SLOVENSKI STANDARD
SIST EN 60601-2-51:2004

01-marec-2004

Medicinska električna oprema - 2-51. del: Posebne varnostne zahteve, vključno z bistvenim delovanjem, za snemanje in analiziranje enokanalskih in večkanalskih elektrokardiografov (IEC 60601-2-51:2003)

Medical electrical equipment - Part 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs (IEC 60601-2-51:2003)

Medizinische elektrische Geräte - Teil 2-51: Besondere Festlegungen für die Sicherheit, einschließlich wesentlicher Leistungsmerkmale von aufzeichnenden und interpretierenden Einkanal- und Mehrkanal-Elektrokardiographen (IEC 60601-2-51:2003)

Appareils électromédicaux - Partie 2-51: Règles particulières de sécurité et performances essentielles des électrocardiographes enregistreurs et analyseurs mono et multi-canaux (CEI 60601-2-51:2003)

Ta slovenski standard je istoveten z: **EN 60601-2-51:2003**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN 60601-2-51:2004 **en**

EUROPEAN STANDARD **EN 60601-2-51**

NORME EUROPÉENNE

EUROPÄISCHE NORM July 2003

ICS 11.040.55

English version

Medical electrical equipment
Part 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs
(IEC 60601-2-51:2003)

Appareils électromédicaux
Partie 2-51: Règles particulières
de sécurité et performances essentielles
des électrocardiographes enregistreurs
et analyseurs mono et multi-canaux
(CEI 60601-2-51:2003)

Medizinische elektrische Geräte
Teil 2-51: Besondere Festlegungen
für die Sicherheit, einschließlich
wesentlicher Leistungsmerkmale von
aufzeichnenden und interpretierenden
Einkanal- und Mehrkanal-
Elektrokardiographen
(IEC 60601-2-51:2003)

This European Standard was approved by CENELEC on 2003-04-01. 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Lithuania, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, 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

Ref. No. EN 60601-2-51:2003 E

Foreword

The text of document 62D/469/FDIS, future edition 1 of IEC 60601-2-51, 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 60601-2-51 on 2003-04-01.

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)	2004-02-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2006-04-01

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annexes GG, HH, ZA and ZB are normative, annexes AA to FF and annex II are informative.
Annexes ZA and ZB have been added by CENELEC.

In this particular standard, the following print types are used:
– requirements, compliance with which can be tested, and definitions: roman type;
– notes, explanations, advice, introductions, general statements, exceptions and references: small roman type;
– *test specifications: italic type;*
– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

Endorsement notice

The text of the International Standard IEC 60601-2-51:2003 was approved by CENELEC as a European Standard without any modification.

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Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
Addition to annex ZB of EN 60601-1:1990/A2:1995				
IEC 60601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 + corr. July	1990 1994
A1	1991		A1 + corr. July	1993 1994
A2	1995		A2 + A13	1995 1996
IEC 60601-1-4	1996	Medical electrical equipment Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems	EN 60601-1-4	1996
IEC 60601-2-25	1993	Part 2-25: Particular requirements for the safety of electrocardiographs	EN 60601-2-25	1995
A1	1999		A1	1999
ENV 1064	1991	Medical Informatics - Standard Communication Protocol - Computer-Assisted Electrocardiopgraphy	-	-

Annex ZB
(normative)

Other international publications mentioned in this standard with the references of the relevant European publications

Publication	Year	Title	EN/HD	Year
Addition to annex ZB of EN 60601-1:1990/A2:1995				
AAMI EC11	1991	Diagnostic electrocardiographic devices	-	-
CSE working group recommendation	1985	Recommendation for Measurement Standards in Quantitative Electrocardiagraphy European Heart Journal. 1985, 6, p.815-825	-	-
IEEE Computer Society Press	1990 1991 1992	Computers in Cardiology: Proceedings	-	-
ISO 1000	1992	SI units and recommendations for the use of their multiples and of certain other units	-	-

INTERNATIONAL STANDARD

IEC 60601-2-51

First edition
2003-02

Medical electrical equipment –

Part 2-51:
Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs

Appareils électromédicaux –

Partie 2-51:
Règles particulières de sécurité et performances essentielles des électrocardiographes enregistreurs et analyseurs mono et multi-canaux

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs

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.
2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, 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.
6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60601-2-51 has been prepared by subcommittee 62D: Electro-medical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this standard is based on the following documents:

FDIS	Report on voting
62D/469/FDIS	62D/473/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.

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

- requirements, compliance with which can be tested, and definitions: roman type;
- notes, explanations, advice, introductions, general statements, exceptions and references: small roman type;
- *test specifications: italic type;*
- TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until 2007. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

A bilingual version of this standard may be issued at a later date.

INTRODUCTION

This Particular Standard concerns additional safety of recording and analysing single channel and multichannel electrocardiographic equipment. It amends and supplements IEC 60601-1 (second edition, 1988), including its amendments 1 (1991) and 2 (1995) 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 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel 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 Standard specifies requirements for the safety, including essential performance, of RECORDING AND ANALYSING SINGLE CHANNEL AND MULTICHANNEL ELECTROCARDIOGRAPHS as defined in 2.101, 2.111, 2.117, 2.123, 2.126, hereinafter referred to as EQUIPMENT. The EQUIPMENT may be attended or unattended.

This Particular Standard complements IEC 60601-2-25 and its Amendment 1 (1999).

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements, in addition to the requirements of IEC 60601-2-25, for the safety, including essential performance of RECORDING AND ANALYSING SINGLE CHANNEL AND MULTICHANNEL ELECTROCARDIOGRAPHS.

These requirements shall apply particularly to

– RECORDING ELECTROCARDIOGRAPHS;

– ELECTROCARDIOGRAPHS which are part of other MEDICAL ELECTRICAL EQUIPMENT, for example exercise testing systems, if this EQUIPMENT is used to record ECGs for diagnostic purposes;

– ELECTROCARDIOGRAPHS which are used as output units for ECG data base management systems or ELECTROCARDIOGRAPHS which are used as output units located at other places than the recording unit;

– ANALYSING ELECTROCARDIOGRAPHS, systems, and computing devices which by means of electronic data processing and pattern recognition derive measurements (e.g. intervals and amplitudes) and diagnostic statements from the ECG;

– those parts of PATIENT monitors or other specialised ELECTROCARDIOGRAPHS that are capable of performing the functions of the ANALYSING ELECTROCARDIOGRAPHS.

This standard shall not apply to Holter ELECTROCARDIOGRAPHS, invasive electrocardiography, PATIENT monitoring systems and high-resolution ELECTROCARDIOGRAPHS (e.g. HIS bundle ELECTROCARDIOGRAPHS, ELECTROCARDIOGRAPHS for late potential detection) other than stated above.

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), hereafter referred to as the General Standard, and to IEC 60601-2-25:1993, *Medical electrical equipment – Part 2-25: Particular requirements for the safety of electrocardiographs* and its Amendment 1 (1999).

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*.

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 Standard mentioned above.

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Additional definitions:

2.101
ANALYSING ELECTROCARDIOGRAPH
ELECTROCARDIOGRAPH capable of analysing heart action potentials, deriving measurements from them and/or making interpretative statements. These may be also capable of communicating ECGs and/or analysis results

2.102
CALIBRATION ("CAL")
facility enabling the CALIBRATION VOLTAGE and zero voltage to be recorded in place of the ELECTROCARDIOGRAM

2.103
CALIBRATION VOLTAGE
voltage step recorded for amplitude CALIBRATION purposes

2.104
CENTRAL TERMINAL ACCORDING TO WILSON (CT)
terminal at the average potential of the R, L and F potentials

2.105
CHANNEL
hardware and/or software selection of a particular electrocardiographic LEAD for purposes of display, recording, or transmission

2.106
COMMON MODE REJECTION
ability of the ELECTROCARDIOGRAPH including the PATIENT CABLE and LEAD ELECTRODES, high frequency FILTERS, protection networks, LEAD networks, amplifier input, etc., to discriminate between signals with differences between amplifier inputs (differential signal) and signals common to amplifier inputs (common signal), in the presence of LEAD ELECTRODE impedance imbalance

2.107
COMMON MODE DC OFFSET VOLTAGE
DC voltage appearing on LEAD ELECTRODES with respect to the NEUTRAL ELECTRODE resulting from ELECTRODE-skin voltages

2.108
ECG RECORD
a registration (e.g. a hard copy write-out or a display) of an ECG signal including the associated data such as date and time of the registration, name and identification of the PATIENT, etc.

2.109
EFFECTIVE RECORDING WIDTH
width of the recording paper within which the signal of a CHANNEL can be recorded according to this performance standard

2.110
ELECTROCARDIOGRAM (ECG)
visible recording of heart action potentials as measured at the body surface (see also definition 2.108 'ECG RECORD')

2.111
ELECTROCARDIOGRAPH (ecg)
MEDICAL ELECTRICAL EQUIPMENT and associated ELECTRODES intended for the production of ELECTROCARDIOGRAMS for diagnostic purposes

2.112
ELECTRODE(S)
means (typically, an electrical sensor) in contact with a specified part of the body to detect heart action voltage in combination with another means (see also Table 109). Both means (electrical sensors) are connected to the ELECTROCARDIOGRAPH via a PATIENT CABLE