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

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard

- i) has any issues related to 3rd party IPR, patent or copyright
- ii) affects other national standard(s)
- iii) requires additional national guidance or information

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This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. No acknowledgement will normally be sent. **See overleaf for information on the submission of comments.**

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/Figure/ Table/Note	Type of comment	Commend (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



PROJECT NUMBER: IEC 60601-2-44 ED4	
DATE OF CIRCULATION: 2025-02-07	CLOSING DATE FOR COMMENTS: 2025-05-02
SUPERSEDES DOCUMENTS: 62B/1375/RR	

IEC SC 62B : MEDICAL IMAGING EQUIPMENT, SOFTWARE, AND SYSTEMS		
SECRETARIAT: Germany		SECRETARY: Ms Regina Geierhofer
OF INTEREST TO THE FOLLOWING COMMITTEES: SC 62A,SC 62C		HORIZONTAL FUNCTION(S):
ASPECTS CONCERNED: Electromagnetic Compatibility,Safety		

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Recipients of this document are invited to submit, with their comments, notification of any local regulations or technical reasons that may exist and should be considered should this proposal proceed, recognizing that failure to address such requirements could result in the need for new or existing "In Some Countries" clauses. (SEE [AC/22/2007](#) OR [NEW GUIDANCE DOC](#)).

TITLE:

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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1 CONTENTS

2	CONTENTS	2
3	FOREWORD.....	4
4	MEDICAL ELECTRICAL EQUIPMENT –	8
5	201.1 Scope, object and related standards	8
6	201.2 Normative references	11
7	201.3 Terms and definitions	11
8	201.4 General requirements	21
9	201.5 General requirements for testing of ME EQUIPMENT	23
10	201.6 Classification of ME EQUIPMENT and ME SYSTEMS	23
11	201.7 ME EQUIPMENT identification, marking and documents	23
12	201.8 Protection against electrical HAZARDS from ME EQUIPMENT	26
13	201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS	29
14	201.10 Protection against unwanted and excessive RADIATION HAZARDS.....	32
15	201.11 Protection against excessive temperatures and other HAZARDS	32
16	201.12 Accuracy of controls and instruments and protection against hazardous	
17	outputs.....	33
18	201.13 Hazardous situations and fault conditions.....	33
19	201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	33
20	201.15 Construction of ME EQUIPMENT	33
21	201.16 ME SYSTEMS.....	34
22	201.17 ELECTROMAGNETIC COMPATIBILITY of ME EQUIPMENT and ME SYSTEMS	34
23	201.101 Requirements for CT SCANNERS providing images for RADIOTHERAPY	
24	TREATMENT PLANNING (RTP).....	34
25	202 Electromagnetic compatibility – Requirements and tests	38
26	203 General requirements for RADIATION protection in diagnostic X-ray equipment	39
27	Annex AA (informative) Choosing LOADING FACTORS for tests.....	63
28	Annex BB (informative)	64
29	Annex CC (informative) The $CTDI_{100}$ concept in IEC 60601-2-44: Relationship	
30	between $CTDI_{100}$ and $CTDI_{\infty}$	65
31	Annex DD (informative) Measuring $CTDI_{free\ air}$	69
32	ANNEX EE (informative) Reference Template for the Content for Listing of REFERENCE	
33	CLINICAL PROTOCOLS	71
34	Bibliography	72
35	Index of defined terms used in this particular standard	74
36		
37	Figure 201.101 – Coordinate system	13
38	Figure 201.102 – Illustration of $\{N \times T\}$, R and $\{N \times T\} + R$	16
39	Figure 201.101.1 – Vertical alignment of TOMOGRAPHIC PLANE	35
40	Figure 201.101.2 – Alignment of the PATIENT SUPPORT and its movement direction.....	36
41	Figure 201.101.3 – Rotational alignment of the reconstructed CT images.....	37
42	Figure 203.101 – Zone of extra-focal RADIATION	45
43	Figure 203.102 – Minimum dimensions for STRAY RADIATION measurement	48

44	Figure CC.1 – $CTDI_W$ versus beam width along z	66
45		
46	Table 203.101 – Test pattern for $CTDI_{free\ air}$	59
47	Table CC.1 – Ratios of $CTDI$ by phantom length.....	68
48		
49		

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

IEC 60601-2-44 has been prepared by subcommittee 62B: Medical imaging equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems.

This fourth edition cancels and replaces the third edition published in 2009, Amendment 1:2012 and Amendment 2:2016. This edition constitutes a technical revision.

This particular standard has been prepared to provide, based on IEC 60601-1:2005+A1:2012+A2:2020 (3.2 edition) and its collaterals, a complete set of safety requirements for ME EQUIPMENT for computed tomography.

This edition 4 of IEC 60601-2-44 includes several changes to account for the evolved technical state-of-the-art of ct-scanner and to harmonize this standard with other international and national standards and regulations. The main changes are:

- a new requirements for calculation, display and recording of SSDE (according to IEC 62985), and of CTDIvol for scan projection radiogram (SPR)
- a revision of the requirements for ct scanner used for radiotherapy planning

- a revision of requirements for dose checks (dose notification, dose alert), in particular for interventional procedures
- a revision of requirements for dose statements in the accompanying documents
- a new requirement for an DICOM image based dose survey

In addition, several other changes and new requirements have been included

In detail, this particular standard compared to the IEC 60601-2-44:2009+A1:2012+A2:2016 (3.2 edition) includes the following changes:

a) New definition of terms for

- RECONSTRUCTED SECTION THICKNESS,
- NOMINAL RECONSTRUCTED SECTION THICKNESS,
- NOMINAL TOTAL ACQUISITION BEAM WIDTH,
- READY STATE,
- INSTRUCTIONS FOR USE,
- REFERENCE CLINICAL PROTOCOL,
- CTDI DOSIMETRY PHANTOM,
- ALTERNATE DOSE ALERT BEHAVIOR,
- CT GUIDED INTERVENTIONAL PROCEDURE,
- $CTDI_{vol}(Z)$,
- $SSDE(Z)$,
- PATIENT SUPPORT

b) Terms revised for $CTDI_{vol}$ and DLP, new definitions for $CTDI_{vol}$ and DLP for scan mode (SPR)

c) New notes for regarding ESSENTIAL PERFORMANCE

d) Requirements deleted for SENSITIVITY PROFILE STATEMENT

e) New requirements for

- specification in ACCOMPANYING DOCUMENTS
- Warning when patient support in unintended movement
- $CTDI_{vol}$ and DLP for SPR
- Display/Recording of SSDE
- Dose Summary as DICOM image and DICOM Dose SR
- REFERENCE CLINICAL PROTOCOLS
- AEC with XYZ-modulation
- prevention of unlimited scanning
- Metal Artifact Reduction (MAR) in Imaging performance

f) Requirements revised for

- Linear movements of the PATIENT SUPPORT and gantry in Emergency stopping devices
- Deterministic Effects
- Dose Checks
- System performance
- RTP (alignments, typ. modes, etc.)
- user information ($CTDI_{100}$, etc.)
- Dose statements
- indicator lights
- Safety measures against excessive X-radiation
- Indication and position of the tomographic Plane and tomographic section(s)
- Indication of loading state
- axial scan modes for CTDI measurements

g) Several changes to account for state-of-the-art and for clarification

h) Add informative Annex for Reference Template for the Content for Listing of REFERENCE CLINICAL PROTOCOLS

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

Draft	Report on voting
62B/XXX/FDIS	62B/XXX/RVD

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

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at http://www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications.

In this document, 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 AND IEC 60601-1:2005/AMD2:2020, IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

- "clause" means one of the eighteen 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this document are by number only.

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

- "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
- "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
- "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in **Error! Reference source not found.**

A list of all parts of the IEC 60601 and IEC 80601 series, published under the general title: *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch/?ref=menu in the data related to the specific document. At this date, the document will be

- 198 • reconfirmed,
- 199 • withdrawn,
- 200 • replaced by a revised edition, or
- 201 • amended.

202

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

203

204

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 head and/or body imaging 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 This standard does not intend to address interventional systems as described in IEC 60601-2-43 and cone-beam CT scanners integrated into a radiotherapy systems as described in IEC 60601-2-68 and dental cone-beam CT scanners as described in IEC 60601-2-63.

NOTE 3 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 previous edition of IEC 60601-2-44. Therefore IEC 60601-2-7 and IEC 60601-2-32 are not part of the 4th edition scheme for COMPUTED TOMOGRAPHY.

NOTE 4 The body includes cardiac, extremities, neck, etc.

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.

¹⁾ The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

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.

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.

A requirement of a particular standard takes priority over applicable collateral standards. IEC 60601-1-2:2014+AMD1:2020 and IEC 60601-1-3:2008+AMD1:2013+AMD2:2021 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.

If a CT-SCANNER is intended for use in EMERGENCY MEDICAL SERVICES ENVIRONMENT, this situation shall be taken into account in the RISK MANAGEMENT FILE.

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*

281 If an ECG monitor is integrated into the CT SYSTEM for the sole purposes of providing triggers
282 for cardiac and vascular examinations and other examinations affected by cardiac motion, the
283 ECG monitor does not need to conform to IEC 60601-2-27.

284 For collateral standards published after this particular standard, MANUFACTURERS need to
285 determine the applicability in accordance with the RISK MANAGEMENT PROCESS.

286

287 **201.1.4 Particular standards**

288 *Replacement:*

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

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

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

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

303 "Replacement" means that the clause or subclause of the general standard or applicable
304 collateral standard is replaced completely by the text of this particular standard.

305 "Addition" means that the text of this particular standard is additional to the requirements of the
306 general standard or applicable collateral standard.

307 "Amendment" means that the clause or subclause of the general standard or applicable
308 collateral standard is amended as indicated by the text of this particular standard.

309 Subclauses, figures or tables which are additional to those of the general standard are
310 numbered starting from 201.101. However, due to the fact that definitions in the general
311 standard are numbered 3.1 through 3.154, additional definitions in this standard are numbered
312 beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items
313 aa), bb), etc.

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

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

319 Where there is no corresponding section, clause or subclause in this particular standard, the
320 section, clause or subclause of the general standard or applicable collateral standard, although
321 possibly not relevant, applies without modification; where it is intended that any parts of the

322 general standard or applicable collateral standard, although possibly relevant, is not to be
323 applied, a statement to that effect is given in this particular standard.

324 **201.2 Normative references**

325 NOTE Informative references are listed in the bibliography.

326 *Addition:*

327 The following referenced documents are indispensable for the application of this document. For dated
328 references, only the edition cited applies. For undated references, the latest edition of the referenced
329 document (including any amendments) applies.

330 IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment – Part 1: General*
331 *requirements for basic safety and essential performance*

332 IEC 61223-3-5:2019, *Evaluation and routine testing in medical imaging departments – Part 3-*
333 *5: Acceptance tests – Imaging performance of computed tomography X-ray equipment*

334 ISO 12052:2017, *Health informatics – Digital imaging and communication in medicine (DICOM)*
335 *including workflow and data management*

336 IEC 60336:2020, *Medical electrical equipment - X-ray tube assemblies for medical diagnosis -*
337 *Focal spot dimensions and related characteristics*

338

339 **201.3 Terms and definitions**

340 For the purposes of this document, the terms and definitions given in IEC 60601-
341 1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC
342 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-
343 3:2008+AMD1:2013+AMD2:2021, and IEC 60788:2004 apply, except as follows:

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

345 NOTE 102 In accordance with the definitions in IEC 60601-1-3, in this standard unless otherwise indicated:

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

347 – values of X-RAY TUBE CURRENT refer to mean values.

348 *Addition:*

349 **201.3.201**

350 **CT SCANNER**

351 X-RAY EQUIPMENT intended to generate cross-sectional images of the head and/or body by
352 computer reconstruction of X-ray transmission data obtained at different angles, which may
353 include signal analysis and display equipment, PATIENT SUPPORT, support parts and
354 ACCESSORIES

355 NOTE 1 The scope of this document is limited to CT SCANNERS intended to be used for head and/or body
356 characterised by an ENCLOSURE of the X-ray source(s) and imaging detector(s) in a common protective cover in the
357 shape of a toroid.

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

359 NOTE 3 The body includes cardiac, extremities, neck, etc.

201.3.202**CT CONDITIONS OF OPERATION**

all selectable acquisition 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.

NOTE 4 Parameters that are solely related to the image reconstruction are not included in CT CONDITIONS OF OPERATION.

201.3.203**COMPUTED TOMOGRAPHY DOSE INDEX 100** **$CTDI_{100}$**

integral of the DOSE PROFILE representative of a single axial scan along z-axis divided by the NOMINAL TOTAL ACQUISITION BEAM WIDTH $\{N \times T\}$ 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 z-axis, 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 $\{N \times T\}_{\text{Ref}}$;

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.

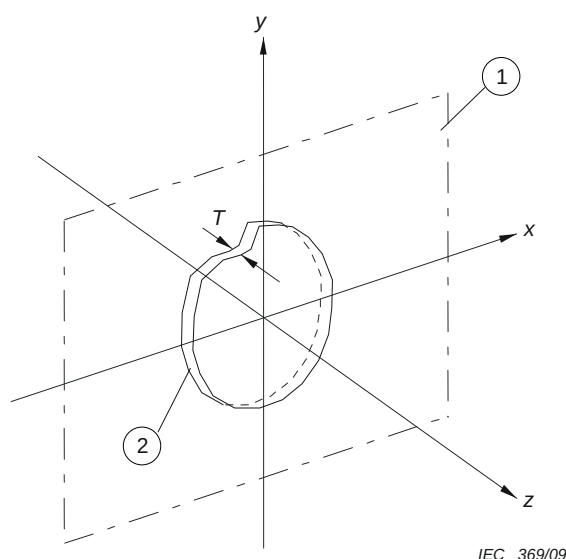
NOTE 2 This definition assumes that the DOSE PROFILE is centred on $z = 0$.

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

NOTE 4 Typically the z-axis is the axis of rotation of the CT SCANNER.

NOTE 5 The $CTDI_{100}$ is designed to include most of the scattered radiation.

NOTE 6 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 NOMINAL TOTAL ACQUISITION BEAM WIDTH $\{N \times T\}$:

$$\text{CT PITCH FACTOR} = \frac{\Delta d}{\{N \times T\}}$$

where

Δd is the PATIENT SUPPORT travel along the z-direction per rotation of the X-ray source;

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 CT PITCH FACTOR will be a function of time when Δd is variable during the exposure.

NOTE 3 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 : The NOMINAL RECONSTRUCTED SECTION THICKNESS might or might not be equal to the NOMINAL TOMOGRAPHIC SECTION THICKNESS. The reconstructed section might not have a one-to-one correspondence with the TOMOGRAPHIC SECTION.

429 **201.3.207**430 **SENSITIVITY PROFILE**

431 relative response of a system for COMPUTED TOMOGRAPHY as a function of position along the z-axis
 432

433 **201.3.208**434 **TOMOGRAPHIC PLANE**

435 geometric plane perpendicular to the z-axis at the ISOCENTER of the X-RAY FIELD (see Figure
 436 201.101)

437 **201.3.209**438 **TOMOGRAPHIC SECTION**

439 The volume over which data for image reconstruction are collected by a single acquisition
 440 channel representing a single detector row or a selected grouping of detector rows.

441 **201.3.210**442 **TOMOGRAPHIC SECTION THICKNESS**

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

445 **201.3.211**446 **WEIGHTED $CTDI_{100}$** 447 **$CTDI_w$**

448 value defined as

$$449 \quad CTDI_w = \frac{1}{3}CTDI_{100(\text{centre})} + \frac{2}{3}CTDI_{100(\text{peripheral})}$$

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

453 **201.3.212**454 **VOLUME $CTDI_w$** 455 **$CTDI_{vol}$**

456
 457 The VOLUME $CTDI_w$ ($CTDI_{vol}$) is an index of dose based on a convention of 100 mm range of
 458 integration along the z-axis. The definition of $CTDI_{vol}$ for different scan modes (axial, helical,
 459 etc.) aims to obtain a consistent index that corresponds to the approximate average dose that
 460 would accrue in the PHANTOM in the central section scanned.
 461

462 While the limitation to 100 mm for dose integration along the z-axis is a general limitation of the
 463 method that leads to a systematic underestimation of the dose, there are further limitations for
 464 the individual scan modes that are addressed in notes to the definitions below.
 465

466 For types of scanning that are not represented by the types of scanning addressed in sections
 467 a) to d) of this clause, the $CTDI_{vol}$ is an according index of dose as specified by the
 468 MANUFACTURER for the type of scanning concerned. This specification follows the meaning of
 469 $CTDI_{vol}$ as described in the first paragraph of this clause and is described by the MANUFACTURER
 470 in the ACCOMPANYING DOCUMENTS (see 203.112).
 471

472 NOTE Examples of such types of scanning are shuttle modes with gaps, shuttle modes with dynamic z-collimation,
 473 switching of tube voltage during scanning, etc.
 474

475 a) for axial scanning

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

where

$\{N \times T\}$ is the NOMINAL TOTAL ACQUISITION BEAM WIDTH;

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

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 approximate 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 is variable during the exposure.

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 scanning 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 scanning 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

$\{N \times T\}$ is the NOMINAL TOTAL ACQUISITION BEAM;

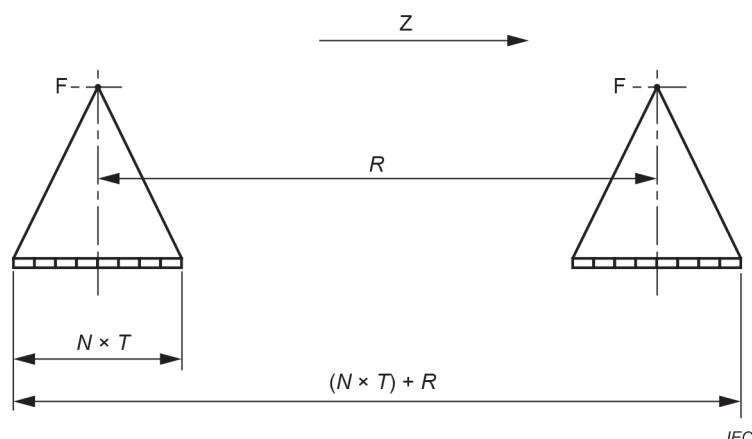
n is equal to the total number of rotations for the entire scan series;

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
Z z-direction

Figure 201.102 – Illustration of $\{N \times T\}$, R and $\{N \times T\} + R$

e) for a scan projection RADIOGRAPHY (SPR): The value of $CTDI_{vol}$ associated with a preview image acquired during scan projection RADIOGRAPHY, can be estimated in terms of $CTDI_w$, $N \times T$, and the table speed for a SPR image acquired with constant table movement and continuous RADIATION at a fixed angle.

$$CTDI_{vol} = (CTDI_w / \text{CURRENT TIME PRODUCT}) \times \text{X-RAY TUBE CURRENT} \times (N \times T) / (\text{table speed}),$$

where the

- ratio $CTDI_w / \text{CURRENT TIME PRODUCT}$ is evaluated independently of the SPR acquisition but with the same settings of TUBE VOLTAGE and $N \times T$ as those of the SPR acquisition;
- X-RAY TUBE CURRENT and table speed are those values used during the SPR acquisition.
- Unless the SPR is exclusively of a Head, the $CTDI_w$ for a 32 cm phantom should be used.

The ACCOMPANYING DOCUMENTS should clearly identify which CTDI phantom is used for different examinations.

NOTE 1 $CTDI_{vol}$ for scan projection RADIOGRAPHY (SPR) may also be designated $CTDI_{vol SPR}$

NOTE 2 With $CTDI_{vol SPR}$ being included as part of the general $CTDI_{vol}$ definition in this section, all succeeding requirements of this standard for display, recording, notification and alert of $CTDI_{vol}$ also apply for $CTDI_{vol SPR}$.

NOTE 3 Although the dose distribution of a SPR within the PHANTOM is different to the dose distribution of a tomographic scan, the average dose expressed by the $CTDI_{vol SPR}$ in the PHANTOM can be considered as the same as for a tomographic scan, if the CT CONDITIONS OF OPERATION are the same.

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.

551 **201.3.214**552 **DOSE-LENGTH PRODUCT**553 **DLP**554 index characterizing the product of the $CTDI_{vol}$ and the total length scanned

555 a) For axial scanning

556
$$DLP = CTDI_{vol} \times \Delta d \times n$$

557 where

558 Δd is the PATIENT SUPPORT travel in z-direction between consecutive scans;559 n is the number of scans in the series.

560 b) For helical scanning

561
$$DLP = CTDI_{vol} \times L$$

562 where

563 L is the table travel during the entire LOADING, adjusted for dynamic collimation modes if
564 applicable.565 NOTE 1 L might be longer than the programmed scan range.566 NOTE 2 The time weighted average of $CTDI_{vol}$ is to be used if $CTDI_{vol}$ is variable.567 NOTE 3 A way for obtaining L could be to use the FWHM along z-axis at isocenter of the free-in-air DOSE PROFILE
568 for the entire scan. In the absence of dynamic collimation this is approximately equivalent to table travel during the
569 entire LOADING.

570 c) For scanning without movement of the PATIENT SUPPORT

571
$$DLP = CTDI_{vol} \times \{N \times T\}$$

572 where

573 $\{N \times T\}$ is the NOMINAL TOTAL ACQUISITION BEAM.574 d) for axial scanning without gaps and helical scanning, both involving back-and-forth PATIENT
575 SUPPORT movement between two positions (shuttle mode)

576
$$DLP = CTDI_{vol} \times (\{N \times T\} + R)$$

577 where

578 $\{N \times T\}$ is the NOMINAL TOTAL ACQUISITION BEAM;579 R is the distance between the two positions.

580

581

- e) for a scan projection RADIOGRAPHY (SPR): The value of DLP associated with a preview image acquired during scan projection RADIOGRAPHY, can be estimated in terms of $CTDI_{vol}$ and the scan length for a SPR image acquired with constant table movement and continuous RADIATION at a fixed angle.

$$DLP = CTDI_{vol} \times scan\ length$$

where the scan length is measured in cm.

NOTE 1 $CTDI_{vol}$ for scan projection RADIOGRAPHY (SPR) may also be designated $CTDI_{vol\ SPR}$

NOTE 2 DLP for scan projection RADIOGRAPHY (SPR) may also be designated DLP_{SPR}

NOTE 3 With DLP_{SPR} being included as part of the general DLP definition in this section, all succeeding requirements of this standard for display, recording, notification and alert of DLP also apply for DLP_{SPR} .

NOTE 4 Although the dose distribution of a SPR within the PHANTOM is different to the dose distribution of a tomographic scan, the average dose expressed by the DLP_{SPR} in the PHANTOM can be considered as the same as for a tomographic scan, if the CT CONDITIONS OF OPERATION are the same.

201.3.215

COMPUTED TOMOGRAPHY DOSE INDEX FREE-IN-AIR

$CTDI_{free\ air}$

integral of the DOSE PROFILE representative of a single axial scan along z-axis to the TOMOGRAPHIC PLANE divided by $N \times T$ according to the following

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

where

$D(z)$ is the DOSE PROFILE representative of a single axial scan along z-axis, 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;

$\{N \times T\}$ is the NOMINAL TOTAL ACQUISITION BEAM;

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 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

625 201.3.218**626 DOSE NOTIFICATION VALUE**

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

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

631 201.3.219**632 DOSE ALERT VALUE**

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

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

637 201.3.220**638 RECONSTRUCTED SECTION THICKNESS**

639 FULL WIDTH AT HALF MAXIMUM of the SENSITIVITY PROFILE of a reconstructed image

640 201.3.221**641 NOMINAL RECONSTRUCTED SECTION THICKNESS**

642 in CT SCANNERS the RECONSTRUCTED SECTION THICKNESS which is selected and indicated on the
643 CONTROL PANEL

644 201.3.222**645 NOMINAL TOTAL ACQUISITION BEAM WIDTH**

646 $\{N \times T\}$

647 The NOMINAL TOTAL ACQUISITION BEAM WIDTH of a CT-scan, expressed as product of $N \times T$, where

648 T the nominal width of the detector elements over which data for image reconstruction are
649 collected by a single acquisition channel representing a single detector row or a selected
650 grouping of detector rows. The nominal width of the detector elements is obtained by
651 projecting the actual detector width onto the z-axis at the ISOCENTRE.

652 N number of adjacent acquisition channels of width T, used to simultaneously acquire data
653 for reconstructing a set of CT images.

654 $\{N \times T\}$ is the acquisition range along the z-axis that is spanned by the selected detector
655 elements, where z-axis length is given as equivalent lengths at the ISOCENTRE (see also
656 201.3.213).

657 In CT SCANNERS where simultaneously acquired TOMOGRAPHIC SECTIONS overlap (i.e. they are
658 not adjacent), N must be corrected for the overlap. For example, if the fraction of overlap is
659 0.5, then N is the number of simultaneously acquired TOMOGRAPHIC SECTIONS multiplied by a
660 factor k , where $k = 1 - \text{overlap} = (1 - 0.5) = 0.5$.

661 NOTE: In multi-slice CT the FWHM of the collimated X-ray beam along the scanner's z-axis is typically somewhat
662 larger than $\{N \times T\}$ to avoid the outer tomographic sections laying within the penumbra of the dose profile.

663

201.3.223**READY STATE**

The state when one further actuation of a control from the CONTROL PANEL will initiate the LOADING of the X-RAY TUBE.

201.3.224**INSTRUCTIONS FOR USE**

Those parts of ACCOMPANYING DOCUMENTS giving the necessary information for safe and proper use, and operation of the equipment.

201.3.225**REFERENCE CLINICAL PROTOCOL**

A PROTOCOL ELEMENT or a group of PROTOCOL ELEMENTS, completed as appropriate by additional parameters, that is pre-installed by the MANUFACTURER on a CT SCANNER and that may be selected and used by the OPERATOR to perform a specific clinical task with the CT SCANNER.

NOTE 1 Examples of additional parameter in a REFERENCE CLINICAL PROTOCOL are specific parameters for image reconstruction and display, timing controls for examinations with contrast agent, workflow information, etc.

NOTE 2 An example for a specific clinical task is abdominal imaging, e.g. for the diagnosis of liver tumors.

NOTE 3 Manufacturers develop reference protocols based on detailed knowledge of the specific performance characteristics of the CT SCANNER and based on their experience from clinical collaborations

NOTE 4 REFERENCE CLINICAL PROTOCOLS represent a starting point for review prior to clinical use.

NOTE 5 CT CONDITIONS OF OPERATION specified as "typical" by IEC 61223-3-5 for Acceptance and Constancy testing may differ from REFERENCE CLINICAL PROTOCOLS to better accommodate ACCEPTANCE TESTS and CONSTANCY TESTS, while remaining representative of the clinical use protocol elements that they are derived from.

201.3.226**CTDI DOSIMETRY PHANTOM**

A phantom consisting of a PMMA cylinder of density $1,19 \pm 0,01$ g/cm³, of diameter 160 mm for all head protocol elements and 320 mm for all body protocol elements. The length of the phantom shall be at least 140 mm. The phantom shall contain holes just large enough to accept a radiation detector and properly fitting inserts of the same material as the phantom. These holes shall be parallel to the axis of symmetry of the phantom, and the centres of the holes shall be located at the centre and 10 mm below the surface of the phantom at 90° intervals.

201.3. 227**ALTERNATE DOSE ALERT BEHAVIOR**

An option provided by the CT SCANNER to the operator to limit the DOSE ALERT to only the first alert occurrence within an examination.

NOTE: The purpose of ALTERNATE DOSE ALERT BEHAVIOR is to avoid situations where a repeated DOSE ALERT might interfere with the progress of a CT GUIDED INTERVENTIONAL PROCEDURE.

NOTE: ALTERNATE DOSE ALERT BEHAVIOUR is limited to CT GUIDED INTERVENTIONAL PROCEDURES, see 203.108.2.2.

NOTE: ALTERNATE DOSE ALERT BEHAVIOUR requires additional information to be provided to the OPERATOR during an EXAMINATION, see 203.108.2.2.

201.3. 228**CT GUIDED INTERVENTIONAL PROCEDURE**

An invasive procedure (e.g., involving the introduction of a device, such as a needle or a catheter into the body of the PATIENT) that includes COMPUTED TOMOGRAPHY as the principal means of guidance.

A CT GUIDED INTERVENTIONAL PROCEDURE is based on either:

a) A dedicated CT interventional PROTOCOL ELEMENT OR PROTOCOL ELEMENT GROUP as indicated by the MANUFACTURER, or

b) a corresponding selection provided by the MANUFACTURER which the OPERATOR activates prior to an EXAMINATION (if configured) or during an EXAMINATION to indicate an interventional procedure (e.g. a checkbox in the DOSE ALERT pop-up window).

NOTE: In contrast to a radioscopically guided interventional procedure, the extraction of needles, where images are not required for guidance, is not to be considered ESSENTIAL PERFORMANCE (see 201.4.3).

201.3.229**CTDI_{vol} AT LONGITUDINAL POSITION Z****CTDI_{vol}(z)**

value quantifying the RADIATION OUTPUT at position z for the selected CT CONDITIONS OF OPERATION.

[SOURCE: IEC 62985:2019, 3.1]

201.3.230**SIZE SPECIFIC DOSE ESTIMATE AT LONGITUDINAL POSITION Z****SSDE(z)**

estimate of the average ABSORBED DOSE to the material contained in an axial plane at longitudinal position z within the RECONSTRUCTION LENGTH, expressed in units of mGy:

$$SSDE(z) = f(D_w(z)) \times CTDI_{vol}(z)$$

[SOURCE: IEC 62985:2019, 3.8]

201.3.231**PATIENT SUPPORT**

PATIENT SUPPORT component such as a tabletop or head holder, in a CT SCANNER, serving to support the PATIENT in order to allow the part of his/her body which is to be irradiated to be positioned or to be displaced.

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 (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 1 An example of what would not be considered ESSENTIAL PERFORMANCE is the use of 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), if for the extraction of needles images are not required for guidance.

NOTE 2 The general functionality of a CT-SCANNER to provide images for diagnosis is not considered as an ESSENTIAL PERFORMANCE because failure of this general functionality does not cause an unacceptable RISK as long as the system transitions to a safe state specified under BASIC SAFETY (in contrast to systems such as life support systems).

Maintaining image quality is not specified in this standard as ESSENTIAL PERFORMANCE, but is considered as an important parameter for the general functionality of providing images for diagnosis. This is ensured by means such as the ACCEPTANCE and CONSTANCY TESTING described in IEC 61223-3-5 and in addition by periodic (daily) calibration and quality assurance procedures as specified by the manufacturer.

Aspects of BASIC SAFETY, such as protection against mechanical and electrical hazards, protection against excessive temperatures and protection against unwanted and excessive radiation hazards are specified within this standard and are required to be indicated in the manufacturer's RISK MANAGEMENT FILE. These items are not considered as Essential Performance.

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

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

Addition:

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

201.4.10.2 SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS

Addition:

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

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

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

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