIALYSIS EQUIPMENT would prevent these LEAKAGE CURRENTS from reaching the PATIENT.

   If the HAEMODIALYSIS EQUIPMENT has a TYPE B APPLIED PART, these LEAKAGE CURRENTS ~~need to~~ shall be minimized by other means.

   Since measures that ~~have to~~ shall be applied to non-HAEMODIALYSIS EQUIPMENT are not subject to this document, the normative requirement of this document is that information ~~has to~~ that shall be provided in the ACCOMPANYING DOCUMENTS for the OPERATOR (201.7.9.2.5, 8th hyphen and 201.7.9.2.2, ~~14th~~16th hyphen) and for the RESPONSIBLE ORGANIZATION (201.7.9.2.6, 3rd hyphen and 201.7.9.2.2, ~~14th~~16th hyphen).

General remarks for the use of central venous catheters considering electrical safety.

- Microshock by catheter LEAKAGE CURRENT is a hypothetical HARM that cannot be excluded. The likelihood of such a shock occurring is limited.
- Only central venous catheters with the venous tip located in the right atrium are relevant.
- This limits the RISK to permanent catheters inserted through jugular or subclavian vein. The tip of non-permanent catheters or femoral catheters is usually not placed in the atrium.
- Side holes in the venous limb will also distribute electrical current to the body outside the heart [19] although most catheters today have no side holes in the return (venous) lumen.
- The withdrawal (arterial) lumen is electrically isolated or only connected with a high resistance to ground [13].

- If the catheter tip is placed in the right atrium as recommended for permanent catheters, the catheter will normally not touch the atrial wall because this ~~may~~ can cause flow problems. The requirements for CF based on the RISK of microshock were established based on measurements with metal electrodes in direct touch with the atrium.
- With the catheter not in direct contact with the myocardium the current density on the myocardial surface will be very much reduced because the current is distributed over a larger surface area. Starmer [20] reports that ~ 500 ~~μ~~∝A were required for fibrillation when applied to a circular surface with 2,5 mm diameter. When the surface area was increased to 2,5 cm in diameter the current required for fibrillation increased to more than 3 000 ~~μ~~∝A.
- In order to create a serious HAZARDOUS SITUATION,
  - the catheter tip ~~has to~~ shall be placed in the right atrium and ~~has to~~ shall touch the atrial wall (by mistake), and
  - the PATIENT ~~has to~~ shall be in touch with a current source.

Subclause 201.8.7.4.7 aa) – Measurement of the PATIENT LEAKAGE CURRENT

"Typical treatment mode [...] with no ALARM CONDITIONS activated" means, for example, that a heater is on during measurement. If valves can block the current path between the heater and the PATIENT, these valves should be in open condition.

Subclause 201.8.11.2 – MULTIPLE SOCKET-OUTLETS

An example is a HAEMODIALYSIS EQUIPMENT which has a MULTIPLE SOCKET-OUTLET. One socket is intended for an external heater which is switched off by the HAEMODIALYSIS EQUIPMENT in case of high temperature ALARM CONDITION. The other socket is intended for a reading lamp and is not switched off in case of ALARM CONDITIONS. It could cause a HAZARDOUS SITUATION if the heater were unintentionally connected into the socket for the reading lamp. This ~~has to~~ shall be prevented, for example by mechanically incompatible sockets.

Subclause 201.11.6 – Overflow, spillage, leakage, ingress of water or particular matter, cleaning, disinfection, sterilization, and compatibility with substances used with the ME EQUIPMENT

Subclause 11.6.2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies only if the HAEMODIALYSIS EQUIPMENT has internal reservoirs that the operator is responsible to fill.

Automatic process control filling of reservoirs is covered by 11.6.4 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

Subclause 201.11.6.6 – Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS

The ENCLOSURE surface of the HAEMODIALYSIS EQUIPMENT should be designed to facilitate ENCLOSURE surface disinfection and minimize gaps, corners and other locations that could harbour microorganisms.

Testing should be performed to validate the microbial control systems of the HAEMODIALYSIS EQUIPMENT per 201.11.6.6.

Cleaning and disinfection can be accomplished through chemical methods, physical methods, or a combination of both. Guidance for testing of disinfectants can be found in ISO 15883 (all parts) [21], EN 14885 [22], JIS Z 2801 [23], AOAC 964 [24] or ASTM E1153 [25]. The microbial control regime should be validated considering organisms relevant to haemodialysis, representing the main microbial categories of microorganisms including Gram positives, Gram negatives, viruses, yeasts and fungi.

The microbial control regime validation should be performed on the HAEMODIALYSIS EQUIPMENT under simulated use conditions. Tests should be performed such that

1) testing is conducted with worst case HAEMODIALYSIS EQUIPMENT configuration per the ACCOMPANYING DOCUMENTS (examples: lowest disinfectant concentration, shortest contact time),
2) the equipment (software and hardware) demonstrates the ability to achieve the required conditions – examples include temperature and concentrations in the fluid path –,
3) the conditions are sufficient through the locations where microbial control is necessary, and
4) when challenged with an appropriate microbial challenge, the HAEMODIALYSIS EQUIPMENT can maintain microbial control.

Sampling is sufficient to represent all locations where microbial control is required.

Testing of disinfectant residuals

The rinsing PROCESS should be validated to remove the disinfectant to a concentration stated safe by local regulations or an acceptable level defined by the MANUFACTURER.

The test is done in the following way:

A normal disinfection and rinse are performed, but a coloured test liquid (e.g. Methylene blue or Fluorescein) is used instead of disinfectant. Then it is checked that in the rinse phase all parts of the fluid path are filled with coloured liquid. No tubes or cavities should be only partly filled or filled with a liquid that is considerably lighter in colour.

After rinsing, no parts of the fluid path should show traces of the coloured liquid. The remaining concentration of the coloured liquid can be measured photometrically or fluorometrically.

Using a coloured test liquid or conductive markers results in higher sensitivity of the measurement than using real disinfectant but being a different substance, does not allow for reliable conclusions regarding the effect of diffusion of the actually applied disinfectant into plastic.

The test with coloured liquid or conductive markers should be supported by a validation aimed at demonstrating that these methods are equivalent to the measurement of the disinfectant residuals concentration.

Subclause 201.11.8 – Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

The focus of 201.11.8 is the interruption of external or internal power sources and on HAZARDOUS SITUATIONS in case of interruption or interruption followed by restoration.

The following items are examples for additional measures which ~~may~~ can be ~~necessary~~ applicable:

– stopping of the DIALYSIS FLUID flow to the DIALYSER;
– interruption of any SUBSTITUTION FLUID flow;
– reduction of ULTRAFILTRATION rate to its minimum value;
– clamping of the venous blood line.

The following are graphical representations for the different designs in items a) to c):

a) Powered by SUPPLY MAINS only

Figure AA.1 refers to the first option of case a), i.e. to ME EQUIPMENT powered by SUPPLY MAINS only.

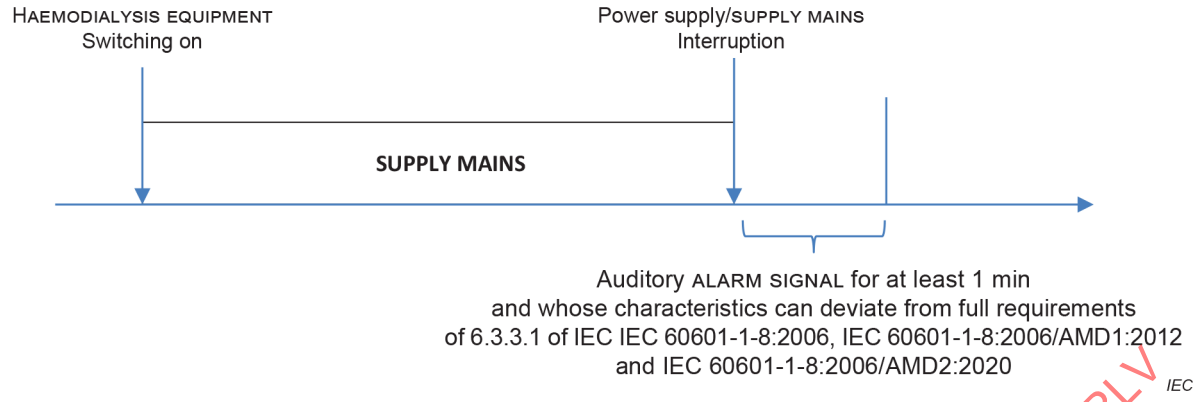


Figure AA.1 – Powered by SUPPLY MAINS only

Regarding the reference to IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, 6.3.3.1, power failure is considered a TECHNICAL ALARM CONDITION for which the ALARM SYSTEM can generate an auditory ALARM SIGNAL that does not comply with the requirements thereof.

b) Powered by SUPPLY MAINS with an INTERNAL ELECTRICAL POWER SOURCE for limited functionality

Examples for limited functionality are:

– graphical user interface only for treatment data management;

– graphical user interface and extracorporeal circulation for coagulation prevention;

– graphical user interface and return of the blood to the PATIENT;

– HAEMODIALYSIS EQUIPMENT which can proceed with the full functionality for limited time.

Note that "limited time" above refers to a gap between the intended dialysis treatment time and the battery duration time. If the battery is not designed to be able to power the HAEMODIALYSIS EQUIPMENT for the full treatment it will fall under type b).

The PROTECTIVE SYSTEM is necessary during limited functionality to protect the PATIENT from HAZARDOUS SITUATION according to 201.12.4.4.104.3 (extracorporeal blood loss due to coagulation, as a consequence of the interruption of the blood flow).

Figure AA.2 refers to the second option of case b), i.e. to alarm given once the battery for limited functionality gets depleted:

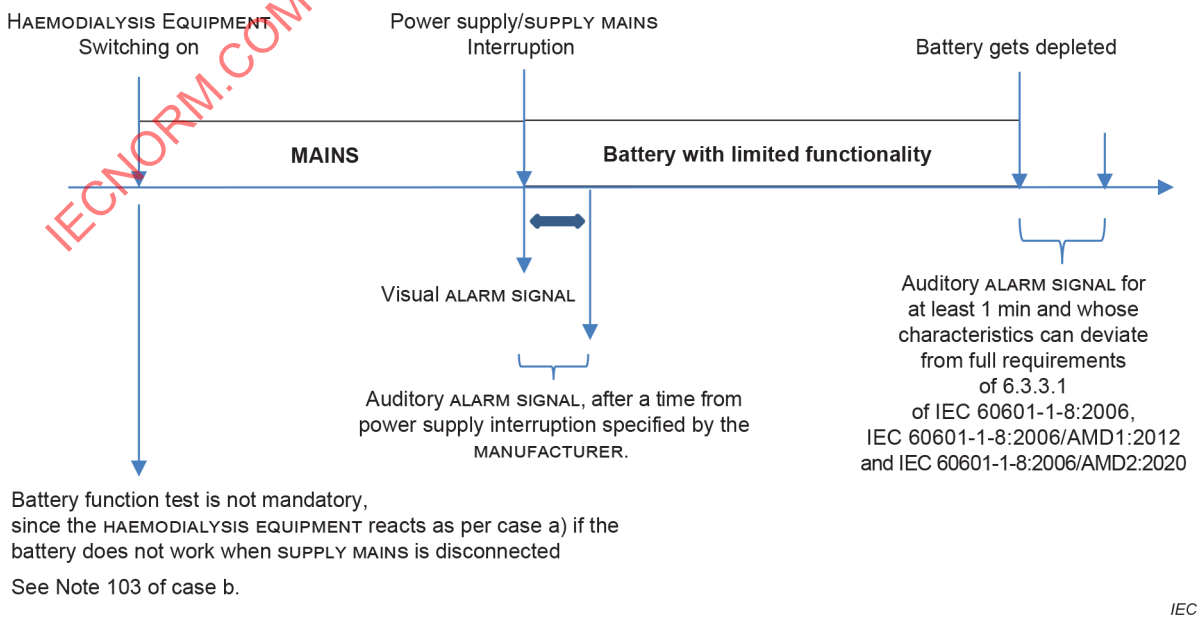


Figure AA.2 – Alarm at depletion of battery for limited functionality

Regarding the reference to IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, Subclause 6.3.3.1, power failure is considered a TECHNICAL ALARM CONDITION for which the ALARM SYSTEM can generate an auditory ALARM SIGNALS that does not comply with the requirements thereof.

Figure AA.3 refers to the first option of case b), i.e. to alarm given no more than 30 min before the battery for limited functionality gets depleted:

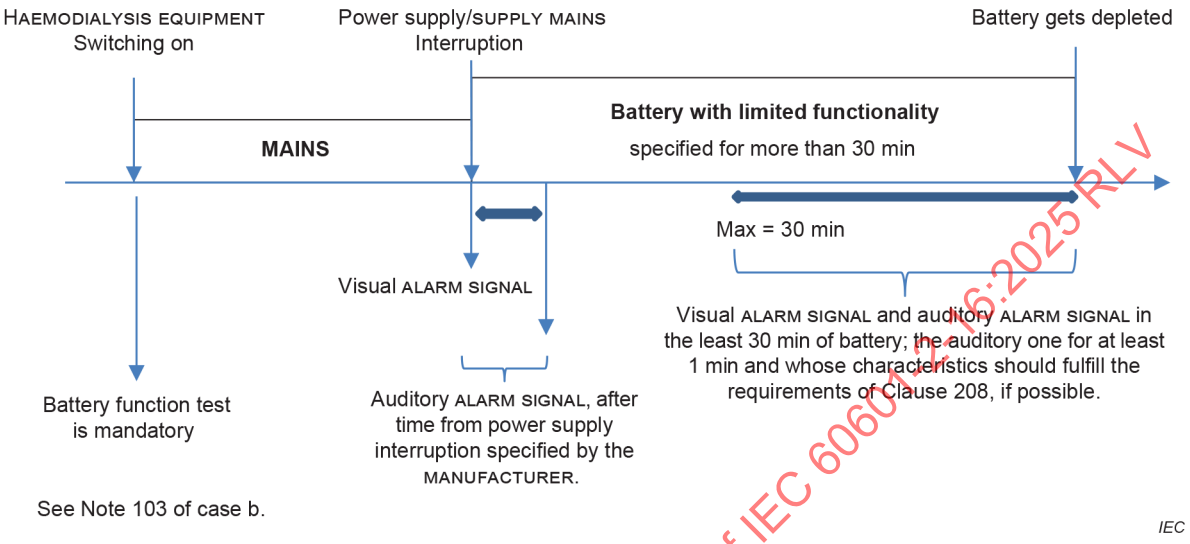


Figure AA.3 – Alarm before battery for limited functionality gets depleted (30 min maximum)

Regarding the battery's function test requirement in Figure AA.3, it shall be noted that, in this design, the battery is relied upon for the alarm generation, therefore the function test is mandatory.

Figure AA.4 refers to the first option of case b) mentioned in Note 4, i.e. to a battery for limited functionality specified for lasting less than / equal to 30 min:

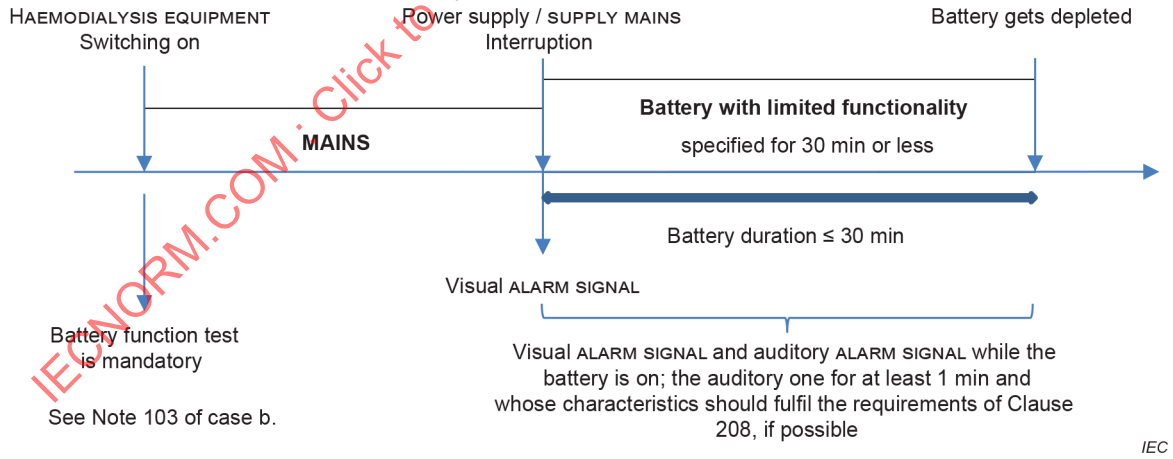


Figure AA.4 – Alarm before battery for limited functionality gets depleted (battery lasting for equal or less than 30 min)

Regarding the battery's function check requirement, it shall be noted that, in this design, the battery is relied upon for the alarm generation. The following items are examples for additional measures which can be applicable:

– stopping of the DIALYSIS FLUID flow to the DIALYSER;
– interruption of any SUBSTITUTION FLUID flow;
– reduction of ULTRAFILTRATION rate to its minimum value;
– clamping of the venous blood line.

c) internally powered

Formerly this design was named INTERNAL ELECTRICAL POWER SOURCE for operation and part of paragraph a).

Figure AA.5 refers to the second option of case c), i.e. to alarm given at battery depletion:

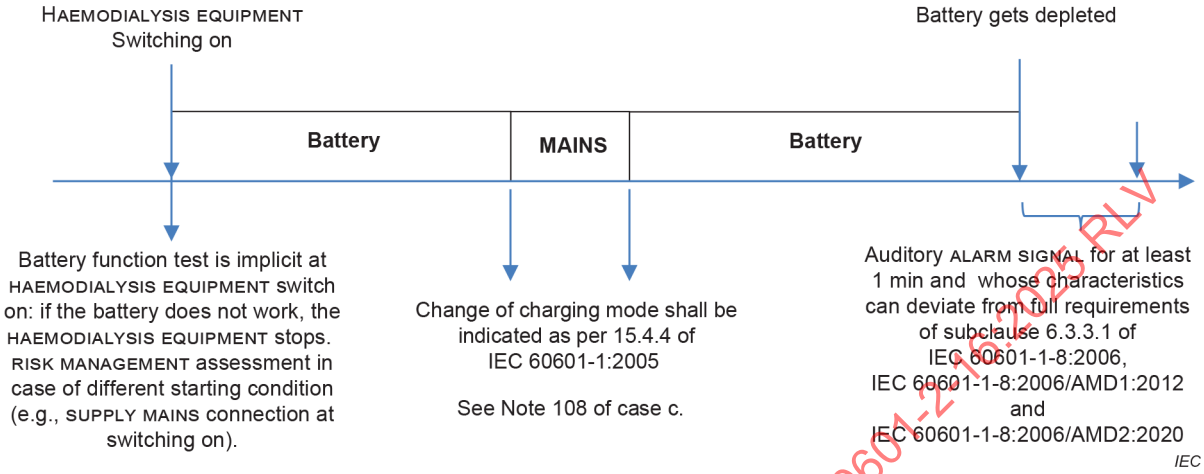


Figure AA.5 – Alarm at battery depletion

Regarding the transition from MAINS to battery mode, a charging mode indicator as per Subclause 15.4.4 of IEC 60601-1:2005 has been considered enough due to the full function provided by the INTERNAL ELECTRICAL POWER SOURCE. Therefore, differently from case b), a visual ALARM SIGNAL has not been required.

Regarding the reference to IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, 6.3.3.1 power failure is considered a TECHNICAL ALARM CONDITION for which the ALARM SYSTEM can generate an auditory ALARM SIGNAL that does not comply with the requirements thereof.

Figure AA.6 refers to the first option of case c), i.e. to alarm given no more than 30 min before the battery gets depleted:

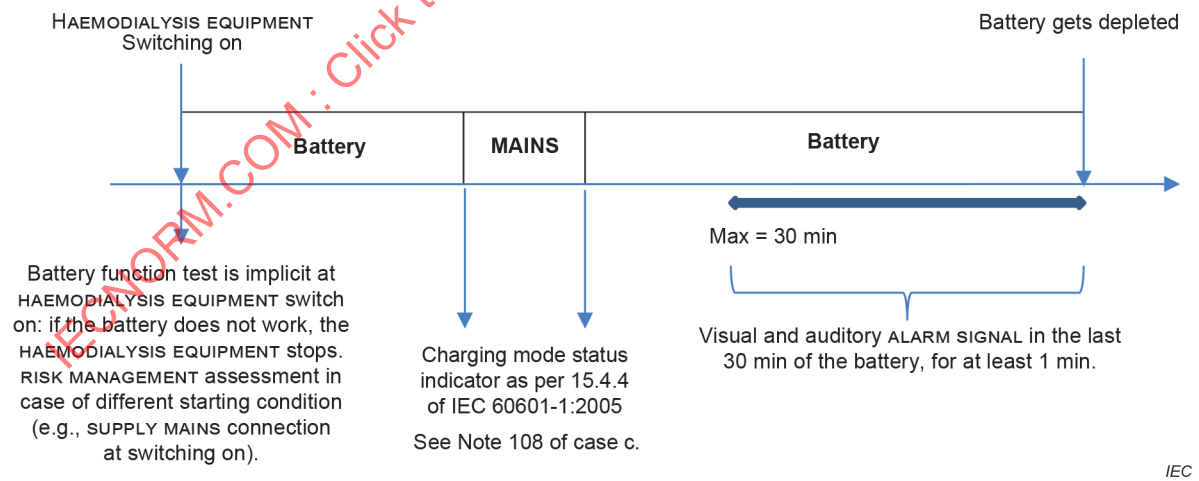


Figure AA.6 – Alarm before battery gets depleted (30 min maximum)

Regarding the transition from mains to battery mode, a charging mode indicator as per 15.4.4 of IEC 60601-1:2005 has been considered enough due to the full function provided by the INTERNAL ELECTRICAL POWER SOURCE. Therefore, differently from case b), a VISUAL ALARM SIGNAL has not been required.

Figure AA.5 and Figure AA.6 are examples of a possible case c designs, starting the HAEMODIALYSIS EQUIPMENT in battery mode.

Subclause 201.12 – Accuracy of controls and instruments and protection against hazardous outputs

The second edition of this particular standard (IEC 60601-2-16:1998) usually did not specify any definite values for the necessary ALARM LIMITS of the PROTECTIVE SYSTEMS. It was up to the MANUFACTURER to define the deviation from the value that presented a HAZARD which had to be detected by the PROTECTIVE SYSTEM and justified in the MANUFACTURER'S RISK MANAGEMENT PROCESS.

The objective of the present edition of this document is to reach an agreement between MANUFACTURERS and other interested organizations as to that part of the RISK MANAGEMENT PROCESS that is applicable to all systems and to describe the result in this document. It is intended to avoid any unnecessary redundant work on the part of the MANUFACTURER and to facilitate a uniform evaluation by testing agencies.

When preparing this document, the committee took a "typical" HAEMODIALYSIS EQUIPMENT for the treatment of acute or chronic renal failures as a basis. If the properties of a HAEMODIALYSIS EQUIPMENT deviate from the "typical" values, the MANUFACTURER should define and justify the ALARM LIMITS in the MANUFACTURER'S RISK MANAGEMENT PROCESS.

If a PROTECTIVE SYSTEM differs in case of different modes either in term of ALARM LIMITS or in term of design, the tests shall be repeated for each mode or the worst case shall be identified by the MANUFACTURER. Examples of modes are double needle treatment, single needle treatment, low weight patient's treatment.

Subclause 201.12.4.4.101 – DIALYSIS FLUID composition

The requirement for a PROTECTIVE SYSTEM is also applicable to USE ERRORS (e.g. mistaking of DIALYSIS FLUID CONCENTRATES) and also refers to Clause 15 (Construction of ME EQUIPMENT) and Clause 16 (ME SYSTEMS).

In acetate treatment, it is considered to be appropriate if the PROTECTIVE SYSTEM is designed such that it prevents a deviation beyond the following limits:

– conductivity of final DIALYSIS FLUID 12 mS/cm to 16 mS/cm
– sodium in DIALYSIS FLUID ±5 % from the set point

Additionally, in bicarbonate treatment:

– bicarbonate in DIALYSIS FLUID ±25 % from the set point

If other components can be added individually, additionally:

– other electrolytes in DIALYSIS FLUID ±20 % from the set point

Where HAEMODIAFILTRATION without buffer (special form of HDF where the buffer is given to the PATIENT not as part of the DIALYSIS FLUID but as part of the SUBSTITUTION FLUID) and other special PROCEDURES (e.g. sorbent regenerative HAEMODIALYSIS EQUIPMENT) are concerned, the technical safety requirements should be defined in the MANUFACTURER'S RISK MANAGEMENT PROCESS, for example by definition of limits for concentration deviations which would indicate system malfunctions and potential harm to the PATIENT.

Regarding Test 1, in order to set the lowest / highest DIALYSIS FLUID composition, this could be achieved by setting all the possible treatment parameters related to DIALYSIS FLUID composition to the lowest / highest values.

Regarding Test 3, in a HAEMODIALYSIS EQUIPMENT with two components, A and B, take A-A, B-B and B-A to the A/B connections, if these misconnections are possible. In a HAEMODIALYSIS EQUIPMENT with more than two components, more combinations should be considered.

Figure AA.7 provides a schematic representation of the four test cases for determining the ALARM SIGNAL activation:

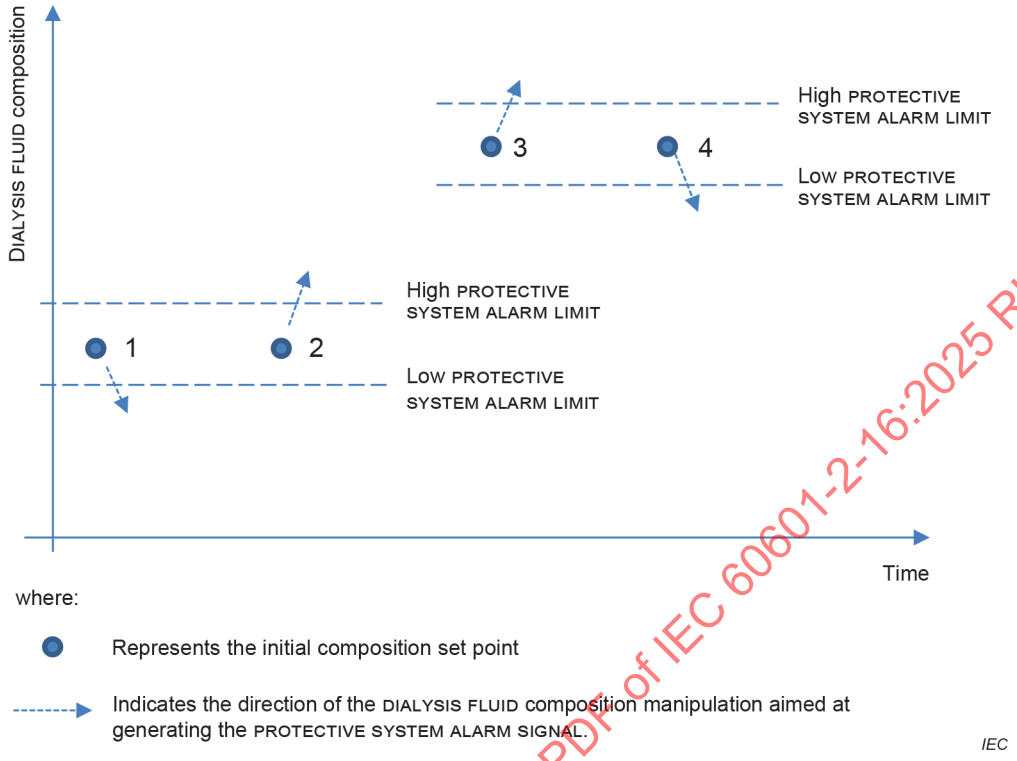


Figure AA.7 – DIALYSIS FLUID composition test cases for determining the ALARM SIGNAL activation

Subclause 201.12.4.4.102 – DIALYSIS FLUID and SUBSTITUTION FLUID temperature

Long-term application of DIALYSIS FLUID temperatures above the body temperature will result in a positive thermal energy balance for the PATIENT, which is associated with physiological reactions. Increased body temperature leads to increased perfusion of the skin and in consequence frequently to clinically relevant blood pressure drop. Temperatures above 46 °C cause haemolysis and denaturation of blood components.

Decrease of body temperature results in discomfort and shivering. The tolerance limits of prolonged core body temperature decrease are some tenths of a °C.

Increasing the temperature above 42 °C for a short time is permitted to enable for example the measurement of recirculation by temperature measurement. A short-term increase is uncritical because it does not lead to perturbation of the energy balance of the body.

Blood damage (thermal haemolysis) occurs when blood is heated to more than 46 °C for a prolonged time. Blood temperatures up to 46 °C in the EXTRACORPOREAL CIRCUIT have been used for hyperthermia treatment. Low temperatures have no adverse effect on blood. Historically, blood has been dialysed at 5 °C. [28]

The DIALYSER is a very efficient heat exchanger, and any temperature gradient will change the thermal energy balance of the PATIENT. A prolonged positive thermal energy balance is known to cause hypotension while a prolonged large negative balance will be uncomfortable for the PATIENT and cause shivering.

To avoid high positive energy balances that ~~may~~ can cause hypotension, the maximum DIALYSIS FLUID temperature is limited to 42 °C or less.

Besides PATIENT discomfort for low DIALYSIS FLUID temperatures adverse effects are uncommon, but in rare cases cold dialysate can cause tachypnea, tachycardia, shivering, energy loss and slight changes in coagulation [14]. Ventricular fibrillation has been reported after cooling of the heart to less than 33 °C by rapid infusion of large amounts (> 5 l) of cold (4 °C) blood. In HAEMODIALYSIS, cooling to 33 °C would take more than 15 min even assuming high blood flow rate, low DIALYSIS FLUID temperature (10 °C) and low body weight (50 kg).

Subclause 201.12.4.4.103 – NET FLUID REMOVAL

Safe limits for an acceptable NET FLUID REMOVAL error cannot be derived from physiological data and are PATIENT-dependent; however, the medical industry has many years of experience with fluid balancing systems. The limits given here are derived from this experience.

The direction of a fluid balancing error is an essential factor: excessive removal is hazardous. Hyperhydration (fluid supplied) can be hazardous and depends on the initial situation. Insufficient removal is not hazardous in case of chronic dialysis, provided it is detected and corrected before the PATIENT is discharged.

Monitoring of the following limits by the PROTECTIVE SYSTEM is usually considered to be appropriate:

– for continuous adult treatments, for example CRRT treatments, which are typically driven by the NET FLUID REMOVAL rate, the sliding average value of the NET FLUID REMOVAL rate measured by the PROTECTIVE SYSTEM – with averaging time defined by the MANUFACTURER'S RISK MANAGEMENT PROCESS – is at all time within ±0,1 l/h of the OPERATOR set point rate.
– The risk of cumulated volume error of the NET FLUID REMOVAL over time should be evaluated by the MANUFACTURERS RISK MANAGEMENT PROCESS.
– for typical 4 h adult chronic dialysis treatments, which are typically driven by the NET FLUID REMOVAL volume, the removed cumulated NET FLUID REMOVAL volume measured by the PROTECTIVE SYSTEM is at all time during the treatment time within ±400 ml of the expected cumulated NET FLUID REMOVAL volume.

It is the responsibility of the MANUFACTURER'S RISK MANAGEMENT PROCESS to specify the NET FLUID REMOVAL limits, i.e. the deviations which could lead to HAZARDOUS SITUATION, considering e.g. the intended patients' population, the intended purpose and the ESSENTIAL PERFORMANCE.

Regarding the test, the highest and the lowest settable values should be set unless this prevents from simulating the failure: if it is not possible to increase the ultrafiltration rate above the highest or decrease the ultrafiltration rate below the lowest, values near the extreme settable values can be applied.

TMP monitoring alone is not considered to be an adequate protection against fluid balancing errors in the case of high-flux DIALYSERS (however, TMP monitoring can improve the safety and performance in a different way, for example with regard to the detection of a secondary membrane in the DIALYSER fibres, interdialytic hyperuraemia, undetected membrane rupture, "rescuing" the DIALYSER by rinsing if heparinisation is inadequate).

Possible sources of fluid balancing errors which should be covered by a PROTECTIVE SYSTEM are, for example: leaks at connectors (including SUBSTITUTION FLUID) and errors in the balancing system (e.g. flow meter, balancing chamber).

Subclause 201.12.4.4.104.1 a) – Extracorporeal blood loss to the environment

Monitoring of the VENOUS PRESSURE is not always suitable for detecting a blood loss in time, in case the venous puncture cannula slips out. The VENOUS PRESSURE is determined mainly by the hydraulic resistance of the venous puncture cannula, particularly with today's usual high blood flow rate of up to 500 ml/min. A VENOUS PRESSURE ALARM SYSTEM is, hence, not able to always detect whether or not the puncture cannula has slipped out.

If dialysis is performed in the single-needle mode with only one blood pump ("single-needle single pump", "SN click-clack"), the VENOUS PRESSURE measurement is an integral part of the control system. An error in this control system (e.g. pressure sensor stuck to low value) might lead to the upper changeover point of the VENOUS PRESSURE never being reached. As a result, the pressure becomes too high, the tubing system ~~may~~ can burst, and the PATIENT ~~may~~ can lose a great amount of blood. This ~~may~~ can require a PROTECTIVE SYSTEM which is independent of the control system, for example monitoring of the phase duration by an independent microprocessor.

Inherent safe design is for example a pump rotor that is spring-mounted so smoothly that bursting of the tubing is not possible. However, in this case a HAZARDOUS SITUATION which will cause haemolysis ~~may~~ can exist.

Other measures for prevention of overpressure are holders for the EXTRACORPOREAL CIRCUIT lines and the DIALYSER which make kinking sufficiently unlikely.

Blood loss to the environment caused by disconnections or faults in the EXTRACORPOREAL CIRCUIT cannot entirely be prevented by any PROTECTIVE SYSTEM. The PROTECTIVE SYSTEM should be designed so that blood loss is detected and major blood loss is prevented. Most reported cases of fatal blood loss are caused by blood access cannulas slipping from the fistula or graft. This cannot be prevented by the HAEMODIALYSIS EQUIPMENT. Traditionally, VENOUS PRESSURE monitors have been used for protection against blood loss to the environment. These monitors detect a drop of the pressure in the return bloodline. In case of a bloodline rupture or disconnection of the bloodline from the blood access device (cannula or central venous catheter), the pressure will drop considerably because of the high flow resistance in the blood access device. When the venous cannula slips from a fistula, the pressure change is usually too low to be detected by the VENOUS PRESSURE monitor. The pressure drops only by the amount of the fistula pressure which is typically 5 mmHg to 20 mmHg. To avoid frequent nuisance ALARM CONDITIONS caused by PATIENT movement, the difference between the actual VENOUS PRESSURE and the lower pressure ALARM LIMIT is usually adjusted to 10 mmHg to 20 mmHg.

An INTELLIGENT ALARM SYSTEM could be introduced to avoid frequent nuisance ALARM CONDITIONS caused by PATIENT movement, making the ALARM generation depending on either speed of change or duration of change of the VENOUS PRESSURE, or both.

Monitors employing pressure pulses or other parameters ~~may~~ can offer greater sensitivity but ~~may~~ can also require up to a minute to detect the fault condition and switch off the blood pump. With high blood flow rate this ~~may~~ can cause blood losses of 500 ml, which are usually not fatal for adults.

This IEC standards committee has ~~published a public available~~ included in Annex CC an example of an open alarm interface specification that enables stopping the blood pump by connected external monitoring devices, that for example can detect blood loss to the environment ~~(IEC PAS 63023 [10])~~. The functionality described in the ~~PAS is an example and~~ Annex CC could be designed in alternative ways by the MANUFACTURERS.

The effects of haemorrhage are described in reference [18].

Subclause 201.12.4.4.104.1 c) – Extracorporeal blood loss to the environment

Stopping of the occluding blood pump is considered a sufficient reaction to extracorporeal blood loss to the environment. Additional closing of the safety clamp adds only little value because a rupture will most likely occur at the point of highest pressure, which normally is between the blood pump and DIALYSER. In this case, "retrograde" blood loss via the venous bloodline is negligible compared to the direct blood loss through the arterial bloodline. "Retrograde" blood loss from the venous access ~~may~~ can become hazardous to the PATIENT if it is not monitored.

Subclause 201.12.4.4.104.2 – BLOOD LEAK to the DIALYSIS FLUID

An acceptable method of complying with this requirement is, for example, a PROTECTIVE SYSTEM utilizing a BLOOD LEAK detector.

BLOOD LEAKS of less than 0,35 ml/min blood (with an Hct of 32 %) ~~are~~ have not considered to present a serious HARM for chronic adult patients. It is the responsibility of the MANUFACTURER'S RISK MANAGEMENT PROCESS to identify the BLOOD LEAKS limit considering e.g. the intended PATIENTS' population and the intended purpose (see for example [36]).

Historically, BLOOD LEAK sensitivity has been specified in milligrams of haemoglobin per litre (mgHb/l) of DIALYSIS FLUID, probably because of the established spectrophotometric tests for determination of haemoglobin. Specification in mgHb/l, however, requires calculation to determine the quantity of blood lost, which is the parameter of interest to the practitioner. The threshold limit of 55 mg Hb/l translated to 0,35 ml/min of blood. Calculations were based on the assumption of 14 gr Hb/100 ml blood in normal subjects, a Hct of 46 % (0,46) in normal subjects, a haematocrit possibly as low as 25 % (0,25) in typical HAEMODIALYSIS PATIENTS, and a DIALYSIS FLUID flow rate of 500 ml/min.

Override is a mean to allow the HAEMODIALYSIS EQUIPMENT to function under ALARM CONDITIONS, if the OPERATOR consciously selects to temporarily disable the PROTECTIVE SYSTEM for the BLOOD LEAK.

The visual indication can be a symbol from IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 (see Table C.1 and Table C.2) or another symbol or text taking into account the appropriate colour as per IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 7.8.1.

It should not be possible to deactivate the blood leak detector inadvertently. Possible solutions might, for example, be two independent actions on the operator's part and automatic restart on commencement of the next treatment. Deactivation of the blood leak detector should not increase the risk of blood loss to a higher degree than necessary. An acceptable method shall design the blood leak detector such that it is not only possible to switch it off completely but also to reduce its sensitivity and that this reduction will be automatically cancelled again on commencement of the next treatment. An example for medical reasons to change the sensitivity of the blood leak detector is the treatment of haemolytic-uraemic syndrome (HUS).

Subclause 201.12.4.4.104.3 – Extracorporeal blood loss due to coagulation

In this case, an independent PROTECTIVE SYSTEM for the blood pumping system is not required because the degree of harm is limited to the blood loss in the EXTRACORPOREAL CIRCUIT.

At the time of writing of this document there were no scientific publications available about coagulation of blood as a function of the stopping time of the extracorporeal blood flow. A maximum ALARM SIGNAL delay time of three minutes has been shown by experience to be appropriate.

Subclause 201.12.4.4.105 – Air infusion

At the time of writing of this document there was not enough scientific literature to define a safe ALARM LIMIT in this document. In [28], chapter 14, Polaschegg and Levin consider the continuous infusion of air of less than 0,03 ml/(kg*min) and infusion of a bolus of 0,1 ml/kg not to be a HAZARD.

Exposure to microbubbles should be taken into account and possible preventive measures should be considered by the MANUFACTURERS' RISK MANAGEMENT PROCESS [29], [35], [26].

An air detector response below the hazardous air infusion limit (e.g. a pre-alarm or a pre-notification) is not considered as part of the PROTECTIVE SYSTEM for air infusion.

If there is no air in the EXTRACORPOREAL CIRCUIT with the HAEMODIALYSIS EQUIPMENT being used as intended, the presence of air presents already a first fault, and it is improbable that an independent second fault (e.g. failure of the air detector) occurs during the same treatment. In this case, the air detector would not need to be SINGLE FAULT SAFE. This ~~has to~~ shall be determined by RISK MANAGEMENT.

If air is permanently present in the tubing system with the HAEMODIALYSIS EQUIPMENT being used as intended, e.g. if a partially filled chamber is used, air in the system is the NORMAL (not SINGLE FAULT) CONDITION. If a normal operating mode (not a technical failure) can cause infusion of this air to the PATIENT, the air detector ~~has to~~ shall be SINGLE FAULT SAFE.

An air detector is SINGLE FAULT SAFE, if, for example,

a) it is designed with two channels and each channel is tested prior to each treatment, or
b) it is designed with one channel and is tested periodically during the treatment, with the test interval shorter than the fault tolerance time (the shortest time required by an air bubble to move from the air detector to the PATIENT CONNECTION).

A SINGLE FAULT SAFE design to stop the blood flow to the PATIENT is for example as follows:

a) design with two independent actors (e.g. stopping of the pumps and closing of the clamps) and both actors are tested; or
b) the blood pump(s) and all pumps delivering in the direction of the PATIENT are turned off via two channels and even a mechanical failure (e.g. breakage of a rotor spring) cannot cause a loss of occlusion.

If air accumulated in the EXTRACORPOREAL CIRCUIT can reach the PATIENT by expansion, even if the blood pump is stopped by an air detector ALARM CONDITION, an additional clamp ~~has to~~ shall be provided to prevent air infusion into the PATIENT. This is typically the case when the air detector is positioned downstream of the DIALYSER.

No additional clamp is typically required if the air detector is positioned downstream of the blood pump but upstream of the DIALYSER and if a leak in the negative pressure section of the EXTRACORPOREAL CIRCUIT is the only pathway for ingress of air.

For HAEMODIALYSIS EQUIPMENT which can raise or lower the level in the drip chamber by means of an electrically operated air pump, a malfunction of this air pump ~~may~~ can cause air in the tubing system. If this air pump is able to build up a pressure that is higher than the occlusion pressure of the venous clamp, the venous clamp no longer presents a safe switch off path. In this case, the air pump has also to be switched off in a SINGLE FAULT SAFE manner. In addition, it should be noted that the air pump might be able to press air into the PATIENT via the arterial bloodline when the blood flow is stopped (e.g. because of an ALARM CONDITION) and that this air would not be detected by the air detector.

In case of single-needle PROCEDURES, it should be noted that, owing to the compressed air present in the system, the actual blood flow rate can be temporarily higher than the set blood flow rate. This should be taken into consideration when the scanning interval of the air detector and the fault tolerance time are determined.

In case of a failure of the power supply, air in the EXTRACORPOREAL CIRCUIT under pressure ~~may~~ can also generate flows in direction of the venous ~~and/~~or arterial PATIENT CONNECTION. In this case, air ~~has to~~ shall be prevented from reaching the PATIENT.

At least the following potential sources of air should be considered in the RISK ANALYSIS:

– air in chamber(s);
– residual air in the bloodline;
– residual air in the DIALYSER;
– air in the monitor lines leading to the pressure transducers;
– air entering the system in the recirculation path of a single-needle treatment;
– air entering the EXTRACORPOREAL CIRCUIT.

The physical principle used for any air detector and any electronic delays or other delays should be taken into account in the RISK ANALYSIS. Today ultrasonic air detectors are used almost exclusively for the detection of air in the EXTRACORPOREAL CIRCUIT. Some of these air detectors are positioned on the partially air-filled venous drip chamber. They are usually designed as level detectors, which means that they will generate an ALARM CONDITION if the level decreases or if the drip chamber is filled with foam.

Other air detectors are positioned directly on the blood tubing and are usually capable of detecting single bubbles with volumes much lower than the volumes believed to cause a HAZARD. The important parameter of the air detector is the accumulated volume of these single bubbles. In order to avoid nuisance ALARM CONDITION, the number of detected bubbles is integrated with a time function.

Non-dissolved air can appear in bulk and in the form of bubbles of different sizes. To address this, the two different test PROCEDURES in Note 4 are required, independently of the air monitoring methods:

– Continuous Air Infusion test to verify that the HAEMODIALYSIS EQUIPMENT is able to prevent a flow of microbubbles in excess of the identified safety limit to the patient. Such microbubbles are formed from the fragmentation of a larger air bubble as it passes through the hollow fibres contained in the dialyser. Note that air which enters downstream of the DIALYSER does not create a similar condition and hence should not be considered equivalent to the test method described by this document.
– Bolus Air Infusion test to verify that the HAEMODIALYSIS EQUIPMENT is able to prevent a bolus of air exceeding the identified safety limit to reach the patient.

Regarding the test setup, the setup for continuous air infusion can contain more than 1 test tube. Two configurations are possible:

– Having 1 tube open at a time:
  - The last tube opened representing the condition at the time of the ALARM CONDITIONS and the other tubes representing the condition before the time of the ALARM CONDITION. This can be used to have a statistical overview of the air infusion over time.
  - Every tube representing an ALARM CONDITIONS at a time. This can be used to have a statistical overview of the repeatability of the test.
– Having multiple tubes opened in parallel. This can be used to increase the statistical accuracy of the air infusion measurement by increasing the blood volume. The test tubes should be clamped separately to improve the measurement of the air volume collected in the test tubes and it should be ensured that no tube is blocked.

~~**Subclause 201.12.4.4.106 – ALARM CONDITION override modes**~~

~~It should not be possible to deactivate the BLOOD LEAK detector inadvertently. Possible solutions might, for example, be two independent actions on the OPERATOR'S part and automatic restart on commencement of the next treatment. Deactivation of the BLOOD LEAK detector should not increase the RISK of blood loss to a higher degree than necessary. An acceptable method is to design the BLOOD LEAK detector such that it is not only possible to switch it off completely but also to reduce its sensitivity and that this reduction will be automatically cancelled again on~~

~~commencement of the next treatment. An example for medical reasons to change the sensitivity of the BLOOD LEAK detector is the treatment of haemolytic-uraemic syndrome (HUS).~~

Subclause 201.12.4.4.~~112~~106 – Anticoagulation

This document includes more detailed requirements for anticoagulant delivery means. 201.12.4.4.~~112~~106 includes design requirements and requirements to address defined HAZARDOUS SITUATIONS in the MANUFACTURERS' RISK MANAGEMENT PROCESS.

Overdelivery of anticoagulant can occur during the PATIENT treatment if the anticoagulant delivery means continues when the blood pump is stopped and can create a HAZARDOUS SITUATION. This can occur when the anticoagulant delivery output is connected downstream of the blood pump by the anticoagulant delivery means continuing with the blood pump stopped and delivering a bolus of anticoagulant to the connection that is then given to the PATIENT when the blood pump starts again. Overdelivery can also occur when the anticoagulant delivery does not stop with the blood pump and its output is connected upstream of the blood pump, without a system controlled clamp on the arterial access line of the PATIENT. In this case, the anticoagulant goes directly to the PATIENT while the HAEMODIALYSIS EQUIPMENT is stopped.

Underdelivery of anticoagulant can occur during the PATIENT treatment if the anticoagulant delivery means is not started when the blood is running. It can also occur due to compliance in the anticoagulant delivery system (including a syringe if used) taking time to deliver at the specified rate. This is of particular importance for low anticoagulant administration rates or in cases of large variations in output pressure in the EXTRACORPOREAL CIRCUIT. This delay in anticoagulant delivery ~~may~~ can cause coagulation and blood loss if not addressed.

IEC 60601-2-24 [30] does not apply, because its scope relates to pumps for infusion of liquids into the PATIENT, and devices for extracorporeal circulation of blood are excluded. Anticoagulant delivery means in the scope of this document are for delivery of anticoagulants into the EXTRACORPOREAL CIRCUIT.

Anticoagulant delivery means in HAEMODIALYSIS EQUIPMENT can be a syringe pump that infuses one anticoagulant (e.g. heparin) or roller pumps that infuse simultaneously Citrate and Calcium at different points of the EXTRACORPOREAL CIRCUIT (CiCa) or other designs not directly matching with IEC 60601-2-24.

All relevant HAZARDOUS SITUATIONS addressed in IEC 60601-2-24 in the use context of HAEMODIALYSIS EQUIPMENT were taken into account in this document: specification of accuracy (201.7.9.3.1, 201.12.4.4.~~112~~106), underinfusion (201.12.4.4.104.3, 201.12.4.4.~~112~~106), overinfusion (201.12.4.4.~~112~~106), unintended bolus (201.12.4.4.~~112~~106), USABILITY issues (201.12.4.4.~~112~~106). Added are HAZARDOUS SITUATIONS not included in IEC 60601-2-24 but necessary for the use scenarios of HAEMODIALYSIS EQUIPMENT.

It is sometimes useful for developers to look into the IEC 60601-2-24 when developing anticoagulant delivery means for HAEMODIALYSIS EQUIPMENT.

If the HAEMODIALYSIS EQUIPMENT includes fluid (medication) delivery means for other substances than anticoagulants or for direct infusion into the PATIENT, IEC 60601-2-24 could be applicable in total or in parts. This is not addressed in this document because such use cases are not in the normal INTENDED USE of HAEMODIALYSIS EQUIPMENT.

Subclause 201.12.4.4.108 – Prevention of contamination by chemicals

Regarding c), possible misconnections should be evaluated in the USABILITY process and in the RISK MANAGEMENT PROCESS. Possible ways to address this can be the usage of specific connectors and colour coding (see 201.15.4.1.101) or detecting a deviation from expected conductivity.

Subclause 201.12.4.4.109 – Blood pump(s) and~~/or~~, if applicable, SUBSTITUTION FLUID pump(s) reversal

Example of a HAZARDOUS SITUATION caused by USE ERROR:

In case of mains power failure in a dialysis unit, it is very likely that the staff is under high stress and therefore USE ERROR is relative likely. In this situation, the HAZARD of air infusion via the arterial bloodline (if applicable) by wrong blood pump direction can be avoided, for example by

a) prevention of wrong hand cranking direction by
   – a unidirectional cranking mechanism, or
   – a clearly marked arrow on the pump(s), or
b) avoidance of hand cranking by continuation of the blood flow with battery power.

Example of a HAZARDOUS SITUATION caused by a technical fault:

A technical fault could cause the blood pump(s) and~~/or~~, if applicable, SUBSTITUTION FLUID pump(s) to rotate in the wrong direction. This can be avoided, for example by

a) wiring a DC motor with electromechanical commutation such that no random hardware failure can reverse the direction of the current, or
b) implementation of a PROTECTIVE SYSTEM independent of the motor control system, which stops the motor if the pump(s) rotate in the wrong direction.

Subclause 201.13.2.6 – Leakage of liquid

The test considers that fluid ~~may~~ can flow out under normal working pressure. Although its performance and reproduction is difficult, the test specified in this document is considered to be suitable for this type of equipment.

Subclause 201.14.13 – PEMS intended to be incorporated into an IT-NETWORK

A method proven to reduce RISK for the transfer of HAEMODIALYSIS EQUIPMENT settings via an IT-NETWORK is the explicit test of the data transferred, performed by the OPERATOR and confirmation by the OPERATOR before these settings become effective in the HAEMODIALYSIS EQUIPMENT.

Subclause 201.14.13.101 – Specific security features for HAEMODIALYSIS EQUIPMENT used in MEDICAL IT-NETWORKS

Other possible ways for fulfilling the requirement can be found in references [32] and [27].

Due to the controlled clinic and home environment the need to follow the recommendations in Table 1 of IEC TR 60601-4-5:2021 can be reduced. Usability and safety risk versus the security risk shall be considered when selecting the appropriate countermeasures to protect the access to the user interface.

Enclosed some explanations on how to apply the IEC TR 60601-4-5 in the context of physical user interface access security in the dialysis environment:

The recommendation in Table 1 of IEC TR 60601-4-5:2021 covers both external data interfaces and human interfaces for processing CONFIDENTIAL PATIENT DATA.

- Due to the access controlled clinical or home environments, HAEMODIALYSIS EQUIPMENT typically do not require authentication when interacting using the user interface for treatment related purposes.

- On the other side there can be the use case for a MANUFACTURER to implement authentication to process CONFIDENTIAL PATIENT DATA e.g. stored in the HAEMODIALYSIS EQUIPMENT or by accessing external databases using the user interface in the above-mentioned environments.

Subclause 201.15.4.1.101 – DIALYSIS FLUID CONCENTRATE connectors

DIALYSIS FLUID CONCENTRATES ~~may~~ can be used in the form of powder or fluid. For DIALYSIS FLUID CONCENTRATES in the form of powder and "DIALYSIS FLUID ions for sodium chloride (powdered)", constructional features preventing their misuse are usually provided in the HAEMODIALYSIS EQUIPMENT designs. Liquid DIALYSIS FLUID CONCENTRATES are taken either from containers or from CENTRAL DELIVERY SYSTEMS, which are not prevented from being misused by constructional features.

At least the following DIALYSIS FLUID CONCENTRATE types should be taken into consideration in the MANUFACTURERS' RISK MANAGEMENT PROCESS:

– acetate dialysis fluid concentrate;
– acid DIALYSIS FLUID CONCENTRATE for use with bicarbonate DIALYSIS FLUID CONCENTRATE without sodium chloride;

NOTE 1 With 35X, 36.83X, 45X dilution.

– acid DIALYSIS FLUID CONCENTRATE for use with bicarbonate DIALYSIS FLUID CONCENTRATE with sodium chloride;

NOTE 2 With 35X, 36.83X, 45X dilution.

– bicarbonate DIALYSIS FLUID CONCENTRATE without sodium chloride;

NOTE 3 Can be supplied as liquid or powder.

– bicarbonate DIALYSIS FLUID CONCENTRATE with sodium chloride;
– sodium chloride;

NOTE 4 Can be supplied as liquid or powder.

– DIALYSIS FLUID concentrates complementary to sodium and bicarbonate.

NOTE 5 Used for mixing systems with separate sodium and bicarbonate DIALYSIS FLUID CONCENTRATE supplies.

NOTE 6 Can be supplied as liquid or powder.

Subclause 201.15.4.1.102 – Connectors for blood pressure transducers

Designs that use an internal transducer protector between the internal pressure transducer and the connection to the external transducer protector prevent contamination of the internal transducer itself, but do not prevent the RISK of cross-contamination between PATIENTS dialysed on the same HAEMODIALYSIS EQUIPMENT.

Subclause 201.16 – ME SYSTEMS

A ME SYSTEM for dialysis can comprise one or more HAEMODIALYSIS EQUIPMENT and one or more of the following (see Figure AA.8):

– DIALYSIS WATER ~~treatment~~ supply system;
– discharge (drain);
– ~~data transfer;~~
– IT-NETWORK;
– central delivery system;
– staff call system.

NOTE Since TOUCH CURRENTS of other equipment exist in the PATIENT ENVIRONMENT (e.g. dialysis chairs), a POTENTIAL EQUALIZATION CONDUCTOR ~~could~~ can be ~~necessary~~ relevant for such equipment.

The DIALYSIS WATER ~~treatment~~ supply systems and the CENTRAL DELIVERY SYSTEMs are usually set up at a location that is remote from the HAEMODIALYSIS EQUIPMENT and cannot be connected via a MULTIPLE SOCKET-OUTLET. HAZARDS ~~have to~~ shall be minimized via the installation, by applying the supply lines, for example, to the same potential as the HAEMODIALYSIS EQUIPMENT.

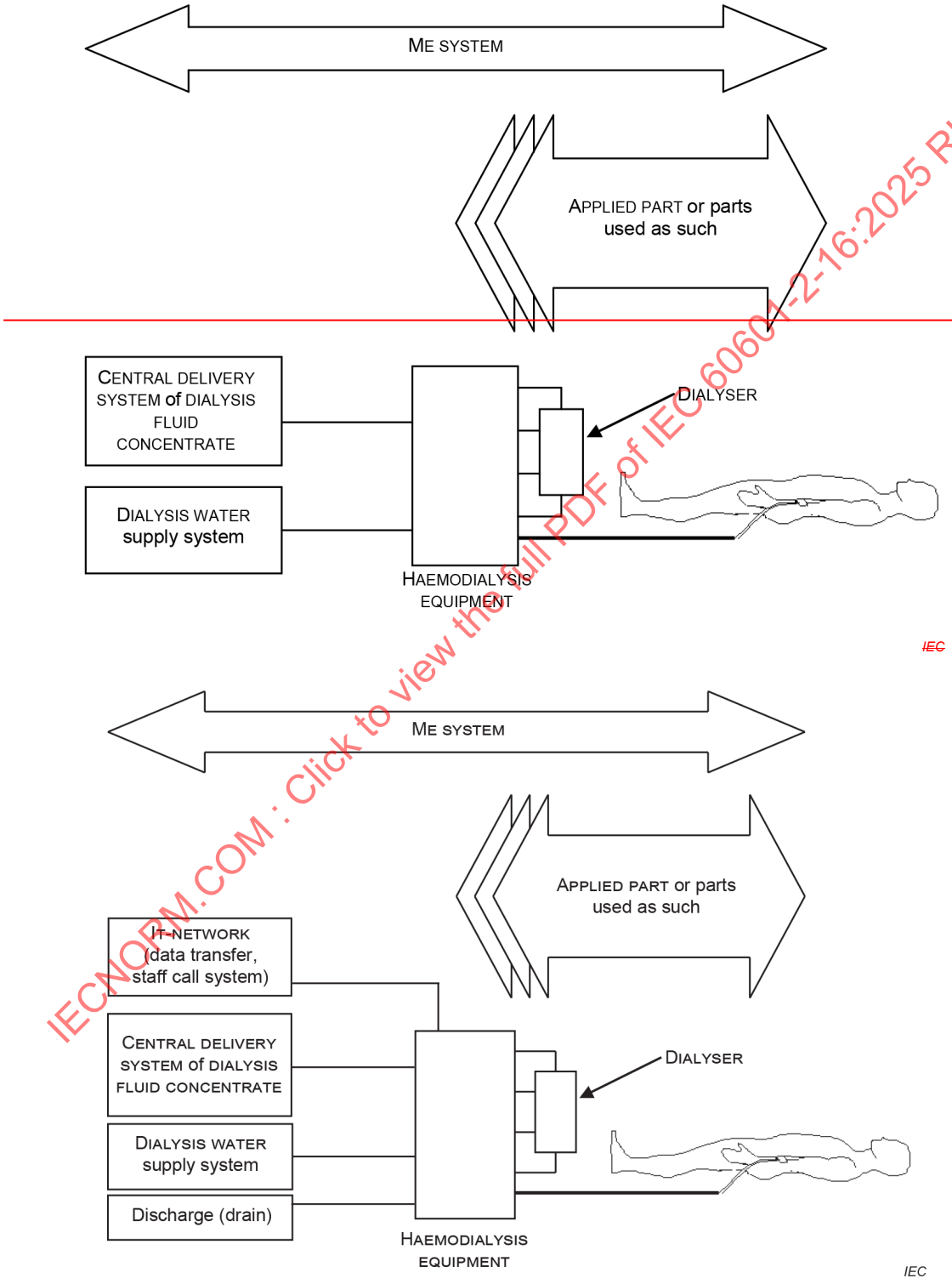


Figure AA.8 – Example of a HAEMODIALYSIS ME SYSTEM

~~For HAEMODIALYSIS EQUIPMENT with TYPE CF APPLIED PARTS, the following item should be considered:~~

~~The bloodlines of the EXTRACORPOREAL CIRCUIT are not considered to be insulating. It should be assumed that conducting solutions in and around the tubing establish an electrical contact with the PATIENT.~~

~~An EXTRACORPOREAL CIRCUIT or DIALYSIS FLUID circuit is considered isolating if~~

~~a) the material is electrically isolating, and~~

~~b) the circuit is built such that a rupture is sufficiently unlikely.~~

~~Point a) is tested by applying 1 500 V AC to the relevant segments of the circuit, filled with 0,9 % NaCl. A conductive foil is wrapped over the tube over a length of 10 cm. No breakthrough between foil and fluid should occur over 1 min.~~

~~Point b) is demonstrated by the MANUFACTURER of the circuit by RISK MANAGEMENT which includes the interface between the HAEMODIALYSIS EQUIPMENT and the circuit and the manufacturing PROCESS.~~

Parts like water treatment systems can be considered as not conductively connected and therefore not a part of the applied part if the following conditions apply.

In case that a DIALYSIS WATER supply system is equipped with a resistivity monitoring alarm and has an isolating material dialysis water output line towards the HAEMODIALYSIS EQUIPMENT water inlet, it can be regarded as electrically isolated from the HAEMODIALYSIS EQUIPMENT if the resulting electrical resistance is 120 MΩ or higher for 120 V mains voltage, or 240 MΩ or higher for 240 V mains voltage. The presence of a continuous resistivity monitoring unit with alarm is needed because the isolation value is only obtained if the dialysis water is pure enough (refer to ISO 23500-2:2019 [4], Subclause 4.2.10 and Subclause 4.2.11).

An example for dialysis water of 1 MΩ·cm resistivity, assuming highly isolating tubing material:

- A connecting tube of 120 cm with an 8 mm inner lumen diameter (equivalent to a cross section of 0,5 cm^2) would yield a worst-case current of 1 µA at 240 V (0,5 µA at 120 V).

It shall also be considered that:

– smaller internal tube diameters or larger tube length increase the resistance, whereas larger internal tube diameters or shorter tube length decrease the resistance;

– higher temperature decreases the resistance, whereas lower temperature increases the resistance (values are given at 25 °C as reference);

– DC increases the resistance, whereas AC decreases the resistance.

Other possible sources for LEAKAGE CURRENTS to be taken into consideration are e.g. the drain part.

Subclause 201.16.9.1 – Connection terminals and connectors

According to the state of the art, the PROTECTIVE SYSTEM for "composition of the DIALYSIS FLUID" is based on the measurement of the conductivity or the volumetric admixture. Depending on the operating mode (acetate, bicarbonate), an incorrect DIALYSIS FLUID CONCENTRATE is frequently detected via the conductivity or the volumetric admixture.

Additional measures besides colour coding of the CENTRAL DELIVERY SYSTEM ~~may~~ could be required by RISK MANAGEMENT in case of DIALYSIS FLUID CONCENTRATES which, although they deliver a conductivity within the expected range, are hazardous for the treatment type

concerned in their composition (e.g. acid DIALYSIS FLUID CONCENTRATE 45X ratio for acetate dialysis).

In such cases, the RESPONSIBLE ORGANIZATION should initiate the appropriate measures which are equivalent to colour coding with the pertinent operating mode, such as disabling the operating mode of acetate HAEMODIALYSIS or mechanically coding the HAEMODIALYSIS EQUIPMENT and the DIALYSIS FLUID CONCENTRATE container.

Subclause 202.8.1 – General

Safe state should be defined in the MANUFACTURER's RISK MANAGEMENT FILE. Examples of a safe state for HAEMODIALYSIS EQUIPMENT are as follows:

– stopping the blood flow;
– stopping of the DIALYSIS FLUID flow to the DIALYSER;
– interruption of any SUBSTITUTION FLUID flow;
– reduction of ULTRAFILTRATION rate to its minimum value;
– clamping of the venous blood line;
– activation of auditory and visual ALARM SIGNALS.

Monitoring of the parameters (e.g. via log files) identified by MANUFACTURER for BASIC SAFETY and ESSENTIAL PERFORMANCE should also be taken into consideration to determine if the HAEMODIALYSIS EQUIPMENT is in a safe state.

Subclause 208.4 – General requirements

IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 are written with the focus on intensive care or surgery environments and add in 6.1.2 a very PATIENT-centric view of potential results of failure to respond to the cause of ALARM CONDITIONS.

HAEMODIALYSIS EQUIPMENT is mainly used in a chronic ambulant approach. The PATIENTS normally do not have life threatening status. ALARM CONDITIONS mostly arise from technical causes and the therapy has in most cases of problems the chance to go to a safe state, which only loses time for PATIENT and OPERATORS, but which is one of the most important issues in a timely exact planned schedule of subsequent following shifts. The environment in a normal chronic HAEMODIALYSIS clinic is dominated by the HAEMODIALYSIS EQUIPMENT, in many cases from one MANUFACTURER. Normally, other ME EQUIPMENT will not be used continuously beside the HAEMODIALYSIS EQUIPMENT in the PATIENT ENVIRONMENT.

In this ambulatory environment the ALARM CONDITION categories need completely different priorities than in an environment where the PATIENTS have life-threatening status and the therapy is life-supporting. In the ambulatory environment, 6.1.2, with Table 1, of IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 would not reflect the needed priorities.

Even in the critical care environments, the HAEMODIALYSIS EQUIPMENT is not life-supporting and most ALARM CONDITION situations would not be a HAZARDOUS SITUATION for PATIENT and OPERATOR and the ALARM CONDITION priority will be low. In some cases, OPERATORS from chronic HAEMODIALYSIS support and operate the HAEMODIALYSIS EQUIPMENT in the intensive care environment.

For HAEMODIALYSIS EQUIPMENT not used in intensive care environments, the actual used – over years of operation optimized – ALARM SYSTEMS should not be worsened by the need of applying IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020.

Because of these reasons, this document only requires the complete implementation of IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020

for HAEMODIALYSIS EQUIPMENT with INTENDED USE in the intensive care environment. For this environment, Table AA.1 shows how possible ALARM CONDITION priorities according to IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 could be adapted for HAEMODIALYSIS EQUIPMENT needs. If the HAEMODIALYSIS EQUIPMENT is intended to be used in both environments, the ALARM SYSTEM according to IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 ~~has to~~ shall be implemented and selectable by the RESPONSIBLE ORGANIZATION, but ALARM SYSTEMS with deviation from 6.1.2, 6.3.2.2 and 6.3.3.1 of IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 are allowed for additional implementation.

For HAEMODIALYSIS EQUIPMENT with a screen, this document does not require that the visual ALARM SIGNAL has to be indicated by an indicator light that is independent of the screen, since there ~~may~~ can be applications where it is appropriate if the ALARM SIGNAL is indicated on the screen. In large-size dialysis units, however, it is probably more appropriate to provide an indicator light that can be seen from a far distance and is installed in such a position (e.g. up-raised) that the HAEMODIALYSIS EQUIPMENT activating the ALARM SIGNAL can be readily located.

Table AA.1 – Example of ALARM CONDITION priorities according to 6.1.2 of IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, adapted for HAEMODIALYSIS EQUIPMENT needs

ALARM CONDITION	ALARM CONDITION priority
Different reasons (e.g. pressures, technical faults)	
Reasons that lead to a stop of the blood flow through the EXTRACORPOREAL CIRCUIT	LOW PRIORITY, yellow
Blood loss due to coagulation in the extracorporeal system	
Blood pump stop ALARM CONDITION (201.12.4.4.104.3), as escalation of above ALARM CONDITION	MEDIUM PRIORITY, yellow flashing
Mains off and backup-battery running system, before battery goes down (201.11.8 b))	
Possible blood loss out of the puncture site or open catheter, following accidental needle or catheter disconnect (201.12.4.4.104.1)	
Detectable by low VENOUS PRESSURE	HIGH PRIORITY, red flashing
PHYSIOLOGICAL ALARM CONDITIONS, if not specified in other standards	
PHYSIOLOGICAL ALARM CONDITIONS, for example non-invasive blood pressure limit ALARM CONDITION	HIGH PRIORITY, red flashing Possible: escalation with two different limits
Treatment deviation, influence on prescription	
For example, balancing ALARM CONDITIONS, long-lasting bypass of DIALYSIS FLUID	LOW PRIORITY, yellow
Technical information	
Technical faults, but blood system is running, for example short bypass of dialysate	INFORMATION SIGNAL, for example green flashing Alternative is the use of LOW PRIORITY, yellow

An ALARM SIGNAL activated in case of extracorporeal blood loss to the environment (see 201.12.4.4.104.1) is one example of a HIGH PRIORITY ALARM SIGNAL that requires immediate response by the OPERATOR. If the blood flow is stopped for an extended period of time (201.12.4.4.104.3), this is an example for a MEDIUM PRIORITY ALARM SIGNAL. In most other ALARM CONDITIONS, the PROTECTIVE SYSTEM puts the HAEMODIALYSIS EQUIPMENT in a state which is safe for the PATIENT, at least temporarily, and therefore is indicated by a LOW PRIORITY ALARM SIGNAL. Other ALARM SIGNALS should be determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS.

Regarding the non-applicability of Subclause 6.3.3.1 item d) 1) i) of IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 to this document, in case more than one set of auditory ALARM SIGNAL is present, it is considered acceptable for the

MANUFACTURER to decide if Annex G of IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 alarm signs shall be included in the design or not.

Subclause 208.6.3.1 – General

If the OPERATOR is allowed to configure the contents of the screen, the MANUFACTURER ~~has to~~ shall use constructive measures (and not just notes in the instructions for use) to ensure that the ALARM SIGNALS can be seen under all circumstances.

Subclause 208.6.3.3.2 – Volume and characteristics of auditory ALARM SIGNALS and INFORMATION SIGNALS

The specification takes into account, that the sound pressure level of 65 dB(A) is focussing on users far away, therefore a detailed specification of the measurement position is not needed, as between the sound generating device and the far distance user there are multiple reflections expected, that have a dominant impact on the sound pressure level reaching the user.

Respect to IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, former Annex F, if the HAEMODIALYSIS EQUIPMENT has implemented melodies according to the above-mentioned Annex and they have demonstrated to fit the purpose of being effectively discriminated by the OPERATOR, then they can be considered appropriate and effectively covering the purpose of the Annex G introduced in IEC 60601-1-8:2006/AMD2:2020.

Subclause 208.6.3.3.101 – Special characteristics of auditory ALARM SIGNALS for HAEMODIALYSIS EQUIPMENT

There are ALARM CONDITIONS which do not present any HAZARDOUS SITUATION if the auditory ALARM SIGNAL is AUDIO PAUSED for more than 3 min, but where elimination of the cause of the ALARM CONDITION often takes more than 3 min, for example in case of a conductivity ALARM CONDITION caused by an empty DIALYSIS FLUID CONCENTRATE container. In this case, the PATIENT'S state will not deteriorate during the AUDIO PAUSED period and the activated bypass mode.

Subclause 211 – Requirements for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS used in the HOME HEALTHCARE ENVIRONMENT

Besides the PERMANENTLY INSTALLED connection to SUPPLY MAINS needed for CLASS I ~~devices~~ HAEMODIALYSIS EQUIPMENT the same level of safety ~~may~~ can be achieved by a unique MAINS PLUG connector that is normally not used in the HOME HEALTHCARE ENVIRONMENT. This allows the PATIENT OPERATOR to disconnect and remove the ~~device~~ HAEMODIALYSIS EQUIPMENT without the problem of reconnecting it to another SUPPLY MAINS socket-outlet with an improper PROTECTIVE EARTH CONNECTION. If a unique SUPPLY MAINS socket-outlet connector is used, it ~~has to~~ shall be installed and tested by the RESPONSIBLE ORGANIZATION.

Annex BB
(informative)

Examples of HAZARDS, foreseeable sequences of events, and HAZARDOUS SITUATIONS in HAEMODIALYSIS EQUIPMENT

Table BB.1 is not intended to be a complete RISK ANALYSIS and is provided partially and for example only. Given HARM levels do not apply to all PATIENT groups. Risk assessment is the responsibility of each MANUFACTURER as per ISO 14971:2019 [34].

Table BB.1 – Example of HAZARDOUS SITUATIONS list following ISO 14971:~~2007~~2019, Annex ~~E~~C

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
Multiple HAZARDS possible	Venous needle punctures vascular access	Extracorporeal blood flow into intertissue through venous needle	Haematoma	
	Delivery rate or amount of heparin too high	Heparin concentration too high inside blood volume	Internal bleeding	– IEC 60601-2-16:2024, 201.~~11.8~~12.4.4.106
	Blood flow was stopped too long	Coagulation of extracorporeal blood	Blood loss	– IEC 60601-2-16:2024, 201.7.9.2.5; 201.7.9.3.1; 201.11.8; 201.12.4.4.104.3 – IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 7.9.2.4
	Delivery rate or amount of heparin too low			– IEC 60601-2-16:2024, 201.12.4.4.106
	Interruption of power supply too long			– IEC 60601-2-16:2024, 201.11.8; 201.7.9.3.1; 201.12.4.4.104.3
	High ULTRAFILTRATION rate over DIALYSER semipermeable membrane in relation to blood flow rate	Increasing haematocrit ~~may~~ can block fibres of DIALYSER		– IEC 60601-2-16:2024, 201.12.4.4.104.3
	Venous needle slips out	Extracorporeal blood is pumped to environment		– IEC 60601-2-16:2024, 201.7.9.2.2, ~~7th~~9th hyphen; 201.7.9.3.1, 2nd bullet, 6th hyphen; 201.12.4.4.104.1
	Connector of disposable behind arterial blood pump opened or leaks			– IEC 60601-2-16:2024, 201.7.9.2.2, 3rd hyphen; 201.12.4.4.104.1
	Pressure higher than disposal resist leading to rupture			– IEC 60601-2-16:2024, 201.12.4.4.104.1
	Syringe plunger of heparin pump, which arranged downstream of blood pump slipping out			– IEC 60601-2-16:2024, 201.12.4.4.104.1
	DIALYSER semi-permeable membrane or fibre broken	BLOOD LEAKS into DIALYSIS FLUID		– IEC 60601-2-16:2024, 201.7.9.3.1, 2nd bullet, 7th hyphen; 201.12.4.4.104.2
	Unintended blood flow reversal and air in the EXTRACORPOREAL CIRCUIT	Air infused over arterial PATIENT CONNECTION	Air infusion	– IEC 60601-2-16:2024, 201.7.9.3.1, 2nd bullet, 2nd hyphen; 201.12.4.4.109
	Level regulator pump pumps air into ARTERIAL PRESSURE monitor upstream of arterial blood pump			– IEC 60601-2-16:2024, 201.7.9.3.1, 2nd bullet, 2nd hyphen; 201.12.4.4.109

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	Air sucked into blood side before blood pump (material damage or unintentional opening of the infusion port)	Air infused over venous PATIENT CONNECTION		– IEC 60601-2-16:2024, 201.7.9.2.2, 8th hyphen; 201.7.9.3.1, 2nd bullet, 2nd hyphen; 201.12.4.4.105; 201.12.4.4.106; 201.12.4.4.107
	Level regulator pump pumps air downstream of arterial blood pump into arterial ~~and/~~(pre-dialyzer) pressure monitor or VENOUS PRESSURE monitor ~~downstream of arterial blood pump~~.			– IEC 60601-2-16:2024, 201.7.9.3.1, 2nd bullet, 2nd hyphen; 201.12.4.4.105, 201.12.4.4.~~106, 201.12.4.4.~~107
	SUBSTITUTION FLUID pump pumps air ~~into~~ downstream of arterial ~~and/or venous~~ blood pump into EXTRACORPOREAL CIRCUIT			– IEC 60601-2-16:2024, 201.7.9.3.1, 2nd bullet, 2nd hyphen; 201.12.4.4.105; 201.12.4.4.~~106; 201.12.4.4.~~107
	Improper function of ultrasonic air detector (e.g. caused by coagulum or ultrasound gel)			– IEC 60601-2-16:2024, 201.7.9.2.2, 10th hyphen
	Air entering the EXTRACORPOREAL CIRCUIT in the recirculation path of single-needle treatment			– IEC 60601-2-16:2024, 201.7.9.2.2, 11th hyphen
	Blood line kinked (specially DIALYSER input)	Erythrocytes exposed to high sheer forces.	Haemolysis	– IEC 60601-2-16:2024, 201.7.9.2.2, 9th hyphen
	Reduced blood flow rate by high negative arterial upstream of pump	Reduced effectiveness of HAEMODIALYSIS treatment	Prescribed HAEMODIALYSIS treatment dose not delivered	– IEC 60601-2-16:2024, 201.7.9.2.2, 13th hyphen
	Insufficient degassing of DIALYSIS FLUID			
	Insufficient flow rate of fresh DIALYSIS FLUID			– IEC 60601-2-16:2024, ~~201.7.9.3.1, 2nd bullet,4th~~ **hyphen** 201.4.3.101
	Blood flow rate too low due to technical defect			– IEC 60601-2-16:2024, 201.4.3.101
	DIALYSIS FLUID bypassing DIALYSER			– IEC 60601-2-16:2024, 201.4.3.101
	Effective HAEMODIALYSIS time too low due to technical defect			– IEC 60601-2-16:2024, 201.4.3.101
	SUBSTITUTION FLUID flow rate too low due to technical defect			– IEC 60601-2-16:2024, 201.4.3.101

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
Biological	Blood of the previous PATIENT flows into the pressure inlet connection of the HAEMODIALYSIS EQUIPMENT	Pyrogens/ endotoxins/bacteria/viruses ~~may~~ can contaminate the blood directly (cross infection)	Virus/bacterial infection/ Pyrogen reaction	– IEC 60601-2-16:2024, 201.15.4.1.102
	Disinfection PROCEDURE of HAEMODIALYSIS EQUIPMENT internally and externally has inadequately removed viral contamination			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 7.9.2.12~~, 11.6.6~~ – IEC 60601-2-16:2024, 201.7.9.2.12, 1st, 2nd, 3rd hyphens; 201.11.6.6
	Infusion of contaminated DIALYSIS FLUID into blood from DIALYSIS FLUID side in ONLINE HDF / HF systems	Pyrogens/ endotoxins/bacteria ~~may~~ can contaminates the blood directly		– IEC 60601-2-16:2024, 201.7.9.3.1, 2nd bullet,14th hyphen; 201.12.4.4.111
	Contaminated surface of ENCLOSURE	Skin contamination with bacteria	Bacterial infection	– IEC 60601-2-16:2024, 201.7.9.2.2, 1st hyphen
Chemical	Treatment of PATIENT when HAEMODIALYSIS EQUIPMENT is in disinfection mode	Blood contamination with toxins	Poisoning / allergy	– IEC 60601-2-16:2024, 201.12.4.4.108
	Disinfectant has been inadequately rinsed from DIALYSIS FLUID circuit			– IEC 60601-2-16:2024, 201.11.6.6
	OPERATOR connects disinfectant canister instead of bicarbonate DIALYSIS FLUID CONCENTRATE or acid/acetate DIALYSIS FLUID CONCENTRATE canister to HAEMODIALYSIS EQUIPMENT			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 15.4.1 – IEC 60601-2-16:2024, 201.15.4.1.101
	Toxic material comes in contact with DIALYSIS FLUID (e.g. via water supply or by components of the hydraulics)			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 11.7 – IEC 60601-2-16:2024, 201.7.9.3.1, 2nd bullet, 13th hyphen
Biological	Returning fluid into CENTRAL DELIVERY SYSTEM or DIALYSIS WATER supply system	Blood contamination with toxins	Poisoning/ allergy	– IEC 60601-2-16:2024, 201.12.4.4.108
Multiple HAZARDS possible	DIALYSIS- / SUBSTITUTION FLUID temperature too low	Blood is cooled directly (infusion) or via DIALYSER	Cooling heart until cardiac arrest	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 12.4.3 – IEC 60601-2-16:2024, 201.7.9.3.1, 2nd bullet,4th hyphen; 201.12.4.4.102; 201.11.8

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	DIALYSIS- / SUBSTITUTION FLUID temperature too high	Blood is heated directly (infusion) or via DIALYSER	Haemolysis	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 12.4.3 – IEC 60601-2-16:2024, 201.7.9.2.6, 4th hyphen; 201.7.9.3.1, 2nd bullet, 4th hyphen; 201.12.4.4.102~~; 201.11.8~~
	DIALYSIS FLUID Na concentration lower than prescribed	Blood is dialysed against or infused with (ONLINE HDF) DIALYSIS FLUID of too low concentration (Na)	Hyponatremia	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 12.4.3 – IEC 60601-2-16: 2024, 201.4.3.101; 201.7.9.3.1, 2nd bullet, 3rd hyphen
	DIALYSIS FLUID Na concentration lower than 120 mmol/l		Haemolysis	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 12.4.3 – IEC 60601-2-16:2024, 201.12.4.4.101
	DIALYSIS FLUID Na concentration higher than prescribed	Blood is dialysed against or infused with (ONLINE HDF) DIALYSIS FLUID of too high concentration (Na)	Hypernatremia	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 12.4.3 – IEC 60601-2-16: 201.4.3.101; 201.7.9.3.1, 2nd bullet, 3rd hyphen
	DIALYSIS FLUID Na concentration higher than 160 mmol/l			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 12.4.3 – IEC 60601-2-16: 201.12.4.4.101
	Bicarbonate DIALYSIS FLUID concentration too low	Blood is dialysed against or infused with (ONLINE HDF) DIALYSIS FLUID of too low concentration (Bicarbonate)	Acidosis	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 12.4.3 – IEC 60601-2-16:2024, 201.12.4.4.101
	Acid DIALYSIS FLUID CONCENTRATE instead of acetate DIALYSIS FLUID CONCENTRATE when acetate HAEMODIALYSIS treatment has been selected			– IEC 60601-2-16:2024, 201.7.9.2.5, 2nd hyphen; 201.12.4.4.101; 201.15.4.1.101; 201.16.9.1
	Acid DIALYSIS FLUID CONCENTRATE instead of bicarbonate DIALYSIS FLUID CONCENTRATE when bicarbonate HAEMODIALYSIS treatment has been selected			– IEC 60601-2-16:2024, 201.7.9.2.5, 2nd hyphen; 201.12.4.4.101; 201.15.4.1.101; 201.16.9.1

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	Acetate DIALYSIS FLUID CONCENTRATE instead of bicarbonate DIALYSIS FLUID CONCENTRATE when bicarbonate HAEMODIALYSIS treatment has been selected			– IEC 60601-2-16:2024, 201.7.9.2.5, 2nd hyphen; 201.12.4.4.101; 201.15.4.1.101; 201.16.9.1
	Acetate HAEMODIALYSIS treatment instead of bicarbonate HAEMODIALYSIS treatment		Hyperacetatemia	– IEC 60601-2-16:2024, 201.12.4.4.110
	Bicarbonate DIALYSIS FLUID concentration too high	Blood is dialysed against or infused with (ONLINE HDF) DIALYSIS FLUID of too high concentration (bicarbonate)	Alkalosis	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 12.4.3 – IEC 60601-2-16:2024, 201.12.4.4.101
	Acetate DIALYSIS FLUID CONCENTRATE instead of acid DIALYSIS FLUID CONCENTRATE when bicarbonate HAEMODIALYSIS treatment has been selected			– IEC 60601-2-16:2024, 201.7.9.2.5, 2nd hyphen; 201.12.4.4.101; 201.15.4.1.101; 201.16.9.1
	SUBSTITUTION FLUID bolus volume too high	Blood volume increased	Extracellular volume change	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 12.4.3 – IEC 60601-2-16:2024, 201.12.4.4.103
	Priming or returning volume too high due to technical faults			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 12.4.3 – IEC 60601-2-16:2024, 201.12.4.4.103
	Inlet DIALYSIS FLUID flow rate into DIALYSER higher than outlet flow rate			– IEC 60601-2-16:2024, 201.12.4.4.103~~; 201.7.9.2.2; 201.7.9.2.5; 201.7.9.3.1~~
	SUBSTITUTION FLUID volume higher than ULTRAFILTRATION volume			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 12.4.3 – IEC 60601-2-16:2024, 201.12.4.4.103
	Dry weight not achieved	Insufficient removal of fluid from the PATIENT	Interdialytic overhydration	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 12.4.3 – IEC 60601-2-16:2024, 201.12.4.4.103
	SUBSTITUTION FLUID bolus volume too low	Insufficient increase of PATIENT blood volume	Extracellular volume change	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 12.4.3

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	NET FLUID REMOVAL volume too high	Excessive removal of fluid from the PATIENT		– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 12.4.3 – IEC 60601-2-16:2024, 201.12.4.4.103
	NET FLUID REMOVAL rate greater than set rate			~~– IEC 60601-1-10:2007: Clause 4~~ – IEC 60601-2-16:2024, 201.12.4.4.103~~; 201.7.9.2.2; 201.7.9.2.5; 201.7.9.3.1; 201.11.8~~
	DIALYSIS FLUID loss from balanced DIALYSIS FLUID circuit			– IEC 60601-2-16:2024, 201.12.4.4.103
	ULTRAFILTRATION volume higher than needed by corresponding SUBSTITUTION FLUID volume			– IEC 60601-2-16:2024, 201.12.4.4.103
Operational	Wrong restoring of data/instructions after power interruption	Incorrect treatment	Multiple harms possible	– IEC 60601-2-16:2024, 201.11.8
	Faulty treatment data/instructions from PATIENT card or IT-NETWORK			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 14.13 – IEC 60601-2-16:2024, 201.14.13
	Faulty treatment instruction(s) on screen from IT-NETWORK			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 14.13 – IEC 60601-2-16:2024, 201.14.13
	A physiologic closed loop controller gives a wrong set value.			– IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
Information	Preventive or corrective maintenance has not or incorrectly been carried out			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 7.9.2.13
	Expected service life is elapsed			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 4.4
	Markings or instruction for use missing or wrong			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 7.1; 7.2; 7.4; 7.5; 7.6; 7.9.2 – IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/~~AMD1:2012~~AMD2:202: 5.2; 6.1; 6.2 – IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020: 5.1; 5.2 – IEC 60601-2-16:2024, 201.7.9.2.2
	Service information missing or wrong			– ~~IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012:~~ IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020: 7.3; 7.7; 7.9.2.13; 7.9.3 – IEC 60601-2-16:2024, 201.7.9.2.6

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	OPERATOR response missing or wrong (USE ERROR)			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 7.8; 7.9.2.8; 7.9.2.9; 7.9.2.10; 7.9.2.11; 7.9.2.14; 9.2.3.1; 12.1; 12.2; 12.4.2 – IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/~~AMD1:2012~~AMD2:202: 6.1.2; 6.3.1; 6.3.2.1 – IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020: 6.1; 6.2; 6.3; 6.4 – IEC 60601-2-16:2024, 201.7.9.2.2; 201.7.9.2.6; 201.7.9.2.14; 201.7.9.3.1; 208.4; 208.6.3.1; 208.6.3.3.2; 208.6.3.3.3; 201.12.4.4.110
Operational	Failure of ALARM CONDITION override mode			– IEC 60601-2-16:2024, 201.12.4.4.~~106~~104.2
	Failure of PROTECTIVE SYSTEMS			– IEC 60601-2-16:2024, 201.12.4.4.107
Electrical	Electrical insulation not sufficient	LEAKAGE CURRENT	Electric shock	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 8.5; 8.6; 8.7; 8.8; 13.1.3; 13.2.2 – IEC 60601-2-16:2024, 201.8.3; 201.8.7.4.7; 201.11.6.~~3~~1, 201.11.6.5.
	CREEPAGE DISTANCES and air clearance not sufficient			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 8.9; 13.2.6 – IEC 60601-2-16:2024, 201.13.2.6
	Internal or external leaks that reduce CREEPAGE DISTANCES and AIR CLEARANCE			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 8.9
	Rapid ageing of insulation			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 11.1; 11.6.6

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	Touching ACCESSIBLE PARTS			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 4.8; 4.9; 5.9.2; 7.9.2.7; 8.4; 8.5; 8.10; 8.11; 9.2.2.4 – IEC 60601-2-16:2024, 201.7.9.2.6; 201.8.11.2
	Ingress of fluid into the HAEMODIALYSIS EQUIPMENT			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 11.6 – IEC 60601-2-16:2024, 201.11.6.3
	Components used outside of specified current ratings			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 13.2.3
	Destruction of parts when replacing			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 15.2
	Excessive mechanical stress caused by pushing, impact, dropping, and rough handling			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 15.3
	Overheating of transformer			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 15.5
	Drain connected to DIALYSIS WATER supply system			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 15.4.1
	DIALYSIS FLUID CONCENTRATE connected to DIALYSIS WATER supply system			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 15.4
	Incorrectly arranged ME SYSTEM			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 16.1; 16.2; 16.3; 16.4; 16.5; 16.6; 16.9 – IEC 60601-2-16:2024, 201.16.2; 201.16.6.3

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	Treatment with central venous catheter whose tip is in the right atrium by HAEMODIALYSIS EQUIPMENT with TYPE B APPLIED PARTS	PATIENT LEAKAGE CURRENT	Electric shock	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 8.7 – IEC 60601-2-16:2024, 201.7.9.2.5; 201.8.3
	Magnetic and electric fields cause disruption of proper operation through interference from other electrical equipment and power supply	Incorrect treatment	Multiple harms	– IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 – IEC 60601-2-16:2024, 202.~~3.188~~
	Magnetic and electric fields cause disruption of proper operation through interference to other ME EQUIPMENT and power supply		Multiple harms to PATIENTS and others	– IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020
Chemical	Escape of chemical substances	Contact with chemicals	Body harm	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 7.9.2.4; 11.6.4
	High pressure fluid ejection			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 9.7
Thermal	Hot external or internal components	Contact with high temperature fluids or surfaces	Body harm	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 11.1; 11.6.4; 11.6.6
	High pressure hot fluid ejection			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 9.7
Mechanical	Finger into roller pump	Crushing/Shearing/Limb breaking	Bruise/ Sprain/Cut/Fractures	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 5.9.2; 9.2.2.4.4
	Limb between moving parts			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 9.2.2.2; 16.7
	Foot under the base			
	HAEMODIALYSIS EQUIPMENT on inclined plane			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 9.4

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	Displacement of HAEMODIALYSIS EQUIPMENT			
	Sharp parts	Cutting	Body harm	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 9.~~3~~8
	Openings in ENCLOSURE with moving parts behind			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 5.9.2
Thermal	Components used outside of specified current ratings	Fire	Multiple harms to PATIENTS and others	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 4.8; 4.9; 13.1.2; 13.2.3; 13.2.13
	Ingress of water into the ~~device~~ HAEMODIALYSIS EQUIPMENT leads to short cut current			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 11.6 – IEC 60601-2-16:2024, 201.11.6.3
	Defective control of heater			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 13.2.4; 13.2.5; 13.2.13; 15.4.2
	Impaired cooling			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 13.2.7
	Interruption and short circuit of motor capacitors			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 13.2.9
	Defects of battery			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 15.4.3.1
	Incorrect polarity of battery connection			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 15.4.3.2
	Overcharging battery			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 15.4.3.3
	Excessive current from battery			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 15.4.3.5

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	Overheating of transformer			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 15.5
[a] IEC 60601-2-16:2024 refers to this document.				

Annex CC
(informative)

Example of an open alarm interface specification

CC.1 General

This specification is identical to the withdrawn IEC PAS 63023 [17].

In extracorporeal treatment different hazardous situations can occur. One major concern is blood loss to the environment. In Subclause 201.12.4.4.104.1 of IEC 60601-2-16:2012, different technical solutions are given. In addition, this IEC standards committee has included in this Annex an open alarm interface specification to connect an EXTERNAL ALARMING DEVICE to the HAEMODIALYSIS EQUIPMENT in order to stop the extracorporeal blood flow in case the EXTERNAL ALARMING DEVICE detects a needle slipping out from the fistula or the graft.

The functionality described hereby is an example of an INPUT INTERFACE for connecting an EXTERNAL ALARMING DEVICE to HAEMODIALYSIS EQUIPMENT simple solution, taking SINGLE FAULT CONDITION of the INPUT INTERFACE into account. Alternative designs could be identified by the MANUFACTURER.

CC.2 Terms and definitions regarding this open alarm interface specification

CC.2.1
EXTERNAL ALARMING DEVICE
ACCESSORY that detects ALARM CONDITIONS

CC.2.2
INPUT INTERFACE
part of HAEMODIALYSIS EQUIPMENT providing the possibility of access to an EXTERNAL ALARMING DEVICE

CC.2.3
INTERNAL SIGNAL PROCESSING
part of HAEMODIALYSIS EQUIPMENT intended to process signals

CC.2.4
SIGNAL PLUG
terminal device of the external alarming device for the connection to the haemodialysis equipment signal socket

CC.2.5
SIGNAL SOCKET
TERMINAL DEVICE of the INPUT INTERFACE

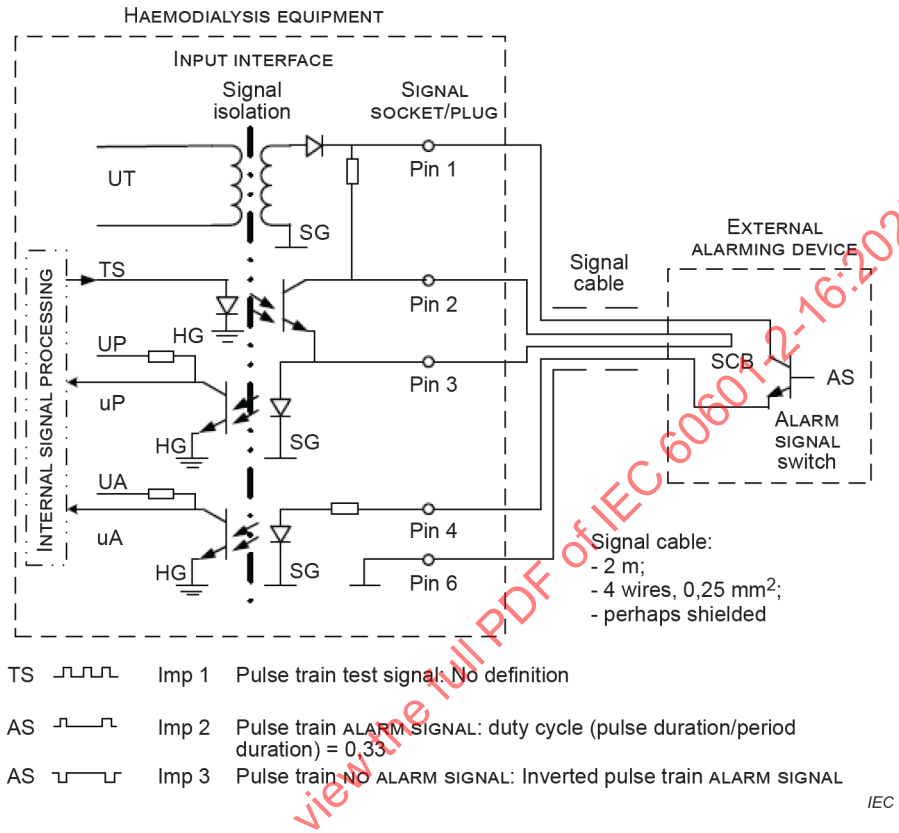
CC.2.6
HAEMODIALYSIS EQUIPMENT GROUND
grounding terminal connected to conductive parts for INTERNAL SIGNAL PROCESSING

CC.2.7
SIGNAL GROUND
grounding terminal connected to conductive parts for external signal processing

CC.3 Application

CC.3.1 Simplified circuit diagram

The simplified circuit diagram in Figure CC.1 provides a hardware solution for an INPUT INTERFACE.



UT	Transformer input voltage	PIN 1	ALARM SIGNAL switch voltage
TS	Test signal	Pin 2	Signal plug connected output
UP	Plug voltage	Pin 3	Signal plug connected input
uP	Signal plug connected	PIN 4	EXTERNAL ALARMING DEVICE signal
UA	ALARM SIGNAL voltage	Pin 6	Signal cable shield
uA	ALARM SIGNAL	SG	Isolated SIGNAL GROUND
HG	HAEMODIALYSIS EQUIPMENT GROUND	SCB	Signal cable bridge

Pulse time duration ALARM SIGNAL: 0,2 s ± 10 %; duration of one period 0,6 s ± 10 %

Switching voltage ALARM SIGNAL switch: minimal 6 V; maximal 30 V

Switching power ALARM SIGNAL switch: 200 mW

Figure CC.1 – Simplified circuit diagram

CC.3.2 Periodic functional check

A failure of the INPUT INTERFACE of the HAEMODIALYSIS EQUIPMENT should become obvious to the OPERATOR at least once per day when in operational use.

In order to detect the failure of the INPUT INTERFACE, the test signal (TS) is used. For this purpose, the test signal is set to the operation voltage (OV) and the test results are monitored by the INTERNAL SIGNAL PROCESSING unit.

The expected test condition signals and test results are listed in Table CC.1.

Table CC.1 – Periodic functional check of the INPUT INTERFACE

Test condition	uP	uA	Test result
Test signal (TS) = operation voltage (OV)	HG	UA	No error
	HG	HG	Error
	HG	Imp2	No error
	HG	Imp3	No error
	Imp1	UA or HG or Imp2 or Imp3	Error
	UP	UA or HG or Imp2 or Imp3	Error

The test results from Table CC.1 lead to the expected reactions of the HAEMODIALYSIS EQUIPMENT, which are listed in Table CC.2.

Table CC.2 – Reaction of HAEMODIALYSIS EQUIPMENT

Test result	Reaction HAEMODIALYSIS EQUIPMENT
No error	Display status: test INPUT INTERFACE passed
Error	Display status: test INPUT INTERFACE failed

CC.3.3 Condition of INPUT INTERFACE

The signals of the connected SIGNAL PLUG (uP) and ALARM SIGNAL (uA) lead to the results listed in Table CC.3.

Table CC.3 – Signal result of signal input to INTERNAL SIGNAL PROCESSING unit

uP	uA	Signal result
Imp1	UA	No EXTERNAL ALARMING DEVICE connected
Imp1	HG	INPUT INTERFACE defective
Imp1	Imp2	EXTERNAL ALARMING DEVICE or INPUT INTERFACE defective
Imp1	Imp3	EXTERNAL ALARMING DEVICE or INPUT INTERFACE defective
UP	UA	INPUT INTERFACE defective
UP	HG	INPUT INTERFACE defective
UP	Imp2	INPUT INTERFACE defective
UP	Imp3	INPUT INTERFACE defective
HG	UA	EXTERNAL ALARMING DEVICE or INPUT INTERFACE defective
HG	HG	EXTERNAL ALARMING DEVICE or INPUT INTERFACE defective
HG	Imp2	No ALARM SIGNAL from EXTERNAL ALARMING DEVICE
HG	Imp3	ALARM SIGNAL from EXTERNAL ALARMING DEVICE

CC.3.4 Reaction of HAEMODIALYSIS EQUIPMENT

During the treatment, the signal result from Table CC.3 leads to the expected reactions of the HAEMODIALYSIS EQUIPMENT, which are listed in Table CC.4.

Table CC.4 – Reaction of HAEMODIALYSIS EQUIPMENT during the treatment

Signal result	Reaction HAEMODIALYSIS EQUIPMENT during the treatment
No EXTERNAL ALARMING DEVICE connected	Display status: no EXTERNAL ALARMING DEVICE connected
INPUT INTERFACE defective	– Visual ALARM SIGNAL – Audible ALARM SIGNAL – Display status: INPUT INTERFACE defective
EXTERNAL ALARMING DEVICE or INPUT INTERFACE defective	– Visual ALARM SIGNAL – Audible ALARM SIGNAL – Display status: EXTERNAL ALARMING DEVICE or INPUT INTERFACE defective
No ALARM SIGNAL from EXTERNAL ALARMING DEVICE	Display status: EXTERNAL ALARMING DEVICE is connected
ALARM SIGNAL from EXTERNAL ALARMING DEVICE	– Stoppage of blood flow – Visual ALARM SIGNAL – Audible ALARM SIGNAL – Display status: EXTERNAL ALARMING DEVICE in ALARM CONDITION

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Index of defined terms used in this document

IEC 60601-2-16

Edition 6.0 2025-01

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

Medical electrical equipment –
Part 2-16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment

Appareils électromédicaux –
Partie 2-16 : Exigences particulières pour la sécurité de base et les performances essentielles des appareils d'hémodialyse, d'hémodiafiltration et d'hémofiltration

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment

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This sixth edition cancels and replaces the fifth edition published in 2018. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) update of references to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, of references to IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, of references to IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, of references to IEC 60601-1-9:2007, IEC 60601-1-9:2007/AMD1:2013 and IEC 60601-1-9:2007/AMD2:2020, of references to IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020 and of references to IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020;

b) consideration of ESSENTIAL PERFORMANCE in SINGLE FAULT CONDITION regarding IEC 60601-1:2005/AMD1:2012/ISH1:2021;

c) including the information given in the document 62D/1771A/INF regarding 201.11.8;

d) including withdrawn IEC PAS 63023[17] as Annex CC;

e) including SECURITY (CYBERSECURITY) requirements;

f) consideration of HAEMODIALYSIS EQUIPMENT using pre-manufactured DIALYSIS FLUID bags;

g) improvements for labelling;

h) other minor technical improvements;

i) editorial improvements.

The text of this International Standard is based on the following documents:

Draft	Report on voting
62D/2163/FDIS	62D/2184/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

In this document, the following print types are used:

– requirements and definitions: roman type;

– *test specifications: italic type;*

– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

– TERMS DEFINED IN CLAUSE 3 OF IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 AND IEC 60601-1:2005/AMD2:2020, IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

– "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes Subclauses 7.1, 7.2, etc.);

– "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this document are preceded by the term "Clause" followed by the clause number. References to subclauses within this document are by number only.

In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 and IEC 80601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

NOTE The attention of the users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committees that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

IMPORTANT – The "colour inside" logo on the cover page of this document indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

The minimum safety requirements specified in this document are considered to provide for a practical degree of safety in the operation of HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION EQUIPMENT.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment

201.1 Scope, object and related standards

Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.1.1 * Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION EQUIPMENT, hereafter referred to as HAEMODIALYSIS EQUIPMENT. It applies to HAEMODIALYSIS EQUIPMENT intended for use either by medical staff or under the supervision of medical experts, including HAEMODIALYSIS EQUIPMENT operated by the PATIENT, regardless of whether the HAEMODIALYSIS EQUIPMENT is used in a hospital or domestic environment.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

This document does not take into consideration specific safety details of the DIALYSIS FLUID control system of HAEMODIALYSIS EQUIPMENT using regeneration of DIALYSIS FLUID or CENTRAL DELIVERY SYSTEMS for DIALYSIS FLUID. It does, however, take into consideration the specific safety requirements of such HAEMODIALYSIS EQUIPMENT concerning electrical safety and PATIENT safety.

This document specifies the minimum safety requirements for HAEMODIALYSIS EQUIPMENT. These HAEMODIALYSIS EQUIPMENT are intended for use either by medical staff or for use by the PATIENT or other trained personnel under medical supervision.

This document includes all ME EQUIPMENT that is intended to deliver a HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION treatment to a PATIENT, independent of the treatment duration and location.

If applicable, this document applies to the relevant parts of ME EQUIPMENT intended for other extracorporeal blood purification treatments.

The particular requirements in this document do not apply to:

– EXTRACORPOREAL CIRCUITS (see ISO 8637-2 [1][1]),
– DIALYSERS (see ISO 8637-1 [2]),
– DIALYSIS FLUID CONCENTRATES (see ISO 23500-4 [3]),
– pre-manufactured DIALYSIS FLUID bags,
– DIALYSIS WATER supply systems (see ISO 23500-2 [4]),

1 Numbers in square brackets refer to the Bibliography.

– CENTRAL DELIVERY SYSTEMS for DIALYSIS FLUID CONCENTRATES (see ISO 23500-4 [3]), described as systems for bulk mixing concentrate at a dialysis facility,

– equipment used to perform PERITONEAL DIALYSIS (see IEC 60601-2-39 [5]).

201.1.2 Object

Replacement:

The object of this document is to establish BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for HAEMODIALYSIS EQUIPMENT.

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and Clause 201.2 of this document.

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020, IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020 apply as modified in Clauses 202, 208, 210 and 211.

IEC 60601-1-3 does not apply. IEC 60601-1-9:2007, IEC 60601-1-9:2007/AMD1:2013 and IEC 60601-1-9:2007/AMD2:2020 does not apply as noted in Clause 209.

All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

The numbering of clauses and subclauses of this document corresponds to that of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this document addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are specified by the use of the following words:

"*Replacement*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is replaced completely by the text of this document.

"*Addition*" means that the text of this document is additional to the requirements of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard.

"*Amendment*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables which are additional to those of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered starting from 201.101. However, due to the fact that definitions in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered 3.1 through 3.154, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, for example 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this document" is used to make reference to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this document, the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 Normative references

NOTE Informative references are listed in the Bibliography.

Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60601-1-10:2007, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*
IEC 60601-1-10:2007/AMD1:2013
IEC 60601-1-10:2007/AMD2:2020

IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*
IEC 60601-1-11:2015/AMD1:2020

IEC 61672-1:2013, *Electroacoustics – Sound level meters – Part 1: Specifications*

ISO 3744:2010, *Acoustics – Determination of sound power levels and sound energy levels of noise sources using sound pressure – Engineering methods for an essentially free field over a reflecting plane*

ISO 23500-3:2024, *Preparation and quality management of fluids for haemodialysis and related therapies – Part 3: Water for haemodialysis and related therapies*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020, IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020, and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at https://www.electropedia.org/
- ISO Online browsing platform: available at https://www.iso.org/obp

NOTE Refer to section "Index of defined terms used in this particular standard" for the index of defined terms.

201.3.8
*** APPLIED PART**

Replacement:

EXTRACORPOREAL CIRCUIT and all parts permanently and conductively connected to it (e.g. DIALYSIS FLUID circuit)

Note 1 to entry: See Figure AA.8 in Informative Annex AA Subclause 201.16 and see 201.16.6.3.

Note 2 to entry: One example of an APPLIED PART is the EXTRACORPOREAL CIRCUIT including any pre-manufactured DIALYSIS FLUID bags, extension lines, and drain bags in a stand-alone system connected during treatment.

Note 3 to entry: Another example of an APPLIED PART is the EXTRACORPOREAL CIRCUIT including connected DIALYSIS FLUID bags, that are online prepared before treatment without the patient connected and drain bags. During treatment the online preparation part of the HAEMODIALYSIS EQUIPMENT is conductively disconnected.

Note 4 to entry: Another example of an APPLIED PART is the EXTRACORPOREAL CIRCUIT including all connected fluid paths of the HAEMODIALYSIS EQUIPMENT and the connection to a drain during the treatment.

201.3.78
PATIENT CONNECTION

Addition:

Note 1 to entry: The PATIENT blood lines connectors are the individual points on the APPLIED PART through which a current can flow between the PATIENT and the HAEMODIALYSIS EQUIPMENT in NORMAL CONDITION or SINGLE FAULT CONDITION.

Additional terms and definitions:

201.3.201
ARTERIAL PRESSURE
pressure measured in the blood withdrawal line of the EXTRACORPOREAL CIRCUIT between the PATIENT CONNECTION and DIALYSER connection

Note 1 to entry: A difference can be made between the pre-pump pressure, which is upstream of the blood pump, and post-pump pressure, which is downstream of the blood pump.

201.3.202
*** BLOOD LEAK**
leakage of blood from the blood compartment to the DIALYSIS FLUID compartment of the DIALYSER

Note 1 to entry: When performing an HF PROCESS, this involves the filtration fluid section.

201.3.203
CENTRAL DELIVERY SYSTEM
part of a ME SYSTEM which proportions DIALYSIS FLUID CONCENTRATE and DIALYSIS WATER for distribution as DIALYSIS FLUID to the HAEMODIALYSIS EQUIPMENT or distributes DIALYSIS FLUID CONCENTRATE

201.3.204
DIALYSER
device containing a semi-permeable membrane that is used to perform HD, HDF or HF

201.3.205
DIALYSIS FLUID
DIALYSATE
DIALYSIS SOLUTION
DIALYSING FLUID
aqueous fluid containing electrolytes and, usually, buffer and glucose, which is intended to exchange solutes with blood during HAEMODIALYSIS

Note 1 to entry: The DIALYSIS FLUID could be pre-manufactured in bags as pharmaceuticals according to the relevant pharmacopoeia monograph or be prepared by the HAEMODIALYSIS EQUIPMENT or be influenced in composition by the HAEMODIALYSIS EQUIPMENT.

[SOURCE: ISO 23500-1:2024 [6], 3.15, modified – The notes have been deleted and a new Note 1 to entry was added.]

201.3.206
DIALYSIS FLUID CONCENTRATE
substances which, when appropriately diluted or dissolved with DIALYSIS WATER, produce the DIALYSIS FLUID

201.3.207
DIALYSIS WATER
water that has been treated to meet the requirements of ISO 23500-3:2024 and which is suitable for use in HAEMODIALYSIS applications, including the preparation of DIALYSIS FLUID, reprocessing of DIALYSERS, preparation of DIALYSIS FLUID CONCENTRATE and preparation of SUBSTITUTION FLUID for online convective therapies

Note 1 to entry: The words "water for dialysis", "permeate" and "reverse osmosis water" are commonly used as synonyms of DIALYSIS WATER.

[SOURCE: ISO 23500-1:2024 [6], 3.17, modified – The note was reworded.]

201.3.208
EXTRACORPOREAL CIRCUIT
blood lines, DIALYSER and any integral ACCESSORY

Note 1 to entry: An alternative for DIALYSER could be a HF-filter, adsorber or other device.

201.3.209
HAEMODIAFILTRATION
HDF
PROCESS whereby concentrations of water-soluble substances in a PATIENT'S blood and an excess of fluid of a PATIENT are corrected by a simultaneous combination of HD and HF

201.3.210
HAEMODIALYSIS
HD
PROCESS whereby concentrations of water-soluble substances in a PATIENT'S blood and an excess of fluid of a PATIENT are corrected by bidirectional diffusive transport and ULTRAFILTRATION across a semi-permeable membrane separating the blood from the DIALYSIS FLUID

Note 1 to entry: This PROCESS typically includes fluid removal by filtration. This PROCESS is usually also accompanied by diffusion of substances from the DIALYSIS FLUID into the blood.

201.3.211
*** HAEMODIALYSIS EQUIPMENT**
ME EQUIPMENT or ME SYSTEM used to perform at least one of the following: HAEMODIALYSIS, HAEMODIAFILTRATION, HAEMOFILTRATION

Note 1 to entry: When the term ME EQUIPMENT is used in headings, it is equivalent to HAEMODIALYSIS EQUIPMENT. When the term ME EQUIPMENT is used in the text, it is referring to a general ME EQUIPMENT.

201.3.212
HAEMOFILTRATION
HF
PROCESS whereby concentrations of water-soluble substances in a PATIENT'S blood and an excess of fluid of a PATIENT are corrected by convective transport via ULTRAFILTRATION and partial replacement by a SUBSTITUTION FLUID resulting in the required NET FLUID REMOVAL

201.3.213
NET FLUID REMOVAL
fluid loss from the PATIENT

Note 1 to entry: Historically, this term was "weight loss".

201.3.214
*** ONLINE HDF**
HAEMODIAFILTRATION PROCEDURE where the HAEMODIALYSIS EQUIPMENT produces SUBSTITUTION FLUID for infusion from DIALYSIS FLUID for the HAEMODIAFILTRATION treatment

201.3.215
*** ONLINE HF**
HAEMOFILTRATION PROCEDURE where the HAEMODIALYSIS EQUIPMENT produces the SUBSTITUTION FLUID for infusion from DIALYSIS FLUID for the HAEMOFILTRATION treatment

201.3.216
*** PROTECTIVE SYSTEM**
automatic system, or a constructional feature, specifically designed to protect the PATIENT against HAZARDOUS SITUATIONS

201.3.217
SUBSTITUTION FLUID
fluid used in HF and HDF treatments which is directly infused into the EXTRACORPOREAL CIRCUIT as a replacement for the fluid that is removed from the blood by filtration

[SOURCE: ISO 23500-1:2024 [6], 3.42, modified – The words "patient's blood" and "ultrafiltration" have been replaced respectively by "EXTRACORPOREAL CIRCUIT" and "filtration" in the definition, and the note has been deleted.]

201.3.218
TRANSMEMBRANE PRESSURE
TMP
fluid pressure difference exerted across the semi-permeable membrane of the DIALYSER

Note 1 to entry: Generally, the mean TMP is used. In practice, the displayed TRANSMEMBRANE PRESSURE is usually estimated from the measured EXTRACORPOREAL CIRCUIT pressure minus the measured DIALYSIS FLUID pressure, each obtained at a single point.

201.3.219
*** ULTRAFILTRATION**
PROCESS of fluid removal from the PATIENT'S blood across the semi-permeable membrane of the DIALYSER

201.3.220
VENOUS PRESSURE
pressure measured in the blood return line of the EXTRACORPOREAL CIRCUIT between the DIALYSER connection and PATIENT CONNECTION

201.4 General requirements

Clause 4 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.4.3 * Essential performance

Additional subclauses:

201.4.3.101 * Additional ESSENTIAL PERFORMANCE requirements

If applicable, the ESSENTIAL PERFORMANCE of HAEMODIALYSIS EQUIPMENT includes, but is not limited to, the functions found in the subclauses listed in Table 201.101, which shall be met within the tolerances specified by the MANUFACTURER under NORMAL CONDITION.

The behaviour of the HAEMODIALYSIS EQUIPMENT for ESSENTIAL PERFORMANCE in SINGLE FAULT CONDITION shall be determined by the MANUFACTURER'S RISK MANAGEMENT.

Table 201.101 – ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Blood flow rate	201.4.3.102
DIALYSIS FLUID flow rate	201.4.3.103
NET FLUID REMOVAL	201.4.3.104
SUBSTITUTION FLUID flow rate	201.4.3.105
Dialysis time	201.4.3.106
DIALYSIS FLUID composition	201.4.3.107
DIALYSIS FLUID temperature	201.4.3.108
SUBSTITUTION FLUID temperature	201.4.3.109

NOTE 1 Some ESSENTIAL PERFORMANCE requirements listed in Table 201.101 are dependent on the characteristics of the disposables used (e.g. blood flow rate is dependent upon the pump segment inner diameter in rotary peristaltic pumps).

NOTE 2 Subclause 7.9.2.5 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 describes requirements giving the specifications for the ESSENTIAL PERFORMANCE in the instruction for use.

201.4.3.102 Blood flow rate

The blood flow rate of the HAEMODIALYSIS EQUIPMENT shall be delivered as specified by the MANUFACTURER. The specification shall take into account the pump segment fatigue for the maximum specified usage life of the EXTRACORPOREAL CIRCUIT.

* NOTE 1 A blood flow rate lower than the set value is considered detrimental for a typical treatment. Therefore, the goal of testing is to find the highest negative blood flow rate error.

Compliance is checked under the following test conditions for typical peristaltic pumps:

– *apply an unused pump segment to the HAEMODIALYSIS EQUIPMENT according to the instructions for use;*
– *apply a fluid source (e.g. water) with a temperature of 37 °C ± 1 °C to the EXTRACORPOREAL CIRCUIT;*
– *either set the NET FLUID REMOVAL rate to 0 ml/h or bypass the DIALYZER, or both;*
– *set the blood flow rate of the HAEMODIALYSIS EQUIPMENT to 400 ml/min or – if not possible – to the highest possible blood flow rate;*
– *create a pre-pump average ARTERIAL PRESSURE of –200 mmHg (± 10 mmHg);*
– *let the pump run for 30 min to 45 min at maximum blood flow rate;*
– *after this preconditioning measure the blood flow rate.*

The value of the measured blood flow rate shall be within the tolerances specified by the MANUFACTURER in the instructions for use.

NOTE 2 Pump segment fatigue can reduce the blood flow rate.

NOTE 3 The blood flow rate in peristaltic pumps can considerably decrease in case of high negative pressures on the suction side.

201.4.3.103 DIALYSIS FLUID flow rate

The DIALYSIS FLUID flow rate of the HAEMODIALYSIS EQUIPMENT shall be delivered as specified by the MANUFACTURER.

NOTE A DIALYSIS FLUID flow rate lower than the set value is considered detrimental for a typical treatment.

Compliance is checked under the following test conditions:

– *set the HAEMODIALYSIS EQUIPMENT to the HAEMODIALYSIS mode as specified by the MANUFACTURER;*
– *set the HAEMODIALYSIS EQUIPMENT to maximum DIALYSIS FLUID flow rate;*
– *measure the DIALYSIS FLUID flow rate over a period of 30 min ± 2 min;*
– *set the HAEMODIALYSIS EQUIPMENT to minimum DIALYSIS FLUID flow rate;*
– *measure the DIALYSIS FLUID flow rate over a period of 30 min ± 2 min.*

The values of the DIALYSIS FLUID flow rate shall be within the tolerances specified by the MANUFACTURER in the instructions for use.

201.4.3.104 NET FLUID REMOVAL

The NET FLUID REMOVAL of the HAEMODIALYSIS EQUIPMENT shall be achieved as specified by the MANUFACTURER.

Compliance is checked under the following test conditions.

Test 1 for the balancing part of the HAEMODIALYSIS EQUIPMENT only:

– *set the HAEMODIALYSIS EQUIPMENT in the HAEMODIALYSIS mode, if applicable, with a DIALYSER according to the MANUFACTURER's recommendation;*

– *apply fluid (e.g. water) in the EXTRACORPOREAL CIRCUIT. If the temperature can have an impact on the NET FLUID REMOVAL measurement, the fluid shall have a temperature of 37 °C ± 1 °C at the arterial patient connection;*

– *set the highest DIALYSIS FLUID flow rate, if applicable;*

– *set the DIALYSIS FLUID temperature to 37 °C, if applicable;*

– *set the NET FLUID REMOVAL rate to 0 ml/h or the lowest adjustable value;*

– *create a DIALYSER blood outlet pressure of 50 mmHg (± 10 mmHg) below the highest operating pressure specified by the MANUFACTURER;*

– *measure the NET FLUID REMOVAL during an appropriate time interval.*

Continue with test 2:

– *set the NET FLUID REMOVAL rate to the maximum value;*

– *measure the NET FLUID REMOVAL during an appropriate time interval.*

Continue with test 3:

– *create a DIALYSER blood outlet pressure of 20 mmHg (± 10 mmHg) above the lowest operating pressure specified by the MANUFACTURER;*

– *measure the NET FLUID REMOVAL during an appropriate time interval.*

The values of the NET FLUID REMOVAL shall be within the tolerances specified by the MANUFACTURER in the instructions for use.

201.4.3.105 SUBSTITUTION FLUID flow rate

For HAEMOFILTRATION and HAEMODIAFILTRATION EQUIPMENT only.

The SUBSTITUTION FLUID flow rate of the HAEMODIALYSIS EQUIPMENT shall be delivered as specified by the MANUFACTURER.

NOTE A SUBSTITUTION FLUID flow rate lower than the set value is considered detrimental for a typical treatment.

Compliance is checked under the following test conditions.

Test 1 for the balancing part of the HAEMODIALYSIS EQUIPMENT and of the therapeutic relevant SUBSTITUTION FLUID flow rate:

– *set the HAEMODIALYSIS EQUIPMENT to the HDF or HF mode with a DIALYSER according to the MANUFACTURER's recommendation;*

– *apply fluid (e.g. water) in the EXTRACORPOREAL CIRCUIT;*

– *set the NET FLUID REMOVAL flow rate to 0 ml/h, or – if not possible – to the minimum;*

– *set the maximum SUBSTITUTION FLUID flow rate;*

– *set the temperature of the SUBSTITUTION FLUID to 37 °C, if applicable;*

– *measure the substitution fluid flow rate and the net fluid removal.*

Continue with test 2:

– *set the minimum SUBSTITUTION FLUID flow rate;*

– *measure the SUBSTITUTION FLUID flow rate and the NET FLUID REMOVAL.*

The values of SUBSTITUTION FLUID flow rate and NET FLUID REMOVAL shall be within the tolerances specified by the MANUFACTURER in the instructions for use.

201.4.3.106 Dialysis time

The accuracy of the dialysis treatment time for the HAEMODIALYSIS EQUIPMENT shall be as specified by the MANUFACTURER.

Compliance is checked by functional tests relevant for the definition of dialysis treatment time specified by the MANUFACTURER.

201.4.3.107 * DIALYSIS FLUID composition

The accuracy of the composition of the DIALYSIS FLUID shall be specified by the MANUFACTURER.

The test method shall be specified by the MANUFACTURER.

Compliance is checked by inspection and by appropriate functional test(s) that demonstrate the MANUFACTURER's limits specified in the instructions for use are maintained.

201.4.3.108 Dialysis fluid temperature

The temperature of the DIALYSIS FLUID shall be achieved as specified by the MANUFACTURER.

NOTE This test applies only to HAEMODIALYSIS EQUIPMENT having a heater for the DIALYSIS FLUID.

Compliance is checked under the following test conditions:

- *let the HAEMODIALYSIS EQUIPMENT run until it is thermally stable at environmental conditions within 20 °C to 25 °C;*
- *set the DIALYSIS FLUID temperature to 37 °C, if applicable;*
- *set the highest DIALYSIS FLUID flow rate;*
- *measure the temperature at the DIALYSER inlet;*
- *record the temperature during a period of 30 min ± 2 min;*
- *set the lowest DIALYSIS FLUID flow rate;*
- *measure the temperature at the DIALYSER inlet;*
- *record the temperature during a period of 30 min ± 2 min.*

The values of the DIALYSIS FLUID temperature shall be within the tolerances specified by the MANUFACTURER in the instructions for use.

201.4.3.109 SUBSTITUTION FLUID temperature

The SUBSTITUTION FLUID temperature of the HAEMODIALYSIS EQUIPMENT shall be achieved as specified by the MANUFACTURER.

NOTE This test applies only to HAEMODIALYSIS EQUIPMENT having a heater for the SUBSTITUTION FLUID.

Compliance is checked under the following test conditions.

- *let the HAEMODIALYSIS EQUIPMENT run until it is in a thermally stable condition within the environment;*
- *the environmental temperature is within 20 °C to 25 °C;*
- *set the SUBSTITUTION FLUID temperature to 37 °C, if applicable;*
- *set the highest SUBSTITUTION FLUID flow rate;*

– *measure the temperature of the SUBSTITUTION FLUID at the connection point of the SUBSTITUTION FLUID line to the blood line;*

– *record the temperature over a period of 30 min ± 2 min;*

– *set the lowest SUBSTITUTION FLUID flow rate;*

– *measure the temperature of the SUBSTITUTION FLUID at the connection point of the SUBSTITUTION FLUID line to the blood line;*

– *record the temperature over a period of 30 min ± 2 min.*

The values of the SUBSTITUTION FLUID temperature shall be within the tolerances specified by the MANUFACTURER in the instructions for use.

201.4.7 SINGLE FAULT CONDITION for ME EQUIPMENT

Addition:

An example of SINGLE FAULT CONDITION is a failure of a PROTECTIVE SYSTEM (see 201.12.4.4.101, 201.12.4.4.102, 201.12.4.4.103, 201.12.4.4.104, 201.12.4.4.105);

NOTE 101 If air is permanently present in the EXTRACORPOREAL CIRCUIT when the HAEMODIALYSIS EQUIPMENT is used as intended by the MANUFACTURER, air is not regarded as a SINGLE FAULT CONDITION, but as a NORMAL CONDITION.

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.5.4 Other conditions

Addition:

aa) When the outcome of a test can be affected by the initial temperature of the pre-manufactured DIALYSIS FLUID bags, the temperature of the DIALYSIS FLUID at the start of the test shall be equal to or less than 4 °C, or the minimum DIALYSIS FLUID temperature specified by the MANUFACTURER of the ME EQUIPMENT.

bb) If the conditions (e.g., temperature, humidity) during either storage or transport, or both, influence NORMAL USE, this shall be addressed by the RISK MANAGEMENT PROCESS.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.7.4.3 Units of measurement

Addition:

mmHg may be used for measurement of pressures in any part of the HAEMODIALYSIS EQUIPMENT.

201.7.8.2 * Colours of controls

Replacement:

The colour red may be used for a control of the blood pump function or for a control by which a function is interrupted in case of emergency.

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.2 Instructions for use

201.7.9.2.1 General

Addition:

The instructions for use shall additionally include the following:

– * minimum weight values of the intended PATIENT population including applicable limitations for specific PATIENTS' groups;

Compliance is checked by inspection of the instructions for use in the ACCOMPANYING DOCUMENTS.

201.7.9.2.2 Warning and safety notices

Addition:

The instructions for use shall additionally include the following, if applicable:

– a warning statement which draws the OPERATOR'S attention to the precautions necessary to prevent any cross-infection between PATIENTS;

– a warning statement which draws the OPERATOR'S attention to the HAZARDOUS SITUATION associated with connection and disconnection of the PATIENT;

– a warning statement that draws the OPERATOR'S attention to the actions required to respond to ALARM SIGNALS from any PROTECTIVE SYSTEM;

– a warning statement that draws the OPERATOR's attention to potential HAZARDS relating to inappropriate selection of the pre-manufactured DIALYSIS FLUID bags;

– a warning statement which draws the OPERATOR'S attention to the HAZARDS, including any HAZARDOUS SITUATIONS, arising from improper installation and improper connections of the EXTRACORPOREAL CIRCUIT;

– a warning statement on the HAZARDS related to incorrect choice of DIALYSIS FLUID CONCENTRATE(S);

– a quantitative description of the possible deviation of each component of the DIALYSIS FLUID in SINGLE FAULT CONDITION depending on the ALARM LIMITS of the PROTECTIVE SYSTEM;

– * a warning statement on the HAZARDS and underlying causes related to a possible transport of undesired substances from the DIALYSIS FLUID compartment to the blood compartment of the DIALYSER;

– for the PROTECTIVE SYSTEM employed according to 201.12.4.4.104.1 a):

  - a warning statement that this PROTECTIVE SYSTEM reduces the RISK in part only and an explanation of the remaining RISK;
  - a description of OPERATOR responsibility for further mitigation of residual RISK;

– a warning statement of the adequate OPERATOR action upon an ALARM CONDITION and associated HAZARD(S), if the ALARM SIGNAL is repeatedly confirmed without solving the underlying problem;

– * a warning statement specifying that any narrow passages in the EXTRACORPOREAL CIRCUIT (such as arising from kinks in the blood line or using needles not suitable for the selected blood flow rates) can cause haemolysis and that this HAZARDOUS SITUATION is possibly not detected by the PROTECTIVE SYSTEM;

– if a PROTECTIVE SYSTEM, according to 201.12.4.4.105, Note 1, is applied: a warning statement that improper functioning of an ultrasonic air detector can be caused by a coagulum or the application of ultrasound gel;

– * a warning statement that air can enter into the EXTRACORPOREAL CIRCUIT downstream of the air detector, at for example insufficiently tightened connection points, if pressures are negative; this can occur in cases such as single needle applications or central venous catheter applications;

– regarding the microbiological quality of fluids:

  - a warning statement that only the disinfection PROCEDURES defined and validated by the MANUFACTURER shall be used;
  - information on the required quality of the incoming DIALYSIS WATER and of the DIALYSIS FLUID CONCENTRATES used;
  - information about the microbiological quality of the DIALYSIS FLUID and the SUBSTITUTION FLUID, prepared by the HAEMODIALYSIS EQUIPMENT;
  - intervals at which wearing parts (e.g. ENDOTOXIN-RETENTIVE FILTER – ETRF) should be exchanged;

– a warning statement that the blood flow rate, and thus the treatment efficacy, can be reduced when the pre-pump ARTERIAL PRESSURE is extremely negative; and the range and accuracy of the blood flow rate of such pump(s) and the inlet and outlet pressure ranges over which this accuracy is maintained;

– for HAEMODIALYSIS EQUIPMENT with APPLIED PARTS other than TYPE CF APPLIED PARTS, a warning statement, addressed to both the OPERATOR and the RESPONSIBLE ORGANIZATION, to ensure that no electrical equipment (non-ME EQUIPMENT and ME EQUIPMENT) with TOUCH CURRENTS and PATIENT LEAKAGE CURRENTS above the respective limits for type CF APPLIED PARTS is used in the PATIENT ENVIRONMENT in combination with a central venous catheter whose tip is in the right atrium;

NOTE 101 For information, see 201.8.3 in Annex AA.

– a warning statement that the use of low delivery rates of HAEMODIALYSIS EQUIPMENT-integrated anticoagulation means (e.g. use of undiluted anticoagulation solution) could lead to delayed and non-continuous delivery due to mechanical compliance in the delivery means including the disposables or output pressure changes in the EXTRACORPOREAL CIRCUIT.

– a warning statement that protective measures should be taken to prevent back siphonage from the drain.

NOTE 102 The term "warning statement" is used in a generic way and it is under the MANUFACTURERS' responsibility to identify how to provide the related information to the user in accordance with the MANUFACTURERS' RISK MANAGEMENT PROCESS.

Compliance is checked by inspection of the instructions for use in the ACCOMPANYING DOCUMENTS.

201.7.9.2.5 ME EQUIPMENT description

Addition:

The instructions for use shall additionally include the following, if applicable:

– a definition of TRANSMEMBRANE PRESSURE if the MANUFACTURER makes use of one different from that stated in 201.3.218;

– an explanation of the coloured markings on the DIALYSIS FLUID CONCENTRATE connectors;

– information on the effective delivered blood flow rate in single-needle treatments;

– information on the recirculation of blood in the EXTRACORPOREAL CIRCUIT in single-needle treatments;
– the delay time after which an auditory ALARM SIGNAL is activated after interruption of the power supply;
– for PHYSIOLOGIC CLOSED-LOOP CONTROLLER functions (see also the collateral standard IEC 60601-1-10):
  a) the technical working principle;
  b) the PATIENT parameters which are measured and the physiological parameters which are controlled;
  c) the methods by which these PHYSIOLOGIC CLOSED-LOOP CONTROLLER modes have been evaluated, including beneficial and adverse effects recorded during clinical evaluation;
– for any data that is displayed or indicated by the HAEMODIALYSIS EQUIPMENT and that can be used for adjusting the treatment or measuring or confirming the treatment efficacy:
  a) a description of the technical working principle;
  b) if the measurement is indirect: information about the accuracy and possible influencing factors;
  c) * the method by which the technical working principle has been evaluated relative to standard medical care;
– for HAEMODIALYSIS EQUIPMENT with APPLIED PARTS other than TYPE CF APPLIED PARTS information, whether this HAEMODIALYSIS EQUIPMENT can be used together with a central venous catheter whose tip is in the right atrium. If the HAEMODIALYSIS EQUIPMENT is not suitable for a central venous catheter whose tip is in the right atrium, associated HAZARDs shall be listed.

Compliance is checked by inspection of the instructions for use in the ACCOMPANYING DOCUMENTS.

201.7.9.2.6 Installation

Addition:

The instructions for use shall additionally include the following, if applicable:

– information that it is essential for the HAEMODIALYSIS EQUIPMENT to be installed and used in compliance with appropriate regulations/recommendations on quality of DIALYSIS WATER and other relevant fluids;
– for CLASS I HAEMODIALYSIS EQUIPMENT, information of the importance of the quality of the protective earth in the electrical installation;
– information of the applications in which a POTENTIAL EQUALIZATION CONDUCTOR should be used;
– the acceptable range of temperature, flow rate and pressure for inlet DIALYSIS WATER and any CENTRAL DELIVERY SYSTEM;
– a note emphasizing the importance of compliance with all local regulations regarding the separation of the HAEMODIALYSIS EQUIPMENT from the water supply, the prevention of back flow to the potable water source, and prevention of contamination via the drain connection of the HAEMODIALYSIS EQUIPMENT from any sewer connection;
– if different schemes for colour coding of visual ALARM SIGNALS can be configured, information that the RESPONSIBLE ORGANIZATION should select the colour coding scheme which minimizes the RISK of ALARM SIGNAL misunderstanding in their environment;
– if settings of operating parameters or PROTECTIVE SYSTEMS can be configured, information that the RESPONSIBLE ORGANIZATION should select the configuration(s) or explicitly confirm the default configuration.

Compliance is checked by inspection of the instructions for use in the ACCOMPANYING DOCUMENTS.

201.7.9.2.12 Cleaning, disinfection and sterilization

Addition:

The instructions for use shall additionally include the following, if applicable:

– * a description of the method(s) by which sanitization or disinfection of the non-single use fluid path inside the HAEMODIALYSIS EQUIPMENT and either the ENCLOSURE surface cleaning or disinfection, or both, is achieved;

– information on how to handle an extended time between sanitization or disinfection, so as to return the system to a state of microbial control;

– * information that the test PROCEDURE by which the effectiveness of sanitization or disinfection of the fluid path inside the HAEMODIALYSIS EQUIPMENT has been validated is available upon request from the MANUFACTURER, including information on how the testing represented the microbial controls risks throughout the EXPECTED SERVICE LIFE;

– a warning statement to follow the MANUFACTURER's instructions to disinfect the HAEMODIALYSIS EQUIPMENT; if other PROCEDURES are used it is the responsibility of the RESPONSIBLE ORGANIZATION to validate the disinfection procedure for efficacy and safety; this warning shall specifically list HAZARDS, including the failure mode that can result from other PROCEDURES;

– a warning statement that the RESPONSIBLE ORGANIZATION is responsible for the hygienic quality of any delivery system(s), for example central DIALYSIS WATER supply system, CENTRAL DELIVERY SYSTEMS, HAEMODIALYSIS EQUIPMENT connecting devices, including the fluid lines from connection points to the HAEMODIALYSIS EQUIPMENT.

NOTE The term "warning statement" is used in a generic way and it is under the MANUFACTURERS' responsibility to identify how to provide the related information to the user in accordance with the MANUFACTURERS' RISK MANAGEMENT PROCESS.

Compliance is checked by inspection of the instructions for use in the ACCOMPANYING DOCUMENTS.

201.7.9.2.14 ACCESSORIES, supplementary equipment, used material

Addition:

The instructions for use shall additionally include the following, if applicable:

– information on pre-manufactured DIALYSIS FLUID bags, DIALYSIS FLUID CONCENTRATES, DIALYSERS and EXTRACORPOREAL CIRCUITS intended to be used together with the HAEMODIALYSIS EQUIPMENT.

Compliance is checked by inspection of the instructions for use in the ACCOMPANYING DOCUMENTS.

201.7.9.3 Technical description

201.7.9.3.1 General

Addition:

The technical description shall additionally include the following, if applicable:

- installation:
  - a description of the particular measures or conditions to be observed when installing, deinstalling and transporting the HAEMODIALYSIS EQUIPMENT or bringing it into use. These shall include guidance on the type and number of tests to be carried out;
  - information about the maximum temperature which can occur at the drain of the HAEMODIALYSIS EQUIPMENT:
  - * information about energy consumption, energy delivery to the environment and energy delivery to the drain under typical operating conditions and as a function of inlet water temperature;
  - * information about consumption of water and DIALYSIS FLUID CONCENTRATE(S) or (pre-manufactured) DIALYSIS FLUID under typical operating conditions;
- HAEMODIALYSIS EQUIPMENT specification:
  - for HAEMODIALYSIS EQUIPMENT that includes integral anticoagulant delivery means: the type of the pump(s), the range and the accuracy of the flow rate for such pump(s) and the pressures against which this accuracy is maintained;
  - any additional measures foreseen by the MANUFACTURER in case of the interruption of the power supply;
  - the type, the measurement accuracy and the value(s) / range(s) of the ALARM LIMIT(s) of the PROTECTIVE SYSTEM required by 201.12.4.4.101 (DIALYSIS FLUID composition);
  - the type, the measurement accuracy and the value(s) / range(s) of the ALARM LIMIT(s) of the PROTECTIVE SYSTEM required by 201.12.4.4.102 (DIALYSIS FLUID and SUBSTITUTION FLUID temperature);
  - the type, the measurement accuracy and the value(s) / range(s) of the ALARM LIMIT(s) of the PROTECTIVE SYSTEM required by 201.12.4.4.103 (NET FLUID REMOVAL);
  - the type, the measurement accuracy and the value(s) / range(s) of the ALARM LIMIT(s) of the PROTECTIVE SYSTEM required by 201.12.4.4.104.1 (extracorporeal blood loss to the environment), and if applicable the delays introduced by an INTELLIGENT ALARM SYSTEM;
  - * the type and the measurement accuracy of the PROTECTIVE SYSTEM required by 201.12.4.4.104.2 (BLOOD LEAK to the DIALYSIS FLUID) and the ALARM LIMIT of the PROTECTIVE SYSTEM at the minimum and maximum flow rate through the BLOOD LEAK detector;
  - the type and the ALARM LIMIT(s) of the PROTECTIVE SYSTEM required by 201.12.4.4.104.3 (extracorporeal blood loss due to coagulation);
  - the method employed and the sensitivity under test conditions specified by the MANUFACTURER for the PROTECTIVE SYSTEM required by 201.12.4.4.105 (air infusion);
  - the override time(s) for any PROTECTIVE SYSTEM;
  - the auditory ALARM SIGNAL AUDIO PAUSED period;
  - the range of sound pressure levels of any adjustable auditory ALARM SIGNAL source;
  - a disclosure of all materials intended to come into contact with the DIALYSIS WATER, DIALYSIS FLUID and DIALYSIS FLUID CONCENTRATE;
  - for ONLINE HDF and ONLINE HF: the method of preparation of the SUBSTITUTION FLUID, if applicable the method of the integrity test of the SUBSTITUTION FLUID filters (e.g. ENDOTOXIN-RETENTIVE FILTER – ETRF) and the accuracy of these tests.

Compliance is checked by inspection of the technical description in the ACCOMPANYING DOCUMENTS.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.8.3 * Classification of APPLIED PARTS

Addition:

HAEMODIALYSIS EQUIPMENT with LEAKAGE CURRENTS complying with TYPE CF APPLIED PARTS requirements are considered to be suitable for being used with a central venous catheter whose tip is in the right atrium.

If HAEMODIALYSIS EQUIPMENT having an APPLIED PART other than a TYPE CF APPLIED PART is intended to be used for treatment of PATIENTS with a central venous catheter whose tip is in the right atrium, the following shall apply:

aa) under NORMAL CONDITION, the PATIENT LEAKAGE CURRENTS and the TOUCH CURRENTS shall be within the limits for TYPE CF APPLIED PARTS;

bb) under SINGLE FAULT CONDITION, the PATIENT LEAKAGE CURRENTS, TOUCH CURRENTS and EARTH LEAKAGE CURRENTS shall be within the limits for TYPE CF APPLIED PARTS.

Compliance is checked by inspection.

If the HAEMODIALYSIS EQUIPMENT does not comply with bb), external means shall be provided and justified by the MANUFACTURER'S RISK MANAGEMENT PROCESS to keep the PATIENT LEAKAGE CURRENTS within the limits for TYPE CF APPLIED PARTS under SINGLE FAULT CONDITION.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

201.8.7.4.7 Measurement of the PATIENT LEAKAGE CURRENT

Addition:

aa) * The measuring device shall be connected where both extracorporeal blood lines are connected to the PATIENT. For the duration of the test, a test solution with the highest selectable conductivity, referenced to a temperature of 25 °C, and to the highest selectable DIALYSIS FLUID temperature in the application, shall be flowing in the DIALYSIS FLUID circuit and in the EXTRACORPOREAL CIRCUIT. The HAEMODIALYSIS EQUIPMENT shall be operated in typical treatment mode with highest possible blood flow rate and no ALARM CONDITIONS activated. For practical reasons the measuring device can be connected to the DIALYSIS FLUID connectors.

NOTE 101 The measurement of PATIENT LEAKAGE CURRENTS described above does not include the measurement according to 8.7.4.7 b) (external voltage on the PATIENT CONNECTION(S)) of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 for HAEMODIALYSIS EQUIPMENT with TYPE B APPLIED PARTS.

NOTE 102 The highest possible blood flow rate leads to the lowest resistance of the air gap in the venous drip chamber.

201.8.11.2 * MULTIPLE SOCKET-OUTLETS

Addition:

If a MULTIPLE SOCKET-OUTLET is provided and a mutual interchange or interchange with other MULTIPLE SOCKET-OUTLETS of the HAEMODIALYSIS EQUIPMENT could create a HAZARDOUS SITUATION, the MULTIPLE SOCKET-OUTLET shall be of a type which prevents such an interchange.

Compliance is checked by inspection and functional tests.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.11.6 * Overflow, spillage, leakage, ingress of water or particular matter, cleaning, disinfection, sterilization, and compatibility with substances used with the ME EQUIPMENT

201.11.6.1 General

Addition:

All the provisions of 11.6.2 to 11.6.4 shall be applied using appropriate liquid.

NOTE Examples for appropriate liquid are saline solution, DIALYSIS FLUID, other as identified by the MANUFACTURER.

201.11.6.5 Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

Addition:

The subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies and IPX1 of IEC 60529 is required as minimum.

201.11.6.6 * Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS

Addition:

For HAEMODIALYSIS EQUIPMENT employing non-disposable (e.g. non-single-use) fluid paths and fluid contacting components where the fluid comes into contact with the PATIENT directly or indirectly, means shall be provided for their hygienic maintenance.

The microbial control PROCESS for HAEMODIALYSIS EQUIPMENT shall be developed and validated by the MANUFACTURER for HAEMODIALYSIS EQUIPMENT using a RISK based approach considering EXPECTED SERVICE LIFE, disposability, filtration, cleaning/disinfection, system maintenance, storage and relevant DIALYSIS FLUID quality standards.

Compliance is checked by inspection of the validation documentation, of the RISK MANAGEMENT FILE, of the ACCOMPANYING DOCUMENTS and of the HAEMODIALYSIS EQUIPMENT.

The disinfection PROCEDURES shall not deteriorate internal components, external surfaces or external ACCESSORIES (e.g. ENDOTOXIN-RETENTIVE FILTER – ETRF) that could lead to a HAZARDOUS SITUATION.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and the validation documentation.

201.11.8 * Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

Addition:

a) HAEMODIALYSIS EQUIPMENT powered only by SUPPLY MAINS without INTERNAL ELECTRICAL POWER SOURCE:

In the event of an interruption of the power supply / SUPPLY MAINS to the HAEMODIALYSIS EQUIPMENT, the following safe conditions shall be achieved:

– activation of an auditory ALARM SIGNAL for at least 1 min;

– additional measures can be needed as determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS;

– the HAEMODIALYSIS EQUIPMENT may restart automatically on restoration of the power supply only if this does not cause any HAZARDOUS SITUATION to the PATIENT as determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS.

NOTE 101 Power sources for the 1 min auditory ALARM SIGNAL are not regarded as INTERNAL ELECTRICAL POWER SOURCE.

NOTE 102 For the 1 min auditory ALARM SIGNAL IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 allow in Subclause 6.3.3.1 deviations from the full requirements thereof. See also 208.6.3.3.2 and 208.6.3.3.101.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and by functional tests.

b) HAEMODIALYSIS EQUIPMENT powered by SUPPLY MAINS with an INTERNAL ELECTRICAL POWER SOURCE for limited functionality in case of interruption of the power supply / SUPPLY MAINS:

In the event of an interruption of the power supply / SUPPLY MAINS to the HAEMODIALYSIS EQUIPMENT, the following safe conditions shall be achieved:

– directly after the loss of SUPPLY MAINS an activation of a visual ALARM SIGNAL;

– activation of an auditory ALARM SIGNAL after a time interval specified by the MANUFACTURER;

While the INTERNAL ELECTRICAL POWER SOURCE is active:

– The limited functionality shall always fulfil the requirements from 201.12.4.4.104.3;

– If applicable, all other requirements from 201.12.4.4 shall be fulfilled.

In the event of starting depletion or loss of the INTERNAL ELECTRICAL POWER SOURCE the following safe condition shall be achieved:

– no more than 30 min before depletion of the INTERNAL ELECTRICAL POWER SOURCE activation of a visual and auditory ALARM SIGNAL. If applicable, the ALARM SIGNAL activation should give the OPERATOR the time usually needed for returning the blood to the PATIENT. The ALARM SIGNAL shall last for at least 1 min.

Or, as an alternative option, after loss of the INTERNAL ELECTRICAL POWER SOURCE:

– activation of an auditory ALARM SIGNAL for at least 1 min.

In both options:

– additional measures can be needed, as determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS;

– If functions of the HAEMODIALYSIS EQUIPMENT were stopped in the event of an interruption of the power supply / SUPPLY MAINS they may restart automatically on restoration of the power supply / SUPPLY MAINS only if this does not cause any HAZARDOUS SITUATION to the PATIENT, as determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS;

NOTE 103 In the second option (i.e. ALARM SIGNAL at the loss of the INTERNAL ELECTRICAL POWER SOURCE), the INTERNAL ELECTRICAL POWER SOURCE does not need to be tested for functionality, if it is not being used to generate the 1 min auditory ALARM SIGNAL.

NOTE 104 In the second option (i.e. ALARM SIGNAL at the loss of the INTERNAL ELECTRICAL POWER SOURCE), power sources for the 1 min auditory ALARM SIGNAL are not regarded as INTERNAL ELECTRICAL POWER SOURCE.

NOTE 105 For the auditory ALARM SIGNAL in the event of interruption of the POWER SUPPLY and for the 1 min auditory ALARM SIGNAL in the event of the loss of the INTERNAL ELECTRICAL POWER SOURCE, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 allow in Subclause 6.3.3.1 deviations from the full requirements thereof. See also 208.6.3.3.2 and 208.6.3.3.101. If possible, the auditory ALARM SIGNAL in the event of interruption of the POWER SUPPLY and the 1 min auditory ALARM SIGNAL generated before depletion of the INTERNAL ELECTRICAL POWER SOURCE are preferred to be compliant with Clause 208.

NOTE 106 Regarding the first option (i.e. ALARM SIGNAL no more than 30 min before the expected loss of the INTERNAL ELECTRICAL POWER SOURCE), an ALARM SIGNAL generated more than 30 min before the expected loss of the INTERNAL ELECTRICAL POWER SOURCE, would not serve the purpose of reminding the OPERATOR to start the blood restitution before the INTERNAL ELECTRICAL POWER SOURCE gets depleted. If the limited functionality is specified for 30 min or less, the SUPPLY MAINS loss ALARM SIGNAL and the INTERNAL ELECTRICAL POWER SOURCE loss ALARM SIGNAL could be combined in one ALARM SIGNAL.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and by functional tests.

c) HAEMODIALYSIS EQUIPMENT that is INTERNALLY POWERED:

In the event of starting depletion or loss of the INTERNAL ELECTRICAL POWER SOURCE the following safe condition shall be achieved:

– no more than 30 min before expected depletion of the INTERNAL ELECTRICAL POWER SOURCE activation of a visual and auditory ALARM SIGNAL. If applicable, the ALARM SIGNAL activation should give the OPERATOR the time usually needed for returning the blood to the PATIENT. The ALARM SIGNAL shall last for at least 1 min and shall be compliant with Clause 208 (with an allowed exception on duration of AUDIO PAUSE, regarding 208.6.3.1 and 208.6.3.3.101).

Or, as an alternative option, after loss of the INTERNAL ELECTRICAL POWER SOURCE:

– activation of an auditory ALARM SIGNAL for at least 1 min.

In both options:

– additional measures can be needed, as determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS.

– The HAEMODIALYSIS EQUIPMENT may restart automatically on restoration of the power supply only if this does not cause any HAZARDOUS SITUATION to the PATIENT, as determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS.

NOTE 107 Case c) applies to HAEMODIALYSIS EQUIPMENT where the INTENDED USE is achieved by INTERNAL ELECTRICAL POWER SOURCE, e.g. wearable HAEMODIALYSIS EQUIPMENT.

NOTE 108 Case c) also applies to HAEMODIALYSIS EQUIPMENT that can provide the INTENDED USE by the INTERNAL ELECTRICAL POWER SOURCE or alternatively by the SUPPLY MAINS or in combination with the SUPPLY MAINS (e.g. for charging the INTERNAL ELECTRICAL POWER SOURCE while in use). See the additional requirement regarding charging mode indication in 15.4.4 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

NOTE 109 Power sources for the 1 min auditory ALARM SIGNAL are not regarded as INTERNAL ELECTRICAL POWER SOURCE.

NOTE 110 For the 1 min auditory ALARM SIGNAL in the event of the loss of the INTERNAL ELECTRICAL POWER SOURCE, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 allow in 6.3.3.1 deviations from the full requirements thereof. See also 208.6.3.3.2 and 208.6.3.3.101.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and by functional tests.

201.12 * Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

See Annex BB for examples of HAZARDS, foreseeable sequences of events, and HAZARDOUS SITUATIONS in HAEMODIALYSIS EQUIPMENT.

201.12.4.4 Incorrect output

Addition:

The test PROCEDURES in 12.4.4.101 to 12.4.4.105 give an overview of the minimum requirements for the validation of a HAEMODIALYSIS EQUIPMENT. All details are not included for each test PROCEDURE and it is incumbent upon the test laboratory to address these details based on the specific HAEMODIALYSIS EQUIPMENT and the MANUFACTURER'S RISK MANAGEMENT PROCESS.

Additional subclauses:

201.12.4.4.101 * DIALYSIS FLUID composition

a) The HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM, independent of any fluid preparation control system, which prevents DIALYSIS FLUID from reaching the DIALYSER that, due to its composition, can cause a HAZARDOUS SITUATION.

NOTE 1 A PROTECTIVE SYSTEM is not necessary for HAEMODIALYSIS EQUIPMENT using only pre-manufactured DIALYSIS FLUID, which is quality controlled for the DIALYSIS FLUID composition, and is not changed in composition by the HAEMODIALYSIS EQUIPMENT, for example using pre-manufactured DIALYSIS FLUID bags.

The design of the PROTECTIVE SYSTEM to prevent a hazardous composition of the DIALYSIS FLUID shall consider a potential failure in any phase of preparation or regeneration of the DIALYSIS FLUID.

Activation of the PROTECTIVE SYSTEM shall achieve the following safe conditions:

– activation of auditory and visual ALARM SIGNALS (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101). The auditory ALARM SIGNAL may be delayed as specified in 208.6.3.3.101 b);

– stopping of the DIALYSIS FLUID flow to the DIALYSER;

– in ONLINE HDF or ONLINE HF mode, stopping of the SUBSTITUTION FLUID flow to the EXTRACORPOREAL CIRCUIT.

b) Conductivity profiles and PHYSIOLOGIC CLOSED-LOOP CONTROLLERS:

In case of pre-programmed time-dependent variation of the DIALYSIS FLUID composition or in case of feedback control of the DIALYSIS FLUID composition by measuring a physiologic relevant parameter of the PATIENT, the HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM, independent of the control system, which prevents any unintentional changes in the control system that could cause a HAZARDOUS SITUATION.

Activation of the PROTECTIVE SYSTEM shall achieve the following safe conditions:

– activation of auditory and visual ALARM SIGNALS (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);

– other measures, if defined by MANUFACTURER'S RISK MANAGEMENT PROCESS.

c) If the HAEMODIALYSIS EQUIPMENT is equipped with a bolus administration feature for temporarily changing the DIALYSIS FLUID composition, the HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM, independent of the control system, which prevents the bolus administration function to result in a HAZARDOUS SITUATION to the PATIENT.

Activation of the PROTECTIVE SYSTEM shall achieve the following safe conditions:

– activation of auditory and visual ALARM SIGNALS (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);

– interruption of the DIALYSIS FLUID composition bolus administration.

Compliance is checked by functional tests and by the following tests in treatment mode.

Test 1 for determining the ALARM SIGNAL activation, beginning with step 1:

– Select one typical concentrate formulation

– Set the treatment parameters of the unit under test to the lowest settable DIALYSIS FLUID composition and wait for stabilization.

– Slowly manipulate the DIALYSIS FLUID composition to a lower DIALYSIS FLUID composition until the PROTECTIVE SYSTEM activates the ALARM SIGNAL according to the specified ALARM CONDITION.

– Take sample at the DIALYSER inlet immediately after the ALARM CONDITION is detected.

– Determine the DIALYSIS FLUID composition of the sample taken after the ALARM CONDITION is detected.

– The measured value shall be within the limits specified by the MANUFACTURER.

– *For step 2, set the treatment parameters to the lowest settable DIALYSIS FLUID composition, wait for stabilization and slowly manipulate the DIALYSIS FLUID composition to a higher DIALYSIS FLUID composition until the PROTECTIVE SYSTEM activates the ALARM SIGNAL according to the specified ALARM CONDITION.*

– *For step 3, set the treatment parameters to the highest settable DIALYSIS FLUID composition, wait for stabilization and slowly manipulate the DIALYSIS FLUID composition to a higher DIALYSIS FLUID composition until the PROTECTIVE SYSTEM activates the ALARM SIGNAL according to the specified ALARM CONDITION.*

– *For step 4, set the treatment parameters to the highest settable DIALYSIS FLUID composition, wait for stabilization and slowly manipulate the DIALYSIS FLUID composition to a lower DIALYSIS FLUID composition until the PROTECTIVE SYSTEM activates the ALARM SIGNAL according to the specified ALARM CONDITION.*

Test 2 for in-time alarm reaction:

– *Set the unit under test to the highest possible DIALYSIS FLUID flow rate*

– *Simulate complete interruption of each DIALYSIS FLUID CONCENTRATE supply, one at a time (for examples see Annex AA, 201.15.4.1.101).*

– *Take sample at the DIALYSER inlet immediately after the ALARM CONDITION is detected.*

– *Determine the DIALYSIS FLUID composition of the samples taken after the ALARM CONDITION is detected.*

– *The measured value shall be within the limits specified by the MANUFACTURER.*

Test 3 for foreseeable misuse:

– *Select one typical correct concentrate connection.*

– *Interchange the connection of the different DIALYSIS FLUID CONCENTRATES components, if possible.*

– *Wait until the PROTECTIVE SYSTEM activates the ALARM SIGNAL according to the specified ALARM CONDITION.*

– *Take sample at the DIALYSER inlet immediately after the ALARM CONDITION is detected.*

– *Determine the DIALYSIS FLUID composition of the sample taken after the ALARM CONDITION is detected.*

– *The measured value shall be within the limits specified by the MANUFACTURER.*

NOTE 2 See 201.4.3.107 for methods for determining DIALYSIS FLUID composition.

201.12.4.4.102 * DIALYSIS FLUID and SUBSTITUTION FLUID temperature

a) It shall not be possible to set the temperature of the DIALYSIS FLUID and SUBSTITUTION FLUIDS outside a range of 33 °C to 42 °C unless justified by the MANUFACTURER'S RISK MANAGEMENT PROCESS.

b) The HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM, independent of any temperature control system, which prevents DIALYSIS FLUID reaching the DIALYSER and SUBSTITUTION FLUID reaching the EXTRACORPOREAL CIRCUIT at a temperature below 33 °C or above 42 °C, measured at the HAEMODIALYSIS EQUIPMENT DIALYSIS FLUID outlet and, if applicable, at the SUBSTITUTION FLUID outlet.

c) Temperatures below 33 °C and for a short time up to 46 °C are acceptable, but time and temperature shall be justified in the MANUFACTURER'S RISK MANAGEMENT PROCESS.

d) Activation of the PROTECTIVE SYSTEM shall achieve the following safe conditions:

– activation of auditory and visual ALARM SIGNALS (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101). The auditory ALARM SIGNAL may be delayed as specified in 208.6.3.3.101 b);

– stopping of the DIALYSIS FLUID flow to the DIALYSER and, if applicable, the SUBSTITUTION FLUID flow to the EXTRACORPOREAL CIRCUIT.

Compliance is checked by functional tests and by the following tests.

Test 1 for DIALYSIS FLUID:

– *Set the unit under test to the highest DIALYSIS FLUID flow rate, if this setting is possible.*

– *Set the highest and in a second test run the lowest DIALYSIS FLUID temperature.*

– *Wait for stable temperatures at the DIALYSER inlet.*

– *Slowly increase and in a second test run decrease the temperature of the DIALYSIS FLUID until the PROTECTIVE SYSTEM activates an ALARM SIGNAL.*

– *Measure the temperature continuously at the DIALYSER inlet and determine the maximum and in a second test run the minimum value.*

– *The measured maximum and in a second test run the minimum value shall be within the values specified at point b) or if applicable c).*

Test 2 for SUBSTITUTION FLUID:

– *Set the unit under test to the highest SUBSTITUTION FLUID flow rate, if this setting is possible.*

– *Set the highest and in a second test run the lowest DIALYSIS FLUID / SUBSTITUTION FLUID temperature.*

– *Wait for a stable temperature at the inlet to the EXTRACORPOREAL CIRCUIT.*

– *Slowly increase and in a second test run decrease the temperature of the DIALYSIS FLUID / SUBSTITUTION FLUID until the PROTECTIVE SYSTEM activates an ALARM SIGNAL.*

– *Measure the temperature of the SUBSTITUTION FLUID continuously at the inlet to the EXTRACORPOREAL CIRCUIT and determine the maximum and in a second test run the minimum value.*

– *The measured maximum and in a second test run the minimum value shall be within the values specified at point b) or if applicable c).*

201.12.4.4.103 * NET FLUID REMOVAL

a) The HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM, independent of any ULTRAFILTRATION control system, which prevents a deviation in the NET FLUID REMOVAL of the HAEMODIALYSIS EQUIPMENT from the set value of the controlling parameters that can cause a HAZARDOUS SITUATION.

In case of HDF and HF the HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM, independent of any SUBSTITUTION FLUID control system, which prevents an incorrect administration of the SUBSTITUTION FLUID that can cause a HAZARDOUS SITUATION.

Activation of the PROTECTIVE SYSTEM shall achieve the following safe conditions:

– activation of auditory and visual ALARM SIGNALS (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);

– prevention of the continuation of the hazardous fluid balancing error.

b) Ultrafiltration profiles and physiologic closed-loop controllers:

In case of pre-programmed time-dependent variation of ULTRAFILTRATION or in case of feedback control of ULTRAFILTRATION by a monitor measuring a physiologic relevant parameter of the PATIENT, the HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM, independent of the control system, which prevents any unintentional changes in the control system that could cause a HAZARDOUS SITUATION.

Activation of the PROTECTIVE SYSTEM shall achieve the following safe conditions:

– activation of auditory and visual ALARM SIGNALS (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);

– other measures, if defined by MANUFACTURER'S RISK MANAGEMENT PROCESS.

c) If the HAEMODIALYSIS EQUIPMENT is equipped with a fluid bolus administration feature, the HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM, independent of the control system, which prevents the fluid bolus administration function to cause a HAZARDOUS SITUATION to the PATIENT.

Activation of the PROTECTIVE SYSTEM shall achieve the following safe conditions:

– activation of auditory and visual ALARM SIGNALS (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);

– interruption of the fluid bolus administration.

Compliance is checked by functional tests and failure simulations, including the following test.

Test for deviations of the NET FLUID REMOVAL:

– *Use a reservoir to simulate the PATIENT and place it on a scale.*
– *Set the unit under test to the highest DIALYSIS FLUID flow rate.*
– *Set the highest SUBSTITUTION FLUID flow rate, if this is adjustable.*
– *Set the DIALYSIS FLUID temperature to 37 °C, if applicable.*
– *Set the highest and the lowest NET FLUID REMOVAL RATE (one at a time).*
– *Simulate an error with a negative and a positive deviation in each of the fluid removal control components (one at a time) which influence the NET FLUID REMOVAL until the PROTECTIVE SYSTEM activates an ALARM SIGNAL.*
– *Monitor the simulated PATIENT's weight by the scale.*
– *At the activation of the ALARM SIGNAL, the NET FLUID REMOVAL value or rate measured by the scale shall be within the NET FLUID REMOVAL limits specified by the MANUFACTURER.*

201.12.4.4.104 Extracorporeal blood loss

201.12.4.4.104.1 Extracorporeal blood loss to the environment

a) * The HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM to protect the PATIENT from extracorporeal blood loss to the environment that can cause a HAZARDOUS SITUATION.

NOTE 1 At the time this document was written, no system that can totally be relied upon to detect blood loss to the environment had been developed.

If a PROTECTIVE SYSTEM is utilizing measurement of the VENOUS PRESSURE, the OPERATOR should have at least a means to adjust the lower ALARM LIMIT manually as closely as possible to the current measurement value. The single-needle treatment mode needs additional or other measures.

b) The HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM to protect the PATIENT from extracorporeal blood loss to the environment caused by a rupture or separation in the EXTRACORPOREAL CIRCUIT due to excessive pressure, unless this is prevented by inherently safe design.

NOTE 2 This is not related to separation of the PATIENT CONNECTION or access needle but related to the potential pressure that can be generated by the pump which could cause tubing rupture or joint separation in the EXTRACORPOREAL CIRCUIT.

c) * Activation of the PROTECTIVE SYSTEM shall achieve the following safe condition:

– activation of auditory and visual ALARM SIGNALS (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);

– stoppage of the blood flow to the environment caused by the HAEMODIALYSIS EQUIPMENT, even under SINGLE FAULT CONDITION;

– In the case of haemofiltration or haemodiafiltration, stoppage of the substitution fluid flow.

Compliance is checked by functional tests and by the following test in treatment mode.

Test for PROTECTIVE SYSTEMS utilizing the VENOUS PRESSURE measurement:

– *Set the unit under test to the medium blood flow rate.*

– *Create a typical treatment value for the VENOUS PRESSURE.*

– *Set the low ALARM LIMIT as close as possible to the venous pressure.*

– *Reduce the VENOUS PRESSURE until an ALARM SIGNAL is activated.*

– *Determine the difference of the measured VENOUS PRESSURE against the set limit when the ALARM SIGNAL is activated.*

– *The calculated difference shall not exceed the accuracy declared by the MANUFACTURER for the ALARM LIMIT(s) of the PROTECTIVE SYSTEM (see 201.7.9.3.1 hyphen 10).*

– *If applicable, the delay introduced by an INTELLIGENT ALARM SYSTEM shall not exceed the value declared by the MANUFACTURER (see 201.7.9.3.1 hyphen 10).*

201.12.4.4.104.2 * BLOOD LEAK to the DIALYSIS FLUID

a) The HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM to protect the PATIENT from a BLOOD LEAK that can cause a HAZARDOUS SITUATION.

b) Activation of the PROTECTIVE SYSTEM shall achieve the following safe condition:

– activation of auditory and visual ALARM SIGNALS (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);

– prevention of further blood loss to the DIALYSIS FLUID.

c) Override of the PROTECTIVE SYSTEM for the blood leak:

- Override time shall not exceed 3 min;
- Under certain clinical conditions it may be accepted by RISK MANAGEMENT to override the BLOOD LEAK detector for more than 3 min with the maximum duration of a single treatment;
- Override activation shall maintain at least a visual indication of the overridden PROTECTIVE SYSTEM for BLOOD LEAK.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS, by functional tests and by the following test.

Test for determining the ALARM LIMITS:

- *Set the maximum flow rate through the BLOOD LEAK detector (highest DIALYSIS FLUID flow rate, highest ULTRAFILTRATION rate, if relevant also highest SUBSTITUTION FLUID flow rate).*
- *Add bovine blood, human blood or porcine blood (Haematocrit Hct 32 % ± 2 %) to the DIALYSIS FLUID until an ALARM SIGNAL is activated.*
- *Determine the difference of the applied BLOOD LEAK against the ALARM LIMIT specified by the MANUFACTURER.*
- *The calculated difference shall not exceed the accuracy declared by the MANUFACTURER for the ALARM LIMIT(s) of the PROTECTIVE SYSTEM (see 201.7.9.3.1 hyphen 11).*

201.12.4.4.104.3 * Extracorporeal blood loss due to coagulation

a) The HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM to protect the PATIENT from blood loss due to coagulation as a consequence of the interruption of the blood flow that can cause a HAZARDOUS SITUATION.

NOTE An acceptable method of complying with this requirement is, for example, a PROTECTIVE SYSTEM operating if the blood pump(s) advertently or inadvertently stop(s) for a longer period of time.

b) Activation of the PROTECTIVE SYSTEM shall activate an auditory and visual ALARM SIGNAL (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101).

c) Other effects, not covered by 201.12.4.4.106, which can result in a blood loss due to coagulation, shall be addressed in the MANUFACTURER'S RISK MANAGEMENT PROCESS, e.g. excessive SUBSTITUTION FLUID flow rates in HDF or HF post-dilution can result in coagulation by haemoconcentration at the blood outlet of the DIALYSER.

Compliance is checked by functional test and failure simulation.

201.12.4.4.105 * Air infusion

a) The HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM to protect the PATIENT from air infusion, under NORMAL CONDITION and SINGLE FAULT CONDITION, that can cause a HAZARDOUS SITUATION.

NOTE 1 An acceptable method of complying with this requirement is, for example, a PROTECTIVE SYSTEM utilizing an air detector (e. g. ultrasonic) capable of detecting non-dissolved air.

b) Activation of the PROTECTIVE SYSTEM shall achieve the following safe condition:

- activation of auditory and visual ALARM SIGNALS (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);
- prevention of further hazardous air infusion via the arterial and venous bloodlines, even under SINGLE FAULT CONDITION.

NOTE 2 The prevention of further air infusion can typically be accomplished by stopping the blood pump and clamping the venous bloodline.

Compliance is checked by functional tests following the principles of the test below and by inspection of the RISK MANAGEMENT FILE.

NOTE 3 Values given in the tests are examples and are defined by the MANUFACTURER.

NOTE 4 There are two methods for monitoring air infusion:

a) at an air trap (e.g. at the venous drip chamber) where buoyancy forces act on the air bubbles so that bubbles are prevented from exiting the air trap with a correctly set level; the air bubble monitoring method used here is the method of monitoring the level;

b) directly at the bloodline (air bubbles are delivered in the fluid stream), where the air volume can be determined by means of the flow velocity.

There are two different test PROCEDURES independent of the air monitoring methods in Note 4.

Continuous air infusion test:

– *Set up the HAEMODIALYSIS EQUIPMENT with a typical capillary DIALYSER (e.g. surface area between 1 m^2 and 1,5 m^2), the recommended EXTRACORPOREAL CIRCUIT and cannulas (e.g. 16 gauge).*

– *Stop the DIALYSIS FLUID flow to and from the DIALYSER.*

NOTE 5 If degassed DIALYSIS FLUID is running, gas will be removed by the DIALYSER. Stopping the flow could be achieved by full bypass of the DIALYSIS FLUID flow, clamping the DIALYSIS FLUID lines or interconnecting the dialyzer inlet and outlet.

– *Operate the EXTRACORPOREAL CIRCUIT with heparinized blood (human, bovine or porcine) with a defined Hct (e.g. Hct between 0,25 and 0,35) or with an appropriate test fluid.*

NOTE 6 If a fluid other than blood is selected, its equivalence with blood is demonstrated and documented in the RISK MANAGEMENT FILE, both in term of viscosity and in term of spallation of gas bubbles.

– *Position a storage container for the test fluid at a level of, for example, 100 cm (±20 cm) from the ground.*

– *Position a collection container for the test fluid at a level of, for example, 100 cm (±20 cm) from the ground or recirculate the fluid into the storage container.*

– *Position at least one vertically positioned test tube with diameter of, for example, 8 mm and a length of, for example, 2,0 m in line with a second tube with smaller diameter of, for example, 4,3 mm and a length of, for example, 20 cm directly at the venous PATIENT connector in the venous path between the PATIENT connector and collection container (see as an example the setup in Figure 201.101). The test tubes shall be completely primed.*

NOTE 7 The volume of the second tube with a smaller diameter allows to collect all of the air expected.

NOTE 8 With regards to the measurement of the air volume collected in the tube with the smaller diameter (hereby referred as air measurement tube), an additional tube can be inserted in order to ensure equalization of the trapped pressure to atmosphere by opening the corresponding clamp before measuring the air volume. If present, the equalization line is positioned below the air measurement tube as well as to prime it before starting the air injection. Regarding the recommended equalization line position, refer to Atmosphere Equalization line in Figure 201.101.

– *Insert a primed cannula (e.g. 22 gauge) into the arterial blood tubing in the section of negative pressures close to the connection to the arterial (blood withdrawal) cannula and connect it to a syringe pump capable of controlling air injection under negative pressure condition.*

NOTE 9 Another possible method is the use of a small reversible peristaltic pump. This pump is initially primed with test fluid by operating it in reverse mode to avoid uncontrolled injection of air when the blood pump is started. A check valve between the needle and the pump could be used.

– *Adjust the blood pump speed with a defined pre-pump negative pressure (e.g., between −200 mmHg and –250 mmHg).*

– *Inject air at increasing rates until the PROTECTIVE SYSTEM activates an ALARM SIGNAL.*

NOTE 10 The rationale of this test is based on the assumption that, with the DIALYSIS FLUID line closed, air cannot escape from the EXTRACORPOREAL CIRCUIT.

– *Clamp the test tube according to Figure 201.101 at both ends immediately after the air detector ALARM SIGNAL.*

– *Open the clamp on the Equalization line, if present; measure the air volume that develops at the vertical top of the small diameter test tube after 15 min when the air bubbles have combined to a solid air volume.*

– *Calculate the air flow rate by blood flow rate, test tube volume and measured air volume as follows:*

$Q_{air} = Q_b \times V_{air}/V_{tube}$

where:

Q_{air} *is the air flow rate;*

Q_b *is the blood flow rate; direct measurement of the blood flow rate in the venous bloodline is recommended;*

V_{air} *is the volume of air collected in the test tube;*

V_{tube} *is the volume of the test tube.*

– *The calculated air flow rate shall be less than the continuous air infusion rate limit identified by* RISK MANAGEMENT.

– *If the* HAEMODIALYSIS EQUIPMENT *allows the* DIALYSER *to be operated with blood flowing upwards through the* DIALYSER *or, alternatively with blood flowing downwards through the* DIALYSER, *separate continuous air infusion tests shall be done with both flow directions.*

– *If* RISK ANALYSIS *reveals pathways for injecting air downstream of the blood pump leading to continuous air infusion that can cause a* HAZARDOUS SITUATION *(e.g., by a level adjust pump) the continuous air infusion test shall be repeated by pumping air at the specified rate into the* EXTRACORPOREAL CIRCUIT *at this point.*

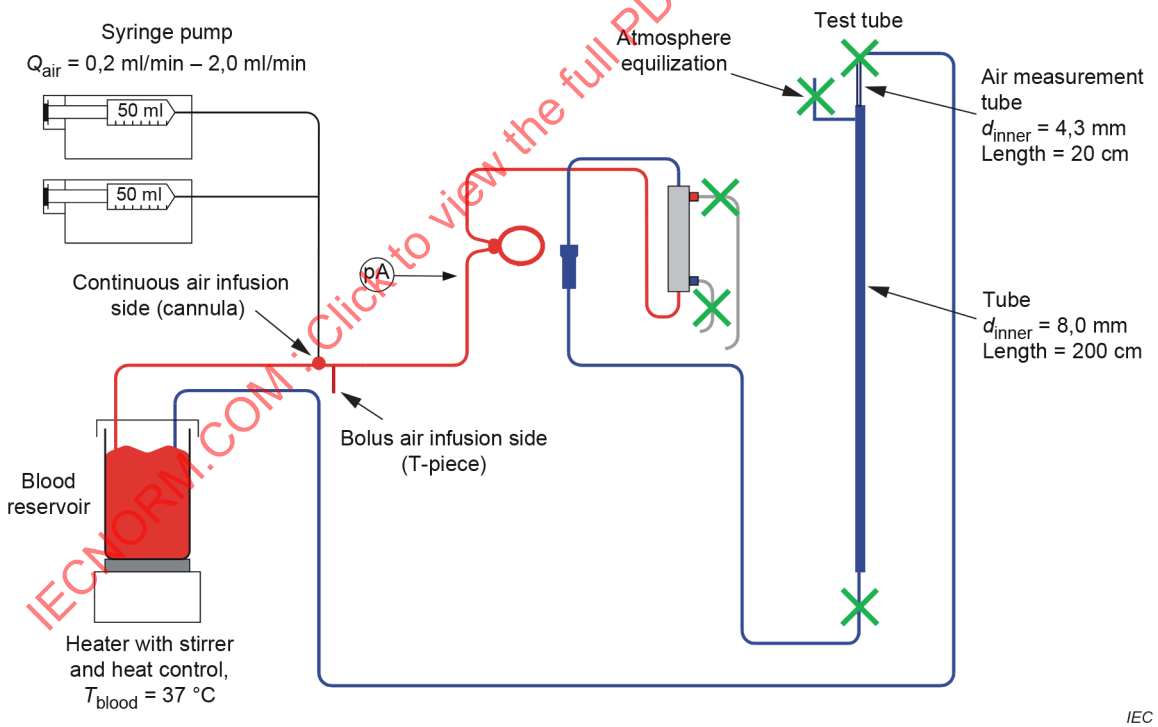


Figure 201.101 – Air infusion test setup with example dimensions

- *Bolus air infusion test:*
  - *Set up the HAEMODIALYSIS EQUIPMENT with a typical capillary DIALYSER (e.g. surface area between 1 m^2 and 1,5 m^2), the recommended EXTRACORPOREAL CIRCUIT and cannulas (e.g. 16 gauge).*
  - *Clamp or close the DIALYSIS FLUID lines after priming.*

    NOTE 11 This is a worst-case condition. If degassed DIALYSIS FLUID is running, gas is removed by the DIALYSER.
  - *Operate the EXTRACORPOREAL CIRCUIT with heparinized blood with a defined Hct (e.g. Hct between 0,25 and 0,35, human blood, bovine blood, porcine blood) or an appropriate test fluid.*

    NOTE 12 If a fluid other than blood is selected, its equivalence with blood is demonstrated and documented in the RISK MANAGEMENT FILE, both in term of viscosity and in term of spallation of gas bubbles.
  - *Position a storage container for the test fluid at a level of, for example, 100 cm (±20 cm) from the ground.*
  - *Position a collection container for the test fluid at a level of, for example, 100 cm (±20 cm) from the ground or recirculate the fluid into the storage container.*
  - *Position a graduated measuring cylinder or the same test tubes as in the continuous air infusion test setup such that any air that is pumped through the return (venous) cannula is collected.*

    NOTE 13 With regards to the measurement of the air volume collected in the small tube, an additional tube can be inserted in order to ensure equalization of the trapped pressure to atmosphere by opening the corresponding clamp before measuring the air volume. If present, the equalization line is positioned above the expected level reachable by air as well as completely primed before starting the air injection. See Atmosphere Equalization line in Figure 201.101.
  - *Connect a T-piece with Luer connectors at the arterial blood tubing in the section of negative pressures close to the connection to the arterial (blood withdrawal) cannula.*
  - *Connect a piece of tubing (e.g. 5 cm long) with a Luer connector to the T-piece.*
  - *Prime the EXTRACORPOREAL CIRCUIT and said piece of tubing. Clamp the piece of tubing.*
  - *Adjust the blood pump speed with a defined pre-pump negative pressure (e.g. between 0 mmHg and –250 mmHg) so that no pressure ALARM CONDITION arises in the EXTRACORPOREAL CIRCUIT with the opening of the clamp.*
  - *Open the clamp at the piece of tubing and wait until an ALARM CONDITION occurs which prevents further hazardous infusion of air.*
  - *Open the clamp on the Equalization line, if present; measure the amount of air collected in the graduated measuring cylinder or in the test tube.*
  - *The collected air volume shall be less than the bolus air infusion limit identified by RISK MANAGEMENT.*
  - *If the HAEMODIALYSIS EQUIPMENT allows the DIALYSER to be operated with blood flowing upwards through the DIALYSER or, alternatively with blood flowing downwards through the DIALYSER, separate bolus air infusion tests shall be done with both flow directions.*
  - *If RISK ANALYSIS reveals pathways for injecting air downstream of the blood pump and leading to bolus air infusion that can cause a HAZARDOUS SITUATION (e.g., by a level adjust pump) the bolus air infusion test shall be repeated by pumping air at the maximum rate into the EXTRACORPOREAL CIRCUIT at this point.*

201.12.4.4.106 * Anticoagulation

If the HAEMODIALYSIS EQUIPMENT is intended to include anticoagulant delivery means and a non-automated stop/start of the anticoagulant delivery means can cause a HAZARDOUS SITUATION, the control system shall stop a running anticoagulant delivery with the stopping of the blood pump during the treatment due to an OPERATOR control input or due to a PROTECTIVE SYSTEM stopping the blood pump, and shall restart ongoing anticoagulant delivery on ALARM CONDITION recovery or resumption of treatment.

NOTE 1 If the blood pump is running, it would be helpful for the user to be able to stop or start the anticoagulation means manually.

NOTE 2 The HAEMODIALYSIS EQUIPMENT can provide an automated function to stop anticoagulation for a specified time period prior to ending the treatment.

The MANUFACTURER'S RISK MANAGEMENT PROCESS shall take into consideration at least the following HAZARDOUS SITUATIONS, if applicable.

– Stopping or missing start of any anticoagulant delivery means.
– Improper dosing of the anticoagulant solution(s) by first fault of the anticoagulant delivery means, for example delivery rate(s), delivery rate(s) ratio, delivery rate(s) ratio versus blood flow rate.
– Improper dosing of the anticoagulant solution under negative pressure conditions in the EXTRACORPOREAL CIRCUIT in the case an anticoagulant delivery means doses upstream of the blood pump.
– Interchanging of solutions by mistake, if more than one anticoagulant solution is used for anticoagulation within one treatment.
– Air infusion or unintended anticoagulant solution fluid flow via the arterial PATIENT CONNECTION because of wrong delivery rate or delivery while the blood pump is not running, especially in the case an anticoagulant delivery means doses upstream of the blood pump.
– Air infusion or unintended anticoagulant solution fluid flow via the venous PATIENT CONNECTION because of wrong delivery rate or delivery while the blood pump is not running, especially in the case an anticoagulant delivery means doses downstream the air detector.
– Blood loss by reversal of anticoagulant solution fluid flow(s) by first fault of the anticoagulant delivery means or by improper fixture of the syringe plunger(s).
– Improper setting of anticoagulation parameters against prescription values.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and by functional tests.

201.12.4.4.107 PROTECTIVE SYSTEMS

All PROTECTIVE SYSTEMS shall be active throughout treatment, when the blood from the EXTRACORPOREAL CIRCUIT reaches the PATIENT until when the venous needle is disconnected. Additionally, the PROTECTIVE SYSTEMS for DIALYSIS FLUID composition and temperature shall be activated before the first contact of DIALYSIS FLUID with blood in the DIALYSER.

A delayed activation of PROTECTIVE SYSTEMS following the start or restart of the treatment is possible if it does not cause a HAZARDOUS SITUATION.

A failure of the PROTECTIVE SYSTEMS required by 201.12.4.4.101 to 201.12.4.4.105 shall become obvious to the OPERATOR within the following time limits:

a) for all PROTECTIVE SYSTEMS except 201.12.4.4.105 (air infusion):
   – at least once per day or, if this is not possible, as determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS;

   NOTE For example, acceptable methods of complying with this requirement are:

   - periodic functional check of the PROTECTIVE SYSTEMS, requested by the HAEMODIALYSIS EQUIPMENT, initiated and controlled by the OPERATOR;
   - periodic functional check of the PROTECTIVE SYSTEMS, requested by the HAEMODIALYSIS EQUIPMENT, initiated by the OPERATOR and controlled by the HAEMODIALYSIS EQUIPMENT;
   - redundancy of the PROTECTIVE SYSTEMS with self-checking by the HAEMODIALYSIS EQUIPMENT;
   - periodic functional check of the PROTECTIVE SYSTEMS initiated by the HAEMODIALYSIS EQUIPMENT and controlled by the HAEMODIALYSIS EQUIPMENT, if the control function is designed such that it cannot fail simultaneously with the corresponding PROTECTIVE SYSTEM by a single failure.

b) for the PROTECTIVE SYSTEM required by 201.12.4.4.105 (air infusion):

- if an amount of air can be infused to the PATIENT which can cause a HAZARDOUS SITUATION as a result of a first fault of the air detector, the maximum detection time for this fault is calculated as the fault tolerance time;
- the minimum volume of the EXTRACORPOREAL CIRCUIT between the position of the air detector and the venous cannula, divided by the highest blood flow rate;
- in all other cases, a) applies.

Every failure of a PROTECTIVE SYSTEM required by 201.12.4.4 shall inhibit the corresponding function supervised by the pertaining PROTECTIVE SYSTEM. This shall be indicated to the OPERATOR.

Compliance is checked by functional tests and failure simulations.

201.12.4.4.108 * Prevention of contamination by chemicals

a) It shall not be possible to treat the PATIENT while the HAEMODIALYSIS EQUIPMENT is in the cleaning, sterilization or disinfection mode. Subclauses 4.7 and 11.8 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 apply.

b) Chemicals (e.g. water, DIALYSIS FLUID, disinfectant or DIALYSIS FLUID CONCENTRATE) shall not flow from the HAEMODIALYSIS EQUIPMENT reverse to any supply line, even under SINGLE FAULT CONDITION.

c) Erroneous connection of disinfectant, specified by the MANUFACTURER for use with the HAEMODIALYSIS EQUIPMENT, instead of DIALYSIS FLUID CONCENTRATE shall not cause a HAZARDOUS SITUATION.

Compliance is checked by functional tests, failure simulations and inspection of the RISK MANAGEMENT FILE.

201.12.4.4.109 * Blood pump(s) and, if applicable, SUBSTITUTION FLUID pump(s) reversal

A method shall be included to prevent inadvertent reversal of the blood and, if applicable, SUBSTITUTION FLUID pump(s) during the treatment that can cause a HAZARDOUS SITUATION.

The applicable HAZARDOUS SITUATIONS (e.g. air infusion via the arterial bloodline) shall be determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS. USE ERRORS as well as technical failures shall be taken into account.

Compliance is checked by inspection and by functional tests.

201.12.4.4.110 Selection and change of operation modes

Inadvertent selection and change of operation modes shall be prevented. USE ERRORS, as well as technical failures, shall be taken into account.

Compliance is checked by inspection and by functional tests.

201.12.4.4.111 ONLINE HDF and ONLINE HF

If the HAEMODIALYSIS EQUIPMENT is intended for ONLINE HAEMOFILTRATION (ONLINE HF), ONLINE HAEMODIAFILTRATION (ONLINE HDF) or online preparation of other infusion or rinsing fluids (e.g. online bolus application or online priming the EXTRACORPOREAL CIRCUIT), the MANUFACTURER shall ensure that the HAEMODIALYSIS EQUIPMENT shall be capable of producing SUBSTITUTION FLUID that complies with the requirements (e.g. microbiological, see ISO 23500-5 [7], and ISO 23500-1 [6]) for a solution intended to be infused directly in the patients' blood when the MANUFACTURER'S instructions are followed. This requirement shall also be complied with under SINGLE FAULT CONDITION according to the MANUFACTURER'S RISK MANAGEMENT PROCESS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and by functional tests.

201.13 Hazardous situations and fault conditions for ME EQUIPMENT

Clause 13 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.13.2.6 * Leakage of liquid

Addition:

The liquid-carrying parts of the HAEMODIALYSIS EQUIPMENT shall be constructed such that liquid which can leak under normal working pressure does not lead to the PATIENT being exposed to HAZARDS caused by contact with electrical parts, for example due to short-circuiting of CREEPAGE DISTANCES.

Compliance is checked by the following test:

a) by means of a pipette, drops of potable water are applied to couplings, to seals and to tubings which might rupture, moving parts being in operation or at rest, whichever is least favourable;

and in case of doubt in test a):

b) by means of a syringe, a jet of an appropriate liquid for the part of the HAEMODIALYSIS EQUIPMENT is directed from couplings, from seals and from tubings which might rupture, moving parts being in operation or at rest, whichever is the least favourable.

After these PROCEDURES, the HAEMODIALYSIS EQUIPMENT shall show no signs of wetting of uninsulated electrical parts or of electrical insulation which is liable to be adversely affected by potable water or the selected liquid. In case of doubt, the HAEMODIALYSIS EQUIPMENT shall be subjected to the dielectric strength test specified in 8.8.3 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

The determination of other HAZARDS and HAZARDOUS SITUATIONS is checked by inspection of the HAEMODIALYSIS EQUIPMENT.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.14.13 * PEMS intended to be incorporated into an IT-NETWORK

Addition:

Data transfer between an IT-NETWORK and the HAEMODIALYSIS EQUIPMENT shall not cause a HAZARDOUS SITUATION to the PATIENT under SINGLE FAULT CONDITION.

NOTE 101 Independent of this document, IEC 80001-1:2021 [8] includes requirements, that every MEDICAL DEVICE MANUFACTURER to make available ACCOMPANYING DOCUMENTS to the RESPONSIBLE ORGANIZATION with information about the IT-NETWORK capabilities of the MEDICAL DEVICE.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

Additional subclause:

201.14.13.101 * Specific security features for HAEMODIALYSIS EQUIPMENT used in MEDICAL IT-NETWORKS

HAEMODIALYSIS EQUIPMENT used in MEDICAL IT-NETWORKS shall contribute to safe operation related to SECURITY (CYBERSECURITY).

This can be fulfilled beside other alternative ways by following the recommendations in the technical report IEC TR 60601-4-5:2021 [9], which gives a guidance in establishing safety-related technical SECURITY (CYBERSECURITY) specifications. This document also encourages the particular standard writers to include basic guidance for determining specific SECURITY (CYBERSECURITY) features for MEDICAL DEVICES by the MANUFACTURERS (Subclause 4.6.3) regarding the specific intended use environments of the MEDICAL DEVICES covered by the particular standard.

If IEC TR 60601-4-5:2021 is used, SECURITY COUNTERMEASURES as specified in Clauses 4 to 7 should be implemented as appropriate, with following specific additions to Subclause 4.6.3 regarding the dialysis specific intended use environments:

– IEC TR 60601-4-5:2021, 4.6.3: "*beside BASIC SAFETY and ESSENTIAL PERFORMANCE, the required product group appropriate ESSENTIAL FUNCTION (e.g. AVAILABILITY in case of ongoing SECURITY attacks on the MEDICAL IT-NETWORK and the connected devices) even with temporarily reduced IT functionality of the MEDICAL DEVICE*"

  Normally, dialysis treatments are performed in an access controlled clinical or home environment under continuous supervision during treatments, where the risk of physical attacks is limited. Regarding this, during or after attacks via the MEDICAL IT-NETWORK or wireless connections to the HAEMODIALYSIS EQUIPMENT, it is recommended, that the operator is able to restart the treatment without IT/wireless connection including disabling of IT/wireless functionality to perform basic treatments with the possibility to set or recall the patient individual ESSENTIAL PERFORMANCE parameters of this document (201.4.3.101) in an offline scenario on the HAEMODIALYSIS EQUIPMENT.

– IEC TR 60601-4-5:2021, 4.6.3: "*specific appropriate FIRECALL functions for emergency access to have the possibility to override SECURITY measures and how they are managed (e.g. by logging, information signalling, alarming) in cases of intentional overriding a SECURITY measure due to higher priority SAFETY needs*"

  Due to the access controlled clinical or home environments with continuous supervision during treatments, HAEMODIALYSIS EQUIPMENT normally do not require authentication or authorization procedures for standard treatment access. Therefore, no additional FIRECALL functions beside the option to disconnect the attacked network access (including wireless connections) are needed.

  If authentication for operators to operator accessible treatment settings is in place for the user interface, a FIRECALL function should be able to overrule that operator authentication combined with a log entry protected against modifications by the operator. IT-NETWORKS interfaces including those for remote access typically require authentication but should not include FIRECALL functions as an operator is always close to the HAEMODIALYSIS EQUIPMENT and to the patient.

– IEC TR 60601-4-5:2021, 4.6.3: "*appropriate minimum target SECURITY LEVEL SL-T for all INTENDED USE environments including the network integrations normally existing in these use environments in which the ME EQUIPMENT is typically used. If SECURITY LEVELS for the use environments are defined by other documents, they should be taken into account and referenced*"

Based on the intended use environments and designs OF HAEMODIALYSIS EQUIPMENT, the following target SECURITY LEVEL SL-T can be assumed as appropriate:

- Not connected home HAEMODIALYSIS EQUIPMENT: SL1 – Protection against casual or coincidental violation;
- HAEMODIALYSIS EQUIPMENT in a dialysis station or clinical environment not connected or connected in a clinic network separated from the public network: SL2 – Protection against intentional violation using simple means with low resources, generic skills and low motivation;
- HAEMODIALYSIS EQUIPMENT in a dialysis station or clinical environment connected in a clinic network not separated from the public network/internet or contain wireless communication: SL3 – Protection against intentional violation using sophisticated means with moderate resources, IACS specific skills and moderate motivation;
- Internet connected home HAEMODIALYSIS EQUIPMENT: SL4 – Protection against intentional violation using sophisticated means with extended resources, IACS specific skills and high motivation.

NOTE Authentication of operators is normally not needed for the physical user interface, only for remote access via data interfaces.

A SL-T of SL2 or better for secure updates or restorage of software, remotely or locally, is recommended.

Compliance is checked by inspection and functional testing.

NOTE For further information how to use above information to implement adequate MEDICAL DEVICE SECURITY COUNTERMEASURES, refer to the IEC TR 60601-4-5:2021[9] itself.

201.15 Construction of ME EQUIPMENT

Clause 15 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.15.4 ME EQUIPMENT components and general assembly

Additional subclauses:

201.15.4.101 EXTRACORPOREAL CIRCUIT or other single-use components

If an incorrect installation of the EXTRACORPOREAL CIRCUIT (or of other single-use components) can cause a HAZARDOUS SITUATION to the PATIENT, means shall be provided to ensure the correct installation of the EXTRACORPOREAL CIRCUIT (or of other single-use components) to the HAEMODIALYSIS EQUIPMENT.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and of the HAEMODIALYSIS EQUIPMENT.

NOTE To assess non-interconnectable characteristics of small-bore connectors based on their inherent design and dimensions in order to reduce the RISK of misconnections between HAEMODIALYSIS EQUIPMENT and ACCESSORIES, see ISO 80369-1:2018 [10].

201.15.4.1 Construction of connectors

Additional subclauses:

201.15.4.1.101 * DIALYSIS FLUID CONCENTRATE connectors

The various DIALYSIS FLUID CONCENTRATE supply containers and cleaning solutions should be differentiated by mechanical connections to the DIALYSIS FLUID CONCENTRATE connectors of the HAEMODIALYSIS EQUIPMENT or shall be permanently colour marked (see ISO 23500-4 [3]).

The HAEMODIALYSIS EQUIPMENT shall additionally prevent a mix-up of the various DIALYSIS FLUID CONCENTRATES and cleaning solutions which can cause a HAZARDOUS SITUATION for the PATIENT, by mechanical differentiation of the connectors or by colour coding of the connectors.

NOTE 1 The use of various DIALYSIS FLUID CONCENTRATES presents a problem in that connection of the wrong DIALYSIS FLUID CONCENTRATE can cause a HAZARDOUS SITUATION to the PATIENT. The design of connectors and colour coding were recognized as methods to minimize this RISK. There is always a residual RISK that the OPERATOR will cause a HAZARDOUS SITUATION by not following the MANUFACTURER's instructions for use.

The MANUFACTURER should make every effort to minimize the possible mix-up in the connection of DIALYSIS FLUID CONCENTRATES.

The following colours shall be used for DIALYSIS FLUID CONCENTRATE connectors:

– the connector for acetate shall be white;
– the connector for acidic component in bicarbonate dialysis shall be red;
– the connector for bicarbonate component in bicarbonate dialysis shall be blue;
– for common usage of one connector for different DIALYSIS FLUID CONCENTRATES, on the HAEMODIALYSIS EQUIPMENT the respective coloured markings shall be affixed on that connector. For example, a common connector for acetate and acidic DIALYSIS FLUID CONCENTRATE shall be marked white/red.

Compliance is checked by inspection.

NOTE 2 ISO 23500-4 [3], gives requirements for the colour coding of DIALYSIS FLUID CONCENTRATE containers.

201.15.4.1.102 * Connectors for blood pressure transducers

Any HAZARDS to the PATIENT, such as blood loss, air infusion or cross contamination, shall be taken into account in the MANUFACTURER'S RISK MANAGEMENT PROCESS.

Compliance is checked by functional tests and inspection of the RISK MANAGEMENT FILE.

201.16 * ME SYSTEMS

Clause 16 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.16.1 General requirements for the ME SYSTEMS

Addition:

ME SYSTEMS have not yet been examined comprehensively with regard to the whole field of dialysis in this particular standard. Application of RISK MANAGEMENT with consideration of ME SYSTEMS is therefore also recommended for MANUFACTURERS of HAEMODIALYSIS EQUIPMENT, since definite identification of a particular MANUFACTURER of the complete ME SYSTEM is often not possible in a dialysis clinic (see Informative Annex Subclause A.4, 4.2 and 16.1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020).

201.16.2 ACCOMPANYING DOCUMENTS of an ME SYSTEM

d) advice to the RESPONSIBLE ORGANIZATION

Addition:

– a listing of HAZARDOUS SITUATIONS (e.g. increased LEAKAGE CURRENTS) and possible protective measures when HAEMODIALYSIS EQUIPMENT is connected to CENTRAL DELIVERY SYSTEMS, DIALYSIS WATER supply systems or other fluid-carrying central systems.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.16.6.3 PATIENT LEAKAGE CURRENT

Addition:

NOTE Possible methods for reducing PATIENT LEAKAGE CURRENTS are the utilization of conductive rings in CENTRAL DELIVERY SYSTEMS and central DIALYSIS WATER supply systems or ensuring that all connection points of the dialysis unit have the same potential and are PROTECTIVELY EARTHED (see ISO 11197 [11]).

201.16.9.1 * Connection terminals and connectors

Addition:

– The connectors on the CENTRAL DELIVERY SYSTEMS for DIALYSIS FLUID CONCENTRATES shall be permanently colour marked. See 201.15.4.1.101.

– Additional markings shall be affixed such that the OPERATOR can easily assign the DIALYSIS FLUID CONCENTRATE to the appropriately marked DIALYSIS FLUID CONCENTRATE connectors of the CENTRAL DELIVERY SYSTEMS for DIALYSIS FLUID CONCENTRATES.

Compliance is checked by inspection.

201.17 ELECTROMAGNETIC COMPATIBILITY of ME EQUIPMENT and ME SYSTEMS

Clause 17 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

202 Electromagnetic disturbances – Requirements and tests

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply except as follows:

202.8 Electromagnetic IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS

202.8.1 * General

Addition:

The following IMMUNITY pass/fail criteria for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to EM DISTURBANCES shall be met by HAEMODIALYSIS EQUIPMENT:

– BASIC SAFETY functions listed in 201.12: The ME EQUIPMENT or ME SYSTEM BASIC SAFETY shall continue to operate as intended without OPERATOR intervention. No degradation of BASIC SAFETY function is allowed below a performance level specified by the MANUFACTURER when the ME EQUIPMENT or ME SYSTEM is used as intended. Alternatively, the ME EQUIPMENT or ME SYSTEM shall reach and remain in the safe state.

– ESSENTIAL PERFORMANCE functions: After the test, the ME EQUIPMENT or ME SYSTEM shall continue to operate as intended without OPERATOR intervention. During the test, degradation of performance is allowed, but no degradation of performance is allowed below a performance level specified by the MANUFACTURER, when the ME EQUIPMENT or ME SYSTEM is used as intended.

– Other functions: Loss of function is allowed, provided the function is self-recoverable, or can be restored by the operation of the controls by the OPERATOR in accordance with the MANUFACTURER'S instructions.

NOTE 101 A HAEMODIALYSIS EQUIPMENT is not considered to be a life-supporting equipment or system, since a premature termination of the dialysis treatment is not likely to lead to serious injury or death of a PATIENT.

202.8.9 IMMUNITY TEST LEVELS

Addition:

NOTE 101 HAEMODIALYSIS EQUIPMENT is normally used in the following EMC environments:

- professional healthcare facility environment (e.g. dialysis centres, intensive care units or dialysis departments in hospitals or self-care environments);
- HOME HEALTHCARE ENVIRONMENT (e.g. home or portable dialysis).

208 General requirements, tests and guidance for ALARM SYSTEMS in MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS

IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 apply except as follows:

208.4 * General requirements

Addition:

If the INTENDED USE of the HAEMODIALYSIS EQUIPMENT includes the intensive care or surgery environment, it is acceptable to implement additional ALARM SYSTEMS deviating from IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 in the following subclauses:

- 6.1.2 Determination of ALARM CONDITIONS and assignment of priority;
- 6.3.2.2 Characteristics of visual ALARM SIGNALS;
- 6.3.3.1 Characteristics of auditory ALARM SIGNALS.

If the INTENDED USE of the HAEMODIALYSIS EQUIPMENT includes the intensive care or surgery environment and additional ALARM SYSTEMS deviating from IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 are implemented, then

a) the ALARM SYSTEM according to IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 should be the MANUFACTURER default setting. If the ALARM SYSTEM according to IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 is not the MANUFACTURER default setting, the ACCOMPANYING DOCUMENTS shall include a statement about these MANUFACTURER default settings;

b) only the RESPONSIBLE ORGANIZATION shall be able to change the ALARM SYSTEM.

The paragraph d) 1) i) in Subclause 6.3.3.1 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD2:2020 is not applicable in the context of this document.

Compliance is checked by functional tests.

NOTE 1 Table AA.1 shows an example of ALARM CONDITION priorities according to IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, 6.1.2, adapted for HAEMODIALYSIS EQUIPMENT needs.

If the INTENDED USE of the HAEMODIALYSIS EQUIPMENT does not include the intensive care or surgery environment, the following subclauses of IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 are not mandatory:

- 6.1.2 Determination of ALARM CONDITIONS and assignment of priority;
- 6.3.2.2 Characteristics of visual ALARM SIGNALS;
- 6.3.3.1 Characteristics of auditory ALARM SIGNALS.

NOTE 2 Subclause 7.8.1 Colours of indicator lights of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, but the urgency of the response of the OPERATOR can have other than PATIENT-centric causes. The changes introduced by this addition are transferable to Subclause 7.8.1.

NOTE 3 If a COMMUNICATOR is equipped with additional set of auditory ALARM SIGNALS to comply with this subclause, it is optional to implement auditory ALARM SIGNALS compliant to Annex G of IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020.

208.5.2.1 Instructions for use

Addition:

NOTE 101 In the listing and description of every possible ALARM CONDITION only the conditions with a remaining HAZARDOUS SITUATION beside the safe state of the HAEMODIALYSIS EQUIPMENT are sufficient.

208.6.3 Generation of ALARM SIGNALS

208.6.3.1 * General

Addition:

Unless otherwise specified by this particular standard, both auditory and visual ALARM SIGNALS shall be activated. The visual ALARM SIGNAL shall remain activated for the entire duration of the ALARM CONDITION, whereas AUDIO PAUSING the auditory ALARM SIGNAL for the amount of time specified in 208.6.3.3.101 a) is allowed.

Compliance is checked by functional tests.

208.6.3.3 Auditory ALARM SIGNALS

208.6.3.3.2 * Volume and characteristics of auditory ALARM SIGNALS and INFORMATION SIGNALS

Replacement:

In the out of factory setting by the MANUFACTURER, for all the auditory ALARM SIGNALS, the HAEMODIALYSIS EQUIPMENT shall generate a sound pressure level of at least 65 dB(A) at a distance of 1 m from the HAEMODIALYSIS EQUIPMENT and at a position specified by the MANUFACTURER.

Compliance is checked by measuring the A-rated sound pressure level and the time weighting F of the sound level meter (i.e. LAF_{max}) with instruments meeting the requirements for measuring instruments of class 1 according to IEC 61672-1:2013 and free field conditions as specified in ISO 3744:2010, but only in above specified position.

208.6.3.3.3 OPERATOR-adjustable sound pressure level

Addition:

If the RESPONSIBLE ORGANIZATION can reduce the auditory ALARM SIGNAL volume to zero, there shall be an alternative means, for example a DISTRIBUTED ALARM SYSTEM, to notify the OPERATOR in an ALARM CONDITION even under SINGLE FAULT CONDITION.

Additional subclause:

208.6.3.3.101 * Special characteristics of auditory ALARM SIGNALS for HAEMODIALYSIS EQUIPMENT

Auditory ALARM SIGNALS shall meet the following requirements.

a) It shall only be possible to inactivate ALARM SIGNALS by using AUDIO PAUSED. The AUDIO PAUSED period shall not exceed 3 min.

   For ALARM SIGNALS as described in 201.12.4.4.101 (DIALYSIS FLUID composition) or 201.12.4.4.102 (DIALYSIS FLUID and SUBSTITUTION FLUID temperature), the AUDIO PAUSED period shall not exceed 10 min.

   NOTE 1 During the preparation phase or during an intended interruption of treatment, when no patient is connected, audible ALARM SIGNALS can be inactivated.

   NOTE 2 For other ALARM SIGNALS, not addressed within the Subclauses 201.12.4.4, the requirement of IEC 60601-1-8 applies, unless differently specified by the subclause itself (e.g., 201.11.8).

b) If, during an AUDIO PAUSED period, another ALARM CONDITION occurs requiring the immediate response by the OPERATOR to prevent any HAZARDOUS SITUATION, then the AUDIO PAUSED period shall be interrupted.

Compliance is checked by functional tests.

208.6.8.4 Termination of inactivation of ALARM SIGNALS

Delete the first paragraph / sentence.

209 Requirements for environmentally conscious design

IEC 60601-1-9:2007, IEC 60601-1-9:2007/AMD1:2013 and IEC 60601-1-9:2007/AMD2:2020 do not apply.

NOTE IEC 60601-1-9 does not include significant content relating to BASIC SAFETY and ESSENTIAL PERFORMANCE for PATIENTS and OPERATORS in the field of HAEMODIALYSIS.

210 Requirements for the development of PHYSIOLOGIC CLOSED-LOOP CONTROLLERS

IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020 apply, with the following addition:

Annex A – General guidance and rationale

A.2 Rationale for particular clauses and subclauses

Definition 3.20 – PHYSIOLOGIC CLOSED-LOOP CONTROLLER

Addition:

Physiological parameters are, for example, blood temperature, blood pressure, pulse and haematocrit. The controller in the control circuit compares the physiological parameter with a reference value and, using the resulting difference, varies a control signal that affects the variable quantities, such as ULTRAFILTRATION rate, DIALYSIS FLUID composition and temperature.

211 * Requirements for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS used in the HOME HEALTHCARE ENVIRONMENT

IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020 apply, with the following addition:

211.6 Classification of ME EQUIPMENT and ME SYSTEMS

Addition:

NOTE 1 IEC 60601-1-11 allows CLASS I ME EQUIPMENT in the HOME HEALTHCARE ENVIRONMENT only when specific additional measures are implemented.

Instead of a PERMANENTLY INSTALLED connection to SUPPLY MAINS, the same level of safety may be achieved by a unique MAINS PLUG connector with a corresponding unique MAINS PLUG outlet that is not normally available in the HOME HEALTHCARE ENVIRONMENT.

NOTE 2 This principle can also be applied to other electrical components of the HAEMODIALYSIS ME SYSTEM, for example the water treatment system.

Annexes

The annexes of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 apply, except as follows:

Annex G
(normative)

Protection against HAZARDS of ignition of flammable anaesthetic mixtures

Annex G of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 does not apply.

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

Clause A.1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclauses in this document, with clause and subclause numbers parallel to those in the body of the document.

Subclause 201.1.1 – Scope

The relevant parts of this document can be applied to other ME EQUIPMENT intended for extracorporeal blood purification treatments beside HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION, if no other specific particular standard exists. Examples of such blood purification treatments are plasmafiltration, hemoperfusion, apheresis, adsorption or liver dialysis. Relevant are for example all contents about the safety of the blood processing system and the EXTRACORPOREAL CIRCUIT.

Safety details of dialysis fluid control systems of haemodialysis equipment using regeneration of dialysis fluid or central delivery systems for dialysis fluid should be part of the manufacturer's risk management process.

The AAMI Renal Disease and Detoxification committee has developed a technical information report on sorbent-based regenerative HAEMODIALYSIS EQUIPMENT. (AAMI TIR 77 [12]).

Subclause 201.3.8 – APPLIED PART

The PATIENT is in direct contact with the HAEMODIALYSIS EQUIPMENT and could be in contact with the ME SYSTEM via fluids or electrical connections. In order to determine the PATIENT LEAKAGE CURRENTS, it is also important to consider the parts of the ME SYSTEM or non-ME SYSTEM coming into direct or indirect contact with the PATIENT e.g. via the OPERATOR.

Refer also to Figure AA.8 in the rationale of Subclause 201.16 for a graphical representation of APPLIED PARTS.

For HAEMODIALYSIS EQUIPMENT, the blood lines of the EXTRACORPOREAL CIRCUIT are not considered to be insulating, indeed, it should be assumed that conducting solutions in and around the tubing establish an electrical contact with the patient.

An EXTRACORPOREAL CIRCUIT or DIALYSIS FLUID circuit is considered isolating if:

a) the material is electrically isolating, and

b) the circuit is built such that a rupture is sufficiently unlikely.

Point a) is tested by applying 1 500 V AC to the relevant segments of the circuit, filled with 0,9 % NaCl. A conductive foil is wrapped over the tube over a length of 10 cm. No breakthrough between foil and fluid should occur over 1 min.

Point b) is demonstrated by the RISK MANAGEMENT of the MANUFACTURER of the EXTRACORPOREAL CIRCUIT, which should include the interface between the HAEMODIALYSIS EQUIPMENT and the circuit and the manufacturing PROCESS (e.g. see requirements of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Subclause 4.9).

Subclause 201.3.202 – BLOOD LEAK

Blood appears in the DIALYSIS FLUID compartment only if there is a pressure gradient from the blood compartment to the DIALYSIS FLUID compartment and a rupture in the semi-permeable membrane in the DIALYSER.

The BLOOD LEAK detector detects a rupture of the semi-permeable membrane only if the blood volume entering the DIALYSIS FLUID exceeds the threshold value of the BLOOD LEAK detector. This threshold depends on the flow rate in the DIALYSIS FLUID circuit because the leaked blood volume dilutes into the DIALYSIS FLUID stream.

Subclause 201.3.211 – HAEMODIALYSIS EQUIPMENT

HD, HDF and HF equipment can be designed as HAEMODIALYSIS EQUIPMENT with integrated preparation of DIALYSIS FLUID or without integrated preparation of DIALYSIS FLUID.

HAEMODIALYSIS EQUIPMENT with integrated preparation of DIALYSIS FLUID usually requires a water treatment system (RO system) and can also be connected to a CENTRAL DELIVERY SYSTEM for DIALYSIS FLUID CONCENTRATE.

HAEMODIALYSIS EQUIPMENT without integrated preparation of DIALYSIS FLUID can use pre-manufactured DIALYSIS FLUID bags.

HAEMODIALYSIS EQUIPMENT can consist of a CENTRAL DELIVERY SYSTEM DIALYSIS FLUID delivery together with the corresponding individual dialysis console(s).

HAEMODIALYSIS EQUIPMENT can consist of a batch treatment HAEMODIALYSIS EQUIPMENT filled with the entire DIALYSIS FLUID prior to the treatment and the corresponding DIALYSIS FLUID preparation unit, which can be a separate device or integrated with the treatment HAEMODIALYSIS EQUIPMENT.

HDF HAEMODIALYSIS EQUIPMENT can also be used for performing the HD or HF treatment PROCEDURES. The treatment PROCEDURE is then defined by the ACCESSORIES and the setting parameters.

Subclause 201.3.214 and 201.3.215 – ONLINE HDF and ONLINE HF

According to the state of the art, the SUBSTITUTION FLUID is produced from the DIALYSIS FLUID produced by the HAEMODIALYSIS EQUIPMENT. The PROCESS comprises microbiological filtering and delivery into the EXTRACORPOREAL CIRCUIT.

Subclause 201.3.216 – PROTECTIVE SYSTEM

See reference [28]. The authors point out that HAEMODIALYSIS EQUIPMENT comprises redundancy or PROTECTIVE SYSTEMS in addition to control systems. A HARM to the PATIENT is only possible if the control system and the PROTECTIVE SYSTEM both fail. The likelihood for any of these systems to fail is less than 10^{-4} per hour resulting in a combined likelihood of less than 10^{-8} per hour. This observation was made by the first author in the mid-1980s based on quality feedback data from ~ 3 000 HAEMODIALYSIS EQUIPMENT and is corroborated by the low number of serious accidents caused by HAEMODIALYSIS EQUIPMENT malfunction in the US where accident reports are published by the FDA.

Subclause 201.3.219 – ULTRAFILTRATION

In HF or HDF treatment, ULTRAFILTRATION should not be confused with the reduction in the PATIENT'S weight (NET FLUID REMOVAL), because in this PROCEDURE, the volume equivalent to the SUBSTITUTION FLUID flow also flows across the DIALYSER membrane.

ULTRAFILTRATION rate = NET FLUID REMOVAL rate + SUBSTITUTION FLUID flow rate.

Subclause 201.4.3 – Essential performance

The following general philosophy for the definition of test PROCEDURES for ESSENTIAL PERFORMANCE items was applied.

When defining the test PROCEDURES, it was the opinion of the committee that a safety standard for HAEMODIALYSIS EQUIPMENT should not duplicate what is common knowledge in test laboratories with good laboratory practice, for example:

– selection of a suitable method of measurement (e.g. flow measurement by flow meter or by volume and time);
– the use of instruments with sufficient accuracy;
– the use of calibrated instruments.

Therefore, the test PROCEDURES contain only the basic information needed for testing HAEMODIALYSIS EQUIPMENT.

When ESSENTIAL PERFORMANCE deviates from its expected NORMAL CONDITION tolerance due to a SINGLE FAULT CONDITION, risk mitigations for example can be:

– Description in the instruction for use of possible deviations from the ESSENTIAL PERFORMANCE specification due to a SINGLE FAULT CONDITION not reaching the PROTECTIVE SYSTEM ALARM LIMITS (for example, blood flow rate lower than the tolerance due to unexpected pump segment degradation);
– Information messaging on the user interface of possible deviations from the ESSENTIAL PERFORMANCE specification due to a SINGLE FAULT CONDITION not reaching the PROTECTIVE SYSTEM ALARM LIMITS (for example, temperature deviating from the set value);
– Alarming by activation of a PROTECTIVE SYSTEM (for example, conductivity deviating from the expected value).

With respect to the Subclauses 4.3 and 4.7 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 including the IEC 60601-1:2005/AMD1:2012/ISH1:2021, the specified performance limits can be different in NORMAL CONDITION and SINGLE FAULT CONDITION.

Regarding ESSENTIAL PERFORMANCE in NORMAL CONDITION tests according to IEC 60601-1:2005/AMD1:2012//ISH1:2021 items 4.3 dd), representative functional tests are given in Subclauses 201.4.3.

Regarding ESSENTIAL PERFORMANCE in SINGLE FAULT CONDITION tests according to IEC 60601-1:2005/AMD1:2012/ISH1:2021 items 4.7 dd), representative tests are given in Subclauses 201.12.4.4.101 to 201.12.4.4.105.

If different modes can impact the tests (e.g. double needle, single needle, low weight patients), the tests shall be repeated for each mode or the worst case shall be identified by the MANUFACTURER.

Subclause 201.4.3.101 – Additional ESSENTIAL PERFORMANCE requirements

The ESSENTIAL PERFORMANCE for HAEMODIALYSIS EQUIPMENT was determined with the following aspects taken into account: on one hand, all parameters required for the therapeutic effectiveness of the PROCEDURE should be included; on the other hand, definition of more parameters than necessary should be avoided, because the ESSENTIAL PERFORMANCE shall be complied even under the irradiation conditions of the ELECTROMAGNETIC COMPATIBILITY – (EMC) IMMUNITY test. The observation and documentation of a great number of ESSENTIAL PERFORMANCE features would cause impractically high time and cost expenditures during the EMC test. The list of ESSENTIAL PERFORMANCE features defined here is a compromise between these two contrary aspects (see IEC 60601-1-2).

Since a standard cannot describe all possible special PROCEDURES modifying or expanding the classical dialysis PROCEDURE, this subclause involves merely a standard HAEMODIALYSIS EQUIPMENT. If special PROCEDURES require further parameters for therapeutic effectiveness or if parameters that are defined as ESSENTIAL PERFORMANCE in this document are not required, the list of ESSENTIAL PERFORMANCE features should be adjusted to the HAEMODIALYSIS EQUIPMENT concerned by the MANUFACTURER. The MANUFACTURER should list ESSENTIAL PERFORMANCES and appropriate rationales.

The MANUFACTURER can specify, beside the accuracy, the averaging period of the specific values, to cover small fluctuations that do not result in an unacceptable RISK.

Subclause 201.4.3.102, Note 1 – Blood flow rate

If the blood flow rate is measured collecting the blood fluid from the venous return line, an ongoing ultrafiltration can influence the measurement results. It is therefore advisable to set either the ultrafiltration to zero or to bypass the dialyzer (clamping the DIALYSIS FLUID lines or interconnecting the dialyzer inlet and outlet), or both.

Subclause 201.4.3.107 – DIALYSIS FLUID composition

Due to the complexity of determining the DIALYSIS FLUID composition, a simple solution practical for all kind of HAEMODIALYSIS EQUIPMENT has not been found to date.

Bicarbonate DIALYSIS FLUID is typically produced by the mixing of three components: the acid concentrate (sometimes referred to as acidified concentrate), the bicarbonate concentrate and the DIALYSIS WATER. Depending on the type of acidified concentrate in use, the acid component can be in the form of acetic acid, sodium di-acetate, citric acid or lactate.

It should also be noted that in the DIALYSIS FLUID the bicarbonate reacts with the acid and this results into a reduction of the bicarbonate.

Therefore, when specifying the DIALYSIS FLUID composition regarding bicarbonate, it is recommended that the MANUFACTURER indicates if the bicarbonate concentration refers to concentration pre or post reaction with the acid. See also ISO 23500-1:2024 [6], Clause B.6 Dialysis fluid proportioning.

In case the post-reaction values are specified, it should be noted that they can differ from that measured in the patients due to the metabolism of the acid component by the body: indeed, acetate and lactate are metabolized to bicarbonate in a 1:1 ratio, while citric acid generates bicarbonate in a 3:1 molar ratio. Therefore, the range for settable values should take this into account.

Moreover, during bicarbonate DIALYSIS, the patient's plasma bicarbonate concentration can never exceed the DIALYSIS FLUID concentration due to the dialysis process since excessive bicarbonate is dialyzed out.

Possible methods for the determination of the DIALYSIS FLUID composition include, but are not necessarily limited to:

– measurement by ion selective electrodes or sensors;
– measurement of electrolyte concentrations by flame photometry;
– measurement of the dilution following the addition of a dye to the DIALYSIS FLUID CONCENTRATE, by optical absorption before and after dilution;
– theoretical calculation of the conductivity based on the known composition of the DIALYSIS FLUID CONCENTRATE, using a systematic matrix of different DIALYSIS FLUID compositions, and comparing the difference or the ratio of the measured and the theoretically derived conductivity values of each dialysate composition. Example of a systematic matrix of different DIALYSIS FLUID compositions:
    - highest sodium with lowest bicarbonate;
    - lowest sodium with highest bicarbonate;
    - highest sodium with highest bicarbonate;
    - lowest sodium with lowest bicarbonate.

It should be noted that ion selective electrodes method and standard laboratory methods used for blood analysis could be not accurate enough for measurement of absolute values in DIALYSIS FLUID.

Accepted tolerances in respect of electrolytes and other chemical constituents of the DIALYSIS FLUID CONCENTRATE are given in ISO 23500-4:2019 [3], 4.1.1.2.

Depending on e.g. the mixing system of the DIALYSIS FLUID, additional tolerances shall be taken into account for a final accuracy specification of the DIALYSIS FLUID composition.

Subclause 201.7.8.2 – Colour of controls

Extracorporeal systems use red and blue indicators, symbols, and nomenclature to identify blood pump function and blood lines to and from the PATIENT. USABILITY improvements can be enabled with red blood pump controls.

Subclause 201.7.9.2.1, 1st hyphen – General

Each MANUFACTURER should define intended PATIENTs' weight limit values and their associated limitations: indeed, certain ESSENTIAL PERFORMANCE functions, such as NET FLUID REMOVAL, and PROTECTIVE SYSTEM limits are dependent on the PATIENT's weight (e.g., smaller values are intended for the paediatric population, such as neonate baby and infants, than for the adult population). The PATIENT's weight should also be considered for e.g. the SUBSTITUTION FLUID non-pyrogenicity, the BLOOD LEAK and the air infusion limits.

The definition of the minimum weight could lead to possible different approaches since the weight normally changes during the treatment.

Subclause 201.7.9.2.2, 8th hyphen – Warning and safety notices

Because of counter current flow in the DIALYSER, backfiltration of DIALYSIS FLUID takes place in at least one part of the DIALYSER even in low-flux DIALYSERS (ULTRAFILTRATION coefficient < 10 ml/(h*mmHg)). If high-flux DIALYSERs are used, backfiltration cannot be avoided even by high ULTRAFILTRATION rates acceptable for fluid removal from the PATIENT.

The effect of backfiltration through an intact DIALYSER membrane is limited to the increased backtransport of larger molecules from the DIALYSIS FLUID to the blood. DIALYSIS FLUID does not contain such substances intentionally. In case of bacterial contamination, the DIALYSIS FLUID contains endotoxins and other bacterial cell debris. Intact endotoxin molecules are too large to pass through the membrane but they can split into smaller components. The molecular weight of lipid A, the active component causing pyrogenic reactions, has a molecular weight of ~ 2 000 mass units and will readily diffuse even through low-flux membranes. Other molecules causing adverse cell reactions in blood have even lower molecular weights.

Backfiltration only contributes less than 50 % to backtransport even for high-flux membranes under unfavourable conditions. Considering that bacterial and endotoxin contamination is scaled by orders of magnitudes, a factor of 2 is not relevant. "Avoiding" backfiltration by increasing TMP or ULTRAFILTRATION cannot be regarded as a sufficient measure to prevent backtransport. It is therefore necessary to avoid contamination of DIALYSIS FLUID by bacteria by using appropriate means.

The effect of backfiltration through structural leaks in the DIALYSER is usually limited to an amount not detected by the BLOOD LEAK detector. Because of the pulsating flow produced by a peristaltic blood pump, back and forward ULTRAFILTRATION will alternate in the DIALYSER. During the backfiltration phase, bacteria can enter into the blood stream undetected. Assuming that the back-flow rate is 1 ml/min (three times larger than the typical sensitivity of a BLOOD LEAK detector), the hypothetical contamination of blood is 100 CFU/min (CFU means "colony-forming units"), if DIALYSIS WATER or DIALYSIS FLUID is according to ISO guidelines. It is extremely unlikely that such a small leak below the detection limit of the BLOOD LEAK detector will persist in a DIALYSER. Usually, small leaks close by clotting within a few minutes.

Subclause 201.7.9.2.2, 11th hyphen – Warnings and safety notices

Haemolysis can be caused by excessive shear which is the result of high blood flow rate through a narrow passage, especially when the flow becomes turbulent. Static pressure (–600 mmHg to +1 000 mmHg) does not cause haemolysis. Elevated pressures measured in the EXTRACORPOREAL CIRCUIT indicate increased flow resistance which can cause subclinical haemolysis. Acute haemolysis has been reported to be caused by obstructions in the blood tubing system downstream of the blood pump but upstream of the VENOUS PRESSURE monitor. Such obstructions are not detected by the VENOUS PRESSURE monitor. For a review of accident reports see reference [28], p. 328-332.

Subclause 201.7.9.2.2, 13th hyphen – Warnings and safety notices

In single-needle applications, depending on the applied connecting configuration, air can enter via the needle luer connector during the arterial phase and be infused back to patient in the venous phase without passing the air detector.

In central venous catheter applications, the respiration-induced intra-venous patient's pressure could lead to negative pressure at the catheter's inlet thus causing air infusion in case of not well tightened connection and this can happen without passing through the air detector.

Subclause 201.7.9.2.5, 7th hyphen, item c) – ME EQUIPMENT description

For Kt/V, applicable recommendations are, for example, KDOQI guidelines [15] and the European best practice guidelines for haemodialysis [31].

Subclause 201.7.9.2.12, 1st hyphen – Cleaning, disinfection and sterilization

ISO 17664 family ([16] and [33]) relates to the information to be provided by the medical device's manufacturer for the processing of the medical devices and the validation of the correctness of the information.

These standards include definitions of cleaning vs. disinfection.

In the HAEMODIALYSIS EQUIPMENT context, the term "processing" in the title of the ISO 17664 family standards ([16] and [33]) implies to consider:

1) the internal hydraulic disinfection,
2) the surface cleaning/disinfection.

The pertaining subclause in the particular standard is 201.7.9.2.12 Cleaning, disinfection and sterilization, including information to be given to the OPERATOR to disinfect/clean the internal non-single use fluid path and the ENCLOSURE of the HAEMODIALYSIS EQUIPMENT. This subclause, like the ISO 17664 family ([16] and [33]), is intended for the content of the instructions for use.

At the time of writing this document there was not enough clarity how to apply the ISO 17664 family ([16] and [33]) to HAEMODIALYSIS EQUIPMENT. The following sections are providing considerations about how to address the ISO 17664 family standards ([16] and [33]) to HAEMODIALYSIS EQUIPMENT.

Internal hydraulic disinfection:

– HAEMODIALYSIS EQUIPMENT (including online HAEMODIALYSIS EQUIPMENT) non disposable (e.g. non-single-use) fluid paths cannot be classified according to the Spaulding scheme of ISO 17664 family ([16] and [33]), since there is no intended direct contact of the device with the patient (tissues).
– The internal fluid path disinfection/cleaning of the HAEMODIALYSIS EQUIPMENT is typically fully automated (i.e. activated by a user's action with no further need for user's intervention during the process).

  ISO 17664-1:2021[16] covers in 6.7.2.2 information for automated disinfection, but the needed information mentioned there is actually covered by 201.7.9.2.12 – 1st hyphen, 3rd hyphen and 4th hyphen and the corresponding informative annex.
– Online HAEMODIALYSIS EQUIPMENT can include a path that carries SUBSTITUTION FLUID that complies with the requirements (e.g. microbiological, see ISO 23500-5 [7], and ISO 23500-1 [6]) for a solution intended to be infused directly in the patients blood. This is covered in 201.12.4.4.111.
– The validation of such disinfection means for non-disposable (e.g. non-single-use) fluid paths is covered in Subclause 201.11.6.6 Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS.
– In case of not fully automatic processing of the hydraulic fluid path, the ISO 17664 family can give additional advice for the information needed regarding 201.7.9.2.12 – 1st hyphen.

Additional information to processing of "Dialysate Delivery Systems" can be found in [16].

Surface cleaning/disinfection:

– The external surfaces of the HAEMODIALYSIS EQUIPMENT should be classified as non-critical in the context of surface disinfection, see also examples in Appendix Table E.1 of ISO 17664-2 [33].
– The ISO 17664-2 [33] can give additional advice for the information needed regarding 201.7.9.2.12 – 1st hyphen.

Subclause 201.7.9.2.12, 3rd hyphen – Cleaning, disinfection and sterilization

This description of the test PROCEDURE should include at least the following:

– the recommended type of disinfectant;
– the required concentration of disinfectant in the container;
– the resulting concentration of disinfectant in the HAEMODIALYSIS EQUIPMENT;
– the required minimum time of the disinfection phase (if not automatically set by the HAEMODIALYSIS EQUIPMENT);
– the required minimum rinse phase (if not automatically set by the HAEMODIALYSIS EQUIPMENT).

Subclause 201.7.9.3.1, 3rd and 4th hyphens – General

Proposal for typical operating conditions of chronic HD treatments with HAEMODIALYSIS EQUIPMENT to compare different features:

– HAEMODIALYSIS time: 4 h, plus preparation time and post treatment operation;
– DIALYSIS FLUID flow rate: 500 ml/min;
– blood flow rate: 300 ml/min;
– ULTRAFILTRATION rate: 0,5 l/h;
– DIALYSIS FLUID temperature: 37 °C;
– either chemical or heat disinfection according to the MANUFACTURER'S specification.

Subclause 201.7.9.3.1, 11th hyphen – General

The flow rate through the BLOOD LEAK detector can depend on the treatment type and position of the BLOOD LEAK detector.

Subclause 201.8.3 – Classification of APPLIED PARTS

Compliance with TYPE CF APPLIED PART requirements for HAEMODIALYSIS EQUIPMENT that are provided with a permanent DIALYSIS WATER connection or connection to a CENTRAL DELIVERY SYSTEM can be achieved with high technical expenditures only. For that reason, an exception rule has been established for the use of HAEMODIALYSIS EQUIPMENT with TYPE B APPLIED PARTS for PATIENTS with a central venous catheter whose tip is in the right atrium.

In addition to the rationale of IEC 60601-1-11:2015, Clause 6, Classification of ME EQUIPMENT and ME SYSTEMS: For HAEMODIALYSIS EQUIPMENT without any installed connections to an external water supply system, central dialysate supply system or drainage line, compliance with TYPE CF APPLIED PART requirements can be obtained much easier. The goal of the exception rule is to protect the PATIENT under NORMAL CONDITION and under SINGLE FAULT CONDITION from LEAKAGE CURRENTS with the same effectiveness as HAEMODIALYSIS EQUIPMENT with TYPE CF APPLIED PART. Two sources of LEAKAGE CURRENTS shall be distinguished.

1) LEAKAGE CURRENTS originating from the HAEMODIALYSIS EQUIPMENT.

   These LEAKAGE CURRENTS could flow through the central venous catheter, whose tip is in the right atrium, via the heart of the PATIENT to the grounded PATIENT bed, chair or other means. Under NORMAL CONDITION, these LEAKAGE CURRENTS flow to earth via the PROTECTIVE EARTH CONDUCTOR of the HAEMODIALYSIS EQUIPMENT. Under SINGLE FAULT CONDITION (PROTECTIVE EARTH CONDUCTOR of the HAEMODIALYSIS EQUIPMENT is interrupted), the LEAKAGE CURRENTS shall be minimized by other means.

   If ME EQUIPMENT complies with these special LEAKAGE CURRENT limits in NORMAL CONDITION, but does not comply in SINGLE FAULT CONDITION (i.e. with the PROTECTIVE EARTH CONDUCTOR interrupted), an external POTENTIAL EQUALIZATION CONDUCTOR can be used for reducing the LEAKAGE CURRENTS to the necessary lower levels.

   The external POTENTIAL EQUALIZATION CONDUCTOR has to be protected against unintentional disconnection (unintentional disconnection of the plug). Intentional disconnection of the plug without the use of TOOLS can be possible.

2) LEAKAGE CURRENTS originating from other electrical equipment and ME EQUIPMENT set up in the PATIENT ENVIRONMENT.

   These LEAKAGE CURRENTS could flow through the body of the PATIENT via the heart and the central venous catheter, whose tip is in the right atrium, to the earth via the HAEMODIALYSIS EQUIPMENT. Under NORMAL CONDITION, these LEAKAGE CURRENTS flows to earth via the PROTECTIVE EARTH CONDUCTOR of the external equipment.

   Under SINGLE FAULT CONDITION (PROTECTIVE EARTH CONDUCTOR of the external equipment is interrupted) and if the HAEMODIALYSIS EQUIPMENT has a TYPE CF APPLIED PART, the isolation barrier between the APPLIED PART and the rest of the HAEMODIALYSIS EQUIPMENT would prevent these LEAKAGE CURRENTS from reaching the PATIENT.

   If the HAEMODIALYSIS EQUIPMENT has a TYPE B APPLIED PART, these LEAKAGE CURRENTS shall be minimized by other means.

   Since measures that shall be applied to non-HAEMODIALYSIS EQUIPMENT are not subject to this document, the normative requirement of this document is that information that shall be provided in the ACCOMPANYING DOCUMENTS for the OPERATOR (201.7.9.2.5, 8th hyphen and 201.7.9.2.2, 16th hyphen) and for the RESPONSIBLE ORGANIZATION (201.7.9.2.6, 3rd hyphen and 201.7.9.2.2, 16th hyphen).

General remarks for the use of central venous catheters considering electrical safety.

- Microshock by catheter LEAKAGE CURRENT is a hypothetical HARM that cannot be excluded. The likelihood of such a shock occurring is limited.
- Only central venous catheters with the venous tip located in the right atrium are relevant.
- This limits the RISK to permanent catheters inserted through jugular or subclavian vein. The tip of non-permanent catheters or femoral catheters is usually not placed in the atrium.
- Side holes in the venous limb will also distribute electrical current to the body outside the heart [19] although most catheters today have no side holes in the return (venous) lumen.
- The withdrawal (arterial) lumen is electrically isolated or only connected with a high resistance to ground [13].
- If the catheter tip is placed in the right atrium as recommended for permanent catheters, the catheter will normally not touch the atrial wall because this can cause flow problems. The requirements for CF based on the RISK of microshock were established based on measurements with metal electrodes in direct touch with the atrium.
- With the catheter not in direct contact with the myocardium the current density on the myocardial surface will be very much reduced because the current is distributed over a larger surface area. Starmer [20] reports that ~ 500 ∝A were required for fibrillation when applied to a circular surface with 2,5 mm diameter. When the surface area was increased to 2,5 cm in diameter the current required for fibrillation increased to more than 3 000 ∝A.

- In order to create a serious HAZARDOUS SITUATION,
  - the catheter tip shall be placed in the right atrium and shall touch the atrial wall (by mistake), and
  - the PATIENT shall be in touch with a current source.

Subclause 201.8.7.4.7 aa) – Measurement of the PATIENT LEAKAGE CURRENT

"Typical treatment mode […] with no ALARM CONDITIONS activated" means, for example, that a heater is on during measurement. If valves can block the current path between the heater and the PATIENT, these valves should be in open condition.

Subclause 201.8.11.2 – MULTIPLE SOCKET-OUTLETS

An example is a HAEMODIALYSIS EQUIPMENT which has a MULTIPLE SOCKET-OUTLET. One socket is intended for an external heater which is switched off by the HAEMODIALYSIS EQUIPMENT in case of high temperature ALARM CONDITION. The other socket is intended for a reading lamp and is not switched off in case of ALARM CONDITIONS. It could cause a HAZARDOUS SITUATION if the heater were unintentionally connected into the socket for the reading lamp. This shall be prevented, for example by mechanically incompatible sockets.

Subclause 201.11.6 – Overflow, spillage, leakage, ingress of water or particular matter, cleaning, disinfection, sterilization, and compatibility with substances used with the ME EQUIPMENT

Subclause 11.6.2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies only if the HAEMODIALYSIS EQUIPMENT has internal reservoirs that the operator is responsible to fill.

Automatic process control filling of reservoirs is covered by 11.6.4 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

Subclause 201.11.6.6 – Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS

The ENCLOSURE surface of the HAEMODIALYSIS EQUIPMENT should be designed to facilitate ENCLOSURE surface disinfection and minimize gaps, corners and other locations that could harbour microorganisms.

Testing should be performed to validate the microbial control systems of the HAEMODIALYSIS EQUIPMENT per 201.11.6.6.

Cleaning and disinfection can be accomplished through chemical methods, physical methods, or a combination of both. Guidance for testing of disinfectants can be found in ISO 15883 (all parts) [21], EN 14885 [22], JIS Z 2801 [23], AOAC 964 [24] or ASTM E1153 [25]. The microbial control regime should be validated considering organisms relevant to haemodialysis, representing the main microbial categories of microorganisms including Gram positives, Gram negatives, viruses, yeasts and fungi.

The microbial control regime validation should be performed on the HAEMODIALYSIS EQUIPMENT under simulated use conditions. Tests should be performed such that

1) testing is conducted with worst case HAEMODIALYSIS EQUIPMENT configuration per the ACCOMPANYING DOCUMENTS (examples: lowest disinfectant concentration, shortest contact time),
2) the equipment (software and hardware) demonstrates the ability to achieve the required conditions – examples include temperature and concentrations in the fluid path –,
3) the conditions are sufficient through the locations where microbial control is necessary, and

4) when challenged with an appropriate microbial challenge, the HAEMODIALYSIS EQUIPMENT can maintain microbial control.

Sampling is sufficient to represent all locations where microbial control is required.

Testing of disinfectant residuals

The rinsing PROCESS should be validated to remove the disinfectant to a concentration stated safe by local regulations or an acceptable level defined by the MANUFACTURER.

The test is done in the following way:

A normal disinfection and rinse are performed, but a coloured test liquid (e.g. Methylene blue or Fluorescein) is used instead of disinfectant. Then it is checked that in the rinse phase all parts of the fluid path are filled with coloured liquid. No tubes or cavities should be only partly filled or filled with a liquid that is considerably lighter in colour.

After rinsing, no parts of the fluid path should show traces of the coloured liquid. The remaining concentration of the coloured liquid can be measured photometrically or fluorometrically.

Using a coloured test liquid or conductive markers results in higher sensitivity of the measurement than using real disinfectant but being a different substance, does not allow for reliable conclusions regarding the effect of diffusion of the actually applied disinfectant into plastic.

The test with coloured liquid or conductive markers should be supported by a validation aimed at demonstrating that these methods are equivalent to the measurement of the disinfectant residuals concentration.

Subclause 201.11.8 – Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

The focus of 201.11.8 is the interruption of external or internal power sources and on HAZARDOUS SITUATIONS in case of interruption or interruption followed by restoration.

The following items are examples for additional measures which can be applicable:

– stopping of the DIALYSIS FLUID flow to the DIALYSER;
– interruption of any SUBSTITUTION FLUID flow;
– reduction of ULTRAFILTRATION rate to its minimum value;
– clamping of the venous blood line.

The following are graphical representations for the different designs in items a) to c):

a) Powered by SUPPLY MAINS only

Figure AA.1 refers to the first option of case a), i.e. to ME EQUIPMENT powered by SUPPLY MAINS only.

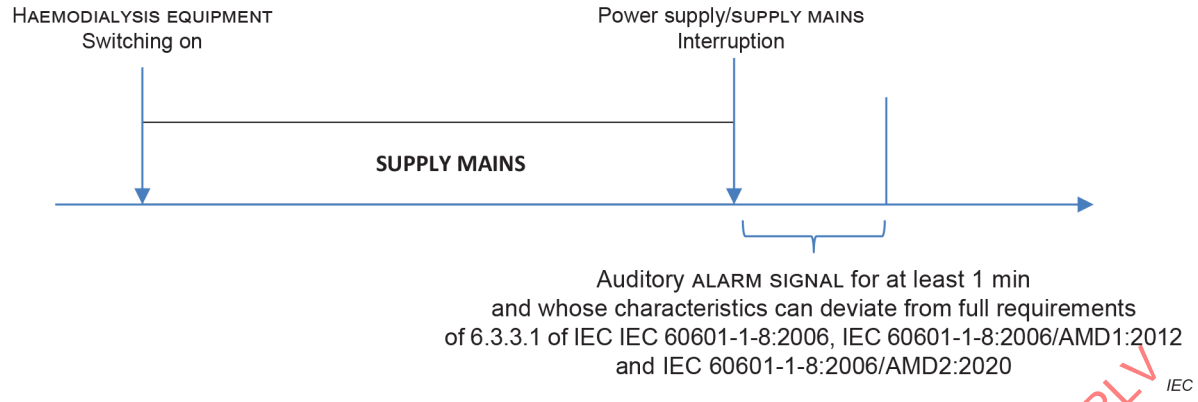


Figure AA.1 – Powered by SUPPLY MAINS only

Regarding the reference to IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, 6.3.3.1, power failure is considered a TECHNICAL ALARM CONDITION for which the ALARM SYSTEM can generate an auditory ALARM SIGNAL that does not comply with the requirements thereof.

b) Powered by SUPPLY MAINS with an INTERNAL ELECTRICAL POWER SOURCE for limited functionality

Examples for limited functionality are:

– graphical user interface only for treatment data management;

– graphical user interface and extracorporeal circulation for coagulation prevention;

– graphical user interface and return of the blood to the PATIENT;

– HAEMODIALYSIS EQUIPMENT which can proceed with the full functionality for limited time.

Note that "limited time" above refers to a gap between the intended dialysis treatment time and the battery duration time. If the battery is not designed to be able to power the HAEMODIALYSIS EQUIPMENT for the full treatment it will fall under type b).

The PROTECTIVE SYSTEM is necessary during limited functionality to protect the PATIENT from HAZARDOUS SITUATION according to 201.12.4.4.104.3 (extracorporeal blood loss due to coagulation, as a consequence of the interruption of the blood flow).

Figure AA.2 refers to the second option of case b), i.e. to alarm given once the battery for limited functionality gets depleted:

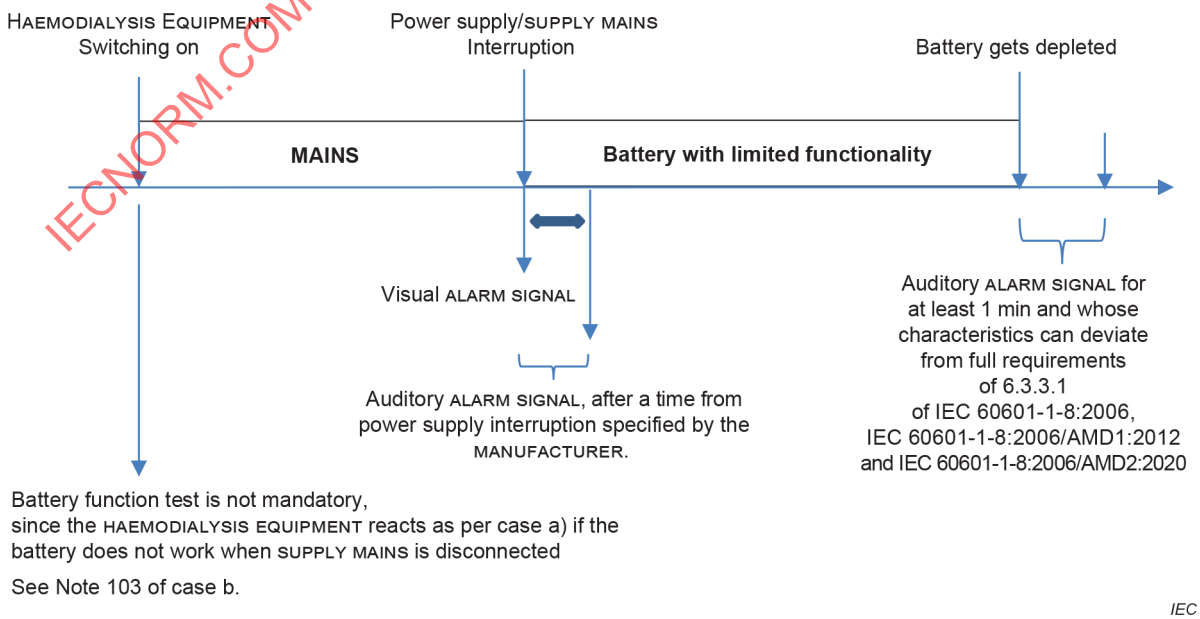


Figure AA.2 – Alarm at depletion of battery for limited functionality

Regarding the reference to IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, Subclause 6.3.3.1, power failure is considered a TECHNICAL ALARM CONDITION for which the ALARM SYSTEM can generate an auditory ALARM SIGNALS that does not comply with the requirements thereof.

Figure AA.3 refers to the first option of case b), i.e. to alarm given no more than 30 min before the battery for limited functionality gets depleted:

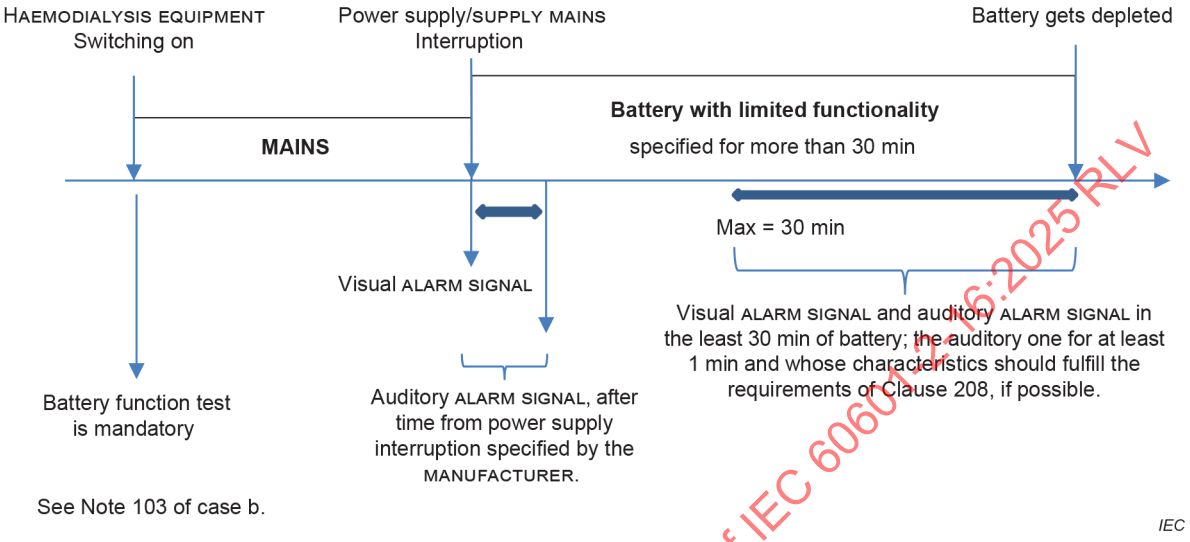


Figure AA.3 – Alarm before battery for limited functionality gets depleted (30 min maximum)

Regarding the battery's function test requirement in Figure AA.3, it shall be noted that, in this design, the battery is relied upon for the alarm generation, therefore the function test is mandatory.

Figure AA.4 refers to the first option of case b) mentioned in Note 4, i.e. to a battery for limited functionality specified for lasting less than / equal to 30 min:

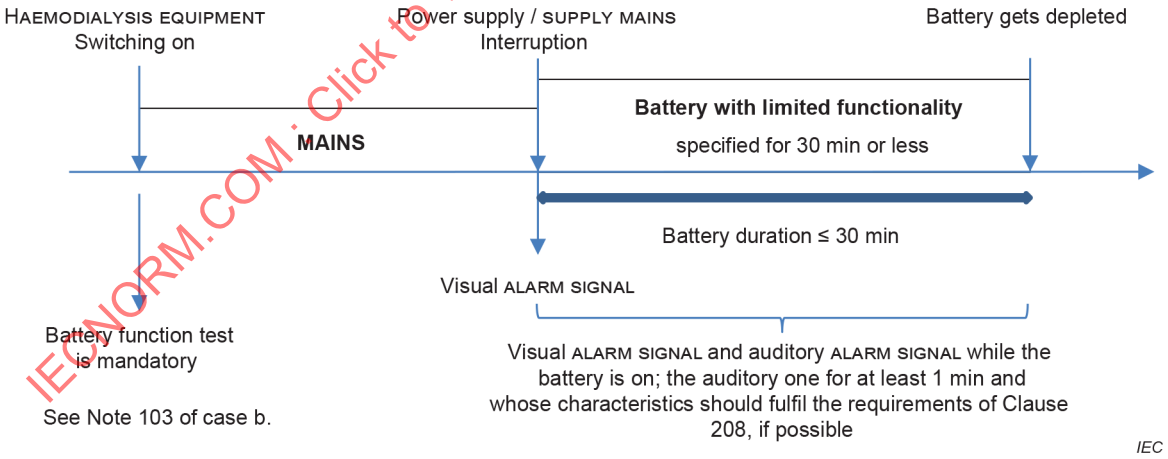


Figure AA.4 – Alarm before battery for limited functionality gets depleted (battery lasting for equal or less than 30 min)

Regarding the battery's function check requirement, it shall be noted that, in this design, the battery is relied upon for the alarm generation. The following items are examples for additional measures which can be applicable:

– stopping of the DIALYSIS FLUID flow to the DIALYSER;
– interruption of any SUBSTITUTION FLUID flow;
– reduction of ULTRAFILTRATION rate to its minimum value;
– clamping of the venous blood line.

c) internally powered

Formerly this design was named INTERNAL ELECTRICAL POWER SOURCE for operation and part of paragraph a).

Figure AA.5 refers to the second option of case c), i.e. to alarm given at battery depletion:

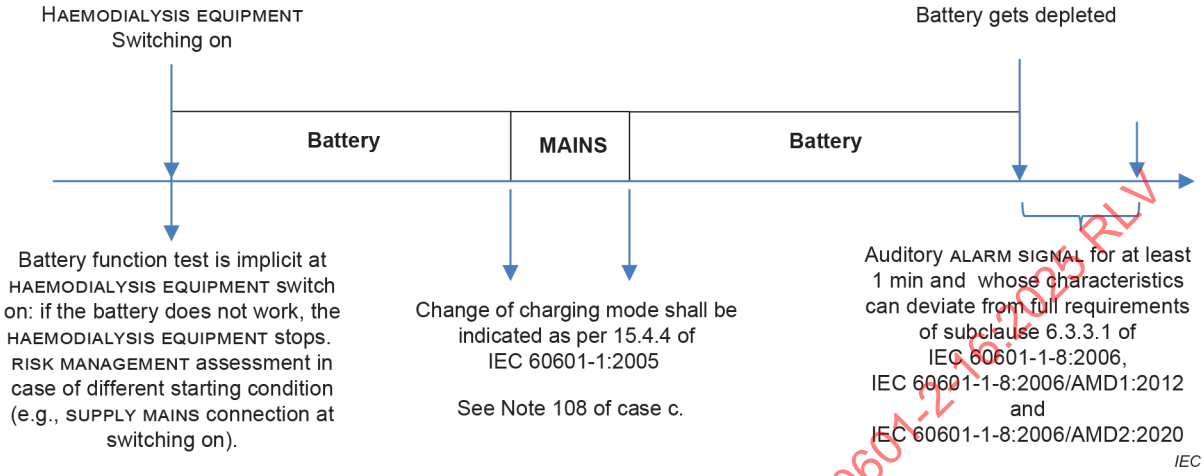


Figure AA.5 – Alarm at battery depletion

Regarding the transition from MAINS to battery mode, a charging mode indicator as per Subclause 15.4.4 of IEC 60601-1:2005 has been considered enough due to the full function provided by the INTERNAL ELECTRICAL POWER SOURCE. Therefore, differently from case b), a visual ALARM SIGNAL has not been required.

Regarding the reference to IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, 6.3.3.1 power failure is considered a TECHNICAL ALARM CONDITION for which the ALARM SYSTEM can generate an auditory ALARM SIGNAL that does not comply with the requirements thereof.

Figure AA.6 refers to the first option of case c), i.e. to alarm given no more than 30 min before the battery gets depleted:

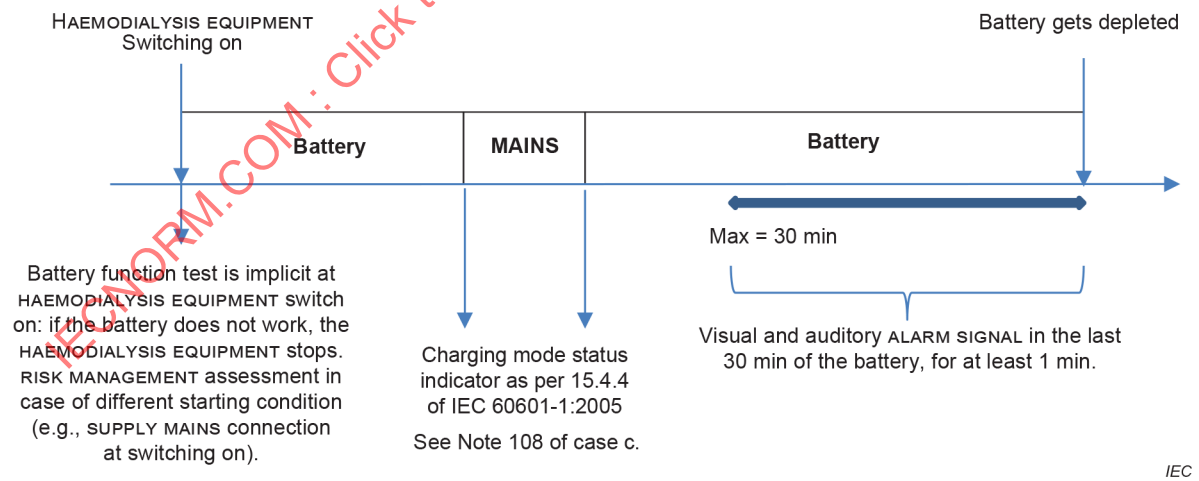


Figure AA.6 – Alarm before battery gets depleted (30 min maximum)

Regarding the transition from mains to battery mode, a charging mode indicator as per 15.4.4 of IEC 60601-1:2005 has been considered enough due to the full function provided by the INTERNAL ELECTRICAL POWER SOURCE. Therefore, differently from case b), a VISUAL ALARM SIGNAL has not been required.

Figure AA.5 and Figure AA.6 are examples of a possible case c designs, starting the HAEMODIALYSIS EQUIPMENT in battery mode.

Subclause 201.12 – Accuracy of controls and instruments and protection against hazardous outputs

The second edition of this particular standard (IEC 60601-2-16:1998) usually did not specify any definite values for the necessary ALARM LIMITS of the PROTECTIVE SYSTEMS. It was up to the MANUFACTURER to define the deviation from the value that presented a HAZARD which had to be detected by the PROTECTIVE SYSTEM and justified in the MANUFACTURER'S RISK MANAGEMENT PROCESS.

The objective of the present edition of this document is to reach an agreement between MANUFACTURERS and other interested organizations as to that part of the RISK MANAGEMENT PROCESS that is applicable to all systems and to describe the result in this document. It is intended to avoid any unnecessary redundant work on the part of the MANUFACTURER and to facilitate a uniform evaluation by testing agencies.

When preparing this document, the committee took a "typical" HAEMODIALYSIS EQUIPMENT for the treatment of acute or chronic renal failures as a basis. If the properties of a HAEMODIALYSIS EQUIPMENT deviate from the "typical" values, the MANUFACTURER should define and justify the ALARM LIMITS in the MANUFACTURER'S RISK MANAGEMENT PROCESS.

If a PROTECTIVE SYSTEM differs in case of different modes either in term of ALARM LIMITS or in term of design, the tests shall be repeated for each mode or the worst case shall be identified by the MANUFACTURER. Examples of modes are double needle treatment, single needle treatment, low weight patient's treatment.

Subclause 201.12.4.4.101 – DIALYSIS FLUID composition

The requirement for a PROTECTIVE SYSTEM is also applicable to USE ERRORS (e.g. mistaking of DIALYSIS FLUID CONCENTRATES) and also refers to Clause 15 (Construction of ME EQUIPMENT) and Clause 16 (ME SYSTEMS).

In acetate treatment, it is considered to be appropriate if the PROTECTIVE SYSTEM is designed such that it prevents a deviation beyond the following limits:

– conductivity of final DIALYSIS FLUID 12 mS/cm to 16 mS/cm
– sodium in DIALYSIS FLUID ±5 % from the set point

Additionally, in bicarbonate treatment:

– bicarbonate in DIALYSIS FLUID ±25 % from the set point

If other components can be added individually, additionally:

– other electrolytes in DIALYSIS FLUID ±20 % from the set point

Where HAEMODIAFILTRATION without buffer (special form of HDF where the buffer is given to the PATIENT not as part of the DIALYSIS FLUID but as part of the SUBSTITUTION FLUID) and other special PROCEDURES (e.g. sorbent regenerative HAEMODIALYSIS EQUIPMENT) are concerned, the technical safety requirements should be defined in the MANUFACTURER'S RISK MANAGEMENT PROCESS, for example by definition of limits for concentration deviations which would indicate system malfunctions and potential harm to the PATIENT.

Regarding Test 1, in order to set the lowest / highest DIALYSIS FLUID composition, this could be achieved by setting all the possible treatment parameters related to DIALYSIS FLUID composition to the lowest / highest values.

Regarding Test 3, in a HAEMODIALYSIS EQUIPMENT with two components, A and B, take A-A, B-B and B-A to the A/B connections, if these misconnections are possible. In a HAEMODIALYSIS EQUIPMENT with more than two components, more combinations should be considered.

Figure AA.7 provides a schematic representation of the four test cases for determining the ALARM SIGNAL activation:

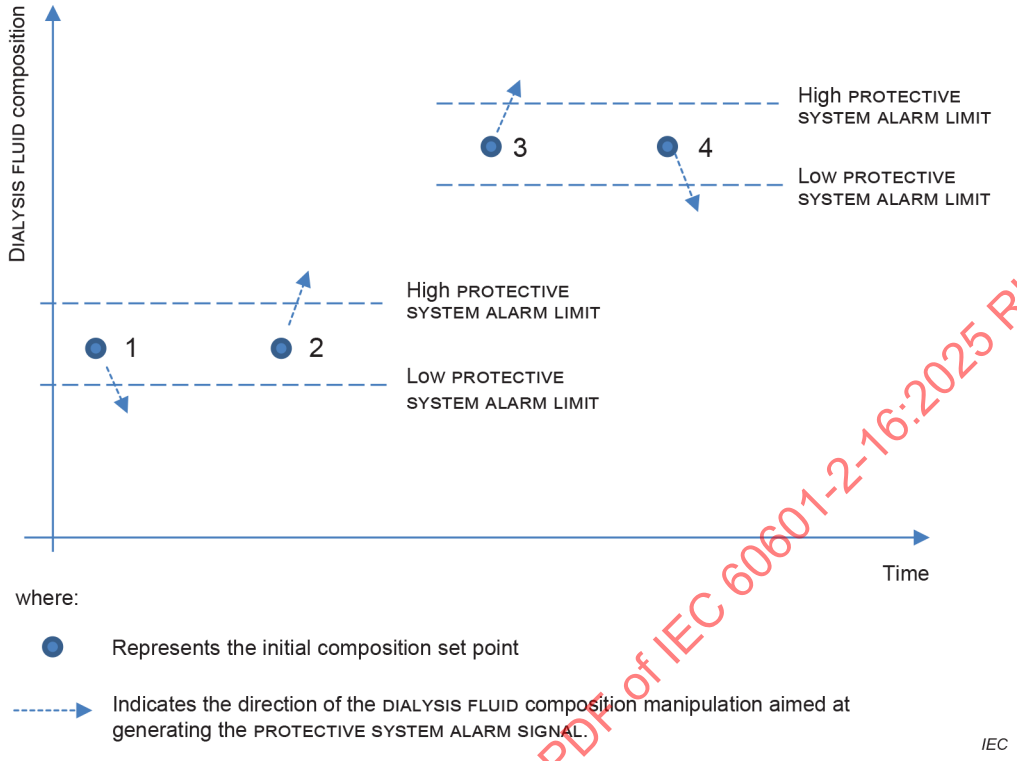


Figure AA.7 – DIALYSIS FLUID composition test cases for determining the ALARM SIGNAL activation

Subclause 201.12.4.4.102 – DIALYSIS FLUID and SUBSTITUTION FLUID temperature

Long-term application of DIALYSIS FLUID temperatures above the body temperature will result in a positive thermal energy balance for the PATIENT, which is associated with physiological reactions. Increased body temperature leads to increased perfusion of the skin and in consequence frequently to clinically relevant blood pressure drop. Temperatures above 46 °C cause haemolysis and denaturation of blood components.

Decrease of body temperature results in discomfort and shivering. The tolerance limits of prolonged core body temperature decrease are some tenths of a °C.

Increasing the temperature above 42 °C for a short time is permitted to enable for example the measurement of recirculation by temperature measurement. A short-term increase is uncritical because it does not lead to perturbation of the energy balance of the body.

Blood damage (thermal haemolysis) occurs when blood is heated to more than 46 °C for a prolonged time. Blood temperatures up to 46 °C in the EXTRACORPOREAL CIRCUIT have been used for hyperthermia treatment. Low temperatures have no adverse effect on blood. Historically, blood has been dialysed at 5 °C. [28]

The DIALYSER is a very efficient heat exchanger, and any temperature gradient will change the thermal energy balance of the PATIENT. A prolonged positive thermal energy balance is known to cause hypotension while a prolonged large negative balance will be uncomfortable for the PATIENT and cause shivering.

To avoid high positive energy balances that can cause hypotension, the maximum DIALYSIS FLUID temperature is limited to 42 °C or less.

Besides PATIENT discomfort for low DIALYSIS FLUID temperatures adverse effects are uncommon, but in rare cases cold dialysate can cause tachypnea, tachycardia, shivering, energy loss and slight changes in coagulation [14]. Ventricular fibrillation has been reported after cooling of the heart to less than 33 °C by rapid infusion of large amounts (> 5 l) of cold (4 °C) blood. In HAEMODIALYSIS, cooling to 33 °C would take more than 15 min even assuming high blood flow rate, low DIALYSIS FLUID temperature (10 °C) and low body weight (50 kg).

Subclause 201.12.4.4.103 – NET FLUID REMOVAL

Safe limits for an acceptable NET FLUID REMOVAL error cannot be derived from physiological data and are PATIENT-dependent; however, the medical industry has many years of experience with fluid balancing systems. The limits given here are derived from this experience.

The direction of a fluid balancing error is an essential factor: excessive removal is hazardous. Hyperhydration (fluid supplied) can be hazardous and depends on the initial situation. Insufficient removal is not hazardous in case of chronic dialysis, provided it is detected and corrected before the PATIENT is discharged.

Monitoring of the following limits by the PROTECTIVE SYSTEM is usually considered to be appropriate:

– for continuous adult treatments, for example CRRT treatments, which are typically driven by the NET FLUID REMOVAL rate, the sliding average value of the NET FLUID REMOVAL rate measured by the PROTECTIVE SYSTEM – with averaging time defined by the MANUFACTURER'S RISK MANAGEMENT PROCESS – is at all time within ±0,1 l/h of the OPERATOR set point rate.
– The risk of cumulated volume error of the NET FLUID REMOVAL over time should be evaluated by the MANUFACTURERS RISK MANAGEMENT PROCESS.
– for typical 4 h adult chronic dialysis treatments, which are typically driven by the NET FLUID REMOVAL volume, the removed cumulated NET FLUID REMOVAL volume measured by the PROTECTIVE SYSTEM is at all time during the treatment time within ±400 ml of the expected cumulated NET FLUID REMOVAL volume.

It is the responsibility of the MANUFACTURER'S RISK MANAGEMENT PROCESS to specify the NET FLUID REMOVAL limits, i.e. the deviations which could lead to HAZARDOUS SITUATION, considering e.g. the intended patients' population, the intended purpose and the ESSENTIAL PERFORMANCE.

Regarding the test, the highest and the lowest settable values should be set unless this prevents from simulating the failure: if it is not possible to increase the ultrafiltration rate above the highest or decrease the ultrafiltration rate below the lowest, values near the extreme settable values can be applied.

TMP monitoring alone is not considered to be an adequate protection against fluid balancing errors in the case of high-flux DIALYSERS (however, TMP monitoring can improve the safety and performance in a different way, for example with regard to the detection of a secondary membrane in the DIALYSER fibres, interdialytic hyperuraemia, undetected membrane rupture, "rescuing" the DIALYSER by rinsing if heparinisation is inadequate).

Possible sources of fluid balancing errors which should be covered by a PROTECTIVE SYSTEM are, for example: leaks at connectors (including SUBSTITUTION FLUID) and errors in the balancing system (e.g. flow meter, balancing chamber).

Subclause 201.12.4.4.104.1 a) – Extracorporeal blood loss to the environment

Monitoring of the VENOUS PRESSURE is not always suitable for detecting a blood loss in time, in case the venous puncture cannula slips out. The VENOUS PRESSURE is determined mainly by the hydraulic resistance of the venous puncture cannula, particularly with today's usual high blood flow rate of up to 500 ml/min. A VENOUS PRESSURE ALARM SYSTEM is, hence, not able to always detect whether or not the puncture cannula has slipped out.

If dialysis is performed in the single-needle mode with only one blood pump ("single-needle single pump", "SN click-clack"), the VENOUS PRESSURE measurement is an integral part of the control system. An error in this control system (e.g. pressure sensor stuck to low value) might lead to the upper changeover point of the VENOUS PRESSURE never being reached. As a result, the pressure becomes too high, the tubing system can burst, and the PATIENT can lose a great amount of blood. This can require a PROTECTIVE SYSTEM which is independent of the control system, for example monitoring of the phase duration by an independent microprocessor.

Inherent safe design is for example a pump rotor that is spring-mounted so smoothly that bursting of the tubing is not possible. However, in this case a HAZARDOUS SITUATION which will cause haemolysis can exist.

Other measures for prevention of overpressure are holders for the EXTRACORPOREAL CIRCUIT lines and the DIALYSER which make kinking sufficiently unlikely.

Blood loss to the environment caused by disconnections or faults in the EXTRACORPOREAL CIRCUIT cannot entirely be prevented by any PROTECTIVE SYSTEM. The PROTECTIVE SYSTEM should be designed so that blood loss is detected and major blood loss is prevented. Most reported cases of fatal blood loss are caused by blood access cannulas slipping from the fistula or graft. This cannot be prevented by the HAEMODIALYSIS EQUIPMENT. Traditionally, VENOUS PRESSURE monitors have been used for protection against blood loss to the environment. These monitors detect a drop of the pressure in the return bloodline. In case of a bloodline rupture or disconnection of the bloodline from the blood access device (cannula or central venous catheter), the pressure will drop considerably because of the high flow resistance in the blood access device. When the venous cannula slips from a fistula, the pressure change is usually too low to be detected by the VENOUS PRESSURE monitor. The pressure drops only by the amount of the fistula pressure which is typically 5 mmHg to 20 mmHg. To avoid frequent nuisance ALARM CONDITIONS caused by PATIENT movement, the difference between the actual VENOUS PRESSURE and the lower pressure ALARM LIMIT is usually adjusted to 10 mmHg to 20 mmHg.

An INTELLIGENT ALARM SYSTEM could be introduced to avoid frequent nuisance ALARM CONDITIONS caused by PATIENT movement, making the ALARM generation depending on either speed of change or duration of change of the VENOUS PRESSURE, or both.

Monitors employing pressure pulses or other parameters can offer greater sensitivity but can also require up to a minute to detect the fault condition and switch off the blood pump. With high blood flow rate this can cause blood losses of 500 ml, which are usually not fatal for adults.

This IEC standards committee has included in Annex CC an example of an open alarm interface specification that enables stopping the blood pump by connected external monitoring devices, that for example can detect blood loss to the environment. The functionality described in the Annex CC could be designed in alternative ways by the MANUFACTURERS.

The effects of haemorrhage are described in reference [18].

Subclause 201.12.4.4.104.1 c) – Extracorporeal blood loss to the environment

Stopping of the occluding blood pump is considered a sufficient reaction to extracorporeal blood loss to the environment. Additional closing of the safety clamp adds only little value because a rupture will most likely occur at the point of highest pressure, which normally is between the blood pump and DIALYSER. In this case, "retrograde" blood loss via the venous bloodline is negligible compared to the direct blood loss through the arterial bloodline. "Retrograde" blood loss from the venous access can become hazardous to the PATIENT if it is not monitored.

Subclause 201.12.4.4.104.2 – BLOOD LEAK to the DIALYSIS FLUID

An acceptable method of complying with this requirement is, for example, a PROTECTIVE SYSTEM utilizing a BLOOD LEAK detector.

BLOOD LEAKS of less than 0,35 ml/min blood (with an Hct of 32 %) have not considered to present a serious HARM for chronic adult patients. It is the responsibility of the MANUFACTURER'S RISK MANAGEMENT PROCESS to identify the BLOOD LEAKS limit considering e.g. the intended PATIENTS' population and the intended purpose (see for example [36]).

Historically, BLOOD LEAK sensitivity has been specified in milligrams of haemoglobin per litre (mgHb/l) of DIALYSIS FLUID, probably because of the established spectrophotometric tests for determination of haemoglobin. Specification in mgHb/l, however, requires calculation to determine the quantity of blood lost, which is the parameter of interest to the practitioner. The threshold limit of 55 mg Hb/l translated to 0,35 ml/min of blood. Calculations were based on the assumption of 14 gr Hb/100 ml blood in normal subjects, a Hct of 46 % (0,46) in normal subjects, a haematocrit possibly as low as 25 % (0,25) in typical HAEMODIALYSIS PATIENTS, and a DIALYSIS FLUID flow rate of 500 ml/min.

Override is a mean to allow the HAEMODIALYSIS EQUIPMENT to function under ALARM CONDITIONS, if the OPERATOR consciously selects to temporarily disable the PROTECTIVE SYSTEM for the BLOOD LEAK.

The visual indication can be a symbol from IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 (see Table C.1 and Table C.2) or another symbol or text taking into account the appropriate colour as per IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 7.8.1.

It should not be possible to deactivate the blood leak detector inadvertently. Possible solutions might, for example, be two independent actions on the operator's part and automatic restart on commencement of the next treatment. Deactivation of the blood leak detector should not increase the risk of blood loss to a higher degree than necessary. An acceptable method shall design the blood leak detector such that it is not only possible to switch it off completely but also to reduce its sensitivity and that this reduction will be automatically cancelled again on commencement of the next treatment. An example for medical reasons to change the sensitivity of the blood leak detector is the treatment of haemolytic-uraemic syndrome (HUS).

Subclause 201.12.4.4.104.3 – Extracorporeal blood loss due to coagulation

In this case, an independent PROTECTIVE SYSTEM for the blood pumping system is not required because the degree of harm is limited to the blood loss in the EXTRACORPOREAL CIRCUIT.

At the time of writing of this document there were no scientific publications available about coagulation of blood as a function of the stopping time of the extracorporeal blood flow. A maximum ALARM SIGNAL delay time of three minutes has been shown by experience to be appropriate.

Subclause 201.12.4.4.105 – Air infusion

At the time of writing of this document there was not enough scientific literature to define a safe ALARM LIMIT in this document. In [28], chapter 14, Polaschegg and Levin consider the continuous infusion of air of less than 0,03 ml/(kg*min) and infusion of a bolus of 0,1 ml/kg not to be a HAZARD.

Exposure to microbubbles should be taken into account and possible preventive measures should be considered by the MANUFACTURERS' RISK MANAGEMENT PROCESS [29], [35], [26].

An air detector response below the hazardous air infusion limit (e.g. a pre-alarm or a pre-notification) is not considered as part of the PROTECTIVE SYSTEM for air infusion.

If there is no air in the EXTRACORPOREAL CIRCUIT with the HAEMODIALYSIS EQUIPMENT being used as intended, the presence of air presents already a first fault, and it is improbable that an independent second fault (e.g. failure of the air detector) occurs during the same treatment. In this case, the air detector would not need to be SINGLE FAULT SAFE. This shall be determined by RISK MANAGEMENT.

If air is permanently present in the tubing system with the HAEMODIALYSIS EQUIPMENT being used as intended, e.g. if a partially filled chamber is used, air in the system is the NORMAL (not SINGLE FAULT) CONDITION. If a normal operating mode (not a technical failure) can cause infusion of this air to the PATIENT, the air detector shall be SINGLE FAULT SAFE.

An air detector is SINGLE FAULT SAFE, if, for example,

a) it is designed with two channels and each channel is tested prior to each treatment, or
b) it is designed with one channel and is tested periodically during the treatment, with the test interval shorter than the fault tolerance time (the shortest time required by an air bubble to move from the air detector to the PATIENT CONNECTION).

A SINGLE FAULT SAFE design to stop the blood flow to the PATIENT is for example as follows:

a) design with two independent actors (e.g. stopping of the pumps and closing of the clamps) and both actors are tested; or
b) the blood pump(s) and all pumps delivering in the direction of the PATIENT are turned off via two channels and even a mechanical failure (e.g. breakage of a rotor spring) cannot cause a loss of occlusion.

If air accumulated in the EXTRACORPOREAL CIRCUIT can reach the PATIENT by expansion, even if the blood pump is stopped by an air detector ALARM CONDITION, an additional clamp shall be provided to prevent air infusion into the PATIENT. This is typically the case when the air detector is positioned downstream of the DIALYSER.

No additional clamp is typically required if the air detector is positioned downstream of the blood pump but upstream of the DIALYSER and if a leak in the negative pressure section of the EXTRACORPOREAL CIRCUIT is the only pathway for ingress of air.

For HAEMODIALYSIS EQUIPMENT which can raise or lower the level in the drip chamber by means of an electrically operated air pump, a malfunction of this air pump can cause air in the tubing system. If this air pump is able to build up a pressure that is higher than the occlusion pressure of the venous clamp, the venous clamp no longer presents a safe switch off path. In this case, the air pump has also to be switched off in a SINGLE FAULT SAFE manner. In addition, it should be noted that the air pump might be able to press air into the PATIENT via the arterial bloodline when the blood flow is stopped (e.g. because of an ALARM CONDITION) and that this air would not be detected by the air detector.

In case of single-needle PROCEDURES, it should be noted that, owing to the compressed air present in the system, the actual blood flow rate can be temporarily higher than the set blood flow rate. This should be taken into consideration when the scanning interval of the air detector and the fault tolerance time are determined.

In case of a failure of the power supply, air in the EXTRACORPOREAL CIRCUIT under pressure can also generate flows in direction of the venous or arterial PATIENT CONNECTION. In this case, air shall be prevented from reaching the PATIENT.

At least the following potential sources of air should be considered in the RISK ANALYSIS:

– air in chamber(s);
– residual air in the bloodline;
– residual air in the DIALYSER;
– air in the monitor lines leading to the pressure transducers;
– air entering the system in the recirculation path of a single-needle treatment;
– air entering the EXTRACORPOREAL CIRCUIT.

The physical principle used for any air detector and any electronic delays or other delays should be taken into account in the RISK ANALYSIS. Today ultrasonic air detectors are used almost exclusively for the detection of air in the EXTRACORPOREAL CIRCUIT. Some of these air detectors are positioned on the partially air-filled venous drip chamber. They are usually designed as level detectors, which means that they will generate an ALARM CONDITION if the level decreases or if the drip chamber is filled with foam.

Other air detectors are positioned directly on the blood tubing and are usually capable of detecting single bubbles with volumes much lower than the volumes believed to cause a HAZARD. The important parameter of the air detector is the accumulated volume of these single bubbles. In order to avoid nuisance ALARM CONDITION, the number of detected bubbles is integrated with a time function.

Non-dissolved air can appear in bulk and in the form of bubbles of different sizes. To address this, the two different test PROCEDURES in Note 4 are required, independently of the air monitoring methods:

– Continuous Air Infusion test to verify that the HAEMODIALYSIS EQUIPMENT is able to prevent a flow of microbubbles in excess of the identified safety limit to the patient. Such microbubbles are formed from the fragmentation of a larger air bubble as it passes through the hollow fibres contained in the dialyser. Note that air which enters downstream of the DIALYSER does not create a similar condition and hence should not be considered equivalent to the test method described by this document.
– Bolus Air Infusion test to verify that the HAEMODIALYSIS EQUIPMENT is able to prevent a bolus of air exceeding the identified safety limit to reach the patient.

Regarding the test setup, the setup for continuous air infusion can contain more than 1 test tube. Two configurations are possible:

– Having 1 tube open at a time:
  - The last tube opened representing the condition at the time of the ALARM CONDITIONS and the other tubes representing the condition before the time of the ALARM CONDITION. This can be used to have a statistical overview of the air infusion over time.
  - Every tube representing an ALARM CONDITIONS at a time. This can be used to have a statistical overview of the repeatability of the test.
– Having multiple tubes opened in parallel. This can be used to increase the statistical accuracy of the air infusion measurement by increasing the blood volume. The test tubes should be clamped separately to improve the measurement of the air volume collected in the test tubes and it should be ensured that no tube is blocked.

Subclause 201.12.4.4.106 – Anticoagulation

This document includes more detailed requirements for anticoagulant delivery means. 201.12.4.4.106 includes design requirements and requirements to address defined HAZARDOUS SITUATIONS in the MANUFACTURERS' RISK MANAGEMENT PROCESS.

Overdelivery of anticoagulant can occur during the PATIENT treatment if the anticoagulant delivery means continues when the blood pump is stopped and can create a HAZARDOUS SITUATION. This can occur when the anticoagulant delivery output is connected downstream of the blood pump by the anticoagulant delivery means continuing with the blood pump stopped and delivering a bolus of anticoagulant to the connection that is then given to the PATIENT when the blood pump starts again. Overdelivery can also occur when the anticoagulant delivery does not stop with the blood pump and its output is connected upstream of the blood pump without a system controlled clamp on the arterial access line of the PATIENT. In this case, the anticoagulant goes directly to the PATIENT while the HAEMODIALYSIS EQUIPMENT is stopped.

Underdelivery of anticoagulant can occur during the PATIENT treatment if the anticoagulant delivery means is not started when the blood is running. It can also occur due to compliance in the anticoagulant delivery system (including a syringe if used) taking time to deliver at the specified rate. This is of particular importance for low anticoagulant administration rates or in cases of large variations in output pressure in the EXTRACORPOREAL CIRCUIT. This delay in anticoagulant delivery can cause coagulation and blood loss if not addressed.

IEC 60601-2-24 [30] does not apply, because its scope relates to pumps for infusion of liquids into the PATIENT, and devices for extracorporeal circulation of blood are excluded. Anticoagulant delivery means in the scope of this document are for delivery of anticoagulants into the EXTRACORPOREAL CIRCUIT.

Anticoagulant delivery means in HAEMODIALYSIS EQUIPMENT can be a syringe pump that infuses one anticoagulant (e.g. heparin) or roller pumps that infuse simultaneously Citrate and Calcium at different points of the EXTRACORPOREAL CIRCUIT (CiCa) or other designs not directly matching with IEC 60601-2-24.

All relevant HAZARDOUS SITUATIONS addressed in IEC 60601-2-24 in the use context of HAEMODIALYSIS EQUIPMENT were taken into account in this document: specification of accuracy (201.7.9.3.1, 201.12.4.4.106), underinfusion (201.12.4.4.104.3, 201.12.4.4.106), overinfusion (201.12.4.4.106), unintended bolus (201.12.4.4.106), USABILITY issues (201.12.4.4.106). Added are HAZARDOUS SITUATIONS not included in IEC 60601-2-24 but necessary for the use scenarios of HAEMODIALYSIS EQUIPMENT.

It is sometimes useful for developers to look into the IEC 60601-2-24 when developing anticoagulant delivery means for HAEMODIALYSIS EQUIPMENT.

If the HAEMODIALYSIS EQUIPMENT includes fluid (medication) delivery means for other substances than anticoagulants or for direct infusion into the PATIENT, IEC 60601-2-24 could be applicable in total or in parts. This is not addressed in this document because such use cases are not in the normal INTENDED USE of HAEMODIALYSIS EQUIPMENT.

Subclause 201.12.4.4.108 – Prevention of contamination by chemicals

Regarding c), possible misconnections should be evaluated in the USABILITY process and in the RISK MANAGEMENT PROCESS. Possible ways to address this can be the usage of specific connectors and colour coding (see 201.15.4.1.101) or detecting a deviation from expected conductivity.

Subclause 201.12.4.4.109 – Blood pump(s) and, if applicable, SUBSTITUTION FLUID pump(s) reversal

Example of a HAZARDOUS SITUATION caused by USE ERROR:

In case of mains power failure in a dialysis unit, it is very likely that the staff is under high stress and therefore USE ERROR is relative likely. In this situation, the HAZARD of air infusion via the arterial bloodline (if applicable) by wrong blood pump direction can be avoided, for example by

a) prevention of wrong hand cranking direction by
   – a unidirectional cranking mechanism, or
   – a clearly marked arrow on the pump(s), or
b) avoidance of hand cranking by continuation of the blood flow with battery power.

Example of a HAZARDOUS SITUATION caused by a technical fault:

A technical fault could cause the blood pump(s) and, if applicable, SUBSTITUTION FLUID pump(s) to rotate in the wrong direction. This can be avoided, for example by

a) wiring a DC motor with electromechanical commutation such that no random hardware failure can reverse the direction of the current, or
b) implementation of a PROTECTIVE SYSTEM independent of the motor control system, which stops the motor if the pump(s) rotate in the wrong direction.

Subclause 201.13.2.6 – Leakage of liquid

The test considers that fluid can flow out under normal working pressure. Although its performance and reproduction is difficult, the test specified in this document is considered to be suitable for this type of equipment.

Subclause 201.14.13 – PEMS intended to be incorporated into an IT-NETWORK

A method proven to reduce RISK for the transfer of HAEMODIALYSIS EQUIPMENT settings via an IT-NETWORK is the explicit test of the data transferred, performed by the OPERATOR and confirmation by the OPERATOR before these settings become effective in the HAEMODIALYSIS EQUIPMENT.

Subclause 201.14.13.101 – Specific security features for HAEMODIALYSIS EQUIPMENT used in MEDICAL IT-NETWORKS

Other possible ways for fulfilling the requirement can be found in references [32] and [27].

Due to the controlled clinic and home environment the need to follow the recommendations in Table 1 of IEC TR 60601-4-5:2021 can be reduced. Usability and safety risk versus the security risk shall be considered when selecting the appropriate countermeasures to protect the access to the user interface.

Enclosed some explanations on how to apply the IEC TR 60601-4-5 in the context of physical user interface access security in the dialysis environment:

The recommendation in Table 1 of IEC TR 60601-4-5:2021 covers both external data interfaces and human interfaces for processing CONFIDENTIAL PATIENT DATA.

- Due to the access controlled clinical or home environments, HAEMODIALYSIS EQUIPMENT typically do not require authentication when interacting using the user interface for treatment related purposes.

- On the other side there can be the use case for a MANUFACTURER to implement authentication to process CONFIDENTIAL PATIENT DATA e.g. stored in the HAEMODIALYSIS EQUIPMENT or by accessing external databases using the user interface in the above-mentioned environments.

Subclause 201.15.4.1.101 – DIALYSIS FLUID CONCENTRATE connectors

DIALYSIS FLUID CONCENTRATEs can be used in the form of powder or fluid. For DIALYSIS FLUID CONCENTRATEs in the form of powder and "DIALYSIS FLUID ions for sodium chloride (powdered)", constructional features preventing their misuse are usually provided in the HAEMODIALYSIS EQUIPMENT designs. Liquid DIALYSIS FLUID CONCENTRATES are taken either from containers or from CENTRAL DELIVERY SYSTEMS, which are not prevented from being misused by constructional features.

At least the following DIALYSIS FLUID CONCENTRATE types should be taken into consideration in the MANUFACTURERS' RISK MANAGEMENT PROCESS:

– acetate dialysis fluid concentrate;
– acid DIALYSIS FLUID CONCENTRATE for use with bicarbonate DIALYSIS FLUID CONCENTRATE without sodium chloride;

  NOTE 1 With 35X, 36.83X, 45X dilution.

– acid DIALYSIS FLUID CONCENTRATE for use with bicarbonate DIALYSIS FLUID CONCENTRATE with sodium chloride;

  NOTE 2 With 35X, 36.83X, 45X dilution.

– bicarbonate DIALYSIS FLUID CONCENTRATE without sodium chloride;

  NOTE 3 Can be supplied as liquid or powder.

– bicarbonate DIALYSIS FLUID CONCENTRATE with sodium chloride;
– sodium chloride;

  NOTE 4 Can be supplied as liquid or powder.

– DIALYSIS FLUID concentrates complementary to sodium and bicarbonate.

  NOTE 5 Used for mixing systems with separate sodium and bicarbonate DIALYSIS FLUID CONCENTRATE supplies.

  NOTE 6 Can be supplied as liquid or powder.

Subclause 201.15.4.1.102 – Connectors for blood pressure transducers

Designs that use an internal transducer protector between the internal pressure transducer and the connection to the external transducer protector prevent contamination of the internal transducer itself, but do not prevent the RISK of cross-contamination between PATIENTS dialysed on the same HAEMODIALYSIS EQUIPMENT.

Subclause 201.16 – ME SYSTEMS

A ME SYSTEM for dialysis can comprise one or more HAEMODIALYSIS EQUIPMENT and one or more of the following (see Figure AA.8):

– DIALYSIS WATER supply system;
– discharge (drain);
– IT-NETWORK;
– central delivery system;
– staff call system.

NOTE Since TOUCH CURRENTS of other equipment exist in the PATIENT ENVIRONMENT (e.g. dialysis chairs), a POTENTIAL EQUALIZATION CONDUCTOR can be relevant for such equipment.

The DIALYSIS WATER supply systems and the CENTRAL DELIVERY SYSTEMs are usually set up at a location that is remote from the HAEMODIALYSIS EQUIPMENT and cannot be connected via a MULTIPLE SOCKET-OUTLET. HAZARDS shall be minimized via the installation, by applying the supply lines, for example, to the same potential as the HAEMODIALYSIS EQUIPMENT.

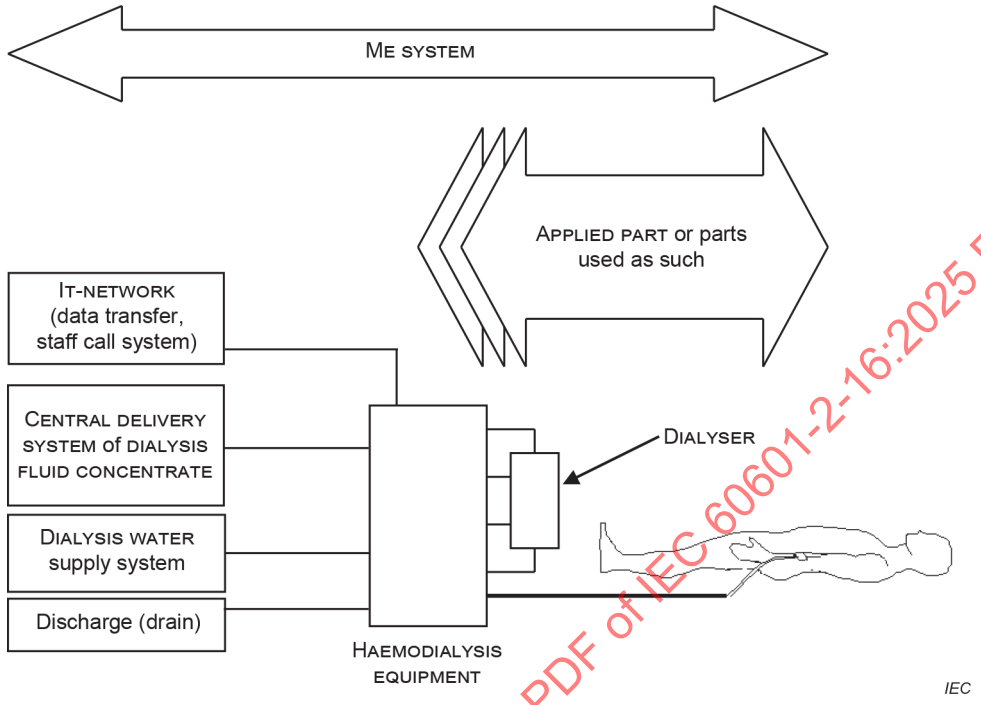


Figure AA.8 – Example of a HAEMODIALYSIS ME SYSTEM

Parts like water treatment systems can be considered as not conductively connected and therefore not a part of the applied part if the following conditions apply.

In case that a DIALYSIS WATER supply system is equipped with a resistivity monitoring alarm and has an isolating material dialysis water output line towards the HAEMODIALYSIS EQUIPMENT water inlet, it can be regarded as electrically isolated from the HAEMODIALYSIS EQUIPMENT if the resulting electrical resistance is 120 MΩ or higher for 120 V mains voltage, or 240 MΩ or higher for 240 V mains voltage. The presence of a continuous resistivity monitoring unit with alarm is needed because the isolation value is only obtained if the dialysis water is pure enough (refer to ISO 23500-2:2019 [4], Subclause 4.2.10 and Subclause 4.2.11).

An example for dialysis water of 1 MΩ·cm resistivity, assuming highly isolating tubing material:

- A connecting tube of 120 cm with an 8 mm inner lumen diameter (equivalent to a cross section of 0,5 cm^2) would yield a worst-case current of 1 µA at 240 V (0,5 µA at 120 V).

It shall also be considered that:

– smaller internal tube diameters or larger tube length increase the resistance, whereas larger internal tube diameters or shorter tube length decrease the resistance;

– higher temperature decreases the resistance, whereas lower temperature increases the resistance (values are given at 25 °C as reference);

– DC increases the resistance, whereas AC decreases the resistance.

Other possible sources for LEAKAGE CURRENTS to be taken into consideration are e.g. the drain part.

Subclause 201.16.9.1 – Connection terminals and connectors

According to the state of the art, the PROTECTIVE SYSTEM for "composition of the DIALYSIS FLUID" is based on the measurement of the conductivity or the volumetric admixture. Depending on the operating mode (acetate, bicarbonate), an incorrect DIALYSIS FLUID CONCENTRATE is frequently detected via the conductivity or the volumetric admixture.

Additional measures besides colour coding of the CENTRAL DELIVERY SYSTEM could be required by RISK MANAGEMENT in case of DIALYSIS FLUID CONCENTRATES which, although they deliver a conductivity within the expected range, are hazardous for the treatment type concerned in their composition (e.g. acid DIALYSIS FLUID CONCENTRATE 45X ratio for acetate dialysis).

In such cases, the RESPONSIBLE ORGANIZATION should initiate the appropriate measures which are equivalent to colour coding with the pertinent operating mode, such as disabling the operating mode of acetate HAEMODIALYSIS or mechanically coding the HAEMODIALYSIS EQUIPMENT and the DIALYSIS FLUID CONCENTRATE container.

Subclause 202.8.1 – General

Safe state should be defined in the MANUFACTURER's RISK MANAGEMENT FILE. Examples of a safe state for HAEMODIALYSIS EQUIPMENT are as follows:

– stopping the blood flow;
– stopping of the DIALYSIS FLUID flow to the DIALYSER;
– interruption of any SUBSTITUTION FLUID flow;
– reduction of ULTRAFILTRATION rate to its minimum value;
– clamping of the venous blood line;
– activation of auditory and visual ALARM SIGNALS.

Monitoring of the parameters (e.g. via log files) identified by MANUFACTURER for BASIC SAFETY and ESSENTIAL PERFORMANCE should also be taken into consideration to determine if the HAEMODIALYSIS EQUIPMENT is in a safe state.

Subclause 208.4 – General requirements

IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 are written with the focus on intensive care or surgery environments and add in 6.1.2 a very PATIENT-centric view of potential results of failure to respond to the cause of ALARM CONDITIONS.

HAEMODIALYSIS EQUIPMENT is mainly used in a chronic ambulant approach. The PATIENTS normally do not have life threatening status. ALARM CONDITIONS mostly arise from technical causes and the therapy has in most cases of problems the chance to go to a safe state, which only loses time for PATIENT and OPERATORS, but which is one of the most important issues in a timely exact planned schedule of subsequent following shifts. The environment in a normal chronic HAEMODIALYSIS clinic is dominated by the HAEMODIALYSIS EQUIPMENT, in many cases from one MANUFACTURER. Normally, other ME EQUIPMENT will not be used continuously beside the HAEMODIALYSIS EQUIPMENT in the PATIENT ENVIRONMENT.

In this ambulatory environment the ALARM CONDITION categories need completely different priorities than in an environment where the PATIENTS have life-threatening status and the therapy is life-supporting. In the ambulatory environment, 6.1.2, with Table 1, of IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 would not reflect the needed priorities.

Even in the critical care environments, the HAEMODIALYSIS EQUIPMENT is not life-supporting and most ALARM CONDITION situations would not be a HAZARDOUS SITUATION for PATIENT and OPERATOR and the ALARM CONDITION priority will be low. In some cases, OPERATORS from chronic HAEMODIALYSIS support and operate the HAEMODIALYSIS EQUIPMENT in the intensive care environment.

For HAEMODIALYSIS EQUIPMENT not used in intensive care environments, the actual used – over years of operation optimized – ALARM SYSTEMS should not be worsened by the need of applying IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020.

Because of these reasons, this document only requires the complete implementation of IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 for HAEMODIALYSIS EQUIPMENT with INTENDED USE in the intensive care environment. For this environment, Table AA.1 shows how possible ALARM CONDITION priorities according to IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 could be adapted for HAEMODIALYSIS EQUIPMENT needs. If the HAEMODIALYSIS EQUIPMENT is intended to be used in both environments, the ALARM SYSTEM according to IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 shall be implemented and selectable by the RESPONSIBLE ORGANIZATION, but ALARM SYSTEMS with deviation from 6.1.2, 6.3.2.2 and 6.3.3.1 of IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 are allowed for additional implementation.

For HAEMODIALYSIS EQUIPMENT with a screen, this document does not require that the visual ALARM SIGNAL has to be indicated by an indicator light that is independent of the screen, since there can be applications where it is appropriate if the ALARM SIGNAL is indicated on the screen. In large-size dialysis units, however, it is probably more appropriate to provide an indicator light that can be seen from a far distance and is installed in such a position (e.g. up-raised) that the HAEMODIALYSIS EQUIPMENT activating the ALARM SIGNAL can be readily located.

Table AA.1 – Example of ALARM CONDITION priorities according to 6.1.2 of IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, adapted for HAEMODIALYSIS EQUIPMENT needs

ALARM CONDITION	ALARM CONDITION priority
Different reasons (e.g. pressures, technical faults)	
Reasons that lead to a stop of the blood flow through the EXTRACORPOREAL CIRCUIT	LOW PRIORITY, yellow
Blood loss due to coagulation in the extracorporeal system	
Blood pump stop ALARM CONDITION (201.12.4.4.104.3), as escalation of above ALARM CONDITION	MEDIUM PRIORITY, yellow flashing
Mains off and backup-battery running system, before battery goes down (201.11.8 b))	
Possible blood loss out of the puncture site or open catheter, following accidental needle or catheter disconnect (201.12.4.4.104.1)	
Detectable by low VENOUS PRESSURE	HIGH PRIORITY, red flashing
PHYSIOLOGICAL ALARM CONDITIONS, if not specified in other standards	
PHYSIOLOGICAL ALARM CONDITIONS, for example non-invasive blood pressure limit ALARM CONDITION	HIGH PRIORITY, red flashing Possible: escalation with two different limits
Treatment deviation, influence on prescription	
For example, balancing ALARM CONDITIONS, long-lasting bypass of DIALYSIS FLUID	LOW PRIORITY, yellow
Technical information	
Technical faults, but blood system is running, for example short bypass of dialysate	INFORMATION SIGNAL, for example green flashing Alternative is the use of LOW PRIORITY, yellow

An ALARM SIGNAL activated in case of extracorporeal blood loss to the environment (see 201.12.4.4.104.1) is one example of a HIGH PRIORITY ALARM SIGNAL that requires immediate response by the OPERATOR. If the blood flow is stopped for an extended period of time (201.12.4.4.104.3), this is an example for a MEDIUM PRIORITY ALARM SIGNAL. In most other ALARM CONDITIONS, the PROTECTIVE SYSTEM puts the HAEMODIALYSIS EQUIPMENT in a state which is safe for the PATIENT, at least temporarily, and therefore is indicated by a LOW PRIORITY ALARM SIGNAL. Other ALARM SIGNALS should be determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS.

Regarding the non-applicability of Subclause 6.3.3.1 item d) 1) i) of IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 to this document, in case more than one set of auditory ALARM SIGNAL is present, it is considered acceptable for the MANUFACTURER to decide if Annex G of IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 alarm signs shall be included in the design or not.

Subclause 208.6.3.1 – General

If the OPERATOR is allowed to configure the contents of the screen, the MANUFACTURER shall use constructive measures (and not just notes in the instructions for use) to ensure that the ALARM SIGNALS can be seen under all circumstances.

Subclause 208.6.3.3.2 – Volume and characteristics of auditory ALARM SIGNALS and INFORMATION SIGNALS

The specification takes into account, that the sound pressure level of 65 dB(A) is focussing on users far away, therefore a detailed specification of the measurement position is not needed, as between the sound generating device and the far distance user there are multiple reflections expected, that have a dominant impact on the sound pressure level reaching the user.

Respect to IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, former Annex F, if the HAEMODIALYSIS EQUIPMENT has implemented melodies according to the above-mentioned Annex and they have demonstrated to fit the purpose of being effectively discriminated by the OPERATOR, then they can be considered appropriate and effectively covering the purpose of the Annex G introduced in IEC 60601-1-8:2006/AMD2:2020.

Subclause 208.6.3.3.101 – Special characteristics of auditory ALARM SIGNALS for HAEMODIALYSIS EQUIPMENT

There are ALARM CONDITIONS which do not present any HAZARDOUS SITUATION if the auditory ALARM SIGNAL is AUDIO PAUSED for more than 3 min, but where elimination of the cause of the ALARM CONDITION often takes more than 3 min, for example in case of a conductivity ALARM CONDITION caused by an empty DIALYSIS FLUID CONCENTRATE container. In this case, the PATIENT'S state will not deteriorate during the AUDIO PAUSED period and the activated bypass mode.

Subclause 211 – Requirements for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS used in the HOME HEALTHCARE ENVIRONMENT

Besides the PERMANENTLY INSTALLED connection to SUPPLY MAINS needed for CLASS I HAEMODIALYSIS EQUIPMENT the same level of safety can be achieved by a unique MAINS PLUG connector that is normally not used in the HOME HEALTHCARE ENVIRONMENT. This allows the PATIENT OPERATOR to disconnect and remove the HAEMODIALYSIS EQUIPMENT without the problem of reconnecting it to another SUPPLY MAINS socket-outlet with an improper PROTECTIVE EARTH CONNECTION. If a unique SUPPLY MAINS socket-outlet connector is used, it shall be installed and tested by the RESPONSIBLE ORGANIZATION.

Annex BB
(informative)

Examples of HAZARDS, foreseeable sequences of events, and HAZARDOUS SITUATIONS in HAEMODIALYSIS EQUIPMENT

Table BB.1 is not intended to be a complete RISK ANALYSIS and is provided partially and for example only. Given HARM levels do not apply to all PATIENT groups. Risk assessment is the responsibility of each MANUFACTURER as per ISO 14971:2019 [34].

Table BB.1 – Example of HAZARDOUS SITUATIONS list following ISO 14971:2019, Annex C

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
Multiple HAZARDS possible	Venous needle punctures vascular access	Extracorporeal blood flow into intertissue through venous needle	Haematoma	
	Delivery rate or amount of heparin too high	Heparin concentration too high inside blood volume	Internal bleeding	– IEC 60601-2-16:2024, 201.12.4.4.106
	Blood flow was stopped too long	Coagulation of extracorporeal blood	Blood loss	– IEC 60601-2-16:2024, 201.7.9.2.5; 201.7.9.3.1; 201.11.8; 201.12.4.4.104.3 – IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 7.9.2.4
	Delivery rate or amount of heparin too low			– IEC 60601-2-16:2024, 201.12.4.4.106
	Interruption of power supply too long			– IEC 60601-2-16:2024, 201.11.8; 201.7.9.3.1; 201.12.4.4.104.3
	High ULTRAFILTRATION rate over DIALYSER semipermeable membrane in relation to blood flow rate	Increasing haematocrit can block fibres of DIALYSER		– IEC 60601-2-16:2024, 201.12.4.4.104.3
	Venous needle slips out	Extracorporeal blood is pumped to environment		– IEC 60601-2-16:2024, 201.7.9.2.2, 9th hyphen; 201.7.9.3.1, 2nd bullet, 6th hyphen; 201.12.4.4.104.1
	Connector of disposable behind arterial blood pump opened or leaks			– IEC 60601-2-16:2024, 201.7.9.2.2, 3rd hyphen; 201.12.4.4.104.1
	Pressure higher than disposal resist leading to rupture			– IEC 60601-2-16:2024, 201.12.4.4.104.1
	Syringe plunger of heparin pump, which arranged downstream of blood pump slipping out			– IEC 60601-2-16:2024, 201.12.4.4.104.1
	DIALYSER semi-permeable membrane or fibre broken	BLOOD LEAKS into DIALYSIS FLUID		– IEC 60601-2-16:2024, 201.7.9.3.1, 2nd bullet, 7th hyphen; 201.12.4.4.104.2
	Unintended blood flow reversal and air in the EXTRACORPOREAL CIRCUIT	Air infused over arterial PATIENT CONNECTION	Air infusion	– IEC 60601-2-16:2024, 201.7.9.3.1, 2nd bullet, 2nd hyphen; 201.12.4.4.109
	Level regulator pump pumps air into ARTERIAL PRESSURE monitor upstream of arterial blood pump			– IEC 60601-2-16:2024, 201.7.9.3.1, 2nd bullet, 2nd hyphen; 201.12.4.4.109

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	Air sucked into blood side before blood pump (material damage or unintentional opening of the infusion port)	Air infused over venous PATIENT CONNECTION		– IEC 60601-2-16:2024, 201.7.9.2.2, 8th hyphen; 201.7.9.3.1, 2nd bullet, 2nd hyphen; 201.12.4.4.105; 201.12.4.4.106; 201.12.4.4.107
	Level regulator pump pumps air downstream of arterial blood pump into arterial (pre-dialyzer) pressure monitor or VENOUS PRESSURE monitor.			– IEC 60601-2-16:2024, 201.7.9.3.1, 2nd bullet, 2nd hyphen; 201.12.4.4.105, 201.12.4.4.107
	SUBSTITUTION FLUID pump pumps air downstream of arterial blood pump into EXTRACORPOREAL CIRCUIT			– IEC 60601-2-16:2024, 201.7.9.3.1, 2nd bullet, 2nd hyphen; 201.12.4.4.105; 201.12.4.4.107
	Improper function of ultrasonic air detector (e.g. caused by coagulum or ultrasound gel)			– IEC 60601-2-16:2024, 201.7.9.2.2, 10th hyphen
	Air entering the EXTRACORPOREAL CIRCUIT in the recirculation path of single-needle treatment			– IEC 60601-2-16:2024, 201.7.9.2.2, 11th hyphen
	Blood line kinked (specially DIALYSER input)	Erythrocytes exposed to high sheer forces.	Haemolysis	– IEC 60601-2-16:2024, 201.7.9.2.2, 9th hyphen
	Reduced blood flow rate by high negative arterial upstream of pump	Reduced effectiveness of HAEMODIALYSIS treatment	Prescribed HAEMODIALYSIS treatment dose not delivered	– IEC 60601-2-16:2024, 201.7.9.2.2, 13th hyphen
	Insufficient degassing of DIALYSIS FLUID			
	Insufficient flow rate of fresh DIALYSIS FLUID			– IEC 60601-2-16:2024, 201.4.3.101
	Blood flow rate too low due to technical defect			– IEC 60601-2-16:2024, 201.4.3.101
	DIALYSIS FLUID bypassing DIALYSER			– IEC 60601-2-16:2024, 201.4.3.101
	Effective HAEMODIALYSIS time too low due to technical defect			– IEC 60601-2-16:2024, 201.4.3.101
	SUBSTITUTION FLUID flow rate too low due to technical defect			– IEC 60601-2-16:2024, 201.4.3.101

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
Biological	Blood of the previous PATIENT flows into the pressure inlet connection of the HAEMODIALYSIS EQUIPMENT	Pyrogens/ endotoxins/bacteria/viruses can contaminate the blood directly (cross infection)	Virus/bacterial infection/ Pyrogen reaction	– IEC 60601-2-16:2024, 201.15.4.1.102
	Disinfection PROCEDURE of HAEMODIALYSIS EQUIPMENT internally and externally has inadequately removed viral contamination			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 7.9.2.12 – IEC 60601-2-16:2024, 201.7.9.2.12, 1st, 2nd, 3rd hyphens; 201.11.6.6
	Infusion of contaminated DIALYSIS FLUID into blood from DIALYSIS FLUID side in ONLINE HDF / HF systems	Pyrogens/ endotoxins/bacteria can contaminates the blood directly		– IEC 60601-2-16:2024, 201.7.9.3.1, 2nd bullet,14th hyphen; 201.12.4.4.111
	Contaminated surface of ENCLOSURE	Skin contamination with bacteria	Bacterial infection	– IEC 60601-2-16:2024, 201.7.9.2.2, 1st hyphen
Chemical	Treatment of PATIENT when HAEMODIALYSIS EQUIPMENT is in disinfection mode	Blood contamination with toxins	Poisoning / allergy	– IEC 60601-2-16:2024, 201.12.4.4.108
	Disinfectant has been inadequately rinsed from DIALYSIS FLUID circuit			– IEC 60601-2-16:2024, 201.11.6.6
	OPERATOR connects disinfectant canister instead of bicarbonate DIALYSIS FLUID CONCENTRATE or acid/acetate DIALYSIS FLUID CONCENTRATE canister to HAEMODIALYSIS EQUIPMENT			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 15.4.1 – IEC 60601-2-16:2024, 201.15.4.1.101
	Toxic material comes in contact with DIALYSIS FLUID (e.g. via water supply or by components of the hydraulics)			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 11.7 – IEC 60601-2-16:2024, 201.7.9.3.1, 2nd bullet, 13th hyphen
Biological	Returning fluid into CENTRAL DELIVERY SYSTEM or DIALYSIS WATER supply system	Blood contamination with toxins	Poisoning/ allergy	– IEC 60601-2-16:2024, 201.12.4.4.108
Multiple HAZARDS possible	DIALYSIS- / SUBSTITUTION FLUID temperature too low	Blood is cooled directly (infusion) or via DIALYSER	Cooling heart until cardiac arrest	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 12.4.3 – IEC 60601-2-16:2024, 201.7.9.3.1, 2nd bullet,4th hyphen; 201.12.4.4.102; 201.11.8

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	DIALYSIS- / SUBSTITUTION FLUID temperature too high	Blood is heated directly (infusion) or via DIALYSER	Haemolysis	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 12.4.3 – IEC 60601-2-16:2024, 201.7.9.2.6, 4th hyphen; 201.7.9.3.1, 2nd bullet, 4th hyphen; 201.12.4.4.102
	DIALYSIS FLUID Na concentration lower than prescribed	Blood is dialysed against or infused with (ONLINE HDF) DIALYSIS FLUID of too low concentration (Na)	Hyponatremia	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 12.4.3 – IEC 60601-2-16: 2024, 201.4.3.101; 201.7.9.3.1, 2nd bullet, 3rd hyphen
	DIALYSIS FLUID Na concentration lower than 120 mmol/l		Haemolysis	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 12.4.3 – IEC 60601-2-16:2024, 201.12.4.4.101
	DIALYSIS FLUID Na concentration higher than prescribed	Blood is dialysed against or infused with (ONLINE HDF) DIALYSIS FLUID of too high concentration (Na)	Hypernatremia	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 12.4.3 – IEC 60601-2-16: 201.4.3.101; 201.7.9.3.1, 2nd bullet, 3rd hyphen
	DIALYSIS FLUID Na concentration higher than 160 mmol/l			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 12.4.3 – IEC 60601-2-16: 201.12.4.4.101
	Bicarbonate DIALYSIS FLUID concentration too low	Blood is dialysed against or infused with (ONLINE HDF) DIALYSIS FLUID of too low concentration (Bicarbonate)	Acidosis	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 12.4.3 – IEC 60601-2-16:2024, 201.12.4.4.101
	Acid DIALYSIS FLUID CONCENTRATE instead of acetate DIALYSIS FLUID CONCENTRATE when acetate HAEMODIALYSIS treatment has been selected			– IEC 60601-2-16:2024, 201.7.9.2.5, 2nd hyphen; 201.12.4.4.101; 201.15.4.1.101; 201.16.9.1
	Acid DIALYSIS FLUID CONCENTRATE instead of bicarbonate DIALYSIS FLUID CONCENTRATE when bicarbonate HAEMODIALYSIS treatment has been selected			– IEC 60601-2-16:2024, 201.7.9.2.5, 2nd hyphen; 201.12.4.4.101; 201.15.4.1.101; 201.16.9.1

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	Acetate DIALYSIS FLUID CONCENTRATE instead of bicarbonate DIALYSIS FLUID CONCENTRATE when bicarbonate HAEMODIALYSIS treatment has been selected			– IEC 60601-2-16:2024, 201.7.9.2.5, 2nd hyphen; 201.12.4.4.101; 201.15.4.1.101; 201.16.9.1
	Acetate HAEMODIALYSIS treatment instead of bicarbonate HAEMODIALYSIS treatment		Hyperacetatemia	– IEC 60601-2-16:2024, 201.12.4.4.110
	Bicarbonate DIALYSIS FLUID concentration too high	Blood is dialysed against or infused with (ONLINE HDF) DIALYSIS FLUID of too high concentration (bicarbonate)	Alkalosis	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 12.4.3 – IEC 60601-2-16:2024, 201.12.4.4.101
	Acetate DIALYSIS FLUID CONCENTRATE instead of acid DIALYSIS FLUID CONCENTRATE when bicarbonate HAEMODIALYSIS treatment has been selected			– IEC 60601-2-16:2024, 201.7.9.2.5, 2nd hyphen; 201.12.4.4.101; 201.15.4.1.101; 201.16.9.1
	SUBSTITUTION FLUID bolus volume too high	Blood volume increased	Extracellular volume change	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 12.4.3 – IEC 60601-2-16:2024, 201.12.4.4.103
	Priming or returning volume too high due to technical faults			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 12.4.3 – IEC 60601-2-16:2024, 201.12.4.4.103
	Inlet DIALYSIS FLUID flow rate into DIALYSER higher than outlet flow rate			– IEC 60601-2-16:2024, 201.12.4.4.103
	SUBSTITUTION FLUID volume higher than ULTRAFILTRATION volume			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 12.4.3 – IEC 60601-2-16:2024, 201.12.4.4.103
	Dry weight not achieved	Insufficient removal of fluid from the PATIENT	Interdialytic overhydration	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 12.4.3 – IEC 60601-2-16:2024, 201.12.4.4.103
	SUBSTITUTION FLUID bolus volume too low	Insufficient increase of PATIENT blood volume	Extracellular volume change	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 12.4.3

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	NET FLUID REMOVAL volume too high	Excessive removal of fluid from the PATIENT		– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 12.4.3 – IEC 60601-2-16:2024, 201.12.4.4.103
	NET FLUID REMOVAL rate greater than set rate			– IEC 60601-2-16:2024, 201.12.4.4.103
	DIALYSIS FLUID loss from balanced DIALYSIS FLUID circuit			– IEC 60601-2-16:2024, 201.12.4.4.103
	ULTRAFILTRATION volume higher than needed by corresponding SUBSTITUTION FLUID volume			– IEC 60601-2-16:2024, 201.12.4.4.103
Operational	Wrong restoring of data/instructions after power interruption	Incorrect treatment	Multiple harms possible	– IEC 60601-2-16:2024, 201.11.8
	Faulty treatment data/instructions from PATIENT card or IT-NETWORK			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 14.13 – IEC 60601-2-16:2024, 201.14.13
	Faulty treatment instruction(s) on screen from IT-NETWORK			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 14.13 – IEC 60601-2-16:2024, 201.14.13
	A physiologic closed loop controller gives a wrong set value.			– IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
Information	Preventive or corrective maintenance has not or incorrectly been carried out			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 7.9.2.13
	Expected service life is elapsed			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 4.4
	Markings or instruction for use missing or wrong			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 7.1; 7.2; 7.4; 7.5; 7.6; 7.9.2 – IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:202: 5.2; 6.1; 6.2 – IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020: 5.1; 5.2 – IEC 60601-2-16:2024, 201.7.9.2.2
	Service information missing or wrong			– IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020: 7.3; 7.7; 7.9.2.13; 7.9.3 – IEC 60601-2-16:2024, 201.7.9.2.6

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	OPERATOR response missing or wrong (USE ERROR)			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 7.8; 7.9.2.8; 7.9.2.9; 7.9.2.10; 7.9.2.11; 7.9.2.14; 9.2.3.1; 12.1; 12.2; 12.4.2 – IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:202: 6.1.2; 6.3.1; 6.3.2.1 – IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020: 6.1; 6.2; 6.3; 6.4 – IEC 60601-2-16:2024, 201.7.9.2.2; 201.7.9.2.6; 201.7.9.2.14; 201.7.9.3.1; 208.4; 208.6.3.1; 208.6.3.3.2; 208.6.3.3.3; 201.12.4.4.110
Operational	Failure of ALARM CONDITION override mode			– IEC 60601-2-16:2024, 201.12.4.4.104.2
	Failure of PROTECTIVE SYSTEMS			– IEC 60601-2-16:2024, 201.12.4.4.107
Electrical	Electrical insulation not sufficient	LEAKAGE CURRENT	Electric shock	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 8.5; 8.6; 8.7; 8.8; 13.1.3; 13.2.2 – IEC 60601-2-16:2024, 201.8.3; 201.8.7.4.7; 201.11.6.1, 201.11.6.5.
	CREEPAGE DISTANCEs and air clearance not sufficient			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 8.9; 13.2.6 – IEC 60601-2-16:2024, 201.13.2.6
	Internal or external leaks that reduce CREEPAGE DISTANCEs and AIR CLEARANCE			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 8.9
	Rapid ageing of insulation			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 11.1; 11.6.6

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	Touching ACCESSIBLE PARTS			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 4.8; 4.9; 5.9.2; 7.9.2.7; 8.4; 8.5; 8.10; 8.11; 9.2.2.4 – IEC 60601-2-16:2024, 201.7.9.2.6; 201.8.11.2
	Ingress of fluid into the HAEMODIALYSIS EQUIPMENT			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 11.6 – IEC 60601-2-16:2024, 201.11.6.3
	Components used outside of specified current ratings			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 13.2.3
	Destruction of parts when replacing			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 15.2
	Excessive mechanical stress caused by pushing, impact, dropping, and rough handling			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 15.3
	Overheating of transformer			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 15.5
	Drain connected to DIALYSIS WATER supply system			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 15.4.1
	DIALYSIS FLUID CONCENTRATE connected to DIALYSIS WATER supply system			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 15.4
	Incorrectly arranged ME SYSTEM			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 16.1; 16.2; 16.3; 16.4; 16.5; 16.6; 16.9 – IEC 60601-2-16:2024, 201.16.2; 201.16.6.3

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	Treatment with central venous catheter whose tip is in the right atrium by HAEMODIALYSIS EQUIPMENT with TYPE B APPLIED PARTS	PATIENT LEAKAGE CURRENT	Electric shock	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 8.7 – IEC 60601-2-16:2024, 201.7.9.2.5; 201.8.3
	Magnetic and electric fields cause disruption of proper operation through interference from other electrical equipment and power supply	Incorrect treatment	Multiple harms	– IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 – IEC 60601-2-16:2024, 202.8
	Magnetic and electric fields cause disruption of proper operation through interference to other ME EQUIPMENT and power supply		Multiple harms to PATIENTS and others	– IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020
Chemical	Escape of chemical substances	Contact with chemicals	Body harm	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 7.9.2.4; 11.6.4
	High pressure fluid ejection			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 9.7
Thermal	Hot external or internal components	Contact with high temperature fluids or surfaces	Body harm	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 11.1; 11.6.4; 11.6.6
	High pressure hot fluid ejection			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 9.7
Mechanical	Finger into roller pump	Crushing/Shearing/Limb breaking	Bruise/ Sprain/Cut/Fractures	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 5.9.2; 9.2.2.4.4
	Limb between moving parts			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 9.2.2.2; 16.7
	Foot under the base			
	HAEMODIALYSIS EQUIPMENT on inclined plane			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 9.4

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	Displacement of HAEMODIALYSIS EQUIPMENT			
	Sharp parts	Cutting	Body harm	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 9.8
	Openings in ENCLOSURE with moving parts behind			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 5.9.2
Thermal	Components used outside of specified current ratings	Fire	Multiple harms to PATIENTS and others	– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 4.8; 4.9; 13.1.2; 13.2.3; 13.2.13
	Ingress of water into the HAEMODIALYSIS EQUIPMENT leads to short cut current			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 11.6 – IEC 60601-2-16:2024, 201.11.6.3
	Defective control of heater			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 13.2.4; 13.2.5; 13.2.13; 15.4.2
	Impaired cooling			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 13.2.7
	Interruption and short circuit of motor capacitors			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 13.2.9
	Defects of battery			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 15.4.3.1
	Incorrect polarity of battery connection			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 15.4.3.2
	Overcharging battery			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 15.4.3.3
	Excessive current from battery			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 15.4.3.5

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	Overheating of transformer			– IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: 15.5
[a] IEC 60601-2-16:2024 refers to this document.				

Annex CC
(informative)

Example of an open alarm interface specification

CC.1 General

This specification is identical to the withdrawn IEC PAS 63023 [17].

In extracorporeal treatment different hazardous situations can occur. One major concern is blood loss to the environment. In Subclause 201.12.4.4.104.1 of IEC 60601-2-16:2012, different technical solutions are given. In addition, this IEC standards committee has included in this Annex an open alarm interface specification to connect an EXTERNAL ALARMING DEVICE to the HAEMODIALYSIS EQUIPMENT in order to stop the extracorporeal blood flow in case the EXTERNAL ALARMING DEVICE detects a needle slipping out from the fistula or the graft.

The functionality described hereby is an example of an INPUT INTERFACE for connecting an EXTERNAL ALARMING DEVICE to HAEMODIALYSIS EQUIPMENT simple solution, taking SINGLE FAULT CONDITION of the INPUT INTERFACE into account. Alternative designs could be identified by the MANUFACTURER.

CC.2 Terms and definitions regarding this open alarm interface specification

CC.2.1
EXTERNAL ALARMING DEVICE
ACCESSORY that detects ALARM CONDITIONS

CC.2.2
INPUT INTERFACE
part of HAEMODIALYSIS EQUIPMENT providing the possibility of access to an EXTERNAL ALARMING DEVICE

CC.2.3
INTERNAL SIGNAL PROCESSING
part of HAEMODIALYSIS EQUIPMENT intended to process signals

CC.2.4
SIGNAL PLUG
terminal device of the external alarming device for the connection to the haemodialysis equipment signal socket

CC.2.5
SIGNAL SOCKET
TERMINAL DEVICE of the INPUT INTERFACE

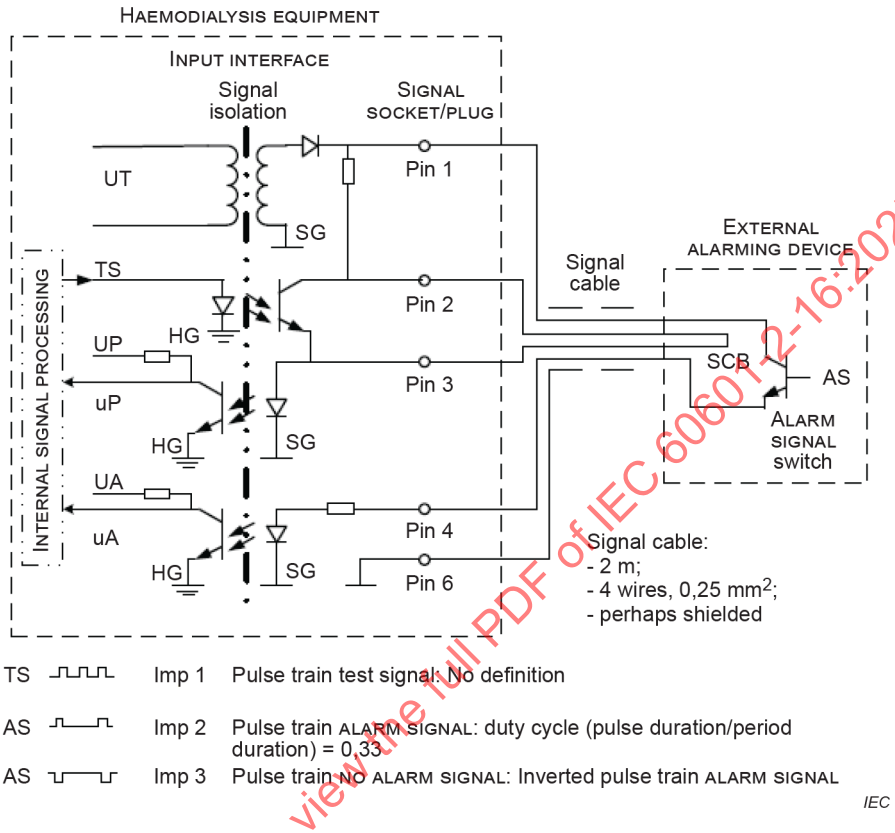
CC.2.6
HAEMODIALYSIS EQUIPMENT GROUND
grounding terminal connected to conductive parts for INTERNAL SIGNAL PROCESSING

CC.2.7
SIGNAL GROUND
grounding terminal connected to conductive parts for external signal processing

CC.3 Application

CC.3.1 Simplified circuit diagram

The simplified circuit diagram in Figure CC.1 provides a hardware solution for an INPUT INTERFACE.



UT	Transformer input voltage	PIN 1	ALARM SIGNAL switch voltage
TS	Test signal	Pin 2	Signal plug connected output
UP	Plug voltage	Pin 3	Signal plug connected input
uP	Signal plug connected	PIN 4	EXTERNAL ALARMING DEVICE signal
UA	ALARM SIGNAL voltage	Pin 6	Signal cable shield
uA	ALARM SIGNAL	SG	Isolated SIGNAL GROUND
HG	HAEMODIALYSIS EQUIPMENT GROUND	SCB	Signal cable bridge

Pulse time duration ALARM SIGNAL: 0,2 s ± 10 %; duration of one period 0,6 s ± 10 %

Switching voltage ALARM SIGNAL switch: minimal 6 V; maximal 30 V

Switching power ALARM SIGNAL switch: 200 mW

Figure CC.1 – Simplified circuit diagram

CC.3.2 Periodic functional check

A failure of the INPUT INTERFACE of the HAEMODIALYSIS EQUIPMENT should become obvious to the OPERATOR at least once per day when in operational use.

In order to detect the failure of the INPUT INTERFACE, the test signal (TS) is used. For this purpose, the test signal is set to the operation voltage (OV) and the test results are monitored by the INTERNAL SIGNAL PROCESSING unit.

The expected test condition signals and test results are listed in Table CC.1.

Table CC.1 – Periodic functional check of the INPUT INTERFACE

Test condition	uP	uA	Test result
Test signal (TS) = operation voltage (OV)	HG	UA	No error
	HG	HG	Error
	HG	Imp2	No error
	HG	Imp3	No error
	Imp1	UA or HG or Imp2 or Imp3	Error
	UP	UA or HG or Imp2 or Imp3	Error

The test results from Table CC.1 lead to the expected reactions of the HAEMODIALYSIS EQUIPMENT, which are listed in Table CC.2.

Table CC.2 – Reaction of HAEMODIALYSIS EQUIPMENT

Test result	Reaction HAEMODIALYSIS EQUIPMENT
No error	Display status: test INPUT INTERFACE passed
Error	Display status: test INPUT INTERFACE failed

CC.3.3 Condition of INPUT INTERFACE

The signals of the connected SIGNAL PLUG (uP) and ALARM SIGNAL (uA) lead to the results listed in Table CC.3.

Table CC.3 – Signal result of signal input to INTERNAL SIGNAL PROCESSING unit

uP	uA	Signal result
Imp1	UA	No EXTERNAL ALARMING DEVICE connected
Imp1	HG	INPUT INTERFACE defective
Imp1	Imp2	EXTERNAL ALARMING DEVICE or INPUT INTERFACE defective
Imp1	Imp3	EXTERNAL ALARMING DEVICE or INPUT INTERFACE defective
UP	UA	INPUT INTERFACE defective
UP	HG	INPUT INTERFACE defective
UP	Imp2	INPUT INTERFACE defective
UP	Imp3	INPUT INTERFACE defective
HG	UA	EXTERNAL ALARMING DEVICE or INPUT INTERFACE defective
HG	HG	EXTERNAL ALARMING DEVICE or INPUT INTERFACE defective
HG	Imp2	No ALARM SIGNAL from EXTERNAL ALARMING DEVICE
HG	Imp3	ALARM SIGNAL from EXTERNAL ALARMING DEVICE

CC.3.4 Reaction of HAEMODIALYSIS EQUIPMENT

During the treatment, the signal result from Table CC.3 leads to the expected reactions of the HAEMODIALYSIS EQUIPMENT, which are listed in Table CC.4.

Table CC.4 – Reaction of HAEMODIALYSIS EQUIPMENT during the treatment

Signal result	Reaction HAEMODIALYSIS EQUIPMENT during the treatment
No EXTERNAL ALARMING DEVICE connected	Display status: no EXTERNAL ALARMING DEVICE connected
INPUT INTERFACE defective	– Visual ALARM SIGNAL – Audible ALARM SIGNAL – Display status: INPUT INTERFACE defective
EXTERNAL ALARMING DEVICE or INPUT INTERFACE defective	– Visual ALARM SIGNAL – Audible ALARM SIGNAL – Display status: EXTERNAL ALARMING DEVICE or INPUT INTERFACE defective
No ALARM SIGNAL from EXTERNAL ALARMING DEVICE	Display status: EXTERNAL ALARMING DEVICE is connected
ALARM SIGNAL from EXTERNAL ALARMING DEVICE	– Stoppage of blood flow – Visual ALARM SIGNAL – Audible ALARM SIGNAL – Display status: EXTERNAL ALARMING DEVICE in ALARM CONDITION

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Index of defined terms used in this document

SOMMAIRE

COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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APPAREILS ÉLECTROMÉDICAUX –

Partie 2-16: Exigences particulières pour la sécurité de base et les performances essentielles des appareils d'hémodialyse, d'hémodiafiltration et d'hémofiltration

AVANT-PROPOS

1) La Commission Électrotechnique Internationale (IEC) est une organisation mondiale de normalisation composée de l'ensemble des comités électrotechniques nationaux (Comités nationaux de l'IEC). L'IEC a pour objet de favoriser la coopération internationale pour toutes les questions de normalisation dans les domaines de l'électricité et de l'électronique. À cet effet, l'IEC – entre autres activités – publie des Normes internationales, des Spécifications techniques, des Rapports techniques, des Spécifications accessibles au public (PAS) et des Guides (ci-après dénommés "Publication(s) de l'IEC"). Leur élaboration est confiée à des comités d'études, aux travaux desquels tout Comité national intéressé par le sujet traité peut participer. Les organisations internationales, gouvernementales et non gouvernementales, en liaison avec l'IEC, participent également aux travaux. L'IEC collabore étroitement avec l'Organisation Internationale de Normalisation (ISO), selon des conditions fixées par accord entre les deux organisations.
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5) L'IEC elle-même ne fournit aucune attestation de conformité. Des organismes de certification indépendants fournissent des services d'évaluation de conformité et, dans certains secteurs, accèdent aux marques de conformité de l'IEC. L'IEC n'est responsable d'aucun des services effectués par les organismes de certification indépendants.
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7) Aucune responsabilité ne doit être imputée à l'IEC, à ses administrateurs, employés, auxiliaires ou mandataires, y compris ses experts particuliers et les membres de ses comités d'études et des Comités nationaux de l'IEC, pour tout préjudice causé en cas de dommages corporels et matériels, ou de tout autre dommage de quelque nature que ce soit, directe ou indirecte, ou pour supporter les coûts (y compris les frais de justice) et les dépenses découlant de la publication ou de l'utilisation de cette Publication de l'IEC ou de toute autre Publication de l'IEC, ou au crédit qui lui est accordé.
8) L'attention est attirée sur les références normatives citées dans cette publication. L'utilisation de publications référencées est obligatoire pour une application correcte de la présente publication.
9) L'IEC attire l'attention sur le fait que la mise en application du présent document peut entraîner l'utilisation d'un ou de plusieurs brevets. L'IEC ne prend pas position quant à la preuve, à la validité et à l'applicabilité de tout droit de brevet revendiqué à cet égard. À la date de publication du présent document, l'IEC n'avait pas reçu notification qu'un ou plusieurs brevets pouvaient être nécessaires à sa mise en application. Toutefois, il y a lieu d'avertir les responsables de la mise en application du présent document que des informations plus récentes sont susceptibles de figurer dans la base de données de brevets, disponible à l'adresse https://patents.iec.ch. L'IEC ne saurait être tenue pour responsable de ne pas avoir identifié de tels droits de brevets.

L'IEC 60601-2-16 a été établie par le sous-comité 62D: Équipements, logiciels et systèmes médicaux particuliers, du comité d'études 62 de l'IEC: Équipement médical, logiciels et systèmes médicaux. Il s'agit d'une Norme internationale.

Cette sixième édition annule et remplace la cinquième édition parue en 2018. Cette édition constitue une révision technique.

Cette édition inclut les modifications techniques majeures suivantes par rapport à l'édition précédente:

a) mise à jour des références à l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020, des références à l'IEC 60601-1-2:2014 et l'IEC 60601-1-2:2014/AMD1:2020, des références à l'IEC 60601-1-8:2006, l'IEC 60601-1-8:2006/AMD1:2012 et l'IEC 60601-1-8:2006/AMD2:2020, des références à l'IEC 60601-1-9:2007, l'IEC 60601-1-9:2007/AMD1:2013 et l'IEC 60601-1-9:2007/AMD2:2020, des références à l'IEC 60601-1-10:2007, l'IEC 60601-1-10:2007/AMD1:2013 et l'IEC 60601-1-10:2007/AMD2:2020 et des références à l'IEC 60601-1-11:2015 et l'IEC 60601-1-11:2015/AMD1:2020;

b) prise en considération des PERFORMANCES ESSENTIELLES en CONDITION DE PREMIER DEFAUT concernant l'IEC 60601-1:2005/AMD1:2012/ISH1:2021;

c) inclusion des informations données dans le document 62D/1771A/INF concernant le 201.11.8;

d) inclusion de l'IEC PAS 63023[17], supprimée, en tant qu'Annexe CC;

e) inclusion des exigences de SECURITE (CYBERSECURITE);

f) prise en considération des APPAREILS D'HEMODIALYSE qui utilisent des sacs pour LIQUIDE DE DIALYSE préproduit;

g) améliorations en matière d'étiquetage;

h) autres améliorations techniques mineures;

i) améliorations d'ordre rédactionnel.

Le texte de cette Norme internationale est issu des documents suivants:

Projet	Rapport de vote
62D/2163/FDIS	62D/2184/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à son approbation.

La langue employée pour l'élaboration de cette Norme internationale est l'anglais.

Ce document a été rédigé selon les Directives ISO/IEC, Partie 2, il a été développé selon les Directives ISO/IEC, Partie 1 et les Directives ISO/IEC, Supplément IEC, disponibles sous www.iec.ch/members_experts/refdocs. Les principaux types de documents développés par l'IEC sont décrits plus en détail sous www.iec.ch/publications.

Dans le présent document, les caractères d'imprimerie suivants sont utilisés:

– exigences et définitions: caractères romains;

– *modalités d'essais: caractères italiques;*

– indications de nature informative qui apparaissent hors des tableaux, comme les notes, les exemples et les références: petits caractères. Le texte normatif à l'intérieur des tableaux est également en petits caractères;

– TERMES DEFINIS A L'ARTICLE 3 DE L'IEC 60601-1:2005, L'IEC 60601-1:2005/AMD1:2012 ET L'IEC 60601-1:2005/AMD2:2020, DANS LE PRESENT DOCUMENT OU COMME CELA EST NOTE: PETITES MAJUSCULES.

Concernant la structure du présent document, le terme:

– "article" désigne l'une des dix-sept sections numérotées dans la table des matières, avec toutes ses subdivisions (par exemple, l'Article 7 inclut les paragraphes 7.1, 7.2, etc.);

– "paragraphe" désigne une subdivision numérotée d'un article (par exemple, le 7.1, le 7.2 et le 7.2.1 sont tous des paragraphes de l'Article 7).

Dans le présent document, les références à des articles sont précédées du mot "Article" suivi du numéro de l'article concerné. Dans le présent document, les références aux paragraphes utilisent uniquement le numéro du paragraphe concerné.

Dans le présent document, la conjonction "ou" a la valeur d'un "ou inclusif". Ainsi, un énoncé est vrai si une combinaison des conditions, quelle qu'elle soit, est vraie.

Les formes verbales utilisées dans le présent document sont conformes à l'usage donné à l'Article 7 des Directives ISO/IEC, Partie 2. Pour les besoins du présent document:

– le verbe "devoir" signifie que la conformité à une exigence ou à un essai est obligatoire pour assurer la conformité au présent document;
– l'expression "il convient" signifie que la conformité à une exigence ou à un essai est recommandée, mais n'est pas obligatoire pour assurer la conformité au présent document;
– le verbe "pouvoir" est utilisé afin de décrire un moyen admissible pour assurer la conformité à exigence ou à un essai.

Lorsqu'un astérisque (*) est utilisé comme premier caractère devant un titre ou au début d'un titre d'alinéa ou de tableau, il indique l'existence de recommandations ou d'une justification à consulter à l'Annexe AA.

Une liste de toutes les parties des séries IEC 60601 et IEC 80601, publiées sous le titre général *Appareils électromédicaux*, se trouve sur le site web de l'IEC.

Le comité a décidé que le contenu de ce document ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous webstore.iec.ch dans les données relatives au document recherché. À cette date, le document sera

- reconduit,
- supprimé, ou
- révisé.

NOTE L'attention des utilisateurs du présent document est attirée sur le fait que les fabricants d'appareils et les organismes d'essai peuvent avoir besoin d'une période transitoire après la publication d'une nouvelle publication IEC, ou d'une publication amendée ou révisée, pour fabriquer des produits conformes aux nouvelles exigences et pour adapter leurs équipements aux nouveaux essais ou aux essais révisés. Les comités recommandent que le contenu de cette publication soit entériné au niveau national au plus tôt trois ans après la date de publication.

IMPORTANT – Le logo "colour inside" qui se trouve sur la page de couverture de ce document indique qu'il contient des couleurs qui sont considérées comme utiles à une bonne compréhension de son contenu. Les utilisateurs devraient, par conséquent, imprimer ce document en utilisant une imprimante couleur.

INTRODUCTION

Les exigences minimales de sécurité spécifiées dans le présent document sont considérées comme fournissant un degré pratique de sécurité pour le fonctionnement des APPAREILS D'HEMODIALYSE, d'HEMODIAFILTRATION et d'HEMOFILTRATION.

APPAREILS ÉLECTROMÉDICAUX –

Partie 2-16: Exigences particulières pour la sécurité de base et les performances essentielles des appareils d'hémodialyse, d'hémodiafiltration et d'hémofiltration

201.1 Domaine d'application, objet et normes connexes

L'Article 1 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.1.1 * Domaine d'application

Remplacement:

La présente partie de l'IEC 60601 s'applique à la SECURITE DE BASE et aux PERFORMANCES ESSENTIELLES des APPAREILS D'HEMODIALYSE, d'HEMODIAFILTRATION et d'HEMOFILTRATION, désignés ci-après sous le terme d'APPAREILS D'HEMODIALYSE. Elle s'applique aux APPAREILS D'HEMODIALYSE destinés à être utilisés soit par le personnel médical, soit sous la surveillance d'experts médicaux, y compris les APPAREILS D'HEMODIALYSE mis en fonctionnement par le PATIENT, que les APPAREILS D'HEMODIALYSE soient utilisés dans un hôpital ou dans un environnement domestique.

Si un article ou un paragraphe est spécifiquement destiné à être applicable uniquement aux APPAREILS EM, ou uniquement aux SYSTEMES EM, le titre et le contenu de cet article ou de ce paragraphe l'indiquent. Si cela n'est pas le cas, l'article ou le paragraphe s'applique à la fois aux APPAREILS EM et aux SYSTEMES EM, selon le cas.

Le présent document ne prend pas en considération les informations spécifiques de sécurité du système de contrôle du LIQUIDE DE DIALYSE de l'APPAREIL D'HEMODIALYSE qui utilise la régénération du LIQUIDE DE DIALYSE ou des SYSTEMES DE TRANSMISSION CENTRALISES pour le LIQUIDE DE DIALYSE. Il prend cependant en considération les exigences spécifiques de sécurité de ces APPAREILS D'HEMODIALYSE relatives à la sécurité électrique et la sécurité du PATIENT.

Le présent document spécifie les exigences minimales de sécurité relatives aux APPAREILS D'HEMODIALYSE. Ces APPAREILS D'HEMODIALYSE sont destinés à être utilisés soit par le personnel médical, soit par le PATIENT, soit par d'autres personnes formées, sous surveillance médicale.

Le présent document s'applique à tous les APPAREILS EM destinés à fournir un traitement d'HEMODIALYSE, d'HEMODIAFILTRATION et d'HEMOFILTRATION à un PATIENT, indépendamment de la durée et du lieu de traitement.

Le cas échéant, le présent document s'applique aux parties correspondantes des APPAREILS EM destinés à d'autres traitements extracorporels de purification du sang.

Les exigences particulières du présent document ne s'appliquent pas aux:

– CIRCUITS EXTRACORPORELS (voir l'ISO 8637-2 [1][1]),
– DIALYSEURS (voir l'ISO 8637-1 [2]),
– CONCENTRES DE LIQUIDE DE DIALYSE (voir l'ISO 23500-4 [3]),

[1] Les chiffres entre crochets renvoient à la Bibliographie.

– sacs pour LIQUIDE DE DIALYSE préproduits,

– systèmes d'alimentation en EAU DE DIALYSE (voir l'ISO 23500-2 [4]),

– SYSTEMES DE TRANSMISSION CENTRALISES pour les CONCENTRES DE LIQUIDE DE DIALYSE (voir l'ISO 23500-4 [3]), décrits comme systèmes de mélange de concentré en vrac dans un centre de dialyse,

– appareils de DIALYSE PERITONEALE (voir l'IEC 60601-2-39 [5]).

201.1.2 Objet

Remplacement:

L'objet du présent document est d'établir des exigences pour la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES des APPAREILS D'HEMODIALYSE.

201.1.3 Normes collatérales

Addition:

Le présent document fait référence aux normes collatérales applicables énumérées à l'Article 2 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 et à l'Article 201.2 du présent document.

L'IEC 60601-1-2:2014 et l'IEC 60601-1-2:2014/AMD1:2020, l'IEC 60601-1-8:2006, l'IEC 60601-1-8:2006/AMD1:2012 et l'IEC 60601-1-8:2006/AMD2:2020, l'IEC 60601-1-10:2007, l'IEC 60601-1-10:2007/AMD1:2013 et l'IEC 60601-1-10:2007/AMD2:2020, l'IEC 60601-1-11:2015 et l'IEC 60601-1-11:2015/AMD1:2020 s'appliquent telles qu'elles sont modifiées dans les Articles 202, 208, 210 et 211.

L'IEC 60601-1-3 ne s'applique pas. L'IEC 60601-1-9:2007, l'IEC 60601-1-9:2007/AMD1:2013 et l'IEC 60601-1-9:2007/AMD2:2020 ne s'appliquent pas comme cela est indiqué à l'Article 209.

Toutes les autres normes collatérales publiées de la série IEC 60601-1 s'appliquent, telles que publiées.

201.1.4 Normes particulières

Remplacement:

Dans la série IEC 60601, des normes particulières peuvent modifier, remplacer ou supprimer des exigences contenues dans l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/ AMD2:2020 et dans les normes collatérales en fonction de l'APPAREIL EM concerné. Elles peuvent également ajouter des exigences supplémentaires pour la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES.

Une exigence d'une norme particulière prévaut sur l'exigence correspondante de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020.

La numérotation des articles et des paragraphes du présent document correspond à celle de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 avec le préfixe "201" (par exemple, le 201.1 du présent document concerne le contenu de l'Article 1 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020) ou à celle de la norme collatérale applicable avec le préfixe "20x", où x représente le ou les derniers chiffres du numéro de document de la norme collatérale (par exemple, le 202.4 du présent document concerne le contenu de l'Article 4 de la norme collatérale IEC 60601-1-2, le 203.4 du présent document concerne le contenu de l'Article 4 de la norme collatérale IEC 60601-1-3, etc.). Les modifications apportées au texte de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 sont précisées en utilisant les termes suivants:

"*Remplacement*" signifie que l'article ou le paragraphe de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable est remplacé complètement par le texte du présent document.

"*Addition*" signifie que le texte du présent document vient s'ajouter aux exigences de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable.

"*Amendement*" signifie que l'article ou le paragraphe de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable est modifié comme cela est indiqué par le texte du présent document.

Les paragraphes, figures ou tableaux qui sont ajoutés à ceux de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 sont numérotés à partir de 201.101. Toutefois, en raison du fait que les définitions dans l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 sont numérotées de 3.1 à 3.154, les définitions qui sont ajoutées dans le présent document sont numérotées à partir de 201.3.201. Les annexes qui sont ajoutées sont notées AA, BB, etc., et les éléments qui sont ajoutés aa), bb), etc.

Les paragraphes, figures ou tableaux qui s'ajoutent à ceux d'une norme collatérale sont numérotés à partir de 20x, où "x" est le chiffre de la norme collatérale, par exemple 202 pour l'IEC 60601-1-2, 203 pour l'IEC 60601-1-3, etc.

L'expression "le présent document" est utilisée pour se référer à l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020, à toutes les normes collatérales applicables et à la présente norme particulière, considérés ensemble.

Lorsque le présent document ne comprend pas d'article ou de paragraphe correspondant, l'article ou le paragraphe de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable, bien qu'il puisse être sans objet, s'applique sans modification; lorsqu'il est demandé qu'une partie quelconque de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable, bien que potentiellement pertinente, ne s'applique pas, cela est expressément mentionné dans le présent document.

201.2 Références normatives

NOTE Une liste des références informatives est donnée dans la Bibliographie.

L'Article 2 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec l'exception suivante:

Addition:

IEC 60601-1:2005, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60601-1-10:2007, *Appareils électromédicaux – Partie 1-10: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Exigences pour le développement des régulateurs physiologiques en boucle fermée*
IEC 60601-1-10:2007/AMD1:2013
IEC 60601-1-10:2007/AMD2:2020

IEC 60601-1-11:2015, *Appareils électromédicaux – Partie 1-11: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Exigences pour les appareils électromédicaux et les systèmes électromédicaux utilisés dans l'environnement des soins à domicile*
IEC 60601-1-11:2015/AMD1:2020

IEC 61672-1:2013, *Électroacoustique – Sonomètres – Partie 1: Spécifications*

ISO 3744:2010, *Acoustique – Détermination des niveaux de puissance acoustique et des niveaux d'énergie acoustique émis par les sources de bruit à partir de la pression acoustique – Méthodes d'expertise pour des conditions approchant celles du champ libre sur plan réfléchissant*

ISO 23500-3:2024, *Préparation et management de la qualité des liquides d'hémodialyse et de thérapies annexes – Partie 3: Eau pour hémodialyse et thérapies apparentées*

201.3 Termes et définitions

Pour les besoins du présent document, les termes et définitions de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020, l'IEC 60601-1-2:2014 et l'IEC 60601-1-2:2014/AMD1:2020, l'IEC 60601-1-8:2006, l'IEC 60601-1-8:2006/AMD1:2012 et l'IEC 60601-1-8:2006/AMD2:2020, l'IEC 60601-1-10:2007, l'IEC 60601-1-10:2007/AMD1:2013 et l'IEC 60601-1-10:2007/AMD2:2020, l'IEC 60601-1-11:2015 et l'IEC 60601-1-11:2015/AMD1:2020 ainsi que les suivants s'appliquent.

L'ISO et l'IEC tiennent à jour des bases de données terminologiques destinées à être utilisées en normalisation, consultables aux adresses suivantes:

- IEC Electropedia: disponible à l'adresse https://www.electropedia.org/
- ISO Online browsing platform: disponible à l'adresse https://www.iso.org/obp

NOTE Se reporter à la section "Index des termes définis" pour l'index des termes définis.

201.3.8
*** PARTIE APPLIQUEE**

Remplacement:

CIRCUIT EXTRACORPOREL et toutes les parties qui lui sont électriquement reliées en continu (par exemple, circuit du LIQUIDE DE DIALYSE)

Note 1 à l'article: Voir la Figure AA.8 à l'Annexe AA informative, 201.16, et voir le 201.16.6.3.

Note 2 à l'article: Un exemple de PARTIE APPLIQUEE est le CIRCUIT EXTRACORPOREL, y compris les sacs pour LIQUIDE DE DIALYSE préproduit, les lignes d'extension et les poches de drainage dans un système autonome relié pendant le traitement.

Note 3 à l'article: Un autre exemple de PARTIE APPLIQUEE est le CIRCUIT EXTRACORPOREL, y compris les sacs pour LIQUIDE DE DIALYSE reliés, qui sont préparés en ligne avant traitement sans le patient relié et les poches de drainage. Pendant le traitement, la partie de préparation en ligne de l'APPAREIL D'HEMODIALYSE est déconnectée en conduction.

Note 4 à l'article: Un autre exemple de PARTIE APPLIQUEE est le CIRCUIT EXTRACORPOREL, y compris tous les trajets de liquide reliés de l'APPAREIL D'HEMODIALYSE et le raccordement à un drain pendant le traitement.

201.3.78
CONNEXION PATIENT

Addition:

Note 1 à l'article: Les connecteurs des lignes de sang du PATIENT sont les points individuels sur la PARTIE APPLIQUEE à travers lesquels un courant peut s'écouler entre le PATIENT et l'APPAREIL D'HEMODIALYSE en CONDITION NORMALE ou en CONDITION DE PREMIER DEFAUT.

Termes et définitions complémentaires:

201.3.201
PRESSION ARTERIELLE
pression mesurée dans la ligne de retrait du sang du CIRCUIT EXTRACORPOREL entre la CONNEXION PATIENT et la connexion DIALYSEUR

Note 1 à l'article: Une différence peut être faite entre la pression en amont de la pompe, qui est en amont de la pompe sanguine, et la pression après la pompe, qui est en aval de la pompe sanguine.

201.3.202
*** FUITE DE SANG**
fuite de sang depuis le compartiment sanguin en direction du compartiment pour LIQUIDE DE DIALYSE du DIALYSEUR

Note 1 à l'article: L'exécution d'un PROCESSUS HF implique la partie liquide de filtration.

201.3.203
SYSTEME DE TRANSMISSION CENTRALISE
partie d'un SYSTEME EM qui dose la proportion de CONCENTRE DE LIQUIDE DE DIALYSE et d'EAU DE DIALYSE pour les distribuer comme LIQUIDE DE DIALYSE à l'APPAREIL D'HEMODIALYSE ou qui répartit le CONCENTRE DE LIQUIDE DE DIALYSE

201.3.204
DIALYSEUR
dispositif contenant une membrane semi-perméable utilisée pour réaliser une HD, une HDF ou une HF

201.3.205
LIQUIDE DE DIALYSE
DIALYSAT
SOLUTION DE DIALYSE
LIQUIDE DIALYSANT
fluide aqueux contenant des électrolytes et, généralement, un tampon et du glucose, destiné à échanger des solutés avec le sang, pendant l'HEMODIALYSE

Note 1 à l'article: Le LIQUIDE DE DIALYSE peut être préproduit dans des poches comme les médicaments, selon la monographie de pharmacopée correspondante, ou être préparé par l'APPAREIL D'HEMODIALYSE. L'APPAREIL D'HEMODIALYSE peut également agir sur sa composition.

[SOURCE: ISO 23500-1:2024 [6], 3.15, modifié – Le mot "liquide dialysant" a été ajouté comme synonyme, les notes ont été supprimées et une nouvelle Note 1 à l'article a été ajoutée.]

201.3.206
CONCENTRE DE LIQUIDE DE DIALYSE
substances qui, lorsqu'elles sont diluées ou dissoutes de manière appropriée dans de l'EAU DE DIALYSE, produisent le LIQUIDE DE DIALYSE

201.3.207
EAU DE DIALYSE
eau qui a été traitée pour satisfaire aux exigences de l'ISO 23500-3:2024 et qui est adaptée pour être utilisée dans des applications en HEMODIALYSE, incluant la préparation de LIQUIDE DE DIALYSE, le retraitement des DIALYSEURS, la préparation de CONCENTRE DE LIQUIDE DE DIALYSE et la préparation du LIQUIDE DE SUBSTITUTION pour les thérapies convectives en ligne

Note 1 à l'article: Les mots "eau pour dialyse", "perméat" et "eau obtenue par osmose inverse" sont couramment utilisés comme synonymes d'EAU DE DIALYSE.

[SOURCE: ISO 23500-1:2024 [6], 3.17, modifié – La note a été reformulée.]

201.3.208
CIRCUIT EXTRACORPOREL
lignes de sang, DIALYSEUR et tout ACCESSOIRE qui en fait partie

Note 1 à l'article: Une variante au DIALYSEUR peut être un filtre HF, un absorbeur ou un autre dispositif.

201.3.209
HEMODIAFILTRATION
HDF
PROCESSUS par lequel les concentrations de substances hydrosolubles dans le sang d'un PATIENT et un excès de liquide d'un PATIENT sont corrigés par une combinaison simultanée de HD et de HF

201.3.210
HEMODIALYSE
HD
PROCESSUS par lequel les concentrations de substances hydrosolubles dans le sang d'un PATIENT et un excès de liquide d'un PATIENT sont corrigés par le transfert bidirectionnel par diffusion et par ULTRAFILTRATION à travers une membrane semi-perméable séparant le sang du LIQUIDE DE DIALYSE

Note 1 à l'article: Ce PROCESSUS implique normalement une extraction du liquide par filtration. Habituellement, ce PROCESSUS est également accompagné de la diffusion de substances du LIQUIDE DE DIALYSE dans le sang.

201.3.211
*** APPAREIL D'HEMODIALYSE**
APPAREIL EM ou SYSTEME EM utilisé pour réaliser au moins l'une des opérations suivantes: HEMODIALYSE, HEMODIAFILTRATION, HEMOFILTRATION

Note 1 à l'article: Lorsque le terme APPAREIL EM est utilisé dans un titre, il est équivalent à APPAREIL D'HEMODIALYSE. Lorsque le terme APPAREIL EM est utilisé dans le texte, il fait référence à un APPAREIL EM générique.

201.3.212
HEMOFILTRATION
HF
PROCESSUS par lequel les concentrations de substances hydrosolubles dans le sang d'un PATIENT et un excès de liquide d'un PATIENT sont corrigés par le transfert convectif, par l'intermédiaire de l'ULTRAFILTRATION, et le remplacement partiel par un LIQUIDE DE SUBSTITUTION conduisant à l'EXTRACTION NETTE DE LIQUIDE exigée

201.3.213
EXTRACTION NETTE DE LIQUIDE
perte de liquide provenant du PATIENT

Note 1 à l'article: Historiquement, le terme utilisé était "perte de poids".

201.3.214
*** HDF EN LIGNE**
PROCEDURE D'HEMODIAFILTRATION par laquelle l'APPAREIL D'HEMODIALYSE produit le LIQUIDE DE SUBSTITUTION pour infusion à partir du LIQUIDE DE DIALYSE pour le traitement par HEMODIAFILTRATION

201.3.215
*** HF EN LIGNE**
PROCEDURE D'HEMOFILTRATION par laquelle l'APPAREIL D'HEMODIALYSE produit le LIQUIDE DE SUBSTITUTION pour infusion à partir du LIQUIDE DE DIALYSE pour le traitement par HEMOFILTRATION

201.3.216
*** SYSTEME DE PROTECTION**
système automatique, ou caractéristique de construction, spécialement conçu(e) pour protéger le PATIENT contre les SITUATIONS DANGEREUSES

201.3.217
LIQUIDE DE SUBSTITUTION
liquide utilisé dans les traitements HF et HDF, qui est directement injecté dans le CIRCUIT EXTRACORPOREL pour remplacer le liquide éliminé du sang par filtration

[SOURCE: ISO 23500-1:2024 [6], 3.42, modifié – Les mots "sang du patient" et "ultrafiltration" ont été remplacés respectivement par "CIRCUIT EXTRACORPOREL" et "filtration" dans la définition, et la note a été supprimée.]

201.3.218
PRESSION TRANSMEMBRANAIRE
TMP
différence de pression de liquide s'exerçant de part et d'autre de la membrane semi-perméable du DIALYSEUR

Note 1 à l'article: La TMP moyenne est généralement utilisée. En pratique, la PRESSION TRANSMEMBRANAIRE affichée est habituellement estimée à partir de la pression dans le CIRCUIT EXTRACORPOREL mesurée moins la pression du LIQUIDE DE DIALYSE mesurée, chacune étant relevée en un même point.

Note 2 à l'article: L'abréviation "TMP" est dérivée du terme anglais développé "*transmembrane pressure*".

201.3.219
*** ULTRAFILTRATION**
PROCESSUS d'extraction de liquides du sang du PATIENT de part et d'autre de la membrane semi-perméable du DIALYSEUR

201.3.220
PRESSION VEINEUSE
pression mesurée dans la ligne de retour du sang du CIRCUIT EXTRACORPOREL entre la connexion DIALYSEUR et la CONNEXION PATIENT

201.4 Exigences générales

L'Article 4 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/ AMD2:2020 s'applique, avec les exceptions suivantes:

201.4.3 * Performances essentielles

Paragraphes supplémentaires:

201.4.3.101 * Exigences complémentaires de PERFORMANCES ESSENTIELLES

Le cas échéant, les PERFORMANCES ESSENTIELLES d'un APPAREIL D'HEMODIALYSE comprennent, entre autres, les fonctions données dans les paragraphes énumérés dans le Tableau 201.101, qui doivent être remplies dans les tolérances spécifiées par le FABRICANT en CONDITION NORMALE.

Le comportement de l'APPAREIL D'HEMODIALYSE pour les PERFORMANCES ESSENTIELLES en CONDITION DE PREMIER DEFAUT doit être déterminé par le PROCESSUS DE GESTION DES RISQUES DU FABRICANT.

Tableau 201.101 – Exigences relatives aux PERFORMANCES ESSENTIELLES

Exigence	Paragraphe
Flux sanguin	201.4.3.102
Débit du LIQUIDE DE DIALYSE	201.4.3.103
EXTRACTION NETTE DE LIQUIDE	201.4.3.104
Débit du LIQUIDE DE SUBSTITUTION	201.4.3.105
Temps de dialyse	201.4.3.106
Composition du LIQUIDE DE DIALYSE	201.4.3.107
Température du LIQUIDE DE DIALYSE	201.4.3.108
Température du LIQUIDE DE SUBSTITUTION	201.4.3.109

NOTE 1 Certaines des exigences de PERFORMANCES ESSENTIELLES énumérées dans le Tableau 201.101 dépendent des caractéristiques des éléments jetables utilisés (par exemple, le flux sanguin dépend du diamètre interne du segment de pompe des pompes péristaltiques rotatives).

NOTE 2 Le 7.9.2.5 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/ AMD2:2020 décrit des exigences qui visent à fournir les spécifications relatives aux PERFORMANCES ESSENTIELLES dans les instructions d'utilisation.

201.4.3.102 Flux sanguin

Le flux sanguin de l'APPAREIL D'HEMODIALYSE doit être tel que spécifié par le FABRICANT. La spécification doit tenir compte de la fatigue du segment de pompe pour la durée de vie d'utilisation maximale spécifiée du CIRCUIT EXTRACORPOREL.

* NOTE 1 Un flux sanguin inférieur à la valeur de consigne est considéré comme préjudiciable pour un traitement type. De ce fait, le but de l'essai est de déterminer l'erreur du flux sanguin négatif le plus élevé.

La conformité est vérifiée dans les conditions d'essai suivantes, pour les pompes péristaltiques types:

– *appliquer un segment de pompe non utilisé à l'APPAREIL D'HEMODIALYSE selon les instructions d'utilisation;*
– *faire circuler une source de liquide (par exemple, de l'eau) à la température de 37 °C ± 1 °C dans le CIRCUIT EXTRACORPOREL;*
– *régler le débit d'EXTRACTION NETTE DE LIQUIDE à 0 ml/h ou contourner le DIALYSEUR, ou les deux;*
– *régler le flux sanguin de l'APPAREIL D'HEMODIALYSE à 400 ml/min ou, si cela n'est pas possible, au flux sanguin le plus élevé possible;*
– *créer une PRESSION ARTERIELLE moyenne en amont de la pompe de –200 mmHg (± 10 mmHg);*
– *laisser la pompe fonctionner pendant une durée comprise entre 30 min et 45 min au flux sanguin maximal;*
– *après ce préconditionnement, mesurer le flux sanguin.*

La valeur du flux sanguin mesuré doit se situer dans les tolérances spécifiées par le FABRICANT dans les instructions d'utilisation.

NOTE 2 La fatigue du segment de pompe peut réduire le flux sanguin.

NOTE 3 Le flux sanguin des pompes péristaltiques peut décroître de manière considérable en cas de pressions négatives élevées sur la partie aspiration.

201.4.3.103 Débit du LIQUIDE DE DIALYSE

Le débit du LIQUIDE DE DIALYSE de l'APPAREIL D'HEMODIALYSE doit être tel que spécifié par le FABRICANT.

NOTE Un débit du LIQUIDE DE DIALYSE inférieur à la valeur de consigne est considéré comme préjudiciable pour un traitement type.

La conformité est vérifiée dans les conditions d'essai suivantes:

– *régler l'APPAREIL D'HEMODIALYSE sur le mode HEMODIALYSE, comme cela est spécifié par le FABRICANT;*
– *régler le débit du LIQUIDE DE DIALYSE de l'APPAREIL D'HEMODIALYSE au niveau maximal;*
– *mesurer le débit du LIQUIDE DE DIALYSE pendant 30 min ± 2 min;*
– *régler le débit du LIQUIDE DE DIALYSE de l'APPAREIL D'HEMODIALYSE au niveau minimal;*
– *mesurer le débit du LIQUIDE DE DIALYSE pendant 30 min ± 2 min.*

Les valeurs de débit du LIQUIDE DE DIALYSE doivent se situer dans les tolérances spécifiées par le FABRICANT dans les instructions d'utilisation.

201.4.3.104 EXTRACTION NETTE DE LIQUIDE

L'EXTRACTION NETTE DE LIQUIDE de l'APPAREIL D'HEMODIALYSE doit être telle que spécifiée par le FABRICANT.

La conformité est vérifiée dans les conditions d'essai suivantes.

Essai 1 pour la partie équilibrage de l'APPAREIL D'HEMODIALYSE uniquement:

– *régler l'APPAREIL D'HEMODIALYSE sur le mode HEMODIALYSE, le cas échéant, avec un DIALYSEUR conformément à la recommandation du FABRICANT;*
– *faire circuler un liquide (par exemple, de l'eau) dans le CIRCUIT EXTRACORPOREL. Si la température peut influer sur le mesurage de l'EXTRACTION NETTE DE LIQUIDE, le liquide doit avoir une température de 37 °C ± 1 °C à la connexion patient artérielle;*
– *définir le débit du LIQUIDE DE DIALYSE le plus élevé, le cas échéant;*
– *régler la température du LIQUIDE DE DIALYSE à 37 °C, le cas échéant;*
– *régler le débit d'EXTRACTION NETTE DE LIQUIDE à 0 ml/h ou à la valeur réglable la plus faible;*
– *créer une pression sanguine de sortie du DIALYSEUR de 50 mmHg (± 10 mmHg) inférieure à la pression de service la plus élevée spécifiée par le FABRICANT;*
– *mesurer l'EXTRACTION NETTE DE LIQUIDE pendant un intervalle de temps approprié.*

Poursuivre avec l'essai 2:

– *régler le débit d'EXTRACTION NETTE DE LIQUIDE à la valeur maximale;*
– *mesurer l'EXTRACTION NETTE DE LIQUIDE pendant un intervalle de temps approprié.*

Poursuivre avec l'essai 3:

– *créer une pression sanguine de sortie du DIALYSEUR de 20 mmHg (± 10 mmHg) supérieure à la pression de service la plus faible spécifiée par le FABRICANT;*
– *mesurer l'EXTRACTION NETTE DE LIQUIDE pendant un intervalle de temps approprié.*

Les valeurs de l'EXTRACTION NETTE DE LIQUIDE doivent se situer dans les tolérances spécifiées par le FABRICANT dans les instructions d'utilisation.

201.4.3.105 Débit du LIQUIDE DE SUBSTITUTION

Uniquement pour les APPAREILS D'HEMOFILTRATION et d'HEMODIAFILTRATION.

Le débit du LIQUIDE DE SUBSTITUTION de l'APPAREIL D'HEMODIALYSE doit être tel que spécifié par le FABRICANT.

NOTE Un débit du LIQUIDE DE SUBSTITUTION inférieur à la valeur de consigne est considéré comme préjudiciable pour un traitement type.

La conformité est vérifiée dans les conditions d'essai suivantes.

Essai 1 pour la partie équilibrage de l'APPAREIL D'HEMODIALYSE et du débit de LIQUIDE DE SUBSTITUTION thérapeutique approprié:

– *régler l'APPAREIL D'HEMODIALYSE sur le mode HDF ou HF avec un DIALYSEUR conformément à la recommandation du FABRICANT;*
– *faire circuler un liquide (par exemple, de l'eau) dans le CIRCUIT EXTRACORPOREL;*
– *régler le débit d'EXTRACTION NETTE DE LIQUIDE à 0 ml/h ou, si cela n'est pas possible, au niveau minimal;*
– *régler le débit du LIQUIDE DE SUBSTITUTION au niveau maximal;*
– *régler la température du LIQUIDE DE SUBSTITUTION à 37 °C, le cas échéant;*
– *mesurer le débit du liquide de substitution et l'extraction nette de liquide.*

Poursuivre avec l'essai 2:

– *régler le débit du LIQUIDE DE SUBSTITUTION au niveau minimal;*

– *mesurer le débit du LIQUIDE DE SUBSTITUTION et l'EXTRACTION NETTE DE LIQUIDE.*

Les valeurs de débit du LIQUIDE DE SUBSTITUTION et de l'EXTRACTION NETTE DE LIQUIDE doivent se situer dans les tolérances spécifiées par le FABRICANT dans les instructions d'utilisation.

201.4.3.106 Temps de dialyse

L'exactitude du temps de traitement de dialyse de l'APPAREIL D'HEMODIALYSE doit être telle que spécifiée par le FABRICANT.

La conformité est vérifiée par des essais fonctionnels appropriés relatifs à la définition du temps de traitement de dialyse spécifié par le FABRICANT.

201.4.3.107 * Composition du LIQUIDE DE DIALYSE

L'exactitude de la composition du LIQUIDE DE DIALYSE doit être spécifiée par le FABRICANT.

La méthode d'essai doit être spécifiée par le FABRICANT.

La conformité est vérifiée par examen et par un ou plusieurs essais fonctionnels appropriés qui démontrent le maintien des limites définies par le FABRICANT, spécifiées dans les instructions d'utilisation.

201.4.3.108 Température du liquide de dialyse

La température du LIQUIDE DE DIALYSE doit être telle que spécifiée par le FABRICANT.

NOTE Cet essai s'applique uniquement aux APPAREILS D'HEMODIALYSE qui comprennent un corps chauffant pour le LIQUIDE DE DIALYSE.

La conformité est vérifiée dans les conditions d'essai suivantes:

– *laisser l'APPAREIL D'HEMODIALYSE fonctionner jusqu'à ce qu'il atteigne des conditions environnementales thermiques stables comprises entre 20 °C et 25 °C;*

– *régler la température du LIQUIDE DE DIALYSE à 37 °C, le cas échéant;*

– *définir le débit du LIQUIDE DE DIALYSE le plus élevé;*

– *mesurer la température à l'entrée du DIALYSEUR;*

– *enregistrer la température pendant 30 min ± 2 min;*

– *définir le débit du LIQUIDE DE DIALYSE le plus faible;*

– *mesurer la température à l'entrée du DIALYSEUR;*

– *enregistrer la température pendant 30 min ± 2 min.*

Les valeurs de température du LIQUIDE DE DIALYSE doivent se situer dans les tolérances spécifiées par le FABRICANT dans les instructions d'utilisation.

201.4.3.109 Température du LIQUIDE DE SUBSTITUTION

La température du LIQUIDE DE SUBSTITUTION de l'APPAREIL D'HEMODIALYSE doit être telle que spécifiée par le FABRICANT.

NOTE Cet essai s'applique uniquement aux APPAREILS D'HEMODIALYSE qui comprennent un corps chauffant pour le LIQUIDE DE SUBSTITUTION.

La conformité est vérifiée dans les conditions d'essai suivantes:

– *laisser l'APPAREIL D'HEMODIALYSE fonctionner jusqu'à ce qu'il atteigne des conditions thermiques stables dans l'environnement;*

– *la température ambiante est comprise entre 20 °C et 25 °C;*

– *régler la température du LIQUIDE DE SUBSTITUTION à 37 °C, le cas échéant;*

– *définir le débit du LIQUIDE DE SUBSTITUTION le plus élevé;*

– *mesurer la température du LIQUIDE DE SUBSTITUTION au point de raccordement de la conduite de LIQUIDE DE SUBSTITUTION à la ligne de sang;*

– *enregistrer la température pendant 30 min ± 2 min;*

– *définir le débit du LIQUIDE DE SUBSTITUTION le plus faible;*

– *mesurer la température du LIQUIDE DE SUBSTITUTION au point de raccordement de la conduite de LIQUIDE DE SUBSTITUTION à la ligne de sang;*

– *enregistrer la température pendant 30 min ± 2 min.*

Les valeurs de température du LIQUIDE DE SUBSTITUTION doivent se situer dans les tolérances spécifiées par le FABRICANT dans les instructions d'utilisation.

201.4.7 CONDITION DE PREMIER DEFAUT pour APPAREILS EM

Addition:

Une défaillance d'un SYSTEME DE PROTECTION est un exemple de CONDITION DE PREMIER DEFAUT (voir 201.12.4.4.101, 201.12.4.4.102, 201.12.4.4.103, 201.12.4.4.104, 201.12.4.4.105);

NOTE 101 Si de l'air est présent en permanence dans le CIRCUIT EXTRACORPOREL lorsque l'APPAREIL D'HEMODIALYSE est utilisé comme cela est prévu par le FABRICANT, l'air n'est pas considéré comme une CONDITION DE PREMIER DEFAUT, mais comme une CONDITION NORMALE.

201.5 Exigences générales relatives aux essais des APPAREILS EM

L'Article 5 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.5.4 Autres conditions

Addition:

aa) Lorsque le résultat d'un essai peut être influencé par la température initiale des sacs pour LIQUIDE DE DIALYSE préproduit, la température du LIQUIDE DE DIALYSE au début de l'essai doit être inférieure ou égale à 4 °C, ou à la température minimale du LIQUIDE DE DIALYSE spécifiée par le FABRICANT de l'APPAREIL EM.

bb) Si les conditions (par exemple, température, humidité) pendant le transport ou le stockage, ou les deux, ont une influence sur l'UTILISATION NORMALE, cela doit être traité dans le PROCESSUS DE GESTION DES RISQUES.

201.6 Classification des APPAREILS EM et des SYSTEMES EM

L'Article 6 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique.

201.7 Identification, marquage et documentation des APPAREILS EM

L'Article 7 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.7.4.3 Unités de mesure

Addition:

L'unité mmHg peut être utilisée pour le mesurage des pressions dans toute partie de L'APPAREIL D'HEMODIALYSE.

201.7.8.2 * Couleurs des organes de commande

Remplacement:

La couleur rouge peut être utilisée pour une commande de fonctionnement de la pompe sanguine ou pour une commande qui interrompt une fonction en cas d'urgence.

201.7.9 DOCUMENTS D'ACCOMPAGNEMENT

201.7.9.2 Instructions d'utilisation

201.7.9.2.1 Généralités

Addition:

Les instructions d'utilisation doivent, de plus, inclure ce qui suit:

– * les valeurs pondérales minimales de la population de PATIENTS prévue, y compris les limites applicables à des groupes spécifiques de PATIENTS.

La conformité est vérifiée par examen des instructions d'utilisation dans les DOCUMENTS D'ACCOMPAGNEMENT.

201.7.9.2.2 Avertissements et consignes de sécurité

Addition:

Les instructions d'utilisation doivent, de plus, inclure ce qui suit, le cas échéant:

– un avertissement attirant l'attention de l'OPERATEUR sur les précautions nécessaires à prendre pour éviter toute infection croisée entre les PATIENTS;
– un avertissement attirant l'attention de l'OPERATEUR sur la SITUATION DANGEREUSE associée à la connexion et à la déconnexion du PATIENT;
– un avertissement attirant l'attention de l'OPERATEUR sur les actions exigées pour répondre aux SIGNAUX D'ALARME provenant de tout SYSTEME DE PROTECTION;
– un avertissement d'avertissement attirant l'attention de l'OPERATEUR sur les DANGERS potentiels dus à un choix inapproprié des sacs pour LIQUIDE DE DIALYSE préproduit;
– un avertissement attirant l'attention de l'OPERATEUR sur les DANGERS, y compris les SITUATIONS DANGEREUSES éventuelles, qui résultent d'une installation et de raccordements incorrects du CIRCUIT EXTRACORPOREL;
– un avertissement sur les DANGERS liés à une erreur dans le choix du ou des CONCENTRES DE LIQUIDE DE DIALYSE;
– une description quantitative de l'écart possible de chaque composant du LIQUIDE DE DIALYSE en CONDITION DE PREMIER DEFAUT, en fonction des LIMITES D'ALARME du SYSTEME DE PROTECTION;

– * un avertissement sur les DANGERS et les causes sous-jacentes liés à un transport possible de substances indésirables du compartiment pour LIQUIDE DE DIALYSE vers le compartiment sanguin du DIALYSEUR;

– pour le SYSTEME DE PROTECTION utilisé selon 201.12.4.4.104.1 a):

  • un avertissement stipulant que ce SYSTEME DE PROTECTION ne réduit que partiellement le RISQUE, ainsi qu'une explication du RISQUE subsistant;

  • une description de la responsabilité de l'OPERATEUR concernant une réduction supplémentaire du RISQUE résiduel;

– un avertissement indiquant l'action adéquate de l'OPERATEUR en cas de CONDITION D'ALARME et du ou des DANGERS associés, si le SIGNAL D'ALARME est confirmé à plusieurs reprises sans avoir résolu le problème sous-jacent;

– * un avertissement spécifiant que tout passage étroit dans le CIRCUIT EXTRACORPOREL (qui résulte par exemple de pliures dans la ligne de sang ou de l'utilisation d'aiguilles non adaptées aux flux sanguins choisis) peut provoquer une hémolyse et qu'il est possible que cette SITUATION DANGEREUSE ne soit pas détectée par le système de protection;

– si un SYSTEME DE PROTECTION, selon la Note 1 du 201.12.4.4.105, est appliqué: un avertissement stipulant qu'un fonctionnement incorrect d'un détecteur d'air à ultrasons peut être dû à un caillot ou à l'application d'un gel pour ultrasons;

– * un avertissement stipulant que de l'air peut entrer dans le CIRCUIT EXTRACORPOREL en aval du détecteur d'air, par exemple en des points de raccordement serrés de manière insuffisante, si les pressions sont négatives; ce phénomène peut se produire dans le cas d'applications avec aiguille unique ou avec des cathéters veineux centraux;

– concernant la qualité microbiologique des liquides:

  • un avertissement indiquant que seules les PROCEDURES de désinfection définies et validées par le FABRICANT doivent être utilisées;

  • des informations sur la qualité exigée de l'EAU DE DIALYSE entrante et des CONCENTRES DE LIQUIDE DE DIALYSE utilisés;

  • les informations sur la qualité microbiologique du LIQUIDE DE DIALYSE et du LIQUIDE DE SUBSTITUTION, préparés par l'APPAREIL D'HEMODIALYSE;

  • les intervalles auxquels il convient de remplacer les pièces d'usure (par exemple, le FILTRE DE RETENTION D'ENDOTOXINES – ETRF, *EndoToxin-Retentive Filter*);

– un avertissement stipulant que le flux sanguin, et par conséquent l'efficacité du traitement, peuvent être diminués, lorsque la PRESSION ARTERIELLE en amont de la pompe est extrêmement négative, et indiquant également la plage et l'exactitude du flux sanguin de cette ou de ces pompes, ainsi que les plages de pressions d'entrée et de sortie pour lesquelles cette exactitude est maintenue;

– pour un APPAREIL D'HEMODIALYSE comportant des PARTIES APPLIQUEES autres que les PARTIES APPLIQUEES DE TYPE CF, un avertissement à l'adresse de l'OPERATEUR et de l'ORGANISME RESPONSABLE destiné à assurer qu'aucun appareil électrique (appareils non EM et APPAREILS EM) comportant des COURANTS DE CONTACT et des COURANTS DE FUITE PATIENT supérieurs aux limites respectives définies pour les PARTIES APPLIQUEES DE TYPE CF n'est utilisé dans l'environnement du patient en conjonction avec un cathéter veineux central dont l'embout est placé dans l'oreillette droite;

NOTE 101 Voir le 201.8.3 de l'Annexe AA pour de plus amples informations.

– un avertissement stipulant que l'application de débits de transmission faibles de dispositifs anticoagulation intégrés à l'APPAREIL D'HEMODIALYSE (par exemple, utilisation d'une solution anticoagulante non diluée) peut entraîner une transmission retardée et non continue due à la conformité mécanique des moyens de transmission, y compris les éléments jetables, ou à des variations de pression de sortie dans le CIRCUIT EXTRACORPOREL;

– un avertissement stipulant qu'il convient de prendre des mesures de protection pour éviter toute rentrée d'eau provenant du drain.

NOTE 102 Le terme "avertissement" est utilisé de manière générique et il incombe aux FABRICANTS d'identifier comment fournir les informations connexes à l'utilisateur conformément au PROCESSUS DE GESTION DES RISQUES DU FABRICANT.

La conformité est vérifiée par examen des instructions d'utilisation dans les DOCUMENTS D'ACCOMPAGNEMENT.

201.7.9.2.5 Description de l'APPAREIL EM

Addition:

Les instructions d'utilisation doivent, de plus, inclure ce qui suit, le cas échéant:

– une définition de la PRESSION TRANSMEMBRANAIRE si le FABRICANT en utilise une différente de celle indiquée au 201.3.218;

– une explication des marquages couleur sur les connecteurs de CONCENTRE DE LIQUIDE DE DIALYSE;

– des informations sur le flux sanguin effectivement délivré pour les traitements à aiguille unique;

– des informations sur la recirculation du sang dans le CIRCUIT EXTRACORPOREL pour les traitements à aiguille unique;

– le délai au bout duquel un SIGNAL D'ALARME sonore est activé après une coupure de l'alimentation;

– pour les fonctions des REGULATEURS PHYSIOLOGIQUES EN BOUCLE FERMEE (voir également la norme collatérale IEC 60601-1-10):

  a) le principe de fonctionnement technique;

  b) les paramètres du PATIENT mesurés et les paramètres physiologiques contrôlés;

  c) les méthodes d'évaluation de ces modes de REGULATEURS PHYSIOLOGIQUES EN BOUCLE FERMEE, y compris les effets bénéfiques et néfastes enregistrés pendant l'évaluation clinique;

– pour toute donnée affichée ou indiquée par l'APPAREIL D'HEMODIALYSE et pouvant être utilisée pour ajuster le traitement ou pour mesurer ou confirmer l'efficacité de celui-ci:

  a) une description du principe de fonctionnement technique;

  b) si le mesurage est indirect: des informations sur l'exactitude et les facteurs éventuels pouvant l'influencer;

  c) * la méthode d'évaluation du principe de fonctionnement technique par rapport à des soins médicaux classiques;

– pour un APPAREIL D'HEMODIALYSE qui comporte des PARTIES APPLIQUEES autres que les PARTIES APPLIQUEES DE TYPE CF, des informations indiquant si cet APPAREIL D'HEMODIALYSE peut être utilisé conjointement avec un cathéter veineux central dont l'embout est placé dans l'oreillette droite. Si l'APPAREIL D'HEMODIALYSE ne convient pas à un cathéter veineux central dont l'embout est placé dans l'oreillette droite, les DANGERS associés doivent être énumérés.

La conformité est vérifiée par examen des instructions d'utilisation dans les DOCUMENTS D'ACCOMPAGNEMENT.

201.7.9.2.6 Installation

Addition:

Les instructions d'utilisation doivent, de plus, inclure ce qui suit, le cas échéant:

– des informations indiquant qu'il est indispensable que l'APPAREIL D'HEMODIALYSE soit installé et utilisé conformément aux réglementations/recommandations appropriées sur la qualité de l'EAU DE DIALYSE et des autres liquides concernés;

– pour les APPAREILS D'HEMODIALYSE de CLASSE I, des informations sur l'importance de la qualité de la terre de protection dans l'installation électrique;

– des informations indiquant les applications pour lesquelles il convient d'utiliser un CONDUCTEUR D'EGALISATION DES POTENTIELS;

– la plage acceptable de températures, de débit et de pression pour l'EAU DE DIALYSE d'entrée et tout SYSTEME DE TRANSMISSION CENTRALISE;

– une note soulignant l'importance de la conformité à toutes les réglementations locales concernant la séparation de l'APPAREIL D'HEMODIALYSE par rapport à l'alimentation en eau, de la prévention du retour d'eau vers la source d'eau potable et de la prévention de la contamination provenant de tout raccordement à l'égout du drain de l'APPAREIL D'HEMODIALYSE;

– si différents systèmes de codes couleur pour les SIGNAUX D'ALARME visuels peuvent être configurés, des informations indiquant qu'il convient que l'ORGANISME RESPONSABLE choisisse le système de codes couleur qui réduit le plus possible le RISQUE de mauvaise interprétation du SIGNAL D'ALARME dans leur environnement;

– si des réglages de paramètres de fonctionnement ou des SYSTEMES DE PROTECTION peuvent être configurés, des informations indiquant qu'il convient que l'ORGANISME RESPONSABLE choisisse la ou les configurations ou confirme explicitement la configuration par défaut.

La conformité est vérifiée par examen des instructions d'utilisation dans les DOCUMENTS D'ACCOMPAGNEMENT.

201.7.9.2.12 Nettoyage, désinfection et stérilisation

Addition:

Les instructions d'utilisation doivent, de plus, inclure ce qui suit, le cas échéant:

– * une description de la ou des méthodes de nettoyage antiseptique ou de désinfection du trajet de liquide réutilisable à l'intérieur de l'APPAREIL D'HEMODIALYSE, ainsi que de nettoyage ou de désinfection, ou les deux, de la surface de l'ENVELOPPE;

– des informations sur la manière de gérer un intervalle de temps prolongé entre le nettoyage antiseptique ou la désinfection, afin de remettre le système dans un état de contrôle microbien;

– * des informations indiquant que la PROCEDURE d'essai selon laquelle l'efficacité du nettoyage antiseptique ou de la désinfection du trajet de liquide à l'intérieur de l'APPAREIL D'HEMODIALYSE a été validée est disponible sur demande auprès du FABRICANT, y compris des informations sur la manière dont les essais ont traduit les risques de contrôle microbien tout au long de la DUREE DE VIE PREVUE;

– un avertissement en vue de suivre les instructions du FABRICANT pour désinfecter l'APPAREIL D'HEMODIALYSE; si d'autres PROCEDURES sont utilisées, il incombe à l'ORGANISME RESPONSABLE de valider l'efficacité et la sécurité de la procédure de désinfection; cet avertissement doit spécifiquement énumérer les DANGERS, y compris le mode de défaillance qui peut résulter d'autres PROCEDURES;

– un avertissement indiquant que l'ORGANISME RESPONSABLE est garant de la qualité hygiénique de tous les systèmes de distribution, par exemple, le système centralisé d'alimentation en EAU DE DIALYSE, les SYSTEMES DE TRANSMISSION CENTRALISES, les dispositifs de raccordement de l'APPAREIL D'HEMODIALYSE, y compris les conduites de liquide entre les points de raccordement et l'APPAREIL D'HEMODIALYSE.

NOTE Le terme "avertissement" est utilisé de manière générique et il incombe aux FABRICANTS d'identifier comment fournir les informations connexes à l'utilisateur conformément au PROCESSUS DE GESTION DES RISQUES DU FABRICANT.

La conformité est vérifiée par examen des instructions d'utilisation dans les DOCUMENTS D'ACCOMPAGNEMENT.

201.7.9.2.14 ACCESSOIRES, équipements supplémentaires, fournitures utilisées

Addition:

Les instructions d'utilisation doivent, de plus, inclure ce qui suit, le cas échéant:

– des informations sur les sacs pour LIQUIDE DE DIALYSE préproduit, les CONCENTRES DE LIQUIDE DE DIALYSE, les DIALYSEURS et les CIRCUITS EXTRACORPORELS destinés à être utilisés avec l'APPAREIL D'HEMODIALYSE.

La conformité est vérifiée par examen des instructions d'utilisation dans les DOCUMENTS D'ACCOMPAGNEMENT.

201.7.9.3 Description technique

201.7.9.3.1 Généralités

Addition:

La description technique doit, de plus, comprendre ce qui suit, le cas échéant:

- installation:
  - une description des mesures ou des conditions particulières à observer lors de l'installation, du démontage et du transport de l'APPAREIL D'HEMODIALYSE ou lors de sa mise en marche. Celles-ci doivent comprendre des recommandations sur le type et le nombre d'essais à effectuer;
  - des informations sur la température maximale qui peut se produire au niveau du drain de l'APPAREIL D'HEMODIALYSE;
  - * des informations sur la consommation d'énergie, la fourniture d'énergie à l'environnement et la fourniture d'énergie au drain dans des conditions de fonctionnement types et en fonction de la température de l'eau d'entrée;
  - * des informations sur la consommation d'eau et du ou des CONCENTRES DE LIQUIDE DE DIALYSE ou du LIQUIDE DE DIALYSE (préproduit) dans les conditions de fonctionnement types;
- spécification des APPAREILS D'HEMODIALYSE:
  - pour les APPAREILS D'HEMODIALYSE qui comprennent des dispositifs de transmission d'anticoagulant intégrés: le type de la ou des pompes, la plage et l'exactitude du débit de cette ou de ces pompes et les pressions auxquelles cette exactitude est maintenue;
  - toutes les mesures supplémentaires prévues par le FABRICANT en cas de coupure de l'alimentation;
  - le type, l'exactitude de mesure et la ou les valeurs/la ou les plages de la ou des LIMITES D'ALARME du SYSTEME DE PROTECTION exigés au 201.12.4.4.101 (composition du LIQUIDE DE DIALYSE);
  - le type, l'exactitude de mesure et la ou les valeurs/la ou les plages de la ou des LIMITES D'ALARME du SYSTEME DE PROTECTION exigés au 201.12.4.4.102 (températures du LIQUIDE DE DIALYSE et du LIQUIDE DE SUBSTITUTION);

- le type, l'exactitude de mesure et la ou les valeurs/la ou les plages de la ou des LIMITES D'ALARME du SYSTEME DE PROTECTION exigés au 201.12.4.4.103 (EXTRACTION NETTE DE LIQUIDE);
- le type, l'exactitude de mesure et la ou les valeurs/la ou les plages de la ou des LIMITES D'ALARME du SYSTEME DE PROTECTION exigés au 201.12.4.4.104.1 (perte de sang extracorporelle à l'extérieur) et, le cas échéant, les délais introduits par un SYSTEME D'ALARME INTELLIGENT;
- * le type et l'exactitude de mesure du SYSTEME DE PROTECTION exigés au 201.12.4.4.104.2 (FUITE DE SANG en direction du LIQUIDE DE DIALYSE), ainsi que la LIMITE D'ALARME du SYSTEME DE PROTECTION aux débits minimal et maximal dans le détecteur de FUITE DE SANG;
- le type et la ou les LIMITES D'ALARME du SYSTEME DE PROTECTION exigés au 201.12.4.4.104.3 (perte de sang extracorporel due à la coagulation);
- la méthode utilisée et la sensibilité dans les conditions d'essai spécifiées par le FABRICANT pour le SYSTEME DE PROTECTION, exigées au 201.12.4.4.105 (infusion d'air);
- le ou les temps d'inhibition pour tout SYSTEME DE PROTECTION;
- la période de PAUSE DU SIGNAL D'ALARME SONORE;
- la plage des niveaux de pression acoustique de toute source de SIGNAL D'ALARME sonore réglable;
- l'indication de tous les matériaux destinés à entrer en contact avec l'EAU DE DIALYSE, le LIQUIDE DE DIALYSE et le CONCENTRE DE LIQUIDE DE DIALYSE;
- pour les HDF EN LIGNE et les HF EN LIGNE: la méthode de préparation du LIQUIDE DE SUBSTITUTION, le cas échéant, la méthode d'essai d'intégrité des filtres du LIQUIDE DE SUBSTITUTION (par exemple, FILTRE DE RETENTION D'ENDOTOXINES – ETRF) et l'exactitude de ces essais.

La conformité est vérifiée par examen de la description technique dans les DOCUMENTS D'ACCOMPAGNEMENT.

201.8 Protection contre les DANGERS d'origine électrique provenant des APPAREILS EM

L'Article 8 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.8.3 * Classification des PARTIES APPLIQUEES

Addition:

Les APPAREILS D'HEMODIALYSE avec des COURANTS DE FUITE qui satisfont aux exigences des PARTIES APPLIQUEES DE TYPE CF sont considérés comme adaptés à une utilisation avec un cathéter veineux central dont l'embout est placé dans l'oreillette droite.

Si les APPAREILS D'HEMODIALYSE qui comportent une PARTIE APPLIQUEE autre qu'une PARTIE APPLIQUEE DE TYPE CF sont destinés à être utilisés pour le traitement de PATIENTS avec un cathéter veineux central dont l'embout est placé dans l'oreillette droite, ce qui suit doit s'appliquer:

aa) en CONDITION NORMALE, les COURANTS DE FUITE PATIENT et les COURANTS DE CONTACT doivent se situer dans les limites admissibles pour les PARTIES APPLIQUEES DE TYPE CF;

bb) en CONDITION DE PREMIER DEFAUT, les COURANTS DE FUITE PATIENT, les COURANTS DE CONTACT et les COURANTS DE FUITE A LA TERRE doivent se situer dans les limites admissibles pour les PARTIES APPLIQUEES DE TYPE CF.

La conformité est vérifiée par examen.

Si l'APPAREIL D'HEMODIALYSE ne satisfait pas au point bb), des moyens externes doivent être fournis et justifiés par le PROCESSUS DE GESTION DES RISQUES DU FABRICANT afin de maintenir les COURANTS DE FUITE PATIENT dans les limites admissibles pour les PARTIES APPLIQUEES DE TYPE CF en CONDITION DE PREMIER DEFAUT.

La conformité est vérifiée par examen du DOSSIER DE GESTION DES RISQUES.

201.8.7.4.7 Mesure du COURANT DE FUITE PATIENT

Addition:

aa) * Le dispositif de mesure doit être raccordé aux points auxquels les deux lignes de sang extracorporel sont raccordées au PATIENT. Pendant la durée de l'essai, une solution d'essai, avec la conductivité la plus élevée pouvant être choisie, référencée à une température de 25 °C, et avec la température du LIQUIDE DE DIALYSE la plus élevée pouvant être choisie dans l'application, doit être mise en circulation dans le circuit du LIQUIDE DE DIALYSE et dans le CIRCUIT EXTRACORPOREL. L'APPAREIL D'HEMODIALYSE doit être mis en fonctionnement dans un mode de traitement type, avec le flux sanguin le plus élevé possible et sans CONDITION D'ALARME activée. Pour des raisons pratiques, le dispositif de mesure peut être raccordé aux connecteurs du LIQUIDE DE DIALYSE.

NOTE 101 Le mesurage des COURANTS DE FUITE PATIENT décrits ci-dessus ne comprend pas le mesurage du 8.7.4.7 b) (tension externe sur la ou les CONNEXIONS PATIENT) de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 pour les APPAREILS D'HEMODIALYSE avec des PARTIES APPLIQUEES DE TYPE B.

NOTE 102 Le flux sanguin le plus élevé possible conduit à la résistance la plus faible de l'espace dans la chambre compte-gouttes du circuit veineux.

201.8.11.2 * SOCLES DE PRISES MULTIPLES

Addition:

Si un SOCLE DE PRISES MULTIPLES est fourni et si un échange mutuel ou un échange avec d'autres SOCLES DE PRISES MULTIPLES de l'APPAREIL D'HEMODIALYSE peut créer une SITUATION DANGEREUSE, le SOCLE DE PRISES MULTIPLES doit être d'un type qui empêche un tel échange.

La conformité est vérifiée par examen et par des essais fonctionnels.

201.9 Protection contre les DANGERS MECANIQUES des APPAREILS EM et SYSTEMES EM

L'Article 9 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique.

201.10 Protection contre les DANGERS dus aux rayonnements involontaires ou excessifs

L'Article 10 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique.

201.11 Protection contre les températures excessives et les autres DANGERS

L'Article 11 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.11.6 * Débordement, renversement, fuites, pénétration d'eau ou de particules, nettoyage, désinfection, stérilisation, et compatibilité avec des substances utilisées avec des APPAREILS EM

201.11.6.1 Généralités

Addition:

Toutes les dispositions du 11.6.2 au 11.6.4 doivent être appliquées en utilisant le fluide approprié.

NOTE La solution saline, le LIQUIDE DE DIALYSE et d'autres liquides identifiés par le FABRICANT sont des exemples de liquides appropriés.

201.11.6.5 Pénétration d'eau ou de matière particulaire dans les APPAREILS EM et les SYSTEMES EM

Addition:

Le paragraphe de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique et IPX1 selon l'IEC 60529 est exigé au minimum.

201.11.6.6 * Nettoyage et désinfection des APPAREILS EM et des SYSTEMES EM

Addition:

Des moyens de maintenance hygiénique doivent être fournis pour les APPAREILS D'HEMODIALYSE utilisant des trajets de liquide qui ne peuvent pas être éliminés (par exemple, réutilisables) et des composants en contact avec un liquide lui-même en contact direct ou indirect avec le PATIENT.

Le PROCESSUS de contrôle microbien des APPAREILS D'HEMODIALYSE doit être développé et validé par le FABRICANT pour les APPAREILS D'HEMODIALYSE à l'aide d'une approche fondée sur les RISQUES en prenant en considération la DUREE DE VIE PREVUE, l'élimination, la filtration, le nettoyage/la désinfection, la maintenance des systèmes, le stockage et les normes de qualité applicables au LIQUIDE DE DIALYSE.

La conformité est vérifiée par examen de la documentation de validation, du DOSSIER DE GESTION DES RISQUES, des DOCUMENTS D'ACCOMPAGNEMENT et de l'APPAREIL D'HEMODIALYSE.

Les PROCEDURES de désinfection ne doivent pas détériorer les composants internes, les surfaces externes ou les ACCESSOIRES externes (par exemple, le FILTRE DE RETENTION D'ENDOTOXINES – ETRF) susceptibles d'entraîner une SITUATION DANGEREUSE.

La conformité est vérifiée par examen du DOSSIER DE GESTION DES RISQUES et de la documentation de validation.

201.11.8 * Coupure de l'alimentation/du RESEAU ELECTRIQUE vers l'APPAREIL EM

Addition:

a) APPAREIL D'HEMODIALYSE alimenté uniquement par le RESEAU D'ALIMENTATION sans SOURCE D'ENERGIE ELECTRIQUE INTERNE:

En cas de coupure de l'alimentation/du RESEAU D'ALIMENTATION vers l'APPAREIL D'HEMODIALYSE, les conditions de sécurité suivantes doivent être remplies:

– activation d'un SIGNAL D'ALARME sonore pendant au moins 1 min;

– des mesures supplémentaires peuvent être nécessaires, comme cela est déterminé par le PROCESSUS DE GESTION DES RISQUES DU FABRICANT;

– l'APPAREIL D'HEMODIALYSE peut redémarrer automatiquement au rétablissement de l'alimentation, seulement si cela ne provoque aucune SITUATION DANGEREUSE pour le PATIENT, comme cela est déterminé par le PROCESSUS DE GESTION DES RISQUES DU FABRICANT.

NOTE 101 Les sources d'énergie du SIGNAL D'ALARME sonore de 1 min ne sont pas considérées comme des SOURCES D'ENERGIE ELECTRIQUE INTERNES.

NOTE 102 Pour le SIGNAL D'ALARME sonore de 1 min, le 6.3.3.1 de l'IEC 60601-1-8:2006, l'IEC 60601-1-8:2006/AMD1:2012 et l'IEC 60601-1-8:2006/AMD2:2020 permet des écarts par rapport à l'ensemble de ses exigences. Voir également 208.6.3.3.2 et 208.6.3.3.101.

La conformité est vérifiée par examen du DOSSIER DE GESTION DES RISQUES et par des essais fonctionnels.

b) APPAREIL D'HEMODIALYSE alimenté par le RESEAU D'ALIMENTATION avec une SOURCE D'ENERGIE ELECTRIQUE INTERNE pour fonctionnalité limitée en cas de coupure de l'alimentation/du RESEAU D'ALIMENTATION:

En cas de coupure de l'alimentation/du RESEAU D'ALIMENTATION vers l'APPAREIL D'HEMODIALYSE, les conditions de sécurité suivantes doivent être remplies:

– directement après la perte du RESEAU D'ALIMENTATION, activation d'un SIGNAL D'ALARME visuel;

– activation d'un SIGNAL D'ALARME sonore après un intervalle de temps spécifié par le FABRICANT.

Alors que la SOURCE D'ENERGIE ELECTRIQUE INTERNE est active:

– la fonctionnalité limitée doit toujours satisfaire aux exigences du 201.12.4.4.104.3;

– le cas échéant, toutes les autres exigences du 201.12.4.4 doivent être respectées.

En cas d'épuisement initial ou de perte de la SOURCE D'ENERGIE ELECTRIQUE INTERNE, la condition de sécurité suivante doit être remplie:

– au plus tard 30 min avant l'épuisement de la SOURCE D'ENERGIE ELECTRIQUE INTERNE, activation d'un SIGNAL D'ALARME visuel et sonore. Le cas échéant, il convient que l'activation du SIGNAL D'ALARME indique à l'OPERATEUR le temps habituellement nécessaire pour le renvoi du sang au PATIENT. Le SIGNAL D'ALARME doit durer au moins 1 min.

Ou, en variante, après la perte de la SOURCE D'ENERGIE ELECTRIQUE INTERNE:

– activation d'un SIGNAL D'ALARME sonore pendant au moins 1 min.

Dans les deux cas:

– des mesures supplémentaires peuvent être nécessaires, comme cela est déterminé par le PROCESSUS DE GESTION DES RISQUES DU FABRICANT;

– si des fonctions de l'APPAREIL D'HEMODIALYSE ont été arrêtées lors d'une coupure de l'alimentation/du RESEAU D'ALIMENTATION, elles ne peuvent redémarrer automatiquement au rétablissement de l'alimentation/du RESEAU D'ALIMENTATION que si cela ne provoque aucune SITUATION DANGEREUSE pour le PATIENT, comme cela est déterminé par le PROCESSUS DE GESTION DES RISQUES DU FABRICANT.

NOTE 103 Dans le second cas (c'est-à-dire un SIGNAL D'ALARME à la perte de la SOURCE D'ENERGIE ELECTRIQUE INTERNE), il n'est pas nécessaire de soumettre la SOURCE D'ENERGIE ELECTRIQUE INTERNE à un essai de fonctionnalité si elle n'est pas utilisée pour générer le SIGNAL D'ALARME sonore de 1 min.

NOTE 104 Dans le second cas (c'est-à-dire un SIGNAL D'ALARME à la perte de la SOURCE D'ENERGIE ELECTRIQUE INTERNE), les sources d'énergie du SIGNAL D'ALARME sonore de 1 min ne sont pas considérées comme des SOURCES D'ENERGIE ELECTRIQUE INTERNES

NOTE 105 Pour le SIGNAL D'ALARME sonore en cas de coupure de l'ALIMENTATION et pour le SIGNAL D'ALARME sonore de 1 min en cas de perte de la SOURCE D'ENERGIE ELECTRIQUE INTERNE, le 6.3.3.1 de l'IEC 60601-1-8:2006, l'IEC 60601-1-8:2006/AMD1:2012 et l'IEC 60601-1-8:2006/AMD2:2020 permet des écarts par rapport à l'ensemble de ses exigences. Voir également 208.6.3.3.2 et 208.6.3.3.101. Dans toute la mesure du possible, il est préférable que le SIGNAL D'ALARME sonore en cas de coupure de l'ALIMENTATION et que le SIGNAL D'ALARME sonore de 1 min généré avant l'épuisement de la SOURCE D'ENERGIE ELECTRIQUE INTERNE soient conformes à l'Article 208.

NOTE 106 En ce qui concerne le premier cas (c'est-à-dire un SIGNAL D'ALARME pas plus de 30 min avant la perte attendue de la SOURCE D'ENERGIE ELECTRIQUE INTERNE), un SIGNAL D'ALARME généré plus de 30 min avant la perte prévue de la SOURCE D'ENERGIE ELECTRIQUE INTERNE, ne permet pas de rappeler à l'OPERATEUR de commencer la restitution du sang avant que la SOURCE D'ENERGIE ELECTRIQUE INTERNE ne soit épuisée. En cas de spécification de la fonctionnalité limitée pour une durée inférieure ou égale à 30 min, le SIGNAL D'ALARME de perte du RESEAU D'ALIMENTATION et le SIGNAL D'ALARME de perte de la SOURCE D'ENERGIE ELECTRIQUE INTERNE peuvent être combinés en un seul SIGNAL D'ALARME.

La conformité est vérifiée par examen du DOSSIER DE GESTION DES RISQUES et par des essais fonctionnels.

c) APPAREIL D'HEMODIALYSE ALIMENTE DE MANIERE INTERNE:

En cas d'épuisement initial ou de perte de la SOURCE D'ENERGIE ELECTRIQUE INTERNE, la condition de sécurité suivante doit être remplie:

– au plus tard 30 min avant l'épuisement prévu de la SOURCE D'ENERGIE ELECTRIQUE INTERNE, activation d'un SIGNAL D'ALARME visuel et sonore. Le cas échéant, il convient que l'activation du SIGNAL D'ALARME indique à l'OPERATEUR le temps habituellement nécessaire pour le renvoi du sang au PATIENT. Le SIGNAL D'ALARME doit durer au moins 1 min et doit être conforme à l'Article 208 (avec une exception admise pour la durée de PAUSE DE L'ALARME SONORE, concernant 208.6.3.1 et 208.6.3.3.101).

Ou, en variante, après la perte de la SOURCE D'ENERGIE ELECTRIQUE INTERNE:

– activation d'un SIGNAL D'ALARME sonore pendant au moins 1 min.

Dans les deux cas:

– des mesures supplémentaires peuvent être nécessaires, comme cela est déterminé par le PROCESSUS DE GESTION DES RISQUES DU FABRICANT;

– l'APPAREIL D'HEMODIALYSE peut redémarrer automatiquement au rétablissement de l'alimentation, seulement si cela ne provoque aucune SITUATION DANGEREUSE pour le PATIENT, comme cela est déterminé par le PROCESSUS DE GESTION DES RISQUES DU FABRICANT.

NOTE 107 Le cas c) s'applique aux APPAREILS D'HEMODIALYSE lorsque l'UTILISATION PREVUE est réalisée par une SOURCE D'ENERGIE ELECTRIQUE INTERNE, par exemple un APPAREIL D'HEMODIALYSE portable.

NOTE 108 Le cas c) s'applique également aux APPAREILS D'HEMODIALYSE qui peuvent assurer l'UTILISATION PREVUE par la SOURCE D'ENERGIE ELECTRIQUE INTERNE ou, en variante, par le RESEAU D'ALIMENTATION, ou en combinaison avec le RESEAU D'ALIMENTATION (par exemple, pour charger la SOURCE D'ENERGIE ELECTRIQUE INTERNE en cours d'utilisation). Voir l'exigence supplémentaire relative à l'indication du mode de charge au 15.4.4 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020.

NOTE 109 Les sources d'énergie du SIGNAL D'ALARME sonore de 1 min ne sont pas considérées comme des SOURCES D'ENERGIE ELECTRIQUE INTERNES.

NOTE 110 Pour le SIGNAL D'ALARME sonore de 1 min en cas de perte de la SOURCE D'ENERGIE ELECTRIQUE INTERNE, le 6.3.3.1 de l'IEC 60601-1-8:2006, l'IEC 60601-1-8:2006/AMD1:2012 et l'IEC 60601-1-8:2006/AMD2:2020 permet des écarts par rapport à l'ensemble de ses exigences. Voir également 208.6.3.3.2 et 208.6.3.3.101.

La conformité est vérifiée par examen du DOSSIER DE GESTION DES RISQUES et par des essais fonctionnels.

201.12 * Précision des commandes, des instruments et protection contre les caractéristiques de sortie présentant des risques

L'Article 12 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

Voir l'Annexe BB pour des exemples de DANGERS, de séquences d'événements prévisibles et de SITUATIONS DANGEREUSES dans les APPAREILS D'HEMODIALYSE.

201.12.4.4 Sortie incorrecte

Addition:

Les PROCEDURES d'essai du 12.4.4.101 au 12.4.4.105 donnent une vue d'ensemble des exigences minimales pour la validation d'un APPAREIL D'HEMODIALYSE. Toutes les précisions ne sont pas données pour chaque PROCEDURE d'essai, et il incombe au laboratoire d'essai d'inclure ces précisions en fonction de l'APPAREIL D'HEMODIALYSE spécifique et du PROCESSUS DE GESTION DES RISQUES DU FABRICANT.

Paragraphes supplémentaires:

201.12.4.4.101 * Composition du LIQUIDE DE DIALYSE

a) L'APPAREIL D'HEMODIALYSE doit comporter un SYSTEME DE PROTECTION, indépendant de tout système de contrôle de préparation de liquide, qui empêche le LIQUIDE DE DIALYSE d'atteindre le DIALYSEUR, ce qui, en raison de sa composition, peut provoquer une SITUATION DANGEREUSE.

NOTE 1 Un SYSTEME DE PROTECTION n'est pas nécessaire pour les APPAREILS D'HEMODIALYSE qui utilisent uniquement un LIQUIDE DE DIALYSE préproduit, dont la composition fait l'objet d'un contrôle qualité. Cette composition n'est par ailleurs pas modifiée par les APPAREILS D'HEMODIALYSE, qui utilisent, par exemple, des sacs pour LIQUIDE DE DIALYSE préproduit.

La conception du SYSTEME DE PROTECTION destinée à prévenir une composition dangereuse du LIQUIDE DE DIALYSE doit prendre en considération l'éventualité d'une défaillance à toute phase de préparation ou de régénération du LIQUIDE DE DIALYSE.

L'activation du SYSTEME DE PROTECTION doit remplir les conditions de sécurité suivantes:

– activation de SIGNAUX D'ALARME sonores et visuels (voir 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101). Le SIGNAL D'ALARME sonore peut être retardé comme cela est spécifié au 208.6.3.3.101 b);

– arrêt de l'écoulement du LIQUIDE DE DIALYSE vers le DIALYSEUR;

– dans le mode HDF EN LIGNE ou HF EN LIGNE, l'arrêt de l'écoulement du LIQUIDE DE SUBSTITUTION vers le CIRCUIT EXTRACORPOREL.

b) Profils de conductivité et REGULATEURS PHYSIOLOGIQUES EN BOUCLE FERMEE:

En cas de variation préprogrammée en fonction du temps de la composition du LIQUIDE DE DIALYSE ou dans le cas d'un contrôle en retour de la composition du LIQUIDE DE DIALYSE par mesurage d'un paramètre physiologique pertinent du PATIENT, l'APPAREIL D'HEMODIALYSE doit inclure un SYSTEME DE PROTECTION, indépendant du système de contrôle, qui prévient les modifications involontaires éventuelles dans le système de contrôle susceptibles de provoquer une SITUATION DANGEREUSE.

L'activation du SYSTEME DE PROTECTION doit remplir les conditions de sécurité suivantes:

– activation de SIGNAUX D'ALARME sonores et visuels (voir 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);

– autres mesures, si elles sont définies par le PROCESSUS DE GESTION DES RISQUES DU FABRICANT.

c) Si l'APPAREIL D'HEMODIALYSE est équipé d'un dispositif d'administration des bolus en vue d'une modification provisoire de la composition du LIQUIDE DE DIALYSE, l'APPAREIL D'HEMODIALYSE doit inclure un SYSTEME DE PROTECTION, indépendant du système de contrôle, qui empêche la fonction d'administration des bolus d'entraîner une SITUATION DANGEREUSE pour le PATIENT.

L'activation du SYSTEME DE PROTECTION doit remplir les conditions de sécurité suivantes:

– activation de SIGNAUX D'ALARME sonores et visuels (voir 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);

– interruption de l'administration des bolus de composition du LIQUIDE DE DIALYSE.

La conformité est vérifiée par des essais fonctionnels et par les essais suivants en mode traitement.

Essai 1 pour la détermination de l'activation des SIGNAUX D'ALARME, à partir de l'étape 1:

– choisir une formulation type de concentré;

– régler les paramètres de traitement de l'unité en essai sur la composition de LIQUIDE DE DIALYSE la plus basse possible et attendre la stabilisation;

– manipuler lentement la composition du LIQUIDE DE DIALYSE vers une composition inférieure jusqu'à ce que le SYSTEME DE PROTECTION active le SIGNAL D'ALARME en fonction de la CONDITION D'ALARME spécifiée;

– prélever un échantillon à l'entrée du DIALYSEUR immédiatement après détection de la CONDITION D'ALARME;

– déterminer la composition du LIQUIDE DE DIALYSE de l'échantillon prélevé après détection de la CONDITION D'ALARME;

– la valeur mesurée doit se situer dans les limites spécifiées par le FABRICANT.

– *Pour l'étape 2, régler les paramètres de traitement sur la composition de LIQUIDE DE DIALYSE la plus basse possible et attendre la stabilisation, puis manipuler lentement la composition de LIQUIDE DE DIALYSE vers une composition supérieure jusqu'à ce que le SYSTEME DE PROTECTION active le SIGNAL D'ALARME en fonction de la CONDITION D'ALARME spécifiée.*

– *Pour l'étape 3, régler les paramètres de traitement sur la composition de LIQUIDE DE DIALYSE la plus élevée possible et attendre la stabilisation, puis manipuler lentement la composition de LIQUIDE DE DIALYSE vers une composition supérieure jusqu'à ce que le SYSTEME DE PROTECTION active le SIGNAL D'ALARME en fonction de la CONDITION D'ALARME spécifiée.*

– *Pour l'étape 4, régler les paramètres de traitement sur la composition de LIQUIDE DE DIALYSE la plus élevée possible et attendre la stabilisation, puis manipuler lentement la composition de LIQUIDE DE DIALYSE vers une composition inférieure jusqu'à ce que le SYSTEME DE PROTECTION active le SIGNAL D'ALARME en fonction de la CONDITION D'ALARME spécifiée.*

Essai 2 pour une réponse à une alarme effectuée à temps:

– *régler l'unité en essai sur le débit de LIQUIDE DE DIALYSE le plus élevé possible*;

– *simuler l'interruption complète de chacune des alimentations de CONCENTRE DE LIQUIDE DE DIALYSE, une par une (pour des exemples, voir l'Annexe AA, 201.15.4.1.101);*

– *prélever un échantillon à l'entrée du DIALYSEUR immédiatement après détection de la CONDITION D'ALARME;*

– *déterminer la composition du LIQUIDE DE DIALYSE des échantillons prélevés après détection de la CONDITION D'ALARME;*

– *la valeur mesurée doit se situer dans les limites spécifiées par le FABRICANT.*

Essai 3 pour un mauvais usage prévisible:

– *choisir une connexion type de concentré correcte;*

– *interchanger si possible la connexion des différents composants des* CONCENTRES DE LIQUIDE DE DIALYSE;

– *attendre que le* SYSTEME DE PROTECTION *active le* SIGNAL D'ALARME *en fonction de la* CONDITION D'ALARME *spécifiée;*

– *prélever un échantillon à l'entrée du* DIALYSEUR *immédiatement après détection de la* CONDITION D'ALARME*;*

– *déterminer la composition du* LIQUIDE DE DIALYSE *de l'échantillon prélevé après détection de la* CONDITION D'ALARME*;*

– *la valeur mesurée doit se situer dans les limites spécifiées par le* FABRICANT.

NOTE 2 Voir le 201.4.3.107 pour des méthodes de détermination de la composition du LIQUIDE DE DIALYSE.

201.12.4.4.102 * Température du LIQUIDE DE DIALYSE et du LIQUIDE DE SUBSTITUTION

a) Il ne doit pas être possible de régler la température du LIQUIDE DE DIALYSE et des LIQUIDES DE SUBSTITUTION en dehors d'une plage comprise entre 33 °C et 42 °C sauf justification par le PROCESSUS DE GESTION DES RISQUES DU FABRICANT.

b) L'APPAREIL D'HEMODIALYSE doit comporter un SYSTEME DE PROTECTION, indépendant de tout système de contrôle de température, qui empêche le LIQUIDE DE DIALYSE d'atteindre le DIALYSEUR et le LIQUIDE DE SUBSTITUTION d'atteindre le CIRCUIT EXTRACORPOREL à une température inférieure à 33 °C ou supérieure à 42 °C, mesurée à la sortie du liquide de dialyse et, le cas échéant, à la sortie du LIQUIDE DE SUBSTITUTION de l'APPAREIL D'HEMODIALYSE.

c) Les températures inférieures à 33 °C et jusqu'à 46 °C sont acceptables pendant une courte période, mais leurs durées et leurs valeurs doivent être justifiées dans le PROCESSUS DE GESTION DES RISQUES DU FABRICANT.

d) L'activation du SYSTEME DE PROTECTION doit remplir les conditions de sécurité suivantes:

   – activation de SIGNAUX D'ALARME sonores et visuels (voir 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101). Le SIGNAL D'ALARME sonore peut être retardé comme cela est spécifié au 208.6.3.3.101 b);

   – arrêt de l'écoulement du LIQUIDE DE DIALYSE en direction du DIALYSEUR et, le cas échéant, du LIQUIDE DE SUBSTITUTION en direction du CIRCUIT EXTRACORPOREL.

La conformité est vérifiée par des essais fonctionnels et par les essais suivants.

Essai 1 pour le LIQUIDE DE DIALYSE*:*

– *régler l'unité en essai sur le débit de* LIQUIDE DE DIALYSE *le plus élevé, si ce réglage est possible;*

– *définir la température du* LIQUIDE DE DIALYSE *la plus élevée et, dans une deuxième séquence d'essai, sa température la plus basse;*

– *attendre que les températures à l'entrée du* DIALYSEUR *soient stables;*

– *augmenter lentement, et dans une deuxième séquence d'essai, diminuer lentement la température du* LIQUIDE DE DIALYSE *jusqu'à ce que le* SYSTEME DE PROTECTION *active un* SIGNAL D'ALARME*;*

– *mesurer la température de manière continue à l'entrée du* DIALYSEUR *et déterminer la valeur maximale et, dans une deuxième séquence d'essai, la valeur minimale;*

– *la valeur maximale mesurée et, dans une deuxième séquence d'essai, la valeur minimale mesurée doivent se situer dans les valeurs spécifiées au point b) ou, le cas échéant, au point c).*

Essai 2 POUR LE LIQUIDE DE SUBSTITUTION:

– *régler l'unité en essai sur le débit de LIQUIDE DE SUBSTITUTION le plus élevé, si ce réglage est possible;*

– *définir la température du LIQUIDE DE DIALYSE/LIQUIDE DE SUBSTITUTION la plus élevée et, dans une deuxième séquence d'essai, leur température la plus basse;*

– *attendre que la température à l'entrée du CIRCUIT EXTRACORPOREL soit stable;*

– *augmenter lentement, et dans une deuxième séquence d'essai, diminuer lentement la température du LIQUIDE DE DIALYSE/LIQUIDE DE SUBSTITUTION jusqu'à ce que le SYSTEME DE PROTECTION active un SIGNAL D'ALARME;*

– *mesurer la température du LIQUIDE DE SUBSTITUTION de manière continue à l'entrée du CIRCUIT EXTRACORPOREL et déterminer la valeur maximale, ainsi que la valeur minimale dans une deuxième séquence d'essai;*

– *la valeur maximale mesurée et, dans une deuxième séquence d'essai, la valeur minimale mesurée doivent se situer dans les valeurs spécifiées au point b) ou, le cas échéant, au point c).*

201.12.4.4.103 * EXTRACTION NETTE DE LIQUIDE

a) L'APPAREIL D'HEMODIALYSE doit comporter un SYSTEME DE PROTECTION, indépendant de tout système de contrôle de l'ULTRAFILTRATION, qui empêche un écart de l'EXTRACTION NETTE DE LIQUIDE de l'APPAREIL D'HEMODIALYSE par rapport à la valeur de consigne des paramètres de contrôle, qui peuvent provoquer une SITUATION DANGEREUSE.

Dans le cas de la HDF et de la HF, l'APPAREIL D'HEMODIALYSE doit comporter un SYSTEME DE PROTECTION, indépendant de tout système de contrôle du LIQUIDE DE SUBSTITUTION, qui empêche toute erreur d'administration du LIQUIDE DE SUBSTITUTION qui peut provoquer une SITUATION DANGEREUSE.

L'activation du SYSTEME DE PROTECTION doit remplir les conditions de sécurité suivantes:

– activation de SIGNAUX D'ALARME sonores et visuels (voir 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);

– prévention de la prolongation d'une erreur d'équilibrage des liquides dangereux.

b) Profils d'ultrafiltration et régulateurs physiologiques en boucle fermée:

En cas de variation préprogrammée en fonction du temps de l'ULTRAFILTRATION ou dans le cas d'un contrôle en retour de l'ULTRAFILTRATION par un moniteur qui mesure un paramètre physiologique pertinent du PATIENT, l'APPAREIL D'HEMODIALYSE doit inclure un SYSTEME DE PROTECTION, indépendant du système de contrôle, qui prévient les modifications involontaires éventuelles dans le système de contrôle susceptibles de provoquer une SITUATION DANGEREUSE.

L'activation du SYSTEME DE PROTECTION doit remplir les conditions de sécurité suivantes:

– activation de SIGNAUX D'ALARME sonores et visuels (voir 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);

– autres mesures, si elles sont définies par le PROCESSUS DE GESTION DES RISQUES DU FABRICANT.

c) Si l'APPAREIL D'HEMODIALYSE est équipé d'un dispositif d'administration du liquide en bolus, l'APPAREIL D'HEMODIALYSE doit inclure un SYSTEME DE PROTECTION, indépendant du système de contrôle, qui empêche la fonction d'administration du liquide en bolus de provoquer une SITUATION DANGEREUSE pour le PATIENT.

L'activation du SYSTEME DE PROTECTION doit remplir les conditions de sécurité suivantes:

– activation de SIGNAUX D'ALARME sonores et visuels (voir 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);

– interruption de l'administration du liquide en bolus.

La conformité est vérifiée par des essais fonctionnels et des simulations de défaillance, y compris l'essai suivant:

Essais pour mesurer les écarts d'EXTRACTION NETTE DE LIQUIDE:

– *utiliser un réservoir pour simuler le PATIENT et le placer sur une balance;*

– *régler l'unité en essai sur le débit de LIQUIDE DE DIALYSE le plus élevé;*

– *définir le débit du LIQUIDE DE SUBSTITUTION le plus élevé, si cela est possible;*

– *régler la température du LIQUIDE DE DIALYSE à 37 °C, le cas échéant;*

– *définir le débit de l'EXTRACTION NETTE DE LIQUIDE le plus élevé et le plus faible (un par un);*

– *simuler une erreur avec un écart négatif et positif dans chacun des composants de contrôle de l'extraction de liquide (un par un) qui influencent l'EXTRACTION NETTE DE LIQUIDE jusqu'à ce que le SYSTEME DE PROTECTION active un SIGNAL D'ALARME;*

– *surveiller le poids du PATIENT simulé à l'aide de la balance;*

– *à l'activation du SIGNAL D'ALARME, la valeur ou le débit d'EXTRACTION NETTE DE LIQUIDE mesuré par la balance doit se situer dans les limites de l'EXTRACTION NETTE DE LIQUIDE spécifiées par le FABRICANT.*

201.12.4.4.104 Perte de sang extracorporelle

201.12.4.4.104.1 Perte de sang extracorporelle à l'extérieur

a) * L'APPAREIL D'HEMODIALYSE doit comporter un SYSTEME DE PROTECTION qui protège le PATIENT contre une perte de sang extracorporelle à l'extérieur, qui peut provoquer une SITUATION DANGEREUSE.

NOTE 1 Au moment de la rédaction du présent document, aucun système qui pouvait être totalement fiable pour détecter une perte de sang à l'extérieur n'avait été développé.

Si un SYSTEME DE PROTECTION utilise le mesurage de la PRESSION VEINEUSE, il convient que l'OPERATEUR dispose au moins d'un moyen de réglage manuel de la LIMITE D'ALARME inférieure à une valeur aussi proche que possible de la valeur de mesure actuelle. Le mode de traitement à aiguille unique nécessite des mesures supplémentaires ou d'autres mesures.

b) L'APPAREIL D'HEMODIALYSE doit comporter un SYSTEME DE PROTECTION qui protège le PATIENT contre une perte de sang extracorporelle à l'extérieur provoquée par une rupture ou une séparation dans le CIRCUIT EXTRACORPOREL, par suite d'une pression excessive, à moins qu'une conception à sécurité intrinsèque ne permette de l'éviter.

NOTE 2 Ce phénomène n'est pas lié à la séparation de la CONNEXION PATIENT ou de l'aiguille d'entrée, mais à la pression potentielle qui peut être générée par la pompe susceptible de provoquer une rupture de la tubulure ou une séparation d'un raccord dans le CIRCUIT EXTRACORPOREL.

c) * L'activation du SYSTEME DE PROTECTION doit remplir les conditions de sécurité suivantes:

– activation de SIGNAUX D'ALARME sonores et visuels (voir 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);

– arrêt de l'écoulement du sang à l'extérieur provoqué par l'APPAREIL D'HEMODIALYSE, même en CONDITION DE PREMIER DEFAUT;

– dans le cas de l'hémofiltration ou de l'hémodiafiltration, arrêt de l'écoulement du liquide de substitution.

La conformité est vérifiée par des essais fonctionnels et par l'essai suivant en mode traitement.

Essai pour les SYSTEMES DE PROTECTION qui utilisent le mesurage de la PRESSION VEINEUSE:

– *régler l'unité en essai sur un flux sanguin moyen;*

– *créer une valeur de traitement type pour la PRESSION VEINEUSE;*

– *régler la LIMITE D'ALARME basse aussi près que possible de la pression veineuse*;

– *réduire la PRESSION VEINEUSE jusqu'à l'activation d'un SIGNAL D'ALARME;*

– *déterminer la différence de la PRESSION VEINEUSE mesurée par rapport à la limite définie lors de l'activation du SIGNAL D'ALARME;*

– *la différence calculée ne doit pas dépasser la précision déclarée par le FABRICANT pour la ou les LIMITES D'ALARME du SYSTEME DE PROTECTION (voir 201.7.9.3.1, tiret 10);*

– *le cas échéant, le retard introduit par un SYSTEME D'ALARME INTELLIGENT ne doit pas dépasser la valeur déclarée par le FABRICANT (voir 201.7.9.3.1, tiret 10).*

201.12.4.4.104.2 * FUITE DE SANG en direction du LIQUIDE DE DIALYSE

a) L'APPAREIL D'HEMODIALYSE doit comporter un SYSTEME DE PROTECTION qui protège le PATIENT contre une FUITE DE SANG, qui peut provoquer une SITUATION DANGEREUSE.

b) L'activation du SYSTEME DE PROTECTION doit remplir les conditions de sécurité suivantes:

– activation de SIGNAUX D'ALARME sonores et visuels (voir 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);

– prévention de perte de sang supplémentaire vers le LIQUIDE DE DIALYSE.

c) Inhibition du SYSTEME DE PROTECTION pour la fuite de sang:

– le temps d'inhibition ne doit pas dépasser 3 min;

– dans certaines conditions cliniques, le PROCESSUS DE GESTION DES RISQUES peut accepter l'inhibition du détecteur de FUITE DE SANG pendant plus de 3 min avec la durée maximale d'un traitement unique;

– l'activation de l'inhibition doit maintenir au moins une indication visuelle du SYSTEME DE PROTECTION inhibé pour la FUITE DE SANG.

La conformité est vérifiée par examen des DOCUMENTS D'ACCOMPAGNEMENT, par des essais fonctionnels et par l'essai suivant.

Essai pour la détermination des LIMITES D'ALARME:

– *régler le débit maximal à travers le détecteur de FUITE DE SANG (débit de LIQUIDE DE DIALYSE le plus élevé, débit d'ULTRAFILTRATION le plus élevé, et également, le cas échéant, débit du LIQUIDE DE SUBSTITUTION le plus élevé);*

– *ajouter du sang bovin, humain ou porcin (hématocrite Hct 32 % ± 2 %) au LIQUIDE DE DIALYSE jusqu'à l'activation d'un SIGNAL D'ALARME;*

– *déterminer la différence de la FUITE DE SANG appliquée par rapport à la LIMITE D'ALARME spécifiée par le FABRICANT;*

– *la différence calculée ne doit pas dépasser la précision déclarée par le FABRICANT pour la ou les LIMITES D'ALARME du SYSTEME DE PROTECTION (voir 201.7.9.3.1, tiret 11).*

201.12.4.4.104.3 * Perte de sang extracorporelle due à la coagulation

a) L'APPAREIL D'HEMODIALYSE doit comporter un SYSTEME DE PROTECTION qui protège le PATIENT contre une perte de sang due à une coagulation consécutive à l'interruption du flux sanguin qui peut provoquer une SITUATION DANGEREUSE.

NOTE Une méthode acceptable pour satisfaire à cette exigence est, par exemple, un SYSTEME DE PROTECTION qui intervient pendant une période plus longue en cas d'arrêt volontaire ou intempestif de la ou des pompes sanguines.

b) L'entrée en action du SYSTEME DE PROTECTION doit activer un SIGNAL D'ALARME sonore et visuel (voir 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101).

c) Les autres effets, non couverts par 201.12.4.4.106, qui peuvent entraîner une perte de sang due à la coagulation, doivent être traités dans le PROCESSUS DE GESTION DES RISQUES DU FABRICANT (par exemple, des débits excessifs du LIQUIDE DE SUBSTITUTION dans le cas de HDF ou HF en post-dilution peuvent entraîner une coagulation par hémoconcentration à la pression sanguine de sortie du DIALYSEUR.

La conformité est vérifiée par un essai fonctionnel et une simulation de défaillance.

201.12.4.4.105 * Infusion d'air

a) L'APPAREIL D'HEMODIALYSE doit comporter un SYSTEME DE PROTECTION qui protège le PATIENT contre une infusion d'air, en CONDITION NORMALE et en CONDITION DE PREMIER DEFAUT, qui peut provoquer une SITUATION DANGEREUSE.

NOTE 1 Une méthode acceptable pour satisfaire à cette exigence est, par exemple, un SYSTEME DE PROTECTION qui utilise un détecteur d'air (par exemple, ultrasonique) capable de détecter de l'air non dissous.

b) L'activation du SYSTEME DE PROTECTION doit remplir les conditions de sécurité suivantes:

– activation de SIGNAUX D'ALARME sonores et visuels (voir 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);

– prévention d'infusion d'air dangereux supplémentaire par les lignes de sang artérielles et veineuses, même en CONDITION DE PREMIER DEFAUT.

NOTE 2 La prévention d'infusion d'air supplémentaire peut habituellement être réalisée par arrêt de la pompe sanguine et par clampage de la ligne de sang veineuse.

La conformité est vérifiée par des essais fonctionnels suivant les principes de l'essai ci-dessous et par examen du DOSSIER DE GESTION DES RISQUES.

NOTE 3 Les valeurs indiquées dans les essais constituent des exemples, et sont définies par le FABRICANT.

NOTE 4 Il existe deux méthodes de surveillance de l'infusion d'air:

a) au niveau d'un piège à air (par exemple, à la chambre compte-gouttes du circuit veineux) dans lequel des forces de poussée agissent sur les bulles d'air de telle sorte que celles-ci sont empêchées de sortir du piège à air avec un niveau de réglage correct, la méthode de surveillance de bulles d'air utilisée ici est la méthode pour surveiller le niveau;

b) directement au niveau de la ligne de sang (les bulles d'air se diffusent dans le liquide en circulation), dans laquelle le volume d'air peut être déterminé par la vitesse d'écoulement.

Deux PROCEDURES d'essai différentes existent, indépendantes des méthodes de surveillance de l'air décrites à la Note 4.

Essai d'infusion d'air continue:

– *installer l'APPAREIL D'HEMODIALYSE avec un dialyseur capillaire étalon (par exemple, de surface comprise entre 1 m^2 et 1,5 m^2), le CIRCUIT EXTRACORPOREL recommandé et des canules (par exemple, de taille 16);*

– *arrêter l'écoulement du LIQUIDE DE DIALYSE vers et en provenance du DIALYSEUR;*

NOTE 5 Si un LIQUIDE DE DIALYSE dégazé est en circulation, le gaz est extrait par le DIALYSEUR. L'arrêt de l'écoulement peut être obtenu par une dérivation totale de l'écoulement de LIQUIDE DE DIALYSE, le clampage des conduites de LIQUIDE DE DIALYSE ou l'interconnexion de l'entrée et de la sortie du dialyseur.

– *faire fonctionner le CIRCUIT EXTRACORPOREL avec du sang hépariné (humain, bovin ou porcin) avec un Hct défini (par exemple, Hct compris entre 0,25 et 0,35) ou avec un liquide d'essai approprié;*

NOTE 6 Si un liquide autre que le sang est choisi, son équivalence avec le sang est démontrée et documentée dans le DOSSIER DE GESTION DES RISQUES, à la fois en matière de viscosité et de spallation des bulles de gaz.

– *positionner un conteneur de stockage du liquide d'essai à un niveau de, par exemple, 100 cm (±20 cm) du sol;*

– *positionner un conteneur de collecte du liquide d'essai à un niveau de, par exemple, 1100 cm (±20 cm) du sol ou faire recirculer le liquide dans le conteneur de stockage;*

– *placer verticalement au moins un tube à essai, de diamètre de, par exemple, 8 mm et d'une longueur de, par exemple, 2,0 m, par suite d'un deuxième tube de plus petit diamètre (par exemple de 4,3 mm et d'une longueur de 20 cm), directement au niveau du connecteur veineux du PATIENT, dans le trajet veineux entre le connecteur PATIENT et le conteneur de collecte (voir, à titre d'exemple, le montage à la Figure 201.101). Les tubes à essai doivent être entièrement amorcés;*

NOTE 7 Le volume du deuxième tube de plus petit diamètre permet de collecter tout l'air prévu.

NOTE 8 Compte tenu du mesurage du volume d'air collecté dans le tube de plus petit diamètre (ci-après dénommé tube de mesure de l'air), un tube supplémentaire peut être inséré afin d'assurer l'égalisation de la pression piégée à l'atmosphère par l'ouverture de la pince à clamper correspondante avant de mesurer le volume d'air. Lorsque la ligne d'équilibre est présente, il est recommandé de la positionner sous le tube de mesure de l'air, ainsi que de l'amorcer avant de commencer l'injection d'air. Concernant la position recommandée de la ligne d'équilibre, se reporter à la Ligne d'équilibre de l'atmosphère à la Figure 201.101.

– *insérer une canule amorcée (par exemple, de taille 22) dans la tubulure de sang artériel, dans la section à pressions négatives, près du raccordement à la canule artérielle (retrait de sang) et la raccorder à une pompe à seringue capable de contrôler l'injection d'air dans des conditions de pression négative;*

NOTE 9 Une autre méthode possible est l'utilisation d'une petite pompe péristaltique réversible. Cette pompe est initialement amorcée avec le liquide d'essai, en la faisant fonctionner en mode inverse pour éviter une injection d'air incontrôlée, lorsque la pompe sanguine est démarrée. Un clapet antiretour entre l'aiguille et la pompe peut être utilisé.

– *régler la vitesse de la pompe sanguine avec une pression négative définie en amont de la pompe (par exemple, entre –200 mmHg et –250 mmHg);*

– *injecter l'air à des débits croissants jusqu'à ce que le SYSTEME DE PROTECTION active un SIGNAL D'ALARME;*

NOTE 10 La justification de cet essai repose sur l'hypothèse selon laquelle, avec la fermeture de la conduite de LIQUIDE DE DIALYSE, l'air ne peut pas s'échapper du CIRCUIT EXTRACORPOREL.

– *serrer le tube à essai à l'aide de la pince à clamper selon la Figure 201.101 aux deux extrémités, immédiatement après le SIGNAL D'ALARME du détecteur d'air;*

– *ouvrir la pince à clamper sur la ligne d'équilibre, lorsqu'elle existe. Mesurer le volume d'air qui se développe au niveau du sommet vertical du tube à essai de petit diamètre après une durée de 15 min lorsque les bulles d'air combinées forment un volume d'air plein;*

– *calculer le débit d'air en fonction du flux sanguin, le volume du tube à essai et le volume d'air mesuré comme suit:*

$$Q_{air} = Q_b \times V_{air}/V_{tube}$$

où:

Q_{air} *est le débit d'air;*

Q_b *est le flux sanguin; le mesurage direct du flux sanguin dans la ligne de sang veineuse est recommandé;*

V_{air} *est le volume d'air collecté dans le tube à essai;*

V_{tube} *est le volume du tube à essai;*

– *le débit d'air calculé doit être inférieur à la limite de débit d'infusion d'air continue identifiée par la GESTION DES RISQUES;*

– *si l'APPAREIL D'HEMODIALYSE permet au DIALYSEUR de fonctionner avec un flux sanguin qui remonte à travers celui-ci ou, en variante, avec un flux sanguin qui descend dans le DIALYSEUR, des essais distincts d'infusion d'air continue doivent être réalisés dans les deux directions du flux;*

– *si l'ANALYSE DE RISQUE révèle des voies d'injection d'air en aval de la pompe sanguine qui conduisent à une infusion d'air continue qui peut provoquer une SITUATION DANGEREUSE (par exemple, par une pompe d'ajustage du niveau), l'essai d'infusion d'air continue doit être répété par un pompage de l'air en ce point, au débit spécifié, dans le CIRCUIT EXTRACORPOREL.*

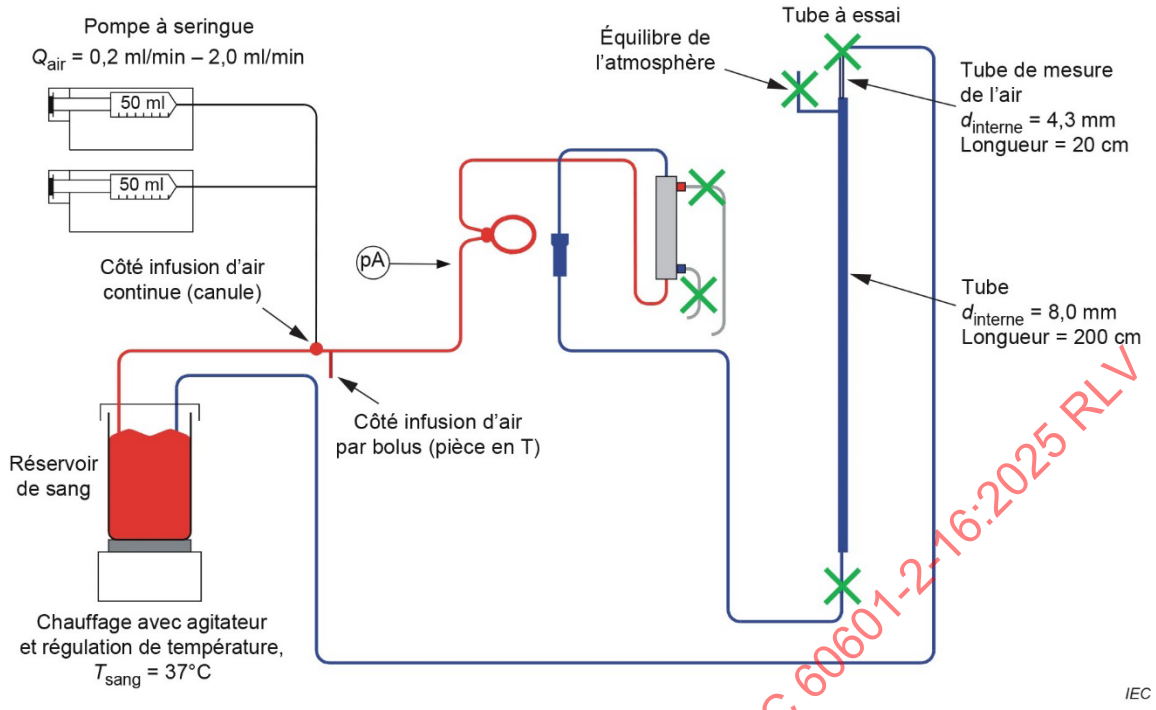

Figure 201.101 – Montage d'essai pour l'infusion d'air avec des exemples de dimensions

- *Essai d'infusion d'air par bolus:*
  - *installer l'APPAREIL D'HEMODIALYSE avec un dialyseur capillaire étalon (par exemple, de surface comprise entre 1 m² et 1,5 m²), le CIRCUIT EXTRACORPOREL recommandé et des canules (par exemple, de taille 16);*
  - *serrer à l'aide de la pince à clamper ou fermer les conduites du LIQUIDE DE DIALYSE après amorçage;*

    NOTE 11 Cette situation est une condition de cas le plus défavorable. Si un LIQUIDE DE DIALYSE dégazé est en circulation, le gaz est extrait par le DIALYSEUR.

  - *faire fonctionner le CIRCUIT EXTRACORPOREL avec du sang hépariné avec un Hct défini (par exemple, compris entre 0,25 et 0,35, sang humain, bovin et porcin) ou avec un liquide d'essai approprié;*

    NOTE 12 Si un liquide autre que le sang est choisi, son équivalence avec le sang est démontrée et documentée dans le DOSSIER DE GESTION DES RISQUES, à la fois en matière de viscosité et de spallation des bulles de gaz.

  - *positionner un conteneur de stockage du liquide d'essai à un niveau de, par exemple, 100 cm (±20 cm) du sol;*
  - *positionner un conteneur de collecte du liquide d'essai à un niveau de, par exemple, 1100 cm (±20 cm) du sol ou faire recirculer le liquide dans le conteneur de stockage;*
  - *placer un cylindre de mesure gradué, ou les mêmes tubes à essai que ceux utilisés dans le montage d'essai d'infusion d'air continue, de telle façon que tout l'air qui est pompé par la canule de retour (veineux) soit collecté;*

    NOTE 13 Compte tenu du mesurage du volume d'air collecté dans le petit tube, un tube supplémentaire peut être inséré afin d'assurer l'égalisation de la pression piégée à l'atmosphère par l'ouverture de la pince à clamper correspondante avant de mesurer le volume d'air. Lorsque la ligne d'équilibre est présente, elle est positionnée au-dessus du niveau attendu atteignable par l'air ainsi que complètement amorcée avant de commencer l'injection d'air. Voir la ligne d'équilibre de l'atmosphère à la Figure 201.101.

  - *relier une pièce en T avec des raccords Luer à la tubulure de sang artériel de la section de pressions négatives à proximité du raccordement à la canule (de retrait du sang) artériel;*

- *raccorder à la pièce en T une section de tube (par exemple de 5 cm de longueur) avec un raccord Luer;*
- *amorcer le CIRCUIT EXTRACORPOREL et ladite section de tube. Serrer la section de tube à l'aide de la pince à clamper;*
- *régler la vitesse de la pompe sanguine avec une pression négative définie en amont de la pompe (par exemple, entre 0 mmHg et –250 mmHg) de sorte qu'aucune CONDITION D'ALARME de pression n'apparaisse dans le CIRCUIT EXTRACORPOREL à l'ouverture de la pince à clamper;*
- *ouvrir la pince à clamper au niveau de la section de tube et attendre l'apparition d'une CONDITION D'ALARME qui empêche toute nouvelle infusion dangereuse d'air;*
- *ouvrir la pince à clamper sur la ligne d'équilibre, lorsqu'elle est présente. Mesurer la quantité d'air collecté dans le cylindre de mesure gradué ou dans le tube à essai;*
- *le volume d'air collecté doit être inférieur à la limite de débit d'infusion d'air par bolus identifiée par la GESTION DES RISQUES;*
- *si l'APPAREIL D'HEMODIALYSE permet au DIALYSEUR de fonctionner avec un flux sanguin qui remonte à travers celui-ci ou, en variante, avec un flux sanguin qui descend dans le DIALYSEUR, des essais distincts d'infusion d'air par bolus doivent être réalisés dans les deux directions du flux;*
- *si l'ANALYSE DE RISQUE révèle des voies d'injection d'air en aval de la pompe sanguine qui conduisent à une infusion d'air par bolus qui peut provoquer une SITUATION DANGEREUSE par exemple, par une pompe d'ajustage du niveau), l'essai d'infusion d'air par bolus doit être répété par un pompage de l'air en ce point, au débit maximal, dans le CIRCUIT EXTRACORPOREL.*

201.12.4.4.106 * Anticoagulation

S'il est prévu que l'APPAREIL D'HEMODIALYSE comporte un dispositif de transmission d'anticoagulant et si un arrêt/démarrage non automatisé de ce dispositif peut provoquer une SITUATION DANGEREUSE, le système de contrôle doit interrompre le fonctionnement du dispositif de transmission d'anticoagulant par l'arrêt de la pompe sanguine pendant le traitement dû à une entrée d'asservissement de l'OPERATEUR ou en raison de l'arrêt par un SYSTEME DE PROTECTION de la pompe sanguine. Le système de contrôle doit également relancer la transmission d'anticoagulant en cours lors du rétablissement de la CONDITION D'ALARME ou de la reprise du traitement.

NOTE 1 Si la pompe sanguine fonctionne, il est pratique que l'utilisateur soit capable d'arrêter ou de démarrer manuellement le dispositif d'anticoagulation.

NOTE 2 L'APPAREIL D'HEMODIALYSE peut fournir une fonction automatisée d'arrêt de l'anticoagulation pendant une durée spécifiée avant la fin du traitement.

Le PROCESSUS DE GESTION DES RISQUES DU FABRICANT doit prendre en considération au moins les SITUATIONS DANGEREUSES suivantes, le cas échéant.

- L'arrêt ou l'absence de démarrage de tout dispositif de transmission d'anticoagulant.
- Un dosage incorrect de la ou des solutions anticoagulantes du fait d'une première anomalie du dispositif de transmission d'anticoagulant, par exemple, débit(s) de transmission, rapport de débit(s) de transmission, rapport de débit(s) de transmission comparé au flux sanguin.
- Un dosage incorrect de la solution anticoagulante dans des conditions de pression négative dans le CIRCUIT EXTRACORPOREL en cas de dosage d'un dispositif de transmission d'anticoagulant en amont de la pompe sanguine.
- Un échange des solutions par erreur, lorsque deux solutions anticoagulantes ou plus sont utilisées à des fins d'anticoagulation dans le cadre d'un traitement.
- Une infusion d'air ou un écoulement intempestif du liquide à solution anticoagulante par l'intermédiaire de la CONNEXION PATIENT artérielle du fait d'un mauvais débit de transmission ou d'une transmission avec la pompe sanguine à l'arrêt, notamment en cas de dosage d'un dispositif de transmission d'anticoagulant en amont de la pompe sanguine.

– Une infusion d'air ou un écoulement intempestif du liquide à solution anticoagulante par l'intermédiaire de la CONNEXION PATIENT veineuse du fait d'un mauvais débit de transmission ou d'une transmission avec la pompe sanguine à l'arrêt, notamment en cas de dosage d'un dispositif de transmission d'anticoagulant en aval du détecteur d'air.
– Une perte de sang par inversion de l'écoulement ou des écoulements du liquide à solution anticoagulante du fait d'une première anomalie du dispositif de transmission d'anticoagulant ou par une fixation incorrecte du ou des pistons de seringue.
– Un réglage incorrect des paramètres d'anticoagulation par rapport aux valeurs prescrites.

La conformité est vérifiée par examen du DOSSIER DE GESTION DES RISQUES et par des essais fonctionnels.

201.12.4.4.107 SYSTEMES DE PROTECTION

Tous les SYSTEMES DE PROTECTION doivent être actifs tout au long du traitement, lorsque le sang du CIRCUIT EXTRACORPOREL atteint le PATIENT jusqu'à la déconnexion de l'aiguille veineuse. De plus, les SYSTEMES DE PROTECTION relatifs à la composition et à la température du LIQUIDE DE DIALYSE doivent être activés avant le premier contact du LIQUIDE DE DIALYSE avec le sang dans le DIALYSEUR.

Une activation retardée des SYSTEMES DE PROTECTION après le début ou la reprise du traitement est possible si elle ne provoque pas de SITUATION DANGEREUSE.

Une défaillance des SYSTEMES DE PROTECTION exigés par les paragraphes 201.12.4.4.101 à 201.12.4.4.105 doit apparaître de manière évidente à l'OPERATEUR, dans les limites de temps suivantes:

a) pour tous les SYSTEMES DE PROTECTION, à l'exception de ceux définis au 201.12.4.4.105 (infusion d'air):
   – au moins une fois par jour, ou, si cela n'est pas possible, comme cela est déterminé par le PROCESSUS DE GESTION DES RISQUES DU FABRICANT;

     NOTE Par exemple, les méthodes acceptables de mise en conformité avec cette exigence sont les suivantes:

     • la vérification fonctionnelle périodique des SYSTEMES DE PROTECTION demandée par l'APPAREIL D'HEMODIALYSE, déclenchée et contrôlée par l'OPERATEUR;
     • la vérification fonctionnelle périodique des SYSTEMES DE PROTECTION demandée par l'APPAREIL D'HEMODIALYSE déclenchée par l'OPERATEUR et contrôlée par l'APPAREIL D'HEMODIALYSE;
     • la redondance des SYSTEMES DE PROTECTION avec l'autovérification par l'APPAREIL D'HEMODIALYSE;
     • la vérification fonctionnelle périodique des SYSTEMES DE PROTECTION déclenchée et contrôlée par l'APPAREIL D'HEMODIALYSE, si la fonction de contrôle est conçue de telle sorte qu'elle ne puisse pas connaître de défaillance en même temps que le SYSTEME DE PROTECTION correspondant du fait d'une défaillance unique.

b) pour le SYSTEME DE PROTECTION exigé par 201.12.4.4.105 (infusion d'air):
   – si une quantité d'air peut être infusée vers le PATIENT, ce qui peut provoquer une SITUATION DANGEREUSE du fait d'un premier défaut du détecteur d'air, le temps de détection maximal pour ce défaut est calculé comme étant le temps de tolérance du défaut:
   – le volume minimal du CIRCUIT EXTRACORPOREL entre la position du détecteur d'air et la canule veineuse, divisé par le flux sanguin le plus élevé;
   – dans tous les autres cas, a) s'applique.

Chaque défaillance d'un SYSTEME DE PROTECTION exigé par 201.12.4.4 doit neutraliser la fonction correspondante contrôlée par le SYSTEME DE PROTECTION associé. L'OPERATEUR doit en être informé.

La conformité est vérifiée par des essais fonctionnels et des simulations de défaillance.

201.12.4.4.108 * Prévention de la contamination par les produits chimiques

a) Il ne doit pas être possible de traiter le PATIENT pendant que l'APPAREIL D'HEMODIALYSE est en mode nettoyage, stérilisation ou désinfection. Les 4.7 et 11.8 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'appliquent.

b) Les produits chimiques (par exemple, l'eau, le LIQUIDE DE DIALYSE, le désinfectant ou le CONCENTRE DE LIQUIDE DE DIALYSE) ne doivent pas s'écouler de l'APPAREIL D'HEMODIALYSE dans le sens inverse d'une ligne d'alimentation, même en CONDITION DE PREMIER DEFAUT.

c) La connexion erronée du désinfectant, spécifié par le FABRICANT pour une utilisation avec l'APPAREIL D'HEMODIALYSE en lieu et place du CONCENTRE DE LIQUIDE DE DIALYSE, ne doit pas provoquer de SITUATION DANGEREUSE.

La conformité est vérifiée par des essais fonctionnels, des simulations de défaillance et l'examen du DOSSIER DE GESTION DES RISQUES.

201.12.4.4.109 * Inversion de la ou des pompes sanguines et, le cas échéant, à LIQUIDE DE SUBSTITUTION

Une méthode doit être comprise pour empêcher l'inversion accidentelle, en cours de traitement, de la ou des pompes sanguines et/ou à LIQUIDE DE SUBSTITUTION, qui peut provoquer une SITUATION DANGEREUSE.

Les SITUATIONS DANGEREUSES applicables (par exemple, infusion d'air par l'intermédiaire de la ligne de sang artérielle) doivent être déterminées par le PROCESSUS DE GESTION DES RISQUES DU FABRICANT. Les ERREURS D'UTILISATION doivent être prises en compte, ainsi que les défaillances techniques.

La conformité est vérifiée par examen et par des essais fonctionnels.

201.12.4.4.110 Sélection et changement des modes de fonctionnement

La sélection et le changement accidentels des modes de fonctionnement doivent être empêchés. Les ERREURS D'UTILISATION ainsi que les défaillances techniques doivent être prises en compte.

La conformité est vérifiée par examen et par des essais fonctionnels.

201.12.4.4.111 HDF EN LIGNE et HF EN LIGNE

Si l'APPAREIL D'HEMODIALYSE est destiné à une HEMOFILTRATION EN LIGNE (HF EN LIGNE), une HEMODIAFILTRATION EN LIGNE (HDF EN LIGNE) ou une préparation en ligne d'autres liquides d'infusion ou de rinçage (par exemple, application de bolus en ligne ou amorçage en ligne du CIRCUIT EXTRACORPOREL), le FABRICANT doit assurer que l'APPAREIL D'HEMODIALYSE doit être capable de produire un LIQUIDE DE SUBSTITUTION qui satisfait aux exigences (par exemple, microbiologiques, voir l'ISO 23500-5 [7] et l'ISO 23500-1 [6]) d'une solution destinée à être injectée directement dans le sang des patients, lorsque les instructions du FABRICANT sont suivies. Cette exigence doit aussi être respectée en CONDITION DE PREMIER DEFAUT selon le PROCESSUS DE GESTION DES RISQUES DU FABRICANT.

La conformité est vérifiée par examen du DOSSIER DE GESTION DES RISQUES et par des essais fonctionnels.

201.13 Situations dangereuses et conditions de défaut pour les APPAREILS EM

L'Article 13 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec l'exception suivante:

201.13.2.6 * Fuite de liquide

Addition:

Les parties de l'APPAREIL D'HEMODIALYSE qui transportent du liquide doivent être construites de sorte que le liquide qui peut fuir sous l'effet d'une pression de fonctionnement normale n'expose pas le PATIENT à des DANGERS dus au contact avec des parties électriques, par exemple en raison d'un court-circuit des LIGNES DE FUITE.

La conformité est vérifiée par l'essai suivant:

a) à l'aide d'une pipette, des gouttes d'eau potable sont appliquées sur les raccords, les joints et les tubulures susceptibles de se rompre, les parties mobiles étant en fonctionnement ou au repos, selon la condition la moins favorable;

et en cas de doute avec l'essai a):

b) à l'aide d'une seringue, un jet d'un liquide approprié pour la partie de l'APPAREIL D'HEMODIALYSE est dirigé depuis les raccords, les joints et les tubulures susceptibles de se rompre, les parties mobiles étant en fonctionnement ou au repos, selon la condition la moins favorable.

Après ces PROCEDURES, l'APPAREIL D'HEMODIALYSE ne doit présenter aucun signe de mouillage des parties des parties électriques non isolées ou d'isolation électrique susceptible d'être dégradée par l'eau potable ou le liquide choisi. En cas de doute, l'APPAREIL D'HEMODIALYSE doit être soumis à l'essai de tension de tenue spécifié au 8.8.3 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020.

La détermination d'autres DANGERS et SITUATIONS DANGEREUSES est vérifiée par examen de l'APPAREIL D'HEMODIALYSE.

201.14 SYSTEMES ELECTROMEDICAUX PROGRAMMABLES (SEMP)

L'Article 14 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.14.13 * SEMP destiné à être incorporé dans un RESEAU IT

Addition:

Le transfert de données entre le RESEAU IT et l'APPAREIL D'HEMODIALYSE ne doit pas provoquer de SITUATION DANGEREUSE pour le PATIENT en CONDITION DE PREMIER DEFAUT.

NOTE 101 Indépendamment du présent document, l'IEC 80001-1:2021 [8] comprend des exigences qui stipulent que chaque FABRICANT DE DISPOSITIFS MEDICAUX mette à disposition de l'ORGANISME RESPONSABLE des DOCUMENTS D'ACCOMPAGNEMENT contenant des informations sur les capacités du RESEAU IT du DISPOSITIF MEDICAL.

La conformité est vérifiée par examen du DOSSIER DE GESTION DES RISQUES.

Paragraphe supplémentaire:

201.14.13.101 * Caractéristiques de sécurité spécifiques pour les APPAREILS D'HEMODIALYSE utilisés dans les RESEAUX IT MEDICAUX

Les APPAREILS D'HEMODIALYSE utilisés dans les RESEAUX IT MEDICAUX doivent contribuer à un fonctionnement sûr en matière de SECURITE (CYBERSECURITE).

Cela peut être réalisé, entre autres, en suivant les recommandations du rapport technique IEC TR 60601-4-5:2021 [9], qui fournit des recommandations pour l'établissement de spécifications techniques de SECURITE (CYBERSECURITE). Le présent document invite également les rédacteurs de normes particulières à inclure des recommandations de base pour la détermination, par les FABRICANTS, des caractéristiques spécifiques de SECURITE (CYBERSECURITE) applicables aux DISPOSITIFS MEDICAUX (4.6.3) pour les environnements spécifiques d'utilisation prévue des DISPOSITIFS MEDICAUX couverts par la norme particulière.

Si l'IEC TR 60601-4-5:2021 est utilisée, il convient de mettre en œuvre, selon le cas, des CONTRE-MESURES DE SECURITE comme cela est spécifié dans les Articles 4 à 7, avec les ajouts spécifiques suivants apportés au 4.6.3 en ce qui concerne les environnements spécifiques d'utilisation prévue à la dialyse:

– IEC TR 60601-4-5:2021, 4.6.3: "*outre la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES, la FONCTION ESSENTIELLE appropriée du groupe de produits exigée (par exemple, la DISPONIBILITE en cas d'attaques de SECURITE contre le RESEAU IT MEDICAL et les dispositifs connectés), même avec une fonctionnalité IT temporairement réduite du DISPOSITIF MEDICAL*".

  Normalement, les traitements de dialyse sont effectués dans un environnement clinique ou à domicile à accès contrôlé sous surveillance continue pendant les traitements, où le risque d'agressions physiques est limité. À cet égard, pendant ou après des attaques sur le RESEAU IT MEDICAL ou les connexions sans fil aux APPAREILS D'HEMODIALYSE, il est recommandé que l'opérateur soit en mesure de redémarrer le traitement sans connexion IT/sans fil, y compris de procéder à la désactivation de la fonctionnalité IT/sans fil pour effectuer des traitements de base, avec la possibilité de définir ou de rappeler les paramètres individuels de PERFORMANCE ESSENTIELLE du patient spécifiés dans le présent document (201.4.3.101) dans un scénario hors ligne sur l'APPAREIL D'HEMODIALYSE.

– IEC TR 60601-4-5:2021, 4.6.3: *"fonctions d'ALERTE INCENDIE spécifiques appropriées pour l'accès d'urgence afin d'avoir la possibilité de contourner les mesures de SECURITE et la façon dont elles sont gérées (par exemple, par la journalisation, la signalisation des informations, le déclenchement d'une alarme) en cas de contournement intentionnel d'une mesure de SECURITE en raison de besoins de SECURITE prioritaires*".

  En raison de l'accès contrôlé aux environnements de soins cliniques ou à domicile avec une surveillance continue pendant les traitements, les APPAREILS D'HEMODIALYSE n'exigent normalement pas de procédure d'authentification ou d'autorisation pour un accès au traitement normal. Par conséquent, aucune fonction supplémentaire d'ALERTE INCENDIE n'est nécessaire, à part la possibilité de déconnecter l'accès au réseau attaqué (y compris les connexions sans fil).

  Si l'authentification des opérateurs pour les réglages de traitement accessibles à l'opérateur est en place pour l'interface utilisateur, il convient qu'une fonction d'ALERTE INCENDIE soit en mesure d'annuler cette authentification de l'opérateur combinée à une entrée de journal protégée contre les modifications par l'opérateur. Les interfaces de RESEAUX IT y compris celles de l'accès à distance, exigent généralement une authentification, mais il convient qu'elles ne comportent pas de fonction d'ALERTE INCENDIE, dans la mesure où un opérateur se trouve toujours à proximité de l'APPAREIL D'HEMODIALYSE et du patient.

– IEC TR 60601-4-5:2021, 4.6.3: "*NIVEAU DE SECURITE SL-T cible minimal approprié pour tous les environnements d'UTILISATION PREVUE, y compris les intégrations de réseau existant normalement dans ces environnements d'utilisation dans lesquels les APPAREILS EM sont généralement utilisés. Si des NIVEAUX DE SECURITE pour les environnements d'utilisation sont définis par d'autres documents, il convient de les prendre en compte et de les référencer*".

Selon les environnements d'utilisation prévue et les conceptions des APPAREILS D'HEMODIALYSE, le NIVEAU DE SECURITE SL-T cible suivant peut être considéré par hypothèse comme approprié:

- APPAREILS D'HEMODIALYSE à domicile non connectés: SL1 – Protection contre les violations occasionnelles ou fortuites;
- APPAREILS D'HEMODIALYSE dans une unité de dialyse ou un environnement clinique non connecté ou connecté dans un réseau médical séparé du réseau public: SL2 – Protection contre les violations intentionnelles par des moyens simples avec de faibles ressources, des compétences génériques et une faible motivation;
- APPAREILS D'HEMODIALYSE dans une unité de dialyse ou un environnement clinique connecté à un réseau médical non séparé du réseau public/de l'Internet ou comprenant une communication sans fil: SL3 – Protection contre les violations intentionnelles par des moyens sophistiqués avec des ressources modérées, des compétences spécifiques à l'IACS et une motivation modérée;
- APPAREILS D'HEMODIALYSE domestiques connectés à l'Internet: SL4 – Protection contre les violations intentionnelles par des moyens sophistiqués avec des ressources étendues, des compétences spécifiques à l'IACS et une forte motivation.

NOTE L'authentification des opérateurs n'est normalement pas nécessaire pour l'interface utilisateur physique, mais uniquement pour un accès à distance par l'intermédiaire d'interfaces de données.

Un niveau de sécurité SL-T SL2 ou supérieur est recommandé pour les mises à jour ou la restauration sécurisées des logiciels, à distance ou localement.

La conformité est vérifiée par examen et par des essais fonctionnels.

NOTE Pour plus d'informations sur la manière d'utiliser les informations ci-dessus pour mettre en œuvre des CONTRE-MESURES DE SECURITE adéquates pour les DISPOSITIFS MEDICAUX, se reporter directement à l'IEC TR 60601-4-5 :2021[9].

201.15 Construction de l'APPAREIL EM

L'Article 15 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.15.4 Composants et assemblage général des APPAREILS EM

Paragraphes supplémentaires:

201.15.4.101 CIRCUIT EXTRACORPOREL ou autres composants à usage unique

Si une installation incorrecte du CIRCUIT EXTRACORPOREL (ou d'autres composants à usage unique) peut provoquer une SITUATION DANGEREUSE pour le PATIENT, des moyens doivent être prévus pour assurer l'installation correcte du CIRCUIT EXTRACORPOREL (ou d'autres composants à usage unique) sur l'APPAREIL D'HEMODIALYSE.

La conformité est vérifiée par examen du DOSSIER DE GESTION DES RISQUES et de l'appareil d'hémodialyse.

NOTE Pour évaluer les caractéristiques de non-raccordabilité des connecteurs de petite taille selon leur conception et leurs dimensions intrinsèques afin de réduire le RISQUE d'erreurs de raccordement entre l'APPAREIL D'HEMODIALYSE et les ACCESSOIRES, voir l'ISO 80369-1:2018 [10].

201.15.4.1 Construction des connecteurs

Paragraphes supplémentaires:

201.15.4.1.101 * Connecteurs de CONCENTRE DE LIQUIDE DE DIALYSE

Il convient de différencier les différents conteneurs d'alimentation en CONCENTRES DE LIQUIDE DE DIALYSE et en solutions de nettoyage par des connexions mécaniques aux connecteurs de CONCENTRE DE LIQUIDE DE DIALYSE de l'APPAREIL D'HEMODIALYSE, ou ces conteneurs et ces solutions doivent porter un marquage de couleur indélébile (voir l'ISO 23500-4 [3]).

L'APPAREIL D'HEMODIALYSE doit, de plus, empêcher le mélange des différents CONCENTRES DE LIQUIDE DE DIALYSE et des solutions de nettoyage, qui peut provoquer une SITUATION DANGEREUSE pour le PATIENT, par une différenciation mécanique des connecteurs ou par un codage couleur de ceux-ci.

NOTE 1 L'utilisation de différents CONCENTRES DE LIQUIDE DE DIALYSE pose un problème dans la mesure où la connexion du mauvais concentré de LIQUIDE DE DIALYSE peut provoquer une SITUATION DANGEREUSE pour le PATIENT. La conception des connecteurs et le codage couleur ont été reconnus comme des méthodes permettant de réduire le plus possible ce RISQUE. Il existe toujours un RISQUE résiduel que l'OPERATEUR provoque une SITUATION DANGEREUSE en ne suivant pas les instructions d'utilisation du FABRICANT.

Il convient que le FABRICANT s'efforce de réduire le plus possible toute erreur de connexion potentielle des CONCENTRES DE LIQUIDE DE DIALYSE.

Les couleurs suivantes doivent être utilisées pour les connecteurs des CONCENTRES DE LIQUIDE DE DIALYSE:

– le connecteur pour l'acétate doit être de couleur blanche;
– le connecteur pour le composant acide dans la dialyse au bicarbonate doit être de couleur rouge;
– le connecteur pour le composant de bicarbonate dans la dialyse au bicarbonate doit être de couleur bleue;
– dans les cas où un même connecteur sert pour différents CONCENTRES DE LIQUIDE DE DIALYSE, sur l'APPAREIL D'HEMODIALYSE, les marquages des couleurs respectives doivent être apposés sur ce connecteur. Par exemple, un connecteur commun pour le CONCENTRE DE LIQUIDE DE DIALYSE à l'acétate et à l'acide doit être marqué en blanc/rouge.

La conformité est vérifiée par examen.

NOTE 2 L'ISO 23500-4 [3], donne les exigences du codage couleur pour les conteneurs de CONCENTRES DE LIQUIDE DE DIALYSE.

201.15.4.1.102 * Connecteurs pour transducteurs de pression sanguine

Le PROCESSUS DE GESTION DES RISQUES DU FABRICANT doit tenir compte des DANGERS potentiels pour le PATIENT, comme la perte de sang, l'infusion d'air ou la contamination croisée.

La conformité est vérifiée par des essais fonctionnels et par examen du DOSSIER DE GESTION DES RISQUES.

201.16 * SYSTEMES EM

L'Article 16 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.16.1 Exigences générales pour les SYSTEMES EM

Addition:

Les SYSTEMES EM n'ont pas encore été examinés de manière exhaustive en ce qui concerne l'ensemble du domaine de la dialyse dans la présente norme particulière. L'application de la GESTION DES RISQUES du point de vue des SYSTEMES EM est donc également recommandée pour les FABRICANTS d'APPAREILS D'HEMODIALYSE, étant donné qu'une identification précise d'un FABRICANT particulier du SYSTEME EM complet est souvent impossible dans une clinique de dialyse (voir l'Article A.4 de l'Annexe A informative, ainsi que les paragraphes 4.2 et 16.1 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020).

201.16.2 DOCUMENTS D'ACCOMPAGNEMENT d'un SYSTEME EM

d) conseils pour l'ORGANISME RESPONSABLE

Addition:

– une liste des SITUATIONS DANGEREUSES (par exemple, augmentation des COURANTS DE FUITE) et des mesures de protection possibles lorsque l'APPAREIL D'HEMODIALYSE est connecté à des SYSTEMES DE TRANSMISSION CENTRALISES, à des systèmes d'alimentation en EAU DE DIALYSE ou à d'autres systèmes centralisés de transport de liquides.

La conformité est vérifiée par examen des DOCUMENTS D'ACCOMPAGNEMENT.

201.16.6.3 COURANT DE FUITE PATIENT

Addition:

NOTE Les méthodes possibles de réduction des COURANTS DE FUITE PATIENT sont l'utilisation des anneaux conducteurs dans les SYSTEMES DE TRANSMISSION CENTRALISES et les systèmes centralisés d'alimentation en EAU DE DIALYSE ou le fait d'assurer que tous les points de raccordement de l'unité de dialyse ont le même potentiel et sont PROTEGES PAR MISE A LA TERRE (voir l'ISO 11197 [11]).

201.16.9.1 * Bornes de branchement et connecteurs

Addition:

– Les connecteurs sur les SYSTEMES DE TRANSMISSION CENTRALISES destinés au raccordement des CONCENTRES DE LIQUIDE DIALYSE doivent avoir un marquage de couleur indélébile. Voir 201.15.4.1.101.
– Les marquages supplémentaires doivent être apposés de telle façon que l'OPERATEUR puisse facilement attribuer le CONCENTRE DE LIQUIDE DE DIALYSE aux connecteurs correspondants de marquage approprié des SYSTEMES DE TRANSMISSION CENTRALISES réservés aux CONCENTRES DE LIQUIDE DE DIALYSE.

La conformité est vérifiée par examen.

201.17 COMPATIBILITE ELECTROMAGNETIQUE des APPAREILS EM et des SYSTEMES EM

L'Article 17 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique.