SLOVENSKI STANDARD
oSIST prEN IEC 60601-2-34:2023

01-januar-2023

Medicinska električna oprema - 2-34. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme za invazivno nadzorovanje krvnega tlaka

Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment

Medizinische elektrische Geräte - Teil 2-34: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von invasiven Blutdruck-Überwachungsgeräten

Amendement 1 - Appareils électromédicaux - Partie 2-34: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de surveillance de la pression sanguine prélevée directement

Ta slovenski standard je istoveten z: **prEN IEC 60601-2-34:2022**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment

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62D/1990/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER:	
IEC 60601-2-34 ED4	
DATE OF CIRCULATION: **2022-11-11**	CLOSING DATE FOR VOTING: **2023-02-03**
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IEC SC 62D : ELECTROMEDICAL EQUIPMENT	
SECRETARIAT: United States of America	SECRETARY: Ms Ladan Bulookbashi
OF INTEREST TO THE FOLLOWING COMMITTEES:	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.
FUNCTIONS CONCERNED: ☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☒ SAFETY	
☒ SUBMITTED FOR CENELEC PARALLEL VOTING **Attention IEC-CENELEC parallel voting** The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting. The CENELEC members are invited to vote through the CENELEC online voting system.	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING

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

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

TITLE:

Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment

PROPOSED STABILITY DATE: 2028

NOTE FROM TC/SC OFFICERS:

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment

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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International standard IEC 60601-2-34 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 ISO subcommittee SC3: Lung ventilators and related equipment, of ISO technical committee 121: Anaesthetic and respiratory equipment.

This fourth edition cancels and replaces the third edition of IEC 60601-2-34 published in 2011 and constitutes a technical revision. This edition was revised to align with Amendment 1:2012 and Amendment 2:2020 of IEC 60601-1:2005 as well as new versions of collateral standards and amendments thereto.

Further it includes the following technical changes:

– Expansion of the scope to the EMERGENCY MEDICAL SERVICE ENVIRONMENT
– Changed ESSENTIAL PERFORMANCE in Table 201.101
– Changed requirement for ingress protection

– Added PRIMARY OPERATING FUNCTIONS

– Added requirements for ALARM SYSTEM logging

– Deleted Annex BB (Alarm diagrams 208/IEC 60601-1-8:2006)

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

FDIS	Report on voting
62D/XXX/FDIS	62D/XXX/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, 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 standard, 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 standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, 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 standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– “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 IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

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

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

NOTE The attention of National Committees and Member Bodies 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 INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT. It amends and supplements 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*, hereinafter referred to as the general standard.

The aim of this fourth edition is to bring this particular standard up to date with reference to Amendment 1:2012 and Amendment 2:2020 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 and collateral standards.

A “General guidance and rationale” for the more important 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, Annex AA does not form part of the requirements of this standard.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment

201.1 Scope, object and related standards

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

201.1.1 *Scope

Replacement:

This particular standard applies to BASIC SAFETY and ESSENTIAL PERFORMANCE of INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT as defined in 201.3.63, hereinafter also referred to as ME EQUIPMENT.

This document applies to INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT intended for use in professional healthcare facilities and in the EMERGENCY MEDICAL SERVICE ENVIRONMENT.

This particular standard does not apply to catheter tubing, catheter needles, Luer locks, taps and tap tables that connect to the DOME.

This particular standard does not apply to non-invasive blood pressure monitoring equipment.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as follows:

The clause or subclause applies to ME EQUIPMENT, as default. For ME EQUIPMENT with the corresponding safety measure or function not completely integrated into the ME EQUIPMENT but instead implemented in an ME SYSTEM, the ME EQUIPMENT MANUFACTURER shall specify in the ACCOMPANYING DOCUMENTS which functionality and safety requirements shall be provided by the ME SYSTEM to comply with this standard. The ME SYSTEM has to be verified accordingly.

201.1.2 Object

Replacement:

The object of this particular standard is to establish BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT, as defined in 201.3.63.

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.

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

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, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD1:2020 apply as modified in Clauses 202, 206 and 208 respectively. IEC 60601-1-3, IEC 60601-1-9 and IEC 60601-1-10 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 ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

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

For brevity, IEC 60601-1 is 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 standard 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 60601-1-2 collateral standard, 208.4 in this particular standard addresses the content of Clause 4 of the 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 standard 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 standard" 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

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

ISO 15223-1:2021 *Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements*

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012
Amendment 2:2020

IEC 60601-2-2, *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*

NOTE Informative references are listed in the bibliography.

201.3 Terms and definitions

NOTE An index of defined terms is found at the end of this document.

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-2:2005/AMD2:2020, 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, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, IEC 60601-1-12:2014 and IEC 60601-1-12:2015/AMD1:2020 apply, except as follows:

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

Replacement:

201.3.63
MEDICAL ELECTRICAL EQUIPMENT
ME EQUIPMENT
INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT (ME EQUIPMENT)
device including associated PRESSURE TRANSDUCERS, that is used for internal measurement or monitoring of circulatory system pressures

Replacement:

201.3.8
APPLIED PART
PRESSURE TRANSDUCER, including its associated catheter and any fluid-filled system

Additional definitions:

201.3.201
CATHETER
tubular device, single or multi-lumen, designed to be partially or totally inserted into the cardiovascular system for diagnostic purposes

201.3.202
CATHETER TIP PRESSURE TRANSDUCER
PRESSURE TRANSDUCER mounted at, or close to, the tip of a CATHETER

201.3.203
DOME
means for hydraulically coupling the PATIENT'S blood pressure to a PRESSURE TRANSDUCER external to the PATIENT

201.3.204
NOMINAL SENSITIVITY
ratio of the change in PRESSURE TRANSDUCER output to a change of the value of the pressure at any selected pressure range

201.3.205
PRESSURE TRANSDUCER
device for converting pressure into an electrical signal

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.3 ESSENTIAL PERFORMANCE

Addition:

201.4.3.101 Additional ESSENTIAL PERFORMANCE requirements

Additional ESSENTIAL PERFORMANCE requirements for INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT are found in subclauses listed in Table 201.101.

Table 201.101 – ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Defibrillator protection	201.8.5.5.1
Accuracy of pressure measurements	201.12.1.101

Electrosurgery interference	202.8.101
PHYSIOLOGICAL ALARM CONDITIONS	208.6.1.2.101
PRESSURE TRANSDUCER disconnect ALARM CONDITION	208.6.1.2.102
PRESSURE TRANSDUCER fault ALARM CONDITION	208.6.1.2.103
Catheter disconnect ALARM CONDITION	208.6.1.2.104
ALARM SYSTEM delays for PHYSIOLOGICAL ALARM CONDITIONS	208.6.4.1.101
ALARM SYSTEM delays for TECHNICAL ALARM CONDITIONS	208.6.4.1.102
Delays to or from a DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS (DIS) or a DISTRIBUTED ALARM SYSTEM (DAS)	208.6.4.2

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.4 Other conditions

Addition:

If necessary for the purpose of conducting the test, the INTERNAL ELECTRICAL POWER SOURCE may be replaced by an external battery or d.c. power supply to provide the necessary test voltage.

The values used in test circuits, unless otherwise specified, shall have at least an accuracy as given below:

– resistors: ± 1 %;
– capacitors: ± 10 %;
– inductors: ± 10 %;
– test voltages: ± 1 %

201.5.8 * Sequence of tests

Amendment:

Tests called for in 201.8.5.5.1 of this particular standard and in 8.5.5 of the general standard shall be carried out prior to the LEAKAGE CURRENT and dielectric strength tests described in subclauses 8.7 and 8.8 of the general standard and prior to the tests specified in subclause 201.12.1.101.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

201.6.2 * Protection against electric shock

Replacement of the last paragraph:

APPLIED PARTS shall be classified as TYPE CF APPLIED PARTS (see 7.2.10 and 8.3 of the general standard). APPLIED PARTS shall be classified as DEFIBRILLATION-PROOF APPLIED PARTS (see 8.5.5 of the general standard).

201.6.6 Mode of operation

Replacement:

ME EQUIPMENT shall be classified for CONTINUOUS OPERATION (see 7.2.11).

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

201.7.2.10 APPLIED PARTS

Addition:

If fulfilment of TYPE CF APPLIED PART isolation depends on the PRESSURE TRANSDUCER, then symbol 27, Table D.1 of the general standard, shall be marked on the PRESSURE TRANSDUCER.

201.7.2.17 * Protective packaging

Addition:

The packaging of PRESSURE TRANSDUCER and DOMES supplied in sterile condition shall be marked with symbol 5.2.1, 5.2.2, 5.2.3, 5.2.4 or 5.2.5 of ISO 15223-1:2021 and the time limit for safe use, expressed as the year and month by which these ACCESSORIES should be used (symbol 5.1.4).

The packaging of PRESSURE TRANSDUCER and DOMES that are for single use shall be marked with symbol 28 in Table D.1 of the general standard.

201.7.9.2.2 Warning and safety notices

Addition:

The instructions for use shall include a warning that defibrillator protection requires the use of MANUFACTURER specified ACCESSORIES including PRESSURE TRANSDUCERS and adapter cables.

201.7.9.2.9 Operating instructions

Addition:

201.7.9.2.9.101 Additional instructions for use

The operating instructions shall include the following:

a) the INTENDED USE including the environment of use;

b) for ME EQUIPMENT a list of the specified ACCESSORIES such as PRESSURE TRANSDUCER(S) and DOME(S);

c) for PRESSURE TRANSDUCERS, a list of ME EQUIPMENT that complies with the requirements of this standard when used with these PRESSURE TRANSDUCERS;

d) descriptions of how to connect the PRESSURE TRANSDUCERS and ACCESSORIES, how to calibrate and zero the PRESSURE TRANSDUCERS and suggested means for removing entrapped air from the hydraulic system;

e) recommended frequency of zeroing

EXAMPLE 1: Every 8 hours.
EXAMPLE 2: After moving the patient.
EXAMPLE 3: Following changes in ambient conditions (pressure, temperature)