

Medical electrical equipment —

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

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

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- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
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Summary of pages

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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
(CEI 60601-2-30:1999)

Medizinische elektrische Geräte
Teil 2-30: Besondere Festlegungen für die
Sicherheit, einschließlich der wesentlichen
Leistungsfähigkeit von automatischen,
zyklischen, nicht-invasiven
Blutdrucküberwachungsgeräten
(IEC 60601-2-30:1999)

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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.

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.

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of document 62D/339/FDIS, future edition 2 of IEC 60601-2-30, 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 60601-2-30 on 2000-02-01.

This European Standard supersedes EN 60601-2-30:1995.

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) 2000-11-01
- latest date by which the national standards conflicting
with the EN have to be withdrawn (dow) 2003-02-01

Annexes designated "normative" are part of the body of the standard.

Annexes designated "informative" are given for information only.

In this standard, annex ZA is normative and annexes AA, BB and ZB are informative.

Annexes ZA and ZB have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-30:1999 was approved by CENELEC as a European Standard without any modification.

CONTENTS

Page

INTRODUCTION	5
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Clause

SECTION ONE – GENERAL

1	Scope and object	6
2	Terminology and definitions	7
3	General requirements	8
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	11

SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS

21	Mechanical strength	11
22	Moving parts	12

SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

36	ELECTROMAGNETIC COMPATIBILITY	13
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SECTION SIX – PROTECTION AGAINST THE 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 and disinfection, and compatibility	17
45	Pressure vessels and parts subject to PRESSURE	17
49	Interruption of the power supply	18

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

50	Accuracy of operating data	19
51	Protection against hazardous output	19

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

56	Components and general assembly	25
57	MAINS PARTS, components and lay-out	26

Annex L (normative)	References – Publications mentioned in this standard	34
Annex AA (informative)	General guidance and rationale	35
Annex BB (informative)	Alarm diagrams	42
Annex ZA (normative)	Normative references to international publications with their corresponding European publications	46
Annex ZB (informative)	Other international publications mentioned in this standard with the references of the relevant European publications	47

Figure 101	– Test for protection against defibrillator discharge	27
Figure 102	– Safety means, SINGLE FAULT CONDITION, adult (neonatal) determination	28
Figure 103	– Safety means, SINGLE FAULT CONDITION, adult (neonatal) determination	28
Figure 104	– Maximum inflation time, NORMAL CONDITION and SINGLE FAULT CONDITION, adult (neonatal) determination	29
Figure 105	– LONG TERM AUTOMATIC MODE NORMAL CONDITION, adult (neonatal) determination	29
Figure 106	– LONG TERM AUTOMATIC MODE SINGLE FAULT CONDITION, adult (neonatal) determination	30
Figure 107	– SHORT TERM AUTOMATIC MODE, adult (neonatal) determination	30
Figure 108	– Test layout	31
Figure 109	– ESU test layout	32
Figure 110	– Patient simulator	33

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.

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.

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.

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.

***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.

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.

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.

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/m³), 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.

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.