SIS - Standardiseringskommissionen i Sverige

SVENSKA ELEKTROTEKNISKA NORMER, SEN

SVENSK STANDARD SS-EN 60 601-1

Handläggande organ	Fastställd	Utgåva	Ingår i
SEK, SVENSKA ELEKTRISKA KOMMISSIONEN	1991-09-11	1	SEK Översikt 62

Registrering
Reg 486 03 01

Elektromedicinsk utrustning — Säkerhet — Del 1: Allmänna fordringar

Medical electrical equipment — Part 1: General requirements for safety

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SVENSKA ELEKTROTEKNISKA NORMER, SEN
SVENSK STANDARD SS-EN 60 601-1

Fastställd	Utgåva	Sida	Ingår i
1991-09-11	1	1 (205)	SEK Översikt 62

Registrering
Reg 486 03 01

Elektromedicinsk utrustning – Säkerhet – Del 1: Allmänna fordringar

Medical electrical equipment –
Part 1: General requirements for safety

Denna svenska standard överensstämmer med europastandard EN 60 601-1, 1990, utarbetad inom CENELEC, vilken ikraftsätter nedan angiven del av den inom International Electrotechnical Commission, IEC, utarbetade internationella standarden:

IEC 601 **Medical electrical equipment**

IEC 601-1, Second edition, 1988 **Part 1: General requirements for safety**

I den svenska standarden återges den engelskspråkiga versionen av IEC 601-1.

Nationellt förord

Standarden anger de säkerhetskrav som, med hänsyn till elchock, brännskador, mekaniska skador och andra riskmoment, kan ställas på elektromedicinsk utrustning i allmänhet, ger anvisningar för konstruktion, installation och underhåll av sådan utrustning samt beskriver provningsmetoder. Även vissa krav på tillförlitlig funktion av betydelse för säkerheten, liksom för transport och lagring anges. Risker orsakade av den avsedda funktionen hos elektromedicinsk utrustning behandlas ej.

Under arbetet med överföring av IEC-standarden till svensk standard har det förutsatts att bruksanvisning enligt avsnitt 6.8.2 samt varningar och förklaringar till varningssymboler som åtföljer utrustning skall vara på svenska språket.

Tidigare utgåva av svensk standard som omfattar allmänna fordringar med avseende på säkerhet, SS IEC 601-1, 1987, skall fortsätta att gälla parallellt med SS EN 60 601-1 så länge någon del i serien IEC 601-2 med särskilda fordringar på speciella apparatslag avsedd att användas tillsammans med IEC 601-1, First edition, är i kraft som svensk standard.

UDK 621.3:615.47 614.845.001.25 003.62

Standarder kan beställas hos SIS som även lämnar allmänna upplysningar om svensk och utländsk standard.
Postadress: SIS, Box 3295, 103 66 Stockholm
Telefon: 08 - 613 52 00. *Telefax*: 08 - 11 70 35

Upplysningar om **sakinnehållet** i standarden lämnas av SEK.
Telefon: 08 - 750 78 20. *Telefax*: 08 - 751 84 70

Prisgrupp Y

Tryckt i november 1991

EUROPEAN STANDARD

NORME EUROPEENNE

EUROPÄISCHE NORM

EN 60601-1

August 1990

UDC 615.84:614.8

Descriptors: Medical electrical equipment, definitions, requirements, testing, construction, safety, symbols

ENGLISH VERSION

MEDICAL ELECTRICAL EQUIPMENT
PART 1: GENERAL REQUIREMENTS FOR SAFETY
(IEC 601-1:1988)

Appareils électromédicaux
Première partie: Règles générales de sécurité
(CEI 601-1:1988)

Medizinische elektrische Geräte
Teil 1: Allgemeine Festlegungen für die Sicherheit
(IEC 601-1:1988)

This European Standard was approved by CENELEC on 1990-06-11.
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 Bréderode 2, B-1000 Brussels

BRIEF HISTORY

The CENELEC Questionnaire Procedure, performed for finding out whether or not IEC 601-1: 1988 could be accepted without textual changes, has shown that no CENELEC common modifications were necessary for the acceptance as a European Standard. The Reference Document was submitted to the CENELEC members for formal vote and acceptance.

The text of the International Standard IEC 601-1:1988 was approved by CENELEC on the 11th of June 1990 as a European Standard.

The following dates were fixed:

Latest date of announcement of the EN at national level	(doa)	1990-09-01
Date of latest publication of a new harmonized standard	(dop)	1991-01-01
Date of withdrawal of conflicting national standards	(dow)	1991-01-01

For products which have complied with HD 395 S2:1988 before 1991-01-01, as shown by the manufacturer or by a certification body, this previous standard may continue to apply for production until 1996-01-01.

Annex ZA (normative) lists the IEC, ISO and other publications quoted in this Standard and the corresponding CENELEC standard.

ENDORSEMENT NOTICE

The text of the International Standard IEC 601-1:1988 was approved by CENELEC as a European Standard without any modification.

ANNEX ZA (normative)

OTHER INTERNATIONAL PUBLICATIONS QUOTED IN THIS STANDARD

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

IEC Publication	Date	Title	EN/HD	Date
65 (mod)	1985	Safety requirements for mains operated electronic and related apparatus for household and similar general use. Fifth edition 1985, incorporating Amendment No. 1 (1978) Amendment No. 2 (1981).	HD 195 S6	1989
68-2-2	1974	Basic environmental testing procedures. Part 2-2: Test B, Dry heat.	HD 323.2.2 S1	1988
73	1984	Colours of indicator lights and push-buttons.	HD 354 S2	1987
79	—	Electrical apparatus for explosive gas atmospheres.	—	
79-2	1983	Electrical apparatus for explosive gas atmospheres. Part 2: Electrical apparatus - type of protection "p".		
79-5:	1967	Electrical apparatus for explosive gas atmospheres. Part 5: Sand-filled apparatus.		
79-6	1968	Electrical apparatus for explosive gas atmospheres. Part 6: Oil-immersed apparatus.		
85	1984	Thermal evaluation and classification of electrical insulation.	HD 566 S1	1990
112	1979	Method for determining the comparative and the proof tracking indices of solid insulating materials under moist conditions.	HD 214 S2	1980
127	1974	Cartridge fuse-links for miniature fuses.	HD 109 S3	1983
227 (mod)	—	Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V. Amendment No. 1 (1985).	HD 21	—
241	1968	Fuses for domestic and similar purposes.	—	
245 (mod)	—	Rubber insulated cables of rated voltages up to and including 450/750V.	HD 22	—
245-4 (mod)	1980	Rubber insulating cables of rated voltages up to and including 450/750V. Part 4: Cords and flexible cords.	HD 22.4 S2	1982
252	1975	A.C. motor capacitors.	—	
309	—	Plugs, socket-outlets and couplers for industrial purposes.	HD 196	—
320 (mod)	1981	Appliance couplers for household and similar general purposes.	EN 60320-1	1987
328	1972	Switches for appliances.	—	
355-1	1970	Safety of household and similar electrical appliances. Part 1: General requirements.	—	

IEC Publication	Date	Title	EN/HD	Date
336	1982	Characteristics of focal spots in diagnostic X-ray tube assemblies for medical use.	HD 509 S1	1988
348	1978	Safety requirements for electronic measuring apparatus.	HD 401 S1	1980
364-4-41	1982	Electrical installations of buildings. Part 4: Protection for safety. Chapter 41: Protection against electric shock.	HD 384.4.41 S1	—
384-14	1981	Fixed capacitors for use in electronic equipment. Part 14: Sectional specification: Fixed capacitors for radio interference suppression. Selection of methods of test and general requirements.		
417	—	Graphical symbols for use on equipment. Index, survey and compilation of the single sheets.	HD 243	—
445	1973	Identification of apparatus terminals and general rules for a uniform system of terminal marking, using an alphanumeric notation.	HD 241 S2	1981
447	1974	Standard directions of movement for actuators which control the operation of electrical apparatus.	HD 331 S1	1977
513	1976	Basic aspects of the safety philosophy of electrical equipment used in medical practice.	—	
529	1976	Classification of degrees of protection provided by enclosures.	HD 365 S3	1985
536	1976	Classification of electrical and electronic equipment with regard to protection against electric shock.	HD 366 S1	1977
601-1	1977	Safety of medical electrical equipment. Part 1: General requirements. First edition 1977. Amendment No. 1 (1984)	HD 395 S2	1988
664	1980	Insulation co-ordination within low-voltage systems including clearances and creepage distances for equipment.	—	
695	—	Fire hazard testing.	HD 444	—
707	1981	Methods of test for the determination of the flammability of solid electrical insulating materials when exposed to an igniting source.	HD 441 S1	1983
742 (mod)	1983	Isolating transformers and safety isolating transformers: Requirements.	EN 60742	1989
878	1988	Graphical symbols for electrical equipment in medical practice.		

ISO Publication		
ISO 32	1977	Gas cylinders for medical use — Marking for identification of content.
ISO 407	1983	Small medical gas cylinders — Yoke-type vale connections.
ISO 471	1983	Rubber — Standard temperatures, humidities and times for the conditioning and testing of test pieces.
ISO 780	1985	Packaging — Pictorial marking for handling of goods.

ISO Publication	Page	Title
ISO 1853	1975	Conducting and antistatic rubbers — Measurement of resistivity.
ISO 2878	1987	Rubber, vulcanized — Antistatic and conductive products — Determination of electrical resistance.
ISO 2882	1979	Rubber, vulcanized — Antistatic and conductive products for hospital use — Electrical resistance limits.
ISO 8185	1988	Humidifiers for medical use — Safety requirements.

CONTENTS

Clause Page

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT

Part 1: General requirements for safety

FOREWORD

1) 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.

2) They have the form of recommendations for international use and they are accepted by the National Committees in that sense.

3) In order to promote international unification, the IEC expresses the wish that all National Committees should adopt the text of the IEC recommendation for their national rules in so far as national conditions will permit. Any divergence between the IEC recommendation and the corresponding national rules should, as far as possible, be clearly indicated in the latter.

PREFACE

This Standard has been prepared by Sub-Committee 62A: Common aspects of electrical equipment used in medical practice, of IEC Technical Committee No. 62: Electrical equipment in medical practice.

It forms the second edition of IEC Publication 601-1 (1977), entitled "Safety of medical electrical equipment, Part 1: General requirements".

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

Six Months' Rule	Report on Voting	Two Months' Procedure	Report on Voting
62A(CO)24	62A(CO)25	62A(CO)27	62A(CO)33

Full information on the voting for the approval of this Standard can be found in the Voting Reports indicated in the above table.

The list of IEC, ISO and other publications quoted in this Standard will be found in Appendix L.

In this Standard, the following print types are used:

Requirements, compliance with which can be tested and definitions: in roman type.

Explanations, advice, introductions, general statements, exceptions and references: in smaller type.

Test specifications: in italic type.

TERMS USED THROUGHOUT THIS STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 AND ALSO GIVEN IN THE INDEX: SMALL CAPITALS.

* Rationale (Appendix A).

INTRODUCTION

Aware of the need and the urgency for a General Standard covering electro-medical equipment, the majority of National Committees voted in 1977 in favour of the first edition of IEC Publication 601-1, based on a draft which at the time represented a first approach to the problem.

The extent of the scope, the complexity of the equipment concerned, and the specific nature of some of the protective measures and the corresponding tests for verifying them, had required years of effort in order to prepare this first Standard, which can now be said to have served as a universal reference since its publication.

However, its frequent application has revealed room for improvement, all the more desirable in view of the considerable success that this Standard has enjoyed since its publication. In fact it is now available in a dozen languages and forms an integral part of the National Standards of several countries.

The careful work of revision subsequently undertaken and continued over a number of years has finally resulted in this second edition. This incorporates all the improvements which can be reasonably expected at the present time, taking into account the level of current scientific knowledge. Further developments will remain under constant study.

The change of the title from "Safety of medical electrical equipment, Part 1: General requirements" in the first edition, to "Medical electrical equipment, Part 1: General requirements for safety", allows for subjects other than safety to be dealt with in other parts of IEC Publication 601.

This General Standard contains requirements of safety which are generally applicable to MEDICAL ELECTRICAL EQUIPMENT. For certain types of EQUIPMENT, these requirements are to be supplemented or modified by the special requirements of a Particular Standard. Where Particular Standards exist, the General Standard should not be used alone. Special care is required in applying the General Standard to EQUIPMENT for which no Particular Standard exists.

In some countries EQUIPMENT may only be certified as complying with this Standard if either a Particular Standard or an authorized document based on the General Standard is available stating which clauses are applicable for the EQUIPMENT concerned.

An appendix on "General guidance and rationale" is added (see Appendix A). It is not a part of this Standard and only gives additional information; it can never be the subject of testing.

Clauses and sub-clauses to which there is a rationale are marked with an asterisk *.

The statement "Not used" refers to clauses and sub-clauses in the first edition that have not been retained in this second edition.

MEDICAL ELECTRICAL EQUIPMENT

Part 1: General requirements for safety

SECTION ONE — GENERAL

*1. Scope and object

1.1 *Scope*

This Standard applies to the safety of MEDICAL ELECTRICAL EQUIPMENT (as defined in Sub-clause 2.2.15).

Although this Standard is primarily concerned with safety, it contains some requirements regarding reliable operation where this is connected with safety.

SAFETY HAZARDS resulting from the intended physiological function of EQUIPMENT covered by this Standard are not considered.

Appendices in this Standard are not mandatory unless made so by an explicit statement in the main text.

1.2 *Object*

The object of this Standard is to specify general requirements for the safety of MEDICAL ELECTRICAL EQUIPMENT and to serve as the basis for the safety requirements of Particular Standards.

*1.3 *Particular Standards*

A requirement of a Particular Standard takes priority over the corresponding requirement of this General Standard.

1.4 *Environmental conditions*

See Section Two.