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

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

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

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Foreword

This document (prEN 14931:2004) has been prepared by Technical Committee CEN/SS S99 “Health, environment and medical equipment - Undetermined”, the secretariat of which is held by CMC.

This document is currently submitted to the CEN Enquiry.

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, B, C or D, 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 or more. Treatment times in the chamber are typically 2 to 3 hours for hyperbaric oxygen treatments while standard treatment for decompression illness may last 8,5 hours 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 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

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.

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

EN 737-3:2000-01, *Medical gas pipeline systems — Part 3: Pipelines for compressed medical gases and vacuum*

ENV 737-6:2003-03, *Medical gas pipeline systems - Part 6: Dimensions and allocation of probes for terminal units for compressed medical gases and vacuum*

EN 739:1998-01*, Low-pressure hose assemblies for use with medical gases*

EN 1041:1998-02*, Information supplied by the manufacturer with medical devices*

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

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

EN ISO 14971, *Medical devices – Application of risk management to medical devices (ISO 14971:2000, including Corrigendum 1:2002)*

EN ISO 6941 , *Textile fabrics — Burning behaviour — Measurement of flame spread properties of vertically oriented specimens (ISO 6941:1984, including Amendment 1:1992)*

ISO 31-3, *Quantities and units — Part 3: Mechanics*

ISO 6309, *Fire protection — Safety signs*

ISO 15001, *Anaesthetic and respiratory equipment - Compatibility with oxygen*

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

IEC 60364-7-710: 2002-11*, Electrical installations of buildings - Part 7-710: Requirements for special installations or locations; Medical locations*

3 Terms and definitions

For the purposes of this European Standard, 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
The symbol p_e is recommended for gauge 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 gas or mixture of gas administered to the patient

4 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. Attention is drawn to EN ISO 14971 on risk analysis.

4.2 General requirements common to ante chamber and main chamber

4.2.1

Pressure chambers shall comprise at least an ante chamber and a main chamber.

4.2.2

Each chamber compartment including supply lock shall be designed for a test pressure according to table 1.

The gas used to pressurise the chamber shall never contain more than 21 % oxygen. If air is used it shall comply with EN 12021.

Testing:

According to EN 13445-5.

4.2.3

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

4.2.4

The maximum operational pressure shall not exceed the value 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/PS
Maximum allowable pressure/Design pressure	1 MAP/PS
Maximum operational pressure	0,91 MAP/PS
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

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 / therapy 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 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

Breathing systems other than demand valve systems (hoods, tubes, free flow systems and other breathing systems) shall be safe in hyperbaric environment and suitable for operation in a hyperbaric chamber system. They shall implement complete overboard dumping. For patient use, the physician should be able to adjust the pressure of the gas supply in "free flow".

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 4.2.2 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 4.2.2 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

If there are seats or stretchers inside the main chamber, the dimensions of the main chamber shall allow a free passageway of 0,6 m width and 1,8 m height.

Testing:

Measuring of width and height of the passageway.

4.2.9

Seating shall be ergonomical 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.

4.2.10

It shall be possible to position stretchers with the minimal dimensions according to EN 1865 in a way that they are accessible from both sides. The space around a patient on a stretcher shall be sufficient for resuscitation procedures.

4.2.11

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.

4.2.12 Closures and openings

All closures and openings (e.g. doors, locks, hatches) 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.

4.2.13

If the pressure chamber is intended to be fitted with a bayonet flange connection for transport chambers, this shall be designed in accordance with STANAG 1079 flange (see Annex A) of this standard.

4.2.14

There shall be at least one observation window in the chamber wall. 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.

4.2.15

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.

Testing:

By measurement (see ISO 8995 for information).

4.2.16

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.

4.2.17

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.

4.2.18

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 misuse.

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.

4.2.19

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:

Visual inspection.