# IEC 60601-2-3

Edition 3.2 2022-09
CONSOLIDATED VERSION

# INTERNATIONAL STANDARD

# NORME INTERNATIONALE

colour inside



**Medical electrical equipment –**
**Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment**



**Appareils électromédicaux –**
**Partie 2-3: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de thérapie à ondes courtes**

IEC 60601-2-3:2012-04+AMD1:2016-04+AMD2:2022-09 CSV(en-fr)

IEC Secretariat
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch


**About the IEC**
The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

**About IEC publications**
The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

**IEC publications search - webstore.iec.ch/advsearchform**
The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee, …). It also gives information on projects, replaced and withdrawn publications.

**IEC Just Published - webstore.iec.ch/justpublished**
Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

**IEC Customer Service Centre - webstore.iec.ch/csc**
If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

**IEC Products & Services Portal - products.iec.ch**
Discover our powerful search engine and read freely all the publications previews. With a subscription you will always have access to up to date content tailored to your needs.

**Electropedia - www.electropedia.org**
The world's leading online dictionary on electrotechnology, containing more than 22 300 terminological entries in English and French, with equivalent terms in 19 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.



---

**A propos de l'IEC**
La Commission Electrotechnique Internationale (IEC) est la première organisation mondiale qui élabore et publie des Normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

**A propos des publications IEC**
Le contenu technique des publications IEC est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

**Recherche de publications IEC - webstore.iec.ch/advsearchform**
La recherche avancée permet de trouver des publications IEC en utilisant différents critères (numéro de référence, texte, comité d'études, …). Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

**IEC Just Published - webstore.iec.ch/justpublished**
Restez informé sur les nouvelles publications IEC. Just Published détaille les nouvelles publications parues. Disponible en ligne et une fois par mois par email.

**Service Clients - webstore.iec.ch/csc**
Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: sales@iec.ch.

**IEC Products & Services Portal - products.iec.ch**
Découvrez notre puissant moteur de recherche et consultez gratuitement tous les aperçus des publications. Avec un abonnement, vous aurez toujours accès à un contenu à jour adapté à vos besoins.

**Electropedia - www.electropedia.org**
Le premier dictionnaire d'électrotechnologie en ligne au monde, avec plus de 22 300 articles terminologiques en anglais et en français, ainsi que les termes équivalents dans 19 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.

# IEC 60601-2-3

Edition 3.2 2022-09
CONSOLIDATED VERSION

# INTERNATIONAL STANDARD

# NORME INTERNATIONALE

colour inside



**Medical electrical equipment –**
**Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment**



**Appareils électromédicaux –**
**Partie 2-3: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de thérapie à ondes courtes**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.60

ISBN 978-2-8322-5707-4

# IEC 60601-2-3

Edition 3.2 2022-09
CONSOLIDATED VERSION

# REDLINE VERSION

# VERSION REDLINE

colour inside



## Medical electrical equipment –
## Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment



## Appareils électromédicaux –
## Partie 2-3: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de thérapie à ondes courtes

IEC 60601-2-3:2012-04+AMD1:2016-04+AMD2:2022-09 CSV(en-fr)

# CONTENTS

FOREWORD ..... 3
INTRODUCTION ..... 6
INTRODUCTION to Amendment 2 ..... 6
201.1 Scope, object and related standards ..... 7
201.2 Normative references ..... 8
201.3 Terms and definitions ..... 8
201.4 General requirements ..... 9
201.5 General requirements for testing of ME EQUIPMENT ..... 9
201.6 Classification of ME EQUIPMENT and ME SYSTEMS ..... 9
201.7 ME EQUIPMENT identification, marking and documents ..... 9
201.8 Protection against electrical HAZARDS from ME EQUIPMENT ..... 11
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS ..... 15
201.10 Protection against unwanted and excessive radiation HAZARDS ..... 15
201.11 Protection against excessive temperatures and other HAZARDS ..... 15
201.12 Accuracy of controls and instruments and protection against hazardous outputs ..... 15
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT ..... 16
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) ..... 17
201.15 Construction of ME EQUIPMENT ..... 17
201.16 ME SYSTEMS ..... 17
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS ..... 17
Annexes ..... 17
ANNEX C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS ..... 18
Annex AA (informative) Particular guidance and rationale ..... 19
Index of defined terms used in this particular standard ..... 21

Figure 201.101 – Dielectric strength test for capacitive APPLICATORS ..... 13
Figure 201.102 – Test probe ..... 14
Figure 201.103 – Dielectric strength test for inductive APPLICATORS ..... 15

Table 201.C.101 – Marking on the outside of SHORT-WAVE THERAPY EQUIPMENT or its parts ..... 18

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

# MEDICAL ELECTRICAL EQUIPMENT –

# Part 2-3: Particular requirements for the basic safety and essential performance of short-wave 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.



**This consolidated version of the official IEC Standard and its amendments has been prepared for user convenience.**

**IEC 60601-2-3 edition 3.2 contains the third edition (2012-04) [documents 62D/977/FDIS and 62D/993/RVD], its amendment 1 (2016-04) [documents 62D/1330/FDIS and 62D/1350/RVD] and its amendment 2 (2022-09) [documents 62D/1846/CDV and 62D/1959/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 60601-2-3 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition of IEC 60601-2-3 published in 1991 and its amendment 1 published in 1998. This edition constitutes a technical revision and has been aligned with IEC 60601-1~~:2005~~.

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.

**IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.**

# INTRODUCTION

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

This particular standard amends and supplements IEC 60601-1 ~~(third edition, 2005)~~: *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 62D1808/INF. The review report for this amendment is 62D/1829/RR.

# MEDICAL ELECTRICAL EQUIPMENT –

# Part 2-3: Particular requirements for the basic safety and essential performance of short-wave 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 particular standard specifies the requirements for the safety of SHORT-WAVE THERAPY EQUIPMENT, hereafter referred to as ME EQUIPMENT, as defined in subclause 201.3.206.

LOW POWER EQUIPMENT as defined in subclause 201.3.202 is exempted from certain requirements of this standard.



### 201.1.2 Object

*Replacement:*

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for SHORT-WAVE THERAPY EQUIPMENT as defined in 201.3.206.



### 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 60601-1-3 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.

---

[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*

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” 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 and IEC 60601-1:2005/AMD2:2020, apply, except as follows:

*Addition:*

**201.3.201**
**APPLICATOR**
part of the ME EQUIPMENT used to couple the radio-frequency power to the PATIENT

**201.3.202**
**LOW POWER EQUIPMENT**
SHORT-WAVE THERAPY EQUIPMENT having a RATED OUTPUT POWER not exceeding 10 W

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

**201.3.204**
**OUTPUT CIRCUIT**
all conductive parts used to couple radio-frequency power from the generator to the APPLICATORS, including conductive parts of the APPLICATORS and their connecting cables

**201.3.205**
*** RATED OUTPUT POWER**
value of the maximum radio-frequency power which can be fed into a MATCHED LOAD

**201.3.206**
*** SHORT-WAVE THERAPY EQUIPMENT**
ME EQUIPMENT for the therapeutic treatment of the PATIENT by exposure to electric or magnetic fields produced in the frequency range of more than 13 MHz but not exceeding 45 MHz



## 201.4 General requirements



Clause 4 of the general standard applies.

## 201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

*Additional subclause:*

### 201.5.101 Routine tests

The testing during manufacture should include:

a) Measurement of the operating frequency with the ME EQUIPMENT operating under the conditions specified in item b) below.

b) Output power test as specified in subclause 201.12.1.101 but only under the conditions [APPLICATOR(S), spacing(s), load resistance] which produces the maximum output power.

c) Measurement of the PATIENT LEAKAGE CURRENT under the conditions stated in subclause 201.8.7.1 of this particular standard.

## 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

SHORT-WAVE THERAPY EQUIPMENT shall be marked with the following information:

- RATED OUTPUT POWER in watts and the load impedance at which this power is available;
- operating frequency in megahertz;
- 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 subclause:*

#### 201.7.3.101 * Marking for access

Symbols number 10 (caution) and number 11 (operating instructions) of Table D.1 in Appendix D of the general standard shall be displayed on or near components or on panels giving access to components if adjustment or replacement might cause the ME EQUIPMENT to fail to comply with IEC 60601-1-2.



*Compliance is checked by inspection.*

#### 201.7.4.2 * Control devices



*Addition:*

The output control shall have a scale and/or an associated indicator representing the radio-frequency output. The numeral “0” shall not be used unless any power delivered in this position is less than 2 % of the RATED OUTPUT POWER. If the output scale or indicator represents watts of output power, it shall be so marked.

*Compliance is checked by inspection and, if appropriate, by measurement of the output power (see 201.12.1.101).*

#### 201.7.9.2 Instructions for use

*Additional subclause:*

#### 201.7.9.2.101 Additional instructions for use

The instructions for use shall contain additionally:

a) Information concerning the compatibility of APPLICATOR connecting cables in order to prevent the use of unsuitable cable.

b) *Notes on the application of ME EQUIPMENT drawing the OPERATOR’S attention to certain precautions which are necessary during treatment.

In particular, advice shall be given on:

1) For all SHORT-WAVE THERAPY EQUIPMENT:

– The function of certain implanted electrical devices, for example pacemakers, may be adversely affected during treatment with short-wave therapy. In case of doubt, the advice of the physician in charge of the PATIENT should be sought.

– The function of other PATIENT connected ME EQUIPMENT may be adversely affected by the operation of SHORT-WAVE THERAPY EQUIPMENT.

2) For all SHORT-WAVE THERAPY EQUIPMENT except LOW POWER EQUIPMENT:

– Short-wave therapy should not be applied to PATIENTS through clothing. Conductive material should be excluded from the treatment area. Additionally, it should not be applied to PATIENTS wearing metallic objects like jewellery or clothing containing metallic material (for example metallic buttons, clips or thread).

– Parts of the PATIENT'S body containing metallic implants (for example a medullary nail) should normally be excluded from the treatment, unless special techniques are used.

– Hearing aids should be removed.

– The PATIENT should not be allowed to come into contact with conductive parts which are earthed or which have an appreciable capacitance to earth and which may provide unwanted pathways for the radio-frequency current. In particular, beds or chairs having metal frames should not be used.

– The connecting cables associated with the APPLICATOR(S) should be positioned in such a way that contact with the PATIENT and with conductive or energy absorbing objects is avoided.

c) Advice for the OPERATOR to inspect regularly the insulation of the APPLICATORS and their cables for possible damage.

*Compliance is checked by inspection of the instructions for use.*



#### 201.7.9.3 Technical description

##### 201.7.9.3.1 * General

*Addition:*



– The technical description shall contain information on measuring the RATED OUTPUT POWER including a description of the MATCHED LOAD.

– For SHORT-WAVE THERAPY EQUIPMENT with interchangeable APPLICATORS, the technical description shall state the maximum safe output power that may be applied to each APPLICATOR.

*Compliance is checked by inspection of the technical description.*

## 201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies except as follows:

#### 201.8.3 Classification of APPLIED PARTS

*Addition:*

aa) APPLICATORS of SHORT-WAVE THERAPY EQUIPMENT shall be TYPE BF or CF.

#### 201.8.7.1 * General requirements

Item b) *Addition:*

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

#### 201.8.8.3 * Dielectric strength

*Addition:*