INTERNATIONAL STANDARD

IEC 60601-2-30

Second edition
1999-12

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Medical electrical equipment –

Part 2-30:
Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment

Appareils électromédicaux –

Partie 2-30:
Règles particulières de sécurité et performances essentielles des appareils de surveillance de la pression sanguine prélevée indirectement, automatiquement et périodiquement

Reference number
IEC 60601-2-30:1999(E)

Numbering

As from 1 January 1997 all IEC publications are issued with a designation in the 60000 series.

Consolidated publications

Consolidated versions of some IEC publications including amendments are available. For example, edition numbers 1.0, 1.1 and 1.2 refer, respectively, to the base publication, the base publication incorporating amendment 1 and the base publication incorporating amendments 1 and 2.

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* See web site address on title page.

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE X

For price, see current catalogue

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment

FOREWORD

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International Standard IEC 60601-2-30 has been prepared by sub-committee 62D: Electro-medical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition of IEC 60601-2-30 cancels and replaces the first edition published in 1995, and constitutes a technical revision.

The text of this standard is based on the following documents:

FDIS	Report on voting
62D/339/FDIS	62D/350/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 3.

Annexes AA and BB are for information only.

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In this Particular Standard, the following print types are used:

– requirements, compliance with which can be tested, and definitions: in roman type;

– notes, explanations, advice, introductions, general statements, exceptions and references: in smaller type;

– *test specifications, headings of subclauses and headings of items: in italic type;*

– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

The committee has decided that this publication remains valid until 2005. At this date, in accordance with the committee's decision, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

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INTRODUCTION

This Particular Standard concerns the safety of automatic cycling non-invasive blood pressure monitoring equipment. It amends and supplements IEC 60601-1 (second edition 1988), hereinafter referred to as the General Standard. The requirements of this Particular Standard take priority over those of the General Standard, entitled *"Medical electrical equipment – Part 1: General requirements for safety".*

A "General guidance and rationale" for the requirements of this Particular Standard is included in annex AA.

It is considered that a 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, this annex 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.

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-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 specifies requirements for the safety, including essential performance, of AUTOMATIC CYCLING NON-INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT as defined in 2.102, hereinafter referred to as EQUIPMENT. The EQUIPMENT may be attended or unattended.

This Particular Standard does not apply to blood pressure measuring equipment which uses finger transducers or to semi-automatic blood pressure measuring equipment, typically in which each determination needs to be initiated manually.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety, including essential performance, of AUTOMATIC CYCLING NON-INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT, with special attention being paid to the avoidance of hazards due to the inflation process.

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 also 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: General requirements for safety – 4. 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 term “this Standard” is used to make reference to the General Standard and this Particular Standard taken together.

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The numbering of sections, clauses or 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 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.

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 Standards mentioned above.

2 Terminology and definitions

This clause of the General Standard applies except as follows:

2.1.5 APPLIED PART

Replacement:

The occluding cuff and any integral transducers, their connecting leads and pressure tubes.

Additional definitions:

2.101 ALARM

A signal which indicates abnormal events occurring to the PATIENT or EQUIPMENT.

2.102 AUTOMATIC CYCLING NON-INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT (EQUIPMENT)

A device, or part of a physiological monitoring or measuring system, including its associated accessories used for intermittent assessment of a PATIENT's blood pressure by an externally applied means.

2.103 INHIBITION

Disabling or SILENCING and disabling an ALARM until revoked intentionally.

2.104 LATCHED ALARM

An ALARM, the visual and auditory manifestation of which does not stop 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.

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2.105 LONG TERM AUTOMATIC MODE

A mode in which a timer, set by the OPERATOR, initiates the measurements.

2.106 MANUAL MODE

A mode in which the OPERATOR has full control of the initiation of each measurement.

2.107 NON-LATCHED ALARM

An 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.

2.108 PHYSIOLOGICAL ALARM

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

***2.109 SHORT TERM AUTOMATIC MODE**

A mode in which as many automatic measurements as possible are made within a specified time period.

2.110 SILENCING

The stopping of an auditory ALARM manifestation by manual action.

2.111 SILENCING/RESET

The stopping of a visual and/or auditory ALARM manifestation and re-enabling of the EQUIPMENT's response to an abnormal PATIENT condition.

2.112 SUSPENSION

Disabling or SILENCING and disabling an ALARM temporarily.

2.113 TECHNICAL ALARM

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

3 General requirements

This clause of the General Standard applies except as follows:

3.6 SINGLE FAULT CONDITION

Addition:

Any single defect which:

aa) results in a failure of the normal pressure regulating means, or,

bb) prevents deflation of the cuff within the specified period, or,

cc) results in a failure of the normal cuff pressurization timing.

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*3.7 Unlikely phenomena

Addition:

aa) Kinking of the hoses, interrupting the flow of air completely, is unlikely to occur.

4 General requirements for tests

This clause of the General Standard applies except as follows:

4.6 Other conditions

Amendment:

Where reference is made in the test specifications to occluding cuffs, connecting leads and pressure tubes, only those parts supplied or recommended by the manufacturer shall be used.

*4.11 Sequence

Amendment:

Tests called for in 17 h) and 51.106 of this Particular Standard shall be performed 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 electric shock

Amendment:

Delete TYPE B 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

Addition:

aa) Cuffs shall be marked with an indication of the limb circumference for which they are appropriate.

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6.8.2 Instructions for use

Addition:

aa) Supplementary instructions for use:

Advice shall be given on the following:

1) Choice of EQUIPMENT and accessories to avoid errors and excessive pressure, for example in the case of neonates.
2) The need to avoid compression or restriction of pressure tubes.
*3) The need to check (for example, by observation of the limb concerned), that operation of the EQUIPMENT does not result in prolonged impairment of the circulation of the PATIENT.
4) If parts of the TRANSDUCERS and EQUIPMENT are provided with protective means against burns to the PATIENT when used with HF SURGICAL EQUIPMENT, such means shall be drawn to the attention of the OPERATOR. If such means are absent, such parts shall be identified in the ACCOMPANYING DOCUMENTS.
5) Description of those parts of the EQUIPMENT that are protected against the effects of the discharge of a defibrillator.
6) Any precautions specific to the EQUIPMENT to be taken when a defibrillator is used on a PATIENT, and any effects on the EQUIPMENT of the discharge of a defibrillator.
7) The action to be taken following accidental wetting of the EQUIPMENT.
8) The possible consequences of the repeated use of the SHORT TERM AUTOMATIC MODE.
9) The suitability of the EQUIPMENT to operate in the presence of electrosurgery. If the EQUIPMENT complies with the requirements of 36.202.7, the following statement shall be included in the instructions for use: “This equipment is suitable for use in the presence of electrosurgery”.
10) The instructions shall specify if the EQUIPMENT is suitable for connection to public mains as defined in CISPR 11.

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 TYPES B, BF AND CF APPLIED PARTS

Replacement:

The APPLIED PARTS of the EQUIPMENT shall be TYPE BF or CF.

14.101

Addition:

EQUIPMENT shall have defibrillator proofed APPLIED PARTS.

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17 Separation

This clause of the General Standard applies except as follows:

Addition:

*17 h) clause which begins "During each test:" add a new dash with explanatory note as follows:

– the cuff shall be inflated to approximately half the specified maximum pressure; that is, for adult and neonatal EQUIPMENT respectively, the cuff pressures for this test shall be approximately 150 mm Hg and 75 mm Hg.

NOTE To achieve this, the cuff may either be half inflated with the EQUIPMENT working normally, the EQUIPMENT then switched off and the measurements made quickly, or, with the EQUIPMENT unenergized, the cuff lines may be clamped and the cuff then half inflated by external means.

Compliance is checked by implementing the test method detailed in the General Standard with the EQUIPMENT set up as detailed in figure 101.

This test does not need to be performed if examination of the construction and circuit arrangement shows that no SAFETY HAZARD is possible.

19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

This clause of the General Standard applies except as follows:

*19.4 Tests

a)1) *Addition:*

All tests shall be made with the APPLIED PART fitted around a metal cylinder (as in figure 101) and with the cuff inflated to approximately half the maximum pressure under NORMAL CONDITION of the highest pressure range of the EQUIPMENT.

20 Dielectric strength

This clause of the General Standard applies except as follows:

*20.2 Particular requirements for EQUIPMENT with an APPLIED PART

Amendment:

B-b is not applicable for this 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 *Replacement:*

The APPLIED PART shall not present a SAFETY HAZARD as a result of a free fall from a height of 1 m onto a hard surface.

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Compliance is checked by the following test. The sample to be tested is allowed to fall freely once from each of three different starting positions from a height of 1 m onto a 50 mm thick hardwood board (for example, hardwood > 600 kg/m^3), which lies flat on a rigid base, such as a concrete block.

After this test, all requirements of this standard shall be satisfied.

This test need not be performed if examination of the construction and circuit arrangement shows that no SAFETY HAZARD is possible.

22 Moving parts

This clause of the General Standard applies except as follows:

***22.4** *Addition*:

Cuff pressure

***22.4.1**

a) The maximum cuff pressure obtainable in NORMAL USE shall not exceed 300 mm Hg for EQUIPMENT specified for adult PATIENTS ("Adult") and 150 mm Hg for EQUIPMENT specified for use on neonatal PATIENTS ("Neonatal").

One, or more than one, range is allowed in one EQUIPMENT.

Compliance is checked by provoking the maximum cuff pressures obtainable in NORMAL USE, and by inspection or measurement.

*b) In any SINGLE FAULT CONDITION as described in 3.6 of this Particular Standard, means shall be provided, functioning independently of the normal pressure control system, which

1) shall prevent the pressure in the cuff from exceeding the maximum NORMAL USE values specified in 22.4.1 a) by more than +10 %, see figure 102, and

2) shall activate if the pressure in the cuff exceeds the maximum NORMAL USE values specified in 22.4.1 a) for 15 s, see figure 103.

When activated this means shall deflate the cuff to 15 mm Hg for adults or 5 mm Hg for neonates within 30 s.

Compliance is checked by introducing any SINGLE FAULT CONDITION as described in 3.6 of this Particular Standard, and by measuring the resulting cuff pressure for a suitable period.

***22.4.2** In any mode of operation, including any SINGLE FAULT CONDITION as described in 3.6 of this Particular Standard, the cuff shall not be inflated above 15 mm Hg for more than 180 s for EQUIPMENT specified for use on adult PATIENTS, and shall not be inflated above 5 mm Hg for more than 90 s for EQUIPMENT specified for use on neonatal PATIENTS, see figure 104.

Compliance is checked by introducing any SINGLE FAULT CONDITION as described in 3.6 of this Particular Standard and by measuring the time for which the cuff remains inflated, beginning the timing measurement as soon as the cuff pressure exceeds either 15 mm Hg or 5 mm Hg, as appropriate.

NOTE The maintenance of pressure, due only to the obstruction of hose(s) by kinking, is excluded from this requirement.

***22.4.3**

a) In LONG TERM AUTOMATIC MODE, cuff pressure shall be released for at least 30 s after each period of cuff pressure above 15 mm Hg for EQUIPMENT specified for use on adult PATIENTS, or 5 mm Hg for EQUIPMENT specified for use on neonatal PATIENTS (see figure 105), except when the total duration of the alternating inflation/deflation periods (see figure 104) does not exceed the maximum inflation time specified in 22.4.2) above. After this the cuff pressure shall be released to below the pressure stated for at least 30 s.

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Compliance is checked by provoking the least favourable inflation/deflation cycle in LONG TERM AUTOMATIC MODE, and by measurement.

*b) In LONG TERM AUTOMATIC MODE, means shall be provided in any SINGLE FAULT CONDITION as described in 3.6, functioning independently of the normal timing control system, which, if the deflated period is less than 30 s, will release cuff pressure to below 15 mm Hg for EQUIPMENT specified for use on adult PATIENTS, or below 5 mm Hg for EQUIPMENT specified for use on neonatal PATIENTS, see figure 106.

Compliance is checked by introducing a SINGLE FAULT, as described in 3.6, in the normal timing system and by measurement.

22.4.4 If any of the means described in 22.4.1 b), 22.4.2 or 22.4.3 b) is activated, any indication of blood pressure shall be cancelled, and a TECHNICAL ALARM activated.

Compliance is checked by test and inspection.

***22.4.5** If a SHORT TERM AUTOMATIC MODE is available, means shall be provided to

1) ensure that following each individual determination the pressure in the cuff shall be reduced to less than 15 mm Hg for adults, 5 mm Hg for neonates, for at least 2 s, to allow venous return, see figure 107, and
2) restrict the duration of this mode to 15 min maximum, see figure 107.

At the end of this time, the EQUIPMENT shall revert to the LONG TERM AUTOMATIC MODE or the MANUAL MODE. A further period of the SHORT TERM AUTOMATIC MODE may be selected by a deliberate action of the OPERATOR.

Compliance is checked by inspection and measurement.

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

IEC 60601-1-2 applies except as follows:

36.201 EMISSIONS

36.201.1.1 *Replacement:*

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

36.201.1.7 *Replacement:*

The EQUIPMENT shall be tested with the PATIENT leads and cuff attached to the EQUIPMENT.

Signal input/output cables (if applicable) shall be attached to the EQUIPMENT during the test (see 36.202.2.2 a).

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36.202 IMMUNITY

Addition to paragraph 4:

Examples of SAFETY HAZARDS include failures involving changes in operating state, irrecoverable loss or change of stored data, errors in control software (e.g. unintended change in output), errors in blood pressure determinations which are outside the manufacturer's specifications or failure to meet the requirements of this standard (re-test of compliance with clause 50.2 is not required).

NOTE It may not be possible to provide simulators for all operating modalities.

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 radio-frequency electromagnetic fields

36.202.2.1 a) *Replacement:*

a) The EQUIPMENT shall be tested in accordance with IEC 61000-4-3.

36.202.2.1 d) *Replacement:*

The field strength of 3 V/m applies.

*36.202.2.2 a) *Replacement:*

80 % amplitude modulation at a single modulation frequency between 1 Hz and 5 Hz shall be used.

The cuff shall be connected to an NIBP simulator. The cuff and cables shall be bundled in a low inductive manner to 1 m overall length, or less if 1 m is not possible, and the signal cable (if applicable) and mains cables shall be arranged horizontally and vertically from the EQUIPMENT. The layout shall be as shown in figure 108.

36.202.2.2 c) *Replacement:*

This clause is not applicable.

36.202.2.2 d) *Replacement:*

The EQUIPMENT error shall not exceed the sum of the allowable EQUIPMENT inaccuracy (see 50.2 a) and the simulator inaccuracy when tested under the following conditions.

Compliance is tested by using the set-up of figure 108. Set the unit under test for LONG TERM AUTOMATIC MODE. Set the timer to minimum interval between determinations. Select neonatal mode (if available).

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36.202.2.2 e) *Replacement:*

This clause is not applicable.

36.202.3.1 BURSTS

36.202.3.1 b) *Addition:*

The cuff and any connecting hoses or patient cables shall be excluded from the test only if they contain no conductive elements.

Compliance with the requirements shall be checked by verifying that the EQUIPMENT returns to the previous operating mode within 10 s.

36.202.5 Conducted disturbances induced by radio frequency fields above 9 kHz

Addition:

When exposed to a conducted radio frequency voltage, 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 power input shall be 3 V r.m.s. over the frequency range of 150 kHz to 80 MHz. It shall be modulated at 80 % index at a single frequency between 1 Hz and 5 Hz.

36.202.6 Magnetic field

Addition:

The EQUIPMENT shall be exposed to an a.c. magnetic field as per IEC 61000-4-8.

Magnetic field intensity: 3 A/m

Frequency: SUPPLY MAINS frequency

The test shall be performed at both 50 Hz and 60 Hz with the exception that EQUIPMENT rated for use at only one of these frequencies need only be tested at that frequency. In either case, the EQUIPMENT shall be powered at the same frequency as the applied magnetic field.

The cuff and any connecting hoses or patient cables shall be excluded from the test. Any electrical connections to the patient shall be shorted at the NIBP device.

Under the following conditions, the EQUIPMENT error shall not exceed the sum of the allowable EQUIPMENT inaccuracy (see 50.2 a) and the simulator inaccuracy.

Using the set-up of figure 108, set the unit under test for LONG TERM AUTOMATIC MODE. Set the timer to minimum interval between determinations. Select neonatal mode (if available).

36.202.7 Electrosurgery interference

Where means are incorporated for protection against electrosurgery interference, the test below applies.

When 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 the HIGH FREQUENCY SURGICAL EQUIPMENT, without loss of any stored data.

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Compliance shall be tested according to figures 109 and 110.

If a filter is available the largest bandwidth shall be selected.

The high frequency surgical equipment which is used shall comply with IEC 60601-2-2, shall have a cut mode of minimum power 300 W, a coagulation mode of minimum power 100 W and a working frequency of 450 kHz ± 100 kHz.

a) Test in cut mode

Set the EQUIPMENT to operate from a simulator indicating a blood pressure of about 150/90 mm Hg. The HF surgical equipment shall be set at the 300 W setting.

Touch the metal plate in the test set-up (see figure 109) with the active electrode and remove the electrode slowly to get a spark.

When the HF interference is terminated the displayed parameters on the EQUIPMENT shall return to their pre-test readings within 10 s.

Repeat the procedure as described five times.

b) Test in coagulation mode

Repeat the test in item a) but with a maximum output power of 100 W.

Test of the spray coagulation is excluded.

NOTE If there is any likelihood that the HF surgical equipment could interfere with the simulator used in these tests, then the simulator needs to be screened to a sufficient level.

SECTION SIX – PROTECTION AGAINST THE 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:

42.3

3) Duty cycle

Replacement:

The EQUIPMENT is operated until the temperature measured according to test specification 42.3.4 of the General Standard does not increase in 1 h by more than 2 °C.

***42.5 Guards**

Amendment:

Not applicable to any heated stylus or printing element of the EQUIPMENT.

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44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and 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 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 clause 20 of this Particular Standard.

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.

45 Pressure vessels and parts subject to PRESSURE

This clause of the General Standard applies except as follows:

*45.101 Toxic and flammable fluids and gases

Addition:

Air or inert gas shall be used for the inflation of the cuff.

Compliance is checked by inspection.

49 Interruption of the power supply

This clause of the General Standard applies except as follows:

49.3 *Replacement:*

a) When the EQUIPMENT is switched off by the OPERATOR, with the cuff inflated, the cuff shall be deflated within 30 s to less than 15 mm Hg adult or 5 mm Hg neonatal.

Compliance is checked by test and measurement.

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b) When SUPPLY MAINS to the EQUIPMENT is interrupted the cuff shall be deflated within 30 s to less than 15 mm Hg adult or 5 mm Hg neonatal and any indication of blood pressure shall be cancelled. When power is restored the EQUIPMENT shall either continue in the same mode of operation and with all OPERATOR settings unchanged, or shall remain inoperative but activate a TECHNICAL ALARM.

Compliance is checked by observing the EQUIPMENT operating mode and interrupting the SUPPLY MAINS for a period exceeding 30 s by disconnecting the POWER SUPPLY CORD.

c) When the EQUIPMENT contains an INTERNAL ELECTRICAL POWER SOURCE and is capable of operating from it, and the MAINS SUPPLY is interrupted, 49.3 b) does not apply. In this case the EQUIPMENT shall continue operation, and the mode of operation and all OPERATOR settings shall not be changed.

Compliance is checked by test and inspection.

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

This clause of the General Standard applies except as follows:

***50.2** *Addition:*

Accuracy of systolic, mean and diastolic pressure for MANUAL MODE and LONG TERM AUTOMATIC MODE. The EQUIPMENT shall have the following accuracy of blood pressure readings:

a) maximum mean error ±5 mm Hg;

b) maximum standard deviation 8 mm Hg.

Compliance shall be demonstrated by clinical data. The use of one of the following three protocols is recommended:

i) Eoin O'Brien, James Petrie, William Littler, Michael de Swiet, Paul L. Padfield, Douglas G. Altman, Martin Bland, Andrew Coats and Neil Atkins; The British Hypertension Society protocol for the evaluation of blood pressure measuring devices. In: Journal of Hypertension 1993, 11 (Suppl 2): S 43-S 62;

ii) DIN 58130:1995, Non-invasive sphygmomanometers – Clinical investigation;

iii) ANSI/AAMI SP10, American National Standard for electronic or automated sphygmomanometers, 1992.

51 Protection against hazardous output

This clause of the General Standard applies except as follows:

Addition:

51.101 ALARMS (see also ALARM diagrams in annex BB)

51.101.1 PHYSIOLOGICAL ALARM device

The EQUIPMENT shall be provided with at least one auditory and one visual PHYSIOLOGICAL ALARM device.

Compliance is checked by inspection.

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51.101.2 TECHNICAL ALARM device

The EQUIPMENT shall be provided with at least one auditory and one visual TECHNICAL ALARM device.

Compliance is checked by inspection.

*51.101.3 SUSPENSION or INHIBITION of all PHYSIOLOGICAL ALARMS and TECHNICAL ALARMS (ALARMS)

a) The EQUIPMENT may be provided with means to SUSPEND or INHIBIT all PHYSIOLOGICAL ALARM(S) and all TECHNICAL ALARM(S) The said means shall INHIBIT or SUSPEND

– the auditory, or

– the auditory and visual manifestations of all PHYSIOLOGICAL ALARMS and the auditory manifestations of all TECHNICAL ALARMS. The OPERATOR shall be allowed to activate these means in NORMAL USE. The selection (configuration) of either the SUSPENSION or the INHIBITION function shall be protected. The ACCOMPANYING DOCUMENTS shall describe the selection procedure.

Compliance testing of INHIBITION: a PHYSIOLOGICAL ALARM is simulated. As soon as the visual and auditory ALARM devices indicate the ALARMS, the function INHIBITION is activated. The function INHIBITION shall disable the auditory or the auditory and visual ALARM manifestations permanently depending on the configuration.

Compliance testing of SUSPENSION: a PHYSIOLOGICAL ALARM is simulated. As soon as the visual and auditory ALARM devices indicate the ALARMS, the function SUSPENSION is activated. The function SUSPENSION shall disable the auditory or the auditory and visual ALARM manifestations temporarily depending on the configuration. After exceeding the pre-adjusted SUSPENSION time, the visual and auditory ALARM manifestations shall be restored automatically.

Both tests are repeated with simulated TECHNICAL ALARM(S). The functions SUSPENSION and INHIBITION shall only disable the auditory ALARM manifestation.

ACCOMPANYING DOCUMENTS are checked by inspection.

b) If the EQUIPMENT is provided with means to SUSPEND or INHIBIT the PHYSIOLOGICAL ALARM(S) and TECHNICAL ALARM(S) only one of the functions SUSPENSION and INHIBITION shall be selectable at a time.

Compliance is checked by inspection.

c) The duration of SUSPENSION may be adjustable. The said means shall not be adjustable by the OPERATOR in NORMAL USE. The duration and/or the adjustment range of the duration shall be specified in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection.

d) If global SUSPENSION or INHIBITION of ALARM(S) is activated by the OPERATOR in NORMAL USE, it shall be visually indicated.

Compliance is checked by inspection.

Except for the case provided for in 51.101.9, the ALARM(S) shall only be INHIBITED or SUSPENDED on the EQUIPMENT.

51.101.4 SILENCE/RESET of ALARM(S)

The EQUIPMENT shall be equipped with means to SILENCE/RESET ALARMS.

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Compliance is checked by inspection.

51.101.5 NON-LATCHED ALARM(S) and LATCHED ALARM(S)

The EQUIPMENT shall be equipped with NON-LATCHED ALARM(S) and/or LATCHED ALARM(S) Only one of the modes shall be selectable for PHYSIOLOGICAL ALARMS.

Compliance is checked by inspection.

51.101.6 NON-LATCHED ALARM(S)

If the EQUIPMENT is equipped with NON-LATCHED ALARM(S), the ALARM is SILENCED and RESET automatically (without any OPERATOR interaction) as soon as the monitored parameter(s) come(s) back within the adjusted limits, or if the abnormal PATIENT condition does not exist any longer.

A PHYSIOLOGICAL ALARM is simulated. As soon as the visual and auditory ALARM devices indicate the ALARM, the simulator settings are changed to a value that no longer exceeds the ALARM limit. When the monitored parameter returns to a value that no longer exceeds the ALARM limit, the auditory or the auditory and visual ALARM manifestations shall cease without activating the function SILENCE/RESET.

51.101.7 LATCHED ALARM(S)

If the EQUIPMENT is equipped with LATCHED ALARM(S), the ALARM shall be SILENCED and RESET manually by the OPERATOR.

A PHYSIOLOGICAL ALARM is simulated. As soon as the visual and auditory ALARM devices indicate the ALARM, the simulator settings are changed to a value that no longer exceeds the ALARM limit. The auditory or the auditory and visual ALARM manifestations shall not cease without activating the function SILENCE/RESET.

51.101.8 SYSTEM ALARM delay time

The ACCOMPANYING DOCUMENTS shall specify the delay time for making ALARM(S) available from this EQUIPMENT to remote equipment at the SIGNAL OUTPUT PART.

Compliance is checked by inspection.

NOTE For guidance on this requirement, it is recommended that the delay time does not exceed 0,5 s.

51.101.9 Remote control of INHIBITION and SUSPENSION of ALARMS

ALARMS may be SUSPENDED or INHIBITED remotely. The selection (configuration) of remote SUSPENSION or INHIBITION shall be protected. The ACCOMPANYING DOCUMENTS shall describe the selection procedure.

51.101.10 Remote control of SILENCE/RESET

SILENCE/RESET may be remotely controlled.

51.102 PHYSIOLOGICAL ALARM

51.102.1 INHIBITION of individual PHYSIOLOGICAL ALARMS

EQUIPMENT that monitors more than one physiological parameter may be equipped with means to INHIBIT its individual PHYSIOLOGICAL ALARMS. The said means INHIBIT the auditory or the auditory and visual manifestations of individual PHYSIOLOGICAL ALARMS).

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A PHYSIOLOGICAL ALARM is simulated. As soon as the visual and auditory ALARM devices indicate the ALARM, the INHIBITION of the individual PHYSIOLOGICAL ALARM is activated. The function INHIBITION shall immediately disable the auditory or the auditory and visual ALARM manifestations permanently depending on the configuration.

*51.102.2 SILENCE/RESET of PHYSIOLOGICAL ALARMS

After SILENCE/RESET, the ALARM device shall reset automatically if the monitored parameter is within the adjusted limits, or if the abnormal PATIENT condition does not exist any longer.

Compliance is checked by testing according to 51.102.5 (Compliance test of the function SILENCE/RESET with LATCHED and NON-LATCHED ALARMS).

51.102.3 PHYSIOLOGICAL ALARM selection, ALARM limit range and delay time of PHYSIOLOGICAL ALARMS

a) EQUIPMENT shall provide at least one of the following physiological parameters for ALARM selection:

- systolic pressure;
- diastolic pressure;
- mean pressure.

Compliance is checked by inspection.

b) The PHYSIOLOGICAL ALARM limits shall cover the whole measurement range provided by the EQUIPMENT. The EQUIPMENT shall provide adjustable high and low ALARM limits for systolic, diastolic, and/or mean pressures. Software controlled EQUIPMENT shall have a default function for all PHYSIOLOGICAL ALARMS.

The EQUIPMENT may provide the option for the OPERATOR to choose whether the high and/or low ALARM limits will apply to systolic and/or diastolic and/or mean pressure.

The adjustment range of PHYSIOLOGICAL ALARM limits shall be specified in the ACCOMPANYING DOCUMENTS.

A short power failure of less than 30 s (e.g. SUPPLY MAINS breakdown) shall not change the set alarm limits.

Compliance is checked by testing and inspection.

c) Delay time: a PHYSIOLOGICAL ALARM shall be immediately indicated (systolic, diastolic, and/or mean pressure) after the monitored value has exceeded an ALARM limit.

Compliance is checked by testing.

51.102.4 Auditory manifestation of PHYSIOLOGICAL ALARMS

The auditory manifestation shall be discontinuous.

Compliance is checked by inspection.

After SILENCE/RESET the auditory manifestation shall disappear.

Compliance is checked by inspection.

*51.102.5 Visual manifestations of PHYSIOLOGICAL ALARMS

The visual manifestation shall be continuous or discontinuous.

Compliance is checked by inspection.

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If the EQUIPMENT monitors more than one physiological parameter, the PHYSIOLOGICAL ALARM generating parameter shall be visually indicated.

If the EQUIPMENT is provided with a means to SUSPEND the visual manifestation of PHYSIOLOGICAL ALARMS, the duration shall be the same as for the auditory ALARM manifestation.

Compliance is checked by inspection.

SILENCE/RESET shall not stop the visual ALARM manifestation as long as the parameter is not within the adjusted limits or if the abnormal PATIENT condition still exists.

LATCHED ALARMS:

After SILENCE/RESET, the visual ALARM device shall reset automatically if the monitored parameter is within the adjusted limits or if the abnormal PATIENT condition does not exist any longer.

NON-LATCHED ALARMS:

The auditory and visual ALARM device shall reset automatically with or without SILENCE/RESET if the monitored parameter is within adjusted limits or if the abnormal PATIENT condition does not exist any longer.

If the EQUIPMENT provides means to INHIBIT or SUSPEND the visual PHYSIOLOGICAL ALARMS, the said means shall also INHIBIT or SUSPEND the auditory PHYSIOLOGICAL ALARMS.

Compliance test of the function SILENCE/RESET with LATCHED ALARMS:

First, a PHYSIOLOGICAL ALARM is simulated. As soon as the visual and auditory ALARM devices indicate the ALARM, the function SILENCE/RESET is activated by the OPERATOR, and this shall disable the auditory ALARM manifestation immediately. Second, the simulator settings are changed to a value that no longer exceeds the alarm limit. The visual ALARM manifestations shall cease without activating the function SILENCE/RESET again.

Compliance test of the function SILENCE/RESET with NON-LATCHED ALARMS:

a) SILENCE/RESET is activated by the OPERATOR before the ALARM condition ceases:

First, a PHYSIOLOGICAL ALARM is simulated. As soon as the visual and auditory ALARM devices indicate the ALARM, the function SILENCE/RESET is activated by the OPERATOR, and this shall disable the auditory ALARM manifestation immediately. Second, the simulator settings are changed to a value that no longer exceeds the alarm limit. The visual ALARM manifestations shall cease without activating the function SILENCE/RESET.

b) SILENCE/RESET is not activated by the OPERATOR:

First, a PHYSIOLOGICAL ALARM is simulated. As soon as the visual and auditory ALARM devices indicate the ALARM, the simulator settings are changed to a value that no longer exceeds the alarm limit. The visual and auditory ALARM manifestations shall cease without activating the function SILENCE/RESET.

Tests a) and b) shall be repeated with simulated TECHNICAL ALARMS.

51.103 TECHNICAL ALARM

TECHNICAL ALARMS shall be NON-LATCHED ALARMS.

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In the case of a TECHNICAL ALARM, the measured value(s) of the parameter(s) might not be capable of initiating PHYSIOLOGICAL ALARMS.

Compliance is checked by inspection.

During the TECHNICAL ALARM status, the physiological parameter(s) concerned might not be capable of initiating PHYSIOLOGICAL ALARMS.

51.103.1 Auditory manifestation of TECHNICAL ALARMS

The auditory manifestation shall be discontinuous.

Compliance is checked by inspection.

The auditory manifestation of a TECHNICAL ALARM shall be indicated as soon as the EQUIPMENT detects the TECHNICAL ALARM condition.

Compliance is checked by inspection.

INHIBITION and SUSPENSION shall disable or SILENCE and disable the auditory manifestation of TECHNICAL ALARMS.

Compliance is checked by inspection.

After SILENCE/RESET the auditory manifestation shall disappear.

Compliance is checked by inspection.

51.103.2 Visual manifestation of TECHNICAL ALARMS

The visual manifestation shall be continuous or discontinuous.

Compliance is checked by inspection.

INHIBITION or SUSPENSION of ALARMS shall not disable or stop and disable the visual manifestation of TECHNICAL ALARMS.

Compliance is checked by inspection.

If the EQUIPMENT can generate more than one TECHNICAL ALARM, the reason for each TECHNICAL ALARM shall be visually indicated.

Compliance is checked by inspection.

SILENCE/RESET shall not stop the visual ALARM manifestation as long as the reason for the TECHNICAL ALARM exists.

Compliance is checked by testing according to 51.102.5 (Compliance test of the function SILENCE/RESET with NON-LATCHED ALARMS).

51.104 Remote equipment

If the EQUIPMENT is equipped with interfaces to remote equipment to duplicate ALARMS, the EQUIPMENT shall be so designed that a failure in the remote equipment or network will not affect the correct ALARM function of the ALARM generating EQUIPMENT.

Compliance is checked by testing.

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51.105 Sound level of the auditory ALARM manifestation

The sound pressure level of the auditory ALARM signals generated by the EQUIPMENT shall be in the range from 45 dB(A) to 85 dB(A) peak value at a distance of 1 m.

*51.106 Recovery from DEFIBRILLATOR discharge

Within 1 min after the discharge of a CARDIAC DEFIBRILLATOR, the EQUIPMENT shall fulfil all the requirements of this Particular Standard, shall function normally, and no deviation from normal function shall be apparent to the OPERATOR.

Compliance is checked by setting the EQUIPMENT to its most rapid cycling mode, and then applying a DEFIBRILLATOR discharge as described in 17 h) of the General Standard. For this test, the cuff shall be inflated to approximately half the specified maximum normal pressure; that is, for adult and neonatal EQUIPMENT, the cuff pressures for this test shall be approximately 150 mm Hg and 75 mm Hg, respectively.

The test arrangements shown in figure 101 shall be used. If the use of the test cylinder shown produces an error code in the EQUIPMENT, due to the lack of a blood pressure derived input signal, then the process may be simulated using a manual start button, if provided, or other means. The test shall be carried out under the following conditions:

– *CLASS I EQUIPMENT: the PROTECTIVE EARTH TERMINAL and any FUNCTIONAL EARTH TERMINAL shall be connected to the PROTECTIVE EARTH of the test circuit.*

– *CLASS II and INTERNALLY POWERED EQUIPMENT: foil as described in 17 h) of the General Standard, and any ACCESSIBLE CONDUCTIVE PART not connected to FUNCTIONAL EARTH TERMINAL, and any FUNCTIONAL EARTH TERMINAL shall be connected to the PROTECTIVE EARTH of the test circuit.*

Record whether the EQUIPMENT has returned to normal function within 1 min.

51.107 Software

Collateral Standard IEC 60601-1-4 applies.

51.108 Units of measurement

The units of measurement shall be in accordance with ISO 1000 except that pressures shall be displayed in mm Hg or kPa.

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

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

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

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

56 Components and general assembly

This clause of the General Standard applies except as follows:

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56.3 aa) Connections – General

Addition:

Tubing connectors

Luer Lock connectors shall not be used.

***56.7 BATTERIES**

56.7 c) Battery state

Replacement:

1) The EQUIPMENT shall provide a TECHNICAL ALARM at least 5 min prior to the time that the EQUIPMENT can no longer function in accordance with the manufacturer's specification when powered from the INTERNAL ELECTRICAL POWER SOURCE.

   Compliance is checked by inspection and measurement.

2) When the state of discharge of any INTERNAL ELECTRICAL POWER SOURCE is such that the EQUIPMENT can no longer function in accordance with the manufacturer's specification, the cuff pressure shall be released below 15 mm Hg (adult) or 5 mm Hg (neonate) within 30 s, and any indication of blood pressure shall be cancelled.

   Compliance is checked by operating the EQUIPMENT from the INTERNAL ELECTRICAL POWER SOURCE and by inspection and measurement.

57 MAINS PARTS, components and lay-out

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

57.3 POWER SUPPLY CORDS

c) *Addition:*

NOTE to Table XV: for CLASS II EQUIPMENT with nominal rated currents up to and including 3 A, the cross-sectional area of the conductors of the POWER SUPPLY CORD shall be not less than 0,5 mm^2.

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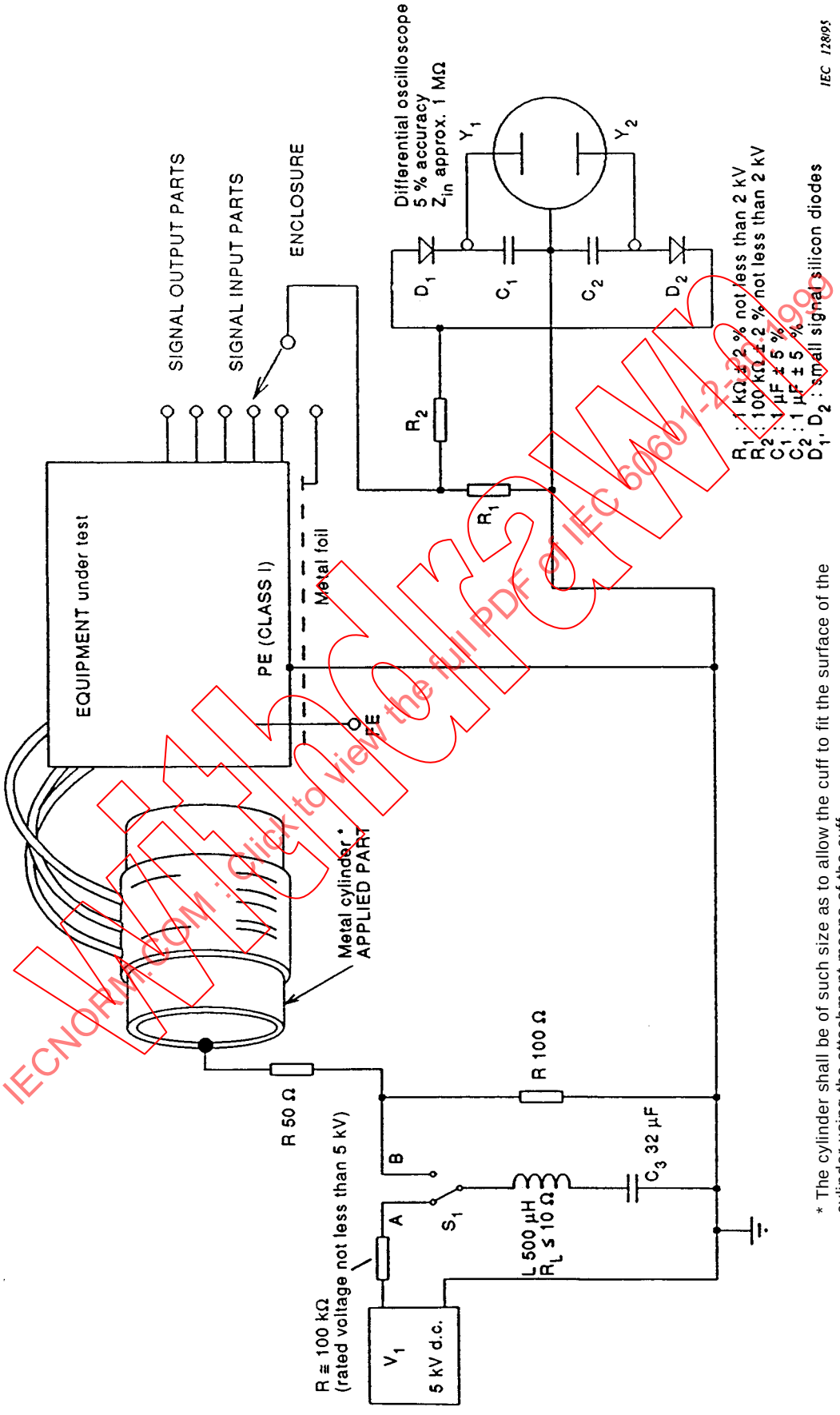

* The cylinder shall be of such size as to allow the cuff to fit the surface of the cylinder using the attachment means of the cuff.

Figure 101 – Test for protection against defibrillator discharge (see 17 h)

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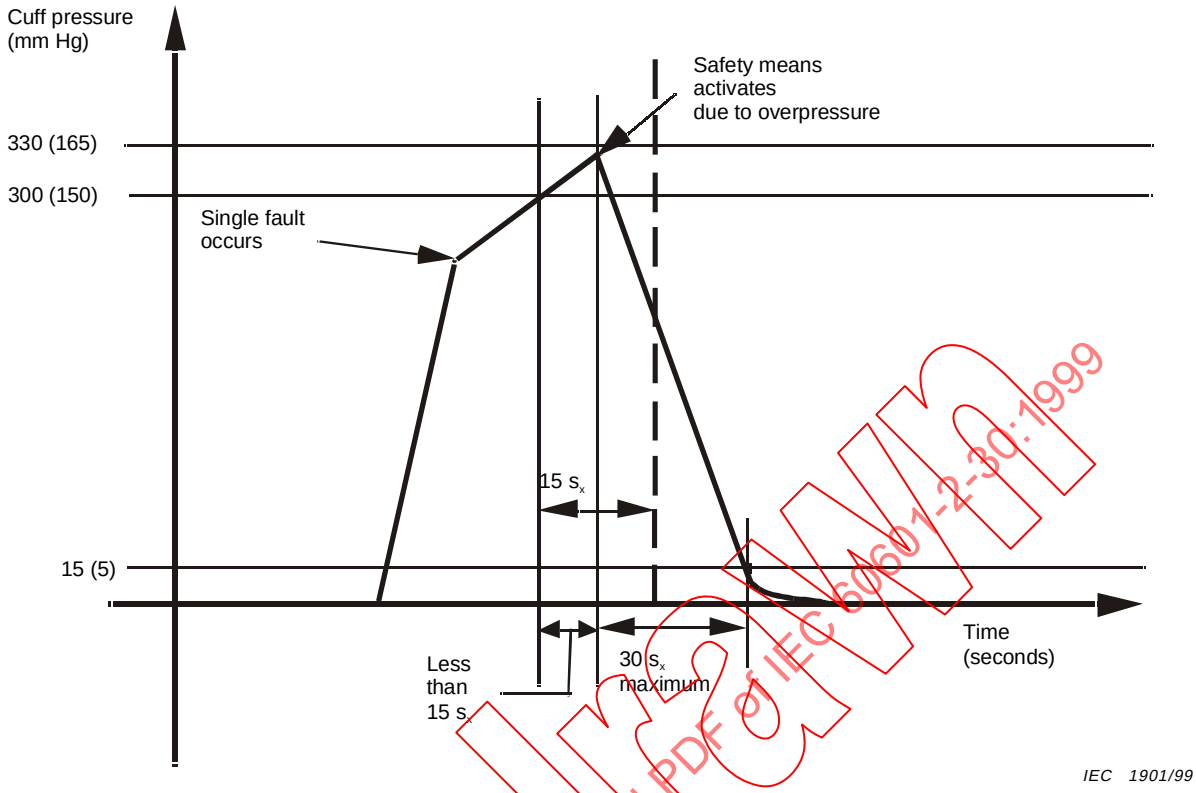

Figure 102 – Safety means, SINGLE FAULT CONDITION, adult (neonatal), determination (see 22.4.1b) 1)

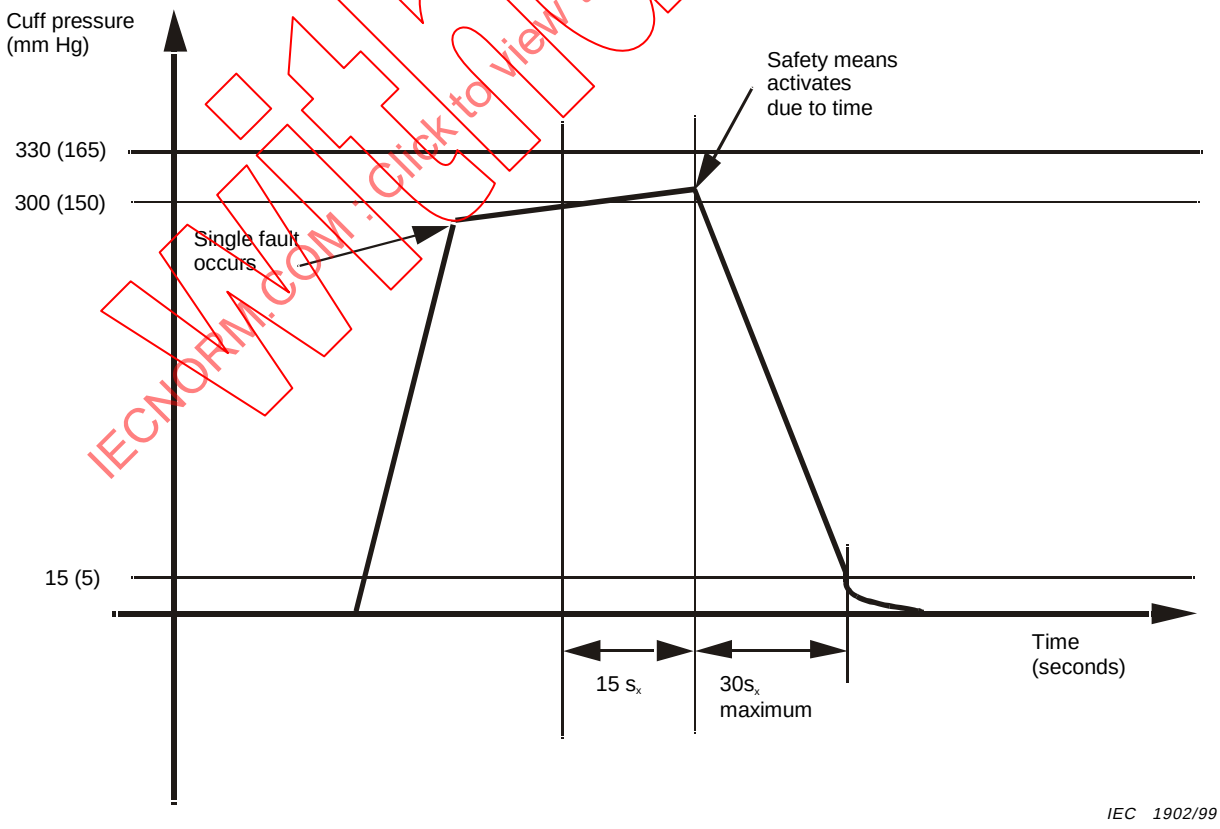

Figure 103 – Safety means, SINGLE FAULT CONDITION, adult (neonatal) determination (see 22.4.1 b) 2)

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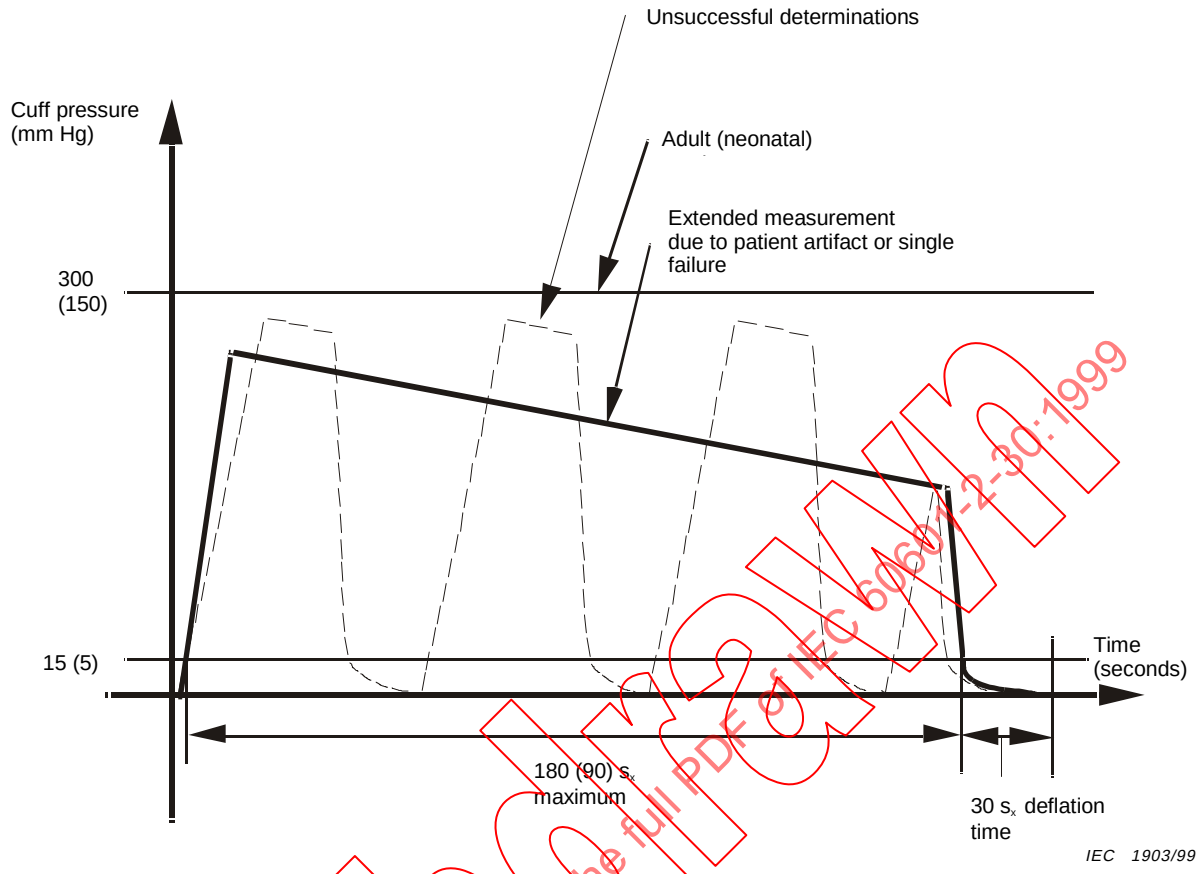

Figure 104 – Maximum inflation time, NORMAL CONDITION and SINGLE FAULT CONDITION, adult (neonatal) determination (see 22.4.2 and 22.4.3)

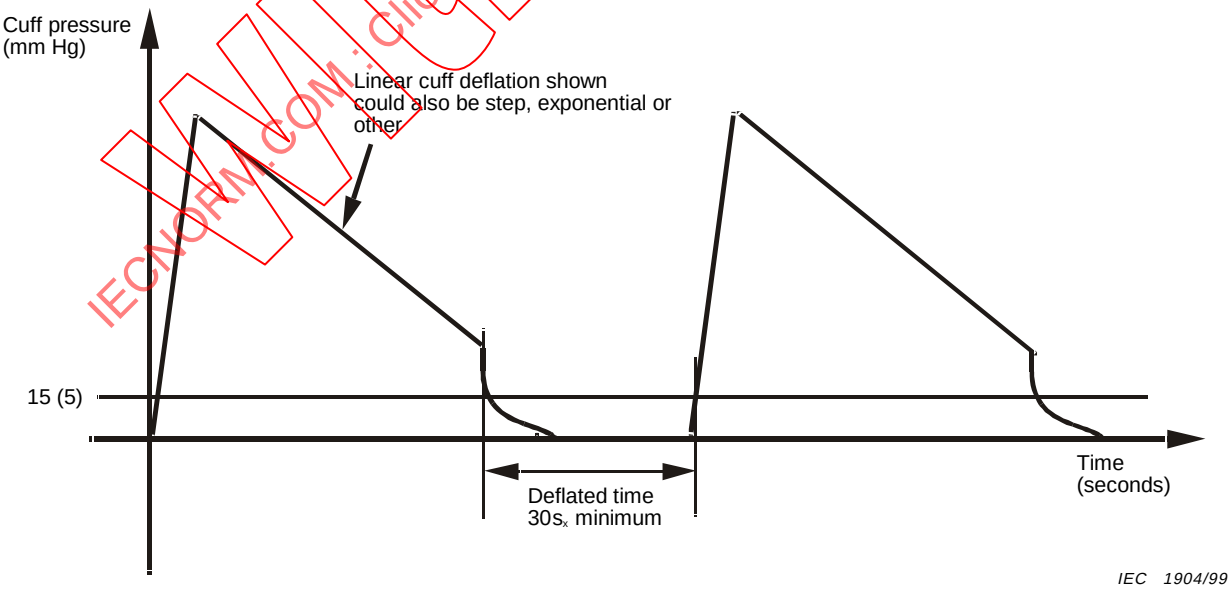

Figure 105 – LONG TERM AUTOMATIC MODE NORMAL CONDITION, adult (neonatal), determination (see 22.4.3 a)

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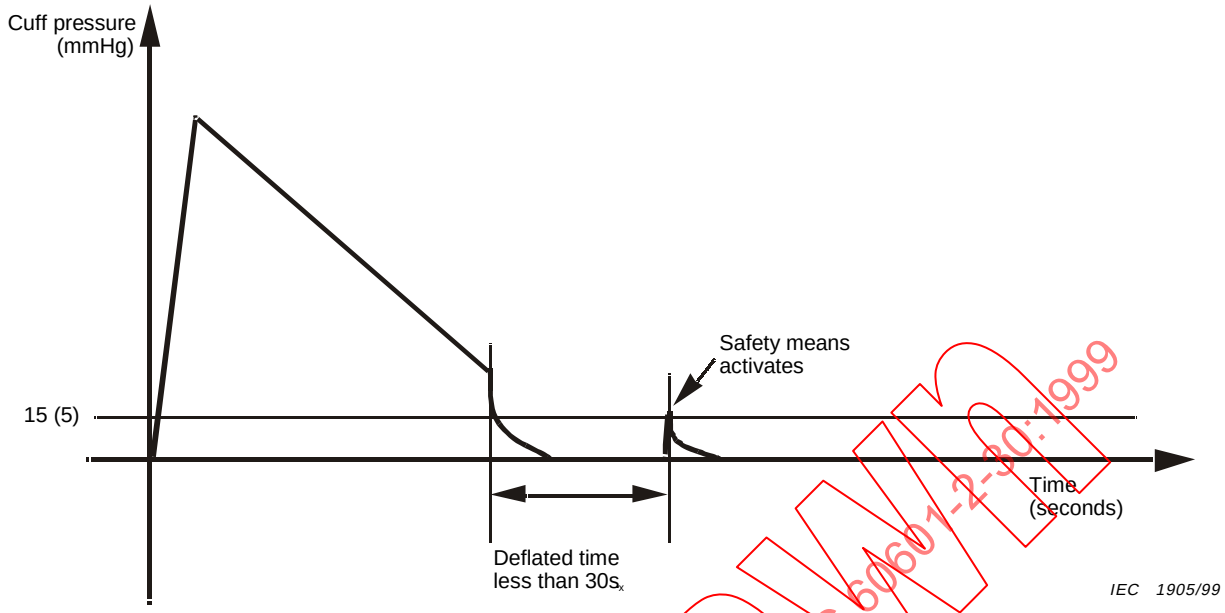

Figure 106 – LONG TERM AUTOMATIC MODE SINGLE FAULT CONDITION, adult (neonatal) determination (see 22.4.3 b)

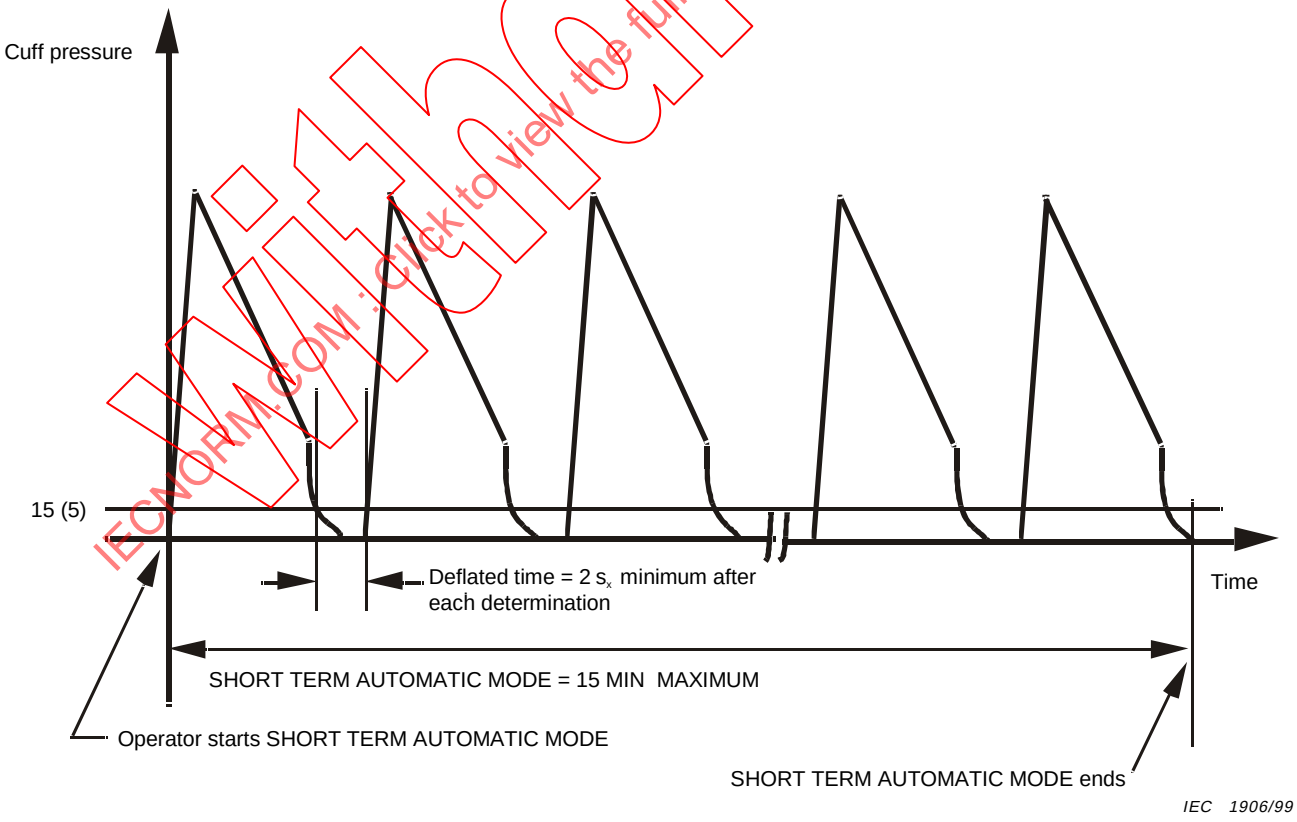

Figure 107 – SHORT TERM AUTOMATIC MODE, adult (neonatal) determination (see 22.4.5)

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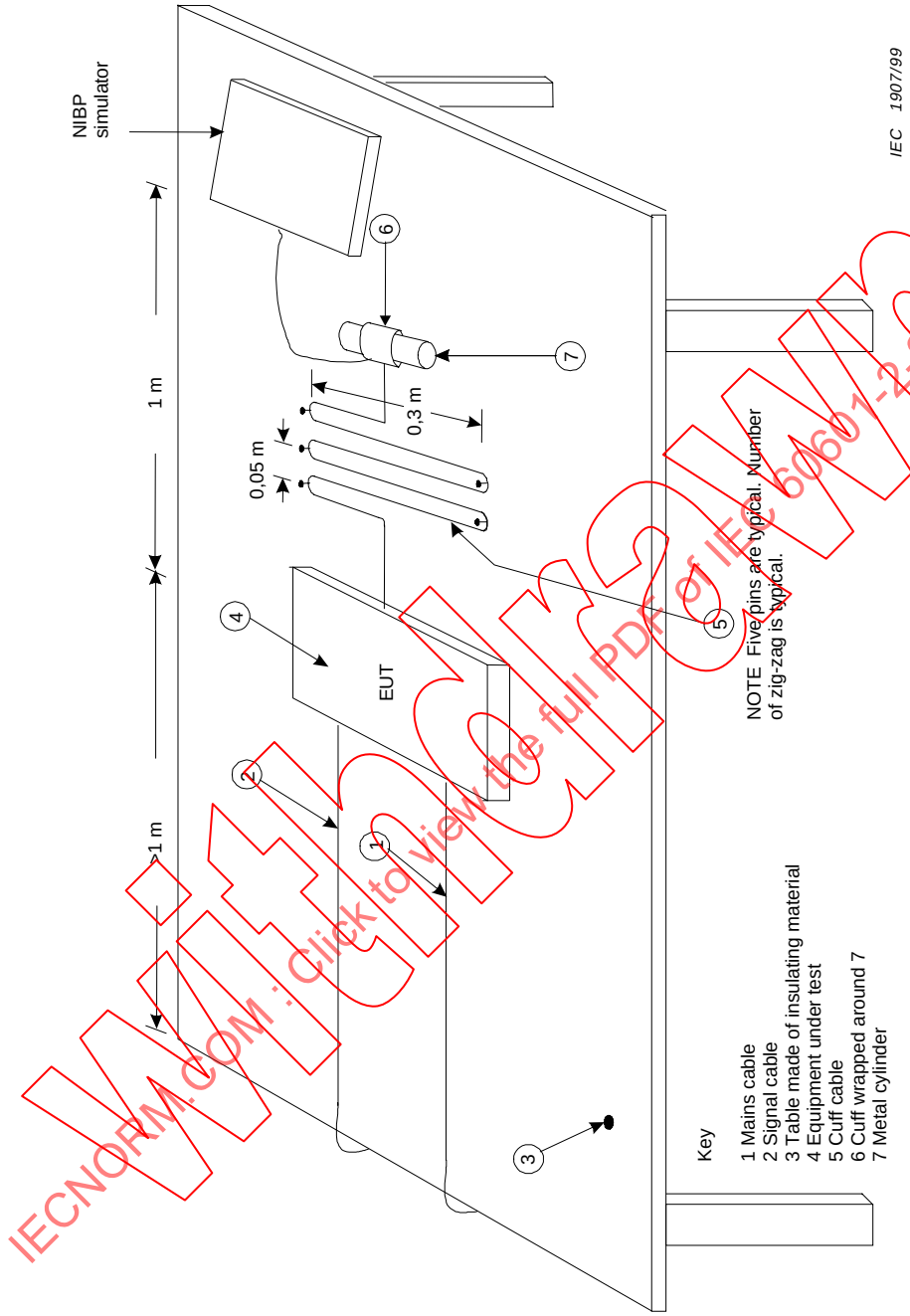

Figure 108 – Test layout (see 36.202.2.2d) and 36.202.6)

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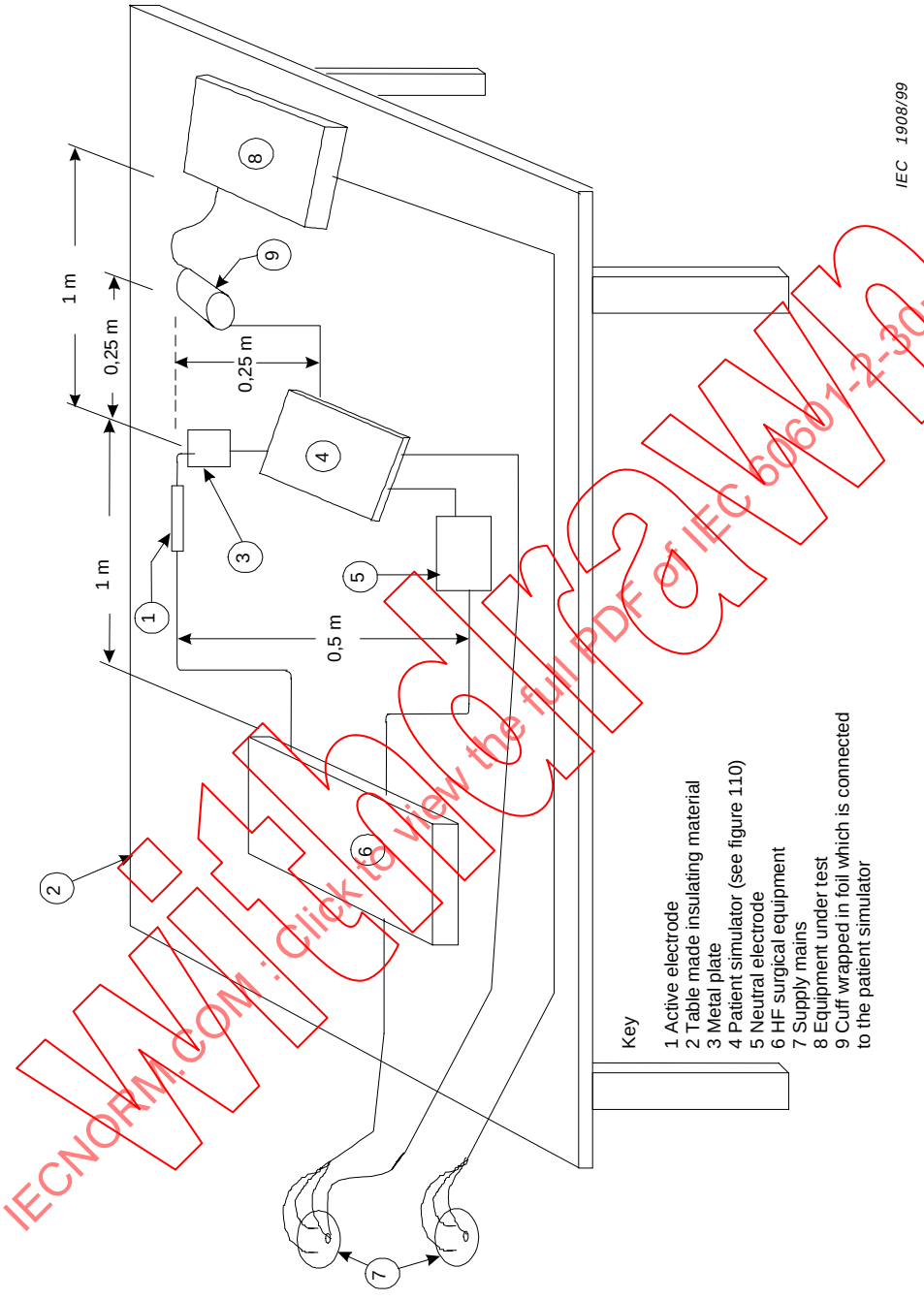

Figure 109 – ESU test layout (see 36.202.7)

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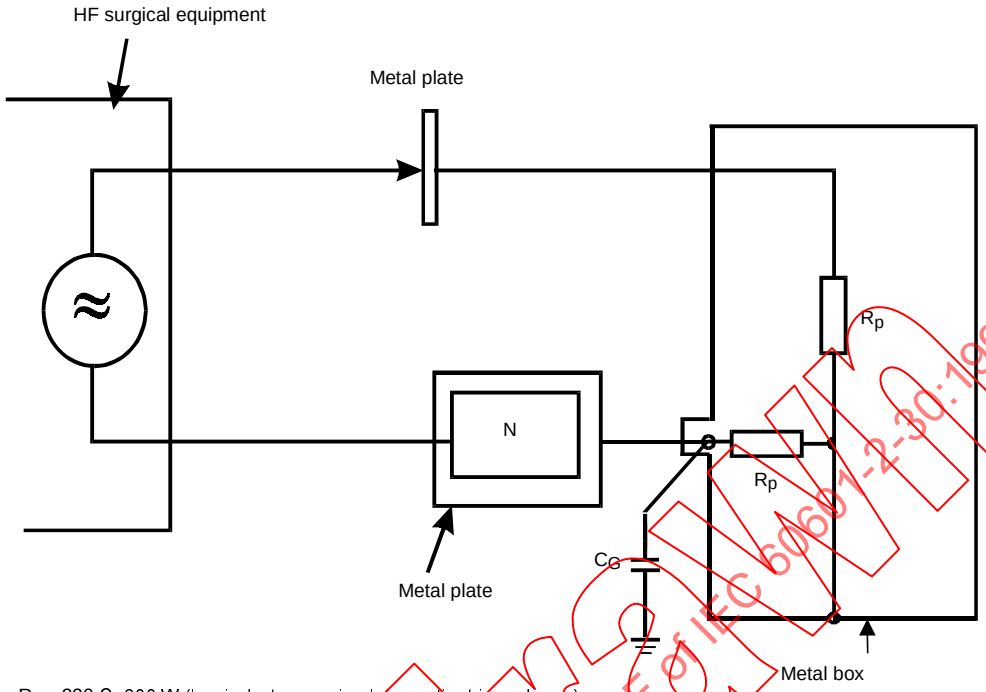

Figure 110 – Patient simulator (see 36.202.7)

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Annex L
(normative)

References – Publications mentioned in this standard

Addition:

IEC standards

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*
Amendment 1 (1991)
Amendment 2 (1995)

IEC 60601-1-2:1993, *Medical electrical equipment – Part 1: General requirements for safety 2. Collateral Standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety 4. Collateral Standard: Programmable electrical medical systems*

IEC 60601-2-2:1982, *Medical electrical equipment – Part 2: Particular requirements for safety of high frequency surgical equipment*

CISPR 11:1990, *Limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment (excluding surgical diathermy apparatus)*

IEC 61000-4-3:1995, *Electromagnetic compatibility (EMC) – Part 4: Testing and measuring techniques – Section 3: Radiated, radio frequency, electromagnetic field immunity test*

IEC 61000-4-6:1996, *Electromagnetic compatibility (EMC) – Part 4: Testing and measuring techniques – Section 6: Immunity to conducted disturbances induced by radio-frequency fields*

IEC 61000-4-8:1993, *Electromagnetic compatibility (EMC) – Part 4: Testing and measuring techniques – Section 8: Power frequency magnetic field immunity test. Basic EMC publication*

IEC 60529:1989, *Classification of degrees of protection provided by enclosures (IP code)*

Other publications:

ISO 1000:1992, *SI units and recommendations for the use of their multiples and of certain other units*

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Annex AA
(informative)

General guidance and rationale

General

Faults in the inflation and deflation cycles of this EQUIPMENT are the main non-electrical hazards.

In the inflation cycle, the problems could be too high an aiming pressure for neonatal or young paediatric use, causing bruising and possibly bone deformation; too long an inflated period resulting in extended venous (and possibly arterial) occlusion, or a repetition rate which is too rapid for an extended period, resulting in excessive venous occlusion, and hence venous blood pooling.

In the deflation cycle, there is only one serious problem that may occur, and that is the failure to deflate. In the short term, this would cause discomfort to a conscious PATIENT, but to an unconscious PATIENT the failure to deflate over an extended period of time may result in irreversible neuromuscular damage.

Various clauses in this standard have as their express purpose the avoidance of the above hazards. The first of these is 3.6, in which three SINGLE FAULT CONDITIONS are named. With any one of these faults present, the EQUIPMENT needs to remain safe, as specified in 22.4.

Subclause 6.8.2 (instructions for use) sets out specific information which needs to be given in the ACCOMPANYING DOCUMENTS to reduce the likelihood of the above and other hazards.

As a further safeguard against the EQUIPMENT maintaining the cuff in an inflated state when the supply is interrupted, the interruption is simulated in two ways in 49.3, the first of these being when the EQUIPMENT is switched off by the OPERATOR (intentionally or unintentionally), the second being an extended interruption of the supply. The EQUIPMENT needs to fail to safety.

As a final precaution against the cuff remaining in an inflated state in battery operated EQUIPMENT, a discharged battery requirement and test are specified in 56.7, and the EQUIPMENT is checked for safe conditions.

The state of the art is such that there is no longer a need for the EQUIPMENT to inflate in the first instance to the maximum aiming pressure of 300 mm Hg (150 mm Hg for neonates). Although it is not stated as a requirement, it is assumed that the EQUIPMENT will only aim for the maximum allowable pressure if initial inflation/deflation cycles have failed to encompass the PATIENT's blood pressure.

Use with defibrillator

The circumstances of use of this EQUIPMENT vary considerably, and may range from accident and emergency units, to operating theatres, and to intensive and coronary care units.

In any of these environments, the use of a defibrillator is to be expected, and defibrillator protection is therefore required.

Following a defibrillator discharge, the EQUIPMENT is not only required to remain safe (17 h), but it is also required to function normally (51.106).

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It is recognized that the measurement intervals of this EQUIPMENT are too long for it to be able to provide the first indication of the outcome of a defibrillation attempt, other categories of monitoring equipment are more suited to this.

It is, however, possible for the present EQUIPMENT to be the only item of monitoring equipment in use on a PATIENT, and it is because it could play a significant role in indicating a return to effective sinus rhythm that normal functioning is required following defibrillation, and that this is apparent to the OPERATOR. Thus, a time constraint of 1 min is stated for its return to normal functioning.

The working group was aware that the use of defibrillators on babies is unusual, but felt that it was not appropriate to exclude "neonatal" EQUIPMENT from the requirement, on the three grounds that defibrillation of neonates is occasionally required, that the neonatal category of this EQUIPMENT is usually combined with an "adult" unit, and that defibrillation protection for this EQUIPMENT poses no technical difficulties.

Rationale for defibrillator test voltages

When a defibrillation voltage is applied to the thorax of a PATIENT via externally applied paddles, the body tissue of the PATIENT in the vicinity of the paddles, and between them, becomes a voltage dividing system.

The voltage distribution can be gauged roughly using three-dimensional field theory, but is modified by local tissue conductivity, which is far from uniform.

If the electrode of an item of ELECTROMEDICAL EQUIPMENT is applied to the thorax or trunk of the PATIENT, roughly within the compass of the defibrillator paddles, the voltage to which such an electrode is subjected depends on its position, but will generally be less than the on-load defibrillator voltage.

Unfortunately, it is not possible to say how much less, as the electrode in question may be placed anywhere in this area, including immediately adjacent to one of the defibrillator paddles. For safety, it should therefore be required that such an electrode and the EQUIPMENT to which it is connected needs to be able to withstand the full defibrillator voltage, and this should be the no-load voltage, as one of the defibrillator paddles may not be making good contact with the PATIENT.

Only in special cases where the electrodes are known with certainty to be placed either almost exactly between the defibrillator paddles (such as oesophageal electrodes), or effectively electrically between them, but at a remote point on the PATIENT (such as EEG or urological electrodes), can it be safely assumed that the voltage applied to the electrode will be less than the voltage of the defibrillator. In such cases, a safe requirement for the electrodes and the EQUIPMENT to which they are connected is that they should be able to withstand somewhat over half the no-load voltage of the defibrillator.

The last set of circumstances to be considered is when the electrode is connected to the PATIENT outside the compass of the defibrillator paddles, such as on the PATIENT's arm or shoulder. The only safe assumption here is that no voltage dividing effect takes place, and the arm or shoulder effectively becomes an open-ended electrical conductor connected to the nearer defibrillator paddle. The electrode and associated EQUIPMENT in such cases should be able to withstand the full no-load voltage of the defibrillator.

In this discussion, as in the requirements of the Particular Safety Standards, it is assumed that one or other of the defibrillator paddles is connected to earth.

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