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)

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

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

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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- withdrawn,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.

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.