



DPC: 22/30448158 DC

BSI Group Headquarters

389 Chiswick High Road London W4 4AL

Tel: +44 (0)20 8996 9000

Fax: +44 (0)20 8996 7400

www.bsigroup.com

Date: 24 January 2022

Origin: European

Latest date for receipt of comments: 09 March 2022

Project No. 2021/03309

Responsible committee: CH/62/2 Diagnostic imaging equipment

Interested committees:

Title: Draft BS EN 60601-2-45 Amd.2 Ed.3.0 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.

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard

- i) has any issues related to 3rd party IPR, patent or copyright
- ii) affects other national standard(s)
- iii) requires additional national guidance or information

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This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. No acknowledgement will normally be sent. **See overleaf for information on the submission of comments.**

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Responsible Committee Secretary: Miss Jacinta Hampton (BSI)

Direct tel:

E-mail: jacinta.hampton@bsigroup.com

Full document details: 22/30448158 DC

Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



62B/1271/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

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

IEC SC 62B : DIAGNOSTIC IMAGING EQUIPMENT	
SECRETARIAT: Germany	SECRETARY: 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.