SLOVENSKI STANDARD
SIST EN 740:2000

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Delovna mesta za anesteziranje in njihova oprema - Posebne zahteve

Anaesthetic workstations and their modules - Particular requirements

Anästhesie-Arbeitsplätze und ihre Module - Besondere Festlegungen

Systemes d'anesthésie et leurs modules - Regles particulieres

Ta slovenski standard je istoveten z: **EN 740:1998**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

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English version

Anaesthetic workstations and their modules - Particular requirements

Systèmes d'anesthésie et leurs modules - Règles particulières

Anästhesie-Arbeitsplätze und ihre Module - Besondere Festlegungen

This European Standard was approved by CEN on 2 March 1998.

CEN 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 CEN 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 CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 1999, and conflicting national standards shall be withdrawn at the latest by February 1999.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this standard.

This European Standard specifies particular requirements for anaesthetic workstations and their modules. It applies in conjunction with EN 60601-1: 1990. As stated in 1.3 of EN 60601-1 : 1990 the requirements in this European Standard take priority over those of EN 60601-1 : 1990. Clauses and subclauses additional to those in EN 60601-1 : 1990 are numbered beginning '101'. Additional annexes are lettered beginning 'AA'. Additional figures and tables are numbered beginning '101'. Additional items in lettered lists are lettered beginning 'aa)'.

Annex BB contains rationale statements for this European Standard. The clauses which have corresponding rationale statements are marked with R after their number.

Because this standard has been developed and structured in the way described in the scope, particular attention is drawn to the clarification printed in bold type in 51.101.

The following date has been fixed:

- latest date of withdrawal of a conflicting national standard (dow) 1998-06-13

Annexes AA, CC, DD, EE, FF, GG, HH, JJ, KK, LL, MM, NN, QQ, RR and TT are normative parts of this European Standard. Annexes BB, PP, SS and ZA are given for information.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Section 1: General

1 R: Scope

Clause 1 of EN 60601-1 : 1990 applies with the following amendment:

This European Standard provides particular requirements for modules which, although considered as individual devices in their own right, may be utilized, in conjunction with other relevant devices, to form an anaesthetic workstation to a given specification.

It is the intent of this European Standard that both anaesthetic workstations supplied complete and individual modules be commercially available to users to allow the configuration of an anaesthetic workstation to meet the needs of their clinical practice. To this end, this European Standard has been structured in such a way as to identify clearly particular requirements of specific modules currently available. Different configurations of anaesthetic workstations are illustrated in table 101 .

This European Standard also specifies the particular requirements for emergency anaesthetic equipment (see table 102).

For the purpose of this European Standard a module is defined as a self-contained unit of an anaesthetic workstation that performs a specific task or class of tasks in support of the major function of the anaesthetic workstation.

Such modules are e.g. anaesthetic gas delivery, anaesthetic vapour delivery, anaesthetic ventilators, anaesthetic breathing systems, anaesthetic gas scavenging systems (AGSS), specific monitoring, alarm and protection modules.

This European Standard also specifies particular requirements for the transfer and receiving system of an active AGSS intended to reduce the exposure of hospital personnel to anaesthetic gases and vapours and specifies the inlet flow conditions for which systems should be designed.

Although this European Standard does not specify the provision of patient monitors, attention is drawn to recommendations for patient monitoring during anaesthesia made by many national clinical and regulatory bodies.

Manufacturers of anaesthetic workstations are encouraged to make provision for additional monitors as well as for devices for the intravenous administration of drugs (see annex SS 'Bibliography' for appropriate equipment standards) so that the user can assimilate more easily the data output and so that the alarm function of the various monitors can be integrated.

2 Normative references

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.

Appendix L of EN 60601-1 : 1990 applies with the following additions:

EN 475	Medical devices - Electrically-generated alarm signals
EN 737-1	Medical gas pipeline systems Part 1: Terminal units for compressed medical gases and vacuum
prEN 737-3	Medical gas pipeline systems Part 3: Pipelines for compressed medical gases and vacuum
EN 737-4	Medical gas pipeline systems Part 4: Terminal units for anaesthetic gas scavenging systems
prEN 737-6	Medical gas pipeline systems Part 6: Dimensions of probes for terminal units for compressed medical gases and vacuum
EN 738 -1	Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow metering devices
EN 739 : 1998	Low pressure flexible hose assemblies for use with medical gases
EN 850	Transportable gas cylinders - Pin-index, yoke-type valve outlet connections for medical use
EN 864	Medical electrical equipment - Capnometers for use with humans - Particular requirememts
EN 980	Graphical symbols for use in the labelling of medical devices
EN 1041	Information supplied by the manufacturer with medical devices
EN 1089-3	Transportable gas cylinders - Cylinder identification - Part 3: Colour coding
EN 1280-1 : 1997	Agent specific filling systems for anaesthetic vaporizers - Part 1 : Rectangular keyed filling systems
EN 1281-1	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets

EN 1281-2	Anaesthetic and respiratory equipment - Conical connectors Part 2: Screw-threaded weight-bearing connectors (ISO 5356-2 : 1987, modified)
EN 1820	Anaesthetic reservoir bags
prEN 12342	Breathing tubes intended for use with anaesthetic apparatus and ventilators
EN ISO 4135	Anaesthesiology - Vocabulary (ISO 4135 : 1995)
prEN 12598	Oxygen monitors for patient breathing mixtures - Particular requirements
EN ISO 8185-1	Humidifiers for medical use - Part 1 : General requirements for humidification systems (ISO/DIS 8185-1 : 1997)
EN ISO 10079-1	Medical suction equipment - Electrically powered suction equipment - Safety requirements (ISO 10079-1: 1991 including Technical corrigendum 1 : 1992 and Technical Corrigendum 2 : 1993)
EN ISO 10079-2	Medical suction equipment Part 2: Manually powered suction equipment (ISO 10079-2 : 1992)
EN ISO 10079-3	Medical suction equipment Part 3: Suction equipment powered from vacuum or pressure source (ISO 10079-3 : 1992)
EN ISO 11196	Anaesthetic gas monitors (ISO 11196 : 1995 including Technical Corrigendum 1 : 1997)
EN 60601-1: 1990	Medical electrical equipment Part 1: General requirements for safety (IEC 60601-1 : 1988)
EN 60601-1-1	Medical electrical equipment Part 1: General requirements for safety 1: Collateral standard: Safety requirements for medical electrical systems (IEC 60601-1-1 : 1992)
EN 60601-1-2	Medical electrical equipment Part 1: General requirements for safety 2. Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2 : 1993)
EN 60801-2	Electromagnetic compatibility for industrial-process measurement and control equipment Part 2: Electrostatic discharge requirements (IEC 801-2 : 1991)
IEC 60079-3	Electrical apparatus for explosive gas atmospheres Part 3: Spark-test apparatus for intrinsically-safe circuits

IEC 60079-4	Electrical apparatus for explosive gas atmospheres Part 4: Method of test for ignition temperature
ISO 2878	Rubber, vulcanized - Antistatic and conductive products - Determination of electrical resistance
ISO 2882	Rubber, vulcanized - Antistatic and conductive products for hospital use - Electrical resistance limits
EN ISO 3746	Acoustics - Determination of sound power levels of noise sources using sound pressure - survey method using an enveloping measurement surface over a reflecting plane (ISO 3746 : 1995)
ISO 9360	Anaesthetic and respiratory equipment - Heat and moisture exchangers for use in humidifying respired gases in humans

3 Terminology and definitions

Clause 2 of EN 60601-1 : 1990 applies together with EN ISO 4135 and the following amendments and additions.

In 2.1.5, replace the text with the following:

2.1.5 R: applied part: The fresh gas outlet, if provided, and all other parts of the anaesthetic workstation intended to be connected with the patient or with the anaesthetic breathing system.

Add the following:

3.1 anaesthetic workstation: System for the administration of inhalation anaesthesia which includes one or more actuator modules, their particular monitoring and alarm modules and essential hazard protection modules.

3.2 R: module: Self-contained unit of an anaesthetic workstation that performs a specific task or class of tasks in support of the major function of the anaesthetic workstation.

3.3 R: actuator module: Module which performs the task of delivery of energy or substances in controlled quantities

3.4 R: monitoring module: Module which performs the task of displaying or indicating a variable to the operator.

3.5 R: alarm module: Module which performs the task of providing a visual and/or audible alarm signal(s) when an alarm condition is present.

3.6 R: protection module: Module which, without intervention of the operator, performs the task of protecting the patient against hazardous output due to incorrect delivery of energy or substances.

3.7 anaesthetic gas scavenging system; AGSS: System which is connected to the exhaust port(s) of an anaesthetic workstation or which is integrated into an anaesthetic workstation for the purpose of conveying expired and/or excess anaesthetic gases to an appropriate place of discharge.

> NOTE: Functionally, an AGSS comprises three different parts, a transfer system, a receiving system and a disposal system. These three functionally discrete parts may be either separate or sequentially combined in part or in total. In addition, one or more parts of an AGSS may be sequentially combined with a breathing system to include the transfer system or transfer and receiving system.

3.8 gas mixing system: Device or assembly which receives separate supplies of oxygen and other medical gas(es) and which delivers the mixed gases in operator-adjustable concentrations.

3.9 machine gas piping: All pipework, including unions, from unidirectional valves in the pipeline inlets and from the pressure regulator outlets to the flow meter controls and auxiliary gas outlets. It includes piping leading to and from pneumatic alarm systems, gauges and oxygen flush valves.

3.10 flow control system: Device or assembly that controls the flow of gas(es).

3.11 anaesthetic vapour delivery module; vaporizer: Device or assembly where anaesthetic agent is transformed from the liquid to the gaseous phase and is mixed in a controllable concentration with the fresh gas or breathing gas.

3.12 pressure regulator: Gas pressure reducing and controlling device designed to provide a constant delivery pressure over a range of variable inlet pressures and/or flows.

3.13 emergency anaesthetic equipment: Transportable system for the administration of inhalation anaesthesia which includes but is not limited to one or more actuator modules, their recommended particular monitoring and alarm modules and particular hazard protection modules for use e.g. in the open field for rescue operation, in disaster areas or in areas where anaesthesia is not normally administered.

3.14 medical gas supply system:

Either

a) a medical gas pipeline system comprising a central supply system, control equipment, a pipeline distribution system and terminal units at the point where non-flammable medical gases or vacuum may be required; or

b) any other installation having no permanent pipeline system but employing a medical gas supply source complete with pressure regulators.

3.15 R: flammable anaesthetic agent: Anaesthetic agent which is ignited by the test specified in annex AA of this European Standard.

3.16 R: non-flammable anaesthetic agent: Anaesthetic agent which is not ignited by the test specified in annex AA of this European Standard.

3.17 anaesthetic ventilator: Automatic actuator module which is connected to the patient's airway and is designed to augment or provide ventilation of the patient during anaesthesia.

3.18 fresh-gas outlet; common gas outlet: That port through which the dispensed mixture from the anaesthetic gas delivery module is delivered to the anaesthetic breathing system.

3.19 anaesthetic gas: Gas and/or the vapour of a volatile agent used in anaesthesia.

3.20 anaesthetic gas delivery module: Actuator module which controls the flow and composition of the fresh gas delivered during anaesthesia. It may consist of a flow control system, flow meters and/or a gas mixing system and may be combined with an anaesthetic vapour delivery module.

3.21 enabled condition: One of the conditions necessary to make an action possible.

3.22 draw-over vaporizer: Calibrated vaporizer intended to be installed in a breathing system from which the flow of a gas vapour mixture is produced by lowering the pressure at its outlet below that at its inlet by the patient's inspiratory effort or by mechanical means.