SLOVENSKI STANDARD
SIST EN 737-2:2000

01-januar-2000

Sistemi napeljav za medicinske pline - 2. del: Sistemi za odstranjevanje anestezijskih plinov in hlapov - Osnovne zahteve

Medical gas pipeline systems - Part 2: Anaesthetic gas scavenging disposal systems - Basic requirements

Rohrleitungssysteme für medizinische Gase - Teil 2: Entsorgungssysteme von Anästhesiegas-Fortleitungssystemen - Grundlegende Anforderungen

Systemes de distribution de gaz médicaux - Partie 2: Systemes finals d'évacuation des gaz d'anesthésie - Regles fondamentales

Ta slovenski standard je istoveten z: **EN 737-2:1998**

ICS:

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

SIST EN 737-2:2000 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 737-2

April 1998

ICS 11.040.10; 23.040.01

Descriptors: medical equipment, gas distribution, medical gases, gas installation, gas pipelines, junctions, disposal, safety, definitions, specifications, tests, agreements, marking, information

English version

Medical gas pipeline systems - Part 2: Anaesthetic gas scavenging disposal systems - Basic requirements

Systèmes de distribution de gaz médicaux - Partie 2: Systèmes finals d'évacuation des gaz d'anesthésie - Régles fondamentales

Rohrleitungssysteme für medizinische Gase - Teil 2: Entsorgungssysteme von Anästhesiegas-Fortleitungssystemen - Grundlelegende Anforderungen

This European Standard was approved by CEN on 3 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.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN 737-2:1998 E

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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 October 1998, and conflicting national standards shall be withdrawn at the latest by October 1998.

EN 737 consists of the following parts under the general title '*Medical gas pipeline systems*'.

Part 1: *Terminal units for compressed medical gases and vacuum*

Part 2: *Anaesthetic gas scavenging disposal systems*

Part 3: *Pipelines for compressed medical gases and vacuum*

Part 4: *Terminal units for anaesthetic gas scavenging systems*

Part 5: *Oxygen concentrators*

Part 6: *Dimensions of probes for terminal units for compressed medical gases and vacuum.*

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.

Annexes A, B, C, D, E, F, and ZA are informative.

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.

Introduction

This Part of this European Standard specifies basic requirements for anaesthetic gas scavenging (AGS) disposal systems.

This Part of this European Standard seeks to ensure the safe operation of anaesthetic gas scavenging systems (AGSS). The AGSS comprises three main parts, the transfer system, the receiving system and the disposal system. The receiving system and the transfer system are specified in prEN 740. Type-specific connections for terminal units are specified in EN 737-4. In this Part of this European Standard specifications and test procedures are given to ensure compatibility between the components of the system.

A schematic diagram of typical anaesthetic gas scavenging systems is shown in figure 1.

1 Scope

This Part of this European Standard specifies basic requirements for the installation, function, performance, documentation, testing and commissioning of anaesthetic gas scavenging (AGS) disposal systems to ensure patient and operator safety by the safe removal of excess anaesthetic gases and vapours from the clinical environment. It includes basic requirements for the power device, pipeline system, performance and for non-interchangeability between key components.

This Part of this European standard specifies:

a) the compatibility and safe performance between the disposal system and the other components of the AGSS by design, installation and commissioning;

b) the use of appropriate materials;

c) the testing of correct installation to ensure achievement of the performance intended by the manufacturer;

d) the marking of pipeline and components.

This Part of this European Standard addresses only those disposal systems which are intended to be connected via AGSS terminal units which comply with EN 737-4 to a receiving system which complies with prEN 740.

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 revision 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.

HD 384	*Electrical installations of buildings*
prEN 737-3	*Medical gas pipeline systems -* *Part 3: Pipelines for compressed medical gases and vacuum - Basic requirements*
EN 737-4	*Medical gas pipeline systems -* *Part 4: Terminal units for anaesthetic gas scavenging systems*

EN 739	*Low pressure hose assemblies for use with medical gases*
prEN 740	*Anaesthetic workstations and their modules - Particular requirements*
EN 1441	*Medical devices - Risk analysis*

3 Definitions

For the purposes of this Part of this European standard the following definitions apply:

3.1 AGSS Type 1 terminal unit: Connection point between the receiving system and disposal system at which an operator makes connections and disconnection.

3.2 AGSS Type 2 terminal unit: Connection point between the power device or the disposal hose and the remainder of the disposal system at which an operator makes connections and disconnections.

3.3 air compressor system: Source of supply with compressor(s) designed to provide air for breathing and/or air for driving surgical tools.

3.4 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 the transfer and receiving system.

3.5 commissioning: Proof of function to verify that the agreed system specification is met and is accepted by the user or the representative of the user.

3.6 design capacity: Total flow of an AGS disposal system taking into account the diversity factor, i.e. the number of terminal units which may be in use at the same time.

3.7 disposal hose: That part of an AGSS which transfers expired and/or excess gases from the power device to the probe of an AGSS Type 2 terminal unit.

3.8 disposal system: Means by which the expired and/or excess anaesthetic gases are conveyed from the receiving system to an appropriate place of discharge.

NOTE: A place of discharge may be e.g. the exterior of a building or a non-recirculating extract ventilation system.

3.9 maximum operating pressure: Maximum pressure at which a terminal unit is designed to operate.

NOTE: Operating pressure for Type 1 terminal unit is negative and for Type 2 terminal unit is positive.

3.10 maximum test pressure: Maximum pressure to which a terminal unit is designed to be subject during pipeline pressure testing.

3.11 non-return valve: Valve which permits flow in one direction only.

3.12 power device: That part of a disposal system of an AGSS which provides the gas flow for scavenging.

3.13 probe: Non-interchangeable male component designed for acceptance by, and retention in, the socket.

3.14 quick-connector: Pair of non-threaded type-specific components which can be easily and rapidly joined together by a single action of one or both hands without the use of tools.

3.15 receiving hose: That part of an AGSS which transfers expired and/or excess gases from the receiving system to the disposal system.

3.16 receiving system: That part of an AGSS which provides an interface between the transfer system and the disposal system, and may contain means of sub-atmospheric and/or positive pressure relief.

3.17 single fault condition: Condition in which a single means for protection against a safety hazard in equipment is defective or a single external abnormal condition is present.

3.18 shut-off valve; isolating valve: Manual or automatic valve which prevents flow in both directions when closed.

3.19 socket: That part of a terminal unit which is either integral or attached to the base block by a type-specific interface and which contains the type-specific connection point.

3.20 terminal unit: Outlet assembly (inlet for vacuum and AGSS) in a medical gas pipeline system at which an operator makes connections and disconnections.

3.21 terminal unit base block: That part of a terminal unit which is attached to the disposal system.

3.22 terminal unit check valve: Valve which remains closed until opened by insertion of an appropriate probe and which then permits flow in either direction.

3.23 transfer system: That part of an AGSS which may or may not incorporate tubing, which transfers expired and/or excess anaesthetic gases from the exhaust port of the anaesthetic breathing system and/or anaesthetic ventilator to the receiving system and may contain a means of pressure relief.

3.24 transfer tube: That part of an AGSS which transfers expired and/or excess gases from the anaesthetic breathing system and/or anaesthetic ventilator to the receiving system.

3.25 type-specific: Having characteristics which prevent interchangeability and thereby allow assignment to one type only.

3.26 type-specific connection point: That part of a terminal unit which is the receptor for a non-interchangeable type-specific probe and which is either integral or attached to the base block by the appropriate non-interchangeable type-specific device.

4 General requirements

4.1 Safety

AGS disposal systems shall, when installed, commissioned, operated in normal use and maintained according to the instructions of the manufacturer, cause no safety hazard which could be foreseen using risk analysis procedures in accordance with EN 1441 and which is connected with their intended application, in normal condition and in single fault condition.

4.2R Alternative construction

AGS disposal system installations and components or parts thereof, using materials or having forms of construction different from those detailed in this Part of this European standard, shall be accepted if it can be demonstrated that an equivalent degree of safety is obtained.

Such evidence shall be provided by the manufacturer.

4.3 Materials

4.3.1 The manufacturer shall disclose, upon request, evidence of the corrosion resistance and of the compatibility of the materials used for pipelines and for all components of the system with anaesthetic gases and vapours under the operating conditions specified by the manufacturer.

NOTE: Corrosion resistance includes resistance against the influence of moisture and the surrounding materials in contact with the components.

4.3.2 R If copper pipes are used, they shall comply with the requirements for copper tubing for pipelines given in prEN 737-3. Evidence shall be provided by the manufacturer.

NOTE: The requirement in **4.3.2** is intended to allow the use of the same stock of copper pipes as is used for the installation of pipeline systems for compressed medical gases and vacuum in accordance with prEN 737-3. It will be replaced by a normative reference to a European Standard currently under preparation (see WI 00133032 in annex E).

4.3.3 R All components of the system shall be supplied clean and free from oil, grease and particulate matter on the surfaces which come in contact with anaesthetic gases and vapours.

Evidence shall be provided by the manufacturer.

NOTE 1: Any method of cleaning and degreasing can be used which effectively removes all surface dirt and hydrocarbons, and which leaves no residue itself. Chemical cleaning methods normally require a subsequent washing and drying process to remove residues.

NOTE 2: Examples of cleaning procedures will be described in ISO/CD 15001 *'Compatibility of medical equipment with oxygen'* which is in preparation by ISO/TC 121/SC6.

4.3.4 R If lubricants are used, they shall be compatible with anaesthetic gases and vapours at the operating conditions.

Evidence shall be provided by the manufacturer.

4.3.5 All precautions shall be taken to maintain cleanliness during transportation, storage and installation.

5 Power device

5.1 The power device shall be used solely to power the AGS disposal system.

5.2 The power device shall be one of the following:

a) an exhaust ejector, for each Type 1 terminal unit, driven by compressed air from an air compressor system and a pipeline system complying with prEN 737-3, provided with means of adjusting the flow from the receiving system through the Type 1 terminal unit to meet the requirements specified in clause **8.1** a) (see figure 2 a));

b) an exhaust ejector for each Type 2 terminal unit, driven by compressed air from an air compressor system and a pipeline system complying with prEN 737-3, provided with means of adjusting the flow from the receiving system to meet the requirements specified in clause **8.1** a) (see figure 2 b));

c) one or more fans, blowers or dedicated vacuum pumps, provided with means of adjusting and controlling the vacuum level in the pipeline system and therefore the flow through each Type 1 terminal unit within the limits specified in clause **8.1** a), regardless of the number of terminal units in use (see figure 2 c)).

6 Indicating systems

Means shall be provided to indicate to the operator that the power device is operating.

7 Pipelines, connecting assemblies and disposable hoses

7.1 If the connecting assemblies or disposal hoses are readily accessible to the operator, the connecting assembly or the disposal hoses shall be type-specific and the dimensions of its connectors shall not comply with EN 739.

NOTE: Examples of assemblies and hoses readily accessible to the operator are those in a ceiling flexible pendant or a rigid ceiling column with access panels.

7.2 If the connecting assemblies or disposal hoses are not readily accessible to the operator without significant disassembly of fixed equipment, the connectors of the assembly need not be type-specific.

NOTE: Examples of assemblies and hoses not readily accessible to the operator are those in hinged-arm booms, tracks and pendants.

7.3 If the connecting assemblies are not normally replaced during their life, the assembly need not be type-specific.

NOTE: Examples of such assemblies are those used for isolation of vibration, building movement and relative movement of the pipelines.

7.4 Means shall be provided to prevent backflow of waste gas to Type 2 terminal units.

NOTE: This may be achieved by e.g. individual piping or non-return valves.

8 Disposal system characteristics

8.1 Characteristics: The characteristics of the AGS disposal system shall be such that:

a) the flow through each Type 1 terminal unit or, if not provided, at the interface point upstream of the power device, (see figure 1), shall not exceed 50 l/min when the resistance to flow is such as to produce a pressure drop of 1 kPa and shall not be lower than 25 l/min when the resistance to flow is such as to produce a pressure drop of 2 kPa.

NOTE: (see also prEN 740, clause **111.4.5.** in the formal vote version of 1997).

The test for compliance is given in **8.2**.

b) with a flow of 50 l/min through the socket of each Type 2 terminal unit, if provided, the pressure drop shall not exceed 7,5 kPa.

The test for compliance is given in **8.2**.

8.2 Test method for flow and pressure drop

8.2.1 General

Adjust all flow control valves (if fitted) for the purpose of controlling the flow at each terminal unit. Test each terminal unit on the system as follows:

a) with only the terminal unit under test in use;

b) for systems with more than one terminal unit, with all terminal units in use which are specified to operate at the same time.

c) Carry out tests with clean, oil-free dry air, nitrogen or carbon dioxide.

d) Before any testing is carried out, label every terminal unit in a system under test to indicate that the system is under test and is not to be used.

e) Use pressure measuring devices with a resolution not greater than 10 % of the specified values to be measured.

8.2.2 Test method for disposal systems fitted with Type 1 terminal units

8.2.2.1 Apparatus

8.2.2.1.1 Test devices 1/50, each fitted with a Type 1 probe and producing a pressure drop of 1kPa at a flow of 50 l/min.

NOTE: This device simulates the resistance to flow of a receiving system that complies with prEN 740. See figure 3 for an example.

8.2.2.1.2 Test devices 2/25, each fitted with a Type 1 probe and producing a pressure drop of 2 kPa at a flow of 25 l/min.

NOTE: See note to 8.2.2.1.1.

8.2.2.2 Procedure

8.2.2.2.1 If the test devices (**8.2.2.1**) are not pre-calibrated, check that the flow and pressure drops of each test device are in accordance with the specified values when connected to a suitable source of suction.

8.2.2.2.2 Activate the power device on the AGS disposal system to be tested.

8.2.2.2.3 Insert test device 1/50 (**8.2.2.1.1**) into each terminal unit in turn with all the other terminal units closed. Record the flow on the test device at each terminal unit.

8.2.2.2.4 Insert test device 2/25 (**8.2.2.1.2**) into each terminal unit in turn with all the other terminal units closed. Record the flow on the test device at each terminal unit.

8.2.2.2.5 Insert a test device 1/50 (**8.2.2.1.1**) into each of several terminal units up to the design capacity of the AGS disposal system with all the other terminal units closed. Record the flow on each test device at the same time.

8.2.2.2.6 Insert a test device 2/25 (**8.2.2.1.2**) into each of several terminal units up to the design capacity of the AGS disposal system with all the other terminal units closed. Record the flow on each test device at the same time.