



BSI Standards Publication

Medical electrical equipment

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

National foreword

This British Standard is the UK implementation of EN IEC 60601-2-39:2025. It is identical to IEC 60601-2-39:2024. It supersedes BS EN IEC 60601-2-39:2019, which will be withdrawn on 31 January 2028.

The UK participation in its preparation was entrusted to Technical Committee CH/62/4, Electromedical equipment.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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Amendments/corrigenda issued since publication

Date	Text affected
<hr/>	

English Version

Medical electrical equipment - Part 2-39: Particular requirements
for the basic safety and essential performance of peritoneal
dialysis equipment
(IEC 60601-2-39:2024)

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)

Medizinische elektrische Geräte - Teil 2-39: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von Peritoneal-Dialyse-
Geräten
(IEC 60601-2-39:2024)

This European Standard was approved by CENELEC on 2025-01-15. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

The text of document 62D/2162/FDIS, future edition 4 of IEC 60601-2-39, prepared by SC 62D "Particular medical equipment, software, and systems" of IEC/TC 62 "Medical equipment, software, and systems" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60601-2-39:2025.

The following dates are fixed:

- latest date by which the document has to be implemented at national (dop) 2026-01-31 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2028-01-31 document have to be withdrawn

This document supersedes EN IEC 60601-2-39:2019 and all of its amendments and corrigenda (if any).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice

The text of the International Standard IEC 60601-2-39:2024 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standard indicated:

IEC 60601-2-16	NOTE	Approved as EN IEC 60601-2-16
ISO 23500-3:2024	NOTE	Approved as EN ISO 23500-3:2024 (not modified)
ISO 23500-1:2024	NOTE	Approved as EN ISO 23500-1:2024 (not modified)
ISO 23500-5:2024	NOTE	Approved as EN ISO 23500-5:2024 (not modified)
ISO 80369-1:2018	NOTE	Approved as EN ISO 80369-1:2018 (not modified)
ISO 23500-4:2024	NOTE	Approved as EN ISO 23500-4:2024 (not modified)
ISO 11197:2019	NOTE	Approved as EN ISO 11197:2019 (not modified)
ISO 17664-1:2021	NOTE	Approved as EN ISO 17664-1:2021 (not modified)
ISO 17664-2:2021	NOTE	Approved as EN ISO 17664-2:2023 (not modified)
ISO 15883 series	NOTE	Approved as EN ISO 15883 series
IEC 80001-1:2021	NOTE	Approved as EN IEC 80001-1:2021 (not modified)
IEC 60601-1-9:2007	NOTE	Approved as EN 60601-1-9:2008 (not modified)
IEC 60601-1-9:2007/A1:2013	NOTE	Approved as EN 60601-1-9:2008/A1:2013 (not modified)
IEC 60601-1-9:2007/A2:2020	NOTE	Approved as EN 60601-1-9:2008/A2:2020 (not modified)

Annex ZA
(normative)

**Normative references to international publications
with their corresponding European publications**

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cencenelec.eu.

Annex ZA of EN 60601-1:2006¹, applies, except as follows:

Add:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ AC	2010
+ A1	2012		+ A1	2013
-	-		+ AC	2014
-	-		+ A12	2014
+ A2	2020		+ A2	2021
-	-		+ AC	2022
-	-		+ A13	2024
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	EN 60601-1-10	2008
+ A1	2013		+ A1	2015
+ A2	2020		+ A2	2021

¹ As impacted by EN 60601-1:2006/AC:2010, EN 60601-1:2006/A1:2013, EN 60601-1:2006/A1:2013/AC:2014, EN 60601-1:2006/A12:2014, EN 60601-1:2006/A2:2021, EN 60601-1:2006/AC:2022-12 and EN 60601-1:2006/A13:2024.

EN IEC 60601-2-39:2025 (E)

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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	EN 60601-1-11	2015
+ A1	2020		+ A1	2021
IEC 61672-1	2013	Electroacoustics - Sound level meters - Part 1: Specifications	EN 61672-1	2013
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	EN ISO 3744	2010

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

- 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.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
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- 9) IEC draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at <https://patents.iec.ch>. IEC shall not be held responsible for identifying any or all such patent rights.

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/AMD2:2020 are numbered 3.1 through 3.154, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

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

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

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

201.2 Normative references

NOTE Informative references are listed in the Bibliography.

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

Addition:

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

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

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

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

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

201.3 Terms and definitions

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

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

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

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

201.3.8

* APPLIED PART

Replacement:

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

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

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

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

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

201.3.78

PATIENT CONNECTION

Addition:

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

Additional terms and definitions:

201.3.201

APD ME EQUIPMENT

ME EQUIPMENT used to perform AUTOMATED PERITONEAL DIALYSIS

201.3.202

AUTOMATED PERITONEAL DIALYSIS

APD

method to perform dialysis with automated fluid exchanges in the peritoneum

201.3.203

CENTRAL DELIVERY SYSTEM

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

201.3.204

DIALYSING SOLUTION

PD SOLUTION

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

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

201.3.205

DIALYSING SOLUTION CIRCUIT

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

201.3.206

DIALYSING SOLUTION CONCENTRATE

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

201.3.207

DIALYSIS WATER

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

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

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

201.3.208

INFLOW

phase during which the peritoneal cavity is filled

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

201.3.209

ONLINE PD

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

201.3.210

OUTFLOW

phase during which the peritoneal cavity is emptied

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

201.3.211

PERITONEAL DIALYSIS

PD

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

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

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

ME EQUIPMENT used to perform PERITONEAL DIALYSIS including APD ME EQUIPMENT

201.3.213**PROTECTIVE SYSTEM**

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

201.4 General requirements

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

201.4.3 * ESSENTIAL PERFORMANCE

Additional subclauses:

201.4.3.101 * Additional ESSENTIAL PERFORMANCE requirements

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

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

Table 201.101 – ESSENTIAL PERFORMANCE requirements

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

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

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

201.4.3.102 * DIALYSING SOLUTION flow rate during INFLOW/OUTFLOW

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

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

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

Compliance is checked under the following test conditions:

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

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

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

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

201.4.3.103 DIALYSING SOLUTION volume balancing (INFLOW/OUTFLOW volume)

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