

Medical electrical equipment —

Part 2: Particular requirements for safety —

Section 2.4 Specification for cardiac defibrillators and cardiac defibrillator-monitors

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Committee (HCC/-) to Technical Committee HCC/93 upon which the following bodies were represented:

- Association of Anaesthetists of Great Britain and Ireland
- Bath Institute of Medical Engineering
- Biological Engineering Society
- British Institute of Radiology
- British Medical Association
- British Surgical Trades Association Incorporated
- College of Radiographers
- Department of Health and Social Security
- Department of Trade and Industry (National Physical Laboratory)
- Electro Medical Trade Association Limited
- GAMBICA (BEAMA Ltd.)
- Hospital Physicists' Association
- Institute of Hospital Engineering
- Intensive Care Society
- Medical Sterile Products Association
- Ministry of Defence
- National Radiological Protection Board
- Royal College of Physicians of London
- Royal College of Surgeons of England
- Scottish Health Services

The following body was also represented in the drafting of the standard, through sub-committees and panels:

Cardiothoracic Institute

This British Standard, having been prepared under the direction of the Health Care Standards Committee, was published under the authority of the Board of BSI and comes into effect on 31 July 1985

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¹⁾ Only clauses with text differing from that given in BS 5724-1 are included in this list.

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National foreword

This British Standard has been prepared under the direction of the Health Care Standards Committee. The text is identical with IEC Publication 601-2-4 “*Medical electrical equipment*” — Part 2 “*Particular requirements for the safety of cardiac defibrillators and cardiac defibrillator-monitors*”, published in 1983 by the International Electrotechnical Commission (IEC). This particular Standard amends and supplements BS 5724-1 hereafter 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; the additional appendix is lettered AA and additional items 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.

A rationale for the most important requirements is given in Appendix 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 appendix does not form part of the standard.

Terminology and conventions. The text of the International Standard has been approved as suitable for publication as a British Standard without deviation. Some terminology and certain conventions are not identical with those used in British Standards. In particular the following print types are used.

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

Explanations, advice, general statements, exceptions and references: in small roman type.

Test specifications: in italic type.

Terms defined in clause 2 of the General Standard and this Particular Standard: small capitals.

Cross-reference

International Standard	Corresponding British Standard
IEC 601-1:1977	BS 5724 <i>Medical electrical equipment</i> Part 1:1979 <i>Specification for general safety requirements</i> (Technically equivalent)

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, pages 1 to 22, 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.

Section 1. General

1 Scope and object

This clause of the General Standard applies except as follows:

1.1 Scope

Addition:

This Particular Standard specifies requirements for the safety of CARDIAC DEFIBRILLATORS and CARDIAC DEFIBRILLATOR-MONITORS as defined in Sub-clauses **2.1.101** and **2.1.102**, hereinafter referred to as EQUIPMENT, incorporating a capacitive energy storage device.

This Standard does not apply to a CARDIAC MONITOR which is not part of a DEFIBRILLATOR-MONITOR.

In combined EQUIPMENT in which the ECG monitoring signal cannot be derived via the DEFIBRILLATOR ELECTRODES, this standard applies to the DEFIBRILLATOR part only.

1.4 Environmental conditions

Item b) Operation

1) Environment

Amendment:

- a) Ambient temperature between 0 °C and + 40 °C.
- b) Relative humidity between 30 % and 95 %, without condensation.

2 Terminology and definitions

This clause of the General Standard applies except as follows:

2.1.5

APPLIED PART

Addition:

for the EQUIPMENT, the APPLIED PART includes the DEFIBRILLATOR ELECTRODES and any separate monitoring electrodes and all parts conductively connected to any of these electrodes

Additional definitions:

2.1.101

CARDIAC DEFIBRILLATOR (DEFIBRILLATOR)

MEDICAL ELECTRICAL EQUIPMENT intended to defibrillate the heart by an electrical pulse via electrodes applied either to the PATIENT's skin (external electrodes), or to the exposed heart (internal electrodes)

2.1.102

CARDIAC DEFIBRILLATOR-MONITOR
(DEFIBRILLATOR-MONITOR)

combination of DEFIBRILLATOR and CARDIAC MONITOR where the ECG monitoring signal can be derived via the external DEFIBRILLATOR ELECTRODES

additionally separate monitoring electrodes may be provided

2.1.103

CARDIAC MONITOR (MONITOR)

part of a DEFIBRILLATOR-MONITOR providing a visible display of the electrical activity of the PATIENT's heart

2.1.104

CHARGING CIRCUIT

circuit within the DEFIBRILLATOR intended for charging the energy storage device. This circuit includes all parts conductively connected to the energy storage device during the charging period

2.1.105

DEFIBRILLATOR ELECTRODES

electrodes intended to deliver an electrical pulse to the PATIENT for the purpose of cardiac defibrillation

2.1.106

DISCHARGE CIRCUIT

circuit within the DEFIBRILLATOR which connects the energy storage device to the DEFIBRILLATOR ELECTRODES. This circuit includes all switching connections between that device and the DEFIBRILLATOR ELECTRODES

2.1.107

DISCHARGE CONTROL CIRCUIT

circuit including the manually operated discharge controls and all parts conductively connected to them

2.1.108

INTERNAL DISCHARGE CIRCUIT

circuit within the DEFIBRILLATOR which discharges the energy storage device without activating the DEFIBRILLATOR ELECTRODES

2.1.109

SYNCHRONIZER

device allowing the DEFIBRILLATOR discharge to be synchronized with a specific phase of the cardiac cycle

2.12.101

DELIVERED ENERGY

energy which is passed through the DEFIBRILLATOR ELECTRODES and dissipated in the PATIENT or in a resistance of specified value

2.12.102**STAND-BY**

mode of operation in which the EQUIPMENT is operational except that the energy storage device is not yet charged

2.12.103**STORED ENERGY**

energy which is stored in the DEFIBRILLATOR energy storage device

3 General requirements

This clause of the General Standard applies.

4 General requirements for tests

This clause of the General Standard applies except as follows:

4.1 Type tests and routine tests

Addition to Item b):

Additional routine tests: see Appendix B.

4.5 Ambient temperature, humidity, atmospheric pressure**d) Replacement:**

The test required in Sub-clause 102.2 shall be performed at an ambient temperature of $0 \pm 2^\circ\text{C}$.

4.11 Sequence

Amendment:

The endurance test required in Clause 103 shall be performed after the test for excessive temperatures (Clause C.20 of Appendix C of the General Standard).

Addition:

The tests required in Clauses 101, 102, 104, 105 and 106 shall be performed after test C.35 of Appendix C of the General Standard.

5 Classification

This clause of the General Standard applies except as follows:

5.1 Amendment:

Delete CLASS III EQUIPMENT.

5.2 Amendment:

Delete TYPE B EQUIPMENT.

6 Identification, marking and documents

This clause of the General Standard applies except as follows:

6.1 Marking on the outside**j) Power input**

Replacement: Lines 39 to 41.

The RATED power input of MAINS OPERATED EQUIPMENT shall be the maximum power input averaged over any period of 2 s.

See also Sub-clause 7.101 of this Standard.

l) Classification

Addition:

For DEFIBRILLATOR-MONITORS providing for the connection of separate ECG, monitoring electrodes shall also be marked as incorporating DEFIBRILLATOR protection. See Figure 101, page 13.

Additional items:

(aa) Concise operating instructions

The EQUIPMENT shall be permanently marked in a prominent place with short instructions for defibrillating and, where relevant, monitoring a PATIENT. This marking shall be in a language recognized where the EQUIPMENT is intended to be used and shall be clearly legible to a person having normal vision from a distance of at least 1 m.

bb) Battery powered EQUIPMENT

EQUIPMENT incorporating a primary or a rechargeable battery and any separate battery charger shall be marked with brief instructions for, as appropriate, the re-charging or replacement of the battery.

In the case of such EQUIPMENT also capable of connection to the SUPPLY MAINS or to a separate battery charger, the equipment and such charger shall be marked to indicate any limitations of operation when the EQUIPMENT is connected to the SUPPLY MAINS or to the battery charger. Such instructions shall include the case of a discharged or missing battery.

6.3 Marking of controls

Additional item:

aa) The control for selecting the output energy or the relevant indicating means shall be calibrated in terms of DELIVERED ENERGY in joules to a resistive load of 50 Ω .

6.8 ACCOMPANYING DOCUMENTS**6.8.2 Instructions for use****e), f), g) Replacement:**

EQUIPMENT incorporating a battery

The instructions for use shall contain additionally:

— Full details of the charging procedure for any rechargeable battery.

— Advice on the periodic replacement of any primary or rechargeable battery and full details of the procedure for such replacement.

— The number of maximum energy discharges which are available from a new and fully charged battery at 20 °C ambient temperature.

— For EQUIPMENT also capable of connection to the SUPPLY MAINS or to a separate battery charger, information on any limitations of operation when such a connection is made. This information shall include the case of a discharged or missing battery.

Additional item:

aa) *Supplementary instructions for use*

The instructions for use shall additionally contain the following:

- 1) A warning not to touch the PATIENT during defibrillation.
- 2) A description of the correct method of handling the DEFIBRILLATOR ELECTRODES in use as well as a prominent warning that DEFIBRILLATOR ELECTRODES should be kept well clear of other electrodes or metal parts in contact with the PATIENT. The USER shall be advised that other MEDICAL ELECTRICAL EQUIPMENT, e.g. blood-flow meters, which may not incorporate defibrillation protection, should be disconnected from the PATIENT during defibrillation.
- 3) Advice for the USER to avoid contact between parts of the PATIENT's body such as exposed skin of head or limbs and metal objects such as a bed frame or a stretcher which may provide unwanted pathways for the defibrillating current.
- 4) Any environmental limitations regarding storing the EQUIPMENT (e.g. in a car or an ambulance under severe climatic conditions) immediately prior to use.
- 5) Where means are provided for monitoring via separate monitoring electrodes, instructions for the placement of these electrodes.
- 6) A recommendation calling the USER's attention to the need for periodic maintenance of the EQUIPMENT irrespective of usage, especially:
 - cleaning of the DEFIBRILLATOR ELECTRODES and the insulating parts of the handles;
 - cleaning of any reusable monitoring electrodes;
 - inspection of cables and electrode handles for possible defects;
 - functional checks;
 - charging of the energy storage device, if it is of a type requiring periodic charging (e.g. electrolytic capacitor).

7) Information on the time for charging of the fully discharged storage capacitor, when the DEFIBRILLATOR is set to maximum energy,

- a) with RATED MAINS VOLTAGE and, for an internally powered DEFIBRILLATOR, with a fully charged battery;
- b) as above, but for a MAINS VOLTAGE of 90 % of the RATED value and for an internally powered DEFIBRILLATOR after 15 maximum energy discharges.

6.8.3 Technical description

Additional item:

aa) The technical description shall additionally provide:

- 1) full details of the waveforms of the delivered pulses when the DEFIBRILLATOR is connected in turn to resistive loads of 25, 50 and 100 Ω and set to its maximum output;
- 2) essential performance data of any SYNCHRONIZER.

7 Power input

This clause of the General Standard applies except as follows:

Addition:

7.101 The power input of MAINS OPERATED EQUIPMENT, averaged over any period of 2 s, shall not exceed 750 W.

Compliance shall be checked by measurement during charging of the energy storage device, the output energy selector being set to maximum.

Section 2. Safety requirements

Clauses 8 to 12 of the General Standard apply.

Section 3. Protection against electric shock hazards

13 General

This clause of the General Standard applies.

14 Requirements related to classification

This clause of the General Standard applies except as follows:

14.3 Class III equipment

Does not apply.

14.4 Item a)

Amendment:

Delete CLASS III EQUIPMENT.