

INTERNATIONAL STANDARD

NORME INTERNATIONALE



Medical electrical equipment –

Part 2-39: Particular requirements for the basic safety and essential performance of peritoneal dialysis equipment

Appareils électromédicaux –

Partie 2-39: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de dialyse péritonéale



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**Medical electrical equipment –
Part 2-39: Particular requirements for the basic safety and essential
performance of peritoneal dialysis equipment**

**Appareils électromédicaux –
Partie 2-39: Exigences particulières pour la sécurité de base et les
performances essentielles des appareils de dialyse péritonéale**

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –**Part 2-39: Particular requirements for the basic safety and essential performance of peritoneal dialysis equipment**

FOREWORD

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IEC 60601-2-39 has been prepared by subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

This fourth edition cancels and replaces the third edition published in 2018. This edition constitutes a technical revision.

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

- a) update of references to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, of references to IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, of references to IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, of references to IEC 60601-1-9:2007, IEC 60601-1-9:2007/AMD1:2013 and IEC 60601-1-9:2007/AMD2:2020, of references to IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020 and of references to IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020;
- b) consideration of ESSENTIAL PERFORMANCE in SINGLE FAULT CONDITION regarding IEC 60601-1:2005/AMD1:2012/ISH1:2021;
- c) including the information given in the document 62D/1771A/INF regarding 201.11.8;
- d) including the information given in the document 62D/1734/INF regarding technical issues of the previous edition;
- e) including SECURITY (CYBERSECURITY) requirements;
- f) additions related to online PD SOLUTION generation (ONLINE PD);
- g) improvements regarding the definition of the APPLIED PART;
- h) improvement of the essential performance requirements clause/subclauses;
- i) improvements for labelling;
- j) other minor technical improvements;
- k) editorial improvements.

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

Draft	Report on voting
62D/2162/FDIS	62D/2182/RVD

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

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

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

In this document, the following print types are used:

- requirements and definitions: roman type;
- *test specifications: italic type;*
- informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;
- terms defined in Clause 3 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, in this document or as noted: SMALL CAPITALS.

In referring to the structure of this document, the term:

- "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

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

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

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

- "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
- "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
- "may" is used to describe a permissible way to achieve compliance with a requirement or test.

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

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

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

- reconfirmed,
- withdrawn, or
- revised.

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

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INTRODUCTION

The minimum safety requirements specified in this document are considered to provide for a practical degree of safety in the operation of PERITONEAL DIALYSIS ME EQUIPMENT.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-39: Particular requirements for the basic safety and essential performance of peritoneal dialysis equipment

201.1 Scope, object and related standards

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

201.1.1 Scope

Replacement:

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

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

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

This document specifies the minimum safety requirements for PD EQUIPMENT. These PD 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 PERITONEAL DIALYSIS treatment to a PATIENT, independent of the treatment duration and location.

These particular requirements do not apply to:

- PRE-MANUFACTURED DIALYSING SOLUTION bags,
- DIALYSING SOLUTION CIRCUITS,
- DIALYSING SOLUTION CONCENTRATE,
- DIALYSIS WATER supply systems (see ISO 23500-2 [1])¹,
- CENTRAL DELIVERY SYSTEMS for DIALYSING SOLUTION CONCENTRATES, described as systems for bulk mixing concentrate at a dialysis facility,
- equipment used to perform HAEMODIALYSIS (see IEC 60601-2-16 [2]).

¹ Numbers in square brackets refer to the Bibliography.

201.1.2 Object

Replacement:

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

201.1.3 Collateral standards

Addition:

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

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

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

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

201.1.4 Particular standards

Replacement:

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

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

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

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

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

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

Subclauses, figures or tables which are additional to those of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered starting from 201.101. However, due to the fact that definitions in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered 3.1 through 3.154, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

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

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

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

201.2 Normative references

NOTE Informative references are listed in the Bibliography.

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

Addition:

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

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

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

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

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

201.3 Terms and definitions

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

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

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

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

201.3.8

* APPLIED PART

Replacement:

DIALYSING SOLUTION CIRCUIT and all parts permanently and conductively connected to it

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

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

Note 3 to entry: Another example of an APPLIED PART is the DIALYSING SOLUTION CIRCUIT including connected DIALYSING SOLUTION bags, that are online prepared before treatment without the PATIENT connected and drain bags. During treatment the online preparation part of the PD EQUIPMENT is conductively disconnected.

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

201.3.78

PATIENT CONNECTION

Addition:

Note 1 to entry: The PATIENT connector(s) is/are the individual point(s) on the APPLIED PART through which a current can flow between the PATIENT and the PD EQUIPMENT in NORMAL CONDITION or SINGLE FAULT CONDITION.

Additional terms and definitions:

201.3.201

APD ME EQUIPMENT

ME EQUIPMENT used to perform AUTOMATED PERITONEAL DIALYSIS

201.3.202

AUTOMATED PERITONEAL DIALYSIS

APD

method to perform dialysis with automated fluid exchanges in the peritoneum

201.3.203

CENTRAL DELIVERY SYSTEM

part of a ME SYSTEM which proportions DIALYSING SOLUTION CONCENTRATE and DIALYSIS WATER for distribution as DIALYSING SOLUTION to the PD EQUIPMENT or distributes DIALYSING SOLUTION CONCENTRATE

201.3.204**DIALYSING SOLUTION****PD SOLUTION**

aqueous fluid containing electrolytes and, usually, buffer and glucose, and which is intended to exchange solutes during PERITONEAL DIALYSIS

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

201.3.205**DIALYSING SOLUTION CIRCUIT**

part of the fluid circuit that conveys DIALYSING SOLUTION from the PD EQUIPMENT to the peritoneal cavity of the PATIENT, from the PATIENT to the PD EQUIPMENT, and from the PD EQUIPMENT to a drainage bag or drain

201.3.206**DIALYSING SOLUTION CONCENTRATE**

substances which, when appropriately diluted or dissolved with DIALYSIS WATER, produce the DIALYSING SOLUTION

201.3.207**DIALYSIS WATER**

water that has been treated to meet the requirements of ISO 23500-3:2024 [3] and which is suitable for use in PD applications, including the preparation of DIALYZING SOLUTION and preparation of DIALYSING SOLUTION CONCENTRATE

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

[SOURCE: ISO 23500-1:2024 [4], 3.17, modified – In the definition, addition of reference number "[3]" and replacement of "dialysis fluid, reprocessing of dialysers, preparation of concentrates and preparation of substitution fluid for online convective therapies" with "DIALYZING SOLUTION and preparation of DIALYSING SOLUTION CONCENTRATE", as well as addition of the note.]

201.3.208**INFLOW**

phase during which the peritoneal cavity is filled

Note 1 to entry: The term "fill" is commonly used as a synonym for "INFLOW".

201.3.209**ONLINE PD**

PERITONEAL DIALYSIS PROCEDURE where the PD EQUIPMENT produces the DIALYSING SOLUTION for the PERITONEAL DIALYSIS treatment

201.3.210**OUTFLOW**

phase during which the peritoneal cavity is emptied

Note 1 to entry: The term "drain" is commonly used as a synonym for "OUTFLOW".

201.3.211**PERITONEAL DIALYSIS****PD**

PROCESS whereby a DIALYSING SOLUTION is introduced into the peritoneal cavity of the PATIENT and is subsequently removed

Note 1 to entry: The DIALYSING SOLUTION can be left in the peritoneal cavity for a dwell time or can be continuously exchanged.

201.3.212**PERITONEAL DIALYSIS ME EQUIPMENT****PD EQUIPMENT**

ME EQUIPMENT used to perform PERITONEAL DIALYSIS including APD ME EQUIPMENT

201.3.213**PROTECTIVE SYSTEM**

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

201.4 General requirements

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

201.4.3 * ESSENTIAL PERFORMANCE

Additional subclauses:

201.4.3.101 * Additional ESSENTIAL PERFORMANCE requirements

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

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

Table 201.101 – ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
DIALYSING SOLUTION flow rate during INFLOW/OUTFLOW	201.4.3.102
DIALYSING SOLUTION volume balancing (INFLOW/OUTFLOW volume)	201.4.3.103
PERITONEAL DIALYSIS dwell time	201.4.3.104
DIALYSING SOLUTION composition	201.4.3.105
DIALYSING SOLUTION temperature	201.4.3.106

NOTE 1 Some ESSENTIAL PERFORMANCES listed in Table 201.101 are dependent on the characteristics of the disposables used. (e.g. length of the patient line, volume of the used DIALYSING SOLUTION bags).

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

201.4.3.102 * DIALYSING SOLUTION flow rate during INFLOW/OUTFLOW

The accuracy of the DIALYSING SOLUTION flow rate administered by the PD EQUIPMENT during INFLOW/OUTFLOW to and from the PATIENT shall be as specified by the MANUFACTURER.

NOTE 1 A DIALYSING SOLUTION flow rate during INFLOW/OUTFLOW lower than the set value is considered detrimental for a typical treatment.

NOTE 2 For PD EQUIPMENT without an OPERATOR adjustable flow rate, it is acceptable for the values specified by the MANUFACTURER in the instructions for use to be the minimum inflow and outflow rates.

Compliance is checked under the following test conditions:

- *Set up the DIALYSING SOLUTION containers as specified by the ACCOMPANYING DOCUMENTS, otherwise at the same height as the PD EQUIPMENT.*
- *Set the PD EQUIPMENT to a total therapy volume of 10 l, or to an appropriate volume specified by the MANUFACTURER.*
- *Set the PD EQUIPMENT to a fill volume or cycle volume of 2,0 l, or to an appropriate fill or cycle volume specified by the MANUFACTURER.*
- *Connect the PD EQUIPMENT to a simulated PATIENT comprising the following elements:*
 - *an appropriately sized empty or partially filled fluid bag simulating the PATIENT's peritoneal cavity, and*
 - *a flow restrictor in line between the PD EQUIPMENT and the fluid bag, simulating the combined flow resistance of the peritoneal catheter, transfer set and fluid connector according to the MANUFACTURER'S recommendation. As flow restrictor for example a 60 cm silicone tube of 2,67 mm inner diameter can be used.*
- *Set the DIALYSING SOLUTION temperature to 37 °C, if applicable.*
- *Set the PD EQUIPMENT to the minimum cycle time, or to a dwell time of 0 min.*
- *Set the PD EQUIPMENT to operate until all DIALYSING SOLUTION processing components are primed.*
- *Place the simulated PATIENT on a weighing scale located 50 cm above the PD EQUIPMENT, or at the maximum allowable height, as specified by the MANUFACTURER.*
- *Set the highest DIALYSING SOLUTION INFLOW and OUTFLOW rate, if applicable.*
- *Measure the DIALYSING SOLUTION flow during at least 2 complete INFLOW and OUTFLOW phases, respectively, by recording the duration of each phase, and the weight of the fluid bag at the start and the end of each phase.*
- *Set the lowest DIALYSING SOLUTION INFLOW and OUTFLOW rate, if applicable.*
- *Measure the DIALYSING SOLUTION flow during at least 2 complete INFLOW and OUTFLOW phases, respectively, by recording the duration of each phase, and the weight of the fluid bag at the start and the end of each phase.*
- *Place the simulated PATIENT on a weighing scale located 50 cm below the PD EQUIPMENT, or at the minimum allowable height, as specified by the MANUFACTURER.*
- *Set the highest DIALYSING SOLUTION INFLOW and OUTFLOW rate, if applicable.*
- *Measure the DIALYSING SOLUTION flow during at least 2 complete INFLOW and OUTFLOW phases, respectively, by recording the duration of each phase, and the weight of the fluid bag at the start and the end of each phase.*
- *Set the lowest DIALYSING SOLUTION INFLOW and OUTFLOW rate, if applicable.*
- *Measure the DIALYSING SOLUTION flow during at least 2 complete INFLOW and OUTFLOW phases, respectively, by recording the duration of each phase, and the weight of the fluid bag at the start and the end of each phase.*

NOTE 3 It is acceptable for the simulated PATIENT to be in an ENCLOSURE controlled to approximately 37 °C to simulate the PATIENT'S body temperature, which can be used for the PD EQUIPMENT to maintain thermal equilibrium appropriate for pumping accuracy.

NOTE 4 It is acceptable for the minimum cycle (dwell) time to also include time needed for the PD EQUIPMENT to reach and maintain thermal equilibrium appropriate for pumping accuracy.

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

201.4.3.103 DIALYSING SOLUTION volume balancing (INFLOW/OUTFLOW volume)

The DIALYSING SOLUTION INFLOW and OUTFLOW volume accuracy and the volume balancing accuracy of the PD EQUIPMENT shall be achieved as specified by the MANUFACTURER.

Compliance is checked under the following test conditions:

Test for APD ME EQUIPMENT

- *Set up the DIALYSING SOLUTION containers as specified by the ACCOMPANYING DOCUMENTS, otherwise at the same height as the PD EQUIPMENT.*
- *Set the PD EQUIPMENT to maximum fill volume or cycle volume.*
- *Connect the PD EQUIPMENT to a simulated PATIENT comprising the following elements:*
 - *an appropriately sized empty or partially filled fluid bag simulating the PATIENT's peritoneal cavity, and*
 - *a flow restrictor in line between the PD EQUIPMENT and the fluid bag, simulating the combined flow resistance of the peritoneal catheter, transfer set and fluid connector according to the MANUFACTURER'S recommendation. As flow restrictor for example a 60 cm silicone tube of 2,67 mm inner diameter can be used.*
- *Set the DIALYSING SOLUTION temperature to 37 °C, if applicable.*
- *Set the PD EQUIPMENT to the minimum cycle time, or to a dwell time of 0 min.*
- *Set the PD EQUIPMENT to operate until all DIALYSING SOLUTION processing components are primed.*
- *Place the simulated PATIENT on a weighing scale located 50 cm above the PD EQUIPMENT, or at the maximum allowable height, as specified by the MANUFACTURER.*
- *Measure the DIALYSING SOLUTION volume of 5 complete INFLOW phases and OUTFLOW phases, respectively, by recording the weight of the simulated PATIENT at the start and the end of each phase.*
- *Place the simulated PATIENT on a weighing scale located 50 cm below the PD EQUIPMENT, or at the minimum allowable height, as specified by the MANUFACTURER.*
- *Measure the DIALYSING SOLUTION volume of 5 complete INFLOW phases and OUTFLOW phases, respectively, by recording the weight of the simulated PATIENT at the start and the end of each phase.*
- *Set the PD EQUIPMENT to the minimum fill volume or cycle volume.*
- *Place the simulated PATIENT on a weighing scale located 50 cm above the PD EQUIPMENT, or at the maximum allowable height, as specified by the MANUFACTURER.*
- *Measure the DIALYSING SOLUTION volume of 5 complete INFLOW phases and OUTFLOW phases, respectively, by recording the weight of the simulated PATIENT at the start and the end of each phase.*
- *Place the simulated PATIENT on a weighing scale located 50 cm below the PD EQUIPMENT, or at the maximum allowable height, as specified by the MANUFACTURER.*
- *Measure the DIALYSING SOLUTION volume of 5 complete INFLOW phases and OUTFLOW phases, respectively, by recording the weight of the simulated PATIENT at the start and the end of each phase.*

NOTE 1 For tidal PD EQUIPMENT, use a partially filled simulated PATIENT fluid bag.

NOTE 2 It is acceptable for the simulated PATIENT to be in an ENCLOSURE controlled to approximately 37 °C to simulate the PATIENT'S body temperature, which can be applicable for the PD EQUIPMENT to maintain thermal equilibrium appropriate for pumping accuracy.

NOTE 3 Setting the PD EQUIPMENT to the minimum cycle time, or to a dwell time of 0 min is done to accelerate the test. It is acceptable for the minimum cycle (dwell) time to also include time needed for the PD EQUIPMENT to reach and maintain thermal equilibrium appropriate for pumping accuracy.

NOTE 4 It is acceptable to integrate 201.4.3.102 tests within this test condition.

If the MANUFACTURER specifies a mean treatment accuracy:

For each test scenario, the mean values of the DIALYSING SOLUTION INFLOW and OUTFLOW volumes and the overall balance accuracies shall be within the tolerances specified by the MANUFACTURER in the instructions for use.

If the MANUFACTURER specifies individual cycle accuracies:

For each test scenario each value of DIALYSING SOLUTION INFLOW and OUTFLOW volume and each cycle balance accuracy shall be within the tolerances specified by the MANUFACTURER in the instructions for use.

201.4.3.104 PERITONEAL DIALYSIS dwell time

The accuracy of the dialysis dwell time for the PD EQUIPMENT shall be as specified by the MANUFACTURER.

Compliance is checked by the functional tests relevant for the definition of dialysis dwell time specified by the MANUFACTURER in the instructions for use.

201.4.3.105 * DIALYSING SOLUTION composition

The accuracy of the DIALYSING SOLUTION composition prepared by the PD EQUIPMENT shall be as specified by the MANUFACTURER.

The test method for accuracy of the composition of the DIALYSING SOLUTION shall be specified by the MANUFACTURER. Compliance is checked by inspection and by appropriate functional test(s) that demonstrate the MANUFACTURER's limits specified in the instructions for use are maintained.

NOTE This test does not apply to PD EQUIPMENT using pre-manufactured DIALYSING SOLUTION in bags.

201.4.3.106 DIALYSING SOLUTION temperature

The DIALYSING SOLUTION temperature of the PD EQUIPMENT shall be achieved as specified by the MANUFACTURER.

NOTE 1 This test applies only to PD EQUIPMENT having a heater for the DIALYSING SOLUTION.

Compliance is checked under the following test conditions:

- *Set the PD EQUIPMENT to a fill volume or cycle volume of 2,0 l, or to an appropriate fill or cycle volume specified by the MANUFACTURER.*
- *Let the PD EQUIPMENT run until it is in a thermally stable condition.*
- *The environmental temperature is within 20 °C to 25 °C.*
- *Set the DIALYSING SOLUTION temperature to 37 °C, if applicable.*
- *Set the PD EQUIPMENT to operate until all DIALYSING SOLUTION processing components are primed.*
- *Set the highest DIALYSING SOLUTION flow, if applicable.*
- *Connect the PD EQUIPMENT to an appropriately sized empty fluid bag simulating the PATIENT's peritoneal cavity ("simulated PATIENT").*
- *Continuously measure the temperature at the simulated PATIENT inlet.*
- *Record the temperatures during at least 2 INFLOW phases.*
- *Set the lowest DIALYSING SOLUTION flow, if applicable.*
- *Continuously measure the temperature at the simulated PATIENT inlet.*

- *Record the temperatures during at least 2 INFLOW phases.*

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

NOTE 2 It is acceptable to integrate this test condition within the 201.4.3.103 tests.

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).

201.5 General requirements for testing ME EQUIPMENT

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

201.5.4 * Other conditions

Addition:

- aa) When the outcome of a test can be affected by the initial temperature of the pre-manufactured DIALYSING SOLUTION bags, the temperature of the DIALYSING SOLUTION at the start of the test shall be equal to or less than 4 °C, or the minimum DIALYSING SOLUTION temperature specified by the ME EQUIPMENT MANUFACTURER.
- bb) If the conditions (e.g., temperature, humidity) during either storage or the transport, or both, can influence NORMAL USE, this shall be addressed by the RISK MANAGEMENT PROCESS.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

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

201.7 ME EQUIPMENT identification, marking and documents

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

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.2 Instructions for use

201.7.9.2.1 General

Addition:

The instructions for use shall additionally include the following:

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

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

201.7.9.2.2 Warning and safety notices

Addition:

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

- a warning statement which draws the OPERATOR'S attention to the HAZARDOUS SITUATION associated with connection and disconnection of the PATIENT;
- a warning statement of the operator's actions required to respond to ALARM SIGNALS from any PROTECTIVE SYSTEM;
- a warning statement that draws the OPERATOR'S attention to potential HAZARDS arising from improper installation and connection of the DIALYSING SOLUTION CIRCUIT;
- a warning statement that draws the OPERATOR'S attention to potential HAZARDS relating to inappropriate selection of the pre-manufactured DIALYSING SOLUTION bags.
- a warning statement on the HAZARDS related to incorrect choice of DIALYSING SOLUTION CONCENTRATE(S);
- a quantitative description of the possible deviation of each component of the DIALYSING SOLUTION in SINGLE FAULT CONDITION depending on the ALARM LIMITS of the PROTECTIVE SYSTEM;
- a warning statement of the adequate OPERATOR action upon an ALARM CONDITION and associated HAZARD(S), if the ALARM SIGNAL is repeatedly confirmed without solving the underlying problem;
- regarding the microbiological quality of fluids:
 - a warning statement that only the disinfection PROCEDURES defined and validated by the MANUFACTURER shall be used;
 - information on the required quality of the incoming DIALYSIS WATER and of the DIALYSING SOLUTION CONCENTRATES used;
 - information about the microbiological quality of the DIALYSING SOLUTION prepared by the PD EQUIPMENT;
 - intervals at which wearing parts (e.g. ENDOTOXIN-RETENTIVE FILTER – ETRF) should be exchanged;
 - a warning statement that protective measures should be taken to prevent back siphonage of the OUTFLOW path.

EXAMPLE A statement pointing out the importance of an air gap between the DIALYSING SOLUTION circuit and the drain in order to prevent back siphonage of the OUTFLOW path.

NOTE 101 Since the drainage of the fluid is normally connected by the PATIENT, it is the responsibility of the MANUFACTURER to warn the PATIENT or OPERATOR of the need for back siphonage protection and the PATIENT'S or OPERATOR'S responsibility to ensure that it is done correctly.

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

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

201.7.9.2.5 ME EQUIPMENT description

Addition:

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

- an explanation of the coloured markings on the DIALYSING SOLUTION CONCENTRATE connectors;
- 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 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 PD EQUIPMENT and that can be used for adjusting the treatment or measuring or confirming the treatment efficacy:
 - a) a description of the technical working principle;
 - b) if the measurement is indirect: information about the accuracy and possible influencing factors;
 - c) the method by which the technical working principle has been evaluated relative to standard medical care.

NOTE An example of PD EQUIPMENT and that can be used for adjusting the treatment or measuring or confirming the treatment efficacy is measurement of urea.

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

201.7.9.2.6 Installation

Addition:

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

- information that it is essential for the PD EQUIPMENT to be installed and used in compliance with appropriate regulations/recommendations on quality of DIALYSIS WATER and other relevant fluids;
- for CLASS I PD EQUIPMENT, information of the importance of the quality of the protective earth in the electrical installation;
- 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 PD 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 PD EQUIPMENT from any sewer connection;
- if different schemes for colour coding of visual ALARM SIGNALS can be configured, information that the RESPONSIBLE ORGANIZATION should select the colour coding scheme which minimizes the RISK of ALARM SIGNAL misunderstanding in their environment;
- if settings of operating parameters or PROTECTIVE SYSTEMS can be configured, information that the RESPONSIBLE ORGANIZATION should select the configuration(s) or explicitly confirm the default configuration.

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

201.7.9.2.12 CLEANING, DISINFECTION AND STERILIZATION*Addition:*

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

- * a description of the method(s) by which sanitization or disinfection of the non-single use fluid path inside the HAEMODIALYSIS EQUIPMENT and either the ENCLOSURE surface cleaning or disinfection, or both, is achieved;
- information on how to handle an extended time between disinfection or sterilization, so as to return the system to a state of microbial control;
- * information that the test PROCEDURE by which the effectiveness of sanitization or disinfection of the fluid path inside the PD EQUIPMENT has been validated is available upon request from the MANUFACTURER, including information on how the testing represented the microbial controls risks throughout the EXPECTED SERVICE LIFE;
- a warning statement to follow the MANUFACTURER'S instructions to disinfect the PD EQUIPMENT; if other PROCEDURES are used it is the responsibility of the RESPONSIBLE ORGANIZATION to validate the disinfection PROCEDURE for efficacy and safety; this warning shall specifically list HAZARDS, including the failure mode that can result from other PROCEDURES;
- a warning statement that the RESPONSIBLE ORGANIZATION is responsible for the hygienic quality of any delivery system(s), for example central DIALYSIS WATER supply system, CENTRAL DELIVERY SYSTEMS, PD EQUIPMENT connecting devices, including the fluid lines from connection points to the PD EQUIPMENT.

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

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

201.7.9.2.14 ACCESSORIES, supplementary equipment, used material*Addition:*

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

- information on pre-manufactured dialysing solution bags, dialysing solution concentrates and dialysing solution circuit intended to be used together with the PD EQUIPMENT.

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

201.7.9.3 Technical description

201.7.9.3.1 General

Addition:

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

- installation:
 - a description of the particular measures or conditions to be observed when installing, deinstalling and transporting the PD 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 PD 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 DIALYSING SOLUTION CONCENTRATE(S) or (pre-manufactured) DIALYSING SOLUTION under typical operating conditions;
- PD EQUIPMENT specification:
 - any additional measures foreseen by the MANUFACTURER in case of the interruption of the power supply;
 - the type, the measurement accuracy and the value(s) / range(s) of the ALARM LIMIT(s) of the PROTECTIVE SYSTEM required by 201.12.4.4.101 (DIALYSING SOLUTION temperature);
 - the type, the measurement accuracy and the ALARM LIMIT(s) of the PROTECTIVE SYSTEM required by 201.12.4.4.102 (pressures);
 - the method employed and the sensitivity under test conditions specified by the MANUFACTURER for the PROTECTIVE SYSTEM required by 201.12.4.4.103 (air infusion);
 - the type, the measurement accuracy and the value(s) / range(s) of the ALARM LIMIT(s) of the PROTECTIVE SYSTEM required by 201.12.4.4.104 (DIALYSING SOLUTION overfill);
 - the type, the measurement accuracy and the value(s) / range(s) of the ALARM LIMIT(s) of the PROTECTIVE SYSTEM required by 201.12.4.4.105 (DIALYSING SOLUTION composition);
 - the time by which the auditory ALARM SIGNAL required in 201.12.4.4.101 b), 201.12.4.4.103 b), 201.12.4.4.104 b) and 201.12.4.4.105 b) is delayed;
 - the auditory ALARM SIGNAL audio paused period;
 - the range of sound pressure levels of any adjustable auditory ALARM SIGNAL source;
 - the maximum positive and negative pressures that can be generated by any pumps used to assist the transfer of DIALYSING SOLUTION to and from the peritoneal cavity of the PATIENT; the MANUFACTURER shall specify where and how the maximum pressure was obtained;
 - a disclosure of all materials intended to come into contact with the DIALYSIS WATER, DIALYSING SOLUTION and DIALYSING SOLUTION CONCENTRATE;
 - for ONLINE PD: the method of preparation of the DIALYSING SOLUTION, if applicable the method of the integrity test of the DIALYSING SOLUTION filters (e.g. ENDOTOXIN-RETENTIVE FILTER – ETRF) and the accuracy of these tests.

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

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

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

201.8.7.4.7 *Measurement of the PATIENT LEAKAGE CURRENT

Addition:

- aa) The point of measurement shall be where the DIALYSING SOLUTION CIRCUIT connects to a peritoneal catheter. For the duration of the test, DIALYSING SOLUTION shall be flowing in the DIALYSING SOLUTION CIRCUIT. The PD EQUIPMENT shall be fully equipped for the INTENDED USE, as specified by the MANUFACTURER.

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

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

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

201.10 Protection against unwanted and excessive radiation HAZARDS

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

201.11 Protection against excessive temperatures and other HAZARDS

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

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

201.11.6.1 General

Addition:

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

NOTE Examples for appropriate liquid are saline solution, DIALYSING SOLUTION, other as identified by MANUFACTURER.

201.11.6.3 Spillage on ME EQUIPMENT and ME SYSTEMS

Replacement:

The PD EQUIPMENT shall be so constructed that, in the event of spillage of liquids from the fluid reservoir or DIALYSING SOLUTION CIRCUIT set when positioned for NORMAL USE, no HAZARDOUS SITUATION shall result.

Compliance is checked by the following test.

With the PD EQUIPMENT placed in the position of NORMAL USE, 3 l of DIALYSING SOLUTION or the maximum volume present in the fluid reservoir and DIALYSING SOLUTION CIRCUIT (whichever is smaller) shall be poured onto the top surface of the PD EQUIPMENT. The solution shall be poured continuously over a period of 15 s.

Immediately after the test, inspection shall show that the DIALYSING SOLUTION which might have entered the PD EQUIPMENT has not wetted parts which might cause a HAZARDOUS SITUATION. In case of doubt, the PD EQUIPMENT shall be subjected to the dielectric strength test described in 8.8.3 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, and the PD EQUIPMENT shall function as intended.

201.11.6.6 * Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS

Addition:

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

The microbial control PROCESS for PD EQUIPMENT shall be developed and validated by the MANUFACTURER for PD EQUIPMENT using a RISK based approach considering EXPECTED SERVICE LIFE, disposability, filtration, cleaning/disinfection, system maintenance, storage, and relevant DIALYSING SOLUTION quality standards.

NOTE Regarding relevant DIALYSING SOLUTION quality standards, the haemodialysis dialysis fluid standard ISO 23500-5 [5] can be taken as relevant standard also for PERITONEAL DIALYSIS DIALYSING SOLUTION.

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

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

Compliance is checked by inspection of the RISK MANAGEMENT FILE and the validation documentation.

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

Addition:

a) PD EQUIPMENT powered only by SUPPLY MAINS without INTERNAL ELECTRICAL POWER SOURCE:

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

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

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

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

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

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

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

- directly after the loss of SUPPLY MAINS an activation of at least a visual indication;

While the INTERNAL ELECTRICAL POWER SOURCE is active:

- If applicable, the requirements from 201.12.4.4 shall be fulfilled.

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

- before depletion of the INTERNAL ELECTRICAL POWER SOURCE an activation of a visual and auditory ALARM SIGNAL at least 10 min before expected loss of power. If applicable, the point in time of the ALARM SIGNAL should give the OPERATOR the time usually needed to disconnect the PATIENT or end therapy. The ALARM SIGNAL shall last for at least 1 min.

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

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

In both options:

- additional measures can be needed, as determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS;
- If functions of the PD EQUIPMENT were stopped in the event of the interruption of the power supply / SUPPLY MAINS, they may restart automatically on restoration of the power supply / SUPPLY MAINS only if this does not cause any HAZARDOUS SITUATION to the PATIENT, as determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS.

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

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

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

NOTE 106 Regarding the first option (i.e. ALARM SIGNAL 10 min before the expected loss of the INTERNAL ELECTRICAL POWER SOURCE), an alarm signal generated more than 30 min before the expected loss of the INTERNAL ELECTRICAL POWER SOURCE would not serve the purpose of reminding the OPERATOR to disconnect the PATIENT or end therapy before the INTERNAL ELECTRICAL POWER SOURCE gets depleted. If the limited functionality is specified for 10 min or less, the SUPPLY MAINS loss ALARM SIGNAL and the INTERNAL ELECTRICAL POWER SOURCE loss ALARM SIGNAL could be combined in one ALARM SIGNAL.

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

- c) PD EQUIPMENT that is INTERNALLY POWERED

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

- before depletion of the INTERNAL ELECTRICAL POWER SOURCE an activation of a visual and auditory ALARM SIGNAL at least 10 min before expected loss of power. If applicable, the point in time of the ALARM SIGNAL should give the OPERATOR the time usually needed to disconnect the PATIENT or end therapy. The ALARM SIGNAL shall have the capability of lasting for at least 1 min and shall be compliant with Clause 208 (with an allowed exception on duration of AUDIO PAUSE, regarding 208.6.3.1 and 208.6.3.3.101).

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

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

In both options:

- additional measures can be needed, as determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS.
- The PD EQUIPMENT may restart automatically on restoration of the power supply only if this does not cause any HAZARDOUS SITUATION to the PATIENT, as determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS.

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

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

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

NOTE 110 For the 1 min auditory ALARM SIGNAL in the event of the loss of the INTERNAL ELECTRICAL POWER SOURCE, IEC 60601-1-8 allows in Subclause 6.3.3.1 deviations from the full requirements thereof. See also 208.6.3.3.2 and 208.6.3.3.101.

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

201.12 Accuracy of controls and instruments and protection against hazardous outputs

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

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 PD 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 PD EQUIPMENT and the MANUFACTURER'S RISK MANAGEMENT PROCESS.

Additional subclauses:

201.12.4.4.101 *DIALYSING SOLUTION temperature

- a) If the PD EQUIPMENT includes a means of heating the DIALYSING SOLUTION, the PD EQUIPMENT shall be provided with a PROTECTIVE SYSTEM, independent of any temperature control system, which prevents the DIALYSING SOLUTION from reaching a temperature greater than 41 °C measured at the PATIENT end of the APPLIED PART. This measurement can be taken at an alternative location but shall be demonstrated to be less than 41 °C at the point of infusion to the PATIENT.

The need for a low temperature limit of the DIALYSING SOLUTION shall be addressed in the MANUFACTURER'S RISK MANAGEMENT PROCESS.

NOTE It is not practical to measure the temperature at the PATIENT CONNECTION.

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

- stopping of the DIALYSING SOLUTION and thermal flow to the PATIENT;
- activation of auditory and visual ALARM SIGNALS. The ALARM SIGNALS may be delayed, as specified by the MANUFACTURER.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and by measuring the temperature of the DIALYSING SOLUTION at the PATIENT end of the APPLIED PART. The test shall be carried out under the most unfavourable flow conditions.

201.12.4.4.102 Pressures

If the PD EQUIPMENT includes a pump designed to assist delivery of the DIALYSING SOLUTION to the peritoneal cavity of the PATIENT, the pump shall be prevented from generating a positive pressure that exceeds the maximum specified by the MANUFACTURER.

If the PD EQUIPMENT includes a pump designed to assist the drainage of the used DIALYSING SOLUTION from the PATIENT, then the pump shall be prevented from generating a negative pressure that exceeds the maximum specified by the MANUFACTURER.

NOTE 1 Excessive pressures can cause damage to the peritoneum.

NOTE 2 Excessive pressures can be prevented by an inherent pump design or by an additional PROTECTIVE SYSTEM.

Compliance is checked by functional tests.

201.12.4.4.103 Air infusion

- a) If the PD EQUIPMENT includes a pump designed to assist delivery of the DIALYSING SOLUTION to the peritoneal cavity of the PATIENT, the PD EQUIPMENT shall be provided with a PROTECTIVE SYSTEM that prevents pumping enough air into the peritoneal cavity to cause a HAZARDOUS SITUATION.

NOTE Small volumes of air, such as individual bubbles in the DIALYSING SOLUTION, are not regarded as a HAZARD in PERITONEAL DIALYSIS.

- b) Activation of the PROTECTIVE SYSTEM shall either stop air from entering the APPLIED PART, or achieve the following safe conditions:
 - stopping of the pump;
 - activation of auditory and visual ALARM SIGNALS. The ALARM SIGNAL may be delayed, as specified by the MANUFACTURER.

Compliance is checked by functional tests.

201.12.4.4.104 DIALYSING SOLUTION overflow

- a) The PD EQUIPMENT shall be provided with a PROTECTIVE SYSTEM which prevents excessive fluid being administered to the peritoneal cavity and causing a HAZARDOUS SITUATION.
- b) Activation of the PROTECTIVE SYSTEM shall achieve the following safe conditions:
 - stopping of the DIALYSING SOLUTION flow to the PATIENT;
 - activation of auditory and visual ALARM SIGNALS. The ALARM SIGNAL may be delayed, as specified by the MANUFACTURER.

Compliance is checked by functional tests.

201.12.4.4.105 DIALYSING SOLUTION composition

- a) If applicable, the PD EQUIPMENT shall include a PROTECTIVE SYSTEM, independent of any fluid preparation control system, which prevents DIALYSING SOLUTION reaching the PATIENT that, due to its composition, can cause a HAZARDOUS SITUATION.
- b) Activation of the PROTECTIVE SYSTEM shall achieve the following safe conditions:
 - preventing DIALYSING SOLUTION with unsafe composition from reaching the PATIENT;
 - activation of auditory and visual ALARM SIGNALS. The auditory ALARM SIGNAL may be delayed, as specified by the MANUFACTURER.

NOTE A PROTECTIVE SYSTEM is not necessary for PD EQUIPMENT using only pre-manufactured DIALYSING SOLUTION bags, which is quality controlled for the DIALYSING SOLUTION composition, and is not changed in composition by the PD EQUIPMENT.

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

201.12.4.4.106 PROTECTIVE SYSTEMS

All PROTECTIVE SYSTEMS shall be active throughout treatment, when the PATIENT is connected until the PATIENT is disconnected. Additionally, the PROTECTIVE SYSTEMS for DIALYZING SOLUTION composition and temperature shall be activated before connecting the PATIENT.

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

Any failure of the PROTECTIVE SYSTEMS required by 201.12.4.4.101 to 201.12.4.4.105 shall become obvious to the OPERATOR before the start of every treatment.

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

Compliance is checked by functional tests and failure simulations.

201.12.4.4.107 Prevention of contamination by chemicals

- a) It shall not be possible to treat the PATIENT while the PD EQUIPMENT is in the cleaning, sterilization or disinfection mode. Subclauses 4.7 and 11.8 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 apply.
- b) Chemicals (e.g. water, DIALYSING SOLUTION, disinfectant or DIALYSING SOLUTION CONCENTRATE) shall not flow from the PD EQUIPMENT reverse to any supply line, even under SINGLE FAULT CONDITION.
- c) Erroneous connection of disinfectant, specified by the MANUFACTURER for use with the PD EQUIPMENT, instead of DIALYSING SOLUTION CONCENTRATE shall not cause a HAZARDOUS SITUATION.

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

201.12.4.4.108 Selection and change of operation modes

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

Compliance is checked by inspection and by functional tests.

201.12.4.4.109 * ONLINE PD DIALYSING SOLUTION preparation

If the PD EQUIPMENT is intended for ONLINE PD SOLUTION preparation, the MANUFACTURER shall ensure that the PD EQUIPMENT shall be capable of producing sterile and nonpyrogenic PD SOLUTION 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.

NOTE This does not apply to PD EQUIPMENT using pre-manufactured DIALYSING SOLUTION in bags.

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

201.13.2.6 *Leakage of liquid

Addition:

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

Compliance is checked by the following test:

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

and in case of doubt in test a):

- b) *by means of a syringe, a jet of an appropriate liquid for the part of the PD 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 PD 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 PD EQUIPMENT shall be subjected to the dielectric strength test specified in 8.8.3 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

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

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

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

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

Addition:

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

NOTE 101 Independent of this document, IEC 80001-1:2021 [1] includes requirements, that every MEDICAL DEVICE MANUFACTURER to make available ACCOMPANYING DOCUMENTS to the RESPONSIBLE ORGANIZATION with information about the IT-NETWORK capabilities of the medical device (3.5 MEDICAL DEVICE MANUFACTURER(S)).

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

Additional subclause:

201.14.13.101 *Specific SECURITY features for PD EQUIPMENT used in MEDICAL IT-NETWORKS

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

This can be fulfilled beside other alternative ways by following the recommendations in the technical report IEC TR 60601-4-5:2021 [6], which gives a guidance in establishing safety-related technical SECURITY specifications. This document also encourages the particular standard writers to include basic guidance for determining specific SECURITY features for medical devices by the MANUFACTURERS (IEC TR 60601-4-5:2021, 4.6.3) regarding the specific intended use environments of the medical devices covered by the particular standard.

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

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

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

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

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

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

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

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

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

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

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

Compliance is checked by inspection and functional testing.

For further information how to use above information to implement adequate medical device SECURITY COUNTERMEASURES, refer to the IEC TR 60601-4-5 itself.

201.15 Construction of ME EQUIPMENT

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

201.15.4 ME EQUIPMENT components and general assembly

Additional subclauses:

201.15.4.101 DIALYSING SOLUTION CIRCUIT

If an incorrect installation of the DIALYSING SOLUTION CIRCUIT can cause a HAZARDOUS SITUATION to the PATIENT, means shall be provided to ensure the correct attachment of the DIALYSING SOLUTION CIRCUIT to the PD EQUIPMENT.

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

NOTE To assess non-interconnectable characteristics of small-bore connectors based on their inherent design and dimensions in order to reduce the RISK of misconnections between PD EQUIPMENT and ACCESSORIES, see ISO 80369-1:2018 [7].

201.15.4.102 OUTFLOW

OUTFLOW shall be available at all times during a therapy.

During the PROCEDURE, it is acceptable for OUTFLOW to be restricted for short periods of time to complete certain steps such as setup and prime before the PATIENT is connected.

Compliance is checked by functional tests.

201.15.4.1 Construction of connectors

Additional subclause:

201.15.4.1.101 DIALYSING SOLUTION CONCENTRATE connectors

The various DIALYSING SOLUTION CONCENTRATE supply containers and cleaning solutions should be differentiated by mechanical connections to the DIALYSING SOLUTION CONCENTRATE connectors of the PD EQUIPMENT or shall be permanently colour marked (see ISO 23500-4:2024 [8]).

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

NOTE 1 The use of various DIALYSING SOLUTION CONCENTRATES presents a problem in that connection of the wrong DIALYSING SOLUTION 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 DIALYSING SOLUTION CONCENTRATES.

The following colours shall be used for DIALYSING SOLUTION CONCENTRATE connectors, if the concentrates are also usable as haemodialysis concentrates:

- 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 DIALYSING SOLUTION CONCENTRATES, on the PD EQUIPMENT the respective coloured markings shall be affixed on that connector. For example, a common connector for acetate and acidic DIALYSING SOLUTION CONCENTRATE shall be marked white/red.

Compliance is checked by inspection.

NOTE 2 ISO 23500-4 [8] gives requirements for the colour coding of DIALYSING SOLUTION CONCENTRATE containers.

201.16 * ME SYSTEMS

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

201.16.1 General requirements for the ME SYSTEMS

Addition:

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

201.16.2 ACCOMPANYING DOCUMENTS of an ME SYSTEM

d) advice to the responsible organization

Addition:

- a listing of HAZARDOUS SITUATIONS (e.g. increased LEAKAGE CURRENTS) and possible protective measures when PD 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 [9]).

201.16.9.1 Connection terminals and connectors

Addition:

- The connectors on the water softening, purification systems, and DIALYSING SOLUTION 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 DIALYSING SOLUTION CONCENTRATES to the appropriately marked DIALYSING SOLUTION CONCENTRATE connectors of the CENTRAL DELIVERY SYSTEMS for DIALYSING SOLUTION CONCENTRATES.

Compliance is checked by inspection.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

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

202 Electromagnetic disturbances – Requirements and tests

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

202.8 Electromagnetic IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS

202.8.1 * General

Addition:

The following IMMUNITY pass/fail criteria for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to EM DISTURBANCES shall be met by PERITONEAL DIALYSIS 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 the 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 the safe state.
- ESSENTIAL PERFORMANCE functions: After the test, the ME EQUIPMENT or ME SYSTEM shall continue to operate as intended without OPERATOR intervention. During the test, degradation of performance is allowed, but no degradation of performance is allowed below a performance level specified by the MANUFACTURER, when the ME EQUIPMENT or ME SYSTEM is used as intended.
- Other functions: Loss of functions 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 PD 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 PD EQUIPMENT is normally used in the following EM environments:

- HOME HEALTHCARE ENVIRONMENT (e.g. home or portable dialysis);
- professional healthcare facility environment (e.g. dialysis centres or dialysis departments in hospitals).

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

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

208.4 General requirements

Addition:

If the INTENDED USE of the PD EQUIPMENT includes the intensive care or surgery environment, it is acceptable to implement additional ALARM SYSTEMS deviating from IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 in the following subclauses:

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

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

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

The paragraph d) 1) i) in subclause 6.3.3.1 of IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 is not applicable in the context of this document.

Compliance is checked by functional tests.

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

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

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

NOTE 2 If a COMMUNICATOR is equipped with additional set of auditory ALARM SIGNALS to comply with this subclause, it is optional to implement auditory ALARM SIGNALS compliant to Annex G of IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020.

208.5.2.1 Instructions for use

Addition:

NOTE 101 In the listing and description of every possible ALARM CONDITION only these conditions with a remaining HAZARDOUS SITUATION beside the safe state of the PD EQUIPMENT are sufficient.