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 essentielles des appareils de surveillance de la pression sanguine prélevée directement

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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 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.

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 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.

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.

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.

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

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

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, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 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 3.139, 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, 203 for IEC 60601-1-3, 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 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

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*

Addition:

IEC 60601-2-2:2009, *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, *Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment*[2]

IEC 60601-2-49, *Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment*[3]

ISO 15223-1:2007 *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*

NOTE Informative references are listed in the bibliography beginning on page 61.

201.3 Terms and definitions

NOTE An index of defined terms is found beginning on page 61.

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 apply, except as follows:

Replacement:

201.3.63
MEDICAL ELECTRICAL EQUIPMENT
ME EQUIPMENT

Addition:

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

Replacement:

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

Additional definitions:

201.3.201
CATHETER TIP TRANSDUCER
TRANSDUCER mounted at, or close to, the tip of a catheter and intended for insertion into the cardiovascular system

201.3.202
DOME
means for hydraulically coupling the PATIENT'S blood pressure to a TRANSDUCER external to the PATIENT

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2 Third edition, to be published.

3 Second edition, to be published.

201.3.203
NOMINAL SENSITIVITY
ratio of the change in TRANSDUCER output to a change of the value of the pressure at any selected pressure range

201.3.204
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	202.6.2.101
Delays to or from a DISTRIBUTED ALARM SYSTEM	208.6.4.2
PHYSIOLOGICAL ALARM CONDITIONS, ALARM LIMITS and delay time of physiological ALARM SIGNALS	208.6.6.2.101
Detection of TRANSDUCER and TRANSDUCER cable fault	208.6.6.2.102
Detection of disconnected catheter	208.6.6.2.103

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:

Unless otherwise stated, tests shall be carried out with the ACCESSORIES specified by the MANUFACTURER.

For ME EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE, if the test result is affected by the INTERNAL ELECTRICAL POWER SOURCE voltage, then the test shall be performed using the least favourable INTERNAL ELECTRICAL POWER SOURCE voltage specified by the MANUFACTURER. If necessary for the purpose of conducting the test, an external battery or d.c. power supply may be used 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 TRANSDUCER, then symbol 27, Table D.1 of the general standard, shall be marked on the TRANSDUCER.

201.7.2.17 * Protective packaging

Addition:

The packaging of TRANSDUCER and DOMES supplied in sterile condition shall be marked with symbol 5.20 of ISO 15223-1:2007 and the time limit for safe use, expressed as the year and month by which these ACCESSORIES should be used (symbol 5.12, and 5.20 to 5.24).

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

201.7.9.2.9 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 TRANSDUCER(S) and DOME(S);

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

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

e) advice to the clinical OPERATOR regarding whether the TRANSDUCERS or ME EQUIPMENT incorporates means to protect the PATIENT against burns when used with HIGH-FREQUENCY (HF) SURGICAL EQUIPMENT. Advice shall be given regarding the location of electrodes, TRANSDUCERS, etc. to reduce the hazards of burns in the event of a defect in the neutral electrode connection of the HF SURGICAL EQUIPMENT;

NOTE 'Neutral electrode' here refers to a term defined in IEC 60601-2-2.

f) precautions to take when using a defibrillator on a PATIENT; a description of how the discharge of a defibrillator affects the ME EQUIPMENT; a warning that defibrillator protection requires use of MANUFACTURER specified ACCESSORIES including TRANSDUCERS and adapter cables. The specification (or type-number) of such ACCESSORIES shall be disclosed;

g) a warning that single-use ACCESSORIES are not to be reused;

h) if the TRANSDUCER and/or DOMES are reusable, information on the appropriate processes for cleaning, disinfection, packaging and, where appropriate, the method of sterilization, and any restriction on the number of reuses;

i) if the ME EQUIPMENT has to be connected to other equipment in order to achieve its INTENDED USE, sufficient details of its characteristics to correctly identify the equipment necessary for safe operation;

j) precautions to be taken in the event of changes in performance of the tubing, TRANSDUCER, or cable as a result of ageing and environmental conditions;

k) the warm-up time for the ME EQUIPMENT and TRANSDUCER(S) if greater than 15 s;

l) * advice regarding testing of the ME EQUIPMENT and ACCESSORIES on a daily basis (by the clinical OPERATOR) and on a scheduled basis (as a service activity). Emphasis should be placed on how the clinician may test visual and auditory ALARM SIGNALS;

m) instructions for connecting a POTENTIAL EQUALIZATION CONDUCTOR, if applicable;

n) the default settings (e.g. ALARM SETTINGS, modes, and filter);

o) performance specification (e.g. accuracy, bandwidth, measurement range) of ME EQUIPMENT including specified TRANSDUCERS and adjustment ranges of all physiological ALARM SETTINGS (see 208.6.6.2.101);

p) explanation of TECHNICAL ALARM CONDITIONS (see 208.6.6.2.102 and 208.6.6.2.103);

q) the configuration procedure that allows the ALARM SIGNAL inactivation states (ALARM PAUSED, AUDIO PAUSED, ALARM OFF or AUDIO OFF) or the function ALARM RESET to be controlled remotely (see 208.6.11.101), if provided;

r) simple fault finding methods for troubleshooting problems by which the clinical OPERATOR can locate problems if the ME EQUIPMENT appears to be functioning incorrectly;

NOTE This relates to simple difficulties, not to technical malfunctions.

s) the subsequent operation of the ME EQUIPMENT after interruption of the SUPPLY MAINS exceeding 30 s (see 201.11.8);

t) * description of how to disable ALARM SIGNALS for TECHNICAL ALARM CONDITIONS if TRANSDUCERS or modules are intentionally disconnected by the clinical OPERATOR (see 208.6.8.101);

u) advice on the preferred ALARM SETTINGS and configurations of the ALARM SYSTEM when the INTENDED USE includes monitoring of PATIENTS that are not continuously attended by a clinical OPERATOR;

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

201.8.3 Classification of APPLIED PARTS

Replacement:

The APPLIED PART shall be a TYPE CF APPLIED PART.

201.8.5.5.1 * Defibrillation protection

Addition:

ME EQUIPMENT shall have DEFIBRILLATOR-PROOF APPLIED PARTS.

Addition to item b):

The recovery time after defibrillation shall not exceed 10 s.

Addition to common-mode test to verify a):

Compliance is checked by testing in accordance with Figure 201.101. The requirement is met when after operation of S_1, the peak voltage between the points Y1 and Y2 does not exceed 1 V.

In the case of a CATHETER TIP TRANSDUCER, the CATHETER with its TRANSDUCER is immersed in the saline solution for a length of 75 cm or 90 % of the actual length of the CATHETER excluding its connector, whichever is the shorter.

– *Remove the diaphragm of the DOME, destructively if necessary.*
– *Disposable TRANSDUCERS and CATHETER TIP TRANSDUCERS must be tested intact and complete.*

Repeat the test with the 5 kV supply (V1) reversed.

After this test the ME EQUIPMENT must meet all requirements and tests of this particular standard and continue to provide BASIC SAFETY and ESSENTIAL PERFORMANCE.

Following this test, replace the DOME with one that has an intact diaphragm and repeat this test. Verify that the diaphragm was not punctured during the test.

Compliance is checked (test described in Figure 201.102) by applying air pressure gradually over about 0,5 s, holding that pressure for about 10 s, and noting the absence of bubbles.

Addition to common-mode test to verify b):