ELEKTRILISED MEDITSIINISEADMED. OSA 2-44: ERINÕUDED KOMPUUTERTOMOGRAAFIAS KASUTATAVATE RÖNTGENSEADMETE ESMASELE OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE

Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 60601-2-44:2009+A11+A1+A2 sisaldab Euroopa standardi EN 60601-2-44:2009 ja selle muudatuste A11:2011, A1:2012 ja A2:2016 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-2-44:2009+A11+A1+A2 consists of the English text of the European standard EN 60601-2-44:2009 and its amendments A11:2011, A1:2012 and A2:2016.
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 20.05.2009, muudatused A11 20.05.2009, A1 19.10.2012 ja A2 03.06.2016.	Date of Availability of the European standard is 20.05.2009, for amendments A11 20.05.2009, A1 19.10.2012 and A2 03.06.2016.
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 11.040.50

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-44

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Supersedes EN 60601-2-44:2001 + A1:2003

English version

Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography

(IEC 60601-2-44:2009)

Appareils électromédicaux -
Partie 2-44: Exigences particulières
pour la sécurité de base
et les performances essentielles
des équipements à rayonnement X
de tomodensitométrie
(CEI 60601-2-44:2009)

Medizinische elektrische Geräte -
Teil 2-44: Besondere Festlegungen
für die Sicherheit einschließlich
der wesentlichen Leistungsmerkmale
von Röntgeneinrichtungen
für die Computertomographie
(IEC 60601-2-44:2009)

CENELEC

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

Central Secretariat: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 60601-2-44:2009 E

Foreword

The text of document 62B/727/FDIS, future edition 3 of IEC 60601-2-44, prepared by SC 62B, Diagnostic imaging 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 60601-2-44 on 2009-05-01.

This European Standard supersedes EN 60601-2-44:2001 + A1:2003.

EN 60601-2-44:2009 constitutes a technical revision primarily related to RADIATION protection and control.

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)	2010-02-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2012-05-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive MDD (93/42/EEC). See Annex ZZ.

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 seventeen 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.

Annexes ZA and ZZ have been added by CENELEC.

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Endorsement notice

The text of the International Standard IEC 60601-2-44:2009 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 60601-2-7	NOTE	Harmonized as EN 60601-2-7:1998 (not modified).
IEC 60601-2-32	NOTE	Harmonized as EN 60601-2-32:1994 (not modified).
IEC 60613	NOTE	Harmonized as EN 60613:1990 (not modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

Annex ZA of EN 60601-1:2006 applies, except as follows:

Publication	Year	Title	EN/HD	Year
***Replace** the reference to IEC 60601-1-3 by:*				
IEC 60601-1-3	2008	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral standard: Radiation protection in diagnostic X-ray equipment	EN 60601-1-3	2008
Addition:				
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
IEC 61223-3-5	2004	Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance tests - Imaging performance of computed tomography X-ray equipment	EN 61223-3-5	2004
ISO 12052	- [1)]	Health informatics - Digital imaging and communication in medicine (DICOM) including workflow and data management	-	-

[1)] Undated reference.

Annex ZZ
(informative)

Coverage of Essential Requirements of EC 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 as given in Annex I of the EC Directive 93/42/EEC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

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CONTENTS

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography

201.1 Scope, object and related standards

Clause 1 of the general standard[1)] applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of CT SCANNERS, hereafter also referred to as ME EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

NOTE 1 See also 4.2 of the general standard.

The scope of this document is limited to CT SCANNERS intended to be used for both head and body characterised by an ENCLOSURE of the X-ray source(s) and imaging detector(s) in a common protective cover in the shape of a toroid. It includes safety requirements for the X-RAY GENERATORS used in CT SCANNERS, including those where HIGH-VOLTAGE GENERATORS are integrated with an X-RAY TUBE ASSEMBLY.

NOTE 2 Requirements for X-RAY GENERATORS and for ASSOCIATED EQUIPMENT, which were previously specified in IEC 60601-2-7 and IEC 60601-2-32, have been included in either IEC 60601-1:2005 (Ed3) or this edition of IEC 60601-2-44. Therefore IEC 60601-2-7 and IEC 60601-2-32 are not part of the 3rd edition scheme for COMPUTED TOMOGRAPHY.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for CT SCANNERS as defined in 201.3.201, to ensure safety, and to specify methods for demonstrating compliance with those requirements, for CT SCANNERS.

NOTE 1 Requirements for reproducibility, linearity, constancy and accuracy are given because of their relationship to the quality and quantity of the IONIZING RADIATION produced and are confined to those considered necessary for safety.

NOTE 2 Both the levels for compliance and the tests prescribed to determine compliance reflect the fact that the safety of HIGH-VOLTAGE GENERATORS is not sensitive to small differences in levels of performance. The combinations of LOADING FACTORS specified for the tests are therefore limited in number but chosen from experience as being appropriate in most cases. It is considered important to standardize the choice of combinations of LOADING FACTORS so that comparison can be made between tests performed in different places on different occasions. However, combinations other than those specified could be of equal technical validity.

NOTE 3 The safety philosophy on which this standard is based is described in the introduction to the general standard and in IEC TR 60513.

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1) IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.