

CONSOLIDATED VERSION

VERSION CONSOLIDÉE



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



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CONSOLIDATED VERSION

VERSION CONSOLIDÉE



**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**

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VERSION REDLINE



Medical electrical equipment –

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

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Partie 2-44: Exigences particulières pour la sécurité de base et les performances essentielles des équipements à rayonnement X de tomодensitométrie

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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

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This Consolidated version of IEC 60601-2-44 bears the edition number 3.2. It consists of 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]. The technical content is identical to the base edition and its amendments.

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.

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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 standard¹⁾ 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.

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 RESPONSIBLE 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 60601-1-10³⁾ 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 60601-1-10⁴⁾, IEC 60601-1-11⁵⁾ and IEC 60601-1-12⁶⁾ 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.

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

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:

"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 64.

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

Replacement:

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

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*

IEC 60601-1-3:2008/AMD1:2013

Addition:

IEC 60336 *Medical electric equipment – X-Ray Tube assemblies for medical diagnosis – Characteristics of focal spots*

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

IEC 60601-1:2005/AMD1:2012

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 and IEC 60601-1:2005/AMD1:2012, IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013, 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.

NOTE 3 CT CONDITIONS OF OPERATION include parameters that are derived by the system from the user-selectable parameters.

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:

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

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.

integral of the DOSE PROFILE representative of a single axial scan along a line perpendicular to the TOMOGRAPHIC PLANE divided by $N \times T$ according to the following:

for $N \times T$ less than or equal to 40 mm

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

for $N \times T$ greater than 40 mm (all CT CONDITIONS OF OPERATION except collimation are kept the same for these measurements)

$$CTDI_{100} = \int_{-50 \text{ mm}}^{+50 \text{ mm}} \frac{D_{\text{Ref}}(z)}{(N \times T)_{\text{Ref}}} dz \times \frac{CTDI_{\text{free air}, N \times T}}{CTDI_{\text{free air}, \text{Ref}}}$$

where

- $D(z)$ is the DOSE PROFILE representative of a single axial scan 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 (see 203.108);
- $(N \times T)_{\text{Ref}}$ is a specific $N \times T$ of 20 mm or the largest $N \times T$ available not greater than 20 mm;
- $D_{\text{Ref}}(z)$ is the DOSE PROFILE representative of a single axial scan 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 (see 203.108) for $(N \times T)_{\text{Ref}}$;
- $CTDI_{\text{free air}, N \times T}$ is the $CTDI_{\text{free air}}$ (201.3.215) for a specific value of $N \times T$;
- $CTDI_{\text{free air}, \text{Ref}}$ is the $CTDI_{\text{free air}}$ (201.3.215) for $(N \times T)_{\text{Ref}}$;
- 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 to air, but for practical purposes the evaluation of ABSORBED DOSE to air within a PMMA dosimetry PHANTOM is well approximated by measurement of the AIR KERMA.

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

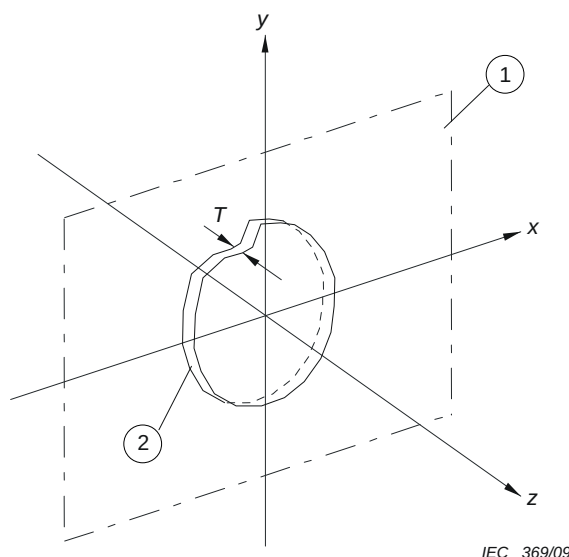
NOTE 3 A single axial scan is typically a 360° rotation of the X-ray source.

NOTE 4 When the TOMOGRAPHIC SECTIONS overlap, e.g. in CT SCANNERS with a “z-flying FOCAL SPOT”, the denominator of the integral needs to be replaced by the total nominal width along z of overlapping tomographic sections. For example, if the percentage of overlap is 50%, then the denominator would be replaced by $0,5 \times N \times T$.

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

NOTE 6 The $CTDI_{100}$ is designed to include most of the scattered radiation.

NOTE 7 See Annex CC for explanation.



IEC 369/09

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 :

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

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

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

where $CTDI_{100(\text{centre})}$ is the value of $CTDI_{100}$ measured in the centre of a dosimetry PHANTOM, and where $CTDI_{100(\text{peripheral})}$ 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 CONDITIONS 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 $\times \Delta d$.~~

NOTE 1 For the selected CT CONDITIONS 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 $\times \Delta d$.

NOTE 2 For axial scanning with a total table travel much less than $N \times T$, $CTDI_{vol}$ as defined overestimates the average dose that would accrue in the PHANTOM central section of volume equal to the cross sectional area $\times \Delta d$.

b) for helical scanning

$$CTDI_{vol} = \frac{CTDI_w}{CT \text{ pitch factor}}$$

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 CONDITIONS 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 $\times \Delta d$.~~

NOTE 2 For the selected CT CONDITIONS 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 centre of a 100 mm scan length.

NOTE 3 For helical scanning, when the product of a small number of rotations times the table travel per rotation is much less than $N \times T$, $CTDI_{vol}$ as defined overestimates the average dose that would accrue in the centre of a 100-mm scan length.

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 $\times N \times T$ were there n congruent sequences of contiguous scanning, each sequence of length 100 mm.

d) for axial scanning without gaps and helical scanning, both involving back-and-forth PATIENT SUPPORT movement between two positions (shuttle mode)

$$CTDI_{vol} = n \frac{N \times T}{(N \times T) + R} CTDI_w$$

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;

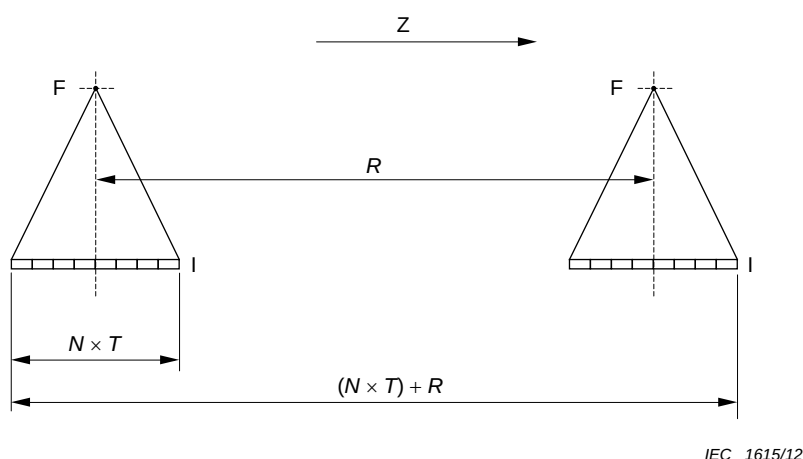
n is equal to the total number of rotations for the entire scan series;

R is the distance between the two positions;

$CTDI_w$ is the WEIGHTED $CTDI_{100}$.

NOTE 1 See Figure 201.102.

NOTE 2 $CTDI_w$ is evaluated as the time weighed $CTDI_w$ reflecting the varying CT CONDITIONS OF OPERATION.



F FOCAL SPOT
I ISOCENTRE
Z z-direction

Figure 201.102 – Illustration of $N \times T$, R and $(N \times T) + R$

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, adjusted for dynamic collimation modes if applicable.

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.

NOTE 3 A way for obtaining L could be to use the FWHM along a line perpendicular to the TOMOGRAPHIC PLANE at isocenter of the free-in-air DOSE PROFILE for the entire scan. In the absence of dynamic collimation this is approximately equivalent to table travel during the entire LOADING.

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.

d) for axial scanning without gaps and helical scanning, both involving back-and-forth PATIENT SUPPORT movement between two positions (shuttle mode)

$$DLP = CTDI_{vol} \times ((N \times T) + R)$$

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;

R is the distance between the two positions.

201.3.215

COMPUTED TOMOGRAPHY DOSE INDEX FREE-IN-AIR

CTDI_{FREE AIR} 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~~

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

~~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 $z = 0$.~~

integral of the DOSE PROFILE representative of a single axial scan along a line through the ISOCENTRE and perpendicular to the TOMOGRAPHIC PLANE divided by $N \times T$ according to the following

$$CTDI_{\text{free air}} = \int_{-L/2}^{+L/2} \frac{D(z)}{N \times T} dz$$

where

$D(z)$ is the DOSE PROFILE representative of a single axial scan along a line z through ISOCENTRE and 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;

L is at least $(N \times T) + 40$ mm, but not less than 100 mm.

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

NOTE 2 When the TOMOGRAPHIC SECTIONS overlap, e.g. in CT SCANNERS with a “z-flying FOCAL SPOT”, the denominator of the integral needs to be replaced by the total nominal width along z of overlapping tomographic sections. For example, if the percentage of overlap is 50 %, then the denominator would be replaced by $0,5 \times N \times T$.

NOTE 3 Typically a RADIATION DETECTOR of length L or longer is used. Annex DD provides an example for alternate measurements.

201.3.216

PROTOCOL ELEMENT

set of the particular CT CONDITIONS OF OPERATION necessary to perform a scan

NOTE 1 The following modes are examples of different types of scan: helical, axial, axial series, scanning without movement of the patient support and shuttle mode.

NOTE 2 To maintain consistency with their respective user interfaces and documentation, various CT SCANNERS might use terminology different from “PROTOCOL ELEMENT”, e.g., “scan”, “scan group”, “scan series”, etc., which actually means “PROTOCOL ELEMENT”

NOTE 3 A PROTOCOL ELEMENT is typically associated with a defined clinical task, clinical context, anatomical region, and/or age or size group. It corresponds to one sequence of scanning in a CT EXAMINATION.

201.3.217

CT EXAMINATION

group of PROTOCOL ELEMENTS used for the entire COMPUTED TOMOGRAPHY PROCEDURE for a particular PATIENT

201.3.218

DOSE NOTIFICATION VALUE

value of $CTDI_{vol}$, $CTDI_{vol}$ per second, or DLP used to trigger a notification on the control panel

NOTE A DOSE NOTIFICATION VALUE could represent a level of concern associated with a dose index value that would exceed a value normally expected for the PROTOCOL ELEMENT (e.g. a diagnostic reference level or similar value determined by the RESPONSIBLE ORGANIZATION).

201.3.219

DOSE ALERT VALUE

value of $CTDI_{vol}$ or DLP used to trigger an alert on the control panel

NOTE A DOSE ALERT VALUE could represent a level of concern (e.g. avoidance of deterministic effects) higher than that of a DOSE NOTIFICATION VALUE, and it would therefore warrant more stringent review and consideration before proceeding."

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.~~

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

NOTE An example of what would not be considered ESSENTIAL PERFORMANCE is the extraction of needles where images are not required for guidance.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and the RISK MANAGEMENT FILE.

201.4.5 ~~Equivalent Safety~~ *Alternative RISK CONTROL measures or test methods 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~~ 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 $\pm 2\%$ 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.

201.6.6 MODE OF OPERATION

Replacement:

Unless otherwise specified, CT SCANNERS or sub-assemblies thereof shall be classified as suitable for continuous connection to the SUPPLY MAINS in the STAND-BY STATE and for specified LOADINGS.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.2.15 Cooling conditions

Addition:

The cooling requirements for the safe operation of a CT SCANNER, or a sub-assembly thereof, shall be indicated in the ACCOMPANYING DOCUMENTS, including as appropriate the maximum heat dissipation.

201.7.8.1 Colours of indicator lights

Addition after the first paragraph:

For CT SCANNERS, the colours to be used for indicator lights shall be as follows:

- the colour green shall be used at the CONTROL PANEL to indicate the state from which one further action leads to the LOADING STATE; see 203.103;
- the colour yellow shall be used at the CONTROL PANEL to indicate the LOADING STATE; see 203.6.4.2.

NOTE 101 The colours of indicator lights need to be chosen according to the message to be given. Thus, the same operational state of an X-RAY EQUIPMENT can have simultaneous indications in different colours depending upon the place of indication, for example green at the CONTROL PANEL and red at the entrance to the examination room.

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.2.2 Warning and safety notices

Addition:

For risks not sufficiently mitigated in 201.9.2, warnings shall be given in the ACCOMPANYING DOCUMENTS, or markings provided on the equipment to mitigate the RISK of injuries that could result from collision of power driven equipment parts with other moving or stationary items likely to be in the environment.

201.7.9.2.9 Operating instructions

Addition:

Electric output data shall be stated in the instructions for use in terms of LOADING FACTORS as required in 201.12.1.103.

For CT SCANNERS in which part of the HIGH-VOLTAGE GENERATOR is integrated with the X-RAY TUBE ASSEMBLY (for example X-RAY TUBE HEADS) the stated values shall refer to the complete device.

The following combinations and data shall be stated:

- 1) the corresponding NOMINAL X-RAY TUBE VOLTAGE together with the highest X-RAY TUBE CURRENT obtainable from the HIGH-VOLTAGE GENERATOR when operated at that X-RAY TUBE VOLTAGE;
- 2) the corresponding highest X-RAY TUBE CURRENT together with the highest X-RAY TUBE VOLTAGE, obtainable from the HIGH-VOLTAGE GENERATOR when operating at that X-RAY TUBE CURRENT;
- 3) the corresponding combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT which results in the highest electric output power;
- 4) the NOMINAL ELECTRIC POWER given as the highest constant electric output power in kilowatts which the HIGH-VOLTAGE GENERATOR can deliver, for a LOADING TIME of 4 s at an X-RAY TUBE VOLTAGE of 120 kV, or if these values are not selectable, with an X-RAY TUBE VOLTAGE nearest to 120 kV and the value of LOADING TIME nearest to but not less than 4 s.

The NOMINAL ELECTRIC POWER shall be given together with the combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT and the LOADING TIME which are used in the CT SCANNER.

201.7.9.3 Technical description

201.7.9.3.1 General

Addition:

The technical description shall contain information about the combination or, if necessary, the combinations of sub-assemblies and ACCESSORIES of a CT SCANNER.

Additional subclause:

201.7.9.101 Reference to ACCOMPANYING DOCUMENTS

Clauses and subclauses of this standard, in which additional requirements concerning the content of ACCOMPANYING DOCUMENTS are given:

– APPARENT RESISTANCE OF SUPPLY MAINS	201.4.10.2
– Controlled environment	201.5.7
– Cooling conditions	201.7.2.15
– Warning and safety notices	201.7.9.2.2
– Operating instructions	201.7.9.2.9
– Suitable combinations	201.7.9.3.1
– Protective measures	201.9.2.2.4.4
– Limits for movements at unintentional interruption	201.9.2.3.1.102
– Means for release of PATIENT	201.9.2.5
– Accuracy of RADIATION output	201.12.1.101
– Compliance with this standard	203.4.1
– General requirements for dose information	203.5.2.4.1
– Dose indication	203.5.2.4.3
– Deterministic effects	203.5.2.4.5
– Image quality related performance	203.6.7.2
– HALF VALUE LAYER and TOTAL FILTRATION	203.7.1
– Indication of FILTER properties	203.7.3
– Constancy of AUTOMATIC EXPOSURE CONTROL(S)	203.6.5

– PRIMARY PROTECTIVE SHIELDING	203.11
– Statement of reference LOADING conditions	203.12.3
– Protection against STRAY RADIATION	203.13.2
– Control of RADIATION OUTPUT	203.106
– $CTDI_{100}$	203.109.1
– $CTDI_{free\ air}$	203.109.2
– DOSE PROFILE statement	203.110
– SENSITIVITY PROFILE statement	203.111
– GEOMETRIC EFFICIENCY IN THE Z DIRECTION	203.113
– ~~LIGHT FIELD~~ Light marker	203.115 c)
– Interaction of CT X-RADIATION with active medical devices	203.5.2.4.101
– ESSENTIAL PERFORMANCE	201.4.3
– Alignment of the top of the PATIENT SUPPORT	201.101.2
– Top of the PATIENT SUPPORT	201.101.3
– Table sag (stiffness of the PATIENT SUPPORT)	201.101.4
– Integral light markers for PATIENT marking	201.101.5
– Typical scan mode to provide images for RTP	201.101.6
– HU-value conversion	201.101.7
– Geometric accuracy of image data	201.101.8
– Information in the ACCOMPANYING DOCUMENTS	203.10.2
– Display and recording of $CTDI_{vol}$ and DLP	203.112

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

201.8.4 Limitation of voltage, current or energy

Addition:

201.8.4.101 Limitation of high voltage to the NOMINAL X-RAY TUBE VOLTAGE

CT SCANNERS shall be designed so as not to deliver a voltage higher than the NOMINAL X-RAY TUBE VOLTAGE for the X-RAY TUBE ASSEMBLY in NORMAL USE associated with PATIENT scanning.

Compliance is checked by inspection of the MANUFACTURER'S data for the component, by inspection of the ME EQUIPMENT, and where necessary, by functional test.

201.8.4.102 Detachable high-voltage cable connections

Detachable high voltage cable connections to the X-RAY TUBE ASSEMBLY shall be designed so that the use of tools is required to disconnect them or to remove their protective covers.

Compliance is checked by inspection.

201.8.4.103 Unacceptably high voltage in the MAINS PART

Provision shall be made to prevent the appearance of an unacceptably high voltage in the MAINS PART or in any other low-voltage circuit.

NOTE This may be achieved for example:

- by provision of a winding layer or a conductive screen connected to the PROTECTIVE EARTH TERMINAL between high-voltage and low-voltage circuits;
- by provision of a voltage-limiting device across terminals to which external devices are connected and between which an excessive voltage might arise if the external path to earth becomes discontinuous.

Compliance is checked by inspection of design data and construction.

201.8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

201.8.7.3 Allowable values

d)

Replacement:

The allowable values of the EARTH LEAKAGE CURRENT are 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION.

For PERMANENTLY INSTALLED CT SCANNERS and sub-assemblies thereof connected to a supply circuit that supplies only this CT SCANNER, the EARTH LEAKAGE CURRENT under NORMAL CONDITION and SINGLE FAULT CONDITION shall not exceed 10 mA.

NOTE 1 Local regulation can establish limits for protective earth currents of the installation. See also IEC 60364-7-710.

The allowable values of the EARTH LEAKAGE CURRENT are permitted for each sub-assembly of the CT SCANNER that is supplied by its own exclusive connection to the SUPPLY MAINS or to a central connection point, if the latter is fixed and PERMANENTLY INSTALLED.

A fixed and PERMANENTLY INSTALLED central PROTECTIVE EARTH TERMINAL may be provided inside the outer ENCLOSURE or cover of the CT SCANNER. If other sub-assemblies or ASSOCIATED EQUIPMENT are connected to the PROTECTIVE EARTH TERMINAL, the EARTH LEAKAGE CURRENT between such a central connection point and the external protective system may exceed the allowable values for any one of the single devices connected.

NOTE 2 The provision of a central PROTECTIVE EARTH TERMINAL is acceptable, since for fixed and PERMANENTLY INSTALLED ME EQUIPMENT the interruption of the PROTECTIVE EARTH CONDUCTOR is not considered to be a SINGLE FAULT CONDITION. However, in such cases, adequate information on the combination of ASSOCIATED EQUIPMENT needs to be provided in accordance with 201.7.9.3.1.

Compliance is checked by inspection and test.

e)

Addition:

For PERMANENTLY INSTALLED CT SCANNERS, regardless of waveform and frequency, the EARTH LEAKAGE CURRENT under NORMAL CONDITION and SINGLE FAULT CONDITION shall not exceed 20 mA when measured with a non-frequency-weighted device.

Compliance is checked by inspection and test.

201.8.8 Insulation

201.8.8.3 Dielectric strength

Addition after the first paragraph:

The dielectric strength of the electrical insulation of high-voltage circuits shall be sufficient to withstand the test voltages for the durations given in 8.8.3 of the general standard.

The test shall be made without an X-RAY TUBE connected and with a test voltage of 1,2 times the NOMINAL X-RAY TUBE VOLTAGE of the HIGH-VOLTAGE GENERATOR.

If the HIGH-VOLTAGE GENERATOR can only be tested with the X-RAY TUBE connected, the test voltage may be lower but shall not be less than 1,1 times the NOMINAL X-RAY TUBE VOLTAGE of the HIGH-VOLTAGE GENERATOR or X-RAY TUBE ASSEMBLY (whichever is lower).

NOTE 101 For the NOMINAL X-RAY TUBE VOLTAGE of the HIGH-VOLTAGE GENERATOR, see also subclause 201.8.4.101, Limitation of high voltage to the NOMINAL X-RAY TUBE VOLTAGE.

Compliance is checked by the following tests:

The high-voltage circuits of HIGH-VOLTAGE GENERATORS or sub-assemblies thereof are tested by applying a test voltage of 50 % of its final value according to 8.5.4 of the general standard and raising it over a period of 10 s or less to the final value, which then is maintained for 3 min.

Addition to item 8.8.3 a):

If during the dielectric strength test there is a RISK of overheating a transformer or associated circuitry under test, it is permitted to carry out the test at a higher supply frequency, or d.c. voltage, equal to the peak value of the a.c. test voltage, or to supply the test voltage to the secondary side by another generator.

During the dielectric strength test, the applied test voltage in the high-voltage circuit should be kept to 100 % to 105 % of the value required.

Addition to item 8.8.3 b):

During the dielectric strength test of HIGH-VOLTAGE GENERATORS, slight corona discharges in the high-voltage circuit are to be disregarded if they cease when the test voltage is lowered to 1,1 times the voltage to which the test condition is referred.

Addition to item 8.8.3.c):

If according to RISK ASSESSMENT the GANTRY or PATIENT SUPPORT is an APPLIED PART or the part treated as an APPLIED PART, and the conductive GANTRY or PATIENT SUPPORT parts accessible to the PATIENT are not fully covered by plastic ENCLOSURE, then such GANTRY or PATIENT SUPPORT parts are protected by MEANS OF PATIENT PROTECTION (MOPP). In this case, the test voltage for the dielectric strength testing of stator and stator circuits used for the operation of the rotating ANODE of the X-RAY TUBE is to be referred to the voltage existing after reduction of the stator supply voltage to its steady state operating value.

Otherwise, the gantry is protected by MEANS OF OPERATOR PROTECTION (MOOP) and Table 6 and Tables 13 to 16 of the general standard or the INSULATION COORDINATION requirements of IEC 60950-1 apply.

HIGH-VOLTAGE GENERATORS or sub-assemblies thereof that are integrated with an X-RAY TUBE ASSEMBLY are to be tested with an appropriately loaded X-RAY TUBE.

If the dielectric strength test is performed with an X-RAY TUBE connected and the high-voltage circuit is not accessible for the measurement of the test voltage applied, appropriate measures are to be taken to ensure that the values lie within the limits required in this subclause.

201.8.9 CREEPAGE DISTANCES and AIR CLEARANCES

201.8.9.1 Values

Additional subclause:

201.8.9.1.101 CREEPAGE DISTANCES and AIR CLEARANCES for CT SCANNERS

For PERMANENTLY INSTALLED CT SCANNERS with protective earthing, the values of Tables 13, 15 and 16 of the general standard for one and two MOOP considering high altitude, material groups, pollution degree classification and over voltage category classification apply up to reference voltages of 1 000 V a.c. r.m.s. or 1 400 V_{peak} d.c. in Tables 13 and 15 of the general standard, and 1 000 V_{dc} in Table 16 of the general standard.

For higher reference voltages the CREEPAGE DISTANCES and AIR CLEARANCES

- shall be not less than those for 1 000 V a.c. r.m.s. or 1 400 V_{peak} or V d.c. in Tables 13 and 15, and 1 000 V d.c. in Table 16 of the general standard; and
- shall comply with the dielectric strength test according to subclause 8.8.3 of the general standard.

The dielectric strength test shall be performed under environmental conditions as described in 8.8.3 of the general standard and 201.5.7 of this particular standard.

NOTE For CT SCANNERS installed with a fixed and PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR it is assumed that there is no unacceptable RISK with regard to the reliability of the PROTECTIVE EARTH CONNECTION. The components with high reference voltages are: parts of X-RAY GENERATOR, X-RAY TUBE ASSEMBLY and in some cases parts of the digital acquisition system therefore, a reliable PROTECTIVE EARTH CONNECTION and sufficient dielectric strength of insulation are considered as equivalent to two MOPs. See also 201.8.8.3.

For the same reason there is a statement in 8.7.3 d) of the general standard that under these circumstances a higher EARTH LEAKAGE CURRENT is admissible. This aligns with the statements on CREEPAGE DISTANCES and AIR CLEARANCES in IEC 60664-1.

201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies, except as follows:

201.9.2.2.4.4 Protective measures

Addition:

When a part is provided with one or more devices designed to reduce, in NORMAL USE, the risk of collision with the PATIENT, the operation and limitations of each device shall be described in the INSTRUCTIONS FOR USE.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.9.2.3 Other HAZARDS associated with moving parts

201.9.2.3.1 Unintended movement

Addition:

201.9.2.3.1.101 Unintended movements for CT SCANNERS

Means shall be provided to minimize the possibility of unintended motion, which could result in physical injury to the PATIENT, in NORMAL USE and SINGLE FAULT CONDITIONS. The following shall apply.

- a) OPERATOR controls shall be so positioned, recessed, or protected by other means such that they are unlikely to be inadvertently actuated in a way resulting in physical injury to the PATIENT.
- b) The equipment shall be SINGLE FAULT SAFE against uncontrolled motion.

201.9.2.3.1.102 Unintentional interruption

If parts involved in powered movements could cause physical injury, such parts shall be stopped in the event of unintentional interruption of the SUPPLY MAINS or power supply within the limits given in the ACCOMPANYING DOCUMENTS. The maximum value of distance and angle for each stopping condition shall be given in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and by interruption of the SUPPLY MAINS to powered movements and measurement of stopping distances. These tests shall be performed with a patient-equivalent mass of 135 kg distributed evenly over the PATIENT SUPPORT.

Additional subclauses:

201.9.2.3.101 Operation of equipment movements from inside the RADIATION room

Any motorized movements of equipment parts which may cause physical injury to the PATIENT shall be controlled by continuous deliberate action by the OPERATOR. The control shall be located close to the PATIENT SUPPORT so that the OPERATOR can continuously observe the PATIENT and thus avoid possible injury to the latter and be positioned in such a way that it cannot easily be touched by the PATIENT. Those movements which are part of a pre-programmed scanning protocol are exempt from these requirements.

The motorized movement of ME EQUIPMENT or ME EQUIPMENT parts which could crush or otherwise directly cause serious injury to the PATIENT, and for which the response of the OPERATOR to actuate an emergency stop cannot be relied on to prevent an injury, shall be operated only by continuous actuation of two switches by the OPERATOR. On release by the OPERATOR, each switch shall be independently capable of interrupting the movement.

NOTE Emergency stops located on the PATIENT SUPPORT or gantry and the CONTROL PANEL(S) per 201.9.2.4.101.1 are considered to be sufficient controls which the OPERATOR can rely upon to avoid injury.

The two switches may be designed into a single control, and one switch may be in a circuit which is common to all motions.

These switches shall be in a location such that possible injury to the PATIENT can be observed by the OPERATOR. At least one set of switches shall be so located as to require the presence of the OPERATOR close to the PATIENT, to observe the moving parts of the ME EQUIPMENT.

201.9.2.3.102 Operation of equipment movements from outside the RADIATION room

Any motorized movements of equipment parts which may cause physical injury to the PATIENT shall be controlled by continuous deliberate action by the OPERATOR.

When the control by continuous deliberate action is applied as a protective measure for the motorized movements, the control shall be located at the position where movements can be visually observed. Those movements which are part of a pre-programmed scanning protocol are exempt from these requirements.

The motorized movement of ME EQUIPMENT or ME EQUIPMENT parts which could crush or otherwise directly cause serious injury to the PATIENT, and for which the response of the OPERATOR to actuate an emergency stop cannot be relied on to prevent an injury, shall be operated only by continuous actuation of two switches by the OPERATOR. On release by the OPERATOR, each switch shall be independently capable of interrupting the movement.

NOTE Emergency stops located on the PATIENT SUPPORT or gantry and the CONTROL PANEL(S) per 201.9.2.4.101.1 are considered sufficient controls for which the OPERATOR can rely upon to avoid injury.

The two switches may be designed into a single control, and one switch may be in a circuit which is common to all motions.

These switches shall be in a location such that the PATIENT can be observed, to enable the OPERATOR to help preclude possible injury to the PATIENT.

201.9.2.4 Emergency stopping devices

Addition:

201.9.2.4.101 GANTRY and PATIENT SUPPORT

201.9.2.4.101.1 Emergency stop of motorized movements

Readily identifiable and accessible control(s) composed of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS shall be provided near to or on the PATIENT SUPPORT or gantry for emergency stopping of motorized movements by interruption of the electric power to the movement system. When operated, tilt or linear movement of the gantry and table movement shall stop within the limits given in 201.9.2.4.101.2 and 201.9.2.4.101.3 of this particular standard. Control(s) shall be positioned in such a way that they cannot be operated accidentally.

Similar controls shall also be provided near to, or on, any remote CONTROL PANEL from which movements can be actuated.

The drive power shall be disconnected within 1 s of emergency-stop activation.

Upon emergency stop activation LOADING shall be terminated according to 203.101.

MOTORIZED MOVEMENT termination and LOADING termination shall be accomplished by the same emergency stop button

NOTE Power required to maintain the electronics and control circuitry may remain energized after emergency-stop activation.

Compliance is checked by the appropriate functional tests. These tests shall be performed with a patient-equivalent mass of 135 kg distributed evenly over the PATIENT SUPPORT.

201.9.2.4.101.2 Tilting of the GANTRY

When the emergency stop control is actuated, the gantry tilt shall stop within an angle of 0,5°.

Compliance is checked by functional test.

201.9.2.4.101.3 Linear movements of the PATIENT SUPPORT and gantry

When the emergency stop control is actuated, the action to stop the PATIENT SUPPORT and gantry linear motion in the z-direction shall be initiated within 10 mm of travel. Z-direction motion shall stop within ~~25~~ 50 mm after actuation of the emergency stop.

If a scan mode is selected in which the PATIENT SUPPORT cannot stop within 25 mm after actuation of the emergency stop, before the scan is initiated the CT SCANNER shall display an alert on the CONTROL PANEL regarding this situation and instruct the OPERATOR to ensure the PATIENT area of travel is free from obstruction.

The ACCOMPANYING DOCUMENTS shall identify the scan modes that cannot meet the 25 mm emergency stop distance.

PATIENT SUPPORT movement (up/down/sideways) shall stop within 10 mm after actuation of the emergency stop.

Compliance is checked by functional test and inspection of the ACCOMPANYING DOCUMENTS.

201.9.2.5 Release of PATIENT

Addition:

201.9.2.5.101 Release means

Where there is a possibility that a failure of a powered movement during NORMAL USE of the ME EQUIPMENT might result in the PATIENT being trapped, control(s) shall be provided to permit the release of the PATIENT. These means shall be described in the INSTRUCTIONS FOR USE.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.9.8.2 TENSILE SAFETY FACTOR

Addition:

For a fully extended cradle, the minimum TENSILE SAFETY FACTOR shall be 2,5 irrespective of the situations listed in Table 21 of the general standard, and the load shall be evenly distributed over a distance of 1,5 m on the cradle. This minimum TENSILE SAFETY FACTOR of 2,5 also applies to the associated cradle attachment accessories according to their specified maximum loads.

NOTE The safety factor for the table base remains as required by the general standard.

201.9.8.3.3 Dynamic forces due to LOADING from persons

Addition:

NOTE The mass is accelerated for 150 mm, and then decelerates during compression of the 60 mm of foam, resulting in a force equivalent from 2 to 3 times the SAFE WORKING LOAD.

Where mechanical analysis proves that the following static load test is more severe than the dynamic load test specified in general standard, it is possible to waive the dynamic load test based on risk management.

Prior to performing this test, a PATIENT SUPPORT/suspension system is positioned horizontally in its most disadvantageous position in NORMAL USE where PATIENT LOADING and unloading takes place.

A mass which results in a force calculated to be greater than the dynamic load shall be placed on the PATIENT SUPPORT. The contact area of this mass is equivalent to that defined in Figure 33 of the general standard and is applied for at least one minute. ~~Any loss of function or structural damage that could result in unacceptable risk constitutes a failure.~~ BASIC SAFETY and ESSENTIAL PERFORMANCE shall be maintained.

NOTE The foam described in Figure 33 is not used in this test.

201.10 Protection against unwanted and excessive RADIATION HAZARDS

Clause 10 of the general standard applies.

NOTE Protection against unwanted and excessive RADIATION HAZARDS is also addressed in Clause 203 of this particular standard and in IEC 60601-1-3.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies, except as follows:

201.11.1 Excessive temperatures in ME EQUIPMENT

201.11.1.1 Maximum temperature during NORMAL USE

Addition:

Restrictions on allowable maximum temperature for parts in contact with oil shall not apply to parts wholly immersed in oil.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

201.12.1 Accuracy of controls and instruments

Addition:

201.12.1.101 Accuracy of RADIATION output

The MANUFACTURER shall provide in the instructions for use information regarding the accuracy of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT, and linearity of RADIATION output.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.12.1.102 Accuracy of recorded CT EXAMINATION data

- a) When a RADIOGRAM ~~of the~~ for preview ~~image~~ (as described in 203.115 of this particular standard) is provided, the position of ~~each the~~ TOMOGRAPHIC SECTION shall be clearly indicated on the RADIOGRAM.

The indication of the position of the TOMOGRAPHIC SECTIONS shall be accurate within ± 2 mm.

- b) In NORMAL USE the information indicating the orientation of the displayed image with respect to the PATIENT shall be displayed with each image.

Compliance is checked by inspection.

201.12.1.103 Indication of electric and RADIATION output

Adequate information shall be available to the OPERATOR, before, during and after the LOADING of an X-RAY TUBE, about fixed, permanently or semi-permanently pre-selected or otherwise predetermined LOADING FACTORS or modes of operation so as to enable the OPERATOR to pre-select appropriate conditions for the IRRADIATION and subsequently to obtain data necessary for the estimation of the ABSORBED DOSE received by the PATIENT.

The units of indication shall be as follows:

- for X-RAY TUBE VOLTAGE: kilovolts;
- for X-RAY TUBE CURRENT: milliamperes;
- for LOADING TIME: seconds;
- for CURRENT TIME PRODUCT: milliampere-seconds.

Compliance is checked by inspection.

201.13 Hazardous situations and fault conditions

Clause 13 of the general standard applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies, *except as follows*:

201.14.1 *General

Addition:

NOTE 6 CT SCANNERS have PEMS with functionality necessary for BASIC SAFETY and, in certain cases, could have functionality necessary for ESSENTIAL PERFORMANCE.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies.

201.16 ME SYSTEMS

Clause 16 of the general standard applies.

201.17 ELECTROMAGNETIC COMPATIBILITY of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies.

201.101 Requirements for CT SCANNERS providing images for RADIOTHERAPY TREATMENT PLANNING (RTP)

201.101.1 General

Clause 201.101 applies only to CT SCANNERS whose INTENDED USE includes providing image data for RADIOTHERAPY TREATMENT PLANNING (RTP).

Requirements related to the CT SCANNER (gantry, PATIENT SUPPORT, light markers) and conversion of Hounsfield Units to electron and mass density are addressed.

201.101.2 Alignment of the top of the PATIENT SUPPORT

201.101.2.1 General

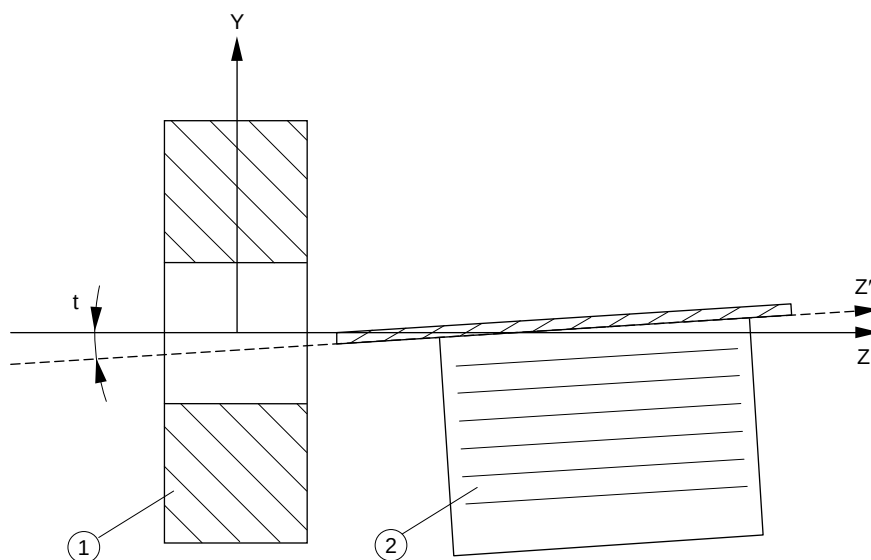
The ACCOMPANYING DOCUMENTS shall describe the procedures for aligning the top of the PATIENT SUPPORT with respect to the TOMOGRAPHIC PLANE such that the long axis of the top of the PATIENT SUPPORT is aligned vertically and horizontally over the maximum scan range along the z direction.

Compliance of the alignment requirements in subclauses 201.101.2.2 and 201.101.2.3 is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.101.2.2 Alignment of the PATIENT SUPPORT in the vertical plane (tilt)

The alignment procedure shall require the accuracy of the alignment to be $\pm 0,5^\circ$ or less with respect to the horizontal plane (Figure 201.103).

The alignment procedure shall require this measurement to be taken on the retracted top of the PATIENT SUPPORT, without load, after installation.



IEC 1616/12

- Z Z-axis
- Z' Axis of the top of the PATIENT SUPPORT
- t Tilt angle
- 1 Gantry
- 2 PATIENT SUPPORT

Figure 201.103 – Vertical alignment of the PATIENT SUPPORT

201.101.2.3 Alignment of the PATIENT SUPPORT in the horizontal plane

- a) The alignment procedure shall require the axis of the horizontal movement of the top of the PATIENT SUPPORT to be perpendicular to the x-axis of the TOMOGRAPHIC PLANE within $\pm 1^\circ$.
- b) The alignment procedure shall require the centerline of the top of the PATIENT SUPPORT to be marked at the front end (M1) and at a distance of 1 m from the front end (M2). The difference between the centerline and the z-axis indicated by the sagittal light marker shall be measured at the position of the scan plane for both M1 and M2. Neither d1 nor d2 shall exceed 2 mm (see Figure 201.104). If the sagittal light marker does not extend to the scan plane, the measurement shall be taken at the external light marker position.

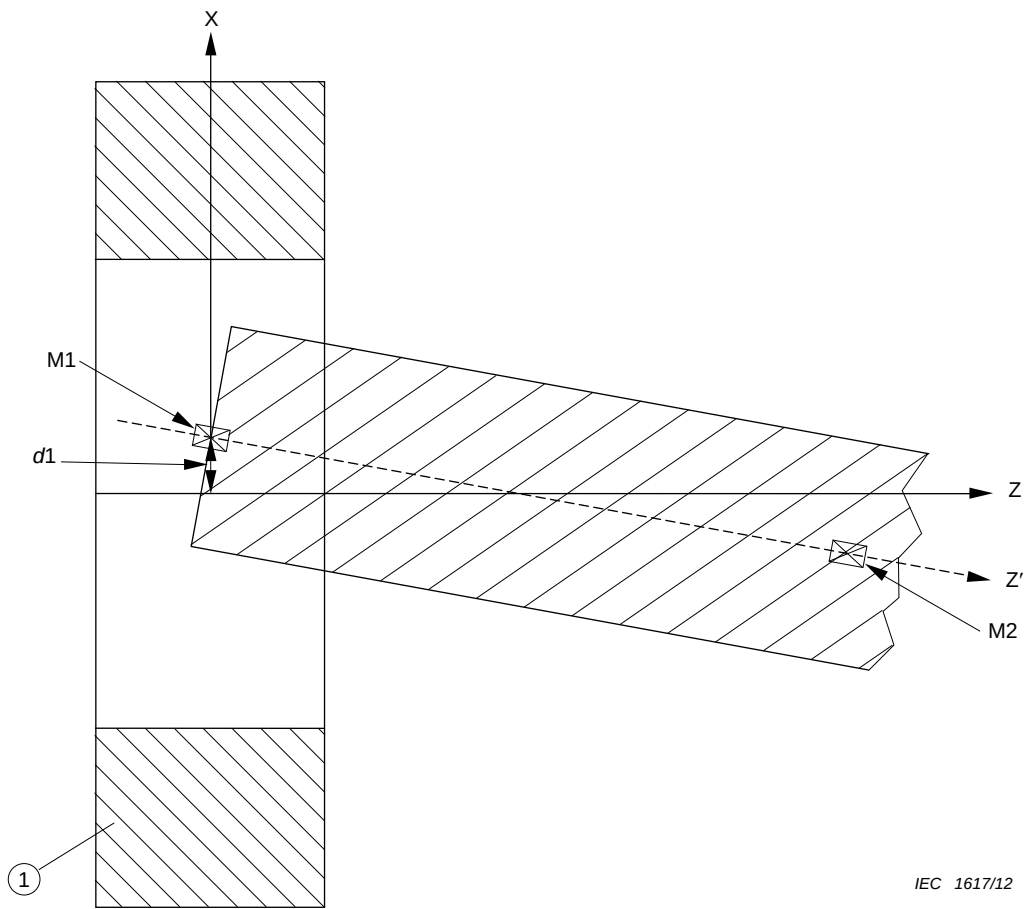


Figure 201.104a

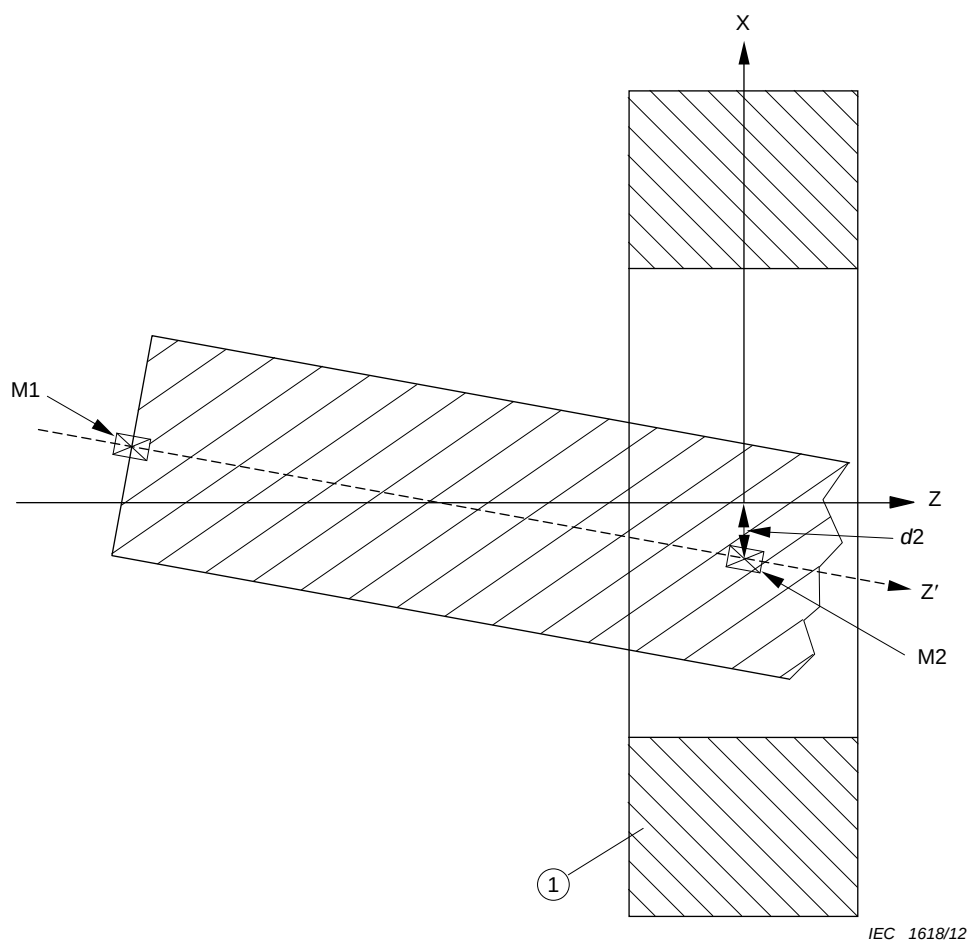


Figure 201.104b

- Z Z-axis
- Z' Axis of the top of the PATIENT SUPPORT
- 1 Gantry
- M1, M2 Markings on the top of the PATIENT SUPPORT
- d1, d2 distance of Markings from Z-axis

Figure 201.104 – Z-axis alignment of the PATIENT SUPPORT in the horizontal plane

201.101.3 Top of the PATIENT SUPPORT

The surface of the PATIENT SUPPORT shall be flat or an ACCESSORY to make it flat shall be specified in the ACCOMPANYING DOCUMENTS and shall be made available.

The PATIENT SUPPORT should allow use of the positioning aids of the therapy system.

201.101.4 Table sag (stiffness of the PATIENT SUPPORT)

Table sag shall be specified for ranges of 40 cm (typical scan length plus shift to reach the scan plane).

NOTE Corrections for table sag might be needed in the process of RTP.

The sag of the PATIENT SUPPORT in the scan plane shall be evaluated according to the following test specification:

- *Starting at the gantry-side end of the top of the PATIENT SUPPORT, distribute a load of 135 kg evenly over a length of 1,9 m (or maximum length of the top of the PATIENT SUPPORT whichever is less);*
- *position the gantry-side end of the top of the PATIENT SUPPORT in the scan plane (position 1);*
- *measure the vertical position of the top of the PATIENT SUPPORT in the scan plane (height 1);*
- *move the top of the PATIENT SUPPORT into the gantry by 400 mm (position 2 = position 1 + 400 mm);*
- *measure the vertical position of the top of the PATIENT SUPPORT in the scan plane (height 2);*
- *move the top of the PATIENT SUPPORT into the gantry by another 400 mm (position 3 = position 2 + 400 mm) and measure the vertical position of the top of the PATIENT SUPPORT in the scan plane (height 3);*
- *move the top of the PATIENT SUPPORT into the gantry by another 400 mm (position 4 = position 3 + 400 mm) and measure the vertical position of the top of the PATIENT SUPPORT in the scan plane (height 4);*
- *calculate and record the differences in height (the sag) between each pair of adjacent positions.*

Images may be generated at the described z-positions to measure the height of the top of the PATIENT SUPPORT (e.g. distance between top of the PATIENT SUPPORT and the ISOCENTRE).

If the mechanical design of the PATIENT SUPPORT can be expected to cause the PATIENT SUPPORT to sag over the exam time (e.g. in the case of a hydraulic device) the PATIENT SUPPORT shall be left loaded in the most extended position for 1 h, and the measurement shall be repeated at this position.

The results of the calculations of the differences in height shall be reported in the ACCOMPANYING DOCUMENTS.

201.101.5 Integral light markers for PATIENT marking

If light markers are integral to the CT SCANNER, the ACCOMPANYING DOCUMENTS shall confirm whether or not they are intended for the purpose of PATIENT marking in RTP.

If the integral light markers are intended for the purpose of PATIENT marking in RTP, they shall have the following accuracy:

The accuracy of the axial light marker shall be ± 1 mm at the ISOCENTRE and ± 2 mm at a distance of ± 250 mm in x-direction.

Sagittal and coronal light markers shall extend into the scan plane and shall be accurate by ± 1 mm with respect to the axis of rotation.

The width of the light markers shall not exceed 1 mm (FWHM) at the ISOCENTRE.

NOTE Other light markers are covered by existing requirements in the CT equipment acceptance-test standard (IEC 61223-3-5) as well as in IEC 60601-2-44. In IEC 61223-3-5, see 5.2.1.3.1 on the internal patient-positioning light indicating the scan plane, and also see 5.2.1.3.2 on the external positioning light. In this standard, see 203.115(c).

201.101.6 Typical scan mode to provide images for RTP

The ACCOMPANYING DOCUMENTS shall specify CT CONDITIONS OF OPERATION that are typical for providing images for RTP. Protocols not suitable for providing images for RTP shall be identified in the ACCOMPANYING DOCUMENTS.

Results of the tests for NOISE, MEAN CT-NUMBER, and UNIFORMITY, as measured with the methodology of IEC 61223-3-5, shall be provided in the ACCOMPANYING DOCUMENTS for CT CONDITIONS OF OPERATION that are typical for RTP.

201.101.7 HU-value conversion

A conversion of measured HU-values to electron and mass density values relative to those of water using CT CONDITIONS OF OPERATION identified in 201.101.6 shall be provided in the ACCOMPANYING DOCUMENTS as a representative figure for that scanner model. At a minimum, conversion factors shall be provided for air, water, one soft-tissue-equivalent material and two different bone-equivalent materials.

The PHANTOM and the CT CONDITIONS OF OPERATION used to provide this conversion shall be specified in the ACCOMPANYING DOCUMENTS. The PHANTOM shall be commercially available.

The ACCOMPANYING DOCUMENTS shall state the limitations of the data for the full field-of-view and specify if there are regions with different levels of accuracy.

201.101.8 Geometric accuracy of image data

201.101.8.1 General

The imaging data shall be geometrically accurate over the full scan field-of-view. The subclauses of 201.101.8 fulfill this requirement.

The ACCOMPANYING DOCUMENTS shall state the limitations in geometric accuracy for the full scan field-of-view and specify if there are regions with different levels of accuracy.

The ACCOMPANYING DOCUMENTS shall describe the test specifications to check the alignment according to subclauses 201.101.8.2, 201.101.8.3 and 201.101.8.4.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.101.8.2 Gantry tilt

It shall be possible to set the gantry tilt to zero-position with an accuracy of within $\pm 1^\circ$ with reference to the plane through the x-axis and perpendicular of table top.

The test method is according to IEC 61223-3-5, Annex D.

201.101.8.3 Angular alignment of CT images

Angular alignment of the reconstructed images is essential for accuracy in RTP. Image alignment shall be checked with an object of known geometry.

- **Test specification**

Position a PHANTOM with markers aligned to the horizontal or vertical plane in the scan field. Scan the PHANTOM and check orientation of the markers in the image.

The deviation of the marker from the vertical or horizontal reference shall be less than 3 mm over a distance of 20 cm.

201.101.8.4 Accuracy of image z-position for helical scans

The accuracy of the actual z-position of the PATIENT SUPPORT and the z-position stated in the image shall be checked.

- *Test specification*

A PHANTOM with markers at z-position 0 cm, 15 cm and 30 cm is used. The markers have to be visible in the CT-image (e.g. metal beads). The PHANTOM is positioned in a way that marker "0 cm" is in the field of the light marker. The table is set to zero for that position. A helical scan with a protocol intended for providing images for RTP is executed over a scan range covering all three markers on the PHANTOM and overlapping images are reconstructed using the thinnest available TOMOGRAPHIC SECTIONS. For each marker the slice position with the maximum contrast for the marker shall be identified and recorded.

The deviation of the image positions from their corresponding nominal z-values shall be less than 1 mm.

202 Electromagnetic compatibility – Requirements and tests

IEC 60601-1-2:2014 applies, except as follows:

Additional subclause:

202.101 Immunity testing of ESSENTIAL PERFORMANCE

The MANUFACTURER may minimize the test requirements of the additional ESSENTIAL PERFORMANCE listed in subclause 201.4.3 to a practical level through the RISK MANAGEMENT PROCESS.

When selecting the requirements to be tested, the MANUFACTURER shall take into account the sensitivity to the EMC environment, probability of EMC condition and severity, probability and contribution to unacceptable RISK through the RISK MANAGEMENT PROCESS.

The accuracy of the test instruments used to assess the immunity of the CT SCANNER shall not be affected by the electromagnetic conditions for the test.

The test instrument shall not have an influence on the immunity of the CT SCANNER.

Only non-invasive measurements shall be performed.

The CT SCANNER being tested shall not be modified to perform this immunity test.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

203 General requirements for RADIATION protection in diagnostic X-ray equipment

IEC 60601-1-3:2008 applies except as follows:

203.4 General requirements

203.4.1 Statement of compliance

Replacement:

If for a CT SCANNER, or a sub-assembly thereof, compliance with this standard is to be stated, the statement shall be stated in the ACCOMPANYING DOCUMENTS:

CT SCANNER... ++) IEC 60601-2-44:2009

++) MODEL OR TYPE REFERENCE

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

203.5 ME EQUIPMENT identification, marking and documents

203.5.2 ACCOMPANYING DOCUMENTS

203.5.2.2 Dosimetric calibration

Amendment:

Subclause 5.2.2 of the collateral standard applies only if the CT SCANNER contains a dosimeter.

203.5.2.3 General requirements for the reference of subassemblies and ACCESSORIES

Subclause 5.2.3 of the collateral standard does not apply.

203.5.2.4 Instructions for use

203.5.2.4.1 General requirements for RADIATION dose information

Addition:

The requirements of subclause 5.2.4.1 of the collateral standard are met if

- the ACCOMPANYING DOCUMENTS describe the features in 203.107 (safety measures against excessive X-RADIATION) paragraphs c) and e) and 203.112 (display and recording of $CTDI_{vol}$ and DLP).
- subclause 203.13.2 (statements in the ACCOMPANYING DOCUMENTS) is fulfilled.

203.5.2.4.2 Quantitative information

Subclause 5.2.4.2 of the collateral standard is fulfilled by conformance to subclauses 203.108 through 203.114 of this particular standard.

203.5.2.4.3 Dose indication

Replacement:

If applicable, the method used to provide RADIATION dose indication in NORMAL USE of the ME EQUIPMENT shall be described directly or by reference to a published reference.

If the CT SCANNER contains a dosimeter, instructions shall be given for maintaining the specified accuracy of all dosimetric indications provided on the ME EQUIPMENT.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

203.5.2.4.5 Deterministic effects

Addition:

Compliance with paragraph b) is fulfilled by provision of information in the ACCOMPANYING DOCUMENTS about CONDITIONS OF OPERATION to achieve maximum dose levels of 1 Gy $CTDI_{100}$ (peripheral) (see 201.3.211) obtained in the PHANTOM in 203.108 (dosimetry PHANTOM).

203.5.2.4.6 RISK to OPERATORS

Replacement:

Subclause 5.2.4.6 of the collateral standard is replaced by 203.13 (protection against STRAY RADIATION).

Additional subclause:

203.5.2.4.101 Interaction of CT X-RADIATION with active medical devices

The ACCOMPANYING DOCUMENTS shall contain a cautionary statement regarding the potential detrimental interaction of the CT X-RADIATION with active implantable medical devices and body worn active medical devices and indicating that the MANUFACTURER of such devices may be contacted for more information.

203.6 RADIATION management

203.6.2 Initiation and termination of the IRRADIATION

203.6.2.1 Normal initiation and termination of the IRRADIATION

Subclause 6.2.1 of the collateral standard does not apply.

NOTE The appropriate alternate requirements for CT SCANNERS are contained in 203.107 and 203.112.

203.6.2.2 Safety measures against failure of normal termination of the IRRADIATION

Subclause 6.2.2 of the collateral standard does not apply.

NOTE The appropriate alternate requirements for CT SCANNERS are contained in 203.107 of this particular standard.

203.6.3 RADIATION dose and RADIATION QUALITY

203.6.3.1 Adjustment OF RADIATION dose and RADIATION QUALITY

Subclause 6.3.1 of the collateral standard does not apply.

NOTE The appropriate alternate requirements for CT SCANNERS are contained in 203.106.

203.6.3.2 Reproducibility of the RADIATION output

Replacement:

RADIATION output shall be measured in terms of $CTDI_{free\ air}$ for the X-RAY TUBE VOLTAGE (kV) selections at the typical collimation specified in 203.109.2 of this particular standard for two X-RAY TUBE CURRENT (mA) settings representative of typical head and body techniques.

For $CTDI_{free\ air}$, each value shall be within $\pm 10\%$ of the mean of a set of 10 measurements.

203.6.4 Indication of operational states

203.6.4.1 Indication of the X-RAY SOURCE ASSEMBLY selected

Subclause 6.4.1 of the collateral standard does not apply.

203.6.4.2 Indication of LOADING STATE

Replacement:

In NORMAL CONDITION when, and only when, RADIATION is produced, visible indication shall be provided on the CONTROL PANEL from which the X-RADIATION is actuated and on or near the gantry. Indicators at or near the gantry shall be visible from any point external to the PATIENT opening where insertion of any part of the human body into the primary RADIATION beam is possible.

The LOADING STATE shall be indicated by a yellow indicator light; see 201.7.8.1.

Compliance is checked by inspection and by the appropriate functional tests.

203.6.4.3 Indication of LOADING FACTORS and MODES OF OPERATION

Replacement:

Compliance with this subclause of the collateral standard is achieved by conformance to the following subclauses of this particular standard:

- Visual indication;
- Display and recording of $CTDI_{vol}$ and DLP;
- Post-exposure display of changed CT CONDITIONS OF OPERATION;
- Accuracy of RADIATION output.

203.6.5 AUTOMATIC CONTROL SYSTEM

Replacement:

Compliance with subclause 6.5 of the collateral standard is achieved by conformance to 203.106.

203.6.6 Scattered RADIATION reduction

Addition:

If the means are not removable a description of their proper use is not required.

203.6.7 Imaging performance

203.6.7.2 System performance

Replacement:

The following performance data shall be provided in the ACCOMPANYING DOCUMENTS for the CT CONDITIONS OF OPERATION used to provide the information required by 203.109.1 for a typical head and a typical body CT and additional CONDITIONS OF OPERATION required by IEC 61223-3-5.

For CT SCANNERS designed to image both the head and body, separate imaging performance information shall be provided for each application:

- a) A statement of the NOISE, MEAN CT NUMBER, UNIFORMITY, MODULATION TRANSFER FUNCTION and TOMOGRAPHIC SECTION THICKNESS in accordance with IEC 61223-3-5.
- b) A graphical presentation of the MODULATION TRANSFER FUNCTION for the same image processing and display mode as that used in the statement of the NOISE and additional CONDITIONS OF OPERATION required by IEC 61223-3-5.

NOTE The slice SENSITIVITY PROFILE is provided per 203.111.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

203.6.7.3 NOMINAL FOCAL SPOT value

Addition:

~~*Compliance with the second paragraph is achieved by conformance to 203.6.7.2.*~~

Amendment:

The requirement "and shall be compatible with each application within the INTENDED USE" shall not apply.

Replacement of the compliance statement:

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

203.6.7.4 RADIATION DETECTOR or X-RAY IMAGE RECEPTOR

Addition:

Compliance is achieved by conformance to 203.6.7.2.

203.7 RADIATION QUALITY

203.7.1 HALF-VALUE LAYERS and TOTAL FILTRATION in X-RAY EQUIPMENT

Addition:

The system's HALF-VALUE LAYER for each selectable FILTER shall be provided in the ACCOMPANYING DOCUMENTS at the minimum, maximum, and one mid-range value of the X-RAY TUBE VOLTAGE.

For CT SCANNERS with shaped FILTERS, measurements of RADIATION QUALITY shall be performed at the system ISOCENTRE, in the centre of the TOMOGRAPHIC PLANE and values shall be provided in the ACCOMPANYING DOCUMENTS.

Replacement of the compliance statement:

Compliance is checked by examination of the ACCOMPANYING DOCUMENTS and by the test described in 203.7.6.

203.7.2 Waveform of the X-RAY TUBE VOLTAGE

Subclause 7.2 of the collateral standard does not apply.

203.7.3 Indication of FILTER properties

Replacement:

FILTER properties shall be indicated as follows:

- X-RAY TUBE ASSEMBLIES shall be marked with the quality equivalent FILTRATION from irremovable materials or with the thicknesses of the materials concerned, together with their chemical symbols;
- For all ADDED FILTERS, the ACCOMPANYING DOCUMENTS shall state the quality equivalent FILTRATION in thickness of aluminium or another suitable reference material, together with the RADIATION QUALITY used for its determination;

EXAMPLE 0,3 mm Al 75 kV/HVL 2,7 mm Al.

- Fixed layers of material in the X-RAY BEAM incident on the PATIENT, other than ADDED FILTERS and irremovable materials in X-RAY TUBE ASSEMBLIES, shall be marked to show the quality equivalent FILTRATION in thickness of aluminium together with the RADIATION QUALITY used for its determination. The marking may be given in the form of a reference to a statement of these particulars in the ACCOMPANYING DOCUMENTS. Such layers need not be marked, if they add altogether no more than a quality equivalent FILTRATION of 0,2 mm Al and are not intended to be taken into account as part of the TOTAL FILTRATION required for compliance with 4th paragraph of subclause 7.1 of the collateral standard.

Compliance is checked by inspection, as appropriate, of the X-RAY TUBE ASSEMBLIES, filtering materials and ADDED FILTERS and by examination of the ACCOMPANYING DOCUMENTS.

203.7.4 Test for FILTRATION by irremovable materials

Subclause 7.4 of the collateral standard does not apply.

203.7.5 Test for ADDED FILTERS and materials

Subclause 7.5 of the collateral standard does not apply.

203.7.6 Test for HALF-VALUE LAYER

Replacement:

At the system ISOCENTRE, measure the first HALF-VALUE LAYER under NARROW BEAM CONDITIONS for all selectable values of the X-RAY TUBE VOLTAGE. If there are more than three selectable values of X-RAY TUBE VOLTAGE, HALF-VALUE LAYER shall be measured for at least the minimum, maximum and one mid-range value of the X-RAY TUBE VOLTAGE.

203.8 Limitation of the extent of the X-RAY BEAM and relationship between X-RAY FIELD and IMAGE RECEPTION AREA

203.8.1 General

Addition:

Compliance is achieved by conformance to the following subclauses of this particular standard:

- 203.8.4 Confinement of extra-focal RADIATION
- 203.113 GEOMETRIC EFFICIENCY IN THE Z-DIRECTION

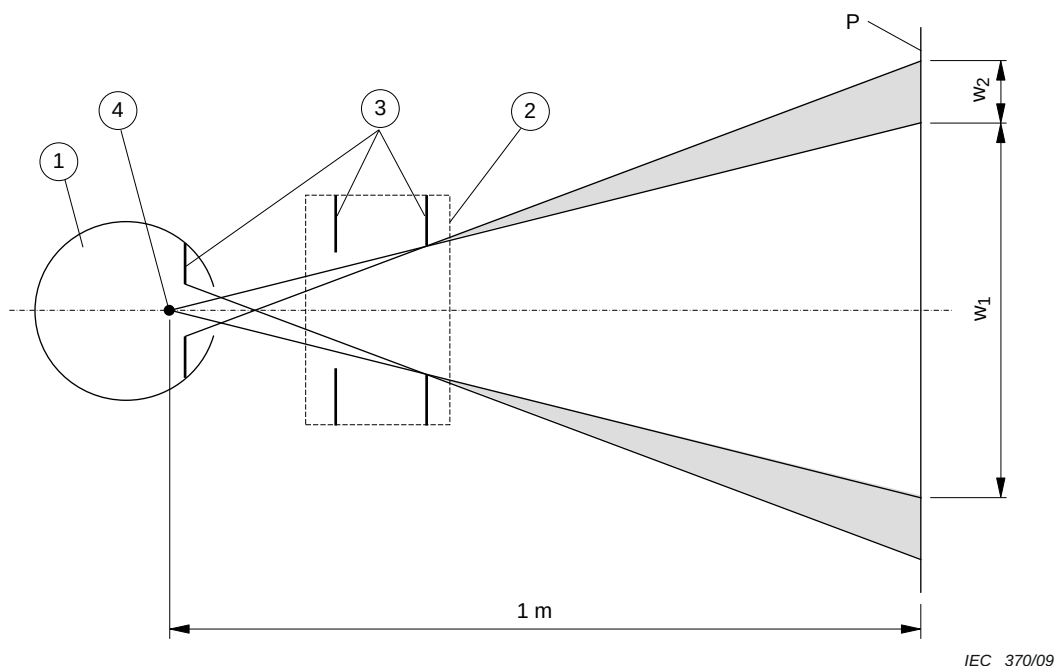
203.8.4 Confinement of extra-focal RADIATION

Replacement:

The X-RAY SOURCE ASSEMBLIES shall be constructed so that the zone of intersection of all straight lines that pass through all RADIATION APERTURES of the X-RAY SOURCE ASSEMBLY, with a plane normal to the REFERENCE AXIS at 1 m from the FOCAL SPOT shall not exceed more than 15 cm outside the boundary of the largest selectable X-RAY FIELD.

This requirement shall apply to the collimation in z-direction only.

Compliance is checked by geometrical/graphical examination of the design documentation. In Figure 201.102, w_1 represents the width of the largest selectable X-RAY FIELD in a plane P, which is perpendicular to the REFERENCE AXIS at 1 m from the FOCAL SPOT. The zone of intersection with plane P of all straight lines passing through all RADIATION APERTURES extends beyond w_1 by the distance w_2 . The shaded portion of this zone is a region where extra-focal RADIATION can extend beyond the largest X-RAY FIELD. Compliance is achieved if w_2 does not exceed 15 cm.



- 1 X-RAY TUBE housing
- 2 Beam limiting device
- 3 RADIATION APERTURES
- 4 FOCAL SPOT

Figure 203.101 – Zone of extra-focal RADIATION

Alternatively, other measures may be employed in design to sufficiently reduce extra focal RADIATION.

This requirement shall apply to the collimation in z-direction only.

Compliance is checked by examination of the design documentation.

203.8.5 Relationship between X-RAY FIELD and IMAGE RECEPTION AREA

Subclause 8.5 of the collateral standard does not apply.

NOTE The appropriate corresponding requirements for CT SCANNERS are contained in 203.111, 203.113, and 203.115.

203.9 FOCAL SPOT TO SKIN DISTANCE

Replacement:

CT SCANNERS shall be constructed such that the minimum FOCAL SPOT TO SKIN DISTANCE is at least 15 cm.

Compliance is checked by inspection.

203.10 ATTENUATION of the X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR

Clause 10 of the collateral standard ~~does not~~ applies with the following exception:

203.10.2 Information in the ACCOMPANYING DOCUMENTS

Subclause 10.2 of the collateral standard does not apply.

203.11 Protection against RESIDUAL RADIATION

Replacement:

The shielding of primary RADIATION is acceptable if the values of STRAY RADIATION, as described in 203.13.2, for the two locations in the horizontal plot which are in the TOMOGRAPHIC PLANE and closest to the gantry, are less than 25% of the values that were measured on the axis of rotation, above the PATIENT support, at the same distances from the ISOCENTRE.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

203.12 Protection against LEAKAGE RADIATION

203.12.1 General

Replacement:

X-RAY EQUIPMENT shall incorporate appropriate measures to protect the PATIENT, the OPERATOR and staff against LEAKAGE RADIATION.

Conformance to 203.13 and to subclause 12.4 of IEC 60601-1-3 is sufficient to demonstrate compliance with the requirements of the subclause above.

203.12.3 Statement of reference LOADING conditions

Replacement:

The ACCOMPANYING DOCUMENTS for all X-RAY TUBE ASSEMBLIES and X-RAY SOURCE ASSEMBLIES shall state the values of CT CONDITIONS OF OPERATION that would, if applied at the NOMINAL X-RAY TUBE VOLTAGE, correspond to the CONTINUOUS ANODE INPUT POWER.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

203.13 Protection against STRAY RADIATION

Replacement:

203.13.1 General

STRAY RADIATION measurements shall be done with those CT CONDITIONS OF OPERATION which result in the maximum STRAY RADIATION dose per CURRENT TIME PRODUCT. These CT CONDITIONS OF OPERATION should at least include the highest selectable X-RAY TUBE VOLTAGE.

A cylindrical PHANTOM of TISSUE EQUIVALENT MATERIAL (e.g. water or PMMA) with a diameter of 320 mm shall be used for the measurements. Its minimum length shall be the greater of $N \times T + 100$ mm or 140 mm. Its maximum length shall be $N \times T + 200$ mm. It shall be positioned in the centre of rotation of the CT SCANNER. The PHANTOM shall be centred on the TOMOGRAPHIC PLANE. The measurement results may be averaged over a volume ~~of 500 cm³~~ of which no principal linear dimension exceeds 200 mm.

203.13.2 Statements in the ACCOMPANYING DOCUMENTS

STRAY RADIATION data shall be measured in the horizontal and vertical planes which include the axis of rotation of the CT SCANNER. For each plane the region of measurement shall be a rectangle defined as follows:

For the horizontal plane the side which is parallel to the axis of rotation is at least 3 m long with its centre at the position of the scan plane and extends as far as necessary to include the region of the PATIENT SUPPORT; the side which is perpendicular to the axis of rotation is at least 3 m long with its centre at the position of the axis of rotation.

For the vertical plane the side which is parallel to the axis of rotation is at least 3 m long with its centre at the position of the scan plane and extends as far as necessary to include the region of the PATIENT SUPPORT; the side which is perpendicular to the axis of rotation shall extend at least 0,5 m below and 1,5 m above the position of the axis of rotation.

Figure 203.102 illustrates the configuration where the PATIENT SUPPORT does not extend beyond the minimum 3 m dimension.

Measurements shall be provided at least at every 50 cm in both directions. Information regarding the PHANTOM and the measurement results shall be provided in the instructions for use.

The unit of measurement shall be AIR KERMA per CURRENT TIME PRODUCT (mAs) applied to the X-RAY TUBE during NORMAL USE.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.