IEC 60601-2-45

Edition 3.0 2022-08

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 2
AMENDEMENT 2

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

Appareils électromédicaux –
Partie 2-45: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de mammographie à rayonnement X et des appareils mammographiques stéréotaxiques

IEC 60601-2-45:2011-02/AMD2:2022-08(en-fr)

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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

AMENDMENT 2

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Amendment 2 to IEC 60601-2-45:2011 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

Draft	Report on voting
62B/1271/CDV	62B/1282/RVC

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

The language used for the development of this Amendment is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications/.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document 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- withdrawn,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.

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INTRODUCTION to Amendment 2

This second 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 the second amendment (2020) to IEC 60601-1:2005 and associated collateral standards. Moreover, in Annex AA the description of the term for ESSENTIAL PERFORMANCE is modified to better reflect the clarification published as interpretation sheet 1 of IEC 60601-1:2005/AMD1:2012. This particular standard addresses the system level of MAMMOGRAPHIC X-RAY EQUIPMENT including the equipment for MAMMOGRAPHIC TOMOSYNTHESIS.

FOREWORD

Replace, in the second paragraph, "IEC 60601-1-3 (2008)", *modified by Amendment 1, with* "IEC 60601-1-3 (2008), Amendment 1 of IEC 60601-1-3 (2013) and Amendment 2 of IEC 60601-1-3 (2021)".

201.1 Scope, object and related standards

Replace, in footnote 1), "IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012", *modified by Amendment 1, with* "IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020".

201.1.3 Collateral standards

Replace the first sentence of the second paragraph with:

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021 apply as modified in Clauses 202 and 203, respectively.

Replace, at the end of the second sentence of the second paragraph, modified by Amendment 1, the existing footnote with:

2).

201.2 Normative references

Replace the existing reference to IEC 60601-1-2:2014, modified by Amendment 1, with:

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*
IEC 60601-1-2:2014/AMD1:2020

Replace the existing reference to IEC 60601-1-3:2008, modified by Amendment 1, with:

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
IEC 60601-1-3:2008/AMD2:2021

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2) IEC 60601-1-8, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.* IEC 60601-1-9, *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, *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, *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, *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 intended for use in the emergency medical services environment.*

Add, under "Addition:", the following reference:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

Replace the existing reference "IEC 60788:2004" *with* "IEC TR 60788:2004".

201.3 Terms and definitions

Replace the first paragraph of this subclause, modified by Amendment 1, with the following:

For the purposes of this document, the terms and definitions given in IEC 60601-1, IEC 60601-1-3 and IEC TR 60788 apply, except as follows:

201.4.3.101 *Additional ESSENTIAL PERFORMANCE requirements

Replace the title of this subclause with the following new title:

201.4.3.101 *Additional potential ESSENTIAL PERFORMANCE requirements

Replace the first paragraph of this subclause with the following:

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

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements

Replace the existing title of the table with the following new title:

Table 201.101 – Distributed potential ESSENTIAL PERFORMANCE requirements

Add, after the existing Subclause 201.7.8.102, the following new subclause:

201.7.8.1 Colours of indicator lights

Addition:

Yellow and green colours of lights which are listed in Table 2 of the general standard should only be used if they are clearly distinguishable from the indication the X-ray related states as required in Subclause 203.6.4.2.

If applicable, conflicts which may arise from using same or similar colours for indication of X-RAY related states and other functions of the ME EQUIPMENT shall be evaluated by using the USABILITY ENGINEERING process.

Colours of indicator lights and alarm indicator lights for ME EQUIPMENT which are designated as HIGH PRIORITY, MEDIUM PRIORITY, and LOW PRIORITY ALARM CONDITION listed in Table 2 of the general standard do not apply to this particular standard.

NOTE Even though 7.8 of the general standard mentions the collateral standard IEC 60601-1-8 which application is excluded in 201.1.3 of this particular standard, the selected specified references therein are considered informative and help to understand the requirements of 7.8.

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

201.7.9.2.17 *ME EQUIPMENT emitting radiation

Replace the first paragraph of this subclause, added by Amendment 1, with the following:

This subclause of IEC 60601-1 does not apply.

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

Replace, in the first paragraph of this subclause, modified by Amendment 1, the reference to "IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013" *with* "IEC 60601-1-3".

202 Electromagnetic compatibility – Requirements and tests

Replace, in the first line, modified by Amendment 1, "IEC 60601-1-2:2007" *with* "IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020".

203 Radiation protection in diagnostic X-ray equipment

*Replace, in the first line, modified by Amendment 1, "*IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013" *with "*IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021".

203.4.1 Statement of compliance

Replace the existing reference to "IEC 60601-2-45:2015", *modified by Amendment 1, with* "IEC 60601-2-45:2011, IEC 60601-2-45:2011/AMD1:2015 and IEC 60601-2-45:2011/AMD2:2022".

203.4.101.2 *LOADING TIME

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

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

Replace in the second paragraph, modified by Amendment 1, the reference to "IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013" *with* "IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021".

203.6.7.104.1 Minimum AIR KERMA RATE

Replace in the third paragraph, modified by Amendment 1, "IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013" *with* "IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021".

203.7.3 Indication of FILTER properties

Delete, in the existing text, the reference to "and IEC 60601-1-3:2008/AMD1:2013", *added by Amendment 1*.

Annex AA – Particular guidance and rationale

AA.1 Rationale for particular clauses and subclauses

Subclause 201.4.3.101 – Additional ESSENTIAL PERFORMANCE requirements

Replace the existing text and title with the following:

Subclause 201.4.3.101 – Additional potential ESSENTIAL PERFORMANCE requirements

IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 state that the term ESSENTIAL PERFORMANCE is directly related to the performance of a clinical function (definition 3.27 in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012). Table 201.101 of this particular standard provides a list of requirements that can be correlated with the performance of a clinical function and that can therefore be ESSENTIAL PERFORMANCE. The decision on whether any of these requirements constitutes ESSENTIAL PERFORMANCE is subject to a RISK EVALUATION that considers the INTENDED USE of the ME EQUIPMENT.

The identification of potential ESSENTIAL PERFORMANCE requirements is justified because the RISK associated with ionizing X-RADIATION used to generate mammographic images is overweighed by the benefits expected from the procedure (e.g., breast screening). Evidence is provided by several state-of-the-art clinical studies [12][13][14][15][16] based on diagnostic data generated by MAMMOGRAPHIC X-RAY EQUIPMENT in the field.

The intent of the requirements in this particular standard is to support manufacturers in providing state-of-the-art X-ray equipment that is safe and effective under normal conditions and SINGLE FAULT CONDITIONS as described below. The effectiveness is ensured by meeting the ESSENTIAL PERFORMANCE requirements.

Requirements under single fault conditions are either stipulated in clauses of the general standard and this particular standard or are determined by the risk evaluation. There can be some cases in which simply detection of a single faults during regular checks within a maintenance or a quality control procedure are considered sufficient. In some other cases, a risk which occurs under single fault conditions is considered acceptable due to its low probability or low severity. However, single fault conditions that result in an unacceptable risk due to the probability of harm or the severity of harm require additional control measures. These could include frequent functional self-monitoring, and installation of redundant parts, or appropriate protective devices.

Refer to IEC 60601-1:2005/AMD1:2012/ISH1:2021 [17] for further information on "ESSENTIAL PERFORMANCE in SINGLE FAULT CONDITION".

Bibliography

Add, after the existing list, modified by Amendment 1, the following new bibliographic references:

[12] Hendrick RE, "Radiation Doses and Risks in Breast Screening," J Breast Imag, vol. 2, pp 188-200, 2020.

[13] Martha B. Pitman, MD, "Current Controversies in Screening Mammography," Cancer Cytopathology, pp. 559-560, 2014.

[14] R.M.K. M.Ali, A. England, M.F. McEntee, C.E. Mercer, A. Tootell, P. Hogg, "Effective lifetime radiation risk for a number of national mammography screening programmes," *Radiography*, pp. 240-246, 2018.

[15] R. Edward Hendrick and Mark A. Helvie, "Mammography Screening: A New Estimate of Number Needed to Screen to Prevent One Breast Cancer Death," American Journal of Roentgenology, pp. 723-728., 2012.

[16] Raed M.K. M.Ali, Andrew England, Claire Mercer, Andrew Tootell, Lucy Walton, Wouter Schaake, Peter Hogg, "Mathematical modelling of radiation-induced cancer risk from breast screening by mammography," *European Journal of Radiology*, pp. 98-103, 2017.

[17] IEC 60601-1:2005/AMD1:2012/ISH1:2021, *Interpretation Sheet 1 – Amendment 1 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

Index of defined terms used in this particular standard

Replace the existing line for HAZARD, modified by Amendment 1, with the following:

HAZARD ..... IEC 60601-1:2005/AMD2:2020, 3.39

Replace the existing line for INTENDED USE, modified by Amendment 1, with the following:

INTENDED USE ..... IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.44

Replace the existing line for MANUFACTURER, modified by Amendment 1, with the following:

MANUFACTURER ..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD2:2020, 3.55

Replace the existing line for PROCESS, modified by Amendment 1, with the following:

PROCESS ..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD2:2020, 3.89

Replace the existing lines for RISK, RISK MANAGEMENT and RISK MANAGEMENT FILE, modified by Amendment 1, with the following:

RISK ..... IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.102

RISK MANAGEMENT ..... IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.107

RISK MANAGEMENT FILE ..... IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.108

Add the following new lines:

PROCEDURE ..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD2:2020, 3.88

USABILITY ENGINEERING ..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD2:2020, 3.137

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