BS EN 60601-2-25:2015

BSI Standards Publication

Medical electrical equipment

Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs

This British Standard is the UK implementation of EN 60601-2-25:2015. It is identical to IEC 60601-2-25:2011. It supersedes BS EN 60601-2-25:1996 and BS EN 60601-2-51:2003, which will be withdrawn on 15 September 2018.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/4, Electromedical equipment.

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

Published by BSI Standards Limited 2015

ISBN 978 0 580 59597 4
ICS 11.040.55; 11.040.99

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

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 November 2015.

Amendments/corrigenda issued since publication

Date	Text affected

EUROPEAN STANDARD **EN 60601-2-25**

EUROPÄISCHE NORM

October 2015

ICS 11.040.55; 11.040.99

Supersedes EN 60601-2-25:1995, EN 60601-2-51:2003

English Version

Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs (IEC 60601-2-25:2011)

Appareils électromédicaux - Partie 2-25: Exigences particulières pour la sécurité de base et les performances essentielles des électrocardiographes (IEC 60601-2-25:2011)

Medizinische elektrische Geräte - Teil 2-25: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Elektrokardiographen (IEC 60601-2-25:2011)

This European Standard was approved by CENELEC on 2015-09-15. 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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre 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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

European foreword

The text of document 62D/944/FDIS, future edition 2 of IEC 60601-2-25, prepared by SC 62D "Electromedical equipment", of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-25:2015.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2016-06-15
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-09-15

This document supersedes EN 60601-2-25:1995 and EN 60601-2-51:2003.

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(s).

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 60601-2-25:2011 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 60601-2-27	NOTE	Harmonized as EN 60601-2-27.
IEC 60601-2-47	NOTE	Harmonized as EN 60601-2-47.

(normative)

Normative references to international publications with their corresponding European publications

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

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

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

Publication	Year	Title	EN/HD	Year
Replacement in Annex ZA of EN 60601-1:2006:				
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2007
-	-		+ corrigendum Mar.	2010
Addition to Annex ZA of EN 60601-1:2006:				
IEC 60601-2-2	2009	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	EN 60601-2-2	2009
-	-		+ A11	2011

(informative)

Coverage of Essential Requirements of EU 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 given in Annex I of EU Directive 93/42/EEC of 14 June 1993 concerning medical devices.

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

WARNING: Other requirements and other EU Directives can be applied to the products falling within the scope of this standard.

CONTENTS