

STN	Zdravotnícke elektrické prístroje Časť 2-49: Osobitné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti multifunkčných patientskych monitorovacích prístrojov Zmena A1	STN EN IEC 80601-2-49/A1 36 4800
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Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 01/25

STN EN IEC 80601-2-49 z februára 2020 sa bez tejto zmeny A1 môže používať do 31. 10. 2027.

Obsahuje: EN IEC 80601-2-49:2019/A1:2024, IEC 80601-2-49:2018/AMD1:2024

139834

Úrad pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky, 2025
Slovenská technická norma a technická normalizačná informácia je chránená zákonom č. 60/2018 Z. z. o technickej normalizácii
v znení neskorších predpisov.

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN IEC 80601-2-49:2019/A1

October 2024

ICS 11.040.55

English Version

**Medical electrical equipment - Part 2-49: Particular requirements
for the basic safety and essential performance of multifunction
patient monitors
(IEC 80601-2-49:2018/AMD1:2024)**

Appareils électromédicaux - Partie 2-49 : Exigences
particulières pour la sécurité de base et les performances
essentielles des moniteurs multifonctions des patients
(IEC 80601-2-49:2018/AMD1:2024)

Medizinische elektrische Geräte - Teil 2-49: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von multifunktionalen
Patientenüberwachungsgeräten
(IEC 80601-2-49:2018/AMD1:2024)

This amendment A1 modifies the European Standard EN IEC 80601-2-49:2019; it was approved by CENELEC on 2024-10-16. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment the status of a national standard without any alteration.

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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

EN IEC 80601-2-49:2019/A1:2024 (E)**European foreword**

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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Endorsement notice

The text of the International Standard IEC 80601-2-49:2018/AMD1:2024 was approved by CENELEC as a European Standard without any modification.

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.cenelec.eu.

The Annex ZA of EN IEC 80601-2-49:2019 applies with the following changes:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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Replace the existing references to IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1, IEC 60601-1-11 and IEC 60601-1-12 with the following new references:

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 60601-1-2	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

EN IEC 80601-2-49:2019/A1:2024 (E)

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 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
+ A1	2020		+ A1	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
+ A1	2020		+ A1	2020



IEC 80601-2-49

Edition 1.0 2024-09

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1 AMENDEMENT 1

**Medical electrical equipment –
Part 2-49: Particular requirements for the basic safety and essential performance
of multifunction patient monitors**

**Appareils électromédicaux –
Partie 2-49: Exigences particulières pour la sécurité de base et les performances
essentielles des moniteurs multifonctions des patients**

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IEC 80601-2-49

Edition 1.0 2024-09

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

**Medical electrical equipment –
Part 2-49: Particular requirements for the basic safety and essential performance
of multifunction patient monitors**

**Appareils électromédicaux –
Partie 2-49: Exigences particulières pour la sécurité de base et les performances
essentiels des moniteurs multifonctions des patients**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

**Part 2-49: Particular requirements for the basic safety
and essential performance of multifunction patient monitors****AMENDMENT 1**

FOREWORD

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Amendment 1 to IEC 80601-2-49:2018 has been prepared by subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems.

The text of this Amendment is based on the following documents:

Draft	Report on voting
62D/2146/FDIS	62D/2164/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this Amendment is English.

IEC 80601-2-49:2018/AMD1:2024

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This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications/.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

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- withdrawn,
- replaced by a revised edition, or
- amended.

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INTRODUCTION to Amendment 1

At the October 2019 meeting of IEC SC 62D in Shanghai, China, the subcommittee discussed the need for administrative/technical changes to most 62D standards after completion of the amendment projects within the IEC 60601-1 series. Those projects were all completed and the amendments published in 2020.

The full list of IEC SC 62D documents that will be amended or revised may be found within the IEC document 62D/1792/DC. The results and comments on the DC may be found within 62D/1808/INF. The review report for this amendment is 62D/1835A/RR.

201.1 Scope, object and related standards

Replace the existing text of footnote 1 with the following new text:

The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

201.1.3 Collateral standards

Replace the existing second paragraph with the following new paragraph:

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020, as well as IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 apply as modified in Clauses 202, 206 and 208 respectively. IEC 60601-1-3 and IEC 60601-1-9 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replace the existing third paragraph with the following new paragraph:

For brevity, IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

Replace, in the second sentence of the 8th paragraph, "3.1 through 3.147" with "3.1 through 3.154".

201.2 Normative references

Replace the existing references to IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1, IEC 60601-1-11 and IEC 60601-1-12 with the following new references:

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*
IEC 60601-1-2:2014/AMD1:2020

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
IEC 60601-1-6:2010/AMD1:2013
IEC 60601-1-6:2010/AMD2:2020

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*
IEC 60601-1-8:2006/AMD1:2012
IEC 60601-1-8:2006/AMD2:2020

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

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*
IEC 60601-1-11:2015/AMD1:2020

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 intended for use in the emergency medical services environment*
IEC 60601-1-12:2014/AMD1:2020

koniec náhľadu – text ďalej pokračuje v platenej verzii STN