INTERNATIONAL STANDARD

IEC 60601-2-30

Second edition
1999-12

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

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Terminology, graphical and letter symbols

For general terminology, readers are referred to IEC 60050: *International Electrotechnical Vocabulary* (IEV).

For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams*.

* See web site address on title page.

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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

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 co-operation 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 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.

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.

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.