



NSAI
Standards

Irish Standard
I.S. EN 60601-2-5:2015

Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment

I.S. EN 60601-2-5:2015

Incorporating amendments/corrigenda/National Annexes issued since publication:

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National Foreword

I.S. EN 60601-2-5:2015 is the adopted Irish version of the European Document EN 60601-2-5:2015, Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment

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EUROPEAN STANDARD

EN 60601-2-5

NORME EUROPÉENNE

EUROPÄISCHE NORM

October 2015

ICS 11.040.60

Supersedes EN 60601-2-5:2000

English Version

**Medical electrical equipment - Part 2-5: Particular requirements
for the basic safety and essential performance of ultrasonic
physiotherapy equipment
(IEC 60601-2-5:2009)**

Appareils électromédicaux - Partie 2-5: Exigences
particulières pour la sécurité de base et les performances
essentielles des appareils à ultrasons pour physiothérapie
(IEC 60601-2-5:2009)

Medizinische elektrische Geräte - Teil 2-5: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von Ultraschall-
Physiotherapiegeräten
(IEC 60601-2-5:2009)

This European Standard was approved by CENELEC on 2015-09-15. 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.

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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

EN 60601-2-5:2015

European foreword

The text of document 62D/693/CDV, future edition 3 of IEC 60601-2-5, 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 60601-2-5:2015.

The following dates are fixed:

- latest date by which the document has to be implemented at (dop) 2016-06-15
national level by publication of an identical national
standard or by endorsement
- latest date by which the national standards conflicting with (dow) 2018-09-15
the document have to be withdrawn

This document supersedes EN 60601-2-5:2000.

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 93/42/EEC, see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 60601-2-5:2009 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-2-36:1997	NOTE	Harmonized as EN 60601-2-36:1997 (not modified).
IEC 61161:2006	NOTE	Harmonized as EN 61161:2007 (not modified).

Annex ZA

(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Annex ZA of EN 60601-1:2006 applies, except as follows:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>Replacement in Annex ZA of EN 60601-1:2006:</i>				
IEC 60601-1-2 (mod)	2007	Medical electrical equipment -	EN 60601-1-2	2007
-	-	Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	+ corrigendum Mar.	2010

Addition to Annex ZA of EN 60601-1:2006:

IEC 61689	2007	Ultrasonics - Physiotherapy systems - Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz	EN 61689	2007
IEC 62127-1	2007	Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz	EN 62127-1	2007
IEC 62127-2	2007	Ultrasonics - Hydrophones - Part 2: Calibration for ultrasonic fields up to 40 MHz	EN 62127-2	2007

EN 60601-2-5:2015

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 60601-2-5

Edition 3.0 2009-07

INTERNATIONAL STANDARD

NORME INTERNATIONALE

**Medical electrical equipment –
Part 2-5: Particular requirements for the basic safety and essential performance
of ultrasonic physiotherapy equipment**

**Appareils électromédicaux –
Partie 2-5: Exigences particulières pour la sécurité de base et les performances
essentielles des appareils à ultrasons pour physiothérapie**



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IEC 60601-2-5

Edition 3.0 2009-07

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –

**Part 2-5: Particular requirements for the basic safety and essential performance
of ultrasonic physiotherapy equipment**

Appareils électromédicaux –

**Partie 2-5: Exigences particulières pour la sécurité de base et les performances
essentielles des appareils à ultrasons pour physiothérapie**

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy 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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International standard IEC 60601-2-5 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published in 2000. This edition constitutes a technical revision.

The numbering was revised to agree with IEC 60601-1:2005 (third edition). Beyond this, essential performance characteristics are defined in 201.4.3.101, guidance on maintenance is added in 201.7.9.2.1, a new requirement regarding dielectric withstand was added in 201.8.8.3. The clause on transducer surface temperature rise, 201.11, has been modified to allow for simulated use conditions. Measurements of ultrasound-related parameters are now referenced to IEC 61689:2007 (second edition). The most important change in the ultrasound-related parameters is the definition of EFFECTIVE RADIATING AREA, 201.3.207. This change will also affect the value of the EFFECTIVE INTENSITY and its uncertainty.

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

Enquiry draft	Report on voting
62D/693/CDV	62D/766/RVC

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 maintenance result 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

In this particular standard, safety and performance requirements additional to those in the general standard are specified for ULTRASONIC PHYSIOTHERAPY EQUIPMENT.

This particular standard takes into account IEC 61689.

The requirements are followed by specifications for the relevant tests.

A rationale for the more important requirements, where appropriate, is given in Annex AA. It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of the particular 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.

The clauses and subclauses which have corresponding rationale statements are marked with an asterisk * after their number.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment

201.1 Scope, object and related standards

Clause 1 of the general standard¹⁾ applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ULTRASONIC PHYSIOTHERAPY EQUIPMENT as defined in 201.3.216, hereafter referred to as ME EQUIPMENT.

This standard only relates to ULTRASONIC PHYSIOTHERAPY EQUIPMENT employing a single plane unfocused circular transducer per TREATMENT HEAD, producing static beams perpendicular to the face of the TREATMENT HEAD.

This standard can also be applied to ULTRASONIC PHYSIOTHERAPY EQUIPMENT used for compensation or alleviation of disease, injury or disability.

In the case of combined EQUIPMENT (e.g. EQUIPMENT additionally provided with a function or an APPLIED PART for electrical stimulation) such EQUIPMENT shall also comply with any particular standard specifying safety requirements for the additional function.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE 1 See also 4.2 of the general standard.

This particular standard does not apply to:

- EQUIPMENT in which a tool is driven by ULTRASOUND (for example EQUIPMENT used in surgery or dentistry);
- EQUIPMENT in which focused ULTRASOUND pulse waves are used to destroy conglomerates such as stones in the kidneys or the bladder (lithotripters) (for information refer to IEC 60601-2-36);
- ULTRASONIC PHYSIOTHERAPY EQUIPMENT in which focused ultrasound pulse waves are used.

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

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ULTRASONIC PHYSIOTHERAPY EQUIPMENT (as defined in 201.3.216).

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 and subclause 201.2 of this particular standard.

IEC 60601-1-2 applies as modified in Clause 202. 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 particular 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 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 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 or figures 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:

Amendment:

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

Addition:

IEC 61689:2007, *Ultrasonics – Physiotherapy systems – Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz*

IEC 62127-1:2007, *Ultrasonics – Hydrophones – Part 1: Measurement and characterisation of medical ultrasonic fields up to 40 MHz*

IEC 62127-2:2007, *Ultrasonics – Hydrophones – Part 2: Calibration for ultrasonic fields up to 40 MHz*

NOTE Informative references are listed in the bibliography on page 32.

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in the general standard and in IEC 61689 (some of which are repeated here for convenience), as well as the following additional definitions apply:

NOTE 1 An index of defined terms is given after the Bibliography.

NOTE 2 A list of symbols used in this particular standard is found in Table 201.101.

Addition:

201.3.201

ACOUSTIC WORKING FREQUENCY

f_{awf}

frequency of an acoustic signal based on the observation of the output of a hydrophone placed in an acoustic field. The signal is analysed using the zero-crossing frequency technique

[IEC 61689:2007, definition 3.3, modified]

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