

INTERNATIONAL STANDARD

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





THIS PUBLICATION IS COPYRIGHT PROTECTED
Copyright © 2019 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester. If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

IEC Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

IEC publications search - webstore.iec.ch/advsearchform

The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee,...). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished

Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

IEC Customer Service Centre - webstore.iec.ch/csc

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

Electropedia - www.electropedia.org

The world's leading online dictionary on electrotechnology, containing more than 22 000 terminological entries in English and French, with equivalent terms in 16 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - webstore.iec.ch/glossary

67 000 electrotechnical terminology entries in English and French extracted from the Terms and Definitions clause of IEC publications issued since 2002. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

INTERNATIONAL STANDARD

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.50

ISBN 978-2-8322-7290-9

Warning! Make sure that you obtained this publication from an authorized distributor.

CONTENTS

FOREWORD.....	4
INTRODUCTION.....	6
1 Scope.....	7
2 Normative references	7
3 Terms and definitions	7
4 Verification of method used to calculate $D_W(z)$	9
4.1 General.....	9
4.2 Characteristics of the water PHANTOMS	9
4.3 Characteristics of the anthropomorphic PHANTOM	10
4.4 Generation of $D_{W,REF}(z)$ for the water PHANTOMS	10
4.5 Verification of $D_{W,REF}$ for the water PHANTOMS	10
4.6 Generation of $D_{W,IMP}$ for the water PHANTOMS	10
4.7 Verification of $D_{W,IMP}(z)$ against $D_{W,REF}(z)$ for the water PHANTOMS	11
4.8 Generation of $D_{W,REF}(z)$ for the anthropomorphic PHANTOM.....	11
4.9 Generation of $D_{W,IMP}(z)$ for the anthropomorphic PHANTOM.....	12
4.10 Verification of $D_{W,IMP}(z)$ against $D_{W,REF}(z)$ for the anthropomorphic PHANTOM	12
5 Requirements and limitations.....	12
5.1 Calculation of SSDE and D_W for CT SCANNERS and FDiMS	12
5.2 Pre-scan display of SSDE for CT SCANNERS.....	12
5.3 Post-scan updating of SSDE and D_W for CT SCANNERS.....	12
5.4 Pre and post-scan display of SSDE and D_W for CT SCANNERS	13
5.5 Post-scan recording of SSDE and D_W for CT SCANNERS.....	13
5.6 Limitations of calculation and display of SSDE and D_W	13
5.7 Requirements for identification of limitations in the ACCOMPANYING DOCUMENTS	13
5.8 Updating SSDE conversion factors, f	14
Annex A (normative) SSDE conversion factors.....	15
A.1 Clarification regarding the use of effective diameter versus D_W	15
A.2 Equation for determination of SSDE conversion factor	15
Annex B (normative) Language regarding the general limitations of the SSDE methodology for use in the ACCOMPANYING DOCUMENTS	17
Annex C (informative) Estimates of the magnitude of uncertainties from special clinical scenarios	18
C.1 General.....	18
C.2 Neck included in scanned anatomy	18
C.3 Range of scan projection radiograph exceeded.....	18
C.4 Single or bilateral extremities scanned.....	18
C.5 PATIENT not positioned at the centre of rotation along the source/detector direction.....	19
C.6 PATIENT anatomy outside the scan field of view	19
C.7 Foreign objects within the scanned projection radiograph or scan volume	19
Bibliography.....	20
Index of defined terms used in this document	21

Figure A.1 – Visualization of $f(D_W)$ versus D_W for the body and head parameters provided in Table A.1 16

Table 1 – Anthropomorphic PHANTOM regions to be scanned 11

Table A.1 – SSDE Conversion factor as a function of D_W 15

Currently in preview, click buy full version

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct interpretation of this publication.
- 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.

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*

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.