SLOVENSKI STANDARD
SIST EN 60601-2-25:1998

01-september-1998

Medicinska električna oprema - 2-25. del: Posebne varnostne zahteve za elektrokardiografe (IEC 60601-2-25:1993)

Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardiographs (IEC 60601-2-25:1993)

Medizinische elektrische Geräte - Teil 2-25: Besondere Festlegungen für die Sicherheit von Elektrokardiographen (IEC 60601-2-25:1993)

Appareils électromédicaux - Partie 2-25: Règles particulières de sécurité des électrocardiographes (CEI 60601-2-25:1993)

Ta slovenski standard je istoveten z: **EN 60601-2-25:1995**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN 60601-2-25:1998 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-25

November 1995

ICS 11.040.50

Descriptors: Medical electrical equipment, electrocardiographs, safety requirements, protection against electric shock, protection against mechanical hazard, radiation protection, fire protection, environmental conditions

English version

Medical electrical equipment
Part 2: Particular requirements for the safety of electrocardiographs
(IEC 601-2-25:1993)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité des électrocardiographes
(CEI 601-2-25:1993)

Medizinische Elektroausrüstungen
Teil 2: Besondere Sicherheitsanforderungen für Elektrokardiografieausrüstungen
(IEC 601-2-25:1993)

This European Standard was approved by CENELEC on 1995-05-15. 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 the International Standard IEC 601-2-25:1993, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the formal vote and was approved by CENELEC as EN 60601-2-25 on 1995-05-15 without any modification.

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) 1996-07-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1996-07-01

Annexes designated "informative" are given for information only.
In this standard, annexes AA and ZAA are informative.
Annex ZAA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 601-2-25:1993 was approved by CENELEC as a European Standard without any modification.

Annex ZAA (informative)

A-deviations

A-deviation: National deviation due to regulations, the alteration of which is for the time being outside the competence of the CEN/CENELEC member.

This European Standard falls under Directive 93/42/EEC.

NOTE (from CEN/CENELEC IR Part 2, 3.1.9): Where standards fall under EC Directives, it is the view of the Commission of the European Communities (OJ No C 59; 1982-03-09) that the effect of the decision of the Court of Justice in case 815/79 Cremonini/Vrankovich (European Court Reports 1980, p. 3583) is that compliance with A-deviations is no longer mandatory and that the free movement of products complying with such a standard should not be restricted except under the safeguard procedure provided for in the relevant Directive.

A-deviations in an EFTA-country are **valid instead** of the relevant provisions of the European Standard in that country until they have been removed.

Deviation

Switzerland (SR 734.261 of 1990-12-14)

Medical electrical equipment, such as electrocardiographs, is subject to compulsory approval.

NORME INTERNATIONALE
INTERNATIONAL STANDARD

CEI
IEC
601-2-25

Première édition
First edition
1993-03

Appareils électromédicaux

Partie 2:
Règles particulières de sécurité des électrocardiographes

Medical electrical equipment

Part 2:
Particular requirements for the safety of electrocardiographs

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

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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.

International Standard IEC 601-2-25 has been prepared by subcommittee 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)17	62D(CO)21

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, instructions, 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 International Standard amends and supplements IEC 601-1 (second edition, 1988): *Medical electrical equipment – Part 1: General requirements for safety,* 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 electrocardiographs

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 International Standard specifies the particular safety requirements for ELECTROCARDIOGRAPHS as defined in 2.102, intended for the production of detachable ELECTROCARDIOGRAMS for diagnostic purposes. It also applies to vector-cardiographs and EQUIPMENT for stress testing.

This Particular Standard covers minimum safety requirements.

Special requirements concerning use in ambulances, phono-cardiographs, cardiographic monitors, polygraphs, telemetering, special tests (for example, His bundle electrocardiographs), etc. are not covered by this Particular Standard.

EQUIPMENT with microelectrodes used directly in the fibres of the heart muscle is also excluded.

1.2 *Object*

Replacement:

The object of this Particular International Standard is to establish particular requirements for the safety of ELECTROCARDIOGRAPHS as defined in 2.102.

1.3 *Particular Standards*

Addition:

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

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