STANDARDISERINGEN I SVERIGE
SWEDISH STANDARDS INSTITUTION

SVENSK STANDARD **SS-EN 60 601-2-25**

Handläggande organ	Fastställd	Utgåva	Sida	Ingår i
Svenska Elektriska Kommissionen, SEK	1996-05-31	1	1 (1+30)	SEK Översikt 62

Registrering
Reg 486 03 45

SIS FASTSTÄLLER OCH UTGER SVENSK STANDARD SAMT SÄLJER NATIONELLA, EUROPEISKA OCH INTERNATIONELLA STANDARDPUBLIKATIONER ©

Elektrisk utrustning för medicinskt bruk - Säkerhet - Del 2: Särskilda fordringar på EKG-utrustning

Medical electrical equipment -
Part 2: Particular requirements for the safety of electrocardiographs

Som svensk standard gäller europastandarden EN 60601-2-25: 1995. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-2-25: 1995.

Nationellt förord

Europastandarden EN 60601-2-25: 1995

består av

- **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC

- **IEC 601-2-25, First edition, 1993 - Medical electrical equipment**
  Part 2: Particular requirements for the safety of electrocardiographs

  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 11.040.50

Standarder kan beställas hos SIS som även lämnar allmänna upplysningar om svensk och utländsk standard.
Postadress: SIS, Box 6455, 113 82 Stockholm
Telefon: 08 - 610 30 00. *Telefax:* 08 - 30 77 57

Upplysningar om **sakinnehållet** i standarden lämnas av SEK.
Telefon: 08 - 444 14 00. *Telefax:* 08 - 444 14 30

Prisgrupp R

Tryckt i augusti 1996

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: Règlesparticulières 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 Eiectrotechnical 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.

CONTENTS

SECTION EIGHT: ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

SECTION NINE: ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

SECTION TEN: CONSTRUCTIONAL REQUIREMENTS

Figures

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)”.

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 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.