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Edition 5.0 2018-04
REDLINE VERSION

INTERNATIONAL STANDARD

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

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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

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

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

International standard IEC 60601-2-16 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This fifth edition cancels and replaces the fourth edition of IEC 60601-2-16 published in 2012. 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 and IEC 60601-1:2005/AMD1:2012, of references and requirements to IEC 60601-1-2:2014, of references to IEC 60601-1-6:2010 and IEC 60601-1-6:2010/AMD1:2013, of references and requirements to IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, of references to IEC 60601-1-9:2007 and IEC 60601-1-9:2007/AMD1:2013, of references to IEC 60601-1-10:2007 and IEC 60601-1-10:2007/AMD1:2013 and of references to IEC 60601-1-11:2015;
b) widening of the scope;
c) editorial improvements;
d) addition of requirements for anticoagulant delivery means;
e) other few small technical changes.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/1557/FDIS	62D/1585/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

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 THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD 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 particular standard 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 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 publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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

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

INTRODUCTION

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

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

201.1.1 * Scope

~~Addition~~ 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.

This document does not take into consideration specific safety details of the DIALYSIS FLUID control system of HAEMODIALYSIS EQUIPMENT using regeneration of DIALYSIS FLUID ~~and~~ 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 ~~devices~~ HAEMODIALYSIS EQUIPMENT are intended for use either by medical staff or for use by the PATIENT or other trained personnel under medical supervision ~~of medical expertise~~.

This document includes all ME EQUIPMENT that is intended to deliver a HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION treatment to a PATIENT ~~suffering from kidney failure~~, 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, [12][2]);
- DIALYSERS (see ISO 8637-1, [11]);
- DIALYSIS FLUID CONCENTRATES (see ISO 23500-4, [18]);
- DIALYSIS WATER ~~treatment equipment~~ supply systems (see ISO 23500-2, [16]);
- CENTRAL DELIVERY SYSTEMS for DIALYSIS FLUID CONCENTRATES (see ISO 23500-4, [18]), described as systems for bulk mixing concentrate at a dialysis facility;
- equipment used to perform PERITONEAL DIALYSIS (see IEC 60601-2-39, [8]).

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

2 Numbers in square brackets refer to the Bibliography.

~~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.~~

~~HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of IEC 60601-1.~~

~~NOTE See also 4.2 of IEC 60601-1:2005.~~

201.1.2 Object

Replacement:

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

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2:2014, IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1-10:2007 and IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-11:2015 apply as modified in Clauses 202, 208, 210 and 211 ~~respectively~~. IEC 60601-1-3 and IEC 60601-1-12 do not apply. IEC 60601-1-9:2007 and IEC 60601-1-9:2007/AMD1:2013 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 the general standard 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 the general standard.

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

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) 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 particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"*Replacement*" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"*Addition*" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"*Amendment*" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.~~139~~147, 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 the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography.

Clause 2 of the general standard applies, except as follows:

~~Amendment~~ Replacement:

IEC 60601-1-2:~~2007~~ 2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic ~~compatibility~~ disturbances – Requirements and tests*

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

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

Addition:

IEC 60601-1-10:2007, *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 60601-1-11:~~2010~~ 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 61672-1, *Electroacoustics – Sound level meters – Part 1: Specifications*

~~IEC 62366:2007, *Medical devices – Application of usability engineering to medical devices*~~

~~ISO 594-2, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings*~~

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

~~ISO 8638, *Cardiovascular implants and artificial organs – Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters*~~

201.3 Terms and definitions

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

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

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

NOTE An index of defined terms is found beginning on page 78.

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.1.

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
~~solution~~ aqueous fluid containing electrolytes and, usually, buffer and glucose, which is intended to exchange solutes ~~and/or water~~ with blood during HAEMODIALYSIS ~~or HDF~~

[SOURCE: ISO 23500-1:— [15], 3.15, modified – The word "dialysing fluid" has been added as synonym, and the notes have been deleted.]

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

201.3.207
EXTRACORPOREAL CIRCUIT
blood lines, DIALYSER and any integral ACCESSORY ~~thereof~~

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

201.3.208
HAEMODIAFILTRATION
HDF
PROCESS whereby concentrations of water-soluble substances in a PATIENT'S blood and an excess of fluid of a PATIENT ~~with renal insufficiency~~ are corrected by a simultaneous combination of HD and HF

201.3.209
HAEMODIALYSIS
HD
PROCESS whereby concentrations of water-soluble substances in a PATIENT'S blood and an excess of fluid of a PATIENT ~~with renal insufficiency~~ 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 ~~normally~~ typically includes fluid removal by filtration. This PROCESS is usually also accompanied by diffusion of substances from the DIALYSIS FLUID into the blood.

201.3.210
*** HAEMODIALYSIS EQUIPMENT**
ME EQUIPMENT or ME SYSTEM used to perform HAEMODIALYSIS, HAEMODIAFILTRATION and/or HAEMOFILTRATION

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

201.3.211
HAEMOFILTRATION
HF
PROCESS whereby concentrations of water-soluble substances in a PATIENT's blood and an excess of fluid of a PATIENT ~~with renal insufficiency are corrected by unidirectional convective transport via ULTRAFILTRATION across a semi-permeable membrane separating the blood from the DIALYSIS FLUID AND ultrafiltrate is simultaneously replaced by an approximately isoosmolar SUBSTITUTION FLUID at a rate such that the difference between the ULTRAFILTRATION rate and the rate of SUBSTITUTION FLUID addition will lead to removal of the excess fluid over the course of the treatment~~ are corrected by convective transport via ULTRAFILTRATION and partial replacement by a SUBSTITUTION FLUID resulting in the required NET FLUID REMOVAL

201.3.212
NET FLUID REMOVAL
fluid loss from the PATIENT

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

201.3.213
*** ONLINE HDF**
HAEMODIAFILTRATION PROCEDURE where the HAEMODIALYSIS EQUIPMENT~~, based on the DIALYSIS FLUID,~~ produces SUBSTITUTION FLUID for infusion from DIALYSIS FLUID for the HAEMODIAFILTRATION treatment~~, suitable for injection~~

201.3.214
*** ONLINE HF**
HAEMOFILTRATION PROCEDURE where the HAEMODIALYSIS EQUIPMENT~~, based on the DIALYSIS FLUID,~~ produces the SUBSTITUTION FLUID for infusion from DIALYSIS FLUID for the HAEMOFILTRATION treatment~~, suitable for injection~~

201.3.215
*** PROTECTIVE SYSTEM**
automatic system, or a constructional feature, specifically designed to protect the PATIENT against ~~HAZARDS which can arise~~ HAZARDOUS SITUATIONS

201.3.216
SUBSTITUTION FLUID
~~a fluid administered to the PATIENT via the EXTRACORPOREAL CIRCUIT during HF or HDF~~
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:—[15], 3.40, modified – The words "patient's blood" and "ultrafiltration" have been replaced respectively by "EXTRACORPOREAL CIRCUIT" and "filtration" in the definition, and the notes have been deleted.]

201.3.217
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 ~~and~~ minus the measured DIALYSIS FLUID pressure, each obtained at a single point.

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

201.3.218
*** ULTRAFILTRATION**
PROCESS of fluid removal from the PATIENT'S blood across the semi-permeable membrane of the DIALYSER

201.3.219
VENOUS PRESSURE
pressure measured in the blood return line of the EXTRACORPOREAL CIRCUIT between the DIALYSER connection and PATIENT CONNECTION

201.3.220
DIALYSIS WATER
water that has been treated to meet the requirements of ISO 23500-3 [17] and which is suitable for use in HAEMODIALYSIS applications, including the preparation of DIALYSIS FLUID, reprocessing of DIALYSERS, preparation of concentrates and preparation of SUBSTITUTION FLUID for online convective therapies

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

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

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.3 * ESSENTIAL PERFORMANCE

Addition:

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.

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 Some ESSENTIAL PERFORMANCES 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).

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 include the pump segment fatigue for the maximum specified usage life of the EXTRACORPOREAL CIRCUIT.

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

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

– *apply an unused pump segment to the HAEMODIALYSIS EQUIPMENT according to the instructions for use and let it run for at least 30 min;*
– *apply a fluid (e.g. water) with a temperature of 37 °C in the EXTRACORPOREAL CIRCUIT;*
– *set the blood flow rate of the HAEMODIALYSIS EQUIPMENT to 400 ml/min or – if not possible – to the highest possible blood flow rate;*
– *set the pre-pump ARTERIAL PRESSURE to –200 mmHg;*
– *measure the blood flow rate.*

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

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

NOTE 3 The blood flow rate in peristaltic pumps can be affected by negative input pressures.

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 ~~Only~~ A DIALYSIS FLUID flow rate lower than the set value is considered ~~as negative~~ detrimental for a typical treatment.

Compliance is checked under the following test conditions:

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

- *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 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 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 ~~Only~~ A SUBSTITUTION FLUID flow rate lower than the set value is considered ~~as negative~~ 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 EXTRA~~-~~CORPOREAL 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 ~~measurements~~ tests relevant for the definition of dialysis treatment time specified by the MANUFACTURER.

201.4.3.107 * DIALYSIS FLUID composition

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

201.4.3.108 DIALYSIS FLUID temperature

The temperature of the DIALYSIS FLUID ~~for the HAEMODIALYSIS EQUIPMENT~~ 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 ~~in a~~ thermally stable ~~condition~~ 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;*
- *set the lowest DIALYSIS FLUID flow rate;*
- *measure the temperature at the DIALYSER inlet;*
- *record the temperature during a period of 30 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 tolerances of~~ 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;*
- *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.*

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, the air is not regarded as a SINGLE FAULT CONDITION, but as NORMAL CONDITION.

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the general standard applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard 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 color 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.

201.7.9.2 Instructions for use

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 ~~HAZARDS~~ HAZARDOUS SITUATION associated with connection and disconnection of the PATIENT;

– a warning statement which draws the OPERATOR'S attention to the ~~potential~~ HAZARDS, including any HAZARDOUS SITUATIONS, arising from 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 ~~potential~~ 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 ~~stating~~ statement that this PROTECTIVE SYSTEM reduces the ~~HAZARD~~ RISK in part only and an explanation of the remaining ~~HAZARDS~~ RISK;
- a description of OPERATOR responsibility for further ~~measures to reduce the~~ mitigation of residual RISK;

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

– * a warning statement specifying that any narrow passages in the EXTRACORPOREAL CIRCUIT (such as kinks in the blood line or cannula that are too thin) may cause haemolysis and that this HAZARDOUS SITUATION may not be detected by the PROTECTIVE SYSTEMS;

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

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

– for ONLINE HDF and ONLINE HF:

- a warning ~~stating~~ statement that only the disinfection PROCEDURES defined and validated by the MANUFACTURER ~~may~~ shall be used for ONLINE HDF and ONLINE HF;
- information on the required quality of the incoming DIALYSIS WATER and of the DIALYSIS FLUID CONCENTRATES used;
- intervals at which wearing parts (e.g. ENDOTOXIN-RETENTIVE FILTER – ETRF) should be exchanged;

– a warning statement that the blood flow rate, and thus the treatment efficacy, may 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~~s with atrial location~~ whose tip is in the right atrium;

NOTE 101 For information, see 201.8.3 in Annex AA.

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

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.

201.7.9.2.5 ME EQUIPMENT description

Addition:

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

- a definition of TRANSMEMBRANE PRESSURE if the MANUFACTURER makes use of one different from that stated in 201.3.217;
- an explanation of the coloured markings on the DIALYSIS FLUID CONCENTRATE connectors;
- information on the effective delivered blood flow rate in single-needle treatments;
- information on the recirculation of blood in the EXTRACORPOREAL CIRCUIT in single-needle treatments;
- the delay time after which an ~~audible~~ 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 ~~feedback control~~ PHYSIOLOGIC CLOSED-LOOP CONTROLLER modes have been evaluated, including beneficial and adverse effects recorded during clinical ~~testing~~ evaluation;

  ~~see also the collateral standard IEC 60601-1-10.~~
- ~~*~~ for any data that is displayed or indicated by the HAEMODIALYSIS EQUIPMENT and that may 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: ~~a statement to~~ 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 ~~a statement~~ information, whether this HAEMODIALYSIS EQUIPMENT can be used together with a central venous catheter~~s with atrial location~~ whose tip is in the right atrium. If the HAEMODIALYSIS EQUIPMENT is not suitable for a central venous catheter~~s with atrial location possible~~ whose tip is in the right atrium, associated HAZARDS shall be listed.

Compliance is checked by inspection of the instructions for use.

201.7.9.2.6 Installation

Addition:

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

- ~~a statement~~ 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, ~~a statement~~ information of the importance of the quality of the protective earth in the electrical installation;
- ~~a statement~~ 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, ~~a statement~~ information that the RESPONSIBLE ORGANIZATION should select the colour coding scheme which minimizes the RISK of ~~confusion~~ ALARM SIGNAL misunderstanding in their environment;

– if settings of operating parameters or PROTECTIVE SYSTEMS can be configured, ~~a statement~~ 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.

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 fluid path inside the HAEMODIALYSIS EQUIPMENT and the ENCLOSURE surface disinfection is achieved;

– * ~~a statement~~ information that the test PROCEDURE by which the effectiveness of sanitization or disinfection of the fluid path inside the HAEMODIALYSIS EQUIPMENT has been ~~verified~~ validated is available upon request from the MANUFACTURER;

– a warning ~~stating~~ statement to follow the MANUFACTURER'S instructions to disinfect the HAEMODIALYSIS EQUIPMENT; if other PROCEDURES are used it is the responsibility of the RESPONSIBLE ORGANIZATION to validate the disinfection PROCEDURE for efficacy and safety; this warning shall specifically list HAZARDS, including the failure mode that may 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.

Compliance is checked by inspection of the instructions for use.

201.7.9.2.14 ACCESSORIES, supplementary equipment, used material

Addition:

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

– information on DIALYSIS FLUID CONCENTRATES, DIALYSERS and blood lines intended to be used together with the HAEMODIALYSIS EQUIPMENT.

Compliance is checked by inspection of the instructions for use.

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;
- ~~Device~~ HAEMODIALYSIS EQUIPMENT specification:
  - ~~*~~ for HAEMODIALYSIS EQUIPMENT that includes integral anticoagulant ~~pump(s)~~ delivery means: the type of the pump(s), the range and the accuracy of the flow rate for such pump(s) and the pressures against which this accuracy is maintained;
  - any additional measures foreseen by the MANUFACTURER in case of the interruption of the power supply;
  - the type, the measurement accuracy and the value(s) or range(s) of the ALARM LIMIT(s) of the PROTECTIVE SYSTEM required by 201.12.4.4.101 (DIALYSIS FLUID composition);
  - the type, the measurement accuracy and the value(s) or range of the ALARM LIMIT(s) of the PROTECTIVE SYSTEM required by 201.12.4.4.102 (DIALYSIS FLUID and SUBSTITUTION FLUID temperature);
  - the type, the measurement accuracy and the value(s) or range(s) of the ALARM LIMIT(s) of the PROTECTIVE SYSTEM required by 201.12.4.4.103 (NET FLUID REMOVAL);
  - the type, the measurement accuracy and the value(s) or range(s) of the ALARM LIMIT(s) of the PROTECTIVE SYSTEM required by 201.12.4.4.104.1 (extracorporeal blood loss to the environment);
  - * 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 ~~audible~~ auditory ALARM SIGNAL AUDIO PAUSED period;
  - the range of sound pressure levels of any adjustable ~~audible~~ 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 ~~automatic~~ 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~~ ACCOMPANYING DOCUMENTS.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard 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~~s~~ ~~with atrial location~~ 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~~(s) with atrial location~~ 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 ~~have to~~ shall be provided and justified by the MANUFACTURER'S RISK MANAGEMENT PROCESS to keep the PATIENT LEAKAGE CURRENTS within the limits for TYPE CF APPLIED PARTS under SINGLE FAULT CONDITION.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

201.8.7.4.7 Measurement of the PATIENT LEAKAGE CURRENT

Addition:

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

NOTE 101 The measurement of PATIENT LEAKAGE CURRENTS described above does not include the measurement according to 8.7.4.7 b) (voltage applied to the APPLIED PART) of the general standard 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 the general standard applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies, except as follows:

201.11.6.3 Spillage on ME EQUIPMENT and ME SYSTEMS

Addition:

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

201.11.6.6 * Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS

Addition:

~~For HAEMODIALYSIS EQUIPMENT employing non-disposable fluid lines, means shall be provided for disinfection of such fluid lines.~~

~~The disinfection procedures shall not deteriorate internal components or external accessories (e.g. DIALYSIS FLUID filters) that could become a HAZARD.~~

~~*Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and of the HAEMODIALYSIS EQUIPMENT.*~~

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

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

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

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

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

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

Addition:

a) HAEMODIALYSIS EQUIPMENT without INTERNAL ELECTRICAL POWER SOURCE for backup, or with INTERNAL ELECTRICAL POWER SOURCE for operation:

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

- activation of an ~~audible~~ auditory ALARM SIGNAL, lasting for at least 1 min;
- additional measures may 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 ~~HAZARD~~ HAZARDOUS SITUATION to the PATIENT as determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS.

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

b) HAEMODIALYSIS EQUIPMENT with INTERNAL ELECTRICAL POWER SOURCE for backup:

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 a visual ALARM SIGNAL;
- activation of an ~~audible~~ auditory ALARM SIGNAL after a time interval specified by the MANUFACTURER;
- additional measures may 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 they may restart automatically on restoration of the power supply only if this does not cause any ~~HAZARD~~ HAZARDOUS SITUATION to the PATIENT as determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS;
- if the INTERNAL ELECTRICAL POWER SOURCE is interrupted or discharged, the HAEMODIALYSIS EQUIPMENT shall meet the requirements described in 201.11.8 a).

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

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

Clause 12 of the general standard applies, except as follows:

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.

Additonal subclauses:

201.12.4.4.101 * DIALYSIS FLUID composition

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

NOTE 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.

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

- activation of ~~an audible~~ auditory and visual ALARM SIGNALS (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101). The ~~audible~~ 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 ~~HAZARD~~ HAZARDOUS SITUATION.

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

– activation of ~~an audible~~ 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 ~~concentration~~ 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 ~~concentration~~ bolus administration function to result in a ~~HAZARD~~ HAZARDOUS SITUATION to the PATIENT.

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

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

– interruption of the ~~concentration~~ DIALYSIS FLUID composition bolus administration.

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

- *Test 1 for determining the ALARM ~~LIMITS~~ SIGNAL activation*
  - *Set the unit under test to the lowest and the highest ~~ALARM SIGNAL free~~ compositions of the DIALYSIS FLUID respectively without generating an ALARM SIGNAL.*
  - *Slowly change the DIALYSIS FLUID composition until the PROTECTIVE SYSTEM activates an ALARM SIGNAL.*
  - *Take samples at the DIALYSER inlet under NORMAL CONDITION and immediately after the ALARM CONDITION is detected.*
  - *Determine and evaluate (e.g. by flame photometry) ~~the difference of~~ the DIALYSIS FLUID composition of the samples taken in NORMAL CONDITION and after the ALARM ~~(e.g. by flame photometry)~~ CONDITION is detected.*
- *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 samples at the DIALYSER inlet under NORMAL CONDITION and immediately after the ALARM CONDITION is detected.*
  - *Determine ~~the difference of~~ and evaluate (e.g. by flame photometry) the DIALYSIS FLUID composition of the samples taken under NORMAL CONDITION and after the ALARM ~~(e.g. by flame photometry)~~ CONDITION is detected.*
- *Test 3 for foreseeable misuse*
  - *Exchange DIALYSIS FLUID CONCENTRATES, if possible.*
  - *Determine the ALARM CONDITION activation.*
  - *Take samples at the DIALYSER inlet under NORMAL CONDITION and immediately after the ALARM CONDITION is detected.*
  - *Determine and evaluate (e.g. by flame photometry) the DIALYSIS FLUID composition of the samples taken under NORMAL CONDITION and after the ALARM CONDITION is detected.*

201.12.4.4.102 * DIALYSIS FLUID and SUBSTITUTION FLUID temperature

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

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

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

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

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

– stopping of the DIALYSIS FLUID flow to the DIALYSER and/or 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 / lowest DIALYSIS FLUID temperature.*
  - *Wait for stable temperatures at the DIALYSER inlet.*
  - *Slowly increase / 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 / minimum value.*
- *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 / lowest DIALYSIS FLUID / SUBSTITUTION FLUID temperature.*
  - *Wait for a stable temperature at the inlet to the EXTRACORPOREAL CIRCUIT.*
  - *Slowly increase / 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 / minimum value.*

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 ~~variation~~ deviation in the NET FLUID REMOVAL of the HAEMODIALYSIS EQUIPMENT from the set value of the controlling parameters that may cause a ~~HAZARD~~ 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~~ may cause a ~~HAZARD~~ HAZARDOUS SITUATION.

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

– activation of ~~an audible~~ 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 ~~HAZARD~~ HAZARDOUS SITUATION.

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

- activation of ~~an audible~~ 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 ~~HAZARD~~ HAZARDOUS SITUATION to the PATIENT.

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

- activation of ~~an audible~~ 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 tests.

- *Test for deviations of the NET FLUID REMOVAL rate*
  - *Set the unit under test to the highest DIALYSIS FLUID flow rate.*
  - *Set the highest SUBSTITUTION FLUID flow rate, if this is adjustable.*
  - *Set the DIALYSIS FLUID temperature to 37 °C, if applicable.*
  - *Set the highest and the lowest ULTRAFILTRATION ~~flow~~ rates (one at a time).*
  - ~~*Simulate a low and a high failure in each of the pump control systems (one at a time) which influence the NET FLUID REMOVAL rate until the PROTECTIVE SYSTEM activates an ALARM SIGNAL.*~~
  - *Simulate an error with a negative and a positive deviation in each of the fluid removal control components (one at a time) which influence the NET FLUID REMOVAL rate until the PROTECTIVE SYSTEM activates an ALARM SIGNAL.*
  - ~~*Determine the volume difference in relation to the theoretical volume.*~~
  - *Determine the difference between the set target volume and the measured NET FLUID REMOVAL at the activation of the ALARM SIGNAL.*

201.12.4.4.104 Extracorporeal blood loss

201.12.4.4.104.1 Extracorporeal blood loss to the environment

* a) The HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM to protect the PATIENT from extracorporeal blood loss to the environment that may cause a ~~HAZARD~~ 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. ~~The following recommendation is the best known system to detect blood loss to the environment.~~

If a PROTECTIVE SYSTEM is utilizing measurement of the VENOUS PRESSURE, the OPERATOR should have at least ~~the possibility~~ 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) ~~Operation~~ Activation of the PROTECTIVE SYSTEM shall achieve the following safe condition:

– activation of ~~an audible~~ 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.

- *Test for PROTECTIVE SYSTEMS utilizing the VENOUS PRESSURE measurement*
  – *Set the unit under test to the medium blood flow rate.*
  – *Adjust the VENOUS PRESSURE to a medium value.*
  – *Lower the VENOUS PRESSURE until an ALARM SIGNAL is activated.*
  – *Determine the difference ~~between the ALARM point and the reference value~~ of the measured VENOUS PRESSURE against the set limit when the ALARM SIGNAL is activated.*

201.12.4.4.104.2 * BLOOD LEAK to the DIALYSIS FLUID

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

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

– activation of ~~an audible~~ 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.

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

- *Test for determining the ALARM LIMITS:*
  – *~~Create~~ Set the maximum flow rate through the BLOOD LEAK detector (highest DIALYSIS FLUID flow ~~rate~~, highest ULTRAFILTRATION ~~flow~~ rate, if relevant also highest SUBSTITUTION FLUID flow rate).*
  – *Add bovine blood, human blood or porcine blood (Haematocrit Hct 32%) to the DIALYSIS FLUID so that the flow through the BLOOD LEAK detector ~~represents~~ exceeds the BLOOD LEAK ALARM LIMIT as specified by the MANUFACTURER.*

201.12.4.4.104.3 * Extracorporeal blood loss due to coagulation

a) The HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM to protect the PATIENT from blood loss due to coagulation as a consequence of the interruption of the blood flow that may cause a ~~HAZARD~~ 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) ~~Operation~~ Activation of the PROTECTIVE SYSTEM shall activate an ~~audible~~ auditory and visual ALARM SIGNAL (see 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101).

c) Other effects which may result in a blood loss due to coagulation, for example stopping or missing start of any ~~anticoagulation pump~~ anticoagulant delivery means, or excessive SUBSTITUTION FLUID flow rate in case of HDF or HF with post-dilution, shall be addressed in the MANUFACTURER'S RISK MANAGEMENT PROCESS.

Compliance is checked by functional tests and failure simulation.

201.12.4.4.105 * Air infusion

a) The HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM to protect the PATIENT from air infusion, under NORMAL CONDITION and SINGLE FAULT CONDITION, that may cause a ~~HAZARD~~ 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) ~~Operation~~ Activation of the PROTECTIVE SYSTEM shall achieve the following safe condition:

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

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

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

Compliance is checked by functional tests taking into account the principles of the test described below.

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

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

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

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

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

- *Continuous air infusion:*

  – *Set up the HAEMODIALYSIS EQUIPMENT with a standard 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 5 This is a worst-case condition. If degassed DIALYSIS FLUID is running, gas will be 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 6 An appropriate test fluid has a viscosity of 3,5 mPa·s at 37 °C and contains a surfactant causing spallation of gas bubbles.

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

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

  – Position ~~at least~~ one vertically positioned test tube with diameter of, for example, 8 mm and a length of, for example, 2,0 m in line with a second tube with smaller diameter of, for example, 4.3 mm and a length of, for example, 20 cm directly at the venous PATIENT connector in the venous path between the PATIENT connector and collection container (see as an example the setup in Figure 201.101). *More than one test tube in parallel configuration can be used to monitor continuously the infused air before the ALARM CONDITION occurs.*

  – *Insert a 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 pump capable of controlling air injection under negative pressure condition.*

NOTE 7 A possible method is the use of a small reversible peristaltic pump. This pump is initially primed with test fluid by operating it in reverse mode to avoid uncontrolled injection of air when the blood pump is started. A check valve between the needle and the pump could be used.

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

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

NOTE 8 The rationale of this test is based on the assumption that, with the DIALYSIS FLUID line closed, air cannot escape from the EXTRACORPOREAL CIRCUIT and will eventually be pumped to the fluid collection vessel at the same rate as pumped in.

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

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

– Calculate the air flow rate by blood flow ~~speed~~ rate, test tube volume and measured air volume. *Direct measurement of the blood flow rate in the venous bloodline is recommended.* The calculated air flow rate shall be less than the continuous air infusion rate limit identified by RISK MANAGEMENT.

a) *If the HAEMODIALYSIS EQUIPMENT allows the DIALYSER to be operated with blood flowing upwards through the DIALYSER and, alternatively with blood flowing downwards through the DIALYSER, separate tests shall be done with both flow directions.*

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

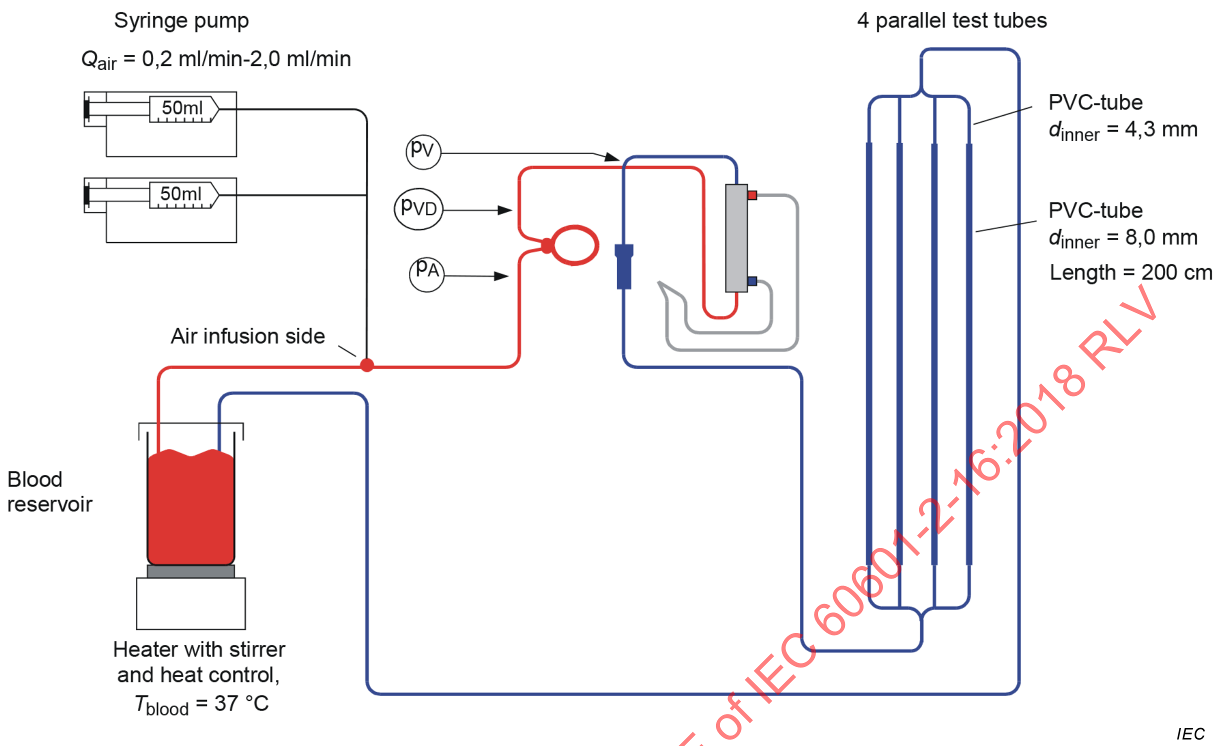

Figure 201.101 – Continuous air infusion test setup with example dimensions

- *Bolus air infusion:*
  - *Set up the* HAEMODIALYSIS EQUIPMENT *with a standard 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 9 This is a worst-case condition. If degassed DIALYSIS FLUID is running, gas will be 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 10 An appropriate test fluid has a viscosity of 3,5 mPa·s at 37 °C and contains a surfactant causing spallation of gas bubbles.

  - *Position a storage container for the test fluid at a level of, for example, 100 cm (±20 cm) from the ground.*
  - *Position a collection container for the test fluid at a level of, for example, 100 cm (±20 cm) from the ground or recirculate the fluid into the storage container.*
  - *Position a graduated measuring cylinder or the same test tubes as in the previous test case such that any air that may be pumped through the return (venous) cannula is collected.*
  - *Insert a T-piece with Luer connectors between the blood tubing and 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) ~~and~~ 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 ~~the air detector activates~~ an ALARM SIGNAL is activated.*

– *Check the amount of air collected in the graduated measuring cylinder or in the test tube. The ~~amount~~ collected air volume shall be less than the ~~specified~~ bolus air infusion limit identified by RISK MANAGEMENT.*

  a) *If the HAEMODIALYSIS EQUIPMENT allows the DIALYSER to be operated with blood flowing upwards through the DIALYSER and, alternatively with blood flowing downwards through the DIALYSER, separate tests shall be done with both flow directions.*

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

201.12.4.4.106 * ALARM CONDITION override modes

~~NOTE~~ Within the meaning of 201.12.4.4.106, override is a means to allow the HAEMODIALYSIS EQUIPMENT to function under ALARM CONDITIONS if the OPERATOR consciously selects to temporarily disable the PROTECTIVE SYSTEM. ~~A delayed start is not regarded as an override of the HAEMODIALYSIS EQUIPMENT if it does not cause a HAZARD.~~

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

   NOTE 1 For exceptions, see item b) below.

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

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

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

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

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

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

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

201.12.4.4.107 PROTECTIVE SYSTEMS

A failure of the PROTECTIVE SYSTEMS required by 201.12.4.4 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 Acceptable methods of complying with this requirement are for example:

- periodic functional check of the PROTECTIVE SYSTEMS, requested by the HAEMODIALYSIS EQUIPMENT, initiated and controlled by the OPERATOR;
- periodic functional check of the PROTECTIVE SYSTEMS, requested by the HAEMODIALYSIS EQUIPMENT, initiated by the OPERATOR and controlled by the HAEMODIALYSIS EQUIPMENT;
- redundancy of the PROTECTIVE SYSTEMS with self-checking by the HAEMODIALYSIS EQUIPMENT;
- periodic functional check of the PROTECTIVE SYSTEMS initiated by the HAEMODIALYSIS EQUIPMENT and controlled by the HAEMODIALYSIS EQUIPMENT, if the control function of the PROTECTIVE SYSTEM is designed such that it cannot fail simultaneously with the PROTECTIVE SYSTEM by a single failure.

b) for the PROTECTIVE SYSTEM required by 12.4.4.105 (air infusion):

– if an amount of air can be infused to the PATIENT which may cause a ~~HAZARD~~ 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 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 the general standard 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.

Compliance is checked by functional tests and failure simulations.

201.12.4.4.109 * Blood pump(s) and/or SUBSTITUTION FLUID pump(s) reversal

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

The applicable ~~HAZARDS~~ HAZARDOUS SITUATIONS (e.g. air infusion via the arterial bloodline) have to be determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS. ~~Human~~ USE ERRORS as well as technical failures have to 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. ~~Human~~ USE ERRORS, as well as technical failures, have to 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 [19] and ISO 23500-1) for a solution intended for ~~large volume~~ intravenous applications 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.

201.12.4.4.112 * Anticoagulation

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

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

NOTE 2 In some treatment situations, it can be desirable 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.

- Improper dosing of the anticoagulant solution(s) by first fault of the anticoagulant delivery means, for example delivery rate(s), delivery rate(s) ratio, delivery rate(s) ratio versus blood flow rate.
- Improper dosing of the anticoagulant solution under negative pressure conditions in the EXTRACORPOREAL CIRCUIT in the case an anticoagulant delivery means doses upstream of the blood pump.
- Interconnecting 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.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of the general standard applies, except as follows:

201.13.2.6 * Leakage of liquid

Addition:

The liquid-carrying parts of the HAEMODIALYSIS EQUIPMENT shall be so shielded against the electrical parts that liquid which may leak under normal working pressure does not lead to the

PATIENT being exposed to HAZARDS, 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 the general standard.

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 the general standard applies, except as follows:

201.14.13 * ~~Connection of PEMS by NETWORK/DATA COUPLING to other equipment~~ PEMS intended to be incorporated into an IT-NETWORK

Addition:

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

NOTE 101 Independent of this document, IEC 80001-1:2010 [9] requires from every MEDICAL DEVICE MANUFACTURER to make available ACCOMPANYING DOCUMENTS to the RESPONSIBLE ORGANIZATION with information about the IT-NETWORK capabilities of the medical device (3.5 MEDICAL DEVICE MANUFACTURER(S)).

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies, except as follows:

201.15.4.1 Construction of connectors

Addition:

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 13958~~ ISO 23500-4, [18]).

The HAEMODIALYSIS EQUIPMENT shall additionally prevent a mix-up of the various DIALYSIS FLUID CONCENTRATES and cleaning solutions which may cause a ~~HAZARD~~ 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 ~~may~~ can cause a ~~HAZARD~~ HAZARDOUS SITUATION to the PATIENT. The design of connectors and colour coding were recognized as methods to minimize this RISK. There is always ~~the possibility~~ a residual RISK that the OPERATOR will cause a ~~HAZARD~~ 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 13958~~ ISO 23500-4 gives requirements for the colour coding of DIALYSIS FLUID CONCENTRATE containers.

201.15.4.1.102 * Connectors for blood pressure transducers

~~The connection between blood lines and blood pressure transducers shall have an equivalent safety according to ISO 594-2, as stipulated by ISO 8638.~~

Any ~~potential~~ 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 the general standard 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 Clause A.4, 4.2 and 16.1 of the general standard).

201.16.2 ACCOMPANYING DOCUMENTS of an ME SYSTEM

d) advice to the RESPONSIBLE ORGANIZATION

Addition:

– a listing of ~~RISKS~~ 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 (increased LEAKAGE CURRENTS).

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 [13]).

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.

– The colour Additional markings shall be affixed such that the OPERATOR can easily assign the DIALYSIS FLUID CONCENTRATE to the appropriately colour marked DIALYSIS FLUID CONCENTRATE container or connectors of the CENTRAL DELIVERY SYSTEMS (see 201.15.4.1.101) for DIALYSIS FLUID CONCENTRATES.

Compliance is checked by inspection and testing.

201.17 ELECTROMAGNETIC COMPATIBILITY of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies.

202 Electromagnetic compatibility disturbances – Requirements and tests

IEC 60601-1-2:2007 2014 applies except as follows:

202.3.18
LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEM

Addition:

NOTE A HAEMODIALYSIS EQUIPMENT is not considered to be a LIFE-SUPPORTING EQUIPMENT or SYSTEM as defined in 3.18 of IEC 60601-1-2:2007, since a premature termination of the dialysis treatment is not likely to lead to serious injury or death of a PATIENT

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 HEMODIALYSIS EQUIPMENT:

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

below a performance level specified by the MANUFACTURER, when the ME EQUIPMENT or ME SYSTEM is used as intended.

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

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

202.8.9 IMMUNITY TEST LEVELS

Addition:

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

- professional healthcare facility environment (e.g. dialysis centers, 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 and IEC 60601-1-8:2006/AMD1:2012 applies except as follows:

208.4 * General requirements

Addition:

If the INTENDED USE of the HEMODIALYSIS EQUIPMENT includes the intensive care or surgery environment, it is acceptable to implement additional ALARM SYSTEMS deviating from IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 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 HEMODIALYSIS EQUIPMENT includes the intensive care or surgery environment and additional ALARM SYSTEMS deviating from IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 are implemented, then

a) the ALARM SYSTEM according to IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 ~~shall~~ should be the ~~factory~~ MANUFACTURER default setting. If the ALARM SYSTEM according to IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 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.

Compliance is checked by functional tests.

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

If the INTENDED USE of the HEMODIALYSIS EQUIPMENT does not include the intensive care or surgery environment, the following subclauses of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 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 7.8.1 Colours of indicator lights of the general standard applies, but the urgency of the response of the OPERATOR can have other than PATIENT-centric causes.

208.5.2.1 Instructions for use

Addition:

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

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 ~~both visually and audibly~~. The visual ALARM SIGNAL shall remain activated for the entire duration of the ALARM CONDITION, whereas ~~it is allowed to pause~~ AUDIO PAUSING the ~~audible~~ auditory ALARM SIGNAL for the amount of time specified in 208.6.3.3.101 b) is allowed.

Compliance is checked by functional tests.

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

~~Addition~~ Replacement:

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

Compliance is checked by measuring the A-rated sound pressure level with instruments meeting the requirements for measuring instruments of class 1 according to IEC 61672-1 and free field conditions as specified in ISO 3744.

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

~~Audible~~ Auditory ALARM SIGNALS shall meet the following requirements:

~~a) If the HAEMODIALYSIS EQUIPMENT enables the OPERATOR to set the audible alarm volume to lower values, a minimum value shall be defined. This minimum value may only be changed~~

by the RESPONSIBLE ORGANIZATION. If the RESPONSIBLE ORGANIZATION can reduce the audible alarm volume to zero, there shall be an alternative means to notify the OPERATOR under SINGLE FAULT CONDITION.

a) If it is possible to pause the audible auditory ALARM SIGNAL, the alarm AUDIO PAUSED period shall not exceed 3 min.

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

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

Compliance is checked by functional tests.

209 Requirements for environmentally conscious design

IEC 60601-1-9:2007 and IEC 60601-1-9:2007/AMD1:2013 does 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 Process Requirements for the development of PHYSIOLOGIC CLOSED-LOOP CONTROLLERS

IEC 60601-1-10:2007 and IEC 60601-1-10:2007/AMD1:2013 applies, except as follows:

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 flow rate, conductivity DIALYSIS FLUID composition and temperature.

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

IEC 60601-1-11:2010 2015 applies, except as follows:

211.6 Classification of ME EQUIPMENT and ME SYSTEMS

Addition:

Besides the PERMANENTLY INSTALLED connection to SUPPLY MAINS, other means of preventing connection to a non-grounded outlet can be used, such as a unique MAINS PLUG connector that is normally not used in the HOME HEALTHCARE ENVIRONMENT.

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 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 the general standard apply, except as follows:

Annex G
(normative)

Protection against HAZARDS of ignition of flammable anaesthetic mixtures

Annex G of the general standard does not apply.

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

Clause A.1 of the general standard applies.

AA.2 Rationale for particular clauses and subclauses

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

Subclause 201.1.1 – Scope

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

Safety details of DIALYSIS FLUID control systems of HAEMODIALYSIS EQUIPMENT using regeneration of DIALYSIS FLUID or CENTRAL DELIVERY SYSTEMS for DIALYSIS FLUID should be part of the MANUFACTURER'S RISK MANAGEMENT PROCESS.

The AAMI Renal Disease and Detoxification committee is working on a technical information report on sorbent-based regenerative HAEMODIALYSIS EQUIPMENT. (AAMI TIR [1]).

Subclause 201.3.8 – APPLIED PART

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

Subclause 201.3.202 – BLOOD LEAK

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

~~A BLOOD LEAK can also be accompanied by back-contamination caused by backfiltration.~~

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

Subclause 201.3.210 – HAEMODIALYSIS EQUIPMENT

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

FLUID usually requires a water treatment system (RO system) and may also be connected to a CENTRAL DELIVERY SYSTEM.

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

Subclause 201.3.213 and 201.3.214 – ONLINE HDF and ONLINE HF

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

Subclause 201.3.215 – PROTECTIVE SYSTEM

See [23], page 342. The authors point out that HAEMODIALYSIS EQUIPMENT comprises redundancy or PROTECTIVE SYSTEMS in addition to control systems. A HAZARD (editors comment: harm) to the PATIENT is only possible if the control system and the PROTECTIVE SYSTEM both fail. The likelihood for any of these systems to fail is less than 10^{-4} per ~~treatment~~ hour resulting in a combined likelihood of less than 10^{-8} per ~~treatment (4 h to 6 h)~~ hour. This observation was made by the first author in the mid-1980s based on quality feedback data from ~ 3 000 HAEMODIALYSIS EQUIPMENTS and is corroborated by the low number of serious accidents caused by HAEMODIALYSIS EQUIPMENT malfunction in the US where accident reports are published by the FDA.

Subclause 201.3.218 – ULTRAFILTRATION

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

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

Subclause 201.4.3 – ESSENTIAL PERFORMANCE

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

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

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

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

Subclause 201.4.3.101 – Additional ESSENTIAL PERFORMANCE requirements

The ESSENTIAL PERFORMANCE for HAEMODIALYSIS EQUIPMENT was determined with the following aspects taken into account: on one hand, all parameters required for the therapeutic effectiveness of the PROCEDURE should be included; on the other hand, definition of more parameters than necessary should be avoided, because the ESSENTIAL PERFORMANCE has to be complied even under the irradiation conditions of the ELECTROMAGNETIC COMPATIBILITY –

(EMC) IMMUNITY test. The observation and documentation of a great number of ESSENTIAL PERFORMANCE features would cause impractically high time and cost expenditures during the EMC test. The list of ESSENTIAL PERFORMANCE features defined here is a compromise between these two contrary aspects (see IEC 60601-1-2).

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

~~Comment to Note:~~

Subclause 201.4.3.102, Note 1 – Blood flow rate

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

Subclause 201.4.3.107 – DIALYSIS FLUID composition

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

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

Ideas for determining the DIALYSIS FLUID composition are:

– measurement by ion selective ~~electrodes~~ sensors;

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

– measurement of the dilution by adding a dye to the DIALYSIS FLUID CONCENTRATE. The optical absorption is measured before and after mixing;

– theoretical calculation of conductivity, based on the known composition of the DIALYSIS FLUID CONCENTRATE. Create a systematic matrix of ~~settings~~ different dialysate compositions, for example:
  - highest sodium with lowest bicarbonate;
  - lowest sodium with highest bicarbonate;
  - highest sodium with highest bicarbonate;
  - lowest sodium with lowest bicarbonate;

  measure the conductivities of the different dialysate compositions and compare the difference or the ratio of the measured and the theoretically derived conductivity values ~~or the relative differences or ratios between the elements of the matrix~~ of each dialysate composition;

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

Subclause 201.7.8.2 – Color of controls

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

Subclause 201.7.9.2.2, 6th hyphen – Warning and safety notices

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

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

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

The effect of backfiltration through structural leaks in the DIALYSER is usually limited to an amount not detected by the BLOOD LEAK detector. Because of the pulsating flow produced by a peristaltic blood pump, back and forward ULTRAFILTRATION will alternate in the DIALYSER. During the backfiltration phase, bacteria may enter into the blood stream undetected. Assuming that the back flow rate is 1 ml/min (three times larger than the typical sensitivity of a BLOOD LEAK detector), the hypothetical contamination of blood is 100 CFU/min ~~– 200 CFU/min~~ (CFU means "colony-forming units"), if DIALYSIS WATER or DIALYSIS FLUID is according to ~~EuPharm or AAMI~~ ISO guidelines ~~respectively~~. It is extremely unlikely that such a small leak below the detection limit of the BLOOD LEAK detector will persist~~s~~ in a DIALYSER. Usually, small leaks close by clotting within a few minutes.

Subclause 201.7.9.2.2, 9th hyphen – Warnings and safety notices

Haemolysis may be caused by excessive shear which is the result of high blood flow rate through a narrow passage, especially when the flow becomes turbulent. Static pressure (– 600 mmHg to +1 000 mmHg) does not cause haemolysis. Elevated pressures measured in the EXTRACORPOREAL CIRCUIT indicate increased flow resistance which may cause subclinical haemolysis. Acute haemolysis has been reported to be caused by obstructions in the blood tubing system downstream of the blood pump but upstream of the VENOUS PRESSURE monitor. Such obstructions are not detected by the VENOUS PRESSURE monitor. For a review of accident reports see [23], p. 328-332.

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

For Kt/V, applicable ~~standards~~ recommendations are, for example, KDOQI guidelines [29] and the European best practice guidelines for haemodialysis [30].

Subclause 201.7.9.2.12, 2nd hyphen – Cleaning, disinfection and sterilization

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

– the recommended type of disinfectant;

– the required concentration of disinfectant in the container;

– the resulting concentration of disinfectant in the HAEMODIALYSIS EQUIPMENT;

– the required minimum time of the disinfection phase (if not automatically set by the HAEMODIALYSIS EQUIPMENT);
– the required minimum rinse phase (if not automatically set by the HAEMODIALYSIS EQUIPMENT).

Subclause 201.7.9.3.1, 3rd and 4th hyphens – General

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

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

~~**Subclause 201.7.9.3.1 – General (5th dash)**~~

~~Where systems with anticoagulant solution-delivering equipment are concerned, it should be considered that the following HAZARDS may occur, if a system / PROTECTIVE SYSTEM fails:~~

~~– fluid flow from the EXTRACORPOREAL CIRCUIT via the arterial PATIENT CONNECTION with the blood delivery equipment not running;~~
~~– HAZARD caused by improperly dosing the anticoagulant solution;~~
~~– air infusion via the arterial PATIENT CONNECTION, because the anticoagulant pump doses upstream of the blood pump (wrong delivery rate or delivery while the blood pump is not running).~~

Subclause 201.7.9.3.1, 11th hyphen – General

The flow rate through the BLOOD LEAK detector can depend~~s~~ on the treatment type and/or position of the BLOOD LEAK detector. ~~In HD and ONLINE HDF it is the DIALYSIS FLUID flow plus the ULTRAFILTRATION flow. In "sequential" therapy it is the ULTRAFILTRATION flow. In HF it is the filtrate flow plus the ULTRAFILTRATION flow.~~

Subclause 201.8.3 – Classification of APPLIED PARTS

Compliance with TYPE CF APPLIED PART requirements for HAEMODIALYSIS EQUIPMENT that are provided with a permanent DIALYSIS WATER connection and/or connection to a CENTRAL DELIVERY SYSTEM can be achieved with high technical expenditures only. For that reason, an exception rule has been established for the use of HAEMODIALYSIS EQUIPMENT with TYPE B APPLIED PARTS for PATIENTS with a central venous catheter ~~with atrial location~~ whose tip is in the right atrium.

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

1) LEAKAGE CURRENTS originating from the HAEMODIALYSIS EQUIPMENT.

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

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

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

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

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

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

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

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

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

- Microshock by catheter LEAKAGE CURRENT is a hypothetical ~~risk~~ HARM that cannot be excluded. The likelihood of such a shock occurring is limited.
- Only central venous catheters with the venous tip located in the right atrium are relevant.
- This limits the ~~catheters at~~ RISK to permanent catheters inserted through ~~an upper limb (~~jugular or subclavian vein~~)~~. The tip of non-permanent catheters or femoral catheters is usually not placed in the atrium.
- Side holes in the venous limb will also distribute electrical current to the body outside the heart [21] although most catheters today have no side holes in the return (venous) lumen.
- The withdrawal (arterial) lumen is electrically isolated or only connected with a high resistance to ground [22].
- If the catheter tip is placed in the right atrium as recommended for permanent catheters, the catheter will normally not touch the ~~atrium~~ atrial wall because this may cause flow problems. The requirements for CF based on the RISK of microshock were established based on measurements with metal electrodes in direct touch with the atrium.
- With the catheter not in direct contact with the myocardium the current density on the myocardial surface will be very much reduced because the current is distributed over a larger surface area. Starmer [26] reports that ~ 500 μA were required for fibrillation when applied to a circular surface with 2,5 mm diameter. When the surface area was increased to 2,5 cm in diameter the current required for fibrillation increased to more than 3 000 μA.
- In order to create a serious ~~HAZARD~~ HAZARDOUS SITUATION,

– the catheter tip ~~must~~ has to be placed in the right atrium and has to touch the ~~atrium~~ atrial wall (by mistake), and

– the PATIENT ~~must~~ has to be in touch with a current source.

Subclause 201.8.7.4.7 aa) – Measurement of the PATIENT LEAKAGE CURRENT

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

Subclause 201.8.11.2 – MULTIPLE SOCKET-OUTLETS

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

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

~~The surface of the HAEMODIALYSIS EQUIPMENT should be designed in such a way that there are no gaps and corners at the surface, where microorganisms may remain after surface disinfection.~~

~~The following is an example how disinfection efficiency and disinfectant residuals can be tested.~~

~~**a) Testing of disinfection efficiency**~~

~~**1) Chemical disinfection**~~

~~The disinfection efficiency test consists of the following steps:~~

~~(1) It has to be shown that in the disinfection phase the fluid in the HAEMODIALYSIS EQUIPMENT really reaches the intended concentration of disinfectant. The goal of this test is to verify the correct function of the hydraulic components and of the software in the disinfection process. The test is done by taking a sample of fluid from the HAEMODIALYSIS EQUIPMENT at different locations of the DIALYSIS FLUID circuit and measuring the disinfectant concentration of these samples.~~

~~(2) It has to be shown that the contact time of the disinfectant in the HAEMODIALYSIS EQUIPMENT is as intended. Using coloured test liquid instead of disinfectant, it is checked by visual inspection in each section of the fluid path that the contact time is as expected.~~

~~(3) It has to be shown that all internal tubing is included in the disinfection process. This is done by performing a normal disinfection, but using a coloured test liquid instead of real disinfectant. Then it is checked by visual inspection that in the disinfection phase all parts of the fluid system are filled with coloured liquid. No tubes or containers should be only partly filled, or filled with a liquid that is considerably lighter in colour. Such test liquids are e.g. "Methylene blue" or "Fluorescein".~~

~~An alternative method is measuring the conductivity of a conductive fluid.~~

~~(4) It has to be shown by a "quantitative suspension test" that in the worst case condition that is acceptable according to the OPERATOR'S manual (lowest concentration, shortest time), the disinfectant concentration and disinfection time deactivate the microorganisms to the necessary degrees. This test includes several types of microorganisms.~~

The following set of microorganisms is considered to cover the typical chemical disinfection methods in HAEMODIALYSIS EQUIPMENT. For validation of a specific chemical disinfection method the relevant subset (at least 4) is chosen:

– pseudomonas aeroginosa;
– staphylococcus aureus;
– bacillus subtilis spores;
– candida albicans;
– aspergillus niger;
– enterococcus hirae.

ATCC strains are recommended.

This step 4 can be done in one of three ways:

a) A disinfection is performed on the HAEMODIALYSIS EQUIPMENT, inserting a known number of microorganisms per ml of fluid, and it is checked that the number of microorganisms is reduced to the necessary degree. The necessary degree is determined by relevant standards, e.g. 10^5 for the bacteria (EN 1040) and 10^4 for the yeast (EN 1275). The test can be done either with each type of microorganism separately or with a mixture of some microorganism types. The relevant subset of microorganisms indicated above is used (at least 4).

b) A laboratory test (in test tubes) is performed, including all of the above types of microorganisms, and using the same conditions (disinfectant concentration, temperature and time) as in the HAEMODIALYSIS EQUIPMENT.

c) By literature, e.g. the validation data of the disinfectant.

2) Heat disinfection

The MANUFACTURER identifies which of the relevant microorganisms is the most heat resistive.

The following highly heat-resistive microorganism can be used: bacillus subtilis spores.

This identified type is added to the pool of at least 4 of the microorganisms indicated above and a heat disinfection is performed in the HAEMODIALYSIS EQUIPMENT.

It has to be shown that in the heat disinfection phase the fluid in the HAEMODIALYSIS EQUIPMENT really reaches the intended temperature for the necessary time. The goal of this test is to verify the correct function of the involved components and of the software in the disinfection process. The test is done by measuring the temperature in the HAEMODIALYSIS EQUIPMENT at different locations of the DIALYSIS FLUID circuit over the time.

3) Combination of chemical and heat disinfection

The temperature and the concentration distribution within the HAEMODIALYSIS EQUIPMENT are verified over the time of the disinfection procedure.

b) Testing of disinfectant residuals

It has to be shown that the rinsing process after disinfection reduces the disinfectant concentration to an acceptable level. As a standard the “Lethal dose” [LD <50] should be used as the reference limit. The test is done in the following way:

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

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

Using a colour test liquid results in higher sensitivity of the measurement than using real disinfectant but does not cover the effect of diffusion of disinfectant into plastic.

~~An alternative method is conductivity measurement as follows: Increase the conductivity level within the fluid and take samples from the most critical parts of the HAEMODIALYSIS EQUIPMENT for analysis.~~

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

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

Cleaning and disinfection can be accomplished through chemical methods, physical methods, or a combination of both. Guidance for testing of disinfectants can be found in ISO 15883 (all parts) [14], EN 14885 [4], JIS Z 2801 [20], AOAC 964 [3] or ASTM E1153 [2]. The microbial control regime should be validated considering organisms relevant to haemodialysis, representing the main microbial categories of microorganisms including Gram positives, Gram negatives, viruses, yeasts and fungi.

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

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

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

Testing of disinfectant residuals

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

The test is done in the following way:

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

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

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

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

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

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

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

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

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

The second edition of this particular standard (IEC 60601-2-16:1998, [6]) usually did not specify any definite values for the necessary ALARM LIMITS of the PROTECTIVE SYSTEMS. It was up to the MANUFACTURER to define the deviation from the value that presented a HAZARD which had to be detected by the PROTECTIVE SYSTEM and justified in the MANUFACTURER'S RISK MANAGEMENT PROCESS.

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

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

Subclause 201.12.4.4.101 – DIALYSIS FLUID composition

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

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

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

Additionally in bicarbonate treatment:

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

If other components can be added individually, additionally:

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

Where HAEMODIAFILTRATION without buffer (special form of HDF where the buffer is given to the PATIENT not as part of the DIALYSIS FLUID but as part of the SUBSTITUTION FLUID) and other special PROCEDURES (e.g. sorbent regenerative HAEMODIALYSIS EQUIPMENT) are concerned, the technical safety requirements should be defined in the scope of the MANUFACTURER'S RISK

MANAGEMENT PROCESS, for example by definition of limits for concentration deviations which would indicate system malfunctions and potential harm to the PATIENT.

Subclause 201.12.4.4.102 – DIALYSIS FLUID and SUBSTITUTION FLUID temperature

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

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

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

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

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

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

~~No adverse effects~~ Besides PATIENT discomfort ~~are known~~ for low DIALYSIS FLUID temperatures adverse effects are uncommon, but in rare cases cold dialysate can cause tachypnea, tachycardia, shivering, energy loss and slight changes in coagulation [28]. Ventricular fibrillation has been reported after cooling of the heart to less than 33 °C by rapid infusion of large amounts (> 5 l) of cold (4 °C) blood. In HAEMODIALYSIS, cooling to 33 °C would take more than 15 min even assuming high blood flow rate, low DIALYSIS FLUID temperature (10 °C) and low body weight (50 kg).

Subclause 201.12.4.4.103 – NET FLUID REMOVAL

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

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

Monitoring of the following limits by the PROTECTIVE SYSTEM is usually considered to be appropriate ~~for 4 h of dialysis~~:

- ~~the NET FLUID REMOVAL is within ±0,1 l/h of the set point~~
  for continuous treatments, for example CRRT treatments, the sliding average value of the NET FLUID REMOVAL rate – with averaging time defined by the MANUFACTURER'S RISK MANAGEMENT PROCESS – is at all time within ±0,1 l/h of the OPERATOR set point rate.

- ~~the target NET FLUID REMOVAL is to be kept within ±400 ml at any time during the treatment~~ for a typical 4 h dialysis treatment, the removed cumulated NET FLUID REMOVAL volume is at all time during the treatment time within ±400 ml of the expected cumulated NET FLUID REMOVAL volume.

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

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

Subclause 201.12.4.4.104.1 a) – Extracorporeal blood loss to the environment

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

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

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

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

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

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

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

The effects of haemorrhage are described in reference [5].

Subclause 201.12.4.4.104.1 c) – Extracorporeal blood loss to the environment

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

~~If staff is not present (e.g. home PATIENT) or delayed for a long period in the case of venous puncture cannula slippage, the blood loss from the venous access (backwards) may become hazardous to the PATIENT.~~

Subclause 201.12.4.4.104.2 – BLOOD LEAK to the DIALYSIS FLUID

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

BLOOD LEAKS of less than 0,35 ml/min blood (with an Hct of 32 %) are not considered to present a ~~HAZARD~~ serious HARM.

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

Subclause 201.12.4.4.104.3 – Extracorporeal blood loss due to coagulation

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

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

Subclause 201.12.4.4.105 – Air infusion

At the time of writing of this document there was not enough scientific literature to define a safe ALARM LIMIT in this particular standard. In [23], chapter 14, Polaschegg and Levin consider the continuous infusion of air of less than 0,03 ml/(kg min) and infusion of a bolus of 0,1 ml/kg not to be a HAZARD.

Exposure to microbubbles should be taken into account and possible preventive measures should be considered by the MANUFACTURERS' RISK MANAGEMENT PROCESS [24] [27].

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

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

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

a) it is designed with two channels and each channel is tested prior to each treatment, or

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

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

a) ~~it is completely designed with two channels~~ design with two independent actors (e.g. stopping of the pumps and closing of the clamps) and both ~~channels~~ actors are tested; or

b) the blood pump(s) and all pumps delivering in the direction of the PATIENT are turned off via two channels and even a mechanical failure (e.g. breakage of a rotor spring) cannot cause a loss of occlusion.

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

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

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

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

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

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

– air in the drip chamber(s);
– residual air in the bloodline;
– residual air in the DIALYSER;
– air in the monitor lines leading to the pressure transducers;
– air entering the system in the recirculation path of a single-needle treatment;
– air entering the EXTRACORPOREAL CIRCUIT.

Non-dissolved air can appear in bulk and in the form of bubbles of different sizes.

The physical principle used for any air detector and any electronic delays or dead times other delays should be taken into account in the RISK ANALYSIS. Today ultrasonic air detectors are used almost exclusively for the detection of air in the EXTRACORPOREAL CIRCUIT. Some of these air detectors are positioned on the partially air-filled venous drip chamber. They are usually designed as level detectors, which means that they will generate an ALARM CONDITION if the level decreases or if the drip chamber is filled with foam.

Other air detectors are positioned directly on the blood tubing and are usually capable of detecting single bubbles with volumes much lower than the volumes believed to cause a HAZARD. The important parameter of the air detector is the accumulated volume of these single bubbles. In order to avoid nuisance ALARM CONDITIONS the number of detected bubbles is integrated with a time function.

Subclause 201.12.4.4.106 – ALARM CONDITION override modes

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

Subclause 201.12.4.4.109 – Blood pump(s) and/or SUBSTITUTION FLUID pump(s) reversal

Example of a HAZARD HAZARDOUS SITUATION caused by human USE ERROR:

In case of mains power failure in a dialysis unit, it is very likely that the staff is under high stress and therefore human USE ERROR is relative likely. In this situation, the HAZARD of air infusion via the arterial bloodline (if applicable) by wrong blood pump direction can be avoided, for example by

a) prevention of wrong hand cranking direction by
   – a unidirectional cranking mechanism, or
   – a clearly marked arrow on the pump(s), or
b) avoidance of hand cranking by continuation of the blood flow with battery power.

Example of a HAZARD HAZARDOUS SITUATION caused by a technical fault:

A technical fault could cause the blood pump(s) and/or SUBSTITUTION FLUID pump(s) to rotate in the wrong direction. This can be avoided, for example by

a) wiring a DC motor with electromechanical commutation such that no random hardware failure can reverse the direction of the current, or

b) implementation of a PROTECTIVE SYSTEM independent of the motor control system, which stops the motor ~~in case of~~ if the pump(s) rotate in the wrong direction.

Subclause 201.12.4.4.112 – Anticoagulation

This document includes more detailed requirements for anticoagulant delivery means. 201.12.4.4.112 includes design requirements and requirements to address defined HAZARDOUS SITUATIONS in the MANUFACTURERS' RISK MANAGEMENT PROCESS.

Overdelivery of anticoagulant can occur during PATIENT treatment if the anticoagulant delivery means continues when the blood pump is stopped and can create a HAZARDOUS SITUATION. This can occur when the anticoagulant delivery output is connected downstream of the blood pump by the anticoagulant delivery means continuing with the blood pump stopped and delivering a bolus of anticoagulant to the connection that is then given to the PATIENT when the blood pump starts again. Overdelivery can also occur when the anticoagulant delivery does not stop with the blood pump and its output is connected upstream of the blood pump, without a system controlled clamp on the arterial access line of the PATIENT. In this case, the anticoagulant goes directly to the PATIENT while the HAEMODIALYSIS EQUIPMENT is stopped.

Underdelivery of anticoagulant can occur during PATIENT treatment if the anticoagulant delivery means is not started when the blood is running. It can also occur due to compliance in the anticoagulant delivery system (including a syringe if used) taking time to deliver at the specified rate. This is of particular importance for low anticoagulant administration rates or in cases of large variations in output pressure in the EXTRACORPOREAL CIRCUIT. This delay in anticoagulant delivery may cause coagulation and blood loss if not addressed.

IEC 60601-2-24 [7] does not apply, because its scope relates to pumps for infusion of liquids into the PATIENT, and devices for extracorporeal circulation of blood are excluded. Anticoagulant delivery means in the scope of this document are for delivery of anticoagulants into the EXTRACORPOREAL CIRCUIT.

Anticoagulant delivery means in HAEMODIALYSIS EQUIPMENT can be a syringe pump that infuses one anticoagulant (e.g. heparin) or roller pumps that infuse simultaneously Citrate and Calcium at different points of the EXTRACORPOREAL CIRCUIT (CiCa) or other designs not directly matching with IEC 60601-2-24.

All relevant HAZARDOUS SITUATIONS addressed in IEC 60601-2-24 in the use context of HAEMODIALYSIS EQUIPMENT were taken into account in this document: specification of accuracy (201.7.9.3.1, 201.12.4.4.112), underinfusion (201.12.4.4.104.3, 201.12.4.4.112), overinfusion (201.12.4.4.112), unintended bolus (201.12.4.4.112), USABILITY issues (201.12.4.4.112). Added are HAZARDOUS SITUATIONS not included in IEC 60601-2-24 but necessary for the use scenarios of HAEMODIALYSIS EQUIPMENT.

It is sometimes useful for developers to look into the IEC 60601-2-24 when developing anticoagulant delivery means for HAEMODIALYSIS EQUIPMENT.

If the HAEMODIALYSIS EQUIPMENT includes fluid (medication) delivery means for other substances than anticoagulants or for direct infusion into the PATIENT, IEC 60601-2-24 could be applicable in total or in parts. This is not addressed in this document because such use cases are not in the normal INTENDED USE of HAEMODIALYSIS EQUIPMENT.

Subclause 201.13.2.6 – Leakage of liquid

The test considers that fluid may flow out under normal working pressure. Although its performance and reproduction is difficult, the test specified in this particular standard is considered to be suitable for this type of equipment.

Subclause 201.14.13 ~~– Connection of PEMS by NETWORK/DATA COUPLING to other equipment~~ – PEMS intended to be incorporated into an IT-NETWORK

A method proven to reduce RISK for the transfer of HAEMODIALYSIS EQUIPMENT settings via an IT-NETWORK is the explicit test of the data transferred, performed by the OPERATOR and confirmation by the OPERATOR before these settings become effective in the HAEMODIALYSIS EQUIPMENT.

Subclause 201.15.4.1.101 – DIALYSIS FLUID CONCENTRATE connectors

DIALYSIS FLUID CONCENTRATES may be used in the form of powder or fluid. For DIALYSIS FLUID CONCENTRATES in the form of powder and "DIALYSIS FLUID ions for sodium chloride (powdered)", constructional features preventing their misuse are usually provided in the HAEMODIALYSIS EQUIPMENT designs. Liquid DIALYSIS FLUID CONCENTRATES are taken either from containers or from CENTRAL DELIVERY SYSTEMS, which are not prevented from being misused by constructional features.

At least the following DIALYSIS FLUID CONCENTRATE types should be taken into consideration in the MANUFACTURERS' RISK MANAGEMENT PROCESS:

- acetate DIALYSIS FLUID CONCENTRATE;
- acid DIALYSIS FLUID CONCENTRATE for use with bicarbonate DIALYSIS FLUID CONCENTRATE without sodium chloride;

  NOTE 1 With 35X, 36.83X, 45X dilution.

- acid DIALYSIS FLUID CONCENTRATE for use with bicarbonate DIALYSIS FLUID CONCENTRATE with sodium chloride;

  NOTE 2 With 35X, 36.83X, 45X dilution.

- bicarbonate DIALYSIS FLUID CONCENTRATE without sodium chloride;

  NOTE 3 Can be supplied as liquid or powder.

- bicarbonate DIALYSIS FLUID CONCENTRATE with sodium chloride;
- sodium chloride;

  NOTE 4 Can be supplied as liquid or powder.

- DIALYSIS FLUID concentrates complementary to sodium and bicarbonate.

  NOTE 5 Used for mixing systems with separate sodium and bicarbonate DIALYSIS FLUID CONCENTRATE supplies.

  NOTE 6 Can be supplied as liquid or powder.

Subclause 201.15.4.1.102 – Connectors for blood pressure transducers

Designs that use an internal transducer protector ~~placed~~ between the internal pressure transducer and the connection to the external transducer protector ~~is one method of preventing HAEMODIALYSIS EQUIPMENT contamination~~ prevent contamination of the internal transducer itself, but do not prevent the RISK of cross-contamination between PATIENTS dialysed on the same HD EQUIPMENT.

Subclause 201.16 – ME SYSTEMS

A ME SYSTEM for dialysis can comprise one or more HAEMODIALYSIS EQUIPMENT and one or more of the following (see Figure AA.1):

- DIALYSIS WATER treatment system;
- discharge (drain);
- data transfer;

– CENTRAL DELIVERY SYSTEM;
– staff call system.

NOTE Since TOUCH CURRENTS of other equipment exist in the PATIENT ENVIRONMENT (e.g. dialysis chairs), a POTENTIAL EQUALIZATION CONDUCTOR could be necessary for such equipment.

The DIALYSIS WATER treatment systems and the CENTRAL DELIVERY SYSTEMS are usually set up at a location that is remote from the HAEMODIALYSIS EQUIPMENT and cannot be connected via a MULTIPLE SOCKET-OUTLET. HAZARDS have to be minimized via the installation, by applying the supply lines, for example, to the same potential as the HAEMODIALYSIS EQUIPMENT.

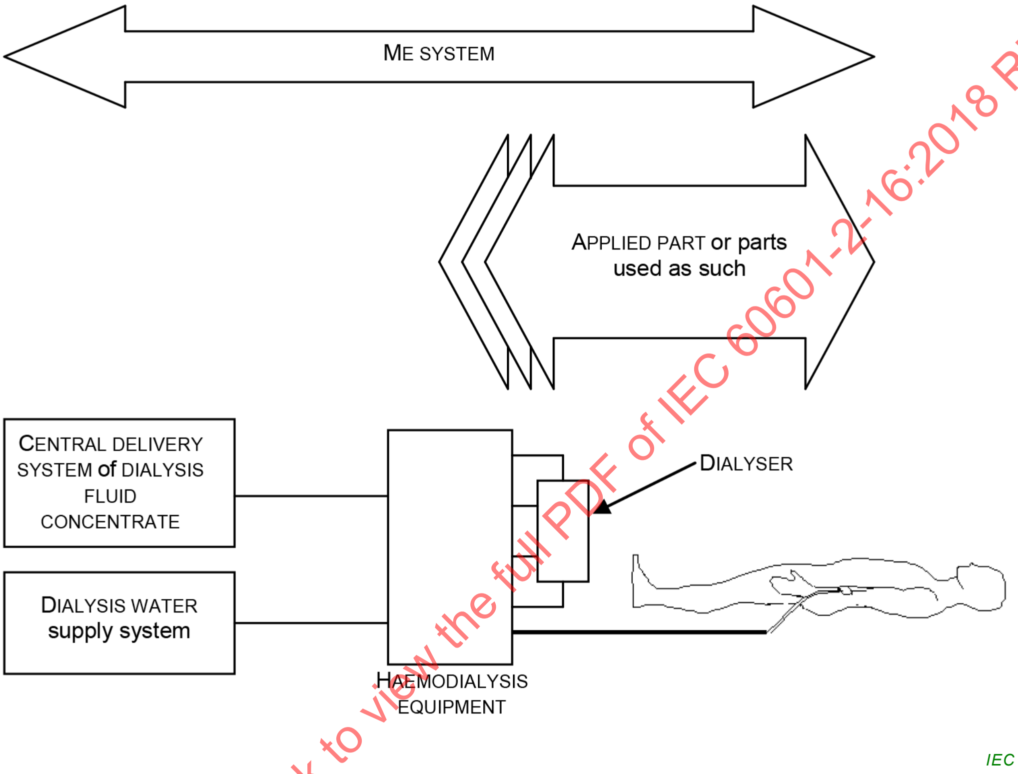

Figure AA.1 – Example of a HAEMODIALYSIS ME SYSTEM

For HAEMODIALYSIS EQUIPMENT with TYPE CF APPLIED PARTS, the following item should be considered:

The bloodlines of the EXTRACORPOREAL CIRCUIT are not considered to be insulating. It should be assumed that conducting solutions in and around the tubing establish an electrical contact with the PATIENT.

An EXTRACORPOREAL CIRCUIT or DIALYSIS FLUID circuit is considered isolating if

a) the material is electrically isolating, and
b) the circuit is built such that a rupture is sufficiently unlikely.

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

Point b) is demonstrated by the MANUFACTURER of the circuit by RISK MANAGEMENT which includes the interface between the HAEMODIALYSIS EQUIPMENT and the circuit and the manufacturing PROCESS.

Subclause 201.16.9.1 – Connection terminals and connectors

According to the state of the art, the PROTECTIVE SYSTEM for "composition of the DIALYSIS FLUID" is based on the measurement of the conductivity or the volumetric admixture. Depending on the operating mode (acetate, bicarbonate), an incorrect DIALYSIS FLUID CONCENTRATE is frequently detected via the conductivity or the volumetric admixture.

Additional measures besides colour coding of the CENTRAL DELIVERY SYSTEM may be required by RISK MANAGEMENT in case of DIALYSIS FLUID CONCENTRATES which, although they deliver a conductivity within the expected range, are hazardous for the treatment type concerned in their composition (e.g. acid DIALYSIS FLUID CONCENTRATE 45X ratio for acetate dialysis).

In such cases, the RESPONSIBLE ORGANIZATION should initiate the appropriate measures which are equivalent to colour coding with the pertinent operating mode, such as disabling the operating mode of acetate HAEMODIALYSIS or mechanically coding the HAEMODIALYSIS EQUIPMENT and the DIALYSIS FLUID CONCENTRATE container.

Subclause 208.4 – General requirements

IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 are written with the focus on intensive care or surgery environments and add in 6.1.2 a very PATIENT-centric view of potential results of failure to respond to the cause of ALARM CONDITIONS. HAEMODIALYSIS EQUIPMENT is mainly used in a chronic ambulant approach. The PATIENTS normally do not have life threatening status. ALARM CONDITIONS mostly arise from technical causes and the therapy has in most cases of problems the chance to go to a safe state, which only loses time for PATIENT and OPERATORS, but which is one of the most important issues in a timely exact planned schedule of subsequent following shifts. The environment in a normal chronic HAEMODIALYSIS clinic is dominated by the HAEMODIALYSIS EQUIPMENT, in many cases from one MANUFACTURER. Normally, other ME EQUIPMENT will not be used continuously beside the HAEMODIALYSIS EQUIPMENT in the PATIENT ENVIRONMENT.

In this ambulatory environment the ALARM CONDITION categories need completely different priorities than in an environment where the PATIENTS have life-threatening status and the therapy is life-supporting. In the ambulatory environment, 6.1.2, with Table 1, of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 would not reflect the needed priorities.

Even in the critical care environments, the HAEMODIALYSIS EQUIPMENT is not life-supporting and most ALARM CONDITION situations would not be a ~~HAZARD~~ HAZARDOUS SITUATION for PATIENT and OPERATOR and the ALARM CONDITION priority will be low. In some cases, OPERATORS from chronic HAEMODIALYSIS support and operate the HAEMODIALYSIS EQUIPMENT in the intensive care environment.

For HAEMODIALYSIS EQUIPMENT not used in intensive care environments, the actual used – over years of operation optimized – ALARM SYSTEMS should not be worsened by the need of applying IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012.

Because of these reasons, this document only requires the complete implementation of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 for HAEMODIALYSIS EQUIPMENT with INTENDED USE in the intensive care environment. For this environment, Table AA.1 shows how possible ALARM CONDITION priorities according to IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 could be adapted for HAEMODIALYSIS EQUIPMENT needs. If the HAEMODIALYSIS EQUIPMENT is intended to be used in both environments, the ALARM SYSTEM according to IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 has to be implemented and selectable by the RESPONSIBLE ORGANIZATION, but ALARM SYSTEMS with deviation from 6.1.2, 6.3.2.2 and 6.3.3.1 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 are allowed for additional implementation.

For HAEMODIALYSIS EQUIPMENT with a screen, this particular standard does not mandatorily require that the visual ALARM SIGNAL has to be indicated by an indicator light that is independent of the screen, since there may be applications where it is appropriate if the ALARM SIGNAL is indicated on the screen. In large-size dialysis units, however, it is probably more appropriate to provide an indicator light that can be seen from a far distance and is installed in such a position (e.g. up-raised) that the HAEMODIALYSIS EQUIPMENT activating the ALARM SIGNAL can be readily located.

Table AA.1 – Possible Example of ALARM CONDITION priorities according to 6.1.2 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, adapted for HAEMODIALYSIS EQUIPMENT needs

ALARM CONDITION	ALARM CONDITION priority
Different reasons (e.g. pressures, technical faults)	
Reasons that lead to a stop of the blood system flow through the EXTRACORPOREAL CIRCUIT	LOW PRIORITY, yellow
Blood loss due to coagulation in the extracorporeal system	
Blood pump stop ALARM CONDITION (201.12.4.4.104.3), as escalation of above ALARM CONDITION	MEDIUM PRIORITY, yellow flashing
Mains off and backup-battery running system, before battery goes down (201.11.8 b))	
Possible blood loss out of the puncture side site or open catheter, following accidental needle or catheter disconnect (201.12.4.4.104.1)	
Detectable by low VENOUS PRESSURE	HIGH PRIORITY, red flashing
PHYSIOLOGICAL ALARM CONDITIONS, if not specified in other standards	
PHYSIOLOGICAL ALARMS CONDITIONS, for example non-invasive blood pressure limit ALARM CONDITION	HIGH PRIORITY, red flashing Possible: escalation with two different limits
Treatment deviation, influence on prescription	
For example balancing ALARMS CONDITIONS, long-lasting bypass of DIALYSING DIALYSIS FLUID	LOW PRIORITY, yellow
Technical information	
Technical faults, but blood system is running, for example short bypass of dialysate	INFORMATION SIGNAL, for example green flashing Alternative is the use of LOW PRIORITY, yellow

An ALARM SIGNAL activated in case of extracorporeal blood loss to the environment (see 201.12.4.4.104.1) is one example of a HIGH PRIORITY ALARM SIGNAL that requires immediate response by the OPERATOR. If the blood flow is stopped for an extended period of time (201.12.4.4.104.3), this is an example for a MEDIUM PRIORITY ALARM SIGNAL. In most other ALARM CONDITIONS, the PROTECTIVE SYSTEM puts the HAEMODIALYSIS EQUIPMENT in a state which is safe for the PATIENT, at least temporarily, and therefore such an ALARM SIGNAL is indicated by a LOW PRIORITY ALARM SIGNAL. Other ALARM SIGNALS should be determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS.

Subclause 208.6.3.1 – General

If the OPERATOR is allowed to configure the contents of the screen, the MANUFACTURER has to use constructive measures (and not just notes in the instructions for use) to ensure that the ALARMS SIGNALS are indicated can be seen under any and all circumstances.

~~**Subclause 208.6.3.3.2 – Volume of auditory ALARM SIGNALS and INFORMATION SIGNALS**~~

~~It is intended to prevent the OPERATOR from misusing the volume adjustment function for silencing alarms, since such a silencing could not be terminated automatically. The RESPONSIBLE ORGANIZATION, however, should have the possibility of adjusting the alarm volume to a reasonable value depending on the sound level on site.~~

Subclause 208.6.3.3.101 – Special characteristics of auditory ALARM SIGNALS for HAEMODIALYSIS EQUIPMENT

There are ALARM CONDITIONS which do not present any HAZARD HAZARDOUS SITUATION if they are the auditory ALARM SIGNAL is AUDIO PAUSED for more than 3 min, but where elimination of the cause of the ALARM CONDITION often takes more than 3 min, for example in case of a conductivity ALARM CONDITION caused by an empty DIALYSIS FLUID CONCENTRATE container. In this case, the PATIENT'S state will not aggravate deteriorate during the alarm AUDIO PAUSED period and the activated bypass mode.

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

Besides the PERMANENTLY INSTALLED connection to SUPPLY MAINS, other means of preventing connection to a non-grounded outlet can be used, such as needed for CLASS I devices the same level of safety may be achieved by a unique MAINS PLUG connector that is normally not used in the HOME HEALTHCARE ENVIRONMENT. This allows the PATIENT OPERATOR to disconnect and remove the device without the problem of reconnecting it to another SUPPLY MAINS socket-outlet with an improper PROTECTIVE EARTH CONNECTION. If a unique SUPPLY MAINS socket-outlet connector is used, it has to be installed and tested by the RESPONSIBLE ORGANIZATION.

Annex BB
(informative)

Examples of HAZARDS, foreseeable sequences of events, and HAZARDOUS SITUATIONS in HAEMODIALYSIS EQUIPMENT

Table BB.1 is not intended to be a complete RISK ANALYSIS and is provided partially and for example only. Given HARM levels do not apply to all PATIENT groups. Risk assessment is the responsibility of each MANUFACTURER.

Table BB.1 – HAZARDOUS SITUATION list following ISO 14971:2007, Annex E

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
Multiple HAZARDS possible	Venous needle punctures vascular access	Extracorporeal blood flow into intertissue through venous needle	Haematoma	
	Delivery rate or amount of heparin too high	Heparin concentration too high inside blood volume	~~Excessive~~ Internal bleeding	– IEC 60601-2-16: 201.11.8
	Blood flow was stopped too long	Coagulation of extracorporeal blood	Blood loss	– IEC 60601-2-16: 201.7.9.2.5; 201.7.9.3.1; 201.11.8; 201.12.4.4.104.3 – IEC 60601-1:2005: 7.9.2.4
	Interruption of power supply too long			– IEC 60601-2-16: 201.11.8; 201.7.9.3.1; 201.12.4.4.104.3
	High ULTRAFILTRATION rate over DIALYSER semipermeable membrane in relation to blood flow rate	Increasing haematocrit may block fibres of DIALYSER		– IEC 60601-2-16: 201.12.4.4.104.3
	Venous needle slips out	Extracorporeal blood is pumped to environment		– IEC 60601-2-16: 201.7.9.2.2, 7th hyphen; 201.7.9.3.1, 2nd bullet, 6th hyphen; 201.12.4.4.104.1
	Connector of disposable behind arterial blood pump opened or leaks			– IEC 60601-2-16: 201.7.9.2.2, 3rd hyphen; 201.12.4.4.104.1
	Pressure higher than disposal resist leading to rupture			– IEC 60601-2-16: 201.12.4.4.104.1
	~~Post-blood pump Heparin pump Syringe plunger slipped out~~ Syringe plunger of heparin pump, which arranged downstream of blood pump slipping out			– IEC 60601-2-16: 201.12.4.4.104.1

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	DIALYSER semi-permeable membrane or fibre broken	BLOOD LEAKS into DIALYSIS FLUID		– IEC 60601-2-16: 201.7.9.3.1, 2nd bullet, 7th hyphen; 201.12.4.4.104.2
	Unintended blood flow reversal and air in the ~~system~~ EXTRACORPOREAL CIRCUIT	Air infused over arterial ~~branch~~ PATIENT CONNECTION	Air infusion	– IEC 60601-2-16: 201.7.9.3.1, 2nd bullet, 2nd hyphen; 201.12.4.4.109
	Level regulator pump pumps air into ARTERIAL PRESSURE monitor ~~pre-~~upstream of arterial blood pump			– IEC 60601-2-16: 201.7.9.3.1, 2nd bullet, 2nd hyphen; 201.12.4.4.109
	Air sucked into blood side before blood pump (material damage or unintentional opening of the infusion port)	Air infused over venous ~~branch~~ PATIENT CONNECTION		– IEC 60601-2-16: 201.7.9.2.2, 8th hyphen; 201.7.9.3.1, 2nd bullet, 2nd hyphen; 201.12.4.4.105; 201.12.4.4.106; 201.12.4.4.107
	Level regulator pump pumps air into arterial and/or VENOUS PRESSURE monitor ~~post~~ downstream of arterial blood pump.			– IEC 60601-2-16: 201.7.9.3.1, 2nd bullet, 2nd hyphen; 201.12.4.4.105, 201.12.4.4.106, 201.12.4.4.107
	SUBSTITUTION FLUID pump pumps air into arterial and/or venous ~~branch~~ EXTRACORPOREAL CIRCUIT			– IEC 60601-2-16: 201.7.9.3.1, 2nd bullet, 2nd hyphen; 201.12.4.4.105; 201.12.4.4.106; 201.12.4.4.107
	Improper function of ultrasonic air detector (e.g. caused by coagulum or ultrasound gel)			– IEC 60601-2-16: 201.7.9.2.2, 10th hyphen
	Air entering the ~~system~~ EXTRACORPOREAL CIRCUIT in the recirculation path of single-needle treatment			– IEC 60601-2-16: 201.7.9.2.2, 11th hyphen
	Blood line kinked (specially DIALYSER input)	~~Red blood cells~~ Erythrocytes exposed to high sheer forces.	Haemolysis	– IEC 60601-2-16: 201.7.9.2.2, 9th hyphen
	Reduced blood flow rate by high negative arterial ~~pre-~~upstream of pump ~~pressure~~	Reduced effectiveness of HAEMODIALYSIS treatment	Prescribed HAEMODIALYSIS treatment dose not delivered	– IEC 60601-2-16: 201.7.9.2.2, 13th hyphen
	Insufficient degassing of DIALYSIS FLUID			
	Insufficient flow rate of fresh DIALYSIS FLUID			– IEC 60601-2-16: 201.7.9.3.1, 2nd bullet,4th hyphen
	Blood flow rate too low due to technical defect			– IEC 60601-2-16: 201.4.3.101
	DIALYSIS FLUID bypassing DIALYSER			– IEC 60601-2-16: 201.4.3.101
	Effective HAEMODIALYSIS time too low due to technical defect			– IEC 60601-2-16: 201.4.3.101
	SUBSTITUTION FLUID flow rate too low due to technical defect			– IEC 60601-2-16: 201.4.3.101

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
Biological	Blood of the previous PATIENT flows into the pressure inlet connection of the ~~machine~~ HAEMODIALYSIS EQUIPMENT	Pyrogens/ endotoxins/bacteria/viruses may contaminate the blood directly (cross infection)	Virus/bacterial infection/ Pyrogen reaction	– IEC 60601-2-16: 201.15.4.1.102
	Disinfection PROCEDURE of ~~machine~~ HAEMODIALYSIS EQUIPMENT internally and externally has inadequately removed ~~viruses~~ viral contamination			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 7.9.2.12, 11.6.6 – IEC 60601-2-16: 201.7.9.2.12, 1st, 2nd, 3rd hyphens; 201.11.6.6
	Infusion of contaminated DIALYSIS FLUID into blood from DIALYSIS FLUID side in ONLINE HDF / HF systems	Pyrogens/ endotoxins/bacteria may contaminates the blood directly		– IEC 60601-2-16: 201.7.9.3.1, 2nd bullet,14th hyphen; 201.12.4.4.111
	Contaminated surface of ENCLOSURE	Skin contamination with bacteria	Bacterial infection	– IEC 60601-2-16: 201.7.9.2.2, 1st hyphen
Chemical	Treatment of PATIENT when ~~machine~~ HAEMODIALYSIS EQUIPMENT is in disinfection mode	Blood contamination with toxins	Poisoning / allergy	– IEC 60601-2-16: 201.12.4.4.108
	~~Dialysis fluid system has been inadequately rinsed out from disinfectant~~ Disinfectant has been inadequately rinsed from DIALYSIS FLUID circuit			– IEC 60601-2-16: 201.11.6.6
	OPERATOR ~~uses~~ connects disinfectant canister instead of bicarbonate DIALYSIS FLUID CONCENTRATE or acid/acetate DIALYSIS FLUID CONCENTRATE canister to ~~machine~~ HAEMODIALYSIS EQUIPMENT			– IEC 60601-1:2005 and IEC 60601-1:2005:AMD1:2012: 15.4.1 – IEC 60601-2-16: 201.15.4.1.101
	Toxic material comes in contact with DIALYSIS FLUID (e.g. via water supply or by components of the hydraulics)			– IEC 60601-1:2005: 11.7 – IEC 60601-2-16: 201.7.9.3.1, 2nd bullet, 13th hyphen
Biological	Returning fluid into CENTRAL DELIVERY SYSTEM or DIALYSIS WATER ~~/concentrate~~ supply	Blood contamination with toxins	Poisoning/ allergy	– IEC 60601-2-16: 201.12.4.4.108
Multiple HAZARDS possible	~~DIALYSING~~ DIALYSIS - / SUBSTITUTION FLUID temperature too low	Blood is cooled directly (infusion) or via DIALYSER	Cooling heart until cardiac arrest	– IEC 60601-1:2005: 12.4.3 – IEC 60601-2-16: 201.7.9.3.1, 2nd bullet,4th hyphen; 201.12.4.4.102; 201.11.8
	~~DIALYSING~~ DIALYSIS - / SUBSTITUTION FLUID temperature too high	Blood is heated directly (infusion) or via DIALYSER	Haemolysis	– IEC 60601-1:2005: 12.4.3 – IEC 60601-2-16: 201.7.9.2.6, 4th hyphen; 201.7.9.3.1, 2nd bullet, 4th hyphen; 201.12.4.4.102; 201.11.8

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	DIALYSIS FLUID ~~composition~~ Na concentration lower than prescribed	Blood is dialysed against or infused with (ONLINE HDF) DIALYSIS FLUID of too low ~~composition (NaCl)~~ concentration (Na)	Hyponatremia	– IEC 60601-1:2005: 12.4.3 – IEC 60601-2-16: 201.4.3.101; 201.7.9.3.1, 2nd bullet, 3rd hyphen
	DIALYSIS FLUID ~~composition~~ Na concentration lower than 120 mmol/l		Haemolysis	– IEC 60601-1:2005: 12.4.3 – IEC 60601-2-16: 201.12.4.4.101
	DIALYSIS FLUID ~~composition~~ Na concentration higher than prescribed	Blood is dialysed against or infused with (ONLINE HDF) DIALYSIS FLUID of too high ~~composition (NaCl)~~ concentration (Na)	Hypernatremia	– IEC 60601-1:2005: 12.4.3 – IEC 60601-2-16: 201.4.3.101; 201.7.9.3.1, 2nd bullet, 3rd hyphen
	DIALYSIS FLUID ~~composition~~ Na concentration higher than 160 mmol/l			– IEC 60601-1:2005: 12.4.3 – IEC 60601-2-16: 201.12.4.4.101
	Bicarbonate DIALYSIS FLUID ~~composition~~ concentration too low	Blood is dialysed against or infused with (ONLINE HDF) DIALYSIS FLUID of too low ~~composition~~ concentration (Bicarbonate)	Acidosis	– IEC 60601-1:2005: 12.4.3 – IEC 60601-2-16: 201.12.4.4.101
	Acid DIALYSIS FLUID CONCENTRATE instead of acetate DIALYSIS FLUID CONCENTRATE when acetate ~~dialysis~~ HAEMODIALYSIS treatment has been selected			– IEC 60601-2-16: 201.7.9.2.5, 2nd hyphen; 201.12.4.4.101; 201.15.4.1.101; 201.16.9.1
	Acid DIALYSIS FLUID CONCENTRATE instead of ~~BIC~~ bicarbonate DIALYSIS FLUID CONCENTRATE when ~~BIC~~ bicarbonate HAEMODIALYSIS treatment has been selected			– IEC 60601-2-16: 201.7.9.2.5, 2nd hyphen; 201.12.4.4.101; 201.15.4.1.101; 201.16.9.1
	Acetate DIALYSIS FLUID CONCENTRATE instead of bicarbonate DIALYSIS FLUID CONCENTRATE when bicarbonate HAEMODIALYSIS treatment has been selected			– IEC 60601-2-16: 201.7.9.2.5, 2nd hyphen; 201.12.4.4.101; 201.15.4.1.101; 201.16.9.1
	Acetate HAEMODIALYSIS treatment instead of bicarbonate HAEMODIALYSIS treatment		Hyperacetatemia	– IEC 60601-2-16: 201.12.4.4.110
	Bicarbonate DIALYSIS FLUID ~~composition~~ concentration too high	Blood is dialysed against or infused with (ONLINE HDF)DIALYSIS FLUID of too high ~~composition~~ concentration (bicarbonate)	Alkalosis	– IEC 60601-1:2005: 12.4.3 – IEC 60601-2-16: 201.12.4.4.101
	Acetate DIALYSIS FLUID CONCENTRATE instead of acid DIALYSIS FLUID CONCENTRATE when bicarbonate HAEMODIALYSIS treatment has been selected			– IEC 60601-2-16: 201.7.9.2.5, 2nd hyphen; 201.12.4.4.101; 201.15.4.1.101; 201.16.9.1
	SUBSTITUTION FLUID bolus volume too high	Blood volume increased	Extracellular volume change	– IEC 60601-1:2005: 12.4.3 – IEC 60601-2-16: 201.12.4.4.103

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	Priming or returning volume too high due to technical faults			– IEC 60601-1:2005: 12.4.3 – IEC 60601-2-16: 201.12.4.4.103
	Inlet DIALYSIS FLUID flow rate into DIALYSER higher than outlet flow rate			– IEC 60601-2-16: 201.12.4.4.103; 201.7.9.2.2; 201.7.9.2.5; 201.7.9.3.1
	SUBSTITUTION FLUID volume higher than ULTRAFILTRATION volume			– IEC 60601-1:2005: 12.4.3 – IEC 60601-2-16: 201.12.4.4.103
	Dry weight not achieved	Insufficient removal of ~~blood water~~ fluid from the PATIENT	Interdialytic overhydration	– IEC 60601-1:2005: 12.4.3 – IEC 60601-2-16: 201.12.4.4.103
	SUBSTITUTION FLUID bolus volume too low	Insufficient increase of PATIENT blood volume	Extracellular volume change	– IEC 60601-1:2005: 12.4.3
	~~Ultrafiltration~~ NET FLUID REMOVAL volume too high	Excessive removal of ~~bloof water~~ fluid from the PATIENT		– IEC 60601-1:2005: 12.4.3 – IEC 60601-2-16: 201.12.4.4.103
	~~Ultrafiltration~~ NET FLUID REMOVAL rate greater than set rate			– IEC 60601-1-10:2007: Clause 4 – IEC 60601-2-16: 201.12.4.4.103; 201.7.9.2.2; 201.7.9.2.5; 201.7.9.3.1; 201.11.8
	DIALYSIS FLUID loss from balanced ~~system~~ DIALYSIS FLUID circuit			– IEC 60601-2-16: 201.12.4.4.103
	ULTRAFILTRATION volume higher than needed by corresponding SUBSTITUTION FLUID volume			– IEC 60601-2-16: 201.12.4.4.103
Operational	Wrong restoring of data/instructions after power interruption	Incorrect treatment	Multiple harms possible	– IEC 60601-2-16: 201.11.8
	Faulty treatment data/instructions from PATIENT card or IT-NETWORK			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 14.13 – IEC 60601-2-16: 201.14.13
	Faulty treatment instruction(s) on screen from IT-NETWORK			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 14.13 – IEC 60601-2-16: 201.14.13
Information	~~Periodical~~ Preventive or corrective maintenance has not or incorrectly been carried out			– IEC 60601-1:2005: 7.9.2.13
	Expected service life is elapsed			– IEC 60601-1:2005: 4.4

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	Markings or ~~information~~ instruction for use missing or wrong			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 7.1; 7.2; 7.4; 7.5; 7.6; 7.9.2 – IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012: 5.2; 6.1; 6.2 – IEC 60601-1-10:2007; 5.1; 5.2 – IEC 60601-2-16: 201.7.9.2.2
	Service information missing or wrong			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 7.3; 7.7; 7.9.2.13; 7.9.3 – IEC 60601-2-16: 201.7.9.2.6
	OPERATOR response missing or wrong (USE ERROR)			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 7.8; 7.9.2.8; 7.9.2.9; 7.9.2.10; 7.9.2.11; 7.9.2.14; 9.2.3.1; 12.1; 12.2; 12.4.2 – IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012: 6.1.2; 6.3.1; 6.3.2.1 – IEC 60601-1-10:2007; 6.1; 6.2; 6.3; 6.4 – IEC 60601-2-16: 201.7.9.2.2; 201.7.9.2.6; 201.7.9.2.14; 201.7.9.3.1; 208.4; 208.6.3.1; 208.6.3.3.2; 208.6.3.3.3; 201.12.4.4.110
Operational	Failure of ALARM CONDITION override mode			– IEC 60601-2-16: 201.12.4.4.106
	Failure of PROTECTIVE SYSTEMS			– IEC 60601-2-16: 201.12.4.4.107
Electrical	~~Reduced~~ Electrical insulation not sufficient	LEAKAGE CURRENT	Electric shock	– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 8.5; 8.6; 8.7; 8.8; 13.1.3; 13.2.2 – IEC 60601-2-16: 201.8.3; 201.8.7.4.7; 201.11.6.3
	~~Reduced~~ CREEPAGE DISTANCES and air clearance not sufficient			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 8.9; 13.2.6 – IEC 60601-2-16: 201.13.2.6
	Internal or external leaks that reduce CREEPAGE DISTANCES and AIR CLEARANCE			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 8.9
	Rapid ageing of insulation			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 11.1; 11.6.6

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	Touching ACCESSIBLE PARTS			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 4.8; 4.9; 5.9.2; 7.9.2.7; 8.4; 8.5; 8.10; 8.11; 9.2.2.4 – IEC 60601-2-16: 201.7.9.2.6; 201.8.11.2
	Ingress of fluid into the ~~device~~ HAEMODIALYSIS EQUIPMENT			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 11.6 – IEC 60601-2-16: 201.11.6.3
	Components used outside of specified current ratings			– IEC 60601-1:2005: 13.2.3
	~~Exchange~~ Destruction of parts when replacing			– IEC 60601-1:2005: 15.2
	~~Mechanical parts of the housing~~ Excessive mechanical stress caused by pushing, impact, dropping, and rough handling			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 15.3
	Overheating of transformer			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 15.5
	Drain connected to ~~central~~ DIALYSIS WATER supply			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 15.4.1
	DIALYSIS FLUID CONCENTRATE connected to ~~central~~ DIALYSIS WATER supply			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 15.4
	~~ME-System within/ outside the PATIENT ENVIRONMENT~~ Incorrectly arranged ME SYSTEM			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 16.1; 16.2; 16.3; 16.4; 16.5; 16.6; 16.9 – IEC 60601-2-16: 201.16.2; 201.16.6.3
	Treatment with ~~atrial~~ central venous catheter whose tip is in the right atrium by HAEMODIALYSIS EQUIPMENT with TYPE B ~~device~~ APPLIED PARTS	PATIENT LEAKAGE CURRENT	Electric shock	– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 8.7 – IEC 60601-2-16: 201.7.9.2.5; 201.8.3
	Magnetic and electric fields cause disruption of proper operation through interference from other electrical equipment and power supply	Incorrect treatment	Multiple harms	– IEC 60601-1-2:~~2007~~ 2014 – IEC 60601-2-16: 202.3.18
	Magnetic and electric fields cause disruption of proper operation through interference to other ME EQUIPMENT and power supply		Multiple harms to PATIENTS and others	– IEC 60601-1-2:~~2007~~ 2014
Chemical	Escape of chemical substances	Contact with chemicals	Body harm	– IEC 60601-1:2005: 7.9.2.4; 11.6.4

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	High pressure fluid ejection			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 9.7
Thermal	Hot external or internal components	Contact with high temperature fluids	Body harm	– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 11.1; 11.6.4; 11.6.6
	High pressure hot fluid ejection			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 9.7
Mechanical	Finger into roller pump	Crushing/Shearing/Limb breaking	Bruise/ Sprain/Cut/Fractures	– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 5.9.2; 9.2.2.4.4
	Limb between moving parts			– IEC 60601-1:2005: 9.2.2.2; 16.7
	Foot under the base			
	~~Machine~~ HAEMODIALYSIS EQUIPMENT on inclined plane			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 9.4
	Displacement of ~~machine~~ HAEMODIALYSIS EQUIPMENT			
	Sharp parts	Cutting	Body harm	– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 9.3
	~~Whole in housing~~ Openings in enclosure with moving parts behind			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 5.9.2
Thermal	Components used outside of specified current ratings	Fire	Multiple harms to PATIENTS and others	– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 4.8; 4.9; 13.1.2; 13.2.3; 13.2.13
	Ingress of water into the device leads to short cut current			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 11.6 – IEC 60601-2-16: 201.11.6.3
	Defective control of heater			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 13.2.4; 13.2.5; 13.2.13 15.4.2
	Impaired cooling			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 13.2.7
	Interruption and short circuit of motor capacitors			– IEC 60601-1:2005: 13.2.9
	Defects of battery			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 15.4.3.1
	Incorrect polarity of battery connection			– IEC 60601-1:2005: 15.4.3.2

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	Overcharging battery			– IEC 60601-1:2005: 15.4.3.3
	Excessive current from battery			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 15.4.3.5
	Overheating of transformer			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 15.5

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3 Under preparation.

4 Second edition, withdrawn ~~and replaced by IEC 60601-2-16:2008~~.

5 This document replaces ISO 8637:2010 and ISO 8637:2010/AMD1:2013.

6 Under preparation. Stage at the time of publication: ISO/FDIS 8637-2:2018. This document will replace ISO 8638:2010.

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Index of defined terms used in this particular standard

IEC 60601-2-16

Edition 5.0 2018-04

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

Appareils électromédicaux –
Partie 2-16: Exigences particulières pour la sécurité de base et les performances essentielles des appareils d'hémodialyse, d'hémodiafiltration et d'hémofiltration

IEC 60601-2-16:2018-04(en-fr)

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International standard IEC 60601-2-16 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This fifth edition cancels and replaces the fourth edition of IEC 60601-2-16 published in 2012. 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 and IEC 60601-1:2005/AMD1:2012, of references and requirements to IEC 60601-1-2:2014, of references to IEC 60601-1-6:2010 and IEC 60601-1-6:2010/AMD1:2013, of references and requirements to IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, of references to

IEC 60601-1-9:2007 and IEC 60601-1-9:2007/AMD1:2013, of references to IEC 60601-1-10:2007 and IEC 60601-1-10:2007/AMD1:2013 and of references to IEC 60601-1-11:2015;

b) widening of the scope;

c) editorial improvements;

d) addition of requirements for anticoagulant delivery means;

e) other few small technical changes.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/1557/FDIS	62D/1585/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

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 THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD 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 particular standard 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 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 publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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

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

INTRODUCTION

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

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of the general standard[1] 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.

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, [12][2]);
– DIALYSERS (see ISO 8637-1, [11]);
– DIALYSIS FLUID CONCENTRATES (see ISO 23500-4, [18]);
– DIALYSIS WATER supply systems (see ISO 23500-2, [16]);
– CENTRAL DELIVERY SYSTEMS for DIALYSIS FLUID CONCENTRATES (see ISO 23500-4, [18]), described as systems for bulk mixing concentrate at a dialysis facility;
– equipment used to perform PERITONEAL DIALYSIS (see IEC 60601-2-39, [8]).

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

2 Numbers in square brackets refer to the Bibliography.

201.1.2 Object

Replacement:

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

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2:2014, IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1-10:2007 and IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-11:2015 apply as modified in Clauses 202, 208, 210 and 211. IEC 60601-1-3 and IEC 60601-1-12 do not apply. IEC 60601-1-9:2007 and IEC 60601-1-9:2007/AMD1:2013 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 the general standard 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 the general standard.

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

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) 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 particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"*Replacement*" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"*Addition*" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"*Amendment*" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.147, 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 the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography.

Clause 2 of the general standard applies, except as follows:

Replacement:

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

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

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

Addition:

IEC 60601-1-10:2007, *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 60601-1-11:2015, *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 61672-1, *Electroacoustics – Sound level meters – Part 1: Specifications*

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

201.3 Terms and definitions

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

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

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

NOTE An index of defined terms is found beginning on page 74.

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.1.

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

[SOURCE: ISO 23500-1:— [15], 3.15, modified – The word "dialysing fluid" has been added as synonym, and the notes have been deleted.]

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

201.3.207
EXTRACORPOREAL CIRCUIT
blood lines, DIALYSER and any integral ACCESSORY

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

201.3.208
HAEMODIAFILTRATION
HDF
PROCESS whereby concentrations of water-soluble substances in a PATIENT'S blood and an excess of fluid of a PATIENT are corrected by a simultaneous combination of HD and HF

201.3.209
HAEMODIALYSIS
HD
PROCESS whereby concentrations of water-soluble substances in a PATIENT'S blood and an excess of fluid of a PATIENT are corrected by bidirectional diffusive transport and ULTRAFILTRATION across a semi-permeable membrane separating the blood from the DIALYSIS FLUID

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

201.3.210
*** HAEMODIALYSIS EQUIPMENT**
ME EQUIPMENT or ME SYSTEM used to perform HAEMODIALYSIS, HAEMODIAFILTRATION and/or HAEMOFILTRATION

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

201.3.211
HAEMOFILTRATION
HF
PROCESS whereby concentrations of water-soluble substances in a PATIENT'S blood and an excess of fluid of a PATIENT are corrected by convective transport via ULTRAFILTRATION and partial replacement by a SUBSTITUTION FLUID resulting in the required NET FLUID REMOVAL

201.3.212
NET FLUID REMOVAL
fluid loss from the PATIENT

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

201.3.213
*** ONLINE HDF**
HAEMODIAFILTRATION PROCEDURE where the HAEMODIALYSIS EQUIPMENT produces SUBSTITUTION FLUID for infusion from DIALYSIS FLUID for the HAEMODIAFILTRATION treatment

201.3.214
*** ONLINE HF**
HAEMOFILTRATION PROCEDURE where the HAEMODIALYSIS EQUIPMENT produces the SUBSTITUTION FLUID for infusion from DIALYSIS FLUID for the HAEMOFILTRATION treatment

201.3.215
*** PROTECTIVE SYSTEM**
automatic system, or a constructional feature, specifically designed to protect the PATIENT against HAZARDOUS SITUATIONS

201.3.216
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:—[15], 3.40, modified – The words "patient's blood" and "ultrafiltration" have been replaced respectively by "EXTRACORPOREAL CIRCUIT" and "filtration" in the definition, and the notes have been deleted.]

201.3.217
TRANSMEMBRANE PRESSURE
TMP
fluid pressure difference exerted across the semi-permeable membrane of the DIALYSER

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

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

201.3.218
*** ULTRAFILTRATION**
PROCESS of fluid removal from the PATIENT'S blood across the semi-permeable membrane of the DIALYSER

201.3.219
VENOUS PRESSURE
pressure measured in the blood return line of the EXTRACORPOREAL CIRCUIT between the DIALYSER connection and PATIENT CONNECTION

201.3.220
DIALYSIS WATER
water that has been treated to meet the requirements of ISO 23500-3 [17] and which is suitable for use in HAEMODIALYSIS applications, including the preparation of DIALYSIS FLUID, reprocessing of DIALYSERS, preparation of concentrates and preparation of SUBSTITUTION FLUID for online convective therapies

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

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

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.3 * ESSENTIAL PERFORMANCE

Addition:

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.

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 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).

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 include the pump segment fatigue for the maximum specified usage life of the EXTRACORPOREAL CIRCUIT.

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

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

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

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

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

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

– *measure the blood flow rate.*

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

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

NOTE 3 The blood flow rate in peristaltic pumps can be affected by negative input pressures.

201.4.3.103 DIALYSIS FLUID flow rate

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

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

Compliance is checked under the following test conditions:

- *set the HAEMODIALYSIS EQUIPMENT to the HAEMODIALYSIS mode as specified by the MANUFACTURER;*
- *set the HAEMODIALYSIS EQUIPMENT to maximum DIALYSIS FLUID flow rate;*
- *measure the* DIALYSIS FLUID *flow rate over a period of 30 min;*
- *set the HAEMODIALYSIS EQUIPMENT to minimum DIALYSIS FLUID flow rate;*
- *measure the DIALYSIS FLUID flow rate over a period of 30 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;*
- *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 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 above the lowest operating pressure specified by the MANUFACTURER;*
- *measure the NET FLUID REMOVAL during an appropriate time interval.*

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

201.4.3.105 SUBSTITUTION FLUID flow rate

For HAEMOFILTRATION and HAEMODIAFILTRATION EQUIPMENT only.

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

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

Compliance is checked under the following test conditions.

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

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

Continue with test 2:

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

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

201.4.3.106 Dialysis time

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

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

201.4.3.107 * DIALYSIS FLUID composition

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

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;*
- *set the lowest DIALYSIS FLUID flow rate;*
- *measure the temperature at the DIALYSER inlet;*
- *record the temperature during a period of 30 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;*
- *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.*

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, the air is not regarded as a SINGLE FAULT CONDITION, but as NORMAL CONDITION.

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the general standard applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard 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 color 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.

201.7.9.2 Instructions for use

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 which draws the OPERATOR'S attention to the HAZARDS, including any HAZARDOUS SITUATIONS, arising from improper connections of the EXTRACORPOREAL CIRCUIT;

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

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

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

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

  - a warning statement that this PROTECTIVE SYSTEM reduces the RISK in part only and an explanation of the remaining RISK;
  - a description of OPERATOR responsibility for further mitigation of residual RISK;

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

– * a warning statement specifying that any narrow passages in the EXTRACORPOREAL CIRCUIT (such as kinks in the blood line or cannula that are too thin) may cause haemolysis and that this HAZARDOUS SITUATION may not be detected by the PROTECTIVE SYSTEMS;

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

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

– for ONLINE HDF and ONLINE HF:

  - a warning statement that only the disinfection PROCEDURES defined and validated by the MANUFACTURER shall be used for ONLINE HDF and ONLINE HF;
  - information on the required quality of the incoming DIALYSIS WATER and of the DIALYSIS FLUID CONCENTRATES used;

  - intervals at which wearing parts (e.g. ENDOTOXIN-RETENTIVE FILTER – ETRF) should be exchanged;
- a warning statement that the blood flow rate, and thus the treatment efficacy, may be reduced when the pre-pump ARTERIAL PRESSURE is extremely negative; and the range and accuracy of the blood flow rate of such pump(s) and the inlet and outlet pressure ranges over which this accuracy is maintained;
- for HAEMODIALYSIS EQUIPMENT with APPLIED PARTS other than TYPE CF APPLIED PARTS, a warning statement, addressed to both the OPERATOR and the RESPONSIBLE ORGANIZATION, to ensure that no electrical equipment (non-ME EQUIPMENT and ME EQUIPMENT) with TOUCH CURRENTS and PATIENT LEAKAGE CURRENTS above the respective limits for type CF APPLIED PARTS is used in the PATIENT ENVIRONMENT in combination with a central venous catheter whose tip is in the right atrium;

  NOTE 101 For information, see 201.8.3 in Annex AA.

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

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.

201.7.9.2.5 ME EQUIPMENT description

Addition:

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

- a definition of TRANSMEMBRANE PRESSURE if the MANUFACTURER makes use of one different from that stated in 201.3.217;
- an explanation of the coloured markings on the DIALYSIS FLUID CONCENTRATE connectors;
- information on the effective delivered blood flow rate in single-needle treatments;
- information on the recirculation of blood in the EXTRACORPOREAL CIRCUIT in single-needle treatments;
- the delay time after which an auditory ALARM SIGNAL is activated after interruption of the power supply;
- for PHYSIOLOGIC CLOSED-LOOP CONTROLLER functions (see also the collateral standard IEC 60601-1-10):
  a) the technical working principle;
  b) the PATIENT parameters which are measured and the physiological parameters which are controlled;
  c) the methods by which these PHYSIOLOGIC CLOSED-LOOP CONTROLLER modes have been evaluated, including beneficial and adverse effects recorded during clinical evaluation;
- for any data that is displayed or indicated by the HAEMODIALYSIS EQUIPMENT and that may 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.

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.

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 fluid path inside the HAEMODIALYSIS EQUIPMENT and the ENCLOSURE surface disinfection is achieved;

– * 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;

– a warning statement to follow the MANUFACTURER'S instructions to disinfect the HAEMODIALYSIS EQUIPMENT; if other PROCEDURES are used it is the responsibility of the RESPONSIBLE ORGANIZATION to validate the disinfection PROCEDURE for efficacy and safety; this warning shall specifically list HAZARDS, including the failure mode that may 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.

Compliance is checked by inspection of the instructions for use.

201.7.9.2.14 ACCESSORIES, supplementary equipment, used material

Addition:

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

– information on DIALYSIS FLUID CONCENTRATES, DIALYSERS and blood lines intended to be used together with the HAEMODIALYSIS EQUIPMENT.

Compliance is checked by inspection of the instructions for use.

201.7.9.3 Technical description

201.7.9.3.1 General

Addition:

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

- installation:
  – a description of the particular measures or conditions to be observed when installing, deinstalling and transporting the HAEMODIALYSIS EQUIPMENT or bringing it into use. These shall include guidance on the type and number of tests to be carried out;
  – information about the maximum temperature which can occur at the drain of the HAEMODIALYSIS EQUIPMENT:
  – * information about energy consumption, energy delivery to the environment and energy delivery to the drain under typical operating conditions and as a function of inlet water temperature;
  – * information about consumption of water and DIALYSIS FLUID CONCENTRATE(S) or (pre-manufactured) DIALYSIS FLUID under typical operating conditions;
- HAEMODIALYSIS EQUIPMENT specification:
  – for HAEMODIALYSIS EQUIPMENT that includes integral anticoagulant delivery means: the type of the pump(s), the range and the accuracy of the flow rate for such pump(s) and the pressures against which this accuracy is maintained;
  – any additional measures foreseen by the MANUFACTURER in case of the interruption of the power supply;
  – the type, the measurement accuracy and the value(s) or range(s) of the ALARM LIMIT(s) of the PROTECTIVE SYSTEM required by 201.12.4.4.101 (DIALYSIS FLUID composition);
  – the type, the measurement accuracy and the value(s) or range of the ALARM LIMIT(s) of the PROTECTIVE SYSTEM required by 201.12.4.4.102 (DIALYSIS FLUID and SUBSTITUTION FLUID temperature);
  – the type, the measurement accuracy and the value(s) or range(s) of the ALARM LIMIT(s) of the PROTECTIVE SYSTEM required by 201.12.4.4.103 (NET FLUID REMOVAL);
  – the type, the measurement accuracy and the value(s) or range(s) of the ALARM LIMIT(s) of the PROTECTIVE SYSTEM required by 201.12.4.4.104.1 (extracorporeal blood loss to the environment);
  – * 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 ACCOMPANYING DOCUMENTS.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

201.8.3 * Classification of APPLIED PARTS

Addition:

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

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

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

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

Compliance is checked by inspection.

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

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

201.8.7.4.7 Measurement of the PATIENT LEAKAGE CURRENT

Addition:

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

NOTE 101 The measurement of PATIENT LEAKAGE CURRENTS described above does not include the measurement according to 8.7.4.7 b) (voltage applied to the APPLIED PART) of the general standard 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 the general standard applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies, except as follows:

201.11.6.3 Spillage on ME EQUIPMENT and ME SYSTEMS

Addition:

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

201.11.6.6 * Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS

Addition:

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

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

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

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

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

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

Addition:

a) HAEMODIALYSIS EQUIPMENT without INTERNAL ELECTRICAL POWER SOURCE for backup, or with INTERNAL ELECTRICAL POWER SOURCE for operation:

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

– activation of an auditory ALARM SIGNAL, lasting for at least 1 min;

– additional measures may 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.

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

b) HAEMODIALYSIS EQUIPMENT with INTERNAL ELECTRICAL POWER SOURCE for backup:

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 a visual ALARM SIGNAL;

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

– additional measures may 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 they 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;

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

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

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

Clause 12 of the general standard applies, except as follows:

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.

Additonal subclauses:

201.12.4.4.101 * DIALYSIS FLUID composition

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

NOTE 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.

- *Test 1 for determining the ALARM SIGNAL activation*
  - *Set the unit under test to the lowest and the highest compositions of the DIALYSIS FLUID respectively without generating an ALARM SIGNAL.*
  - *Slowly change the DIALYSIS FLUID composition until the PROTECTIVE SYSTEM activates an ALARM SIGNAL.*
  - *Take samples at the DIALYSER inlet under NORMAL CONDITION and immediately after the ALARM CONDITION is detected.*
  - *Determine and evaluate (e.g. by flame photometry) the DIALYSIS FLUID composition of the samples taken in NORMAL CONDITION and after the ALARM CONDITION is detected.*
- *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 samples at the DIALYSER inlet under NORMAL CONDITION and immediately after the ALARM CONDITION is detected.*
  - *Determine and evaluate (e.g. by flame photometry) the DIALYSIS FLUID composition of the samples taken under NORMAL CONDITION and after the ALARM CONDITION is detected.*
- *Test 3 for foreseeable misuse*
  - *Exchange DIALYSIS FLUID CONCENTRATES, if possible.*
  - *Determine the ALARM CONDITION activation.*

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

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

201.12.4.4.102 * DIALYSIS FLUID and SUBSTITUTION FLUID temperature

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

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

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

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

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

– stopping of the DIALYSIS FLUID flow to the DIALYSER and/or 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 / lowest DIALYSIS FLUID temperature.*

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

  – *Slowly increase / 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 / minimum value.*

- *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 / lowest DIALYSIS FLUID / SUBSTITUTION FLUID temperature.*

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

  – *Slowly increase / 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 / minimum value.*

201.12.4.4.103 * NET FLUID REMOVAL

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

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

• *Test for deviations of the NET FLUID REMOVAL rate*

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

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

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

– *Set the highest and the lowest ULTRAFILTRATION rates (one at a time).*

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

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

201.12.4.4.104 Extracorporeal blood loss

201.12.4.4.104.1 Extracorporeal blood loss to the environment

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

- *Test for PROTECTIVE SYSTEMS utilizing the VENOUS PRESSURE measurement*
  - *Set the unit under test to the medium blood flow rate.*
  - *Adjust the VENOUS PRESSURE to a medium value.*
  - *Lower 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.*

201.12.4.4.104.2 * BLOOD LEAK to the DIALYSIS FLUID

a) The HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM to protect the PATIENT from a BLOOD LEAK that may 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.

Compliance is checked 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%) to the DIALYSIS FLUID so that the flow through the BLOOD LEAK detector exceeds the BLOOD LEAK ALARM LIMIT as specified by the MANUFACTURER.*

201.12.4.4.104.3 * Extracorporeal blood loss due to coagulation

a) The HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM to protect the PATIENT from blood loss due to coagulation as a consequence of the interruption of the blood flow that may 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 which may result in a blood loss due to coagulation, for example stopping or missing start of any anticoagulant delivery means, or excessive SUBSTITUTION FLUID flow rate in case of HDF or HF with post-dilution, shall be addressed in the MANUFACTURER'S RISK MANAGEMENT PROCESS.

Compliance is checked by functional tests and failure simulation.

201.12.4.4.105 * Air infusion

a) The HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM to protect the PATIENT from air infusion, under NORMAL CONDITION and SINGLE FAULT CONDITION, that may 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 air infusion via the arterial and venous bloodlines, even under SINGLE FAULT CONDITION.

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

Compliance is checked by functional tests taking into account the principles of the test described below.

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

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

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

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

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

- *Continuous air infusion:*

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

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

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

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

  – *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 one vertically positioned test tube with diameter of, for example, 8 mm and a length of, for example, 2,0 m in line with a second tube with smaller diameter of, for example, 4.3 mm and a length of, for example, 20 cm directly at the venous PATIENT connector in the venous path between the PATIENT connector and collection container (see as an example the setup in Figure 201.101). *More than one test tube in parallel configuration can be used to monitor continuously the infused air before the* ALARM CONDITION *occurs.*

  – *Insert a 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 pump capable of controlling air injection under negative pressure condition.*

NOTE 7 A possible method is the use of a small reversible peristaltic pump. This pump is initially primed with test fluid by operating it in reverse mode to avoid uncontrolled injection of air when the blood pump is started. A check valve between the needle and the pump could be used.

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

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

NOTE 8 The rationale of this test is based on the assumption that, with the DIALYSIS FLUID line closed, air cannot escape from the EXTRACORPOREAL CIRCUIT and will eventually be pumped to the fluid collection vessel at the same rate as pumped in.

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

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

– Calculate the air flow rate by blood flow rate, test tube volume and measured air volume. *Direct measurement of the blood flow rate in the venous bloodline is recommended.* The calculated air flow rate shall be less than the continuous air infusion rate limit identified by RISK MANAGEMENT.

a) *If the* HAEMODIALYSIS EQUIPMENT *allows the* DIALYSER *to be operated with blood flowing upwards through the* DIALYSER *and, alternatively with blood flowing downwards through the* DIALYSER*, separate tests shall be done with both flow directions.*

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

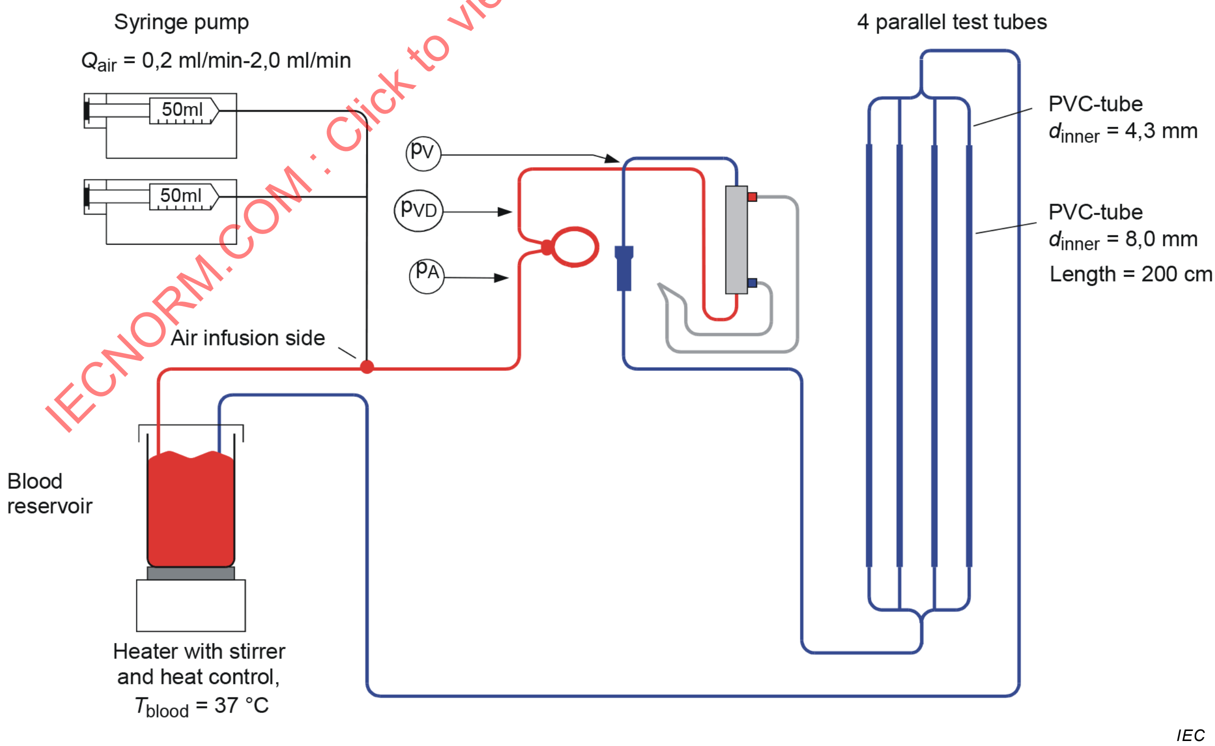

Figure 201.101 – Continuous air infusion test setup with example dimensions

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

    NOTE 9 This is a worst-case condition. If degassed DIALYSIS FLUID is running, gas will be 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 10 An appropriate test fluid has a viscosity of 3,5 mPa·s at 37 °C and contains a surfactant causing spallation of gas bubbles.

  - *Position a storage container for the test fluid at a level of, for example, 100 cm (±20 cm) from the ground.*
  - *Position a collection container for the test fluid at a level of, for example, 100 cm (±20 cm) from the ground or recirculate the fluid into the storage container.*
  - *Position a graduated measuring cylinder or the same test tubes as in the previous test case such that any air that may be pumped through the return (venous) cannula is collected.*
  - *Insert a T-piece with Luer connectors between the blood tubing and the arterial (blood withdrawal) cannula.*
  - *Connect a piece of tubing (e.g. 5 cm long) with a Luer connector to the T-piece.*
  - *Prime the EXTRACORPOREAL CIRCUIT and said piece of tubing. Clamp the piece of tubing.*
  - *Adjust the blood pump speed with a defined pre-pump negative pressure (e.g. between 0 mmHg and –250 mmHg) so that no pressure ALARM CONDITION arises in the EXTRACORPOREAL CIRCUIT with the opening of the clamp.*
  - *Open the clamp at the piece of tubing and wait until an ALARM SIGNAL is activated.*
  - *Check 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.*

    a) *If the HAEMODIALYSIS EQUIPMENT allows the DIALYSER to be operated with blood flowing upwards through the DIALYSER and, alternatively with blood flowing downwards through the DIALYSER, separate tests shall be done with both flow directions.*

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

201.12.4.4.106 * ALARM CONDITION override modes

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

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

   NOTE 1 For exceptions, see item b) below.

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

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

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

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

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

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

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

201.12.4.4.107 PROTECTIVE SYSTEMS

A failure of the PROTECTIVE SYSTEMS required by 201.12.4.4 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 Acceptable methods of complying with this requirement are for example:

   - periodic functional check of the PROTECTIVE SYSTEMS, requested by the HAEMODIALYSIS EQUIPMENT, initiated and controlled by the OPERATOR;
   - periodic functional check of the PROTECTIVE SYSTEMS, requested by the HAEMODIALYSIS EQUIPMENT, initiated by the OPERATOR and controlled by the HAEMODIALYSIS EQUIPMENT;
   - redundancy of the PROTECTIVE SYSTEMS with self-checking by the HAEMODIALYSIS EQUIPMENT;
   - periodic functional check of the PROTECTIVE SYSTEMS initiated by the HAEMODIALYSIS EQUIPMENT and controlled by the HAEMODIALYSIS EQUIPMENT, if the control function of the PROTECTIVE SYSTEM is designed such that it cannot fail simultaneously with the PROTECTIVE SYSTEM by a single failure.

b) for the PROTECTIVE SYSTEM required by 12.4.4.105 (air infusion):

   – if an amount of air can be infused to the PATIENT which may 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 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 the general standard 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.

Compliance is checked by functional tests and failure simulations.

201.12.4.4.109 * Blood pump(s) and/or SUBSTITUTION FLUID pump(s) reversal

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

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

Compliance is checked by inspection and by functional tests.

201.12.4.4.110 Selection and change of operation modes

Inadvertent selection and change of operation modes shall be prevented. USE ERRORS, as well as technical failures, have to 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 [19] and ISO 23500-1) for a solution intended for intravenous applications 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.

201.12.4.4.112 * Anticoagulation

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

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

NOTE 2 In some treatment situations, it can be desirable 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.

– Improper dosing of the anticoagulant solution(s) by first fault of the anticoagulant delivery means, for example delivery rate(s), delivery rate(s) ratio, delivery rate(s) ratio versus blood flow rate.
– Improper dosing of the anticoagulant solution under negative pressure conditions in the EXTRACORPOREAL CIRCUIT in the case an anticoagulant delivery means doses upstream of the blood pump.
– Interconnecting 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.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of the general standard applies, except as follows:

201.13.2.6 * Leakage of liquid

Addition:

The liquid-carrying parts of the HAEMODIALYSIS EQUIPMENT shall be so shielded against the electrical parts that liquid which may leak under normal working pressure does not lead to the PATIENT being exposed to HAZARDS, 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 the general standard.

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 the general standard 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 80001-1:2010 [9] requires from every MEDICAL DEVICE MANUFACTURER to make available ACCOMPANYING DOCUMENTS to the RESPONSIBLE ORGANIZATION with information about the IT-NETWORK capabilities of the medical device (3.5 MEDICAL DEVICE MANUFACTURER(S)).

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies, except as follows:

201.15.4.1 Construction of connectors

Addition:

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, [18]).

The HAEMODIALYSIS EQUIPMENT shall additionally prevent a mix-up of the various DIALYSIS FLUID CONCENTRATES and cleaning solutions which may 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 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 the general standard 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 Clause A.4, 4.2 and 16.1 of the general standard).

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 [13]).

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 the general standard applies.

202 Electromagnetic disturbances – Requirements and tests

IEC 60601-1-2:2014 applies 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 HEMODIALYSIS EQUIPMENT:

- BASIC SAFETY functions listed in 201.12: The ME EQUIPMENT or ME SYSTEM BASIC SAFETY shall continue to operate as intended without OPERATOR intervention. No degradation of BASIC SAFETY function is allowed below a performance level specified by the MANUFACTURER when the ME EQUIPMENT or ME SYSTEM is used as intended. Alternatively, the ME EQUIPMENT or ME SYSTEM shall reach and remain in the safe state of the device.
- ESSENTIAL PERFORMANCE functions: After the test, the ME EQUIPMENT or ME SYSTEM shall continue to operate as intended without OPERATOR intervention. During the test, degradation of performance is allowed, but no degradation of performance is allowed below a performance level specified by the MANUFACTURER, when the ME EQUIPMENT or ME SYSTEM is used as intended.
- Other functions: Loss of function is allowed, provided the function is self-recoverable, or can be restored by the operation of the controls by the OPERATOR in accordance with the MANUFACTURER'S instructions.

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

202.8.9 IMMUNITY TEST LEVELS

Addition:

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

- professional healthcare facility environment (e.g. dialysis centers, 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 and IEC 60601-1-8:2006/AMD1:2012 applies except as follows:

208.4 * General requirements

Addition:

If the INTENDED USE of the HEMODIALYSIS EQUIPMENT includes the intensive care or surgery environment, it is acceptable to implement additional ALARM SYSTEMS deviating from IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 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 HEMODIALYSIS EQUIPMENT includes the intensive care or surgery environment and additional ALARM SYSTEMS deviating from IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 are implemented, then

a) the ALARM SYSTEM according to IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 should be the MANUFACTURER default setting. If the ALARM SYSTEM according to IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 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.

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 and IEC 60601-1-8:2006/AMD1:2012, 6.1.2, adapted for HAEMODIALYSIS EQUIPMENT needs.

If the INTENDED USE of the HEMODIALYSIS EQUIPMENT does not include the intensive care or surgery environment, the following subclauses of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 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 7.8.1 Colours of indicator lights of the general standard applies, but the urgency of the response of the OPERATOR can have other than PATIENT-centric causes.

208.5.2.1 Instructions for use

Addition:

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

208.6.3 Generation of ALARM SIGNALS

208.6.3.1 * General

Addition:

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

Compliance is checked by functional tests.

208.6.3.3.2 Volume and characteristics of auditory ALARM SIGNALS and INFORMATION SIGNALS

Replacement:

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

Compliance is checked by measuring the A-rated sound pressure level with instruments meeting the requirements for measuring instruments of class 1 according to IEC 61672-1 and free field conditions as specified in ISO 3744.

208.6.3.3.3 OPERATOR-adjustable sound pressure level

Addition:

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

Additional subclause:

208.6.3.3.101 * Special characteristics of auditory ALARM SIGNALS for HAEMODIALYSIS EQUIPMENT

Auditory ALARM SIGNALS shall meet the following requirements.

a) If it is possible to pause the auditory ALARM SIGNAL, the AUDIO PAUSED period shall not exceed 3 min.

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

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.

209 Requirements for environmentally conscious design

IEC 60601-1-9:2007 and IEC 60601-1-9:2007/AMD1:2013 does 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 and IEC 60601-1-10:2007/AMD1:2013 applies, except as follows:

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 applies, except as follows:

211.6 Classification of ME EQUIPMENT and ME SYSTEMS

Addition:

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 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 the general standard apply, except as follows:

Annex G
(normative)

Protection against HAZARDS of ignition of flammable anaesthetic mixtures

Annex G of the general standard does not apply.

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

Clause A.1 of the general standard applies.

AA.2 Rationale for particular clauses and subclauses

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

Subclause 201.1.1 – Scope

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

Safety details of DIALYSIS FLUID control systems of HAEMODIALYSIS EQUIPMENT using regeneration of DIALYSIS FLUID or CENTRAL DELIVERY SYSTEMS for DIALYSIS FLUID should be part of the MANUFACTURER'S RISK MANAGEMENT PROCESS.

The AAMI Renal Disease and Detoxification committee is working on a technical information report on sorbent-based regenerative HAEMODIALYSIS EQUIPMENT. (AAMI TIR [1]).

Subclause 201.3.8 – APPLIED PART

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

Subclause 201.3.202 – BLOOD LEAK

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

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

Subclause 201.3.210 – HAEMODIALYSIS EQUIPMENT

The type of HD, HDF and HF equipment can be classified as HAEMODIALYSIS EQUIPMENT with or without preparation of DIALYSIS FLUID. HAEMODIALYSIS EQUIPMENT with preparation of DIALYSIS FLUID usually requires a water treatment system (RO system) and may also be connected to a CENTRAL DELIVERY SYSTEM.

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

Subclause 201.3.213 and 201.3.214 – ONLINE HDF and ONLINE HF

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

Subclause 201.3.215 – PROTECTIVE SYSTEM

See [23], page 342. The authors point out that HAEMODIALYSIS EQUIPMENT comprises redundancy or PROTECTIVE SYSTEMS in addition to control systems. A HAZARD (editors comment: harm) to the PATIENT is only possible if the control system and the PROTECTIVE SYSTEM both fail. The likelihood for any of these systems to fail is less than 10^{-4} per hour resulting in a combined likelihood of less than 10^{-8} per hour. This observation was made by the first author in the mid-1980s based on quality feedback data from ~ 3 000 HAEMODIALYSIS EQUIPMENTS and is corroborated by the low number of serious accidents caused by HAEMODIALYSIS EQUIPMENT malfunction in the US where accident reports are published by the FDA.

Subclause 201.3.218 – ULTRAFILTRATION

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

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

Subclause 201.4.3 – ESSENTIAL PERFORMANCE

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

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

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

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

Subclause 201.4.3.101 – Additional ESSENTIAL PERFORMANCE requirements

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

EMC test. The list of ESSENTIAL PERFORMANCE features defined here is a compromise between these two contrary aspects (see IEC 60601-1-2).

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

Subclause 201.4.3.102, Note 1 – Blood flow rate

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

Subclause 201.4.3.107 – DIALYSIS FLUID composition

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

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

Ideas for determining the DIALYSIS FLUID composition are:

– measurement by ion selective sensors;

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

– measurement of the dilution by adding a dye to the DIALYSIS FLUID CONCENTRATE. The optical absorption is measured before and after mixing;

– theoretical calculation of conductivity, based on the known composition of the DIALYSIS FLUID CONCENTRATE. Create a systematic matrix of different dialysate compositions, for example:

  - highest sodium with lowest bicarbonate;
  - lowest sodium with highest bicarbonate;
  - highest sodium with highest bicarbonate;
  - lowest sodium with lowest bicarbonate;

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

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

Subclause 201.7.8.2 – Color of controls

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

Subclause 201.7.9.2.2, 6th hyphen – Warning and safety notices

Because of counter current flow in the DIALYSER, backfiltration of DIALYSIS FLUID takes place in at least one part of the DIALYSER even in low-flux DIALYSERS (ULTRAFILTRATION coefficient

< 10 ml/(h mmHg)). If high-flux DIALYSERS are used, backfiltration cannot be avoided even by high ULTRAFILTRATION rates acceptable for fluid removal from the PATIENT.

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

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

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

Subclause 201.7.9.2.2, 9th hyphen – Warnings and safety notices

Haemolysis may be caused by excessive shear which is the result of high blood flow rate through a narrow passage, especially when the flow becomes turbulent. Static pressure (–600 mmHg to +1 000 mmHg) does not cause haemolysis. Elevated pressures measured in the EXTRACORPOREAL CIRCUIT indicate increased flow resistance which may cause subclinical haemolysis. Acute haemolysis has been reported to be caused by obstructions in the blood tubing system downstream of the blood pump but upstream of the VENOUS PRESSURE monitor. Such obstructions are not detected by the VENOUS PRESSURE monitor. For a review of accident reports see [23], p. 328-332.

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

For Kt/V, applicable recommendations are, for example, KDOQI guidelines [29] and the European best practice guidelines for haemodialysis [30].

Subclause 201.7.9.2.12, 2nd hyphen – Cleaning, disinfection and sterilization

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

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

Subclause 201.7.9.3.1, 3rd and 4th hyphens – General

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

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

Subclause 201.7.9.3.1, 11th hyphen – General

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

Subclause 201.8.3 – Classification of APPLIED PARTS

Compliance with TYPE CF APPLIED PART requirements for HAEMODIALYSIS EQUIPMENT that are provided with a permanent DIALYSIS WATER connection and/or connection to a CENTRAL DELIVERY SYSTEM can be achieved with high technical expenditures only. For that reason, an exception rule has been established for the use of HAEMODIALYSIS EQUIPMENT with TYPE B APPLIED PARTS for PATIENTS with a central venous catheter whose tip is in the right atrium.

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

1) LEAKAGE CURRENTS originating from the HAEMODIALYSIS EQUIPMENT.

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

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

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

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

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

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

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

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

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

- Microshock by catheter LEAKAGE CURRENT is a hypothetical HARM that cannot be excluded. The likelihood of such a shock occurring is limited.
- Only central venous catheters with the venous tip located in the right atrium are relevant.
- This limits the RISK to permanent catheters inserted through jugular or subclavian vein. The tip of non-permanent catheters or femoral catheters is usually not placed in the atrium.
- Side holes in the venous limb will also distribute electrical current to the body outside the heart [21] although most catheters today have no side holes in the return (venous) lumen.
- The withdrawal (arterial) lumen is electrically isolated or only connected with a high resistance to ground [22].
- If the catheter tip is placed in the right atrium as recommended for permanent catheters, the catheter will normally not touch the atrial wall because this may cause flow problems. The requirements for CF based on the RISK of microshock were established based on measurements with metal electrodes in direct touch with the atrium.
- With the catheter not in direct contact with the myocardium the current density on the myocardial surface will be very much reduced because the current is distributed over a larger surface area. Starmer [26] reports that ~ 500 μA were required for fibrillation when applied to a circular surface with 2,5 mm diameter. When the surface area was increased to 2,5 cm in diameter the current required for fibrillation increased to more than 3 000 μA.
- In order to create a serious HAZARDOUS SITUATION,
  - the catheter tip has to be placed in the right atrium and has to touch the atrial wall (by mistake), and
  - the PATIENT has to be in touch with a current source.

Subclause 201.8.7.4.7 aa) – Measurement of the PATIENT LEAKAGE CURRENT

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

Subclause 201.8.11.2 – MULTIPLE SOCKET-OUTLETS

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

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

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

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

Cleaning and disinfection can be accomplished through chemical methods, physical methods, or a combination of both. Guidance for testing of disinfectants can be found in ISO 15883 (all parts) [14], EN 14885 [4], JIS Z 2801 [20], AOAC 964 [3] or ASTM E1153 [2]. The microbial control regime should be validated considering organisms relevant to haemodialysis, representing the main microbial categories of microorganisms including Gram positives, Gram negatives, viruses, yeasts and fungi.

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

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

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

Testing of disinfectant residuals

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

The test is done in the following way:

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

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

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

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

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

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

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

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

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

The second edition of this particular standard (IEC 60601-2-16:1998, [6]) usually did not specify any definite values for the necessary ALARM LIMITS of the PROTECTIVE SYSTEMS. It was up to the MANUFACTURER to define the deviation from the value that presented a HAZARD which had to be detected by the PROTECTIVE SYSTEM and justified in the MANUFACTURER'S RISK MANAGEMENT PROCESS.

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

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

Subclause 201.12.4.4.101 – DIALYSIS FLUID composition

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

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

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

Additionally in bicarbonate treatment:

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

If other components can be added individually, additionally:

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

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

Subclause 201.12.4.4.102 – DIALYSIS FLUID and SUBSTITUTION FLUID temperature

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

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

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

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

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

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

Besides PATIENT discomfort for low DIALYSIS FLUID temperatures adverse effects are uncommon, but in rare cases cold dialysate can cause tachypnea, tachycardia, shivering, energy loss and slight changes in coagulation [28]. Ventricular fibrillation has been reported after cooling of the heart to less than 33 °C by rapid infusion of large amounts (> 5 l) of cold (4 °C) blood. In HAEMODIALYSIS, cooling to 33 °C would take more than 15 min even assuming high blood flow rate, low DIALYSIS FLUID temperature (10 °C) and low body weight (50 kg).

Subclause 201.12.4.4.103 – NET FLUID REMOVAL

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

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

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

- for continuous treatments, for example CRRT treatments, the sliding average value of the NET FLUID REMOVAL rate – with averaging time defined by the MANUFACTURER'S RISK MANAGEMENT PROCESS – is at all time within ±0,1 l/h of the OPERATOR set point rate.
- for a typical 4 h dialysis treatment, the removed cumulated NET FLUID REMOVAL volume is at all time during the treatment time within ±400 ml of the expected cumulated NET FLUID REMOVAL volume.

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

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

Subclause 201.12.4.4.104.1 a) – Extracorporeal blood loss to the environment

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

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

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

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

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

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

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

The effects of haemorrhage are described in reference [5].

Subclause 201.12.4.4.104.1 c) – Extracorporeal blood loss to the environment

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

Subclause 201.12.4.4.104.2 – BLOOD LEAK to the DIALYSIS FLUID

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

BLOOD LEAKS of less than 0,35 ml/min blood (with an Hct of 32 %) are not considered to present a serious HARM.

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

Subclause 201.12.4.4.104.3 – Extracorporeal blood loss due to coagulation

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

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

Subclause 201.12.4.4.105 – Air infusion

At the time of writing of this document there was not enough scientific literature to define a safe ALARM LIMIT in this particular standard. In [23], chapter 14, Polaschegg and Levin consider the continuous infusion of air of less than 0,03 ml/(kg min) and infusion of a bolus of 0,1 ml/kg not to be a HAZARD.

Exposure to microbubbles should be taken into account and possible preventive measures should be considered by the MANUFACTURERS' RISK MANAGEMENT PROCESS [24] [27].

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

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

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

a) it is designed with two channels and each channel is tested prior to each treatment, or

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

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

a) design with two independent actors (e.g. stopping of the pumps and closing of the clamps) and both actors are tested; or

b) the blood pump(s) and all pumps delivering in the direction of the PATIENT are turned off via two channels and even a mechanical failure (e.g. breakage of a rotor spring) cannot cause a loss of occlusion.

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

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

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

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

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

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

– air in chamber(s);
– residual air in the bloodline;
– residual air in the DIALYSER;
– air in the monitor lines leading to the pressure transducers;
– air entering the system in the recirculation path of a single-needle treatment;
– air entering the EXTRACORPOREAL CIRCUIT.

Non-dissolved air can appear in bulk and in the form of bubbles of different sizes.

The physical principle used for any air detector and any electronic delays or other delays should be taken into account in the RISK ANALYSIS. Today ultrasonic air detectors are used almost exclusively for the detection of air in the EXTRACORPOREAL CIRCUIT. Some of these air detectors are positioned on the partially air-filled venous drip chamber. They are usually designed as level detectors, which means that they will generate an ALARM CONDITION if the level decreases or if the drip chamber is filled with foam.

Other air detectors are positioned directly on the blood tubing and are usually capable of detecting single bubbles with volumes much lower than the volumes believed to cause a HAZARD. The important parameter of the air detector is the accumulated volume of these single bubbles. In order to avoid nuisance ALARM CONDITIONS the number of detected bubbles is integrated with a time function.

Subclause 201.12.4.4.106 – ALARM CONDITION override modes

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

Subclause 201.12.4.4.109 – Blood pump(s) and/or SUBSTITUTION FLUID pump(s) reversal

Example of a HAZARDOUS SITUATION caused by USE ERROR:

In case of mains power failure in a dialysis unit, it is very likely that the staff is under high stress and therefore USE ERROR is relative likely. In this situation, the HAZARD of air infusion via the arterial bloodline (if applicable) by wrong blood pump direction can be avoided, for example by

a) prevention of wrong hand cranking direction by
   – a unidirectional cranking mechanism, or
   – a clearly marked arrow on the pump(s), or
b) avoidance of hand cranking by continuation of the blood flow with battery power.

Example of a HAZARDOUS SITUATION caused by a technical fault:

A technical fault could cause the blood pump(s) and/or SUBSTITUTION FLUID pump(s) to rotate in the wrong direction. This can be avoided, for example by

a) wiring a DC motor with electromechanical commutation such that no random hardware failure can reverse the direction of the current, or
b) implementation of a PROTECTIVE SYSTEM independent of the motor control system, which stops the motor if the pump(s) rotate in the wrong direction.

Subclause 201.12.4.4.112 – Anticoagulation

This document includes more detailed requirements for anticoagulant delivery means. 201.12.4.4.112 includes design requirements and requirements to address defined HAZARDOUS SITUATIONS in the MANUFACTURERS' RISK MANAGEMENT PROCESS.

Overdelivery of anticoagulant can occur during PATIENT treatment if the anticoagulant delivery means continues when the blood pump is stopped and can create a HAZARDOUS SITUATION. This can occur when the anticoagulant delivery output is connected downstream of the blood pump by the anticoagulant delivery means continuing with the blood pump stopped and delivering a bolus of anticoagulant to the connection that is then given to the PATIENT when the blood pump starts again. Overdelivery can also occur when the anticoagulant delivery does not stop with the blood pump and its output is connected upstream of the blood pump, without a system controlled clamp on the arterial access line of the PATIENT. In this case, the anticoagulant goes directly to the PATIENT while the HAEMODIALYSIS EQUIPMENT is stopped.

Underdelivery of anticoagulant can occur during PATIENT treatment if the anticoagulant delivery means is not started when the blood is running. It can also occur due to compliance in the anticoagulant delivery system (including a syringe if used) taking time to deliver at the specified rate. This is of particular importance for low anticoagulant administration rates or in cases of large variations in output pressure in the EXTRACORPOREAL CIRCUIT. This delay in anticoagulant delivery may cause coagulation and blood loss if not addressed.

IEC 60601-2-24 [7] does not apply, because its scope relates to pumps for infusion of liquids into the PATIENT, and devices for extracorporeal circulation of blood are excluded. Anticoagulant delivery means in the scope of this document are for delivery of anticoagulants into the EXTRACORPOREAL CIRCUIT.

Anticoagulant delivery means in HAEMODIALYSIS EQUIPMENT can be a syringe pump that infuses one anticoagulant (e.g. heparin) or roller pumps that infuse simultaneously Citrate and Calcium at different points of the EXTRACORPOREAL CIRCUIT (CiCa) or other designs not directly matching with IEC 60601-2-24.

All relevant HAZARDOUS SITUATIONS addressed in IEC 60601-2-24 in the use context of HAEMODIALYSIS EQUIPMENT were taken into account in this document: specification of accuracy (201.7.9.3.1, 201.12.4.4.112), underinfusion (201.12.4.4.104.3, 201.12.4.4.112), overinfusion (201.12.4.4.112), unintended bolus (201.12.4.4.112), USABILITY issues (201.12.4.4.112). Added are HAZARDOUS SITUATIONS not included in IEC 60601-2-24 but necessary for the use scenarios of HAEMODIALYSIS EQUIPMENT.

It is sometimes useful for developers to look into the IEC 60601-2-24 when developing anticoagulant delivery means for HAEMODIALYSIS EQUIPMENT.

If the HAEMODIALYSIS EQUIPMENT includes fluid (medication) delivery means for other substances than anticoagulants or for direct infusion into the PATIENT, IEC 60601-2-24 could be applicable in total or in parts. This is not addressed in this document because such use cases are not in the normal INTENDED USE of HAEMODIALYSIS EQUIPMENT.

Subclause 201.13.2.6 – Leakage of liquid

The test considers that fluid may flow out under normal working pressure. Although its performance and reproduction is difficult, the test specified in this particular standard is considered to be suitable for this type of equipment.

Subclause 201.14.13 – PEMS intended to be incorporated into an IT-NETWORK

A method proven to reduce RISK for the transfer of HAEMODIALYSIS EQUIPMENT settings via an IT-NETWORK is the explicit test of the data transferred, performed by the OPERATOR and confirmation by the OPERATOR before these settings become effective in the HAEMODIALYSIS EQUIPMENT.

Subclause 201.15.4.1.101 – DIALYSIS FLUID CONCENTRATE connectors

DIALYSIS FLUID CONCENTRATES may be used in the form of powder or fluid. For DIALYSIS FLUID CONCENTRATES in the form of powder and "DIALYSIS FLUID ions for sodium chloride (powdered)", constructional features preventing their misuse are usually provided in the HAEMODIALYSIS EQUIPMENT designs. Liquid DIALYSIS FLUID CONCENTRATES are taken either from containers or from CENTRAL DELIVERY SYSTEMS, which are not prevented from being misused by constructional features.

At least the following DIALYSIS FLUID CONCENTRATE types should be taken into consideration in the MANUFACTURERS' RISK MANAGEMENT PROCESS:

– acetate DIALYSIS FLUID CONCENTRATE;
– acid DIALYSIS FLUID CONCENTRATE for use with bicarbonate DIALYSIS FLUID CONCENTRATE without sodium chloride;

  NOTE 1 With 35X, 36.83X, 45X dilution.

– acid DIALYSIS FLUID CONCENTRATE for use with bicarbonate DIALYSIS FLUID CONCENTRATE with sodium chloride;

  NOTE 2 With 35X, 36.83X, 45X dilution.

– bicarbonate DIALYSIS FLUID CONCENTRATE without sodium chloride;

  NOTE 3 Can be supplied as liquid or powder.

– bicarbonate DIALYSIS FLUID CONCENTRATE with sodium chloride;
– sodium chloride;

  NOTE 4 Can be supplied as liquid or powder.

– DIALYSIS FLUID concentrates complementary to sodium and bicarbonate.

  NOTE 5 Used for mixing systems with separate sodium and bicarbonate DIALYSIS FLUID CONCENTRATE supplies.

  NOTE 6 Can be supplied as liquid or powder.

Subclause 201.15.4.1.102 – Connectors for blood pressure transducers

Designs that use an internal transducer protector between the internal pressure transducer and the connection to the external transducer protector prevent contamination of the internal transducer itself, but do not prevent the RISK of cross-contamination between PATIENTS dialysed on the same HD EQUIPMENT.

Subclause 201.16 – ME SYSTEMS

A ME SYSTEM for dialysis can comprise one or more HAEMODIALYSIS EQUIPMENT and one or more of the following (see Figure AA.1):

– DIALYSIS WATER treatment system;
– discharge (drain);
– data transfer;
– CENTRAL DELIVERY SYSTEM;
– staff call system.

NOTE Since TOUCH CURRENTS of other equipment exist in the PATIENT ENVIRONMENT (e.g. dialysis chairs), a POTENTIAL EQUALIZATION CONDUCTOR could be necessary for such equipment.

The DIALYSIS WATER treatment systems and the CENTRAL DELIVERY SYSTEMS are usually set up at a location that is remote from the HAEMODIALYSIS EQUIPMENT and cannot be connected via a MULTIPLE SOCKET-OUTLET. HAZARDS have to be minimized via the installation, by applying the supply lines, for example, to the same potential as the HAEMODIALYSIS EQUIPMENT.

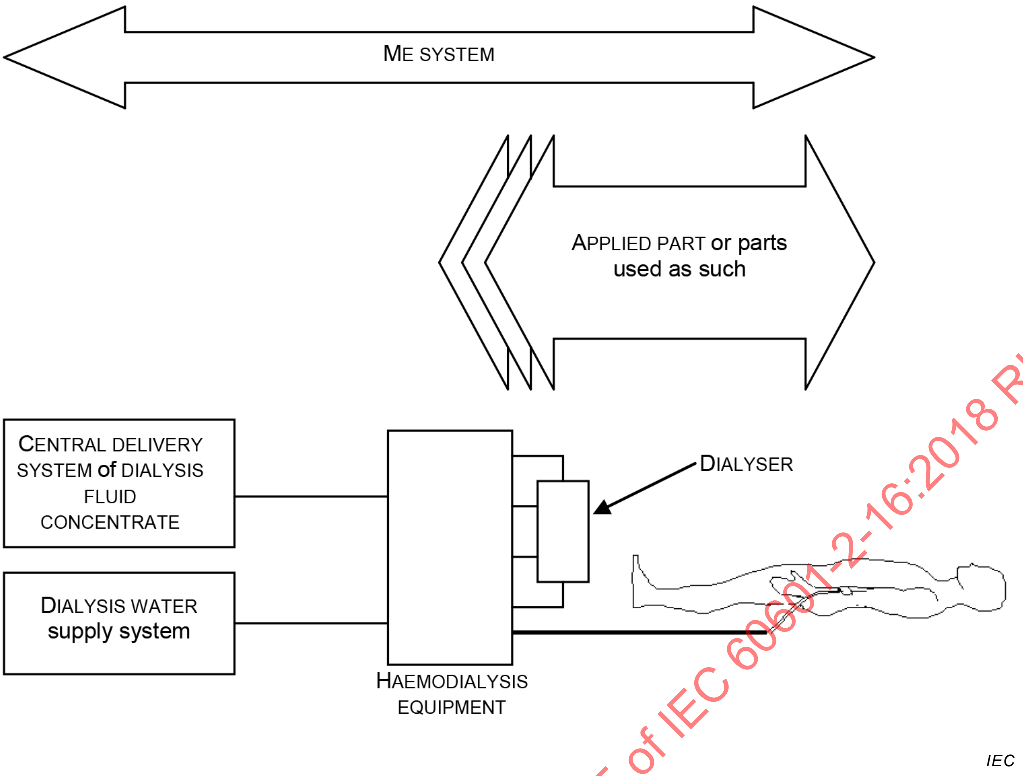

Figure AA.1 – Example of a HAEMODIALYSIS ME SYSTEM

For HAEMODIALYSIS EQUIPMENT with TYPE CF APPLIED PARTS, the following item should be considered:

The bloodlines of the EXTRACORPOREAL CIRCUIT are not considered to be insulating. It should be assumed that conducting solutions in and around the tubing establish an electrical contact with the PATIENT.

An EXTRACORPOREAL CIRCUIT or DIALYSIS FLUID circuit is considered isolating if

a) the material is electrically isolating, and

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

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

Point b) is demonstrated by the MANUFACTURER of the circuit by RISK MANAGEMENT which includes the interface between the HAEMODIALYSIS EQUIPMENT and the circuit and the manufacturing PROCESS.

Subclause 201.16.9.1 – Connection terminals and connectors

According to the state of the art, the PROTECTIVE SYSTEM for "composition of the DIALYSIS FLUID" is based on the measurement of the conductivity or the volumetric admixture. Depending on the operating mode (acetate, bicarbonate), an incorrect DIALYSIS FLUID CONCENTRATE is frequently detected via the conductivity or the volumetric admixture.

Additional measures besides colour coding of the CENTRAL DELIVERY SYSTEM may be required by RISK MANAGEMENT in case of DIALYSIS FLUID CONCENTRATES which, although they deliver a conductivity within the expected range, are hazardous for the treatment type concerned in their composition (e.g. acid DIALYSIS FLUID CONCENTRATE 45X ratio for acetate dialysis).

In such cases, the RESPONSIBLE ORGANIZATION should initiate the appropriate measures which are equivalent to colour coding with the pertinent operating mode, such as disabling the operating mode of acetate HAEMODIALYSIS or mechanically coding the HAEMODIALYSIS EQUIPMENT and the DIALYSIS FLUID CONCENTRATE container.

Subclause 208.4 – General requirements

IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 are written with the focus on intensive care or surgery environments and add in 6.1.2 a very PATIENT-centric view of potential results of failure to respond to the cause of ALARM CONDITIONS. HAEMODIALYSIS EQUIPMENT is mainly used in a chronic ambulant approach. The PATIENTS normally do not have life threatening status. ALARM CONDITIONS mostly arise from technical causes and the therapy has in most cases of problems the chance to go to a safe state, which only loses time for PATIENT and OPERATORS, but which is one of the most important issues in a timely exact planned schedule of subsequent following shifts. The environment in a normal chronic HAEMODIALYSIS clinic is dominated by the HAEMODIALYSIS EQUIPMENT, in many cases from one MANUFACTURER. Normally, other ME EQUIPMENT will not be used continuously beside the HAEMODIALYSIS EQUIPMENT in the PATIENT ENVIRONMENT.

In this ambulatory environment the ALARM CONDITION categories need completely different priorities than in an environment where the PATIENTS have life-threatening status and the therapy is life-supporting. In the ambulatory environment, 6.1.2, with Table 1, of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 would not reflect the needed priorities.

Even in the critical care environments, the HAEMODIALYSIS EQUIPMENT is not life-supporting and most ALARM CONDITION situations would not be a HAZARDOUS SITUATION for PATIENT and OPERATOR and the ALARM CONDITION priority will be low. In some cases, OPERATORS from chronic HAEMODIALYSIS support and operate the HAEMODIALYSIS EQUIPMENT in the intensive care environment.

For HAEMODIALYSIS EQUIPMENT not used in intensive care environments, the actual used – over years of operation optimized – ALARM SYSTEMS should not be worsened by the need of applying IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012.

Because of these reasons, this document only requires the complete implementation of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 for HAEMODIALYSIS EQUIPMENT with INTENDED USE in the intensive care environment. For this environment, Table AA.1 shows how possible ALARM CONDITION priorities according to IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 could be adapted for HAEMODIALYSIS EQUIPMENT needs. If the HAEMODIALYSIS EQUIPMENT is intended to be used in both environments, the ALARM SYSTEM according to IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 has to be implemented and selectable by the RESPONSIBLE ORGANIZATION, but ALARM SYSTEMS with deviation from 6.1.2, 6.3.2.2 and 6.3.3.1 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 are allowed for additional implementation.

For HAEMODIALYSIS EQUIPMENT with a screen, this particular standard does not require that the visual ALARM SIGNAL has to be indicated by an indicator light that is independent of the screen, since there may be applications where it is appropriate if the ALARM SIGNAL is indicated on the screen. In large-size dialysis units, however, it is probably more appropriate to provide an indicator light that can be seen from a far distance and is installed in such a position (e.g. up-raised) that the HAEMODIALYSIS EQUIPMENT activating the ALARM SIGNAL can be readily located.

Table AA.1 – Example of ALARM CONDITION priorities according to 6.1.2 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, adapted for HAEMODIALYSIS EQUIPMENT needs

ALARM CONDITION	ALARM CONDITION priority
Different reasons (e.g. pressures, technical faults)	
Reasons that lead to a stop of the blood flow through the EXTRACORPOREAL CIRCUIT	LOW PRIORITY, yellow
Blood loss due to coagulation in the extracorporeal system	
Blood pump stop ALARM CONDITION (201.12.4.4.104.3), as escalation of above ALARM CONDITION	MEDIUM PRIORITY, yellow flashing
Mains off and backup-battery running system, before battery goes down (201.11.8 b))	
Possible blood loss out of the puncture site or open catheter, following accidental needle or catheter disconnect (201.12.4.4.104.1)	
Detectable by low VENOUS PRESSURE	HIGH PRIORITY, red flashing
PHYSIOLOGICAL ALARM CONDITIONS, if not specified in other standards	
PHYSIOLOGICAL ALARM CONDITIONS, for example non-invasive blood pressure limit ALARM CONDITION	HIGH PRIORITY, red flashing Possible: escalation with two different limits
Treatment deviation, influence on prescription	
For example balancing ALARM CONDITIONS, long-lasting bypass of DIALYSIS FLUID	LOW PRIORITY, yellow
Technical information	
Technical faults, but blood system is running, for example short bypass of dialysate	INFORMATION SIGNAL, for example green flashing Alternative is the use of LOW PRIORITY, yellow

An ALARM SIGNAL activated in case of extracorporeal blood loss to the environment (see 201.12.4.4.104.1) is one example of a HIGH PRIORITY ALARM SIGNAL that requires immediate response by the OPERATOR. If the blood flow is stopped for an extended period of time (201.12.4.4.104.3), this is an example for a MEDIUM PRIORITY ALARM SIGNAL. In most other ALARM CONDITIONS, the PROTECTIVE SYSTEM puts the HAEMODIALYSIS EQUIPMENT in a state which is safe for the PATIENT, at least temporarily, and therefore is indicated by a LOW PRIORITY ALARM SIGNAL. Other ALARM SIGNALS should be determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS.

Subclause 208.6.3.1 – General

If the OPERATOR is allowed to configure the contents of the screen, the MANUFACTURER has to use constructive measures (and not just notes in the instructions for use) to ensure that the ALARM SIGNALS can be seen under all circumstances.

Subclause 208.6.3.3.101 – Special characteristics of auditory ALARM SIGNALS for HAEMODIALYSIS EQUIPMENT

There are ALARM CONDITIONS which do not present any HAZARDOUS SITUATION if the auditory ALARM SIGNAL is AUDIO PAUSED for more than 3 min, but where elimination of the cause of the ALARM CONDITION often takes more than 3 min, for example in case of a conductivity ALARM CONDITION caused by an empty DIALYSIS FLUID CONCENTRATE container. In this case, the PATIENT'S state will not deteriorate during the AUDIO PAUSED period and the activated bypass mode.

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

Besides the PERMANENTLY INSTALLED connection to SUPPLY MAINS needed for CLASS I devices the same level of safety may be achieved by a unique MAINS PLUG connector that is normally not used in the HOME HEALTHCARE ENVIRONMENT. This allows the PATIENT OPERATOR to disconnect and remove the device without the problem of reconnecting it to another SUPPLY MAINS socket-outlet with an improper PROTECTIVE EARTH CONNECTION. If a unique SUPPLY MAINS socket-outlet connector is used, it has to be installed and tested by the RESPONSIBLE ORGANIZATION.

Annex BB
(informative)

Examples of HAZARDS, foreseeable sequences of events, and HAZARDOUS SITUATIONS in HAEMODIALYSIS EQUIPMENT

Table BB.1 is not intended to be a complete RISK ANALYSIS and is provided partially and for example only. Given HARM levels do not apply to all PATIENT groups. Risk assessment is the responsibility of each MANUFACTURER.

Table BB.1 – HAZARDOUS SITUATION list following ISO 14971:2007, Annex E

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
Multiple HAZARDS possible	Venous needle punctures vascular access	Extracorporeal blood flow into intertissue through venous needle	Haematoma	
	Delivery rate or amount of heparin too high	Heparin concentration too high inside blood volume	Internal bleeding	– IEC 60601-2-16: 201.11.8
	Blood flow was stopped too long	Coagulation of extracorporeal blood	Blood loss	– IEC 60601-2-16: 201.7.9.2.5; 201.7.9.3.1; 201.11.8; 201.12.4.4.104.3 – IEC 60601-1:2005: 7.9.2.4
	Interruption of power supply too long			– IEC 60601-2-16: 201.11.8; 201.7.9.3.1; 201.12.4.4.104.3
	High ULTRAFILTRATION rate over DIALYSER semipermeable membrane in relation to blood flow rate	Increasing haematocrit may block fibres of DIALYSER		– IEC 60601-2-16: 201.12.4.4.104.3
	Venous needle slips out	Extracorporeal blood is pumped to environment		– IEC 60601-2-16: 201.7.9.2.2, 7th hyphen; 201.7.9.3.1, 2nd bullet, 6th hyphen; 201.12.4.4.104.1
	Connector of disposable behind arterial blood pump opened or leaks			– IEC 60601-2-16: 201.7.9.2.2, 3rd hyphen; 201.12.4.4.104.1
	Pressure higher than disposal resist leading to rupture			– IEC 60601-2-16: 201.12.4.4.104.1
	Syringe plunger of heparin pump, which arranged downstream of blood pump slipping out			– IEC 60601-2-16: 201.12.4.4.104.1
	DIALYSER semi-permeable membrane or fibre broken	BLOOD LEAKS into DIALYSIS FLUID		– IEC 60601-2-16: 201.7.9.3.1, 2nd bullet, 7th hyphen; 201.12.4.4.104.2

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	Unintended blood flow reversal and air in the EXTRACORPOREAL CIRCUIT	Air infused over arterial PATIENT CONNECTION	Air infusion	– IEC 60601-2-16: 201.7.9.3.1, 2nd bullet, 2nd hyphen; 201.12.4.4.109
	Level regulator pump pumps air into ARTERIAL PRESSURE monitor upstream of arterial blood pump			– IEC 60601-2-16: 201.7.9.3.1, 2nd bullet, 2nd hyphen; 201.12.4.4.109
	Air sucked into blood side before blood pump (material damage or unintentional opening of the infusion port)	Air infused over venous PATIENT CONNECTION		– IEC 60601-2-16: 201.7.9.2.2, 8th hyphen; 201.7.9.3.1, 2nd bullet, 2nd hyphen; 201.12.4.4.105; 201.12.4.4.106; 201.12.4.4.107
	Level regulator pump pumps air into arterial and/or VENOUS PRESSURE monitor downstream of arterial blood pump.			– IEC 60601-2-16: 201.7.9.3.1, 2nd bullet, 2nd hyphen; 201.12.4.4.105, 201.12.4.4.106, 201.12.4.4.107
	SUBSTITUTION FLUID pump pumps air into arterial and/or venous EXTRACORPOREAL CIRCUIT			– IEC 60601-2-16: 201.7.9.3.1, 2nd bullet, 2nd hyphen; 201.12.4.4.105; 201.12.4.4.106; 201.12.4.4.107
	Improper function of ultrasonic air detector (e.g. caused by coagulum or ultrasound gel)			– IEC 60601-2-16: 201.7.9.2.2, 10th hyphen
	Air entering the EXTRACORPOREAL CIRCUIT in the recirculation path of single-needle treatment			– IEC 60601-2-16: 201.7.9.2.2, 11th hyphen
	Blood line kinked (specially DIALYSER input)	Erythrocytes exposed to high sheer forces.	Haemolysis	– IEC 60601-2-16: 201.7.9.2.2, 9th hyphen
	Reduced blood flow rate by high negative arterial upstream of pump	Reduced effectiveness of HAEMODIALYSIS treatment	Prescribed HAEMODIALYSIS treatment dose not delivered	– IEC 60601-2-16: 201.7.9.2.2, 13th hyphen
	Insufficient degassing of DIALYSIS FLUID			
	Insufficient flow rate of fresh DIALYSIS FLUID			– IEC 60601-2-16: 201.7.9.3.1, 2nd bullet,4th hyphen
	Blood flow rate too low due to technical defect			– IEC 60601-2-16: 201.4.3.101
	DIALYSIS FLUID bypassing DIALYSER			– IEC 60601-2-16: 201.4.3.101
	Effective HAEMODIALYSIS time too low due to technical defect			– IEC 60601-2-16: 201.4.3.101
	SUBSTITUTION FLUID flow rate too low due to technical defect			– IEC 60601-2-16: 201.4.3.101

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
Biological	Blood of the previous PATIENT flows into the pressure inlet connection of the HAEMODIALYSIS EQUIPMENT	Pyrogens/ endotoxins/bacteria/viruses may contaminate the blood directly (cross infection)	Virus/bacterial infection/ Pyrogen reaction	– IEC 60601-2-16: 201.15.4.1.102
	Disinfection PROCEDURE of HAEMODIALYSIS EQUIPMENT internally and externally has inadequately removed viral contamination			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 7.9.2.12, 11.6.6 – IEC 60601-2-16: 201.7.9.2.12, 1st, 2nd, 3rd hyphens; 201.11.6.6
	Infusion of contaminated DIALYSIS FLUID into blood from DIALYSIS FLUID side in ONLINE HDF / HF systems	Pyrogens/ endotoxins/bacteria may contaminates the blood directly		– IEC 60601-2-16: 201.7.9.3.1, 2nd bullet,14th hyphen; 201.12.4.4.111
	Contaminated surface of ENCLOSURE	Skin contamination with bacteria	Bacterial infection	– IEC 60601-2-16: 201.7.9.2.2, 1st hyphen
Chemical	Treatment of PATIENT when HAEMODIALYSIS EQUIPMENT is in disinfection mode	Blood contamination with toxins	Poisoning / allergy	– IEC 60601-2-16: 201.12.4.4.108
	Disinfectant has been inadequately rinsed from DIALYSIS FLUID circuit			– IEC 60601-2-16: 201.11.6.6
	OPERATOR connects disinfectant canister instead of bicarbonate DIALYSIS FLUID CONCENTRATE or acid/acetate DIALYSIS FLUID CONCENTRATE canister to HAEMODIALYSIS EQUIPMENT			– IEC 60601-1:2005 and IEC 60601-1:2005:AMD1:2012: 15.4.1 – IEC 60601-2-16: 201.15.4.1.101
	Toxic material comes in contact with DIALYSIS FLUID (e.g. via water supply or by components of the hydraulics)			– IEC 60601-1:2005: 11.7 – IEC 60601-2-16: 201.7.9.3.1, 2nd bullet, 13th hyphen
Biological	Returning fluid into CENTRAL DELIVERY SYSTEM or DIALYSIS WATER supply	Blood contamination with toxins	Poisoning/ allergy	– IEC 60601-2-16: 201.12.4.4.108
Multiple HAZARDS possible	DIALYSIS- / SUBSTITUTION FLUID temperature too low	Blood is cooled directly (infusion) or via DIALYSER	Cooling heart until cardiac arrest	– IEC 60601-1:2005: 12.4.3 – IEC 60601-2-16: 201.7.9.3.1, 2nd bullet,4th hyphen; 201.12.4.4.102; 201.11.8
	DIALYSIS- / SUBSTITUTION FLUID temperature too high	Blood is heated directly (infusion) or via DIALYSER	Haemolysis	– IEC 60601-1:2005: 12.4.3 – IEC 60601-2-16: 201.7.9.2.6, 4th hyphen; 201.7.9.3.1, 2nd bullet, 4th hyphen; 201.12.4.4.102; 201.11.8

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	DIALYSIS FLUID Na concentration lower than prescribed	Blood is dialysed against or infused with (ONLINE HDF) DIALYSIS FLUID of too low concentration (Na)	Hyponatremia	– IEC 60601-1:2005: 12.4.3 – IEC 60601-2-16: 201.4.3.101; 201.7.9.3.1, 2nd bullet, 3rd hyphen
	DIALYSIS FLUID Na concentration lower than 120 mmol/l		Haemolysis	– IEC 60601-1:2005: 12.4.3 – IEC 60601-2-16: 201.12.4.4.101
	DIALYSIS FLUID Na concentration higher than prescribed	Blood is dialysed against or infused with (ONLINE HDF) DIALYSIS FLUID of too high concentration (Na)	Hypernatremia	– IEC 60601-1:2005: 12.4.3 – IEC 60601-2-16: 201.4.3.101; 201.7.9.3.1, 2nd bullet, 3rd hyphen
	DIALYSIS FLUID Na concentration higher than 160 mmol/l			– IEC 60601-1:2005: 12.4.3 – IEC 60601-2-16: 201.12.4.4.101
	Bicarbonate DIALYSIS FLUID concentration too low	Blood is dialysed against or infused with (ONLINE HDF) DIALYSIS FLUID of too low concentration (Bicarbonate)	Acidosis	– IEC 60601-1:2005: 12.4.3 – IEC 60601-2-16: 201.12.4.4.101
	Acid DIALYSIS FLUID CONCENTRATE instead of acetate DIALYSIS FLUID CONCENTRATE when acetate HAEMODIALYSIS treatment has been selected			– IEC 60601-2-16: 201.7.9.2.5, 2nd hyphen; 201.12.4.4.101; 201.15.4.1.101; 201.16.9.1
	Acid DIALYSIS FLUID CONCENTRATE instead of bicarbonate DIALYSIS FLUID CONCENTRATE when bicarbonate HAEMODIALYSIS treatment has been selected			– IEC 60601-2-16: 201.7.9.2.5, 2nd hyphen; 201.12.4.4.101; 201.15.4.1.101; 201.16.9.1
	Acetate DIALYSIS FLUID CONCENTRATE instead of bicarbonate DIALYSIS FLUID CONCENTRATE when bicarbonate HAEMODIALYSIS treatment has been selected			– IEC 60601-2-16: 201.7.9.2.5, 2nd hyphen; 201.12.4.4.101; 201.15.4.1.101; 201.16.9.1
	Acetate HAEMODIALYSIS treatment instead of bicarbonate HAEMODIALYSIS treatment		Hyperacetatemia	– IEC 60601-2-16: 201.12.4.4.110
	Bicarbonate DIALYSIS FLUID concentration too high	Blood is dialysed against or infused with (ONLINE HDF) DIALYSIS FLUID of too high concentration (bicarbonate)	Alkalosis	– IEC 60601-1:2005: 12.4.3 – IEC 60601-2-16: 201.12.4.4.101
	Acetate DIALYSIS FLUID CONCENTRATE instead of acid DIALYSIS FLUID CONCENTRATE when bicarbonate HAEMODIALYSIS treatment has been selected			– IEC 60601-2-16: 201.7.9.2.5, 2nd hyphen; 201.12.4.4.101; 201.15.4.1.101; 201.16.9.1
	SUBSTITUTION FLUID bolus volume too high	Blood volume increased	Extracellular volume change	– IEC 60601-1:2005: 12.4.3 – IEC 60601-2-16: 201.12.4.4.103

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	Priming or returning volume too high due to technical faults			– IEC 60601-1:2005: 12.4.3 – IEC 60601-2-16: 201.12.4.4.103
	Inlet DIALYSIS FLUID flow rate into DIALYSER higher than outlet flow rate			– IEC 60601-2-16: 201.12.4.4.103; 201.7.9.2.2; 201.7.9.2.5; 201.7.9.3.1
	SUBSTITUTION FLUID volume higher than ULTRAFILTRATION volume			– IEC 60601-1:2005: 12.4.3 – IEC 60601-2-16: 201.12.4.4.103
	Dry weight not achieved	Insufficient removal of fluid from the PATIENT	Interdialytic overhydration	– IEC 60601-1:2005: 12.4.3 – IEC 60601-2-16: 201.12.4.4.103
	SUBSTITUTION FLUID bolus volume too low	Insufficient increase of PATIENT blood volume	Extracellular volume change	– IEC 60601-1:2005: 12.4.3
	NET FLUID REMOVAL volume too high	Excessive removal of fluid from the PATIENT		– IEC 60601-1:2005: 12.4.3 – IEC 60601-2-16: 201.12.4.4.103
	NET FLUID REMOVAL rate greater than set rate			– IEC 60601-1-10:2007: Clause 4 – IEC 60601-2-16: 201.12.4.4.103; 201.7.9.2.2; 201.7.9.2.5; 201.7.9.3.1; 201.11.8
	DIALYSIS FLUID loss from balanced DIALYSIS FLUID circuit			– IEC 60601-2-16: 201.12.4.4.103
	ULTRAFILTRATION volume higher than needed by corresponding SUBSTITUTION FLUID volume			– IEC 60601-2-16: 201.12.4.4.103
Operational	Wrong restoring of data/instructions after power interruption	Incorrect treatment	Multiple harms possible	– IEC 60601-2-16: 201.11.8
	Faulty treatment data/instructions from PATIENT card or IT-NETWORK			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 14.13 – IEC 60601-2-16: 201.14.13
	Faulty treatment instruction(s) on screen from IT-NETWORK			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 14.13 – IEC 60601-2-16: 201.14.13
Information	Preventive or corrective maintenance has not or incorrectly been carried out			– IEC 60601-1:2005: 7.9.2.13
	Expected service life is elapsed			– IEC 60601-1:2005: 4.4

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	Markings or instruction for use missing or wrong			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 7.1; 7.2; 7.4; 7.5; 7.6; 7.9.2 – IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012: 5.2; 6.1; 6.2 – IEC 60601-1-10:2007; 5.1; 5.2 – IEC 60601-2-16: 201.7.9.2.2
	Service information missing or wrong			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 7.3; 7.7; 7.9.2.13; 7.9.3 – IEC 60601-2-16: 201.7.9.2.6
	OPERATOR response missing or wrong (USE ERROR)			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 7.8; 7.9.2.8; 7.9.2.9; 7.9.2.10; 7.9.2.11; 7.9.2.14; 9.2.3.1; 12.1; 12.2; 12.4.2 – IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012: 6.1.2; 6.3.1; 6.3.2.1 – IEC 60601-1-10:2007; 6.1; 6.2; 6.3; 6.4 – IEC 60601-2-16: 201.7.9.2.2; 201.7.9.2.6; 201.7.9.2.14; 201.7.9.3.1; 208.4; 208.6.3.1; 208.6.3.3.2; 208.6.3.3.3; 201.12.4.4.110
Operational	Failure of ALARM CONDITION override mode			– IEC 60601-2-16: 201.12.4.4.106
	Failure of PROTECTIVE SYSTEMS			– IEC 60601-2-16: 201.12.4.4.107
Electrical	Electrical insulation not sufficient	LEAKAGE CURRENT	Electric shock	– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 8.5; 8.6; 8.7; 8.8; 13.1.3; 13.2.2 – IEC 60601-2-16: 201.8.3; 201.8.7.4.7; 201.11.6.3
	CREEPAGE DISTANCES and air clearance not sufficient			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 8.9; 13.2.6 – IEC 60601-2-16: 201.13.2.6
	Internal or external leaks that reduce CREEPAGE DISTANCES and AIR CLEARANCE			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 8.9
	Rapid ageing of insulation			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 11.1; 11.6.6

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	Touching ACCESSIBLE PARTS			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 4.8; 4.9; 5.9.2; 7.9.2.7; 8.4; 8.5; 8.10; 8.11; 9.2.2.4 – IEC 60601-2-16: 201.7.9.2.6; 201.8.11.2
	Ingress of fluid into the HAEMODIALYSIS EQUIPMENT			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 11.6 – IEC 60601-2-16: 201.11.6.3
	Components used outside of specified current ratings			– IEC 60601-1:2005: 13.2.3
	Destruction of parts when replacing			– IEC 60601-1:2005: 15.2
	Excessive mechanical stress caused by pushing, impact, dropping, and rough handling			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 15.3
	Overheating of transformer			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 15.5
	Drain connected to DIALYSIS WATER supply			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 15.4.1
	DIALYSIS FLUID CONCENTRATE connected to DIALYSIS WATER supply			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 15.4
	Incorrectly arranged ME SYSTEM			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 16.1; 16.2; 16.3; 16.4; 16.5; 16.6; 16.9 – IEC 60601-2-16: 201.16.2; 201.16.6.3
	Treatment with central venous catheter whose tip is in the right atrium by HAEMODIALYSIS EQUIPMENT with TYPE B APPLIED PARTS	PATIENT LEAKAGE CURRENT	Electric shock	– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 8.7 – IEC 60601-2-16: 201.7.9.2.5; 201.8.3
	Magnetic and electric fields cause disruption of proper operation through interference from other electrical equipment and power supply	Incorrect treatment	Multiple harms	– IEC 60601-1-2:2014 – IEC 60601-2-16: 202.3.18
	Magnetic and electric fields cause disruption of proper operation through interference to other ME EQUIPMENT and power supply		Multiple harms to PATIENTS and others	– IEC 60601-1-2:2014
Chemical	Escape of chemical substances	Contact with chemicals	Body harm	– IEC 60601-1:2005: 7.9.2.4; 11.6.4

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	High pressure fluid ejection			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 9.7
Thermal	Hot external or internal components	Contact with high temperature fluids	Body harm	– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 11.1; 11.6.4; 11.6.6
	High pressure hot fluid ejection			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 9.7
Mechanical	Finger into roller pump	Crushing/Shearing/Limb breaking	Bruise/ Sprain/Cut/Fractures	– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 5.9.2; 9.2.2.4.4
	Limb between moving parts			– IEC 60601-1:2005: 9.2.2.2; 16.7
	Foot under the base			
	HAEMODIALYSIS EQUIPMENT on inclined plane			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 9.4
	Displacement of HAEMODIALYSIS EQUIPMENT			
	Sharp parts	Cutting	Body harm	– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 9.3
	Openings in enclosure with moving parts behind			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 5.9.2
Thermal	Components used outside of specified current ratings	Fire	Multiple harms to PATIENTS and others	– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 4.8; 4.9; 13.1.2; 13.2.3; 13.2.13
	Ingress of water into the device leads to short cut current			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 11.6 – IEC 60601-2-16: 201.11.6.3
	Defective control of heater			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 13.2.4; 13.2.5; 13.2.13; 15.4.2
	Impaired cooling			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 13.2.7
	Interruption and short circuit of motor capacitors			– IEC 60601-1:2005: 13.2.9
	Defects of battery			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 15.4.3.1
	Incorrect polarity of battery connection			– IEC 60601-1:2005: 15.4.3.2
	Overcharging battery			– IEC 60601-1:2005: 15.4.3.3

HAZARD	Foreseeable sequence of events	HAZARDOUS SITUATION	Harm	Reference standard[a]
	Excessive current from battery			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 15.4.3.5
	Overheating of transformer			– IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012: 15.5

[a] IEC 60601-2-16 refers to this document.

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[13] ISO 11197, *Medical supply units*

[14] ISO 15883 (all parts), *Washer-disinfectors*

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3 Under preparation.

4 Second edition, withdrawn.

5 This document replaces ISO 8637:2010 and ISO 8637:2010/AMD1:2013.

6 Under preparation. Stage at the time of publication: ISO/FDIS 8637-2:2018. This document will replace ISO 8638:2010.

7 Under preparation. Stage at the time of publication: IEC/DIS 23500-1:2018. This document will replace ISO 23500:2014.

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[17] ISO 23500-3, *Guidance for the preparation and quality management of fluids for haemodialysis and related therapies – Part 3: Water for haemodialysis and related therapies*[9]

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Index of defined terms used in this particular standard

SOMMAIRE

COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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APPAREILS ÉLECTROMÉDICAUX –

Partie 2-16: Exigences particulières pour la sécurité de base et les performances essentielles des appareils d'hémodialyse, d'hémodiafiltration et d'hémofiltration

AVANT-PROPOS

La Norme internationale IEC 60601-2-16 a été établie par le sous-comité 62D: Appareils électromédicaux, du comité d'études 62 de l'IEC: Équipements électriques dans la pratique médicale.

Cette cinquième édition annule et remplace la quatrième édition de l'IEC 60601-2-16 parue en 2012. Cette édition constitue une révision technique.

Cette édition inclut les modifications techniques majeures suivantes par rapport à l'édition précédente:

a) actualisation des références à l'IEC 60601-1:2005 et l'IEC 60601-1:2005/AMD1:2012, des références et des exigences à l'IEC 60601-1-2:2014, des références à l'IEC 60601-1-6:2010 et l'IEC 60601-1-6:2010/AMD1:2013, des références et des exigences à l'IEC 60601-1-8:2006 et l'IEC 60601-1-8:2006/AMD1:2012, des références à l'IEC 60601-1-9:2007 et l'IEC 60601-1-9:2007/AMD1:2013, des références à l'IEC 60601-1-10:2007 et l'IEC 60601-1-10:2007/AMD1:2013 ainsi que des références à l'IEC 60601-1-11:2015;

b) élargissement du domaine d'application;

c) améliorations d'ordre rédactionnel;

d) ajout d'exigences concernant les dispositifs de transmission d'anticoagulant;

e) quelques autres modifications techniques limitées.

Le texte de cette norme particulière est issu des documents suivants:

FDIS	Rapport de vote
62D/1557/FDIS	62D/1585/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation de cette norme particulière.

Cette publication a été rédigée selon les Directives ISO/IEC, Partie 2.

Dans le présent document, les caractères d'imprimerie suivants sont utilisés:

– exigences et définitions: caractères romains;
– *modalités d'essais: caractères italiques;*
– indications de nature informative apparaissant hors des tableaux, comme les notes, les exemples et les références: petits caractères. Le texte normatif à l'intérieur des tableaux est également en petits caractères;
– TERMES DEFINIS A L'ARTICLE 3 DE LA NORME GENERALE, DE LA PRESENTE NORME PARTICULIERE OU COMME NOTES: PETITES MAJUSCULES.

Concernant la structure du présent document, le terme

– "article" désigne l'une des dix-sept divisions numérotées dans la table des matières, avec toutes ses subdivisions (par exemple, l'Article 7 inclut les paragraphes 7.1, 7.2, etc.);
– "paragraphe" désigne une subdivision numérotée d'un article (par exemple 7.1, 7.2 et 7.2.1 sont tous des paragraphes appartenant à l'Article 7).

Dans le présent document, les références à des articles sont précédées du mot "Article" suivi du numéro de l'article concerné. Dans la présente norme particulière, les références aux paragraphes utilisent uniquement le numéro du paragraphe concerné.

Dans le présent document, la conjonction "ou" est utilisée avec la valeur d'un "ou inclusif", ainsi un énoncé est vrai si une combinaison des conditions, quelle qu'elle soit, est vraie.

Les formes verbales utilisées dans le présent document sont conformes à l'usage donné à l'Article 7 des Directives ISO/IEC, Partie 2. Pour les besoins du présent document:

– "devoir" mis au présent de l'indicatif signifie que la satisfaction à une exigence ou à un essai est obligatoire pour la conformité au présent document;
– "il convient" signifie que la satisfaction à une exigence ou à un essai est recommandée, mais n'est pas obligatoire pour la conformité au présent document;
– "pouvoir" mis au présent de l'indicatif est utilisé pour décrire un moyen admissible pour satisfaire à une exigence ou à un essai.

Lorsqu'un astérisque (*) est utilisé comme premier caractère devant un titre ou au début d'un titre d'alinéa ou de tableau, il indique l'existence d'un guide ou d'une justification à consulter à l'Annexe AA.

Une liste de toutes les parties de la série IEC 60601, publiées sous le titre général *Appareils électromédicaux*, peut être consultée sur le site web de l'IEC.

Le comité a décidé que le contenu de cette publication ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous "http://webstore.iec.ch" dans les données relatives à la publication recherchée. À cette date, la publication sera

- reconduite,
- supprimée,
- remplacée par une édition révisée, ou
- amendée.

IMPORTANT – Le logo "*colour inside*" qui se trouve sur la page de couverture de cette publication indique qu'elle contient des couleurs qui sont considérées comme utiles à une bonne compréhension de son contenu. Les utilisateurs devraient, par conséquent, imprimer cette publication en utilisant une imprimante couleur.

NOTE L'attention des utilisateurs du présent document est attirée sur le fait que les fabricants d'appareils et les organismes d'essai peuvent avoir besoin d'une période transitoire après la publication d'une nouvelle publication IEC, ou d'une publication amendée ou révisée, pour fabriquer des produits conformes aux nouvelles exigences et pour adapter leurs équipements aux nouveaux essais ou aux essais révisés. Le comité recommande que le contenu de cette publication soit entériné au niveau national au plus tôt 3 ans après la date de publication.

INTRODUCTION

Les exigences minimales de sécurité spécifiées dans la présente norme particulière sont considérées comme fournissant un degré pratique de sécurité pour le fonctionnement des APPAREILS D'HEMODIALYSE, D'HEMODIAFILTRATION et D'HEMOFILTRATION.

APPAREILS ÉLECTROMÉDICAUX –

Partie 2-16: Exigences particulières pour la sécurité de base et les performances essentielles des appareils d'hémodialyse, d'hémodiafiltration et d'hémofiltration

201.1 Domaine d'application, objet et normes connexes

L'Article 1 de la norme générale[1] s'applique, avec les exceptions suivantes:

201.1.1 * Domaine d'application

Remplacement:

La présente partie de l'IEC 60601 s'applique à la SECURITE DE BASE et aux PERFORMANCES ESSENTIELLES des APPAREILS D'HEMODIALYSE, D'HEMODIAFILTRATION et D'HEMOFILTRATION, désignés ci-après sous le terme d'APPAREILS D'HEMODIALYSE.

Le présent document ne prend pas en considération les informations détaillées de sécurité spécifiques du système de contrôle du LIQUIDE DE DIALYSE de l'APPAREIL D'HEMODIALYSE utilisant la régénération du LIQUIDE DE DIALYSE ou les SYSTEMES DE TRANSMISSION CENTRALISES pour le LIQUIDE DE DIALYSE. Toutefois, il prend en considération les exigences de sécurité spécifiques de l'APPAREIL D'HEMODIALYSE concernant la sécurité électrique et la sécurité du PATIENT.

Le présent document spécifie les exigences minimales de sécurité relatives aux APPAREILS D'HEMODIALYSE. Ces APPAREILS D'HEMODIALYSE sont destinés à être utilisés soit par le personnel médical, soit par le PATIENT, soit par d'autres personnes formées, sous le contrôle d'un personnel ayant une compétence médicale.

Le présent document s'applique à tous les APPAREILS EM destinés à fournir un traitement d'HEMODIALYSE, d'HEMODIAFILTRATION et d'HEMOFILTRATION à un PATIENT, indépendamment de la durée et du lieu de traitement.

Le cas échéant, le présent document s'applique aux parties correspondantes des APPAREILS EM destinés à d'autres traitements extracorporels de purification du sang.

Les exigences particulières du présent document ne s'appliquent pas aux:

– CIRCUITS EXTRACORPORELS (voir ISO 8637-2 [12][2]);
– DIALYSEURS (voir ISO 8637-1 [11]);
– CONCENTRES DE LIQUIDE DE DIALYSE (voir ISO 23500-4 [18]);
– systèmes d'approvisionnement en EAU DE DIALYSE (voir ISO 23500-2 [16]);
– SYSTEMES DE TRANSMISSION CENTRALISES pour LES CONCENTRES DE LIQUIDE DE DIALYSE (voir ISO 23500-4 [18]), décrits comme systèmes de mélange de concentré en vrac dans un centre de dialyse;

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[1] La norme générale est l'IEC 60601-1:2005 et l'IEC 60601-1:2005/AMD1:2012, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles.*

[2] Les chiffres entre crochets se réfèrent à la Bibliographie.

– appareils de DIALYSE PERITONEALE (voir IEC 60601-2-39 [8]).

201.1.2 Objet

Remplacement:

L'objet de la présente norme particulière est d'établir les exigences pour la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES des APPAREILS D'HEMODIALYSE.

201.1.3 Normes collatérales

Addition:

La présente norme particulière fait référence aux normes collatérales applicables énumérées à l'Article 2 de la norme générale et à l'Article 201.2 de la présente norme particulière.

L'IEC 60601-1-2:2014, l'IEC 60601-1-8:2006 et l'IEC 60601-1-8:2006/AMD1:2012, l'IEC 60601-1-10:2007 et l'IEC 60601-1-10:2007/AMD1:2013, ainsi que l'IEC 60601-1-11:2015 s'appliquent telles que modifiées dans les Articles 202, 208, 210 et 211. L'IEC 60601-1-3 et l'IEC 60601-1-12 ne s'appliquent pas. L'IEC 60601-1-9:2007 et l'IEC 60601-1-9:2007/AMD1:2013 ne s'appliquent pas comme indiqué à l'Article 209. Toutes les autres normes collatérales publiées de la série IEC 60601-1 s'appliquent telles qu'elles sont publiées.

201.1.4 Normes particulières

Remplacement:

Dans la série IEC 60601, des normes particulières peuvent modifier, remplacer ou supprimer des exigences contenues dans la norme générale et dans les normes collatérales en fonction de ce qui est approprié à l'APPAREIL EM à l'étude, et elles peuvent ajouter d'autres exigences de SECURITE DE BASE et de PERFORMANCES ESSENTIELLES.

Une exigence d'une norme particulière prévaut sur l'exigence de la norme générale.

Par souci de concision, dans la présente norme particulière, le terme "norme générale" désigne les normes IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012. Les normes collatérales sont désignées par leur numéro de document.

La numérotation des articles et paragraphes de la présente norme particulière correspond à celle de la norme générale avec le préfixe "201" (par exemple 201.1 dans le présent document aborde le contenu de l'Article 1 de la norme générale) ou de la norme collatérale applicable avec le préfixe "20x" où x est (sont) le (les) dernier(s) chiffre(s) du numéro de document de la norme collatérale (par exemple 202.4 dans la présente norme particulière aborde le contenu de l'Article 4 de la norme collatérale IEC 60601-1-2, 203.4 dans la présente norme particulière aborde le contenu de l'Article 4 de la norme collatérale IEC 60601-1-3, etc.). Les modifications apportées au texte de la norme générale sont précisées en utilisant les termes suivants:

"Remplacement" signifie que l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable est remplacé complètement par le texte de la présente norme particulière.

"Addition" signifie que le texte de la présente norme particulière vient s'ajouter aux exigences de la norme générale ou de la norme collatérale applicable.

"*Amendement"* signifie que l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable est modifié comme indiqué par le texte de la présente norme particulière.

Les paragraphes, les figures ou les tableaux qui sont ajoutés à ceux de la norme générale sont numérotés à partir de 201.101. Toutefois, en raison du fait que les définitions dans la norme générale sont numérotées de 3.1 à 3.147, les définitions complémentaires dans le présent document sont numérotées à partir de 201.3.201. Les annexes supplémentaires sont notées AA, BB, etc., et les points complémentaires aa), bb), etc.

Les paragraphes, les figures ou les tableaux qui sont ajoutés à ceux d'une norme collatérale sont numérotés à partir de 20x, où "x" est le chiffre de la norme collatérale, par exemple 202 pour l'IEC 60601-1-2, 203 pour l'IEC 60601-1-3, etc.

L'expression "le présent document" est utilisée pour se référer à la norme générale, à toutes les normes collatérales applicables et à la présente norme particulière, considérées ensemble.

Lorsque la présente norme particulière ne comprend pas d'article ou de paragraphe correspondant, l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable, qui peut être sans objet, s'applique sans modification; lorsqu'il est demandé qu'une partie quelconque de la norme générale ou de la norme collatérale applicable, bien que pertinente, ne s'applique pas, cela est expressément mentionné dans la présente norme particulière.

201.2 Références normatives

NOTE Les références informatives sont énumérées dans la bibliographie.

L'Article 2 de la norme générale s'applique, avec les exceptions suivantes:

Remplacement:

IEC 60601-1-2:2014, *Appareils électromédicaux – Partie 1-2: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Perturbations électromagnétiques – Exigences et essais*

IEC 60601-1-6:2010, *Appareils électromédicaux – Partie 1-6: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Aptitude à l'utilisation*
IEC 60601-1-6:2010/AMD1:2013

IEC 60601-1-8:2006, *Appareils électromédicaux – Partie 1-8: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Exigences générales, essais et guide pour les systèmes d'alarme des appareils et des systèmes électromédicaux*
IEC 60601-1-8:2006/AMD1:2012

Addition:

IEC 60601-1-10:2007, *Appareils électromédicaux – Partie 1-10: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Exigences pour le développement des régulateurs physiologiques en boucle fermée*
IEC 60601-1-10:2007/AMD1:2013

IEC 60601-1-11:2015, *Appareils électromédicaux – Partie 1-11: Exigences générales pour la sécurité de base et les performances essentielles – Norme Collatérale: Exigences pour les appareils électromédicaux et les systèmes électromédicaux utilisés dans l'environnement des soins à domicile*

IEC 61672-1, *Electroacoustique – Sonomètres – Partie 1: Spécifications*

ISO 3744, *Acoustique – Détermination des niveaux de puissance acoustique et des niveaux d'énergie acoustique émis par les sources de bruit à partir de la pression acoustique – Méthode d'expertise pour des conditions approchant celles du champ libre sur plan réfléchissant*

201.3 Termes et définitions

Pour les besoins du présent document, les termes et définitions de l'IEC 60601-1:2005 et l'IEC 60601-1:2005/AMD1:2012, l'IEC 60601-1-2:2014, l'IEC 60601-1-8:2006, l'IEC 60601-1-8:2006/AMD1:2012, l'IEC 60601-1-10:2007, l'IEC 60601-1-10:2007/AMD1:2013, l'IEC 60601-1-11:2015, ainsi que les suivants, s'appliquent.

L'ISO et l'IEC tiennent à jour des bases de données terminologiques destinées à être utilisées en normalisation, consultables aux adresses suivantes:

- IEC Electropedia: disponible à l'adresse http://www.electropedia.org/
- ISO Online browsing platform: disponible à l'adresse http://www.iso.org/obp

NOTE Un index des termes définis est donné à partir de la page 154.

201.3.8
*** PARTIE APPLIQUEE**

Remplacement:

CIRCUIT EXTRACORPOREL et toutes les parties qui lui sont reliées en permanence et en conduction (par exemple, circuit du LIQUIDE DE DIALYSE)

Note 1 à l'article: Voir Figure AA.1.

201.3.78
CONNEXION PATIENT

Addition:

Note 1 à l'article: Les raccords des lignes de sang du PATIENT sont les points individuels sur la PARTIE APPLIQUEE à travers lesquels le courant peut s'écouler entre le PATIENT et l'APPAREIL D'HEMODIALYSE en CONDITION NORMALE ou en CONDITION DE PREMIER DEFAUT.

Termes et définitions complémentaires:

201.3.201
PRESSION ARTERIELLE
pression mesurée dans la ligne de retrait du sang du CIRCUIT EXTRACORPOREL entre la CONNEXION PATIENT et la connexion DIALYSEUR

Note 1 à l'article: Une différence peut être faite entre la pression avant la pompe, qui est en amont de la pompe à sang, et la pression après la pompe, qui est en aval de la pompe à sang.

201.3.202
*** FUITE DE SANG**
fuite du sang depuis le compartiment du sang en direction du compartiment du LIQUIDE DE DIALYSE du DIALYSEUR

Note 1 à l'article: L'exécution d'un PROCESSUS HF implique la partie liquide de filtration.

201.3.203
SYSTEME DE TRANSMISSION CENTRALISE
partie d'un SYSTEME EM qui dose la proportion de CONCENTRE DE LIQUIDE DE DIALYSE et d'EAU DE DIALYSE pour les distribuer comme LIQUIDE DE DIALYSE à l'APPAREIL D'HEMODIALYSE ou qui répartit le CONCENTRE DE LIQUIDE DE DIALYSE

201.3.204
DIALYSEUR
dispositif contenant une membrane semi-perméable utilisée pour réaliser une HD, UNE HDF ou une HF

201.3.205
LIQUIDE DE DIALYSE
DIALYSAT
SOLUTION DE DIALYSE
FLUIDE DE DIALYSE
fluide aqueux contenant des électrolytes et, généralement, un tampon et du glucose, destiné à échanger des solutés avec le sang, pendant l'HEMODIALYSE

[SOURCE: ISO 23500-1:— [15], 3.15, modifié – Le mot "fluide de dialyse" a été ajouté comme synonyme, et les notes ont été supprimées.]

201.3.206
CONCENTRE DE LIQUIDE DE DIALYSE
substances qui, lorsqu'elles sont diluées ou dissoutes de manière appropriée dans de l'EAU DE DIALYSE, produisent le LIQUIDE DE DIALYSE

201.3.207
CIRCUIT EXTRACORPOREL
lignes de circulation du sang, DIALYSEUR et tout ACCESSOIRE qui en fait partie

Note 1 à l'article: Une variante au DIALYSEUR peut être un filtre HF, un absorbeur ou autre dispositif.

201.3.208
HEMODIAFILTRATION
HDF
PROCESSUS dans lequel les concentrations de substances hydrosolubles dans le sang d'un PATIENT et un excès de liquide d'un PATIENT sont corrigés par une combinaison simultanée de HD et de HF

201.3.209
HEMODIALYSE
HD
PROCESSUS dans lequel les concentrations de substances hydrosolubles dans le sang d'un PATIENT et un excès de liquide d'un PATIENT sont corrigés par le transfert bidirectionnel par diffusion et par ULTRAFILTRATION à travers une membrane semi-perméable séparant le sang du LIQUIDE DE DIALYSE

Note 1 à l'article: Ce PROCESSUS implique normalement une extraction du liquide par filtration. Habituellement, ce PROCESSUS est également accompagné de la diffusion de substances du LIQUIDE DE DIALYSE dans le sang.

201.3.210
*** APPAREIL D'HEMODIALYSE**
APPAREIL EM ou SYSTEME EM utilisé pour réaliser une HEMODIALYSE, UNE HEMODIAFILTRATION et/ou une HEMOFILTRATION

Note 1 à l'article: Lorsque le terme APPAREIL EM est utilisé dans un titre, il est équivalent à APPAREIL D'HEMODIALYSE. Lorsque le terme APPAREIL EM est utilisé dans le texte, il fait référence à un APPAREIL EM générique.

201.3.211
HEMOFILTRATION
HF
PROCESSUS dans lequel les concentrations de substances hydrosolubles dans le sang d'un PATIENT et un excès de liquide d'un PATIENT sont corrigés par le transfert par convection, par l'intermédiaire de l'ULTRAFILTRATION, et le remplacement partiel par un LIQUIDE DE SUBSTITUTION conduisant à l'EXTRACTION NETTE DE LIQUIDE exigée

201.3.212
EXTRACTION NETTE DE LIQUIDE
perte de liquide provenant du PATIENT

Note 1 à l'article: Historiquement, le terme utilisé était "perte de poids".

201.3.213
*** HDF EN LIGNE**
PROCEDURE D'HEMODIAFILTRATION dans laquelle l'APPAREIL D'HEMODIALYSE produit le LIQUIDE DE SUBSTITUTION pour infusion à partir du LIQUIDE DE DIALYSE pour le traitement par HEMODIAFILTRATION

201.3.214
*** HF EN LIGNE**
PROCEDURE D'HEMOFILTRATION dans laquelle l'APPAREIL D'HEMODIALYSE produit le LIQUIDE DE SUBSTITUTION pour infusion à partir du LIQUIDE DE DIALYSE pour le traitement par HEMOFILTRATION

201.3.215
*** SYSTEME DE PROTECTION**
système automatique, ou caractéristique de construction, spécialement conçu(e) pour protéger le PATIENT contre les SITUATIONS DANGEREUSES

201.3.216
LIQUIDE DE SUBSTITUTION
liquide utilisé dans les traitements HF et HDF qui est directement injecté dans le CIRCUIT EXTRACORPOREL pour remplacer du liquide éliminé du sang par filtration

[SOURCE: ISO 23500-1:— [15], 3.40, modifié – Les mots "sang du patient" et "ultrafiltration" ont été remplacés respectivement par "CIRCUIT EXTRACORPOREL" et "filtration" dans la définition, et les notes ont été supprimées.]

201.3.217
PRESSION TRANSMEMBRANIQUE
TMP
différence de pression de liquide s'exerçant de part et d'autre de la membrane semi-perméable du DIALYSEUR

Note 1 à l'article: La TMP moyenne est généralement utilisée. En pratique, la PRESSION TRANSMEMBRANIQUE affichée est habituellement estimée à partir de la pression dans le CIRCUIT EXTRACORPOREL mesurée moins la pression du LIQUIDE DE DIALYSE mesurée, chacune étant relevée en un même point.

Note 2 à l'article: L'abréviation "tmp" est dérivée du terme anglais développé correspondant "transmembrane pressure".

201.3.218
*** ULTRAFILTRATION**
PROCESSUS d'extraction de liquides du sang du PATIENT de part et d'autre de la membrane semi-perméable du DIALYSEUR

201.3.219
PRESSION VEINEUSE
pression mesurée dans la ligne de retour du sang du CIRCUIT EXTRACORPOREL entre la connexion DIALYSEUR et la CONNEXION PATIENT

201.3.220
EAU DE DIALYSE
eau traitée afin de satisfaire aux exigences de l'ISO 23500-3 [17] et adaptée à une utilisation dans les applications d'HEMODIALYSE, y compris la préparation du LIQUIDE DE DIALYSE, le retraitement des DIALYSEURS, la préparation des concentrés et la préparation du LIQUIDE DE SUBSTITUTION pour les thérapies par convection en ligne

Note 1 à l'article: Les mots "eau pour dialyse", "perméat", "eau obtenue par osmose inverse" et "eau purifiée" sont couramment employés comme synonymes d'EAU DE DIALYSE.

[SOURCE: ISO 23500-1:— [15], 3.17, modifié – La définition a été reformulée, et le numéro de référence "[17]" ainsi que la note ont été ajoutés.]

201.4 Exigences générales

L'Article 4 de la norme générale s'applique, avec les exceptions suivantes:

201.4.3 * Performance essentielle

Addition:

201.4.3.101 * Exigences complémentaires de PERFORMANCES ESSENTIELLES

Le cas échéant, les PERFORMANCES ESSENTIELLES d'un APPAREIL D'HEMODIALYSE comprennent, entre autres, les fonctions données dans les paragraphes énumérés dans le Tableau 201.101, qui doivent être satisfaites dans les tolérances spécifiées par le FABRICANT en CONDITION NORMALE.

Tableau 201.101 – Exigences de PERFORMANCES ESSENTIELLES

Exigence	Paragraphe
Flux sanguin	201.4.3.102
Débit du LIQUIDE DE DIALYSE	201.4.3.103
EXTRACTION NETTE DE LIQUIDE	201.4.3.104
Débit du LIQUIDE DE substitution	201.4.3.105
Temps de dialyse	201.4.3.106
Composition du LIQUIDE DE DIALYSE	201.4.3.107
Température du LIQUIDE DE DIALYSE	201.4.3.108
Température du LIQUIDE DE SUBSTITUTION	201.4.3.109

NOTE Certaines des exigences de PERFORMANCES ESSENTIELLES énumérées dans le Tableau 201.101 dépendent des caractéristiques des éléments à usage unique utilisés (par exemple, le flux sanguin dépend du diamètre interne du segment de pompe des pompes péristaltiques rotatives).

201.4.3.102 Flux sanguin

Le flux sanguin de l'APPAREIL D'HEMODIALYSE doit être tel que spécifié par le FABRICANT. La spécification doit inclure la fatigue du segment de pompe pour la durée de vie d'utilisation maximale spécifiée du CIRCUIT EXTRACORPOREL.

* NOTE 1 Un flux sanguin inférieur à la valeur de consigne est considéré comme préjudiciable pour un traitement type. De ce fait, le but de l'essai est de déterminer l'erreur du flux sanguin négatif le plus élevé.

La conformité est vérifiée dans les conditions d'essai suivantes, pour les pompes péristaltiques types:

– *brancher un segment de pompe inutilisé à l'APPAREIL D'HEMODIALYSE selon les instructions d'utilisation et le faire fonctionner pendant au moins 30 min;*
– *faire circuler un liquide (par exemple, de l'eau) à la température de 37 °C dans le CIRCUIT EXTRACORPOREL;*
– *régler le flux sanguin de l'APPAREIL D'HEMODIALYSE à 400 ml/min ou (si cela n'est pas possible) au flux sanguin le plus élevé possible;*
– *régler la PRESSION ARTERIELLE avant la pompe à –200 mmHg;*
– *mesurer le flux sanguin.*

La valeur du flux sanguin mesuré doit se situer dans les tolérances spécifiées par le FABRICANT dans les instructions d'utilisation.

NOTE 2 La fatigue du segment de pompe peut réduire le flux sanguin.

NOTE 3 Le flux sanguin des pompes péristaltiques peut être affecté par les pressions d'entrée négatives.

201.4.3.103 Débit du LIQUIDE DE DIALYSE

Le débit du LIQUIDE DE DIALYSE de l'APPAREIL D'HEMODIALYSE doit être tel que spécifié par le FABRICANT.

NOTE Un débit du LIQUIDE DE DIALYSE inférieur à la valeur de consigne est considéré comme préjudiciable pour un traitement type.

La conformité est vérifiée dans les conditions d'essai suivantes:

– *régler l'APPAREIL D'HEMODIALYSE sur le mode HEMODIALYSE, comme spécifié par le FABRICANT;*
– *régler le débit du LIQUIDE DE DIALYSE de l'APPAREIL D'HEMODIALYSE à son maximum;*
– *mesurer le débit du LIQUIDE DE DIALYSE pendant 30 min;*
– *régler le débit du LIQUIDE DE DIALYSE de l'APPAREIL D'HEMODIALYSE à son minimum;*
– mesurer le débit du LIQUIDE DE DIALYSE pendant 30 min.

Les valeurs de débit du LIQUIDE DE DIALYSE doivent se situer dans les tolérances spécifiées par le FABRICANT dans les instructions d'utilisation.

201.4.3.104 EXTRACTION NETTE DE LIQUIDE

L'EXTRACTION NETTE DE LIQUIDE de l'APPAREIL D'HEMODIALYSE doit être telle que spécifiée par le FABRICANT.

La conformité est vérifiée dans les conditions d'essai suivantes.

Essai 1 pour la partie équilibrage de l'APPAREIL D'HEMODIALYSE uniquement:

– *régler l'APPAREIL D'HEMODIALYSE sur le mode HEMODIALYSE, le cas échéant, avec un DIALYSEUR conformément à la recommandation du FABRICANT.*
– *faire circuler un liquide (par exemple, de l'eau) dans le CIRCUIT EXTRACORPOREL;*
– *régler le débit du LIQUIDE DE DIALYSE au maximum, le cas échéant;*
– *régler la température du LIQUIDE DE DIALYSE à 37 °C, le cas échéant;*
– *régler le débit d'EXTRACTION NETTE DE LIQUIDE à 0 ml/h ou à la valeur réglable la plus faible;*

– *créer une pression sanguine de sortie du DIALYSEUR de 50 mmHg inférieure à la pression de service la plus élevée spécifiée par le FABRICANT;*

– *mesurer l'EXTRACTION NETTE DE LIQUIDE pendant un intervalle de temps approprié.*

Poursuivre avec l'essai 2:

– *régler le débit d'EXTRACTION NETTE DE LIQUIDE à la valeur maximale;*

– *mesurer l'EXTRACTION NETTE DE LIQUIDE pendant un intervalle de temps approprié.*

Poursuivre avec l'essai 3:

– *créer une pression sanguine de sortie du DIALYSEUR de 20 mmHg supérieure à la pression de service la plus faible spécifiée par le FABRICANT;*

– *mesurer l'EXTRACTION NETTE DE LIQUIDE pendant un intervalle de temps approprié.*

Les valeurs de l'EXTRACTION NETTE DE LIQUIDE doivent se situer dans les tolérances spécifiées par le FABRICANT dans les instructions d'utilisation.

201.4.3.105 Débit du LIQUIDE DE SUBSTITUTION

Uniquement pour les APPAREILS d'HEMOFILTRATION et d'HEMODIAFILTRATION

Le débit du LIQUIDE DE SUBSTITUTION de l'APPAREIL D'HEMODIALYSE doit être tel que spécifié par le FABRICANT.

NOTE Un débit du LIQUIDE DE SUBSTITUTION inférieur à la valeur de consigne est considéré comme préjudiciable pour un traitement type.

La conformité est vérifiée dans les conditions d'essai suivantes.

Essai 1 pour la partie équilibrage de l'APPAREIL D'HEMODIALYSE et du débit de LIQUIDE DE SUBSTITUTION thérapeutique approprié:

– *régler l'APPAREIL D'HEMODIALYSE sur le mode HDF ou HF avec un DIALYSEUR conformément à la recommandation du FABRICANT;*

– *faire circuler un liquide (par exemple, de l'eau) dans le* CIRCUIT EXTRACORPOREL*;*

– *régler le débit d'EXTRACTION NETTE DE LIQUIDE à 0 ml/h ou (si cela n'est pas possible) au minimum;*

– *régler le débit du LIQUIDE DE SUBSTITUTION au maximum;*

– *régler la température du LIQUIDE DE SUBSTITUTION à 37 °C, le cas échéant;*

– *mesurer le débit du LIQUIDE DE SUBSTITUTION et l'EXTRACTION NETTE DE LIQUIDE.*

Poursuivre avec l'essai 2:

– *régler le débit du LIQUIDE DE SUBSTITUTION au minimum;*

– *mesurer le débit du LIQUIDE DE SUBSTITUTION et l'EXTRACTION NETTE DE LIQUIDE.*

Les valeurs de débit du LIQUIDE DE SUBSTITUTION et de l'EXTRACTION NETTE DE LIQUIDE doivent se situer dans les tolérances spécifiées par le FABRICANT dans les instructions d'utilisation.

201.4.3.106 Temps de dialyse

La précision du temps de traitement de dialyse de l'APPAREIL D'HEMODIALYSE doit être telle que spécifiée par le FABRICANT.

La conformité est vérifiée par des essais fonctionnels appropriés relatifs à la définition du temps de traitement de dialyse spécifié par le FABRICANT.

201.4.3.107 * Composition du LIQUIDE DE DIALYSE

La méthode d'essai applicable à la précision de la composition du LIQUIDE DE DIALYSE doit être spécifiée par le FABRICANT et la conformité doit être vérifiée en conséquence.

201.4.3.108 Température du LIQUIDE DE DIALYSE

La température du LIQUIDE DE DIALYSE doit être telle que spécifiée par le FABRICANT.

NOTE Cet essai s'applique uniquement aux APPAREILS D'HEMODIALYSE comprenant un chauffage pour le LIQUIDE DE DIALYSE.

La conformité est vérifiée dans les conditions d'essai suivantes:

- *laisser l'APPAREIL D'HEMODIALYSE fonctionner jusqu'à ce qu'il atteigne des conditions environnementales thermiques stables comprises entre 20 °C et 25 °C.*
- *régler la température du LIQUIDE DE DIALYSE à 37 °C, le cas échéant;*
- *régler le débit du LIQUIDE DE DIALYSE au maximum;*
- *mesurer la température à l'entrée du DIALYSEUR;*
- *enregistrer la température pendant 30 min;*
- *régler le débit du LIQUIDE DE DIALYSE au minimum;*
- *mesurer la température à l'entrée du DIALYSEUR;*
- *enregistrer la température pendant 30 min.*

Les valeurs de température du LIQUIDE DE DIALYSE doivent se situer dans les tolérances spécifiées par le FABRICANT dans les instructions d'utilisation.

201.4.3.109 Température du LIQUIDE DE SUBSTITUTION

La température du LIQUIDE DE SUBSTITUTION de l'APPAREIL D'HEMODIALYSE doit être telle que spécifiée par le FABRICANT.

NOTE Cet essai s'applique uniquement aux APPAREILS D'HEMODIALYSE comprenant un chauffage pour le LIQUIDE DE SUBSTITUTION.

La conformité est vérifiée dans les conditions d'essai suivantes.

- *laisser l'APPAREIL D'HEMODIALYSE fonctionner jusqu'à ce qu'il atteigne des conditions thermiques stables dans l'environnement;*
- *la température ambiante est comprise entre 20 °C et 25 °C;*
- *régler la température du LIQUIDE DE SUBSTITUTION à 37 °C, le cas échéant;*
- *régler le débit du LIQUIDE DE SUBSTITUTION au maximum;*
- *mesurer la température du LIQUIDE DE SUBSTITUTION au point de raccordement de la ligne de LIQUIDE DE SUBSTITUTION à la ligne de sang;*
- *enregistrer la température pendant 30 min;*
- *régler le débit du LIQUIDE DE SUBSTITUTION au minimum;*
- *mesurer la température du LIQUIDE DE SUBSTITUTION au point de raccordement de la ligne de LIQUIDE DE SUBSTITUTION à la ligne de sang;*
- *enregistrer la température pendant 30 min.*

Les valeurs de température du LIQUIDE DE SUBSTITUTION doivent se situer dans les tolérances spécifiées par le FABRICANT dans les instructions d'utilisation.

201.4.7 CONDITION DE PREMIER DEFAUT pour APPAREILS EM

Addition:

Un exemple de CONDITION DE PREMIER DEFAUT est une défaillance d'un SYSTEME DE PROTECTION (voir 201.12.4.4.101, 201.12.4.4.102, 201.12.4.4.103, 201.12.4.4.104, 201.12.4.4.105);

NOTE 101 Si de l'air est présent en permanence dans le CIRCUIT EXTRACORPOREL lorsque l'APPAREIL D'HEMODIALYSE est utilisé comme spécifié par le FABRICANT, l'air n'est pas considéré comme une CONDITION DE PREMIER DEFAUT, mais comme une CONDITION NORMALE.

201.5 Exigences générales relatives aux essais des APPAREILS EM

L'Article 5 de la norme générale s'applique.

201.6 Classification des APPAREILS EM et des SYSTEMES EM

L'Article 6 de la norme générale s'applique.

201.7 Identification, marquage et documentation des APPAREILS EM

L'Article 7 de la norme générale s'applique, avec les exceptions suivantes:

201.7.4.3 Unités de mesure

Addition:

L'unité mmHg peut être utilisée pour le mesurage des pressions dans toute partie de L'APPAREIL D'HEMODIALYSE.

201.7.8.2 * Couleurs des organes de commande

Remplacement:

La couleur rouge peut être utilisée pour une commande de fonctionnement de la pompe à sang ou pour une commande interrompant une fonction en cas d'urgence.

201.7.9.2 Instructions d'utilisation

201.7.9.2.2 Avertissement et consignes de sécurité

Addition:

Les instructions d'utilisation doivent, de plus, inclure ce qui suit, le cas échéant:

– une déclaration d'avertissement attirant l'attention de l'OPERATEUR sur les précautions nécessaires à prendre pour éviter toute infection croisée entre les PATIENTS;

– une déclaration d'avertissement attirant l'attention de l'OPERATEUR sur la SITUATION DANGEREUSE associée à la connexion et à la déconnexion du PATIENT;

– une déclaration d'avertissement attirant l'attention de l'OPERATEUR sur les DANGERS, y compris les SITUATIONS DANGEREUSES éventuelles, résultant de raccordements incorrects du CIRCUIT EXTRACORPOREL;

– une déclaration d'avertissement sur les DANGERS liés à une erreur dans le choix du ou des CONCENTRES DE LIQUIDE DE DIALYSE;

– une description quantitative de l'écart possible de chaque composant du LIQUIDE DE DIALYSE en CONDITION DE PREMIER DEFAUT, en fonction des LIMITES D'ALARME du SYSTEME DE PROTECTION;

– * une déclaration d'avertissement sur les DANGERS et les causes sous-jacentes liés à un transport possible de substances indésirables du compartiment du LIQUIDE DE DIALYSE vers le compartiment du sang du DIALYSEUR;

– pour le SYSTEME DE PROTECTION employé conformément au 201.12.4.4.104 1 a):
  - une déclaration d'avertissement stipulant que ce SYSTEME DE PROTECTION ne réduit que partiellement le RISQUE et donnant une explication du RISQUE subsistant;
  - une description de la responsabilité de l'OPERATEUR concernant une réduction supplémentaire du RISQUE résiduel;

– une déclaration d'avertissement concernant l'action adaptée de l'OPERATEUR en cas de CONDITION D'ALARME et du ou des DANGERS associés, si la CONDITION D'ALARME est réinitialisée à plusieurs reprises sans avoir résolu le problème sous-jacent;

– * une déclaration d'avertissement spécifiant que tout passage étroit dans le CIRCUIT EXTRACORPOREL (comme des pliures dans la ligne de sang ou des canules trop minces) peut provoquer une hémolyse et que cette SITUATION DANGEREUSE peut ne pas être détectée par les SYSTEMES DE PROTECTION;

– si un SYSTEME DE PROTECTION, conformément à la Note 1 du 201.12.4.4.105, est appliqué: une déclaration d'avertissement indiquant qu'un fonctionnement incorrect d'un détecteur d'air à ultrasons peut être dû à un caillot ou à l'application d'un gel pour ultrasons;

– une déclaration d'avertissement indiquant que de l'air peut entrer dans le CIRCUIT EXTRACORPOREL en aval du détecteur d'air, par exemple en des points de raccordement serrés de manière insuffisante, si les pressions sont négatives; cela peut se produire dans le cas d'applications avec aiguille unique ou avec des cathéters veineux centraux;

– pour les HDF EN LIGNE et les HF EN LIGNE:
  - une déclaration d'avertissement indiquant que seules les PROCEDURES de désinfection définies et validées par le FABRICANT doivent être utilisées pour les HDF EN LIGNE et les HF EN LIGNE;
  - les informations sur la qualité exigée de l'EAU DE DIALYSE entrante et des CONCENTRES DE LIQUIDE DE DIALYSE utilisés;
  - la périodicité avec laquelle il convient de remplacer les pièces d'usure (par exemple, FILTRE DE RETENTION D'ENDOTOXINES OU ETRF (ENDOTOXIN-RETENTIVE FILTER));

– une déclaration d'avertissement indiquant que le flux sanguin, et par conséquent l'efficacité du traitement, peuvent être diminués, lorsque la PRESSION ARTERIELLE en amont de la pompe est extrêmement négative, et indiquant également la plage et la précision du flux sanguin de cette ou de ces pompes, ainsi que les plages de pressions d'entrée et de sortie pour lesquelles cette précision est maintenue;

– pour un APPAREIL D'HEMODIALYSE ayant des PARTIES APPLIQUEES autres que les PARTIES APPLIQUEES DE TYPE CF, une déclaration d'avertissement à l'adresse de l'OPERATEUR et de l'ORGANISME RESPONSABLE destinée à assurer qu'aucun appareil électrique (APPAREILS non-EM et APPAREILS EM) comportant des COURANTS DE CONTACT et des COURANTS DE FUITE PATIENT supérieurs aux limites définies pour les PARTIES APPLIQUEES de type CF n'est utilisé dans l'ENVIRONNEMENT DU PATIENT en conjonction avec un cathéter veineux central dont l'embout est placé dans l'oreillette droite;

  NOTE 101 Voir le 201.8.3 de l'Annexe AA pour de plus amples informations.

– le cas échéant, une déclaration d'avertissement indiquant que l'application de débits de transmission faibles de dispositifs anticoagulation intégrés (par exemple, emploi d'une solution anticoagulante non diluée) peut entraîner une transmission retardée et non continue due à la conformité des moyens de transmission ou à des variations de pression de sortie dans le CIRCUIT EXTRACORPOREL.

NOTE 102 Le terme «déclaration d'avertissement» est utilisé de manière générique. Par ailleurs, l'identification du mode de transmission à l'utilisateur des informations associées conformément au PROCESSUS de GESTION DES RISQUES du FABRICANT relève de la responsabilité de ce dernier.

La conformité est vérifiée par examen des instructions d'utilisation.

201.7.9.2.5 Description de l'APPAREIL EM

Addition:

Les instructions d'utilisation doivent, de plus, inclure ce qui suit, le cas échéant:

- une définition de la PRESSION TRANSMEMBRANIQUE si le FABRICANT en emploie une différente de celle indiquée en 201.3.217;
- une explication des marquages couleur sur les raccords de CONCENTRE DE LIQUIDE DE DIALYSE;
- des informations sur le flux sanguin effectivement délivré pour les traitements à aiguille unique;
- des informations sur la recirculation du sang dans le CIRCUIT EXTRACORPOREL pour les traitements à aiguille unique;
- le retard avec lequel un SIGNAL D'ALARME sonore est activé après une coupure de l'alimentation;
- pour les fonctions des REGULATEURS PHYSIOLOGIQUES EN BOUCLE FERMEE (voir également la norme collatérale IEC 60601-1-10):
  a) le principe de fonctionnement technique;
  b) les paramètres du PATIENT mesurés et les paramètres physiologiques contrôlés;
  c) les méthodes suivant lesquelles ces modes de REGULATEURS PHYSIOLOGIQUES EN BOUCLE FERMEE ont été évalués, y compris les effets bénéfiques et néfastes enregistrés pendant l'évaluation clinique;
- pour toute donnée affichée ou indiquée par l'APPAREIL D'HEMODIALYSE et qui peut être utilisée pour ajuster le traitement ou pour mesurer ou confirmer l'efficacité de celui-ci:
  a) une description du principe de fonctionnement technique;
  b) si le mesurage est indirect: des informations sur la précision et les facteurs éventuels pouvant l'influencer;
  c) * la méthode suivant laquelle le principe de fonctionnement technique a été évalué par rapport à des soins médicaux normaux;
- pour un APPAREIL D'HEMODIALYSE ayant des PARTIES APPLIQUEES autres que les PARTIES APPLIQUEES DE TYPE CF, des informations indiquant si cet APPAREIL D'HEMODIALYSE peut être utilisé conjointement avec un cathéter veineux central dont l'embout est placé dans l'oreillette droite. Si l'APPAREIL D'HEMODIALYSE ne convient pas à un cathéter veineux central dont l'embout est placé dans l'oreillette droite, les DANGERS associés doivent être énumérés.

La conformité est vérifiée par examen des instructions d'utilisation.

201.7.9.2.6 Installation

Addition:

Les instructions d'utilisation doivent, de plus, inclure ce qui suit, le cas échéant:

- des informations selon lesquelles il est essentiel d'installer et d'utiliser l'APPAREIL D'HEMODIALYSE conformément aux réglementations et recommandations en vigueur relatives à la qualité de L'EAU DE DIALYSE et des autres liquides concernés;
- pour les APPAREILS D'HEMODIALYSE de CLASSE I, des informations indiquant l'importance de la qualité de la terre de protection de l'installation électrique;
- des informations indiquant les applications pour lesquelles il convient d'utiliser un CONDUCTEUR D'EGALISATION DES POTENTIELS;
- les plages acceptables de température, de débit et de pression de l'EAU DE DIALYSE d'admission et tout SYSTEME DE TRANSMISSION CENTRALISE;
- une note mettant l'accent sur l'importance de la conformité à tous les règlements locaux concernant la séparation de l'APPAREIL D'HEMODIALYSE par rapport à l'approvisionnement en eau, sur l'importance de la prévention du flux de retour vers la source d'eau potable et

sur l'importance de la prévention de la contamination par le raccordement du drain de l'APPAREIL D'HEMODIALYSE à partir de tout raccordement à l'égout;

– si différents systèmes de codes couleur pour les SIGNAUX D'ALARME visuels peuvent être configurés, des informations selon lesquelles il convient que l'ORGANISME RESPONSABLE sélectionne le système de codes couleur, ce qui réduit le plus possible le RISQUE de mauvaise interprétation du SIGNAL D'ALARME dans leur environnement;
– si des réglages de paramètres de fonctionnement ou de SYSTEMES DE PROTECTION peuvent être configurés, des informations selon lesquelles il convient que l'ORGANISME RESPONSABLE sélectionne la ou les configurations ou confirme explicitement la configuration par défaut.

La conformité est vérifiée par examen des instructions d'utilisation.

201.7.9.2.12 Nettoyage, désinfection et stérilisation

Addition:

Les instructions d'utilisation doivent, de plus, inclure ce qui suit, le cas échéant:

– une description de la ou des méthodes par lesquelles la stérilisation ou la désinfection du trajet du liquide à l'intérieur de l'APPAREIL D'HEMODIALYSE et la désinfection de la surface de l'ENVELOPPE sont obtenues;
– * des informations indiquant que la PROCEDURE d'essai selon laquelle l'efficacité de la stérilisation ou de la désinfection du trajet du liquide à l'intérieur de l'APPAREIL D'HEMODIALYSE a été validée est disponible sur demande auprès du FABRICANT;
– une déclaration d'avertissement indiquant de suivre les instructions du FABRICANT pour désinfecter l'APPAREIL D'HEMODIALYSE; si d'autres PROCEDURES sont utilisées, l'ORGANISME RESPONSABLE est chargé de valider la PROCEDURE de désinfection pour plus d'efficacité et de sécurité; cet avertissement doit spécifiquement énumérer les DANGERS, y compris le mode de défaillance qui peut résulter d'autres PROCEDURES;
– une déclaration d'avertissement indiquant que l'ORGANISME RESPONSABLE est garant de la qualité sur le plan hygiénique du ou des systèmes de transmission éventuels, par exemple, le système central d'approvisionnement en EAU DE DIALYSE, les SYSTEMES DE TRANSMISSION CENTRALISES, les dispositifs de raccordement de l'APPAREIL D'HEMODIALYSE, y compris les lignes de liquides des points de raccordement à l'APPAREIL D'HEMODIALYSE.

La conformité est vérifiée par examen des instructions d'utilisation.

201.7.9.2.14 ACCESSOIRES, équipements supplémentaires, fournitures utilisées

Addition:

Les instructions d'utilisation doivent, de plus, inclure ce qui suit, le cas échéant:

– des informations sur les CONCENTRES DE LIQUIDE DE DIALYSE, les DIALYSEURS et les lignes de sang destinés à être utilisés conjointement avec l'APPAREIL D'HEMODIALYSE.

La conformité est vérifiée par examen des instructions d'utilisation.

201.7.9.3 Description technique

201.7.9.3.1 Généralités

Addition:

La description technique doit, de plus, comprendre ce qui suit, le cas échéant:

- installation:

- une description des mesures particulières ou des conditions à observer lors de l'installation, du démontage et du transport de l'APPAREIL D'HEMODIALYSE ou lors de sa mise en marche. Celles-ci doivent inclure des recommandations concernant le type et le nombre d'essais à effectuer;
- des informations sur la température maximale qui peut être observée au niveau du drain de l'APPAREIL D'HEMODIALYSE;
- * des informations sur la consommation d'énergie, sur la fourniture d'énergie à l'environnement et sur la fourniture d'énergie au drainage, dans les conditions de fonctionnement type et en fonction de la température de l'eau d'admission;
- * des informations sur la consommation d'eau et du ou des CONCENTRES DE LIQUIDE DE DIALYSE ou du LIQUIDE DE DIALYSE (pré-produit) dans les conditions de fonctionnement type;

• spécification des APPAREILS D'HEMODIALYSE:

- pour les APPAREILS D'HEMODIALYSE comprenant des dispositifs de transmission d'anticoagulant intégrés: le type de la ou des pompes, la plage et la précision du débit de cette ou de ces pompes et les pressions auxquelles cette précision est maintenue;
- les mesures supplémentaires éventuelles prévues par le FABRICANT en cas de coupure de l'alimentation;
- le type, l'exactitude de mesure et la ou les valeurs ou la ou les plages de la ou des LIMITES D'ALARME du SYSTEME DE PROTECTION exigés en 201.12.4.4.101 (composition du LIQUIDE DE DIALYSE);
- le type, l'exactitude de mesure et la ou les valeurs ou la ou les plages de la ou des LIMITES D'ALARME du SYSTEME DE PROTECTION exigés en 201.12.4.4.102 (températures du LIQUIDE DE DIALYSE et du LIQUIDE DE SUBSTITUTION);
- le type, l'exactitude de mesure et la ou les valeurs ou la ou les plages de la ou des LIMITES D'ALARME du SYSTEME DE PROTECTION exigés en 201.12.4.4.103 (EXTRACTION NETTE DE LIQUIDE);
- le type, l'exactitude de mesure et la ou les valeurs ou la ou les plages de la ou des LIMITES D'ALARME du SYSTEME DE PROTECTION exigés en 201.12.4.4.104.1 (perte de sang extracorporelle à l'extérieur);
- * le type et l'exactitude de mesure du SYSTEME DE PROTECTION exigés en 201.12.4.4.104.2 (FUITE DE SANG en direction du LIQUIDE DE DIALYSE), ainsi que la LIMITE D'ALARME du SYSTEME DE PROTECTION aux débits minimum et maximum dans le détecteur de FUITE DE SANG;
- le type et la ou les LIMITES D'ALARME du SYSTEME DE PROTECTION exigés en 201.12.4.4.104.3 (perte de sang extracorporel due à la coagulation);
- la méthode employée et la sensibilité dans les conditions d'essai spécifiées par le FABRICANT, pour le SYSTEME DE PROTECTION, exigées en 201.12.4.4.105 (infusion d'air);
- le ou les temps d'inhibition pour tout SYSTEME DE PROTECTION;
- la période de PAUSE DU SIGNAL d'alarme sonore;
- la plage des niveaux de pression acoustique de toute source de SIGNAL D'ALARME sonore réglable;
- l'indication de tous les matériaux destinés à entrer en contact avec l'EAU DE DIALYSE, le LIQUIDE DE DIALYSE et le CONCENTRE DE LIQUIDE DE DIALYSE;
- pour les HDF EN LIGNE et les HF EN LIGNE: la méthode de préparation du LIQUIDE DE SUBSTITUTION, le cas échéant, la méthode d'essai d'intégrité des filtres du LIQUIDE DE SUBSTITUTION (par exemple, FILTRE DE RETENTION D'ENDOTOXINE – ETRF) et la précision de ces essais.

La conformité est vérifiée par examen des documents d'accompagnement.

201.8 Protection contre les DANGERS d'origine électrique provenant des APPAREILS EM

L'Article 8 de la norme générale s'applique, avec les exceptions suivantes:

201.8.3 * Classification des PARTIES APPLIQUEES

Addition:

Les APPAREILS D'HEMODIALYSE avec des COURANTS DE FUITE satisfaisant aux exigences des PARTIES APPLIQUEES de TYPE CF sont considérés comme étant adaptés à une utilisation avec un cathéter veineux central dont l'embout est placé dans l'oreillette droite.

Si les APPAREILS D'HEMODIALYSE ayant une PARTIE APPLIQUEE autre qu'une PARTIE APPLIQUEE DE TYPE CF sont destinés à être utilisés pour le traitement de PATIENTS avec un cathéter veineux central dont l'embout est placé dans l'oreillette droite, ce qui suit doit s'appliquer:

aa) en CONDITION NORMALE, les COURANTS DE FUITE PATIENT et les COURANTS DE CONTACT doivent être dans les limites admissibles pour les PARTIES APPLIQUEES de TYPE CF;

bb) en CONDITION DE PREMIER DEFAUT, les COURANTS DE FUITE PATIENT, les COURANTS DE CONTACT et les COURANTS DE FUITE A LA TERRE doivent être dans les limites admissibles pour les PARTIES APPLIQUEES de TYPE CF.

La conformité est vérifiée par examen.

Si l'APPAREIL D'HEMODIALYSE ne satisfait pas à bb), des moyens externes doivent être fournis et justifiés par le PROCESSUS DE GESTION DES RISQUES établi par le FABRICANT afin de maintenir les COURANTS DE FUITE PATIENT dans les limites admissibles pour les PARTIES APPLIQUEES DE TYPE CF en CONDITION DE PREMIER DEFAUT.

La conformité est vérifiée par examen du DOSSIER DE GESTION DES RISQUES.

201.8.7.4.7 Mesure du COURANT DE FUITE PATIENT

Addition:

* *aa) Le dispositif de mesure doit être raccordé aux points auxquels les deux lignes de sang extracorporel sont raccordées au PATIENT. Pendant la durée de l'essai, une solution d'essai, avec la conductivité la plus élevée pouvant être choisie, référencée à une température de 25 °C, et avec la température du LIQUIDE DE DIALYSE la plus élevée pouvant être choisie dans l'application, doit être mise en circulation dans le circuit du LIQUIDE DE DIALYSE et dans le CIRCUIT EXTRACORPOREL. L'APPAREIL D'HEMODIALYSE doit être mis en fonctionnement dans un mode de traitement type, avec le flux sanguin le plus élevé possible et sans CONDITION D'ALARME activée. Pour des raisons pratiques, le dispositif de mesure peut être raccordé aux connecteurs du LIQUIDE DE DIALYSE.*

NOTE 101 La mesure des COURANTS DE FUITE PATIENT décrits ci-dessus ne comprend pas la mesure spécifiée au point b) du 8.7.4.7 (tension appliquée à la PARTIE APPLIQUEE) de la norme générale pour les APPAREILS D'HEMODIALYSE avec des PARTIES APPLIQUEES DE TYPE B.

NOTE 102 Le flux sanguin le plus élevé possible conduit à la résistance la plus faible de l'espace d'air dans la chambre compte-gouttes du circuit veineux.

201.8.11.2 *SOCLES DE PRISE DE COURANT MULTIPLE

Addition:

Si un SOCLE DE PRISE DE COURANT MULTIPLE est fourni et si un échange mutuel ou un échange avec d'autres SOCLES DE PRISE DE COURANT MULTIPLE de l'APPAREIL D'HEMODIALYSE peut créer une SITUATION DANGEREUSE, le SOCLE DE PRISE DE COURANT MULTIPLE doit être d'un type qui empêche un tel échange.

La conformité est vérifiée par examen et par des essais fonctionnels.

201.9 Protection contre les DANGERS MECANIQUES des APPAREILS EM et des SYSTEMES EM

L'Article 9 de la norme générale s'applique.

201.10 Protection contre les DANGERS dus aux rayonnements involontaires ou excessifs

L'Article 10 de la norme générale s'applique.

201.11 Protection contre les températures excessives et les autres DANGERS

L'Article 11 de la norme générale s'applique, avec les exceptions suivantes:

201.11.6.3 Renversement sur des APPAREILS EM et sur des SYSTEMES EM

Addition:

La conformité est vérifiée par un essai, conformément au code IPX1 de l'IEC 60529.

201.11.6.6 * Nettoyage et désinfection des APPAREILS EM et des SYSTEMES EM

Addition:

Pour les APPAREILS D'HEMODIALYSE utilisant des trajets de liquide qui ne peuvent être éliminés (par exemple, qui ne sont pas à usage unique) et des composants en contact avec un liquide lui-même en contact direct ou indirect avec le PATIENT, des moyens doivent être fournis pour leur désinfection.

Les conditions de fonctionnement et le PROCESSUS de contrôle microbien pour les APPAREILS D'HEMODIALYSE doivent être développés et validés par le FABRICANT pour les APPAREILS D'HEMODIALYSE qui utilisent une approche fondée sur le RISQUE qui prend en considération la durée de vie prévue, la mise au rebut, la filtration, le nettoyage/la désinfection, la maintenance des systèmes et/ou des normes de qualité correspondantes relatives au LIQUIDE DE DIALYSE.

La conformité est vérifiée par examen de la documentation de validation, du DOSSIER DE GESTION DES RISQUES, des DOCUMENTS D'ACCOMPAGNEMENT et de L'APPAREIL D'HEMODIALYSE.

Les procédures de désinfection ne doivent pas détériorer les composants internes, les surfaces externes ou les ACCESSOIRES externes (par exemple, FILTRE DE RETENTION D'ENDOTOXINES – ETRF) susceptibles d'entraîner une SITUATION DANGEREUSE.

La conformité est vérifiée par examen du DOSSIER DE GESTION DES RISQUES et par des essais fonctionnels des APPAREILS D'HEMODIALYSE.

201.11.8 *Coupure de l'alimentation / du RESEAU D'ALIMENTATION vers l'APPAREIL EM

Addition:

a) APPAREIL D'HEMODIALYSE sans SOURCE D'ENERGIE ELECTRIQUE INTERNE de secours, ou avec SOURCE D'ENERGIE ELECTRIQUE INTERNE de fonctionnement:

En cas de coupure de l'alimentation / du RESEAU D'ALIMENTATION vers l'APPAREIL D'HEMODIALYSE, les conditions de sécurité suivantes doivent être remplies:

– l'activation d'un SIGNAL D'ALARME sonore pendant au moins 1 min;
– des mesures supplémentaires peuvent être nécessaires, comme cela est déterminé par le PROCESSUS DE GESTION DES RISQUES du FABRICANT;
– L'APPAREIL D'HEMODIALYSE peut redémarrer automatiquement au rétablissement de l'alimentation, seulement si cela ne provoque aucune SITUATION DANGEREUSE pour le PATIENT comme déterminé par le PROCESSUS DE GESTION DES RISQUES du FABRICANT.

La conformité est vérifiée par examen du DOSSIER DE GESTION DES RISQUES et par des essais fonctionnels.

b) APPAREIL D'HEMODIALYSE avec SOURCE D'ENERGIE ELECTRIQUE INTERNE de secours:

En cas de coupure de l'alimentation / du RESEAU D'ALIMENTATION vers l'APPAREIL D'HEMODIALYSE, les conditions de sécurité suivantes doivent être remplies:

– activation d'un SIGNAL D'ALARME visuel;
– activation d'un SIGNAL D'ALARME sonore après un intervalle de temps spécifié par le FABRICANT;
– des mesures supplémentaires peuvent être nécessaires, comme cela est déterminé par le PROCESSUS DE GESTION DES RISQUES du FABRICANT;
– si des fonctions de l'APPAREIL D'HEMODIALYSE ont été arrêtées lors d'une coupure de l'alimentation, elles ne peuvent redémarrer automatiquement au rétablissement de l'alimentation que si cela ne provoque aucune SITUATION DANGEREUSE pour le PATIENT, comme déterminé par le PROCESSUS DE GESTION DES RISQUES DU FABRICANT;
– si la SOURCE D'ENERGIE ELECTRIQUE INTERNE est coupée ou déchargée, l'APPAREIL D'HEMODIALYSE doit satisfaire aux exigences décrites en 201.11.8 a).

La conformité est vérifiée par examen du DOSSIER DE GESTION DES RISQUES et par des essais fonctionnels.

201.12 * Précision des commandes, des instruments et protection contre les caractéristiques de sortie présentant des risques

L'Article 12 de la norme générale s'applique, avec les exceptions suivantes:

201.12.4.4 Sortie incorrecte

Addition:

Les PROCEDURES d'essai de 12.4.4.101 à 12.4.4.105 donnent une vue d'ensemble des exigences minimales relatives à la validation d'un APPAREIL D'HEMODIALYSE. Toutes les informations détaillées ne sont pas incluses pour chaque PROCEDURE d'essai, et il incombe au laboratoire d'essai d'introduire ces informations détaillées sur la base de l'APPAREIL D'HEMODIALYSE particulier et sur le PROCESSUS DE GESTION DES RISQUES du FABRICANT.

Paragraphes complémentaires:

201.12.4.4.101 * Composition du LIQUIDE DE DIALYSE

a) L'APPAREIL D'HEMODIALYSE doit comporter un SYSTEME DE PROTECTION, indépendant de tout système de contrôle de préparation de liquide, empêchant le LIQUIDE DE DIALYSE d'atteindre le DIALYSEUR ce qui, compte tenu de sa composition, peut provoquer une SITUATION DANGEREUSE.

NOTE Un SYSTEME DE PROTECTION n'est pas nécessaire pour les APPAREILS D'HEMODIALYSE qui utilisent uniquement un LIQUIDE DE DIALYSE pré-produit, dont la composition fait l'objet d'un contrôle qualité. Cette composition n'est par ailleurs pas modifiée par les APPAREILS D'HEMODIALYSE, qui utilisent, par exemple, des sacs pour LIQUIDE DE DIALYSE pré-produit.

La conception du SYSTEME DE PROTECTION destinée à prévenir une composition dangereuse du LIQUIDE DE DIALYSE doit prendre en considération l'éventualité d'une défaillance à toute phase de préparation ou de régénération du LIQUIDE.

L'activation du SYSTEME DE PROTECTION doit remplir les conditions de sécurité suivantes:

– activation de SIGNAUX D'ALARME sonores et visuels (voir 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101). Le SIGNAL D'ALARME sonore peut être retardé comme cela est spécifié au 208.6.3.3.101 b);
– arrêt de l'écoulement du LIQUIDE DE DIALYSE vers le DIALYSEUR;
– dans le mode HDF EN LIGNE ou HF EN LIGNE, l'arrêt de l'écoulement du LIQUIDE DE SUBSTITUTION vers le CIRCUIT EXTRACORPOREL.

b) Profils de conductivité et REGULATEURS PHYSIOLOGIQUES EN BOUCLE FERMEE:

En cas de variation préprogrammée en fonction du temps de la composition du LIQUIDE DE DIALYSE ou dans le cas d'un asservissement de la composition du LIQUIDE DE DIALYSE sur la base de la mesure d'un paramètre physiologique pertinent du PATIENT, l'APPAREIL D'HEMODIALYSE doit inclure un SYSTEME DE PROTECTION, indépendant du système de contrôle, qui prévient les modifications involontaires éventuelles dans le système de contrôle susceptibles de provoquer une SITUATION DANGEREUSE.

L'activation du SYSTEME DE PROTECTION doit remplir les conditions de sécurité suivantes:

– activation de SIGNAUX D'ALARME sonores et visuels (voir 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);
– autres mesures, si elles sont définies par le PROCESSUS DE GESTION DES RISQUES DU FABRICANT.

c) Si L'APPAREIL D'HEMODIALYSE est équipé d'un dispositif d'administration du bolus en vue d'une modification provisoire de la composition du LIQUIDE DE DIALYSE, l'APPAREIL D'HEMODIALYSE doit inclure un SYSTEME DE PROTECTION, indépendant du système de contrôle, qui empêche la fonction d'administration du bolus d'entraîner une SITUATION DANGEREUSE pour le PATIENT.

L'activation du SYSTEME DE PROTECTION doit remplir les conditions de sécurité suivantes:

– activation de SIGNAUX D'ALARME sonores et visuels (voir 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);
– interruption d'administration du bolus de composition du LIQUIDE DE DIALYSE.

La conformité est vérifiée par des essais fonctionnels et par les essais suivants:

- *Essai 1 pour la détermination de l'activation des SIGNAUX D'ALARME*
  – *Régler l'unité en essai aux compositions de LIQUIDE DE DIALYSE respectivement la plus basse et la plus haute, sans déclenchement d'un SIGNAL D'ALARME.*
  – *Modifier lentement la composition du LIQUIDE DE DIALYSE jusqu'à ce que le SYSTEME DE PROTECTION active un SIGNAL D'ALARME.*
  – *Prélever des échantillons à l'entrée du DIALYSEUR en CONDITION NORMALE et immédiatement après détection de la CONDITION D'ALARME.*
  – *Déterminer et évaluer (par exemple, par photométrie de flamme), la composition du LIQUIDE DE DIALYSE des échantillons prélevés en CONDITION NORMALE et après détection de la CONDITION D'ALARME.*
- *Essai 2 pour une réponse à une alarme effectuée à temps*
  – *Régler l'unité en essai avec l'écoulement du LIQUIDE DE DIALYSE à son plus haut débit possible.*
  – *Simuler l'interruption complète de chacune des alimentations de CONCENTRE DE LIQUIDE DE DIALYSE, une par une (pour des exemples, voir l'Annexe AA 201.15.4.1.101).*
  – *Prélever des échantillons à l'entrée du DIALYSEUR en CONDITION NORMALE et immédiatement après détection de la CONDITION D'ALARME.*

- *Déterminer et évaluer (par exemple, par photométrie de flamme), la composition du LIQUIDE DE DIALYSE des échantillons prélevés en CONDITION NORMALE et après détection de la CONDITION D'ALARME.*

- *Essai 3 pour un mauvais usage prévisible*
  - *Échanger les CONCENTRES de LIQUIDE DE DIALYSE, si possible.*
  - *Déterminer l'activation de la CONDITION D'ALARME.*
  - *Prélever des échantillons à l'entrée du DIALYSEUR en CONDITION NORMALE et immédiatement après détection de la CONDITION D'ALARME.*
  - *Déterminer et évaluer (par exemple, par photométrie de flamme), la composition du LIQUIDE DE DIALYSE des échantillons prélevés en CONDITION NORMALE et après détection de la CONDITION D'ALARME.*

201.12.4.4.102 * Température du LIQUIDE DE DIALYSE et du LIQUIDE DE SUBSTITUTION

a) Il ne doit pas être possible de régler la température du LIQUIDE DE DIALYSE et des LIQUIDES DE SUBSTITUTION en dehors d'une plage comprise entre 33 °C et 42 °C sauf justification par le PROCESSUS DE GESTION DES RISQUES du FABRICANT.

b) L'APPAREIL D'HEMODIALYSE doit comporter un SYSTEME DE PROTECTION, indépendant de tout système de contrôle de température, empêchant le LIQUIDE DE DIALYSE d'atteindre le DIALYSEUR et le LIQUIDE DE SUBSTITUTION d'atteindre le CIRCUIT EXTRACORPOREL à une température inférieure à 33 °C ou supérieure à 42 °C, mesurée à la sortie du LIQUIDE DE DIALYSE et/ou à la sortie du LIQUIDE DE SUBSTITUTION de l'APPAREIL D'HEMODIALYSE.

c) Les températures inférieures à 33 °C et jusqu'à 46 °C sont acceptables pendant une courte période, mais leurs durées et leurs valeurs doivent être justifiées dans le PROCESSUS DE GESTION DES RISQUES DU FABRICANT.

d) L'activation du SYSTEME DE PROTECTION doit remplir les conditions de sécurité suivantes:
   - activation de SIGNAUX D'ALARME sonores et visuels (voir 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101). Le SIGNAL D'ALARME sonore peut être retardé comme cela est spécifié au 208.6.3.3.101 b);
   - arrêt de l'écoulement du LIQUIDE DE DIALYSE en direction du DIALYSEUR et/ou du LIQUIDE DE SUBSTITUTION en direction du CIRCUIT EXTRACORPOREL.

La conformité est vérifiée par des essais fonctionnels et par les essais suivants.

- *Essai 1 pour le LIQUIDE DE DIALYSE*
  - *Régler l'unité en essai avec l'écoulement du LIQUIDE DE DIALYSE à son plus haut débit, si ce réglage est possible.*
  - *Régler la température du LIQUIDE DE DIALYSE au maximum/minimum.*
  - *Attendre que les températures à l'entrée du DIALYSEUR soient stables.*
  - *Augmenter/diminuer lentement la température du LIQUIDE DE DIALYSE jusqu'à ce que le SYSTEME DE PROTECTION active un SIGNAL D'ALARME.*
  - *Mesurer la température de manière continue à l'entrée du DIALYSEUR et déterminer la valeur maximale/minimale.*

- *Essai 2 pour le LIQUIDE DE SUBSTITUTION*
  - *Régler l'unité en essai avec l'écoulement du LIQUIDE DE SUBSTITUTION à son plus haut débit, si ce réglage est possible.*
  - *Régler la température du LIQUIDE DE DIALYSE / LIQUIDE DE SUBSTITUTION au maximum/minimum.*
  - *Attendre que la température à l'entrée du CIRCUIT EXTRACORPOREL soit stable.*
  - *Augmenter/diminuer lentement la température du LIQUIDE DE DIALYSE / LIQUIDE DE SUBSTITUTION jusqu'à ce que le SYSTEME DE PROTECTION active un SIGNAL D'ALARME.*
  - *Mesurer la température du LIQUIDE DE SUBSTITUTION de manière continue à l'entrée du CIRCUIT EXTRACORPOREL et déterminer la valeur maximale / minimale.*

201.12.4.4.103 * EXTRACTION NETTE DE LIQUIDE

a) L'APPAREIL D'HEMODIALYSE doit comporter un SYSTEME DE PROTECTION, indépendant de tout système de contrôle de l'ULTRAFILTRATION, empêchant un écart de l'EXTRACTION NETTE DE LIQUIDE de l'APPAREIL D'HEMODIALYSE par rapport à la valeur de consigne des paramètres de contrôle, qui peuvent être à l'origine d'une SITUATION DANGEREUSE.

Dans le cas de la HDF et de la HF, l'APPAREIL D'HEMODIALYSE doit comporter un SYSTEME DE PROTECTION, indépendant de tout système de contrôle du LIQUIDE DE SUBSTITUTION, empêchant toute erreur d'administration du LIQUIDE DE SUBSTITUTION qui peut être à l'origine d'une SITUATION DANGEREUSE.

L'activation du SYSTEME DE PROTECTION doit remplir les conditions de sécurité suivantes:

– activation de SIGNAUX D'ALARME sonores et visuels (voir 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);

– prévention de la prolongation d'une erreur d'équilibrage des liquides dangereux.

b) Profils d'ULTRAFILTRATION et REGULATEURS PHYSIOLOGIQUES EN BOUCLE FERMEE:

En cas de variation préprogrammée en fonction du temps de l'ULTRAFILTRATION ou dans le cas d'un asservissement de l'ULTRAFILTRATION sur la base d'un moniteur mesurant un paramètre physiologique pertinent du PATIENT, l'APPAREIL D'HEMODIALYSE doit inclure un SYSTEME DE PROTECTION, indépendant du système de contrôle, qui prévient les modifications involontaires éventuelles dans le système de contrôle susceptibles de provoquer une SITUATION DANGEREUSE.

L'activation du SYSTEME DE PROTECTION doit remplir les conditions de sécurité suivantes:

– activation de SIGNAUX D'ALARME sonores et visuels (voir 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);

– autres mesures, si elles sont définies par le PROCESSUS DE GESTION DES RISQUES DU FABRICANT.

c) Si l'APPAREIL D'HEMODIALYSE est équipé d'un dispositif d'administration de liquide en bolus, l'APPAREIL D'HEMODIALYSE doit inclure un SYSTEME DE PROTECTION, indépendant du système de contrôle, qui empêche la fonction d'administration de liquide en bolus de provoquer une SITUATION DANGEREUSE pour le PATIENT.

L'activation du SYSTEME DE PROTECTION doit remplir les conditions de sécurité suivantes:

– activation de SIGNAUX D'ALARME sonores et visuels (voir 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);

– interruption de l'administration de liquide en bolus.

La conformité est vérifiée par des essais fonctionnels et des simulations de défaillance, incluant les essais suivants:

- *Essais pour mesurer les écarts du débit d'EXTRACTION NETTE DE LIQUIDE*
  – *Régler l'unité en essai avec l'écoulement du LIQUIDE DE DIALYSE à son plus haut débit.*
  – *Régler l'écoulement du LIQUIDE DE SUBSTITUTION à son plus haut débit, si cela est possible.*
  – *Régler la température du LIQUIDE DE DIALYSE à 37 °C, le cas échéant.*
  – *Régler l'ULTRAFILTRATION à ses plus hauts et plus faibles débits (un par un).*
  – *Simuler une erreur avec un écart négatif et positif dans chacun des composants de contrôle de l'extraction de liquide (un par un) qui influencent le débit d'EXTRACTION NETTE DE LIQUIDE jusqu'à ce que le SYSTEME DE PROTECTION active un SIGNAL D'ALARME.*
  – *Déterminer la différence entre le volume cible réglé et l'EXTRACTION NETTE DE LIQUIDE mesurée à l'activation du SIGNAL D'ALARME.*

201.12.4.4.104 Perte de sang extracorporelle

201.12.4.4.104.1 Perte de sang extracorporelle à l'extérieur

* a) L'APPAREIL D'HEMODIALYSE doit comporter un SYSTEME DE PROTECTION protégeant le PATIENT contre une perte de sang extracorporelle à l'extérieur, qui peut provoquer une SITUATION DANGEREUSE.

NOTE 1 Au moment de la rédaction du présent document, aucun système qui pouvait être totalement fiable pour détecter une perte de sang à l'extérieur n'avait été développé.

Si un SYSTEME DE PROTECTION utilise la mesure de la PRESSION VEINEUSE, il convient que l'OPERATEUR dispose au moins d'un moyen de réglage manuel de la LIMITE D'ALARME inférieure à une valeur aussi proche que possible de la valeur de mesure actuelle. Le mode de traitement à aiguille unique nécessite des mesures supplémentaires ou d'autres mesures.

b) L'APPAREIL D'HEMODIALYSE doit comporter un SYSTEME DE PROTECTION protégeant le PATIENT contre une perte de sang extracorporelle à l'extérieur provoquée par une rupture ou une séparation dans le CIRCUIT EXTRACORPOREL, à la suite d'une pression excessive, à moins qu'une conception à sécurité intrinsèque ne permette de l'éviter.

NOTE 2 Ceci n'est pas lié à la séparation de la CONNEXION PATIENT ou de l'aiguille d'entrée, mais à la pression potentielle qui peut être générée par la pompe susceptible de provoquer une rupture de la tubulure ou une séparation d'un raccord dans le CIRCUIT EXTRACORPOREL.

* c) L'activation du SYSTEME DE PROTECTION doit remplir les conditions de sécurité suivantes:

– activation de SIGNAUX D'ALARME sonores et visuels (voir 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);

– arrêt de l'écoulement du sang à l'extérieur causé par l'APPAREIL D'HEMODIALYSE, même en CONDITION DE PREMIER DEFAUT;

– dans le cas de l'HEMOFILTRATION ou de l'HEMODIAFILTRATION, arrêt de l'écoulement du LIQUIDE DE SUBSTITUTION.

La conformité est vérifiée par des essais fonctionnels et par l'essai suivant.

- *Essai pour les SYSTEMES DE PROTECTION utilisant la mesure de la PRESSION VEINEUSE*
  - *Régler l'unité en essai avec un flux sanguin moyen.*
  - *Régler la PRESSION VEINEUSE à une valeur moyenne.*
  - *Diminuer la PRESSION VEINEUSE jusqu'à l'activation d'un* SIGNAL D'ALARME.
  - *Déterminer la différence de la PRESSION VEINEUSE mesurée par rapport à la limite définie lors de l'activation du SIGNAL D'ALARME.*

201.12.4.4.104.2 * FUITE DE SANG en direction du LIQUIDE DE DIALYSE

a) L'APPAREIL D'HEMODIALYSE doit comporter un SYSTEME DE PROTECTION protégeant le PATIENT contre une FUITE DE SANG, qui peut provoquer une SITUATION DANGEREUSE.

b) L'activation du SYSTEME DE PROTECTION doit remplir les conditions de sécurité suivantes:

– activation de SIGNAUX D'ALARME sonores et visuels (voir 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);

– prévention de perte de sang supplémentaire vers le LIQUIDE DE DIALYSE.

La conformité est vérifiée par des essais fonctionnels et par l'essai suivant.

- *Essai pour la détermination des LIMITES D'ALARME:*
  - *Régler le débit maximum à travers le détecteur de FUITE DE SANG (débit de LIQUIDE DE DIALYSE le plus élevé, débit d'ULTRAFILTRATION le plus élevé, et également, le cas échéant, le débit du LIQUIDE DE SUBSTITUTION le plus élevé.*
  - *Ajouter du sang bovin, humain ou porcin (hématocrite Hct 32 %) au LIQUIDE DE DIALYSE de sorte que le flux à travers le détecteur de FUITE DE SANG dépasse la LIMITE D'ALARME de FUITE DE SANG, telle que spécifiée par le* FABRICANT.

201.12.4.4.104.3 * Perte de sang extracorporelle due à la coagulation

a) L'APPAREIL D'HEMODIALYSE doit comporter un SYSTEME DE PROTECTION protégeant le PATIENT contre une perte de sang due à une coagulation consécutive à l'interruption du flux sanguin qui peut provoquer une SITUATION DANGEREUSE.

NOTE Une méthode acceptable de mise en conformité avec cette exigence est, par exemple, un SYSTEME DE PROTECTION intervenant pendant une période plus longue en cas d'arrêt volontaire ou intempestif de la ou des pompes à sang.

b) L'entrée en action du SYSTEME DE PROTECTION doit activer un SIGNAL D'ALARME sonore et visuel (voir 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101).

c) Les autres effets qui peuvent entraîner une perte de sang due à la coagulation, par exemple l'arrêt ou le non-démarrage d'un dispositif de transmission d'anticoagulant éventuel, ou un débit de LIQUIDE DE SUBSTITUTION excessif dans le cas de HDF ou de HF avec post-dilution, doivent être traités dans le PROCESSUS DE GESTION DES RISQUES DU FABRICANT.

La conformité est vérifiée par des essais fonctionnels et une simulation de défaillance.

201.12.4.4.105 * Infusion d'air

a) L'APPAREIL D'HEMODIALYSE doit comporter un SYSTEME DE PROTECTION protégeant le PATIENT contre une infusion d'air, en CONDITION NORMALE et en CONDITION DE PREMIER DEFAUT, qui peut provoquer une SITUATION DANGEREUSE.

NOTE 1 Une méthode acceptable de mise en conformité avec cette exigence est, par exemple, un SYSTEME DE PROTECTION utilisant un détecteur d'air (par exemple, ultrasonique) capable de détecter de l'air non dissous.

b) L'activation du SYSTEME DE PROTECTION doit remplir les conditions de sécurité suivantes:

   – activation de SIGNAUX D'ALARME sonores et visuels (voir 208.6.3.1, 208.6.3.3.2, 208.6.3.3.101);

   – prévention d'infusion d'air supplémentaire par les lignes de sang artérielles et veineuses, même en CONDITION DE PREMIER DEFAUT.

NOTE 2 La prévention d'infusion d'air supplémentaire peut habituellement être réalisée en arrêtant la pompe à sang et en clampant la ligne de sang veineuse.

La conformité est vérifiée par des essais fonctionnels en tenant compte des principes d'essai décrit ci-dessous.

NOTE 3 Les chiffres donnés dans les essais sont des exemples. Le FABRICANT doit définir les valeurs à l'aide de son PROCESSUS DE GESTION DES RISQUES.

NOTE 4 En principe, il existe deux méthodes de surveillance de l'infusion d'air:

a) au niveau d'un piège à air (par exemple, à la chambre compte-gouttes du circuit veineux) dans lequel des forces de poussée agissent sur les bulles d'air de telle sorte que celles-ci sont empêchées de sortir du piège à air avec un niveau de réglage correct; la méthode de surveillance de bulles d'air utilisée ici est la méthode pour surveiller le niveau;

b) directement au niveau de la ligne de sang (les bulles d'air se diffusent dans le liquide en circulation), dans laquelle le volume d'air peut être déterminé par la vitesse d'écoulement.

Deux PROCEDURES d'essai différentes existent, indépendantes des méthodes de surveillance de l'air décrites en Note 4.

- *Infusion d'air continue:*

   – *Installer l'appareil d'hémodialyse avec un DIALYSEUR capillaire standard (par exemple, de surface comprise entre 1 m^2 et 1,5 m^2), le CIRCUIT EXTRACORPOREL recommandé et des canules (par exemple, de taille 16).*

   – *Clamper ou fermer les lignes du LIQUIDE DE DIALYSE après amorçage.*

   NOTE 5 Ceci est une condition de cas le plus défavorable. Si un LIQUIDE DE DIALYSE dégazé est en circulation, le gaz est extrait par le DIALYSEUR.

– *Faire fonctionner le CIRCUIT EXTRACORPOREL avec du sang hépariné avec un Hct défini (par exemple, compris entre 0,25 et 0,35, sang humain, sang bovin, sang porcin) ou avec un liquide d'essai approprié.*

NOTE 6 Un liquide d'essai approprié a une viscosité de 3,5 mPa·s à 37 °C et contient un surfactant entraînant la spallation des bulles de gaz.

– *Positionner un récipient de stockage du liquide d'essai à un niveau de, par exemple, 100 cm (±20 cm) du sol.*

– *Positionner un récipient de collecte du liquide d'essai à un niveau de, par exemple, 100 cm (±20 cm) du sol ou faire recirculer le liquide dans le récipient de stockage.*

– Placer verticalement un tube d'essai, de diamètre de, par exemple, 8 mm et d'une longueur de, par exemple, 2,0 m, à la suite d'un second tube de plus petit diamètre (par exemple de 4,3 mm et d'une longueur de 20 cm), directement au niveau du raccord veineux du PATIENT, dans le trajet veineux entre le raccord PATIENT et le récipient de collecte (voir, à titre d'exemple, le montage donné en Figure 201.101). *Deux tubes d'essai ou plus disposés en parallèle peuvent être utilisés pour une surveillance continue de l'air infusé avant que la CONDITION D'ALARME se produise.*

– *Insérer une canule (par exemple, de taille 22) dans la tubulure de sang artériel, dans la section à pressions négatives, près du raccordement à la canule artérielle (retrait de sang) et la raccorder à une pompe capable de contrôler l'injection d'air dans des conditions de pression négative.*

NOTE 7 Une méthode possible est l'utilisation d'une petite pompe péristaltique réversible. Cette pompe est initialement amorcée avec le liquide d'essai, en la faisant fonctionner en mode inverse pour éviter une injection d'air incontrôlée, lorsque la pompe est démarrée. Un clapet antiretour entre l'aiguille et la pompe peut être utilisé.

– *Régler la vitesse de la pompe à sang avec une pression négative définie avant la pompe (par exemple, entre –200 mmHg et –250 mmHg).*

– *Injecter l'air à des débits augmentant lentement, spécifiés par le FABRICANT, jusqu'à ce qu'une CONDITION D'ALARME du détecteur d'air se produise. Cette opération empêche toute infusion supplémentaire dangereuse de l'air.*

NOTE 8 La justification de cet essai est fondée sur l'hypothèse selon laquelle, avec la ligne du LIQUIDE DE DIALYSE fermée, l'air ne peut pas s'échapper du CIRCUIT EXTRACORPOREL et est finalement pompé vers le récipient collecteur de liquide au même débit qu'il y est injecté.

– Clamper le tube d'essai selon la Figure 201.101 aux deux extrémités, immédiatement après le SIGNAL D'ALARME du détecteur d'air.

– *Mesurer le volume d'air qui se développe au niveau du sommet vertical du tube d'essai de petit diamètre après une durée de 15 min lorsque les bulles d'air combinées forment un volume d'air plein.* La répétabilité des résultats de mesure peut être améliorée par l'égalisation de la pression piégée dans l'atmosphère de la partie liquide du tube de mesure par l'ouverture d'une pince à clamper pour égalisation de la pression avant de mesurer les volumes.

– Calculer le débit d'air en fonction du flux sanguin, le volume du tube d'essai et le volume d'air mesuré. *Le mesurage direct du flux sanguin dans la ligne de sang veineuse est recommandé.* Le débit d'air calculé doit être inférieur à la limite de débit d'infusion d'air continu identifiée par la GESTION DES RISQUES.

a) *Si l'APPAREIL D'HEMODIALYSE permet au DIALYSEUR de fonctionner avec un flux sanguin remontant à travers CELUI-CI et, en variante, avec un flux sanguin descendant dans le DIALYSEUR, des essais distincts doivent être effectués dans les deux directions du flux.*

b) *Si l'ANALYSE DE RISQUE révèle des voies d'injection d'air en aval de la pompe à sang conduisant à une infusion d'air continue qui peut provoquer une SITUATION DANGEREUSE par exemple, par une pompe d'ajustage du niveau), l'essai doit être répété en pompant l'air en ce point, au débit spécifié, dans le CIRCUIT EXTRACORPOREL.*

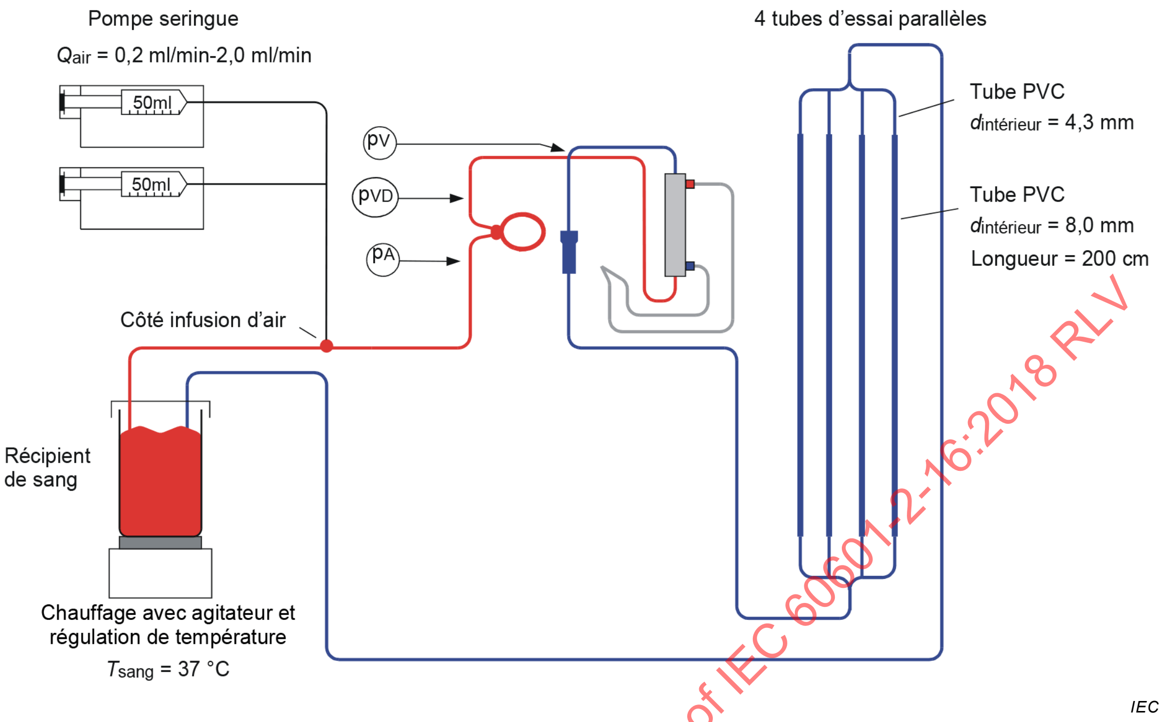

Figure 201.101 – Montage d'essai pour l'infusion d'air continue avec des exemples de dimensions

- *Infusion d'air par bolus:*
  - *Installer L'APPAREIL D'HEMODIALYSE avec un DIALYSEUR capillaire standard (par exemple, de surface comprise entre 1 m² et 1,5 m²), le CIRCUIT EXTRACORPOREL recommandé et des canules (par exemple, de taille 16).*
  - *Clamper ou fermer les lignes du LIQUIDE DE DIALYSE après amorçage.*

  NOTE 9 Ceci est une condition de cas le plus défavorable. Si un LIQUIDE DE DIALYSE dégazé est en circulation, le gaz est extrait par le DIALYSEUR.

  - *Faire fonctionner le CIRCUIT EXTRACORPOREL avec du sang hépariné avec un Hct défini (par exemple, compris entre 0,25 et 0,35, sang humain, sang bovin, sang porcin) ou avec un liquide d'essai approprié.*

  NOTE 10 Un liquide d'essai approprié a une viscosité de 3,5 mPa·s à 37 °C et contient un surfactant entraînant la spallation des bulles de gaz.

  - *Positionner un récipient de stockage du liquide d'essai à un niveau de, par exemple, 100 cm (±20 cm) du sol.*
  - *Positionner un récipient de collecte du liquide d'essai à un niveau de, par exemple, 100 cm (±20 cm) du sol ou faire recirculer le liquide dans le récipient de stockage.*
  - *Placer un cylindre de mesure gradué, ou les mêmes tubes d'essai que ceux utilisés dans l'essai précédent, de telle façon que tout l'air qui peut être pompé par la canule de retour (veineux) soit collecté.*
  - *Insérer une pièce en T avec des raccords Luer entre la tubulure de sang et la canule artérielle (retrait de sang).*
  - *Raccorder à la pièce en T une section de tube (par exemple de 5 cm de longueur) avec un raccord Luer.*
  - *Amorcer le CIRCUIT EXTRACORPOREL et ladite section de tube. Clamper la section de tube.*
  - *Régler la vitesse de la pompe à sang avec une pression négative définie avant la pompe (par exemple, entre 0 mmHg et –250 mmHg) de sorte qu'aucune CONDITION*

D'ALARME de pression n'apparaisse dans le CIRCUIT EXTRACORPOREL à l'ouverture de la pince à clamper.

– *Ouvrir la pince à clamper sur la section de tube et attendre l'activation d'un SIGNAL D'ALARME.*

– *Vérifier la quantité d'air collectée dans le cylindre de mesure gradué ou dans le tube d'essai. Le volume d'air collecté doit être inférieur à la limite de débit d'infusion d'air de bolus identifiée par la GESTION DES RISQUES.*

  a) *Si l'APPAREIL D'HEMODIALYSE permet au DIALYSEUR de fonctionner avec un flux sanguin remontant à travers CELUI-CI et, en variante, avec un flux sanguin descendant dans le DIALYSEUR, des essais distincts doivent être effectués dans les deux directions du flux.*

  b) *Si l'ANALYSE DE RISQUE révèle des voies d'injection d'air en aval de la pompe à sang et conduisant à une infusion d'air de bolus qui peut provoquer une SITUATION DANGEREUSE (par exemple, par une pompe d'ajustage du niveau), l'essai doit être répété en pompant l'air en ce point, au débit maximum, dans le CIRCUIT EXTRACORPOREL.*

201.12.4.4.106 * Modes d'inhibition de CONDITION D'ALARME

Au sens de 201.12.4.4.106, l'inhibition est la possibilité de laisser l'APPAREIL D'HEMODIALYSE fonctionner en CONDITION D'ALARME, si l'OPERATEUR choisit en connaissance de cause de désactiver temporairement le SYSTEME DE PROTECTION.

a) Tous les SYSTEMES DE PROTECTION doivent être actifs pendant toute la durée du traitement. Une activation retardée des SYSTEMES DE PROTECTION après le début ou à un nouveau lancement du traitement n'est pas considérée comme un mode d'inhibition de l'APPAREIL D'HEMODIALYSE si elle ne provoque pas une SITUATION DANGEREUSE.

   NOTE 1 Pour les exceptions, voir le point b) ci-après.

   NOTE 2 Au sens de 201.12.4.4.106, le traitement est considéré comme ayant débuté lorsque le sang du PATIENT lui est renvoyé par le CIRCUIT EXTRACORPOREL. Le traitement est considéré comme étant terminé lorsque l'aiguille de veine est retirée.

b) Les SYSTEMES DE PROTECTION relatifs à la composition et à la température du LIQUIDE DE DIALYSE doivent être activés avant le premier contact du LIQUIDE DE DIALYSE avec le sang dans le DIALYSEUR.

c) Pendant une CONDITION D'ALARME de tout SYSTEME DE PROTECTION définie en 201.12.4.4, un mode d'inhibition temporaire peut s'appliquer uniquement au SYSTEME DE PROTECTION suivant:

   – au moyen de la surveillance de toute FUITE DE SANG (voir 201.12.4.4.104.2), le temps d'inhibition ne doit pas dépasser 3 min. Toutefois, dans certaines conditions cliniques, il peut être nécessaire d'inhiber complètement ou partiellement le détecteur de FUITE DE SANG pendant la durée maximale d'un traitement unique.

d) L'activation d'un mode d'inhibition doit maintenir une indication visuelle signalant l'inhibition d'un SYSTEME DE PROTECTION associé.

e) L'inhibition d'un SYSTEME DE PROTECTION particulier (voir le point c) ne doit avoir aucun effet sur les autres CONDITIONS D'ALARME qui s'ensuivent. Les CONDITIONS D'ALARME qui s'ensuivent doivent remplir les conditions de sécurité spécifiées. Une CONDITION D'ALARME subsistante doit, après écoulement de la période d'inhibition, revenir à la condition de sécurité spécifiée.

La conformité est vérifiée par examen des DOCUMENTS D'ACCOMPAGNEMENT et par des essais fonctionnels.

201.12.4.4.107 SYSTEMES DE PROTECTION

Une défaillance des SYSTEMES DE PROTECTION exigés au 201.12.4.4 doit apparaître de manière évidente à l'OPERATEUR, dans les limites de temps suivantes:

a) pour tous les SYSTEMES DE PROTECTION, à l'exception de ceux définis en 201.12.4.4.105 (infusion d'air):
   – au moins une fois par jour, ou, si cela n'est pas possible, comme déterminé par le PROCESSUS de GESTION DES RISQUES du FABRICANT;

NOTE Les méthodes acceptables de mise en conformité avec cette exigence sont par exemple:

- la vérification fonctionnelle périodique des SYSTEMES DE PROTECTION demandée par l'APPAREIL D'HEMODIALYSE, déclenchée et contrôlée par l'OPERATEUR;
- la vérification fonctionnelle périodique des SYSTEMES DE PROTECTION demandée par l'APPAREIL D'HEMODIALYSE, déclenchée par l'OPERATEUR et contrôlée par l'APPAREIL D'HEMODIALYSE;
- la redondance des SYSTEMES DE PROTECTION avec l'autovérification par l'APPAREIL D'HEMODIALYSE;
- la vérification fonctionnelle périodique des SYSTEMES DE PROTECTION déclenchée par l'APPAREIL D'HEMODIALYSE et contrôlée par l'APPAREIL D'HEMODIALYSE, si la fonction de contrôle du SYSTEME DE PROTECTION est conçue de telle sorte qu'elle ne puisse pas connaître de défaillance en même temps que le SYSTEME DE PROTECTION du fait d'une défaillance unique.

b) pour le SYSTEME DE PROTECTION exigé par 12.4.4.105 (infusion d'air):
   – si une quantité d'air peut être infusée vers le PATIENT, ce qui peut provoquer une SITUATION DANGEREUSE résultant d'un premier défaut du détecteur d'air, le temps de détection maximal pour ce défaut est calculé comme étant le temps de tolérance du défaut, c'est-à-dire:

     le volume minimum du CIRCUIT EXTRACORPOREL entre la position du détecteur d'air et la canule veineuse, divisé par le flux sanguin le plus élevé;
   – dans tous les autres cas, a) s'applique.

Chaque défaillance d'un SYSTEME DE PROTECTION doit neutraliser la fonction correspondante contrôlée par le SYSTEME DE PROTECTION associé. Cette disposition doit être indiquée à l'OPERATEUR.

La conformité est vérifiée par des essais fonctionnels et des simulations de défaillance.

201.12.4.4.108 Prévention de la contamination par les produits chimiques

a) Il ne doit pas être possible de traiter le PATIENT pendant que l'APPAREIL D'HEMODIALYSE est en mode nettoyage, stérilisation ou désinfection. Les paragraphes 4.7 et 11.8 de la norme générale s'appliquent.

b) Les produits chimiques (par exemple, l'eau, le LIQUIDE DE DIALYSE, le désinfectant ou le CONCENTRE DE LIQUIDE DE DIALYSE) ne doivent pas s'écouler de l'APPAREIL D'HEMODIALYSE dans le sens inverse d'une ligne d'alimentation, même en CONDITION DE PREMIER DEFAUT.

La conformité est vérifiée par des essais fonctionnels et des simulations de défaillance.

201.12.4.4.109 * Inversion de la ou des pompes à sang et/ou à LIQUIDE DE SUBSTITUTION

Une méthode doit être comprise pour empêcher l'inversion accidentelle, en cours de traitement, de la ou des pompes à sang et/ou à LIQUIDE DE SUBSTITUTION, qui peut provoquer une SITUATION DANGEREUSE.

Les SITUATIONS DANGEREUSES applicables (par exemple, infusion d'air via la ligne de sang artérielle) doivent être déterminées par le PROCESSUS DE GESTION DES RISQUES DU FABRICANT. Les ERREURS D'UTILISATION doivent être prises en considération, ainsi que les défaillances techniques.

La conformité est vérifiée par examen et par des essais fonctionnels.