INTERNATIONAL STANDARD

IEC 60601-2-44

First edition
1999-02

Medical electrical equipment –

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

Appareils électromédicaux –

Partie 2-44: Règles particulières de sécurité pour les équipements à rayonnement X de tomodensitométrie

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Terminology, graphical and letter symbols

For general terminology, readers are referred to IEC 60050: *International Electrotechnical Vocabulary* (IEV).

For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams*.

* See web site address on title page.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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

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 60601-2-44 has been prepared by subcommittee 62B: Diagnostic imaging 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
62B/360/FDIS	62B/364/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 forms an integral part of this standard.

In this standard, the following print types are used:

– requirements, compliance with which can be tested and definitions: roman type;
– explanations, advice, notes, general statements and exceptions: small roman type;
– *test specifications: italic type;*
– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR OF THIS PARTICULAR STANDARD OR IN IEC 60788: SMALL CAPITALS.

A bilingual version of this Standard may be issued at a later date.

INTRODUCTION

The relationship of this Particular Standard with IEC 60601-1 (including the amendments) and the Collateral Standards is explained in 1.3.

MEDICAL ELECTRICAL EQUIPMENT –

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

SECTION 1: 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 X-RAY EQUIPMENT for COMPUTED TOMOGRAPHY (CT SCANNERS). It does not cover the safety requirements for HV-generators which will be the subject of another standard.

1.2 Object

Replacement:

The object of this standard is to establish requirements for safe operation of CT SCANNERS in as far as those requirements have not yet been specified in the General Standard, the Collateral Standards or other Particular Standards.

1.3 Particular Standards

Addition:

This Particular Standard, hereinafter referred to as "this standard", amends and supplements a set of IEC publications, hereinafter referred to as "General Standard", consisting of IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*, its amendments 1 (1991) and 2 (1995), and any Collateral Standard.

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:

– "Replacement" means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

– "Addition" means that the text of this Particular Standard is additional to the requirements of the General Standard.

– "Amendment" means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses, figures or tables which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard applies without modification.

Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

A requirement of this Particular Standard replacing or modifying requirements of the General Standard takes precedence over the original requirements concerned.

1.3.101 Related international standards

IEC 60601-1-1:1992, *Medical electrical equipment – Part 1: General requirements for safety – 1. Collateral Standard: Safety requirements for medical electrical systems*

IEC 60601-1-2:1993, *Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral Standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-3:1994, *Medical electrical equipment – Part 1: General requirements for safety – 3. Collateral Standard: General requirements for radiation protection in diagnostic X-ray equipment*

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems*

IEC 60601-2-32:1994, *Medical electrical equipment – Part 2: Particular requirements for the safety of associated equipment of X-ray equipment*

IEC 60788:1984, *Medical radiology – Terminology*

ISO 2092:1981, *Light metals and their alloys – Code of designation based on chemical symbols*

2 Terminology and definitions

This clause of the General Standard applies, except as follows:

Addition:

2.101 Definitions

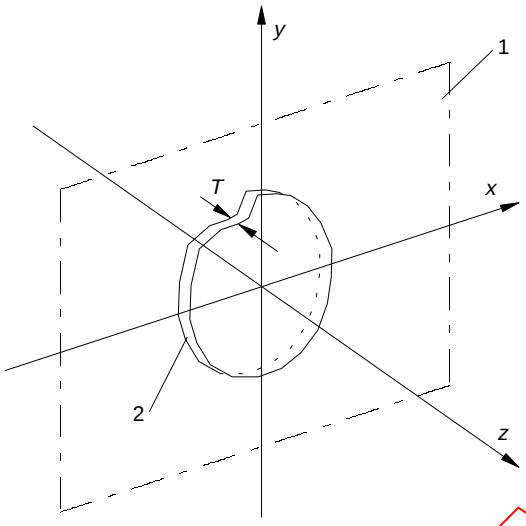
In this Particular Standard, terms printed in SMALL CAPITALS are used in accordance with their definitions in the General Standard, in this standard or in IEC 60788.

An index of defined terms used in this Particular Standard is given in annex AA.

Additional definitions:

2.101.1
CT SCANNER
X-RAY EQUIPMENT for COMPUTED TOMOGRAPHY

2.101.2
CT CONDITIONS OF OPERATION
all selectable parameters governing the operation of a CT SCANNER, for example NOMINAL TOMOGRAPHIC SECTION THICKNESS, PITCH FACTOR, FILTRATION, PEAK X-RAY TUBE VOLTAGE and either X-RAY TUBE CURRENT and LOADING TIME, or CURRENT TIME PRODUCT



1 TOMOGRAPHIC PLANE
2 PHANTOM

IEC 210/99

Figure 101 – Coordinate system

2.101.3
DOSE PROFILE
representation of the dose as a function of position along a line

2.101.4
SENSITIVITY PROFILE
relative response of a system for COMPUTED TOMOGRAPHY as a function of position along a line perpendicular to the TOMOGRAPHIC PLANE

2.101.5
TOMOGRAPHIC PLANE
geometric plane defined by the FOCAL SPOT and perpendicular to the axis of rotation; see figure 101

2.101.6
COMPUTED TOMOGRAPHY DOSE INDEX 100 ($CTDI_{100}$)
integral of the DOSE PROFILE along a line perpendicular to the TOMOGRAPHIC PLANE from –50 mm to +50 mm, divided by the product of the number of TOMOGRAPHIC SECTIONS N produced in a single 360° rotation of the RADIATION SOURCE and the NOMINAL TOMOGRAPHIC SECTION THICKNESS T in a single rotation of the RADIATION SOURCE

$$CTDI_{100} = \int_{-50\ \mathrm{mm}}^{+50\ \mathrm{mm}} \frac{D(z)}{N \times T}\, dz$$

where

$D(z)$ is the DOSE PROFILE along a line z perpendicular to the TOMOGRAPHIC PLANE, where dose is measured as ABSORBED DOSE to air;

N is the number of TOMOGRAPHIC SECTIONS produced in a single rotation of the RADIATION SOURCE;

T is the NOMINAL TOMOGRAPHIC SECTION THICKNESS.

NOTE 1 – The term $CTDI_{100}$ has been introduced as a more representative value for dose than the traditional $CTDI$ integrated from $-7T$ to $+7T$ as defined by the FDA in 21 CFR Ch. I § 1020.33.

NOTE 2 – Dose is calculated as ABSORBED DOSE to air. This is required in order to avoid present confusion, as some MANUFACTURERS of CT SCANNERS express dose values calculated as ABSORBED DOSE to air and others as ABSORBED DOSE to polymethyl-methacrylate (PMMA).

NOTE 3 – When the RADIATION SOURCE rotation is limited to less than 360°, the $CTDI_{100}$ should be scaled accordingly.

NOTE 4 – This definition assumes that the DOSE PROFILE is centred on $z = 0$ and that for CT SCANNERS, which acquire two or more TOMOGRAPHIC SECTIONS in one rotation, the increment between adjacent scans is $N \times T$ and for helical scans the CT PITCH FACTOR is equal to 1.

2.101.7
CT PITCH FACTOR
ratio of the PATIENT SUPPORT travel in the horizontal direction per rotation of the X-RAY TUBE divided by the product of the number N of TOMOGRAPHIC SECTIONS irradiated simultaneously by the X-RAY TUBE, and the NOMINAL TOMOGRAPHIC SECTION THICKNESS T.

$$CT\ pitch\ factor = \frac{\Delta d}{N \times T}$$

where:

Δd is the PATIENT SUPPORT travel in horizontal direction;

N is the number of TOMOGRAPHIC SECTIONS produced by a single rotation of the X-RAY TUBE;

T is the NOMINAL TOMOGRAPHIC SECTION THICKNESS.

2.101.8
TOMOGRAPHIC SECTION
volume of an object in which the properties of ATTENUATION of X-RADIATION are imaged

2.101.9
TOMOGRAPHIC SECTION THICKNESS
FULL WIDTH AT HALF MAXIMUM of the SENSITIVITY PROFILE taken at the centre of the cross-sectional volume over which TRANSMISSION data of X-RADIATION are collected

2.101.10
NOMINAL TOMOGRAPHIC SECTION THICKNESS
in CT SCANNERS the TOMOGRAPHIC SECTION THICKNESS which is selected and indicated on the CONTROL PANEL

2.202 Qualifying conditions for defined terms

This subclause of the General Standard does not apply.

6 Identification, marking and documents

This clause of the General Standard applies, except as follows:

6.8 ACCOMPANYING DOCUMENTS

Additional subclause:

6.8.101 Site test report

When means for emergency switching of the SUPPLY MAINS are to be incorporated on site by the USER, the requirements and site test procedures shall be specified in the ACCOMPANYING DOCUMENTS. The test results should be incorporated in the site test report.