ELEKTRILISED MEDITSIINISEADMED. OSA 2-36: ERINÕUDED KEHAVÄLISELT INDUTSEERITAVA PÕIEKIVIDE PURUSTAMISE SEADMETE ESMASELE OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 60601-2-36:2015 sisaldab Euroopa standardi EN 60601-2-36:2015 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-2-36:2015 consists of the English text of the European standard EN 60601-2-36:2015.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 22.05.2015.	Date of Availability of the European standard is 22.05.2015.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.01

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.

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

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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.

CONTENTS

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*