SLOVENSKI STANDARD
SIST EN 60601-2-34:2002

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Nadomešča:
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Medicinska električna oprema - 2-34. del: Posebne varnostne zahteve za opremo za neposredno nadzorovanje krvnega tlaka, vključno z njenimi osnovnimi lastnostmi (IEC 60601-2-34:2000)

Medical electrical equipment - Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment (IEC 60601-2-34:2000)

Medizinische elektrische Geräte - Teil 2-34: Besondere Festlegungen für die Sicherheit einschließlich wesentlicher Leistungsmerkmale, von invasiven Blutdruck-Überwachungsgeräten (IEC 60601-2-34:2000)

Appareils électromédicaux - Partie 2-34: Règles particulières de sécurité pour les appareils de surveillance de la pression sanguine prélevée directement (CEI 60601-2-34:2000)

Ta slovenski standard je istoveten z: **EN 60601-2-34:2000**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment

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EUROPEAN STANDARD

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English version

Medical electrical equipment
Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment
(IEC 60601-2-34:2000)

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Medizinische elektrische Geräte
Teil 2-34: Besondere Festlegungen für die Sicherheit einschließlich wesentlicher Leistungsmerkmale, von invasiven Blutdruck-Überwachungsgeräten
(IEC 60601-2-34:2000)

This European Standard was approved by CENELEC on 2000-11-01. 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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CENELEC

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of document 62D/367/FDIS, future edition 2 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 was approved by CENELEC as EN 60601-2-34 on 2000-11-01.

This European Standard supersedes EN 60601-2-34:1995.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2001-08-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2003-11-01

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annexes AA and BB are informative.

Endorsement notice

The text of the International Standard IEC 60601-2-34:2000 was approved by CENELEC as a European Standard without any modification.

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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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.
2) The formal decisions or agreements of the 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 National Committees.
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.
4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

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.

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.

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 $mm^3/100$ 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.