SLOVENSKI STANDARD
SIST EN 60601-2-47:2002

01-junij-2002

Medicinska električna oprema - 2-47. del: Posebne varnostne zahteve za ambulantne elektrokardiografske sisteme, vključno z bistvenimi zmogljivostmi (IEC 60601-2-47:2001)

Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems (IEC 60601-2-47:2001)

Medizinische elektrische Geräte - Teil 2-47: Besondere Festlegungen für die Sicherheit einschließlich wesentlicher Leistungsmerkmale von ambulanten elektrokardiographischen Systemen (IEC 60601-2-47:2001)

Appareils électromédicaux - Partie 2-47: Règles particulières de sécurité et performances essentielles des systèmes d'électrocardiographie ambulatoires (CEI 60601-2-47:2001)

Ta slovenski standard je istoveten z: **EN 60601-2-47:2001**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN 60601-2-47:2002 **en**

EUROPEAN STANDARD **EN 60601-2-47**

NORME EUROPÉENNE

EUROPÄISCHE NORM October 2001

ICS 11.040.55

English version

Medical electrical equipment
Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
(IEC 60601-2-47:2001)

Appareils électromédicaux
Partie 2-47: Règles particulières de sécurité et performances essentielles des systèmes d'électrocardiographie ambulatoires
(CEI 60601-2-47:2001)

Medizinische elektrische Geräte
Teil 2-47: Besondere Festlegungen für die Sicherheit einschließlich wesentlicher Leistungsmerkmale von ambulanten elektrokardiographischen Systemen
(IEC 60601-2-47:2001)

This European Standard was approved by CENELEC on 2001-10-01. 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, Iceland, Ireland, Italy, Luxembourg, Malta, 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

Ref. No. EN 60601-2-47:2001 E

Foreword

The text of document 62D/408/FDIS, future edition 1 of IEC 60601-2-47, 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 60601-2-47 on 2001-10-01.

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)	2002-07-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2004-10-01

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

In this standard, the following print types are used:
– requirements, compliance with which can be tested, and definitions: roman type;
– explanations, advice, notes, general statements and exceptions: smaller 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 60601-2-47:2001 was approved by CENELEC as a European Standard without any modification.

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
IEC 60601-1	1988	Medical electrical equipment	EN 60601-1	1990
+ A1	1991	Part 1: General requirements for safety	+ A1	1993
			+ corr. July	1994
+ A2	1995		+ A2	1995
			+ A13	1996

Annex ZB
(informative)

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

Publication	Year	Title	EN/HD	Year
IEC 60601-2-25 + A1	1993 1999	Medical electrical equipment Part 2-25: Particular requirements for the safety of electrocardiographs	EN 60601-2-25 + A1	1995 1999
IEC 60601-2-27	1994	Part 2-27: Particular requirements for the safety of electrocardiographic monitoring equipment	EN 60601-2-27	1994
SHEFFIELD, L.T., et al	1985	Recommendations for standards of instrumentation and practice in the use of ambulatory electrocardiography (AHA special report from the task force of the Committee on Electrocardiography and Cardiac Electrophysiology of the Council on Clinical Cardiology)	-	-

INTERNATIONAL STANDARD

IEC 60601-2-47

First edition
2001-07

Medical electrical equipment –

Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems

Appareils électromédicaux –

Partie 2-47: Règles particulières de sécurité et performances essentielles des systèmes d'électrocardiographie ambulatoires

International Electrotechnical Commission 3, rue de Varembé Geneva, Switzerland
Telefax: +41 22 919 0300 e-mail: inmail@iec.ch IEC web site http://www.iec.ch

Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE S

For price, see current catalogue

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems

FOREWORD

1) The IEC (International Electrotechnical Commission) is a world-wide organisation for standardisation comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international co-operation on all questions concerning standardisation 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 organisations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organisation for Standardisation (ISO) in accordance with conditions determined by agreement between the two organisations.
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 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 60601-2-47 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62D/408/FDIS	62D/411/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.

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 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 2005. At this date, the publication will be

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

A bilingual edition of this publication may be issued at a later date.

INTRODUCTION

This Particular Standard concerns the safety of AMBULATORY ELECTROCARDIOGRAPHIC SYSTEMS. It amends and supplements IEC 60601-1 (second edition 1988): *Medical electrical equipment – Part 1: General requirements for safety*, as amended by its amendment 1 (1991) and its amendment 2 (1995), hereinafter referred to as the General Standard. The requirements of this Particular Standard take priority over those of the General Standard.

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 of this Particular Standard.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems

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 the particular safety requirements for AMBULATORY ELECTROCARDIOGRAPHIC SYSTEMS, as defined in 2.101.

Within the scope of this standard are systems of the following types:

a) systems that provide continuous recording and continuous analysis of the ECG allowing full re-analysis giving essentially similar results. The systems may first record and store the ECG and analyse it later on a separate unit, or record and analyse the ECG simultaneously. The type of storage media used is irrelevant with regard to this standard;

b) systems that provide continuous analysis and only partial or limited recording not allowing a full re-analysis of the ECG.

The safety aspects of this standard apply to all types of systems falling in one of the above-mentioned categories.

If the ambulatory electrocardiographic system offers automatic ECG analysis, minimal performance requirements for measurement and analysis functions apply. Medical electrical equipment covered by IEC 60601-2-25 and IEC 60601-2-27 are excluded from the scope of this standard.

This standard does not apply to systems that do not continuously record and analyse the ECG (for example, 'intermittent event recorders').

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety, including essential performance, of AMBULATORY ELECTROCARDIOGRAPHIC SYSTEMS.

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 its amendment 2 (1995).

For brevity, IEC 60601-1 is referred to in this Particular Standard either as the General Standard including its collateral standards or as the General Requirement(s).

The numbering of sections and subclauses of this Particular Standard corresponds to that of the General Standard. Changes to the text of the General Standard are specified by 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.

Clauses, subclauses, tables and figures which are additional to those of the General Standard are numbered starting from 101, additional appendices 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.

1.5 Collateral Standards

Addition:

IEC 60601-1-2:1993, *Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral standard: Electromagnetic compatibility – Requirements and tests*

*2 Terminology and definitions

This clause of the General standard applies except as follows:

Additional definitions:

2.101
AMBULATORY ELECTROCARDIOGRAPHIC SYSTEM (EQUIPMENT)
AMBULATORY RECORDER and a PLAYBACK EQUIPMENT, both of which may contain an analysis function

NOTE This EQUIPMENT is often referred to as Holter monitoring equipment after its inventor Dr. Norman Holter.

2.102
AMBULATORY RECORDER
recording EQUIPMENT worn or carried by the PATIENT including associated ELECTRODES and cables for recording or recording and analysing heart action potentials

2.103
PLAYBACK EQUIPMENT
EQUIPMENT for monitoring and documenting functions into which data from the RECORDER is fed

NOTE This EQUIPMENT is usually stationary and commonly includes computing facilities.

2.104
ELECTROCARDIOGRAM (ECG)
visual record of heart action potentials

[IEC 60601-2-25:1993, definition 2.101]

2.105
LEAD
ELECTRODE and LEAD WIRE combination(s) used for a certain recording of ECG. Examples: Einthoven limb LEAD II, Unipolar chest LEAD V5

[IEC 60601-2-25:1993, definition 2.103, modified]

2.106
PATIENT ELECTRODE
means in contact with a specified part of the body to detect heart action voltage in combination with another means

[IEC 60601-2-25:1993, definition 2.104]

2.107
NEUTRAL ELECTRODE
reference point for differential amplifiers and/or interference suppression circuits, not forming part of any ELECTROCARDIOGRAPH LEAD

[IEC 60601-2-25:1993, definition 2.107]

2.108
PATIENT CABLE
multiwire cable and associated connector(s) to connect the ELECTRODES to the AMBULATORY RECORDER

[IEC 60601-2-25:1993, definition 2.109]

2.109
LEAD WIRE(S)
cable connected between the ELECTRODE and the AMBULATORY RECORDER.

2.110
CONTINUOUS RECORDER
EQUIPMENT which performs continuous analysis and/or recording of the ECG.