BRITISH STANDARD

BS EN
737-2:1998

Incorporating
Amendment No. 1

Medical gas pipeline systems —

Part 2: Anaesthetic gas scavenging disposal systems — Basic requirements

The European Standard EN 737-2:1998, with the incorporation of amendment A1:1999, has the status of a British Standard

ICS 11.040.10

National foreword

This British Standard is the English language version of EN 737-2:1998 including amendment A1:1999. Together with BS EN 737-4:1998 and clause **111** of BS EN 740:1998, it supersedes BS 6834:1987, which was withdrawn on 15 December 1998.

The UK participation in its preparation was entrusted by Technical Committee CH/44, Anaesthetic machines, breathing attachments, medical gas pipeline systems and hose assemblies, to Subcommittee CH/44/2, Medical gas supply systems, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

Rationales for some of the requirements of this standard are given in annex F. These requirements are indicated by the letter "**R**" after the clause number.

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled "International Standards Correspondence Index", or by using the "Find" facility of the BSI Standards Electronic Catalogue.

This British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

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Summary of pages

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(includes amendment A1:1999)

Systèmes de distribution de gaz médicaux — Partie 2: Systèmes finals d'évacuation des gaz d'anesthésie — Règles fondamentales (inclut l'amendement A1:1999)

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CEN

European Committee for Standardization
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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 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.

Foreword to amendment A1

This amendment EN 737-2:1998/A1:1999 to EN 737-2:1998 has been prepared by Technical Committee CEN/TC 215, Respiratory and anaesthetic equipment, the Secretariat of which is held by BSI.

This amendment to the European Standard EN 737-2:1998 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2000, and conflicting national standards shall be withdrawn at the latest by June 2000.

This amendment to the European Standard EN 737-2:1998 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).

According to the CEN/CENELEC Internal Regulations, the national standard 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.

Contents

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 EN 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 and 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 EN 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 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.

HD 384, *Electrical installations of buildings.*

EN 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.*

EN 739, *Low-pressure hose assemblies for use with medical gases.*

EN 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 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

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, for example, 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 a Type 1 terminal unit is negative and for a 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 which 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 which 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.

4.3.2R If copper pipes are used, they shall comply with the requirements for copper tubing for pipelines given in EN 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 EN 737-3. It will be replaced by a normative reference to a European Standard currently in preparation (see prEN 13348:1998 in annex E).

4.3.3R 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 are described in prEN 13159:1997.

4.3.4R If lubricants are used, they shall be compatible with anaesthetic gases and vapours under 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 EN 737-3, provided with a means of adjusting the flow from the receiving system through the Type 1 terminal unit to meet the requirements specified in **8.1**a (see Figure 2a);

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 EN 737-3, provided with a means of adjusting the flow from the receiving system to meet the requirements specified in **8.1**b (see Figure 2b);

c) one or more fans, blowers or dedicated vacuum pumps, provided with a 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 **8.1**a, regardless of the number of terminal units in use (see Figure 2c).

6 Indicating systems

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

7 Pipelines, connecting assemblies and disposal 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, for example, 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 EN 740, **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 ambient air;

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 1 kPa at a flow of 50 l/min.

NOTE This device simulates the resistance to flow of a receiving system that complies with EN 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 a 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 a 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.

8.2.3 ***Test method for disposal systems fitted with Type 2 terminal units***

8.2.3.1 *Test devices*

8.2.3.1.1 *Test devices 50*, each fitted with a Type 2 probe and providing flows up to 50 l/min.

8.2.3.2 *Procedure*

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

8.2.3.2.2 Insert the test device (**8.2.3.1.1**) into each terminal unit in turn, with all the other terminal units closed.

Adjust the flow to (50 ± 5) l/min.

Record the pressure at the inlet to the terminal unit.

8.2.3.2.3 Insert a test device (**8.2.3.1.1**) into each of several terminal units up to the design capacity of the AGS disposal system with all the other terminal units closed. Adjust each flow to (50 ± 5) l/min. Record the pressure at the inlet to each terminal unit at the same time.

9 Terminal units

Terminal units shall comply with EN 737-4.

10 Marking

10.1 Pipelines shall be marked “AGSS” and shall have arrows denoting the direction of flow adjacent to valves, if fitted, at junctions and changes of direction, before and after walls and partitions etc., at intervals of no more than 10 m and adjacent to terminal units.

10.2 Connecting assemblies and disposal hoses shall be marked “AGSS”.

10.3 Marking shall be:

a) durable;

b) with letters not less than 6 mm high for the pipelines, and not less than 2,5 mm high for connecting assemblies and disposal hoses.

10.4 If colour coding is used, it shall be red magenta.

NOTE An example of red magenta is 3050-R40B in accordance with SS 01 91 02.

10.5 Colour coding shall be durable. The test for durability is given in **10.6**.

10.6 Test the durability of marking and colour coding as follows.

Rub markings and colour coding by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with methylated spirit, and then for 15 s with a cloth rag soaked with isopropyl alcohol.

Carry out this test at ambient temperature.

11 Pipeline installation

11.1 Pipelines and electrical services shall be either:

a) run in separate compartments; or

b) separated by more than 50 mm.

11.2 The pipelines, if metallic, shall be bonded to an earth terminal as near as possible to the point at which the pipeline enters the building. The pipelines shall not be used for earthing the electrical equipment. The relevant parts of HD 384 shall apply.

11.3 Pipelines shall be protected from physical damage.

NOTE Examples of physical damage are damage which might be sustained from the movement of portable equipment such as trolleys, stretchers and trucks in corridors and in other locations.

11.4 Unprotected pipelines shall not be installed in areas of special hazard. If installation of pipelines in such a location is unavoidable, the pipeline shall be protected by an enclosure which will prevent the escape of anaesthetic gas within the room should leaks occur in the pipeline system installed in the area.

NOTE 1 Attention is drawn to national building requirements and fire regulations.

NOTE 2 An example of a special hazard is an area where flammable materials are stored.

11.5 If pipelines are placed in the same tunnel, trench or duct with fuel pipelines, steam lines or other services, they shall be separated by more than 50 mm.

Ducts in which pipelines are installed shall be ventilated.

11.6 Pipelines shall not be installed in elevator shafts.

11.7 Damage due to contact with corrosive materials shall be minimized by the use of impermeable non-metallic materials applied to the outer surface of the pipework in the areas where the contact can occur.

11.8 Allowances shall be made for expansion and contraction of pipelines.

11.9 Appropriate drain points shall be provided to drain condensation.

11.10 Pipeline supports

11.10.1 Pipelines shall be supported at intervals to prevent sagging or distortion.

NOTE Recommended intervals for rigid metallic pipes are given in Table 1.

Table 1 — Recommended intervals between supports for rigid metallic pipes

Outside diameter mm	Maximum intervals between supports[1)] m
≤ 15	1,5
22 to 28	2,0
35 to 54	2,5
> 54	3,0

[1)] Shorter intervals may be required when using rigid non-metallic pipes.

11.10.2 The supports shall ensure that the pipeline cannot be displaced accidentally from its position.

11.10.3 The supports shall either be of corrosion-resistant material, or shall be treated to prevent corrosion. Means shall be provided to prevent electrolytic corrosion.

11.10.4 Where pipelines cross electric cables, the pipes shall be supported adjacent to the cables.

11.10.5 Pipelines shall not be used as support for, nor shall they be supported by, other pipelines or conduits.

11.11 Pipeline joints

Except for threaded or special joints used in valves, terminal units and where plastics materials are used, all pipeline joints shall be brazed or welded. The methods used for brazing or welding shall permit the joints to maintain their mechanical characteristics up to an ambient temperature of 450 °C.

11.12 The exhaust from the disposal system shall be piped to the outside or into the exhaust conduit of a non-recirculating ventilation system and shall be provided with a means to prevent the ingress of insects. It shall be in a position where risk of contamination of occupied buildings is minimized.

12 Testing, commissioning and certification

NOTE 1 The aim of testing and commissioning of AGS disposal systems is to verify that all safety aspects and performance requirements of the systems are met.

NOTE 2 An example of a procedure and test methods for testing and commissioning is given in annex B. Tests after completion of installation should be carried out by the manufacturer and witnessed by an authorized person qualified in the testing of medical gas pipeline systems, who should certify the results of the tests to the owner or client. The authorization can be given within a certified quality system complying with appropriate parts of the series EN ISO 9000 and EN 46000, or by a notified body.

NOTE 3 The results of tests showing details of the services and areas tested should be part of the permanent record of the hospital.

12.1 Leakage

12.1.1 Pipelines downstream of the power device shall be visually inspected for the integrity of all connections.

12.1.2 Pipelines between a Type 1 terminal unit and a power device shall be tested at a pressure of 70 kPa ± 10 %. The pressure drop in these sections, after a test period of 15 min, shall be less than 10 kPa with the terminal units blanked off.

12.2 Marking and support intervals of the pipeline systems

The marking of the pipeline system shall meet the requirements of clause **10**, and the support intervals shall meet the requirements of **11.10**.

12.3 Mechanical function and inspection for cleanliness of terminal units

It shall be demonstrated for each terminal unit that the appropriate probe can be inserted, captured and released.

All terminal units shall be inspected for the absence of visible particulate matter.

12.4 Cross-connection

There shall be no cross-connection to any other pipeline system.

12.5 Function of power devices

All power devices shall be tested for operation according to the manufacturer's manuals and specifications.

12.6 Flow and pressure drop

It shall be demonstrated that the flow and pressure drop at each terminal unit are in accordance with clause **8** when the AGS disposal system is operating at the design capacity.

12.7 Indicating systems

Check that the indicating system complies with clause **6**.

12.8 Disposal system exhaust

Verify that the exhaust from the disposal system complies with **11.12**.

12.9 Identification and labelling of the terminal units

On satisfactory completion of the tests and procedures described in **12.1** to **12.8**, the labels indicating that the system is under test shall be removed. At the same time, check the correct identification and labelling of each terminal unit.

12.10 Certification of the system

12.10.1 Before an AGS disposal system is used, it shall be certified in writing that all the requirements of **12.1** to **12.9** have been met.

12.10.2 The manufacturer shall certify that all drawings and manuals, as specified in clause **13**, have been supplied to the owner or client.

13 Information to be supplied by the manufacturer

13.1 Instruction manuals

The manufacturer shall provide to the owner instructions for use of the complete system.

Particular attention shall be paid to:

— the power device;

— the indicating system;

— the danger of fire or explosion due to the use of oil and grease in oxygen-enriched atmospheres.

13.2 Maintenance schedules

The manufacturer shall provide to the owner instructions for recommended maintenance tasks and their frequency, and a list of recommended spare parts.

13.3 "As installed" drawings

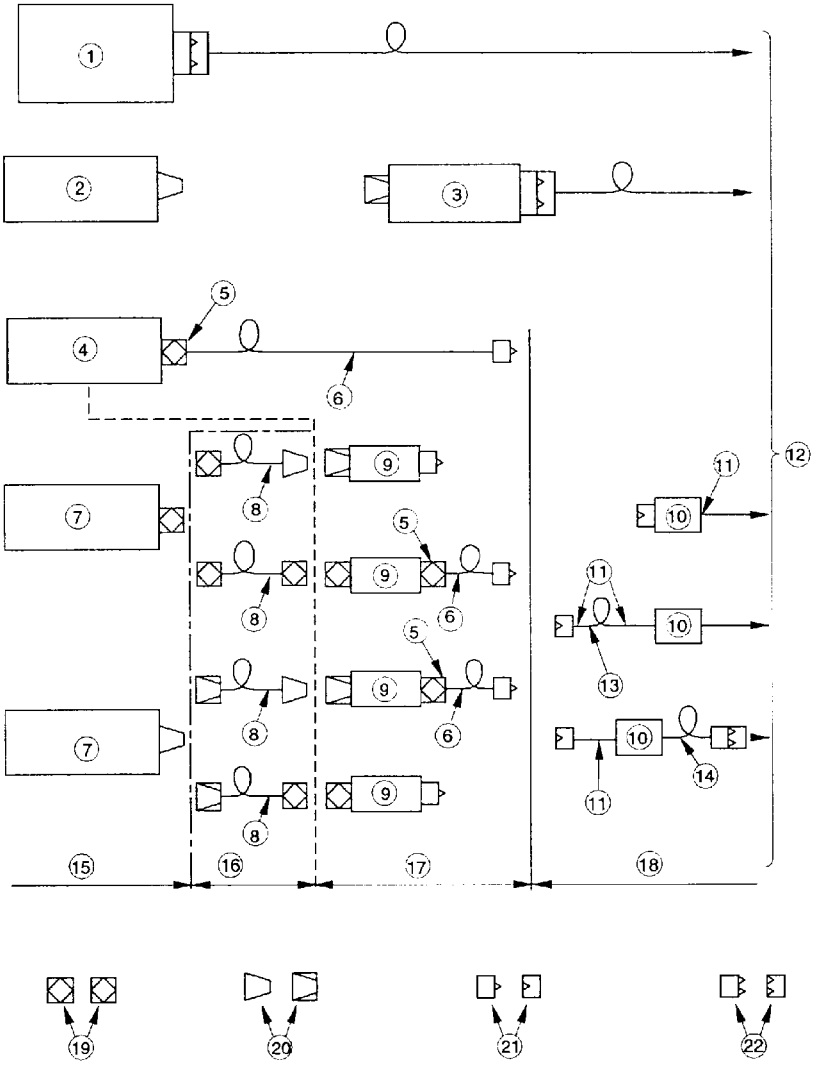
13.3.1 A set of "as installed" mechanical drawings which show the actual location and the diameters of the pipeline systems shall be maintained during construction, and shall be brought up to date as variations are made. These drawings shall include details which will enable buried or concealed pipelines to be located.

13.3.2 Complete "as installed" drawings, as specified in **13.3.1**, shall be supplied to the owner of the pipeline system as a set of drawings, marked "as installed", for inclusion as part of the permanent record of the pipeline system.

NOTE If a pipeline system is altered subsequent to the transfer of the drawings to the owner, then the "as installed" drawings specified in **13.3.2** should be brought up to date.

13.4 Electrical diagrams

Electrical diagrams for the complete installation shall be provided by the manufacturer to the owner.

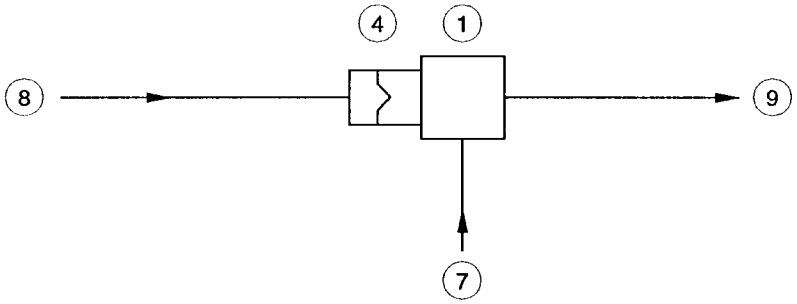


1 Apparatus including breathing system and integral transfer/receiving system and power device
2 Apparatus including breathing system
3 Transfer/receiving system and power device
4 Apparatus including breathing system and integral transfer/receiving system
5 Permanent or proprietary connector
6 Receiving hose
7 Breathing system or anaesthetic ventilator
8 Transfer tube
9 Receiving system
10 Power device
11 Permanent connection
12 Discharge
13 Flexible hose or pendant
14 Disposal hose
15 Limit of breathing system
16 Limit of transfer system
17 Limit of receiving system
18 Limit of disposal system
19 Proprietary connection (functionally specific)
20 30 mm conical connection
21 Type 1 terminal unit probe/socket
22 Type 2 terminal unit probe/socket

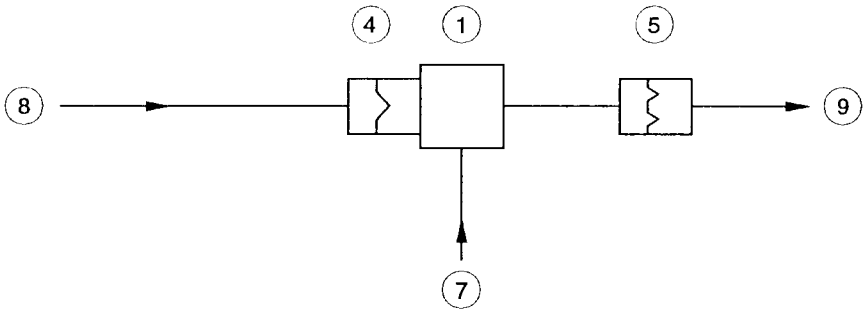
NOTE 1 Type 1 terminal unit probe/socket is for negative pressure. Type 2 terminal unit probe/socket is for positive pressure (see note 2).

NOTE 2 The limit between the receiving system and the disposal system as shown may not coincide with an actual physical limit such as a wall. In the arrangement shown a terminal unit on a wall would be located on the inlet to the power device.

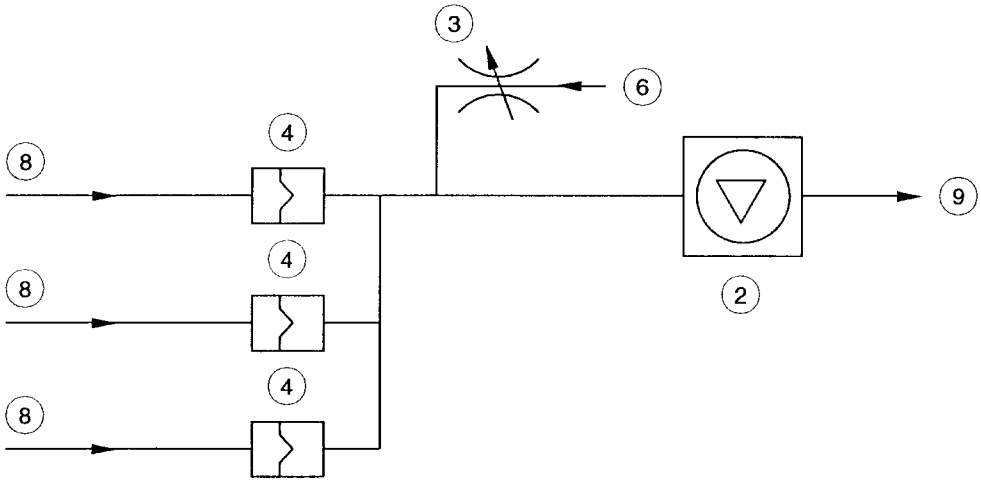
Figure 1 — Schematic diagram of typical AGSS connections



(a)



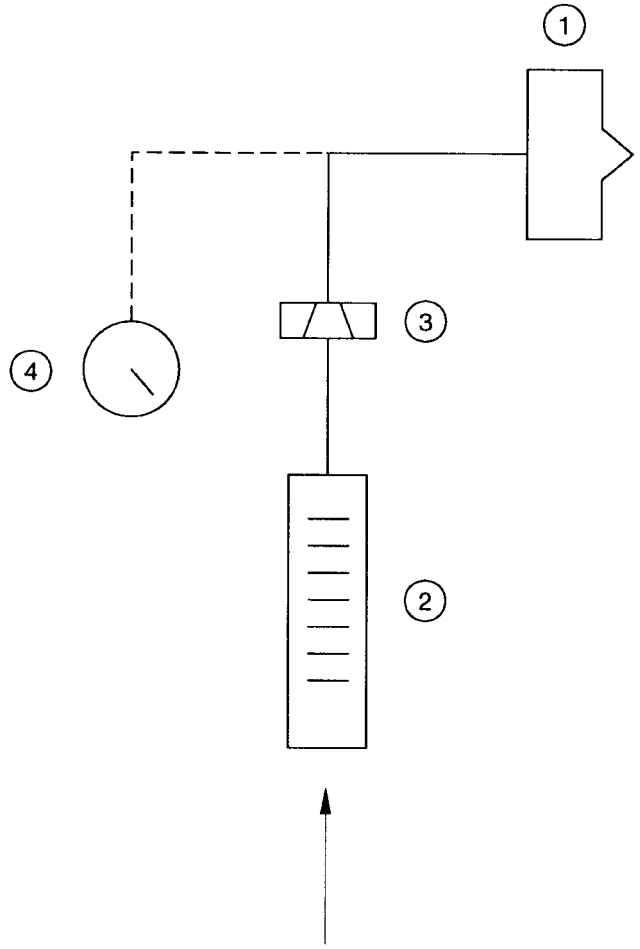
(b)



(c)

1 Compressed-air-driven power device
2 Vacuum pump/fan/blower power device
3 Flow regulating valve
4 Type 1 terminal unit
5 Type 2 terminal unit
6 Ambient air
7 Compressed air
8 Receiving system
9 Discharge

Figure 2 — Typical examples of power devices



1 Type 1 probe
2 Flowmeter
3 Fixed orifice (1 kPa at 50 l/min and 2 kPa at 25 l/min)
4 Pressure-measuring device (for calibration only)

Figure 3 — Typical test devices for AGS disposal system characteristics (with Type 1 terminal units)

Annex A (informative)
Guidelines for general requirements for power devices

A.1 Only nominated persons should be authorized to operate and attend the plant.

A.2 Services containing combustible gases or liquids should not be permitted within the power device area.

A.3 Any heating system can be used to heat the power device room, provided that no part of the heating system which is in contact with the air within the room exceeds a temperature of 225 °C.

A.4 All electrical fittings in power device rooms should be located in fixed positions to minimize the risk of physical damage.

A.5 Firefighting equipment should be provided.

A.6 The room should be well ventilated to the open air, and ducting for such ventilation should not be connected to ducting servicing any other building.

A.7 The doors or gate should be capable of being locked. An emergency exit should be provided which should be free from obstructions at all times. At any time, all doors should be capable of being opened from the inside without a key. All doors should open outwards.

A.8 Power device rooms should:

a) comply with local building codes;

b) have concrete floors;

c) have a warning notice “NO SMOKING” or similar clearly displayed on both sides of each door or gate.

A.9 The inlet of an air compressor should be located in a position where there is minimal contamination from internal combustion engine exhaust, vacuum systems, anaesthetic gas scavenging systems, ventilation system discharge and other contaminants. The air intake should be provided with a means to prevent the ingress of insects.

A.10 The exhaust from fans, blowers or vacuum pumps should be piped to the outside and should be provided with a means to prevent the ingress of insects. It should be in a position where risk of contamination of occupied buildings is minimized.

A.11 Subclauses **A.1** to **A.10** apply to power devices which are centrally located. Power devices that are not centrally located and may or may not be connected to a pipeline system should be installed and serviced in accordance with the instructions supplied by the manufacturer.

Annex B (informative)
Procedure for testing and commissioning

B.1 General

This testing procedure is given as an example of how the requirements of clause **12** can be verified so that the system can be commissioned and certified. Other procedures can be devised. In this procedure, the given sequence of tests is important and should be followed. Typical forms for certification of the system are given in annex C. A summary of the tests, which lists the specification, procedure and report form for each test, is given in Table B.1.

B.2 General requirements for tests

B.2.1 Carry out tests with ambient air.

B.2.2 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.

B.2.3 Use pressure-measuring devices with a resolution not greater than 10 % of the specified values to be measured.

B.3 Test methods for leakage

B.3.1 *Inspection*

Visually inspect the exhaust pipeline system for the integrity of all connections.

B.3.2 *Test for leakage*

B.3.2.1 *General conditions*

Fit all terminal units and valves. Isolate the power device from the pipeline. Open the valves and blank off the Type 1 terminal units.

B.3.2.2 *Procedure*

Connect a suitable pressure-measuring device to the system under test. Fill the system with test gas at a pressure of 70 kPa $\pm$ 10 %. Record the pressure and, after a period of 15 min, record the pressure again.

NOTE There is no allowance for temperature variation in this test.

B.3.2.3 *Results*

Record the results on form C.1.

B.4 Test method for checking marking and support intervals of the pipeline system

B.4.1 *Procedure*

Visually inspect that marking has been correctly placed on the pipeline system, especially adjacent to T-connectors and where the pipeline system passes through walls or partitions. Check that the marking complies with clause **10** and that the support intervals comply with **11.10**.

B.4.2 *Results*

Record the results on form C.2.

B.5 Test methods for mechanical function and cleanliness of terminal units

B.5.1 *Procedure*

B.5.1.1 Inspect the test probes to ensure that they conform to EN 737-4.

B.5.1.2 Insert a test probe into each terminal unit in turn. Check that the probe can be inserted, captured and released.

B.5.1.3 Check each terminal unit for the absence of visible particulate matter.

B.5.2 *Results*

Record the results on form C.3.

B.6 Test method for checking for cross-connection

B.6.1 *Procedure*

Visually inspect the pipeline system of the AGS disposal system for cross-connection to any other pipeline system.

B.6.2 *Results*

Record the results on form C.4.

B.7 Test method for function of power devices

B.7.1 *Procedure*

Test all power devices for operation according to the manufacturer's manuals and specifications.

B.7.2 *Results*

Record the results on form C.5.

B.8 Test methods for flow and pressure drop

B.8.1 *Procedure*

The test methods given in **8.2** can be used.

B.8.2 *Results*

Record the results on form C.6/1 for Type 1 terminal units and on form C.6/2 for Type 2 terminal units.

B.9 Test method for indicating systems

B.9.1 *Procedure*

Check that the means provided to indicate to the operator that the power device is operating is functioning.

B.9.2 *Results*

Record the results on form C.7.

B.10 Test method for the AGS disposal system exhaust

B.10.1 *Procedure*

Verify that the exhaust from the AGS disposal system is piped either to the outside or into the exhaust conduit of a non-recirculating ventilation system, that it is provided with a means to prevent the ingress of insects and that the exhaust is in a position where the risk of contamination of occupied buildings is minimized.

B.10.2 *Results*

Record the results on form C.8.

B.11 Test method for identification and labelling of the terminal units

B.11.1 *Procedure*

Check that the tests in **B.1** to **B.10** have been completed satisfactorily.

Remove the label on each terminal unit which indicates that the system is not to be used. Do not remove these labels unless all preceding tests have been completed satisfactorily. At the same time, check the correct identification and labelling of each terminal unit.

B.11.2 *Results*

Record the results on form C.9.

Annex C (informative)

Typical forms for use in testing and commissioning of AGS disposal systems in accordance with annex B

C.1 General

Annex C (on the following pages) gives examples of forms for use in testing and commissioning AGS disposal systems.

Table B.1 — Summary of tests

Test number	Description	Specification clause	Procedure clause	Form
—	Summary of tests done	—	—	C.0
1	Leakage	**12.1**	**B.3**	C.1
2	Marking and support intervals	**12.2**	**B.4**	C.2
3	Mechanical function and cleanliness	**12.3**	**B.5**	C.3
4	Cross-connection	**12.4**	**B.6**	C.4
5	Power devices	**12.5**	**B.7**	C.5
6	Flow and pressure drop:			
	— for Type 1 terminal units	**12.6**	**B.8**	C.6/1
	— for Type 2 terminal units	**12.6**	**B.8**	C.6/2
7	Indicating system	**12.7**	**B.9**	C.7
8	Disposal system exhaust	**12.8**	**B.10**	C.8
9	Identification of terminal units	**12.9**	**B.11**	C.9

Form C.0 (sheet of)

Summary of tests

This is to certify that the following tests and procedures have been carried out satisfactorily on the anaesthetic gas scavenging disposal system at ..... hospital.

Test number	Description	Form	Test completed on (date)
1	Leakage	C.1	
2	Marking and support intervals	C.2	
3	Mechanical function and cleanliness	C.3	
4	Cross-connection	C.4	
5	Power devices	C.5	
6	Flow and pressure drop		
	— for Type 1 terminal units	C.6/1	
	— for Type 2 terminal units	C.6/2	
7	Indicating system	C.7	
8	Disposal system exhaust	C.8	
9	Identification of terminal units	C.9	
Construction labels removed			

Contractor's representative

Status _____ Signed _____

Date _____ Name _____

Hospital representative

Status _____ Signed _____

Date _____ Name _____

Authorized person

Status _____ Signed _____

Date _____ Name _____

Anaesthetic gas scavenging disposal system

Form C.1 (sheet of)

Hospital _____ Scheme _____

Inspection and tests for leakage

This is to certify that the pipeline system was inspected and tested for leakage, and meets the requirements of **12.1**. At a test pressure of 70 kPa, the pressure drop after 15 min was ..... kPa (maximum permitted: 10 kPa).

Contractor's representative

Status _____ Signed _____

Date _____ Name _____

Hospital representative

Status _____ Signed _____

Date _____ Name _____

Authorized person

Status _____ Signed _____

Date _____ Name _____

Anaesthetic gas scavenging disposal system

Form C.2 (sheet of)

Hospital _____ Scheme _____

Inspection for marking and support intervals of the pipeline system

This is to certify that the pipeline system was inspected for marking and support intervals, and meets the requirements of clause **10** and **11.10** respectively.

Contractor's representative

Status _____ Signed _____

Date _____ Name _____

Hospital representative

Status _____ Signed _____

Date _____ Name _____

Authorized person

Status _____ Signed _____

Date _____ Name _____

Anaesthetic gas scavenging disposal system

Form C.3 (sheet of)

Hospital _____ Scheme _____

Check of mechanical function and inspection for cleanliness of terminal units

This is certify that all terminal units were checked for mechanical function and inspected for cleanliness, and meet the requirements of **12.3**.

Contractor's representative

Status _____ Signed _____

Date _____ Name _____

Hospital representative

Status _____ Signed _____

Date _____ Name _____

Authorized person

Status _____ Signed _____

Date _____ Name _____

Anaesthetic gas scavenging disposal system

Form C.4 (sheet of)

Hospital _____ Scheme _____

Inspection for cross-connection

This is to certify that the pipeline system was inspected for cross-connection to any other pipeline system, and meets the requirements of **12.4**.

Contractor's representative

Status _____ Signed _____

Date _____ Name _____

Hospital representative

Status _____ Signed _____

Date _____ Name _____

Authorized person

Status _____ Signed _____

Date _____ Name _____

Anaesthetic gas scavenging disposal system

Form C.5 (sheet of)

Hospital _____ Scheme _____

Functional tests of power devices

This is to certify that all power devices have been tested in accordance with the manufacturer's manuals and specifications, and meet the requirements of **12.5**.

Contractor's representative

Status _____ Signed _____

Date _____ Name _____

Hospital representative

Status _____ Signed _____

Date _____ Name _____

Authorized person

Status _____ Signed _____

Date _____ Name _____

Anaesthetic gas scavenging disposal system

Form C.6/1 (sheet of)

Hospital _____ Scheme _____

Tests of flow and pressure drop for Type 1 terminal units

This is to certify that the Type 1 terminal units were tested in accordance with **B.8.1** (with test device 1/50, maximum flow: 50 l/min; with test device 2/25, minimum flow: 25 l/min), and meet the requirements of **8.1**a.

One terminal unit in use				All terminal units in use			
Terminal unit number	Room number	Flow measured		Terminal unit number	Room number	Flow measured	
		Test device 1/50	Test device 2/25			Test device 1/50	Test device 2/25

Contractor's representative

Status _____ Signed _____

Date _____ Name _____

Hospital representative

Status _____ Signed _____

Date _____ Name _____

Authorized person

Status _____ Signed _____

Date _____ Name _____

Anaesthetic gas scavenging disposal system

Form C.6/2 (sheet of)

Hospital _____ Scheme _____

Tests of flow and pressure drop for Type 2 terminal units

This is to certify that the Type 2 terminal units were tested in accordance with **B.8.1** (test flow: 50 l/min; maximum pressure drop: 7,5 kPa), and meet the requirements of **8.1**b.

One terminal unit in use			All terminal units in use		
Terminal unit number	**Room number**	**Pressure drop**	**Terminal unit number**	**Room number**	**Pressure drop**

Contractor's representative

Status _____ Signed _____

Date _____ Name _____

Hospital representative

Status _____ Signed _____

Date _____ Name _____

Authorized person

Status _____ Signed _____

Date _____ Name _____

Anaesthetic gas scavenging disposal system

Form C.7 (sheet of)

Hospital _____ Scheme _____

Check of indicating systems

This is to certify that the indicating system has been tested for operation and meets the requirements of **12.7**.

Contractor's representative

Status _____ Signed _____

Date _____ Name _____

Hospital representative

Status _____ Signed _____

Date _____ Name _____

Authorized person

Status _____ Signed _____

Date _____ Name _____

Anaesthetic gas scavenging disposal system

Form C.8 (sheet of)

Hospital _____ Scheme _____

Verification of the AGS disposal system exhaust

This is to certify that the AGS disposal system exhaust has been verified and meets the requirements of **12.8**.

Contractor's representative

Status _____ Signed _____

Date _____ Name _____

Hospital representative

Status _____ Signed _____

Date _____ Name _____

Authorized person

Status _____ Signed _____

Date _____ Name _____

Anaesthetic gas scavenging disposal system

Form C.9 (sheet of)

Hospital _____ Scheme _____

Check of identification and labelling of the terminal units

This is to certify that all terminal units have been checked for identification and labelling, and meet the requirements of **12.9**.

Labels indicating that the system is not to be used have been removed.

Contractor's representative

Status _____ Signed _____

Date _____ Name _____

Hospital representative

Status _____ Signed _____

Date _____ Name _____

Authorized person

Status _____ Signed _____

Date _____ Name _____

Annex D (informative)

Recommended minimum requirements for the organization of maintenance

D.1 General

A systematic approach to the maintenance of the AGS disposal system is essential. This annex provides information that should be used when setting up a maintenance programme, but does not include actual maintenance tasks or frequencies.

D.2 Organization

D.2.1 *Staff*

Only qualified staff, familiar with the functioning of the equipment and with the proper practices for installation, testing and commissioning of AGS disposal systems, should be appointed to supervise and carry out maintenance work.

D.2.2 *Maintenance programme*

A maintenance programme should be established which includes specified maintenance tasks and their frequency. This programme should include, as a minimum, the manufacturer's recommendations concerning service and maintenance instructions.

Particular attention should be paid to:

a) performance of the system and its components;

b) leakage;

c) wear and tear;

d) contamination;

e) preventive maintenance.

A procedure should be instituted for the immediate reporting of defective or suspect equipment and its prompt repair or replacement.

D.2.3 *Safe practices*

The procedure for maintenance should include proper communications and documented control of the work.

If a maintenance operation involves shutting down parts of an AGS disposal system:

a) the shut-down should be fully coordinated with the clinical staff in the area affected;

b) any valve(s) and terminal unit(s) affected should be marked to warn against their use.

If a maintenance operation involves breaking into an AGS disposal system pipeline, further action should be taken:

a) to ensure safe working conditions;

b) to reduce contamination;

c) to purge the system to clear any contamination.

D.3 Documentation

A permanent documentation system should be set up which includes the documents specified in clause **13**, and this documentation system should be brought up to date when required and be reviewed once a year.

The results of all tests and observations should be recorded in the documentation system.

D.4 Spare parts

The owner should ensure that spare parts as recommended in the list supplied by the manufacturer are readily available.

D.5 Retesting and recommissioning

Following any maintenance activity, the appropriate tests in accordance with clause **12** should be carried out.

Annex E (informative)

Bibliography

pr EN13159:1997, *Compatibility of medical equipment with oxygen.*

prEN 13348:1998, *Copper and copper alloys — Seamless, round copper tubes for medical gases.*

EN 46001, *Quality systems — Medical devices — Particular requirements for the application of EN ISO 9001.*

EN ISO 9001, *Quality systems — Model for quality assurance in design /development, production, installation and servicing.* (ISO 9001:1994)

SS 01 91 02, *Colour atlas.*

Annex F (informative)

Rationale

F.4.2 Evidence will be provided to e.g. a Notified Body during CE conformity assessment and, upon request, to the Competent Authority. Attention is drawn to EN 1441 on risk analysis and to the standards under development by ISO/TC 210 on risk evaluation and risk control.

F.4.3.2 Evidence will be provided e.g. to a Notified Body during CE conformity assessment and Competent Authority upon request.

F.4.3.3 Evidence will be provided e.g. to a Notified Body during CE conformity assessment and Competent Authority upon request.

F.4.3.4 Evidence of such compatibility will be provided e.g. to a Notified Body during CE conformity assessment and Competent Authority upon request.

Annex ZA (informative)

Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

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 93/42/EEC.

WARNING. Other requirements and other EU Directives *may* be applicable to the product(s) falling within the scope of this standard.

The clauses of this standard (see Table ZA.1) are likely to support requirements of Directive 93/42/EEC.

Compliance with these clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and EU Directives

Clause/subclause of this European Standard	Corresponding essential requirement of Directive 93/42/EEC	Comments
4.1	1	
4.2	2	
4.3	2	
4.3.1	4, 7.1, 7.3, 9.2, 9.3	
4.3.3	4, 7.1, 9.3	
4.3.4	4, 7.1, 7.3, 9.3	
4.3.5	5	
5.1	1	
5.2	12.8.1, 12.8.2	
6	2, 12.2, 12.3	
7	1	
7.4	7.2	
8.1	1, 3, 9.1, 12.8.1, 12.8.2	
8.2	1, 3, 9.1, 12.8.1, 12.8.2	
9	9.1, 12.7.4	
10	13.2	
10.6	13.2	
11	1, 3	
11.2	9.2	
11.11	7.2, 7.5	
11.12	7.2, 7.5, 7.6	
12	1, 3	
12.1	7.2, 7.5	
12.2	12.6, 13.2	
12.3	9.1, 12.7.4	
12.5	12.8.1, 12.8.2	
12.7	2, 12.2, 12.3	
12.8	7.2, 7.5, 7.6	
12.9	9.1, 12.7.4	
12.10.2	9.1, 13.1, 13.3 a), 13.3 i), 13.3 j), 13.6 a), 13.6 c), 13.6 d)	
13.1	9.1, 13.1, 13.3 a), 13.3 i), 13.3 j), 13.6 a), 13.6 c), 13.6 d)	

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