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INTERNATIONAL STANDARD

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

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

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FOREWORD

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

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.

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- withdrawn,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.

The contents of the corrigendum 1 (2022-06) have been included in this copy.

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 $\mathrm{CTDI}_{\mathrm{VOL}}$).

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 ($\mathrm{CTDI}_{\mathrm{VOL}}$, 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 $\mathrm{CTDI}_{\mathrm{VOL}}$ AT LONGITUDINAL POSITION Z, $\mathrm{CTDI}_{\mathrm{VOL}}(z)$, where f is a function of the WATER EQUIVALENT DIAMETER AT LONGITUDINAL POSITION Z, $D_{\mathrm{W}}(z)$, and the size of the CTDI PHANTOM used to report $\mathrm{CTDI}_{\mathrm{VOL}}$. f is given in normative Annex A.

This document provides a methodology (in Clause 4) for a MANUFACTURER to validate their method for calculating $D_{\mathrm{W}}(z)$, 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, $D_{\mathrm{W,REF}}(z)$, and compares it against a known PHANTOM dimension and the implemented values of WATER EQUIVALENT DIAMETER AT LONGITUDINAL POSITION Z, $D_{\mathrm{W,IMP}}(z)$. 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 $\mathrm{CTDI}_{\mathrm{VOL}}$ 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 $\mathrm{CTDI}_{\mathrm{VOL}}$ values increases as the difference between the PATIENT size and the size of the CTDI PHANTOM used to measure the $\mathrm{CTDI}_{\mathrm{VOL}}$ increases. For infants, the calculated SSDE value may be 3 times as much as the corresponding $\mathrm{CTDI}_{\mathrm{VOL}}$ dose index value. Conversely, the $\mathrm{CTDI}_{\mathrm{VOL}}$ value for large PATIENTS overestimates SSDE, which is representative of the PATIENT's actual absorbed RADIATION DOSE. For extra-large adult PATIENTS, the $\mathrm{CTDI}_{\mathrm{VOL}}$ 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 can 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