

# Mild Hyperbaric Oxygen Therapy—mHbOT



Fire Marshal's Association of Utah

## **Code Applicability and Requirements for mHBOT Facilities**

## **The mHbOT Problem –**

The trend in the health and wellness industry is to offer the public a variety of innovative new treatments and services. One of these new services is "Mild Hyperbaric Oxygen Therapy – or mHbOT." This treatment claims to help reduce pain, boost the immune system, increase energy, alleviate sleep issues, decrease cognitive dysfunction and improve exercise recovery. This treatment is becoming increasingly popular and a quick Google search of "mHBOT near me" will show the extent to which it has.

Unfortunately the soft shell, low pressure mHbOT chambers used to provide these treatments do not meet code required design and construction standards. Elevated oxygen levels and the potential for static build up, increases the risk of fire within the chamber and the treatment room. Businesses using these chambers may not have required fire protection systems or staffing and operational procedures in place. Because of these issues, the mHbot chambers and the businesses promoting their use are not operating in compliance with the adopted codes and standards.

## **Background –**

The Gamow Hyperbaric Bag received FDA approval in February 1988 for the treatment altitude sickness. Mountain rescue teams and clinics utilized this bag to temporarily treat patients until they could be transferred to a lower altitude. Manufacturers today market new chambers, similar to the original Gamow Bag. The new chambers have received FDA "clearance" for use based on the original Gamow Bag as the predicate device and its FDA "approval". The FDA classifies these chambers as Class II Medical devices requiring a physician's prescription for use.

The equipment used to provide mHBOT treatments includes the following:

- a. The soft-shell chamber
- b. Air compressor
- c. Oxygen concentrator, tubing & mask.

Mild hyperbaric oxygen therapy chambers typically operate at pressures between 2 to 4.5 psi. Oxygen is administered to the occupant via an oxygen concentrator and mask or nasal cannula. Oxygen concentration provided to the occupant is typically 90 to 95 percent at 10LPM.

Before the mHBOT therapy can be administered, a telemedicine appointment is necessary. The mHBOT treatment is supervised by a licensed registered nurse and treatments range from 60-90 minutes per session. Although mHBOT chambers may be located within a healthcare facility, many are located in non-healthcare occupancies.

## **IBC and IFC Code Requirements -**

The International Building Code and International Fire Code each have a section that applies to hyperbaric facilities and requires compliance with NFPA 99, Chapter 14.

### **2018 IBC, Section 425 - Hyperbaric Facilities**

425.1 Hyperbaric facilities shall meet the requirements contained in Chapter 14 of NFPA 99.

### **2018 IFC, Section 609 - Hyperbaric Facilities**

609.1 General. Hyperbaric facilities shall be inspected, tested, and maintained in accordance with NFPA 99.

609.2 Records. Records of all testing and repair conducted on the hyperbaric chamber and associated devices and equipment shall be maintained. Records shall be available to the fire code official.

## **NFPA 99, Chapter 14 Code Applicability -**

In the 2018 codes, IBC 425.1 and IFC 609.1 direct the AHJ to NFPA 99 Chapter 14 for the requirements of "hyperbaric facilities." The 2018 edition of NFPA 99 is a referenced standard approved by the legislature through the code adoption process.

The following NFPA 99 sections and annex material establish the applicability of Chapter 14 for the use of soft-shell, low-pressure hyperbaric chambers and the facilities using them:

- Chapter 14 establishes criteria for designing and operating hyperbaric chambers and facilities. Chapter 14 covers electrical, fire, pressure, and gas hazards associated with hyperbaric facilities used or intended for medical and experimental procedures at gauge pressures from 0 kPa to 690 kPa(0 psi-100 psi). §1.1.2
- Hyperbaric chambers are found in various settings, including but not limited to hospitals, doctor's offices, private clinics, and business occupancies. Not all hyperbaric facilities are designed or equipped the same. Hyperbaric treatment and facilities are used for various emergent and non-emergent conditions, and the acuity of patients ranges from stable to critical. These variations lead to differences in hyperbaric equipment, ancillary support equipment, and facility location. Chapter 14 is intended to provide minimum safeguards for hyperbaric patients and personnel regardless of the facility's location. §A.1.1.2
- Chapter 14 applies to both new and existing facilities. §14.1.1
- Hyperbaric facilities conducting any form of treatment and not located in a designated health care facility, including residential occupancies, shall comply with the requirements of the applicable code. §14.1.4
- Health Care Occupancies vs. Health Care Facilities:  
Health care facilities include but are not limited to hospitals, nursing homes, limited care facilities, clinics, medical and dental offices, and ambulatory health care centers. A health care facility is not a type of occupancy classification defined by NFPA 101. Therefore, health care facilities should not be confused with health care occupancy. All health care occupancies are considered health care facilities; however, not all are considered health care occupancies, as health care facilities include ambulatory and business occupancies. §A.3.3.71
- ANSI/ASME PVHO-1 Standard for Pressure Vessels for Human Occupancy.  
A PVHO is a pressure vessel that encloses a human being within its pressure boundary while under internal or external pressure that exceeds a 2 psi differential pressure. This Standard provides requirements for the design, fabrication, inspection, testing, marking, and stamping of pressure vessels for human occupancy, having an internal or external pressure differential exceeding 2 psi. §14.2.2.1

## **NFPA 99, Chapter 14 Requirements**

Chapter 14 classifies and categorizes hyperbaric chambers by their use and the type and number of occupants receiving treatment. Chamber classification establishes the minimum standards for construction and operation.

### **mHBOT chambers are Class B and Category 3.**

- Class B hyperbaric chambers are for single human occupancy.
- Category 3 hyperbaric care includes treatments where the interruption or failure of medical gas supply or electrical service is not likely to cause injury to patients, staff, or visitors.

**Construction & Operational Standards** - Requirements are divided into three primary areas:

- a. The chamber & related equipment.
- b. The building – fire & life safety systems/equipment
- c. The facility & staff – SOPs, SOGs

*\*The following are essential requirements for class B, category 3 hyperbaric chambers and facilities. Refer to Chapter 14 for all requirements.*

**Chamber Requirements:**

- a. Design & fabrication compliant with ANSI/ASME PVHO-1 Standard. §14.2.2.1
- b. Piping systems compliant with the ANSI/ASME PVHO-1 Standard. §14.2.1.3.1
- c. ANSI/ASME PVHO-1 Compliance stamp. §14.2.2.2
- d. Piping for both air and oxygen requires a 66-micron particulate filter. §A14.2.1.3.3
- e. Chamber ventilation rate of 1cuft/min. §14.2.4.4.1
- f. Chamber exhaust piped directly to the exterior of the building. §14.2.11.2
- g. Chamber hulls are electrically bonded & grounded. §14.2.9.4.1
- h. Occupant grounding – atmospheric oxygen exceeds 23.5% by volume. §14.3.1.6.3.2
- i. CGA Grade E compressed air supplied to the chamber. §14.2.10.6.2.

**Building Requirements:**

- a. NFPA 13 Fire protection system §14.2.1.2
- b. NFPA 72 Fire Alarm System - Manual pull station in the treatment room. §14.2.8.2.1
- c. 2A10BC rated fire extinguisher in the treatment room. §14.2.1.2.2
- d. Emergency lighting with battery backup in the treatment room. §14.2.3.3
- e. Warning signage at the entrance to the treatment room. §14.2.8.1
- f. NEC / NFPA 70 Compliant electrical system. §14.2.9.1.1

**Facility & Staff Requirements:**

- a. On-site Hyperbaric Safety Director. §14.3.1.3.2
- b. Minimum staff qualifications. §14.3.1.4.2
- c. Establish facility policies & procedures §14.3.1.4.1
- d. Establish an emergency plan & provide staff emergency training. §14.3.1.4.3
- e. Conduct annual emergency evacuation training. §14.3.1.5.4.2

**The Compliance Issue –**

Businesses providing mHBOT treatments utilizing the low pressure, soft shell chamber currently cannot meet all of the requirements specified in NFPA 99, Chapter 14.

The requirements for building systems and staffing / operational procedures can be addressed. Business may need to install expensive upgrades such as fire protection systems or move to a location where these systems already exist. Appropriate staffing can be hired and trained. Policies and procedures can be developed and implemented. These requirements can be addressed to achieve compliance.

It is the chamber itself that cannot meet the requirements for code compliance. The soft shell, the low-pressure chamber was not designed or fabricated to meet the ANSI/ASME PVHO-1 requirements. Therefore, the chamber does not have the ANSI/ASME PVHO-1 certification stamp required by Chapter 14. The chamber design does not allow for bonding and grounding as required for oxygen-enriched atmospheres. The chamber does not have the ability to vent directly to the exterior of the building. Because of these current design limitations, the mHBOT chambers cannot achieve compliance.

## **Addressing the Problem -**

AHJs must be vigilant of businesses offering this type of service within their jurisdictions. When found, follow the requirements of the 2018 IBC, IFC, and NFPA 99 Chpt 14. Educate the business on these code requirements. Make them aware of the compliance issue and have them remove these chambers from service.

AHJs can educate fire companies performing the annual inspections in these occupancies. Provide them with information necessary to be aware of the issue and know what to look for when inspecting these businesses. Fire companies are an excellent resource for locating non-compliant businesses and informing the Fire Prevention staff of mHOBT chamber use.

AHJs can inform local Building Officials and Planning Departments of this issue. The Building Official has the primary responsibility of ensuring code compliance for new construction and tenant improvements that a "hyperbaric facility" may occupy. Planning & Zoning Departments oversee conditional use permits and development review. Planning Departments may receive inquiries from businesses wanting to provide this service concerning zoning issues and special requirements. Planners should be aware of the building and fire code requirements that apply to this use. It will be better for all parties to catch this issue on the front end of a project rather than enforce it after a business has been issued occupancy.

Increasing awareness of the issue and the applicable code requirements will create consistent code interpretations and enforcement from AHJs across the state. Locating and removing non-compliant chambers from service will reduce risk and improve the overall safety within our communities.