SLOVENSKI STANDARD
SIST EN 60601-2-30:1998

01-september-1998

Medical electrical equipment - Part 2: Particular requirements for the safety of automatic cycling indirect blood pressure monitoring equipment (IEC 60601-2-30:1995)

Medical electrical equipment -- Part 2: Particular requirements for the safety of automatic cycling indirect blood pressure monitoring equipment

Medizinische elektrische Geräte -- Teil 2: Besondere Festlegungen für die Sicherheit von automatischen zyklischen indirekten Blutdrucküberwachungsgeräten

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

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Medical electrical equipment
Part 2: Particular requirements for the safety of automatic cycling indirect blood pressure monitoring equipment
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Appareils électromédicaux
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(CEI 601-2-30:1995)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die Sicherheit von automatischen zyklischen indirekten Blutdrucküberwachungs-geräten
(IEC 601-2-30:1995)

This European Standard was approved by CENELEC on 1995-07-04. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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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(CO)72, future edition 1 of IEC 601-2-30, 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 1995-07-04.

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) 1996-04-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1996-04-01

Endorsement notice

The text of the International Standard IEC 601-2-30:1995 was approved by CENELEC as a European Standard without any modification.

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Appareils électromédicaux –

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

Medical electrical equipment –

Part 2:
Particular requirements for the safety of automatic cycling indirect blood pressure monitoring equipment

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2: Particular requirements for the safety of automatic cycling indirect blood pressure monitoring equipment

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international cooperation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International Standard IEC 601-2-30 has been prepared by sub-committee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this Particular Standard is based on the following documents:

DIS	Report on voting
62D(CO)72	62D/165/RVD

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

Annexes AA and BB are for information only.

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

- requirements, compliance with which can be tested, and definitions: in roman type.
- explanations, advice, introductions, general statements, exceptions and references: in smaller type.
- *test specifications: in italic type.*
- TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 AND IN IEC 601-1: SMALL CAPITALS.

INTRODUCTION

This Particular Standard concerns the safety of automatic cycling indirect blood pressure monitoring equipment. It amends and supplements IEC 601-1 (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 the "General guidance and rationale" section at the end of this Particular Standard.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2: Particular requirements for the safety of automatic cycling indirect 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 Standard specifies the particular safety requirements for AUTOMATIC CYCLING INDIRECT BLOOD PRESSURE MONITORING EQUIPMENT as defined in 2.101 and hereinafter also referred to as EQUIPMENT.

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 specify particular requirements for the safety of AUTOMATIC CYCLING INDIRECT 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 601-1 (1988): *Medical electrical equipment – Part 1: General requirements for safety.*

For brevity Part 1 is referred to in this Particular Standard either as the "General Standard" or as the "General Requirement(s)".

The numbering of sections, clauses and 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 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.

The term "this Standard" is used to make reference to the General Standard and this Particular Standard taken together.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification; where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

2 Terminology and definitions

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

2.1.5 *APPLIED PART*

Replacement:

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

Additional definitions:

2.101* *AUTOMATIC CYCLING INDIRECT BLOOD PRESSURE MONITORING EQUIPMENT (EQUIPMENT)*

MEDICAL ELECTRICAL EQUIPMENT including its associated accessories intended for the unattended automatic repetitive measurement of blood pressure by means of an occluding cuff and an associated detector.

2.102* *SHORT TERM AUTOMATIC MODE*

A mode in which the maximum repetition rate specified may be exceeded.

2.103 *MANUAL MODE*

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

2.104 *LONG TERM AUTOMATIC MODE*

A mode not being SHORT TERM AUTOMATIC MODE or MANUAL MODE.

3 General requirements

This clause of the General Standard applies except as follows:

3.6 *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 pressurisation timing.

3.7* *Addition:*

aa) Kinking of the hoses, interrupting the flow of air completely.

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 17.101 and 51.101 of this Particular Standard shall be carried out prior to the LEAKAGE CURRENT and dielectric strength tests described in clauses 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 EQUIPMENT.