

Elektrisk utrustning för medicinskt bruk – Säkerhet – Del 2-5: Särskilda fordringar på apparater för ultraljudsterapi

Medical electrical equipment –

Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment

Som svensk standard gäller europastandarden EN 60601-2-5:2000. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-2-5:2000.

Nationellt förord

Europastandarden EN 60601-2-5:2000

består av:

- **europastandardens ikraftsättningsdokument**, utarbetat inom CENELEC
- **IEC 60601-2-5, Second edition, 2000 - Medical electrical equipment - Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment**

utarbetad inom International Electrotechnical Commission, IEC.

Standarden skall användas tillsammans med SS-EN 60601-1, Elektromedicinsk utrustning - Säkerhet - Del 1: Allmänna fordringar, och dess separat utgivna ändringar och tillägg.

Till SS-EN 60601-1 utges en serie tilläggsstandarder som anger allmänna fordringar på säkerhet som är tillämpliga på

- en grupp av elektrisk utrustning för medicinskt bruk, t ex radiologisk utrustning
- särskilda egenskaper hos all elektrisk utrustning för medicinskt bruk, ej särskilt behandlade i SS-EN 60601-1, t ex elektromagnetisk kompatibilitet.

Tidigare utgiven svensk standard SS-IEC 601-2-5, utgåva 1, 1986, gäller ej fr o m 2003-09-01.

EUROPEAN STANDARD

EN 60601-2-5

NORME EUROPÉENNE

EUROPÄISCHE NORM

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English version

Medical electrical equipment
Part 2-5: Particular requirements for the safety of
ultrasonic physiotherapy equipment
(IEC 60601-2-5:2000)

Appareils électromédicaux
Partie 2-5: Règles particulières de
sécurité des appareils à ultrasons
pour physiothérapie
(CEI 60601-2-5:2000)

Medizinische elektrische Geräte
Teil 2-5: Besondere Festlegungen
für die Sicherheit von Ultraschall-
Physiotherapiegeräten
(IEC 60601-2-5:2000)

This European Standard was approved by CENELEC on 2000-09-01. 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

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Foreword

The text of document 62D/361/FDIS, future edition 2 of IEC 60601-2-5, 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 60601-2-5 on 2000-09-01.

This European Standard supersedes HD 395.2.5 S1:1986.

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) 2001-06-01
- latest date by which the national standards conflicting
with the EN have to be withdrawn (dow) 2003-09-01

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annex ZA is normative and annexes AA and ZB are informative.
Annexes ZA and ZB have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-5:2000 was approved by CENELEC as a European Standard without any modification.

Annex ZA
(normative)

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

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>Addition to annex ZA of EN 60601-1:1990/A2:1995:</i>				
IEC 60050-801	1994	International Electrotechnical Vocabulary (IEV) - Chapter 801: Acoustics and electroacoustics	-	-
IEC 60469-1	1987	Pulse techniques and apparatus Part 1: Pulse terms and definitions	-	-
IEC 61102	1991	Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz	EN 61102	1993
IEC 61161	1992	Ultrasonic power measurement in liquids in the frequency range 0,5 MHz to 25 MHz	EN 61161	1994
A1	1998		A1	1998
IEC 61689	1996	Ultrasonics - Physiotherapy systems - Performance requirements and methods of measurement in the frequency range 0,5 MHz to 5 MHz	EN 61689	1996

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment

SECTION ONE – GENERAL

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

1 Scope and object

1.1 Scope

Addition:

This Particular Standard specifies the requirements for safety of ULTRASONIC PHYSIOTHERAPY EQUIPMENT used in medical practice, as defined in 2.1.101.

This Particular Standard does not apply to:

- EQUIPMENT in which a tool is driven by ULTRASOUND (for example EQUIPMENT used in surgery or dentistry);
- EQUIPMENT in which focused ULTRASOUND pulse waves are used to destroy conglomerates such as stones in the kidneys or the bladder (lithotrites) (for information refer to IEC 60601-2-36);
- ULTRASONIC PHYSIOTHERAPY EQUIPMENT in which focused ULTRASOUND pulse waves are used.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety of ULTRASONIC PHYSIOTHERAPY EQUIPMENT used in medical practice, as defined in 2.1.101.

1.3 Particular Standards

Addition:

This Particular Standard refers to IEC 60601-1 (1988): *Medical electrical equipment – Part 1: General requirements for safety*, as amended by its amendment 1 (1991) and amendment 2 (1995).

For brevity, Part 1 is referred to in this Particular Standard as the “General Standard” .

The numbering of sections, clauses and subclauses of this Particular Standard corresponds with 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 Particular Standard.

“Addition” means that the text of this Particular 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 Particular 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.

The term “this standard” is used to make reference to the General Standard 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, although possibly not relevant, 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 Particular Standard.

The requirements of this Particular Standard take priority over those of the General Standard and Collateral Standards mentioned below.

1.5 Collateral Standards

Addition:

The following Collateral Standards apply:

IEC 60601-1-1:1992, *Medical electrical equipment – Part 1: General requirements for safety – Section 1 – Collateral standard: Safety requirements for medical electrical systems*

IEC 60601-1-2:1993, *Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral Standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems*