

Medical electrical equipment —

Part 2: Particular requirements for safety —

Specification for electrocardiographic monitoring equipment

The European Standard EN 60601-2-27:1994 has the status of a
British Standard

Cooperating organizations

The European Committee for Electrotechnical Standardization (CENELEC), under whose supervision this European Standard was prepared, comprises the national committees of the following countries:

Austria	Italy
Belgium	Luxembourg
Denmark	Netherlands
Finland	Norway
France	Portugal
Germany	Spain
Greece	Sweden
Iceland	Switzerland
Ireland	United Kingdom

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National foreword

This British Standard has been prepared under the direction of the Health and Environment Sector Board. It is the English language version of EN 60601-2-27:1994 *Medical electrical equipment — Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment*, published by the European Committee for Electrotechnical Standardization (CENELEC). It is identical with IEC 601-2-27:1994, 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. This annex does not form part of the requirements of the standard.

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.

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.

ICS 11.040.50

Descriptors: Medical electrical equipment, monitoring equipment, electrocardiograph, safety requirements, equipment specifications, equipment protection, test

English version

**Medical electrical equipment
Part 2: Particular requirements for the safety of
electrocardiographic monitoring equipment**

(IEC 601-2-27:1994)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité des
appareils de surveillance
d'électrocardiographie
(CEI 601-2-27:1994)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die
Sicherheit von
Elektrokardiographie-Überwachungsgeräten
(IEC 601-2-27:1994)

This European Standard was approved by CENELEC on 1994-07-05. 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

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Foreword

The text of document 62D(CO)68, as prepared by Sub-Committee 62D: Electromedical equipment, of IEC Technical Committee 62: Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote in October 1992.

The reference document was approved by CENELEC as EN 60601-2-27 on 5 July 1994.

The following dates were fixed:

- latest date of publication of an identical national standard (dop) 1995-07-01
- latest date of withdrawal of conflicting national standards (dow) 1995-07-01

For products which have complied with the relevant national standard before 1995-07-01, as shown by the manufacturer or by a certification body, this previous standard may continue to apply for production until 2000-07-01.

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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 Standard specifies the particular safety requirements for ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT as defined in **2.101** and hereinafter also referred to as EQUIPMENT.

Telemetry monitors, ambulatory ("Holter") monitors and other recording devices are outside the scope of this Particular Standard.

1.2 Object

Replacement:

The object of this Particular Standard is to specify particular requirements for the safety of ELECTROCARDIOGRAPHIC MONITORING EQUIPMENT as defined in **2.101**.

1.3 Particular Standards

Addition:

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

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.

3 Terminology and definitions

This clause of the General Standard applies, except as follows:

Additional definitions:

2.101

ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT

EQUIPMENT and associated ELECTRODES for the monitoring and/or recording of heart action potentials and displaying the resultant data locally and/or transmitting to a central station

2.102

LEAD(S) (ECG)

ELECTRODE combination used for a certain ECG recording

2.103

ELECTRODE

conductor attached to a specified part of the body to detect heart action voltages in combination with another ELECTRODE or ELECTRODES

2.104

LEAD SELECTOR

system to select LEADS

2.105

NEUTRAL ELECTRODE

reference point for differential amplifiers and/or interference suppression circuits, not forming part of any ECG LEAD

2.106

SENSITIVITY (ECG)

ratio of the amplitude of a displayed signal to the amplitude of the signal producing it, expressed in mm/mV

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**, **51.101** and **51.102** of this Particular Standard shall be carried out prior to the LEAKAGE CURRENT and dielectric strength tests described in clauses **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

Addition:

aa) Parts of an ECG MONITORING EQUIPMENT (for example, PATIENT cables) specified as being protected against the effects of defibrillation shall be marked with the symbol given in Appendix D (addition to Table DII) of this Particular Standard.

6.8.2 Instructions for use

Addition:

aa) Advice shall be given on the following:

- 1) That conductive parts of ELECTRODES and associated connectors for APPLIED PARTS, including the NEUTRAL ELECTRODE, should not contact other conductive parts including earth.
- 2) The type of electrical installation to which the EQUIPMENT may be safely connected, including the connection of any POTENTIAL EQUALIZATION CONDUCTOR.

3) The specification (or type-number) of ACCESSORIES such as patient cables which shall be used in order to provide defibrillation protection (see **17.101** and **51.101**, **51.102** and **51.103**) and protection against high frequency burns, and any precautions to be taken when a defibrillator is used on a PATIENT.

4) If parts of the ECG MONITORING EQUIPMENT are provided with protective means against burning of the PATIENT when used with high frequency (HF) surgical equipment, this shall be drawn to the attention of the OPERATOR. If no such means are incorporated, advice shall be given regarding the location of the ELECTRODES and leads etc, to reduce the hazard of burns in the event of a defect in the HF surgical neutral electrode connection.

5) The choice and application of ELECTRODES (see **51.102** and **51.103**).

6) Any possible hazard caused by the summation of LEAKAGE CURRENTS when several items of EQUIPMENT are interconnected.

7) Any safety hazard due to the simultaneous use of other PATIENT-connected EQUIPMENT, for example, a cardiac pacemaker or other electrical stimulators.

8) The need for regular testing of the EQUIPMENT and ACCESSORIES.*

9) The means of indicating an inoperative ECG MONITORING EQUIPMENT (see **51.103**).

10) If indication of the heart-rate may be adversely affected by the operation of cardiac pacemaker pulses or by cardiac arrhythmias.

Section 2. Environmental conditions

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

Section 3. 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 TYPES B, BF AND CF EQUIPMENT*

Replacement:

The EQUIPMENT shall be of TYPE CF.