



BSI Standards Publication

Medical electrical equipment

Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors

This is a preview of BS EN IEC 80601-2-49:2018+A1:2024. [Click here to purchase the full version from the ANSI s](#)

National foreword

This British Standard is the UK implementation of EN IEC 80601-2-49:2019+A1:2024. It is identical to IEC 80601-2-49:2018, incorporating amendment 1:2024. It supersedes BS EN IEC 80601-2-49:2019, which is withdrawn.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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Amendments/corrigenda issued since publication

Date	Text affected
31 October 2024	Implementation of IEC amendment 1:2024 with CENELEC endorsement A1:2024

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EUROPÄISCHE NORM

October 2024

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Supersedes EN 60601-2-49:2015 and all of its amendments and corrigenda (if any)

English Version

**Medical electrical equipment - Part 2-49: Particular requirements
for the basic safety and essential performance of multifunction
patient monitoring equipment
(IEC 80601-2-49:2018)**

Appareils électromédicaux - Partie 2-49: Exigences
particulières pour la sécurité de base et les performances
essentielles des appareils de surveillance multifonction des
patients
(IEC 80601-2-49:2018)

Medizinische elektrische Geräte - Teil 2-49: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von multifunktionalen
Patientenüberwachungsgeräten
(IEC 80601-2-49:2018)

This European Standard was approved by CENELEC on 2019-08-07. 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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, 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: Rue de la Science 23, B-1040 Brussels

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European foreword

The text of document 62D/1547/FDIS, future edition 1.0 of IEC 80601-2-49, 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 IEC 80601-2-49:2019.

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) 2020-05-07
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2022-08-07

This document supersedes EN 60601-2-49:2015.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

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The text of the International Standard IEC 80601-2-49:2018 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 60601-2-16	NOTE	Harmonized as EN IEC 60601-2-16
ISO 80601-2-13	NOTE	Harmonized as EN ISO 80601-2-13
ISO 80601-2-56	NOTE	Harmonized as EN ISO 80601-2-56
ISO 80601-2-72	NOTE	Harmonized as EN ISO 80601-2-72
IEC 62366-1:2015	NOTE	Harmonized as EN 62366-1:2015 (not modified)

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European foreword to amendment A1

The text of document 62D/2146/FDIS, future edition 1 of IEC 80601-2-49/AMD1, 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 IEC 80601-2-49:2019/A1:2024.

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) 2025-10-31
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2027-10-31

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(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.

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

<u>Publication</u> <i>Replacement</i>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60601-1-2	2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	EN 60601-1-2	2015
+ A1	2020		+ A1	2021
IEC 60601-1-6	2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6	2010
+ A1	2013		+ A1	2015
+ A2	2020		+ A2	2021
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
+ A1	2012		+ A1	2013
-	-		+ AC	2014
+ A2	2020		+ A2	2021
IEC 60529	1989	Degrees of protection provided by enclosures (IP Code)	EN 60529	1991
			+EN 60529:1991/corrige ndum May 1993	1993

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Addition

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
-	-		+ A13	2024
IEC 60601-1-11	2015	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	EN 60601-1-11	2015
+ 1	2020		+ 1	2021
IEC 60601-1-12	2014	Medical Electrical Equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment	EN 60601-1-12	2015
+ 1	2020		+ 1	2020
IEC 60601-2-2	2017	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 IEC 60601-2-2	2018
IEC 60601-2-27	2011	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment	EN 60601-2-27	2014
IEC 60601-2-34	2011	Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment	EN 60601-2-34	2014

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