IEC 80601-2-49

Edition 1.1 2024-09
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

colour inside

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.55

ISBN 978-2-8322-9710-0

Warning! Make sure that you obtained this publication from an authorized distributor.

CONTENTS

FOREWORD 4
INTRODUCTION 7
INTRODUCTION to Amendment 1 7
201.1 Scope, object and related standards 8
201.2 Normative references 10
201.3 Terms and definitions 11
201.4 General requirements 11
201.5 General requirements for testing ME EQUIPMENT 12
201.6 Classification of ME EQUIPMENT and ME SYSTEMS 12
201.7 ME EQUIPMENT identification, marking and documents 13
201.8 Protection against electrical HAZARDS from ME EQUIPMENT 14
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS 16
201.10 Protection against unwanted and excessive radiation HAZARDS 16
201.11 Protection against excessive temperatures and other HAZARDS 16
201.12 Accuracy of controls and instruments and protection against hazardous outputs 17
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT 18
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 18
201.15 Construction of ME EQUIPMENT 18
201.16 ME SYSTEMS 19
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS 19
202 Electromagnetic disturbances – Requirements and tests 19
206 USABILITY 24
208 General requirements, tests and guidance for ALARM SYSTEMS IN MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS 24
Annexes 28
Annex AA (informative) Particular guidance and rationale 29
Bibliography 38
Index of defined terms used in this particular standard 39

Figure 201.101 – MULTIFUNCTION PATIENT MONITOR with single PATIENT circuit (6) with multiple PHYSIOLOGICAL MONITORING UNITS and multiple PATIENT circuits (7) each with a single PHYSIOLOGICAL MONITORING UNIT 15
Figure 202.101 – Test layout for conducted and radiated EMISSIONS and IMMUNITY test 20
Figure 202.102 – Test circuit for HF SURGICAL EQUIPMENT protection measurement according to 202.8.102 with PATIENT CONNECTIONS 22
Figure 202.103 – Test setup for HF SURGICAL EQUIPMENT protection measurement according to 202.8.102 23
Figure 202.104 – Test circuit for HF SURGICAL EQUIPMENT protection measurement according to 202.8.102 with non-conductive APPLIED PART 24
Figure AA.1 – Example of a pre-configured MULTIFUNCTION PATIENT MONITOR 30
Figure AA.2 – Example of a modular MULTIFUNCTION PATIENT MONITOR 30
Figure AA.3 – Example of a MULTIFUNCTION PATIENT MONITOR connected to a central station 30

Figure AA.4 – Example of a MULTIFUNCTION PATIENT MONITOR integrated into a ventilator 31

Figure AA.5 – Single PATIENT circuit with multiple PHYSIOLOGICAL MONITORING UNITS and PATIENT cables 33

Table 201.101 – ESSENTIAL PERFORMANCE requirements.....12

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

MEDICAL ELECTRICAL EQUIPMENT –

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

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.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
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.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
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 document may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

This consolidated version of the official IEC Standard and its amendment has been prepared for user convenience.

IEC 80601-2-49 edition 1.1 contains the first edition (2018-03) [documents 62D/1547/FDIS and 62D/1559/RVD] and its amendment 1 (2024-09) [documents 62D/2146/FDIS and 62D/2164/RVD].

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

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.

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 and its amendment 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

- reconfirmed,
- withdrawn, or
- revised.

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.

IMPORTANT – The "colour inside" logo on the cover page of this document 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.

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.

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.

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.

201.1.2 Object

Replacement:

The object of this particular standard is to establish BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for MULTIFUNCTION PATIENT MONITORS as defined in 201.3.201.

---

[1] 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

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

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

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular MULTIFUNCTION PATIENT MONITORS under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

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.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x", where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 208.6 in this particular standard addresses the content of Clause 6 of the IEC 60601-1-8 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"*Replacement*" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"*Addition*" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"*Amendment*" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.~~147~~154, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 208 for IEC 60601-1-8, etc.

The term "this document" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

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

IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)*
IEC 60529:1989/AMD1:1999
IEC 60529:1989/AMD2:2013

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*

CONTENTS

FOREWORD 4
INTRODUCTION 7
INTRODUCTION to Amendment 1 7
201.1 Scope, object and related standards 8
201.2 Normative references 10
201.3 Terms and definitions 11
201.4 General requirements 11
201.5 General requirements for testing ME EQUIPMENT 12
201.6 Classification of ME EQUIPMENT and ME SYSTEMS 12
201.7 ME EQUIPMENT identification, marking and documents 13
201.8 Protection against electrical HAZARDS from ME EQUIPMENT 14
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS 16
201.10 Protection against unwanted and excessive radiation HAZARDS 16
201.11 Protection against excessive temperatures and other HAZARDS 16
201.12 Accuracy of controls and instruments and protection against hazardous outputs 17
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT 18
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 18
201.15 Construction of ME EQUIPMENT 18
201.16 ME SYSTEMS 19
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS 19
202 Electromagnetic disturbances – Requirements and tests 19
206 USABILITY 24
208 General requirements, tests and guidance for ALARM SYSTEMS IN MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS 24
Annexes 27
Annex AA (informative) Particular guidance and rationale 28
Bibliography 36
Index of defined terms used in this particular standard 37

Figure 201.101 – MULTIFUNCTION PATIENT MONITOR with single PATIENT circuit (6) with multiple PHYSIOLOGICAL MONITORING UNITS and multiple PATIENT circuits (7) each with a single PHYSIOLOGICAL MONITORING UNIT 15
Figure 202.101 – Test layout for conducted and radiated EMISSIONS and IMMUNITY test 20
Figure 202.102 – Test circuit for HF SURGICAL EQUIPMENT protection measurement according to 202.8.102 with PATIENT CONNECTIONS 22
Figure 202.103 – Test setup for HF SURGICAL EQUIPMENT protection measurement according to 202.8.102 23
Figure 202.104 – Test circuit for HF SURGICAL EQUIPMENT protection measurement according to 202.8.102 with non-conductive APPLIED PART 24
Figure AA.1 – Example of a pre-configured MULTIFUNCTION PATIENT MONITOR 29
Figure AA.2 – Example of a modular MULTIFUNCTION PATIENT MONITOR 29
Figure AA.3 – Example of a MULTIFUNCTION PATIENT MONITOR connected to a central station 29

Figure AA.4 – Example of a MULTIFUNCTION PATIENT MONITOR integrated into a ventilator 30

Figure AA.5 – Single PATIENT circuit with multiple PHYSIOLOGICAL MONITORING UNITS and PATIENT cables 32

Table 201.101 – ESSENTIAL PERFORMANCE requirements.....12

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

MEDICAL ELECTRICAL EQUIPMENT –

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

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.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
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.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
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 document may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

This consolidated version of the official IEC Standard and its amendment has been prepared for user convenience.

IEC 80601-2-49 edition 1.1 contains the first edition (2018-03) [documents 62D/1547/FDIS and 62D/1559/RVD] and its amendment 1 (2024-09) [documents 62D/2146/FDIS and 62D/2164/RVD].

This Final version does not show where the technical content is modified by amendment 1. A separate Redline version with all changes highlighted is available in this publication.

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.

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 and its amendment 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

- reconfirmed,
- withdrawn, or
- revised.

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.

IMPORTANT – The "colour inside" logo on the cover page of this document 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.

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.

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.

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.

201.1.2 Object

Replacement:

The object of this particular standard is to establish BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for MULTIFUNCTION PATIENT MONITORS as defined in 201.3.201.

---

[1] 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

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

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

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular MULTIFUNCTION PATIENT MONITORS under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

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.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x", where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 208.6 in this particular standard addresses the content of Clause 6 of the IEC 60601-1-8 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"*Replacement*" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"*Addition*" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"*Amendment*" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.154, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 208 for IEC 60601-1-8, etc.

The term "this document" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 36.

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

IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)*
IEC 60529:1989/AMD1:1999
IEC 60529:1989/AMD2:2013

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*