BS EN 60601-1-6:2010

BSI Standards Publication

Medical electrical equipment

Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability

This British Standard is the UK implementation of EN 60601-1-6:2010. It is identical to IEC 60601-1-6:2010. It supersedes BS EN 60601-1-6:2007 which will be withdrawn on 1 April 2013.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/1, Common aspects of Electrical Equipment used in Medical Practice.

A list of organizations represented on this committee 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.

ISBN 978 0 580 65037 6

ICS 11.040.01

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 31 May 2010.

Amendments issued since publication

Amd. No.	Date	Text affected

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

April 2010

ICS 11.040

Supersedes EN 60601-1-6:2007

English version

Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

(IEC 60601-1-6:2010)

Appareils électromédicaux - Partie 1-6: Exigences générales pour la sécurité de base et les performances essentielles - Norme collatérale: Aptitude à l'utilisation (CEI 60601-1-6:2010)

Medizinische elektrische Geräte - Teil 1-6: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Ergänzungsnorm: Gebrauchstauglichkeit (IEC 60601-1-6:2010)

This European Standard was approved by CENELEC on 2010-04-01. 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

Central Secretariat: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 60601-1-6:2010 E

Foreword

The text of document 62A/682/FDIS, future edition 3 of IEC 60601-1-6, prepared by SC 62A, Common aspects of electrical equipment used in medical practice, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-1-6 on 2010-04-01.

This standard supersedes EN 60601-1-6:2007.

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.

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)	2011-01-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2013-04-01

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 Directives 93/42/EEC and 90/385/EEC. See Annex ZZ.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-1-6:2010 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:

[1]	ISO 9241-2:1992	NOTE Harmonized as EN 29241:1993 (not modified).
[2]	ISO 9241-11:1998	NOTE Harmonized as EN ISO 9241-11:1998 (not modified).
[3]	ISO 9241-20:2008	NOTE Harmonized as EN ISO 9241-20:2009 (not modified).
[4]	ISO 9241-110:2006	NOTE Harmonized as EN ISO 9241-110:2006 (not modified).
[5]	ISO 9241-171:2008	NOTE Harmonized as EN ISO 9241-171:2008 (not modified).
[7]	ISO 9241-300:2008	NOTE Harmonized as EN ISO 9241-300:2008 (not modified).
[8]	ISO 9241-302:2008	NOTE Harmonized as EN ISO 9241-302:2008 (not modified).
[9]	ISO 9241-303:2008	NOTE Harmonized as EN ISO 9241-303:2008 (not modified).
[10]	ISO 9241-304:2008	NOTE Harmonized as EN ISO 9241-304:2008 (not modified).
[11]	ISO 9241-305:2008	NOTE Harmonized as EN ISO 9241-305:2008 (not modified).
[12]	ISO 9241-307:2008	NOTE Harmonized as EN ISO 9241-307:2008 (not modified).
[13]	ISO 9241-400:2007	NOTE Harmonized as EN ISO 9241-400:2007 (not modified).
[14]	ISO 9241-410:2008	NOTE Harmonized as EN ISO 9241-410:2008 (not modified).
[16]	ISO 13407:1999	NOTE Harmonized as EN ISO 13407:1999 (not modified).

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.

Publication	Year	Title	EN/HD	Year
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
IEC 60601-1-8	2006	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	EN 60601-1-8	2007
IEC 62366	2007	Medical devices - Application of usability engineering to medical devices	EN 62366	2008
ISO 14971	2007	Medical devices - Application of risk management to medical devices	EN ISO 14971	2009

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 as well as Annex I of the EC Directive 90/385/EEC.

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

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

CONTENTS