SLOVENSKI STANDARD
SIST EN 60601-2-45:2011/oprA2:2022

01-marec-2022

Medicinska električna oprema - 2-45. del: Posebne zahteve za osnovno varnost in bistvene lastnosti rentgenske opreme za mamografijo in stereotaktičnih naprav za mamografijo - Dopolnilo A2

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 sécurite de base et les performances essentielles des appareils de mammographie à rayonnement X et des appareils mammographiques stéréotaxiques

Ta slovenski standard je istoveten z: **EN 60601-2-45:2011/prA2:2022**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
13.280	Varstvo pred sevanjem	Radiation protection

SIST EN 60601-2-45:2011/oprA2:2022 **en**

62B/1271/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER:	
IEC 60601-2-45/AMD2 ED3	
DATE OF CIRCULATION:	CLOSING DATE FOR VOTING:
2022-01-14	**2022-04-08**
SUPERSEDES DOCUMENTS:	

IEC SC 62B : DIAGNOSTIC IMAGING EQUIPMENT	
SECRETARIAT:	SECRETARY:
Germany	Ms Regina Geierhofer
OF INTEREST TO THE FOLLOWING COMMITTEES:	PROPOSED HORIZONTAL STANDARD: ☐
	Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.
FUNCTIONS CONCERNED:	
☒ EMC ☐ ENVIRONMENT	☐ QUALITY ASSURANCE ☒ SAFETY
☐ SUBMITTED FOR CENELEC PARALLEL VOTING	☒ NOT SUBMITTED FOR CENELEC PARALLEL VOTING

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

Amendment 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

PROPOSED STABILITY DATE: 2025

NOTE FROM TC/SC OFFICERS:

FOREWORD

This amendment has been prepared by subcommittee 62B: DIAGNOSTIC IMAGING EQUIPMENT, of IEC technical committee 62: ELECTRICAL EQUIPMENT IN MEDICAL PRACTICE.

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

FDIS	Report on voting
62B/xxx/FDIS	62B/xxx/RVD

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

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

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- withdrawn,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

NOTE The attention of National Committees is drawn to the fact that equipment MANUFACTURERS and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

INTRODUCTION TO THE AMENDMENT 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.

35 FOREWORD

36 *Replace, in the second paragraph, the reference to*

37 IEC 60601-1-3 (2010)

38 *by*

39 IEC 60601-1-3 (2021)

40 **201.1 Scope, object and related standards**

41 *Replace, in footnote 1, the reference to*

42 IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012

43 *by*

44 IEC 60601-1

45 **201.1.3 Collateral standards**

46 *Replace the first sentence of the second paragraph by*

47 IEC 60601-1-2 and IEC 60601-1-3 apply as modified in Clauses 202 and 203, respectively.

48 *Replace the second sentence of the second paragraph, including its footnote, by*

49 IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 do not
50 apply[2)].

51

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2) 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 used in the emergency medical services environment.*

201.2 Normative references

Add the following new reference after the text "Clause 2 of the general standard applies, except as follows:"

Addition:
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 references to IEC 60601-1-2:2014 by

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 60601-1-2:2014/AMD1:2020

Replace the existing references to IEC 60601-1-3:2008 by

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

Add the following reference after "Addition":

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

by

IEC TR 60788:2004

201.3 Terms and definitions

Replace in this subclause the first paragraph by

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 Essential performance

Replace the headline of the following subclause by

201.4.3.101 *Additional potential ESSENTIAL PERFORMANCE requirements

Replace in this subclause the first paragraph by

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

Replace the title of the following table by

Table 201.101 – Distributed potential ESSENTIAL PERFORMANCE requirements

201.7 ME EQUIPMENT identification, marking and documents

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

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.2.17 *ME EQUIPMENT emitting radiation

Replace in this subclause the first paragraph by

This subclause of IEC 60601-1 does not apply.

201.10 Protection against unwanted and excessive radiation HAZARDS

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

Replace, in the first paragraph, the reference to

IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013

by

IEC 60601-1-3

202 Electromagnetic compatibility – Requirements and tests

Replace, in the first line, the reference to

IEC 60601-1-2:2007

by

IEC 60601-1-2

203 Radiation protection in diagnostic X-ray equipment

Replace, in the first line, the reference to

IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013

by

IEC 60601-1-3

203.4 General requirements

203.4.1 Statement of compliance

Replace the reference to

IEC 60601-2-45:2011

by

IEC 60601-2-45:20XX

203.4.101.2 *LOADING TIME

Replace in Note 1 the reference to

IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013

by

IEC 60601-1-3

203.6.3 RADIATION dose and RADIATION QUALITY

203.6.3.1 Adjustment of RADIATION dose and RADIATION QUALITY

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

Replace in the second paragraph the reference to

IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013

by

IEC 60601-1-3

203.7.3 Indication of FILTER properties

Replace the reference to

IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013

by

IEC 60601-1-3

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 by

IEC 60601-1:2005/AMD1:2012 states that the term ESSENTIAL PERFORMANCE is directly related to the performance of a clinical function (definition 3.27 in IEC 60601-1:2005/AMD1:2012). Table 201.101 of this particular standard provides a list of requirements that may be correlated with the performance of a clinical function and that may 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 may be some cases in which simply detection of a single faults during regular checks within a maintenance or a quality control procedure is 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 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*