

Medical electrical equipment —

Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment

The European Standard EN 60601-2-27:2006 has the status of a
British Standard

ICS 11.040.50

National foreword

This British Standard is the UK implementation of EN 60601-2-27:2006, incorporating corrigendum December 2006. It is identical with IEC 60601-2-27:2005. It supersedes BS EN 60601-2-27:1995 which is withdrawn.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electromedical equipment in medical practice, to Subcommittee CH/62/4, Electromedical equipment.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

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17508 Corrigendum No. 1	31 December 2007	In the EN foreword the 6th paragraph has been replaced. Addition of Annex ZA

**Medical electrical equipment
Part 2-27: Particular requirements for the safety,
including essential performance,
of electrocardiographic monitoring equipment
(IEC 60601-2-27:2005)**

Appareils électromédicaux
Partie 2-27: Exigences particulières
de sécurité, incluant les performances
essentiels, des appareils de surveillance
d'électrocardiographie
(CEI 60601-2-27:2005)

Medizinische elektrische Geräte
Teil 2-27: Besondere Festlegungen
für die Sicherheit einschließlich
der wesentlichen Leistungsmerkmale
von Elektrokardiographie-
Überwachungsgeräten
(IEC 60601-2-27:2005)

This European Standard was approved by CENELEC on 2005-11-01. 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, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the 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/529/FDIS, future edition 2 of IEC 60601-2-27, 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 60601-2-27 on 2005-11-01.

This European Standard supersedes EN 60601-2-27:1994.

It introduces essential performance to electrocardiographic monitoring equipment such as defibrillator protection, performance requirements and alarming.

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) 2006-11-01
- latest date by which the national standards conflicting
with the EN have to be withdrawn (dow) 2008-11-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 93/42/EEC. See Annex ZZ.

Annexes ZA and ZZ have been added by CENELEC.

In this standard, the following print types are used:

- requirements, compliance with which can be tested, and definitions: roman type;
- notes, explanations, advice, introductions, general statements, exceptions and references: small roman type;
- *test specifications: italic type;*
- TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

Endorsement notice

The text of the International Standard IEC 60601-2-27:2005 was approved by CENELEC as a European Standard without any modification.

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INTRODUCTION

This Particular Standard concerns the safety of electrocardiographic monitoring equipment including essential performance. It amends and supplements IEC 60601-1 (second edition 1988): *Medical electrical equipment – Part 1: General requirements for safety* and its Amendment 1 (1991) and Amendment 2 (1995), hereinafter referred to as the General Standard. The requirements of this Particular Standard take priority over those of the General Standard.

A “General guidance and rationale” for the requirements of this Particular Standard is included in Annex AA. It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, Annex AA does not form part of the requirements of this Standard.

An asterisk (*) by a clause or subclause number indicates that some explanatory notes are given in Annex AA.

At the time of publication of this Particular Standard work was in progress to create a joint ISO/IEC collateral standard addressing “General requirements and guidelines for the application of alarms in medical electrical equipment”. It is intended to harmonize this standard with the above-mentioned collateral standard following its publication.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic 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 specifies the particular safety requirements, including essential performance, for ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT as defined in 2.101 and hereinafter also referred to as EQUIPMENT. This standard is applicable to EQUIPMENT used in a hospital environment.

If the EQUIPMENT is used outside the hospital environment, such as in ambulances and air transport, the EQUIPMENT shall comply with this standard.

NOTE Additional standards apply to the EQUIPMENT covering specifically use outside the hospital environment.

This standard is not applicable to electrocardiographic monitors for home use. However, manufacturers should consider using relevant clauses of this standard as appropriate for their intended use.

ECG telemetry systems, ambulatory ("Holter") monitors and other ECG 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, including 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 Amendment 2 (1995). The General Standard takes into account IEC 60601-1-1:2000, *Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems*, IEC 60601-1-2:2001, *Medical electrical*

equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests and IEC 60601-1-4:1996, Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral standard: Programmable electric medical systems and its Amendment 1 (1999).

For brevity, Part 1 is referred to in this Particular Standard either as the “General Standard” or as the “General Requirement(s)”, and IEC 60601-1-1, IEC 60601-1-2 and IEC 60601-1-4 as the “Collateral Standards”.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds with 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, tables 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 and Collateral Standard mentioned above.

2 Terminology and definitions

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

Addition:

2.101

ELECTROCARDIOGRAPHIC (ECG) MONITORING EQUIPMENT (EQUIPMENT)

device and associated LEAD WIRES and ELECTRODES for the monitoring and/or recording of heart action potentials and displaying the resultant data of one PATIENT

2.102

LEAD WIRE(S)

cable(s) connected between ELECTRODE(S) and the device

2.103**LEAD(S)**

combination(s) of ELECTRODES and LEAD WIRES used for a certain ECG recording

2.104**ELECTRODE(S)**

means (typically, an electrical sensor) in contact with a specified part of the body to detect heart action voltage in combination with another means

2.105**LEAD SELECTOR**

system to select certain LEADS and CALIBRATION (CAL)

2.106**NEUTRAL ELECTRODE**

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

2.107**SENSITIVITY**

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

2.108**ALARM**

signal, which indicates abnormal events occurring to the PATIENT or EQUIPMENT

2.109**INHIBITION**

disabling or SILENCING and disabling an ALARM until revoked intentionally

2.110**LATCHED ALARM**

ALARM, the visual and auditory manifestations of which do not stop when the ALARM condition no longer exists

2.111**NON-LATCHED ALARM**

ALARM, the auditory or visual and auditory manifestation of which stop when ALARM condition no longer exists

2.112**PHYSIOLOGICAL ALARM**

signal which either indicates that a monitored physiological function is out of specified limits or indicates an abnormal PATIENT condition

2.113**SILENCE**

stopping of an auditory ALARM manifestation by OPERATOR action

2.114*SILENCE/RESET**

stopping of an auditory or auditory and visual ALARM manifestation and re-enabling system response to an ALARM condition

2.115

SUSPENSION

disabling or SILENCING and disabling an ALARM temporarily

2.116

TECHNICAL ALARM

signal, which indicates that the EQUIPMENT or part(s) of the EQUIPMENT is not capable of accurately monitoring the PATIENT'S condition

4 General requirements for tests

This clause of the General Standard applies except as follows:

4.6 Other conditions

Amendment:

Unless otherwise stated, tests shall be carried out with the accessories and the recording materials specified by the manufacturer.

For EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE, if the test result is affected by the INTERNAL ELECTRICAL POWER SOURCE voltage, then the test shall be performed using the least favourable INTERNAL ELECTRICAL POWER SOURCE voltage specified by the manufacturer. If necessary for the purpose of conducting the test, an external battery or d.c. power supply may be used to provide the necessary test voltage.

The values used in test circuits, unless otherwise specified, shall have at least an accuracy as given below:

- resistors: ± 2 %;
- capacitors: ± 10 %;
- inductors: ± 10 %;
- test voltages: ± 1 %

***4.11 Sequence**

Amendment:

Tests called for in 17 h) and 17.101 of this Particular Standard shall be carried out prior to the LEAKAGE CURRENT and dielectric strength tests described in Clauses C.24 and C.25 of Appendix C of the General Standard and prior to the tests specified in Clause 50.

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 TYPE BF APPLIED PARTS.

5.6 According to the mode of operation:

Replacement:

Delete all items but CONTINUOUS OPERATION.

6 Identification, marking and documents

6.1 Marking on the outside of the EQUIPMENT or EQUIPMENT parts

Addition:

In order to minimize the possibility of incorrect connections the PATIENT CABLE shall be permanently marked with one of the identifiers (ELECTRODE identifier and/or colour code) specified in Table 101.

**Table 101 – ELECTRODES and NEUTRAL ELECTRODE,
their position, identification and colour**

System	Code 1 (usually European)		Code 2 (usually American)		Position on body surface
	ELECTRODES		ELECTRODES		
	Identifier	Colour code	Identifier	Colour code	
Limb	R	Red	RA	White	Right arm
	L	Yellow	LA	Black	Left arm
	F	Green	LL	Red	Left leg
Chest according to Wilson	C	White	V	Brown	Single movable chest electrode
	C1	White/red	V1	Brown/Red	Fourth intercostal space at right border of sternum
	C2	White/yellow	V2	Brown/Yellow	Fourth intercostal space at left border of sternum
	C3	White/green	V3	Brown/Green	Fifth rib between C2 and C4
	C4	White/brown	V4	Brown/Blue	Fifth intercostal space on left midclavicular line
	C5	White/black	V5	Brown/Orange	Left anterior axillary line at the horizontal level of C4
	C6	White/violet	V6	Brown/Violet	Left midaxillary line at the horizontal level of C4
Position according to Frank	I	Light blue/red	I	Orange/Red	At the right midaxillary line ^a
	E	Light blue/yellow	E	Orange/Yellow	At the front midline ^a
	C	Light blue/green	C	Orange/Green	Between the front midline and left midaxillary line of 45 degrees
	A	Light blue/black	A	Orange/Brown	At the left midaxillary line ^a
	M	Light blue/brown	M	Orange/Black	At the back midline ^a
	H	Light blue/violet	H	Orange/Violet	On the back of the neck
	F	Green	F	Red	On the left leg
	N	Black	RL	Green	Right leg (NEUTRAL ELECTRODE)
^a Located at the transverse level of the ventricles, if known, or otherwise at the fifth intercostal space					

6.8 Accompanying documents

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) A warning that only PATIENT-related ACCESSORIES including LEAD WIRES as specified by the manufacturer shall be used to guarantee defibrillator protection. The specification (or type-number) of such ACCESSORIES (see 17.101) shall be disclosed.
- 4) If parts of the EQUIPMENT are provided with protections against burning of the PATIENT when used with high frequency (HF) surgical equipment, this shall be drawn to the attention of the OPERATOR. Advice shall be given regarding the location of the electrodes and LEAD WIRES 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.
- 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 EQUIPMENT (see 51.101).
- 10) If indication of the heart-rate may be adversely affected by the operation of cardiac pacemaker pulses or by cardiac arrhythmias.
- 11) The delay time of making ALARMS available from the ALARMING EQUIPMENT to remote equipment at the SIGNAL OUTPUT PART (see 51.102.7)
- 12) The selection procedure for suspending or inhibiting ALARMS remotely (see 51.102.8)
- 13) The selection procedure provided to SILENCE/RESET ALARMS remotely (see 51.102.9)
- 14) The intended environment of use.
- 15) The amplitude, pulse width and overshoot of pacemaker pulses that are rejected by the EQUIPMENT.
- 16) The operation of the EQUIPMENT after interruption of supply mains exceeding 30 s (see 49.2.bb)).

bb) The following performance specification shall be disclosed:

- 1) **Respiration, leads-off sensing, and active noise suppression.** For EQUIPMENT designed to intentionally apply a current to the PATIENT for the purpose of respiration sensing, leads-off sensing or active noise suppression, the manufacturer shall disclose the waveforms (in the form of voltage, current, frequency, or other appropriate electrical parameters) which are applied to the PATIENT.

- 2) **Tall T-wave rejection capability.** Disclosure shall be made of the maximum T-wave amplitude according to clause 50.102.17.
- 3) **Heart rate averaging.** The type of averaging done to compute the minute heart rate and, if applicable, the updating rate of the display shall be disclosed.
- 4) **Heart rate meter accuracy and response to irregular rhythm.** Disclosure shall be made of the indicated heart rate, after a 20 s EQUIPMENT stabilization period, for the four types of alternating ECG complexes A1 to A4 described in Figure 101.
- 5) **Response time of heart rate meter to change in heart rate.** Disclosure shall be made of the maximum time, to the nearest second and including the update time of the EQUIPMENT, required for the heart rate meter to indicate a new heart rate for a step increase from 80 1/min to 120 1/min and a step decrease from 80 1/min to 40 1/min. The response time is measured from the time of the first QRS complex of the new rate to the time the heart rate meter first reads 37 % of the heart rate indication at 80 1/min plus (a) for the step increase, 63 % of the steady state indication at 120 1/min or greater, and (b) for the step decrease, 63 % of the steady state indication at 40 1/min or less.
- 6) **Time to ALARM for tachycardia.** Disclosure shall be made of the time to ALARM for the two ventricular tachycardia waveforms B1 and B2 shown in Figure 101, following a normal 80 1/min rate with the upper ALARM limit set closest to 100 1/min and the lower ALARM limit set closest to 60 1/min. Disclosure shall also be made of EQUIPMENT failure to ALARM on either of these waveforms. In addition, the time to ALARM shall be disclosed for these waveforms when their amplitudes are one-half and twice the indicated amplitudes.
- 7) **Pacemaker pulse rejection warning label.** The following or a similar warning shall be displayed in the operator manual: “WARNING — PACEMAKER PATIENTS. Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter ALARMS. Keep pacemaker patients under close surveillance. See this manual for disclosure of the pacemaker pulse rejection capability of this instrument” (see 50.102.13 m).
- 8) **Visual and auditory ALARM disclosure.** The manufacturer shall disclose the ALARM'S location (i.e., central station, bedside, or both), colour, size, and modulation (flashing), and the frequency or other descriptive characteristics of the sounds.
- 9) For **INTERNALLY POWERED EQUIPMENT**, the minimum operating time of the EQUIPMENT shall be disclosed, provided that the battery is new and fully charged. If rechargeable batteries are used, the manufacturer shall disclose the battery charge time from depletion to 90 % charge. In addition, the function of the indicator of clause 56.8 c) and the battery charging cycle or charging procedure shall also be clearly stated.
- 10) **Auxiliary output.** Disclosure shall be made regarding proper connection of other devices to the auxiliary ECG signal output, if provided. In addition, the manufacturer shall disclose the bandwidth, gain and propagation delay time of all auxiliary outputs. Manufacturers also shall disclose how internal pacemaker pulses are represented in the auxiliary output (their inclusion or absence, and whether enhanced pace pulses are summed with the ECG signal).

- 11) **Pacer pulse detection disabling.** If OPERATOR accessible controls are provided that disable the pace pulse detection capability of the EQUIPMENT, the mode selection shall be disclosed.
- 12) The inputs and their minimum input impedance that are also used for other measurements (e.g. respiration) shall be disclosed (see 50.102.3).
- 13) The available time bases of permanent and non-permanent displays of the equipment shall be disclosed.

SECTION TWO – ENVIRONMENTAL CONDITIONS

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

SECTION THREE – 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

*14.6 TYPES B, BF and CF APPLIED PARTS

Replacement:

EQUIPMENT shall have TYPE CF APPLIED PARTS.

17 Separation

This clause of the general standard applies with the following addition:

Addition :

*17h) 101 Protection against the effects of defibrillation and blocking after defibrillation

Protection against the effects of defibrillation shall be provided for all EQUIPMENT.

For defibrillator testing the EQUIPMENT is operated using the PATIENT CABLES as specified by the manufacturer.

– Warning –

The following tests are hazardous and precautions must be enforced for protection of test personnel. It is recommended that an enclosed test fixture be used such that defibrillator voltages will not reach test personnel!

17h) 101.1 Defibrillator energy delivered to the patient

The EQUIPMENT and/or PATIENT CONNECTIONS shall incorporate a means so that the defibrillator energy delivered to a 100 Ω load is reduced by a maximum of 10 % relative to the energy delivered to this load with the EQUIPMENT disconnected.

Compliance is checked by the following test:

The test circuit is shown in Figure 106. For this test, the manufacturer's recommended accessories such as PATIENT CABLES and LEAD WIRES shall be used. The test is applied between a single LEAD WIRE and all other LEAD WIRES connected together. The EQUIPMENT shall be energized for this test. The procedure is as follows:

- a) Connect a single LEAD WIRE to point C of the test circuit. Connect the remaining LEAD WIRES to point D of the test circuit.*
- b) Charge the capacitor to 5 kV with switch S in position A.*
- c) Discharge the test circuit by moving the switch S to position B, and measure the energy E1 delivered to the 100 Ω load across points E and F.*
- d) Remove the EQUIPMENT under test from the test circuit (disconnect points C and D.)*
- e) Charge the capacitor to 5 kV with switch S in position A.*
- f) Discharge the test circuit by moving the switch S to position B, and measure the energy E2 delivered to the 100 Ω load across points E and F.*
- g) Verify that the energy E1 is at least 90 % of E2.*
- h) Repeat the test for each available LEAD WIRE, with the test voltage applied between the LEAD WIRE being tested and all other LEAD WIRES connected together.*

17h) 101.2 Differential mode test of EQUIPMENT

After exposure to the defibrillation voltage, the EQUIPMENT shall resume within 5 s normal operation in the previous operating mode, without loss of any OPERATOR settings or stored data, and shall continue to perform its intended function as described in the ACCOMPANYING DOCUMENTS.

The EQUIPMENT is connected to the test circuit shown in Figure 107. The test voltage is applied to each LEAD WIRE in turn with all the remaining LEAD WIRES being connected to earth. Initially, the test is conducted applying the test voltage between the R (RA) LEAD WIRE and all remaining LEAD WIRES connected to the N (RL) LEAD WIRE. The EQUIPMENT shall be energized for these tests.

EQUIPMENT having an INTERNAL ELECTRICAL POWER SOURCE which is rechargeable from the SUPPLY MAINS shall be tested with and without the SUPPLY MAINS connection if the EQUIPMENT is capable of operating while connected to the SUPPLY MAINS.

Compliance is checked by the following test:

Set the SENSITIVITY of the EQUIPMENT such that a 5 mV signal produces a maximum display deflection without clipping the signal. With S2 open, adjust the 10 Hz sine wave generator to produce a 5 mV peak-to-valley output signal. Close switch S2.

Connect S1 to position A and charge the capacitor C. After about 10 s, connect S1 to position B. Leave in position B for at least 200 ms $\pm$ 50 %.

Open S1 in order to remove residual voltages from the EQUIPMENT and allow recovery to begin.

S2 is then immediately opened. The test signal shall be recorded at not less than 4 mV peak-to-valley referred to the input within 5 s.

Repeat the test for any other LEAD WIRE according to Table 102 with all remaining LEAD WIRES connected to the N (RL) LEAD WIRE.

Table 102 – Protection against the effect of defibrillation (test conditions)

	P1	P2	Lead setting	Number of tests
5 electrode cables	L (LA)	R, F, N, C (RA, LL, RL, V)	I	1
	R (RA)	F, L, N, C (LL, LA, RL, V)	II	1
	F (LL)	L, R, N, C (LA, RA, RL, V)	III	1
	N (RL)	L, R, F, C (LA, RA, LL, V)	Standby	1
	C (V)	L, R, F, N (LA, RA, LL, RL)	V	1
3 electrode cables	L (LA)	R, F, or N (RA, LL or RL)	I	2
	R (RA)	L, F, or N (LA, LL or RL)	I	2
	F (LL) or N (RL)	R, L (RA, LA)	II or standby	2
2 electrode cables	L (LA)	R (RA)	I	1

17h) 101.3 Common mode test of EQUIPMENT

After exposure to the defibrillation voltage, the EQUIPMENT shall resume within 5 s normal operation in the previous operating mode, without loss of any OPERATOR settings or stored data, and shall continue to perform its intended function as specified in the ACCOMPANYING DOCUMENTS.

Compliance is checked according to Figure 108. The test voltage shall be applied between all LEAD WIRES, including the NEUTRAL ELECTRODE, connected together and the FUNCTIONAL EARTH TERMINAL. The EQUIPMENT shall be energized for these tests.

In the case of CLASS II EQUIPMENT and EQUIPMENT with an INTERNAL ELECTRICAL POWER SOURCE, the test voltage shall be applied between all LEAD WIRES, including the NEUTRAL ELECTRODE, connected together and the FUNCTIONAL EARTH TERMINAL and/or metal foil in close contact with the ENCLOSURE.

EGG MONITORING EQUIPMENT having an INTERNAL ELECTRICAL POWER SOURCE, which is rechargeable from the SUPPLY MAINS, shall be tested with and without the SUPPLY MAINS connection if the EQUIPMENT is capable of operating while connected to SUPPLY MAINS.

Connect S1 to position A and charge the capacitor C. After about 10 s, connect S1 to position B. Leave in position B for at least 200 ms ± 50 %.

Open S1 in order to remove residual voltages from the EQUIPMENT and allow recovery to begin.

Repeat the above test with the polarity of the high voltage source reversed. The tests with positive and negative polarities shall be repeated 5 times.

The EQUIPMENT shall resume normal operation in the previous operating mode, without loss of any OPERATOR settings or stored data within 5 s and shall continue to perform its intended function as specified in the ACCOMPANYING DOCUMENTS.

17h) 101.4 Recovery time of EQUIPMENT from electrode polarization after defibrillation

After defibrillation discharge when the EQUIPMENT is operated using PATIENT CABLE and ELECTRODES as specified by the manufacturer, the ECG signal shall be readable on the EQUIPMENT display within 10 s and shall remain so.

Compliance is checked by the following test.

A pair of ECG monitoring ELECTRODES is connected to the EQUIPMENT by the PATIENT CABLE.

The ELECTRODES are positioned either on opposite sides or on the same side of a sponge saturated with physiologically normal saline as shown in Figure 109. (The saline-filled troughs serve to maintain saturation; physiologically normal saline is 9 g/l NaCl).

The ELECTRODES may be held in position by insulated clamps. Care needs to be taken to avoid direct contact between the ELECTRODES.

The EQUIPMENT is connected to the test circuit as shown in Figure 110 with, any LEAD SELECTOR being set to display the test signal.

With S2 opened, the signal generator output is adjusted to give a displayed signal of 10 mm peak-to-valley.

With S2 closed, S1 is switched from position A to position B for a period of 200 ms $\pm$ 50 %, and then back to position A again.

Immediately after restoration of S1 to position A, S2 is opened. Directly after a period of 10 s the test signal shall be readable and shall remain so, and its amplitude shall not be less than 5 mm.

The test is repeated with the opposite polarity of the test voltage.

20 Dielectric strength

This clause of the General Standard applies except as follows,

***20.2 Requirements for EQUIPMENT with an APPLIED PART**

Amendment:

B-b Does not apply to EQUIPMENT.

***20.3 Values of test voltages**

Amendment:

B-d For EQUIPMENT, the test voltage shall be 1 500 V (CLASS I and CLASS II and INTERNALLY POWERED EQUIPMENT).

SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS

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

***21.5 Addition:**

ELECTRODES and PATIENT cables, which contain electronic components, shall not present a safety hazard and shall continue functioning normally after falling freely from a height of one meter onto a hard surface.

Testing need not be performed if examination of the construction and circuit arrangement shows that no safety hazard is possible and that normal function will not be impaired.

Compliance is checked by the following test:

The sample to be tested is allowed to fall freely once from each of three different starting attitudes from a height of 1 m onto a 50 mm thick hardwood board (for example, hardwood >700 kg/m³), which lies flat on a rigid base (concrete block).

After this test, no LIVE parts shall become accessible. Cracks not visible to the naked eye and surface cracks in fibre-reinforced mouldings and the like shall be ignored. After this test all requirements of this Particular Standard shall be satisfied and the EQUIPMENT shall function normally.

SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

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

36 Electromagnetic compatibility

Replacement:

IEC 60601-1-2 applies except as follows:

36.201 EMISSIONS

36.201.1 b) 1)

Replacement:

The EQUIPMENT shall be tested with the PATIENT CABLE as specified by the manufacturer with all the SIGNAL INPUT cables and SIGNAL OUTPUT cables connected (see Figure 102 of this standard).

36.202 IMMUNITY

The EQUIPMENT shall comply with the requirements of 36.202.1 j) and the accuracy requirements of 50.102.15 except subclauses 36.202.2 and 36.202.101 in this Particular Standard.

36.202.2 Electrostatic discharge (ESD)

Addition:

The EQUIPMENT may show temporary degradation during discharges. Within 10 s the EQUIPMENT shall resume normal operation in the previous operating mode, without loss of any OPERATOR settings or stored data, and shall continue to perform its intended function as described in the ACCOMPANYING DOCUMENTS.

36.202.3 Radiated RF electromagnetic fields

Addition:

Any SIGNAL INPUT PART/SIGNAL OUTPUT PART cable and mains cable shall be arranged generally as in Figure 103.

36.202.6 Conducted disturbances, induced by RF fields**a) Requirements**

Addition:

When exposed to a conducted radio frequency voltage, via the POWER SUPPLY CORD, the EQUIPMENT shall operate within normal specifications.

***36.202.6 b) 3)**

This item does not apply.

Addition:

***36.202.101 Electrosurgery protection**

Means shall be provided for protection against malfunction caused by electrosurgery. The test below, using any PATIENT CABLES, LEAD WIRES, accessories or settings recommended by the manufacturer, applies.

When the EQUIPMENT has been used together with HF SURGICAL EQUIPMENT it shall return to previous operating mode within 10 s after exposure to the field produced by the HF SURGICAL EQUIPMENT, without loss of any stored data.

Compliance is checked according to Figures 104 and 105.

The HF SURGICAL EQUIPMENT which is used shall comply with IEC 60601-2-2 and shall have a minimum power cut mode capability of 300 W, a minimum coagulation mode of 100 W and working frequency of 400 kHz ± 10 %.

a) *Test in pure cut mode:*

Set the output power of the HF SURGICAL to the 300 W position.

Touch the metal contact/block in the test set-up (see Figures 104 and 105) with the active electrode and remove the electrode slowly to get an arc.

Repeat the procedure five times.

b) *Test in coag mode:*

Repeat the test in item a) except with an output power of 100 W.

Test of the spray coagulation mode is excluded.

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

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

SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

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

***42.5 Guards**

This subclause does not apply to any heated stylus or printing element of the EQUIPMENT.

44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection

***44.3 Spillage**

Replacement:

EQUIPMENT shall be so constructed that, in the event of spillage of liquids (accidental wetting), no SAFETY HAZARD shall result.

EQUIPMENT shall not be subjected to the following test, unless the EQUIPMENT is PORTABLE/TRANSPORTABLE or part of the EQUIPMENT is separable while remaining functioning, in which case said EQUIPMENT or parts of the EQUIPMENT shall be subjected to the test below.

Compliance is checked by the following test:

The EQUIPMENT shall be placed in the least favourable position of NORMAL USE. The EQUIPMENT is then subjected for 30 s to an artificial rainfall of 3 mm/min falling vertically from a height of 0,5 m above the top of the EQUIPMENT.

A test apparatus is shown in Figure 3 of IEC 60529.

An intercepting device may be used to determine the duration of the test.

Immediately after 30 s exposure, visible moisture on the ENCLOSURE shall be removed.

Immediately after the above test, inspection shall show that any water which may have entered the EQUIPMENT cannot adversely affect the safety of the EQUIPMENT. In particular, the EQUIPMENT shall be capable of meeting the relevant dielectric strength tests specified in 20.1 to 20.4 of the General Standard.

49 Interruption of the power supply

***49.2**

Addition:

- aa) When the SUPPLY MAINS to the EQUIPMENT is interrupted for less than 30 s, no change of OPERATOR settings shall occur, including the mode of operation, or all stored PATIENT data.

NOTE The EQUIPMENT does not have to be operating during the interruption of the SUPPLY MAINS.

Compliance is checked by observing the EQUIPMENT operating mode, OPERATOR settings, and stored data and interrupting the SUPPLY MAINS for a period of between 25 s and 30 s by disconnecting the POWER SUPPLY CORD.

- bb) When the SUPPLY MAINS is interrupted for more than 30 s:

The subsequent operation shall be one of the following:

- reversion to the manufacturer's default settings,
- reversion to a previous USER's default settings or
- reversion to the last settings used.

NOTE There may be provision for the OPERATOR to select one or more than one of the above options.

Compliance shall be checked by inspection.

- cc) When the EQUIPMENT contains an INTERNAL ELECTRICAL POWER SOURCE and the SUPPLY MAINS is interrupted, the EQUIPMENT shall continue normal operation by switching automatically to operating from its INTERNAL ELECTRICAL POWER SOURCE, and the mode of operation, all OPERATOR settings and stored data shall not be changed. Power-saving measures may be taken provided the EQUIPMENT continues to conform to this standard.

EQUIPMENT shall visually indicate the operation from its INTERNAL ELECTRICAL POWER SOURCE.

Compliance is checked by interrupting the SUPPLY MAINS and observing that OPERATOR settings and stored data are not changed. The 'on-off' switch shall remain in the 'on' position.

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

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

50 Accuracy of operating data

Addition:

50.101 Software

IEC 60601-1-4, *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems* shall be applied.

50.102 Essential performance

50.102.1 Accuracy of signal reproduction

Input signals in the range of ± 5 mV, varying at a rate to 125 mV/s, shall be reproduced on the output with an error of $\leq \pm 20$ % of the nominal value of the output or ± 100 μ V, whichever is greater.

Compliance is checked using the test circuit of Figure 111.

Close switches S, S2 and S4. Connect the signal generator to apply a triangular wave of 2 Hz to any LEAD WIRE with all other LEAD WIRES connected to the N (RL) LEAD WIRE as defined in Table 102. Adjust the SENSITIVITY of the EQUIPMENT to 10 mm/mV. Adjust the signal generator to produce a peak-to-valley output on a display device that is 10 % of the full scale peak-to-valley output. Increase the output of the signal generator by factors of 2, 5 and 10. The displayed output shall be linear within ± 20 % of the full scale output.

Repeat for each LEAD WIRE and display device until all combinations of LEAD WIRES and display devices have been tested as defined in Table 102.

Connect the signal generator to any LEAD WIRE with all other LEAD WIRES connected to the N (RL) LEAD WIRE. Adjust the signal generator to apply a 1 mV peak-to-valley input 20 Hz sinusoidal signal at a SENSITIVITY of 10 mm/mV. Verify that the output display is completely visible and the peak-to-valley amplitude is within 8-12 mm.

Repeat for each display device.

*50.102.2 Input dynamic range and differential offset voltage

With a d.c. offset voltage in the range of ± 300 mV and differential input signal voltages of ± 5 mV that vary at rates up to 320 mV/s, when applied to any lead wire, the time-varying output signal amplitude shall not change by more than ± 10 % over the specified range of d.c. offset.

Compliance is checked using the test circuit of Figure 111.

Close switches, S, S2 and S4. Adjust the signal generator to produce a 16 Hz triangular or sinusoidal signal of 10 mV peak-to-valley to any LEAD WIRE and all other LEAD WIRES connected to the N (RL) LEAD WIRE as defined in Table 102. Adjust the SENSITIVITY of the EQUIPMENT such that the 10 mV peak-to-valley signal produces an output of 80% of the full scale peak-to-valley output capability of the display. Apply a d.c. offset voltage of +300 mV by