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

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

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

Ta slovenski standard je istoveten z: EN 60601-2-34:2014

ICS:

11.040.55 Diagnostična oprema Diagnostic equipment

SIST EN 60601-2-34:2014 **en**

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN 60601-2-34:2014](#)

<https://standards.iteh.ai/catalog/standards/sist/1d1bda01-3830-4aa5-b6d7-3c096482ca04/sist-en-60601-2-34-2014>

EUROPEAN STANDARD

EN 60601-2-34

NORME EUROPÉENNE

EUROPÄISCHE NORM

June 2014

ICS 11.040.55

Supersedes EN 60601-2-34:2000

English Version

**Medical electrical equipment - Part 2-34: Particular requirements
for the basic safety and essential performance of invasive blood
pressure monitoring equipment
(IEC 60601-2-34:2011)**

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
(CEI 60601-2-34:2011)

Medizinische elektrische Geräte - Teil 2-34: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von invasiven Blutdruck-
Überwachungsgeräten
(IEC 60601-2-34:2011)

This European Standard was approved by CENELEC on 2011-05-16. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.



European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

The text of document 62D/906/FDIS, future edition 3 of IEC 60601-2-34, 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 60601-2-34:2014.

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) 2014-12-27
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2017-06-27

This document supersedes EN 60601-2-34:2000.

EN 60601-2-34:2014 was revised to align structurally with EN 60601-1:2006.

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. <https://standards.iteh.ai/catalog/standards/sist/1d1bda01-3830-4aa5-b6d7-3c096482ca04/sist-en-60601-2-34-2014>

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.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annex ZZ, which is an integral part of this document.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

Endorsement notice

The text of the International Standard IEC 60601-2-34:2011 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

IEC 80601-2-30 NOTE Harmonized as EN 80601-2-30.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN 60601-2-34:2014](https://standards.iteh.ai/catalog/standards/sist/1d1bda01-3830-4aa5-b6d7-3c096482ca04/sist-en-60601-2-34-2014)

<https://standards.iteh.ai/catalog/standards/sist/1d1bda01-3830-4aa5-b6d7-3c096482ca04/sist-en-60601-2-34-2014>

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Annex ZA of the general standard applies, except as follows:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>Replacement:</i>				
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2 + corr. March	2007 2010
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	EN 60601-1-8 + corr. March	2007 2010
<i>Addition:</i>				
IEC 60601-2-2	2009	Medical electrical equipment - Part 2-2: Particular requirements for basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	EN 60601-2-2 + A11	2009 2011
IEC 60601-2-27	-	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment	EN 60601-2-27 ¹⁾	-
IEC 60601-2-49	-	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment	EN 60601-2-49 ¹⁾	-
ISO 15223-1	2007	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	EN ISO 15223-1	2012

¹⁾ At draft stage.

Annex ZZ (informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC except as follows:

- Essential Requirement 6a
- Essential Requirement 7.4
- Essential Requirement 7.5 paragraph 2 & 3
- Essential Requirement 13.6 (q)

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING - Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN 60601-2-34:2014](https://standards.iteh.ai/catalog/standards/sist/1d1bda01-3830-4aa5-b6d7-3c096482ca04/sist-en-60601-2-34-2014)

<https://standards.iteh.ai/catalog/standards/sist/1d1bda01-3830-4aa5-b6d7-3c096482ca04/sist-en-60601-2-34-2014>

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN 60601-2-34:2014](#)

<https://standards.iteh.ai/catalog/standards/sist/1d1bda01-3830-4aa5-b6d7-3c096482ca04/sist-en-60601-2-34-2014>



IEC 60601-2-34

Edition 3.0 2011-05

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
essentiels des appareils de surveillance de la pression sanguine prélevée
directement

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

PRICE CODE **XB**
CODE PRIX

ICS 11.040.55

ISBN 978-2-88912-495-4

CONTENTS

FOREWORD.....	4
INTRODUCTION.....	6
201.1 Scope, object and related standards	7
201.2 Normative references	8
201.3 Terms and definitions.....	9
201.4 General requirements.....	10
201.5 General requirements for testing of ME EQUIPMENT.....	10
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	11
201.7 ME EQUIPMENT identification, marking and documents.....	11
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	13
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	20
201.10 Protection against unwanted and excessive radiation HAZARDS.....	21
201.11 Protection against excessive temperatures and other HAZARDS.....	21
201.12 Accuracy of controls and instruments and protection against hazardous outputs.....	23
201.13 HAZARDOUS SITUATIONS and fault conditions.....	29
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).....	29
201.15 Construction of ME EQUIPMENT	29
201.16 ME SYSTEMS	30
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	30
202 Electromagnetic compatibility – Requirements and tests.....	30
208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.....	36
Annexes	45
Annex AA (informative) Particular guidance and rationale	46
Annex BB (informative) Alarm diagrams 208/IEC 60601-1-8:2006.....	59
Bibliography.....	61
Index of defined terms used in this particular standard.....	62
Figure 201.101 – Dynamic test for limitation of energy from different parts – Recovery test	15
Figure 201.102 – Diaphragm leak test.....	16
Figure 201.103 – Measuring circuit for PATIENT LEAKAGE CURRENT via the PATIENT CONNECTION(S) of an F-TYPE APPLIED PART to earth caused by an external voltage on the PATIENT CONNECTION(S)	17
Figure 201.104 – Measuring circuit for the PATIENT LEAKAGE CURRENT from the APPLIED PART to earth of CLASS I ME EQUIPMENT caused by an external voltage on a metal ACCESSIBLE PART that is not PROTECTIVELY EARTHED.....	18
Figure 201.105 – Measuring circuit for the PATIENT LEAKAGE CURRENT from the APPLIED PART to earth of INTERNALLY POWERED ME EQUIPMENT caused by an external voltage on a metal ACCESSIBLE PART that is not PROTECTIVELY EARTHED.....	19
Figure 201.106– Clarification of leakage current tests.....	20
Figure 201.107 – Over-pressure test.....	21
Figure 201.108 – Test for accuracy of pressure measurements	25

Figure 201.109 – Test sequence for sensitivity, repeatability, non-linearity, drift and hysteresis	26
Figure 201.110 – Pressure measurement system for accuracy of systolic and diastolic pressure	27
Figure 201.111 – Frequency response of ME EQUIPMENT and TRANSDUCER	28
Figure 202.101 – Test layout for conducted and radiated emission and radiated immunity test	31
Figure 202.102 – Test circuit for high-frequency surgery interference measurement, when the isolation of the APPLIED PART is in the monitor	34
Figure 202.103 – Test circuit for high-frequency surgery protection, when the isolation of the APPLIED PART is in the TRANSDUCER	35
Figure 202.104 – Test set-up for high-frequency surgery protection	36
Figure 208.101 – Test for delay times of ALARM SIGNALS indicating PHYSIOLOGICAL ALARM CONDITIONS	41
Figure 208.102 – Test for delay times of ALARM SIGNALS indicating PHYSIOLOGICAL ALARM CONDITIONS	42
Figure AA.1 – Pressure TRANSDUCER error band	53
Figure BB.101 – NON-LATCHING ALARM SIGNALS without ALARM RESET	59
Figure BB.102 – NON-LATCHING ALARM SIGNALS with ALARM RESET	59
Figure BB.103 – LATCHING ALARM SIGNALS with ALARM RESET	60
Figure BB.104 – Two ALARM CONDITIONS with ALARM RESET	60
ITeh STANDARD PREVIEW (standards.iteh.ai)	
Table 201.101 – ESSENTIAL PERFORMANCE requirements	10
Table 208.101 – ALARM CONDITION priorities	37
Table 208.102 – Characteristics of the BURST of auditory ALARM SIGNALS	38

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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.
- 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 IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International standard IEC 60601-2-34 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition of IEC 60601-2-34 published in 2001 and constitutes a technical revision. This edition was revised to align structurally with the 2005 edition of IEC 60601-1.

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

FDIS	Report on voting
62D/906/FDIS	62D/923/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.

INTRODUCTION

This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT. It amends and supplements IEC 60601-1 (third edition, 2005): *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard.

The aim of this third edition is to bring this particular standard up to date with reference to the third edition of the general standard through reformatting and technical changes.

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

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.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN 60601-2-34:2014](https://standards.iteh.ai/catalog/standards/sist/1d1bda01-3830-4aa5-b6d7-3c096482ca04/sist-en-60601-2-34-2014)

<https://standards.iteh.ai/catalog/standards/sist/1d1bda01-3830-4aa5-b6d7-3c096482ca04/sist-en-60601-2-34-2014>

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 standard¹ 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 referred to as ME EQUIPMENT.

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

201.1.2 Object

[SIST EN 60601-2-34:2014](https://standards.iteh.ai/catalog/standards/sist/1d1bda01-3830-4aa5-b6d7-3c096482ca04/sist-en-60601-2-34-2014)

Replacement: <https://standards.iteh.ai/catalog/standards/sist/1d1bda01-3830-4aa5-b6d7-3c096482ca04/sist-en-60601-2-34-2014>

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.

IEC 60601-1-2:2007 and IEC 60601-1-8:2006 apply as modified in Clauses 202 and 208 respectively. IEC 60601-1-3 does 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.

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