IEC 60601-2-6

Edition 2.2 2022-09
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

IEC 60601-2-6:2012-04+AMD1:2016-04+AMD2:2022-09 CSV(en-fr)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy 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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This consolidated version of the official IEC Standard and its amendments has been prepared for user convenience.

IEC 60601-2-6 edition 2.2 contains the second edition (2012-04) [documents 62D/985/FDIS and 62D/1008/RVD], its amendment 1 (2016-04) [documents 62D/1331/FDIS and 62D/1351/RVD] and its amendment 2 (2022-09) [documents 62D/1847/CDV and 62D/1960/RVC].

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendments 1 and 2. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

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~~ with IEC 60601-1~~:2005+A1:2012~~.

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 the base publication and its amendments 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.

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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.

INTRODUCTION to Amendment 2

At the October 2019 meeting of IEC SC 62D in Shanghai, China, the subcommittee discussed the need for administrative/technical changes to most 62D standards after completion of the amendment projects within the IEC 60601-1 series. Those projects were all completed and the amendments published in 2020.

The full list of IEC SC 62D documents that will be amended or revised may be found within the IEC document 62D/1792/DC. The results and comments on the DC may be found within 62D/1808/INF. The review report for this amendment is 62D/1830/RR.

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard specifies requirements for the safety of MICROWAVE THERAPY EQUIPMENT used in medical practice, as defined in 201.3.204.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for MICROWAVE THERAPY EQUIPMENT as defined in 201.3.204.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard.

IEC 60601-1-2 applies as modified in Clause 202. IEC 60601-1-3 and IEC 60601-1-12 do~~es~~ not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content

[1] The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). 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 or applicable collateral 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 or applicable collateral standard.

“Amendment” means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term “this standard” is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

Clause 2 of the general standard applies, except as follows:

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC TR 60878:2015, *Graphical symbols for electrical equipment in medical practice*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012[2] and IEC 60601-1:2005/AMD2:2020, apply, except as follows:

[2] ~~A1:2012 To be published~~

Addition:

201.3.201
APPLICATOR
microwave radiator for local application of microwave energy to the PATIENT

Note 1 to entry: Some examples are dipoles, dipoles with reflectors, modified dipoles, dipole arrays, open waveguides, and dielectric radiators.

201.3.202
*** CONTACT APPLICATOR**
APPLICATOR that contacts the PATIENT and is thus an APPLIED PART

201.3.203
MATCHED LOAD
complex load which, when connected, results in the maximum power being delivered from the MICROWAVE THERAPY EQUIPMENT into the load

201.3.204
MICROWAVE THERAPY EQUIPMENT
MEDICAL ELECTRICAL EQUIPMENT for the treatment of the PATIENT by means of a propagated electromagnetic field in the frequency range of more than 300 MHz but not exceeding 30 GHz

201.3.205
*** NON-CONTACT APPLICATOR**
an APPLICATOR that does not contact or touch the PATIENT

201.3.206
PHANTOM
device which receives the radiated microwave energy and is intended to simulate the PATIENT for test purposes

201.3.207
*** RATED OUTPUT POWER**
value of the maximum high-frequency power which can be fed into a MATCHED LOAD

201.3.208
*** UNWANTED RADIATION**
microwave radiation which is not incident on or in the PATIENT for treatment purposes

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.3 ESSENTIAL PERFORMANCE

Addition:

201.4.3.101 * Additional ESSENTIAL PERFORMANCE requirements

Additional ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in Table 201.101.

Table 201.101 – Additional ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Free from the display of incorrect numerical values associated with the therapy to be performed.	201.12.1

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

Additional subclause:

201.7.2.101 Output

MICROWAVE THERAPY EQUIPMENT shall be marked with the following information:

- RATED OUTPUT POWER in watts;
- MATCHED LOAD in ohms;
- operating frequency in megahertz or gigahertz;
- symbol number 5140 (non-ionizing electromagnetic radiation) of IEC 60878.

Compliance is checked by inspection.

201.7.3 * Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts

Additional subclauses:

201.7.3.101

Symbol number 5140 (non-ionizing electromagnetic radiation) of IEC 60878 shall be applied to any internal ACCESS COVER if the removal of that cover might cause the ME EQUIPMENT to fail the requirement of 201.10.3.102.

Compliance is checked by the test of 201.10.3.102 with any internal ACCESS COVER removed if it is not marked with the above symbol and also with any external ACCESS COVER not bearing this symbol removed.

201.7.3.102

Symbols number 2 (general warning sign) and number 10 (follow operating instructions) of Table D.2 in Annex D of the general standard shall be displayed on or near components or on panels giving access to components if adjustment or replacement of these components might cause the ME EQUIPMENT to fail to comply with IEC 60601-1-2 and Clause 202.

Compliance is checked by inspection.

201.7.4.2 * Control devices

Addition:

The output control shall have a scale and/or associated indicator representing the microwave energy output. The numeral "0" shall not be used unless any microwave energy delivered in this position is less than 10 mW. If the output scale or indicator represents watts of output power, it shall be so marked.

Compliance is checked by inspection.

201.7.9.2 Instructions for use

Additional subclause:

201.7.9.2.101 Additional instructions for use

The instructions for use shall include the following information where applicable:

a) A warning that MICROWAVE THERAPY EQUIPMENT should not be used in the presence of flammable anesthetics.

b) A description of the expected effect on the target tissue (e.g. diffuse gentle heating, localized gentle heating, localized intense heating for the purpose of tissue destruction, etc.)

c) A description of the area of intended tissue effect with relation to the APPLICATOR.

d) The correct procedures for positioning the APPLICATOR for a particular treatment while minimizing the irradiation of other parts of the body.

e) Advice that the output power should be switched off when the APPLICATOR is being positioned for treatment.

f) Advice on the potential HAZARDS of having conductive objects or materials near to the PATIENT:

   – Microwave energy should not be applied to persons wearing metallic jewellery or clothing containing metallic material (for example metallic buttons, clips or thread).

   – Parts of the body of the PATIENT containing metallic implants (for example a medullary nail) should not be treated unless specialized medical advice is obtained.

   – Hearing aids should be removed.

   – PATIENTS with implanted electronic devices and/or electrodes should be excluded from treatment with microwaves and from areas where the ME EQUIPMENT is operated.

g) A warning to be careful when handling APPLICATORS, since rough handling may change the directional characteristics of the APPLICATOR.

h) Information on the type and size of APPLICATOR recommended for treating various parts of the body and the maximum power allowable for a particular APPLICATOR.

i) During use of NON-CONTACT APPLICATORS:

   – advice that PATIENTS with reduced thermal sensitivity in the proposed area of treatment should normally not be treated with NON-CONTACT APPLICATORS of microwave therapy;

   – advice that PATIENTS who are unable to provide real time feedback regarding the treatment should normally not be treated with NON-CONTACT APPLICATORS of microwave therapy;

   – advice that a NON-CONTACT APPLICATOR should not be directed towards the eyes or testes;