

Medical electrical equipment —

**Part 2-34: Particular requirements for the
safety, including essential performance,
of invasive blood pressure monitoring
equipment**

The European Standard EN 60601-2-34:2000 has the status of a
British Standard

ICS 11.040.55

National foreword

This British Standard is the official English language version of EN 60601-2-34:2000. It is identical with IEC 60601-2-34:2000. It supersedes BS EN 60601-2-34:1994 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/96, Monitoring equipment, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

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Leistungsmerkmale, von invasiven
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(IEC 60601-2-34:2000)

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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.

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CENELEC

European Committee for Electrotechnical Standardization
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Foreword

The text of document 62D/367/FDIS, future edition 2 of IEC 60601-2-34, 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 2000-11-01.

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- latest date by which the EN has to be implemented
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with the EN have to be withdrawn (dow) 2003-11-01

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annexes AA and BB are informative.

Endorsement notice

The text of the International Standard IEC 60601-2-34:2000 was approved by CENELEC as a European Standard without any modification.

CONTENTS

	Page
INTRODUCTION	5
Clause	
SECTION ONE – GENERAL	
1 Scope and object	6
2 Terminology and definitions	7
4 General requirements for tests	9
5 Classification	9
6 Identification, marking and documents	9
SECTION TWO – ENVIRONMENTAL CONDITIONS	
SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS	
14 Requirements related to classification	10
17 Separation	11
19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	11
20 Dielectric strength	12
SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS	
21 Mechanical strength	12
SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION	
36 ELECTROMAGNETIC COMPATIBILITY	13
SECTION SIX – PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES	
SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS	
42 Excessive temperatures	16
44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility	16
45 Pressure vessel and parts subject to pressure	17
46 Human errors	18
SECTION EIGHT – ACCURACY OF OPERATION DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT	
50 Accuracy of operating data	18
51 Protection against hazardous output	18
SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS	
SECTION TEN – CONSTRUCTIONAL REQUIREMENTS	
56 Components and general assembly	28
57 Mains parts, components and layout	28

Annex AA (informative) Guidance and rationale for particular clauses and subclauses	45
Annex BB (informative) ALARM diagrams	54
INDEX of defined terms	57
Bibliography	58
Figure 101 – Measuring circuit for PATIENT LEAKAGE CURRENT via an F-TYPE (FLOATING) earth caused by an external voltage on the APPLIED PART	29
Figure 102 – Dynamic test for limitation of energy from different parts – Recovery test	30
Figure 103 – Measuring circuit for the PATIENT LEAKAGE CURRENT from the APPLIED PART to earth of CLASS I EQUIPMENT caused by an external voltage on the FUNCTIONAL EARTH TERMINAL	31
Figure 104 – Measuring circuit for the PATIENT LEAKAGE CURRENT from the APPLIED PART to EARTH of INTERNALLY POWERED EQUIPMENT, caused by an external voltage on a FUNCTIONAL EARTH TERMINAL	32
Figure 105 – Clarification of leakage current tests	33
Figure 106 – Diaphragm leak test	34
Figure 107 – Over-pressure test	34
Figure 108 – Test layout for conducted and radiated emission and radiated immunity test	35
Figure 109 – Test circuit for high-frequency surgery interference measurement, when the PATIENT isolation is in the monitor	36
Figure 110 – Test circuit for HIGH-FREQUENCY surgery interference measurement, when the PATIENT isolation is in the TRANSDUCER	37
Figure 111 – Test set-up for HIGH-FREQUENCY SURGICAL EQUIPMENT interference measurement	38
Figure 112 – Test for accuracy of pressure measurements	39
Figure 113 – Test for sensitivity, repeatability, non-linearity, drift and hysteresis	40
Figure 114 – Pressure measurement system for accuracy of systolic and diastolic pressure	41
Figure 115 – Frequency response of EQUIPMENT and TRANSDUCER	42
Figure 116 – Test for ALARM DELAY	43
Figure 117 – Test for ALARM DELAY	44
Figure AA.1 – Pressure TRANSDUCER error band	53

INTRODUCTION

The General Standard does not include requirements specific to the safety, including essential performance, of DIRECT BLOOD PRESSURE MONITORING EQUIPMENT. Hence, changes need to be made to include these unique requirements. This particular standard takes into account *Collateral Standard 60601-1-2:(1993) Electromagnetic compatibility* and *Collateral Standard 60601-1-4:(1996) Medical electrical equipment incorporating programmable electrical systems*. A section on ALARMS has been included because ALARMS are necessary for MONITORING EQUIPMENT.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure 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 applies to INVASIVE BLOOD PRESSURE MONITORING and measuring 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 tap tables.

This Particular Standard also does not apply to NON-INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety, including the 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 its amendment 2 (1995).

The General Standard takes into account IEC 60601-1-2:1993, *Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral Standard: Electromagnetic compatibility – Requirements and tests* and IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: Collateral Standard: Programmable electrical medical systems*.

For brevity, IEC 60601 is referred to in this Particular Standard either as the “General Standard” or as the “General Requirement(s)”.

The numbering of sections, clauses or 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 clause or subclause 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.

An asterisk (*) notes clauses for which there is rationale comment in annex AA or annex BB. It is considered that a knowledge of the reasons for these requirements will facilitate the proper application of the standard and be of use in any revision that may be necessitated by changes in clinical practice or as a result of developments in technology.

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 of the Collateral Standards mentioned above.

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.

Additional definitions:

2.101 INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT (EQUIPMENT)

stand-alone measuring equipment or part of a physiological monitoring or measuring system, including associated TRANSDUCERS, that is used for the internal measurement of circulatory system pressures

2.102

TRANSDUCER

device for converting pressure into an electrical signal for monitoring or measuring

2.103

CATHETER TIP TRANSDUCER

TRANSDUCER mounted at, or close to, the tip of a catheter and intended for insertion into the cardiovascular system

2.104

DOME

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

2.12.101

ALARM

signal which indicates abnormal events occurring to the PATIENT or EQUIPMENT

2.12.102

PHYSIOLOGICAL ALARM

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

2.12.103

TECHNICAL ALARM

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

2.12.104

SILENCING

stopping an auditory ALARM manifestation by manual action

2.12.105

SILENCING/RESET

stopping a visual and/or auditory ALARM manifestation and reenabling system response to an abnormal PATIENT condition

2.12.106

INHIBITION

disabling or SILENCING and disabling an ALARM until revoked intentionally

2.12.107

SUSPENSION

disabling or SILENCING and disabling an ALARM temporarily

2.12.108

LATCHED ALARM

ALARM, the visual and auditory manifestation of which does not stop when the parameter returns to a value which no longer exceeds the alarm limit or if the abnormal PATIENT condition does not exist any longer

2.12.109

NON-LATCHED ALARM

ALARM, the visual and auditory manifestation of which stops when the parameter (which caused the alarm) returns to a value which no longer exceeds the alarm limit or if the abnormal PATIENT condition does not exist any longer

2.12.110

NOMINAL SENSITIVITY

ratio of the change in TRANSDUCER output to a change of the value of the pressure at any selected pressure range

4 General requirements for tests

This clause of the General Standard applies except as follows:

*4.11 Sequence

Amendment:

Tests called for in 17 h), 17.101.1, 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 electrical shock

Delete TYPE B and TYPE BF APPLIED PART.

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

aa) *Addition:*

If fulfilment of Type CF isolation depends on the TRANSDUCER then symbol No. 14, table D1, IEC 60601-1, shall be marked on the EQUIPMENT.

*6.8.2 Instructions for use

Additional items:

aa) Supplementary instructions for use

Advice shall be provided for the following:

- 1) The connection of the TRANSDUCER and ACCESSORIES, the pressure calibration of the TRANSDUCER and suggested means for removing entrapped air from the hydraulic system connected to the TRANSDUCER.

- 2) 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 the ACCOMPANYING DOCUMENTS must include the recommended types of TRANSDUCERS.
- 3) 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.)
- 4) 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.
- 5) If parts of the TRANSDUCERS or EQUIPMENT are provided with protective means against hazards to the PATIENT when used with HIGH-FREQUENCY 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.
- 6) The action to be taken following accidental wetting of the EQUIPMENT.
- 7) Description of those parts of the EQUIPMENT that are protected against the effects of a discharge of a cardiac defibrillator.
- 8) 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 the effects of a discharge of a cardiac defibrillator.
- 9) A warning that single-use devices are not to be reused.
- *10) TRANSDUCER or ACCESSORIES supplied as sterile shall be identified as sterile.
- *11) If appropriate, an indication of the time limit for safe use of the TRANSDUCER and ACCESSORIES, expressed as the year and month.
- 12) If the EQUIPMENT has to be connected to other devices in order to achieve its intended purpose, sufficient details of its characteristics to identify correctly the devices necessary for safe operation.
- *13) Precautions to be taken in the event of changes in performance of the device as a result of ageing and environmental conditions.
- 14) The warm-up time for the TRANSDUCER and EQUIPMENT if greater than 15 s.
- *15) The volume displacement in mm³/100 mm Hg for any TRANSDUCER and/or DOME that is supplied with the EQUIPMENT.

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

This clause of the General Standard applies except as follows:

14.6 Replacement:

The APPLIED PART shall be TYPE CF.

14.8 The EQUIPMENT shall have DEFIBRILLATOR PROOF APPLIED PARTS.

17 Separation

This clause of the General Standard applies except as follows:

17 h)

Addition:

- a) The ENCLOSURE excluding accessible conductive parts in the hydraulic circuit beyond the DOME.

Addition:

Compliance shall be checked by testing in accordance with figure 102. The requirement is met when after operation of S1, the peak voltage between the points Y1 and Y2 does not exceed 1 V.

- The diaphragm of the DOME shall be removed, destructively if necessary.*
- Disposable TRANSDUCERS and CATHETER TIP TRANSDUCERS shall be tested intact and complete.*

Repeat the test with the 5 kV supply (V1) reversed.

After this test the EQUIPMENT shall be capable of meeting all requirements and tests of this Particular Standard and shall function normally (see also 51.101).

17.101.1 *Following the test of 17 h), the DOME shall be replaced with one having an intact diaphragm and the test shall then be repeated. The diaphragm shall not have been punctured during the test.*

Compliance shall be checked by performing the test as described in figure 106 with the air pressure being applied gradually over about 1/2 s and held for about 10 s, and by noting the absence of bubbles.

19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

This clause of the General Standard applies except as follows:

***19.3 Allowable values**

Addition:

- aa) For EQUIPMENT having a FUNCTIONAL EARTH TERMINAL, the PATIENT LEAKAGE CURRENT flowing from the APPLIED PART to EARTH shall be no greater than 0,05 mA, when a voltage equal to 110 % of the highest RATED MAINS VOLTAGE is applied between the FUNCTIONAL EARTH TERMINAL and earth.

The following test shall not be performed when the FUNCTIONAL EARTH TERMINAL is connected direct to the PROTECTIVE EARTH TERMINAL inside the EQUIPMENT.

Compliance shall be checked by measurement according to figures 103 and 104.

All tests shall be performed with any reusable and/or disposable DOME removed.

Disposable TRANSDUCERS and CATHETER TIP TRANSDUCERS shall be tested intact and complete, in which case the EQUIPMENT shall be further tested with a reusable TRANSDUCER (where the F-TYPE APPLIED PART isolation is accomplished in the input circuits of the EQUIPMENT) from which the reusable or disposable DOME has been removed.

19.4 Tests

a) General

1) Addition:

All tests shall be made with any disposable DOME removed. Disposable and CATHETER TIP TRANSDUCERS shall be tested complete and intact.

For the MAINS VOLTAGE on the APPLIED PART test, see figure 101. A more pictorial representation providing additional clarification is shown in figure 105.

h) Measurement of the PATIENT LEAKAGE CURRENT

Addition:

All tests are made with any disposable DOME removed. Disposable and CATHETER TIP TRANSDUCERS are tested complete and intact.

2) Amendment:

ACCESSIBLE CONDUCTIVE PARTS in the hydraulic circuit beyond the DOME and parts within the cardiovascular system in NORMAL USE are excluded.

20 Dielectric strength

This clause of the General Standard applies except as follows:

20.2 Requirements for EQUIPMENT with an APPLIED PART

***20.3 Values of test voltage**

Amendment:

B-d for EQUIPMENT the test voltage shall be 1 500 V (CLASS I, 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 Mechanical strength

This clause of the General Standard applies except as follows:

***21.5 Mechanical strength – Free fall**

Addition:

The TRANSDUCER, if separable from the EQUIPMENT by the OPERATOR, without its DOME if removable, shall not present a safety hazard after a free fall from a height of 1 m onto a hard surface.

Compliance shall be checked by the following test:

The TRANSDUCER sample to be tested is allowed to fall freely once from each of three different attitudes from a height of 1 m onto a 50 mm thick hardwood board (for example, hardwood > 600 kg/m³) which lies flat on a rigid base (concrete block).

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:

Addition:

36 ELECTROMAGNETIC COMPATIBILITY

IEC 60601-1-2 applies except as follows:

***36.201 Emission**

36.201.1.1

Replacement:

The EQUIPMENT shall comply with the requirements of CISPR 11, Group 1, Class A or Class B, depending on the environment of intended use.

The INSTRUCTIONS FOR USE shall specify where the EQUIPMENT is to be used.

***36.201.1.7**

Replacement:

The EQUIPMENT shall be tested with one of the TRANSDUCER(S) that is specified by the manufacturer (see 36.202.2.2a and figure 108).

The EQUIPMENT shall comply with the test requirements for any TRANSDUCER specified by the manufacturer.

NOTE This may be established either by testing or constructional equivalence.

SIGNAL INPUT and SIGNAL OUTPUT cables (if applicable) shall be attached to the EQUIPMENT during the test.

***36.202 Immunity**

Addition to paragraph 4:

Compliance is checked by the following test:

- *Setup the EQUIPMENT and TRANSDUCER as outlined in figure 108.*
- *Balance the TRANSDUCER to obtain zero pressure at zero pressure input.*
- *Expose the EQUIPMENT and TRANSDUCER sequentially to the specified disturbances (radiofrequency, transients, magnetic) at any NOMINAL SENSITIVITY.*

The EQUIPMENT shall not change the operating state, lose or change any stored data, generate errors in control software that cause an unintended change in output, or cause errors in blood pressure readings that are outside of the manufacturer's specifications. These criteria do not apply to ESD testing.

36.202.1 Electrostatic discharge

Replacement:

A level of 6 kV shall apply for contact discharge to conductive ACCESSIBLE PARTS and coupling planes.

A level of 8 kV shall apply for air discharge to non-conductive ACCESSIBLE PARTS.

Addition:

The EQUIPMENT shall return to the previous operating mode within 10 s without loss of any stored data.

36.202.2 Radiated radiofrequency electromagnetic fields

36.202.2.1 a)

Replacement:

1a) The EQUIPMENT shall comply with IEC 61000-4-3.

36.202.2.1 d)

Replacement:

A level of 3 V/m shall apply.

36.202.2.2 a) Test conditions

Replacement:

The EQUIPMENT shall be exposed to an RF field that is 80 % modulated with a sine wave between 1 Hz and 5 Hz. The TRANSDUCER cable, if longer than 1 m, shall be shortened to 1 m as shown in figure 108. The signal cable (if applicable) and mains cable shall be arranged horizontally and vertically from the EQUIPMENT (figure 108). The EQUIPMENT shall comply with the test requirements for any TRANSDUCER specified by the manufacturer.

36.202.3 Transients

Addition:

The EQUIPMENT shall return to the previous operating mode within 10 s without the loss of any stored data.

36.202.5 Conducted disturbances, induced by radiofrequency fields above 9 kHz

When exposed to conducted electromagnetic fields, via the POWER SUPPLY CORD, the EQUIPMENT shall operate within normal specifications.

The test methods and instruments shall be as described in IEC 61000-4-6.

The noise voltage that is injected into the MAINS VOLTAGE input shall be 3 V r.m.s. over the frequency range of 150 kHz to 80 MHz. It shall be modulated at 80 % amplitude modulation at any single frequency within the range 1 Hz to 5 Hz.

36.202.6 Magnetic fields

Addition:

The EQUIPMENT shall be exposed to an a.c. magnetic field at the power line frequency or frequencies as specified by the manufacturer according to IEC 61000-4-8.

There is to be no loss of system performance or functionality.

Magnetic field intensity: 3 A/m

The EQUIPMENT shall be exposed on all its faces.

The EQUIPMENT shall operate within the NORMAL limits of this standard when exposed to these fields.

*36.202.7 Electrosurgery interference

If the EQUIPMENT has been used together with HIGH-FREQUENCY SURGICAL EQUIPMENT it shall return to the previous operating mode within 10 s after exposure to the field produced by a HIGH-FREQUENCY SURGICAL EQUIPMENT without loss of any stored data.

Compliance shall be tested according to figures 109, 110 and 111. If the TYPE CF isolation is in the TRANSDUCER, the compliance test shall be according to figures 110 and 111.

The HIGH-FREQUENCY SURGICAL EQUIPMENT which is used shall comply with IEC 60601-2-2, shall have 300 W of minimum power cut mode capability, 100 W of minimum power coagulating mode capability, and a working frequency of 450 kHz $\pm$ 100 kHz.

a) Test in cut mode

Set the blood pressure monitor to a range of 120 mm Hg to 150 mm Hg and the output power of the HIGH-FREQUENCY SURGICAL EQUIPMENT to the 300 W setting. The monitor shall be calibrated with the zero line visible. Any filter shall be in a wideband position.

Touch the metal contact/block in the test set-up (see figures 109 and 110) with the active electrode and remove the electrode slowly to get a spark.

Repeat the procedure as described five times. Immediately after the operation S1 shall be opened. The test signal shall be recorded/displayed within 10 s.

b) Test in the coagulation mode

Repeat the test in item a) except with a maximum 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 Excessive temperatures

This clause of the General Standard applies except as follows:

42.5 Guards

Amendment:

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, disinfection and compatibility

This clause of the General Standard applies except as follows:

***44.3 Spillage**

Replacement:

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

Compliance shall be checked by the following test:

A test pressure is applied to the TRANSDUCER sufficient to produce 50 % of full-scale deflection at any NOMINAL SENSITIVITY. The pressure and the resultant deflection (output) are noted and the EQUIPMENT switched off. The EQUIPMENT shall then be placed in the least favourable position of NORMAL use and subjected to 30 s of 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 the 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 case of doubt, the EQUIPMENT shall be capable of meeting the relevant dielectric strength tests specified in 20.1 to 20.4 of the General Standard followed by the functional test described below.

The same test pressure as before is applied again to the TRANSDUCER. The deflection shall be the same as that noted at the beginning of this test, the tolerance allowed by the specification in the ACCOMPANYING DOCUMENTS.

If the EQUIPMENT forms part of a medical electrical system, then the system and the EQUIPMENT shall not be subjected to the above test, unless the EQUIPMENT or part of the EQUIPMENT is separable from the system while remaining functional, in which case the said EQUIPMENT or parts of the EQUIPMENT shall be subjected to the above test.

44.6 Ingress of liquids

Replacement:

TRANSDUCERS and EQUIPMENT parts containing insulation, the failure of which could result in a safety hazard or changes in essential aspects of performance according to this standard, and which in NORMAL USE are subject to immersion in liquids, shall be watertight according to IPX7 of IEC 60529. Connectors are excluded from this requirement. After the test all requirements of this Particular Standard shall be satisfied. The test need not be performed if examination of the construction and circuit arrangement shows that no safety hazard is possible.

45 Pressure vessel and parts subject to pressure

This part of the General Standard applies except as follows:

***45.101 Additional subclause**

a) Pressure above atmospheric

The TRANSDUCER with reusable and/or disposable DOME, if applicable, shall withstand a pressure of 500 kPa (4 000 mm Hg) above standard atmospheric pressure applied gradually over approximately 1/2 s and held for approximately 1 s.

The test shall be as in figure 107 and shall be repeated once within 10 s.

The requirements of this test do not apply to CATHETER TIP TRANSDUCERS.

b) Pressures below atmospheric

The TRANSDUCER, with reusable and/or disposable DOME, if applicable, shall withstand a pressure of 50 kPa (400 mm Hg) below standard atmospheric pressure, applied gradually over approximately 0,5 s and held for approximately 1 s.

The test shall be as in figure 107 and shall be repeated once within 10 s.

After these tests the requirements of this Particular Standard shall be satisfied (see 4.11). The requirements of this test do not apply to CATHETER TIP TRANSDUCERS.