



BSI Standards Publication

Medical electrical equipment

Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment

National foreword

This British Standard is the UK implementation of EN 60601-2-6:2015+A2:2024. It is identical to IEC 60601-2-6:2012, incorporating amendments 1:2016 and 2:2022. It supersedes BS EN 60601-2-6:2015+A1:2016, which is withdrawn.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/62/4, Electromedical equipment.

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

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31 October 2024	Implementation of IEC amendment 1:2022 with CENELEC endorsement A1:2024

English Version

Medical electrical equipment - Part 2-6: Particular requirements
for the basic safety and essential performance of microwave
therapy equipment
(IEC 60601-2-6:2012)

Appareils électromédicaux - Partie 2-6: Exigences
particulières pour la sécurité de base et les performances
essentielles des appareils de thérapie à micro-ondes
(IEC 60601-2-6:2012)

Medizinische elektrische Geräte - Teil 2-6: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von Mikrowellen-
Therapiegeräten
(IEC 60601-2-6:2012)

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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

Foreword

The text of document 62D/985/FDIS, future edition 2 of IEC 60601-2-6, 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 60601-2-6:2015.

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- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-04-14

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

Endorsement notice

The text of the International Standard IEC 60601-2-6:2012 was approved by CENELEC as a European Standard without any modification.

Foreword to amendment A1

The text of document 62D/1331/FDIS, future IEC 60601-2-6:2012/A1, 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 60601-2-6:2015/A1:2016.

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- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2019-09-30

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For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, included in EN 60601-2-6:2015.

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The text of the International Standard IEC 60601-2-6:2012/A1:2016 was approved by CENELEC as a European Standard without any modification.

European foreword to amendment A2

The text of document 62D/1847/CDV, future edition 2 of IEC 60601-2-6/AMD2, prepared by SC 62D "Particular medical equipment, software, and systems" of IEC/TC 62 "Medical equipment, software, and systems" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-6:2015/A2:2024.

The following dates are fixed:

- latest date by which the document has to be implemented at national (dop) 2025-05-01 level by publication of an identical national standard or by endorsement
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Annex ZA (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.cencenelec.eu.

Add:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ AC	2010
+ A1	2012		+ 1	2013
-	-		+ AC	2014
-	-		+ A12	2014
+ 2	2020		+ 2	2021
-	-		+ AC	2022
-	-		+ A13	2024
IEC/TR 60878	2015	Graphical symbols for electrical equipment in medical practice	-	-

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 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.

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