IEC 60601-2-45

Edition 3.1 2015-06

CONSOLIDATED VERSION

colour inside

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 CSV(en)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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

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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This Consolidated version is not an official IEC Standard and has been prepared for user convenience. Only the current versions of the standard and its amendment(s) are to be considered the official documents.

This Consolidated version of IEC 60601-2-45 bears the edition number 3.1. It consists of the third edition (2011-02) [documents 62B/817/FDIS and 62B/821/RVD] and its amendment 1 (2015-06) [documents 62B/917/CDV and 62B/954/RVC]. The technical content is identical to the base edition and its amendment.

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions and deletions are displayed in red, with deletions being struck through. A separate Final version with all changes accepted is available in this publication.

International standard IEC 60601-2-45 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published in 2001. This edition constitutes a technical revision. The document has been aligned to the 3rd edition of IEC 60601-1 (2005) and to IEC 60601-1-3 (~~2010~~ 2008). Further modifications have been made with respect to the current technology of MAMMOGRAPHIC X-RAY EQUIPMENT.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

– Requirements and definitions: roman type.
– *Test specifications: italic 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 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g., Clause 7 includes subclauses 7.1, 7.2, etc.);
– “subclause” means a numbered subdivision of a clause (e.g., 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” , so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title: *Medical electrical equipment*, can be found on the IEC website

The committee has decided that the contents of the base publication and its amendment 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.

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.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

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 (3rd edition) and its collaterals. This particular standard addresses the system level of MAMMOGRAPHIC X-RAY EQUIPMENT, which consists of a combination of an X-RAY GENERATOR, associated equipment and ACCESSORIES. Components functions are addressed as far as necessary.

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of MAMMOGRAPHIC X-RAY EQUIPMENT.

Like the previous edition of this Part 2-45, the present third edition includes requirements on HIGH-VOLTAGE GENERATORS for mammography.

INTRODUCTION to Amendment 1

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.

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of the general standard[1)] applies, except as follows:

201.1.1 Scope

Replacement:

This international standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MAMMOGRAPHIC X-RAY EQUIPMENT, including equipment for MAMMOGRAPHIC TOMOSYNTHESIS, and MAMMOGRAPHIC STEREOTACTIC DEVICES, hereafter also referred to as ME EQUIPMENT.

NOTE 1 This includes MAMMOGRAPHIC X-RAY EQUIPMENT using integrated digital X-RAY IMAGE RECEPTORS or integrated storage phosphor subsystems.

Excluded from the scope of this document are:

– reconstructive tomography ~~modes of operation~~ other than MAMMOGRAPHIC TOMOSYNTHESIS;
– CT SCANNERS covered by IEC 60601-2-44;
– diagnostic consoles;
– picture archiving and communication systems (PACS);
– non-integrated storage phosphor readers;
– hard copy cameras;
– films, screens and cassettes;
– computer aided detection (CAD);
– devices for performing core biopsy and other biopsy instruments;
– modes of operation intended to demonstrate local contrast medium uptake (contrast enhanced digital mammography);

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

NOTE 2 IEC 60601-2-7:1998 and IEC 60601-2-32 are not part of the 3rd edition scheme for MAMMOGRAPHIC X-RAY EQUIPMENT and MAMMOGRAPHIC STEREOTACTIC DEVICES.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for MAMMOGRAPHIC X-RAY EQUIPMENT and MAMMOGRAPHIC

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1) The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

STEREOTACTIC DEVICES, to ensure safety, to specify methods for demonstrating compliance with those requirements and to provide guidance for RISK MANAGEMENT.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2:~~2007~~ 2014 and IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013 apply as modified in Clauses 202 and 203, respectively. IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 do not apply[2)]. All other published collateral standards in the IEC 60601-1-X series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard or a collateral standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g., 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g., 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

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2) 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.*

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g., 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding, clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 49.

Clause 2 of the general standard applies, except as follows:

Replacement:

IEC 60601-1-2:~~2007~~ 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

Addition:

IEC 60336:2005, *Medical electrical equipment – X-ray tube assemblies for medical diagnosis – Characteristics of focal spots*

IEC 60613:2010, *Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis*

IEC 60788:2004, *Medical electrical equipment – Glossary of defined terms*

~~*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*~~

IEC 62220-1-2:2007, *Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 1-2: Determination of the detective quantum efficiency – Detectors used in mammography*

ISO 9236-3:1999, *Photography – Sensitometry of screen/film systems for medical radiography – Part 3: Determination of sensitometric curve shape, speed and average gradient for mammography*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013, and IEC/TR 60788:2004 apply, except as follows:

NOTE An index of defined terms is found beginning on page 49.

Addition:

201.3.201
APPARENT RESISTANCE OF SUPPLY MAINS
resistance of the SUPPLY MAINS determined under specific load conditions

201.3.202
AVERAGE GLANDULAR DOSE
AGD
<X-ray mammography> average absorbed dose in the glandular tissue (excluding skin) in a uniformly compressed breast of known tissue composition, using a specified calculation method

[IEC 61223-3-2:2007, definition 3.7]

NOTE The terms "AVERAGE GLANDULAR DOSE" and "mean glandular dose" are interchangeable according to literature use.

201.3.203
BREAST COMPRESSION DEVICE
device used to exert pressure upon the breast of a PATIENT during either examination or treatment

201.3.204
DEFECTIVE DETECTOR ELEMENT
element of an X-RAY IMAGE RECEPTOR whose response is out of acceptable tolerance, such as when output is independent of the entrance AIR KERMA, or there is an excessive NOISE level

201.3.205
DIRECT FOCAL DISTANCE
<X-ray mammography> shortest ~~achievable~~ 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**
device ~~for three-dimensional localization of a point within the breast, and~~ for mechanically guided placement of a needle or position marker ~~for such purposes as fine-needle aspiration, core biopsy, and pre-surgical localization,~~ based on radiographic images of an immobilized breast acquired at different known angles

NOTE 1 Such a device may be a dedicated system or an ACCESSORY for MAMMOGRAPHIC X-RAY EQUIPMENT.

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

201.3.207
MAMMOGRAPHIC X-RAY EQUIPMENT
X-RAY EQUIPMENT where the INTENDED USE is breast imaging

201.3.208
ORIGINAL DATA
DN
RAW DATA to which the corrections allowed in this standard have been applied

[IEC 62220-1-2:2007, definition 3.11]

NOTE Here "this standard" is to be understood in the context of IEC 62220-1-2:2007.

201.3.209
RAW DATA
PIXEL values read directly after the analogue-digital-conversion from the digital X-ray imaging device or counts from photon counting systems without any software corrections

[IEC 62220-1-2:2007, definition 3.13]

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

Clause 4 of the general standard applies, except as follows:

201.4.3 ESSENTIAL PERFORMANCE

Addition:

201.4.3.101 *Additional ESSENTIAL PERFORMANCE requirements

Additional ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in Table 201.101.

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Accuracy of LOADING FACTORS	203.6.4.3.~~103~~ 102
AUTOMATIC CONTROL SYSTEM	203.6.5
Imaging performance	203.6.7
Missed tissue at chest wall side	203.8.5.4.101
BREAST COMPRESSION DEVICE	203.8.5.4.102
Linearity of AIR KERMA over limited intervals of LOADING FACTORS	203.6.3.1.2
Reproducibility of the X-RADIATION output	203.6.3.2

201.4.10.2 SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS

Addition:

The internal impedance of SUPPLY MAINS is to be considered sufficiently low for the operation of MAMMOGRAPHIC X-RAY EQUIPMENT if the value of the APPARENT RESISTANCE OF SUPPLY MAINS does not exceed the value specified in the ACCOMPANYING DOCUMENTS.

The required APPARENT RESISTANCE OF SUPPLY MAINS and other appropriate SUPPLY MAINS requirements shall be provided in the ACCOMPANYING DOCUMENTS.

MAMMOGRAPHIC X-RAY EQUIPMENT is considered to comply with the requirements of this standard only if its specified NOMINAL electric power can be demonstrated at an APPARENT RESISTANCE OF SUPPLY MAINS having a value not less than that specified by the MANUFACTURER in the ACCOMPANYING DOCUMENTS.

NOTE If a NOMINAL voltage is claimed for a mains power supply system, it is assumed that there is no voltage of a higher value between any of the conductors of the system or between any of these conductors and earth.

An alternating voltage is considered in practice to be sinusoidal if any instantaneous value of the waveform concerned differs from the instantaneous value of the ideal waveform at the same moment by no more than ± 2 % of the peak value of the ideal waveform.

Three-phase SUPPLY MAINS are considered to have a practical symmetry if it delivers symmetrical voltages and produces, when loaded symmetrically, symmetrical currents.

The requirements of this standard are based upon the assumption that three-phase systems have a symmetrical configuration of the MAINS VOLTAGE with respect to earth. Single-phase systems may be derived from such three-phase systems. Where the supply system is not earthed at the source, it is assumed that adequate measures have been provided to detect, limit and remedy any disturbance of symmetry within a reasonably short time.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

Additional subclause:

201.4.101 Data recording

Means shall be incorporated into the ME EQUIPMENT to record the following information with the image when acquired with an integrated digital X-RAY IMAGE RECEPTOR,:

– identity of the PATIENT (at least name and date of birth);
– positioning information (left/right breast, angulations, PATIENT positioning);
– acquisition parameters;
– place and date of the image acquisition;
– 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.

When transferring any of the above noted information as image data, it is recommended to use the objects identified in the DICOM standard (ISO 12052).

The instructions for use shall give appropriate guidance to the OPERATOR.

Compliance is checked by inspection.

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

201.6.2 Protection against electrical shock

Replacement:

MAMMOGRAPHIC X-RAY EQUIPMENT shall be CLASS I ME EQUIPMENT or INTERNALLY POWERED equipment.

If MAMMOGRAPHIC X-RAY EQUIPMENT is classified as INTERNALLY POWERED ME EQUIPMENT, the related clauses of the general standard apply and the RISK MANAGEMENT is to be provided accordingly.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

201.7.2.6 Connection to the SUPPLY MAINS

Addition:

For MAMMOGRAPHIC X-RAY EQUIPMENT that is specified to be PERMANENTLY INSTALLED, the information required in 7.2.6 of the general standard may be stated in the ACCOMPANYING DOCUMENTS only.

201.7.2.7 Electrical input power from the SUPPLY MAINS

Addition:

For MAMMOGRAPHIC X-RAY EQUIPMENT that is intended to be PERMANENTLY INSTALLED, the information required in 7.2.7 of the general standard may be stated in the ACCOMPANYING DOCUMENTS only.

The information on the input power shall be specified in terms of combinations of

a) the rated MAINS VOLTAGE of the ME EQUIPMENT in volts; see 7.2.1 and 7.2.6 of the general standard,
b) the number of phases; see 7.2.1 and 7.2.6 of the general standard,
c) the frequency, in hertz; see 7.2.1 and 7.2.6 of the general standard,
d) the maximum permissible value for APPARENT RESISTANCE OF SUPPLY MAINS, in ohms;
e) the characteristics of over-current releases required in the SUPPLY MAINS.

NOTE These requirements are adapted from IEC 60601-2-7:1998, subclause 6.1j).

201.7.2.15 Cooling conditions

Addition:

If cooling is necessary for safe operation of ME EQUIPMENT, or a subassembly thereof, the cooling requirements shall be indicated in the ACCOMPANYING DOCUMENTS, including as appropriate:

– the maximum heat dissipation into the surrounding air, given separately for each subassembly that dissipates more than 100 W and might be separately located on installation;

– the maximum heat dissipation into forced air cooling devices, and the corresponding flow rate and temperature rise of the forced air stream;

– the maximum heat dissipation into a cooling medium utility and the permissible input temperature range, minimum flow rate and pressure requirements for the utility.

Additional subclause:

201.7.2.101 BEAM LIMITING DEVICE

BEAM LIMITING DEVICES shall be provided with the following markings:

– those required in 7.2.2 of the general standard;

– serial designation or individual identification;

– PERMANENT FILTRATION in terms of QUALITY EQUIVALENT FILTRATION.

The markings on the BEAM LIMITING DEVICE may be hidden by covers in NORMAL USE. In this case the marking for PERMANENT FILTRATION shall be repeated in the ACCOMPANYING DOCUMENTS.

NOTE The BEAM LIMITING DEVICE is not in the scope of IEC 60601-2-28:2010. Therefore these requirements have been adapted from IEC 60601-2-28:1993 subclause 6.1.

201.7.8 Indicator lights and controls

Additional subclauses:

201.7.8.101 Indication of X-ray related states

The indication of X-ray related states shall be excluded from 7.8 in the general standard.

Subclause 203.6.4.2 shall apply instead.

201.7.8.102 Alternate visual indication means

Alternate unambiguous visual indication means may be used instead of indicator lights. Alternate unambiguous visual indication means may use indicator lights of red, yellow, and green colour.

These means shall be explained in the instructions for use.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.1 General

Addition:

The ACCOMPANYING DOCUMENTS shall state the dimensions and locations of all available EFFECTIVE IMAGE RECEPTION AREAS.

For MAMMOGRAPHIC X-RAY EQUIPMENT the ACCOMPANYING DOCUMENTS shall contain quality control procedures to be performed on the MAMMOGRAPHIC X-RAY EQUIPMENT by the RESPONSIBLE ORGANISATION. These shall include acceptance criteria and frequency for the tests.

The performance of means required to present the images for diagnostic purpose shall be stated in the ACCOMPANYING DOCUMENTS.

NOTE Examples of such means are image display devices or hard copy cameras.

Additionally for MAMMOGRAPHIC X-RAY EQUIPMENT provided with an integrated digital X-RAY IMAGE RECEPTOR, the ACCOMPANYING DOCUMENTS shall contain:

– a description of the file transfer format of the images acquired with this unit and of any data associated with these images;
– identification of the version of image processing applied to ORIGINAL DATA.

Information displayed on the user interface may be considered to satisfy the second requirement above.

The ACCOMPANYING DOCUMENTS of any MAMMOGRAPHIC STEREOTACTIC DEVICE designed as an ACCESSORY for MAMMOGRAPHIC X-RAY EQUIPMENT shall contain:

– at least one MODEL OR TYPE REFERENCE to MAMMOGRAPHIC X-RAY EQUIPMENT with which it is designed to operate;
– a reference to the relevant standards with which the MAMMOGRAPHIC STEREOTACTIC DEVICE complies.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.7.9.2 Instructions for use

201.7.9.2.1 General

Addition:

The instructions for use shall describe

– inspection and safe use of all compression plates that are provided with MAMMOGRAPHIC X-RAY EQUIPMENT,
– methods for determining and resolving problems with ARTEFACTS;
– for MAMMOGRAPHIC X-RAY EQUIPMENT provided with an integrated digital X-RAY IMAGE RECEPTOR,
  - particular handling and maintenance of X-RAY IMAGE RECEPTOR,
  - how to use the means required in 203.6.7.4.2 related to
    – DEFECTIVE DETECTOR ELEMENTS,
    – replacement of data originating from DEFECTIVE DETECTOR ELEMENTS,
    – image homogeneity problems;
  - the procedure for performing quality control of X-RAY IMAGE RECEPTOR;
  - requirements for image presentation.

Electric output data shall be stated in the instructions for use in terms of LOADING FACTORS as described below in items a) to j) of this subclause 201.7.9.2.1.

The following combinations and data shall be stated:

a) the NOMINAL X-RAY TUBE VOLTAGE and the highest X-RAY TUBE CURRENT available at that voltage;
b) the highest X-RAY TUBE CURRENT and the highest X-RAY TUBE VOLTAGE available at that current;

c) the corresponding combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT which results in the highest electric output power;

d) the NOMINAL electric power given as the highest constant electric output power in kilowatts which the X-RAY GENERATOR can deliver at an X-RAY TUBE VOLTAGE of 30 kV, for a LOADING TIME of 1 s, a CYCLE TIME of 1,0 minute and for an indefinite number of cycles, or if these values are not selectable, at an X-RAY TUBE VOLTAGE nearest to 30 kV, for a LOADING TIME nearest to but not less than 1 s and a CYCLE TIME of 1,0 minute and for an indefinite number of cycles.

NOTE 101 The limitation in the NOMINAL electric power may be caused by the HIGH-VOLTAGE GENERATOR, the X-RAY TUBE ASSEMBLY or other parts.

e) The NOMINAL electric power shall be given together with the combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT and the LOADING TIME;

NOTE 102 The values stated are only for characterising the equipment.

f) for MAMMOGRAPHIC X-RAY EQUIPMENT indicating pre-calculated or measured CURRENT TIME PRODUCT, the lowest CURRENT TIME PRODUCT or the combinations of LOADING FACTORS resulting in the lowest CURRENT TIME PRODUCT;

g) if the value of the lowest CURRENT TIME PRODUCT depends upon the X-RAY TUBE VOLTAGE or upon certain combinations of values of LOADING FACTORS, the lowest CURRENT TIME PRODUCT may be given as a table or curve showing the dependence;

h) for MAMMOGRAPHIC X-RAY EQUIPMENT provided with AUTOMATIC EXPOSURE CONTROL controlling the LOADING TIME, the shortest LOADING TIME and/or the lowest resulting CURRENT TIME PRODUCT;

i) if the X-RAY TUBE VOLTAGE or the X-RAY TUBE CURRENT in MAMMOGRAPHIC X-RAY EQUIPMENT is controlled by an AUTOMATIC EXPOSURE CONTROL, the range of the X-RAY TUBE VOLTAGE or the X-RAY TUBE CURRENT during the IRRADIATION shall be stated in the instructions for use;

j) if the shortest LOADING TIME depends upon LOADING FACTORS such as X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT, the ranges of these LOADING FACTORS for which the shortest LOADING TIME is valid shall be stated.

The instructions for use shall draw the attention of the RESPONSIBLE ORGANISATION to the need to restrict access to ME EQUIPMENT in accordance with local regulations for RADIATION PROTECTION.

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 Technical description

Additional subclauses:

201.7.9.3.101 Specification of X-RAY SOURCE ASSEMBLY and its position

The technical description of the integrated X-RAY SOURCE ASSEMBLIES shall specify the following:

a) specification of the REFERENCE AXIS to which the TARGET angle(s) and the FOCAL SPOT characteristics of the X-RAY TUBE of the X-RAY SOURCE ASSEMBLY refer;

b) TARGET angle(s) with respect to the specified REFERENCE AXIS;

c) position with tolerances of the FOCAL SPOTS on the REFERENCE AXIS;

d) NOMINAL FOCAL SPOT VALUE(S) determined according to IEC 60336 for the specified REFERENCE AXIS;

NOTE These requirements are adapted from IEC 60601-2-28:1993 subclause 6.8.3 dd).

e) possible values for DIRECT FOCAL DISTANCE and in MAMMOGRAPHIC TOMOSYNTHESIS, for specified positions of the source;

f) position of the intersection of the REFERENCE AXIS with the IMAGE RECEPTION AREA for a specified DIRECT FOCAL DISTANCE and in MAMMOGRAPHIC TOMOSYNTHESIS, for specified positions of the source;

g) angle of the REFERENCE AXIS to the plane of the IMAGE RECEPTION AREA and, in MAMMOGRAPHIC TOMOSYNTHESIS, for specified positions of the source.

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.

Additional paragraph:

201.7.9.101 Reference to ACCOMPANYING DOCUMENTS

The following subclauses of this standard contain additional requirements concerning the content of ACCOMPANYING DOCUMENTS:

201.4.10.2 ..... SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS
201.7.2.6 ..... Connection to the SUPPLY MAINS
201.7.2.7 ..... Electrical input power from the SUPPLY MAINS
201.7.2.15 ..... Cooling conditions
203.5.2 ..... ACCOMPANYING DOCUMENTS
203.6.2.1.101 ..... Connections of external interlocks
203.6.5 ..... AUTOMATIC CONTROL SYSTEM
203.6.7.4 ..... RADIATION DETECTOR or X-RAY IMAGE RECEPTOR
203.7.3 ..... Indication of FILTER properties
203.11.101 ..... Additional requirements for protection against RESIDUAL RADIATION

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

201.8.4 Limitation of voltage, current or energy

Additional subclauses:

201.8.4.101 HIGH-VOLTAGE CABLE CONNECTIONS

Detachable HIGH-VOLTAGE CABLE CONNECTIONS shall either be designed so that the use of tools is required to disconnect them or they shall be provided with interlocks so that at all times when protective covers or high-voltage connections are removed:

– the ME EQUIPMENT is disconnected from its power supply, and
– capacitances in the high-voltage circuit are discharged within the minimum time necessary to gain access to the high-voltage circuit, and
– the discharged state is maintained.

Compliance is checked by inspection and by measurement.

NOTE These requirements are adapted from IEC 60601-2-7:1998 subclause 15 aa).

201.8.4.102 Limitation of X-RAY TUBE VOLTAGE

ME EQUIPMENT shall be designed so as not to deliver in INTENDED USE, to any connected X-RAY TUBE ASSEMBLY, a voltage greater than the NOMINAL X-RAY TUBE VOLTAGE for the X-RAY TUBE

concerned or greater than the NOMINAL X-RAY TUBE VOLTAGE the X-RAY TUBE ASSEMBLY is designed for, whichever is the lower voltage.

NOTE These requirements are adapted from IEC 60601-2-7:1998 subclause 3.1.

201.8.5 Separation of parts

201.8.5.4 Working voltage

Addition:

201.8.5.4.101 Stator and stator circuit dielectric strength testing

The test voltage for the dielectric strength testing of stator and stator circuit used for the operation of the rotating anode of the X-RAY TUBE is to be referred to the voltage existing after reduction of the stator supply voltage to its steady state operating value.

NOTE These requirements are adapted from IEC 60601-2-7:1998 subclause 20.4 l).

201.8.6 Protective earthing, functional earthing and potential equalization of ME EQUIPMENT

Additional paragraphs:

201.8.6.101 X-RAY TUBE ASSEMBLY

Accessible high-voltage cables connecting the X-RAY TUBE ASSEMBLY to the HIGH-VOLTAGE GENERATOR shall incorporate a flexible conductive screen, having a resistance per unit length not exceeding 1 $\Omega\ m^{-1}$, and covered with a non-conductive material capable of protecting the screen against mechanical damage. The screen shall be connected to the protective earth conductive ENCLOSURE of the HIGH-VOLTAGE GENERATOR in low impedance.

Compliance is checked by visual inspection and by measurement.

201.8.6.102 X-RAY SOURCE ASSEMBLY

In all cases, there shall be electrical continuity between the screen of a fitted high-voltage cable and the accessible metal parts of its receptacle on the X-RAY SOURCE ASSEMBLY.

The flexible conductive screen is not to be recognized as satisfying a requirement for a protective earth connection between the devices connected by the cable.

Compliance is checked by visual inspection and by measurement.

201.8.7 LEAKAGE CURRENTS and PATIENT auxiliary currents

201.8.7.3 Allowable values

Addition:

The allowable values of EARTH LEAKAGE CURRENT are permitted for each subassembly of MAMMOGRAPHIC X-RAY EQUIPMENT that is supplied by its own exclusive connection to the SUPPLY MAINS or to a central connection point, if the latter is fixed and PERMANENTLY INSTALLED.

A fixed and PERMANENTLY INSTALLED central connection point may be provided inside the outer ENCLOSURE or cover of the MAMMOGRAPHIC X-RAY EQUIPMENT. If other subassemblies such as an X-RAY SOURCE ASSEMBLY or associated equipment are connected to the central connection point, the EARTH LEAKAGE CURRENT between such a central connection point and the external

protective system may exceed the allowable values for any one of the single devices connected.

NOTE 101 The limitation of the EARTH LEAKAGE CURRENTS within the environment of MAMMOGRAPHIC X-RAY EQUIPMENT is intended to prevent interference in other electrical equipment. The provision of a central connection point is acceptable, as for fixed and PERMANENTLY INSTALLED ME EQUIPMENT the interruption of the PROTECTIVE EARTH CONDUCTOR is not considered to be a SINGLE FAULT CONDITION. However, in such cases, adequate information on the combination of sub-assemblies needs to be provided.

201.8.8 Insulation

201.8.8.3 Dielectric strength

Amendment to the compliance test for high-voltage circuit:

The high-voltage circuit of ME EQUIPMENT is tested by applying no more than half the test voltage, and then the test voltage is gradually raised over a period of 10 s to the full value, which is maintained for 3 min.

Addition to the test conditions for high-voltage circuit:

The test for the high-voltage circuit shall be made without an X-RAY TUBE connected and with a test voltage of 1,2 times the NOMINAL X-RAY TUBE VOLTAGE of the ME EQUIPMENT.

If the ME EQUIPMENT can be tested only with the X-RAY TUBE connected and if the X-RAY TUBE does not allow the ME EQUIPMENT to be tested with a test voltage of 1,2 times the NOMINAL X-RAY TUBE VOLTAGE, the test voltage may be lower but not less than 1,1 times that voltage.

If during the dielectric strength test there is a RISK of overheating a transformer under test, it is permitted to carry out the test at a higher supply frequency.

During the dielectric strength test, the test voltage in the high-voltage circuit should be kept as close as possible to 100 %, and is not to be outside the range of 100 % and 105 % of the value required.

During the dielectric strength test, slight corona discharges in the high-voltage circuit are to be disregarded if they cease when the test voltage is lowered to 110 % of the voltage to which the test condition is referred.

Additions:

aa) HIGH-VOLTAGE GENERATORS or subassemblies thereof, that are integrated with an X-RAY TUBE ASSEMBLY are to be tested with an appropriately loaded X-RAY TUBE.

bb) If such HIGH-VOLTAGE GENERATORS do not have separate adjustment of the X-RAY TUBE CURRENT, the duration of the dielectric strength test is to be reduced to such an extent that the allowable X-RAY TUBE load at the increased X-RAY TUBE VOLTAGE will not be exceeded.

cc) If the high-voltage circuit is not accessible for the measurement of the test voltage applied, appropriate measures should to be taken to ensure that the value is kept as close as possible to 100 %, and is not to be outside the range of 100 % and 105 %, of the value required.

NOTE These requirements are adapted from IEC 60601-2-7:1998 subclause 20.4.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies, except as follows:

201.9.1 MECHANICAL HAZARDS of ME EQUIPMENT

Addition:

Subclause 203.8.5.4.102 BREAST COMPRESSION DEVICE of this particular standard applies.

201.9.2 MECHANICAL HAZARDS associated with moving parts

201.9.2.1 General

Addition:

The movement of ME EQUIPMENT or ME EQUIPMENT parts which could cause physical injury to the PATIENT in NORMAL USE shall require the continuous activation by the OPERATOR except in cases when MAMMOGRAPHIC X-RAY EQUIPMENT is designed for a specified clinical application (e.g., prepositioning, stereotactic imaging) that justifies intentional motion of accessible moving parts during INTENDED USE. The HAZARDS of the moving parts shall be treated by the RISK MANAGEMENT PROCESSES of the MANUFACTURER.

If in NORMAL USE a power-driven ME EQUIPMENT part is intended or likely to contact the PATIENT, and when appropriate for the designed application, means shall be provided to ~~detect PATIENT contact and~~ stop the motion if the contact could cause physical injury to the PATIENT.

Means shall be provided or warnings given in the ACCOMPANYING DOCUMENTS, to prevent injuries that could result from collision of power-driven ME EQUIPMENT parts with other moving or stationary items likely to be in proximity.

Compliance is checked by functional test and by inspection of the instructions for use.

NOTE These requirements are adapted from IEC 60601-2-32 subclause 22.4.1.

201.9.2.2 TRAPPING ZONE

201.9.2.2.6 Speed of movement(s)

Addition:

When the BREAST COMPRESSION DEVICE is actuated to apply a force of more than 50 N, the speed or step size of any power-driven movements of the accessible moving parts shall be limited so that the OPERATOR will have adequate control for fine correction of its position without endangering the PATIENT.

201.9.2.3 Other MECHANICAL HAZARDS associated with moving parts

201.9.2.3.1 Unintended movement

Addition:

Accessible moving parts shall be capable of being fixed in any position where they are designed to operate. Once fixed in such positions, these parts shall not undergo unintended motion.

In the event of interruption of the SUPPLY MAINS, the accessible moving parts shall not put any resultant force exceeding 20 N on any part of the PATIENT.

201.9.2.4 Emergency stopping devices

Addition:

All power-driven motions which could cause physical injury shall be provided with an emergency stop control. In the event of an emergency stop, means shall be provided for PATIENT access and removal while ME EQUIPMENT is disabled.

Compliance is checked by functional test and by inspection of the instructions for use.

NOTE These requirements are adapted from IEC 60601-2-32 subclause 22.4.1.

Additional subclauses:

201.9.2.101 * ~~MAMMOGRAPHIC STEREOTACTIC DEVICE~~ Three dimensional localization and interventional mammographic guidance

201.9.2.101.1 Positioning of X-RAY SOURCE ASSEMBLY for stereotactic imaging

In stereotactic imaging, defined angular positions shall be provided for the X-RAY SOURCE ASSEMBLY. The X-RAY SOURCE ASSEMBLY shall be capable of being rigidly fixed in any of these positions. Once fixed in any such position, subsequent movement of the X-RAY SOURCE ASSEMBLY shall require OPERATOR control.

This subclause does not apply for MAMMOGRAPHIC TOMOSYNTHESIS.

Compliance is checked by measurement according to the test in 201.9.2.101.3.

201.9.2.101.2 Motion of APPLIED PARTS during biopsy or marker placement

Under constant compression force, there shall be no displacement in any direction between the PATIENT SUPPORT and the compression plate of more than ± 0,5 mm and ± 0,5° relative to each other, and their displacement relative to the PATIENT shall not exceed ± 2 mm and ± 2° in any direction.

The movement of the needle holder or core biopsy gun holder with a needle inserted in it shall require continuous actuation and control by the OPERATOR.

Compliance is checked by measurement according to the test in 201.9.2.101.3.

201.9.2.101.3 Biopsy needle positioning accuracy ~~of MAMMOGRAPHIC STEREOTACTIC DEVICES~~

The accuracy of biopsy needle tip position in x, y, and z directions shall be within ± 1 mm in the specified ~~stereotactic~~ biopsy volume.

Compliance is checked by measurement according to the following test.

a) Test equipment

A ~~stereotactic~~ TEST DEVICE of a design that allows testing for different biopsy needle directions is required for the test. It consists of a mounting plate that is perforated so that it can serve as a locator for the test needles. At least three steel needles of different lengths are to be fixed in the mounting plate, the outer parts perpendicular to its surface and pointing in the same direction.

The steel needles are test needles; their tips serve as test objects. They shall be placed in a pattern so that the specified ~~stereotactic~~ biopsy volume can be covered. It shall be possible to locate one of them within ± 5 mm of the centre of that volume, and two of the other test needle tips also inside the specified ~~stereotactic~~ biopsy volume and within 10 mm of the extreme x, y, z points that are intended to be reconstructed ~~with the MAMMOGRAPHIC STEREOTACTIC DEVICE~~.

b) Test procedure

Measure the biopsy needle length and compare the result either to the NOMINAL biopsy needle length or to the biopsy needle length value stored or programmed in the MAMMOGRAPHIC STEREOTACTIC DEVICE. The measured length shall agree with the NOMINAL length to within ± 0,3 mm. Place the TEST DEVICE on the PATIENT SUPPORT ~~of the MAMMOGRAPHIC STEREOTACTIC DEVICE~~ specified so that one of the test needle tips is located to within ± 5 mm of the centre of the specified ~~stereotactic~~ biopsy volume and two of the other test needle tips are also located inside the specified ~~stereotactic~~ biopsy volume and within 10 mm of the extreme x, y, z points that are intended to be reconstructed. An attenuating, homogeneous material, for example 2 mm Al, may be attached close to the X-RAY SOURCE ASSEMBLY.

Select a FOCAL SPOT ~~with which the MAMMOGRAPHIC STEREOTACTIC DEVICE is~~ specified to be used.

Position the MAMMOGRAPHIC X-RAY EQUIPMENT to acquire a cranio-caudal projection of the breast. ~~Acquire a pair of stereo views. On each image select all projections of the test needle tips within the specified stereotactic biopsy volume and reconstruct their x, y, z positions.~~ Determine x, y, z positions of the test needle tips as specified by the MANUFACTURER for clinical use. For each test needle, position the biopsy needle tip according to the position calculated ~~by the MAMMOGRAPHIC STEREOTACTIC DEVICE~~. Measure and record the differences in x, y, z positions between each test needle tip and the biopsy needle tip. Repeat the procedure with the MAMMOGRAPHIC X-RAY EQUIPMENT rotated to the extremities in each direction of the range of angular deviation specified by the MANUFACTURER for clinical use of angular deviation in each direction and also to any intermediate deviations of 90° or multiples thereof. If the MAMMOGRAPHIC STEREOTACTIC DEVICE is designed for more than one biopsy needle direction relative to the test device, then repeat the procedure at as many directions as possible up to a maximum of six within the range specified by the MANUFACTURER for clinical use, including at least two directions at extremities of the specified range.

c) Interpretation of measured data

Compare the differences in x, y, and z directions to the requirement above.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies, except as follows:

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

Addition:

MAMMOGRAPHIC X-RAY EQUIPMENT shall comply with the applicable requirements of IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013; see Clause 203 of this particular standard.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies~~, except as follows:~~.

~~**201.12.4 Protection against hazardous output**~~

~~**201.12.4.5 Diagnostic or therapeutic radiation**~~

~~**201.12.4.5.2 Diagnostic X-ray equipment**~~

~~*Addition:*~~

~~NOTE 1 Many variable factors affect the relationship between the output parameters of MAMMOGRAPHIC X-RAY EQUIPMENT and the attainment of particular mammographic results in the X-RAY EQUIPMENT. Even when there is compliance with this standard, it is not to be expected in daily radiographic practice that LOADING FACTORS determined for any purpose on one installation can be transferred to other installations for the same purpose, without correction.~~

~~NOTE 2 According to 12.4.5.2 of the general standard, the dose-related aspects of "Accuracy of controls and instruments and protection against hazardous outputs" are addressed in the collateral standard IEC 60601-1-3; consequently, in this particular standard, the related subclauses have been regrouped under subclause 203.6.4.3.~~

201.13 Hazardous situations and fault conditions for ME EQUIPMENT

Clause 13 of the general standard applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies, except as follows:

201.15.4 ME EQUIPMENT components and general assembly

201.15.4.3 Batteries

Additional subclause:

201.15.4.3.101 Charging mode interlock

Every MOBILE ME EQUIPMENT having an incorporated battery charger shall be provided with means whereby powered movements and the generation of X-RADIATION by unauthorised persons can be prevented without preventing the charging of batteries.

NOTE An example of suitable means to comply with this requirement is the provision of a key-operated switch arranged so that powered movements and the generation of X-RADIATION are possible only when the key is present, but battery charging is also possible in the absence of the key.

201.16 ME SYSTEMS

Clause 16 of the general standard applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies.

202 Electromagnetic compatibility – Requirements and tests

IEC 60601-1-2:~~2007~~ 2014 applies, except as follows:

Addition:

202.101 Immunity testing of ESSENTIAL PERFORMANCE

The MANUFACTURER may minimize the test requirements of the additional ESSENTIAL PERFORMANCE listed in Table 201.101 to a practical level through the RISK MANAGEMENT PROCESS.

When selecting the requirements to be tested, the MANUFACTURER needs to take into account the sensitivity to the EMC environment, probability of EMC condition and severity, probability and contribution to unacceptable RISK through the RISK MANAGEMENT PROCESS.

The accuracy of the test instruments used to assess the immunity of the ME EQUIPMENT shall not be affected by the electromagnetic conditions for the test.

The test instrument shall not have an influence on the immunity of the ME EQUIPMENT.

Only non-invasive measurements shall be performed.

ME EQUIPMENT being tested shall not be modified to perform this immunity test.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

203 Radiation protection in diagnostic X-ray equipment

IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013 applies except as follows:

203.4 General requirements

203.4.1 Statement of compliance

Replacement:

For MAMMOGRAPHIC X-RAY EQUIPMENT, or a subassembly, any statement of compliance with the requirements of this standard shall be given in the following form:

MAMMOGRAPHIC X-RAY EQUIPMENT [++)] IEC 60601-2-45:~~2011~~ 2015

[++)] MODEL OR TYPE REFERENCE

NOTE This includes marking on the outside of ME EQUIPMENT.

Additional subclause:

203.4.101 Qualifying conditions for defined terms

203.4.101.1 Electric power

The electric power in the high-voltage circuit, mentioned in this particular standard in 201.7.9.2.1, general items c), d), and e) is calculated according to the formula: $P = f\ U\ I$

where

P is the electric power

f is the factor depending on the waveform of the X-RAY TUBE VOLTAGE, selected as below and is

a) 0,95 for ME EQUIPMENT including a six-peak HIGH-VOLTAGE GENERATOR, or

b) 1,00 for ME EQUIPMENT including a twelve-peak HIGH-VOLTAGE GENERATOR or a constant potential HIGH-VOLTAGE GENERATOR; or

c) for other ME EQUIPMENT, the most appropriate value, as above, chosen according to the waveform of the X-RAY TUBE VOLTAGE, with a statement of the value selected.

U is the X-RAY TUBE VOLTAGE

I is the X-RAY TUBE CURRENT

203.4.101.2 * LOADING TIME

LOADING TIME is measured as the time interval between:

– the instant that the X-RAY TUBE VOLTAGE has risen for the first time to a value of 75 % of the peak value; and

– the instant at which it finally drops below the same value.

For ME EQUIPMENT in which LOADING is controlled by electronic switching of the high voltage, using a grid in an electronic tube or in the X-RAY TUBE, the LOADING TIME shall be determined as the time interval between the instant when the timing device generates the signal to start the IRRADIATION and the instant when it generates the signal to terminate the IRRADIATION.

For ME EQUIPMENT in which LOADING is controlled by simultaneous switching in the primaries of both the high-voltage circuit and the heating supply for the filament of the X-RAY TUBE, the LOADING TIME shall be determined as the time interval between the instant when the X-RAY TUBE CURRENT first rises above 25 % of its maximum value and the instant when it finally falls below the same value.

For other cases, the way the LOADING TIME is controlled and determined shall be described in the RISK MANAGEMENT FILE.

NOTE 1 See also definition 3.37 of IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013.

NOTE 2 These requirements are adapted from IEC 60601-2-7:1998 subclause 2.101.4.

203.5 ME EQUIPMENT identification, marking and documents

203.5.2 ACCOMPANYING DOCUMENTS

203.5.2.4 Instructions for use

203.5.2.4.2 Quantitative information

Addition:

For MAMMOGRAPHIC X-RAY EQUIPMENT, the X-RADIATION dose to the PATIENT shall be described using both the entrance AIR KERMA and the AVERAGE GLANDULAR DOSE, determined according to the method specified by the MANUFACTURER.

203.6 RADIATION management

203.6.2 Initiation and termination of the IRRADIATION

203.6.2.1 Normal initiation and termination of the IRRADIATION

Addition:

203.6.2.1.101 Connections of external interlocks

MAMMOGRAPHIC X-RAY EQUIPMENT, except MOBILE MAMMOGRAPHIC X-RAY EQUIPMENT, shall be provided with connections for at least one external electrical device separate from the MAMMOGRAPHIC X-RAY EQUIPMENT that can prevent the X-RAY GENERATOR from starting to emit X-RADIATION.

MAMMOGRAPHIC X-RAY EQUIPMENT, except MOBILE MAMMOGRAPHIC X-RAY EQUIPMENT, shall be provided with connections for at least one external electrical device separate from the MAMMOGRAPHIC X-RAY EQUIPMENT that can cause the X-RAY GENERATOR to stop emitting X-RADIATION.

If the state of the signals from these external electrical devices is not displayed on the CONTROL PANEL, the ACCOMPANYING DOCUMENTS shall contain information to the RESPONSIBLE ORGANISATION that this state should be displayed by visual means in the installation.

203.6.2.2 Safety measures against failure of normal termination of the IRRADIATION

Replacement:

a) Each LOADING shall be initiated and maintained by means of a control requiring continuous actuation by the OPERATOR.

b) It shall not be possible to initiate any unintended subsequent IRRADIATION without releasing the control by which the previous IRRADIATION was initiated.

c) Means shall be provided for the OPERATOR to terminate each IRRADIATION at any time before its intended completion.

d) In the case of a failure of its normal termination the IRRADIATION shall be terminated by a safety measure.

e) If the normal termination is not effected upon the basis of an on-going X-RADIATION measurement, continuous actuation by the OPERATOR in accordance with item a) shall suffice as the safety measure required in item d) above.

f) If the normal termination depends upon an on-going X-RADIATION measurement,

   – the safety measure shall comprise means for termination of IRRADIATION in the event of a failure of the normal termination;

   – the CURRENT TIME PRODUCT shall be limited to no more than 800 mAs per IRRADIATION unless specified and justified by the MANUFACTURER;

   – the system for normal termination of IRRADIATION and the system used for the safety measure shall be separated so that a failure in one system does not affect termination by the other system;

   – a visible indication at the CONTROL PANEL shall be provided whenever a LOADING has been terminated by the safety means required. Another LOADING in the same MODE OF OPERATION shall not be possible until a control device provided for resetting has been operated at the CONTROL PANEL.

g) For MAMMOGRAPHIC X-RAY EQUIPMENT provided with AUTOMATIC EXPOSURE CONTROL a method by which the OPERATOR can verify the functioning of the AUTOMATIC EXPOSURE CONTROL shall be provided and the instructions for use shall contain the description of that method.

Compliance is checked by inspection and by the appropriate functional tests.

203.6.3 RADIATION dose and RADIATION QUALITY

Replacement:

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

It shall be possible to adjust the RADIATION QUALITY and the quantity of X-RADIATION to match the range of breast thickness and composition corresponding to the INTENDED USE of the MAMMOGRAPHIC X-RAY EQUIPMENT.

When the adjustment of the quantity of X-RADIATION contributing to the image is made through a manual selection among discrete values of LOADING FACTORS having an essentially proportional relation to the quantity of X-RADIATION produced, particularly values for X-RAY TUBE CURRENT, LOADING TIME or CURRENT TIME PRODUCT, these values shall be chosen from the series R'10 or R'20 according to IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013, Annex B.

NOTE Using values according to this geometric progression helps the OPERATOR in adjusting the quantity of X-RADIATION by amounts that are just significant, both in terms of X-RADIATION dose to the PATIENT and image quality.

Compliance is checked by inspection.

203.6.3.1.2 Linearity of AIR KERMA over limited intervals of LOADING FACTORS

The variation of the MEASURED VALUES of AIR KERMA shall linearly follow the change of the selected CURRENT TIME PRODUCTS over the whole range of CURRENT TIME PRODUCT selections available, with an accuracy equal or better than 0,2.

Compliance is checked by the following functional test:

The linearity test shall be performed at 30 kV or at the nearest X-RAY TUBE VOLTAGE setting available. For the test, pairs of X-RAY TUBE CURRENT TIME PRODUCT settings shall be selected as follows:

- *The lower value of the first pair shall correspond to the lowest available CURRENT TIME PRODUCT setting. 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.*
- *The ratio of the values of the selected CURRENT TIME PRODUCT settings in each pair shall be as close as possible to 2, but not exceeding 2.*
- *The higher value of the CURRENT TIME PRODUCT settings in each pair to be measured shall be used as the lower value of the next pair of CURRENT TIME PRODUCT settings.*
- *The higher value of the last pair shall correspond to the highest available CURRENT TIME PRODUCT setting and the lower value shall be half or next of half of the value corresponding to the highest available CURRENT TIME PRODUCT setting.*

NOTE An example of this selection rule is the following: If the available CURRENT TIME PRODUCT settings are 10, 12, 16, 20, 25, 32, 40, 50, 63, 80, 100 and 125 mAs, the pairs to be tested are: 10 and 20 mAs, 20 and 40 mAs, 40 and 80 mAs and 63 and 125 mAs.

The whole series of measurements required for the test shall be performed without long pauses and preferably within a period of one hour.

Perform ten LOADINGS for each selected X-RAY TUBE CURRENT TIME PRODUCT setting and measure the AIR KERMA at a fixed location 40 mm above the PATIENT SUPPORT. Calculate the average of the MEASURED VALUES of AIR KERMA for each series of ten measurements.

Calculate the linearity in relation to each pair of settings according to the following formula. The quotients of the averages divided by the respective selected X-RAY TUBE CURRENT TIME PRODUCTS shall not differ by more than 0,2 times the mean value of the following quotients:

$$\left|\frac{\bar{K}_1}{Q_1}-\frac{\bar{K}_2}{Q_2}\right| \leq 0{,}2\,\frac{\frac{\bar{K}_1}{Q_1}+\frac{\bar{K}_2}{Q_2}}{2}$$

where

$\bar{K}_1, \bar{K}_2$ *are the averages of the* MEASURED VALUES *of* AIR KERMA *and*

Q_1, Q_2 *are the selected* CURRENT TIME PRODUCTS.

203.6.3.2 Reproducibility of the X-RADIATION output

The coefficient of variation of the MEASURED VALUES of AIR KERMA shall be not greater than 0,05 for any combination of LOADING FACTORS over the range for INTENDED USE.

Compliance is checked by the following functional test:

Select a set of LOADING FACTOR *combinations for the reproducibility tests, including at least the following combinations:*

- *highest available* X-RAY TUBE VOLTAGE *with the lowest available* X-RAY TUBE CURRENT *for that* X-RAY TUBE VOLTAGE
- *lowest available* X-RAY TUBE VOLTAGE *with the highest available* X-RAY TUBE CURRENT *for that* X-RAY TUBE VOLTAGE
- *a combination of* X-RAY TUBE VOLTAGE *and* X-RAY TUBE CURRENT *for the highest electrical power*
- *a combination of* X-RAY TUBE VOLTAGE *and* X-RAY TUBE CURRENT *for the lowest electrical power*
- *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*

The series of measurements required for the test shall be performed without long pauses, preferably within a period of one hour.

Perform ten LOADINGS *for each of the combinations of* LOADING FACTORS *selected and measure the* AIR KERMA *at a fixed location 40 mm above the* PATIENT SUPPORT

Calculate the coefficient of variation for each series of MEASURED VALUES *of* AIR KERMA.

$$\bar{K} = \frac{K_1 + K_2 + \ldots + K_n}{n}$$

where

K_1, K_2, K_n *are the* MEASURED VALUES *of* AIR KERMA

n *is the number of measurements (10)*

$\bar{K}$ *is the average of ten measurements*

$$cv = \frac{\sqrt{\frac{\left(K_1-\bar{K}\right)^2+\left(K_2-\bar{K}\right)^2+\ldots+\left(K_n-\bar{K}\right)^2}{n-1}}}{\bar{K}}$$

203.6.4 Indication of operational states

203.6.4.2 Indication of LOADING STATE

Addition:

203.6.4.2.101 LOADING STATE in mammography

A visual indication on the CONTROL PANEL shall indicate the LOADING STATE.

Termination of the LOADING STATE shall be unambiguously indicated at the location of the OPERATOR by an audible signal, regardless of whether termination is determined by the ME EQUIPMENT or by the OPERATOR.

If the LOADING STATE is indicated by means of a single function visual indicator, the colour yellow shall be used.

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

Compliance is checked by inspection

203.6.4.2.102 READY STATE in mammography

Visible indication shall be provided on the CONTROL PANEL indicating the state when one further actuation of a control from that CONTROL PANEL will initiate the LOADING of the X-RAY TUBE in RADIOGRAPHY.

If this state is indicated by means of a single function visual indicator, the colour green shall be used.

Compliance is checked by inspection.

203.6.4.2.103 Remote indication of READY STATE in mammography

Means shall be provided for a connection to enable the READY STATE to be indicated remotely from the CONTROL PANEL. This requirement does not apply to MOBILE MAMMOGRAPHIC X-RAY EQUIPMENT.

203.6.4.3 Indication of LOADING FACTORS and MODES of OPERATION

Addition:

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.

203.6.4.3.101 Units of indication

The units of indication shall be as follows:

– for X-RAY TUBE VOLTAGE, kilovolts (kV);
– for X-RAY TUBE CURRENT, milliamperes (mA);
– for LOADING TIME, seconds (s) or milliseconds (ms);
– for IRRADIATION TIME, seconds (s) or milliseconds (ms);
– for CURRENT TIME PRODUCT, milliampere-seconds (mAs).

Compliance is checked by inspection.

203.6.4.3.102 Accuracy of LOADING FACTORS

203.6.4.3.102.1 General

NOTE Subclauses 203.6.4.3.102 and 203.6.4.3.103 contain requirements on operating data for MAMMOGRAPHIC X-RAY EQUIPMENT, as part of X-RAY GENERATORS that are considered essential for protection against incorrect output.

The requirements of this subclause apply to the accuracy of all values of LOADING FACTORS, whether indicated, fixed or preselected when compared with MEASURED VALUES of the same LOADING FACTOR.

Compliance is determined by tests according to 203.6.4.3.~~104~~ 103.

203.6.4.3.102.2 Accuracy and reproducibility of X-RAY TUBE VOLTAGE

a) The X-RAY TUBE VOLTAGE shall be accurate within ± 5 % of the INDICATED VALUE within the selectable range.

b) The coefficient of variation of the X-RAY TUBE VOLTAGE shall be equal to or less than 0,05.

c) The PERCENTAGE RIPPLE of output voltage of the HIGH-VOLTAGE GENERATOR shall not exceed 4.

203.6.4.3.102.3 Accuracy of X-RAY TUBE CURRENT

For operation of MAMMOGRAPHIC X-RAY EQUIPMENT where the X-RAY TUBE CURRENT ~~shall~~ 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

~~In any specified combination of MAMMOGRAPHIC X-RAY EQUIPMENT with sub-assemblies~~ 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.

This subclause is applicable only if the LOADING TIME is equal to the IRRADIATION TIME of the EFFECTIVE IMAGE RECEPTION AREA at each point or element of the X-RAY IMAGE RECEPTOR.

NOTE An example for MAMMOGRAPHIC X-RAY EQUIPMENT where this subclause is not applicable are slot scanning systems.

203.6.4.3.102.5 Accuracy of CURRENT TIME PRODUCT

In any specified combination of MAMMOGRAPHIC X-RAY EQUIPMENT with sub-assemblies, the error on the value of the X-RAY TUBE CURRENT TIME PRODUCT shall not be greater than ± (10 % + 0,2 mAs) from its selected value for any combination of LOADING FACTORS. This requirement also applies in cases when the CURRENT TIME PRODUCT is derived by calculation.

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

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 ~~30 kV,~~ 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.

Complete each set of ten measurements for each combination of X-RAY TUBE VOLTAGE and CURRENT TIME PRODUCT preferably within a time period of one hour.

~~*Calculate the average*~~ *Check each measured value and the coefficient of variation for each series of measurement to verify compliance.*

203.6.4.3.103.2 Accuracy of X-RAY TUBE CURRENT

One measurement shall be made for the lowest INDICATED VALUE of X-RAY TUBE CURRENT with the highest INDICATED VALUE of X-RAY TUBE VOLTAGE and the shortest INDICATED VALUE of LOADING TIME.

One measurement shall be made for the lowest INDICATED VALUE of X-RAY TUBE CURRENT with the highest INDICATED VALUE of X-RAY TUBE VOLTAGE and a LOADING TIME of approximately 1 s.

One measurement shall be made for the highest INDICATED VALUE of X-RAY TUBE CURRENT with the highest available X-RAY TUBE VOLTAGE and a LOADING TIME of approximately 1 s.

203.6.4.3.103.3 Accuracy of LOADING TIME

One measurement shall be made for the lowest INDICATED VALUE of LOADING TIME with the highest INDICATED VALUE of X-RAY TUBE VOLTAGE and any INDICATED VALUE of X-RAY TUBE CURRENT.

One measurement shall be made for the lowest INDICATED VALUE of LOADING TIME and the highest available electric power, P.

203.6.4.3.103.4 Accuracy of CURRENT TIME PRODUCT

One measurement shall be made for the lowest INDICATED VALUE of CURRENT TIME PRODUCT and the highest available X-RAY TUBE VOLTAGE.

One measurement shall be made for the highest INDICATED VALUE of CURRENT TIME PRODUCT and the lowest available X-RAY TUBE VOLTAGE.

203.6.4.3.104 Indication of ADDED FILTERS

If X-RAY EQUIPMENT has provisions to select ADDED FILTERS by remote control or automatic systems, the selected ADDED FILTER shall be indicated on the CONTROL PANEL. In cases where the FILTER change is automatic, this indication may be displayed after the termination of IRRADIATION.

Compliance is checked by inspection and by the appropriate functional tests.

203.6.4.4 Indication of automatic modes

Addition:

For MAMMOGRAPHIC X-RAY EQUIPMENT in which control of exposure conditions is achieved by automatic variation of one or more LOADING FACTORS, ADDED FILTERS or TARGET, information about the range and interrelation of these LOADING FACTORS shall be given in the instructions for use.

Compliance is checked by inspection and by the appropriate functional tests.

203.6.4.5 Dosimetric Indications

Addition:

For MAMMOGRAPHIC X-RAY EQUIPMENT with an integrated digital X-RAY IMAGE RECEPTOR the AVERAGE GLANDULAR DOSE shall be indicated for each acquired image.

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 AUTOMATIC CONTROL SYSTEM

Replacement:

203.6.5.1 General AEC requirements for MAMMOGRAPHIC X-RAY EQUIPMENT

MAMMOGRAPHIC X-RAY EQUIPMENT shall be provided with AUTOMATIC EXPOSURE CONTROL.

NOTE The inclusion of a manual mode option is not in contradiction to these requirements and may be useful in special cases.

The performance required for the INTENDED USE of AUTOMATIC EXPOSURE CONTROLS shall be determined in the RISK MANAGEMENT PROCESS and be verified by appropriate tests.

Compliance is checked by inspection and by the appropriate functional tests.

203.6.5.2 AEC requirements for MAMMOGRAPHIC X-RAY EQUIPMENT without an integrated X-RAY IMAGE RECEPTOR

NOTE Within this subclause a storage phosphor reader, included with the original MAMMOGRAPHIC X-RAY EQUIPMENT, or indicated as compatible with its INTENDED USE, is considered as an integrated digital X-RAY IMAGE RECEPTOR. The type test for a combination of MAMMOGRAPHIC X-RAY EQUIPMENT without an integrated X-RAY IMAGE RECEPTOR with a storage phosphor plate and/or reader or other digital detector is the responsibility of the system integrator and may be carried out according to 203.6.5.3.

MAMMOGRAPHIC X-RAY EQUIPMENT without an integrated X-RAY IMAGE RECEPTOR only require the use of film for testing the AEC performance. For MAMMOGRAPHIC X-RAY EQUIPMENT without an integrated X-RAY IMAGE RECEPTOR, the ACCOMPANYING DOCUMENTS shall contain necessary information or limitations on the characteristics of the X-RAY IMAGE RECEPTOR that can be used in order to meet the required performance.

MAMMOGRAPHIC X-RAY EQUIPMENT intended to be used with certain non-integrated digital X-RAY IMAGE RECEPTORS only may be tested with such digital X-RAY IMAGE RECEPTORS according to 203.6.5.3.

In other cases the AEC function shall maintain film optical density within an appropriate range when the thickness of a breast equivalent material is varied over an appropriate range and the X-RAY TUBE VOLTAGE is varied appropriately for such thickness over the range recommended by the MANUFACTURER for clinical use. The appropriate combination of X-RAY TUBE VOLTAGE and thickness of the object is to be stated by the MANUFACTURER. The AEC shall be operable in all combinations of clinically relevant configurations of the MAMMOGRAPHIC X-RAY EQUIPMENT, e.g., grid, no grid, magnification and (if applicable) stereotactic modes, and with various TARGET/FILTER combinations.

a) Test method

Measure the optical density of radiograms of PHANTOMS made of breast tissue equivalent material, produced with the AUTOMATIC EXPOSURE CONTROL in operation. Determine the variations in density for different PHANTOM thickness and for different X-RAY TUBE VOLTAGES.

b) Test arrangement

Use a test arrangement with the following characteristics:

1) *A DIRECT FOCAL DISTANCE, remaining unchanged for all tests in a series.*

2) *Select the X-RAY TUBE VOLTAGE, TARGET, and FILTRATION to reflect the PHANTOM thickness. Select the density control to the value that is typically used clinically.*

3) *An 18 cm × 24 cm radiographic cassette for mammography, the same cassette being used for all tests in a series. If the MAMMOGRAPHIC X-RAY EQUIPMENT includes more than one PATIENT SUPPORT then the AEC shall also be tested using these arrangements.*

4) *Test the thickness range from 20 mm to 70 mm in steps of 10 mm. The size of the PHANTOMS shall provide sufficient coverage of the AEC detector, for example 10 cm × 15 cm or a semicircle with a radius of 100 mm. A larger size is recommended to generate clinically relevant distributions of SCATTERED RADIATION. The PHANTOM shall extend 10 mm beyond the chest wall edge of the PATIENT SUPPORT and at least 10 mm beyond the edge of the AEC detector.*

5) *If the grid can be removed, or PATIENT SUPPORT without a grid is provided, the AEC function shall also be tested for these configurations.*

6) *Provision for accurate and reproducible film processing and for measuring the optical density of processed films. The film processor stability during the AEC test shall regularly be tested and demonstrated with a sensitometer test, at least at the beginning, half way through the test and at the end. It is not appropriate to divide the test into different parts, and it is also impossible to make this test if the processor is not stable. If there is a small drift in processor performance during the test period, this drift must be taken into consideration when making the evaluation.*

c) *Radiographic film and intensifying screen*

Use the same combination of radiographic film, intensifying screen and radiographic cassette according to the information given in the instructions for use. If a different intensifying screen is recommended for special procedures, i.e., stereotaxy or magnification, the AEC shall also be tested using this arrangement.

d) *Setting the AUTOMATIC EXPOSURE CONTROL*

– *Position the PHANTOM on the PATIENT SUPPORT and ensure that it overlaps the area of the AEC sensor.*

– *For settings follow the instructions for use.*

e) *Compliance criteria*

MEASURED VALUES of optical density shall be within 0,3 for 20 mm to 70 mm of tissue-equivalent material.

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

NOTE Within this subclause a storage phosphor reader, included with the original MAMMOGRAPHIC X-RAY EQUIPMENT, or indicated as compatible with its INTENDED USE, is considered as an integrated digital X-RAY IMAGE RECEPTOR.

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

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

The appropriate combination of X-RAY TUBE VOLTAGE and thickness of the object is to be stated by the MANUFACTURER. The AEC shall be operable in all combinations of clinically relevant configurations of the MAMMOGRAPHIC X-RAY EQUIPMENT, e.g., grid, no grid, magnification (if applicable) tomosynthesis and stereotactic modes, and, when applicable, with the different TARGET/FILTER combinations.

All configurations of combinations of settings of the MAMMOGRAPHIC X-RAY EQUIPMENT (e.g., magnification, tomosynthesis and stereotactic modes) that use AEC LOADINGS shall be evaluated per the specifications of the MANUFACTURER.

NOTE An example for these tests can be found in IEC 61223-3-2:2007 and is included in 203.6.5.3.3.

203.6.5.3.2 AEC reproducibility

The reproducibility of the AEC shall be evaluated by repeatedly imaging a PHANTOM under specified conditions, measuring the variations in X-RAY TUBE LOADING (mAs), AIR KERMA or average PIXEL value, and comparing the results with the specifications as described in c) Compliance criteria, below.

a) Test method

Using clinically relevant X-RAY TUBE VOLTAGE and TARGET/FILTER combinations, measure one of the quantities

- *X-RAY TUBE LOADING (mAs);*
- *AIR KERMA at a fixed position between the X-RAY SOURCE ASSEMBLY and the X-RAY IMAGE RECEPTOR;*
- *average value of linearised PIXEL values in a region of interest of the image of the PHANTOM;*

for five routine LOADINGS with PHANTOMS made of breast tissue-equivalent material, water or Polymethylmethacrylate (PMMA), determine the variation in the measured quantity for each LOADING relative to the mean value for the LOADING series.

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

Additionally, if an AEC adjustment or correction control is provided, measure the selected quantity as listed in a) above at each MANUFACTURER specified control step using the same X-RAY TUBE VOLTAGE, TARGET/FILTER, and PHANTOM configurations and determine the variation for each respective LOADING.

b) Test arrangement

Use a test arrangement with the following characteristics:

1) *a DIRECT FOCAL DISTANCE remaining unchanged for all tests in a series;*
2) *dosimeters or other measurement instrumentation should be positioned to avoid interference with AEC sensor.*

c) Compliance criteria

Compliance is achieved if no MEASURED VALUE of the selected quantity differs by more than ± 15 % from the mean value for the test LOADINGS or, as appropriate, the MANUFACTURER'S specification.

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 Imaging performance

203.6.7.3 NOMINAL FOCAL SPOT VALUE

Addition:

The requirements of the collateral standard are considered as met if the NOMINAL FOCAL SPOT VALUE of the X-RAY TUBE specified to be used in contact mode is smaller than or equal to 0,4 according to IEC 60336, and if the NOMINAL FOCAL SPOT VALUE specified to be used in geometric magnification conditions is smaller than or equal to 0,2 according to IEC 60336.

203.6.7.4 RADIATION DETECTOR or X-RAY IMAGE RECEPTOR

Replacement:

203.6.7.4.1 Non-integrated X-RAY IMAGE RECEPTOR

If no X-RAY IMAGE RECEPTOR is integrated in the system, examples of X-RAY IMAGE RECEPTOR types or required performances shall be described in the ACCOMPANYING DOCUMENTS. This may include

– radiographic cassettes with intensifying screens, radiographic films: sensitometric properties according to ISO 9236-3:1999;

– non-integrated storage phosphor screens and readers.

203.6.7.4. 2 Integrated X-RAY IMAGE RECEPTOR

203.6.7.4.2.1 General

If a digital X-RAY IMAGE RECEPTOR is integrated in the MAMMOGRAPHIC X-RAY EQUIPMENT, its contribution to the metrics of imaging performance shall be specified in the RISK MANAGEMENT FILE in accordance with IEC 62220-1-2. This contribution should ensure the efficient use of X-RADIATION.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

203.6.7.4.2.2 DEFECTIVE DETECTOR ELEMENTS

The MANUFACTURER shall specify

– the maximum acceptable number of isolated DEFECTIVE DETECTOR ELEMENTS in the entire IMAGE RECEPTION AREA and the maximum acceptable number in any subdivision with their distribution over the IMAGE RECEPTION AREA;

– the maximum acceptable size and number of connecting DEFECTIVE DETECTOR ELEMENTS and their distribution in the entire IMAGE RECEPTION AREA and the maximum acceptable number in any subdivision and distribution over the IMAGE RECEPTION AREA of connecting DEFECTIVE DETECTOR ELEMENTS grouped by topology type (e.g., 2 adjacent detector elements, 3 adjacent detector elements, 2 × 2 adjacent detector elements, etc.);

– the maximum acceptable number of defective lines, columns and segments, and the minimum acceptable distance between defective lines or columns with their width, length and distribution over the entire IMAGE RECEPTION AREA and the maximum acceptable number in any subdivision and distribution over the IMAGE RECEPTION AREA.

These defects shall not significantly degrade the level of image quality required for the INTENDED USE.

The MANUFACTURER shall determine, describe, and specify the acceptable properties, numbers, positions and arrangements of the DEFECTIVE DETECTOR ELEMENTS in the RISK MANAGEMENT FILE.

Means shall be provided

– to determine and identify the DEFECTIVE DETECTOR ELEMENTS present in the digital X-RAY IMAGE RECEPTOR according to the categories above;
– to allow the RESPONSIBLE ORGANISATION to determine whether the digital X-RAY IMAGE RECEPTOR performs according to its specifications, before degradation of the image quality performance required for the INTENDED USE occurs;
– to generate or update the description of the DEFECTIVE DETECTOR ELEMENTS to be used during the replacement PROCESS specified in 203.6.7.4.2.3, if required. Means may be provided to make this description available to the RESPONSIBLE ORGANISATION.

The instructions for use shall contain instructions on how and when to use the provided means as a part of the quality control procedures, or of the maintenance of ME EQUIPMENT, to be performed by the RESPONSIBLE ORGANISATION or under its responsibility.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and the ACCOMPANYING DOCUMENTS.

203.6.7.4.2.3 * Replacement of data originating from DEFECTIVE DETECTOR ELEMENTS

Means shall be provided to replace the RAW DATA originating from the DEFECTIVE DETECTOR ELEMENTS by appropriate data, in such a way that the corresponding picture elements do not show a significant visual degradation compared to the data provided by the non-defective detector element of an otherwise equivalent digital X-RAY IMAGE RECEPTOR.

This replacement PROCESS shall match the current state of the digital X-RAY IMAGE RECEPTOR, or the latest description of its DEFECTIVE DETECTOR ELEMENTS.

The replacement PROCESS shall be applied to all images specified for the INTENDED USE in clinical practice.

The RISK MANAGEMENT FILE shall include

– the description of the replacement PROCESS,
– the specification of the performance provided by the replacement PROCESS,
– the justification for its capability to fulfil the need.

Means shall be provided to inform the RESPONSIBLE ORGANISATION if the currently applied replacement PROCESS does or does not allow achievement of the specified performance. These means may be automatic, or part of the quality control procedures to be performed by the RESPONSIBLE ORGANISATION. The instructions for use shall contain instructions on how and when to use these means, together with the description of the measures to be taken in cases of failure.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and the ACCOMPANYING DOCUMENTS.

203.6.7.4.2.4 Image homogeneity

The local variations in the image generated by the integrated digital X-RAY IMAGE RECEPTOR of MAMMOGRAPHIC X-RAY EQUIPMENT shall not degrade the image quality performance required for the INTENDED USE.

NOTE 1 Particular sources of image non-homogeneity include

– offset variability of individual detector elements;

– gain variability of the individual detector elements;

– for scanning MAMMOGRAPHIC X-RAY EQUIPMENT scan velocity variability.

NOTE 2 An additional source of image non-homogeneity is the non-uniformity of the X-RAY FIELD.

The RISK MANAGEMENT FILE shall contain the specification and justification for the image homogeneity required in clinical practice according to the INTENDED USE, over the range of X-ray energies effectively used (combinations of TARGET material, TOTAL FILTRATION, X-RAY TUBE VOLTAGE, object thickness), and the dynamic range of the X-RAY IMAGE RECEPTOR expressed relative to the NOMINAL operating level (or levels).

Means shall be provided

– to correct each image used in clinical practice in order to reach the specified homogeneity;
– to inform the RESPONSIBLE ORGANISATION if the current homogeneity of images is acceptable or not. These means may be automatic or part of the quality control procedures to be performed by the RESPONSIBLE ORGANISATION. In the latter case, the instructions for use shall contain instructions on how and when to use these means, together with the description of the measures to be taken in cases of failure.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and the ACCOMPANYING DOCUMENTS.

Additional subclauses:

203.6.7.101 Homogeneity of intercepting layers in the X-RAY SOURCE ASSEMBLY

The intercepting layers in the X-RAY SOURCE ASSEMBLY shall not generate unacceptable ARTEFACTS in the radiographic image.

This requirement shall be met

– for all FOCAL SPOT/geometric magnification combinations provided;
– for all available combinations of TARGET material and ADDITIONAL FILTRATIONS at the lowest applicable X-RAY TUBE VOLTAGE;
– when imaging a PHANTOM made of a uniform plate sufficient in overall area to cover the EFFECTIVE IMAGE RECEPTION AREA and with the minimum thickness compatible with this X-ray energy;
– for non-integrated X-RAY IMAGE RECEPTORS: using the X-RAY IMAGE RECEPTOR specified in 203.6.7.4.1 providing the highest sensitivity to the ARTEFACTS; in that case, the X-RAY IMAGE RECEPTOR shall be placed on an auxiliary support, avoiding the influence of the regular X-RAY IMAGE RECEPTOR support;
– for integrated X-RAY IMAGE RECEPTORS, after removal of all layers between the PHANTOM and the ENTRANCE SURFACE of the X-RAY IMAGE RECEPTOR;
– using the most sensitive image viewing conditions used in clinical practice.

The detailed method for determination and specification of the acceptable ARTEFACTS shall be included in the RISK MANAGEMENT FILE.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and the ACCOMPANYING DOCUMENTS.

203.6.7.102 Motion of the ANTI-SCATTER GRID under maximum compression force

For MAMMOGRAPHIC X-RAY EQUIPMENT with a moving ANTI-SCATTER GRID, the application of the maximum force attainable for the BREAST COMPRESSION DEVICE shall not impede the motion of the ANTI-SCATTER GRID.

Compliance is checked by the following test:

The speed of the grid movement may be determined indirectly by using a parameter that is related to the speed of the grid motion (e.g., frequency of the motor).

Actuate the grid operation and determine the speed of the grid motion without compression force.

Apply the maximum attainable compression force to the BREAST COMPRESSION DEVICE. Use the test object and procedure as explained in 203.8.5.4.102.5.

Actuate the grid operation and determine the speed of the grid motion.

Release the compression force.

Repeat the test at ± 90º, and at 180º or as close as possible to the suggested angles from the initial orientation of the MAMMOGRAPHIC X-RAY EQUIPMENT.

Repeat the test procedure for all X-RAY IMAGE RECEPTOR formats.

Compliance is achieved if the application of the compression force does not significantly alter the speed of the ANTI-SCATTER GRID motion.

NOTE It is reasonable to combine the test in 203.8.5.4.102.5 with the above test.

203.6.7.103 ARTEFACTS from grid lines

203.6.7.103.1 Requirements

Under viewing conditions as applied for diagnosis and at the specified range of phantom thickness, rotation of MAMMOGRAPHIC X-RAY EQUIPMENT and compression force, no anti-scatter grid artefacts shall be discernable.

203.6.7.103.2 Test equipment

The following test equipment is required:

- *PHANTOM of 20 mm PMMA having sufficient cross-section to cover the EFFECTIVE IMAGE RECEPTION AREA with the PHANTOM;*
- *an aluminium plate of 2 mm thickness and of dimensions sufficient to intercept the whole X-RAY BEAM when mounted as described below;*
- *if the X-RAY EQUIPMENT uses radiographic films: densitometer, covering the optical density range from 0 to 4,0; radiographic cassettes with intensifying screens and radiographic films for each image format.*

203.6.7.103.3 Test procedure

Position the MAMMOGRAPHIC X-RAY EQUIPMENT to acquire a cranio-caudal projection of the breast and set the X-RAY EQUIPMENT in a condition that is provided for grid mammography.

Mount a compression plate that is designed for the maximum attainable compression force and for the X-RAY IMAGE RECEPTOR format used. Fix the aluminium plate between the X-RAY SOURCE ASSEMBLY and the compression plate so that it will completely cover the X-RAY BEAM. Make an exposure in AEC mode to determine the proper CURRENT TIME PRODUCT. Remove the aluminium plate, and place the PMMA PHANTOM on the PATIENT SUPPORT, centred laterally, and with one edge as close as possible to that edge of the PATIENT SUPPORT that is intended to be adjacent to the PATIENT'S chest wall. Irradiate, using the previously determined proper CURRENT TIME PRODUCT and PROCESS the X-ray image.

The test shall be performed at 90-degree intervals of the rotational position of the MAMMOGRAPHIC X-RAY EQUIPMENT (0º, ± 90º and 180º or as close as possible to the suggested angles).

203.6.7.103.4 Test evaluation

Compliance is achieved if no grid lines are visible in any of the test images.

203.6.7.104 Maximum LOADING TIME

203.6.7.104.1 Minimum AIR KERMA RATE

Requirements in this subclause apply to MAMMOGRAPHIC X-RAY EQUIPMENT without an integrated X-RAY IMAGE RECEPTOR, for the largest selectable FOCAL SPOT and an X-RAY TUBE VOLTAGE of 28 kV.

If molybdenum is used as material for the TARGET and for the EDGE FILTER, MAMMOGRAPHIC X-RAY EQUIPMENT shall be capable of producing a minimum AIR KERMA RATE of 7,0 $mGys^{-1}$ at any DIRECT FOCAL DISTANCE within the INTENDED USE. For other combinations of TARGET and edge FILTER the minimum AIR KERMA RATES shall be determined by applying the factors given in table 203.101. The MAMMOGRAPHIC X-RAY EQUIPMENT shall be capable of maintaining the required minimum AIR KERMA RATE for a LOADING TIME of at least 3 s.

Table 203.101 – Minimum values of TOTAL FILTRATION and factors for determining the minimum AIR KERMA RATE

TARGET/ EDGE FILTER	Mo/ Mo	Mo/ Rh	W/ Mo	W/ Rh	Rh/ Rh
Minimum TOTAL FILTRATION	30 μm Mo	25 μm Rh	60 μm Mo	50 μm Rh	25 μm Rh
Factor	1,0	0,86	0,41	0,38	0,58
NOTE Each factor is given as the ratio between typical specific X-RADIATION output values (μGy/mAs) for the respective TARGET/FILTER combination and for the combination Mo/Mo, at an X-RAY TUBE VOLTAGE of 28 kV.					

Test arrangement:

Arrange the X-RAY SOURCE ASSEMBLY, the DIAPHRAGM and the RADIATION DETECTOR for measurement under NARROW BEAM CONDITION without the compression plate. Ensure that the RADIATION QUALITY of the X-RAY BEAM emerging from the X-RAY SOURCE ASSEMBLY complies with applicable specified conditions for NORMAL USE. If no such conditions are specified, ensure that the TOTAL FILTRATION in the X-RAY SOURCE ASSEMBLY is such as to comply with IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013 as applicable. Measure the AIR KERMA at a point 40 mm above the PATIENT SUPPORT and 60 mm from the chest wall side on the centre line.

Compliance is checked by tests.

203.6.7.104.2 Maximum LOADING TIME using a typical MODE OF OPERATION

Requirements in this subclause apply to non-scanning MAMMOGRAPHIC X-RAY EQUIPMENT with an integrated X-RAY IMAGE RECEPTOR.

The LOADING TIME on an average 45 mm compressed breast in NORMAL USE shall be not more than 2 s when the large FOCAL SPOT is used.

Compliance is checked by the following test:

– *Use a 40 mm thick rectangular Polymethylmethacrylate (PMMA) PHANTOM (the PHANTOM may be fabricated from layers of material) with sides equal to or exceeding 150 mm.*

– *Position the PHANTOM on the PATIENT SUPPORT.*

– *Perform an exposure using the same procedure as prescribed for an average 45 mm compressed breast.*

– *Measure the LOADING TIME.*

203.7 RADIATION QUALITY

203.7.1 HALF-VALUE LAYERS and TOTAL FILTRATION in X-RAY EQUIPMENT

Replacement:

The RADIATION QUALITY of the X-RAY BEAM provided by the X-RAY EQUIPMENT shall be appropriate for producing the intended images without administering unnecessarily high doses to the PATIENT.

The TOTAL FILTRATION in the beam needs to be sufficient in order to achieve the preceding goal. Requirements for minimum FILTRATION are given here in terms of total QUALITY EQUIVALENT FILTRATION or of the first HALF-VALUE LAYER for specified X-RAY TUBE VOLTAGE.

In MAMMOGRAPHIC X-RAY EQUIPMENT, for all configurations available in NORMAL USE and for all combinations of TARGET and FILTER materials given in Table 203.101, the TOTAL FILTRATION shall not be less than the value given in Table 203.101 for the respective EDGE FILTER.

For combinations of TARGET and FILTER materials not given in Table 203.101, the TOTAL FILTRATION shall be high enough so that the first HALF-VALUE LAYER (expressed in mm of aluminum) attained in the X-RAY BEAM incident on the PATIENT, excluding the material of any compression plate, is not less than the value of the high voltage (expressed in kV) divided by 100, for all configurations available in NORMAL USE.

The material of any compression plate is not included in the TOTAL FILTRATION.

Addition:

203.7.1.101 Unfiltered IRRADIATION prevention

If an X-RAY SOURCE ASSEMBLY includes selectable ADDED FILTERS, means shall be provided to prevent IRRADIATION in absence of the appropriate ADDED FILTER.

203.7.3 Indication of FILTER properties

Addition:

Alternative to the marking of X-RAY TUBE ASSEMBLIES required in subclause 7.3 of IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013, the FILTER properties of X-RAY TUBE ASSEMBLIES may be provided in the ACCOMPANYING DOCUMENTS when a single type of X-RAY

TUBE ASSEMBLY can be fitted on the equipment or when the X-RAY TUBE ASSEMBLY is not accessible in NORMAL USE.

203.7.6 Test for HALF-VALUE LAYER

Replacement:

For X-RAY EQUIPMENT specified exclusively for mammography, ensure that the compression plate is not in the X-RAY BEAM during the determination of the HALF-VALUE LAYER.

NOTE The exclusion of the compression plate from the measurement is not in contradiction with 7.6 of IEC 60601-1-3 because MAMMOGRAPHIC X-RAY EQUIPMENT usually includes perforated compression plates for breast biopsy.

For each ADDED FILTER specified as necessary to attain the requirements for TOTAL FILTRATION in the MAMMOGRAPHIC X-RAY EQUIPMENT, given in 203.7.1, measure the first HALF-VALUE LAYER under NARROW BEAM CONDITIONS with the MAMMOGRAPHIC X-RAY EQUIPMENT operating at

– *minimum selectable value of X-RAY TUBE VOLTAGE;*
– *one typical intermediate value of X-RAY TUBE VOLTAGE specified as representative of the INTENDED USE,*

using LOADING FACTORS corresponding to the range of NORMAL USE.

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

Addition:

In non-magnification mode the X-RAY FIELD

a) shall not extend more than 2 mm beyond the edge of the PATIENT SUPPORT that is designed to be adjacent to the chest wall of the PATIENT,
b) for non-scanning MAMMOGRAPHIC X-RAY EQUIPMENT, shall extend beyond the edge of the EFFECTIVE IMAGE RECEPTION AREA that is designed to be adjacent to the chest wall of the PATIENT,
c) for non-scanning MAMMOGRAPHIC X-RAY EQUIPMENT, shall not extend by more than 2 % of the DIRECT FOCAL DISTANCE beyond all other edges of the EFFECTIVE IMAGE RECEPTION AREA. For MAMMOGRAPHIC TOMOSYNTHESIS this requirement is excluded.

In this particular standard, the boundary of an X-RAY FIELD is described by the locus of points at which the AIR KERMA RATE is 25 % of the mean of the AIR KERMA RATES at the approximate centres of the quarters of the area enclosed.

For MAMMOGRAPHIC X-RAY EQUIPMENT based on scanning that varies the position for receiving an X-RAY PATTERN during the exposure, the total area, that is being imaged, is to be used instead of the EFFECTIVE IMAGE RECEPTION AREA.

203.8.5.4 Positioning of the PATIENT and restriction of the irradiated area

Addition:

ME EQUIPMENT shall be equipped with a LIGHT FIELD INDICATOR.

For non-scanning MAMMOGRAPHIC X-RAY EQUIPMENT, the LIGHT FIELD shall be aligned with the X-RAY FIELD so that the misalignment of the edges of the LIGHT FIELD and the X-RAY FIELD along either the length or the width of the visually defined field at the plane of the breast support surface does not exceed 2 % of the DIRECT FOCAL DISTANCE.

203.8.5.4.101 *Missed tissue at chest wall side

203.8.5.4.101.1 Requirement

In non-magnification mode the maximum distance between the edge of the IMAGE RECEPTION AREA that is designed to be adjacent to the chest wall of the PATIENT and the adjacent edge of the PATIENT SUPPORT, when projected on the PATIENT SUPPORT, shall be smaller than 5 mm.

203.8.5.4.101.2 Test method

Position a TEST DEVICE on the PATIENT SUPPORT; this TEST DEVICE shall include test objects in contact with the PATIENT SUPPORT and allow measurement of distances from the chest wall edge of the PATIENT SUPPORT in the resulting radiograms with a precision of 0,5 mm over a length of 6 mm or more. This TEST DEVICE shall include means to position it repeatedly relative to the edge of the PATIENT SUPPORT.

Make a radiogram of the TEST DEVICE.

On the radiogram, measure the distance from the edge of the PATIENT SUPPORT to the edge of the IMAGE RECEPTION AREA.

For MAMMOGRAPHIC X-RAY EQUIPMENT with non-integrated X-RAY IMAGE RECEPTORS, the test shall be repeated 5 times, including repositioning the TEST DEVICE, to identify the largest value. The largest value shall be kept as the final one.

Compliance is checked by the appropriate test.

203.8.5.4.102 BREAST COMPRESSION DEVICE

203.8.5.4.102.1 General

All MAMMOGRAPHIC X-RAY EQUIPMENT shall be fitted with a power-driven BREAST COMPRESSION DEVICE.

203.8.5.4.102.2 Control of compression movements

All switches controlling movement for the application of compression shall be of the type requiring continuous actuation while movement takes place.

The X-RAY EQUIPMENT shall

– provide means for hands-free,(e.g. foot), control of the power-driven compression accessible from both sides of the position of the PATIENT;

– include means for fine adjustment of the compression force accessible from both sides of the position of the PATIENT and;

– provide means for the OPERATOR to prevent automatic decompression.

In the event of interruption of SUPPLY MAINS during biopsy or marking operations, the compression shall be maintained. However, means shall be provided for manually achieving complete decompression.

203.8.5.4.102.3 Range of movement

In all conditions of NORMAL USE, the available range of movement of the BREAST COMPRESSION DEVICE shall allow all those parts of the compression plate that are designed to be in contact with the breast to be brought within 10 mm of the surface of the PATIENT SUPPORT.

NOTE This requirement is intended to ensure that adequate compression of small or thin breasts is not prevented by limitation of the available movement of the compression plate. The extent of compression applied to any particular PATIENT is controlled by the OPERATOR and may be limited by restriction of the available operating force; see 203.8.5.4.102.6.

203.8.5.4.102.4 Design of compression plates

Compression plates intended for special purposes are not subject to the requirements of this subclause.

Compression plates matching the sizes of all breast supports shall be provided.

Compression plates shall be transparent so that the skin of the PATIENT remains visible when in contact with them.

When predefined AEC sensor positions are provided and when other means for indication are not provided, the MAMMOGRAPHIC X-RAY EQUIPMENT shall include at least one compression plate for each X-RAY IMAGE RECEPTOR format used in an AUTOMATIC EXPOSURE CONTROL mode marked to indicate the range of sensor positions available in NORMAL USE.

The edge of the compression plate intended to be in contact with the chest wall of the PATIENT shall not extend beyond the chest wall edge of the EFFECTIVE IMAGE RECEPTION AREA by more than one percent of the DIRECT FOCAL DISTANCE when the compression plate is placed 45 mm above the surface of the breast support.

No image of this edge of the compression plate shall be visible.

203.8.5.4.102.5 Strength of compression plates

Compression plates and their mountings, unless marked to indicate the maximum compression force permitted to be applied, shall withstand the maximum compression force attainable when they are fitted to ME EQUIPMENT. The marking may take the form of coding related to an explanation in the instructions for use.

Compliance is determined by the following test:

a) Test equipment

The following test equipment is required:

– *appropriately sized objects, one for each X-RAY IMAGE RECEPTOR format, leading to sufficiently realistic force distributions when under compression. E.g., the objects can be sand-filled bags or soft rubber blocks. Their thickness shall be in the range from 20 mm to 50 mm. The objects shall be 100 mm to 120 mm long and wide for the smallest X-RAY IMAGE RECEPTOR format and 120 mm to 150 mm long and wide for larger formats.*

b) Test procedure

Position the MAMMOGRAPHIC X-RAY EQUIPMENT to acquire a cranio-caudal projection of the breast. Mount a compression plate. Take the test object designed for the same X-RAY IMAGE RECEPTOR format as the compression plate and place it on the PATIENT SUPPORT, centred laterally, and with one edge as close as possible to that edge of the PATIENT SUPPORT that is provided to be adjacent to the PATIENT'S chest wall. If the object is a sand-filled bag, shape it by hand to maximize the surface areas that will be in contact with the PATIENT SUPPORT and the compression plate.

Actuate the BREAST COMPRESSION DEVICE to the maximum attainable compression force or to the maximum compression force permitted to be applied to the plate. Then relax the force. Repeat the test for all compression plates.

c) Interpretation of test results

Inspect the compression plates and associated parts for any signs of damage, especially for fissures. For compliance, the compression plates and associated parts are to be free from breakage, visible damage and permanent distortion.

203.8.5.4.102.6 Compression force

BREAST COMPRESSION DEVICES shall satisfy the following requirements in respect of the application and indication of the compression force in all orientations specified for NORMAL USE:

– no BREAST COMPRESSION DEVICE shall be able to apply a force exceeding 300 N;

– for power-driven compression, the BREAST COMPRESSION DEVICE shall be able to apply a force of at least 150 N, and it shall be unable to apply a force exceeding 200 N;

NOTE Equipment configurations that limit the maximum power-driven compression force to less than 150N in clinical use are permissible. See following bullet.

– for power-driven compression, the available operating force shall be adjustable down to 70 N or less;

– if the value of the applied force is displayed, the indication shall be accurate to ± 20 N.

Compliance is checked by measurement.

a) Test equipment

The following test equipment is required:

– *a force balance;*

– *a soft rubber block, 20 mm to 50 mm thick, and 100 mm to 120 mm long and wide.*

b) Test procedure

Position the MAMMOGRAPHIC X-RAY EQUIPMENT to acquire a cranio-caudal projection of the breast. Fix the force balance onto the PATIENT SUPPORT so that it will remain secure in any orientation of the MAMMOGRAPHIC X-RAY EQUIPMENT. Place the soft rubber block on the sensitive area of the force balance. Operate the BREAST COMPRESSION DEVICE, thus clamping the soft rubber block, and record the reading of the balance. Measure the highest achievable forces for all compression modes. If the force is displayed at the X-RAY EQUIPMENT then perform at least five additional measurements for lower compression forces, equally distributed over the range from zero compression to the maximum attainable compression force and record all displayed values in combination with the readings of the balance. Repeat the test procedure for at least three other orientations of the MAMMOGRAPHIC X-RAY EQUIPMENT in order to cover sufficiently the whole range of angles possible with the X-RAY EQUIPMENT.

c) Interpretation of measured data

Determine compliance by comparing MEASURED VALUES with required values and, if the compression force is displayed, with the above requirements for accuracy.

203.9 FOCAL SPOT TO SKIN DISTANCE

Replacement:

The FOCAL SPOT TO SKIN DISTANCES in NORMAL USE shall be sufficiently large to keep the RADIATION dose to the PATIENT as low as reasonably achievable. This is obtained by compliance with the following requirements.

Except when a MAMMOGRAPHIC STEREOTACTIC DEVICE is used, the DIRECT FOCAL DISTANCE shall be at least 600 mm.

The magnification factor in the plane of the PATIENT SUPPORT to be used for geometric magnification shall not exceed 2.

Compliance is checked by measurement.

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

203.10.1 General

Addition:

The ATTENUATION EQUIVALENT of the total of all layers of the breast support located in the path of the X-RAY BEAM between the breast and the X-RAY IMAGE RECEPTOR shall not exceed 0,3 mm Al when measured perpendicular to these layers.

This requirement does not apply to protective layers of X-RAY IMAGE RECEPTORS, to radiographic cassettes, and to ANTI-SCATTER GRIDS.

Compliance is checked by measurement. Determine the ATTENUATION EQUIVALENT as the thickness of aluminium that gives the same degree of attenuation as the breast support, from measurements of AIR KERMA under NARROW BEAM CONDITION. Use an X-RAY TUBE VOLTAGE of approximately 30 kV, a ripple of not more than 10%, and a first HALF-VALUE LAYER of 0,3 mm +/- 0,01 mm Al.

203.11 Protection against RESIDUAL RADIATION

Additional subclause:

203.11.101 Additional requirements for protection against RESIDUAL RADIATION

MAMMOGRAPHIC X-RAY EQUIPMENT shall be provided with PRIMARY PROTECTIVE SHIELDING in accordance with the requirements below. These requirements shall be met for all combinations of X-RAY FIELDS, DIRECT FOCAL DISTANCES, LOADING FACTORS and FILTRATION in NORMAL USE.

The PRIMARY PROTECTIVE SHIELDING shall extend at least to the projection of the PATIENT SUPPORT at the edge designed to be adjacent to the PATIENT'S chest wall and at the other edges shall extend beyond the X-RAY FIELD by at least 1 % of the DIRECT FOCAL DISTANCE.

The RESIDUAL RADIATION behind the X-RAY IMAGE RECEPTOR supporting device shall not exceed an AIR KERMA of 1,0 μGy per IRRADIATION.

Compliance is checked by visual inspection and by the following measurement.

The AIR KERMA measurement shall be averaged over a detection area that is 100 cm^2, of which no linear dimension is greater than 200 mm, centred at 50 mm from any ACCESSIBLE SURFACE beyond the X-RAY IMAGE RECEPTOR supporting device. Fit shielding in the plane of the PATIENT SUPPORT as necessary ~~in the region outside the PRIMARY PROTECTIVE SHIELDING~~ to exclude from the measurement any X-RADIATION not transmitted through the PRIMARY PROTECTIVE SHIELDING. ~~The measurements relate to the plane of the X-RAY IMAGE RECEPTOR.~~ For MAMMOGRAPHIC TOMOSYNTHESIS mode of operation, the test shall be performed using a tomosynthesis sweep. It shall be tested for all available tomosynthesis configurations.

The reference X-RAY TUBE VOLTAGE for compliance shall be the NOMINAL X-RAY TUBE VOLTAGE.

The reference LOADING FACTORS for compliance shall be those corresponding to the maximum energy input in a single LOADING according to the RADIOGRAPHIC RATINGS.

If the maximum energy input in a single LOADING according to the RADIOGRAPHIC RATINGS cannot be obtained at the NOMINAL X-RAY TUBE VOLTAGE, the worst case of combinations of the LOADING FACTORS and FILTRATION shall be determined and used.

If LOADING FACTORS can be controlled only by an AUTOMATIC CONTROL SYSTEM, the ACCOMPANYING DOCUMENTS shall include instructions for obtaining appropriate LOADING FACTORS for test.

Compliance is checked by inspection of the test results and by examination of the design documentation and ACCOMPANYING DOCUMENTS.

203.13 Protection against STRAY RADIATION

Additional subclause:

203.13.101 PROTECTIVE BARRIER

MAMMOGRAPHIC X-RAY EQUIPMENT for which a SIGNIFICANT ZONE OF OCCUPANCY is designated shall have a PROTECTIVE BARRIER which is designed to be placed between the SIGNIFICANT ZONE OF OCCUPANCY and the region of the PATIENT SUPPORT. The PROTECTIVE BARRIER shall not prevent the OPERATOR from observing the PATIENT during the acquisition of mammograms. It shall extend from not more than 150 mm above the floor to a height of not less than 185 cm, and its width shall not be less than 60 cm.

NOTE The height of a SIGNIFICANT ZONE OF OCCUPANCY as specified in IEC 60601-1-3 does not necessarily imply that the PROTECTIVE BARRIER as specified in this standard has the same height.

With an emitting TARGET of molybdenum, an X-RAY TUBE VOLTAGE of 35 kV with a percentage ripple of not more than 4 and a TOTAL FILTRATION of 0,03 mm molybdenum, the ATTENUATION EQUIVALENT of this PROTECTIVE BARRIER shall not be less than 0,08 mm of lead.

The PROTECTIVE BARRIER shall be permanently marked with its ATTENUATION EQUIVALENT with reference to this standard.

Annex AA
(informative)

Particular guidance and rationale

AA.1 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclauses in this particular standard, with clause and subclause numbers parallel to those in the body of the document.

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 201.4.3.101 – Additional ESSENTIAL PERFORMANCE requirements

The identification of ESSENTIAL PERFORMANCE requirements has been justified by the fact that the RISK associated with ionizing X-RADIATION used to generate mammographic images should be compensated by the benefit expected from the procedure (e.g., breast screening).

This particular standard takes care by adequate requirements that the imaging performance of MAMMOGRAPHIC X-RAY EQUIPMENT complies with the technically and economically viable state of the art to produce images of sufficient quality in NORMAL CONDITIONS.

This imaging performance may be made single fault safe (e.g., against undetected degradation) by adequate maintenance procedures (including acceptance and constancy testing) for the installed equipment.

Consequently requirements that have not been identified as BASIC SAFETY are listed in table 201.101.

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.

Subclause 201.9.2.101 – ~~MAMMOGRAPHIC STEREOTACTIC DEVICE~~ Three dimensional localization and interventional mammographic guidance

Accurate positioning of the X-RAY SOURCE ASSEMBLY is required to ensure the positioning accuracy of the biopsy needle.

Stability of the COMPRESSION DEVICE and PATIENT SUPPORT are necessary to ensure the positioning accuracy of the biopsy needle and PATIENT safety.

The RISK associated with this subclause strongly depends on the construction details of the ME EQUIPMENT under consideration and is subject to the RISK MANAGEMENT PROCESS of the MANUFACTURER.

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

Subclause 203.4.101.2 – LOADING TIME

The first paragraph gives the specified method for the measurement of the loading time according to IEC 60601-1-3. The 2nd and 3rd paragraph are the respective tests for the technical implementations of x-ray generator designs. Technical designs not covered by the second or third paragraph are subject to the 4th paragraph.

Subclause 203.6.7.4.2.3 – Replacement of data originating from DEFECTIVE DETECTOR ELEMENTS

For MAMMOGRAPHIC X-RAY EQUIPMENT with an integrated digital detector, quality control is used to verify the systems compliance with the MANUFACTURER'S specification. It is the RESPONSIBLE ORGANISATION'S task to perform this quality control.

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

Since the first edition of IEC 60601-1-3, it has been required that the X-RAY FIELD extends to the edge of the PATIENT SUPPORT, and a 5 mm extension beyond that edge has been allowed. This subclause was justified by the fact that the capability to cover the film fully up to its very edge was then given special attention when considering limitation of excessive IRRADIATION. The benefit was to ensure complete blackening of the film near the edge adjacent to the chest wall of the PATIENT, essential for good viewing conditions, thus increasing the imaged area towards the chest wall where some pathologies may reside.

This new requirement helps to satisfy Clause 11, protection against RESIDUAL RADIATION, of IEC 60601-1-3:2008 by preventing parts of the PATIENT other than from those being currently imaged, to be reached by direct unattenuated X-RADIATION (e.g., on both sides of the breast), and therefore gives full effectiveness to 203.11.101 of this standard.

Because it is technically difficult to achieve no X-RADIATION beyond the PATIENT SUPPORT, a 2 mm tolerance is permitted.

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

[1] IEC 60417, *Graphical symbols for use on equipment*

[2] IEC 60601-2-7:1998, *Medical electrical equipment – Part 2-7: Particular requirements for the safety of high voltage generators of diagnostic X-ray generators*

[3] IEC 60601-2-28:1993, *Medical electrical equipment – Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis* (withdrawn).

[4] IEC 60601-2-28:2010, *Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis*

[5] IEC 60601-2-32:1994, *Medical electrical equipment – Part 2: Particular requirements for the safety of associated equipment of X-ray equipment*

[6] IEC 60664-1:2007, *Insulation coordination for equipment within low-voltage systems – Part 1: Principles, requirements and tests*

[7] ISO 4090:2001, *Photography – Medical radiographic cassettes/screens/films and hard-copy imaging films – Dimensions and specifications*

[8] ISO 7000:2004, *Graphical symbols for use on equipment – Index and synopsis*

[9] ISO 9236-3:1999, *Photography – Sensitometry of screen/film systems for medical radiography – Part 3: Determination of sensitometric curve shape, speed and average gradient for mammography*

[10] ISO 12052, *Health informatics – Digital imaging and communication in medicine (DICOM) including workflow and data management*

[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*

Index of defined terms used in this particular standard

NOTE 1 In the present document only terms defined either in IEC 60601-1:2005, its collateral standards, in IEC/TR 60788:2004 or in Clause 201.3 of this particular standard were used.

PIXEL ..... IEC/TR 60788:2004, rm-32-60
PRIMARY PROTECTIVE SHIELDING ..... IEC 60601-1-3:2008, 3.47
PROCESS ..... IEC 60601-1:2005/AMD1:2012, 3.89
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IEC 60601-2-45

Edition 3.1 2015-06

FINAL VERSION

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 60000:2000-00+AMDX:2015-01 CSV(EN)

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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

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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DISCLAIMER
This Consolidated version is not an official IEC Standard and has been prepared for user convenience. Only the current versions of the standard and its amendment(s) are to be considered the official documents.

This Consolidated version of IEC 60601-2-45 bears the edition number 3.1. It consists of the third edition (2011-02) [documents 62B/817/FDIS and 62B/821/RVD] and its amendment 1 (2015-06) [documents 62B/917/CDV and 62B/954/RVC]. The technical content is identical to the base edition and its amendment.

This Final version does not show where the technical content is modified by amendment 1. A separate Redline version with all changes highlighted is available in this publication.

International standard IEC 60601-2-45 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published in 2001. This edition constitutes a technical revision. The document has been aligned to the 3rd edition of IEC 60601-1 (2005) and to IEC 60601-1-3 (2008). Further modifications have been made with respect to the current technology of MAMMOGRAPHIC X-RAY EQUIPMENT.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

– Requirements and definitions: roman type.
– *Test specifications: italic 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 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g., Clause 7 includes subclauses 7.1, 7.2, etc.);
– “subclause” means a numbered subdivision of a clause (e.g., 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” , so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title: *Medical electrical equipment*, can be found on the IEC website

The committee has decided that the contents of the base publication and its amendment 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.

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

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 (3rd edition) and its collaterals. This particular standard addresses the system level of MAMMOGRAPHIC X-RAY EQUIPMENT, which consists of a combination of an X-RAY GENERATOR, associated equipment and ACCESSORIES. Components functions are addressed as far as necessary.

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of MAMMOGRAPHIC X-RAY EQUIPMENT.

Like the previous edition of this Part 2-45, the present third edition includes requirements on HIGH-VOLTAGE GENERATORS for mammography.

INTRODUCTION to Amendment 1

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.

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of the general standard[1)] applies, except as follows:

201.1.1 Scope

Replacement:

This international standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MAMMOGRAPHIC X-RAY EQUIPMENT, including equipment for MAMMOGRAPHIC TOMOSYNTHESIS, and MAMMOGRAPHIC STEREOTACTIC DEVICES, hereafter also referred to as ME EQUIPMENT.

NOTE 1 This includes MAMMOGRAPHIC X-RAY EQUIPMENT using integrated digital X-RAY IMAGE RECEPTORS or integrated storage phosphor subsystems.

Excluded from the scope of this document are:

– reconstructive tomography other than MAMMOGRAPHIC TOMOSYNTHESIS;
– CT SCANNERS covered by IEC 60601-2-44;
– diagnostic consoles;
– picture archiving and communication systems (PACS);
– non-integrated storage phosphor readers;
– hard copy cameras;
– films, screens and cassettes;
– computer aided detection (CAD);
– devices for performing core biopsy and other biopsy instruments;
– modes of operation intended to demonstrate local contrast medium uptake (contrast enhanced digital mammography);

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

NOTE 2 IEC 60601-2-7:1998 and IEC 60601-2-32 are not part of the 3rd edition scheme for MAMMOGRAPHIC X-RAY EQUIPMENT and MAMMOGRAPHIC STEREOTACTIC DEVICES.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for MAMMOGRAPHIC X-RAY EQUIPMENT and MAMMOGRAPHIC

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1) The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

STEREOTACTIC DEVICES, to ensure safety, to specify methods for demonstrating compliance with those requirements and to provide guidance for RISK MANAGEMENT.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2:2014 and IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013 apply as modified in Clauses 202 and 203, respectively. IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 do not apply[2)]. All other published collateral standards in the IEC 60601-1-X series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard or a collateral standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g., 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g., 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

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2) 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.*

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g., 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding, clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 49.

Clause 2 of the general standard applies, except as follows:

Replacement:

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

Addition:

IEC 60336:2005, *Medical electrical equipment – X-ray tube assemblies for medical diagnosis – Characteristics of focal spots*

IEC 60613:2010, *Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis*

IEC 60788:2004, *Medical electrical equipment – Glossary of defined terms*

IEC 62220-1-2:2007, *Medical electrical equipment – Characteristics of digital X-ray imaging devices – Part 1-2: Determination of the detective quantum efficiency – Detectors used in mammography*

ISO 9236-3:1999, *Photography – Sensitometry of screen/film systems for medical radiography – Part 3: Determination of sensitometric curve shape, speed and average gradient for mammography*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013, and IEC/TR 60788:2004 apply, except as follows:

NOTE An index of defined terms is found beginning on page 49.

Addition:

201.3.201
APPARENT RESISTANCE OF SUPPLY MAINS
resistance of the SUPPLY MAINS determined under specific load conditions

201.3.202
AVERAGE GLANDULAR DOSE
AGD
<X-ray mammography> average absorbed dose in the glandular tissue (excluding skin) in a uniformly compressed breast of known tissue composition, using a specified calculation method

[IEC 61223-3-2:2007, definition 3.7]

NOTE The terms "AVERAGE GLANDULAR DOSE" and "mean glandular dose" are interchangeable according to literature use.

201.3.203
BREAST COMPRESSION DEVICE
device used to exert pressure upon the breast of a PATIENT during either examination or treatment

201.3.204
DEFECTIVE DETECTOR ELEMENT
element of an X-RAY IMAGE RECEPTOR whose response is out of acceptable tolerance, such as when output is independent of the entrance AIR KERMA, or there is an excessive NOISE level

201.3.205
DIRECT FOCAL DISTANCE
<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**
device for mechanically guided placement of a needle or position marker based on radiographic images of an immobilized breast acquired at different known angles

NOTE 1 Such a device may be a dedicated system or an ACCESSORY for MAMMOGRAPHIC X-RAY EQUIPMENT.

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

201.3.207
MAMMOGRAPHIC X-RAY EQUIPMENT
X-RAY EQUIPMENT where the INTENDED USE is breast imaging

201.3.208
ORIGINAL DATA
DN
RAW DATA to which the corrections allowed in this standard have been applied

[IEC 62220-1-2:2007, definition 3.11]

NOTE Here “this standard” is to be understood in the context of IEC 62220-1-2:2007.

201.3.209
RAW DATA
PIXEL values read directly after the analogue-digital-conversion from the digital X-ray imaging device or counts from photon counting systems without any software corrections

[IEC 62220-1-2:2007, definition 3.13]

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

Clause 4 of the general standard applies, except as follows:

201.4.3 ESSENTIAL PERFORMANCE

Addition:

201.4.3.101 *Additional ESSENTIAL PERFORMANCE requirements

Additional ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in Table 201.101.

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Accuracy of LOADING FACTORS	203.6.4.3.102
AUTOMATIC CONTROL SYSTEM	203.6.5
Imaging performance	203.6.7
Missed tissue at chest wall side	203.8.5.4.101
BREAST COMPRESSION DEVICE	203.8.5.4.102
Linearity of AIR KERMA over limited intervals of LOADING FACTORS	203.6.3.1.2
Reproducibility of the X-RADIATION output	203.6.3.2

201.4.10.2 SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS

Addition:

The internal impedance of SUPPLY MAINS is to be considered sufficiently low for the operation of MAMMOGRAPHIC X-RAY EQUIPMENT if the value of the APPARENT RESISTANCE OF SUPPLY MAINS does not exceed the value specified in the ACCOMPANYING DOCUMENTS.

The required APPARENT RESISTANCE OF SUPPLY MAINS and other appropriate SUPPLY MAINS requirements shall be provided in the ACCOMPANYING DOCUMENTS.

MAMMOGRAPHIC X-RAY EQUIPMENT is considered to comply with the requirements of this standard only if its specified NOMINAL electric power can be demonstrated at an APPARENT RESISTANCE OF SUPPLY MAINS having a value not less than that specified by the MANUFACTURER in the ACCOMPANYING DOCUMENTS.

NOTE If a NOMINAL voltage is claimed for a mains power supply system, it is assumed that there is no voltage of a higher value between any of the conductors of the system or between any of these conductors and earth.

An alternating voltage is considered in practice to be sinusoidal if any instantaneous value of the waveform concerned differs from the instantaneous value of the ideal waveform at the same moment by no more than ± 2 % of the peak value of the ideal waveform.

Three-phase SUPPLY MAINS are considered to have a practical symmetry if it delivers symmetrical voltages and produces, when loaded symmetrically, symmetrical currents.

The requirements of this standard are based upon the assumption that three-phase systems have a symmetrical configuration of the MAINS VOLTAGE with respect to earth. Single-phase systems may be derived from such three-phase systems. Where the supply system is not earthed at the source, it is assumed that adequate measures have been provided to detect, limit and remedy any disturbance of symmetry within a reasonably short time.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

Additional subclause:

201.4.101 Data recording

Means shall be incorporated into the ME EQUIPMENT to record the following information with the image when acquired with an integrated digital X-RAY IMAGE RECEPTOR,:

– identity of the PATIENT (at least name and date of birth);
– positioning information (left/right breast, angulations, PATIENT positioning);
– acquisition parameters;
– place and date of the image acquisition;
– 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.

When transferring any of the above noted information as image data, it is recommended to use the objects identified in the DICOM standard (ISO 12052).

The instructions for use shall give appropriate guidance to the OPERATOR.

Compliance is checked by inspection.

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

201.6.2 Protection against electrical shock

Replacement:

MAMMOGRAPHIC X-RAY EQUIPMENT shall be CLASS I ME EQUIPMENT or INTERNALLY POWERED equipment.

If MAMMOGRAPHIC X-RAY EQUIPMENT is classified as INTERNALLY POWERED ME EQUIPMENT, the related clauses of the general standard apply and the RISK MANAGEMENT is to be provided accordingly.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

201.7.2.6 Connection to the SUPPLY MAINS

Addition:

For MAMMOGRAPHIC X-RAY EQUIPMENT that is specified to be PERMANENTLY INSTALLED, the information required in 7.2.6 of the general standard may be stated in the ACCOMPANYING DOCUMENTS only.

201.7.2.7 Electrical input power from the SUPPLY MAINS

Addition:

For MAMMOGRAPHIC X-RAY EQUIPMENT that is intended to be PERMANENTLY INSTALLED, the information required in 7.2.7 of the general standard may be stated in the ACCOMPANYING DOCUMENTS only.

The information on the input power shall be specified in terms of combinations of

a) the rated MAINS VOLTAGE of the ME EQUIPMENT in volts; see 7.2.1 and 7.2.6 of the general standard,
b) the number of phases; see 7.2.1 and 7.2.6 of the general standard,
c) the frequency, in hertz; see 7.2.1 and 7.2.6 of the general standard,
d) the maximum permissible value for APPARENT RESISTANCE OF SUPPLY MAINS, in ohms;
e) the characteristics of over-current releases required in the SUPPLY MAINS.

NOTE These requirements are adapted from IEC 60601-2-7:1998, subclause 6.1j).

201.7.2.15 Cooling conditions

Addition:

If cooling is necessary for safe operation of ME EQUIPMENT, or a subassembly thereof, the cooling requirements shall be indicated in the ACCOMPANYING DOCUMENTS, including as appropriate:

– the maximum heat dissipation into the surrounding air, given separately for each subassembly that dissipates more than 100 W and might be separately located on installation;

– the maximum heat dissipation into forced air cooling devices, and the corresponding flow rate and temperature rise of the forced air stream;

– the maximum heat dissipation into a cooling medium utility and the permissible input temperature range, minimum flow rate and pressure requirements for the utility.

Additional subclause:

201.7.2.101 BEAM LIMITING DEVICE

BEAM LIMITING DEVICES shall be provided with the following markings:

– those required in 7.2.2 of the general standard;

– serial designation or individual identification;

– PERMANENT FILTRATION in terms of QUALITY EQUIVALENT FILTRATION.

The markings on the BEAM LIMITING DEVICE may be hidden by covers in NORMAL USE. In this case the marking for PERMANENT FILTRATION shall be repeated in the ACCOMPANYING DOCUMENTS.

NOTE The BEAM LIMITING DEVICE is not in the scope of IEC 60601-2-28:2010. Therefore these requirements have been adapted from IEC 60601-2-28:1993 subclause 6.1.

201.7.8 Indicator lights and controls

Additional subclauses:

201.7.8.101 Indication of X-ray related states

The indication of X-ray related states shall be excluded from 7.8 in the general standard.

Subclause 203.6.4.2 shall apply instead.

201.7.8.102 Alternate visual indication means

Alternate unambiguous visual indication means may be used instead of indicator lights. Alternate unambiguous visual indication means may use indicator lights of red, yellow, and green colour.

These means shall be explained in the instructions for use.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.1 General

Addition:

The ACCOMPANYING DOCUMENTS shall state the dimensions and locations of all available EFFECTIVE IMAGE RECEPTION AREAS.

For MAMMOGRAPHIC X-RAY EQUIPMENT the ACCOMPANYING DOCUMENTS shall contain quality control procedures to be performed on the MAMMOGRAPHIC X-RAY EQUIPMENT by the RESPONSIBLE ORGANISATION. These shall include acceptance criteria and frequency for the tests.

The performance of means required to present the images for diagnostic purpose shall be stated in the ACCOMPANYING DOCUMENTS.

NOTE Examples of such means are image display devices or hard copy cameras.

Additionally for MAMMOGRAPHIC X-RAY EQUIPMENT provided with an integrated digital X-RAY IMAGE RECEPTOR, the ACCOMPANYING DOCUMENTS shall contain:

– a description of the file transfer format of the images acquired with this unit and of any data associated with these images;
– identification of the version of image processing applied to ORIGINAL DATA.

Information displayed on the user interface may be considered to satisfy the second requirement above.

The ACCOMPANYING DOCUMENTS of any MAMMOGRAPHIC STEREOTACTIC DEVICE designed as an ACCESSORY for MAMMOGRAPHIC X-RAY EQUIPMENT shall contain:

– at least one MODEL OR TYPE REFERENCE to MAMMOGRAPHIC X-RAY EQUIPMENT with which it is designed to operate;
– a reference to the relevant standards with which the MAMMOGRAPHIC STEREOTACTIC DEVICE complies.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

201.7.9.2 Instructions for use

201.7.9.2.1 General

Addition:

The instructions for use shall describe

– inspection and safe use of all compression plates that are provided with MAMMOGRAPHIC X-RAY EQUIPMENT,
– methods for determining and resolving problems with ARTEFACTS;
– for MAMMOGRAPHIC X-RAY EQUIPMENT provided with an integrated digital X-RAY IMAGE RECEPTOR,
  - particular handling and maintenance of X-RAY IMAGE RECEPTOR,
  - how to use the means required in 203.6.7.4.2 related to
    – DEFECTIVE DETECTOR ELEMENTS,
    – replacement of data originating from DEFECTIVE DETECTOR ELEMENTS,
    – image homogeneity problems;
  - the procedure for performing quality control of X-RAY IMAGE RECEPTOR;
  - requirements for image presentation.

Electric output data shall be stated in the instructions for use in terms of LOADING FACTORS as described below in items a) to j) of this subclause 201.7.9.2.1.

The following combinations and data shall be stated:

a) the NOMINAL X-RAY TUBE VOLTAGE and the highest X-RAY TUBE CURRENT available at that voltage;
b) the highest X-RAY TUBE CURRENT and the highest X-RAY TUBE VOLTAGE available at that current;

c) the corresponding combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT which results in the highest electric output power;

d) the NOMINAL electric power given as the highest constant electric output power in kilowatts which the X-RAY GENERATOR can deliver at an X-RAY TUBE VOLTAGE of 30 kV, for a LOADING TIME of 1 s, a CYCLE TIME of 1,0 minute and for an indefinite number of cycles, or if these values are not selectable, at an X-RAY TUBE VOLTAGE nearest to 30 kV, for a LOADING TIME nearest to but not less than 1 s and a CYCLE TIME of 1,0 minute and for an indefinite number of cycles.

NOTE 101 The limitation in the NOMINAL electric power may be caused by the HIGH-VOLTAGE GENERATOR, the X-RAY TUBE ASSEMBLY or other parts.

e) The NOMINAL electric power shall be given together with the combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT and the LOADING TIME;

NOTE 102 The values stated are only for characterising the equipment.

f) for MAMMOGRAPHIC X-RAY EQUIPMENT indicating pre-calculated or measured CURRENT TIME PRODUCT, the lowest CURRENT TIME PRODUCT or the combinations of LOADING FACTORS resulting in the lowest CURRENT TIME PRODUCT;

g) if the value of the lowest CURRENT TIME PRODUCT depends upon the X-RAY TUBE VOLTAGE or upon certain combinations of values of LOADING FACTORS, the lowest CURRENT TIME PRODUCT may be given as a table or curve showing the dependence;

h) for MAMMOGRAPHIC X-RAY EQUIPMENT provided with AUTOMATIC EXPOSURE CONTROL controlling the LOADING TIME, the shortest LOADING TIME and/or the lowest resulting CURRENT TIME PRODUCT;

i) if the X-RAY TUBE VOLTAGE or the X-RAY TUBE CURRENT in MAMMOGRAPHIC X-RAY EQUIPMENT is controlled by an AUTOMATIC EXPOSURE CONTROL, the range of the X-RAY TUBE VOLTAGE or the X-RAY TUBE CURRENT during the IRRADIATION shall be stated in the instructions for use;

j) if the shortest LOADING TIME depends upon LOADING FACTORS such as X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT, the ranges of these LOADING FACTORS for which the shortest LOADING TIME is valid shall be stated.

The instructions for use shall draw the attention of the RESPONSIBLE ORGANISATION to the need to restrict access to ME EQUIPMENT in accordance with local regulations for RADIATION PROTECTION.

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 Technical description

Additional subclauses:

201.7.9.3.101 Specification of X-RAY SOURCE ASSEMBLY and its position

The technical description of the integrated X-RAY SOURCE ASSEMBLIES shall specify the following:

a) specification of the REFERENCE AXIS to which the TARGET angle(s) and the FOCAL SPOT characteristics of the X-RAY TUBE of the X-RAY SOURCE ASSEMBLY refer;

b) TARGET angle(s) with respect to the specified REFERENCE AXIS;

c) position with tolerances of the FOCAL SPOTS on the REFERENCE AXIS;

d) NOMINAL FOCAL SPOT VALUE(S) determined according to IEC 60336 for the specified REFERENCE AXIS;

NOTE These requirements are adapted from IEC 60601-2-28:1993 subclause 6.8.3 dd).

e) possible values for DIRECT FOCAL DISTANCE and in MAMMOGRAPHIC TOMOSYNTHESIS, for specified positions of the source;

f) position of the intersection of the REFERENCE AXIS with the IMAGE RECEPTION AREA for a specified DIRECT FOCAL DISTANCE and in MAMMOGRAPHIC TOMOSYNTHESIS, for specified positions of the source;

g) angle of the REFERENCE AXIS to the plane of the IMAGE RECEPTION AREA and, in MAMMOGRAPHIC TOMOSYNTHESIS, for specified positions of the source.

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.

Additional paragraph:

201.7.9.101 Reference to ACCOMPANYING DOCUMENTS

The following subclauses of this standard contain additional requirements concerning the content of ACCOMPANYING DOCUMENTS:

201.4.10.2 ..... SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS
201.7.2.6 ..... Connection to the SUPPLY MAINS
201.7.2.7 ..... Electrical input power from the SUPPLY MAINS
201.7.2.15 ..... Cooling conditions
203.5.2 ..... ACCOMPANYING DOCUMENTS
203.6.2.1.101 ..... Connections of external interlocks
203.6.5 ..... AUTOMATIC CONTROL SYSTEM
203.6.7.4 ..... RADIATION DETECTOR or X-RAY IMAGE RECEPTOR
203.7.3 ..... Indication of FILTER properties
203.11.101 ..... Additional requirements for protection against RESIDUAL RADIATION

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

201.8.4 Limitation of voltage, current or energy

Additional subclauses:

201.8.4.101 HIGH-VOLTAGE CABLE CONNECTIONS

Detachable HIGH-VOLTAGE CABLE CONNECTIONS shall either be designed so that the use of tools is required to disconnect them or they shall be provided with interlocks so that at all times when protective covers or high-voltage connections are removed:

– the ME EQUIPMENT is disconnected from its power supply, and
– capacitances in the high-voltage circuit are discharged within the minimum time necessary to gain access to the high-voltage circuit, and
– the discharged state is maintained.

Compliance is checked by inspection and by measurement.

NOTE These requirements are adapted from IEC 60601-2-7:1998 subclause 15 aa).

201.8.4.102 Limitation of X-RAY TUBE VOLTAGE

ME EQUIPMENT shall be designed so as not to deliver in INTENDED USE, to any connected X-RAY TUBE ASSEMBLY, a voltage greater than the NOMINAL X-RAY TUBE VOLTAGE for the X-RAY TUBE

concerned or greater than the NOMINAL X-RAY TUBE VOLTAGE the X-RAY TUBE ASSEMBLY is designed for, whichever is the lower voltage.

NOTE These requirements are adapted from IEC 60601-2-7:1998 subclause 3.1.

201.8.5 Separation of parts

201.8.5.4 Working voltage

Addition:

201.8.5.4.101 Stator and stator circuit dielectric strength testing

The test voltage for the dielectric strength testing of stator and stator circuit used for the operation of the rotating anode of the X-RAY TUBE is to be referred to the voltage existing after reduction of the stator supply voltage to its steady state operating value.

NOTE These requirements are adapted from IEC 60601-2-7:1998 subclause 20.4 l).

201.8.6 Protective earthing, functional earthing and potential equalization of ME EQUIPMENT

Additional paragraphs:

201.8.6.101 X-RAY TUBE ASSEMBLY

Accessible high-voltage cables connecting the X-RAY TUBE ASSEMBLY to the HIGH-VOLTAGE GENERATOR shall incorporate a flexible conductive screen, having a resistance per unit length not exceeding 1 $\Omega\ m^{-1}$, and covered with a non-conductive material capable of protecting the screen against mechanical damage. The screen shall be connected to the protective earth conductive ENCLOSURE of the HIGH-VOLTAGE GENERATOR in low impedance.

Compliance is checked by visual inspection and by measurement.

201.8.6.102 X-RAY SOURCE ASSEMBLY

In all cases, there shall be electrical continuity between the screen of a fitted high-voltage cable and the accessible metal parts of its receptacle on the X-RAY SOURCE ASSEMBLY.

The flexible conductive screen is not to be recognized as satisfying a requirement for a protective earth connection between the devices connected by the cable.

Compliance is checked by visual inspection and by measurement.

201.8.7 LEAKAGE CURRENTS and PATIENT auxiliary currents

201.8.7.3 Allowable values

Addition:

The allowable values of EARTH LEAKAGE CURRENT are permitted for each subassembly of MAMMOGRAPHIC X-RAY EQUIPMENT that is supplied by its own exclusive connection to the SUPPLY MAINS or to a central connection point, if the latter is fixed and PERMANENTLY INSTALLED.

A fixed and PERMANENTLY INSTALLED central connection point may be provided inside the outer ENCLOSURE or cover of the MAMMOGRAPHIC X-RAY EQUIPMENT. If other subassemblies such as an X-RAY SOURCE ASSEMBLY or associated equipment are connected to the central connection point, the EARTH LEAKAGE CURRENT between such a central connection point and the external

protective system may exceed the allowable values for any one of the single devices connected.

NOTE 101 The limitation of the EARTH LEAKAGE CURRENTS within the environment of MAMMOGRAPHIC X-RAY EQUIPMENT is intended to prevent interference in other electrical equipment. The provision of a central connection point is acceptable, as for fixed and PERMANENTLY INSTALLED ME EQUIPMENT the interruption of the PROTECTIVE EARTH CONDUCTOR is not considered to be a SINGLE FAULT CONDITION. However, in such cases, adequate information on the combination of sub-assemblies needs to be provided.

201.8.8 Insulation

201.8.8.3 Dielectric strength

Amendment to the compliance test for high-voltage circuit:

The high-voltage circuit of ME EQUIPMENT is tested by applying no more than half the test voltage, and then the test voltage is gradually raised over a period of 10 s to the full value, which is maintained for 3 min.

Addition to the test conditions for high-voltage circuit:

The test for the high-voltage circuit shall be made without an X-RAY TUBE connected and with a test voltage of 1,2 times the NOMINAL X-RAY TUBE VOLTAGE of the ME EQUIPMENT.

If the ME EQUIPMENT can be tested only with the X-RAY TUBE connected and if the X-RAY TUBE does not allow the ME EQUIPMENT to be tested with a test voltage of 1,2 times the NOMINAL X-RAY TUBE VOLTAGE, the test voltage may be lower but not less than 1,1 times that voltage.

If during the dielectric strength test there is a RISK of overheating a transformer under test, it is permitted to carry out the test at a higher supply frequency.

During the dielectric strength test, the test voltage in the high-voltage circuit should be kept as close as possible to 100 %, and is not to be outside the range of 100 % and 105 % of the value required.

During the dielectric strength test, slight corona discharges in the high-voltage circuit are to be disregarded if they cease when the test voltage is lowered to 110 % of the voltage to which the test condition is referred.

Additions:

aa) HIGH-VOLTAGE GENERATORS or subassemblies thereof, that are integrated with an X-RAY TUBE ASSEMBLY are to be tested with an appropriately loaded X-RAY TUBE.

bb) If such HIGH-VOLTAGE GENERATORS do not have separate adjustment of the X-RAY TUBE CURRENT, the duration of the dielectric strength test is to be reduced to such an extent that the allowable X-RAY TUBE load at the increased X-RAY TUBE VOLTAGE will not be exceeded.

cc) If the high-voltage circuit is not accessible for the measurement of the test voltage applied, appropriate measures should to be taken to ensure that the value is kept as close as possible to 100 %, and is not to be outside the range of 100 % and 105 %, of the value required.

NOTE These requirements are adapted from IEC 60601-2-7:1998 subclause 20.4.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies, except as follows:

201.9.1 MECHANICAL HAZARDS of ME EQUIPMENT

Addition:

Subclause 203.8.5.4.102 BREAST COMPRESSION DEVICE of this particular standard applies.

201.9.2 MECHANICAL HAZARDS associated with moving parts

201.9.2.1 General

Addition:

The movement of ME EQUIPMENT or ME EQUIPMENT parts which could cause physical injury to the PATIENT in NORMAL USE shall require the continuous activation by the OPERATOR except in cases when MAMMOGRAPHIC X-RAY EQUIPMENT is designed for a specified clinical application (e.g., prepositioning, stereotactic imaging) that justifies intentional motion of accessible moving parts during INTENDED USE. The HAZARDS of the moving parts shall be treated by the RISK MANAGEMENT PROCESSES of the MANUFACTURER.

If in NORMAL USE a power-driven ME EQUIPMENT part is intended or likely to contact the PATIENT, and when appropriate for the designed application, means shall be provided to stop the motion if the contact could cause physical injury to the PATIENT.

Means shall be provided or warnings given in the ACCOMPANYING DOCUMENTS, to prevent injuries that could result from collision of power-driven ME EQUIPMENT parts with other moving or stationary items likely to be in proximity.

Compliance is checked by functional test and by inspection of the instructions for use.

NOTE These requirements are adapted from IEC 60601-2-32 subclause 22.4.1.

201.9.2.2 TRAPPING ZONE

201.9.2.2.6 Speed of movement(s)

Addition:

When the BREAST COMPRESSION DEVICE is actuated to apply a force of more than 50 N, the speed or step size of any power-driven movements of the accessible moving parts shall be limited so that the OPERATOR will have adequate control for fine correction of its position without endangering the PATIENT.

201.9.2.3 Other MECHANICAL HAZARDS associated with moving parts

201.9.2.3.1 Unintended movement

Addition:

Accessible moving parts shall be capable of being fixed in any position where they are designed to operate. Once fixed in such positions, these parts shall not undergo unintended motion.

In the event of interruption of the SUPPLY MAINS, the accessible moving parts shall not put any resultant force exceeding 20 N on any part of the PATIENT.

201.9.2.4 Emergency stopping devices

Addition:

All power-driven motions which could cause physical injury shall be provided with an emergency stop control. In the event of an emergency stop, means shall be provided for PATIENT access and removal while ME EQUIPMENT is disabled.

Compliance is checked by functional test and by inspection of the instructions for use.

NOTE These requirements are adapted from IEC 60601-2-32 subclause 22.4.1.

Additional subclauses:

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

In stereotactic imaging, defined angular positions shall be provided for the X-RAY SOURCE ASSEMBLY. The X-RAY SOURCE ASSEMBLY shall be capable of being rigidly fixed in any of these positions. Once fixed in any such position, subsequent movement of the X-RAY SOURCE ASSEMBLY shall require OPERATOR control.

This subclause does not apply for MAMMOGRAPHIC TOMOSYNTHESIS.

Compliance is checked by measurement according to the test in 201.9.2.101.3.

201.9.2.101.2 Motion of APPLIED PARTS during biopsy or marker placement

Under constant compression force, there shall be no displacement in any direction between the PATIENT SUPPORT and the compression plate of more than ± 0,5 mm and ± 0,5° relative to each other, and their displacement relative to the PATIENT shall not exceed ± 2 mm and ± 2° in any direction.

The movement of the needle holder or core biopsy gun holder with a needle inserted in it shall require continuous actuation and control by the OPERATOR.

Compliance is checked by measurement according to the test in 201.9.2.101.3.

201.9.2.101.3 Biopsy needle positioning accuracy

The accuracy of biopsy needle tip position in x, y, and z directions shall be within ± 1 mm in the specified biopsy volume.

Compliance is checked by measurement according to the following test.

a) Test equipment

A TEST DEVICE of a design that allows testing for different biopsy needle directions is required for the test. It consists of a mounting plate that is perforated so that it can serve as a locator for the test needles. At least three steel needles of different lengths are to be fixed in the mounting plate, the outer parts perpendicular to its surface and pointing in the same direction.

The steel needles are test needles; their tips serve as test objects. They shall be placed in a pattern so that the specified biopsy volume can be covered. It shall be possible to locate one of them within ± 5 mm of the centre of that volume, and two of the other test needle tips also inside the specified biopsy volume and within 10 mm of the extreme x, y, z points that are intended to be reconstructed.

b) Test procedure

Measure the biopsy needle length and compare the result either to the NOMINAL biopsy needle length or to the biopsy needle length value stored or programmed in the MAMMOGRAPHIC STEREOTACTIC DEVICE. The measured length shall agree with the NOMINAL length to within ± 0,3 mm. Place the TEST DEVICE on the PATIENT SUPPORT specified so that one of the test needle tips is located to within ± 5 mm of the centre of the specified biopsy volume and two of the other test needle tips are also located inside the specified biopsy volume and within 10 mm of the extreme x, y, z points that are intended to be reconstructed. An attenuating, homogeneous material, for example 2 mm Al, may be attached close to the X-RAY SOURCE ASSEMBLY.

Select a FOCAL SPOT specified to be used.

Position the MAMMOGRAPHIC X-RAY EQUIPMENT to acquire a cranio-caudal projection of the breast. Determine x, y, z positions of the test needle tips as specified by the MANUFACTURER for clinical use. For each test needle, position the biopsy needle tip according to the position calculated. Measure and record the differences in x, y, z positions between each test needle tip and the biopsy needle tip. Repeat the procedure with the MAMMOGRAPHIC X-RAY EQUIPMENT rotated to the extremities in each direction of the range of angular deviation specified by the MANUFACTURER for clinical use of angular deviation in each direction and also to any intermediate deviations of 90° or multiples thereof. If the MAMMOGRAPHIC STEREOTACTIC DEVICE is designed for more than one biopsy needle direction relative to the test device, then repeat the procedure at as many directions as possible up to a maximum of six within the range specified by the MANUFACTURER for clinical use, including at least two directions at extremities of the specified range.

c) Interpretation of measured data

Compare the differences in x, y, and z directions to the requirement above.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies, except as follows:

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

Addition:

MAMMOGRAPHIC X-RAY EQUIPMENT shall comply with the applicable requirements of IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013; see Clause 203 of this particular standard.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies.

201.13 Hazardous situations and fault conditions for ME EQUIPMENT

Clause 13 of the general standard applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies, except as follows:

201.15.4 ME EQUIPMENT components and general assembly

201.15.4.3 Batteries

Additional subclause:

201.15.4.3.101 Charging mode interlock

Every MOBILE ME EQUIPMENT having an incorporated battery charger shall be provided with means whereby powered movements and the generation of X-RADIATION by unauthorised persons can be prevented without preventing the charging of batteries.

NOTE An example of suitable means to comply with this requirement is the provision of a key-operated switch arranged so that powered movements and the generation of X-RADIATION are possible only when the key is present, but battery charging is also possible in the absence of the key.

201.16 ME SYSTEMS

Clause 16 of the general standard applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies.

202 Electromagnetic compatibility – Requirements and tests

IEC 60601-1-2:2014 applies, except as follows:

Addition:

202.101 Immunity testing of ESSENTIAL PERFORMANCE

The MANUFACTURER may minimize the test requirements of the additional ESSENTIAL PERFORMANCE listed in Table 201.101 to a practical level through the RISK MANAGEMENT PROCESS.

When selecting the requirements to be tested, the MANUFACTURER needs to take into account the sensitivity to the EMC environment, probability of EMC condition and severity, probability and contribution to unacceptable RISK through the RISK MANAGEMENT PROCESS.

The accuracy of the test instruments used to assess the immunity of the ME EQUIPMENT shall not be affected by the electromagnetic conditions for the test.

The test instrument shall not have an influence on the immunity of the ME EQUIPMENT.

Only non-invasive measurements shall be performed.

ME EQUIPMENT being tested shall not be modified to perform this immunity test.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

203 Radiation protection in diagnostic X-ray equipment

IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013 applies except as follows:

203.4 General requirements

203.4.1 Statement of compliance

Replacement:

For MAMMOGRAPHIC X-RAY EQUIPMENT, or a subassembly, any statement of compliance with the requirements of this standard shall be given in the following form:

MAMMOGRAPHIC X-RAY EQUIPMENT [++)] IEC 60601-2-45:2015

[++)] MODEL OR TYPE REFERENCE

NOTE This includes marking on the outside of ME EQUIPMENT.

Additional subclause:

203.4.101 Qualifying conditions for defined terms

203.4.101.1 Electric power

The electric power in the high-voltage circuit, mentioned in this particular standard in 201.7.9.2.1, general items c), d), and e) is calculated according to the formula: $P = f\ U\ I$

where

P is the electric power

f is the factor depending on the waveform of the X-RAY TUBE VOLTAGE, selected as below and is

a) 0,95 for ME EQUIPMENT including a six-peak HIGH-VOLTAGE GENERATOR, or

b) 1,00 for ME EQUIPMENT including a twelve-peak HIGH-VOLTAGE GENERATOR or a constant potential HIGH-VOLTAGE GENERATOR; or

c) for other ME EQUIPMENT, the most appropriate value, as above, chosen according to the waveform of the X-RAY TUBE VOLTAGE, with a statement of the value selected.

U is the X-RAY TUBE VOLTAGE

I is the X-RAY TUBE CURRENT

203.4.101.2 * LOADING TIME

LOADING TIME is measured as the time interval between:

– the instant that the X-RAY TUBE VOLTAGE has risen for the first time to a value of 75 % of the peak value; and

– the instant at which it finally drops below the same value.

For ME EQUIPMENT in which LOADING is controlled by electronic switching of the high voltage, using a grid in an electronic tube or in the X-RAY TUBE, the LOADING TIME shall be determined as the time interval between the instant when the timing device generates the signal to start the IRRADIATION and the instant when it generates the signal to terminate the IRRADIATION.

For ME EQUIPMENT in which LOADING is controlled by simultaneous switching in the primaries of both the high-voltage circuit and the heating supply for the filament of the X-RAY TUBE, the LOADING TIME shall be determined as the time interval between the instant when the X-RAY TUBE CURRENT first rises above 25 % of its maximum value and the instant when it finally falls below the same value.

For other cases, the way the LOADING TIME is controlled and determined shall be described in the RISK MANAGEMENT FILE.

NOTE 1 See also definition 3.37 of IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013.

NOTE 2 These requirements are adapted from IEC 60601-2-7:1998 subclause 2.101.4.

203.5 ME EQUIPMENT identification, marking and documents

203.5.2 ACCOMPANYING DOCUMENTS

203.5.2.4 Instructions for use

203.5.2.4.2 Quantitative information

Addition:

For MAMMOGRAPHIC X-RAY EQUIPMENT, the X-RADIATION dose to the PATIENT shall be described using both the entrance AIR KERMA and the AVERAGE GLANDULAR DOSE, determined according to the method specified by the MANUFACTURER.

203.6 RADIATION management

203.6.2 Initiation and termination of the IRRADIATION

203.6.2.1 Normal initiation and termination of the IRRADIATION

Addition:

203.6.2.1.101 Connections of external interlocks

MAMMOGRAPHIC X-RAY EQUIPMENT, except MOBILE MAMMOGRAPHIC X-RAY EQUIPMENT, shall be provided with connections for at least one external electrical device separate from the MAMMOGRAPHIC X-RAY EQUIPMENT that can prevent the X-RAY GENERATOR from starting to emit X-RADIATION.

MAMMOGRAPHIC X-RAY EQUIPMENT, except MOBILE MAMMOGRAPHIC X-RAY EQUIPMENT, shall be provided with connections for at least one external electrical device separate from the MAMMOGRAPHIC X-RAY EQUIPMENT that can cause the X-RAY GENERATOR to stop emitting X-RADIATION.

If the state of the signals from these external electrical devices is not displayed on the CONTROL PANEL, the ACCOMPANYING DOCUMENTS shall contain information to the RESPONSIBLE ORGANISATION that this state should be displayed by visual means in the installation.

203.6.2.2 Safety measures against failure of normal termination of the IRRADIATION

Replacement:

a) Each LOADING shall be initiated and maintained by means of a control requiring continuous actuation by the OPERATOR.

b) It shall not be possible to initiate any unintended subsequent IRRADIATION without releasing the control by which the previous IRRADIATION was initiated.

c) Means shall be provided for the OPERATOR to terminate each IRRADIATION at any time before its intended completion.

d) In the case of a failure of its normal termination the IRRADIATION shall be terminated by a safety measure.

e) If the normal termination is not effected upon the basis of an on-going X-RADIATION measurement, continuous actuation by the OPERATOR in accordance with item a) shall suffice as the safety measure required in item d) above.

f) If the normal termination depends upon an on-going X-RADIATION measurement,

– the safety measure shall comprise means for termination of IRRADIATION in the event of a failure of the normal termination;

– the CURRENT TIME PRODUCT shall be limited to no more than 800 mAs per IRRADIATION unless specified and justified by the MANUFACTURER;

– the system for normal termination of IRRADIATION and the system used for the safety measure shall be separated so that a failure in one system does not affect termination by the other system;

– a visible indication at the CONTROL PANEL shall be provided whenever a LOADING has been terminated by the safety means required. Another LOADING in the same MODE OF OPERATION shall not be possible until a control device provided for resetting has been operated at the CONTROL PANEL.

g) For MAMMOGRAPHIC X-RAY EQUIPMENT provided with AUTOMATIC EXPOSURE CONTROL a method by which the OPERATOR can verify the functioning of the AUTOMATIC EXPOSURE CONTROL shall be provided and the instructions for use shall contain the description of that method.

Compliance is checked by inspection and by the appropriate functional tests.

203.6.3 RADIATION dose and RADIATION QUALITY

Replacement:

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

It shall be possible to adjust the RADIATION QUALITY and the quantity of X-RADIATION to match the range of breast thickness and composition corresponding to the INTENDED USE of the MAMMOGRAPHIC X-RAY EQUIPMENT.

When the adjustment of the quantity of X-RADIATION contributing to the image is made through a manual selection among discrete values of LOADING FACTORS having an essentially proportional relation to the quantity of X-RADIATION produced, particularly values for X-RAY TUBE CURRENT, LOADING TIME or CURRENT TIME PRODUCT, these values shall be chosen from the series R'10 or R'20 according to IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013, Annex B.

NOTE Using values according to this geometric progression helps the OPERATOR in adjusting the quantity of X-RADIATION by amounts that are just significant, both in terms of X-RADIATION dose to the PATIENT and image quality.

Compliance is checked by inspection.

203.6.3.1.2 Linearity of AIR KERMA over limited intervals of LOADING FACTORS

The variation of the MEASURED VALUES of AIR KERMA shall linearly follow the change of the selected CURRENT TIME PRODUCTS over the whole range of CURRENT TIME PRODUCT selections available, with an accuracy equal or better than 0,2.

Compliance is checked by the following functional test:

The linearity test shall be performed at 30 kV or at the nearest X-RAY TUBE VOLTAGE setting available. For the test, pairs of X-RAY TUBE CURRENT TIME PRODUCT settings shall be selected as follows:

- *The lower value of the first pair shall correspond to the lowest available CURRENT TIME PRODUCT setting. 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.*
- *The ratio of the values of the selected CURRENT TIME PRODUCT settings in each pair shall be as close as possible to 2, but not exceeding 2.*
- *The higher value of the CURRENT TIME PRODUCT settings in each pair to be measured shall be used as the lower value of the next pair of CURRENT TIME PRODUCT settings.*
- *The higher value of the last pair shall correspond to the highest available CURRENT TIME PRODUCT setting and the lower value shall be half or next of half of the value corresponding to the highest available CURRENT TIME PRODUCT setting.*

NOTE An example of this selection rule is the following: If the available CURRENT TIME PRODUCT settings are 10, 12, 16, 20, 25, 32, 40, 50, 63, 80, 100 and 125 mAs, the pairs to be tested are: 10 and 20 mAs, 20 and 40 mAs, 40 and 80 mAs and 63 and 125 mAs.

The whole series of measurements required for the test shall be performed without long pauses and preferably within a period of one hour.

Perform ten LOADINGS for each selected X-RAY TUBE CURRENT TIME PRODUCT setting and measure the AIR KERMA at a fixed location 40 mm above the PATIENT SUPPORT. Calculate the average of the MEASURED VALUES of AIR KERMA for each series of ten measurements.

Calculate the linearity in relation to each pair of settings according to the following formula. The quotients of the averages divided by the respective selected X-RAY TUBE CURRENT TIME PRODUCTS shall not differ by more than 0,2 times the mean value of the following quotients:

$$\left|\frac{\bar{K}_1}{Q_1}-\frac{\bar{K}_2}{Q_2}\right| \leq 0{,}2\,\frac{\frac{\bar{K}_1}{Q_1}+\frac{\bar{K}_2}{Q_2}}{2}$$

where

$\bar{K}_1, \bar{K}_2$ *are the averages of the MEASURED VALUES of AIR KERMA and*

Q_1, Q_2 *are the selected CURRENT TIME PRODUCTS.*

203.6.3.2 Reproducibility of the X-RADIATION output

The coefficient of variation of the MEASURED VALUES of AIR KERMA shall be not greater than 0,05 for any combination of LOADING FACTORS over the range for INTENDED USE.

Compliance is checked by the following functional test:

Select a set of LOADING FACTOR combinations for the reproducibility tests, including at least the following combinations:

– *highest available X-RAY TUBE VOLTAGE with the lowest available X-RAY TUBE CURRENT for that X-RAY TUBE VOLTAGE*

– *lowest available X-RAY TUBE VOLTAGE with the highest available X-RAY TUBE CURRENT for that X-RAY TUBE VOLTAGE*

– *a combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT for the highest electrical power*

– *a combination of X-RAY TUBE VOLTAGE and X-RAY TUBE CURRENT for the lowest electrical power*

– *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*

The series of measurements required for the test shall be performed without long pauses, preferably within a period of one hour.

Perform ten LOADINGS for each of the combinations of LOADING FACTORS selected and measure the AIR KERMA at a fixed location 40 mm above the PATIENT SUPPORT

Calculate the coefficient of variation for each series of MEASURED VALUES of AIR KERMA.

$$\overline{K} = \frac{K_1 + K_2 + \ldots + K_n}{n}$$

where

K_1, K_2, K_n *are the MEASURED VALUES of AIR KERMA*

n *is the number of measurements (10)*

$\overline{K}$ *is the average of ten measurements*

$$cv = \frac{\sqrt{\frac{\left(K_1 - \overline{K}\right)^2 + \left(K_2 - \overline{K}\right)^2 + \ldots + \left(K_n - \overline{K}\right)^2}{n-1}}}{\overline{K}}$$

203.6.4 Indication of operational states

203.6.4.2 Indication of LOADING STATE

Addition:

203.6.4.2.101 LOADING STATE in mammography

A visual indication on the CONTROL PANEL shall indicate the LOADING STATE.

Termination of the LOADING STATE shall be unambiguously indicated at the location of the OPERATOR by an audible signal, regardless of whether termination is determined by the ME EQUIPMENT or by the OPERATOR.

If the LOADING STATE is indicated by means of a single function visual indicator, the colour yellow shall be used.

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

Compliance is checked by inspection

203.6.4.2.102 READY STATE in mammography

Visible indication shall be provided on the CONTROL PANEL indicating the state when one further actuation of a control from that CONTROL PANEL will initiate the LOADING of the X-RAY TUBE in RADIOGRAPHY.

If this state is indicated by means of a single function visual indicator, the colour green shall be used.

Compliance is checked by inspection.

203.6.4.2.103 Remote indication of READY STATE in mammography

Means shall be provided for a connection to enable the READY STATE to be indicated remotely from the CONTROL PANEL. This requirement does not apply to MOBILE MAMMOGRAPHIC X-RAY EQUIPMENT.

203.6.4.3 Indication of LOADING FACTORS and MODES of OPERATION

Addition:

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.

203.6.4.3.101 Units of indication

The units of indication shall be as follows:

– for X-RAY TUBE VOLTAGE, kilovolts (kV);
– for X-RAY TUBE CURRENT, milliamperes (mA);
– for LOADING TIME, seconds (s) or milliseconds (ms);
– for IRRADIATION TIME, seconds (s) or milliseconds (ms);
– for CURRENT TIME PRODUCT, milliampere-seconds (mAs).

Compliance is checked by inspection.

203.6.4.3.102 Accuracy of LOADING FACTORS

203.6.4.3.102.1 General

NOTE Subclauses 203.6.4.3.102 and 203.6.4.3.103 contain requirements on operating data for MAMMOGRAPHIC X-RAY EQUIPMENT, as part of X-RAY GENERATORS that are considered essential for protection against incorrect output.

The requirements of this subclause apply to the accuracy of all values of LOADING FACTORS, whether indicated, fixed or preselected when compared with MEASURED VALUES of the same LOADING FACTOR.

Compliance is determined by tests according to 203.6.4.3.103.

203.6.4.3.102.2 Accuracy and reproducibility of X-RAY TUBE VOLTAGE

a) The X-RAY TUBE VOLTAGE shall be accurate within ± 5 % of the INDICATED VALUE within the selectable range.
b) The coefficient of variation of the X-RAY TUBE VOLTAGE shall be equal to or less than 0,05.

c) The PERCENTAGE RIPPLE of output voltage of the HIGH-VOLTAGE GENERATOR shall not exceed 4.

203.6.4.3.102.3 Accuracy of X-RAY TUBE CURRENT

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

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.

This subclause is applicable only if the LOADING TIME is equal to the IRRADIATION TIME of the EFFECTIVE IMAGE RECEPTION AREA at each point or element of the X-RAY IMAGE RECEPTOR.

NOTE An example for MAMMOGRAPHIC X-RAY EQUIPMENT where this subclause is not applicable are slot scanning systems.

203.6.4.3.102.5 Accuracy of CURRENT TIME PRODUCT

In any specified combination of MAMMOGRAPHIC X-RAY EQUIPMENT with sub-assemblies, the error on the value of the X-RAY TUBE CURRENT TIME PRODUCT shall not be greater than ± (10 % + 0,2 mAs) from its selected value for any combination of LOADING FACTORS. This requirement also applies in cases when the CURRENT TIME PRODUCT is derived by calculation.

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

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.

Complete each set of ten measurements for each combination of X-RAY TUBE VOLTAGE and CURRENT TIME PRODUCT preferably within a time period of one hour.

Check each measured value and the coefficient of variation for each series of measurement to verify compliance.

203.6.4.3.103.2 Accuracy of X-RAY TUBE CURRENT

One measurement shall be made for the lowest INDICATED VALUE of X-RAY TUBE CURRENT with the highest INDICATED VALUE of X-RAY TUBE VOLTAGE and the shortest INDICATED VALUE of LOADING TIME.

One measurement shall be made for the lowest INDICATED VALUE of X-RAY TUBE CURRENT with the highest INDICATED VALUE of X-RAY TUBE VOLTAGE and a LOADING TIME of approximately 1 s.

One measurement shall be made for the highest INDICATED VALUE of X-RAY TUBE CURRENT with the highest available X-RAY TUBE VOLTAGE and a LOADING TIME of approximately 1 s.

203.6.4.3.103.3 Accuracy of LOADING TIME

One measurement shall be made for the lowest INDICATED VALUE of LOADING TIME with the highest INDICATED VALUE of X-RAY TUBE VOLTAGE and any INDICATED VALUE of X-RAY TUBE CURRENT.

One measurement shall be made for the lowest INDICATED VALUE of LOADING TIME and the highest available electric power, P.

203.6.4.3.103.4 Accuracy of CURRENT TIME PRODUCT

One measurement shall be made for the lowest INDICATED VALUE of CURRENT TIME PRODUCT and the highest available X-RAY TUBE VOLTAGE.

One measurement shall be made for the highest INDICATED VALUE of CURRENT TIME PRODUCT and the lowest available X-RAY TUBE VOLTAGE.

203.6.4.3.104 Indication of ADDED FILTERS

If X-RAY EQUIPMENT has provisions to select ADDED FILTERS by remote control or automatic systems, the selected ADDED FILTER shall be indicated on the CONTROL PANEL. In cases where the FILTER change is automatic, this indication may be displayed after the termination of IRRADIATION.

Compliance is checked by inspection and by the appropriate functional tests.

203.6.4.4 Indication of automatic modes

Addition:

For MAMMOGRAPHIC X-RAY EQUIPMENT in which control of exposure conditions is achieved by automatic variation of one or more LOADING FACTORS, ADDED FILTERS or TARGET, information about the range and interrelation of these LOADING FACTORS shall be given in the instructions for use.

Compliance is checked by inspection and by the appropriate functional tests.

203.6.4.5 Dosimetric Indications

Addition:

For MAMMOGRAPHIC X-RAY EQUIPMENT with an integrated digital X-RAY IMAGE RECEPTOR the AVERAGE GLANDULAR DOSE shall be indicated for each acquired image.

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 AUTOMATIC CONTROL SYSTEM

Replacement:

203.6.5.1 General AEC requirements for MAMMOGRAPHIC X-RAY EQUIPMENT

MAMMOGRAPHIC X-RAY EQUIPMENT shall be provided with AUTOMATIC EXPOSURE CONTROL.

NOTE The inclusion of a manual mode option is not in contradiction to these requirements and may be useful in special cases.

The performance required for the INTENDED USE of AUTOMATIC EXPOSURE CONTROLS shall be determined in the RISK MANAGEMENT PROCESS and be verified by appropriate tests.

Compliance is checked by inspection and by the appropriate functional tests.

203.6.5.2 AEC requirements for MAMMOGRAPHIC X-RAY EQUIPMENT without an integrated X-RAY IMAGE RECEPTOR

NOTE Within this subclause a storage phosphor reader, included with the original MAMMOGRAPHIC X-RAY EQUIPMENT, or indicated as compatible with its INTENDED USE, is considered as an integrated digital X-RAY IMAGE RECEPTOR. The type test for a combination of MAMMOGRAPHIC X-RAY EQUIPMENT without an integrated X-RAY IMAGE RECEPTOR with a storage phosphor plate and/or reader or other digital detector is the responsibility of the system integrator and may be carried out according to 203.6.5.3.

MAMMOGRAPHIC X-RAY EQUIPMENT without an integrated X-RAY IMAGE RECEPTOR only require the use of film for testing the AEC performance. For MAMMOGRAPHIC X-RAY EQUIPMENT without an integrated X-RAY IMAGE RECEPTOR, the ACCOMPANYING DOCUMENTS shall contain necessary information or limitations on the characteristics of the X-RAY IMAGE RECEPTOR that can be used in order to meet the required performance.

MAMMOGRAPHIC X-RAY EQUIPMENT intended to be used with certain non-integrated digital X-RAY IMAGE RECEPTORS only may be tested with such digital X-RAY IMAGE RECEPTORS according to 203.6.5.3.

In other cases the AEC function shall maintain film optical density within an appropriate range when the thickness of a breast equivalent material is varied over an appropriate range and the X-RAY TUBE VOLTAGE is varied appropriately for such thickness over the range recommended by the MANUFACTURER for clinical use. The appropriate combination of X-RAY TUBE VOLTAGE and thickness of the object is to be stated by the MANUFACTURER. The AEC shall be operable in all combinations of clinically relevant configurations of the MAMMOGRAPHIC X-RAY EQUIPMENT, e.g., grid, no grid, magnification and (if applicable) stereotactic modes, and with various TARGET/FILTER combinations.

a) Test method

Measure the optical density of radiograms of PHANTOMS made of breast tissue equivalent material, produced with the AUTOMATIC EXPOSURE CONTROL in operation. Determine the variations in density for different PHANTOM thickness and for different X-RAY TUBE VOLTAGES.

b) Test arrangement

Use a test arrangement with the following characteristics:

1) *A DIRECT FOCAL DISTANCE, remaining unchanged for all tests in a series.*
2) *Select the X-RAY TUBE VOLTAGE, TARGET, and FILTRATION to reflect the PHANTOM thickness. Select the density control to the value that is typically used clinically.*
3) *An 18 cm × 24 cm radiographic cassette for mammography, the same cassette being used for all tests in a series. If the MAMMOGRAPHIC X-RAY EQUIPMENT includes more than one PATIENT SUPPORT then the AEC shall also be tested using these arrangements.*
4) *Test the thickness range from 20 mm to 70 mm in steps of 10 mm. The size of the PHANTOMS shall provide sufficient coverage of the AEC detector, for example 10 cm × 15 cm or a semicircle with a radius of 100 mm. A larger size is recommended to generate clinically relevant distributions of SCATTERED RADIATION. The PHANTOM shall extend 10 mm beyond the chest wall edge of the PATIENT SUPPORT and at least 10 mm beyond the edge of the AEC detector.*
5) *If the grid can be removed, or PATIENT SUPPORT without a grid is provided, the AEC function shall also be tested for these configurations.*
6) *Provision for accurate and reproducible film processing and for measuring the optical density of processed films. The film processor stability during the AEC test shall*

regularly be tested and demonstrated with a sensitometer test, at least at the beginning, half way through the test and at the end. It is not appropriate to divide the test into different parts, and it is also impossible to make this test if the processor is not stable. If there is a small drift in processor performance during the test period, this drift must be taken into consideration when making the evaluation.

c) Radiographic film and intensifying screen

Use the same combination of radiographic film, intensifying screen and radiographic cassette according to the information given in the instructions for use. If a different intensifying screen is recommended for special procedures, i.e., stereotaxy or magnification, the AEC shall also be tested using this arrangement.

d) Setting the AUTOMATIC EXPOSURE CONTROL

– *Position the PHANTOM on the PATIENT SUPPORT and ensure that it overlaps the area of the AEC sensor.*

– *For settings follow the instructions for use.*

e) Compliance criteria

MEASURED VALUES of optical density shall be within 0,3 for 20 mm to 70 mm of tissue-equivalent material.

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

NOTE Within this subclause a storage phosphor reader, included with the original MAMMOGRAPHIC X-RAY EQUIPMENT, or indicated as compatible with its INTENDED USE, is considered as an integrated digital X-RAY IMAGE RECEPTOR.

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

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

The appropriate combination of X-RAY TUBE VOLTAGE and thickness of the object is to be stated by the MANUFACTURER. The AEC shall be operable in all combinations of clinically relevant configurations of the MAMMOGRAPHIC X-RAY EQUIPMENT, e.g., grid, no grid, magnification (if applicable) tomosynthesis and stereotactic modes, and, when applicable, with the different TARGET/FILTER combinations.

All configurations of combinations of settings of the MAMMOGRAPHIC X-RAY EQUIPMENT (e.g., magnification, tomosynthesis and stereotactic modes) that use AEC LOADINGS shall be evaluated per the specifications of the MANUFACTURER.

NOTE An example for these tests can be found in IEC 61223-3-2:2007 and is included in 203.6.5.3.3.

203.6.5.3.2 AEC reproducibility

The reproducibility of the AEC shall be evaluated by repeatedly imaging a PHANTOM under specified conditions, measuring the variations in X-RAY TUBE LOADING (mAs), AIR KERMA or average PIXEL value, and comparing the results with the specifications as described in c) Compliance criteria, below.

a) Test method

Using clinically relevant X-RAY TUBE VOLTAGE and TARGET/FILTER combinations, measure one of the quantities

– *X-RAY TUBE LOADING (mAs);*

– *AIR KERMA at a fixed position between the X-RAY SOURCE ASSEMBLY and the X-RAY IMAGE RECEPTOR;*

– *average value of linearised PIXEL values in a region of interest of the image of the PHANTOM;*

for five routine LOADINGS with PHANTOMS made of breast tissue-equivalent material, water or Polymethylmethacrylate (PMMA), determine the variation in the measured quantity for each LOADING relative to the mean value for the LOADING series.

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

Additionally, if an AEC adjustment or correction control is provided, measure the selected quantity as listed in a) above at each MANUFACTURER specified control step using the same X-RAY TUBE VOLTAGE, TARGET/FILTER, and PHANTOM configurations and determine the variation for each respective LOADING.

b) Test arrangement

Use a test arrangement with the following characteristics:

1) a DIRECT FOCAL DISTANCE remaining unchanged for all tests in a series;

2) dosimeters or other measurement instrumentation should be positioned to avoid interference with AEC sensor.

c) Compliance criteria

Compliance is achieved if no MEASURED VALUE of the selected quantity differs by more than ± 15 % from the mean value for the test LOADINGS or, as appropriate, the MANUFACTURER'S specification.

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 Imaging performance

203.6.7.3 NOMINAL FOCAL SPOT VALUE

Addition:

The requirements of the collateral standard are considered as met if the NOMINAL FOCAL SPOT VALUE of the X-RAY TUBE specified to be used in contact mode is smaller than or equal to 0,4 according to IEC 60336, and if the NOMINAL FOCAL SPOT VALUE specified to be used in geometric magnification conditions is smaller than or equal to 0,2 according to IEC 60336.

203.6.7.4 RADIATION DETECTOR or X-RAY IMAGE RECEPTOR

Replacement:

203.6.7.4.1 Non-integrated X-RAY IMAGE RECEPTOR

If no X-RAY IMAGE RECEPTOR is integrated in the system, examples of X-RAY IMAGE RECEPTOR types or required performances shall be described in the ACCOMPANYING DOCUMENTS. This may include

– radiographic cassettes with intensifying screens, radiographic films: sensitometric properties according to ISO 9236-3:1999;

– non-integrated storage phosphor screens and readers.

203.6.7.4. 2 Integrated X-RAY IMAGE RECEPTOR

203.6.7.4.2.1 General

If a digital X-RAY IMAGE RECEPTOR is integrated in the MAMMOGRAPHIC X-RAY EQUIPMENT, its contribution to the metrics of imaging performance shall be specified in the RISK MANAGEMENT FILE in accordance with IEC 62220-1-2. This contribution should ensure the efficient use of X-RADIATION.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

203.6.7.4.2.2 DEFECTIVE DETECTOR ELEMENTS

The MANUFACTURER shall specify

– the maximum acceptable number of isolated DEFECTIVE DETECTOR ELEMENTS in the entire IMAGE RECEPTION AREA and the maximum acceptable number in any subdivision with their distribution over the IMAGE RECEPTION AREA;

– the maximum acceptable size and number of connecting DEFECTIVE DETECTOR ELEMENTS and their distribution in the entire IMAGE RECEPTION AREA and the maximum acceptable number in any subdivision and distribution over the IMAGE RECEPTION AREA of connecting DEFECTIVE DETECTOR ELEMENTS grouped by topology type (e.g., 2 adjacent detector elements, 3 adjacent detector elements, 2 × 2 adjacent detector elements, etc.);

– the maximum acceptable number of defective lines, columns and segments, and the minimum acceptable distance between defective lines or columns with their width, length and distribution over the entire IMAGE RECEPTION AREA and the maximum acceptable number in any subdivision and distribution over the IMAGE RECEPTION AREA.

These defects shall not significantly degrade the level of image quality required for the INTENDED USE.

The MANUFACTURER shall determine, describe, and specify the acceptable properties, numbers, positions and arrangements of the DEFECTIVE DETECTOR ELEMENTS in the RISK MANAGEMENT FILE.

Means shall be provided

– to determine and identify the DEFECTIVE DETECTOR ELEMENTS present in the digital X-RAY IMAGE RECEPTOR according to the categories above;
– to allow the RESPONSIBLE ORGANISATION to determine whether the digital X-RAY IMAGE RECEPTOR performs according to its specifications, before degradation of the image quality performance required for the INTENDED USE occurs;
– to generate or update the description of the DEFECTIVE DETECTOR ELEMENTS to be used during the replacement PROCESS specified in 203.6.7.4.2.3, if required. Means may be provided to make this description available to the RESPONSIBLE ORGANISATION.

The instructions for use shall contain instructions on how and when to use the provided means as a part of the quality control procedures, or of the maintenance of ME EQUIPMENT, to be performed by the RESPONSIBLE ORGANISATION or under its responsibility.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and the ACCOMPANYING DOCUMENTS.

203.6.7.4.2.3 * Replacement of data originating from DEFECTIVE DETECTOR ELEMENTS

Means shall be provided to replace the RAW DATA originating from the DEFECTIVE DETECTOR ELEMENTS by appropriate data, in such a way that the corresponding picture elements do not show a significant visual degradation compared to the data provided by the non-defective detector element of an otherwise equivalent digital X-RAY IMAGE RECEPTOR.

This replacement PROCESS shall match the current state of the digital X-RAY IMAGE RECEPTOR, or the latest description of its DEFECTIVE DETECTOR ELEMENTS.

The replacement PROCESS shall be applied to all images specified for the INTENDED USE in clinical practice.

The RISK MANAGEMENT FILE shall include

– the description of the replacement PROCESS,
– the specification of the performance provided by the replacement PROCESS,
– the justification for its capability to fulfil the need.

Means shall be provided to inform the RESPONSIBLE ORGANISATION if the currently applied replacement PROCESS does or does not allow achievement of the specified performance. These means may be automatic, or part of the quality control procedures to be performed by the RESPONSIBLE ORGANISATION. The instructions for use shall contain instructions on how and when to use these means, together with the description of the measures to be taken in cases of failure.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and the ACCOMPANYING DOCUMENTS.

203.6.7.4.2.4 Image homogeneity

The local variations in the image generated by the integrated digital X-RAY IMAGE RECEPTOR of MAMMOGRAPHIC X-RAY EQUIPMENT shall not degrade the image quality performance required for the INTENDED USE.

NOTE 1 Particular sources of image non-homogeneity include

– offset variability of individual detector elements;
– gain variability of the individual detector elements;

– for scanning MAMMOGRAPHIC X-RAY EQUIPMENT scan velocity variability.

NOTE 2 An additional source of image non-homogeneity is the non-uniformity of the X-RAY FIELD.

The RISK MANAGEMENT FILE shall contain the specification and justification for the image homogeneity required in clinical practice according to the INTENDED USE, over the range of X-ray energies effectively used (combinations of TARGET material, TOTAL FILTRATION, X-RAY TUBE VOLTAGE, object thickness), and the dynamic range of the X-RAY IMAGE RECEPTOR expressed relative to the NOMINAL operating level (or levels).

Means shall be provided

– to correct each image used in clinical practice in order to reach the specified homogeneity;
– to inform the RESPONSIBLE ORGANISATION if the current homogeneity of images is acceptable or not. These means may be automatic or part of the quality control procedures to be performed by the RESPONSIBLE ORGANISATION. In the latter case, the instructions for use shall contain instructions on how and when to use these means, together with the description of the measures to be taken in cases of failure.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and the ACCOMPANYING DOCUMENTS.

Additional subclauses:

203.6.7.101 Homogeneity of intercepting layers in the X-RAY SOURCE ASSEMBLY

The intercepting layers in the X-RAY SOURCE ASSEMBLY shall not generate unacceptable ARTEFACTS in the radiographic image.

This requirement shall be met

– for all FOCAL SPOT/geometric magnification combinations provided;
– for all available combinations of TARGET material and ADDITIONAL FILTRATIONS at the lowest applicable X-RAY TUBE VOLTAGE;
– when imaging a PHANTOM made of a uniform plate sufficient in overall area to cover the EFFECTIVE IMAGE RECEPTION AREA and with the minimum thickness compatible with this X-ray energy;
– for non-integrated X-RAY IMAGE RECEPTORS: using the X-RAY IMAGE RECEPTOR specified in 203.6.7.4.1 providing the highest sensitivity to the ARTEFACTS; in that case, the X-RAY IMAGE RECEPTOR shall be placed on an auxiliary support, avoiding the influence of the regular X-RAY IMAGE RECEPTOR support;
– for integrated X-RAY IMAGE RECEPTORS, after removal of all layers between the PHANTOM and the ENTRANCE SURFACE of the X-RAY IMAGE RECEPTOR;
– using the most sensitive image viewing conditions used in clinical practice.

The detailed method for determination and specification of the acceptable ARTEFACTS shall be included in the RISK MANAGEMENT FILE.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and the ACCOMPANYING DOCUMENTS.

203.6.7.102 Motion of the ANTI-SCATTER GRID under maximum compression force

For MAMMOGRAPHIC X-RAY EQUIPMENT with a moving ANTI-SCATTER GRID, the application of the maximum force attainable for the BREAST COMPRESSION DEVICE shall not impede the motion of the ANTI-SCATTER GRID.

Compliance is checked by the following test:

The speed of the grid movement may be determined indirectly by using a parameter that is related to the speed of the grid motion (e.g., frequency of the motor).

Actuate the grid operation and determine the speed of the grid motion without compression force.

Apply the maximum attainable compression force to the BREAST COMPRESSION DEVICE. Use the test object and procedure as explained in 203.8.5.4.102.5.

Actuate the grid operation and determine the speed of the grid motion.

Release the compression force.

Repeat the test at ± 90º, and at 180º or as close as possible to the suggested angles from the initial orientation of the MAMMOGRAPHIC X-RAY EQUIPMENT.

Repeat the test procedure for all X-RAY IMAGE RECEPTOR formats.

Compliance is achieved if the application of the compression force does not significantly alter the speed of the ANTI-SCATTER GRID motion.

NOTE It is reasonable to combine the test in 203.8.5.4.102.5 with the above test.

203.6.7.103 ARTEFACTS from grid lines

203.6.7.103.1 Requirements

Under viewing conditions as applied for diagnosis and at the specified range of phantom thickness, rotation of MAMMOGRAPHIC X-RAY EQUIPMENT and compression force, no anti-scatter grid artefacts shall be discernable.

203.6.7.103.2 Test equipment

The following test equipment is required:

- *PHANTOM of 20 mm PMMA having sufficient cross-section to cover the EFFECTIVE IMAGE RECEPTION AREA with the PHANTOM;*
- *an aluminium plate of 2 mm thickness and of dimensions sufficient to intercept the whole X-RAY BEAM when mounted as described below;*
- *if the X-RAY EQUIPMENT uses radiographic films: densitometer, covering the optical density range from 0 to 4,0; radiographic cassettes with intensifying screens and radiographic films for each image format.*

203.6.7.103.3 Test procedure

Position the MAMMOGRAPHIC X-RAY EQUIPMENT to acquire a cranio-caudal projection of the breast and set the X-RAY EQUIPMENT in a condition that is provided for grid mammography. Mount a compression plate that is designed for the maximum attainable compression force and for the X-RAY IMAGE RECEPTOR format used. Fix the aluminium plate between the X-RAY SOURCE ASSEMBLY and the compression plate so that it will completely cover the X-RAY BEAM. Make an exposure in AEC mode to determine the proper CURRENT TIME PRODUCT. Remove the aluminium plate, and place the PMMA PHANTOM on the PATIENT SUPPORT, centred laterally, and with one edge as close as possible to that edge of the PATIENT SUPPORT that is intended to be adjacent to the PATIENT'S chest wall. Irradiate, using the previously determined proper CURRENT TIME PRODUCT and PROCESS the X-ray image.

The test shall be performed at 90-degree intervals of the rotational position of the MAMMOGRAPHIC X-RAY EQUIPMENT (0º, ± 90º and 180º or as close as possible to the suggested angles).

203.6.7.103.4 Test evaluation

Compliance is achieved if no grid lines are visible in any of the test images.

203.6.7.104 Maximum LOADING TIME

203.6.7.104.1 Minimum AIR KERMA RATE

Requirements in this subclause apply to MAMMOGRAPHIC X-RAY EQUIPMENT without an integrated X-RAY IMAGE RECEPTOR, for the largest selectable FOCAL SPOT and an X-RAY TUBE VOLTAGE of 28 kV.

If molybdenum is used as material for the TARGET and for the EDGE FILTER, MAMMOGRAPHIC X-RAY EQUIPMENT shall be capable of producing a minimum AIR KERMA RATE of 7,0 $mGys^{-1}$ at any DIRECT FOCAL DISTANCE within the INTENDED USE. For other combinations of TARGET and edge FILTER the minimum AIR KERMA RATES shall be determined by applying the factors given in table 203.101. The MAMMOGRAPHIC X-RAY EQUIPMENT shall be capable of maintaining the required minimum AIR KERMA RATE for a LOADING TIME of at least 3 s.

Table 203.101 – Minimum values of TOTAL FILTRATION and factors for determining the minimum AIR KERMA RATE

TARGET/ EDGE FILTER	Mo/ Mo	Mo/ Rh	W/ Mo	W/ Rh	Rh/ Rh
Minimum TOTAL FILTRATION	30 μm Mo	25 μm Rh	60 μm Mo	50 μm Rh	25 μm Rh
Factor	1,0	0,86	0,41	0,38	0,58
NOTE Each factor is given as the ratio between typical specific X-RADIATION output values (μGy/mAs) for the respective TARGET/FILTER combination and for the combination Mo/Mo, at an X-RAY TUBE VOLTAGE of 28 kV.					

Test arrangement:

Arrange the X-RAY SOURCE ASSEMBLY, the DIAPHRAGM and the RADIATION DETECTOR for measurement under NARROW BEAM CONDITION without the compression plate. Ensure that the RADIATION QUALITY of the X-RAY BEAM emerging from the X-RAY SOURCE ASSEMBLY complies with applicable specified conditions for NORMAL USE. If no such conditions are specified, ensure that the TOTAL FILTRATION in the X-RAY SOURCE ASSEMBLY is such as to comply with IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013 *as applicable. Measure the AIR KERMA at a point 40 mm above the PATIENT SUPPORT and 60 mm from the chest wall side on the centre line.*

Compliance is checked by tests.

203.6.7.104.2 Maximum LOADING TIME using a typical MODE OF OPERATION

Requirements in this subclause apply to non-scanning MAMMOGRAPHIC X-RAY EQUIPMENT with an integrated X-RAY IMAGE RECEPTOR.

The LOADING TIME on an average 45 mm compressed breast in NORMAL USE shall be not more than 2 s when the large FOCAL SPOT is used.

Compliance is checked by the following test:

– *Use a 40 mm thick rectangular Polymethylmethacrylate (PMMA) PHANTOM (the PHANTOM may be fabricated from layers of material) with sides equal to or exceeding 150 mm.*

– *Position the PHANTOM on the PATIENT SUPPORT.*

– *Perform an exposure using the same procedure as prescribed for an average 45 mm compressed breast.*

– *Measure the LOADING TIME.*

203.7 RADIATION QUALITY

203.7.1 HALF-VALUE LAYERS and TOTAL FILTRATION in X-RAY EQUIPMENT

Replacement:

The RADIATION QUALITY of the X-RAY BEAM provided by the X-RAY EQUIPMENT shall be appropriate for producing the intended images without administering unnecessarily high doses to the PATIENT.

The TOTAL FILTRATION in the beam needs to be sufficient in order to achieve the preceding goal. Requirements for minimum FILTRATION are given here in terms of total QUALITY EQUIVALENT FILTRATION or of the first HALF-VALUE LAYER for specified X-RAY TUBE VOLTAGE.

In MAMMOGRAPHIC X-RAY EQUIPMENT, for all configurations available in NORMAL USE and for all combinations of TARGET and FILTER materials given in Table 203.101, the TOTAL FILTRATION shall not be less than the value given in Table 203.101 for the respective EDGE FILTER.

For combinations of TARGET and FILTER materials not given in Table 203.101, the TOTAL FILTRATION shall be high enough so that the first HALF-VALUE LAYER (expressed in mm of aluminum) attained in the X-RAY BEAM incident on the PATIENT, excluding the material of any compression plate, is not less than the value of the high voltage (expressed in kV) divided by 100, for all configurations available in NORMAL USE.

The material of any compression plate is not included in the TOTAL FILTRATION.

Addition:

203.7.1.101 Unfiltered IRRADIATION prevention

If an X-RAY SOURCE ASSEMBLY includes selectable ADDED FILTERS, means shall be provided to prevent IRRADIATION in absence of the appropriate ADDED FILTER.

203.7.3 Indication of FILTER properties

Addition:

Alternative to the marking of X-RAY TUBE ASSEMBLIES required in subclause 7.3 of IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013, the FILTER properties of X-RAY TUBE ASSEMBLIES may be provided in the ACCOMPANYING DOCUMENTS when a single type of X-RAY TUBE ASSEMBLY can be fitted on the equipment or when the X-RAY TUBE ASSEMBLY is not accessible in NORMAL USE.

203.7.6 Test for HALF-VALUE LAYER

Replacement:

For X-RAY EQUIPMENT specified exclusively for mammography, ensure that the compression plate is not in the X-RAY BEAM during the determination of the HALF-VALUE LAYER.

NOTE The exclusion of the compression plate from the measurement is not in contradiction with 7.6 of IEC 60601-1-3 because MAMMOGRAPHIC X-RAY EQUIPMENT usually includes perforated compression plates for breast biopsy.

For each ADDED FILTER specified as necessary to attain the requirements for TOTAL FILTRATION in the MAMMOGRAPHIC X-RAY EQUIPMENT, given in 203.7.1, measure the first HALF-VALUE LAYER under NARROW BEAM CONDITIONS with the MAMMOGRAPHIC X-RAY EQUIPMENT operating at

– *minimum selectable value of X-RAY TUBE VOLTAGE;*
– *one typical intermediate value of X-RAY TUBE VOLTAGE specified as representative of the INTENDED USE,*

using LOADING FACTORS corresponding to the range of NORMAL USE.

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

Addition:

In non-magnification mode the X-RAY FIELD

a) shall not extend more than 2 mm beyond the edge of the PATIENT SUPPORT that is designed to be adjacent to the chest wall of the PATIENT,
b) for non-scanning MAMMOGRAPHIC X-RAY EQUIPMENT, shall extend beyond the edge of the EFFECTIVE IMAGE RECEPTION AREA that is designed to be adjacent to the chest wall of the PATIENT,
c) for non-scanning MAMMOGRAPHIC X-RAY EQUIPMENT, shall not extend by more than 2 % of the DIRECT FOCAL DISTANCE beyond all other edges of the EFFECTIVE IMAGE RECEPTION AREA. For MAMMOGRAPHIC TOMOSYNTHESIS this requirement is excluded.

In this particular standard, the boundary of an X-RAY FIELD is described by the locus of points at which the AIR KERMA RATE is 25 % of the mean of the AIR KERMA RATES at the approximate centres of the quarters of the area enclosed.

For MAMMOGRAPHIC X-RAY EQUIPMENT based on scanning that varies the position for receiving an X-RAY PATTERN during the exposure, the total area, that is being imaged, is to be used instead of the EFFECTIVE IMAGE RECEPTION AREA.

203.8.5.4 Positioning of the PATIENT and restriction of the irradiated area

Addition:

ME EQUIPMENT shall be equipped with a LIGHT FIELD INDICATOR.

For non-scanning MAMMOGRAPHIC X-RAY EQUIPMENT, the LIGHT FIELD shall be aligned with the X-RAY FIELD so that the misalignment of the edges of the LIGHT FIELD and the X-RAY FIELD along either the length or the width of the visually defined field at the plane of the breast support surface does not exceed 2 % of the DIRECT FOCAL DISTANCE.

203.8.5.4.101 *Missed tissue at chest wall side

203.8.5.4.101.1 Requirement

In non-magnification mode the maximum distance between the edge of the IMAGE RECEPTION AREA that is designed to be adjacent to the chest wall of the PATIENT and the adjacent edge of the PATIENT SUPPORT, when projected on the PATIENT SUPPORT, shall be smaller than 5 mm.

203.8.5.4.101.2 Test method

Position a TEST DEVICE on the PATIENT SUPPORT; this TEST DEVICE shall include test objects in contact with the PATIENT SUPPORT and allow measurement of distances from the chest wall edge of the PATIENT SUPPORT in the resulting radiograms with a precision of 0,5 mm over a length of 6 mm or more. This TEST DEVICE shall include means to position it repeatedly relative to the edge of the PATIENT SUPPORT.

Make a radiogram of the TEST DEVICE.

On the radiogram, measure the distance from the edge of the PATIENT SUPPORT to the edge of the IMAGE RECEPTION AREA.

For MAMMOGRAPHIC X-RAY EQUIPMENT with non-integrated X-RAY IMAGE RECEPTORS, the test shall be repeated 5 times, including repositioning the TEST DEVICE, to identify the largest value. The largest value shall be kept as the final one.

Compliance is checked by the appropriate test.

203.8.5.4.102 BREAST COMPRESSION DEVICE

203.8.5.4.102.1 General

All MAMMOGRAPHIC X-RAY EQUIPMENT shall be fitted with a power-driven BREAST COMPRESSION DEVICE.

203.8.5.4.102.2 Control of compression movements

All switches controlling movement for the application of compression shall be of the type requiring continuous actuation while movement takes place.

The X-RAY EQUIPMENT shall

– provide means for hands-free,(e.g. foot), control of the power-driven compression accessible from both sides of the position of the PATIENT;
– include means for fine adjustment of the compression force accessible from both sides of the position of the PATIENT and;
– provide means for the OPERATOR to prevent automatic decompression.

In the event of interruption of SUPPLY MAINS during biopsy or marking operations, the compression shall be maintained. However, means shall be provided for manually achieving complete decompression.

203.8.5.4.102.3 Range of movement

In all conditions of NORMAL USE, the available range of movement of the BREAST COMPRESSION DEVICE shall allow all those parts of the compression plate that are designed to be in contact with the breast to be brought within 10 mm of the surface of the PATIENT SUPPORT.

NOTE This requirement is intended to ensure that adequate compression of small or thin breasts is not prevented by limitation of the available movement of the compression plate. The extent of compression applied to any particular PATIENT is controlled by the OPERATOR and may be limited by restriction of the available operating force; see 203.8.5.4.102.6.

203.8.5.4.102.4 Design of compression plates

Compression plates intended for special purposes are not subject to the requirements of this subclause.

Compression plates matching the sizes of all breast supports shall be provided.

Compression plates shall be transparent so that the skin of the PATIENT remains visible when in contact with them.

When predefined AEC sensor positions are provided and when other means for indication are not provided, the MAMMOGRAPHIC X-RAY EQUIPMENT shall include at least one compression plate for each X-RAY IMAGE RECEPTOR format used in an AUTOMATIC EXPOSURE CONTROL mode marked to indicate the range of sensor positions available in NORMAL USE.

The edge of the compression plate intended to be in contact with the chest wall of the PATIENT shall not extend beyond the chest wall edge of the EFFECTIVE IMAGE RECEPTION AREA by more than one percent of the DIRECT FOCAL DISTANCE when the compression plate is placed 45 mm above the surface of the breast support.

No image of this edge of the compression plate shall be visible.

203.8.5.4.102.5 Strength of compression plates

Compression plates and their mountings, unless marked to indicate the maximum compression force permitted to be applied, shall withstand the maximum compression force attainable when they are fitted to ME EQUIPMENT. The marking may take the form of coding related to an explanation in the instructions for use.

Compliance is determined by the following test:

a) Test equipment

The following test equipment is required:

– *appropriately sized objects, one for each X-RAY IMAGE RECEPTOR format, leading to sufficiently realistic force distributions when under compression. E.g., the objects can be sand-filled bags or soft rubber blocks. Their thickness shall be in the range from 20 mm to 50 mm. The objects shall be 100 mm to 120 mm long and wide for the smallest X-RAY IMAGE RECEPTOR format and 120 mm to 150 mm long and wide for larger formats.*

b) Test procedure

Position the MAMMOGRAPHIC X-RAY EQUIPMENT to acquire a cranio-caudal projection of the breast. Mount a compression plate. Take the test object designed for the same X-RAY IMAGE RECEPTOR format as the compression plate and place it on the PATIENT SUPPORT, centred laterally, and with one edge as close as possible to that edge of the PATIENT SUPPORT that is provided to be adjacent to the PATIENT'S chest wall. If the object is a sand-filled bag, shape it by hand to maximize the surface areas that will be in contact with the PATIENT SUPPORT and the compression plate.

Actuate the BREAST COMPRESSION DEVICE to the maximum attainable compression force or to the maximum compression force permitted to be applied to the plate. Then relax the force. Repeat the test for all compression plates.

c) Interpretation of test results

Inspect the compression plates and associated parts for any signs of damage, especially for fissures. For compliance, the compression plates and associated parts are to be free from breakage, visible damage and permanent distortion.

203.8.5.4.102.6 Compression force

BREAST COMPRESSION DEVICES shall satisfy the following requirements in respect of the application and indication of the compression force in all orientations specified for NORMAL USE:

– no BREAST COMPRESSION DEVICE shall be able to apply a force exceeding 300 N;

– for power-driven compression, the BREAST COMPRESSION DEVICE shall be able to apply a force of at least 150 N, and it shall be unable to apply a force exceeding 200 N;

NOTE Equipment configurations that limit the maximum power-driven compression force to less than 150N in clinical use are permissible. See following bullet.

– for power-driven compression, the available operating force shall be adjustable down to 70 N or less;

– if the value of the applied force is displayed, the indication shall be accurate to ± 20 N.

Compliance is checked by measurement.

a) Test equipment

The following test equipment is required:

– *a force balance;*

– *a soft rubber block, 20 mm to 50 mm thick, and 100 mm to 120 mm long and wide.*

b) Test procedure

Position the MAMMOGRAPHIC X-RAY EQUIPMENT to acquire a cranio-caudal projection of the breast. Fix the force balance onto the PATIENT SUPPORT so that it will remain secure in any orientation of the MAMMOGRAPHIC X-RAY EQUIPMENT. Place the soft rubber block on the sensitive area of the force balance. Operate the BREAST COMPRESSION DEVICE, thus clamping the soft rubber block, and record the reading of the balance. Measure the highest achievable forces for all compression modes. If the force is displayed at the X-RAY EQUIPMENT then perform at least five additional measurements for lower compression forces, equally distributed over the range from zero compression to the maximum attainable compression force and record all displayed values in combination with the readings of the balance. Repeat the test procedure for at least three other orientations of the MAMMOGRAPHIC X-RAY EQUIPMENT in order to cover sufficiently the whole range of angles possible with the X-RAY EQUIPMENT.

c) Interpretation of measured data

Determine compliance by comparing MEASURED VALUES with required values and, if the compression force is displayed, with the above requirements for accuracy.

203.9 FOCAL SPOT TO SKIN DISTANCE

Replacement:

The FOCAL SPOT TO SKIN DISTANCES in NORMAL USE shall be sufficiently large to keep the RADIATION dose to the PATIENT as low as reasonably achievable. This is obtained by compliance with the following requirements.

Except when a MAMMOGRAPHIC STEREOTACTIC DEVICE is used, the DIRECT FOCAL DISTANCE shall be at least 600 mm.

The magnification factor in the plane of the PATIENT SUPPORT to be used for geometric magnification shall not exceed 2.

Compliance is checked by measurement.

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

203.10.1 General

Addition:

The ATTENUATION EQUIVALENT of the total of all layers of the breast support located in the path of the X-RAY BEAM between the breast and the X-RAY IMAGE RECEPTOR shall not exceed 0,3 mm Al when measured perpendicular to these layers.

This requirement does not apply to protective layers of X-RAY IMAGE RECEPTORS, to radiographic cassettes, and to ANTI-SCATTER GRIDS.

Compliance is checked by measurement. Determine the ATTENUATION EQUIVALENT as the thickness of aluminium that gives the same degree of attenuation as the breast support, from measurements of AIR KERMA under NARROW BEAM CONDITION. Use an X-RAY TUBE VOLTAGE of approximately 30 kV, a ripple of not more than 10%, and a first HALF-VALUE LAYER of 0,3 mm +/- 0,01 mm Al.

203.11 Protection against RESIDUAL RADIATION

Additional subclause:

203.11.101 Additional requirements for protection against RESIDUAL RADIATION

MAMMOGRAPHIC X-RAY EQUIPMENT shall be provided with PRIMARY PROTECTIVE SHIELDING in accordance with the requirements below. These requirements shall be met for all combinations of X-RAY FIELDS, DIRECT FOCAL DISTANCES, LOADING FACTORS and FILTRATION in NORMAL USE.

The PRIMARY PROTECTIVE SHIELDING shall extend at least to the projection of the PATIENT SUPPORT at the edge designed to be adjacent to the PATIENT'S chest wall and at the other edges shall extend beyond the X-RAY FIELD by at least 1 % of the DIRECT FOCAL DISTANCE.

The RESIDUAL RADIATION behind the X-RAY IMAGE RECEPTOR supporting device shall not exceed an AIR KERMA of 1,0 μGy per IRRADIATION.

Compliance is checked by visual inspection and by the following measurement.

The AIR KERMA measurement shall be averaged over a detection area that is 100 cm^2, of which no linear dimension is greater than 200 mm, centred at 50 mm from any ACCESSIBLE SURFACE beyond the X-RAY IMAGE RECEPTOR supporting device. 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.

The reference X-RAY TUBE VOLTAGE for compliance shall be the NOMINAL X-RAY TUBE VOLTAGE.

The reference LOADING FACTORS for compliance shall be those corresponding to the maximum energy input in a single LOADING according to the RADIOGRAPHIC RATINGS.

If the maximum energy input in a single LOADING according to the RADIOGRAPHIC RATINGS cannot be obtained at the NOMINAL X-RAY TUBE VOLTAGE, the worst case of combinations of the LOADING FACTORS and FILTRATION shall be determined and used.

If LOADING FACTORS can be controlled only by an AUTOMATIC CONTROL SYSTEM, the ACCOMPANYING DOCUMENTS shall include instructions for obtaining appropriate LOADING FACTORS for test.

Compliance is checked by inspection of the test results and by examination of the design documentation and ACCOMPANYING DOCUMENTS.

203.13 Protection against STRAY RADIATION

Additional subclause:

203.13.101 PROTECTIVE BARRIER

MAMMOGRAPHIC X-RAY EQUIPMENT for which a SIGNIFICANT ZONE OF OCCUPANCY is designated shall have a PROTECTIVE BARRIER which is designed to be placed between the SIGNIFICANT ZONE OF OCCUPANCY and the region of the PATIENT SUPPORT. The PROTECTIVE BARRIER shall not prevent the OPERATOR from observing the PATIENT during the acquisition of mammograms. It shall extend from not more than 150 mm above the floor to a height of not less than 185 cm, and its width shall not be less than 60 cm.

NOTE The height of a SIGNIFICANT ZONE OF OCCUPANCY as specified in IEC 60601-1-3 does not necessarily imply that the PROTECTIVE BARRIER as specified in this standard has the same height.

With an emitting TARGET of molybdenum, an X-RAY TUBE VOLTAGE of 35 kV with a percentage ripple of not more than 4 and a TOTAL FILTRATION of 0,03 mm molybdenum, the ATTENUATION EQUIVALENT of this PROTECTIVE BARRIER shall not be less than 0,08 mm of lead.

The PROTECTIVE BARRIER shall be permanently marked with its ATTENUATION EQUIVALENT with reference to this standard.

Annex AA
(informative)

Particular guidance and rationale

AA.1 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclauses in this particular standard, with clause and subclause numbers parallel to those in the body of the document.

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 201.4.3.101 – Additional ESSENTIAL PERFORMANCE requirements

The identification of ESSENTIAL PERFORMANCE requirements has been justified by the fact that the RISK associated with ionizing X-RADIATION used to generate mammographic images should be compensated by the benefit expected from the procedure (e.g., breast screening).

This particular standard takes care by adequate requirements that the imaging performance of MAMMOGRAPHIC X-RAY EQUIPMENT complies with the technically and economically viable state of the art to produce images of sufficient quality in NORMAL CONDITIONS.

This imaging performance may be made single fault safe (e.g., against undetected degradation) by adequate maintenance procedures (including acceptance and constancy testing) for the installed equipment.

Consequently requirements that have not been identified as BASIC SAFETY are listed in table 201.101.

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.

Subclause 201.9.2.101 – Three dimensional localization and interventional mammographic guidance

Accurate positioning of the X-RAY SOURCE ASSEMBLY is required to ensure the positioning accuracy of the biopsy needle.

Stability of the COMPRESSION DEVICE and PATIENT SUPPORT are necessary to ensure the positioning accuracy of the biopsy needle and PATIENT safety.

The RISK associated with this subclause strongly depends on the construction details of the ME EQUIPMENT under consideration and is subject to the RISK MANAGEMENT PROCESS of the MANUFACTURER.

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

Subclause 203.4.101.2 – LOADING TIME

The first paragraph gives the specified method for the measurement of the loading time according to IEC 60601-1-3. The 2nd and 3rd paragraph are the respective tests for the technical implementations of x-ray generator designs. Technical designs not covered by the second or third paragraph are subject to the 4th paragraph.

Subclause 203.6.7.4.2.3 – Replacement of data originating from DEFECTIVE DETECTOR ELEMENTS

For MAMMOGRAPHIC X-RAY EQUIPMENT with an integrated digital detector, quality control is used to verify the systems compliance with the MANUFACTURER'S specification. It is the RESPONSIBLE ORGANISATION'S task to perform this quality control.

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

Since the first edition of IEC 60601-1-3, it has been required that the X-RAY FIELD extends to the edge of the PATIENT SUPPORT, and a 5 mm extension beyond that edge has been allowed. This subclause was justified by the fact that the capability to cover the film fully up to its very edge was then given special attention when considering limitation of excessive IRRADIATION. The benefit was to ensure complete blackening of the film near the edge adjacent to the chest wall of the PATIENT, essential for good viewing conditions, thus increasing the imaged area towards the chest wall where some pathologies may reside.

This new requirement helps to satisfy Clause 11, protection against RESIDUAL RADIATION, of IEC 60601-1-3:2008 by preventing parts of the PATIENT other than from those being currently imaged, to be reached by direct unattenuated X-RADIATION (e.g., on both sides of the breast), and therefore gives full effectiveness to 203.11.101 of this standard.

Because it is technically difficult to achieve no X-RADIATION beyond the PATIENT SUPPORT, a 2 mm tolerance is permitted.

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

[1] IEC 60417, *Graphical symbols for use on equipment*

[2] IEC 60601-2-7:1998, *Medical electrical equipment – Part 2-7: Particular requirements for the safety of high voltage generators of diagnostic X-ray generators*

[3] IEC 60601-2-28:1993, *Medical electrical equipment – Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis* (withdrawn).

[4] IEC 60601-2-28:2010, *Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis*

[5] IEC 60601-2-32:1994, *Medical electrical equipment – Part 2: Particular requirements for the safety of associated equipment of X-ray equipment*

[6] IEC 60664-1:2007, *Insulation coordination for equipment within low-voltage systems – Part 1: Principles, requirements and tests*

[7] ISO 4090:2001, *Photography – Medical radiographic cassettes/screens/films and hard-copy imaging films – Dimensions and specifications*

[8] ISO 7000:2004, *Graphical symbols for use on equipment – Index and synopsis*

[9] ISO 9236-3:1999, *Photography – Sensitometry of screen/film systems for medical radiography – Part 3: Determination of sensitometric curve shape, speed and average gradient for mammography*

[10] ISO 12052, *Health informatics – Digital imaging and communication in medicine (DICOM) including workflow and data management*

[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*

Index of defined terms used in this particular standard

NOTE 1 In the present document only terms defined either in IEC 60601-1:2005, its collateral standards, in IEC/TR 60788:2004 or in Clause 201.3 of this particular standard were used.

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