SLOVENSKI STANDARD
SIST EN 60601-2-3:1995

01-maj-1995

Medicinska električna oprema - 2. del: Posebne varnostne zahteve za opremo za kratkovalovno terapijo (IEC 601-2-3:1991)

Medical electrical equipment - Part 2: Particular requirements for the safety of short-wave therapy equipment

Medizinische elektrische Geräte - Teil 2: Besondere Festlegungen für die Sicherheit von Kurzwellen-Therapiegeräten

Appareils électromédicaux - Partie 2: Règles particulières de sécurité pour appareils de thérapie à ondes courtes

Ta slovenski standard je istoveten z: **EN 60601-2-3:1993**

ICS:

11.040.60	Terapevtska oprema	Therapy equipment

SIST EN 60601-2-3:1995 **en**

EUROPEAN STANDARD EN 60601-2-3

NORME EUROPEENNE

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Descriptors: Medical electrical equipment, short wave therapy, instructions for use, electrical safety, testing, construction, definitions, requirements

ENGLISH VERSION

Medical electrical equipment
Part 2: Particular requirements for the safety of short-wave therapy equipment
(IEC 601-2-3:1991)

Appareils électromédicaux
Deuxième partie: Règles particulières de sécurité pour appareils de thérapie à ondes courtes
(CEI 601-2-3:1991)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die Sicherheit von Kurzwellen-Therapiegeräten
(IEC 601-2-3:1991)

This European Standard was approved by CENELEC on 1992-12-09. 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, 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

At the request of the CENELEC Technical Committee TC 62, Electrical equipment in medical practice, the International Standard IEC 601-2-3:1991 was submitted to the CENELEC Unique Acceptance Procedure (UAP) in February 1992 for acceptance as a European Standard.

The text of the International Standard was approved by CENELEC as EN 60601-2-3 on 9 December 1992.

This European Standard supersedes HD 395.2.3 S1:1985.

The following dates were fixed:

- latest date of publication of an identical national standard	(dop)	1993-09-15
- latest date of withdrawal of conflicting national standards	(dow)	1993-09-15

For products which have complied with HD 395.2.3 S1:1985 before 1993-09-15, as shown by the manufacturer or by a certification body, this previous standard may continue to apply for production until 1998-09-15.

Annexes designated "normative" are part of the body of the standard. In this standard, annex ZA is normative.

ENDORSEMENT NOTICE

The text of the International Standard IEC 601-2-3:1991 was approved by CENELEC as a European Standard without any modification.

ANNEX ZA (normative)

OTHER INTERNATIONAL PUBLICATIONS QUOTED IN THIS STANDARD WITH THE REFERENCES OF THE RELEVANT EUROPEAN PUBLICATIONS

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

IEC Publication	Date	Title	EN/HD	Date
601-1	1977	Safety of medical electrical equipment	HD 395.1 S2	1988
A1	1984	Part 1: General requirements	+ A1	1993
601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1	1990
601-2-3	1982	Part 2: Particular requirements for the safety of short-wave therapy equipment	HD 395.2.3 S1	1985

NORME INTERNATIONALE
INTERNATIONAL STANDARD

CEI
IEC
601-2-3

Deuxième édition
Second edition
1991-06

Appareils électromédicaux

Deuxième partie:
Règles particulières de sécurité pour appareils de thérapie à ondes courtes

Medical electrical equipment

Part 2:
Particular requirements for the safety of short-wave therapy equipment

Numéro de référence
Reference number
CEI/IEC 601-2-3: 1991

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SECTION SEVEN - PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

Clause

SECTION EIGHT - ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

SECTION NINE - ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

SECTION TEN - CONSTRUCTIONAL REQUIREMENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for the safety of short-wave therapy equipment

FOREWORD

1) The formal decisions or agreements of the IEC on technical matters, prepared by Technical Committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.

2) They have the form of recommendations for international use and they are accepted by the National Committees in that sense.

3) In order to promote international unification, the IEC expresses the wish that all National Committees should adopt the text of the IEC recommendation for their national rules in so far as national conditions will permit. Any divergence between the IEC recommendation and the corresponding national rules should, as far as possible, be clearly indicated in the latter.

PREFACE

This Particular Standard has been prepared by Sub-Committee 62D: Electromedical equipment, of IEC Technical Committee No. 62: Electrical equipment in medical practice.

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

Six Months' Rule	Report on Voting
62D(CO)52	62D(CO)58

Full information on the voting for the approval of this Standard can be found in the Voting Report indicated in the above table.

The following IEC publications are quoted in this Standard:

Publications Nos. 601-1 (1977): Safety of medical electrical equipment. Part 1: General requirements.
601-1 (1988): Medical electrical equipment. Part 1: General requirements for safety.
601-2-3 (1982): Medical electrical equipment. Part 2: Particular requirements for the safety of short-wave therapy equipment. (First edition.)

INTRODUCTION

This standard concerns the safety of short-wave therapy equipment. A first edition of this Particular Standard was published in 1982, based on the first edition of the General Standard, IEC Publication 601-1 (1977). The present second edition of the Particular Standard refers to the second edition (1988) of the General Standard.

The revision of this second edition concerns mainly the following:

1. Low power equipment (<10 W) is exempted from certain requirements as it is considered that no hazard exists.
2. Equipment with inductive applicators is dealt with in more detail.
3. Some shortcomings of the first edition detected in the application of the Standard are removed.

The requirements of this Particular Standard take priority over those of the General Standard. The title of the General Standard has been changed in the second edition (1988) to read: "Medical electrical equipment, Part 1: General requirements for safety". The change is reflected in this Particular Standard.

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 numbering of sections, clauses and sub-clauses of this Particular Standard corresponds with that of the General Standard.

Sub-clauses or figures which are additional to those of the General Standard are numbered starting from 101; additional appendices are lettered AA, BB, etc., and additional items *aa)*, *bb)*, etc.

In this Standard, the following print types are used:

- requirements, compliance with which can be tested, and definitions: in roman type;
- 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 requirements are followed by specifications for the relevant tests.

A rationale for the more important requirements, where appropriate, is given in Appendix AA. It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of the 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 appendix does not form part of the requirements of this Standard. The sub-clauses which have corresponding rationale statements are marked with an * after their number.