BS EN 60601-2-36:2015

BSI Standards Publication

Medical electrical equipment

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

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National foreword

This British Standard is the UK implementation of EN 60601-2-36:2015. It is identical to IEC 60601-2-36:2014. It supersedes BS EN 60601-2-36:1997, which will be withdrawn on 22 May 2018.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.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-36

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English Version

Medical electrical equipment - Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy (IEC 60601-2-36:2014)

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)

Medizinische elektrische Geräte - Teil 2-36: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmal von Geräten zur extrakorporal induzierten Lithotripsie
(IEC 60601-2-36:2014)

This European Standard was approved by CENELEC on 2014-05-15. 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.

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

Ref. No. EN 60601-2-36:2015 E

Foreword

The text of document 62D/1109/FDIS, future edition 2 of IEC 60601-2-36, prepared by IEC/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 60601-2-36:2015.

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)	2015-11-22
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-05-22

This document supersedes EN 60601-2-36:1997.

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 60601-2-36:2014 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 61689:2013	NOTE	Harmonized as EN 61689:2013 (not modified).
IEC 62555	NOTE	Harmonized as EN 62555.

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 with the following exceptions:

Publication	Year	Title	EN/HD	Year
Replacement:				
IEC 60601-1-2 (mod)	2007	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2007
			+AC	2010
Addition:				
IEC 60601-1	2005	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
			+AC	2010
			+AC	2014
			+A11	2011
+A1	2012		+A1	2013
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 - Characteristics of fields	EN 61846	1998

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.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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.
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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 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.

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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.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

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

201.8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

201.8.7.1 * General requirements

Addition to the third dash:

The PATIENT LEAKAGE CURRENT shall not be measured during the PRESSURE PULSE release.

201.8.8.3 Dielectric strength

Table 6 – Test voltages for solid insulation forming a MEANS OF PROTECTION

Addition:

Voltages higher than 14 140 V shall be tested with a factor of 1,2.

Table 7 – Test voltages for MEANS OF OPERATOR PROTECTION

Addition:

Voltages higher than 10 000 V shall be tested with a factor of 1,2.

201.9 Protection against MECHANICAL HAZARDS OF ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies, except as follows:

201.9.2.2.5 Continuous activation

Addition:

Systems which have powered movements shall be designed to avoid excessive force being exerted on the PATIENT. ME EQUIPMENT movements which may endanger the PATIENT during compression shall be prevented.

ACCESSORY parts shall be secured against falling out in all operating positions.

201.9.4.2.4.3 Movement over a threshold

Replacement of the compliance statement:

Compliance is checked by the following test: MOBILE ME EQUIPMENT shall be moved forward using a contact as close as possible to the floor in its usual direction, at a speed to be specified by the MANUFACTURER, but not more than 0,1 m/s, over a dimensionally stable obstacle which has a rectangular cross-section, 10 mm high by 80 mm wide, which is placed flat on the plane. The ME EQUIPMENT shall operate normally after this test.

201.9.6.2.1 * Audible acoustic energy

Replacement of the first dash by the two following dashes:

– 90 dBA for a cumulative exposure of 8 h over a 24 h period; an offset of 3 dBA is to be added to this value when halving the cumulative exposure time over a 24 h period (e.g. 93 dBA for 4 h over a 24 h period);
– 105 dBA for a cumulative exposure of 1 h over a 24 h period; an offset of 3 dBA is to be added to this value when halving the cumulative exposure time over a 24 h period (e.g. 108 dBA for 1/2 h over a 24 h period);

Addition before the compliance statement:

If the A-weighted sound pressure level exceeds 80 dBA, noise protection measures should be considered

201.9.8.4.1 General

Addition:

Ropes, chains or belts running parallel to other ropes, chains or belts may be regarded as antidrop safety devices if they remain unloaded during operation. Wire ropes may be used as anti-drop devices only if they are checked at regular intervals.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

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:

The surface temperature of the APPLIED PART shall not be lower than 5 °C below ambient temperature, after a warm-up period specified by the MANUFACTURER.

201.11.7 Biocompatibility of ME EQUIPMENT and ME SYSTEMS

Addition:

If a coupling liquid (e.g. ULTRASOUND gel, oil, etc.) is used, then this liquid is considered to be the ACCESSORY to come into direct or indirect contact with the biological tissues, cell or body fluids.

201.11.8 Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

Addition:

Upon restoration of the power supply, a deliberate action, for example the release and repressing of a switch, is required to initiate PRESSURE PULSE release.

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:

201.12.1.101 Precision of TARGET MARKERS and TARGET LOCATIONS

Specifications of testing methods to test the alignment precision of TARGET MARKER and TARGET LOCATION, including permissible deviations, shall be provided by the MANUFACTURER in the instructions for use.

Compliance is checked by inspection.

201.12.1.102 Testing methods to recognize any deviation

Specification of testing methods to recognize any deviation of physical variables that may result in an increased RISK to the PATIENT shall be provided by the MANUFACTURER.

Compliance is checked by inspection.

201.12.1.103 Constancy testing methods

Constancy testing methods shall be the responsibility of the MANUFACTURER, for both initial ME EQUIPMENT quality control and for testing over the lifetime of the ME EQUIPMENT.

Compliance is checked by inspection.

201.12.4.3 Accidental selection of excessive output values

Addition:

The means to protect PATIENTS from unintended levels of the PRESSURE PULSES shall be safe in SINGLE FAULT CONDITION.

Compliance is checked by inspection.

201.12.4.4 Incorrect output

Addition:

If the PRESSURE PULSE control device can be controlled by more than one device, these devices shall be mutually interlocked.

Compliance is checked by inspection.

201.12.4.6 * Diagnostic or therapeutic acoustic pressure

Addition:

The release of PRESSURE PULSES shall be under the control of the OPERATOR through deliberate and continued action.

Compliance is checked by inspection.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

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:

201.15.4.7.1 Mechanical strength

Addition:

The force required to actuate the foot switches shall not be smaller than 10 N.

Compliance is checked by measuring the operating force.

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 applies except as follows:

Addition:

Compliance with IEC 60601-1-2 will be maintained, except during the triggering and generation cycle of the PRESSURE PULSE release.

Annexes

The annexes of the general standard apply.

Annex AA
(informative)

Particular guidance and rationale

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 201.1.2 – Object

Parts of this standard that may not be applicable are: ME EQUIPMENT for other medical applications of therapeutic pressure pulses which include unfocused pressure pulse sources, pneumatically generated ballistic sources or ME EQUIPMENT without LOCALIZATION and/or POSITIONING DEVICES, however, subclause 201.7.9.3.101 c) and d) may be applicable.

Subclause 201.3.207 – LOCALIZATION DEVICE

Means currently in use include X-ray, fluoroscopy and ULTRASOUND.

Subclause 201.7.9.3 – Technical description

The test methodologies for reporting item a) are at the discretion of the MANUFACTURER. Items c), d) and e) refer to IEC 61846 ("Ultrasonics – Pressure pulse lithotripters – Characteristics of field").

Subclause 201.8.7.1 – General requirements

During PRESSURE PULSE release it is not technically feasible to measure PATIENT LEAKAGE CURRENT.

Subclause 201.9.6.2.1 – Audible acoustic energy

These levels were established by the Occupational Safety and Health Administration (OSHA) in the United States. Transmission of excessive structureborne noise into the building is to be minimized by appropriate design.

Subclause 201.11.1.2 – APPLIED PARTS intended to supply heat to a PATIENT

This additional paragraph has been inserted to prevent temperature shock to the PATIENT.

NOTE The surface temperature of the applied part should be chosen such as to avoid patient discomfort or pain

Subclause 201.12.4.6 – Diagnostic and therapeutic acoustic pressure

This requirement is motivated by the desire to ensure that the treatment is always under control of the OPERATOR.

Clause 202 – ELECTROMAGNETIC COMPATIBILITY – Requirements and tests

During the triggering and generation cycle of the PRESSURE PULSE, it is not technically feasible to maintain EMC, because this ME EQUIPMENT involves high-voltage electric discharges

Annex BB
(informative)

Definition of coordinates, FOCUS and TARGET LOCATION

In order to achieve consistent statements on the geometrical FOCUS distribution, the following sketch gives definitions of an appropriate coordinate system and the positions of relevant parameters:

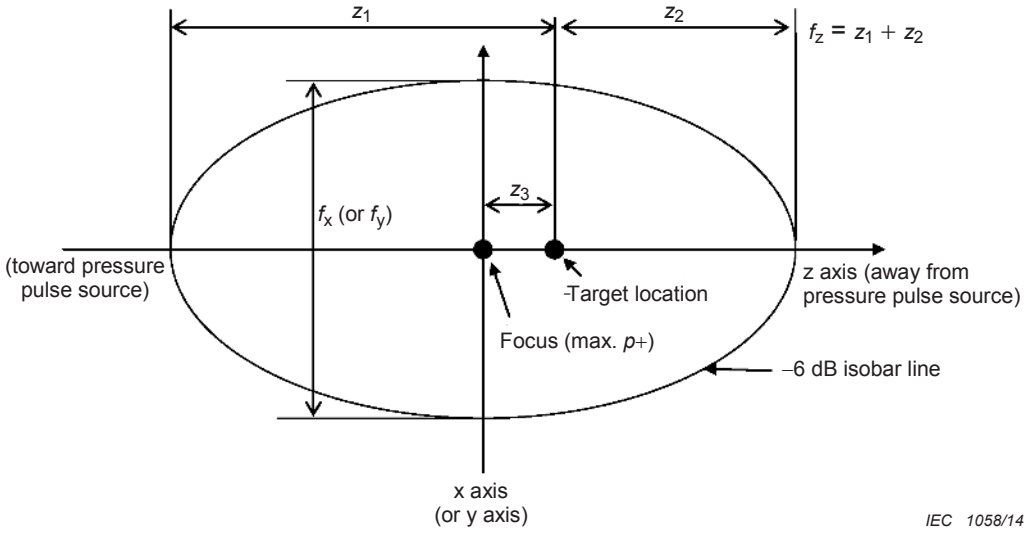

Figure BB.1 – Geometrical FOCUS distribution

NOTE The –6 dB isobar line represents a physical property of the pressure pulse source, it does not per se state the elegible therapy area

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Index of defined terms used in this particular standard

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