INTERNATIONAL STANDARD

IEC 60601-2-39

First edition
1999-06

Medical electrical equipment –

Part 2-39: Particular requirements for the safety of peritoneal dialysis equipment

Appareils électromédicaux –

Partie 2-39: Règles particulières de sécurité pour les équipements de dialyse péritonéale

Reference number
IEC 60601-2-39:1999(E)

Numbering

As from 1 January 1997 all IEC publications are issued with a designation in the 60000 series.

Consolidated publications

Consolidated versions of some IEC publications including amendments are available. For example, edition numbers 1.0, 1.1 and 1.2 refer, respectively, to the base publication, the base publication incorporating amendment 1 and the base publication incorporating amendments 1 and 2.

Validity of this publication

The technical content of IEC publications is kept under constant review by the IEC, thus ensuring that the content reflects current technology.

Information relating to the date of the reconfirmation of the publication is available in the IEC catalogue.

Information on the subjects under consideration and work in progress undertaken by the technical committee which has prepared this publication, as well as the list of publications issued, is to be found at the following IEC sources:

- **IEC web site***
- **Catalogue of IEC publications**
  Published yearly with regular updates
  (On-line catalogue)*
- **IEC Bulletin**
  Available both at the IEC web site* and as a printed periodical

Terminology, graphical and letter symbols

For general terminology, readers are referred to IEC 60050: *International Electrotechnical Vocabulary* (IEV).

For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams*.

* See web site address on title page.

INTERNATIONAL STANDARD

IEC 60601-2-39

First edition
1999-06

Medical electrical equipment –

Part 2-39: Particular requirements for the safety of peritoneal dialysis equipment

Appareils électromédicaux –

Partie 2-39: Règles particulières de sécurité pour les équipements de dialyse péritonéale

International Electrotechnical Commission 3, rue de Varembé Geneva, Switzerland
Telefax: +41 22 919 0300 e-mail: inmail@iec.ch IEC web site http://www.iec.ch

Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE M

For price, see current catalogue

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-39: Particular requirements for the safety of peritoneal dialysis equipment

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The 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 the 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 National Committees.
3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.
4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
6) Attention is drawn to the possibility that some of the elements of this technical report may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard 60601-2-39 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62D/311/FDIS	62D/326/RVD

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

This publication has not been drafted in complete accordance with the ISO/IEC Directives, Part 3.

Annex AA is for information only.

In this Particular Standard the following print types are used:

– requirements, compliance with which can be tested, and definitions: in roman type;
– notes, explanations, advice, introductions, general statements, exceptions and references: in smaller type;
– *test specifications: in italic type*;
– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

The committee has decided that this publication remains valid until 2007. At this date, in accordance with the committee's decision, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition; or
- amended.

A bilingual version of this standard may be issued at a later date.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-39: Particular requirements for the safety of peritoneal dialysis equipment

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

1.1 Scope

Addition:

This Particular Standard specifies the minimum safety requirements for PERITONEAL DIALYSIS EQUIPMENT as defined in 2.1.102, hereinafter referred to as EQUIPMENT. It applies to EQUIPMENT intended for use either by medical staff or under the supervision of medical experts, including EQUIPMENT operated by the PATIENT, regardless of whether the equipment is used in a hospital or domestic environment.

These particular requirements do not apply to the DIALYSING SOLUTION, the DIALYSING SOLUTION circuit, or to EQUIPMENT solely intended for use as continuous ambulatory PERITONEAL DIALYSIS EQUIPMENT.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety of EQUIPMENT as defined in 2.1.102.

1.3 Particular Standards

Addition:

This Particular Standard amends and supplements a set of IEC publications consisting of IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*, amendment 1 (1991), amendment 2 (1995); IEC 60601-1-1, amendment 1 (1995), IEC 60601-1-2 (1993) and IEC 60601-1-4 (1996).

For brevity, IEC 60601-1 is referred to in this Particular Standard either as the “General Standard” or as the “General Requirement(s)”, and IEC 60601-1-1, 60601-1-2, and 60601-1-4 as the "Collateral Standards".

The term “this standard” covers the Particular Standard used together with the General Standard and any Collateral Standards.

The numbering of sections, clauses and subclauses of this standard corresponds to that of the General Standard. 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 is replaced completely by the text of this standard.

"Addition" means that the text of this standard is additional to the requirements of the General Standard.

"Amendment" means that the clause or subclause of the General Standard is amended as indicated by the text of this standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Where there is no corresponding section, clause or subclause in this standard, the section, clause or subclause of the General Standard, applies without modification.

Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this standard.

A requirement of this standard replacing or modifying requirements of the General Standards takes precedence over the original requirements concerned.

2 Terminology and definitions

This clause of the General Standard applies except as follows:

2.1.5
APPLIED PART

Replacement:

The part of the DIALYSING SOLUTION circuit, that conveys DIALYSING SOLUTION from the EQUIPMENT to the peritoneal cavity of the PATIENT, and subsequently to a drainage bag or drain, or parts permanently and conductively connected to it, shall be considered as the APPLIED PART.

Additional definitions:

2.1.101
PERITONEAL DIALYSIS
process whereby a DIALYSING SOLUTION is introduced into the peritoneal cavity of the PATIENT and is subsequently removed

2.1.102
PERITONEAL DIALYSIS EQUIPMENT
EQUIPMENT used to perform PERITONEAL DIALYSIS

2.1.103
DIALYSING SOLUTION
pharmaceutical preparation (solution), according to the relevant pharmacopoeia monograph for use with EQUIPMENT

2.1.104
INFLOW
phase during which the peritoneal cavity is filled

NOTE – The term "fill" is commonly used as a synonym for "inflow".

2.1.105
OUTFLOW
phase during which the peritoneal cavity is emptied

NOTE – The term “drain” is commonly used as a synonym for “outflow”.

2.1.106
PROTECTIVE SYSTEM
automatic system which senses a specified parameter (or parameters) or a constructional feature, specially designed to protect the PATIENT against the SAFETY HAZARDS which may arise

3 General requirements

This clause of the General Standard applies except as follows:

3.6 *Additional item:*

aa) Failure of any PROTECTIVE SYSTEM.

4 General requirements for tests

This clause of the General Standard applies except as follows:

4.6 Other conditions

Addition:

When the outcome of a test may 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.

6 Identification, marking and documentation

This clause of the General Standard applies except as follows:

6.8.1 General

Addition:

The ACCOMPANYING DOCUMENTS shall additionally include

– a statement pointing out the importance of an air gap between the DIALYSING SOLUTION circuit and the drain in order to prevent back syphonage if the OUTFLOW path is open.

6.8.2 Instructions for use

Addition:

aa) The instructions for use shall additionally include the following:

1) a description of the method(s) by which any necessary disinfection or sterilization is achieved;
2) a statement that the test procedure by which the effectiveness of any sterilization or disinfection has been verified is available on request;
3) a statement which draws the OPERATOR's attention to the SAFETY HAZARDS associated with the connection and disconnection of the PATIENT;

4) an explanation of the OPERATOR's actions required to respond to alarm(s) from any PROTECTIVE SYSTEM;

5) a list of recommended DIALYSING SOLUTION circuits for use with the EQUIPMENT;

6) a statement on the possible SAFETY HAZARDS associated with electromagnetic radiation which may affect the safe operation of the EQUIPMENT. This statement should include examples of typical EQUIPMENT which may generate such radiation and also take account of potential conditions in domestic environments;

7) a statement of the importance of the quality of the protective earth in the installation when CLASS I EQUIPMENT is used;

8) a statement of the applications in which a POTENTIAL EQUALIZATION CONDUCTOR should be used;

9) a statement that draws the OPERATOR's attention to potential SAFETY HAZARDS arising from improper installation and connection of the DIALYSING FLUID circuit;

10) a statement that draws the USER's/OPERATOR's attention to potential SAFETY HAZARDS relating to inappropriate selection of the DIALYSING SOLUTION.

Compliance is checked by inspection.

6.8.3 Technical description

Addition:

aa) The technical description shall additionally include the following:

1) the particular measures or conditions to be observed when installing the EQUIPMENT or bringing it into use, including guidance on the type and number of tests to be carried out;

2) the type and accuracy of the PROTECTIVE SYSTEM required in 51.101;

3) the time by which the audible alarm required in 51.101 b) may be delayed;

4) the audible alarm silence period;

5) the range of sound pressure levels of any adjustable audible alarm;

6) the maximum positive and/or negative pressures that can be generated by any pumps used to assist the transfer of DIALYSING SOLUTION to and/or from the peritoneal cavity of the PATIENT;

7) the method and the sensitivity employed for the PROTECTIVE SYSTEM required by 51.103;

8) the method and the sensitivity employed for the PROTECTIVE SYSTEM required by 51.104.

Compliance is checked by inspection.

SECTION TWO – ENVIRONMENTAL CONDITIONS

The clauses and subclauses of this section of the General Standard apply.

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

The clauses and subclauses of this section of the General Standard apply except as follows.

19 Continuous LEAKAGE CURRENT and PATIENT AUXILIARY CURRENTS

This subclause of the General Standard applies except as follows:

19.4 Tests

h) Measurement of the PATIENT LEAKAGE CURRENT