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

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EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN 14931:2006 sisaldab Euroopa standardi EN 14931:2006 ingliskeelset teksti. Käesolev dokument on jõustatud 31.07.2006 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 14931:2006 consists of the English text of the European standard EN 14931:2006. This document is endorsed on 31.07.2006 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: 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.	**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.

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

This European Standard was approved by CEN on 27 April 2006.

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Contents

Foreword

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

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of an identical text or by endorsement, at the latest by December 2006, and conflicting national standards shall be withdrawn at the latest by December 2006.

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.

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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 6309:1987, *Fire protection — Safety signs*

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