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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)

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

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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.

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.*