INTERNATIONAL STANDARD

IEC 60601-2-44

Second edition
2001-06

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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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.
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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 second edition cancels and replaces the first edition published in 1999 and constitutes a technical revision.

The text of this Particular Standard is based on the following documents:

FDIS	Report of voting
62B/426/FDIS	62B/437/RVD

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

Annex AA forms an integral part of this standard.

Annex BB is for information only.

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: smaller type;

– *test specifications and headings of subclauses: italic type;*

– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR IN IEC 60788: SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until 2002-12. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

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

The contents of the corrigendum of April 2006 have been included in this copy.

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 includes safety requirements for the X-RAY GENERATOR, and those where HIGH VOLTAGE GENERATORS are integrated with an X-RAY TUBE ASSEMBLY.

1.2 Object

Replacement:

The object of this standard is to establish particular requirements 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 60513.

NOTE 4 Concerning RADIOLOGICAL PROTECTION it has been assumed in the preparation of this standard that MANUFACTURERS and USERS do accept the general principles of the ICRP as stated in ICRP 60, 1990, paragraph 112,[1)] namely:

"(a) No practice involving exposures to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes. (The justification of a practice.)

(b) In relation to any particular source within a practice, the magnitude of individual doses, the number of people exposed, and the likelihood of incurring exposures where these are not certain to be received should all be kept as low as reasonably achievable, economic and social factors being taken into account. This procedure should be constrained by restrictions on the doses to individuals (dose constraints), or the risks to individuals in the case of potential exposures (risk constraints), so as to limit the inequity likely to result from the inherent economic and social judgements. (The optimisation of protection.)

[1)] ICRP Publication 60: *Recommendations of the International Commission on Radiological Protection (Annals of the ICRP Vol. 21 No 1-3, 1990).* Published by Pergamon Press

(c) The exposure of individuals resulting from the combination of all the relevant practices should be subject to dose limits, or to some control of risk in the case of potential exposures. These are aimed at ensuring that no individual is exposed to radiation risks that are judged to be unacceptable from these practices in any normal circumstances. Not all sources are susceptible of control by action at the source and it is necessary to specify the sources to be included as relevant before selecting a dose limit. (Individual dose and risk limits.)"

NOTE 5 Most of the requirements on X-RAY EQUIPMENT and its sub-assemblies for protection against IONIZING RADIATION are given in the Collateral Standard IEC 60601-1-3.

This standard does, however, deal with some aspects of RADIOLOGICAL PROTECTION, mainly those that depend upon the supply, control and indication of electrical energy from the HIGH-VOLTAGE GENERATOR.

NOTE 6 It is recognized that many of the judgements necessary to follow the ICRP general principles have to be made by the USER and not by the MANUFACTURER of the EQUIPMENT.

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 No. 1 (1991) and No. 2 (1995), and all Collateral Standards. The numbering of sections, clauses and subclauses of this 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 standard.

"Addition" means that the text of this 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 standard.

Subclauses or figures 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 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 standard.

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

1.3.101 Related International Standards

IEC 60601-1-2:1993, *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 60601-2-28:1993, *Medical electrical equipment – Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis*

IEC 60664-1:1992, *Insulation coordination for equipment within low-voltage systems – Part 1: Principles, requirements and tests*

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 before 2.1:

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

NOTE Attention is drawn to the fact, that in cases where the concept addressed is not strongly confined to the definition given in one of the publications listed above a corresponding term is printed in lower case letters.

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

Associated conditions qualifying the usage of certain terms are given in the additional definitions below.

In this standard unless otherwise indicated:

– values of X-RAY TUBE VOLTAGE refer to peak values, transients being disregarded;

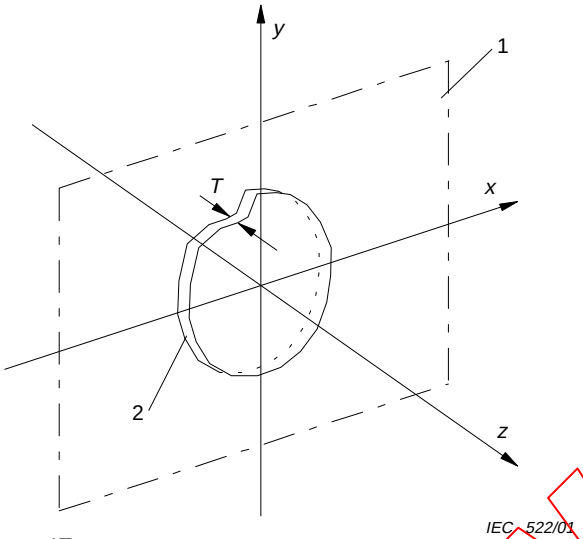
– values of X-RAY TUBE CURRENT refer to average values.

Additional definitions:

2.101
CT SCANNER
X-RAY EQUIPMENT for COMPUTED TOMOGRAPHY (CT). A computed tomography X-ray system is a diagnostic X-ray system intended to generate cross-sectional images of the body by computer reconstruction of X-ray transmission data from the same axial plane at different angles. This generic type of device may include signal analysis and display equipment, patient and equipment supports, support parts and ACCESSORIES.

NOTE Secondary imaging processing is not included in the scope of this standard.

2.102
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

Figure 101 – Coordinate system

2.103
DOSE PROFILE
the representation of the dose as a function of position along a line

2.104
SENSITIVITY PROFILE
the relative response of a system for COMPUTED TOMOGRAPHY as a function of position along a line perpendicular to the TOMOGRAPHIC PLANE

2.105
TOMOGRAPHIC PLANE
the geometric plane perpendicular to the axis of rotation (see figure 101)

2.106
COMPUTED TOMOGRAPHY DOSE INDEX 100 (*CTDI* $_{100}$)
the 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 scan and the NOMINAL TOMOGRAPHIC SECTION THICKNESS T

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

where

$D(z)$ is the DOSE PROFILE along a line z perpendicular to the TOMOGRAPHIC PLANE, where dose is measured in AIR KERMA;

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

T is the NOMINAL TOMOGRAPHIC SECTION THICKNESS.