IEC 62985

Edition 1.0 2019-09

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Methods for calculating size specific dose estimates (SSDE) for computed tomography

Méthodes de calcul de l'estimateur de dose morphologique (SSDE) en tomodensitométrie

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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METHODS FOR CALCULATING SIZE SPECIFIC DOSE ESTIMATES (SSDE) FOR COMPUTED TOMOGRAPHY

FOREWORD

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International Standard IEC 62985 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This bilingual version (2020-03) corresponds to the monolingual English version, published in 2019-09.

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

FDIS	Report on voting
62B/1133/FDIS	62B/1144/RVD

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

The French version of this standard has not been voted upon.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this document, the following print types are used:

– requirements and definitions: roman 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, IN CLAUSE 3 OF IEC 60601-1:2005 AND IEC 60601-1:2005/AMD1:2012, OF THE COLLATERAL STANDARDS, OF IEC TR 60788:2004 OR AS NOTED: SMALL CAPITALS.

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

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- withdrawn,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

NOTE The attention of the user of this document is drawn to the fact that equipment MANUFACTURERS and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

INTRODUCTION

The SIZE SPECIFIC DOSE ESTIMATE (SSDE) is an estimate of the average ABSORBED DOSE to the scan volume that takes into account the ATTENUATION of the anatomy being scanned (using the WATER EQUIVALENT DIAMETER D_W) and the RADIATION OUTPUT of the CT SCANNER (using $CTDI_{VOL}$).

SSDE is intended to provide a dose estimate for PATIENTS of all sizes. SSDE, which is given in units of mGy, is especially important for small paediatric PATIENTS since the corresponding applied level of RADIATION ($CTDI_{VOL}$, also given in units of mGy) does not adequately indicate the absorbed RADIATION DOSE.

SSDE is calculated using a SSDE CONVERSION FACTOR AT LONGITUDINAL POSITION Z (f) and the $CTDI_{VOL}$ AT LONGITUDINAL POSITION Z, $CTDI_{VOL}(z)$, where f is a function of the WATER EQUIVALENT DIAMETER AT LONGITUDINAL POSITION Z, $D_W(z)$, and the size of the CTDI PHANTOM used to report $CTDI_{VOL}$. f is given in normative Annex A.

This document provides a methodology (in Clause 4) for a MANUFACTURER to validate their method for calculating $D_W(z)$, which is used for the determination of f and the calculation of SSDE. This method calculates a reference WATER EQUIVALENT DIAMETER AT LONGITUDINAL POSITION Z, $D_{W,REF}(z)$, and compares it against a known PHANTOM dimension and the implemented values of WATER EQUIVALENT DIAMETER AT LONGITUDINAL POSITION Z, $D_{W,IMP}(z)$. PHANTOM types and tolerances are also specified.

NOTE 1 The definition of SSDE used in this document differs from that of AAPM Report No. 204 [1][1] in that AAPM Report No. 204 estimates the average dose at the centre of the scan volume, whereas in this document, SSDE estimates the average dose across the whole scan volume.

NOTE 2 $CTDI_{VOL}$ is a dose index that allows quantitation of the RADIATION OUTPUT of CT SCANNERS in terms of one of two PMMA test objects. These test objects are 16 cm and 32 cm in diameter. SSDE is calculated by conversion of one of these PHANTOM-based dose indices to an estimate of the RADIATION dose absorbed by a PATIENT of a specific size. The magnitude of the difference between SSDE and $CTDI_{VOL}$ values increases as the difference between the PATIENT size and the size of the CTDI PHANTOM used to measure the $CTDI_{VOL}$ increases. For infants, the calculated SSDE value may be 3 times as much as the corresponding $CTDI_{VOL}$ dose index value. Conversely, the $CTDI_{VOL}$ value for large PATIENTS overestimates SSDE, which is representative of the PATIENT's actual absorbed RADIATION DOSE. For extra-large adult PATIENTS, the $CTDI_{VOL}$ dose index can overestimate the SSDE by as much as 40 % [1].

Potential uses of SSDE include the following:

1) evaluating PATIENT ABSORBED DOSE for quality assurance programs;
2) establishing diagnostic reference levels across PATIENT sizes;
3) displaying to the OPERATOR an estimate of PATIENT ABSORBED DOSE prior to initiation of the CT scan;
4) providing an estimate of ABSORBED DOSE for the DICOM RDSR;
5) developing DOSE NOTIFICATION VALUE and DOSE ALERT VALUES that better take into account PATIENT size;
6) providing an estimate of PATIENT ABSORBED DOSE for dose registries.

1 Numbers in square brackets refer to the Bibliography.

METHODS FOR CALCULATING SIZE SPECIFIC DOSE ESTIMATES (SSDE) FOR COMPUTED TOMOGRAPHY

1 Scope

This document applies to

– CT SCANNERS that are able to display and report $CTDI_{VOL}$ in accordance with IEC 60601-2-44, and

– RADIATION dose index monitoring software (RDIMS)

for the purpose of calculating, displaying and recording the SIZE SPECIFIC DOSE ESTIMATE (SSDE) and its associated components.

Specifically, this document provides standardized methods and requirements for calculating, displaying, or recording of SSDE, SSDE(z), WATER EQUIVALENT DIAMETER (D_W), and D_W(z), where z represents a specific longitudinal position of the scanned object.

This document provides a method of determining a reference WATER EQUIVALENT DIAMETER, $D_{W,REF}$(z), using CT scans of two cylindrical water PHANTOMS and one or more anthropomorphic PHANTOM(S), which conform to the specifications defined in this document. The method of calculating the WATER EQUIVALENT DIAMETER that is implemented by the MANUFACTURER, $D_{W,IMP}$(z), is tested and validated against $D_{W,REF}$(z) using the TEST OBJECTS and methods defined within this document. This document also describes the methods for calculating SSDE and D_W, which represent the average values of SSDE(z) and D_W(z) over the RECONSTRUCTION LENGTH.

NOTE This standardization is important to ensure that comparisons between reported SSDEs are valid.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC TR 60788:2004, *Medical electrical equipment – Glossary of defined terms*

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

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

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

3 Terms and definitions

For the purposes of this document, the terms and definitions of IEC TR 60788, IEC 60601-1, IEC 60601-1-3, IEC 60601-2-44, and the following apply.

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

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
CTDI$_{VOL}$ AT LONGITUDINAL POSITION Z

CTDI$_{VOL}$(z)

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

3.2
RECONSTRUCTION LENGTH

distance between the centre of the first reconstructed image and the centre of the last reconstructed image, where the centres of the first and last reconstructed images are spaced as far apart as possible given the CT CONDITIONS OF OPERATION for the PROTOCOL ELEMENT and the width of the reconstructed images, being essentially the maximum range of reconstructed images over the scan range for a given reconstruction section thickness

3.3
WATER EQUIVALENT DIAMETER AT LONGITUDINAL POSITION Z

D_W(z)

diameter, in cm, of a cylinder of water having the same averaged ABSORBED DOSE as the material contained in an axial plane at longitudinal position z of the object scanned, calculable for a material of any composition, and quantifying the ATTENUATION of any material in terms of the ATTENUATION of water

Note 1 to entry: The average ABSORBED DOSE correlates with the average X-ray ATTENUATION. See [2].

Note 2 to entry: If it is not feasible for the RADIATION dose index monitoring software (RDIMS) devices to access the ATTENUATION-based D_W(z) from the CT SCANNER or to calculate D_W(z) from the available reconstructed images, then estimates of D_W(z) can be made from the scanned projection radiograph using alternate methods [2] [3]. However, validation of the $D_{W,IMP}$(z) implemented by the RDIMS device shall be performed according to Clause 4.

3.4
WATER EQUIVALENT DIAMETER

D_W

arithmetic average of D_W(z) values at equally spaced z position intervals of ≤ 5 mm, calculated over the RECONSTRUCTION LENGTH, for RDIMS systems or PROTOCOL ELEMENTS in the CT SCANNER where it is not possible to achieve ≤ 5 mm z position intervals, the smallest available image interval

3.5
REFERENCE WATER EQUIVALENT DIAMETER AT LONGITUDINAL POSITION Z

$D_{W,REF}$(z)

D_w(z) calculated using the following equation and being calculated for each of the reconstructed images for all pixels in the image corresponding to the PHANTOM being scanned by means of the following equation:

$$D_{W,REF}(z) = 2\sqrt{\sum_{x,y}\left(\frac{CT(x,y,z)}{1\,000}+1\right)\times\frac{A_{pixel}}{\pi}}$$

where

$CT(x,y,z)$ is the CT number of the pixel at cross-sectional position x,y and longitudinal position z;

A_{pixel} is the area of the image pixel

Note 1 to entry: The $D_{W,REF}(z)$ is used to validate the suitability of the method implemented by the MANUFACTURER to calculate $D_W(z)$.

3.6
IMPLEMENTED WATER EQUIVALENT DIAMETER AT LONGITUDINAL POSITION Z
$D_{W,IMP}(z)$
$D_W(z)$ calculated with the method implemented by MANUFACTURER for the calculation of SSDE

3.7
SSDE CONVERSION FACTOR AT LONGITUDINAL POSITION Z
$f(D_W(z))$
unitless, empirically-derived value relating the RADIATION OUTPUT delivered by the scanner (as quantified using $CTDI_{VOL}$) to the ABSORBED DOSE to soft tissue for a specific size PATIENT or PHANTOM, determined for a specific-size CTDI PHANTOM, a specific anatomic region (i.e., head or body), and a specific z-position within the scanned PATIENT or object, the calculation of which is performed using the equations provided in Annex A

3.8
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:

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

3.9
SIZE SPECIFIC DOSE ESTIMATE
SSDE
arithmetic average of SSDE(z), calculated over the RECONSTRUCTION LENGTH at the same z-positions as the corresponding $D_W(z)$ values used to calculate D_W:

$$SSDE = \frac{1}{n} \times \sum_{i=1}^{n} SSDE(z_i)$$

where

n is the number of z positions (z_i, i = 1, 2, …, n) (within the RECONSTRUCTION LENGTH

4 Verification of method used to calculate $D_W(z)$

4.1 General

The purpose of Clause 4 is to provide a method to verify a MANUFACTURER's IMPLEMENTED WATER EQUIVALENT DIAMETER AT LONGITUDINAL POSITION Z, $D_{W,IMP}(z)$, against the REFERENCE WATER EQUIVALENT DIAMETER AT LONGITUDINAL POSITION Z $D_{W,REF}(z)$. This verification compares a set of $D_{W,IMP}(z)$ values calculated for water PHANTOMs and an anthropomorphic PHANTOM to the corresponding set of $D_{W,REF}(z)$ values calculated for the same PHANTOMs.

4.2 Characteristics of the water PHANTOMS

Each PHANTOM'S structural material thickness shall be the minimum practicable and shall have a length of at least 10 cm:

- Small water PHANTOM

  The small water PHANTOM shall be cylindrical and have an inner water diameter (d) of 14 cm ≤ d ≤ 20 cm.
- Large water PHANTOM

  The larger water PHANTOM shall be cylindrical and have an inner water diameter (d) of 28 cm ≤ d ≤ 34 cm.

These PHANTOM specifications shall apply unless otherwise stated in the ACCOMPANYING DOCUMENTS, in order to accommodate minor variations from these specifications.

4.3 Characteristics of the anthropomorphic PHANTOM

The anthropomorphic PHANTOM shall be a representative of an average adult human from the top of the head to the bottom of the pelvis. It shall have a comprehensive set of simulated internal organs and bones designed to yield the CT NUMBERS of their anatomical counterparts. The PHANTOM shall include a minimum of simulated soft tissue, lung, and bone.

More than one anthropomorphic PHANTOM may be utilized if, as a set, they are representative of average adult head, chest, abdomen and pelvis regions. In addition, verification with a paediatric PHANTOM(S) may also be performed.

A description of the anthropomorphic PHANTOMS(S) used shall be provided in the ACCOMPANYING DOCUMENTS.

NOTE If an end user is evaluating the accuracy of $D_{W,IMP}(z)$ values, differences between $D_{W,IMP}(z)$ and $D_{W,REF}(z)$ that are larger than the allowed tolerances (4.10) can occur if different PHANTOMS are used compared to those used by the MANUFACTURER.

4.4 Generation of $D_{W,REF}(z)$ for the water PHANTOMS

Scans of each water PHANTOM shall be used to obtain the axial images for the calculation of $D_{W,REF}(z)$, generated using 120 kV (or the closest available kV setting). The PHANTOMS shall be placed on the PATIENT SUPPORT (including pad) and positioned in a clinically relevant-manner without additional material in the scan field.

The CT CONDITIONS OF OPERATION and reconstruction parameters shall be suitable for

– a small water PHANTOM, and
– a large water PHANTOM.

Cardiac acquisitions, acquisitions without table movement, and shuttle mode acquisitions shall not be used. The use of AUTOMATIC EXPOSURE CONTROL shall correspond to its use in the clinical protocol selected. The reconstructed field of view shall be large enough to fully encompass the PHANTOMS.

The scan(s) shall be at least 5 cm in length and centred cross-sectionally and longitudinally on the PHANTOM. Contiguous images of approximately 5 mm nominal reconstruction thickness shall be reconstructed.

The CT CONDITIONS OF OPERATION, scan positioning, and reconstruction parameters for the scanning of each PHANTOM shall be included in the ACCOMPANYING DOCUMENTS.

NOTE Image reconstruction kernels, such as those for edge enhancement, with a non-linear relationship between the CT NUMBER and the linear ATTENUATION coefficients can adversely affect the determination of D_W.

4.5 Verification of $D_{W,REF}$ for the water PHANTOMS

$D_{W,REF}(z)$ shall be calculated at each longitudinal position z. The set of $D_{W,REF}(z)$ values shall be compared to the corresponding outer diameter of each water PHANTOM. The two values at each position shall agree to within 7 %, for each PHANTOM size.

4.6 Generation of $D_{W,IMP}$ for the water PHANTOMS

$D_{W,IMP}(z)$ shall be calculated at each of the z positions where $D_{W,\ REF}(z)$ values were obtained.

The CT CONDITIONS OF OPERATION, and reconstruction parameters for the scanning of each water PHANTOM shall be included in the ACCOMPANYING DOCUMENTS.

4.7 Verification of $D_{W,IMP}(z)$ against $D_{W,REF}(z)$ for the water PHANTOMS

The set of $D_{W,IMP}(z)$ values shall be compared to the corresponding set of $D_{W,REF}(z)$ values at each z position and evaluated for both water PHANTOMS.

The absolute value of the relative difference $\Delta_{REL}(z)$ shall be calculated at each z location for each PHANTOM according to the following equation:

$$\Delta_{REL}(z) = \left| \left(D_{W,IMP}(z) - D_{W,REF}(z)\right) / D_{W,REF}(z) \right|$$

The maximum of $\Delta_{REL}(z)$ calculated for each water PHANTOM size shall be less than 0,12.

4.8 Generation of $D_{W,REF}(z)$ for the anthropomorphic PHANTOM

Scans of the anthropomorphic PHANTOM(S) shall be used to obtain axial images for the calculation of $D_{W,REF}(z)$. The PHANTOMS shall be placed on the PATIENT SUPPORT (including pad) and positioned in a clinically relevant manner without additional material in the scan field. The head region of the PHANTOM shall be positioned either in the head holder or on top of the PATIENT SUPPORT. If the head region of the PHANTOM is an individual PHANTOM, it should be placed in the head holder.

The CT CONDITIONS OF OPERATION and reconstruction parameters shall correspond to the clinical protocol typically used for the relevant anatomical region; cardiac acquisitions, acquisitions without table movement, and shuttle mode acquisitions shall not be used. The use of AUTOMATIC EXPOSURE CONTROL shall correspond to its use in the clinical protocol selected. The reconstructed field of view shall be large enough to fully encompass the PHANTOM region scanned.

One continuous scan may be used to cover the entire range in the torso and its data divided accordingly.

Each of the following anatomical regions in Table 1 shall have at least 5 cm of scan coverage. The scan(s) field of view shall be centred cross-sectionally and the scan range centred longitudinally in each anatomic region. Contiguous images of approximately 5 mm nominal reconstruction thickness shall be reconstructed.

Table 1 – Anthropomorphic PHANTOM regions to be scanned

Anatomical region	Anatomy at centre of scan range
Head	Centre of brain region
Lung	Lung field superior to the heart
Heart and Lung	Centre of the heart
Abdomen	Umbilicus
Pelvis	Centre between iliac crest and the acetabulum