SLOVENSKI STANDARD

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

ICS 11.040.99

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SIST EN 60601-2-39:2002(en)

EUROPEAN STANDARD

NORME EUROPÉENNE

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EN 60601-2-39

August 1999

ICS 11.040.99

English version

Medical electrical equipment
Part 2-39: Particular requirements for the safety of peritoneal dialysis equipment
(IEC 60601-2-39:1999)

Appareils électromédicaux
Partie 2-39: Règles particulières
de sécurité pour les équipements
de dialyse péritonéale
(CEI 60601-2-39:1999)

Medizinische elektrische Geräte
Teil 2-39: Besondere Festlegungen
für die Sicherheit von
Peritoneal-Dialyse-Geräten
(IEC 60601-2-39:1999)

This European Standard was approved by CENELEC on 1999-08-01. 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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CENELEC

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of document 62D/311/FDIS, future edition 1 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 was approved by CENELEC as EN 60601-2-39 on 1999-08-01.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2000-05-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2002-08-01

Endorsement notice

The text of the International Standard IEC 60601-2-39:1999 was approved by CENELEC as a European Standard without any modification.

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

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IEC Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

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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: