

BS EN 60601-2-45:2011+A1:2015



BSI Standards Publication

Medical electrical equipment

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

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National foreword

This British Standard is the UK implementation of EN 60601-2-45:2011+A1:2015. It is identical to IEC 60601-2-45:2011, incorporating amendment 1:2015. It supersedes BS EN 60601-2-45:2011 which will be withdrawn on 23 July 2018.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to IEC text carry the number of the IEC amendment. For example, text altered by IEC amendment 1 is indicated by A1 A1.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/2, Diagnostic imaging equipment.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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

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Date	Text affected
31 October 2015	Implementation of IEC amendment 1:2015 with CENELEC endorsement A1:2015. Annex ZA updated

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 60601-2-45:2011+A1

September 2015

ICS 11.040.50

English 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 60601-2-45:2011)**

Appareils électromédicaux -
Partie 2-45: Exigences particulières pour
la sécurité de base et les performances
essentiels des appareils de
mammographie à rayonnement X et des
appareils mammographiques
stéréotaxiques
(CEI 60601-2-45:2011)

Medizinische elektrische Geräte -
Teil 2-45: Besondere Festlegungen für die
Sicherheit einschließlich der wesentlichen
Leistungsmerkmale von Röntgen-
Mammographiegeräten und
mammographischen Stereotaxie-
Einrichtungen
(IEC 60601-2-45:2011)

This European Standard was approved by CENELEC on 2011-03-17. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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

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

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

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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Foreword

The text of document 62B/817/FDIS, future edition 3 of IEC 60601-2-45, prepared by SC 62B, Diagnostic imaging equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-45 on 2011-03-17.

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

This European Standard supersedes EN 60601-2-45:2001.

EN 60601-2-45:2011 has been aligned to EN 60601-1:2006 and to EN 60601-1-3:2008 + corrigendum March 2010. Further modifications have been made with respect to the current technology of MAMMOGRAPHIC X-RAY EQUIPMENT.

The following dates were fixed:

- | | | |
|--|-------|------------|
| – latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement | (dop) | 2011-12-17 |
| – latest date by which the national standards conflicting with the EN have to be withdrawn | (dow) | 2014-03-17 |

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.

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive MDD (93/423/EEC). See Annex ZZ.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-45:2011 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-2-7:1998	NOTE Harmonized as EN 60601-2-7:1998 (not modified).
IEC 60601-2-28:2010	NOTE Harmonized as EN 60601-2-28:2010 (not modified).
IEC 60601-2-32:1994	NOTE Harmonized as EN 60601-2-32:1994 (not modified).
IEC 60664-1:2007	NOTE Harmonized as EN 60664-1:2007 (not modified).
ISO 4090:2001	NOTE Harmonized as EN ISO 4090:2004 (not modified).
ISO 12052	NOTE Harmonized as EN ISO 12052 (not modified).

Foreword to amendment A1

The text of document 62B/917/CDV, future IEC 60601-2-45:2011/A1, prepared by SC 62B "Diagnostic imaging equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-45:2011/A1:2015.

The following dates are fixed:

- latest date by which the document has to be (dop) 2016-04-23
implemented at national level by
publication of an identical national
standard or by endorsement
- latest date by which the national (dow) 2018-07-23
standards conflicting with the
document have to be withdrawn

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

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, included in EN 60601-2-45:2011.

Endorsement notice

The text of the International Standard IEC 60601-2-45:2011/A1:2015 was approved by CENELEC as a European Standard without any modification.

In the Bibliography of EN 60601-2-45:2011, the following note has to be **added** for the standard indicated:

IEC 61223-3-2:2007	NOTE	Harmonized as EN 61223-3-2:2008 (not modified).
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Annex ZA (normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Annex ZA of EN 60601-1:2006 applies, except as follows:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
Replace IEC 60601-1-2 and IEC 60601-1-3 by:				
IEC 60601-1-2	2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests	EN 60601-1-2	2015
IEC 60601-1-3	2008	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance -	EN 60601-1-3	2008
+A1	2013	Collateral Standard: Radiation protection in diagnostic X-ray equipment	+ corr. March +A1 +A1/AC	2010 2013 2014
Add:				
IEC 60336	2005	Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Characteristics of focal spots	EN 60336	2005
IEC 60613	2010	Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis	EN 60613	2010
IEC/TR 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 use in mammography	EN 62220-1-2	2007
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	-	-

Annex ZZ (informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

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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.

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 standard¹⁾ 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 ^{A1} including equipment for MAMMOGRAPHIC TOMOSYNTHESIS ^{A1} 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 ^{A1} other than MAMMOGRAPHIC TOMOSYNTHESIS ^{A1};
- ^{A1} – CT SCANNERS covered by IEC 60601-2-44; ^{A1}
- 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 STEREOTACTIC DEVICES, to ensure safety, to specify methods for demonstrating compliance with those requirements and to provide guidance for RISK MANAGEMENT.

¹⁾ The general standard is ^{A1} IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 ^{A1}, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

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 ^{A1} and IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013 ^{A1} 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 apply²⁾. 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.

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.

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*. ^{A1}

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 48.

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

Replacement:

A1 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 **A1**

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*

A1 Text deleted **A1**

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 ^{A1} IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013 ^{A1} 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

^{A1} <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 ^{A1}

201.3.206

^{A1} *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 ^{A1}

^{A1} NOTE 1 ^{A1} Such a device may be a dedicated system or an ACCESSORY for MAMMOGRAPHIC X-RAY EQUIPMENT.

^{A1} NOTE 2 The purposes of such devices may be fine-needle aspiration, core biopsy, or pre-surgical localization. ^{A1}

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 $\pm 2\%$ 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;
- A1 – 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. A1

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;