BS EN 60601-2-6:2015

BSI Standards Publication

Medical electrical equipment

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

bsi.

...making excellence a habit.™

National foreword

This British Standard is the UK implementation of EN 60601-2-6:2015. It is identical to IEC 60601-2-6:2012. It supersedes BS 5724-2.6:1985, which will be withdrawn on 14 April 2018.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/4, Electromedical equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Published by BSI Standards Limited 2015

ISBN 978 0 580 69338 0
ICS 11.040.60

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 June 2015.

Amendments/corrigenda issued since publication

Date	Text affected

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-6

May 2015

ICS 11.040.60

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)

This European Standard was approved by CENELEC on 2015-04-14. 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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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.

CONTENTS

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.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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.

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 does 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 of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x”

---

[1] The general standard is IEC 60601-1:2005+A1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

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.

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+A1:2012[2], apply, except as follows:

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.

2 A1:2012 To be published

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;

   – advice that the PATIENT should be provided with microwave protection goggles, where appropriate;

   – a warning statement that persons not receiving treatment should remain more than 1,5 meters from a NON-CONTACT APPLICATOR during the production of microwave energy;

   – a description of the potential dangers to OPERATORS.

201.7.9.3 Technical description

201.7.9.3.1 General

Addition to the first paragraph:

– instructions on how to test the output power of the MICROWAVE THERAPY EQUIPMENT;
– where the MICROWAVE THERAPY EQUIPMENT has an output power control:
  • a diagram showing the power output versus the output control setting at the MATCHED LOAD;
– information on the precautions to be observed when the warning symbols mentioned in 201.7.3.101 and/or 201.7.3.102 are displayed.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

201.8.7.1 * General requirements

Addition to item b):

– with the microwave output not energized but in such a way that the LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS are not affected.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies, except as follows:

201.10.1 X-radiation

This subclause clause of the general standard is not applicable

201.10.2 Alpha, beta, gamma, neutron radiation and other particle radiation

This clause of the general standard is not applicable.

201.10.3 Microwave radiation

Addition:

201.10.3.101 * UNWANTED RADIATION

UNWANTED RADIATION shall not exceed 10 mW/cm^2 at a distance of 1 m from the front of a NON-CONTACT APPLICATOR and 0,25 m from the rear of a NON-CONTACT APPLICATOR when tested as described below.

Compliance is checked by the following test:

Adjust the output to the maximum output power specified for each NON-CONTACT APPLICATOR. Measure the power density of the UNWANTED RADIATION after placing the NON-CONTACT APPLICATOR at the maximum distance the MANUFACTURER recommends from a suitable PHANTOM. If a suitable PHANTOM is not specified by the MANUFACTURER, the phantom shall consist of a cylindrical container 0,20 m diameter x 0,50 m long made of low-loss material, for example acrylic, filled with a solution of 9 g NaCl per litre of water.

201.10.3.102 * Leakage of microwave radiation

The leakage of microwave radiation from the ME EQUIPMENT ENCLOSURE, cables or waveguides, and cable/waveguide connectors shall not exceed 10 mW/cm^2 when measured as described below.

Compliance is checked by the following test:

Connect the MICROWAVE THERAPY EQUIPMENT to a matched load and operate it at the rated output power. Using a calibrated field probe, measure the microwave power density at various points along the external surfaces of the EQUIPMENT, connectors, and cables/waveguides.

NOTE Annex AA contains a guide to assist the reader in making repeatable measurements.

201.10.3.103 Limitation of microwave power

The RATED OUTPUT POWER of MICROWAVE THERAPY EQUIPMENT having a single output channel or multiple output channels that can only be operated one channel at a time shall not exceed 250 W. The rated output power of microwave therapy equipment having multiple output channels which can be operated simultaneously shall not exceed 125 W per channel.

Compliance is checked by inspection of the markings specified in 201.7.2.101.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies, except as follows:

201.11.1.2.1 APPLIED PARTS intended to supply heat to a PATIENT

Addition:

CONTACT APPLICATORS are APPLIED PARTS intended to supply heat to a PATIENT as part of the intended clinical effect. Disclosure of temperatures is not required.

201.11.4 * ME EQUIPMENT and ME SYSTEMS intended for use with flammable anesthetics

Replacement:

MICROWAVE THERAPY EQUIPMENT shall not be CATEGORY AP or CATEGORY APG ME EQUIPMENT and thus shall not be used in the presence of flammable anesthetics.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

201.12.1 Accuracy of controls and instruments

Addition:

Any incorporated indication of the output power may be in absolute units or in relative units.

For an absolute indication, the measured output power shall not deviate from the indicated value by more than ± 20 % of the indicated value.

Compliance is checked by measurement of the output power as follows:

Replace the APPLICATOR *with a* *MATCHED LOAD* *and measure the maximum output power.*

201.12.4 Protection against hazardous output

201.12.4.2 Indication of parameters relevant to safety

Addition:

201.12.4.2.101 * Output indicator

MICROWAVE THERAPY EQUIPMENT shall emit an audible signal when microwave energy is being produced. The sound level produced shall be at least 30 dBA for NON-CONTACT APPLICATORS and at least 40 dBA for all other APPLICATORS at a distance of 1 m from the front of the ME EQUIPMENT.

Compliance is checked by functional check and measurement of the sound level.

Additional subclauses:

201.12.4.101 * Output reduction means

MICROWAVE THERAPY EQUIPMENT employing NON-CONTACT APPLICATORS shall provide means to reduce the power output to 5 % or less of the maximum output power for each range/mode or to 10 W, whichever is the least.

Compliance is checked by measurement of the output power according to 201.12.1.

201.12.4.102 * Energizing the output

MICROWAVE THERAPY EQUIPMENT employing NON-CONTACT APPLICATORS shall be so designed that the output cannot be energized unless the output control is first set to the minimum position.

This requirement shall also be met after the interruption and restoration of the mains supply.

Compliance is checked by inspection and functional test.

201.12.4.103 * Adjustable timer

MICROWAVE THERAPY EQUIPMENT employing NON-CONTACT APPLICATORS shall be provided with an adjustable timer which de-energizes the output after a preselected operating period has elapsed. The timer shall have a range not exceeding 30 min and an accuracy of ± 1 min.

Compliance is checked by inspection, functional test and measurement of the operating time.

201.12.4.104 De-energizing the output

MICROWAVE THERAPY EQUIPMENT shall have a means to manually de-energize the microwave output at any time regardless of the status of any automatic control means or timer.

Compliance is checked by functional inspection.

201.12.4.105 Maximum power output

When measured immediately after any warming up period specified in the instructions for use, the maximum output power shall not be greater than the RATED OUTPUT POWER plus 20 %.

Compliance is checked by replacing the APPLICATOR with a MATCHED LOAD, setting any output controls to maximum and measuring the output power.

201.13 HAZARDOUS SITUATIONS and fault conditions

Clause 13 of the general standard applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies, except as follows:

201.15.4 ME EQUIPMENT components and general assembly

Additional subclause:

201.15.4.101 * ENCLOSURES and covers

Any ACCESS COVER or ENCLOSURE, the removal of which can result in the ME EQUIPMENT failing to comply with the requirement of 201.10.3.102, shall be removable only with the aid of a TOOL.

Compliance is checked by inspection.

201.16 ME SYSTEMS

Clause 16 of the general standard applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies:

202 Electromagnetic compatibility – Requirements and tests

IEC 60601-1-2:2007 applies except as follows:

202.4 General requirements

Additional subclause:

202.4.101 General test setup

Compliance testing of MICROWAVE THERAPY EQUIPMENT shall occur while radiating into a suitable PHANTOM as specified by the MANUFACTURER or with the APPLICATOR replaced by a MATCHED LOAD.

Annexes

The annexes of the general standard apply except as follows:

Annex C
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

201.C.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts

Additional requirements for marking on the outside of MICROWAVE THERAPY EQUIPMENT are found in Table 201.C.101.

Table 201.C.101 – Marking on the outside of MICROWAVE THERAPY EQUIPMENT or its parts

Description of marking	Subclause
RATED OUTPUT POWER	201.7.2.101
MATCHED LOAD	201.7.2.101
Operating frequency	201.7.2.101
Non-ionizing radiation symbol	201.7.2.101

201.C.2 Marking on the inside of ME EQUIPMENT, ME SYSTEMS or their parts

Additional requirements for marking on the inside of MICROWAVE THERAPY EQUIPMENT are found in Table 201.C.102.

Table 201.C.102 – Marking on the inside of MICROWAVE THERAPY EQUIPMENT or its parts

Description of marking	Subclause
Non-ionizing radiation symbol	201.7.3.101
Symbols No. 2 and 10 of Table D.2 in Annex D of the general standard.	201.7.3.102

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This annex provides a concise rationale for the important requirements of the standard and is intended for those who are familiar with the subject of the standard but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for the proper application of the standard. Furthermore as clinical practice and technology change it is believed that a rationale for the present requirements will facilitate any revision of the standard necessitated by these developments.

AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclause in this particular standard, with clause and subclause numbers parallel to those in the body of the document.

Subclause 201.1.1 – Scope

The scope was expanded to include additional uses of microwave energy in medical equipment developed since the first edition. This standard was originally written to cover microwave devices that were used to gently heat tissue as a means to improve circulation. New uses for microwave energy include devices that are used to intentionally heat tissue to temperatures that cause cell death.

Definition 201.3.202 – CONTACT APPLICATOR

These are APPLICATORS that must intentionally touch or be introduced into the patient in order to be used. The intent of a CONTACT APPLICATOR is to use microwave radiation to heat a specific area of tissue to a temperature sufficient to cause tissue death. The clinical reason for this treatment may include (but is not limited to) shrinkage of tissue or treatment of diseased tissue. Depending on the type of treatment, the patient may or may not be anesthetized. This definition was created to clearly differentiate it from NON-CONTACT APPLICATORS.

Definition 201.3.205 – NON-CONTACT APPLICATOR

These are APPLICATORS that are not intended to touch the PATIENT during use. These APPLICATORS are used to gently heat PATIENT tissue. In general, the PATIENT is awake during this treatment and able to comment if the heating causes discomfort or pain.

Definition 201.3.207 – RATED OUTPUT POWER

Selection of the power measurement equipment and technique will depend on whether the output is continuous or pulsed.

Definition 201.3.208 – UNWANTED RADIATION

Microwave energy other than that responsible for creating the desired clinical effect. This definition allows the creation of requirements and tests to measure this energy so as to protect tissue that is not in the treatment area. This includes PATIENT tissue as well as that of the OPERATOR.

Subclause 201.4.3.101 – Additional ESSENTIAL PERFORMANCE requirements

If a device does display numerical values representing the output power, then the correct display of such values is considered ESSENTIAL PERFORMANCE.

Subclause 201.7.3 – Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts

The aim of the marking is to protect SERVICE PERSONNEL from UNWANTED RADIATION and notify them that ELECTROMAGNETIC DISTURBANCE suppression may be degraded during maintenance or repair.

Subclause 201.7.4.2 – Control devices

As the power delivered to the load depends on the load resistance, a graduation in relative units is considered to be adequate. If the numeral "0" is displayed, the OPERATOR will expect zero output at this position of the control.

Subclause 201.8.7.1 – General requirements

As small LEAKAGE CURRENTS at mains frequency cannot easily be measured in the presence of high frequency power, the high-frequency generator is disabled during the tests.

Subclause 201.10.3.101 – UNWANTED RADIATION

This requirement limits UNWANTED RADIATION and creates a "safety zone" around a NON-CONTACT APPLICATOR. In NORMAL USE, the OPERATOR is not continuously exposed to microwave radiation. During positioning of the PATIENT, and the NON-CONTACT APPLICATOR, the output is supposed to be switched off, and the instructions for use warn the OPERATOR to be more than 1.5 meters from a NON-CONTACT APPLICATOR during treatment.

Subclause 201.10.3.102 – Leakage of microwave radiation

This requirement limits UNWANTED RADIATION associated with the ENCLOSURE, cables, waveguides, and cable/waveguide connectors.

To make the measurements repeatable, the following is suggested.

- Determine the fundamental and harmonic content of the RF energy present in the ME EQUIPMENT to be measured.
- Select a meter/sensor appropriate for the measurement given the sensor/meter requirements listed below.
- Set the meter to display mW/cm^2 and set the display to a mode which displays the current field reading (no averaging).
- Slowly sweep the probe continuously to cover the surfaces being tested keeping the electrical center of the sensor within 38 mm of the surface being investigated. Note the location(s) of readings greater than or equal to 5 mW/cm^2.
- Clear data in meter, set for max hold and investigate the locations recorded above one at a time. Rotate the surface of the probe so that all axis of the probe are exposed to the location under test. Record the maximum reading and repeat for each location.
- Verify that all maximum readings are less than or equal to the limit.

It is recommended that the RF sensor used be an electric field sensor with the following or better specifications:

- Maximum sensor size: 70 mm in diameter
- Sensor and meter frequency response includes the lowest frequency to be measured up to the highest harmonic present, ± 1 dB (Note: Calibrations can be performed at all the frequencies of interest, if the probe is not specified to cover the full frequency range

needed, provided that the response of the probe is not down by more than 6 dB from frequencies within its specified range.)

- Sensor and meter isotropic response better than ± 2 dB at a frequency within the sensors calibrated range.
- Maximum spacing between sensor and ME EQUIPMENT: 38 mm from the center of the diameter of the sensor to the surface of the ME EQUIPMENT.

Subclause 201.11.4 – ME EQUIPMENT and ME SYSTEMS intended for use with flammable anesthetics

Microwave energy can cause flammable gases to quickly heat to the flash point so MICROWAVE THERAPY EQUIPMENT should never be used with flammable anesthetics.

Subclause 201.12.4.2.101 – Output indicator

The unexpected delivery of microwave energy is a HAZARD for the OPERATOR.

Subclause 201.12.4.101 – Output reduction means

MICROWAVE THERAPY EQUIPMENT utilizing NON-CONTACT APPLICATORS should have the ability to treat PATIENTS with low power.

Subclause 201.12.4.102 – Energizing the output

This requirement prevents a PATIENT from being treated inadvertently at an excessive power level.

201.12.4.103 – Adjustable timer

MICROWAVE THERAPY EQUIPMENT using NON-CONTACT APPLICATORS may be used without continuous supervision. Therefore a timer for switching off the output is essential.

201.15.4.101 – ENCLOSURES and covers

Parts which are important for shielding against UNWANTED RADIATION shall not be removable without a TOOL.

Index of defined terms used in this particular standard

This page deliberately left blank

British Standards Institution (BSI)

BSI is the national body responsible for preparing British Standards and other standards-related publications, information and services.

BSI is incorporated by Royal Charter. British Standards and other standardization products are published by BSI Standards Limited.

About us

We bring together business, industry, government, consumers, innovators and others to shape their combined experience and expertise into standards -based solutions.

The knowledge embodied in our standards has been carefully assembled in a dependable format and refined through our open consultation process. Organizations of all sizes and across all sectors choose standards to help them achieve their goals.

Information on standards

We can provide you with the knowledge that your organization needs to succeed. Find out more about British Standards by visiting our website at bsigroup.com/standards or contacting our Customer Services team or Knowledge Centre.

Buying standards

You can buy and download PDF versions of BSI publications, including British and adopted European and international standards, through our website at bsigroup.com/shop, where hard copies can also be purchased.

If you need international and foreign standards from other Standards Development Organizations, hard copies can be ordered from our Customer Services team.

Subscriptions

Our range of subscription services are designed to make using standards easier for you. For further information on our subscription products go to bsigroup.com/subscriptions.

With **British Standards Online (BSOL)** you'll have instant access to over 55,000 British and adopted European and international standards from your desktop. It's available 24/7 and is refreshed daily so you'll always be up to date.

You can keep in touch with standards developments and receive substantial discounts on the purchase price of standards, both in single copy and subscription format, by becoming a **BSI Subscribing Member**.

PLUS is an updating service exclusive to BSI Subscribing Members. You will automatically receive the latest hard copy of your standards when they're revised or replaced.

To find out more about becoming a BSI Subscribing Member and the benefits of membership, please visit bsigroup.com/shop.

With a **Multi-User Network Licence (MUNL)** you are able to host standards publications on your intranet. Licences can cover as few or as many users as you wish. With updates supplied as soon as they're available, you can be sure your documentation is current. For further information, email bsmusales@bsigroup.com.

BSI Group Headquarters

389 Chiswick High Road London W4 4AL UK

Revisions

Our British Standards and other publications are updated by amendment or revision.

We continually improve the quality of our products and services to benefit your business. If you find an inaccuracy or ambiguity within a British Standard or other BSI publication please inform the Knowledge Centre.

Copyright

Useful Contacts:

Customer Services
Tel: +44 845 086 9001
Email (orders): orders@bsigroup.com
Email (enquiries): cservices@bsigroup.com

Subscriptions
Tel: +44 845 086 9001
Email: subscriptions@bsigroup.com

Knowledge Centre
Tel: +44 20 8996 7004
Email: knowledgecentre@bsigroup.com

Copyright & Licensing
Tel: +44 20 8996 7070
Email: copyright@bsigroup.com

bsi.

...making excellence a habit.™