American National Standard

ANSI/AAMI MP80601-2-49:2020

(IEC 80601-2-49:2020, MOD)

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

AAMI
Advancing Safety in Health Technology

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

Approved 24 March 2020 by
AAMI

Approved 26 March 2020 by
American National Standards Institute

Abstract: Applies to basic safety and essential performance requirements of multifunction patient monitors, hereafter referred to as ME equipment or medical electrical systems. This particular standard applies to multifunction patient monitors intended for use in professional healthcare facilities as well as in the emergency medical service environment or the home healthcare environment. The scope of this document is restricted to ME equipment or medical electrical systems intended for connection to a single patient that has two or more physiological monitoring units.

Keywords: electromedical, patient monitors, diagnostic equipment

AAMI Standard

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Contents

Page

Committee representation

Association for the Advancement of Medical Instrumentation

Multiparameter Patient Monitoring Equipment Committee

The adoption of IEC 80601-2-49 as an American National Standard was initiated by the AAMI Multiparameter Patient Monitoring Equipment Committee. AAMI MP provides input to the U.S. TAG to IEC/SC 62D which is the responsible group for providing the U.S. input to the relevant group in IEC/SC 62D/JWG 22. U.S. representatives from AAMI Multiparameter Patient Monitoring Equipment Committee and the TAG played an active part in developing the IEC document.

At the time this document was published, the **AAMI Multiparameter Patient Monitoring Equipment Committee** has the following members:

Cochairs: Kenneth Fuchs
Pamela Gwynn

Members: Frank Block, American Society of Anesthesiologists (ASA)
Shawn Forrest, FDA/CDRH
Kenneth Fuchs, Draeger Medical Systems Inc.
Richard Gagliardo, Spacelabs Healthcare
Pamela Gwynn, UL LLC
John Hedley-Whyte
David Hernke, GE Healthcare
Samantha Jacques, McLaren Flint
Joshua Kim, Hill-Rom Holdings
Sean Kirkwood, Stryker Instruments Division
Melanie Kitchens, Kaiser Foundation Health Plan/Hospitals
Todd Konieczny, Intertek
Colleen Lindell, Regions Hospital
David Osborn, Philips
Patricia Regal, Massachusetts General Hospital
Robert Steurer, Steurer Consulting Group
David Wirick
Daidi Zhong, Chongqing University

Alternates: Brian Gross, Philips
Bernie Kohler, Draeger Medical Systems Inc.

NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Background of ANSI/AAMI adoption of IEC 80601-2-49:2018 with deviations

As indicated in the foreword to the main body of this document (page viii), the International Electrotechnical Commission (IEC) is a worldwide federation of national standards bodies. The United States is one of the IEC members that took an active role in the development of this standard, which was developed by IEC/SC62D/JWG 22 to provide requirements for the basic safety and essential performance of multifunction patient monitors used in professional healthcare facilities and EMS or home care environments.

U.S. participation in IEC/SC62D/JWG 22 is organized through the U.S. Technical Advisory Group, U.S. TAG to IEC/SC62D, administered by the Association for the Advancement of Medical Instrumentation. Experts from the United States made a considerable contribution to this standard.

AAMI encourages its committees to harmonize their work with International Standards in the area of multiparameter patient monitors. Upon review of IEC 80601-2-49, the U.S. TAG to IEC/SC62D and the AAMI Multiparameter Patient Monitoring Equipment Committee decided to adopt it with national deviations, as a first edition of ANSI/AAMI MP80601-2-49.

AAMI and ANSI procedures require that standards be reviewed and, if necessary, revised every five years to reflect technological advances that may have occurred since publication.

As used within the context of this document, “shall” indicates requirements strictly to be followed to conform to the recommended practice. “Should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited.

“May” is used to indicate that a course of action is permissible within the limits of the standard. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

NOTE Users of this standard are advised that this document is an AAMI identical adoption of an IEC document and that the following international conventions have been carried over to the AAMI publication:

- British English spelling (e.g. colour instead of color)
- Use of SI units (e.g. metre instead of feet, Celsius instead of Fahrenheit, etc.)
- Decimal comma instead of a decimal point (e.g. 1 000,15 instead of 1,000.15)

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data comes to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

NOTE—Beginning with the IEC foreword on page viii, this American National Standard is identical to IEC 80601-2-49:2018.

U.S. Deviations to IEC 80601-2-49:2018

As part of an effort to harmonize medical device standards throughout a global industry, the AAMI Multiparameter Patient Monitoring Equipment Committee voted in 2019 to adopt IEC 80601-2-49, *Medical electrical equipment — Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment*. The AAMI Multiparameter Patient Monitoring Equipment Committee also agreed that a number of U.S. deviations to the IEC standard would improve the document.

Deviations are listed below. A rationale for each change has also been provided by the committee. Within the document, deletions are indicated by ~~strikethrough~~ and additions are indicated by <u>underline</u>.

Table 201.101

1. Table footnote and cross-reference deleted.

Rationale: It is not clear that it can be assumed that a completely non-functional multifunction patient monitor, or a nonfunctional physiological monitoring unit would be readily identified, particularly in an unattended monitoring use pattern.

208.6.10

2. Paragraph and NOTE 1 deleted.

Rationale: Latching alarm signals contribute to alarm fatigue, as the standard already acknowledges. Therefore this standard should not recommend or require functionality that would make it easier for users to enable latching alarm signals.

208.6.12

3. Changed “should” to “shall”.

Rationale: Optimal management of a patient requires the ability to review the history of important alarm conditions, therefore we require that all multifunction patient monitors include an alarm log. Additional information is also found in IEC 60601-1:2005+AMD1:2012, Annex A, rationale for 6.12, Alarm condition logging.

Foreword

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
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5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
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8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International standard IEC 80601-2-49 has been prepared by a Joint Working Group of IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice, and of ISO subcommittee SC3: Lung ventilators and related equipment, of ISO technical committee 121: Anaesthetic and respiratory equipment.

This first edition cancels and replaces the second edition of IEC 60601-2-49, published in 2011. This edition constitutes a technical revision to align with the current edition and Amendment to IEC 60601-1, new versions of collateral standards and amendments thereto. Major changes are in Clause 208 because many of the former requirements are now addressed by IEC 60601-1-8.

It is published as a double logo standard.

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

FDIS	Report on voting
62D/1547/FDIS	62D/1559/RVD

Full information on the voting for the approval of this document can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by XXX P members out of YYY having cast a vote.

In this document, the following print types are used:

– requirements and definitions: roman type;

– *test specifications: italic type;*

– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

– "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the 80601 International Standard, published under the general title *Medical electrical equipment*, can be found on the IEC website.

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 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 committees that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

Introduction

This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of MULTIFUNCTION PATIENT MONITORS. It amends and supplements IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard.

The aim of this edition is to bring this particular standard up to date with reference to the edition 3.1 of the general standard and new versions of collateral standards and amendments thereto through technical changes.

The requirements of this particular standard take priority over those of the general standard.

A "Particular guidance and rationale" for the requirements of this particular standard is included in Annex AA. It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this Annex AA does not form part of the requirements of this document.

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

201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

201.1.1 * Scope

Replacement:

This part of the 80601 International Standard applies to BASIC SAFETY and ESSENTIAL PERFORMANCE requirements of MULTIFUNCTION PATIENT MONITORS as defined in 201.3.201, hereafter referred to as ME EQUIPMENT or MEDICAL ELECTRICAL SYSTEMS. This particular standard applies to MULTIFUNCTION PATIENT MONITORS intended for use in professional healthcare facilities as well as in the EMERGENCY MEDICAL SERVICE ENVIRONMENT or the HOME HEALTHCARE ENVIRONMENT.

The scope of this document is restricted to ME EQUIPMENT or MEDICAL ELECTRICAL SYSTEMS intended for connection to a single PATIENT that has two or more PHYSIOLOGICAL MONITORING UNITS.

NOTE For purposes of this document, a pregnant mother and her fetus(es) are considered a single PATIENT.

This document does not specify requirements for individual PHYSIOLOGICAL MONITORING UNITS such as ECG, invasive pressure and pulse oximetry. The particular standards related to these PHYSIOLOGICAL MONITORING UNITS specify requirements from the perspective of stand-alone ME EQUIPMENT. This particular standard addresses the additional requirements related to MULTIFUNCTION PATIENT MONITORS.MULTIFUNCTION PATIENT MONITORS can be integrated into other ME EQUIPMENT or MEDICAL ELECTRICAL SYSTEMS. When this is the case, other relevant standards also apply.

EXAMPLE 1 MULTIFUNCTION PATIENT MONITOR incorporated into a critical care ventilator where ISO 80601-2-12 also applies.

EXAMPLE 2 MULTIFUNCTION PATIENT MONITOR incorporated into a homecare ventilator for dependent PATIENT where ISO 80601-2-72 also applies.

EXAMPLE 3 MULTIFUNCTION PATIENT MONITOR incorporated into anesthetic workstation where ISO 80601-2-13 also applies.

EXAMPLE 4 MULTIFUNCTION PATIENT MONITOR incorporated into haemodialysis equipment, IEC 60601-2-16 also applies.

This document does not apply to implantable parts of MULTIFUNCTION PATIENT MONITORS.

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