

**ELEKTRILISED MEDITSIINISEADMED.
OSA 2-49: ERINÕUDED MULTIFUNKTSIONAALSE
PATSIENDIMONITORI ESMASELE OHUTUSELE JA
OLULISTELE TOIMIMISNÄITAJATELE**

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN IEC 80601-2-49:2019+A1:2024 sisaldab Euroopa standardi EN IEC 80601-2-49:2019 ja selle muudatuse A1:2024 ingliskeelset teksti.	This Estonian standard EVS-EN IEC 80601-2-49:2019+A1:2024 consists of the English text of the European standard EN IEC 80601-2-49:2019 and its amendments A1:2024.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 11.10.2019, muudatus A1 18.10.2024.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation. Date of Availability of the European standard is 11.10.2019, for A1 18.10.2024.
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ICS 11.040.55

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EUROPEAN STANDARD

EN IEC 80601-2-49 + A1

NORME EUROPÉENNE

EUROPÄISCHE NORM

October 2019, October 2024

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Supersedes EN 60601-2-49:2015 and all of its amendments and corrigenda (if any)

English Version

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

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

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European foreword

The text of document 62D/1547/FDIS, future edition 1.0 of IEC 80601-2-49, prepared by SC 62D "Electromedical equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 80601-2-49:2019.

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) 2020-05-07
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2022-08-07

This document supersedes EN 60601-2-49:2015.

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In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-2-16	NOTE	Harmonized as EN IEC 60601-2-16
ISO 80601-2-13	NOTE	Harmonized as EN ISO 80601-2-13
ISO 80601-2-56	NOTE	Harmonized as EN ISO 80601-2-56
ISO 80601-2-72	NOTE	Harmonized as EN ISO 80601-2-72
IEC 62366-1:2015	NOTE	Harmonized as EN 62366-1:2015 (not modified)

A1 Amendment A1 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
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The text of the International Standard IEC 80601-2-49:2018/AMD1:2024 was approved by CENELEC as a European Standard without any modification. **A1**



IEC 80601-2-49

Edition 1.1 2024-09
CONSOLIDATED VERSION

INTERNATIONAL STANDARD



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



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IEC 80601-2-49

Edition 1.1 2024-09
CONSOLIDATED VERSION

INTERNATIONAL STANDARD



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

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

FOREWORD

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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

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A1 Amendment A1 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.
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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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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.

A1 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. **A1**

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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 standard¹ 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.

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.* 

201.1.2 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.

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.

^{A1} 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. ^{A1}

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.

^{A1} 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. ^{A1}

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 **A1** 3.1 through 3.154 **A1**, 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 40.

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

Replacement:

A1 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 **A1**

A1 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 **A1**

A1 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 **A1**

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

Addition:

A1 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 **A1**

A1 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 **A1**

A1 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 **A1**

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

A1 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. **A1**

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

NOTE An index of defined terms is found beginning on page 43.

Addition:

201.3.201

* MULTIFUNCTION PATIENT MONITOR

modular or pre-configured ME EQUIPMENT or MEDICAL ELECTRICAL SYSTEMS whose primary intended function is monitoring of a single PATIENT, has more than one PHYSIOLOGICAL MONITORING UNIT, either displays those information or distributes the information for remote display, and either includes an ALARM SYSTEM or is a component of a DISTRIBUTED ALARM SYSTEM

201.3.202

PHYSIOLOGICAL MONITORING UNIT

part of the MULTIFUNCTION PATIENT MONITOR whose purpose is to collect physiological signal(s) from a single sensor type and to process it for monitoring

EXAMPLE 1 The pulse oximetry signal can provide information about oxygen saturation, pulse rate, perfusion, etc.

EXAMPLE 2 The signals from ECG ELECTRODES can provide information about ECG and thoracic respiration rate.

Note 1 to entry: Examples of physiological signals include (a) electrocardiography, (b) non-invasive blood pressure, (c) invasive blood pressure, (d) pulse oximetry, (e) temperature, (f) electroencephalography, (g) transcutaneous gas analysis, and (h) respiratory gas analysis. Each of these is a single physiological signal within the meaning of this definition.