IEC 60601-2-36

Edition 2.0 2014-04

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy

Appareils électromédicaux –
Partie 2-36: Exigences particulières pour la sécurité de base et les performances essentielles des appareils pour lithotritie créée de façon extracorporelle

IEC 60601-2-36:2014-04(en-fr)

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

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
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 corrigenda or an amendment might have been published.

IEC Catalogue - webstore.iec.ch/catalogue
The stand-alone application for consulting the entire bibliographical information on IEC International Standards, Technical Specifications, Technical Reports and other documents. Available for PC, Mac OS, Android Tablets and iPad.

IEC publications search - www.iec.ch/searchpub
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 It also gives information on projects, replaced and withdrawn publications.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 also once a month by email.

Electropedia - www.electropedia.org
The world's leading online dictionary of electronic and electrical terms containing more than 30 000 terms and definitions in English and French, with equivalent terms in 14 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary
More than 55 000 electrotechnical terminology entries in English and French extracted from the Terms and Definitions clause of IEC publications issued since 2002. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

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: csc@iec.ch.

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.

Catalogue IEC - webstore.iec.ch/catalogue
Application autonome pour consulter tous les renseignements bibliographiques sur les Normes internationales, Spécifications techniques, Rapports techniques et autres documents de l'IEC. Disponible pour PC, Mac OS, tablettes Android et iPad.

Recherche de publications IEC - www.iec.ch/searchpub
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 aussi une fois par mois par email.

Electropedia - www.electropedia.org
Le premier dictionnaire en ligne de termes électroniques et électriques. Il contient plus de 30 000 termes et définitions en anglais et en français, ainsi que les termes équivalents dans 14 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.

Glossaire IEC - std.iec.ch/glossary
Plus de 55 000 entrées terminologiques électrotechniques, en anglais et en français, extraites des articles Termes et Définitions des publications IEC parues depuis 2002. Plus certaines entrées antérieures extraites des publications des CE 37, 77, 86 et CISPR de l'IEC.

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

IEC 60601-2-36

Edition 2.0 2014-04

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy

Appareils électromédicaux –
Partie 2-36: Exigences particulières pour la sécurité de base et les performances essentielles des appareils pour lithotritie créée de façon extracorporelle

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

PRICE CODE
CODE PRIX S

ICS 11.040.01

ISBN 978-2-8322-1498-5

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy

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 60601-2-36 has been prepared by IEC 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 60601-2-36 published in 1997. This edition constitutes a technical revision to align structurally with IEC 60601-1:2005 and its Amendment 1:2012).

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

FDIS	Report on voting
62D/1109/FDIS	62D/1122/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 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

This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of equipment for EXTRACORPOREALLY INDUCED LITHOTRIPSY. It amends and supplements IEC 60601-1/A1:2012 (Ed. 3.1): *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance)*, hereinafter referred to as the general standard.

The aim of this second edition is to bring this particular standard up to date with reference to the third edition of the general standard through reformatting and technical changes.

The requirements of this particular standard take priority over those of the general standard.

A “General guidance and rationale” for the more important requirements of this particular standard is included in Annex AA. It is considered that 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, Annex AA does not form part of the requirements of this standard.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-36: Particular requirements for basic safety and essential performance of equipment for extracorporeally induced lithotripsy

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 applies to BASIC SAFETY and ESSENTIAL PERFORMANCE of equipment for EXTRACORPOREALLY INDUCED LITHOTRIPSY as defined in 201.3.206 including equipment for other medical applications of therapeutic extracorporeally induced focused PRESSURE PULSES, hereafter referred to as ME EQUIPMENT. The applicability of this particular standard is limited to components directly involved in the LITHOTRIPSY treatment, such as, but not limited to, the generator of the PRESSURE PULSE, PATIENT support device, and their interactions with imaging and monitoring devices. Other devices, such as PATIENT treatment planning computers, X-ray and ultrasonic devices, are excluded from this standard, because they are treated in other applicable IEC standards.

This particular standard does not apply to:

- ULTRASOUND PHYSIOTHERAPY EQUIPMENT intended to be used for physiotherapy;
- ULTRASOUND equipment intended to be used for high intensity therapeutic ULTRASOUND (HITU) and other therapy equipment as described in Annex AA;

201.1.2 * Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements of equipment for EXTRACORPOREALLY INDUCED LITHOTRIPSY as defined in 201.3.206 including equipment for other medical applications of therapeutic extracorporeal focused PRESSURE PULSES.

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 Clause 201.2 of this particular standard.

IEC 60601-1-2:2007 applies as modified in Clause 202. IEC 60601-1-3 and IEC 60601-1-10[2] do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

---

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

[2] IEC 60601-1-10:2007, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

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” 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:

Replacement:

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 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012

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

IEC 61846:1998, *Ultrasonics – Pressure pulse lithotripters: Characterization of fields*

201.3 Terms and definitions

NOTE An index of defined terms is found beginning on page 20.

For the purpose of this document, the terms and definitions given in IEC 60601-1:2005/A1:2012 apply, except as follows:

Additional definitions:

201.3.201
ENERGY FLUX DENSITY
derived pulse-intensity integral as defined in 3.4 and 7.3.2 of IEC 61846 at the position of the FOCUS

201.3.202
ENERGY PER PULSE
derived acoustic pulse energy as defined in 7.3.4 of IEC 61846

Note 1 to entry: The temporal integration limits (3.23 of IEC 61846) and the radius *R* of the chosen circular cross section area shall be stated in order to allow for proper interpretation of the values.

201.3.203
EXTRACORPOREALLY INDUCED LITHOTRIPSY
LITHOTRIPSY inside the PATIENT by pressure pulses generated outside the PATIENT

201.3.204
FOCAL VOLUME
volume in space contained within the surface defined by the –6 dB isobar of the maximum peak compressional acoustic pressure

201.3.205
LITHOTRIPSY
comminution or fragmentation of calculi

201.3.206
LITHOTRIPSY EQUIPMENT
ME-EQUIPMENT intended to be used for LITHOTRIPSY treatment

201.3.207
*** LOCALIZATION DEVICE**
device used to determine the position of the calculi in (three-dimensional) space

201.3.208
POSITIONING DEVICE
device which brings the calculi into coincidence with the TARGET LOCATION

Note 1 to entry: See also IEC 61846:1998, 3.22, TARGET LOCATION.

201.3.209
PRESSURE PULSE
acoustic wave emitted by the LITHOTRIPSY EQUIPMENT

[SOURCE: IEC 61846, definition 3.18 and Clause C.4]

201.3.210
PRESSURE PULSE COUPLING
any means allowing transition of the PRESSURE PULSE from the ME EQUIPMENT into the PATIENT

201.3.211
TARGET MARKER
marker which is used to indicate the TARGET LOCATION¨

EXAMPLE A marker on the imaging device.

Note 1 to entry: See also IEC 61846:1998, 3.22, TARGET LOCATION.

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 requirements for ESSENTIAL PERFORMANCE

The ME EQUIPMENT shall be free from incorrect display of energy levels (see 201.12.1.102).

The ME EQUIPMENT shall be free from unintended shock wave release (see 201.12.4.6).

201.4.7 SINGLE FAULT CONDITION for ME EQUIPMENT

Addition:

Safety in SINGLE FAULT CONDITION of the PRESSURE PULSE release (avoiding faulty release) and safety in SINGLE FAULT CONDITION in motor supported positioning (to avoid unintentional changes of position during PRESSURE PULSE release and mechanical danger) shall be ensured. These requirements may be met by mutually interlocking the two systems, e.g. by mutually interlocking the PRESSURE PULSE release with a SINGLE FAULT CONDITION secured positioning device, or by mutually interlocking the POSITIONING DEVICE with a SINGLE FAULT CONDITION secured PRESSURE PULSE release. This mutual interlocking may be overridden by a deliberate action of the OPERATOR, for example by pressing a separate switch, if the position of the calculus is monitored.

Compliance is checked by functional testing and fault analysis.

201.5 General requirements for testing 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:

201.7.9.2 Instructions for use

Addition:

201.7.9.2.101 Additional instructions for use

The instructions for use shall also include:

a) description of the relevant safety precautions to be used to avoid HAZARDOUS SITUATIONS, e.g. the danger resulting from delivering PRESSURE PULSES to organs which contain gas;

b) caution that PRESSURE PULSES may cause unwanted cardiac activity;

c) when using ECG monitoring equipment to trigger the generation of the PRESSURE PULSE, only those ECG monitors specified by the MANUFACTURER of the ME EQUIPMENT shall be used;

d) caution that the OPERATOR shall check the position of the calculi as often as necessary to ensure proper treatment;

e) description of the schedule and measures to be performed within the scope of a regular performance check;

f) description concerning the correct use of the PRESSURE PULSE COUPLING including a reminder that it shall be free of bubbles;

g) reminder that the PRESSURE PULSE is attenuated during passage through tissue, and that additional energy is absorbed by bone;

h) reminder that, even if anti-collision devices are installed, the OPERATOR shall always watch for any movements that may cause danger to the PATIENT or OPERATOR.

201.7.9.3 * Technical description

Addition:

201.7.9.3.101 Additional technical description

The technical description for use shall also include:

a) positional precision of the TARGET MARKER with respect to the TARGET LOCATION;

b) position and size of the FOCAL VOLUME at minimum, typical and maximum shockwave generator output settings with respect to the TARGET LOCATION, stating the positions of the -6 dB pressure values along the shockwave source axis and perpendicular to the shock wave axis at the position of the FOCUS (See Annex BB);

c) peak compressional and rarefactional acoustic pressures at the minimum, typical and maximum output settings;

d) ENERGY FLUX DENSITY at the minimum, typical and maximum output settings, including the specification of the temporal integration limits;

e) ENERGY PER PULSE including the specification of the temporal integration limits and the radius *R* of the chosen circular cross section area at the minimum, typical and maximum output settings.