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Interested committees:

Title: Draft BS EN 60601-2-36 Ed.3.0 BS EN 60601-2-36 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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- i) has any issues related to 3rd party IPR, patent or copyright
- ii) affects other national standard(s)
- iii) requires additional national guidance or information

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This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. No acknowledgement will normally be sent. **See overleaf for information on the submission of comments.**

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



62D/2240/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER:

IEC 60601-2-36 ED3

DATE OF CIRCULATION:

2025-07-04

CLOSING DATE FOR COMMENTS:

2025-08-29

SUPERSEDES DOCUMENTS:

62D/2100/RR

IEC SC 62D : PARTICULAR MEDICAL EQUIPMENT, SOFTWARE, AND SYSTEMS

SECRETARIAT:

United States of America

SECRETARY:

Ms Ladan Bulookbashi

OF INTEREST TO THE FOLLOWING COMMITTEES:

TC 87

HORIZONTAL FUNCTION(S):

ASPECTS CONCERNED:

Electromagnetic Compatibility, Safety

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Recipients of this document are invited to submit, with their comments, notification of any local regulations or technical reasons that may exist and should be considered should this proposal proceed, recognizing that failure to address such requirements could result in the need for new or existing "In Some Countries" clauses. (SEE [AC/22/2007](#) OR [NEW GUIDANCE DOC](#)).

TITLE:

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

NOTE FROM TC/SC OFFICERS:

SC 62D National Committees are invited to review the Committee Draft and submit their comments. Please pay particular attention to the proposed changes to the title of the standard, and provide feedback if you disagree with the revised title. Below is the rationale for the proposed changes to the title for your consideration:

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.

Only naming extracorporeal shock wave lithotripsy (ESWL) in the title is misleading because that method does only describe the medical application for stone fragmentation (lithotripsy) and does not cover other applications where for example tissue is stimulated by extracorporeal shock waves therapy (ESWT).

In order to generalize the title and don't restrict it to a medical application method the title was changed as following.

"Particular requirements for the basic safety and essential performance of therapy equipment for extracorporeally induced focused pressure pulses",

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ESWL and ESWT are both representing therapies where extracorporeally induced focused pressure pulses are used. The title change reflects the change from a possibly restricted description of the medical application method to the universal description of the physical mode of action.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-36: Particular requirements for the basic safety and essential performance of therapy equipment for extracorporeally induced focused pressure pulses

FOREWORD

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- International standard IEC 60601-2-36 has been prepared by IEC subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems.
- This third edition cancels and replaces the second edition of IEC 60601-2-36 published in 2014. This edition constitutes a technical revision to align structurally with IEC 60601-1:2005 and its Amendment 1:2012 and Amendment 2:2020.

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

FDIS	Report on voting
62D/xxxx/FDIS	62D/xxxx/RVD

82
83 Full information on the voting for the approval of this particular standard can be found in the
84 report on voting indicated in the above table.

85 This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

86 In this standard, the following print types are used:

- 87 – Requirements and definitions: roman type.
- 88 – *Test specifications: italic type.*
- 89 – Informative material appearing outside of tables, such as notes, examples and references: in smaller type.
90 Normative text of tables is also in a smaller type.
- 91 – TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS
92 NOTED: SMALL CAPITALS.

93 In referring to the structure of this standard, the term

- 94 – “clause” means one of the numbered divisions within the table of contents, inclusive of all
95 subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- 96 – “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all
97 subclauses of Clause 7).

98 References to clauses within this standard are preceded by the term “Clause” followed by the
99 clause number. References to subclauses within this particular standard are by number only.

100 In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any
101 combination of the conditions is true.

102 The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC
103 Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- 104 – “shall” means that compliance with a requirement or a test is mandatory for compliance with
105 this standard;
- 106 – “should” means that compliance with a requirement or a test is recommended but is not
107 mandatory for compliance with this standard;
- 108 – “may” is used to describe a permissible way to achieve compliance with a requirement or
109 test.

110 An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title
111 indicates that there is guidance or rationale related to that item in Annex AA.

112 A list of all parts of the IEC 60601 series, published under the general title *Medical electrical*
113 *equipment*, can be found on the IEC website.

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