EESTI STANDARD EVS-EN 60601-2-34:2002



# Elektrilised meditsiiniseadmed. Osa 2-34: Erinõuded kehasseviidava vererõhu seireseadmestiku ohutusele, sealhulgas olulisele jõudlusele

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

EESTI STANDARDIKESKUS

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

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|---|---|
| Käesolev Eesti standard EVS-EN 60601-2-34:2002 sisaldab Euroopa standardi EN 60601-2-34:2000 ingliskeelset teksti. | This Estonian standard EVS-EN 60601-2-34:2002 consists of the English text of the European standard EN 60601-2-34:2000. |
| Käesolev dokument on jõustatud 18.12.2002 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. | This document is endorsed on 18.12.2002 with the notification being published in the official publication of the Estonian national standardisation organisation. |
| Standard on kättesaadav Eesti standardiorganisatsioonist. | The standard is available from Estonian standardisation organisation. |

**ICS** 11.040.55

EUROPEAN STANDARD **EN 60601-2-34**

NORME EUROPÉENNE

EUROPÄISCHE NORM December 2000

ICS 11.040.55 Supersedes EN 60601-2-34:1995

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)

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)

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**



Ref. No. EN 60601-2-34:2000 E

## 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.

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## Endorsement notice

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

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# 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*



Reference number
IEC 60601-2-34:2000(E)

## Publication numbering

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# INTERNATIONAL STANDARD

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Commission Electrotechnique Internationale
International Electrotechnical Commission
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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# 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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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