SVENSK STANDARD SS-EN 60601-2-47

Fastställd	Utgåva	Sida	Ingår i
2002-04-18	1	1 (1+43)	SEK Område 62

Svenska Elektriska Kommissionen, SEK

Elektrisk utrustning för medicinskt bruk – Säkerhet och väsentliga prestanda – Del 2-47: Särskilda fordringar på EKG-system med kroppsburen registreringsutrustning (Holtersystem)

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

Som svensk standard gäller europastandarden EN 60601-2-47:2001. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-2-47:2001.

Nationellt förord

Europastandarden EN 60601-2-47:2001

består av:

- **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC
- **IEC 60601-2-47, First edition, 2001 - Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems**

  utarbetad inom International Electrotechnical Commission, IEC.

Standarden skall användas tillsammans med SS-EN 60601-1, Elektromedicinsk utrustning - Säkerhet - Del 1: Allmänna fordringar, och dess separat utgivna ändringar och tillägg.

Till SS-EN 60601-1 utges en serie tilläggsstandarder som anger allmänna fordringar på säkerhet som är tillämpliga på

- en grupp av elektrisk utrustning för medicinskt bruk, t ex radiologisk utrustning
- särskilda egenskaper hos all elektrisk utrustning för medicinskt bruk, ej särskilt behandlade i SS-EN 60601-1, t ex elektromagnetisk kompatibilitet.

ICS 11.040.55

Denna standard är fastställd av Svenska Elektriska Kommissionen, SEK,
som också kan lämna upplysningar om **sakinnehållet** i standarden.
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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	1993	Medical electrical equipment	EN 60601-2-25	1995
+ A1	1999	Part 2-25: Particular requirements for the safety of electrocardiographs	+ A1	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)	-	-

CONTENTS

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.