# SLOVENSKI STANDARD
# SIST EN 737-4:2000

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**Sistemi napeljav za medicinske pline - 4. del: Končni deli sistemov za odstranjevanje anestezijskih plinov in hlapov**

Medical gas pipeline systems - Part 4: Terminal units for anaesthetic gas scavenging systems

Rohrleitungssysteme für medizinische Gase - Teil 4: Entnahmestellen für Anästhesiegas - Fortleitungssysteme



Systemes de distribution de gaz médicaux - Partie 4: Prises murales pour systemes d'évacuation des gaz d'anesthésie



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

**SIST EN 737-4:2000** **en**

# EUROPEAN STANDARD
# NORME EUROPÉENNE
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Descriptors: gas distribution, disposal, medical gases, anesthesia, junctions, walls, definitions, materials, design, tests, marking, colour codes, packing

English version

## Medical gas pipeline systems - Part 4: Terminal units for anaesthetic gas scavenging systems

Systèmes de distribution de gaz médicaux - Partie 4: Prises murales pour systèmes d'évacuation des gaz d'anesthésie

Rohrleitungssysteme für medizinische Gase - Teil 4: Entnahmestellen für Anästhesiegas-Fortleitungssysteme

This European Standard was approved by CEN on 5 July 1997.

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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**Foreword**

This European Standard has been prepared by Technical Committee CEN/TC 215 'Respiratory and anaesthetic equipment' of which the Secretariat 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 July 1998, and conflicting national standards shall be withdrawn at the latest by July 1998.

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).

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 5 - *Oxygen concentrators*

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

Annexes A and B are informative.

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

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**

Anaesthetic gas scavenging system (AGSS) terminal units are the points in an AGSS where the operator makes connections and disconnections for the disposal of medical gases and anaesthetic vapours from anaesthetic machines or other items of medical equipment, and where a wrong connection may create a hazard to the life of a patient.

It is important that terminal units and their components are designed, manufactured, installed and maintained in such a way as to meet the basic requirements specified in this Part of this European Standard.

This Part of this European Standard pays particular attention to:

- suitability of materials;
- type-specificity;
- dimensions of probes and type-specific connection points;
- cleanliness;
- testing;
- identification;
- information supplied.

In any health care facility, it is strongly recommended that terminal units of only one type are used for any particular service.

This Part of this European Standard specifies the provision of information for the installation and testing of terminal units. Testing after installation is critical to patient safety and it is essential that terminal units are not used until full testing in accordance with prEN 737-2 has been completed.



Rationales for some of the requirements of this Part of this European Standard are given in annex B. These requirements are indicated by the letter 'R' after the clause number.

## 1 Scope

This Part of this European Standard specifies requirements and dimensions for terminal units intended for use in anaesthetic gas scavenging systems specified in prEN 737-2 for the scavenging of medical gases and anaesthetic vapours.

It is intended especially to ensure the type-specific assembly of terminal units and to prevent their interchange between different services.

This Part of this European Standard also specifies requirements and dimensions for the mating counterpart (probe) of the type-specific connection point which is part of the terminal unit.

This Part of this European Standard does not specify the ranges of nominal operating pressures for terminal units (see prEN 737-2).

This Part of this European Standard specifies two types of terminal units which are non-interchangeable, for use where the power device is upstream or downstream of the terminal unit. Figure 1 shows the use of the two types of terminal units.

## 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.

| | |
|---|---|
| prEN 737-2 | *Medical gas pipeline systems - Part 2: Anaesthetic gas scavenging disposal systems* |
| prEN 1441 | *Medical devices - Risk analysis.* |
| ISO 554 | *Standard atmospheres for conditioning and/or testing - Specifications* |



## 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 disconnections.

**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 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.

**3.4 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.

**3.5 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, eg. the exterior of a building or a non - recirculating exhaust ventilation system.

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

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

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

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

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

**3.10 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.

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



**3.12 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.



**3.13 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.

**3.14 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.

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

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

**3.17 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 which can contain a means of pressure relief.

**3.18 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.

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

**3.20 type-specific connection point**: That part of a socket which is the receptor for a type-specific probe.

## 4 Terminology

A diagram of a typical terminal unit with examples of terminology is given in figure 2.

## 5 General requirements

### 5.1 Safety

Terminal units shall, when transported, stored, installed, 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 prEN 1441 and which is connected with their intended application, in normal condition and in single fault condition.

### 5.2 R Alternative construction

Terminal units and components or parts thereof, using materials or having forms of construction (except for dimensions and allocation of probes and the type-specific connection points) 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.



### 5.3 Materials

**5.3.1** The materials in contact with the gas shall be compatible with the medical gases and anaesthetic vapours in the temperature range specified in 5.3.2.

NOTE : Corrosion resistance includes resistance against moisture and surrounding materials.

**5.3.2** The materials shall permit the terminal units and their components to meet the requirements of 5.4 in the temperature range of - 20 ° C to + 60 ° C.

**5.3.3** Terminal units shall be capable, while packed for transport and storage, of being exposed to environmental conditions as stated by the manufacturer.

**5.3.4 R** Evidence of conformity with the requirements of 5.3.1, 5.3.2 and 5.3.3 shall be provided by the manufacturer.

**5.4 Design requirements**

**5.4.1** ***Incomplete assembly***

If any type-specific component is removed from the terminal unit, either the terminal unit shall be rendered inoperable or the type-specificity of the terminal unit shall be maintained.

If the terminal unit can be dismantled, the components shall not be capable of being reassembled in such a way that the fully assembled terminal unit is no longer type-specific.

**5.4.2** ***Type-specific connection point***

Each terminal unit shall include a type-specific connection point which shall accept the appropriate type-specific probe only. This connection point shall be included in a socket.

**5.4.3** ***Terminal unit check valve***

Each Type 1 terminal unit socket shall include a check valve which shall open when the probe is connected and which shall shut off automatically when the probe is disconnected.

**5.4.4** ***Connection of terminal units to the disposal system***

**5.4.4.1** The base block of the terminal unit shall be designed and manufactured for either permanent or type-specific connection to a pipeline. (see also 8.2).

**5.4.4.2** Such type-specific connections shall be incompatible with those used for compressed medical gases and vacuum pipeline systems, hose assemblies, breathing systems and other AGSS components.



**5.4.5** ***Connection of receiving or disposal hoses to hose inserts***



**5.4.5.1** Hoses shall be attached to the hose inserts of connectors by means of compression swaging, a crimped ferrule or other method which permits compliance with 5.4.5.2 and 5.4.5.3.



**5.4.5.2** It shall be impossible to remove the fitted sleeve or ferrule without it becoming unfit for reuse.

**5.4.5.3** The connection shall withstand the application of a steady axial tensile force of 600 N for 60 s.

The test is given in 6.10.

### 5.4.6 *Socket*

The arrangement for attaching a socket to its base block for a particular service shall be of a design which prevents interchangeability with the base block of any other service.

### 5.4.7 *Test methods for compliance*

Compliance with 5.4.1 to 5.4.6 (except for 5.4.5.3) shall be tested by visual inspection and functional testing where applicable.

### 5.4.8 *Pressure drop*

The pressure drop across the terminal unit and its probe shall not exceed the values given in table 1.

The test for pressure drop is given in 6.3.

**Table 1: Requirements for flow and pressure drop across terminal units with probe inserted**

| Terminal unit type | Test pressure | Test flow<br>l/min | Maximum pressure drop across a terminal unit<br>kPa |
|---|---|---|---|
| 1 | atmospheric pressure | 90 | 15 |
| 2 | atmospheric pressure | 50 | 5 |

### 5.4.9 *Connection force*

The force required to insert the probe into the terminal unit shall be an axial force not exceeding 100 N.



The test for connection force is given in 6.4.



### 5.4.10 *Disconnection force*



The force required to release the locking mechanism shall be a push or pull of not more than 110 N and not less than 20 N.

When all locking provisions have been released, according to the manufacturer's instructions, disconnection of the probe from the terminal unit shall require a force of not more than 100 N.

The test for disconnection force is given in 6.5.