SLOVENSKI STANDARD
SIST EN 60601-2-5:2002

01-februar-2002

Nadomešča:
SIST HD 395.2.5 S1:1998

Medicinska električna oprema - 2-5. del: Posebne varnostne zahteve za ultrazvočno psihoterapevtsko opremo (IEC 60601-2-5:2000)

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

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

Ta slovenski standard je istoveten z: **EN 60601-2-5:2000**

ICS:

11.040.60	Terapevtska oprema	Therapy equipment

SIST EN 60601-2-5:2002 **en**

EUROPEAN STANDARD **EN 60601-2-5**

NORME EUROPÉENNE

EUROPÄISCHE NORM December 2000

ICS 11.040.60 Supersedes HD 395.2.5 S1:1986

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
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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

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

Ref. No. EN 60601-2-5:2000 E

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.

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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.

Publication	Year	Title	EN/HD	Year
Addition to annex ZA of EN 60601-1:1990/A2:1995:				
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

Annex ZB
(informative)

Other international publications mentioned in this standard with the references of the relevant European publications

Publication	Year	Title	EN/HD	Year
Addition to annex ZB of EN 60601-1:1990/A2:1995:				
IEC 60601-2-36	1997	Medical electrical equipment Part 2: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy	EN 60601-2-36	1997

NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
IEC
60601-2-5

Deuxième édition
Second edition
2000-07

Appareils électromédicaux –

Partie 2-5:
Règles particulières de sécurité des appareils à ultrasons pour physiothérapie

Medical electrical equipment –

Part 2-5:

Particular requirements for the safety of ultrasonic physiotherapy equipment

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International Electrotechnical Commission
Международная Электротехническая Комиссия

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For price, see current catalogue

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy 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 60601-2-5 has been prepared by sub-committee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition of IEC 60601-2-5 cancels and replaces the first edition published in 1984 of which it constitutes a technical revision.

This bilingual version (2005-11) replaces the English version.

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

FDIS	Report on voting
62D/361/FDIS	62D/366/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.

The French version of this standard has not been voted upon.

In this Particular Standard the following print types are used:

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

The committee has decided that the contents of this publication 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.

INTRODUCTION

This Particular Standard specifies requirements and tests for the safety of ULTRASONIC PHYSIOTHERAPY EQUIPMENT. It amends and supplements IEC 60601-1 (second edition, 1988) including Amendments 1 and 2, hereinafter referred to as the General Standard. This Particular Standard takes into account IEC 60601-1-2 and IEC 61689.

A first edition of this Particular Standard was published in 1984, based on the first edition (1977) of IEC 60601-1 and making reference to IEC 60150. The aim of this second edition is to bring this Particular Standard up to date with reference to the publications and documents mentioned above. The title has been changed to better reflect its scope based on developments in the therapeutic application of ultrasound and in line with changes in the above IEC standards.

The requirements are followed by specifications for the relevant tests.

A rationale for the more important requirements, where appropriate, is given in Annex AA. It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of the Particular Standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However this annex does not form part of the requirements of this Standard.

The clauses and subclauses which have corresponding rationale statements are marked with an asterisk * before their number.