

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**



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Medical electrical equipment –

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Appareils électromédicaux –

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

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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

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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 standard¹ 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 60601-1-10² 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