IEC 60601-2-39

Edition 3.0 2018-04
REDLINE VERSION

INTERNATIONAL STANDARD

colour inside

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

IEC 60601-2-39:2018-04 RLV(en)

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis 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 60601-2-39 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published in 2007. This edition constitutes a technical revision.

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

a) update of the 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 and of references and requirements to IEC 60601-1-11:2015;

b) editorial improvements;

c) improvement of the essential performance requirements clause/subclauses;

d) new requirements for the interruption of the power supply.

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

FDIS	Report on voting
62D/1558/FDIS	62D/1586/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.

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.

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 publication using a colour printer.

INTRODUCTION

The minimum safety requirements specified in this particular standard 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 basic safety and essential performance of peritoneal dialysis 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 PERITONEAL DIALYSIS ME EQUIPMENT as defined in 201.3.208, 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.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this document are not covered by specific requirements in this document except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

This document can also be applied to PD EQUIPMENT used for compensation or alleviation of disease, injury or disability.

These particular requirements do not apply to the DIALYSING SOLUTION, or the DIALYSING SOLUTION CIRCUIT.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for PD EQUIPMENT as defined in 201.3.208.

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.

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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.*

~~The requirements of IEC 60601-1-3 and IEC 60601-1-8 do not apply to this standard.~~

IEC 60601-1-2:2014, IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, and IEC 60601-1-11:2015 apply as modified in Clauses 202, 208 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 do 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 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 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 60601-1-9:2007, *Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design*~~

~~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 60601-1-11:2015, *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*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions specified 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 60601-1-11:2015 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 28.

Addition:

201.3.201
APD ME EQUIPMENT
ME EQUIPMENT used to perform AUTOMATED PERITONEAL DIALYSIS ~~(APD)~~

201.3.202
AUTOMATED PERITONEAL DIALYSIS
APD
method to perform dialysis with automated fluid exchanges in the peritoneum

201.3.203
DIALYSING SOLUTION
PD SOLUTION
~~a pharmaceutical preparation (solution), according to the relevant pharmacopoeia monograph, for use with PD EQUIPMENT~~

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.

201.3.204
DIALYSING SOLUTION CIRCUIT
part of the fluid circuit that conveys DIALYSING SOLUTION from the PD EQUIPMENT to the peritoneal cavity of the PATIENT, and subsequently to a drainage bag or drain, or parts permanently and conductively connected to the fluid circuit

Note 1 to entry: This is an APPLIED PART.

201.3.205
INFLOW
phase during which the peritoneal cavity is filled

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

201.3.206
OUTFLOW
phase during which the peritoneal cavity is emptied

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

201.3.207
PERITONEAL DIALYSIS
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 may be left in the peritoneal cavity for a dwell time or may be continuously exchanged.

201.3.208
PERITONEAL DIALYSIS ME EQUIPMENT
PD EQUIPMENT
ME EQUIPMENT used to perform PERITONEAL DIALYSIS including APD ME EQUIPMENT

201.3.209
PROTECTIVE SYSTEM
automatic system, or a constructional feature, specifically designed to protect the PATIENT against ~~HAZARDS which can arise~~ HAZARDOUS SITUATIONS

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

~~Additional ESSENTIAL PERFORMANCE requirements:~~

~~– DIALYSING SOLUTION flow to the patient;~~

~~– DIALYSING SOLUTION flow from the patient;~~

~~– temperature of dialysate;~~

~~– adherence to and accuracy of the volume balancing (inflow/outflow volume).~~

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.

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 Some ESSENTIAL PERFORMANCES listed in Table 201.101 are dependent on the characteristics of the disposables.

201.4.3.102 * DIALYSING SOLUTION flow rate during INFLOW/OUTFLOW

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

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

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.*

– *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. The flow restrictor may for example be a 60 cm silicone tube of 2,67 mm inner diameter.*

– *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 5 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 5 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 5 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 5 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.*

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 of the PD EQUIPMENT shall be achieved as specified by the MANUFACTURER.

NOTE 1 A DIALYSING SOLUTION volume imbalance larger than the set value is considered as more negative for a typical treatment.

Compliance is checked under the following test conditions:

Test for APD ME 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. The flow restrictor may for example be a 60 cm silicone tube of 2,67 mm inner diameter.*

– *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 INFLOW 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 INFLOW 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 INFLOW 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 INFLOW and OUTFLOW phases, respectively, by recording the weight of the simulated PATIENT at the start and the end of each phase.*

NOTE 2 For tidal PD EQUIPMENT, use a partially filled simulated PATIENT fluid bag.

The values of the DIALYSING SOLUTION volume accuracies 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 functional tests relevant for the definition of dialysis dwell time specified by the MANUFACTURER.

201.4.3.105 DIALYSING SOLUTION composition

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

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

Compliance is checked under the following test conditions:

– *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.*
– *Connect the PD EQUIPMENT to an appropriately sized empty fluid bag simulating the PATIENT's peritoneal cavity ("simulated PATIENT").*
– *Measure the temperature at the simulated PATIENT inlet.*
– *Record the temperature during 5 INFLOW phases.*
– *Set the lowest DIALYSING SOLUTION flow.*
– *Measure the temperature at the simulated PATIENT inlet.*

– *Record the temperature during 5 INFLOW phases.*

The values of the DIALYSING SOLUTION 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:

201.4.7.101 NORMAL CONDITION and SINGLE FAULT CONDITION for ~~PD~~ ME EQUIPMENT

Failure of any PROTECTIVE SYSTEM. Example of SINGLE FAULT CONDITION: 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 ~~of PD~~ ME EQUIPMENT

Clause 5 of the general standard 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 DIALYSING SOLUTION, the temperature of the DIALYSING SOLUTION at the start of the test shall be less than 4 °C or the minimum temperature specified by the MANUFACTURER.

bb) If temperatures of storage and transport conditions can influence NORMAL USE shortly after transport, this shall be addressed by the RISK MANAGEMENT PROCESS.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ~~PD~~ ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.1 General

Addition:

The ACCOMPANYING DOCUMENTS shall additionally include

– a statement that protective measures should be taken to prevent back syphonage of the OUTFLOW path.

EXAMPLE 101 A statement pointing out the importance of an air gap between the DIALYSING SOLUTION circuit and the drain in order to prevent back syphonage 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 of the need for back syphonage protection and the PATIENT's responsibility to ensure that it is done correctly.

201.7.9.2 Instructions for use

Additional subclause:

201.7.9.2.101 Additional requirements regarding PD EQUIPMENT

The instructions for use shall additionally include the following:

a) a description of the method(s) by which any necessary disinfection or sterilization is achieved;

b) a statement that the test procedure by which the effectiveness of any sterilization or disinfection has been verified is available upon request;

c) a statement which draws the operator's attention to the hazards associated with the connection and disconnection of the patient;

d) an explanation of the operator's actions required to respond to alarm signals from any protective system;

e) a list of recommended dialysing solution circuits for use with the pd equipment;

f) a statement on the possible hazards associated with electromagnetic radiation which can affect the safe operation of the me equipment. This statement should include examples of typical me equipment which can generate such radiation and also take account of potential conditions in domestic environments;

g) a statement of the importance of the quality of the protective earth in the installation when CLASS I ME EQUIPMENT is used;

h) a statement of the applications in which a POTENTIAL EQUALIZATION CONDUCTOR should be used;

i) a statement that draws the OPERATOR'S attention to potential HAZARDS arising from improper installation and connection of the DIALYSING ~~FLUID~~ SOLUTION CIRCUIT;

j) a statement that draws the OPERATOR's attention to potential HAZARDS relating to inappropriate selection of the DIALYSING SOLUTION.

k) descriptions about the behaviours of PD EQUIPMENT out of the NORMAL USE condition defined in its specification.

Compliance is checked by inspection of the instructions for use.

201.7.9.3 Technical description

Additional subclause:

201.7.9.3.101 Additional requirements regarding PD EQUIPMENT

The technical description shall additionally include the following:

a) the particular measures or conditions to be observed when installing the PD EQUIPMENT or bringing it into use, including guidance on the type and number of tests to be carried out;

b) the type and accuracy of the PROTECTIVE SYSTEM required in 201.12.4.4.101;

c) the time by which the ~~audible~~ auditory ALARM SIGNAL required in 201.12.4.4.101 b) and 201.12.4.4.105 b) may be delayed;

d) the ~~audible alarm silence~~ AUDIO PAUSED period;

e) the range of sound pressure levels of any adjustable ~~audible~~ auditory ALARM SIGNAL;

f) the maximum positive and/or negative pressures that can be generated by any pumps used to assist the transfer of DIALYSING SOLUTION to and/or from the peritoneal cavity of the PATIENT;

~~g) NOTE~~ the MANUFACTURER shall specify where and how the maximum pressure was obtained;

g) the method and the sensitivity employed for the PROTECTIVE SYSTEM required by 201.12.4.4.103;

h) the method and the sensitivity employed for the PROTECTIVE SYSTEM required by 201.12.4.4.104.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.8 Protection against electrical HAZARDS from ~~PD~~ ME EQUIPMENT

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

201.8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

201.8.7.4 Measurements

201.8.7.4.7 Measurement of the PATIENT LEAKAGE CURRENT

Amendment:

Delete item h).

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.

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 Overflow, spillage, leakage, ingress of ~~liquids~~ 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 the DIALYSING SOLUTION.

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 ~~CONDITION~~ 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 ~~HAZARD~~ HAZARDOUS SITUATION. In case of doubt, the PD EQUIPMENT shall be subjected to the dielectric strength test described in 8.8.3 of the general standard, and the PD EQUIPMENT shall function as intended.

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

Addition:

a) PD 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 PD EQUIPMENT, the following safe conditions shall be achieved:

- activation of an auditory ALARM SIGNAL, lasting for at least 1 min, if the DIALYZING SOLUTION flow to or from the PATIENT is not stopped completely;
- additional measures may 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.

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

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

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 a visual ALARM SIGNAL;
- in case of external powered operation, 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 PD 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 PD 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 ~~Protection against hazardous~~ Incorrect output

Addition:

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 may 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 lower 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) ~~The operation~~ Activation of the PROTECTIVE SYSTEM shall achieve the following safe conditions:

– stopping of the DIALYSING SOLUTION and thermal flow to the PATIENT;

– activation of ~~an audible~~ auditory and visual ALARM SIGNALS.
~~NOTE~~ The ~~audible~~ auditory ALARM SIGNAL 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 inspection of the ACCOMPANYING DOCUMENTS and~~ 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 ~~HAZARD~~ 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) ~~The operation~~ 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 ~~an audible~~ auditory and visual ALARM SIGNALS.

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

201.12.4.4.104 DIALYSING SOLUTION overfill

a) The PD EQUIPMENT shall be provided with a PROTECTIVE SYSTEM which prevents excessive fluid being delivered to the peritoneal cavity and causing a ~~HAZARD~~ HAZARDOUS SITUATION.

b) ~~The operation~~ Activation of the PROTECTIVE SYSTEM shall achieve the following safe conditions:

– stopping of the DIALYSING SOLUTION flow to the PATIENT;

– activation of ~~an audible~~ auditory and visual ALARM SIGNALS.

Compliance is checked ~~by inspection of the ACCOMPANYING DOCUMENTS and~~ 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, may cause a HAZARDOUS SITUATION.

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

– stopping of the DIALYSING SOLUTION and diffusive flow to 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 DIALYSIS FLUID, which is quality controlled for the DIALYSIS FLUID composition, and is not changed in composition by the PD EQUIPMENT, for example using pre-manufactured DIALYSIS FLUID bags.

Compliance is checked by functional tests.

201.12.4.4.106 PROTECTIVE SYSTEMS

Any failure of the PROTECTIVE SYSTEMS required by 201.12.4.4 shall become obvious to the OPERATOR ~~at the beginning of the~~ 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.

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

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of the general standard applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

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

201.15.4 ME EQUIPMENT components and general assembly

Additional subclauses:

201.15.4.101 DIALYSING SOLUTION CIRCUIT guides

If an incorrect installation of the DIALYSING SOLUTION CIRCUIT can cause a ~~HAZARD~~ 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.

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 80369-1:2010.

201.15.4.102 OUTFLOW

OUTFLOW shall be available at all times during a therapy.

~~NOTE From time to time~~ During the PROCEDURE, it might be necessary to restrict the OUTFLOW 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.

201.16 ME SYSTEMS

Clause 16 of the general standard applies.

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**~~

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: The ME EQUIPMENT or ME SYSTEM should continue to operate as intended without OPERATOR intervention. No degradation of performance 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 should continue to operate as intended without OPERATOR intervention. No degradation of performance is allowed below the performance level specified by the MANUFACTURER, when the ME EQUIPMENT or ME SYSTEM is used as intended. During the test, degradation of performance is allowed.

- 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 PD 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

202.8.9 IMMUNITY TEST LEVELS

Addition:

NOTE 101 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 centers, intensive care units or dialysis departments in hospitals).

~~203 General requirements for radiation protection in diagnostic X-ray equipment~~

~~IEC 60601-1-3:2008 does not apply.~~

~~206 Usability~~

~~IEC 60601-1-6:2006 applies.~~

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

IEC 60601-1-8:2006 ~~does not apply~~ and IEC 60601-1-8:2006/AMD1:2012 applies except as follows:

208.6.1.2 Determination of ALARM CONDITIONS and assignment of priority

Addition:

ALARM CONDITIONS shall be assigned to high priority, medium priority, or low priority based on the MANUFACTURER'S RISK MANAGEMENT PROCESS. This assignment should follow Table 1 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012. As the PATIENT RISKS in PD are generally low, it may be acceptable to deviate from Table 1 by assigning higher priorities even to lower RISK conditions, especially in the HOME HEALTHCARE ENVIRONMENT.

208.6.3.2.2.1 4 m (distant) visual ALARM SIGNALS

Addition:

Subclause 6.3.2.2.1 and Table 2 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 both do not apply to PD EQUIPMENT intended for use in HOME HEALTHCARE ENVIRONMENT solely, as there is generally only one single machine the OPERATOR (usually the PATIENT) uses.

208.6.3.3 Auditory ALARM SIGNALS

208.6.3.3.1 Characteristics of auditory ALARM SIGNALS

Addition:

If the PD EQUIPMENT is only intended for use in the HOME HEALTHCARE ENVIRONMENT, it is acceptable for the MANUFACTURER to use auditory ALARM SIGNALS deviating from 6.3.3.1 of

IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, in order to meet the needs of a sleeping PATIENT who usually is the OPERATOR of the PD EQUIPMENT.

208.6.3.3.2 Volume and characteristics of auditory ALARM SIGNALS and INFORMATION SIGNALS

Addition:

In the default setting by the MANUFACTURER the PD EQUIPMENT shall generate an alarm sound pressure level of at least 65 dB(A) at a distance of 1 m.

NOTE 101 An algorithm that escalates unresolved active auditory ALARM SIGNALS by increasing their sound pressure level over time can be appropriate for a sleeping PATIENT who usually is the OPERATOR.

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 PD 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 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 ~~the reduction of environmental impacts~~ environmentally conscious design

IEC 60601-1-9:2007 ~~applies~~ 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 PERITONEAL DIALYSIS.

~~210 Process requirements for the development of physiologic closed-loop controllers~~

~~IEC 60601-1-10:2007 applies.~~

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:

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

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

The following is the rationale for a specific clause in this particular standard, with the subclause number parallel to that in the body of the document.

Subclause 201.4.3.102 – DIALYSING SOLUTION flow rate during INFLOW/OUTFLOW

In tidal flow PERITONEAL DIALYSIS and continuous flow PERITONEAL DIALYSIS, the effective rate of fluid replacement is more indicative for performance than the individual INFLOW and OUTFLOW rates.

For devices using such techniques, the test methods may thus be modified to measure the effective rate of fluid replacement, as indicated by the total time required to fill and drain a given volume of dialysis fluid in consecutive INFLOW and OUTFLOW phases.

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 item is an example for additional measures which may be necessary;

– stopping of the INFLOW / OUTFLOW to/from the PATIENT.

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

PD EQUIPMENT in most cases is used in the HOME HEALTHCARE CARE ENVIRONMENT. As the use in ambulatory care or intensive care environments is very rare, the ALARM SYSTEMS for ~~home care use~~ PD EQUIPMENT used in HOME HEALTHCARE ENVIRONMENT need a different focus~~, as written in~~ compared to the focus of the IEC 60601-1-8.

Bibliography

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 60601-1-9:2007, *Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design*
IEC 60601-1-9:2007/AMD1:2013

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

ISO 80369-1:2010, *Small-bore connectors for liquids and gases in healthcare applications – Part 1: General requirements*

Index of defined terms used in this particular standard

SUPPLY MAINS ..... IEC 60601-1:2005, 3.120

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IEC 60601-2-39

Edition 3.0 2018-04

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 2-39: Particular requirements for 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

IEC 60601-2-39:2018-04(en-fr)

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis 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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9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International standard IEC 60601-2-39 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published in 2007. This edition constitutes a technical revision.

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

a) update of the 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 and of references and requirements to IEC 60601-1-11:2015;

b) editorial improvements;

c) improvement of the essential performance requirements clause/subclauses;

d) new requirements for the interruption of the power supply.

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

FDIS	Report on voting
62D/1558/FDIS	62D/1586/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.

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 PERITONEAL DIALYSIS ME EQUIPMENT.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis 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 PERITONEAL DIALYSIS ME EQUIPMENT as defined in 201.3.208, 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.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this document are not covered by specific requirements in this document except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

This document can also be applied to PD EQUIPMENT used for compensation or alleviation of disease, injury or disability.

These particular requirements do not apply to the DIALYSING SOLUTION, or the DIALYSING SOLUTION CIRCUIT.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for PD EQUIPMENT as defined in 201.3.208.

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.

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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.*

IEC 60601-1-2:2014, IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, and IEC 60601-1-11:2015 apply as modified in Clauses 202, 208 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 do 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 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 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 60601-1-11:2015, *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*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions specified 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 60601-1-11:2015 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 27.

Addition:

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
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.

201.3.204
DIALYSING SOLUTION CIRCUIT
part of the fluid circuit that conveys DIALYSING SOLUTION from the PD EQUIPMENT to the peritoneal cavity of the PATIENT, and subsequently to a drainage bag or drain, or parts permanently and conductively connected to the fluid circuit

Note 1 to entry: This is an APPLIED PART.

201.3.205
INFLOW
phase during which the peritoneal cavity is filled

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

201.3.206
OUTFLOW
phase during which the peritoneal cavity is emptied

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

201.3.207
PERITONEAL DIALYSIS
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 may be left in the peritoneal cavity for a dwell time or may be continuously exchanged.

201.3.208
PERITONEAL DIALYSIS ME EQUIPMENT
PD EQUIPMENT
ME EQUIPMENT used to perform PERITONEAL DIALYSIS including APD ME EQUIPMENT

201.3.209
PROTECTIVE SYSTEM
automatic system, or a constructional feature, specifically designed to protect the PATIENT against HAZARDOUS SITUATIONS

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 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.

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 Some ESSENTIAL PERFORMANCES listed in Table 201.101 are dependent on the characteristics of the disposables.

201.4.3.102 * DIALYSING SOLUTION flow rate during INFLOW/OUTFLOW

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

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

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.*

– *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. The flow restrictor may for example be a 60 cm silicone tube of 2,67 mm inner diameter.*

– *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 5 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 5 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 5 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 5 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.*

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 of the PD EQUIPMENT shall be achieved as specified by the MANUFACTURER.

NOTE 1 A DIALYSING SOLUTION volume imbalance larger than the set value is considered as more negative for a typical treatment.

Compliance is checked under the following test conditions:

Test for APD ME 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. The flow restrictor may for example be a 60 cm silicone tube of 2,67 mm inner diameter.*
– *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 INFLOW 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 INFLOW 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 INFLOW 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 INFLOW and OUTFLOW phases, respectively, by recording the weight of the simulated PATIENT at the start and the end of each phase.*

NOTE 2 For tidal PD EQUIPMENT, use a partially filled simulated PATIENT fluid bag.

The values of the DIALYSING SOLUTION volume accuracies 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 functional tests relevant for the definition of dialysis dwell time specified by the MANUFACTURER.

201.4.3.105 DIALYSING SOLUTION composition

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

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

Compliance is checked under the following test conditions:

– *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.*
– *Connect the PD EQUIPMENT to an appropriately sized empty fluid bag simulating the PATIENT's peritoneal cavity ("simulated PATIENT").*
– *Measure the temperature at the simulated PATIENT inlet.*
– *Record the temperature during 5 INFLOW phases.*
– *Set the lowest DIALYSING SOLUTION flow.*
– *Measure the temperature at the simulated PATIENT inlet.*
– *Record the temperature during 5 INFLOW phases.*

The values of the DIALYSING SOLUTION 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:

201.4.7.101 NORMAL CONDITION and SINGLE FAULT CONDITION for ME EQUIPMENT

Failure of any PROTECTIVE SYSTEM. Example of SINGLE FAULT CONDITION: 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 the general standard 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 DIALYSING SOLUTION, the temperature of the DIALYSING SOLUTION at the start of the test shall be less than 4 °C or the minimum temperature specified by the MANUFACTURER.

bb) If temperatures of storage and transport conditions can influence NORMAL USE shortly after transport, this shall be addressed by the RISK MANAGEMENT PROCESS.

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:

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.1 General

Addition:

The ACCOMPANYING DOCUMENTS shall additionally include

– a statement that protective measures should be taken to prevent back syphonage of the OUTFLOW path.

EXAMPLE 101 A statement pointing out the importance of an air gap between the DIALYSING SOLUTION circuit and the drain in order to prevent back syphonage 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 of the need for back syphonage protection and the PATIENT's responsibility to ensure that it is done correctly.

201.7.9.2 Instructions for use

Additional subclause:

201.7.9.2.101 Additional requirements regarding PD EQUIPMENT

The instructions for use shall additionally include the following:

a) a description of the method(s) by which any necessary disinfection or sterilization is achieved;

b) a statement that the test procedure by which the effectiveness of any sterilization or disinfection has been verified is available upon request;

c) a statement which draws the operator's attention to the hazards associated with the connection and disconnection of the patient;

d) an explanation of the operator's actions required to respond to alarm signals from any protective system;

e) a list of recommended dialysing solution circuits for use with the pd equipment;

f) a statement on the possible hazards associated with electromagnetic radiation which can affect the safe operation of the me equipment. This statement should include examples of typical me equipment which can generate such radiation and also take account of potential conditions in domestic environments;

g) a statement of the importance of the quality of the protective earth in the installation when CLASS I ME EQUIPMENT is used;

h) a statement of the applications in which a POTENTIAL EQUALIZATION CONDUCTOR should be used;

i) a statement that draws the OPERATOR'S attention to potential HAZARDS arising from improper installation and connection of the DIALYSING SOLUTION CIRCUIT;

j) a statement that draws the OPERATOR's attention to potential HAZARDS relating to inappropriate selection of the DIALYSING SOLUTION.

k) descriptions about the behaviours of PD EQUIPMENT out of the NORMAL USE condition defined in its specification.

Compliance is checked by inspection of the instructions for use.

201.7.9.3 Technical description

Additional subclause:

201.7.9.3.101 Additional requirements regarding PD EQUIPMENT

The technical description shall additionally include the following:

a) the particular measures or conditions to be observed when installing the PD EQUIPMENT or bringing it into use, including guidance on the type and number of tests to be carried out;

b) the type and accuracy of the PROTECTIVE SYSTEM required in 201.12.4.4.101;

c) the time by which the auditory ALARM SIGNAL required in 201.12.4.4.101 b) and 201.12.4.4.105 b) may be delayed;

d) the AUDIO PAUSED period;

e) the range of sound pressure levels of any adjustable auditory ALARM SIGNAL;

f) the maximum positive and/or negative pressures that can be generated by any pumps used to assist the transfer of DIALYSING SOLUTION to and/or from the peritoneal cavity of the PATIENT; the MANUFACTURER shall specify where and how the maximum pressure was obtained;

g) the method and the sensitivity employed for the PROTECTIVE SYSTEM required by 201.12.4.4.103;

h) the method and the sensitivity employed for the PROTECTIVE SYSTEM required by 201.12.4.4.104.

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:

201.8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

201.8.7.4 Measurements

201.8.7.4.7 Measurement of the PATIENT LEAKAGE CURRENT

Amendment:

Delete item h).

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.

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 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 the DIALYSING SOLUTION.

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 the general standard, and the PD EQUIPMENT shall function as intended.

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

Addition:

a) PD 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 PD EQUIPMENT, the following safe conditions shall be achieved:

- activation of an auditory ALARM SIGNAL, lasting for at least 1 min, if the DIALYZING SOLUTION flow to or from the PATIENT is not stopped completely;
- additional measures may 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.

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

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

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 a visual ALARM SIGNAL;
- in case of external powered operation, 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 PD 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 PD 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:

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 may 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 lower 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 auditory ALARM SIGNAL 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.

Compliance is checked by functional tests.

201.12.4.4.104 DIALYSING SOLUTION overfill

a) The PD EQUIPMENT shall be provided with a PROTECTIVE SYSTEM which prevents excessive fluid being delivered 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.

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, may cause a HAZARDOUS SITUATION.

b) Activation of the PROTECTIVE SYSTEM shall achieve the following safe conditions:
   - stopping of the DIALYSING SOLUTION and diffusive flow to 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 DIALYSIS FLUID, which is quality controlled for the DIALYSIS FLUID composition, and is not changed in composition by the PD EQUIPMENT, for example using pre-manufactured DIALYSIS FLUID bags.

Compliance is checked by functional tests.

201.12.4.4.106 PROTECTIVE SYSTEMS

Any failure of the PROTECTIVE SYSTEMS required by 201.12.4.4 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.

Compliance is checked by functional tests and failure simulations.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of the general standard applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

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

201.15.4 ME EQUIPMENT components and general assembly

Additional subclauses:

201.15.4.101 DIALYSING SOLUTION CIRCUIT guides

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.

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 80369-1:2010.

201.15.4.102 OUTFLOW

OUTFLOW shall be available at all times during a therapy.

During the PROCEDURE, it might be necessary to restrict the OUTFLOW 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.

201.16 ME SYSTEMS

Clause 16 of the general standard applies.

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 PERITONEAL DIALYSIS EQUIPMENT:

- BASIC SAFETY functions: The ME EQUIPMENT or ME SYSTEM should continue to operate as intended without OPERATOR intervention. No degradation of performance 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 should continue to operate as intended without OPERATOR intervention. No degradation of performance is allowed below the performance level specified by the MANUFACTURER, when the ME EQUIPMENT or ME SYSTEM is used as intended. During the test, degradation of performance is allowed.
- 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 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 101 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 centers, intensive care units 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 and IEC 60601-1-8:2006/AMD1:2012 applies except as follows:

208.6.1.2 Determination of ALARM CONDITIONS and assignment of priority

Addition:

ALARM CONDITIONS shall be assigned to high priority, medium priority, or low priority based on the MANUFACTURER'S RISK MANAGEMENT PROCESS. This assignment should follow Table 1 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012. As the PATIENT RISKS in PD are generally low, it may be acceptable to deviate from Table 1 by assigning higher priorities even to lower RISK conditions, especially in the HOME HEALTHCARE ENVIRONMENT.

208.6.3.2.2.1 4 m (distant) visual ALARM SIGNALS

Addition:

Subclause 6.3.2.2.1 and Table 2 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 both do not apply to PD EQUIPMENT intended for use in HOME HEALTHCARE ENVIRONMENT solely, as there is generally only one single machine the OPERATOR (usually the PATIENT) uses.

208.6.3.3 Auditory ALARM SIGNALS

208.6.3.3.1 Characteristics of auditory ALARM SIGNALS

Addition:

If the PD EQUIPMENT is only intended for use in the HOME HEALTHCARE ENVIRONMENT, it is acceptable for the MANUFACTURER to use auditory ALARM SIGNALS deviating from 6.3.3.1 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, in order to meet the needs of a sleeping PATIENT who usually is the OPERATOR of the PD EQUIPMENT.

208.6.3.3.2 Volume and characteristics of auditory ALARM SIGNALS and INFORMATION SIGNALS

Addition:

In the default setting by the MANUFACTURER the PD EQUIPMENT shall generate an alarm sound pressure level of at least 65 dB(A) at a distance of 1 m.

NOTE 101 An algorithm that escalates unresolved active auditory ALARM SIGNALS by increasing their sound pressure level over time can be appropriate for a sleeping PATIENT who usually is the OPERATOR.

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 PD 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 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 PERITONEAL DIALYSIS.

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:

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

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

The following is the rationale for a specific clause in this particular standard, with the subclause number parallel to that in the body of the document.

Subclause 201.4.3.102 – DIALYSING SOLUTION flow rate during INFLOW/OUTFLOW

In tidal flow PERITONEAL DIALYSIS and continuous flow PERITONEAL DIALYSIS, the effective rate of fluid replacement is more indicative for performance than the individual INFLOW and OUTFLOW rates.

For devices using such techniques, the test methods may thus be modified to measure the effective rate of fluid replacement, as indicated by the total time required to fill and drain a given volume of dialysis fluid in consecutive INFLOW and OUTFLOW phases.

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 item is an example for additional measures which may be necessary;

– stopping of the INFLOW / OUTFLOW to/from the PATIENT.

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

PD EQUIPMENT in most cases is used in the HOME HEALTHCARE CARE ENVIRONMENT. As the use in ambulatory care or intensive care environments is very rare, the ALARM SYSTEMS for PD EQUIPMENT used in HOME HEALTHCARE ENVIRONMENT need a different focus compared to the focus of the IEC 60601-1-8.

Bibliography

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 60601-1-9:2007, *Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design*
IEC 60601-1-9:2007/AMD1:2013

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

ISO 80369-1:2010, *Small-bore connectors for liquids and gases in healthcare applications – Part 1: General requirements*

Index of defined terms used in this particular standard

SUPPLY MAINS ..... IEC 60601-1:2005, 3.120

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COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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APPAREILS ÉLECTROMÉDICAUX –

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

AVANT-PROPOS

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La Norme internationale IEC 60601-2-39 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 troisième édition annule et remplace la deuxième édition publiée en 2007. 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, et des références et des exigences à l'IEC 60601-1-11:2015;

b) améliorations d'ordre rédactionnel;

c) amélioration des articles/paragraphes traitant des exigences relatives aux performances essentielles;

d) nouvelles exigences concernant la coupure de l'alimentation.

Le texte de cette norme particulière est issu des documents suivants:

FDIS	Rapport de vote
62D/1558/FDIS	62D/1586/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.

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 EM DE DIALYSE PERITONEALE.

APPAREILS ÉLECTROMÉDICAUX –

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

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 EM DE DIALYSE PERITONEALE, définis en 201.3.208, désignés ci-après sous le terme d'APPAREILS DP. Elle s'applique aux APPAREILS DP destinés à être utilisés soit par le personnel médical soit sous la supervision d'experts médicaux, y compris les APPAREILS DP mis en fonctionnement par le PATIENT, que l'APPAREIL DP soit utilisé dans un hôpital ou dans un environnement domestique.

Si un article ou un paragraphe est spécifiquement destiné à être applicable uniquement aux APPAREILS EM ou uniquement aux SYSTEMES EM, le titre et le contenu de cet article ou de ce paragraphe l'indique. Si cela n'est pas le cas, l'article ou le paragraphe s'applique à la fois aux APPAREILS EM et aux SYSTEMES EM, selon le cas.

Les DANGERS inhérents à la fonction physiologique prévue des APPAREILS EM ou des SYSTEMES EM dans le cadre du domaine d'application du présent document ne sont pas couverts par des exigences spécifiques contenues dans le présent document à l'exception de 7.2.13 et de 8.4.1 de la norme générale.

NOTE Voir aussi 4.2 de la norme générale.

Le présent document peut également être appliqué aux APPAREILS DP utilisés pour le traitement ou le soulagement des maladies, des blessures ou des incapacités.

Ces exigences particulières ne s'appliquent pas à la SOLUTION DE DIALYSE, ou au CIRCUIT DE LA SOLUTION DE DIALYSE.

201.1.2 Objet

Remplacement:

L'objet de la présente norme particulière est d'établir des exigences particulières pour la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES des APPAREILS DP définis en 201.3.208.

201.1.3 Normes collatérales

Addition:

[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.*

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, et l'IEC 60601-1-11:2015 s'appliquent telles que modifiées dans les Articles 202, 208 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 60601-1-11:2015, *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*

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 et l'IEC 60601-1-8:2006/AMD1:2012, l'IEC 60601-1-10:2007 et l'IEC 60601-1-10:2007/AMD1:2013, l'IEC 60601-1-11:2010, 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 56.

Addition:

201.3.201
APPAREIL EM DPA
APPAREIL EM utilisé pour réaliser la DIALYSE PERITONEALE AUTOMATISEE

201.3.202
DIALYSE PERITONEALE AUTOMATISEE
DPA
méthode en vue de réaliser une dialyse avec échanges liquidiens automatisés dans le péritoine

201.3.203
SOLUTION DE DIALYSE
SOLUTION DP
liquide aqueux contenant des électrolytes et, en général, des tampons et du glucose, destiné à échanger des solutés au cours d'une DIALYSE PERITONEALE

Note 1 à l'article: La SOLUTION DE DIALYSE peut être pré-produite dans des poches comme des médicaments, selon la monographie de pharmacopée correspondante, ou être préparée par l'APPAREIL DP. L'APPAREIL DP peut également agir sur sa composition.

201.3.204
CIRCUIT DE LA SOLUTION DE DIALYSE
partie du circuit de liquide qui transporte la SOLUTION DE DIALYSE de l'APPAREIL DP à la cavité péritonéale du PATIENT, et par la suite à une poche de drainage ou à un drain, ou des parties qui lui sont électriquement reliées en continu

Note 1 à l'article: Il s'agit d'une PARTIE APPLIQUEE.

201.3.205
INFLUX
phase au cours de laquelle la cavité péritonéale est remplie

Note 1 à l'article: Le terme "remplissage" est communément utilisé comme synonyme de "INFLUX".

201.3.206
ECOULEMENT
phase au cours de laquelle la cavité péritonéale est vidée

Note 1 à l'article: Le terme "drain" est communément utilisé comme synonyme "d'ECOULEMENT".

201.3.207
DIALYSE PERITONEALE
PROCESSUS par lequel la SOLUTION DE DIALYSE est introduite dans la cavité péritonéale du PATIENT puis retirée de celle-ci

Note 1 à l'article: La SOLUTION DE DIALYSE peut être maintenue dans la cavité péritonéale pendant un laps de temps donné ou peut être échangée en continu.

201.3.208
APPAREIL EM DE DIALYSE PERITONEALE
APPAREIL DP
APPAREIL EM utilisé pour réaliser la DIALYSE PERITONEALE comprenant l'APPAREIL EM DPA

201.3.209
SYSTEME DE PROTECTION
système automatique, ou caractéristique de construction, spécialement conçu(e) pour protéger le PATIENT contre les SITUATIONS DANGEREUSES

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 DP 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
Débit de la SOLUTION DE DIALYSE en cours d'INFLUX/ECOULEMENT	201.4.3.102
Equilibrage du volume de la SOLUTION DE DIALYSE (volume de l'INFLUX/ECOULEMENT)	201.4.3.103
Temps pendant lequel la solution est maintenue dans la cavité péritonéale au cours de la DIALYSE PERITONEALE	201.4.3.104
Composition de la SOLUTION DE DIALYSE	201.4.3.105
Température de la SOLUTION DE DIALYSE	201.4.3.106

NOTE Certaines des PERFORMANCES ESSENTIELLES énumérées dans le Tableau 201.101 dépendent des caractéristiques des éléments jetables.

201.4.3.102 * Débit de la SOLUTION DE DIALYSE en cours d'INFLUX/ECOULEMENT

L'exactitude du débit de la SOLUTION DE DIALYSE fournie par l'APPAREIL DP en cours d'INFLUX/ECOULEMENT provenant du PATIENT et se dirigeant vers lui doit être spécifiée par le FABRICANT.

NOTE Un débit de SOLUTION DE DIALYSE en cours d'INFLUX/ECOULEMENT inférieur à la valeur de consigne est considéré comme préjudiciable pour un traitement type.

La conformité est vérifiée dans les conditions d'essai suivantes:

– *Définir un volume de remplissage ou un volume de cycle de 2,0 l pour l'APPAREIL DP, ou un volume de remplissage ou un volume de cycle approprié spécifié par le FABRICANT.*

– *Connecter l'APPAREIL DP à un PATIENT simulé comprenant les éléments suivants:*

  - *Une poche de liquide vide ou partiellement remplie de dimensions appropriées simulant la cavité péritonéale du PATIENT, et*
  - *Un limiteur de débit en ligne entre l'APPAREIL DP et la poche de liquide, simulant la résistance de débit combinée du cathéter péritonéal, du nécessaire de transfert et du connecteur de liquide, conformément aux recommandations du FABRICANT. Le limiteur de débit peut, par exemple, être un tube de silicone de 60 cm de long et de 2,67 mm de diamètre intérieur.*

– *Définir la température de la SOLUTION DE DIALYSE à 37 °C, le cas échéant;*

– *Définir la durée minimale de cycle pour l'APPAREIL DP, ou un temps de maintien de la solution dans la cavité péritonéale de 0 min.*

– *Régler l'APPAREIL DP de sorte qu'il fonctionne jusqu'à ce que tous les composants de traitement de la SOLUTION DE DIALYSE soient amorcés.*

– *Placer le PATIENT simulé sur une balance située à 50 cm au-dessus de l'APPAREIL DP, ou à la hauteur maximale autorisée, tel que spécifié par le FABRICANT.*

– *Définir le débit d'INFLUX et le débit d'ECOULEMENT les plus élevés de la SOLUTION DE DIALYSE, le cas échéant.*

– *Mesurer le flux de la SOLUTION DE DIALYSE au cours de 5 phases d'INFLUX et d'ECOULEMENT, respectivement, en consignant la durée de chaque phase, et mesurer le poids de la poche de liquide au début et à la fin de chaque phase.*

– *Définir le débit d'INFLUX et le débit d'ECOULEMENT les plus faibles de la* SOLUTION DE DIALYSE, *le cas échéant.*

– *Mesurer le flux de la SOLUTION DE DIALYSE au cours de 5 phases d'INFLUX et d'ECOULEMENT, respectivement, en consignant la durée de chaque phase, et mesurer le poids de la poche de liquide au début et à la fin de chaque phase.*

– *Placer le PATIENT simulé sur une balance située à 50 cm en dessous de l'APPAREIL DP, ou à la hauteur minimale autorisée, tel que spécifié par le FABRICANT.*

– *Définir le débit d'INFLUX et le débit d'ECOULEMENT les plus élevés de la* SOLUTION DE DIALYSE, *le cas échéant.*

– *Mesurer le flux de la SOLUTION DE DIALYSE au cours de 5 phases d'INFLUX et d'ECOULEMENT, respectivement, en consignant la durée de chaque phase, et mesurer le poids de la poche de liquide au début et à la fin de chaque phase.*

– *Définir le débit d'INFLUX et le débit d'ECOULEMENT les plus faibles de la* SOLUTION DE DIALYSE, *le cas échéant.*

– *Mesurer le flux de la SOLUTION DE DIALYSE au cours de 5 phases d'INFLUX et d'ECOULEMENT, respectivement, en consignant la durée de chaque phase, et mesurer le poids de la poche de liquide au début et à la fin de chaque phase.*

Les valeurs de débit DE LA SOLUTION DE DIALYSE doivent se situer dans les tolérances spécifiées par le FABRICANT dans les instructions d'utilisation.

201.4.3.103 Équilibrage du volume de la SOLUTION DE DIALYSE (volume de l'INFLUX/ECOULEMENT)

L'exactitude du volume de l'INFLUX et de l'ECOULEMENT de la SOLUTION DE DIALYSE fournie par l'appareil dp doit être atteinte tel que spécifié par le FABRICANT.

NOTE 1 Un déséquilibre de volume de la SOLUTION DE DIALYSE supérieur à la valeur de consigne est considéré comme étant plus défavorable pour un traitement type.

La conformité est vérifiée dans les conditions d'essai suivantes:

Essai pour APPAREIL EM DPA

– *Définir le volume de remplissage ou le volume de cycle maximal pour l'APPAREIL DP.*

– *Connecter l'APPAREIL DP à un PATIENT simulé comprenant les éléments suivants:*

  - *Une poche de liquide vide ou partiellement remplie de dimensions appropriées simulant la cavité péritonéale du PATIENT, et*
  - *Un limiteur de débit en ligne entre l'APPAREIL DP et la poche de liquide, simulant la résistance de débit combinée du cathéter péritonéal, du nécessaire de transfert et du connecteur de liquide, conformément aux recommandations du FABRICANT. Le limiteur de débit peut, par exemple, être un tube de silicone de 60 cm de long et de 2,67 mm de diamètre intérieur.*

– *Définir la température de la* SOLUTION DE DIALYSE *à 37 °C, le cas échéant;*

– *Définir la durée minimale de cycle pour l'APPAREIL DP, ou un temps de maintien de la solution dans la cavité péritonéale de 0 min.*

– *Régler l'APPAREIL DP de sorte qu'il fonctionne jusqu'à ce que tous les composants de traitement de la SOLUTION DE DIALYSE soient amorcés.*

– *Placer le PATIENT simulé sur une balance située à 50 cm au-dessus de l'APPAREIL DP, ou à la hauteur maximale autorisée, tel que spécifié par le FABRICANT.*

– *Mesurer le volume de la SOLUTION DE DIALYSE au cours de 5 phases d'INFLUX et d'ECOULEMENT, respectivement, en consignant le poids du PATIENT simulé au début et à la fin de chaque phase.*

– *Placer le PATIENT simulé sur une balance située à 50 cm en dessous de l'APPAREIL DP, ou à la hauteur minimale autorisée, tel que spécifié par le FABRICANT.*

– *Mesurer le volume de la SOLUTION DE DIALYSE au cours de 5 phases d'INFLUX et d'ECOULEMENT, respectivement, en consignant le poids du PATIENT simulé au début et à la fin de chaque phase.*

– *Définir le volume de remplissage ou le volume de cycle minimal pour l'APPAREIL DP.*

– *Placer le PATIENT simulé sur une balance située à 50 cm au-dessus de l'APPAREIL DP, ou à la hauteur maximale autorisée, tel que spécifié par le FABRICANT.*

– *Mesurer le volume de la SOLUTION DE DIALYSE au cours de 5 phases d'INFLUX et d'ECOULEMENT, respectivement, en consignant le poids du PATIENT simulé au début et à la fin de chaque phase.*

– *Placer le PATIENT simulé sur une balance située à 50 cm en dessous de l'APPAREIL DP, ou à la hauteur maximale autorisée, tel que spécifié par le FABRICANT.*

– *Mesurer le volume de la SOLUTION DE DIALYSE au cours de 5 phases d'INFLUX et d'ECOULEMENT, respectivement, en consignant le poids du PATIENT simulé au début et à la fin de chaque phase.*

NOTE 2 Pour les APPAREILS DP à énergie cyclique, utiliser une poche de liquide partiellement remplie de PATIENT simulé.

Les valeurs correspondant aux exactitudes du volume de la SOLUTION DE DIALYSE *doivent se situer dans les tolérances spécifiées par le FABRICANT dans les instructions d'utilisation.*

201.4.3.104 Temps de maintien de la solution dans la cavité au cours de la DIALYSE PERITONEALE

La précision du temps de maintien de la solution dans la cavité au cours de la dialyse assurée par l'APPAREIL DP doit être telle que spécifiée par le FABRICANT.

La conformité est vérifiée par des essais fonctionnels appropriés relatifs à la définition du temps de maintien de la solution dans la cavité au cours de la dialyse spécifié par le FABRICANT.

201.4.3.105 Composition de la SOLUTION DE DIALYSE

La méthode d'essai applicable à la précision de la composition de la SOLUTION DE DIALYSE doit être spécifiée par le FABRICANT, et la conformité doit être vérifiée en conséquence.

NOTE Cet essai ne s'applique pas aux APPAREILS DP qui utilisent une SOLUTION DE DIALYSE pré-produite mise à disposition dans des poches.

201.4.3.106 Température de la SOLUTION DE DIALYSE

La température de la SOLUTION DE DIALYSE de l'APPAREIL DP doit être telle que spécifiée par le FABRICANT.

NOTE Cet essai s'applique uniquement aux APPAREILS Dp comprenant un chauffage pour la SOLUTION DE DIALYSE.

La conformité est vérifiée dans les conditions d'essai suivantes:

– *Laisser l'APPAREIL DP fonctionner jusqu'à ce qu'il atteigne des conditions thermiques stables.*

– *La température ambiante est comprise entre 20 °C et 25 °C.*

– *Définir la température de la* SOLUTION DE DIALYSE *à 37 °C, le cas échéant.*