

Medical electrical equipment —

Part 2-25: Particular requirements for the safety of electrocardiographs

The European Standard EN 60601-2-25:1995 including its
amendment A1:1999 has the status of a British Standard

ICS 11.040.50

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60601-2-25:
1996
IEC
60601-2-25:
1993

*Incorporating
Amendment No. 1 to
BS 5724-2.125:1993
(renumbers the BS as
BS EN
60601-2-25:1996) and
incorporating
Amendment No.1 to
BS EN
60601-2-25:1996*

Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Healthcare Standards Policy Committee (HCC/-) to Technical Committee HCC/95, upon which the following bodies were represented:

- Biological Engineering Society
- British Cardiac Society
- Department of Health
- Electro Medical Trade Association Limited
- Institute of Hospital Engineering
- Institute of Physical Sciences in Medicine
- Ministry of Defence

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National foreword

This British Standard is the English language version of EN 60601-2-25:1995, including its amendment A1:1999. It is identical with IEC 60601-2-25:1993 *Medical electrical equipment — Part 2: Particular requirements for the safety of electrocardiographs*, including amendment 1:1999, published by the International Electrotechnical Commission (IEC).

This Particular Standard amends and supplements BS EN 60601-1:1990 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.

As in the General Standard, the requirements are followed by compliance tests. The numbers of the sections and clauses in this standard refer to the related sections and clauses in the General Standard. Clauses, subclauses or figures that are additional to those of the General Standard are numbered starting from 101; additional appendices are lettered AA, BB, etc., and additional items are lettered aa), bb), etc. The changes from the text of the General Standard are specified by the use of the following words.

“Replacement” means that the clause, subclause or specified paragraph of the General Standard is replaced by the text of this standard.

“Amendment” means that the clause, subclause or specified paragraph of the General Standard is amended as indicated by the text of this standard.

“Addition” means that the text of this standard is additional to the requirements of the General Standard.

Guidance and a rationale for the more important requirements are 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 standard.

The start and finish of text introduced or altered by amendment is indicated in the text by tags **A1** **A1** **A7**. Tags indicating changes to IEC text carry the number of the IEC amendment. For example, text altered by IEC amendment 1 is indicated by **A1** **A1** **A7**.

From 1 January 1997, all IEC publications have the number 60000 added to the old number. For instance, IEC 27-1 has been renumbered as IEC 60027-1. For a period of time during the change over from one numbering system to the other, publications may contain identifiers from both systems.

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 AND IN THIS STANDARD: IN SMALL CAPITALS.

NOTE *Typographical error.* In 1.3, paragraph 2, line 1 “brievity” should be read as “brevity”.

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 to iv, the EN title page, pages 2 to 18, an inside back cover and a back cover.

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Descriptors: Medical electrical equipment, electrocardiographs, safety requirements, protection against electric shock, protection against mechanical hazard, radiation protection, fire protection, environmental conditions

English version

Medical electrical equipment — Part 2-25: Particular requirements for the safety of electrocardiographs

(includes amendment A1:1999)

(IEC 60601-2-25:1993 + A1:1999)

Appareils électromédicaux —
Partie 2-25: Règles particulières de sécurité des
électrocardiographes
(inclut l'amendement A1:1999)
(CEI 60601-2-25:1993 + A1:1999)

Medizinische Elektroausrüstungen —
Teil 2-25: Besondere
Sicherheitsanforderungen für
Elektrokardiografieausrüstungen
(enthält Änderung A1:1999)
(IEC 60601-2-25:1993 + A1:1999)

This European Standard was approved by CENELEC on 1995-05-15; amendment A1 was approved by CENELEC on 1999-05-01. 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, 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 the International Standard IEC 601-2-25:1993, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the formal vote and was approved by CENELEC as EN 60601-2-25 on 1995-05-15 without any modification.

The following dates were fixed:

- latest date by which the (dop) 1996-07-01
EN has to be implemented
at national level by
publication of an identical
national standard or by
endorsement
- latest date by which the (dow) 1996-07-01
national standards
conflicting with the EN
have to be withdrawn

Annexes designated “informative” are given for information only. In this standard, Annex AA and Annex ZAA are informative. Annex ZAA has been added by CENELEC.

Foreword to amendment A1

The text of document 62D/309/FDIS, future amendment 1 to IEC 60601-2-25, 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 amendment A1 to EN 60601-2-25:1995 on 1999-05-01.

The following dates were fixed:

- latest date by which the (dop) 2000-03-01
amendment has to be
implemented at national
level by publication of an
identical national standard
or by endorsement
- latest date by which the (dow) 2002-05-01
national standards
conflicting with the
amendment have to be
withdrawn

Annexes designated “normative” are part of the body of the standard. Annexes designated “informative” are given for information only. In this standard, Annex ZA is normative and Annex AA is informative. Annex ZA has been added by CENELEC.

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 International Standard specifies the particular safety requirements for ELECTROCARDIOGRAPHS as defined in **2.102**, intended for the production of detachable ELECTROCARDIOGRAMS for diagnostic purposes. It also applies to vector-cardiographs and EQUIPMENT for stress testing.

This Particular Standard covers minimum safety requirements.

Special requirements concerning use in ambulances, phono-cardiographs, cardiographic monitors, polygraphs, telemetering, special tests (for example, His bundle electrocardiographs), etc. are not covered by this Particular Standard.

EQUIPMENT with microelectrodes used directly in the fibres of the heart muscle is also excluded.

1.2 Object

Replacement:

The object of this Particular International Standard is to establish particular requirements for the safety of ELECTROCARDIOGRAPHS as defined in **2.102**.

1.3 Particular Standards

Addition:

[A₁] 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 amendment 2 (1995). The General Standard takes into account IEC 60601-2 (1993), *Medical electrical equipment — Part 1 General requirements for safety — 2. Collateral Standard: Electromagnetic compatibility — Requirements and tests*. **[A₁]**

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 appendices 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.

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Additional definitions:

2.101

ELECTROCARDIOGRAM (ECG)

visible record of heart action potentials

2.102

ELECTROCARDIOGRAPH (ecg)

MEDICAL ELECTRICAL EQUIPMENT and associated ELECTRODES intended for the production of detachable ELECTROCARDIOGRAMS for diagnostic purposes

2.103

LEAD(S)

ELECTRODE combination used for a certain ECG recording

2.104

ELECTRODE

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

2.105

LEAD SELECTOR

system to select certain LEADS and TEST

2.106

MULTICHANNEL ELECTROCARDIOGRAPH

EQUIPMENT for the simultaneous recording of several ecg LEADS

This EQUIPMENT may also provide facilities for phonocardiography and pulse recording, etc.

2.107**NEUTRAL ELECTRODE**

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

2.108**NORMAL SENSITIVITY**

SENSITIVITY of 10 mm/mV

2.109**PATIENT CABLE**

multiwire cable and associated connector(s) to connect the ELECTRODES to the ELECTROCARDIOGRAPH

2.110**SENSITIVITY**

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

2.111**SINGLE CHANNEL ELECTROCARDIOGRAPH**

EQUIPMENT for the recording of one ecg LEAD at a time

2.112**STANDARDIZATION VOLTAGE**

voltage step recorded for amplitude calibration purposes

2.113**TEST**

facility enabling the STANDARDIZATION VOLTAGE or zero voltage to be recorded in place of the ELECTROCARDIOGRAM

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 and 51.101 of this Particular Standard shall be carried out in that order prior to the LEAKAGE CURRENT and dielectric strength tests of clauses C24 and C25 of Appendix C of the General Standard.

5 Classification

This clause of the General Standard applies except as follows:

5.6 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

A₁

A₁

Addition:

The ELECTROCARDIOGRAPH and parts thereof that are specified as being protected against the effects of defibrillation shall be marked with one of the symbols as appropriate, given in Appendix D of this Particular Standard. (See also 17.101 and 51.101.)

6.8.2 Instructions for use

Additional item:

aa) Advice shall be given on the following:

1) The procedures necessary for safe operation, drawing attention in the case of TYPE B **A₁** APPLIED PARTS **A₁** to the safety hazards which may occur as a result of an inadequate electrical installation.

2) The type of electrical installation to which the EQUIPMENT may be safely connected, including the connection of any POTENTIAL EQUALIZATION CONDUCTOR.

3) That conductive parts of ELECTRODES and associated connectors for TYPE BF or CF **A₁** APPLIED PARTS **A₁**, including the NEUTRAL ELECTRODE, should not contact other conductive parts including earth.

4) The specification (and type number, if necessary) of the PATIENT CABLE which needs to be used to provide protection against the effect of the discharge of a cardiac defibrillator and against high-frequency burns.

5) If the ELECTROCARDIOGRAPH is provided with protective means against burns 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 ECG ELECTRODES to reduce the hazard of burns in the event of a defect in the HF surgical neutral electrode connection.

- 6) The choice and application of ELECTRODES.
- 7) The suitability of the ELECTROCARDIOGRAPH for DIRECT CARDIAC APPLICATION.
- 8) The possible hazard caused by the summation of LEAKAGE CURRENTS when several EQUIPMENTS are interconnected.
- 9) Any safety hazard due to the operation of a cardiac pacemaker or other electrical stimulators.
- 10) *Instructions for regular testing of the ELECTROCARDIOGRAPH and the PATIENT CABLE.
- 11) The precautions to be taken when a defibrillator is used on a PATIENT.
- 12) The means of indicating an inoperative ELECTROCARDIOGRAPH (see **51.103** of this Particular Standard).

A1

- 13) Where relevant, a statement that the EQUIPMENT is protected against malfunction caused by electrosurgery. **A1**

Section 2. Environmental conditions

The clauses and subclauses of this section of the General Standard apply except as follows:

10 Environmental conditions

This clause of the General Standard applies except as follows:

10.2.1 b)* *Replacement:*

Relative humidity between 25 % and 95 % (without condensation).

