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

IEC 80601-2-49:2018-03/AMD1:2024-09(en-fr)

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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.

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/.

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- 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- withdrawn,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.

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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.

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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

201.3 Terms and definitions

Replace the existing introductory paragraph with the following new paragraph:

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.

Table 201.101 – ESSENTIAL PERFORMANCE requirements

Replace the existing table with the following new table:

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 the existing first sentence of Clause 202 with the following new sentence:

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

202.8.1 General

Replace, in the first sentence of the second paragraph, "voltage interruptions" *with* "proximity magnetic fields".

Add, after the second paragraph, the following new paragraph:

For requirements for voltage interruptions, see 201.11.8.

202.8.102 * Disturbances from HF SURGICAL EQUIPMENT

Replace, in the third paragraph, "of 300 kHz to 600 kHz" *with* "between 300 kHz and 600 kHz".

206 Usability

Replace the existing first sentence of Clause 206 with the following new sentence:

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 existing first sentence of Clause 208 with the following:

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

208.6.10 * NON-LATCHING and LATCHING ALARM SIGNALS

Delete the existing text until "Additional subclause:".

208.6.11.1 Existence of DISTRIBUTED ALARM SYSTEM

Replace the existing title to "Existence of a DIS or DAS".

208.6.12 * ALARM SYSTEM logging

Replace the existing text with the following new Subclauses 208.6.12.1 to 208.6.12.3:

208.6.12.1 General

Replacement of the 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 1 000 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

Subclause 208.6.12 – ALARM SYSTEM logging

Replace the existing text with the new following text:

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 makes the ALARM SYSTEM logs critical elements of ensuring their safe use. The associated ALARM SYSTEM complexity can often make analysis of the causal factors for 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

Add the following new term:

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

Delete the terms "ELECTROMAGNETIC COMPATIBILITY" and "HAZARD".

Replace

HAZARDOUS SITUATION.....IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.40

with

HAZARDOUS SITUATION.....IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and 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, IEC 60601-1:2005/AMD1:2012 and 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, IEC 60601-1:2005/AMD1:2012 and 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

PROCEDURE ..... IEC 60601-1:2005, 3.88

with

PROCEDURE ..... IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.88

Replace

PROCESS ..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.89

with

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

Replace

RISK CONTROL ..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.105

RISK CONTROL ..... IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.105

Replace

RISK MANAGEMENT ..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.107

with

RISK MANAGEMENT ..... IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and 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, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.136

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