IEC 60601-2-44

Edition 3.2 2016-03
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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 tomodensitométrie

IEC 60601-2-44:2009-02+AMD1:2012-08+AMD22016-03 CSV(en-fr)

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REDLINE VERSION

VERSION REDLINE

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of 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, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). 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. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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This consolidated version of the official IEC Standard and its amendments has been prepared for user convenience.

IEC 60601-2-44 edition 3.2 contains the third edition (2009-02) [documents 62B/727/FDIS and 62B/734/RVD] and its corrigendum (May 2010), its amendment 1 (2012-08) [documents 62B/879/FDIS and 62B/890/RVD] and its amendment 2 (2016-03) [documents 62B/976/CDV and 62B/994/CDV].

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendments 1 and 2. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

International standard IEC 60601-2-44 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

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.

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

The committee has decided that the contents of the base publication and its amendments will remain unchanged until the stability date indicated on the IEC web site 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.

NOTE The attention of National Committees is drawn to the fact that equipment MANUFACTURERS and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

Introduction to Amendment 1

The main topic addressed in this amendment is an extended concept of *CTDI* to accommodate CT SCANNERS with very large z-coverage. The other principal subject areas include:

1) a dose-check feature associated with a pre-scanning alert if expected values of dose indices exceed user-configurable DOSE NOTIFICATION VALUES or DOSE ALERT VALUES and
2) requirements covering the use of CT data in radiotherapy treatment planning (RTP).

The CT dose metric in use has been based on the $CTDI_{100}$, i.e. measurement of dose in PHANTOMs and limited integration of scattered radiation, and it is used in many countries' legislation to define "dose reference values" (also called "diagnostic reference levels") for CT examinations. Many people use these indices, $CTDI_{vol}$ and *DLP*, to derive estimates for effective dose via conversion factors. $CTDI_{100}$ is also part of CT acceptance and constancy testing. The introduction of a new dose index would change all CT SCANNERS' *CTDI* values. Therefore the intention is to stay with the $CTDI_{100}$, i.e. the integration of primary radiation and scatter over 100 mm, but adapt the way of measuring and reporting the dose index to incorporate large collimations and to rate all collimations the same way, i.e. to reflect approximately the same percentage of $CTDI_{\infty}$ for all collimations.

As defined in the amendment, $CTDI_{100}$ is to be measured only for collimations up to 40 mm with the current equipment, i.e. the PMMA PHANTOMs and a 100-mm chamber, or other suitable methods that use a RADIATION DETECTOR. For these collimations there is no significant change of the ratio $CTDI_{100}$ / $CTDI_{\infty}$ according to published data. For larger collimations at the same CT CONDITIONS OF OPERATION, the z-efficiency may be different and must be evaluated in the dose measurement. This can be accomplished by the measurement of dose 'free air'. Based on these considerations $CTDI_{100}$ and the $CTDI_{free\ air}$ have been refined. Both types of measurement are combined now to determine the *CTDI* values for larger collimations and they are explained in detail in informative Annexes CC and DD.

Some additional requirements and refinements related to dose have been added: $CTDI_{vol}$ and *DLP* are defined for a new type of scan mode ('shuttle mode'). In body CT EXAMINATION it is clarified that the $CTDI_{vol}$ and *DLP* always be reported for the 32-cm diameter PHANTOM. In the amendment it is now required that CT SCANNERS support user-configurable DOSE NOTIFICATION VALUES and DOSE ALERT VALUES.

A new subject area in this Amendment 1 covers requirements for CT SCANNERS providing images for radiotherapy treatment planning. With this amendment begins the implementation of this important CT application into the CT safety standard with a set of requirements that is considered to be safety relevant. It mainly covers scanner hardware adjustments, accuracy of CT image data, and the conversion of HU to electron and mass density.

Introduction to Amendment 2

The main topics addressed in this amendment are editorial corrections and implementation of the last publications of the general and collateral standards as normative references.

Given the degree and significance of the changes to the normative references cited in this amendment, the committee has determined that a 4 year transition period is warranted and appropriate.

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.

The scope of this International Standard excludes RADIOTHERAPY SIMULATORS and systems where the image is created by a source other than an X-RAY TUBE.

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.

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1) The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

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.

NOTE 4 Concerning RADIOLOGICAL PROTECTION, it is assumed that MANUFACTURERS and RESPONSIBILE ORGANIZATIONS accept the general principles of justification, optimisation, and application of dose limits of the International Commission on Radiological Protection as stated in ICRP 103, 2007, paragraph 203, [12][2] namely:

(a) “The principle of justification: Any decision that alters the RADIATION exposure situation should do more good than harm.”

(b) “The principle of optimisation of protection: The likelihood of incurring exposures, the number of people exposed, and the magnitude of their individual doses should all be kept as low as reasonably achievable, taking into account economic and societal factors.”

(c) “The principle of application of dose limits: The total dose to any individual from regulated sources in planned exposure situations other than medical exposure of PATIENTS should not exceed the appropriate limits recommended by the Commission.”

(d) "Application of dose limits for the PATIENT dose might be to the PATIENT’S detriment. Therefore dose limits should not be applied to medical exposures. However, considerations should be given to the use of dose constraints or investigation levels for some common diagnostic procedures. This concept, now renamed as diagnostic reference levels, has been introduced in a large number of countries."

NOTE 5 It is recognized that many of the judgements necessary to follow the ICRP general principles have to be made by the RESPONSIBLE ORGANIZATIONS and not by the MANUFACTURER of the ME EQUIPMENT.

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 60601-1-3 applies as modified in Clause 203. IEC 60601-1-8, IEC 60601-1-9 and IEC 60601-1-10[3] do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.~~

IEC 60601-1-2 and IEC 60601-1-3 apply as modified in Clauses 202 and 203. IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10[4], IEC 60601-1-11[5] and IEC 60601-1-12[6] do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

For collateral standards published after this particular standard, MANUFACTURERS need to determine the applicability in accordance with the RISK MANAGEMENT PROCESS.

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2) Figures in square brackets refer to the Bibliography.

~~3) IEC 60601-1-10, *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*~~

4) IEC 60601-1-10, *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*

5) IEC 60601-1-11, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

6) IEC 60601-1-12, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended to be used in the emergency medical services environment*