SLOVENSKI STANDARD
SIST HD 395.2.5 S1:1998

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Medical electrical equipment - Part 2: Particular requirements for the safety of ultrasonic therapy equipment (IEC 60601-2-5:1984)

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

Elektromedizinische Geräte -- Teil 2: Besondere Festlegungen für die Sicherheit von Ultraschall-Therapiegeräten

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

Ta slovenski standard je istoveten z: **HD 395.2.5 S1:1986**

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MEDICAL ELECTRICAL EQUIPMENT
PART 2 :
PARTICULAR REQUIREMENTS FOR THE SAFETY OF ULTRASONIC THERAPY EQUIPMENT

Appareils électromédicaux
Deuxième partie :
Règles particulières de sécurité pour appareils de thérapie à micro-ondes

Elektromedizinische Geräte
Teil 2 :
Besondere Festlegungen für die Sicherheit von Ultraschall-Therapiegeräten

BODY OF THE HD

The Harmonization Document consists of:

- IEC 601-2-5 (1984) ed 1 ;IEC/SC 62D; not appended

This Harmonization Document was approved by CENELEC on 1986-06-26

The English and French versions of the HD are provided by the text of the IEC publication and the German version is the official translation of the IEC text.

According to the CENELEC Internal Regulations the CENELEC member National Committees are bound :

to announce the existence of this Harmonization Document at national level by or before 1987-01-01

to publish their new harmonized national standard by or before 1987-07-01

to withdraw all conflicting national standards by or before 1987-07-01

Harmonized national standards are listed on the HD information sheet, which is available from the CENELEC National Committees or from the CENELEC General Secretariat.

The CENELEC National Committees are the national electrotechnical committees of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxemburg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom.

COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

NORME DE LA CEI

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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Appareils électromédicaux

Deuxième partie: Règles particulières de sécurité pour appareils à ultrasons pour thérapie

Medical electrical equipment

Part 2: Particular requirements for the safety of ultrasonic therapy equipment

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for the safety of ultrasonic 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 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 upon the following documents:

Six Months' Rule	Report on Voting
62D(CO)18	62D(CO)22

Further information can be found in the Report on Voting indicated in the table above.

This Particular Standard amends and supplements IEC Publication 601-1 (first edition 1977): Safety of Medical Electrical Equipment, Part 1: General Requirements, hereinafter referred to as the General Standard. The requirements of this Particular Standard take priority over those of the General Standard.

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

Clauses, 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, 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.

Following the decision taken by Sub-Committee 62D at the meeting in Washington in 1979, a rationale for the more important requirements 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 practices or as a result of developments in technology. However, this appendix does not form part of the requirements of this Standard.

In the case of some definitions and measurements, reference is made to IEC Publication 150: Testing and Calibration of Ultrasonic Therapeutic Equipment (1963), prepared by Sub-Committee 29D. It has been considered by Sub-Committee 62D that some of these definitions and measurement methods are obsolete, but the task of revising them is beyond the scope of Sub-Committee 62D. However, despite these shortcomings, the Montreux meeting of Sub-Committee 62D decided that this Standard should be completed because it is urgently needed.

When a new edition of IEC Publication 150 is available, an amendment to Publication 601-2-5 will be published. In the meantime, alternative measuring methods to those specified or referenced in this Standard may be used provided that evidence of an equivalent or better degree of accuracy can be demonstrated.

MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for the safety of ultrasonic therapy equipment

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SECTION ONE — GENERAL

1. Scope and object

This clause of the General Standard applies except as follows:

Addition:

This Particular Standard specifies the requirements for safety of ULTRASONIC THERAPY EQUIPMENT used in medical practice, as defined in Sub-clause 2.1.101, hereinafter referred to as EQUIPMENT.

This Particular Standard does not apply to EQUIPMENT in which a tool is driven by ULTRASOUND (for example EQUIPMENT used in surgery or dentistry) or in which focused ULTRASOUND pulse waves are used to destroy conglomerates such as stones in the kidneys or the bladder (lithotrites).

2. Terminology and definitions

This clause of the General Standard applies except as follows:

2.1.5 *APPLIED PART*

Addition:

Radiating area and the other accessible parts of the TREATMENT HEAD, including any ADAPTOR.

Additional definitions:

2.1.101 *ULTRASONIC THERAPY EQUIPMENT*

EQUIPMENT for the generation and application of ULTRASOUND to a PATIENT for therapeutic purposes.

Essentially the EQUIPMENT comprises a generator of electric high-frequency power and a transducer for converting this to ULTRASOUND.

2.1.102 *ULTRASONIC TRANSDUCER*

Device capable of converting electrical energy to mechanical energy within the ultrasonic frequency range.

2.1.103 *TREATMENT HEAD*

Assembly comprising one or more ULTRASONIC TRANSDUCER(S) and associated parts for local application of ULTRASOUND to the PATIENT.

A TREATMENT HEAD is also referred to as an applicator.

2.1.104 *ADAPTOR*

ACCESSORY intended to be attached to the TREATMENT HEAD for the purpose of modifying the EFFECTIVE INTENSITY and/or the EFFECTIVE RADIATING AREA.

2.12.101 *ULTRASOUND*

Mechanical oscillation the frequency of which is above 20 kHz.

2.12.102 *RATED OUTPUT POWER*

Maximum EFFECTIVE ULTRASOUND OUTPUT POWER of the EQUIPMENT. It is expressed in watts.

2.12.103 *EFFECTIVE ULTRASOUND OUTPUT POWER*

ULTRASOUND power radiated by the TREATMENT HEAD in the forward direction into an approximately free field in water under standard conditions specified in IEC Publication 150: Testing and Calibration of Ultrasonic Therapeutic Equipment. It is expressed in watts. In the case of modulated ULTRASOUND radiation, the ULTRASOUND power is averaged over at least three periods of the lowest MODULATION frequency.

2.12.104 *MODULATION*

Periodic variation of the amplitude of an ultrasonic wave. It may be sinusoidal, pulsed, or may result from full or half-wave rectification of the mains frequency power supply. When the degree of MODULATION is less than 25%, the wave will be considered continuous.

The degree of MODULATION is the quotient of the difference and the sum of maximum and minimum amplitudes of the wave.

2.12.105 *EFFECTIVE RADIATING AREA*

In the case of TREATMENT HEADS having a flat circular radiating surface it is 1.11 times the area of a particular circular baffle chosen to allow transmission of 90% of the EFFECTIVE ULTRASOUND OUTPUT POWER, measured near the radiating surface (see IEC Publication 150). It is expressed in square centimetres.

Definitions for other types of radiating surfaces are under consideration.

2.12.106 *EFFECTIVE INTENSITY*

The quotient of the EFFECTIVE ULTRASOUND OUTPUT POWER and the EFFECTIVE RADIATING AREA. It is expressed in watts per square centimetre.

2.12.107 *MAXIMUM INTENSITY*

In the case of TREATMENT HEADS having a flat circular radiating surface with a diameter not less than 2 cm it is $4/\pi$ times the maximum EFFECTIVE ULTRASOUND OUTPUT POWER when measured with a circular baffle of 1 cm diameter near the centre of the radiating surface (see IEC Publication 150). It is expressed in watts per square centimetre.

A definition of MAXIMUM INTENSITY for TREATMENT HEADS having smaller diameters and/or other types of radiating surface is under consideration.

2.12.108 *INTENSITY RATIO*

The quotient of the MAXIMUM INTENSITY and the EFFECTIVE INTENSITY of a TREATMENT HEAD.