
Irish Standard
I.S. EN IEC 60601-2-39:2019

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

**I.S. EN IEC 60601-2-39:2019**

*Incorporating amendments/corrigenda/National Annexes issued since publication:*

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## National Foreword

I.S. EN IEC 60601-2-39:2019 is the adopted Irish version of the European Document EN IEC 60601-2-39:2019, Medical electrical equipment - Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment

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*In line with international standards practice the decimal point is shown as a comma (,) throughout this document.*

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN IEC 60601-2-39

May 2019

ICS 11.040.99

Supersedes EN 60601-2-39:2008

English Version

# Medical electrical equipment - Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment (IEC 60601-2-39:2018)

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)

Medizinische elektrische Geräte - Teil 2-39: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Peritoneal-Dialyse-Geräten (IEC 60601-2-39:2018)

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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/1558/FDIS, future edition 3 of IEC 60601-2-39, prepared by SC 62D "Electromedical equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60601-2-39:2019.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2019-11-24
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2022-05-24

This document supersedes EN 60601-2-39:2008.

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.

## Endorsement notice

The text of the International Standard IEC 60601-2-39:2018 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 standards indicated:

IEC 60601-1-6:2010 NOTE Harmonized as EN 60601-1-6:2010 (not modified)
IEC 60601-1-9:2007 NOTE Harmonized as EN 60601-1-9:2008 (not modified)
IEC 60601-1-10:2007 NOTE Harmonized as EN 60601-1-10:2008 (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.cenelec.eu.

*Annex ZA of EN 60601-1:2006 applies, except as follows:*

| Publication | Year | Title | EN/HD | Year |
|---|---|---|---|---|
| *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 | EN 60601-1-2 | 2015 |
| IEC 60601-1-6 | 2010 | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability | EN 60601-1-6 | 2010 |
| + A1 | 2013 | | + A1 | 2015 |
| 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 | EN 60601-1-8 | 2007 |
| - | - | | + corrigendum Mar. | 2010 |
| + A1 | 2012 | | + A1 | 2013 |
| - | - | | + AC | 2014 |
| - | - | | + A11 | 2017 |
| *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 | EN 60601-1-11 | 2015 |

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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)

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IEC 60601-2-39

Edition 3.0 2018-04

# INTERNATIONAL STANDARD

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## Medical electrical equipment –
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# 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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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.

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# 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*.