SLOVENSKI STANDARD
SIST EN 60601-2-34:1998

01-september-1998

Medical electrical equipment - Part 2: Particular requirements for the safety of direct blood pressure monitoring equipment (IEC 60601-2-34:1994)

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

Medizinische elektrische Geräte -- Teil 2: Besondere Festlegungen für die Sicherheit von invasiven Blutdruck-Überwachungsgeräten

Appareils électromédicaux -- Partie 2: Règles particulières de sécurité pour les appareils de surveillance de la pression sanguine prélevée directement

Ta slovenski standard je istoveten z: **EN 60601-2-34:1995**

ICS:

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Medical electrical equipment
Part 2: Particular requirements for the safety of direct blood-pressure monitoring equipment
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This European Standard was approved by CENELEC on 1995-03-06. 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.

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.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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)79, future edition 1 of IEC 601-2-34, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-34 on 1995-03-06.

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) 1996-03-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1996-03-01

For products which have complied with the relevant national standard before 1996-03-01, as shown by the manufacturer or by a certification body, this previous standard may continue to apply for production until 2001-03-01.

Endorsement notice

The text of the International Standard IEC 601-2-34:1994 was approved by CENELEC as a European Standard without any modification.

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Appareils électromédicaux –

Partie 2:
Règles particulières de sécurité pour les appareils de surveillance de la pression sanguine prélevée directement

Medical electrical equipment –

Part 2:
Particular requirements for the safety of direct blood pressure monitoring equipment

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Международная Электротехническая Комиссия

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for the safety of direct 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.

2) The formal decisions or agreements of the IEC on technical matters, prepared by technical committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.

3) They have the form of recommendations for international use published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.

4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.

5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.

International Standard IEC 601-2-34 has been prepared by sub-committee 62D: Electro-medical 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)79	62D/155/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.

Annex AA is 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: 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 amends and supplements IEC 601-1 (second edition, 1988): *Medical electrical equipment – Part 1: General requirements for safety,* as amended by its amendment 1 (1991), hereinafter referred to as the General Standard (see 1.3).

The requirements are followed by specifications for the relevant tests.

Following the decision taken by subcommittee 62D at the meeting in Washington in 1979, a "General guidance and rationale" section giving some explanatory notes, where appropriate, about the more important requirements is included in annex AA.

Clauses or subclauses for which there are explanatory notes in annex AA are marked with an asterisk (*).

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.

MEDICAL ELECTRICAL EQUIPMENT

Part 2: Particular requirements for the safety of direct blood-pressure monitoring equipment

SECTION ONE: GENERAL

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

1 Scope and object

This clause of the General Standard applies except as follows:

1.1* *Scope*

Addition:

This Particular Standard applies to DIRECT BLOOD-PRESSURE MONITORING EQUIPMENT as defined in 2.101, hereinafter referred to as EQUIPMENT.

This Particular Standard does not apply to catheter tubing, catheter needles, Luer locks, taps and taptables, etc.

This Particular Standard also does not apply to indirect blood-pressure monitoring equipment.

1.2 *Object*

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety of DIRECT BLOOD-PRESSURE MONITORING EQUIPMENT and the electrical safety requirements for CATHETER TIP TRANSDUCERS as defined in 2.103.

1.3 *Particular Standards*

Addition:

This Particular Standard refers to IEC 601-1 (1988): *Medical electrical equipment – Part 1: General requirements for safety* as amended by its amendment 1 (1991).

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.

The requirements of this Particular Standard take priority over those of the General Standard.

2 Terminology and definitions

This clause of the General Standard applies except as follows:

2.1.5 *APPLIED PART*

Replacement:

The TRANSDUCER, including any fluid-filled system up to the point at which the electrical isolation of the APPLIED PART is completed.

Additional definitions:

2.101 *DIRECT BLOOD-PRESSURE MONITORING EQUIPMENT (EQUIPMENT)*

MEDICAL ELECTRICAL EQUIPMENT including TRANSDUCERS for the monitoring and/or recording of the internal blood-pressure of PATIENTS.

2.102 *TRANSDUCER*

Part for converting pressure into a signal for monitoring or recording.

2.103 *CATHETER TIP TRANSDUCER*

TRANSDUCER intended for insertion into the cardiovascular system.

2.104 *DOME*

The means for hydraulically coupling the PATIENT's blood-pressure to the TRANSDUCER, where a TRANSDUCER external to the PATIENT is used.

4 General requirements for tests

This clause of the General Standard applies except as follows:

4.11* *Sequence*

Amendment:

Tests called for in 17.101, 45.101 and 51.101 of this Particular Standard shall be performed in that order prior to the LEAKAGE CURRENT and dielectric strength tests of C24 and C25 of appendix C of the General Standard.

5 Classification

This clause of the General Standard applies except as follows:

5.2 According to the degree of protection against electric shock

Amendment:

Delete TYPE B and BF EQUIPMENT.

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*

Additional item:

aa) EQUIPMENT and/or the TRANSDUCER as appropriate shall be marked with the symbol given in the addition to appendix D of this Particular Standard unless such parts are too small or otherwise have limitations on their ability to be marked (for example, disposable DOMES). Parts excepted from such markings shall contain information on the protection against the effects of defibrillation in the ACCOMPANYING DOCUMENTS.