



BSI Standards Publication

Medical electrical equipment

Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography
(IEC 60601-2-44:2009)

National foreword

This British Standard is the UK implementation of EN 60601-2-44:2009+A2:2016. It is identical to IEC 60601-2-44:2009, incorporating amendment 1:2012 and amendment 2:2016. It supersedes BS EN 60601-2-44:2009+A1:2012 which will be withdrawn on 5 May 2019.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to IEC text carry the number of the IEC amendment. For example, text altered by IEC amendment 1 is indicated by **A1** **A1**.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/2, Diagnostic imaging equipment.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Amendments/corrigenda issued since publication

Date	Text affected
31 March 2012	Implementation of CENELEC amendment A11:2012: Annex ZZ replaced
30 June 2013	Implementation of IEC amendment 1:2012 with CENELEC endorsement A1:2012
31 July 2016	Implementation of IEC amendment 2:2016 with CENELEC endorsement A2:2016. Annex ZA amended

**Medical electrical equipment -
Part 2-44: Particular requirements
for the basic safety and essential performance
of X-ray equipment for computed tomography
(IEC 60601-2-44:2009)**

Appareils électromédicaux -
Partie 2-44: Exigences particulières
pour la sécurité de base
et les performances essentielles
des équipements à rayonnement X
de tomodensitométrie
(CEI 60601-2-44:2009)

Medizinische elektrische Geräte -
Teil 2-44: Besondere Festlegungen
für die Sicherheit einschließlich
der wesentlichen Leistungsmerkmale
von Röntgeneinrichtungen
für die Computertomographie
(IEC 60601-2-44:2009)

This European Standard was approved by CENELEC on 2009-05-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: Avenue Marnix 17, B - 1000 Brussels

Foreword

The text of document 62B/727/FDIS, future edition 3 of IEC 60601-2-44, prepared by SC 62B, Diagnostic imaging equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-44 on 2009-05-01.

This European Standard supersedes EN 60601-2-44:2001 + A1:2003.

EN 60601-2-44:2009 constitutes a technical revision primarily related to RADIATION protection and control.

The following dates were fixed:

- latest date by which the EN has to be implemented
at national level by publication of an identical
national standard or by endorsement (dop) 2010-02-01
- latest date by which the national standards conflicting
with the EN have to be withdrawn (dow) 2012-05-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive MDD (93/42/EEC). See Annex ZZ.

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.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-44:2009 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-2-7	NOTE	Harmonized as EN 60601-2-7:1998 (not modified).
IEC 60601-2-32	NOTE	Harmonized as EN 60601-2-32:1994 (not modified).
IEC 60613	NOTE	Harmonized as EN 60613:1990 (not modified).

Foreword to amendment A11

This document (EN 60601-2-44:2009/A11:2011) has been prepared by CLC/TC 62 "Electrical equipment in medical practice".

The following dates are fixed:

- latest date by which this document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2012-10-01
- latest date by which the national standards conflicting with this document have to be withdrawn (dow) 2014-10-01

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

Foreword to amendment A1

The text of document 62B/869/FDIS, future amendment 1 to edition 3 of IEC 60601-2-44, prepared by SC 62B "Diagnostic imaging equipment" of IEC TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-44:2009/A1:2012.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2013-07-04
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2015-10-04

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

Endorsement notice

The text of the International Standard IEC 60601-2-44:2009/A1:2012 was approved by CENELEC as a European Standard without any modification.

Foreword to amendment A2

The text of document 62B/976/CDV, future IEC 60601-2-44:2009/A2, prepared by SC 62B "Diagnostic imaging equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-44:2009/A2:2016.

The following dates are fixed:

- latest date by which the document has to be implemented at (dop) 2017-02-05
national level by publication of an identical national
standard or by endorsement
- latest date by which the national standards conflicting with (dow) 2019-05-05
the document have to be withdrawn

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s), see informative Annex ZZ, included in EN 60601-2-44:2009.

Endorsement notice

The text of the International Standard IEC 60601-2-44:2009/A2:2016 was approved by CENELEC as a European Standard without any modification.

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Annex ZA of EN 60601-1:2006 applies, except as follows:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
Replace the reference to IEC 60601-1-3 by:				
IEC 60601-1-3	2008	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance -	EN 60601-1-3	2008
-	-		+ corrigendum Mar.	2010
+ A1	2013	Collateral Standard: Radiation protection in diagnostic X-ray equipment	+ A1	2013
-	-		+ A1/AC	2014
IEC 60601-1-2	2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests	EN 60601-1-2	2015
Addition:				
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
-	-		+ A12	2014
IEC 61223-3-5	2004	Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance tests - Imaging performance of computed tomography X-ray equipment	EN 61223-3-5	2004
ISO 12052	- ¹⁾	Health informatics - Digital imaging and communication in medicine (DICOM) including workflow and data management	-	-
IEC 60336	-	Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Characteristics of focal spots	EN 60336	-

¹⁾ Undated reference.

Annex ZZ (informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC except as follows:

- Essential Requirement 6a
- Essential Requirement 7.4
- Essential Requirement 7.5 paragraph 2 & 3
- Essential Requirement 13.6 (q)

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

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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.

A1 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. **A1**

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for CT SCANNERS as defined in 201.3.201, to ensure safety, and to specify methods for demonstrating compliance with those requirements, for CT SCANNERS.

NOTE 1 Requirements for reproducibility, linearity, constancy and accuracy are given because of their relationship to the quality and quantity of the IONIZING RADIATION produced and are confined to those considered necessary for safety.

NOTE 2 Both the levels for compliance and the tests prescribed to determine compliance reflect the fact that the safety of HIGH-VOLTAGE GENERATORS is not sensitive to small differences in levels of performance. The combinations of LOADING FACTORS specified for the tests are therefore limited in number but chosen from experience as being appropriate in most cases. It is considered important to standardize the choice of combinations of LOADING FACTORS so that comparison can be made between tests performed in different places on different occasions. However, combinations other than those specified could be of equal technical validity.

NOTE 3 The safety philosophy on which this standard is based is described in the introduction to the general standard and in IEC TR 60513.

1) **A2** 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*. **A2**

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 60601-1-2 and IEC 60601-1-3 apply as modified in Clauses 202 and 203. IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10³⁾, IEC 60601-1-11⁴⁾ and IEC 60601-1-12⁵⁾ 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. 

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,

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 60601-1-11, *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*
- ⁵⁾ 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* 

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 41.

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

Replacement:

Ⓐ₂ 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* Ⓐ₂

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*

Ⓐ₂ IEC 60601-1-3:2008/AMD1:2013 Ⓐ₂

Addition:

Ⓐ₁ IEC 60336 *Medical electric equipment – X-Ray Tube assemblies for medical diagnosis – Characteristics of focal spots* Ⓐ₁

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

Ⓐ₂ IEC 60601-1:2005/AMD1:2012 Ⓐ₂

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 ^[A2] IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013 ^[A2] 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.

^[A1] NOTE 3 CT CONDITIONS OF OPERATION include parameters that are derived by the system from the user-selectable parameters. ^[A1]

201.3.203

COMPUTED TOMOGRAPHY DOSE INDEX 100

CTDI₁₀₀

^[A1] 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)

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

A1 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 $(N \times T)_{\text{Ref}}$;
- $\text{CTDI}_{\text{free air}, N \times T}$ is the $\text{CTDI}_{\text{free air}}$ (201.3.215) for a specific value of $N \times T$;
- $\text{CTDI}_{\text{free air}, \text{Ref}}$ is the $\text{CTDI}_{\text{free air}}$ (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 $z = 0$.

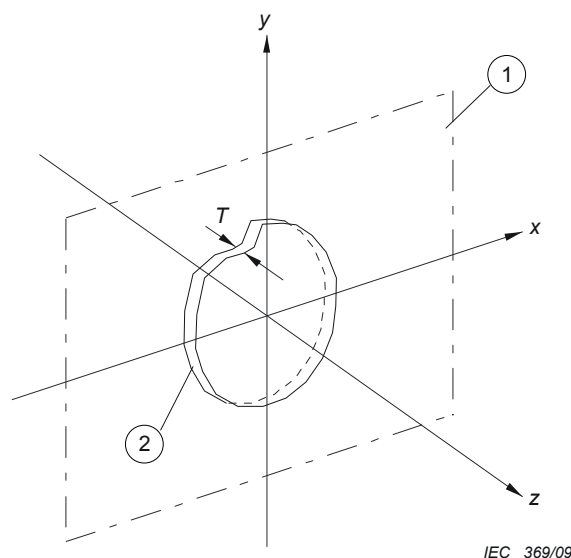
NOTE 3 A single axial scan is typically a 360° rotation of the X-ray source.

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. **A1**



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 is a 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.

[A1] 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 $\times \Delta d$. **[A1]**

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 **[A1]** is **[A1]** variable during the exposure.

[A1] 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. **[A1]**

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.

- A1** 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 Seen Figure 201.102.

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

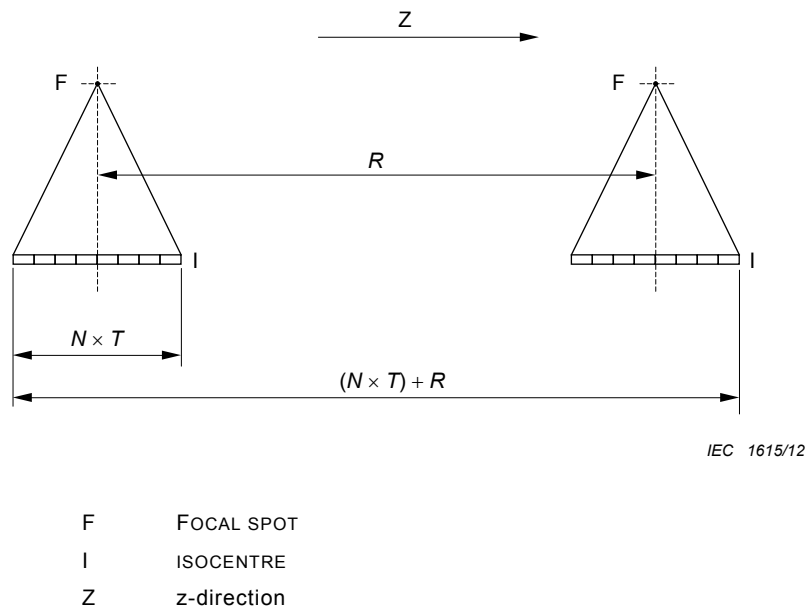


Figure 201.102 – Illustration of $N \times T, R$ and $(N \times T) + R$ **A1**

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. $\langle A_1 \rangle$

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.

$\langle A_1 \rangle$ 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. $\langle A_1 \rangle$

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.

$\langle A_1 \rangle$ 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. $\langle A_1 \rangle$

201.3.215

COMPUTED TOMOGRAPHY DOSE INDEX FREE-IN-AIR

$\langle A_1 \rangle$ $CTDI_{free\ air}$

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

$$CTDI_{free\ air} = \int_{-L/2}^{+L/2} \frac{D(z)}{N \times T} dz \quad \langle A_1 \rangle$$

A₁ 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.” **A₁**

201.4 General requirements

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

201.4.3 ESSENTIAL PERFORMANCE

A1 Addition:

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. **A1**

201.4.5 **A2** *Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS **A2**

Addition:

A2 Because state of the art technology changes for CT SCANNERS may result in the inability to strictly comply with all clauses of this particular standard, alternate means of addressing risks via risk management are acceptable. Alternate means are acceptable only when the RESIDUAL RISKS resulting from application of the alternative are equal to or less than the RESIDUAL RISKS that would ensue when the particular standards requirements are met. **A2**

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.