

**Elektrilised meditsiiniseadmed. Osa 2-39:
Erinõuded kõhukelmedialüüsiseadmete esmasele
ohutusele ja olulistele toimivusnäitajatele**

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 60601-2-39:2008 sisaldab Euroopa standardi EN 60601-2-39:2008 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 05.12.2008 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 24.04.2008.

Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN 60601-2-39:2008 consists of the English text of the European standard EN 60601-2-39:2008.

This standard is ratified with the order of Estonian Centre for Standardisation dated 05.12.2008 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.

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The standard is available from Estonian standardisation organisation.

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Võtmesõnad: dialysis, electro medical equipment, peritoneal, requirement, safety

Standardite reprodutseerimis- ja levitamiseõigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonilisse süsteemi või edastamine ükskõik millises vormis või millisel teel on keelatud ilma Eesti Standardikeskuse poolt antud kirjaliku loata.

Kui Teil on küsimusi standardite autorikaitse kohta, palun võtke ühendust Eesti Standardikeskusega:
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English version

**Medical electrical equipment -
Part 2-39: Particular requirements for basic safety
and essential performance of peritoneal dialysis equipment
(IEC 60601-2-39:2007)**

Appareils électromédicaux -
Partie 2-39: Exigences particulières
pour la sécurité de base
et les performances essentielles
des appareils de dialyse péritonéale
(CEI 60601-2-39:2007)

Medizinische elektrische Geräte -
Teil 2-39: Besondere Festlegungen
für die Sicherheit einschließlich
der wesentlichen Leistungsmerkmale
von Peritoneal-Dialyse-Geräten
(IEC 60601-2-39:2007)

This European Standard was approved by CENELEC on 2008-03-01. 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, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

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

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Foreword

The text of document 62D/555/CDV, future edition 2 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 Unique Acceptance Procedure and was approved by CENELEC as EN 60601-2-39 on 2008-03-01.

This European Standard supersedes EN 60601-2-39:1999 + corrigendum December 1999.

Major changes since EN 60601-2-39:1999 include a summary of additional essential performance requirements.

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) 2008-12-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2011-03-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 93/42/EEC. See Annex ZZ.

In this standard, the following print types are used:

- requirements and definitions: in roman type;
- *test specifications: in 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: IN 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. 7.1.1, 7.1.2 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 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.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-39:2007 was approved by CENELEC as a European Standard without any modification.

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Annex ZA
(normative)

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

Addition to Annex ZA of EN 60601-1:2006:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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	EN 60601-1-9	2008
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

Annex ZZ
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

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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.