

Medical electrical equipment —

**Part 2: Particular requirements for
safety**

**Section 2.34 Specification for direct
blood-pressure monitoring equipment**

The European Standard EN 60601-2-34:1995 has the status of a
British Standard

ICS 11.040.50

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/96, Patient monitoring, upon which the following bodies were represented:

- Association of Anaesthetists of Great Britain and Ireland
- Department of Health
- Electro Medical Trade Association Limited
- Institute of Hospital Engineering
- Institute of Physical Sciences in Medicine (IPSM)
- Ministry of Defence
- Royal College of Physicians in London

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National foreword

This Section of BS EN 60601 has been prepared by Technical Committee CH/96 and is the English language version of EN 60601-2-34:1995 *Medical electrical equipment — Part 2: Particular requirements for the safety of direct blood-pressure monitoring equipment*, published by the European Committee for Electrotechnical Standardization (CENELEC). It is identical with IEC 601-2-34:1994, published by the International Electrotechnical Commission (IEC).

This Particular Standard amends and supplements BS EN 60601-1¹⁾ hereinafter called the General Standard. As stated in 1.3 of the General Standard, the requirements of this Particular Standard take precedence over those of the General Standard.

A rationale for the most important requirements is given in Annex AA. It is considered that a knowledge of the reasons for the requirements will not only facilitate the proper application of the standard, but will expedite any subsequent revision. Annex AA does not form part of the requirements of the standard.

Cross-references

Publication referred to	Corresponding British Standard
IEC 601-1:1988	BS EN 60601-1 (BS 5724-1) <i>Medical electrical equipment — General requirements for safety</i>
IEC 529:1989	BS EN 60529:1992 <i>Specification for degrees of protection provided by enclosures (IP code)</i>

Additional information. The following print types are used in this standard.

Requirements, compliance with which can be tested, and definitions: in roman type

Explanations, advice and general statements in small roman type

Test procedures: in *italic type*

Terms defined in clause 2 of the General Standard: in SMALL CAPITALS

For the purposes of this British Standard, any references to IEC page numbers in the text should be ignored.

Textual errors. When adopting the text of the European Standard, the following errors in the IEC reference document were discovered. As they are minor errors resulting from the transposition of English language and French language texts they have been corrected in the text, have been indicated by marginal marks and have been reported to both IEC and CENELEC with a request that the IEC reference document should be amended.

In Figure 102 the titles in English and French have been transposed.

In Figure 105 the inscriptions in English and French have been transposed.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 18, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

¹⁾ Also numbered BS 5724-1.

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Descriptors: Medical electrical equipment, monitoring equipment, blood-pressure, safety

English version

Medical electrical equipment
Part 2: Particular requirements for the safety of direct
blood-pressure monitoring equipment

(IEC 601-2-34:1994)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité pour
les appareils de surveillance de la pression
sanguine prélevée directement
(CEI 601-2-34:1994)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die
Sicherheit von invasiven
Blutdruck-Überwachungsgeräten
(IEC 601-2-34:1994)

This European Standard was approved by CENELEC on 1995-03-06. 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, 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

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Foreword

The text of document 62D(CO)79, future edition 1 of IEC 601-2-34, 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 1995-03-06.

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) 1996-03-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1996-03-01

For products which have complied with the relevant national standard before 1996-03-01, as shown by the manufacturer or by a certification body, this previous standard may continue to apply for production until 2001-03-01.

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Section 1. 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 DIRECT BLOOD-PRESSURE MONITORING 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 taptables, etc.

This Particular Standard also does not apply to indirect blood-pressure monitoring equipment.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety of DIRECT BLOOD-PRESSURE MONITORING EQUIPMENT and the electrical safety requirements for CATHETER TIP TRANSDUCERS as defined in **2.103**.

1.3 Particular Standards

Addition:

This Particular Standard refers to IEC 601-1 (1988): *Medical electrical equipment — Part 1: General requirements for safety* as amended by its amendment 1 (1991).

For brevity, Part 1 is referred to in this Particular Standard either as the “General Standard” or as the “General Requirement(s)”.

The numbering of sections, clauses and 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 text 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.

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.

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 up to the point at which the electrical isolation of the APPLIED PART is completed.

Additional definitions:

2.101

DIRECT BLOOD-PRESSURE MONITORING EQUIPMENT (EQUIPMENT)

MEDICAL ELECTRICAL EQUIPMENT including TRANSDUCERS for the monitoring and/or recording of the internal blood-pressure of PATIENTS

2.102

TRANSDUCER

part for converting pressure into a signal for monitoring or recording

2.103

CATHETER TIP TRANSDUCER

TRANSDUCER intended for insertion into the cardiovascular system

2.104

DOMES

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

4 General requirements for tests

This clause of the General Standard applies except as follows:

4.11 Sequence*

Amendment:

Tests called for in **17.101**, **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 electric shock

Amendment:

delete TYPE B and BF EQUIPMENT.

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

Additional item:

aa) EQUIPMENT and/or the TRANSDUCER as appropriate shall be marked with the symbol given in the addition to Appendix D of this Particular Standard unless such parts are too small or otherwise have limitations on their ability to be marked (for example, disposable DOMES). Parts excepted from such markings shall contain information on the protection against the effects of defibrillation in the ACCOMPANYING DOCUMENTS.

6.8.2 Instructions for use

Additional item:

aa) *Supplementary instructions for use*

Advice shall be provided on the following:

— The connection of the TRANSDUCER and ACCESSORIES, the pressure calibration of the TRANSDUCER and suggested means for removing trapped air from the hydraulic system connected to the TRANSDUCER.

— 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 recommended types of TRANSDUCERS shall be mentioned in the ACCOMPANYING DOCUMENTS and the OPERATOR shall be alerted by appropriate marking on the EQUIPMENT.

— 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.)

— 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.

— If parts of the TRANSDUCERS and EQUIPMENT are provided with protective means against burns to the PATIENT when used with HF 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.

— In connection with the above, advice shall also be given on the use of the EQUIPMENT with HF surgical equipment, for example, to avoid burns to the PATIENT.

— The action to be taken following accidental wetting of the EQUIPMENT.

— Description of those parts of the EQUIPMENT that are protected against the effects of a discharge of a cardiac defibrillator.

— 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 a discharge of a cardiac defibrillator.

— A warning that single-use devices are not designed to be reused. (ISO 7000²⁾ symbol 1051 may be used.)

Section 2. Environmental conditions

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

²⁾ ISO 7000:1989, *Graphical symbols for use on equipment — Index and synopsis*