

Low-Pressure Fabric Hyperbaric Chambers

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Overview

The low-pressure, fabric hyperbaric chambers (operating at less than 1.4 ATA) marketed for sports and alternative medicine, have a U.S. Food & Drug Administration (FDA) 510(k) clearance for Acute Mountain Sickness only and are designed to be compressed only with air. The FDA prohibits the use of these devices with supplemental oxygen. ⁽¹⁾

The *NFPA 101 Life Safety Code* and *NFPA 99 Health Care Facilities Code* describe the requirements for the construction, operation, and maintenance of hyperbaric facilities. ^(2, 3) Accordingly, hyperbaric chamber construction is required to meet *ASME-PVHO-1*. The *ASME-PVHO-1* standard applies to any pressure vessel that encloses a human within the pressure boundary, with an external or internal pressure exceeding 2 psig above ambient pressure (1.14 atmospheres absolute). ⁽⁴⁾

The facility housing the hyperbaric chamber(s) shall meet NFPA 99, Chapter 14's requirements. ⁽³⁾ The Life Safety Code states that any building occupancy shall meet the requirements of NFPA 99 Hyperbaric facilities. ⁽²⁾ The UHMS does not endorse the concept of "In Home" therapy at any time. ⁽⁵⁾

Conclusions and Recommendations

- Hyperbaric oxygen therapy is defined as an intervention in which an individual breathes near 100% oxygen while [wholly enclosed] inside a hyperbaric chamber at a pressure equal to or greater than 1.4 ATA.
- Hyperbaric facilities must meet the construction, operational and maintenance requirements of the NFPA 99, Health Care Facilities Code

- Soft chamber treatments are FDA approved for *acute mountain sickness* only.
- Exposure to treatment pressures less than 1.4 ATA while breathing air does NOT meet the definition of therapeutic hyperbaric oxygen therapy and does NOT achieve the minimum pressure and oxygen levels required for any UHMS approved indication.
- ALL UHMS approved indications require that patients breath near 100% oxygen while enclosed in a chamber pressurized to a minimum of 2 ATA.
- Mild hyperbaric exposures with air, deliver no more oxygen to the body than breathing oxygen by mask at sea level pressure.
The UHMS does not recommend the use of mild hyperbaric therapy for any medical purpose other than *acute mountain sickness*.

Rationale

It is the position of the Undersea and Hyperbaric Medical Society (UHMS) that hyperbaric chambers be constructed, operated, and maintained according to current Codes and Standards.

The FDA lists hyperbaric chambers as Class II medical devices. Hyperbaric Therapy requires physician prescription for procurement and use.⁽¹⁾ The UHMS recommends that physicians or, as permitted by local regulations supervised non –physician providers who are appropriately trained in Undersea and Hyperbaric Medicine, be immediately available throughout the administration of hyperbaric oxygen therapy.⁽⁶⁾

The marketing and operation of portable low-pressure fabric hyperbaric chambers for indications other than Acute Mountain Sickness is considered off-label.⁽¹⁾ Low-pressure fabric chambers are not designed to be used in conjunction with supplemental oxygen therapy and are not designed to be pressurized to greater than 1.4 atmospheres pressure . All UHMS approved indications for hyperbaric oxygen therapy currently require a minimum of 2.0 ATA while breathing near 100% oxygen. Low pressure fabric (soft) chambers do not meet therapy guidelines currently adopted by the UHMS definition of clinical hyperbaric oxygen therapy (HBO₂); breathing oxygen (USP Oxygen 99%) while at an increased atmospheric pressure of at least 1.4 ATA.⁽⁷⁾

The use of the low-pressure fabric hyperbaric chambers is commonly called mild hyperbaric therapy (MHT or mHBOT). Marketing and use of these devices as clinical hyperbaric chambers is also common, and consumers should use caution.⁽⁸⁾ Using mHBOT with air as designed, will deliver no more oxygen to the body than breathing oxygen by mask at sea level pressure. We are not aware of any reliable clinical evidence that mild compression to less than 1.4 ATA has any therapeutic effect.^(7, 9) Mild Hyperbaric therapy is being offered in clinical

chambers as well as the low pressure fabric hyperbaric chambers. The UHMS does not recommend the use of mHBOT for any medical purpose other than acute mountain sickness. (7, 9),

We encourage all hyperbaric facilities to become accredited by the UHMS Facility Accreditation Program and to be operated and maintained by qualified personnel.(11)

References

- (1) Food and Drug Administration, CFR _Code of Federal Regulations Title 21
- (2) National Fire Protection Association, 101 Life Safety Code 2015 edition
- (3) National Fire Protection Association, 99 Health Care Facilities Code, 2015 edition
- (4) ASME-PVHO-1- 2012 edition
- (5) Undersea and Hyperbaric Medical Society Position Statement on the Conduct of Hyperbaric Oxygen Therapy
- (6) Undersea and Hyperbaric Medical Society Position Statement on Clinician Attendance of Hyperbaric Oxygen Therapy
- (7) Undersea and Hyperbaric Medical Society, Hyperbaric Oxygen Indications, 13th edition
- (8) Food and Drug Administration, Consumer Health Information; Hyperbaric Oxygen, Aug 2013
- (9) ANZHMG statement on mild hyperbaric oxygen therapy, Rubicon – Foundation. Org
- (10) National Board of Diving and Hyperbaric Medical Technology, Position statement on Portable, Fabric Low-Pressure Hyperbaric Chambers

- (11) Undersea and Hyperbaric Medical Society Accreditation Manual

Associated Documents

- FDA Letter / position statement regarding soft chambers.