IEC 60601-2-39

Edition 4.0 2024-12

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

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

IEC 60601-2-39:2024-12(en-fr)

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ELECTROTECHNICAL
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

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

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

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

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

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

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

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

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

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

In this document, the following print types are used:

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

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

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

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

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

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

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

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

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

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

- reconfirmed,
- withdrawn, or
- revised.

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

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

INTRODUCTION

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

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

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

201.1.1 Scope

Replacement:

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

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

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

This document specifies the minimum safety requirements for PD EQUIPMENT. These PD EQUIPMENT are intended for use either by medical staff or for use by the PATIENT or other trained personnel under medical supervision.

This document includes all ME EQUIPMENT that is intended to deliver a PERITONEAL DIALYSIS treatment to a PATIENT, independent of the treatment duration and location.

These particular requirements do not apply to:

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

[1] Numbers in square brackets refer to the Bibliography.

201.1.2 Object

Replacement:

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

201.1.3 Collateral standards

Addition:

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

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

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

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

201.1.4 Particular standards

Replacement:

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

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

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

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

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

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

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

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

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

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

201.2 Normative references

NOTE Informative references are listed in the Bibliography.

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

Addition:

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

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

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

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

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

201.3 Terms and definitions

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

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

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

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

201.3.8
*** APPLIED PART**

Replacement:

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

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

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

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

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

201.3.78
PATIENT CONNECTION

Addition:

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

Additional terms and definitions:

201.3.201
APD ME EQUIPMENT
ME EQUIPMENT used to perform AUTOMATED PERITONEAL DIALYSIS

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

201.3.203
CENTRAL DELIVERY SYSTEM
part of a ME SYSTEM which proportions DIALYSING SOLUTION CONCENTRATE and DIALYSIS WATER for distribution as DIALYSING SOLUTION to the PD EQUIPMENT or distributes DIALYSING SOLUTION CONCENTRATE

201.3.204
DIALYSING SOLUTION
PD SOLUTION
aqueous fluid containing electrolytes and, usually, buffer and glucose, and which is intended to exchange solutes during PERITONEAL DIALYSIS

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

201.3.205
DIALYSING SOLUTION CIRCUIT
part of the fluid circuit that conveys DIALYSING SOLUTION from the PD EQUIPMENT to the peritoneal cavity of the PATIENT, from the PATIENT to the PD EQUIPMENT, and from the PD EQUIPMENT to a drainage bag or drain

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

201.3.207
DIALYSIS WATER
water that has been treated to meet the requirements of ISO 23500-3:2024 [3] and which is suitable for use in PD applications, including the preparation of DIALYZING SOLUTION and preparation of DIALYSING SOLUTION CONCENTRATE

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

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

201.3.208
INFLOW
phase during which the peritoneal cavity is filled

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

201.3.209
ONLINE PD
PERITONEAL DIALYSIS PROCEDURE where the PD EQUIPMENT produces the DIALYSING SOLUTION for the PERITONEAL DIALYSIS treatment

201.3.210
OUTFLOW
phase during which the peritoneal cavity is emptied

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

201.3.211
PERITONEAL DIALYSIS
PD
PROCESS whereby a DIALYSING SOLUTION is introduced into the peritoneal cavity of the PATIENT and is subsequently removed

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