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English Version

**Pressure vessels for human occupancy (PVHO) - Multi-place
pressure chamber systems for hyperbaric therapy -
Performance, safety requirements and testing**

Chambres hyperbares à occupation humaine - Chambres
hyperbares multiplaces à usage thérapeutique -
Performances, exigences de sécurité et essais

Druckkammern für Personen - Mehrpersonen-
Druckkammersysteme für hyperbare Therapie - Leistung,
sicherheitstechnische Anforderungen und Prüfung

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Contents

| | Page |
|---|-----------|
| Foreword..... | 3 |
| Introduction | 4 |
| 1 Scope | 4 |
| 2 Normative references | 4 |
| 3 Terms and definitions | 5 |
| 4 Performance, safety requirements and testing | 6 |
| 4.1 General..... | 6 |
| 4.2 General requirements common to ante chamber and main chamber..... | 6 |
| 4.3 Main chamber requirements..... | 12 |
| 4.4 Ante chamber requirements | 14 |
| 4.5 Control console..... | 15 |
| 4.6 Compressed air supply system..... | 18 |
| 4.7 Treatment gas supply..... | 19 |
| 4.8 Communications..... | 22 |
| 4.9 Emergency power supply | 22 |
| 5 Operating instructions | 23 |
| 6 Marking | 23 |
| Annex A (normative) Adaptor set for compression chambers | 25 |
| A.1 General..... | 25 |
| A.2 Standard connections or adaptor set required for the interchangeability of compression chambers | 25 |
| A.3 Adaptor set female coupling (locking ring) | 26 |
| A.4 Adaptor set male coupling (reducing ring) | 27 |
| A.5 Basic dimensions for a treatment chamber to allow mating with a transport chamber | 28 |
| A.6 Basic dimensions for a transport chamber to allow mating with a treatment chamber | 29 |
| Annex B (informative) Recommendations for medical devices used in hyperbaric chamber systems | 30 |
| B.1 General..... | 30 |
| B.2 Pressure..... | 30 |
| B.3 Oxygen..... | 31 |
| B.4 Electricity..... | 32 |
| B.5 Typical medical equipment which may be required for critical care..... | 33 |
| Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EC | 36 |
| Bibliography..... | 39 |

Foreword

This document (prEN 14931:2006) has been prepared by Technical Committee CEN/BT/TF 127 “Hyperbaric therapy chambers”, the secretariat of which is held by DIN.

This document is currently submitted to the Formal Vote.

This document 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 document.

Introduction

Pressure chambers for therapeutic use are required for the administration of hyperbaric oxygen therapy and for the treatment of decompression illness. These chambers are made to allow the safe administration of hyperoxic gas mixtures at pressure while avoiding the risks of fire within the chamber and of uncontrolled compression or decompression. They need to allow all levels of patient care up to intensive care with all the necessary equipment and provide a safe working environment for patient carers. Standards on ergonomics for the design of pressure chambers for therapeutic use are not available. Nevertheless guidance for the application of ergonomics standards is given in the bibliography.

Chambers providing exclusively for hyperbaric oxygen therapy operate typically with a maximum operational pressure of 200 kPa (2 bar) above atmospheric pressure. Pressure chambers providing treatment for decompression illness have a maximum operating pressure of 500 kPa (5 bar) or more. Treatment times in the chamber are typically 2 h to 3 h for hyperbaric oxygen treatments while standard treatment for decompression illness may last 8,5 h or more. Atmospheric conditions within the chamber need to be comfortable and, in particular, oxygen levels require control in order to avoid hypoxia, oxygen toxicity and undue risk of fire.

1 Scope

This European Standard is applicable to the performance and safety requirements and their associated test methods for multi-place pressure chambers designed for pressures in excess of ambient atmospheric pressure and employed in medical installations for therapeutic purposes, in the following referred to as pressure chambers.

2 Normative references

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

EN 737-1:1998, *Medical gas pipeline systems — Part 1: Terminal units for compressed medical gases and vacuum*

EN 739:1998, *Low-pressure hose assemblies for use with medical gases*

EN 837-1, *Pressure gauges — Part 1: Bourdon tube pressure gauges — Dimensions, metrology, requirements and testing*

EN 1041:1998, *Information supplied by the manufacturer with medical devices*

EN 1865, *Specifications for stretchers and other patient handling equipment used in road ambulances*

EN 12021, *Respiratory protective devices — Compressed air for breathing apparatus*

EN 13348, *Copper and copper alloys — Seamless, round copper tubes for medical gases or vacuum*

EN 13445-5, *Unfired pressure vessels — Part 5: Inspection and testing*

EN ISO 6941, *Textile fabrics — Burning behaviour — Measurement of flame spread properties of vertically oriented specimens (ISO 6941:2003)*

EN ISO 14971, *Medical devices — Application of risk management to medical devices (ISO 14971:2000)*

EN ISO 15001, *Anaesthetic and respiratory equipment — Compatibility with oxygen (ISO 15001:2003)*

ISO 6309, *Fire protection — Safety signs*

ISO/IEC Guide 37, *Instructions for use of products of consumer interest*

IEC 60364-7-710, *Electrical installations of buildings — Part 7-710: Requirements for special installations or locations — Medical locations*

FMVSS 49 CFR 571 302, *Flammability of interior materials*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

hyperbaric chamber system

consists of a pressure chamber and its supporting equipment

NOTE Supporting equipment is equipment needed to operate the pressure chamber, e.g. gas supply, control panel, and safety equipment.

3.2

main chamber/main lock

part of the pressure chamber used for carrying out therapy

3.3

ante chamber/entry lock

part of the pressure chamber used for locking in and out persons and equipment

3.4

relative (gauge) pressure

pressure defined as $p - p_{amb}$, where p_{amb} is the ambient pressure. Thus the gauge pressure is positive or negative according as p is larger or smaller than p_{amb} respectively

[ISO 31-3:1992, 3-15.1]

NOTE All pressures in this European Standard are expressed as relative (gauge) pressures. The Directive defines: "Pressure means pressure relative to atmospheric pressure, i.e. gauge pressure. As a consequence, vacuum is designated by a negative value."

3.5

maximum allowable pressure/design pressure (MAP)

maximum pressure for which the equipment is designed, as specified by the manufacturer

3.6

test pressure

excess pressure to which components or one component are subjected for test purposes

NOTE Test pressure is referred as "hydrostatic test pressure" in Directive 97/23/EC.

3.7

maximum operational pressure

maximum pressure under which the equipment is used for therapeutic purposes

NOTE The operational pressure is referred as "pressure" in Directive 97/23/EC.

3.8

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

3.9

treatment gas

any medical gas or mixture of gases administered to the patient for treatment

4 Performance, safety requirements and testing

4.1 General

As medical devices, hyperbaric chamber systems shall be in accordance with the Directive 93/42/EC on medical devices. Pressurised components within such systems shall be in accordance with the Directive 97/23/EC on pressure equipment.

Hyperbaric pressure chamber 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 ISO 14971 in regard to their intended application, in normal condition and in single fault condition.

Hyperbaric chamber systems and components or parts thereof, using materials or having forms of construction different from those detailed in 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.

NOTE Evidence will be provided to e.g. a Notified Body during EC conformity assessment and on request to the competent authority. An example of risk analysis is given in the European Code of Good Practice for Hyperbaric Oxygen Therapy.

4.2 General requirements common to ante chamber and main chamber

4.2.1

Pressure chambers shall comprise at least two compartments an ante chamber and a main chamber. Each compartment including supply lock shall be designed for a test pressure according to Table 1.

Testing:

Shall be according to EN 13445-5.

4.2.2

The gas used to pressurise the chamber shall never contain more than 21 % oxygen.

4.2.3

Pressure chambers shall be designed such that an operational pressure of at least 200 kPa (2 bar) can be reached and maintained.

4.2.4

The relationship between test pressure, maximum allowable pressure/design pressure, maximum operational pressure and atmospheric pressure is specified in Table 1.

Table 1 — Relationship between test pressure, maximum allowable pressure/design pressure, maximum operational pressure and atmospheric pressure

| Pressure | Value |
|--|---------------|
| Test pressure | 1,43 MAP |
| Maximum allowable pressure/Design pressure | 1 MAP |
| Maximum operational pressure | 0,91 MAP |
| Atmospheric pressure | 0 kPa (0 bar) |

Testing:

Verification as to whether the values stipulated for the ante chamber and the main chamber are complied with.

4.2.5 Breathing units

4.2.5.1

For each person to be accommodated according to 4.3.3 and 4.4.1 a breathing unit for treatment gas shall be available independent from chamber atmosphere.

Testing:

Checking by inspection of the installation as to whether an adequate number of breathing units are provided.

4.2.5.2

The treatment gas can be delivered by a free flow system or by a demand system or by a system for the artificial ventilation of the lung. Each individual breathing unit shall be suitable for operation in a hyperbaric chamber system (for information refer to Annex B) It shall be equipped with a system able to completely discharge exhaled gas / ventilation gas out of the chamber (overboard dumping).

Testing:

Checking by inspection of the piping system as to whether it is possible for the gas to be passed out from the chamber.

4.2.5.3

If the treatment gas is supplied via a demand system then, with a chamber pressure of 150 kPa (1,5 bar) and a minimum breathing volume of 22,5 l/min (1,5 l/breath x 15 breaths/minute), measured at the pressure within the chamber, the pressure drop to open inhalation and exhalation valves shall not be higher than - 0,3 kPa (- 3 mbar) and + 0,3 kPa (+ 3 mbar), respectively. The maximum pressure in the mask shall not exceed + 0,5 kPa (+ 5 mbar) and the minimum pressure in the mask shall not be less than - 0,5 kPa (- 5 mbar).

Testing:

Checking of manufacturers' certificate as to compliance of the source for treatment gas with the requirements;

operational test of each breathing unit under pressure.

4.2.5.4

Means to regulate the flow in breathing systems other than demand valve systems shall be provided.

Testing:

Operational test of each breathing unit under pressure.

4.2.6

Pressure chambers shall be equipped with safety devices which shall not respond until the maximum operational pressure to be maintained according to 4.2.4 has been exceeded and shall close before the pressure drops below this maximum operational pressure.

The safety devices shall be mounted to the pressure chamber in such a way that they are protected from mechanical damage and accidental operation.

The opening in the pressure chamber through which the air can flow off to the safety device is to be protected such that it cannot be sealed off unintentionally.

With the maximum possible flow of air supplied as the worst single fault condition, the chamber pressure shall not exceed the maximum allowable pressure according to 4.2.4 by more than 10 %, once the safety device has responded.

Testing:

After completion of the installation, on site.

4.2.7

The main chamber and the ante chamber shall both have separate controls and pipework for compression, decompression, ventilation and treatment gas.

Testing:

Testing of the control functions of the ante chamber and of the main chamber. Interaction between main chamber and ante chamber shall not occur.

4.2.8

Seating shall be ergonomic and prevent person contact with cold, hot or sharp materials. Seating shall provide each person with a seat width of at least 0,5 m and a seat depth of at least 0,4 m. If upholstery is used it shall be compatible with hyperbaric conditions.

Testing:

Inspection of seats and upholstery, measuring of seat area.

4.2.9

Patient access through door openings shall have a minimum height of 1,55 m and a minimum width of 0,7 m and shall allow the passage of a patient lying flat on a stretcher with the dimensions according to EN 1865.

Other ante chamber or main chamber door openings shall have a minimum height of 1,1 m and a minimum width of 0,6 m, if they are rectangular, and a minimum inside diameter of 0,6 m, if they are round.

Testing:

Measuring of door openings.

4.2.10

All closures and openings (e.g. doors, locks, hatches) not intrinsically safe shall be equipped with an automatic or manual device enabling the user easily to ascertain that the opening will not present any hazard.

Furthermore, where the opening can be operated quickly, the pressure equipment shall be intrinsically safe (e.g. doors closing with the pressure and manually operated) or shall be fitted with a device to prevent it being opened whenever the pressure presents a hazard.

Testing:

Functional test.

4.2.11

If the pressure chamber is intended to be fitted with a bayonet flange connection for transport chambers, this shall be designed in accordance with Annex A.

4.2.12

There shall be at least one observation window in each compartment. The window/s shall be arranged in such a way that all seats in the chamber can be observed from the outside.

The panes shall be made of suitable material. Currently acrylic is suitable following the ASME PVHO specifications, glass is not allowed.

Testing:

Inspection of panes and checking as to whether a certificate as defined by the Pressure Equipment Directive 97/23/EC is on hand.

4.2.13

To allow visual surveillance of patients, the lighting in ante chambers and main chambers shall provide a minimum illumination of 300 lx at the seating level. Means shall be provided to bring the lighting level down to 10 lx. Means shall be provided to provide a focussed illumination of at least 500 lx.

An emergency lighting independent of mains power supply shall be available with a minimum illumination of 90 lx to proceed or end the therapy.

Testing:

By measurement (see ISO 8995 for information).

4.2.14

If remote-controlled valves are used, means shall be provided to ensure continuous operation of the pressure chamber system in a single fault condition using at least a manual backup.

NOTE Single fault condition is a loss of either mains electrical power or pneumatic power or computer control.

Testing:

Evidence shall be provided by the manufacturer.

4.2.15

In any gas or liquid filled connection to the interior of the pressure chamber a shutoff device shall be fitted to the pressure chamber such that in the event of the line bursting the pressure chamber will neither be compressed nor

decompressed. The shutoff devices shall be easily accessible. This shutoff device is not required for short metal pipework which is mechanically protected up to the first valve.

Testing:

Visual inspection and operational test.

4.2.16

If means are provided inside the chamber

— to stop an increase or decrease of pressure or

— to change from treatment gas to air,

they shall be protected against unintentional use.

The overall control of the pressure chamber system shall be at all times under the control of an external operator.

Testing:

Visual inspection and function testing.

4.2.17

Within each compartment there shall be an internal pressure measuring and indicating device. The internal pressure measuring device shall be accurate to 1 % of full scale deflection. It shall be possible to calibrate it.

Testing:

Manufacturer's proof.

4.2.18

Structural measures shall be taken to prevent the development of noise exceeding an evaluation level of 70 dB(A) inside the pressure chamber at head level of seated persons under isobaric pressure conditions with ventilation according to the maximum number of persons.

A noise level of 90 dB(A) shall not be exceeded during compression or decompression.

Testing:

Measurement under most stressful operational conditions as specified by the manufacturer.

NOTE The microphone should be arranged in the pressure chamber centre at a seated person's head level.

4.2.19

The following fire protection measures shall be taken:

- a) The use of combustible material for pressure chamber equipment should be avoided or if impossible, shall be kept to a minimum. Materials covering large areas, e.g. expanded plastic coverings and linings, shall be flame-retardant. Combustible materials shall comply with EN ISO 6941, FMVSS 49 CFR 571 302 or equivalent standards. Electrical and heating equipment shall be protected to prevent spark generation and overheating during normal operation and in case of single fault condition.

NOTE 1 Criteria for the selection of non-metallic materials are given in EN ISO 15001, NFPA 99 and NFPA 53.

- b) The pressure chamber shall be equipped with a fire-extinguishing system in all compartments.

NOTE 2 Criteria for the design and the performance of the fire-extinguishing system are given in NFPA 99 and DIN 13256-3.

NOTE 3 The fire-fighting system consists of a fire-extinguishing system, means to switch over from oxygen to air, and an alarm system activator. A separate European Standard for fire extinguishing systems in pressure chambers is in preparation.

- c) Activation shall be possible by hand inside and outside the chamber.
- d) Additionally, a fire extinguisher designed for manual use under hyperbaric conditions shall be provided in each lock.
- e) Inside the pressure chamber readily ignitable materials, combustible liquids, gases and vapours and spark-generating devices are not permitted. In the immediate vicinity of the entrance to the pressure chamber and inside the chamber a prohibition sign according to ISO 6309, No. 19 is to be posted in a prominent position.
- f) It shall be possible for the chamber operator to shift from treatment gas to air on the control panel.
- g) An alternative source of breathing air shall be available outside the chamber for use by personnel in the event that the air in the vicinity of the chamber is not breathable.

Testing:

- a) Checking of certificates in respect of fire-retardant properties according to EN ISO 6941, FMVSS 49 CFR 571 302 or equivalent testing procedures.
- b) Operational test of the fire-extinguishing appliance. In the case of sprinkler or similar systems proof of testing at maximum operational pressure is required in connection with the system as well as of an operational test on the spot with reduced extinguishing period and appropriate protective measures to prevent flooding / spraying of the pressure chamber with water.

NOTE An example of a test method is given in DIN 13256-3.

- c) Checking of whether the 1 prohibition signs according to ISO 6309 are posted such as to be in full view.
- d) Checking of whether at the entrance to the pressure chamber notices are provided indicating that pressure-sensitive, combustible or readily ignitable objects are not permitted to be introduced into the chamber.

4.2.20

It shall be possible for the pressure chamber and its equipment, including breathing units and underfloor and overceiling spaces, if any, to be easily cleaned and disinfected. The manufacturers shall provide instructions for cleaning and disinfection.

Testing:

Visual inspection.

4.2.21

Electrical installation of the pressure chamber system outside the pressure chamber shall conform to IEC 60364-7-710.

Electrical equipment and installation inside the pressure chamber, including lighting, shall conform to the application category specified by IEC 60364-7-710 for such spaces, depending on the kind of medical use and medical equipment, but at least to application category 1. The voltage of the installations in the pressure chamber can be allowed to exceed 42 V only if the installations are of a construction proven to eliminate the hazard of this higher voltage.

The interior floor shall be antistatic.

NOTE For patient connected medical electrical equipment see Annex B.

prEN 14931:2006 (E)

Testing:

Checking of whether the requirements according to IEC 60364-7-710 for spaces of the respective application category are complied with.

4.2.22

Chamber paint shall be compatible with hyperbaric conditions.

4.3 Main chamber requirements

4.3.1

The maximum compression rate shall be greater than 80 kPa/min (0,8 bar/min) and not exceed 300 kPa/min (3,0 bar/min).

Testing:

Checking as to whether the values are complied with.

4.3.2

During normal operation it shall be possible for the pressure in the main chamber to be reduced from 40 kPa (0,4 bar) to 20 kPa (0,2 bar) within 1 min ± 20 s. Slower decompression rate during operation shall be possible. The main chamber shall be provided with a separate emergency discharge valve marked accordingly and sealed and permitting the pressure in the main chamber to be reduced from 200 kPa (2 bar) to ambient pressure within a period not exceeding 2 min.

The location of the emergency discharge shall be defined using risk management procedure in accordance with EN ISO 14971 manufacturer in cooperation with the operator.

Testing:

Checking as to whether the values stipulated are complied with.

4.3.3

The number of occupants allowed in the main chamber is to be stated on a plate prominently and permanently fixed above the entrance.

Testing:

Inspection.

4.3.4

For each person to be accommodated, a seat or stretcher shall be provided and, after deduction for interior equipment, a volume within the chamber of at least 1 m³.

Testing:

Checking of number of seats by inspection; checking of space within the chamber on the basis of design documents.

4.3.5

The main chamber shall be equipped with means ensuring a ventilation to maintain the chamber atmosphere within specified limits given in Table 2. Means shall be provided so that during ventilation the pressure does not vary by more than ±5 %.

Table 2 — Values to be maintained by ventilation

| | |
|---|---|
| Oxygen | $\leq 23,5 \%$ ^a |
| Carbon dioxide | $< 0,5 \text{ kPa}$ (absolute pressure) |
| Impurities organic compounds | $< 0,5 \text{ mg/m}^3$ |
| Relative humidity | 40 % to 60 % |
| Values are given in concentration in dry gas. | |
| ^a The oxygen content in the chamber atmosphere shall at no place in the chamber exceed 23,5 %. | |

Testing:

Operational test.

4.3.6

It shall be possible to position at least one stretcher with the minimal dimensions according to EN 1865. Any patient on a stretcher should be accessible from both sides and the space shall be sufficient for resuscitation procedures.

Testing:

Inspection.

4.3.7

In any configuration the dimensions shall allow a free passageway of 0,6 m width and 1,8 m height. Regardless of the position of seats and stretchers in the main chamber there shall be space for at least one lying person.

Testing:

Measuring of width and height of the passageway.

4.3.8

The temperature inside the main chamber shall not exceed ambient $+7 \text{ }^\circ\text{C}$ except during compression phase and the first 10 min following a phase of compression from ambient pressure to 200 kPa (2 bar) with a rate of 60 kPa/min (0,6 bar/min).

The temperature inside the main chamber shall not be lower than ambient $-5 \text{ }^\circ\text{C}$ except during the decompression phase from 200 kPa to ambient pressure with a decompression rate greater than 10 kPa/min (0,1 bar/min).

The maximum transient temperature of $40 \text{ }^\circ\text{C}$ shall not be exceeded during compression. The maximum operating temperature in the chamber shall not exceed $32 \text{ }^\circ\text{C}$.

Testing:

Operational test at seat level to verify compliance of the minimum and maximum allowable temperatures.

4.3.9

The wall of the main chamber shall be fitted with at least two \geq DN 80 blind flanges for later installations.

Testing:

Inspection and measurement.

4.3.10

In the wall of the main chamber a supply lock shall be installed easily accessible for operator. The dimensions of the supply lock shall not be less than 200 mm in diameter and 300 mm in length.

Testing:

- a) Checking for compliance with the dimensions stipulated by measurement;
- b) performance of operational test by an object being passed in and out at a pressure not exceeding 150 kPa (1,5 bar).

Proof for the whole pressure range has to be provided by the manufacturer.

4.4 Ante chamber requirements

4.4.1

The ante chamber shall be suited to accommodate at least two seated persons. For each person to be accommodated a seat shall be provided and, after deduction for interior equipment, a volume within the chamber of at least 1 m³.

Testing:

Checking of number of seats by inspection; checking of space within the chamber on the basis of design documents.

4.4.2

The number of occupants allowed in the ante chamber is to be stated on a plate prominently and permanently fixed above the entrance.

Testing:

Inspection.

4.4.3

The ante chamber shall be equipped with means ensuring a ventilation to maintain the chamber atmosphere within specified limits (see Table 2). Means shall be provided so that during ventilation the pressure does not vary by more than ± 5 %

Testing:

Operational test.

4.4.4

The maximum compression rate shall be greater than 160 kPa/min (1,6 bar/min) and not exceed 300 kPa/min (3,0 bar/min).

Testing:

Checking as to whether the values are complied with.

4.4.5

During normal operation it shall be possible for the pressure in the ante chamber to be reduced from 200 kPa (2 bar) to ambient pressure within 1,5 min. Slower decompression rate during operation shall be possible.

If the ante chamber is suited to accommodate more than 4 seated persons the requirements according to 4.3.2 are applicable.

Testing:

Checking as to whether the values stipulated are complied with.

4.4.6

The wall of the ante chamber shall be fitted with at least one \geq DN 80 blind flange for later installations.

Testing:

Inspection and measurement.

4.5 Control console

4.5.1

The control console shall be located outside the chamber. There shall be an area on the panel dedicated to the control of each compartment such that the control of each compartment is functionally distinct. The instruments shall be clearly marked, arranged according to function and adequately illuminated. The control console shall be designed such that all its elements can be observed from a central observation point. The console shall have at least the following controls:

- for compression;
- for decompression;
- for ventilation;
- for delivery of each treatment gas;
- for the communication system;
- for activation of fire fighting systems.

The control console shall display at least the following:

- pressure of each compartment;
- pressure of compressed air storage;
- pressure of each treatment gas storage;

NOTE If taken from a central supply system, indication of the supply pressure will suffice.

- ventilation rate of ante chamber and main chamber;

prEN 14931:2006 (E)

- inside temperature for each compartment;
- oxygen concentration for each compartment;
- CO₂ partial pressure in the main chamber;
- supply pressure of the breathing system;
- status of the fire-extinguishing system (filling level, supply pressure) for each chamber;
- time;
- status of the electrical power supply.

Testing:

- a) Inspection of controls and indicating instruments;
- b) checking as to whether controls and instruments are clearly marked and illuminated.

4.5.2

The pressure in the ante chamber and main chamber shall be indicated by at least one analogue pressure gauge each.

Analogue pressure gauges shall have a minimum diameter of 120 mm and conform to at least precision class 0,25 (see EN 837-1).

Testing:

Manufacturers' proof.

Each main chamber shall be provided with a pressure test connection arranged such as to be easily accessible.

Testing:

Inspection.

4.5.3

Facilities shall be provided for continuously recording the pressure in each ante chamber and main chamber. The system shall indicate pressure variations of 3 kPa (0,03 bar) and time intervals of 1,0 min in a manner which enables the data to be evaluated. The pressure variations over the previous 3 h shall be visible.

Testing:

Inspection to check whether equipment is provided for recording the working pressure in the ante chamber and main chamber.

Manufacturers' proof regarding the pressure gauge of the recording instruments.

4.5.4

Continuous measurement, display and recording of the oxygen concentration in percent by volume shall be possible separately for each ante chamber and main chamber. The sampling point shall be located close to the ventilation outlet. For chambers designed to accommodate more than 12 persons a second measuring device shall be installed. This second sampling point should be located close to the point where the highest oxygen concentration is to be expected.

The readout of the oxygen analyser shall display to 0,1 % between 20 % and 30 %. The 95 % response time for oxygen analysis shall be 60 s or less.

Testing:

Inspection to check whether the instruments required for recording volumetric oxygen concentration are provided.

For checking volumetric oxygen concentration the devices are required to be checked in accordance with the operating instructions and to be calibrated as needed.

4.5.5

The control console shall be provided with an incident alarm system, as follows:

- a) When the 23 % volumetric oxygen concentration of the air inside the chamber is exceeded, a visual and audible alarm shall be tripped at the control console. The audible alarm may be capable of being suppressed. The visual alarm signal shall indicate the required interruption of oxygen supply.

Testing:

Inspection of whether the principle of measurement applied enables oxygen control, and performance of operational test with compressed air and air with increased oxygen content.

- b) For chambers with a maximum allowable pressure over 2 bar and equipped to deliver to the patient treatment gases other than pure oxygen, when the oxygen partial pressure of the treatment gas exceeds $320 \text{ kPa} \pm 10 \text{ kPa}$ ($3,2 \text{ bar} \pm 0,1 \text{ bar}$), a visual and audible alarm should be raised at the control console. The audible alarm signal should be capable of being suppressed until the next time the alarm is given.

Testing:

Operational test.

4.5.6

A time indicator backup with an independent power supply shall be mounted where it can be seen by the operator at the control console. Time indicators with a digital display as the sole indicator are not permitted.

Testing:

Inspection and checking of independent power supply and operation.

4.5.7

Chamber windows or video monitoring shall be provided ensuring continuous observation of all persons inside the main and ante chambers, without the operators losing sight of the controls and indicating instruments of the control console.

Testing:

Compliance shall be checked by visual inspection.

4.6 Compressed air supply system

4.6.1

The air supplied to the pressure chamber shall conform at least to the purity requirements specified in EN 12021.

Testing:

Checking compliance with the test protocol.

4.6.2

A compressed-air supply system comprises at least two sources of compressed air for operation and emergency supply. One of these sources shall be a compressed air container.

4.6.3

The compressed-air supply system shall be capable of providing sufficient compressed air:

- a) to increase of pressure in the main chamber once from ambient pressure to maximum operational pressure with a maximum compression rate according to 4.3.1;
- b) to increase of pressure in the ante chamber twice from ambient pressure to maximum operational pressure;
- c) to maintain 200 kPa (2 bar) in the main chamber at an air-change rate of 30 l/min per person x absolute pressure (measured decompressed) for at least 150 min for the maximum allowable number of occupants in the main chamber according to 4.3.3;
- d) in addition, for pressure chambers with a maximum operational pressure greater than 200 kPa (2 bar), to maintain the maximum operational pressure in the main chamber at an air-change rate of 30 l/min per person x absolute pressure (measured decompressed) for at least 60 min for three persons;
- e) at the end of each treatment it shall be possible to treat a patient at 200 kPa (2 bar) for 5 h at least.

Testing:

The quantity of air required for cases a) to d) is to be calculated. Subsequently it is to be checked by inspection whether the air supply system provided is capable of supplying the total quantity of air required.

A tightness test of the overall compressed-air system is to be performed at 100 % of the maximum allowable working pressure to be expected at the respective location (test medium: compressed air) and tightness is to be certified. A system is considered to be sufficiently tight if during a period of 10 min the pressure in the individual compressed-air subsystems has not dropped by more than 1 %.

4.6.4

If multiple compressors are used they shall be independent of each other.

4.6.5

At least 50 % of the total quantity of air calculated in accordance with 4.6.3 shall be available as compressed air supply in compressed air containers.

Testing:

It is to be checked whether the air supply system provided meets the requirements stipulated. To this effect the capacity of the compressed air containers provided is to be determined on the basis of the data stated on them.

4.6.6

In addition to the compressed air supply referred to in 4.6.5, during normal operation 50 % of the total quantity of the compressed air supply calculated in accordance with 4.6.3 shall be available in compressed air containers as an emergency supply and shall not be fallen short of.

Testing:

It is to be checked whether compliance with the requirement is ensured technically or by way of the operating instructions.

4.6.7

The compressed-air supply system shall be provided with an additional inlet for compressed air.

NOTE This can take the form of a connection for high-pressure cylinders with pressure-reducing valve, if required.

Testing:

Inspection.

4.7 Treatment gas supply

4.7.1

At each breathing unit in the chambers a flow of at least 75 l/min at atmospheric pressure shall be supplied. The capacity of the supply system shall be calculated using the following equation:

Supply capacity [m³/h] = (operational pressure + 1 [bar]) x breathing minute volume [l/min] x π x number of installed breathing units x K x 60 / 1 000

where K is the coefficient from Table 3.

NOTE The equation is taken from Germanischer Lloyd – Rules for Classification and Construction Part 5: Under Water Technology – Chapter 1: Diving Systems and Diving Simulators.

Table 3- Values for coefficient K

| Number of breathing units | Coefficient K ("simultaneity") |
|---------------------------|--------------------------------|
| 1 | 1 |
| 2 | 0,75 |
| 3 | 0,6 |
| 4 | 0,55 |
| 5 | 0,5 |
| 6 | 0,45 |
| 7 | 0,4 |
| 8 | 0,37 |
| >8 | 0,35 |

Testing:

Checking the flow at each breathing unit of total supply capacity on the basis of manufacturers' documentation.

4.7.2

If treatment gas is supplied by the hospital gas distribution system the required pressure, flow and storage capacity of the chamber system as well as the hospital system shall not be impaired.

4.7.3

An additional oxygen supply of $V_n = 1,5 \text{ m}^3$ per person with a minimum of 30 m^3 in any case according to 4.3.3 shall be kept available at any time.

If oxygen is supplied by an existing hospital pipeline system this additional oxygen supply is not required if 4.7.2 is fulfilled.

Testing:

Functional test.

Leak test:

A leakage test of the treatment gas supply system is to be performed at 100 % of the maximum distribution pressure of the piping system.

4.7.4 Piping systems, valves and fittings

4.7.4.1 General

The different treatment gases used in the hyperbaric system may be delivered through one single pipe and gas specific connector(s) of proprietary design. If terminal units are used for treatment gases within the chambers they shall comply with EN 737-1. If threaded connectors are used for treatment gases within the chambers they shall have NIST bodies connectors complying with EN 739. All components shall be designed such as to withstand the mechanical, chemical and thermal stresses to be expected.

Means shall be provided to avoid any backflow pollution in the hyperbaric chamber system and the piping system.

Testing:

Conformity to the requirements of 4.7.4.1 to 4.7.8.7 shall be done by manufacturers certificates or checked by inspection. Piping is to be subjected to pressure testing with the appropriate test pressure and to tightness testing at maximum allowable working pressure using an appropriate leak detection test.

4.7.4.2 Compatibility with oxygen

Components of the piping system other than pipes shall comply with EN ISO 15001 if appropriate.

4.7.4.3 Pipes

Metallic materials shall be used for treatment gas pipelines. If copper pipes are used they shall comply with EN 13348. Pipes of materials other than copper shall comply with cleanliness requirements of EN 13348

Between the high-pressure manifold and the succeeding pressure-regulating valve a bronze-sintered filter with a pore size of less than $100 \mu\text{m}$ and a shutoff valve shall be installed. Pressure regulator with safety valves shall be capable of venting unobstructed through an own line to the outside.

NOTE Requirements for manifolds and line pressure regulators are given in prEN ISO 10524-2.

4.7.5 Valves

4.7.5.1

Ball valves shall not be used as shutoff or intermediate valves for pressures exceeding 2 MPa (20 bar).

4.7.5.2

Valves used under high-pressure conditions shall have been granted type approval.

4.7.5.3

Shut-off valves shall be marked with the direction of closure.

4.7.5.4

Means shall be provided to ensure that all valves are in the intended position.

4.7.6 Pressure gauges

Pressure gauges shall conform to EN 837-1 and have a sign affixed to their scale stating "keep free of oil and grease" or be provided with a corresponding symbol.

4.7.7 Installation of piping

4.7.7.1

Dedicated piping for hyperbaric chamber system is not required to meet the requirements of EN 737-3. Evidence of protection against mechanical damage, corrosion, frost and contact with oil shall be provided by the manufacturer. The exhaust from the hyperbaric chamber shall be piped to the outside and shall be provided with means to prevent the ingress of insects, debris and water. The exhaust shall be located remote from any air intakes, doors, windows, or other openings in buildings and passage ways.

4.7.7.2

For high pressure oxygen enriched gas mixtures, the piping shall not contain sharp bends, bending radius shall be equal or greater than 5 x pipe diameter.

4.7.7.3

Piping shall be grounded. The piping themselves shall not be used for grounding other equipment.

4.7.7.4

In areas exposed to increased fire risks piping are to be protected by appropriate measures. Installation in elevator shafts is not permissible.

4.7.7.5

Piping is to be adequately fastened and marked.

4.7.7.6

Fastening devices of piping are to be made of corrosion-resistant material.

4.7.7.7

Piping shall not be used for fastening other installations.

4.8 Communications

4.8.1

A communication system with loudspeaker shall be provided between ante chamber and control console and between main chamber and control console. The communication system shall be permanently switched to "Receive" on the control console, and reversal of the direction of communication shall be possible only by self-resetting switches.

Testing:

Inspection and testing of communications at ambient pressure and 150 kPa (1,5 bar) excess pressure.

A telephone link independent of the mains supply shall be provided in addition to the communication system required in 4.8.1.

Testing:

Operational check of telephone link independent of mains supply.

4.8.2

At least one emergency signalling system each shall be installed between the ante chamber and the control console and between the main chamber and the control console. The signal buttons in the chambers shall be clearly marked and easily accessible.

Testing:

Signal button operation at ambient pressure and 150 kPa (1,5 bar) excess pressure.

4.9 Emergency power supply

4.9.1

The pressure chamber emergency lighting, the control console lighting and the other equipment required to ensure operational safety shall be supplied with electrical power by an uninterrupted power supply system (UPS). In case of mains failure, this shall take over the power supply to the other equipment and shall ensure continued operation for at least 20 min.

Testing:

Checking of UPS operating period.

4.9.2

For therapy operation at pressures exceeding 200 kPa (2 bar) the following shall be provided additionally:

- a) Connection for an emergency power supply system for pressure chamber installations operated exceptionally only in emergencies for therapy at working pressures exceeding 200 kPa (2 bar) provided this system guarantees the continuation of operation for at least 5 h.
- b) Emergency electrical power supply for continued operation for at least 5 h of pressure chambers envisaged to be regularly used for therapy at working pressures up to 500 kPa (5 bar).

Testing:

Checking of emergency power supply system.

Checking of trouble-free switching processes.

Functional testing.

5 Operating instructions

For pressure chambers conforming to the present standard manufacturers shall supply operating instructions. These shall be prepared in accordance with EN 1041 and contain at least the details required for operation on:

- checking of operating condition prior to each session (operational check);
- the respective session;
- fire protection (see 4.2.19);
- measures to restore readiness to operate;
- maintenance;
- repair;
- handling of gas bottles, cylinders and compressors;
- emergency procedures;
- the use of oxygen for medical purposes;
- cleaning and disinfection

as well as information regarding:

- initiation and physical aptitude and technical qualification of users;
- periodical exercises for troubleshooting of simulated incidents;
- an incident alarm plan;
- documentation of materials used in direct contact with patients and members of staff.

NOTE Attention is drawn to the European Code of Good Practice for Hyperbaric Oxygen Therapy.

6 Marking

The pressure chamber is to be fitted in a prominent position with a permanently legible name plate which, in addition to the information stipulated in the Pressure Equipment Directive 97/23/EC, if appropriate, contains details on:

- maximum operational pressure;
- type;

prEN 14931:2006 (E)

- maximum allowable number of occupants;
- name or trade name and address of the manufacturer;
- year of manufacturer and serial number.

Annex A

(normative)

Adaptor set for compression chambers

A.1 General

Compression chambers with entrances of various dimensions are used. To achieve the interchangeability of compression chambers a common STANAG flange was agreed. An adaptor set consists of a female coupling (locking ring) and a male coupling (reducing ring).

A.2 Standard connections or adaptor set required for the interchangeability of compression chambers

Chamber adaptor sets as described in A.3 and A.4 will be adopted for use between fixed multi-personnel compressions chambers and transportable compression chambers and be provided with a safety interlock preferably in the main chamber. These adaptor sets allow for a transportable compression chamber provided with a reducing ring as described in A.4 to be locked onto the fixed multi-place chamber, for the door of the transportable chamber to be opened, and if necessary removed, and for the patient to be transferred without loss of pressure. They should be clearly marked to indicate that they are NATO compatible adaptors, and are to be manufactured to withstand a working pressure of at least 500 kPa (5 bar, 71 psi) and a test pressure of at least 750 kPa (7,5 bar, 107 psi). The minimum dimensions required for the fixed multi-place chamber are given in A.5, and for the transportable chamber in A.6. The required free space to connect an adapter and / or a transport chamber are to be examined regarding to the respective system configuration.

A.3 Adaptor set female coupling (locking ring)

The dimensions of the standard female coupling (locking ring) are given in Figure A.1 below.

Dimensions in millimetres

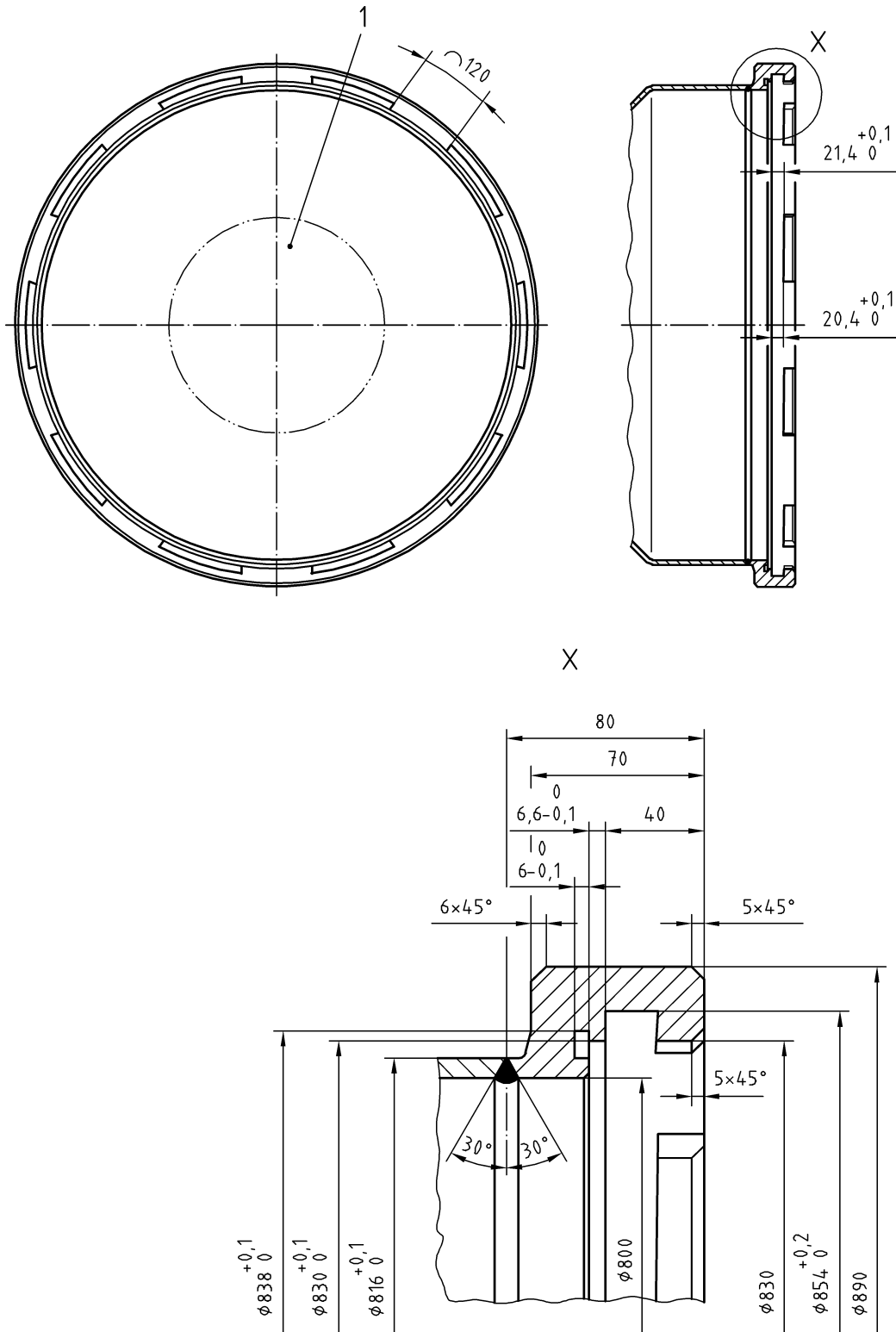


Figure A.1 — Female coupling (locking ring)

A.4 Adaptor set male coupling (reducing ring)

The dimensions of the standard male coupling (reducing ring) are given in Figure A.2 below.

Dimensions in millimetres

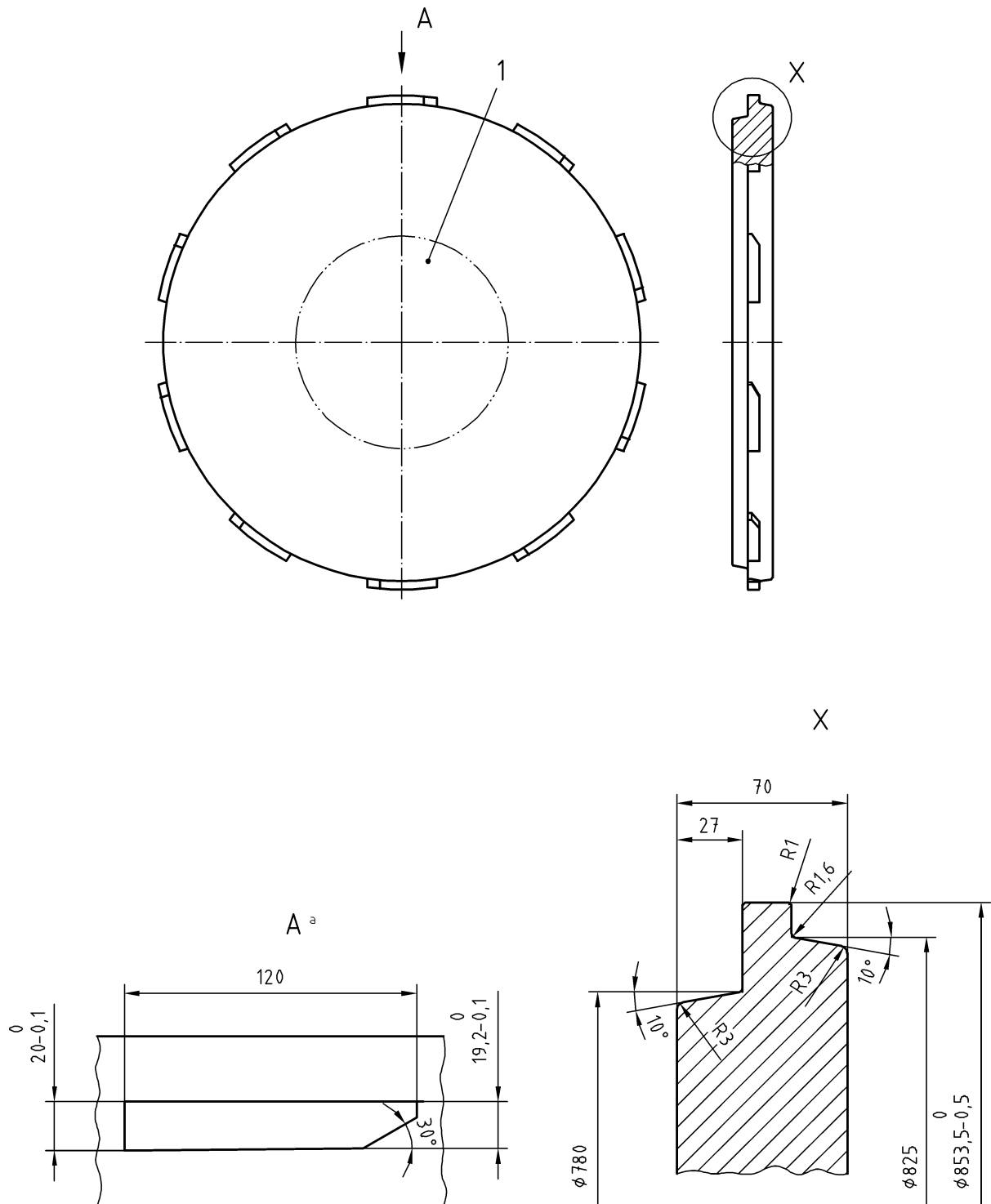
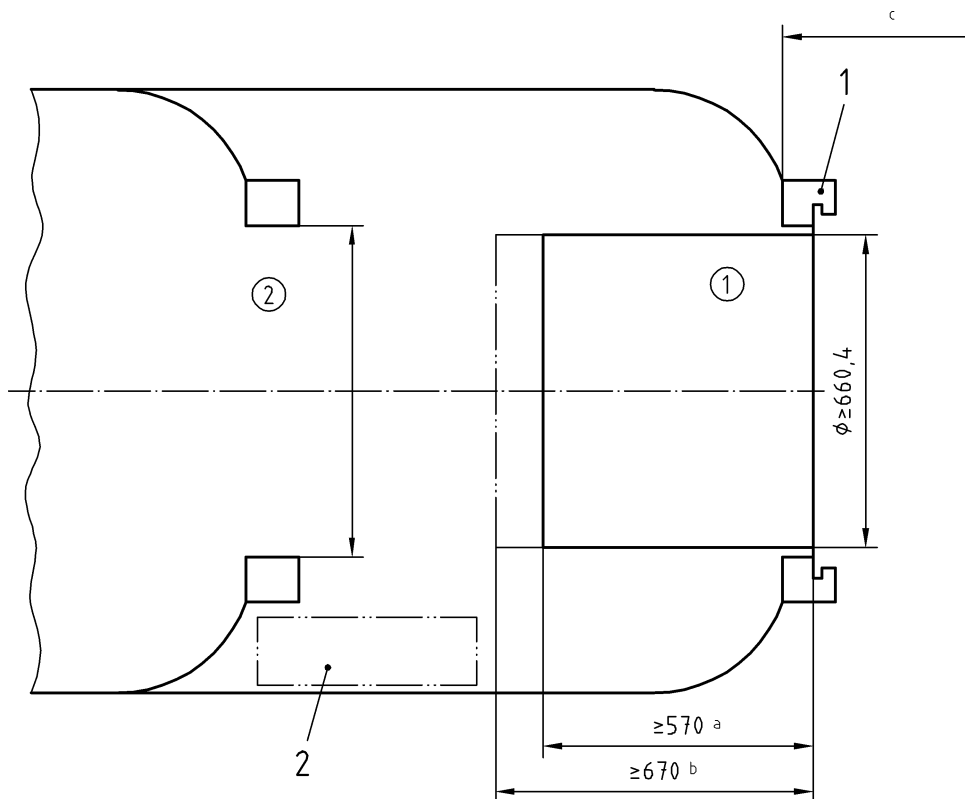


Figure A.2 — Male coupling (reducing ring)

A.5 Basic dimensions for a treatment chamber to allow mating with a transport chamber

The required dimensions for a treatment chamber to allow mating with a transport chamber are given in Figure A.3 below.



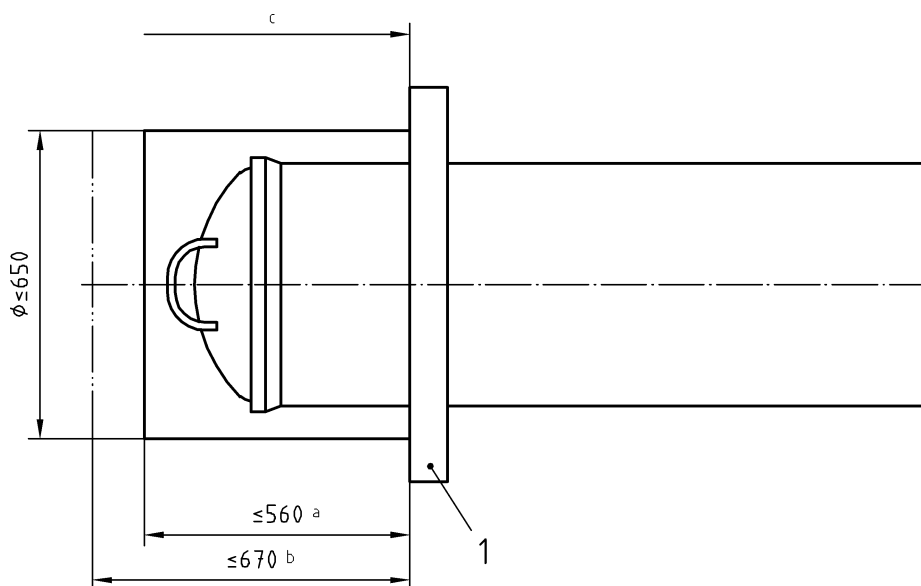
Key

- 1 flange
- 2 door volume being stored, $\varnothing = 650$ mm, H = 200 mm
- ^a minimum length for mating with door of transport chamber locked
- ^b minimum length to allow removal of transport chamber door
- ^c seal face

Figure A.3 — Dimensions for treatment chamber

A.6 Basic dimensions for a transport chamber to allow mating with a treatment chamber

The required dimensions for a transport chamber to allow mating with a treatment chamber are given in Figure A.4 below.



Key

- 1 STANAG 1079 flange
- ^a Maximum length for mating with door of transport chamber locked
- ^b Maximum length to allow removal of transport chamber door
- ^c seal face

Figure A.4 — Dimensions of transport chamber

It shall be possible to equalize the pressure and remove the door when the end of the transport chamber is placed in a cylinder of 650 mm diameter and 700 mm long.

Annex B (informative)

Recommendations for medical devices used in hyperbaric chamber systems

B.1 General

This annex refers to medical devices defined as any item of equipment required for the treatment of the patient, introduced punctually in the hyperbaric chamber and not concerned by this European Standard.

This annex describes:

- the potential hazards which certain medical devices represent;
- the risks induced by medical devices likely to be used within hyperbaric chamber systems intended for hyperbaric oxygen therapy;
- the recommendations for manufacturers of medical devices and users of hyperbaric chamber systems, in order to achieve the highest possible level of safety of the patient and the attendants.

B.2 Pressure

B.2.1 Potential hazard

A hyperbaric chamber realises an environment where the internal pressure is increased over the atmospheric pressure.

B.2.2 Risk

Certain medical devices, designed and manufactured for use at atmospheric pressure, cannot be used under hyperbaric conditions. Indeed, their introduction into a hyperbaric chamber can give rise to several types of problems:

- crushing, implosion or explosion of certain components under the effect of the variation in pressure, together with, as secondary effects, risks of failure, of short circuits, of formation of sparks, of overflowing, projection of fragments or of liquids;
- a modification of the rated performances of the device with in particular:
 - a deterioration of the measurements recorded by the probes;
 - a deterioration of the display reading which no longer corresponds to the measured values;
 - a deterioration of the flowrate, pressure and frequency with which the device dispenses the medical products to the patients;
 - a possible creation of gaseous bubbles at time of decompression within the liquids contained in, or conveyed by, the medical device.

B.2.3 Recommendations

Prior to installing a medical device in a hyperbaric chamber:

- make certain that it does not contain any closed compartments under atmospheric pressure and that the pressure in all the compartments of the device is equivalent with that of the environment or that it is pressure resistant;
- ensure by conducting hyperbaric tests that in particular:
 - the controls, e.g. the keyboard pads, do not remain blocked;
 - the performances of the device's probes are not deteriorated or can be rectified;
 - the operating of the device's built-in electronics is not deteriorated;
 - the device's display is not deteriorated;
 - the flowrates, pressures and frequencies with which the device dispenses the medical products to the patients are not deteriorated or at least are accurately evaluated;
- in case of doubt, do not install the medicinal device in hyperbaric chambers.

B.3 Oxygen

B.3.1 Potential hazard

A hyperbaric chamber is pressurised with air, namely 21 % oxygen and 79 % nitrogen. The partial pressure of oxygen within the hyperbaric chamber's atmosphere increases proportionally with the pressure level inside the chamber.

Patients treated inside the hyperbaric chamber breathe pure oxygen and/or over-oxygenated mixtures via half-masks or breathing systems. These breathing systems cannot guarantee a perfect tightness and leakages of pure oxygen and of over-oxygenated mixture occur within the chamber's atmosphere. There results a rise in the percentage of oxygen, the maximum allowable limit in the chambers being 23,5 %.

B.3.2 Risk

The high partial pressure and percentage of oxygen in the atmosphere of a hyperbaric chamber, associated:

- with a combustible product,
- with a source of ignition, e.g. sparks,

are aggravating factors of fire risk.

Furthermore, the medical devices introduced into a hyperbaric chamber can:

- be lubricated with a product that is flammable in the presence of oxygen enriched atmosphere and consequently cause a fire;
- be made of materials or convey substances which are easily combustible in an oxygen enriched atmosphere;
- be made of materials that become toxic by a chemical reaction in an oxygen enriched atmosphere.

B.3.3 Recommendations

Prior to installing a medical device in a hyperbaric chamber:

- ensure that it does not contain any lubricant that is incompatible with an oxygen enriched atmosphere. Where this is the case, remove all grease from it and lubricate it with a product compatible with pure oxygen and materials of the device;
- ensure that it is not made from an easily combustible material or that it does not convey any flammable products such as gels or alcohol;
- ensure that it does not contain a product which reacts with oxygen enriched atmosphere;
- in case of doubt, do not install the medical device in hyperbaric chambers.

B.4 Electricity

B.4.1 Potential hazard

Medical and other electrical devices are a potential source of ignition and this is more of a problem in the atmosphere of a compressed air pressure chamber where partial pressures of oxygen are raised.

B.4.2 Risk

Sources of ignition such as sparking for any reason or overheating associated:

- with the oxidizer, i.e. the oxygen, with a high partial pressure and percentage in the atmosphere of a chamber and
- with the materials present in the chamber, the latter being rendered more combustible by the presence of this oxygen,

can cause a fire.

B.4.3 Recommendations

A single fault condition should not lead to a hazard.

Electrical medical devices in a hyperbaric chamber should not cause a risk of ignition. Information regarding this area is available in NFPA 99.

The manufacturer may consider:

- using low energy (low voltage and low current) devices;
- placing the power source of the device outside the chamber;
- placing the power switches of the device outside the chamber.

In any doubt, the medical device should not be installed in a hyperbaric chamber.

Table B.1 — Possible environmental conditions within pressure chambers for therapeutic use

| Chamber type | Hyperbaric oxygen therapy only | Decompression illness | Decompression illness (advanced) |
|---------------------------------|--------------------------------|--------------------------|----------------------------------|
| Operating pressure | 0 to 200 kPa (2 bar) | 0 to 500 kPa (5 bar) | 0 to no limit |
| Oxygen (%) | 21 to 23,5 | 21 to 23,5 ¹⁾ | ≤ 23,5 ^a |
| Carbon dioxide (kPa) | 0 to 0,5 | 0 to 0,5 | 0 to 0,5 |
| Humidity (%) | | | |
| mean | 40 to 60 | 40 to 60 | 40 to 80 |
| maximum | 100 | 100 | 100 |
| Temperature (°C) | 15 to 40 | 15 to 40 | 15 to 40 |
| Pressure cycle | | | |
| Compression rate (kPa/min) | 80 to 300 | 80 to 300 | 80 to 300 |
| Decompression rate | | | |
| For equipment in medical lock | 100 kPa/min | 100 kPa/min | 100 kPa/min |
| For equipment in chamber | | | |
| From 200 kPa to 0 kPa | 100 kPa/min | 100 kPa/min | 100 kPa/min |
| From 500 kPa to 200 kPa | | 100 kPa/min | 100 kPa/min |
| Higher than 500 kPa | | | 8,5 kPa/min |
| Pressurisation period | | | |
| Non-saturation: | 2 h to 5 h | 5 h to 9 h | 5 h to 9 h |
| Saturation | | 10 days | 10 days |
| Compression media | Air | Air Helium:oxygen | Air Helium:oxygen |

^a Lower percentages of oxygen are dictated by the partial pressure of oxygen.
The oxygen content in the chamber atmosphere shall at no place in the chamber exceed 23,5 %.

B.5 Typical medical equipment which may be required for critical care

B.5.1 Airway management

Suction operating at ambient and increased pressure

Artificial ventilation of the lungs

PEEP valves and similar valves

Patient connected demand valve systems

Airway pressure measurement

Spirometry

Airway and fresh gas supply oxygen analysis

Exhaled carbon dioxide measurement

Cuffed endotracheal tubes with cuff pressure control (automatic or manual)

B.5.2 Non-invasive monitoring

Blood pressure

Pulse oximetry

Transcutaneous oxygen

Transcutaneous carbon dioxide

Temperature

Electrocardiography

Electroencephalography

B.5.3 Invasive monitoring

Central venous pressure monitoring

Arterial pressure monitoring

Pulmonary artery pressure monitoring

Intracranial pressure monitoring

Continuous arterial blood gas monitoring

B.5.4 Intravenous access

Syringe pumps

Infusion controllers – electric

Infusion controllers – manual

Patient controlled analgesia devices

Insulin infusion pumps

B.5.5 Cardiac support

Defibrillation

External pacing (transthoracic)

Implanted pacemakers

Wire/catheter based pacing

External pacemakers

B.5.6 Others

Drainage systems

Epidural and cerebrospinal infusion controllers

Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EC

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EC

| Clause(s)/subclause(s) of this EN | Essential requirements (ERs) of Directive 93/42/EEC | Qualifying remarks/Notes |
|--------------------------------------|--|-----------------------------|
| 4 | 1, 2, 3, 4 | |
| 4.1 | 2 | |
| 4.2.1 | 3 | |
| 4.2.2 | 3, 7.1, 9.3 | |
| 4.2.3 | 3 | |
| 4.2.4 | 3, 9.2, 12.7.1 | |
| 4.2.5 | 3, 7.2 12.8.1 | |
| 4.2.6 | 3, 4, 9.2, 12.7.1, 12.8.1 | |
| 4.2.7 | 3, 4, 9.2 | |
| 4.2.8 | 9.2 | |
| 4.2.9 | 3 | |
| 4.2.10 | 2, 4 | |
| 4.2.11 | 9.1 | |
| 4.2.12 | 2 | |
| 4.2.13 | 2 | |
| 4.2.14 to 4.2.16 | 2, 4, 12.8.1 | |
| 4.2.17 | 3, 9.2, 10.1, 12.2 | |

Table ZA.1 (concluded)

| | | |
|-----------------|---|--|
| 4.2.18 | 12.7.3 | |
| 4.2.19 | 7.1, 9.3 | |
| 4.2.20 | 8.1 | |
| 4.2.21 | 9.2, 9.3, 12.6 | |
| 4.2.22 | 7.1 | |
| 4.3.1 | 3 | |
| 4.3.2 | 2, 3 | |
| 4.3.3 | 2 | |
| 4.3.4 to 4.3.7 | 3 | |
| 4.3.8 | 12.7.5 | |
| 4.3.9 to 4.3.10 | 3 | |
| 4.4.1 to 4.4.6 | 3 | |
| 4.5.1 to 4.5.3 | 12.8, 12.9 | |
| 4.5.4 | 10, 12.8 | |
| 4.5.5 | 2, 12.3, 12.8 | |
| 4.5.6 to 4.5.7 | 2, 4 | |
| 4.6.1 | 7.3 | |
| 4.6.2 | 12.8.1 | |
| 4.6.3 to 4.6.7 | 3, 12.8.1 | |
| 4.7.1 to 4.7.3 | 3, 12.8.1 | |
| 4.7.4 to 4.7.5 | 2, 3, 7.1, 9.3 | |
| 4.7.6 | 2, 9.3 | |
| 4.7.7 | 2 | |
| 4.8 | 2 | |
| 4.9 | 4, 12.2, 12.3 | |
| 5 | 13.1, 13.3.i, 13.3.j, 13.3.k, 13.6.d, 13.6.h | |
| 6 | 13.3.a, 13.3.b, 13.3.j, 13.3.k, 13.3.l | |
| Annex A | 9.1 | |

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

Bibliography

- [1] EN 737-3:1998, *Medical gas pipeline systems — Part 3: Pipelines for compressed medical gases and vacuum*
- [2] EN 13445-1, *Unfired pressure vessels — Part 1: General*
- [3] EN 13445-2, *Unfired pressure vessels — Part 2: Materials*
- [4] EN 13445-4, *Unfired pressure vessels — Part 4: Fabrication*
- [5] EN 13445-6, *Unfired pressure vessels — Part 6: Requirements for the design and fabrication of pressure vessels and pressure parts constructed from spheroidal graphite cast iron*
- [6] EN 13861, *Safety of machinery — Guidance for the application of ergonomics standards in the design of machinery*
- [7] prEN ISO 10524-2, *Pressure regulators for use with medical gases — Part 2: Manifold and line pressure regulators*
- [8] ISO 31-3, *Quantities and units — Part 3: Mechanics*
- [9] ISO 8995, *Lighting of indoor work places*
- [10] DIN 13256-3, *Pressure vessels for human occupancy — Part 3: Fire extinguishing systems in pressure vessels; Safety requirements and testing*
- [11] NFPA 53, *Recommended practice on Materials, Equipment, and Systems used in Oxygen-Enriched Atmospheres*
- [12] NFPA 99, *Standard for Health Care Facilities*
- [13] ASME PVHO 1, *Safety standard for pressure vessels for human occupancy* (see also <http://www.asme.org/>)
- [14] European Code of Good Practice for Hyperbaric Oxygen Therapy, May 2004
- [15] Germanischer Lloyd – Rules for Classification and Construction Part 5: Underwater Technology – Chapter 1: Diving Systems and Diving Simulators (see also <http://www.gl-group.com/maritime/newbuilding/pdf/publications.pdf>)