SVENSK STANDARD SS-EN 60601-2-34

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| 2001-06-29 | 2 | 1 (1+57) | SEK Översikt 62 |

Svenska Elektriska Kommissionen, SEK



# Elektrisk utrustning för medicinskt bruk – Säkerhet och väsentliga prestanda – Del 2-34: Särskilda fordringar på utrustning för invasiv blodtrycksövervakning

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

Som svensk standard gäller europastandarden EN 60601-2-34:2000. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-2-34:2000.

**Nationellt förord**

Europastandarden EN 60601-2-34:2000

består av:

– **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC
– **IEC 60601-2-34, Second edition, 2000 - Medical electrical equipment - Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment**

utarbetad inom International Electrotechnical Commission, IEC.

Standarden skall användas tillsammans med SS-EN 60601-1, och dess separat utgivna ändringar och tillägg.

Tidigare utgiven svensk standard SS-EN 60601-2-34, utgåva 1, 1996, gäller ej fr o m 2003-11-01.

Till SS-EN 60601-1 utges en serie tilläggstandarder som anger allmänna fordringar på säkerhet som är tillämpliga på

– en grupp av elektrisk utrustning för medicinskt bruk, t ex radiologisk utrustning
– särskilda egenskaper hos all elektrisk utrustning för medicinskt bruk, ej särskilt behandlade i SS-EN 60601-1, t ex elektromagnetisk kompatibilitet.

ICS 11.040.55

Denna standard är fastställd av Svenska Elektriska Kommissionen, SEK,
som också kan lämna upplysningar om **sakinnehållet** i standarden.
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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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Clause

# 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)”.