BSI Standards Publication

Medical electrical equipment

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

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National foreword

This British Standard is the UK implementation of EN 60601-1-6:2010+A2:2021. It is identical to IEC 60601-1-6:2010, incorporating amendments 1:2013 and 2:2020. It supersedes BS EN 60601-1-6:2010+A1:2015, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to IEC text carry the number of the IEC amendment. For example, text altered by IEC amendment 1 is indicated by A1 A1.

The UK participation in its preparation was entrusted to Technical Committee 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 committee manager.

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For the Great Britain market (England, Scotland and Wales), if UK Government has designated this publication for conformity with UKCA marking (or similar) legislation, it may contain an additional National Annex. Where such a National Annex exists, it shows the correlation between this publication and the relevant UK legislation. If there is no National Annex of this kind, the relevant Annex ZA or ZZ in the body of the European text will indicate the relationship to UK regulation applicable in Great Britain. References to EU legislation may need to be read in accordance with the UK designation and the applicable UK law. Further information on designated standards can be found at www.bsigroup.com/standardsandregulation.

For the Northern Ireland market, UK law will continue to implement relevant EU law subject to periodic confirmation. Therefore Annex ZA/ZZ in the European text, and references to EU legislation, are still valid for this market.

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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/corrigenda issued since publication

Date	Text affected
31 July 2015	Implementation of IEC amendment 1:2013 with CENELEC endorsement A1:2015. Annexes ZA and ZZ updated
31 August 2021	Implementation of IEC amendment 2:2020 with CENELEC endorsement A2:2021. Annex ZA replaced

EUROPÄISCHE NORM

July 2021

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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.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European 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).

The text of document 62A/890/FDIS, future IEC 60601-1-6:2010/A1, 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 approved by CENELEC as EN 60601-1-6:2010/A1:2015.

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)	2016-01-14
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-12-31

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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.

For the relationship with EU Directive 90/385/EEC, see informative Annex ZZ, which is an integral part of this document.

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, included in EN 60601-1-6:2010.

Endorsement notice

The text of the International Standard IEC 60601-1-6:2010/A1:2013 was approved by CENELEC as a European Standard without any modification.

Foreword to amendment A2

The text of document 62A/1391/FDIS, future IEC 60601-1-6/A2, 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 approved by CENELEC as EN 60601-1-6:2010/A2:2021.

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)	2022-01-16
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2024-07-16

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Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice

The text of the International Standard IEC 60601-1-6:2010/A2:2020 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

ISO 14155	NOTE	Harmonized as EN ISO 14155

(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1 Where 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.

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
-	-		+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
-	-		+ A12	2014
+ A2	2020		+ A2	2021
IEC 62366-1	2015	Medical devices - Part 1: Application of usability engineering to medical devices	EN 62366-1	2015
-	-		+ AC	2015
+ A1	2020		+ A1	2020
ISO 14971	2019	Medical devices – Application of risk management to medical devices	EN ISO 14971	2019

Annex ZZ

(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 1 of EU Directive 90/385/EEC of 20 June 1990 relating to active implantable 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.