

INTERNATIONAL STANDARD

NORME INTERNATIONALE



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

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

FOREWORD

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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- d) including withdrawn IEC PAS 63023[17] as Annex CC;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,
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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 $37\text{ °C} \pm 1\text{ °C}$ 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 ($\pm 10\text{ mmHg}$);*
- *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 $30\text{ min} \pm 2\text{ min}$;*
- *set the HAEMODIALYSIS EQUIPMENT to minimum DIALYSIS FLUID flow rate;*
- *measure the DIALYSIS FLUID flow rate over a period of $30\text{ min} \pm 2\text{ min}$.*

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 $37\text{ °C} \pm 1\text{ °C}$ 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 ($\pm 10\text{ mmHg}$) 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 ($\pm 10\text{ mmHg}$) 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 treatment;

- 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 m² and 1,5 m²), 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:

$$Q_{\text{air}} = Q_{\text{b}} \times V_{\text{air}}/V_{\text{tube}}$$

where:

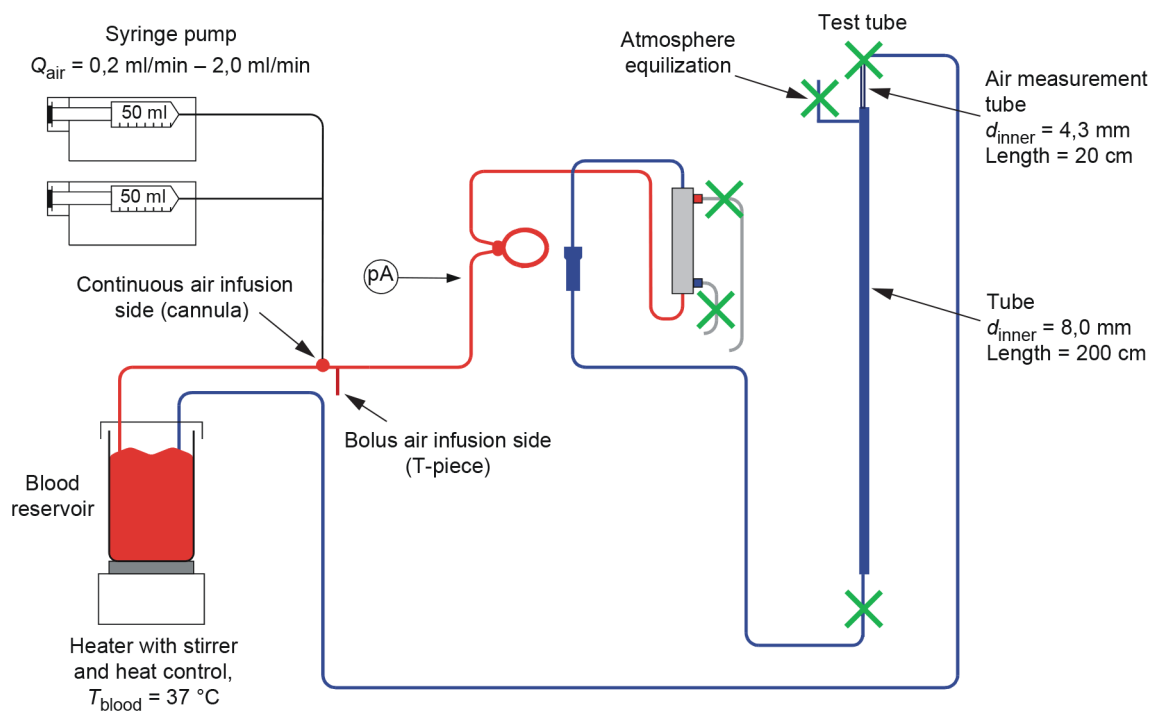
Q_{air} is the air flow rate;

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.



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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 m² and 1,5 m²), 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 [31]).

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: