

STN	Zdravotnícke elektrické prístroje. Časť 2-44: Osobitné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti röntgenových prístrojov na výpočtovú tomografiu. Zmena A2	STN EN 60601-2-44/A2
		36 4800

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 12/16

STN EN 60601-2-44 z júla 2010 sa bez zmeny A2 môže používať do 5. 5. 2019.

Obsahuje: EN 60601-2-44:2009/A2:2016, IEC 60601-2-44:2009/AMD2:2016

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EUROPEAN STANDARD

EN 60601-2-44:2009/A2

NORME EUROPÉENNE

EUROPÄISCHE NORM

June 2016

ICS 11.040.50

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/A2:2016)**

Appareils électromédicaux - Partie 2-44: Exigences
particulières pour la sécurité de base et les performances
essentiels des équipements à rayonnement X de
tomodensitométrie
(IEC 60601-2-44:2009/A2:2016)

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/A2:2016)

This amendment A2 modifies the European Standard EN 60601-2-44:2009; it was approved by CENELEC on 2016-05-05. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment 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.

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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

European foreword

The text of document 62B/976/CDV, future IEC 60601-2-44:2009/A2, 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 approved by CENELEC as EN 60601-2-44:2009/A2:2016.

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) 2017-02-05
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2019-05-05

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For the relationship with EU Directive(s), see informative Annex ZZ, included in EN 60601-2-44:2009.

Endorsement notice

The text of the International Standard IEC 60601-2-44:2009/A2:2016 was approved by CENELEC as a European Standard without any modification.

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.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>In Annex ZA of EN 60601-2-44:2009, replace the existing references to the following publications as follows:</i>				
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
-	-		+ A12	2014
IEC 60601-1-2	2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests	EN 60601-1-2	2015
IEC 60601-1-3	2008	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance -	EN 60601-1-3	2008
-	-		+ corrigendum Mar.	2010
+ A1	2013	Collateral Standard: Radiation protection in diagnostic X-ray equipment	+ A1	2013
-	-		+ A1/AC	2014



INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 2
AMENDEMENT 2

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

**Appareils électromédicaux –
Partie 2-44: Exigences particulières pour la sécurité de base et les performances
essentielles des équipements à rayonnement X de tomographie**





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INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 2
AMENDEMENT 2

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FOREWORD

This amendment has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

CDV	Report on voting
62B/976/CDV	62B/994/RVC

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC website 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.

koniec náhľadu – text ďalej pokračuje v platenej verzii STN