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BSI Group Headquarters

389 Chiswick High Road London W4 4AL

Tel: +44 (0)20 8996 9000

Fax: +44 (0)20 8996 7400

www.bsigroup.com

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Interested committees:

Title: Draft BS EN 60601-2-68 Amendment 1 - Electrical medical equipment. Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment.

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- i) has any issues related to 3rd party IPR, patent or copyright
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Responsible Committee Secretary: Miss Jacinta Hampton (BSI)

Direct tel:

E-mail: jacinta.hampton@bsigroup.com

Full document details: 20/30425201 DC

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 Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.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.	



62C/774/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER: IEC 60601-2-68/AMD1 ED1	
DATE OF CIRCULATION: 2020-08-07	CLOSING DATE FOR COMMENTS: 2020-10-02
SUPERSEDES DOCUMENTS: 62C/773/RR	

IEC SC 62C : EQUIPMENT FOR RADIOTHERAPY, NUCLEAR MEDICINE AND RADIATION DOSIMETRY	
SECRETARIAT: Germany	SECRETARY: Mr Norbert Bischof
OF INTEREST TO THE FOLLOWING COMMITTEES: SC 62B	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CD to the secretary.
FUNCTIONS CONCERNED: ☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☒ 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.

TITLE:

Amendment 1 - Electrical medical equipment - Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment

NOTE FROM TC/SC OFFICERS:

The modifications relative to edition 1 are going to be indicated in a separate INF document.

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1 FOREWORD

This first amendment to International Standard IEC 60601-2-68, Ed. 1 has been prepared by Subcommittee 62C "Equipment for radiotherapy, nuclear medicine and radiation dosimetry", Working Group 1 "Beam teletherapy and particle accelerators", of IEC Technical Committee 62 "Electrical equipment in medical practice".

The text of this amendment is based on the following documents:

CD	Report on voting
62C/XXX/CD	XX/XX/RVD

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

The committee has decided that the contents of the base publication and its amendments will remain unchanged until the stability date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

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

INTRODUCTION to Amendment 1

Since the edition 1 was published changes took place in the standards environment.

The following standards relevant to X-IGRT EQUIPMENT were updated, or newly published:

- IEC 60601-2-1:2020, *Requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV*
- IEC 60601-2-64, *Requirements for the basic safety and essential performance of light ion beam medical electrical equipment*
- IEC TR 62926 has been modified during it's development and was not published as an international standard but as a technical report and provides guidance for integration of electron accelerators with other equipment.
- IEC TR 63183 provides guidance on the construction of error and warning messages.

This amendment extends the scope of IEC 60601-2-68 to CT SCANNERS, intended to be used in the same room with an EXTERNAL BEAM EQUIPMENT (EBE).

This amendment introduces updated requirements related to MECHANICAL HAZARDS, radiation HAZARDS, PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS), ACCOMPANYING DOCUMENTATION of an ME SYSTEM, and REMOTE OPERATION.

201.1**201.1.1 Scope**

Replace the existing third paragraph with:

This particular standard deals with equipment for REAL-TIME X-IGRT, ONLINE X-IGRT and OFFLINE X-IGRT. It covers procedures to reduce the risk of over-reliance on the X-IGRT EXTERNAL BEAM SYSTEM (X-IGRT EBS). For example the MANUFACTURER will provide an interactive interface for user interaction with the correction suggested by the system.

Add after third paragraph:

This particular standard does not apply to standard CT SCANNERS, which are not used for IGRT. However, if a CT SCANNER is used in the same room with an EBE for IGRT then this particular standard applies.

This particular standard applies for X-RAY EQUIPMENT for RADIOGRAPHY and RADIOSCOPY used for IGRT and replaces other standards.

Add forth paragraph:

If the X-IGRT EQUIPMENT is combined with an EBE any requirement that is the same for the X-IGRT EQUIPMENT and the EBE, such as a PATIENT POSITIONER, need not to be tested twice, but can be accepted as tested by the EBE.

Replace the existing fifth paragraph with:

This particular standard, with the inclusion of TYPE TESTS and SITE TESTS, applies respectively to the MANUFACTURER and some installation aspects of X-IGRT EBE SYSTEMS intended to be

- for NORMAL USE, operated under the authority of the RESPONSIBLE ORGANIZATION by QUALIFIED PERSONS having the required skills for a particular medical application, for particular specified clinical purposes, e.g. STATIONARY RADIOTHERAPY or MOVING BEAM RADIOTHERAPY,
- maintained in accordance with the recommendations given in the INSTRUCTIONS FOR USE,
- subject to regular quality assurance performance and calibration checks by a QUALIFIED PERSON.

NOTE In this particular standard, all references to installation refer to installation in the RESPONSIBLE ORGANIZATION'S premises

201.1.4 Particular standards

Replace the existing first paragraph with:

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 MEE under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

201.2 Normative references

Update the following normative references:

IEC 60601-1-3:2008+A1:2013, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment*

IEC 60601-2-1:2019, *Medical electrical equipment – Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV*

57 IEC 60601-2-44:2009+A1:2012, *Medical electrical equipment – Part 2-44: Particular requirements for*
 58 *the basic safety and essential performance of X-ray equipment for computed tomography*

59 IEC 60601-2-64:2014, *Medical electrical equipment – Part 2-44: Particular requirements for the basic*
 60 *safety and essential performance of light ion beam medical electrical equipment*

61 IEC 62366:2014, *Medical devices – Application of usability engineering to medical devices*

62 *Delete the following normative references:*

63 IEC 60976:2007, *Medical electrical equipment – Medical electron accelerators – Functional*
 64 *performance characteristics*

65 **201.3 Terms and definitions**

66 *After the existing first paragraph add:*

67 ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- 68 • IEC Electropedia: available at <http://www.electropedia.org/>
- 69 • ISO Online browsing platform: available at <http://www.iso.org/obp>

70 *Replace the existing term and definition 201.3.201 with:*

71 **201.3.201**

72 COMPUTED TOMOGRAPHY DOSE INDEX 100

73 **$CTDI_{100}$**

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

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

$$77 \quad CTDI_{100} = \int_{-50 \text{ mm}}^{+50 \text{ mm}} \frac{D(y)}{N \times T} dy$$

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

$$80 \quad CTDI_{100} = \int_{-50 \text{ mm}}^{+50 \text{ mm}} \frac{D_{\text{Ref}}(y)}{(N \times T)_{\text{Ref}}} dz \times \frac{CTDI_{\text{free air}, N \times T}}{CTDI_{\text{free air}, \text{Ref}}}$$

81 where:

82 $D(y)$ is the DOSE PROFILE representative of a single axial scan along a line perpendicular to
 83 the TOMOGRAPHIC PLANE, where dose is reported as ABSORBED DOSE in air and is
 84 evaluated within a polymethylmethacrylate (PMMA) dosimetry PHANTOM (see
 85 201.102.5.2);

86 $(N \times T)_{\text{Ref}}$ is a specific $N \times T$ of 20 mm or the largest $N \times T$ available not greater than 20 mm;

87 $D_{\text{Ref}}(y)$ is the DOSE PROFILE representative of a single axial scan along a line perpendicular to
 88 the TOMOGRAPHIC PLANE, where dose is reported as ABSORBED DOSE in air and is
 89 evaluated within a polymethylmethacrylate (PMMA) dosimetry PHANTOM (see
 90 201.102.5.2) for $(N \times T)_{\text{Ref}}$;

- 91 $CTDI_{\text{free air}, N \times T}$ is the $CTDI_{\text{free air}}$ (201.3.202) for a specific value of $N \times T$;
- 92 $CTDI_{\text{free air, Ref}}$ is the $CTDI_{\text{free air}}$ (201.3.202) for $(N \times T)_{\text{Ref}}$;
- 93 N is the number of TOMOGRAPHIC SECTIONS produced in a single axial scan of the X-ray
94 source;
- 95 T is the NOMINAL TOMOGRAPHIC SECTION THICKNESS.
- 96 Note 1 to entry: The dose is reported as ABSORBED DOSE to air, but for practical purposes the evaluation of ABSORBED DOSE to air within a
97 PMMA dosimetry PHANTOM is well approximated by measurement of the AIR KERMA.
- 98 Note 2 to entry: This definition assumes that the DOSE PROFILE is centred on $y = 0$.
- 99 Note 3 to entry: A single axial scan is typically a 360° rotation of the X-ray source. For CBCT partial rotations are still considered as a
100 single axial scan.
- 101 Note 4 to entry: When the TOMOGRAPHIC SECTIONS overlap, e.g. in CT SCANNERS with a “y-flying FOCAL SPOT” or with CBCT modes that
102 merge multiple scans, the denominator of the integral needs to be replaced by the total nominal width along y of overlapping tomographic
103 sections. For example, if the percentage of overlap is 50%, then the denominator would be replaced by $0,5 \times N \times T$.
- 104 Note 5 to entry: Typically the y -axis is the axis of rotation (the y -axis corresponds to the z -axis in the DICOM coordinate system.)
- 105 Note 6 to entry: The $CTDI_{100}$ is designed to include most of the scattered RADIATION.
- 106 Note 7 to entry: See IEC 60601-2-44:2009/AMD1:2012, Annex CC for more explanation.
- 107 Note 8 to entry: It is assumed for MV CBCT that an appropriate calibrated pencil chamber is used.
- 108 Note 9 to entry: The note to entry concerning the origin of the abbreviation $CTDI$ APPLIES TO THE FRENCH TEXT ONLY.
- 109 [SOURCE: IEC 60601-2-44:2009/AMD1:2012, 201.3.203, modified – Notes 3, 4 and 5 to entry have been
110 extended, and Note 8 to entry added.]

111 *Replace the existing term and definition 201.3.202 with:*

112 **201.3.202**

113 COMPUTED TOMOGRAPHY DOSE INDEX FREE-IN-AIR

114 **$CTDI_{\text{free air}}$**

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

117
$$CTDI_{\text{free air}} = \int_{-L/2}^{+L/2} \frac{D(y)}{N \times T} dy$$

118 where

119 $D(y)$ is the DOSE PROFILE representative of a single axial scan along a line through ISOCENTRE and
120 perpendicular to the TOMOGRAPHIC PLANE, where dose is reported as ABSORBED DOSE in air and is
121 evaluated free-in-air in the absence of a PHANTOM and the PATIENT SUPPORT;

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

123 T is the NOMINAL TOMOGRAPHIC SECTION THICKNESS;

124 L is at least $(N \times T) + 40$ mm.

125 Note 1 to entry: This definition assumes that the DOSE PROFILE is centered on $y = 0$. The y axis corresponds to the z axis in the DICOM
126 coordinate system

127 Note 2 to entry: When the TOMOGRAPHIC SECTIONS overlap, e.g. in CT SCANNERS with a “y-flying FOCAL SPOT” or with CBCT modes that
128 merges multiple scans, the denominator of the integral needs to be replaced by the total nominal width along y of overlapping tomographic
129 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 to entry: Typically a RADIATION DETECTOR of length L or longer is used. Annex DD provides an example for alternate measurements.

Note 4 to entry: For CBCT the imaging is not slice based and $N \times T$ is the scan length along a line perpendicular to the TOMOGRAPHIC PLANE with the NOMINAL collimation.

Note 5 to entry: It is assumed for MV CBCT that an appropriate calibrated pencil chamber or ion chamber, and a build-up cap is used.

[SOURCE: IEC 60601-2-44:2009/AMD1:2012, 201.3.215, modified – Note 1 and 2 to entry have been extended and Notes 4 and 5 to entry added.]

Replace the existing term and definition 201.3.206 with:

201.3.206

DOSE-LENGTH PRODUCT

DLP

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

Note 1 to entry: For axial, helical scanning, and scanning involving back-and-forth PATIENT SUPPORT movement between two positions (shuttle mode) use the definition provided in IEC 60601-2-44.

a) For axial scanning

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

where

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

n is the number of scans in the series.

b) For helical scanning

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

where

L is the table travel during the entire LOADING, adjusted for dynamic collimation modes if applicable.

Note 1 to entry: L might be longer than the programmed scan length.

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

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

c) For scanning without movement of the PATIENT SUPPORT

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

where

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

T is the NOMINAL TOMOGRAPHIC SECTION THICKNESS.

Note 4 to entry: For CBCT, usually only c) is applicable where $N \times T$ is the scan length along a line perpendicular to the TOMOGRAPHIC PLANE with the NOMINAL collimation.

Note 5 to entry: Typically the y-axis is the axis of rotation. The y axis corresponds to the z axis in the DICOM coordinate system.

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.

Note 6 to entry: The note to entry concerning the origin of the abbreviation DLP APPLIES TO THE FRENCH TEXT ONLY.

[SOURCE: IEC 60601-2-44:2009/AMD1:2012, 201.3.214, modified – Notes 4 and 5 to entry have been added.]

Add definition 201.3.207 with:

201.3.207 EQUIPMENT REFERENCE POINT

ERP

point in space used for referencing dimensions and positions of equipment and performing dosimetry measurements

Note 1 to entry: Typically the EQUIPMENT REFERENCE POINT is coincident with the ISOCENTRE. If the beam delivery equipment is not ISOCENTRIC, then the centre of the PATIENT alignment system may be used.

Note 2 to entry: This note applies to the French text only.

Replace the existing term and definition 201.3.210 with:

201.3.210

IMAGE-GUIDED RADIOTHERAPY

IGRT

radiotherapy process by which the location of a radiotherapy beam relative to the intended TARGET VOLUME within a patient's anatomy is determined by imaging of the TARGET VOLUME and surrounding anatomical structures at the time of TREATMENT, so as to enable any necessary positional corrections to the intended relative location of beam to TARGET VOLUME

Note 1 to entry: The note to entry concerning the origin of the abbreviation IGRT APPLIES TO THE FRENCH TEXT ONLY.

[SOURCE: IEC 60976:2007, 3.8]

Add definition 201.3.216:

201.3.216

NOMINAL REFERENCE DISTANCE

SPECIFIED distance measured along the REFERENCE AXIS from the TARGET surface of the exiting beam to a SPECIFIED plane containing the EQUIPMENT REFERENCE POINT

Replace the existing term and definition 201.3.219 with:

201.3.219

OFFLINE IGRT

IGRT for the purpose of PATIENT setup and/or TREATMENT PLAN adjustment to be applied in subsequent TREATMENT delivery

Replace the existing term and definition 201.3.220 with:

204 **201.3.220**
205 ONLINE IGRT

206 IGRT for the purpose of PATIENT setup or TREATMENT PLAN adjustment immediately prior to or during the
207 therapeutic IRRADIATION session requiring operator initiated adjustments.

208 Note 1 to entry: The PATIENT stays on the PATIENT positioning device and is immobile during and in-between imaging and TREATMENT.

209 *Replace the existing term and definition 201.3.222 with:*

210 **201.3.222**
211 PROTOCOL ELEMENT

212 set of the particular CBCT X-IGRT CONDITIONS OF OPERATION necessary to perform a scan

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

215 Note 2 to entry: To maintain consistency with their respective user interfaces and documentation, various X-IGRT EQUIPMENT
216 might use terminology different from "PROTOCOL ELEMENT", e.g., "scan", "scan group", "scan series", "presets", "CBCT modes"
217 etc., which actually means "PROTOCOL ELEMENT"

218 Note 3 to entry: A PROTOCOL ELEMENT is typically associated with a IGRT task, anatomical region, and/or age or size group.

219 [SOURCE: IEC 60601-2-44:2009/AMD1:2012, 201.3.216, modified – The reference to "CT" in the original
220 definition has been replaced by a reference to "CBCT" and Notes 2 and 3 to entry have been changed.]

221 *Replace the existing term and definition 201.3.225 with:*

222 **201.3.225**
223 REAL-TIME IGRT

224 IGRT that images throughout therapeutic IRRADIATION and based upon that information, allows automatic
225 adjustments of TREATMENT PARAMETERS throughout the therapeutic IRRADIATION without OPERATOR intervention

226 *Replace the existing term and definition 201.3.226 with:*

227 **201.3.226**
228 REFERENCE IMAGE

229 an image related to the TREATMENT PLAN to which subsequent images will be compared to align the PATIENT or
230 adjust the TREATMENT PLAN

231 Note 1 to entry: REFERENCE IMAGES could be acquired during the first TREATMENT fraction from an ELECTRONIC PORTAL IMAGING DEVICE

232 Note 2 to entry: There may be more than one REFERENCE IMAGE

233 Note 3 to entry: Examples of REFERENCE IMAGES can be digital reconstructed radiographs generated by the planning system for
234 comparison to 2D images taken at time of TREATMENT or TREATMENT planning CT images used for CBCT registration.

235 *Replace the existing term and definition 201.3.232 with:*

236 **201.3.232**
237 VOLUME $CTDI_w$

238 $CTDI_{vol}$

239 Note 1 to entry: For axial, helical scanning, and scanning involving back-and-forth PATIENT SUPPORT movement between two positions
240 (shuttle mode) use the definition of VOLUME $CTDI_w$ provided in IEC 60601-2-44:2009+AMD1:2012+AMD2:2016.

241 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 y-direction between consecutive scans.

Note 1 to entry: 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 y-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 to entry: For axial scanning with a total table travel of 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 $\times \Delta d$.

Note 3 to entry: Typically the y-axis is the axis of rotation. The y axis corresponds to the z axis in the DICOM coordinate system.

b) for helical scanning

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

Note 4 to entry: CT PITCH FACTOR will be a function of time when Δd is variable during the exposure.

Note 5 to entry: 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 y-axis. For helical scanning, $CTDI_{vol}$ corresponds to the average dose that would accrue in the centre of a 100 mm scan length.

Note 6 to entry: For helical scanning, when the product 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.

Note 7 to entry: Typically the y-axis is the axis of rotation. The y axis corresponds to the z axis in the DICOM coordinate system.

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 8 to entry: c) includes situations where the PATIENT SUPPORT may be moved manually, for example, during an interventional procedure.

Note 9 to entry: 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 10 to entry: 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.

Note 11 to entry: For CBCT, usually only c) is applicable.

Note 12 to entry: Typically the y-axis is the axis of rotation. The y axis corresponds to the z axis in the DICOM coordinate system.

Note 13 to entry: For CBCT n is typically 1 and for partial rotations n is considered as 1.

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

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