SLOVENSKI STANDARD
SIST EN 60601-2-6:2015

01-september-2015

Medicinska električna oprema - 2-6. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme za mikrovalovno terapijo

Medical electrical equipment - Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment

Medizinische elektrische Geräte - Teil 2-6: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Mikrowellen-Therapiegeräten

Appareils électromédicaux - Partie 2-6: Règles particulières de sécurité de base et de performances essentielles des appareils de thérapie à micro-ondes

Ta slovenski standard je istoveten z: **EN 60601-2-6:2015**

ICS:

11.040.60	Terapevtska oprema	Therapy equipment

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-6

May 2015

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English Version

Medical electrical equipment - Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment (IEC 60601-2-6:2012)

Appareils électromédicaux - Partie 2-6: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de thérapie à micro-ondes (IEC 60601-2-6:2012)

Medizinische elektrische Geräte - Teil 2-6: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Mikrowellen-Therapiegeräten (IEC 60601-2-6:2012)

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

The text of document 62D/985/FDIS, future edition 2 of IEC 60601-2-6, prepared by SC 62D, "Electromedical equipment", of IEC TC 62, "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-6:2015.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2016-01-14
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-04-14

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 60601-2-6:2012 was approved by CENELEC as a European Standard without any modification.

Annex ZZ
(informative)

Coverage of Essential Requirements of EU 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 given in Annex I of EU Directive 93/42/EEC of 14 June 1993 concerning medical devices.

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

WARNING: Other requirements and other EU Directives can be applied to the products falling within the scope of this standard.

IEC 60601-2-6

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment

Appareils électromédicaux –
Partie 2-6: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de thérapie à micro-ondes

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment

FOREWORD

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International standard IEC 60601-2-6 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition of IEC 60601-2-6, published in 1984. This edition constitutes a technical revision and has been aligned to the third edition of IEC 60601-1:2005+A1:2012.

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

FDIS	Report on voting
62D/985/FDIS	62D/1008/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

– Requirements and definitions: roman type.
– *Test specifications: 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: 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, 7.2 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 particular 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.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability 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

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of microwave therapy equipment.

This particular standard amends and supplements IEC 60601-1 (third edition, 2005 and amendment 1,2012): *Medical electrical equipment – Part 1: General requirements for safety and essential performance*, hereinafter referred to as the general standard (see 201.1.4).

The requirements are followed by specifications for the relevant tests.

A "Particular guidance and rationale" section giving some explanatory notes, where appropriate, about the more important requirements is included in Annex AA.

Clauses or subclauses for which there are explanatory notes in Annex AA are marked with an asterisk (*).

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 annex does not form part of the requirements of this standard.