IEC 60601-2-39

Edition 2.0 2007-11

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 60601-2-39:2007

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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 second edition cancels and replaces the first edition of IEC 60601-2-39. It constitutes a technical revision. Major changes since the last edition include a summary of additional essential performance requirements.

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

Enquiry draft	Report on voting
62D/555/CDV	62D/638/RVC

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 standard, 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 standard, 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 standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this collateral standard are by number only.

In this standard, 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 standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;

– should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– 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 collateral standard will remain unchanged until the maintenance result date indicated on the IEC web site 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.

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 applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard 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 standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

This standard 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 2 of this particular standard.

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

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard 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 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of sections, clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard 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 or figures which are additional to those of the general standard are numbered starting from 201.101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

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

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding section, clause or subclause in this particular standard, the section, 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

Clause 2 of the general standard applies, except as follows:

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*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 apply, except as follows:

NOTE An index of defined terms is found beginning on page 17.

Addition:

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

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

201.3.203
DIALYSING SOLUTION
a pharmaceutical preparation (solution), according to the relevant pharmacopoeia monograph, for use with 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 This is an APPLIED PART.

201.3.205
INFLOW
phase during which the peritoneal cavity is filled

NOTE The term “fill” is commonly used as a synonym for “inflow”.

201.3.206
OUTFLOW
phase during which the peritoneal cavity is emptied

NOTE 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

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

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.3 ESSENTIAL PERFORMANCE

Additional subclause:

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).

201.4.7 SINGLE FAULT CONDITION for ME EQUIPMENT

Additional subclause:

201.4.7.101 NORMAL CONDITION and SINGLE FAULT CONDITION for PD EQUIPMENT

Failure of any PROTECTIVE SYSTEM. Example of SINGLE FAULT CONDITION: failure of a PROTECTIVE SYSTEM (see 201.12.4.101, 201.12.4.103, 201.12.4.104)

201.5 General requirements for testing of PD 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 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: 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 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

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 on 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(s) 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 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.

201.7.9.3 Technical description

Additional subclause: