IEC 60601-2-44

Edition 3.0 2009-02

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

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CONTENTS

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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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 third edition cancels and replaces the second edition published in 2001 and its Amendment 1 (2002). This edition constitutes a technical revision primarily related to RADIATION protection and control.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62B/727/FDIS	62B/734/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.

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 this particular standard will remain unchanged until the maintenance result 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.

The contents of the corrigendum of May 2010 have been included in this copy.

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*.

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.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document numbers.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

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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*

"Replacement" means that the clause or subclause of the general standard or applicable collateral 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 or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral 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 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding section, clause or subclause in this particular standard, the section, clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any parts of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 41.

Clause 2 of the general standard applies, except as follows:

Replacement:

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*

Addition:

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

IEC 61223-3-5, *Evaluation and routine testing in medical imaging departments – Part 3-5: Acceptance tests – Imaging performance of computed tomography X-ray equipment*

ISO 12052, *Health informatics – Digital imaging and communication in medicine (DICOM) including workflow and data management*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1-3:2008 and IEC 60788:2004 apply, except as follows:

NOTE 101 An index of defined terms is to be found at the end of this document.

NOTE 102 In accordance with the definitions in IEC 60601-1-3, 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.

Addition:

201.3.201
CT SCANNER
X-RAY EQUIPMENT intended to generate cross-sectional images of the body by computer reconstruction of X-ray transmission data obtained at different angles, which may include signal analysis and display equipment, PATIENT SUPPORT, support parts and ACCESSORIES

NOTE 1 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.

NOTE 2 Secondary imaging processing is not included in the scope of this standard.

201.3.202
CT CONDITIONS OF OPERATION
all selectable parameters governing the operation of a CT SCANNER

NOTE 1 Examples of such conditions include NOMINAL TOMOGRAPHIC SECTION THICKNESS, CT PITCH FACTOR, FILTRATION, peak X-RAY TUBE VOLTAGE and either X-RAY TUBE CURRENT and LOADING TIME or CURRENT TIME PRODUCT.

NOTE 2 Some CT CONDITIONS OF OPERATION may vary during the exposure.

201.3.203
COMPUTED TOMOGRAPHY DOSE INDEX 100
***CTDI*$_{100}$**

integral of the DOSE PROFILE produced in a single axial scan 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 and the NOMINAL TOMOGRAPHIC SECTION THICKNESS T, or divided by 100 mm, whichever is less:

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

where

$D(z)$ is the DOSE PROFILE along a line z perpendicular to the TOMOGRAPHIC PLANE, where dose is reported as ABSORBED DOSE in air and is evaluated within a polymethylmethacrylate (PMMA) dosimetry PHANTOM (203.108);

N is the number of TOMOGRAPHIC SECTIONS produced in a single axial scan of the X-ray source;

T is the NOMINAL TOMOGRAPHIC SECTION THICKNESS.

NOTE 1 The dose is reported as ABSORBED DOSE in air. Air is explicitly designated the reference medium for dose in order to avoid potential confusion, since some MANUFACTURERS of CT SCANNERS express dose values calculated as ABSORBED DOSE to air and others as ABSORBED DOSE to PMMA.

Although $CTDI_{100}$ refers to ABSORBED DOSE in air, for practical purposes the evaluation of ABSORBED DOSE to air within a PMMA dosimetry PHANTOM is well approximated by measurement of the AIR KERMA with an ionization chamber in the PHANTOM. Generally there is traceability of ionization chambers to AIR KERMA.

NOTE 2 This definition assumes that the DOSE PROFILE is centred on $z = 0$.

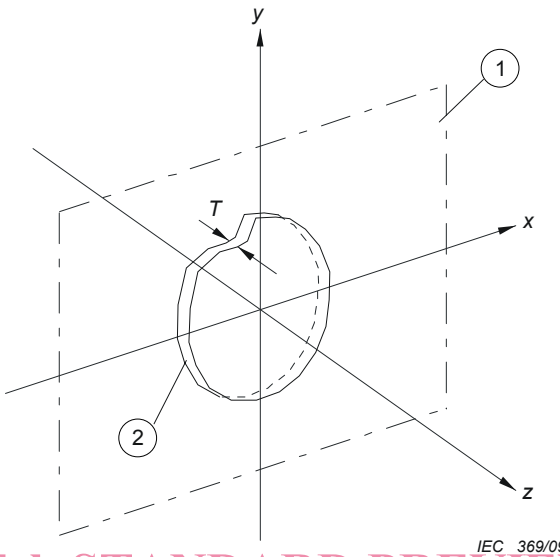
NOTE 3 A single axial scan is typically a 360° rotation of the X-ray source.

NOTE 4 When the TOMOGRAPHIC SECTIONS overlap, e.g. in CT SCANNERS with “flying FOCAL SPOT”, the product $N \times T$ needs to be adjusted for overlap.

NOTE 5 Typically the *z*-axis is the axis of rotation.

NOTE 6 If $N \times T$ is greater than 100 mm, the physical meaning of $CTDI_{100}$ changes from the average dose at the centre of a 100 mm scan length to the average dose over the central 100 mm region for a single axial scan.

NOTE 7 The value of $CTDI_{100}$ will be lower if the length of the dosimetry PHANTOM is less than $N \times T + 100$ mm, since the contribution from scattered RADIATION will be underestimated.



1 TOMOGRAPHIC PLANE

2 PHANTOM

Figure 201.101 – Coordinate system

201.3.204
CT PITCH FACTOR

in helical scanning the ratio of the PATIENT SUPPORT travel Δd along the z-direction per rotation of the X-ray source divided by the product of the NOMINAL TOMOGRAPHIC SECTION THICKNESS T and the number of TOMOGRAPHIC SECTIONS N:

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

where

Δd is the PATIENT SUPPORT travel along the z-direction per rotation of the X-RAY SOURCE;

T is the NOMINAL TOMOGRAPHIC SECTION THICKNESS;

N is the number of TOMOGRAPHIC SECTIONS produced in a single axial scan of the X-RAY SOURCE.

NOTE 1 Although the CT PITCH FACTOR is associated with helical scanning, its definition refers to parameters T and N that are defined only for axial scanning. Definition 201.3.204 presumes that these axial-scanning parameters T and N correspond to the same collimation and active-detector configuration as that of the helical scanning for which the CT PITCH FACTOR is being evaluated.

NOTE 2 When the TOMOGRAPHIC SECTIONS overlap, e.g. in CT SCANNERS with "flying FOCAL SPOT", the product $N \times T$ needs to be adjusted for overlap.

NOTE 3 CT PITCH FACTOR will be a function of time when Δd or $N \times T$ are variable during the exposure.

NOTE 4 The terms "helical" is used in this document as a synonym for the term "spiral".

201.3.205
DOSE PROFILE

representation of the dose as a function of position along a line

201.3.206
NOMINAL TOMOGRAPHIC SECTION THICKNESS
in CT SCANNERS the TOMOGRAPHIC SECTION THICKNESS which is selected and indicated on the CONTROL PANEL

NOTE In helical scanning the thickness of a section associated with the reconstructed image depends on the helical reconstruction algorithm and pitch. This thickness might or might not be equal to the NOMINAL TOMOGRAPHIC SECTION THICKNESS.

201.3.207
SENSITIVITY PROFILE
relative response of a system for COMPUTED TOMOGRAPHY as a function of position along a line perpendicular to the TOMOGRAPHIC PLANE

201.3.208
TOMOGRAPHIC PLANE
geometric plane perpendicular to the axis of rotation at the centre of the X-RAY FIELD in z (see Figure 201.101)

201.3.209
TOMOGRAPHIC SECTION
for CT SCANNERS with a single detector row, the volume over which TRANSMISSION data of X-RADIATION are collected in a single axial scan; for CT SCANNERS with multiple detector rows along the z-axis, the volume over which data are collected by a single acquisition channel representing a single row or a selected grouping of rows

201.3.210
TOMOGRAPHIC SECTION THICKNESS

FULL WIDTH AT HALF MAXIMUM of the SENSITIVITY PROFILE taken at the ISOCENTRE of a TOMOGRAPHIC SECTION

201.3.211
WEIGHTED $CTDI_{100}$
$CTDI_{W}$
value defined as

$$CTDI_{W} = \frac{1}{3} CTDI_{100(centre)} + \frac{2}{3} CTDI_{100(peripheral)}$$

where $CTDI_{100(centre)}$ is the value of $CTDI_{100}$ measured in the centre of a dosimetry PHANTOM, and where $CTDI_{100(peripheral)}$ is the average of the four values of $CTDI_{100}$ measured around the dosimetry PHANTOM periphery according to 203.109.1 a)2) and 3)

201.3.212
VOLUME $CTDI_{W}$
$CTDI_{vol}$
a) for axial scanning

$$CTDI_{vol} = \frac{N \times T}{\Delta d} CTDI_{W}$$

where

N is the number of TOMOGRAPHIC SECTIONS produced in a single axial scan of the X-ray source;

T is the NOMINAL TOMOGRAPHIC SECTION THICKNESS;

Δd is the PATIENT SUPPORT travel in z-direction between consecutive scans.

NOTE 1 For axial scanning with a total table travel of less than $N \times T$ this definition may overestimate the dose.

NOTE 2 For the selected CT CONDTIONS OF OPERATION, but irrespective of any scanning length that may be used clinically, the VOLUME $CTDI_{W}$ ($CTDI_{VOL}$) is an index of dose based on a convention of 100 mm range of integration along the *z*-axis. For axial scanning, $CTDI_{vol}$ corresponds to the average dose that would accrue in the PHANTOM central section of volume equal to the cross sectional area × Δd .

b) for helical scanning

$$CTDI_{vol} = \frac{CTDI_{w}}{CT\ pitch\ factor}$$

NOTE 1 CT PITCH FACTOR will be a function of time when Δd or $N \times T$ are variable during the exposure.

NOTE 2 For helical scanning with a small number of rotations and a table travel per rotation of less than $N \times T$ this definition may overestimate the dose.

NOTE 3 For the selected CT CONDTIONS OF OPERATION, but irrespective of any scanning length that may be used clinically, the VOLUME $CTDI_{W}$ ($CTDI_{VOL}$) is an index of dose based on a convention of 100 mm range of integration along the *z*-axis. For helical scanning, $CTDI_{vol}$ corresponds to the average dose that would accrue in the PHANTOM central section of volume equal to the cross sectional area × Δd.

c) for scanning without movement of the PATIENT SUPPORT

$$CTDI_{vol} = n \times CTDI_{w}$$

where n is equal to the number of rotations.

NOTE 1 c) includes situations where the PATIENT SUPPORT may be moved manually, for example, during an interventional procedure.

NOTE 2 For scanning without movement of the PATIENT SUPPORT and for situations where the PATIENT SUPPORT may be moved manually, this definition overestimates the dose as it includes assumed scatter contribution from adjacent slices.

NOTE 3 For scanning without movement of the PATIENT SUPPORT, $CTDI_{vol}$ corresponds to the dose that would accrue in the PHANTOM central section of volume equal to the cross sectional area × $N \times T$ were there n congruent sequences of contiguous scanning, each sequence of length 100 mm.

201.3.213

GEOMETRIC EFFICIENCY IN THE Z-DIRECTION

integral of the DOSE PROFILE determined at the ISOCENTRE without any object in the X-RAY BEAM, over the acquisition range in the z-direction, expressed as percentage of the total integral of the DOSE PROFILE in the z-direction, where the acquisition range is the length along the z-axis spanned by the selected detector elements, or it is the z-axis length of the post-patient collimation, whichever is less and where z-axis lengths are given as equivalent lengths at the ISOCENTRE

NOTE Detector 'combs' or grids will reduce geometric efficiency.

201.3.214

DOSE-LENGTH PRODUCT

DLP

index characterizing the product of the $CTDI_{vol}$ and the total length scanned

a) For axial scanning

$$DLP = CTDI_{vol} \times \Delta d \times n$$

where

Δd is the PATIENT SUPPORT travel in z-direction between consecutive scans;

n is the number of scans in the series.

b) For helical scanning

$$DLP = CTDI_{vol} \times L$$

where

L is the table travel during the entire LOADING.

NOTE 1 *L* might be longer than the programmed scan length.

NOTE 2 The time weighted average of $CTDI_{vol}$ is to be used if $CTDI_{vol}$ is variable.

c) For scanning without movement of the PATIENT SUPPORT

$$DLP = CTDI_{vol} \times N \times T$$

where

N is the number of TOMOGRAPHIC SECTIONS produced in a single axial scan of the X-ray source;

T is the NOMINAL TOMOGRAPHIC SECTION THICKNESS.

201.3.215
COMPUTED TOMOGRAPHY DOSE INDEX FREE-IN-AIR
***CTDI*$_{\text{FREE AIR}}$**
integral of the DOSE PROFILE produced in a single axial scan 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* and the NOMINAL TOMOGRAPHIC SECTION THICKNESS *T,* or divided by 100 mm, whichever is less

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

where

D(z) is the DOSE PROFILE along a line *z* perpendicular to the TOMOGRAPHIC PLANE, where dose is reported as ABSORBED DOSE in air and is evaluated free-in-air in the absence of a PHANTOM and the PATIENT SUPPORT;

N is the number of TOMOGRAPHIC SECTIONS produced in a single axial scan of the X-ray source;

T is the NOMINAL TOMOGRAPHIC SECTION THICKNESS.

NOTE 1 This definition assumes that the DOSE PROFILE is centred on $z = 0$.

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.3 ESSENTIAL PERFORMANCE

Addition:

For CT SCANNERS for which the INTENDED USE includes COMPUTED TOMOGRAPHY as the principal means of guidance in invasive procedures (involving the introduction of a device, such as a needle or a catheter into the body of the PATIENT), any ESSENTIAL PERFORMANCE related to such use shall be identified.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

201.4.5 Equivalent Safety for ME EQUIPMENT or ME SYSTEMS

Addition:

NOTE Because state of the art technology changes for CT SCANNERS may result in the inability to strictly comply with all clauses of this particular standard, alternate means of addressing risks via risk management are acceptable. Alternate means are acceptable only when the residual risks resulting from application of the alternative are equal to or less than the RESIDUAL RISKS that would ensue when the particular standards requirements are met.

201.4.10.2 SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS

Addition:

The internal impedance of a SUPPLY MAINS is to be considered sufficiently low for the operation of a CT SCANNER if the value of the APPARENT RESISTANCE OF SUPPLY MAINS does not exceed the value specified in the ACCOMPANYING DOCUMENTS.

Either the APPARENT RESISTANCE OF SUPPLY MAINS or the proper gauge/length of supply cables or other appropriate SUPPLY MAINS specifications used in a facility shall be specified in the ACCOMPANYING DOCUMENTS.

NOTE If a NOMINAL voltage is claimed for a mains power supply system, it is assumed that there is no voltage of a higher value between any of the conductors of the system or between any of these conductors and earth.

An alternating voltage is considered in practice to be sinusoidal if any instantaneous value of the waveform concerned differs from the instantaneous value of the ideal waveform at the same moment by no more than ±2 % of the peak value of the ideal waveform.

A three-phase SUPPLY MAINS is considered to have a practical symmetry if it delivers symmetrical voltages and produces, when loaded symmetrically, symmetrical currents.

The requirements of this standard are based upon the assumption that three-phase systems have a symmetrical configuration of the MAINS VOLTAGE with respect to earth. Single-phase systems may be derived from such three-phase systems. Where the supply system is not earthed at the source it is assumed that adequate measures have been provided to detect, limit and remedy any disturbance of symmetry within a reasonably short time.

A CT SCANNER is considered to comply with the requirements of this standard only if its specified NOMINAL ELECTRIC POWER can be demonstrated at an APPARENT RESISTANCE OF SUPPLY MAINS having a value not less than the APPARENT RESISTANCE OF SUPPLY MAINS specified by the MANUFACTURER in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.7 Humidity preconditioning treatment

Addition:

For those CT SCANNERS that are to be used only in controlled environments, as to be specified in the ACCOMPANYING DOCUMENTS, no humidity preconditioning is required.

The ACCOMPANYING DOCUMENTS shall include the time period that the room environmental operating conditions must be maintained prior to powering the system on.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

201.6.2 Protection against electric shock

Replacement:

HIGH-VOLTAGE GENERATORS in CT SCANNERS shall be CLASS I ME EQUIPMENT or INTERNALLY POWERED ME EQUIPMENT.