

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

**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**

<https://www.intelstandards.com/standards/iec/71cc43ef-f21e-4d24-b18a-a471cc5a0b4d/iec-60601-2-34-2024>



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IEC Secretariat
3, rue de Varembe
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

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sanguine prélevée directement**

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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

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IEC 60601-2-34 has been prepared by a Joint Working Group of IEC subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems, and ISO subcommittee SC3: Respiratory devices and related equipment used for patient care, of ISO technical committee 121: Anaesthetic and respiratory equipment. It is an International Standard.

This fourth edition cancels and replaces the third edition of IEC 60601-2-34 published in 2011 and constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

- a) revision to align with IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, as well as new versions of collateral standards and amendments thereto;
- b) expansion of the scope to the emergency medical service environment;
- c) changed essential performance in Table 201.101;
- d) changed requirement for ingress protection;
- e) added primary operating functions;
- f) deleted Annex BB Alarm diagrams.

The text of this International Standard is based on the following documents:

Draft	Report on voting
62D/2155/FDIS	62D/2167/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 International Standard 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.

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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 AND IEC 60601-1:2005/AMD2:2020, 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 IEC 60601 and IEC 80601 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 document 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 the 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.

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INTRODUCTION

This document 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.

The aim of this fourth edition is to bring this document up to date with reference to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and new versions of collateral standards and amendments thereto through technical changes.

The requirements of this document take priority over those of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and collateral standards.

A "General guidance and rationale" for the more important requirements of this document 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 document.

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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

201.1 Scope, object and related standards

Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.1.1 *Scope

Replacement:

This part of IEC 60601 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 document does not apply to catheter tubing, catheter needles, Luer locks, taps and tap tables that connect to the DOME.

This document 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 and, only if the corresponding safety measure or function is not completely integrated into the ME EQUIPMENT but implemented as part of an ME SYSTEM, the clause or subclause applies to the ME SYSTEM.

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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 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, 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and collateral standards.

The numbering of clauses and subclauses of this particular standard corresponds to that of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) 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, 208.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-8 collateral standard, etc.). The changes to the text of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are specified by the use of the following words:

"*Replacement*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard.

"*Amendment*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered starting from 201.101. However, due to the fact that definitions in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

NOTE Informative references are listed in the bibliography.

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 60529:1989, *Degrees of protection provided by enclosures (IP Code)*

IEC 60529:1989/AMD1:1999

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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 60601-1-12:2014, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*

IEC 60601-1-12:2014/AMD1:2020

201.3 Terms and definitions

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 60601-1-12:2014/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:

201.3.8

APPLIED PART

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

201.3.63

INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT

MEDICAL ELECTRICAL EQUIPMENT including associated PRESSURE TRANSDUCERS, that is used for internal measurement or monitoring of circulatory system pressures

Additional terms and 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.4.3 ESSENTIAL PERFORMANCE

Additional subclause:

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

[IEC 60601-2-34:2024](https://standards.iteh.ai/catalog/standards/iec/71cc43ef-f21e-4d24-b18a-a471cc5a0b4d/iec-60601-2-34-2024)

<https://standards.iteh.ai/catalog/standards/iec/71cc43ef-f21e-4d24-b18a-a471cc5a0b4d/iec-60601-2-34-2024>

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.5.4 Other conditions

Addition:

If necessary for the purpose of conducting the test, the INTERNAL ELECTRICAL POWER SOURCE can be replaced by an external battery or DC power supply to provide the appropriate 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 %.

The temperature of the physiological saline solution shall be 25 °C ± 5 °C.