SLOVENSKI STANDARD
SIST EN IEC 80601-2-49:2019/oprA1:2023

01-januar-2023

Medicinska električna oprema - 2-49. del: Posebne zahteve za osnovno varnost in bistvene lastnosti večfunkcijske opreme za nadzor pacientov - Dopolnilo A1

Amendment 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

Ta slovenski standard je istoveten z: **EN IEC 80601-2-49:2019/prA1:2022**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN IEC 80601-2-49:2019/oprA1:2023 **en**

62D/1991/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 80601-2-49/AMD1 ED1**	
DATE OF CIRCULATION: **2022-11-11**	CLOSING DATE FOR VOTING: **2023-02-03**
SUPERSEDES DOCUMENTS: **62D/1894/CD, 62D/1923A/CC**	

IEC SC 62D : ELECTROMEDICAL EQUIPMENT

SECRETARIAT: United States of America	SECRETARY: Ms Ladan Bulookbashi
OF INTEREST TO THE FOLLOWING COMMITTEES:	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.

FUNCTIONS CONCERNED:

☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☒ SAFETY

☒ SUBMITTED FOR CENELEC PARALLEL VOTING	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING
Attention IEC-CENELEC parallel voting The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting. The CENELEC members are invited to vote through the CENELEC online voting system.	

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

Amendment 1 - Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors

PROPOSED STABILITY DATE: 2028

NOTE FROM TC/SC OFFICERS:

FOREWORD

This amendment has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

Draft	Report on voting
XX/XX/FDIS	XX/XX/RVD

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

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

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

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

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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 62D1808/INF. The review report for this amendment is 62D/1835A/RR.

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Replace the text in footnote 1 with:

"The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-2:2005/AMD2:2020, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance".

201.1.3 Collateral standards

Replace the second paragraph with:

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 third paragraph with:

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.

In the second sentence of the 8th paragraph replace " 3.1 through 3.147" *with* "3.1 through 1.54"

201.2 Normative references

Replace existing text with:

NOTE Informative references are listed in the Bibliography beginning on page 38.

Clause 2 of the general standard applies, except as follows.

Replacement:

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

Addition:

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

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*

IEC 60601-2-27:2011, *Medical electrical equipment – Part 2-27, Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment*

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*

201.3 Terms and definitions

Change first paragraph to:

For the purposes of this document, the terms and definitions given in IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-11, IEC 60601-1-12, IEC 60601-2-2, IEC 60601-2-27, IEC 60601-2-34 and the following apply.

201.4.3.101 Additional ESSENTIAL PERFORMANCE requirements

Replace existing Table 201.101 with:

Table 201.101 – ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Displaying data according PRIMARY OPERATING FUNCTIONS	206.101 c)
Determination of ALARM CONDITIONS and assignment of priority	208.6.1.2
Indication of validity of measured values	208.6.3.2.101
or generating a TECHNICAL ALARM CONDITION	208.6.1.2

202 Electromagnetic disturbances – Requirements and tests

Replace existing text with:

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply, except as follows:

202.8.1 General

In the second paragraph replace

"During transient phenomena (i.e. electrostatic discharge, electrical fast transients/bursts, surges, electrical transient conduction along supply lines and voltage interruptions),"

with

"During transient phenomena (i.e. electrostatic discharge, electrical fast transients/bursts, surges, electrical transient conduction along supply lines and proximity magnetic fields),

Add the following after the second paragraph:

For requirements for voltage interruptions see 201.11.8.

202.8.102 * Disturbances from HF SURGICAL EQUIPMENT

In the second paragraph of the compliance check replace "of300 kHz to 600 kHz" with "between 300 kHz and 600 kHz":

206 Usability

Replace the first sentence with:

IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020 apply, except as follows:

208 General requirements, tests and guidance for alarm systems in MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS

Replace the first sentence with:

IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 apply, except as follows:

208.6.3.2 Visual ALARM SIGNALS

Replace "sublcause" with "subclause".

208.6.8.1 General

In the second paragraph replace

"Symbols IEC 60417-5319:2002-11 or IEC 60417-5319:2002-11 (symbol 3 and 4 in Table C.1 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012) or alternative marking 2 and 4 in Table C.2 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012,"

with

Symbols IEC 60417-5319:2002-11 or IEC 60417-5319:2002-11 (symbol 3 and 4 in Table C.1 of IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020) or alternative marking 2 and 4 in Table C.2 of IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020,

208.6.10 * Non-latching and latching alarm signals

Delete existing text until "*Additional sublause:*"

208.6.11.1 Existence of DISTRIBUTED ALARM SYSTEM

Change title to "Existence of a DIS or DAS"

208.6.12 * ALARM SYSTEM logging

Delete existing text.

Addition:

208.6.12.1 General

Replace first paragraph:

The ALARM SYSTEM of a MULTIFUNCTION PATIENT MONITOR shall be equipped with an OPERATOR ALARM SYSTEM log and a RESPONSIBLE ORGANIZATION ALARM SYSTEM log.

208.6.12.2 OPERATOR ALARM SYSTEM logging

Addition before the compliance statement:

aa) the ALARM SYSTEM log shall have a capacity of at least 1000 events.

208.6.12.3 RESPONSIBLE ORGANIZATION ALARM SYSTEM logging

Addition before the compliance statement:

aa) MULTIFUNCTION PATIENT MONITORS should be equipped with a FUNCTIONAL CONNECTION to export the contents of the RESPONSIBLE ORGANIZATION ALARM SYSTEM log as well as the identification of the PATIENT, MULTIFUNCTION PATIENT MONITOR or location.

Annex AA

Replace guidance and rationale for Subclause 208.6.12 with:

Because MULTIFUNCTION PATIENT MONITORS are used for vigilance monitoring, the ALARM SYSTEM logs are particularly related to PATIENT safety. While not necessarily life-supporting or life-sustaining, MULTIFUNCTION PATIENT MONITORS are often relied upon to provide timely responses to critical ALARM CONDITIONS. The typical use of MULTIFUNCTION PATIENT MONITORS make the ALARM SYSTEM logs critical elements of ensuring their safe use. The associated ALARM SYSTEM complexity can often make root cause analysis of adverse events occurring during or after monitoring difficult or impossible without detailed retrospective information.

To enable a meaningful analysis of adverse events it is important that the log has adequate capacity.

Index of defined terms used in this particular standard

Replace

“DISTRIBUTED ALARM SYSTEM .... IEC 60601-1-8:2006”

with

“DISTRIBUTED ALARM SYSTEM .... IEC 60601-1-8:2006/AMD2:2020”

Addition:

DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS .. IEC 60601-1-8:2006/AMD2:2020, ...3.48

Delete:

ELECTROMAGNETIC COMPATIBILITY ....IEC 60601-1-2:2014, 3.2

Replace
HAZARDOUS SITUATION ..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.40
with
HAZARDOUS SITUATION .....IEC 60601-1:2005/AMD2:2020, 3.40

Replace
HIGH PRIORITY .....IEC 60601-1-8:2006, 3.22
with
HIGH PRIORITY .....IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD2:2020, 3.22

Replace
INFORMATION SIGNAL .....IEC 60601-1-8:2006, 3.23
with
INFORMATION SIGNAL ..... IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD2:2020, 3.23

Replace
INTENDED USE/INTENDED PURPOSE... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.44
with
INTENDED USE/INTENDED PURPOSE .....IEC 60601-1:2005/AMD2:2020, 3.44

Replace
LOW PRIORITY.....IEC 60601-1-8:2006,3.27
with
LOW PRIORITY.....IEC 60601-1-8:2006/AMD2:2020,3.27

Replace
MANUFACTURER..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.55
with
MANUFACTURER.....IEC 60601-1:2005/AMD2:2020, 3.55

Replace
MEDIUM PRIORITY.....IEC 60601-1-8:2006, 3.28
with
MEDIUM PRIORITY..... IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD2:2020, 3.28

Replace
PROCESS ..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.89
with
PROCESS .....IEC 60601-1:2005/AMD2:2020, 3.89

Replace
RISK MANAGEMENT..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.107
with
RISK MANAGEMENT.....IEC 60601-1:2005/AMD2:2020, 3.107

Replace
USABILITY..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.136
with
USABILITY.....IEC 60601-1:2005/AMD2:2020, 3.136