
Medicinska električna oprema - 2. del: Posebne varnostne zahteve za opremo za zunajtelesno inducirano litotripsijo (IEC 60601-2-36:1997)

Medical electrical equipment - Part 2: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy (IEC 60601-2-36:1997)

Medizinische elektrische Geräte - Teil 2: Besondere Festlegungen für die Sicherheit von Geräten zur extrakorporal induzierten Lithotripsie (IEC 60601-2-36:1997)

Appareils électromédicaux - Partie 2: Règles particulières de sécurité des appareils pour lithotritie créée de façon extra-corporelle (CEI 60601-2-36:1997)

<https://standards.iteh.ai/catalog/standards/sist/6a3339d4-b85e-4f69-b010-6fae32e4d2a8/sist-en-60601-2-36-1998>

Ta slovenski standard je istoveten z: EN 60601-2-36:1997

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general
11.040.60	Terapevtska oprema	Therapy equipment

SIST EN 60601-2-36:1998

en

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN 60601-2-36:1998](https://standards.iteh.ai/catalog/standards/sist/6a3339d4-b85e-4f69-b010-6fae32e4d2a8/sist-en-60601-2-36-1998)

<https://standards.iteh.ai/catalog/standards/sist/6a3339d4-b85e-4f69-b010-6fae32e4d2a8/sist-en-60601-2-36-1998>

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 60601-2-36

May 1997

ICS 11.040.60

Descriptors: Medical electrical equipment, equipment for lithotripsy, safety requirements, protection against electric shock, protection against mechanical hazard, radiation protection, fire protection, environmental conditions

English version

Medical electrical equipment
Part 2: Particular requirements for the safety of
equipment for extracorporeally induced lithotripsy
(IEC 60601-2-36:1997)

Appareils électromédicaux
Partie 2: Règles particulières de
sécurité des appareils pour lithotritie
créée de façon extra-corporelle
(CEI 60601-2-36:1997)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen
für die Sicherheit von Geräten zur
extrakorporal induzierten Lithotripsie
(IEC 60601-2-36:1997)

This European Standard was approved by CENELEC on 1997-03-11. 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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

[SIST EN 60601-2-36:1998](https://standards.iteh.ai/catalog/standards/sist/6a3339d4-b85e-4f69-b010-6fae32e4d2a8/sist-en-60601-2-36-1998)

<https://standards.iteh.ai/catalog/standards/sist/6a3339d4-b85e-4f69-b010-6fae32e4d2a8/sist-en-60601-2-36-1998>

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of document 62D/211/FDIS, future edition 1 of IEC 60601-2-36, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-36 on 1997-03-11.

The following dates were fixed:

- latest date by which the EN has to be implemented
at national level by publication of an identical
national standard or by endorsement (dop) 1997-12-01
- latest date by which the national standards conflicting
with the EN have to be withdrawn (dow) 1997-12-01

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annex ZA is normative and annexes AA and ZB are informative.
Annexes ZA and ZB have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-36:1997 was approved by CENELEC as a European Standard without any modification.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN 60601-2-36:1998](https://standards.iteh.ai/catalog/standards/sist/6a3339d4-b85e-4f69-b010-6fae32e4d2a8/sist-en-60601-2-36-1998)

<https://standards.iteh.ai/catalog/standards/sist/6a3339d4-b85e-4f69-b010-6fae32e4d2a8/sist-en-60601-2-36-1998>

Annex ZA (normative)**Normative references to international publications
with their corresponding European publications**

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE: When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Addition to annex ZA of EN 60601-1:1990/A2:1995:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
-	-	Metallic materials - Tensile testing Part 1: Method of test (at ambient temperature)	EN 10002-1	1990
IEC 601-1-2	1993	Medical electrical equipment Part 1: General requirements for safety 2. Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	1993

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN 60601-2-36:1998](https://standards.iteh.ai/catalog/standards/sist/6a3339d4-b85e-4f69-b010-6fae32e4d2a8/sist-en-60601-2-36-1998)

<https://standards.iteh.ai/catalog/standards/sist/6a3339d4-b85e-4f69-b010-6fae32e4d2a8/sist-en-60601-2-36-1998>

Annex ZB (informative)**Normative references to international publications
with their corresponding European publications**

Addition to annex ZB of EN 60601-1:1990/A2:1995:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
DIN 50 100	1978	Testing of materials, continuous vibration test - Definitions, symbols, procedure, evaluation	-	-

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN 60601-2-36:1998](https://standards.iteh.ai/catalog/standards/sist/6a3339d4-b85e-4f69-b010-6fae32e4d2a8/sist-en-60601-2-36-1998)

<https://standards.iteh.ai/catalog/standards/sist/6a3339d4-b85e-4f69-b010-6fae32e4d2a8/sist-en-60601-2-36-1998>

**NORME
INTERNATIONALE
INTERNATIONAL
STANDARD**

**CEI
IEC**

60601-2-36

Première édition
First edition
1997-03

Appareils électromédicaux –

**Partie 2:
Règles particulières de sécurité des appareils
pour lithotritie créée de façon extra-corporelle**

iTeh STANDARD PREVIEW

Medical electrical equipment –

**Part 2:
Particular requirements for the safety of equipment
for extracorporeally induced lithotripsy**

© IEC 1997 Droits de reproduction réservés — Copyright - all rights reserved

Aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de l'éditeur.

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

International Electrotechnical Commission
Telefax: +41 22 919 0300

3, rue de Varembé Geneva, Switzerland
e-mail: inmail@iec.ch IEC web site <http://www.iec.ch>



Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

CODE PRIX
PRICE CODE

Q

Pour prix, voir catalogue en vigueur
For price, see current catalogue

CONTENTS

	Page
FOREWORD	5
INTRODUCTION	7
Clause	
SECTION ONE: GENERAL	
1 Scope and object	9
2 Terminology and definitions	11
6 Identification, marking and documents	13
SECTION TWO: ENVIRONMENTAL CONDITIONS	
10 Environmental conditions	15
SECTION THREE: PROTECTION AGAINST ELECTRIC SHOCK HAZARDS	
19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	17
20 Dielectric strength	17
SECTION FOUR: PROTECTION AGAINST MECHANICAL HAZARDS	
21 Mechanical strength	17
22 Moving parts	21
24 Stability in NORMAL USE	23
26 Vibration and noise	23
28 Suspended masses	25
SECTION FIVE: PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION	
35 Acoustical energy (including ultrasonics)	25
36 Electromagnetic compatibility	25
SECTION SEVEN: PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS	
42 Excessive temperatures	27
49 Interruption of the power supply	27
SECTION EIGHT: ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT	
50 Accuracy of operating data	27
51 Protection against hazardous output	29
SECTION TEN: CONSTRUCTIONAL REQUIREMENTS	
54 General	29
56 Components and general assembly	31
57 MAINS PARTS, components and layout	31
Annexes	
L References – Publications mentioned in this Standard	33
AA General guidance and rationale	35

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

**Part 2: Particular requirements for the safety of equipment
for extracorporeally induced lithotripsy**

FOREWORD

- 1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The 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 the 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 National Committees.
- 3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.
- 4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
- 5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
- 6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60601-2-36 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this Particular Standard is based on the following documents:

FDIS	Report on voting
62D/211/FDIS	62D/231/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.

Annex AA is for information only.

In this Particular Standard the following print types are used:

- requirements, compliance with which can be tested, and definitions: in roman type;
- notes, explanations, advice, introductions, general statements, exceptions and references: in smaller type;
- *test specifications: in italic type;*
- TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 AND IN IEC 601-1: SMALL CAPITALS.

INTRODUCTION

This Particular Standard supplements IEC 601-1 (second edition, 1988) *Medical electrical equipment – Part 1: General requirements for safety*, and its amendments 1 (1991) and 2 (1995), hereinafter referred to as the General Standard (see 1.3).

The requirements are followed by specifications for the relevant tests.

Following the decision taken by subcommittee 62D at the meeting in Washington in 1979, a "General guidance and rationale" section giving some explanatory notes, where appropriate, about the more important requirements is included in annex AA.

Clauses or subclauses for which there are explanatory notes in annex AA are marked with an asterisk (*).

It is considered that a 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, this annex does not form part of the requirements of this Standard.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN 60601-2-36:1998](https://standards.iteh.ai/catalog/standards/sist/6a3339d4-b85e-4f69-b010-6fae32e4d2a8/sist-en-60601-2-36-1998)

<https://standards.iteh.ai/catalog/standards/sist/6a3339d4-b85e-4f69-b010-6fae32e4d2a8/sist-en-60601-2-36-1998>

MEDICAL ELECTRICAL EQUIPMENT –

Part 2: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy

SECTION ONE: GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

1.1 Scope

Addition:

This Particular Standard applies to the safety of EQUIPMENT FOR EXTRACORPOREALLY INDUCED LITHOTRIPSY as defined in 2.1.101.

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.

SIST EN 60601-2-36:1998

While this Particular Standard has been developed for EQUIPMENT intended for use in LITHOTRIPSY, it has been developed such that, as long as no other specific standards are available to be used for other medical applications of therapeutic extracorporeal PRESSURE PULSE equipment, this Standard may be used as a guideline.

1.2 Object

Addition:

This Particular Standard specifies requirements for the safety of EQUIPMENT for EXTRACORPOREALLY INDUCED LITHOTRIPSY.

1.3 Particular Standards

Addition:

This Particular Standard refers to IEC 601-1 (1988): *Medical electrical equipment – Part 1: General requirements for safety*, and its amendments 1 (1991) and 2 (1995).

For brevity, Part 1 is referred to in this Particular Standard either as the "General Standard" or as the "General Requirement(s)".

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words: