

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.

EUROPEAN STANDARD

EN 60601-2-34

NORME EUROPÉENNE

EUROPÄISCHE NORM

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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)**

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

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.

CONTENTS

Page

Clause

SECTION ONE – GENERAL

1	Scope and object	7
2	Terminology and definitions	8
4	General requirements for tests	10
5	Classification	10
6	Identification, marking and documents	10

SECTION TWO – ENVIRONMENTAL CONDITIONS

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

14	Requirements related to classification	11
17	Separation	12
19	Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	12
20	Dielectric strength	13

SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS

21	Mechanical strength	13
----	---------------------------	----

SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

36	ELECTROMAGNETIC COMPATIBILITY	14
----	-------------------------------------	----

SECTION SIX – PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

42	Excessive temperatures	17
44	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility	17
45	Pressure vessel and parts subject to pressure	18
46	Human errors	19

SECTION EIGHT – ACCURACY OF OPERATION DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

50	Accuracy of operating data	19
51	Protection against hazardous output	19

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

56	Components and general assembly	29
57	Mains parts, components and layout	29

Annex AA (informative) Guidance and rationale for particular clauses and subclauses	46
Annex BB (informative) ALARM diagrams	55
INDEX of defined terms.....	58
Bibliography	59
Figure 101 – Measuring circuit for PATIENT LEAKAGE CURRENT via an F-TYPE (FLOATING) earth caused by an external voltage on the APPLIED PART	30
Figure 102 – Dynamic test for limitation of energy from different parts – Recovery test	31
Figure 103 – Measuring circuit for the PATIENT LEAKAGE CURRENT from the APPLIED PART to earth of CLASS I EQUIPMENT caused by an external voltage on the FUNCTIONAL EARTH TERMINAL	32
Figure 104 – Measuring circuit for the PATIENT LEAKAGE CURRENT from the APPLIED PART to EARTH of INTERNALLY POWERED EQUIPMENT, caused by an external voltage on a FUNCTIONAL EARTH TERMINAL.....	33
Figure 105 – Clarification of leakage current tests	34
Figure 106 – Diaphragm leak test.....	35
Figure 107 – Over-pressure test.....	35
Figure 108 – Test layout for conducted and radiated emission and radiated immunity test....	36
Figure 109 – Test circuit for high-frequency surgery interference measurement, when the PATIENT isolation is in the monitor.....	37
Figure 110 – Test circuit for HIGH-FREQUENCY surgery interference measurement, when the PATIENT isolation is in the TRANSDUCER	38
Figure 111 – Test set-up for HIGH-FREQUENCY SURGICAL EQUIPMENT interference measurement.....	39
Figure 112 – Test for accuracy of pressure measurements.....	40
Figure 113 – Test for sensitivity, repeatability, non-linearity, drift and hysteresis	41
Figure 114 – Pressure measurement system for accuracy of systolic and diastolic pressure.....	42
Figure 115 – Frequency response of EQUIPMENT and TRANSDUCER	43
Figure 116 – Test for ALARM DELAY	44
Figure 117 – Test for ALARM DELAY	45
Figure AA.1 – Pressure TRANSDUCER error band.....	54

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)”.