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STN	**Metódy na výpočet odhadu dávky vzhľadom na veľkosť pacienta (SSDE) pri výpočtovej tomografii**	**STN EN IEC 62985** 36 4767

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

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EUROPEAN STANDARD

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EUROPÄISCHE NORM

EN IEC 62985

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English Version

Methods for calculating size specific dose estimates (SSDE) on computed tomography (IEC 62985:2019)

Méthodes de calcul de l'estimateur de dose morphologique (SSDE) en tomodensitométrie (IEC 62985:2019)

Verfahren für die Berechnung größenspezifischer Dosisschätzungen (SSDE) für die Computertomographie (IEC 62985:2019)

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN IEC 62985:2019 E

European foreword

The text of document 62B/1133/FDIS, future edition 1 of IEC 62985, prepared by SC 62B "Diagnostic imaging equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 62985:2019.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2020-07-18
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2022-10-18

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Endorsement notice

The text of the International Standard IEC 62985:2019 was approved by CENELEC as a European Standard without any modification.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents 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.

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

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

Publication	Year	Title	EN/HD	Year
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	EN 60601-1	2006
+ A1	2012		+ A1	2013
-	-		+ A12	2014
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	EN 60601-1-3	2008
-	-		+ A11	2016
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	EN 60601-2-44	2009
-	-		+ A11	2011

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INTERNATIONAL STANDARD

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

IEC 62985:2019-09(en)

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INTERNATIONAL STANDARD

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

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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METHODS FOR CALCULATING SIZE SPECIFIC DOSE ESTIMATES (SSDE) 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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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.

A bilingual version of this publication may be issued at a later date.

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*