



BSI Standards Publication

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

National foreword

This British Standard is the UK implementation of EN IEC 62985:2019. It is identical to IEC 62985:2019, incorporating corrigendum June 2022.

The start and finish of text introduced or altered by corrigendum is indicated in the text by tags. Text altered by IEC corrigendum June 2022 is indicated in the text by AC1 AC1.

The UK participation in its preparation was entrusted to Technical Committee CH/62/2, Diagnostic imaging equipment.

A list of organizations represented on this committee can be obtained on request to its committee manager.

Contractual and legal considerations

This publication has been prepared in good faith, however no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by BSI in relation to the adequacy, accuracy, completeness or reasonableness of this publication. All and any such responsibility and liability is expressly disclaimed to the full extent permitted by the law.

This publication is provided as is, and is to be used at the recipient's own risk.

The recipient is advised to consider seeking professional guidance with respect to its use of this publication.

This publication is not intended to constitute a contract. Users are responsible for its correct application.

This publication has been prepared under a mandate given to the European Standards Organizations by the European Commission and the European Free Trade Association. It is intended to support requirements of the EU legislation detailed in the European Foreword. A European Annex, usually Annex ZA or ZZ, describes how this publication relates to that EU legislation.

For the Great Britain market (England, Scotland and Wales), if UK Government has designated this publication for conformity with UKCA marking (or similar) legislation, it may contain an additional National Annex. Where such a National Annex exists, it shows the correlation between this publication and the relevant UK legislation. If there is no National Annex of this kind, the relevant Annex ZA or ZZ in the body of the European text will indicate the relationship to UK regulation applicable in Great Britain. References to EU legislation may need to be read in accordance with the UK designation and the applicable UK law. Further information on designated standards can be found at www.bsigroup.com/standardsandregulation.

For the Northern Ireland market, UK law will continue to implement relevant EU law subject to periodic confirmation. Therefore Annex ZA/ZZ in the European text, and references to EU legislation, are still valid for this market.

UK Government is responsible for legislation. For information on legislation and policies relating to that legislation, consult the relevant pages of www.gov.uk.

© The British Standards Institution 2022
Published by BSI Standards Limited 2022

ISBN 978 0 539 23208 0

ICS 11.040.50

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 November 2019.

Amendments/corrigenda issued since publication

Date	Text affected
30 September 2022	Implementation of IEC corrigendum June 2022

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN IEC 62985

November 2019

ICS 11.040.50

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)

This European Standard was approved by CENELEC on 2019-10-18. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.



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

© 2019 CENELEC All rights of exploitation in any form and by any means reserved worldwide for CENELEC Members.

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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

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.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC/TR 60788	2004	Medical electrical equipment - Glossary of - defined terms		-
IEC 60601-1	2005	Medical electrical equipment - Part 1: EN 60601-1 General requirements for basic safety and essential performance		2006
+ A1	2012		+ A1	2013
-	-		+ A12	2014
IEC 60601-1-3	2008	Medical electrical equipment - Part 1-3: EN 60601-1-3 General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment		2008
-	-		+ A11	2016
IEC 60601-2-44	2009	Medical electrical equipment - Part 2-44: EN 60601-2-44 Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography		2009
-	-		+ A11	2011

CONTENTS

CONTENTS	2
FOREWORD	4
INTRODUCTION	6
1 Scope	7
2 Normative references	7
3 Terms and definitions	8
4 Verification of method used to calculate $D_W(z)$	9
4.1 General	9
4.2 Characteristics of the water PHANTOMS	10
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	11
4.6 Generation of $D_{W,IMP}$ for the water PHANTOMS	11
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 RDIMS	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	14
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