IEC 60601-2-45

Edition 3.0 2015-06

INTERNATIONAL STANDARD

AMENDMENT 1

Medical electrical equipment –
Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices

IEC 60601-2-45:2011-02/AMD1:2015-06(en)

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Medical electrical equipment – Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices

INTERNATIONAL ELECTROTECHNICAL COMMISSION

ICS 11.040.50

ISBN 978-2-8322-2727-5

FOREWORD

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

The text of this amendment is based on the following documents:

CDV	Report on voting
62B/917/CDV	62B/954/RVC

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

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

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- withdrawn,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

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

NOTE The attention of National Committees 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.

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INTRODUCTION TO THE AMENDMENT

This first amendment to the third edition of this particular standard has been prepared to provide a complete set of safety requirements for MAMMOGRAPHIC X-RAY EQUIPMENT, based on IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 60601-1-2:2014, and IEC60601-1-3:2008 and IEC60601-1-3:2008/AMD1:2013. This particular standard addresses the system level of MAMMOGRAPHIC X-RAY EQUIPMENT and introduces equipment for MAMMOGRAPHIC TOMOSYNTHESIS.

FOREWORD

Replace, in the second paragraph, the reference to "IEC 60601-1-3 (2010)" *by* "IEC 60601-1-3 (2008)".

201.1 Scope, object and related standards

*Replace, in footnote 1, the reference to "*IEC 60601-1:2005" *by "*IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012".

201.1.1 Scope

*Add, in the first paragraph, after the term "*MAMMOGRAPHIC X-RAY EQUIPMENT*" the phrase "*including equipment for MAMMOGRAPHIC TOMOSYNTHESIS,*".*

*Replace, in the first dashed item of the third paragraph, the words "*modes of operation*" by "*other than MAMMOGRAPHIC TOMOSYNTHESIS*"*

Add, after this first dashed item, the following new dashed item:

– CT SCANNERS covered by IEC 60601-2-44;

201.1.3 Collateral standards

*Replace, in the first sentence of the second paragraph, the reference to "*IEC 60601-1-2:2007" *by* "IEC 60601-1-2:2014

*Replace the reference to "*IEC 60601-1-3:2008*" by "*IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013*"*

Replace the second sentence of the second paragraph, including its footnote, with the following new sentence and footnote:

IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 do not apply[1].

1 IEC 60601-1-9:2007, *Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design.* IEC 60601-1-10:2007, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers.* IEC 60601-1-11:2010, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.* IEC 60601-1-12:2004, *Medical Electrical Equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment.*

201.2 Normative references

Replace the existing references to IEC 60601-1-2:2007 and IEC 60601-1-3:2008 by the following:

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

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 60601-1-3:2008/AMD1:2013

Delete the following normative reference:

IEC 61223-3-2:2007, *Evaluation and routine testing in medical imaging departments – Part 3-2: Acceptance tests – Imaging performance of mammographic X-ray equipment*

201.3 Terms and definitions

*Replace, in the first paragraph, the reference "*IEC 60601-1:2005, IEC 60601-1-3:2008*" by "*IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013*".*

201.3.205
DIRECT FOCAL DISTANCE

Replace the existing text of the definition by the following:

<X-ray mammography> shortest distance from the FOCAL SPOT to the axis of symmetry of the EFFECTIVE IMAGE RECEPTION AREA perpendicular to its chest wall edge for a specified position of the source

201.3.206
MAMMOGRAPHIC STEREOTACTIC DEVICE

*Add an asterisk * in front of the term to read*

***MAMMOGRAPHIC STEREOTACTIC DEVICE**

Replace the existing text of the definition by the following:

device for mechanically guided placement of a needle or position marker based on radiographic images of an immobilized breast acquired at different known angles

Renumber the existing note as Note 1 and add the following new note:

NOTE 2 The purposes of such devices may be fine-needle aspiration, core biopsy, or pre-surgical localization.

Add the following new definitions:

201.3.210
MAMMOGRAPHIC TOMOSYNTHESIS
technique using MAMMOGRAPHIC X-RAY EQUIPMENT to produce multiple tomographic images reconstructed from multiple PROJECTIONS acquired over a total angular range of less than 180°

201.3.211
CONTRAST TO NOISE RATIO
CNR
physical quantity describing the ability to distinguish between various contrast objects of a digital image and the inherent noise within the image, defined as the difference of mean pixel values of the contrast objects and image background, and divided by the standard deviation of the image background pixel value

[SOURCE: IEC 61223-3-2:2007, definition 3.8]

201.4 General requirements

201.4.3 ESSENTIAL PERFORMANCE

201.4.3.101 *Additional ESSENTIAL PERFORMANCE requirements

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements

*Replace the subclause reference for "*Accuracy of LOADING FACTORS*" in the first row, by "*203.6.4.3.102"

201.4.101 Data recording

Add, after the final dashed item in the first paragraph, the following new dashed item and note:

– identification and version of image processing applied to ORIGINAL DATA and, in MAMMOGRAPHIC TOMOSYNTHESIS, identification and version of reconstruction processing applied.

NOTE An example for processed images are DICOM images for presentation.

201.7 ME EQUIPMENT identification, marking and documents

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.2 Instructions for use

Add the following new subclause:

201.7.9.2.17 *ME EQUIPMENT emitting radiation

This subclause of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 does not apply.

201.7.9.3.101 Specification of X-RAY SOURCE ASSEMBLY and its position

*Add, in item e), after the term ""*DIRECT FOCAL DISTANCE*", the following new text:*

and, in MAMMOGRAPHIC TOMOSYNTHESIS, for specified positions of the source

*Add, in item f), after the term "*DIRECT FOCAL DISTANCE*" the following new text:*

and, in MAMMOGRAPHIC TOMOSYNTHESIS, for specified positions of the source

*Add, in item g) after the term "*IMAGE RECEPTION AREA*" the following new text:*

and, in MAMMOGRAPHIC TOMOSYNTHESIS, for specified positions of the source

Add the following new items:

h) in MAMMOGRAPHIC TOMOSYNTHESIS, the number of PROJECTIONS, and the geometric configuration for the acquisition of the PROJECTIONS;

i) in MAMMOGRAPHIC TOMOSYNTHESIS, description of the distribution of x-ray LOADING FACTORS for the acquisition of the PROJECTIONS.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

201.9.2 HAZARDS associated with moving parts

Replace the existing title with the following:

201.9.2 MECHANICAL HAZARDS associated with moving parts

201.9.2.1 General

*Delete, in the second paragraph, the phrase "*detect PATIENT contact and*".*

201.9.2.3 Other HAZARDS associated with moving parts

Replace the existing title with the following:

201.9.2.3 Other MECHANICAL HAZARDS associated with moving parts

201.9.2.101 * MAMMOGRAPHIC STEREOTACTIC DEVICE

Replace the existing title by the following:

201.9.2.101 * Three dimensional localization and interventional mammographic guidance

201.9.2.101.1 Positioning of X-RAY SOURCE ASSEMBLY for stereotactic imaging

Add after the first paragraph, before the compliance statement, the following new paragraph:

This subclause does not apply for MAMMOGRAPHIC TOMOSYNTHESIS.

201.9.2.101.3 Biopsy needle positioning accuracy of MAMMOGRAPHIC STEREOTACTIC DEVICES

Replace the existing title by the following:

201.9.2.101.3 Biopsy needle positioning accuracy

*Delete, in the first paragraph, the word "*stereotactic*".*

a) Test equipment

Delete, in the first sentence of the first paragraph and in the second and third sentences of the second paragraph, the word "stereotactic".

Delete, at the end of the second paragraph, the phrase "with the MAMMOGRAPHIC STEREOTACTIC DEVICE".

b) Test procedure

Replace, in the third sentence of the first paragraph the phrase "of the MAMMOGRAPHIC STEREOTACTIC DEVICE" by the word "SPECIFIED". Delete the two other instances of the word "stereotactic" in this sentence.

Delete in the second paragraph the phrase "with which the MAMMOGRAPHIC STEREOTACTIC DEVICE is".

Replace the second and third sentences of the third paragraph by the following new text: "Determine x, y, z positions of the test needle tips as specified by the MANUFACTURER for clinical use."

Delete, in the fourth sentence of the third paragraph, the phrase "by the MAMMOGRAPHIC STEREOTACTIC DEVICE".

201.10 Protection against unwanted and excessive radiation HAZARDS

201.10.1.2 ME EQUIPMENT intended to produce diagnostic or therapeutic X-radiation

*Replace, in the first paragraph, the reference to "*IEC 60601-1-3:2008*" by "*IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013*".*

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Replace the existing text of this clause by the following:

Clause 12 of the general standard applies.

201.13 Hazardous situations and fault conditions

Replace the existing title of this clause by the following:

201.13 Hazardous situations and fault conditions for ME EQUIPMENT

202 Electromagnetic compatibility – Requirements and tests

Replace, in the first line, the reference to "IEC 60601-1-2:2007" *by* "IEC 60601-1-2:2014".

203 Radiation protection in diagnostic X-ray equipment

Replace, in the first line, the reference to "IEC 60601-1-3:2008" *by* "IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013".

203.4 General requirements

203.4.1 Statement of compliance

Replace the reference to "IEC 60601-2-45:2011" *by* "IEC 60601-2-45:2015".

203.4.101.2 * LOADING TIME

Replace in Note 1 the reference to "IEC 60601-1-3:2008" *by* "IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013".

203.6.3 RADIATION dose and RADIATION QUALITY

203.6.3.1 Adjustment of RADIATION dose and RADIATION QUALITY

203.6.3.1.1 General requirements for the adjustment of RADIATION dose and RADIATION QUALITY

Replace, in the second paragraph, the reference to "IEC 60601-1-3:2008" *by* "IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013".

203.6.3.1.2 Linearity of AIR KERMA over limited intervals of LOADING FACTORS

Add, at the end of the first dashed item, the following sentence:

For MAMMOGRAPHIC TOMOSYNTHESIS this lower value shall be the lowest CURRENT TIME PRODUCT setting available in a LOADING of a TOMOSYNTHESIS projection image acquisition series.

203.6.3.2 Reproducibility of the X-RADIATION output

Add, after the fourth dashed item, the following new dashed item:

– *for MAMMOGRAPHIC TOMOSYNTHESIS a combination of X-RAY TUBE VOLTAGE specified by the MANUFACTURER and clinically justified, with the lowest CURRENT TIME PRODUCT setting available in a complete LOADING of a TOMOSYNTHESIS acquisition series*

203.6.4.2.101 LOADING STATE in mammography

Add, after the third paragraph, before the compliance statement, the following new paragraph:

For MAMMOGRAPHIC TOMOSYNTHESIS operation the LOADING STATE shall encompass all acquired projections.

203.6.4.3 Indication of LOADING FACTORS and MODES of OPERATION

Add, at the beginning of the subclause, after the instruction "Addition:", the following new text:

For MAMMOGRAPHIC TOMOSYNTHESIS acquisition, which involves multiple IRRADIATIONS, LOADING FACTORS shall be provided after completion of the acquisition for each of these IRRADIATIONS.

NOTE An example of implementation of this requirement is through usage of DICOM objects.

203.6.4.3.102 Accuracy of LOADING FACTORS

203.6.4.3.102.1 General

Replace, in the compliance statement, the reference to "203.6.4.3.104" *by* "203.6.4.3.103".

203.6.4.3.102.3 Accuracy of X-RAY TUBE CURRENT

Replace the existing text of this subclause by the following:

For operation of MAMMOGRAPHIC X-RAY EQUIPMENT where the X-RAY TUBE CURRENT can be independently selected, its value shall be accurate within ± 20 % of the INDICATED VALUE within the selectable range.

203.6.4.3.102.4 Accuracy of LOADING TIME

Replace the existing first paragraph by the following;

For operation of MAMMOGRAPHIC X-RAY EQUIPMENT where the LOADING TIME can be independently selected, the error on the value of the LOADING TIME shall not be greater than ± (10 % + 1 ms) for combinations of LOADING FACTORS representing the selectable range.

203.6.4.3.102.5 Accuracy of CURRENT TIME PRODUCT

Add at the end of this subclause the following new paragraph:

For MAMMOGRAPHIC TOMOSYNTHESIS operation the CURRENT TIME PRODUCT shall be the sum of the respective CURRENT TIME PRODUCTS of the individual projections.

203.6.4.3.103 Test conditions for the accuracy of loading factors

203.6.4.3.103.1 Accuracy and reproducibility of X-RAY TUBE VOLTAGE

Replace the existing first paragraph by the following:

Measurements shall be made at 30 kV or at the X-RAY TUBE VOLTAGE specified by the MANUFACTURER if clinically justified. Measurements shall also be made at the lowest and highest selectable values of the X-RAY TUBE VOLTAGE and at the lowest, medium and highest selectable values of CURRENT TIME PRODUCT.

Replace, at the beginning of the third paragraph, the phrase "Calculate the average" by "Check each measured".

203.6.4.5 Dosimetric indications

Add, at the end of this subclause, the following new paragraph:

For MAMMOGRAPHIC TOMOSYNTHESIS the AVERAGE GLANDULAR DOSE to be indicated shall be the cumulative AVERAGE GLANDULAR DOSE over the entire tomographic acquisition.

203.6.5.3 AEC requirements for MAMMOGRAPHIC X-RAY EQUIPMENT provided with an integrated digital X-RAY IMAGE RECEPTOR

203.6.5.3.1 General requirements

Add, after the existing first paragraph, the following new paragraph:

For MAMMOGRAPHIC TOMOSYNTHESIS equipment this requirement may be assessed in projection images.

*Replace, in the second sentence of the existing second paragraph, the phrase "*magnification and (if applicable)*" by "*magnification, (if applicable) tomosynthesis and*".*

Replace, in the existing third paragraph the phrase "(e.g. magnification and stereotactic modes)*" by "*(e.g. magnification, tomosynthesis and stereotactic modes)".

Add the following new text at the end of the note:

and is included in 203.6.5.3.3,

203.6.5.3.2 AEC reproducibility

a) Test method

Add, after the dashed list of item a), the following new paragraph:

For MAMMOGRAPHIC TOMOSYNTHESIS equipment the PIXEL values in a region of interest shall be assessed in projection images of the *PHANTOM*.

Add the following new subclause:

203.6.5.3.3 AEC thickness response

The response of the AEC to different breast thicknesses shall be evaluated by jointly assessing image quality, as measured by the CONTRAST TO NOISE RATIO, and the dose to the PATIENT, as characterized by the AVERAGE GLANDULAR DOSE, and comparing them to the specifications provided.

a) Test method

Measure the CONTRAST TO NOISE RATIO of radiograms and AVERAGE GLANDULAR DOSE of PHANTOMS made of breast tissue equivalent material, produced with the AUTOMATIC EXPOSURE CONTROL in operation. Determine these quantities, in all operational modes, for PHANTOM thicknesses from 20 mm to 70 mm in steps of 10 mm.

b) Compliance criteria

The MEASURED VALUE of the AVERAGE GLANDULAR DOSE shall not exceed the MANUFACTURER's specification, and the CONTRAST TO NOISE RATIO shall not be lower than the MANUFACTURER's specification.

For MAMMOGRAPHIC TOMOSYNTHESIS the AVERAGE GLANDULAR DOSE shall be the cumulative AVERAGE GLANDULAR DOSE over the entire tomographic acquisition.

For MAMMOGRAPHIC TOMOSYNTHESIS the CONTRAST TO NOISE RATIO shall be assessed in each of the projection images.

203.6.7.104.1 Minimum AIR KERMA RATE

*Replace, in the penultimate paragraph before the compliance statement, the reference to "*IEC 60601-1-3:2008*" by "*IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013*".*

203.7.3 Indication of FILTER properties

*Replace the reference to "*IEC 60601-1-3:2008*" by "*IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013*".*

203.8 Limitation and indication of the extent of the X-RAY BEAM and relationship between X-RAY FIELD and IMAGE RECEPTION AREA

203.8.5 Relationship between X-RAY FIELD and IMAGE RECEPTION AREA

203.8.5.3 *Correspondence between X-RAY FIELD and EFFECTIVE IMAGE RECEPTION AREA

Add, at the end of item c), the following new sentence:

For MAMMOGRAPHIC TOMOSYNTHESIS this requirement is excluded.

203.10 ATTENUATION of the X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR

203.10.1 General

Add the following new phrase at the end of the existing first paragraph:

when measured perpendicular to these layers.

203.11 Protection against RESIDUAL RADIATION

203.11.101 Additional requirements for protection against RESIDUAL RADIATION

Replace the second and third sentences of the second paragraph of the compliance statement by the following text:

Fit shielding in the plane of the PATIENT SUPPORT as necessary to exclude from the measurement any X-RADIATION not transmitted through the PRIMARY PROTECTIVE SHIELDING. For

MAMMOGRAPHIC TOMOSYNTHESIS mode of operation, the test shall be performed using a tomosynthesis sweep. It shall be tested for all available tomosynthesis configurations.

Annex AA – Particular guidance and rationale

AA.1 Rationale for particular clauses and subclauses

Add the following new rationales:

Subclause 201.3.206 – MAMMOGRAPHIC STEREOTACTIC DEVICE

This defined term has been clarified and modified to include MAMMOGRAPHIC TOMOSYNTHESIS equipment that can be used for three dimensional localization and interventional mammographic guidance.

Subclause 201.7.9.2.17 ME EQUIPMENT emitting radiation

This requirement of the general standard is sufficiently addressed through IEC 60601-1-3 and additional requirements in 201.7.9.

Replace the existing header text of the rationale for subclause 201.9.2.101 by the following:

Subclause 201.9.2.101 – Three dimensional localization and interventional mammographic guidance

Add, at the end of the rationale to this subclause, the following new paragraph:

Tomosynthesis has been specifically excluded from this subclause because of the possible movement of the x-ray source during acquisition.

Subclauses 203.8.5.3 – Correspondence between X-RAY FIELD and EFFECTIVE IMAGE RECEPTION AREA and 203.8.5.4.101 – Missed tissue at chest wall side

Add, at the end of the rationale to this subclause, the following new paragraph:

Because in MAMMOGRAPHIC TOMOSYNTHESIS equipment the angulation of the source may generate a translation of the beam, the restriction for the correspondence between X-ray field and effective image reception area has been relaxed, with the exception of the chest wall side. However, patient protection is ensured by 203.11 Protection against RESIDUAL RADIATION where the primary protective barrier requirement has been maintained.

Bibliography

Add the following new bibliographic reference

[11] IEC 61223-3-2:2007, *Evaluation and routine testing in medical imaging departments – Part 3-2: Acceptance tests – Imaging performance of mammographic X-ray equipment*