SVENSK STANDARD SS-EN 60601-2-13

Fastställd	Utgåva	Sida	Ingår i
2006-08-21	1	1 (1+45)	SEK Område 62

Svenska Elektriska Kommissionen, SEK

Elektrisk utrustning för medicinskt bruk – Säkerhet och väsentliga prestanda – Del 2-13: Särskilda fordringar på anestesisystem

Medical electrical equipment – Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems

Som svensk standard gäller europastandarden EN 60601-2-13:2006. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-2-13:2006.

Nationellt förord

Europastandarden EN 60601-2-13:2006

består av:

– **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC
– **IEC 60601-2-13, Third edition, 2003 - Medical electrical equipment - Part 2-13: Particular requirements for the safety and essential performance of anaesthetic 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 11.040.10

Denna standard är fastställd av Svenska Elektriska Kommissionen, SEK, som också kan lämna upplysningar om **sakinnehållet** i standarden.
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Standarder underlättar utvecklingen och höjer elsäkerheten

Det finns många fördelar med att ha gemensamma tekniska regler för bl a säkerhet, prestanda, dokumentation, utförande och skötsel av elprodukter, elanläggningar och metoder. Genom att utforma sådana standarder blir säkerhetskraven tydliga och utvecklingskostnaderna rimliga samtidigt som marknadens acceptans för produkten eller tjänsten ökar.

Många standarder inom elområdet beskriver tekniska lösningar och metoder som åstadkommer den elsäkerhet som föreskrivs av svenska myndigheter och av EU.

SEK är Sveriges röst i standardiseringsarbetet inom elområdet

Svenska Elektriska Kommissionen, SEK, svarar för standardiseringen inom elområdet i Sverige och samordnar svensk medverkan i internationell och europeisk standardisering. SEK är en ideell organisation med frivilligt deltagande från svenska myndigheter, företag och organisationer som vill medverka till och påverka utformningen av tekniska regler inom elektrotekniken.

SEK samordnar svenska intressenters medverkan i SEKs tekniska kommittéer och stödjer svenska experters medverkan i internationella och europeiska projekt.

Stora delar av arbetet sker internationellt

Utformningen av standarder sker i allt väsentligt i internationellt och europeiskt samarbete. SEK är svensk nationalkommitté av International Electrotechnical Commission (IEC) och Comité Européen de Normalisation Electrotechnique (CENELEC).

Standardiseringsarbetet inom SEK är organiserat i referensgrupper bestående av ett antal tekniska kommittéer som speglar hur arbetet inom IEC och CENELEC är organiserat.

Arbetet i de tekniska kommittéerna är öppet för alla svenska organisationer, företag, institutioner, myndigheter och statliga verk. Den årliga avgiften för deltagandet och intäkter från försäljning finansierar SEKs standardiseringsverksamhet och medlemsavgift till IEC och CENELEC.

Var med och påverka!

Den som deltar i SEKs tekniska kommittéarbete har möjlighet att påverka framtida standarder och får tidig tillgång till information och dokumentation om utvecklingen inom sitt teknikområde. Arbetet och kontakterna med kollegor, kunder och konkurrenter kan gynnsamt påverka enskilda företags affärsutveckling och bidrar till deltagarnas egen kompetensutveckling.

Du som vill dra nytta av dessa möjligheter är välkommen att kontakta SEKs kansli för mer information.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-13

June 2006

ICS 11.040.10

English version

Medical electrical equipment
Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems
(IEC 60601-2-13:2003)

Appareils électromédicaux
Partie 2-13: Règles particulières de sécurité et performance essentielle pour les systèmes d'anesthésie
(CEI 60601-2-13:2003)

Medizinische elektrische Geräte
Teil 2-13: Besondere Festlegungen für die Sicherheit von Anästhesiesystemen
(IEC 60601-2-13:2003)

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 60601-2-13:2006 E

Foreword

The text of the International Standard IEC 60601-2-13:2003, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, and ISO TC 121/SC 1, Breathing attachments and anaesthetic machines, was submitted to the Unique Acceptance Procedure and was approved by CENELEC as EN 60601-2-13 on 2006-05-01.

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) 2007-05-01

- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2009-05-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 93/42/EEC. See Annex ZZ.

This European Standard partly replaces EN 740:1998, *Anaesthetic workstations and their modules - Particular requirements.*

Other European Standards relating to anaesthetic workstations and their components prepared or in preparation by CEN/TC215 which, when all published will together with EN 60601-2-13:2006 replace EN 740:1998 in total, are:

– prEN ISO/DIS 8835-2:2005, *Inhalational anaesthesia systems – Part 2: Anaesthetic breathing systems for adults*

– prEN ISO/DIS 8835-3.2:2005, *Inhalational anaesthesia systems – Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems*

– EN ISO 8835-4:2004, *Inhalational anaesthesia systems – Part 4: Anaesthetic vapour delivery devices*

– EN ISO 8835-5:2004, *Inhalational anaesthesia systems – Part 5: Anaesthetic ventilators*

Attention is also drawn to ISO/TS 18835:2004, *Inhalational anaesthesia systems — Draw-over vaporizers and associated equipment.*

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, exceptions and references: small roman type;

– *test specifications: italic type;*

– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR OF THIS PARTICULAR STANDARD: SMALL CAPITALS.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-13:2003 was approved by CENELEC as a European Standard without any modification.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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 60079-4	1975	Electrical apparatus for explosive gas atmospheres Part 4: Method of test for ignition temperature	-	-
IEC 60079-11	1999	Electrical apparatus for explosive gas atmospheres Part 11: Intrinsic safety "i"	-	-
ISO 32	1977	Gas cylinders for medical use - Marking for identification of content	-	-
ISO 407	1991	Small medical gas cylinders - Pin-index yoke-type valve connections	-	-
ISO 3746	1995	Acoustics - Determination of sound power levels of noise sources using sound pressure Survey method using an enveloping measurement surface over a reflecting plane	-	-
ISO 4135	2001	Anaesthetic and respiratory equipment - Vocabulary	-	-
ISO 5145	1990	Cylinder valve outlets for gases and gas mixtures - Selection and dimensioning	-	-
ISO 5356-1	1996	Anaesthetic and respiratory equipment - Conical connectors Part 1: Cones and sockets	-	-
ISO 5356-2	1987	Anaesthetic and respiratory equipment - Conical connectors Part 2: Screw-threaded weight-bearing connectors	-	-
ISO 5359	2000	Low-pressure hose assemblies for use with medical gas systems	-	-
ISO 5362	2000	Anaesthetic reservoir bags	-	-
ISO 7396-1	2002	Medical gas pipeline systems Part 1: Pipelines for compressed medical gases and vacuum	-	-

Publication	Year	Title	EN/HD	Year
ISO 7767[1)]	1997	Oxygen monitors for monitoring patient breathing mixtures - Safety requirements	-	-
ISO 8835-2	1999	Inhalational anaesthesia systems Part 2: Anaesthetic breathing systems for adults	-	-
ISO 8835-3	1997	Inhalational anaesthesia systems Part 3: Anaesthetic gas scavenging systems - Transfer and receiving systems	-	-
ISO 8835-4	2004	Inhalational anaesthesia systems Part 4: Anaesthetic vapour delivery devices	-	-
ISO 8835-5	2004	Inhalational anaesthesia systems Part 5: Anaesthetic ventilators	-	-
ISO 9170-1	1999	Terminal units for medical gas pipeline systems Part 1: Terminal units for use with compressed medical gases and vacuum	-	-
ISO 9703-1[2)]	1992	Anaesthesia and respiratory care alarm signals Part 1: Visual alarm signals	-	-
ISO 9703-2[2)]	1994	Anaesthesia and respiratory care alarm signals Part 2: Auditory alarm signals	-	-
ISO 9703-3[2)]	1998	Anaesthesia and respiratory care alarm signals Part 3: Guidance on application of alarms	-	-
ISO 9918[1)]	1993	Capnometers for use with humans - Requirements	-	-
ISO 10524[3)]	1995	Pressure regulators and pressure regulators with flow-metering devices for medical gas systems	-	-
ISO 11196[1)]	1995	Anaesthetic gas monitors	-	-
ISO 15223	2000	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied	-	-

[1)] ISO 7767:1997, ISO 9918:1993 and ISO 11196:1995 are superseded by ISO 21647:2004, which is harmonized as EN ISO 21647:2004, *Medical electrical equipment -- Particular requirements for the basic safety and essential performance of respiratory gas monitors.*

[2)] The ISO 9703 series is superseded by IEC 60601-1-8:2003, which is harmonized as EN 60601-1-8:2004.

[3)] ISO 10524:1995 is superseded by ISO 10524-1:2006, which is harmonized as EN ISO 10524-1:2006, *Pressure regulators for use with medical gases -- Part 1: Pressure regulators and pressure regulators with flow-metering devices.*

CONTENTS

SECTION ONE – GENERAL

1 Scope and object 7
2 Terminology and definitions 10
3 General requirements 12
4 General requirements for tests 12
6 Identification, marking and documents 12

SECTION TWO – ENVIRONMENTAL CONDITIONS

10 Environmental conditions 16

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS

SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

SECTION SIX – PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

*43 Fire prevention 18
44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection 18
49 Interruption of the POWER SUPPLY 19

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

51 Protection against hazardous output 19

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS ENVIRONMENTAL TESTS

52 Abnormal opertion and fault conditions 23

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

54 General 24
56 Components and general assembly 24
57 MAINS PARTS, components and layout 24

SECTION 101 – ADDITIONAL CLAUSES SPECIFIC TO ANAESTHETIC GAS DELIVERY SYSTEMS

101 Medical gas supply....25
102 Medical gas pipeline inlet connections....25
103 Medical gas supply pressure monitoring....26
104 Medical gas supply PRESSURE REGULATORS....26
105 Anaesthetic gas delivery system piping....26
106 Gas flow metering....27
107 Gas mixer....28
108 Oxygen flush....29
109 Fresh gas outlet....29
110 Checklist....29

Annex AA (informative) Guidance and rationale for particular clauses and subclauses in this particular standard....30
Annex BB (informative) MONITORING DEVICES, ALARM SYSTEM(S) and PROTECTION DEVICES....34
Annex CC (informative) Separate devices of an ANAESTHETIC SYSTEM....35
Annex DD (normative) Test for flammability of anaesthetic agent....37
Annex EE (informative) Clauses of this International Standard addressing the essential requirements or other provisions of EU directives....38

Bibliography....43
Index of defined terms....44

Figure 101 – Profile of oxygen flow control knob for applications other than anaesthetic vapour delivery device flow control (See 106.3)....28

Table 101 – Test conditions for expiratory volume tests....21
Table 102 – Force of axial pulls....25
Table BB.1 – Summary of the relationship of MONITORING DEVICES, ALARM SYSTEM(S) and PROTECTION DEVICES with regard to delivery devices....34
Table CC.1 – Applicable requirement clauses for separate devices of an ANAESTHETIC SYSTEM....35
Table EE.1 – Correspondence between this International Standard and EEC Directive 93/42/EEC....38

MEDICAL ELECTRICAL EQUIPMENT–

Part 2-13: Particular requirements for the safety and essential performance of anaesthetic 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 safety and essential performance requirements for an ANAESTHETIC SYSTEM (as defined in 2.101.7) as well as individual devices designed for use in an ANAESTHETIC SYSTEM.

This Particular Standard does not apply to:

– ANAESTHETIC SYSTEM(S) intended for use with flammable anaesthetic agents, as determined by Annex DD,

– portable ANAESTHETIC SYSTEM(S) for use in remote sites, open fields for rescue operations or in disaster areas,

– dental analgesia apparatus.

1.2 Object

Replacement:

The object of this Particular Standard is to specify particular safety and essential performance requirements for individual devices designed for use in an ANAESTHETIC SYSTEM as well as specific requirements for the ANAESTHETIC GAS DELIVERY SYSTEM. This standard specifies requirements and defines interfaces for:

– individual devices designed for use in an ANAESTHETIC SYSTEM(S), and

– integrated ANAESTHETIC SYSTEMS.

1.3 Particular Standards

This Particular Standard amends and supplements a set of IEC publications consisting of IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*, its amendment 1 (1991) and amendment 2 (1995), hereinafter referred to as the “General Standard”.

The General Standard takes into account IEC 60601-1-1:2000, *Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems* and IEC 60601-1-2 2001, *Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests.*

The numbering of sections, clauses and 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.

The term "this standard" covers this Particular Standard, used together with the General Standard and the Collateral Standards.

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 replacing or modifying requirements of the General Standard or a Collateral Standard take precedence over the corresponding general requirement(s).

1.3.101 Related International Standards

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60079-4:1975, *Electrical apparatus for explosive gas atmospheres – Part 4: Method of test for ignition temperature*

IEC 60079-11:1999, *Electrical apparatus for explosive gas atmospheres – Part 11: Intrinsic safety"*

ISO 32:1977, *Gas cylinders for medical use – Marking for identification of content*

ISO 407:1991, *Small medical gas cylinders – Pin-index yoke-type valve connections*

ISO 3746:1995, *Acoustics – Determination of sound power levels of noise sources using sound pressure – Survey method using an enveloping measurement surface over a reflecting plane*

ISO 4135:2001, *Anaesthetic and respiratory equipment – Vocabulary*

ISO 5145:1990, *Cylinder valve outlets for gases and gas mixtures – Selection and dimensioning*