

INTERNATIONAL STANDARD

IEC 60601-2-34

Second edition
2000-10

Medical electrical equipment –

Part 2-34:

Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment

Appareils électromédicaux –

Partie 2-34:

Règles particulières de sécurité pour les appareils de surveillance de la pression sanguine prélevée directement



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Commission Electrotechnique Internationale
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

- 1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The 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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- 3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.
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International Standard IEC 60601-2-34 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition of IEC 60601-2-34 cancels and replaces the first edition published in 1994 and constitutes a technical revision.

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

FDIS	Report on voting
62D/367/FDIS	62D/373/RVD

Full information on the voting for the approval of this 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 3.

Annexes AA and BB are for information only.

This Particular Standard amends and supplements IEC 60601-1 (second edition 1988): *Medical Electrical Equipment – Part 1: General Requirements for Safety*, modified by amendment 1 and amendment 2, hereinafter referred to as the General Standard. The requirements of this Particular Standard take priority over those of the General Standard.

In this Particular Standard the following print types are used:

- requirements, compliance with which can be tested and definitions: in roman type;
- notes, explanations, advice, introductions, general statements, exceptions and references: in smaller type;
- *test specifications, headings of subclauses and headings of items: in italic type:*
- TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until 2005. At this date, the publication will be

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

A bilingual version of this standard may be issued at a later date.

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INTRODUCTION

The General Standard does not include requirements specific to the safety, including essential performance, of DIRECT BLOOD PRESSURE MONITORING EQUIPMENT. Hence, changes need to be made to include these unique requirements. This particular standard takes into account *Collateral Standard 60601-1-2:(1993) Electromagnetic compatibility* and *Collateral Standard 60601-1-4:(1996) Medical electrical equipment incorporating programmable electrical systems*. A section on ALARMS has been included because ALARMS are necessary for MONITORING EQUIPMENT.

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MEDICAL ELECTRICAL EQUIPMENT –

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

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

*1.1 Scope

Addition:

This Particular Standard applies to INVASIVE BLOOD PRESSURE MONITORING and measuring EQUIPMENT as defined in 2.101, hereinafter referred to as EQUIPMENT.

This Particular Standard does not apply to catheter tubing, catheter needles, Luer locks, taps and tap tables.

This Particular Standard also does not apply to NON-INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety, including the essential performance of EQUIPMENT, as defined in 2.101.

1.3 Particular Standards

Addition:

This Particular Standard refers to IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety* as amended by its amendment 1 (1991) and its amendment 2 (1995).

The General Standard takes into account IEC 60601-1-2:1993, *Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral Standard: Electromagnetic compatibility – Requirements and tests* and IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: Collateral Standard: Programmable electrical medical systems*.

For brevity, IEC 60601 is referred to in this Particular Standard either as the “General Standard” or as the “General Requirement(s)”.

The numbering of sections, clauses or subclauses of this Particular Standard corresponds to that of the General Standard. 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 is replaced completely by the text of this Particular Standard.

“Addition” means that the clause or subclause of this Particular Standard is additional to the requirements of the General Standard.

“Amendment” means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc, and additional items aa), bb), etc.

The term “this Standard” is used to make reference to the General Standard and this Particular Standard taken together.

An asterisk (*) notes clauses for which there is rationale comment in annex AA or annex BB. It is considered that a knowledge of the reasons for these requirements will facilitate the proper application of the standard and be of use in any revision that may be necessitated by changes in clinical practice or as a result of developments in technology.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification; where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

The requirements of this Particular Standard take priority over those of the General Standard and of the Collateral Standards mentioned above.

2 Terminology and definitions

This clause of the General Standard applies except as follows:

2.1.5 APPLIED PART

Replacement:

The TRANSDUCER, including any fluid-filled system.

Additional definitions:

2.101

INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT (EQUIPMENT)

stand-alone measuring equipment or part of a physiological monitoring or measuring system, including associated TRANSDUCERS, that is used for the internal measurement of circulatory system pressures

2.102**TRANSDUCER**

device for converting pressure into an electrical signal for monitoring or measuring

2.103**CATHETER TIP TRANSDUCER**

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

2.104**DOME**

means for hydraulically coupling the PATIENT'S blood pressure to the TRANSDUCER, where a TRANSDUCER external to the PATIENT is used

2.12.101**ALARM**

signal which indicates abnormal events occurring to the PATIENT or EQUIPMENT

2.12.102**PHYSIOLOGICAL ALARM**

signal which either indicates that a monitored physiological parameter is out of specified limits or indicates an abnormal PATIENT condition

2.12.103**TECHNICAL ALARM**

signal which indicates that the EQUIPMENT or part(s) of the EQUIPMENT are not capable of accurately monitoring the PATIENT'S condition

2.12.104**SILENCING**

stopping an auditory ALARM manifestation by manual action

2.12.105**SILENCING/RESET**

stopping a visual and/or auditory ALARM manifestation and reenabling system response to an abnormal PATIENT condition

2.12.106**INHIBITION**

disabling or SILENCING and disabling an ALARM until revoked intentionally

2.12.107**SUSPENSION**

disabling or SILENCING and disabling an ALARM temporarily

2.12.108**LATCHED ALARM**

ALARM, the visual and auditory manifestation of which does not stop when the parameter returns to a value which no longer exceeds the alarm limit or if the abnormal PATIENT condition does not exist any longer

2.12.109**NON-LATCHED ALARM**

ALARM, the visual and auditory manifestation of which stops when the parameter (which caused the alarm) returns to a value which no longer exceeds the alarm limit or if the abnormal PATIENT condition does not exist any longer

2.12.110

NOMINAL SENSITIVITY

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

4 General requirements for tests

This clause of the General Standard applies except as follows:

*4.11 Sequence

Amendment:

Tests called for in 17 h), 17.101.1, 45.101 and 51.101 of this Particular Standard shall be performed in that order prior to the LEAKAGE CURRENT and dielectric strength tests of C24 and C25 of Appendix C of the General Standard.

5 Classification

This clause of the General Standard applies except as follows:

5.2 According to the degree of protection against electrical shock

Delete TYPE B and TYPE BF APPLIED PART.

5.6 According to the mode of operation

Amendment:

Delete all but CONTINUOUS OPERATION.

6 Identification, marking and documents

This clause of the General Standard applies except as follows:

6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts

aa) *Addition:*

If fulfilment of Type CF isolation depends on the TRANSDUCER then symbol No. 14, table D1, IEC 60601-1, shall be marked on the EQUIPMENT.

*6.8.2 Instructions for use

Additional items:

aa) Supplementary instructions for use

Advice shall be provided for the following:

- 1) The connection of the TRANSDUCER and ACCESSORIES, the pressure calibration of the TRANSDUCER and suggested means for removing entrapped air from the hydraulic system connected to the TRANSDUCER.

- 2) The safe use of TRANSDUCERS and ACCESSORIES and also on their choice, where the use of other parts could degrade the safety of the EQUIPMENT. In particular, if fulfilment of TYPE CF depends on the TRANSDUCER, then the ACCOMPANYING DOCUMENTS must include the recommended types of TRANSDUCERS.
- 3) The need for the OPERATOR to avoid conductive connection to the APPLIED PART likely to degrade safety. (For example, by not contacting metal cocks, if used.)
- 4) The type of electrical installation to which the EQUIPMENT may be safely connected, including the connection to any POTENTIAL EQUALIZATION CONDUCTOR terminal on the EQUIPMENT, if provided.
- 5) If parts of the TRANSDUCERS or EQUIPMENT are provided with protective means against hazards to the PATIENT when used with HIGH-FREQUENCY SURGICAL EQUIPMENT, such means shall be drawn to the attention of the OPERATOR. If such means are absent, notice shall be given in the ACCOMPANYING DOCUMENTS.
- 6) The action to be taken following accidental wetting of the EQUIPMENT.
- 7) Description of those parts of the EQUIPMENT that are protected against the effects of a discharge of a cardiac defibrillator.
- 8) Any precautions specific to the EQUIPMENT to be taken when a defibrillator is used on a PATIENT and on any effects on the EQUIPMENT of the effects of a discharge of a cardiac defibrillator.
- 9) A warning that single-use devices are not to be reused.
- *10) TRANSDUCER or ACCESSORIES supplied as sterile shall be identified as sterile.
- *11) If appropriate, an indication of the time limit for safe use of the TRANSDUCER and ACCESSORIES, expressed as the year and month.
- 12) If the EQUIPMENT has to be connected to other devices in order to achieve its intended purpose, sufficient details of its characteristics to identify correctly the devices necessary for safe operation.
- *13) Precautions to be taken in the event of changes in performance of the device as a result of ageing and environmental conditions.
- 14) The warm-up time for the TRANSDUCER and EQUIPMENT if greater than 15 s.
- *15) The volume displacement in mm³/100 mm Hg for any TRANSDUCER and/or DOME that is supplied with the EQUIPMENT.

SECTION TWO – ENVIRONMENTAL CONDITIONS

The clauses and subclauses of this section of the General Standard apply.

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

The clauses and subclauses of this section of the General Standard apply except as follows:

14 Requirements related to classification

This clause of the General Standard applies except as follows:

14.6 Replacement:

The APPLIED PART shall be TYPE CF.

14.8 The EQUIPMENT shall have DEFIBRILLATOR PROOF APPLIED PARTS.

17 Separation

This clause of the General Standard applies except as follows:

17 h)

Addition:

- a) The ENCLOSURE excluding accessible conductive parts in the hydraulic circuit beyond the DOME.

Addition:

Compliance shall be checked by testing in accordance with figure 102. The requirement is met when after operation of S1, the peak voltage between the points Y1 and Y2 does not exceed 1 V.

- *The diaphragm of the DOME shall be removed, destructively if necessary.*
- *Disposable TRANSDUCERS and CATHETER TIP TRANSDUCERS shall be tested intact and complete.*

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

After this test the EQUIPMENT shall be capable of meeting all requirements and tests of this Particular Standard and shall function normally (see also 51.101).

17.101.1 *Following the test of 17 h), the DOME shall be replaced with one having an intact diaphragm and the test shall then be repeated. The diaphragm shall not have been punctured during the test.*

Compliance shall be checked by performing the test as described in figure 106 with the air pressure being applied gradually over about 1/2 s and held for about 10 s, and by noting the absence of bubbles.

19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

This clause of the General Standard applies except as follows:

*19.3 Allowable values

Addition:

- aa) For EQUIPMENT having a FUNCTIONAL EARTH TERMINAL, the PATIENT LEAKAGE CURRENT flowing from the APPLIED PART to EARTH shall be no greater than 0,05 mA, when a voltage equal to 110 % of the highest RATED MAINS VOLTAGE is applied between the FUNCTIONAL EARTH TERMINAL and earth.

The following test shall not be performed when the FUNCTIONAL EARTH TERMINAL is connected direct to the PROTECTIVE EARTH TERMINAL inside the EQUIPMENT.

Compliance shall be checked by measurement according to figures 103 and 104.

All tests shall be performed with any reusable and/or disposable DOME removed.