CHAPTER 5 CHAPTER

Multiplace Hyperbaric Chamber

CHAPTER FIVE OVERVIEW

Multiplace Hyperbaric Chamber

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INTRODUCTION

The multiplace hyperbaric oxygen therapy chamber has reached safety and comfort levels for occupants that were unthinkable a few years ago. Advancements in this apparatus have significantly challenged builders who had to comply with a myriad of rules and regulations to certify their product as a potent medical therapy and not just a space under pressure. They consist normally of a cylindrical structure with diameter sufficient to allow access to the standing occupants. However, more recently, there are several hyperbaric facilities built with square dimensions simulating standard therapeutic room space (see Karolinska Hospital-Stockolm), ideal to make the most of the internal space available.

To minimize the risk of fire, pressurization occurs with compressed air rather than with oxygen. This key feature of multiplace chambers makes them preferable to monoplace chambers, which are usually compressed with 100% O_2. Within the walls of a hyperbaric multiplace chamber, it is possible to treat patients from intensive care units (ICUs), while they are still attached to electronic medical equipment to ensure continuity of care and maintain ventilator support if necessary. Some monoplace chambers can also be configured to provide most specialized implements, but personnel need to remain outside the compressed space.

The initial cost for multiplace chambers is very high because of the space construction and the equipment necessary for the operation of the hyperbaric chamber (i.e., pressurized air production and storage, dryers, humidity control equipment, sprinklers and water deluge systems to extinguish fires, and filters for air quality according to strict standards of control). Maintaining these complex pieces of equipment also requires specially trained personnel who are kept abreast of advancements.

The following table summarizes these key points (Table 1).

CONSTRUCTION REQUIREMENTS

The hyperbaric chamber is not simply a pressurized vessel but rather an officially recognized medical device named Device Class IIB (Rule 11, Subset IX, Directive 93/42/EEC; also named in guidelines MEDDEV 2.4/1 2010) (European Standards).[1,3] The European Community marking is affixed outside the chamber, and the manufacturer must submit a technical file with notification of the equipment's compliance with required directives. Below is a list of European standards to which

TABLE 1. ADVANTAGES AND DISADVANTAGES OF MULTIPLACE HYPERBARIC CHAMBERS VERSUS MONOPLACE HYPERBARIC CHAMBERS.

ADVANTAGES	DISADVANTAGES
Greater fire safety	High costs of purchase and management
Enhanced comfort for patients	Risk for service staff (physician, nursing, and technical personnel)
Possibility of treating patients from ICU with suitable support and monitoring equipment	
Higher working pressures	
Abililty to deal with emergencies without having to decompress the chamber	

the manufacturer must comply in the construction of the product. To those there are additional regulations for individual components of the hyperbaric chamber which are added to the facility. [1])

The U.S. regulations can be traced to a single important document: the National Fire Protection Association NFPA-99-2015, Chapter 14, which defined Class A hyperbaric chambers as chambers which could accommodate two or more people simultaneously.[5]

MULTIPLACE HYBERBARIC CHAMBER

These multiplace clinical hyperbaric chambers consist of large rooms designed to accommodate more occupants inside simultaneously, with a maximum limit imposed by the European standard of 14 patients (Figure 1). They are usually constructed from two adjoining structures to simultaneously allow treatment of several people in a so-called "master pressurized chamber" with individual workstations dedicated to each patient for treatment and a pressurization compartment, usually smaller (Figure 2).

Hyperbaric chambers are normally made up of two adjoining sections separated by an airtight door: a main compartment used for therapy and a secondary compartment called a pressure lock, which can be pressurized when it is necessary to enter or exit the main compartment, while the main compartment remains under pressure (Figure 2).

The main treatment room usually consists of a cylindrical body enclosed by a rounded ceiling on the top and a flat bottom below, fitted with a flat door with a pressurized closure, usually with a rubber O-ring but without locking devices or additional mechanical closures, for safety (Figure 3).

A rectangular door facilitates the entry of patients with walking difficulties and is large enough to allow passage of wheelchairs and stretchers. The pressure inside the chamber is ensured by an airtight simple seal. The main body of the chamber is made of carbon steel, suitable for pressure equipment and hyperbaric chambers, painted with enamel epoxy 2-component polyacrylic, subject to corrosion. In particular, the interior finish will be inorganic zinc epoxy fire retardant, without exhalation of toxic vapors or combustible mixtures production in case of fire, as provided by law.

Figure 1. In the hyperbaric chamber with HCV-12d Vecom SRL (Padova, Italy)

Figure 3. Main entry through the airlock which is made up of a rectangular door with an O-ring.

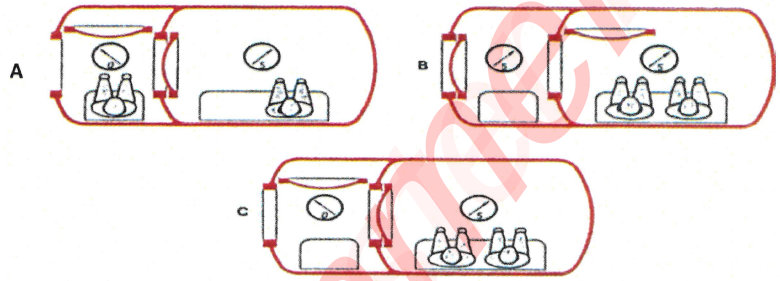

Figure 2. Pressurization schematic between the main treatment room and airlock. In A, we have a patient inside the treatment chamber at high pressure while a second individual is in room air entering the lock of the compression chamber. In B, the compression compartment is compressed at the same pressure as the treatment chamber, and the individual can enter the treatment chamber. In C, the compression lock is decompressed to be available at the surface again. Both subjects are inside the multiplace chamber.

The main treatment chamber can be accessed directly from outside through the appropriate door when the chamber is not pressurized, or through the airlock if it is necessary to access a pressurized chamber. In this case, the airlock is closed, and the pressure inside the airlock is increased to reach the same pressure as the treatment chamber (Figure 2). When the two compartment pressures are equal, then open access will be involved between the airlock and the treatment chamber. As illustrated in Figures 2 and 3, the doors of the main treatment chamber and the access to the airlock are O-ring–lined without lock mechanism, and they will passively open when pressures are equal in the two compartments, in agreement with the regulation.

The main treatment chamber is also equipped with a special device called an object pass-through lock, normally located on the farther side of the chamber and open to the outside with interposition of dual doors. Pressure seals are built in to allow passage, in and out, of small objects to use or small medical devices for medical personnel, while the chamber is under pressure. There are doors on both sides of the pass-through lock to enable the pressure equalization while the treatment chamber is at pressure.

There are transparent portholes on the side walls of the main room to ensure the vision from the outside and inside of the treatment chamber and of the airlock (Figure 4). The window material is made of a clear Perspex cover which is also scratch resistant. This is annealed with "O" rings to maintain pressure in the internal side of the chamber. The portholes are made of thick acrylic safety glass according to specific ASME PVHO regulations: two layers for each window, and the inner acrylic glass has a small hole to equalize pressure to the inside chamber.

Smaller observatories are also planned, constructed similarly to side portholes, but smaller and placed on the top area of the hyperbaric chamber, to allow the appropriate lighting fixtures and provide at least 300 lux level with the option of dimming to 10 lux. Similar observatories are used for internal observation via video cameras (Figure 4). The chamber is equipped with video cameras which allow digital recording.

Emergency lighting is provided independent of the main lighting power supply, in compliance with EN 14931 (paragraph 4.2.13) in case of failure or blackout. When designing and constructing the body of the room, it is necessary to grant access to some pipe penetrations and cable connections intended for instrumentation control, excess in number compared to the penetration used. Those not in use are sealed tightly.[4]

These multiplace chambers are pressurized with air; patients are exposed to oxygen or other breathing-gas mixtures through various devices (mask, helmet, endotracheal tube) via a demand valve connected to a gas circuit separate from the inside of the room, which emits exhausted gas to the outside.

PRESSURIZATION

Pressurization systems and control for the treatment chamber and airlock are completely independent and autonomous, as specified in the standard (Figure 6). There is a line of compressed air supply, with dual power supply upstream as required by standard, which can power the room either from the control system or manually. This is achieved by valve bypasses for maneuvers in the event of an emergency or breakdown.

Figure 4. Rear view of the hyperbaric chamber. Sprinkler lines can be identified (red) and the portholes (on both walls) of larger size for direct vision inside the room and to admit light from outside. Smaller portholes are used to house video cameras to record activities inside the chamber.

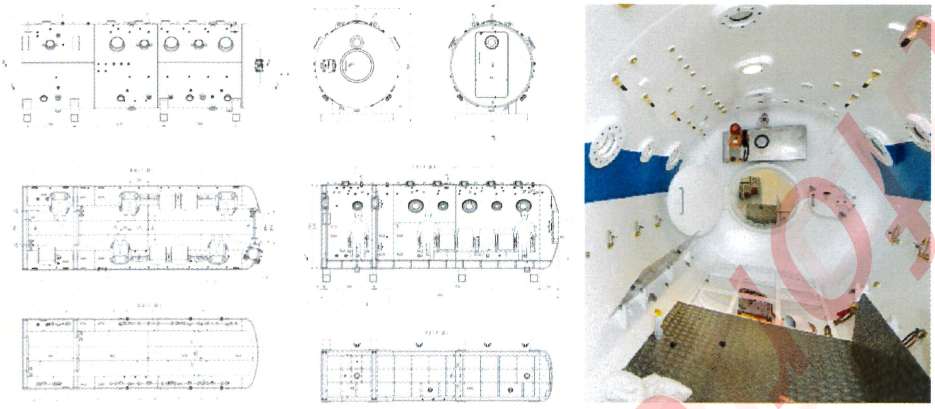

Figure 5. Outline design of a hyperbaric chamber. You can see the numerous necessary hull penetrators (Vecom, SRL). Pictured beside the schematic is a photo demonstrating penetrations.

Power lines, both automatic (control system) and manual (for emergency maneuvers), are automatically stopped in case of maximum chamber pressure. These lines are designed for a minimum inlet pressure of at least 30–40 m3/min. These courses are those expected to reach the maximum speed limit pressure within the range established by EN 14931. The loads are fitted with a silencer.

The power system and distribution of oxygen is made with external systems to the hyperbaric chamber. The oxygen supply to the main room is via external manifolds, with inside-the-room shut-off valves prior to the attack on the regulator. Similarly, there are two outside collectors, for connecting the exhalations of patients being treated (gas vented). The supervision of pressurization and control and the administration of oxygen or other breathable mixtures is managed by specially trained technicians, via a control panel.

Breathing systems, which are used in the administration of pure oxygen to patients, consist of a normal oxygen tap which is opened and closed by the operator every time therapy is needed, a "demand valve," similar to an underwater breathing valve, which will provide gas-derived oxygen through a flexible hose connected to an oronasal mask applied to the patient's face snugly to prevent the entry of air into the mask; that would lower the percentage of oxygen breathed, making it a less effective therapy. Expiration is allowed through a corrugated tube similar to the expiration circuit.

The other possibility is a "dispensing controller" which measures the amount of gas in liters per minute to be transferred to the patient through a helmet. This case requires continuous flow to keep the helmet inflated. However any increase in percentage of oxygen in the room, which could be caused by leakage of oxygen from the helmet makes this potentially dangerous, and possibility of fire hazard exists. European legislation is rigid and requires no more than a single helmet used during the therapy session.

Fuel system and distribution of medical air is operated from control system (console) and bypass with solenoid valves and manual valves in case of emergency. Medical air supply and distribution is controlled with solenoid valves and manual valves in case of emergency. Medical air supply and distribution can be intentionally sent to supply mask if the sensor encounters oxygen concentration exceeding 23% (23.5% max limit allowed by this from EN14931). The breathing system includes valves that prevent oxygen flushing into the chamber accidentally.

The water sprinkler can be located in the main treatment chamber or in the airlock chamber as required by 14931 and must provide compressed water deluge,pressurized water to flood, with pressures and flow rates of no less than guaranteed minimum standards or minimum pressure > 8.5 bar and capacity of at least 50 L/m2 per minute, equivalent to approximately 1000 L/min altogether (640 L/min for main chamber and 360 L/min for airlock), which must be distributed by sprinklers throughout both chambers.

A great deal of emphasis has been placed on fire alarms, fire suppression, and active surveillance: the activation of the fire-extinguishing system is by two opposing, distinct fire extinguishing systems, both in the Penal Code and are C.E. identified, (required in EU legislation, NFPA standards optional) that are activated only with simultaneous flame detection by both within a maximum time of 1 second. The alarm can be manually deactivated within 3 seconds. In this short interval of time, it is still possible to exclude deluge fire protection with the appropriate action manual present in the console in order to avoid flooding in case of false alarms.

Two water spray extinguishing systems can still be activated manually by the operator in the console or intentionally by staff inside the room, using manual valves identified. Within airlock and treatment chambers a special hose for manual intervention will also be installed, as specified in the standard. In the case of automatic activation of sprinklers, gas flow blocks the administration of oxygen or breathing gas, and the bottom valve of the interested area is decompressed. The tanks are always loaded with water pressure maintained at the chamber pressure; their pressurization occurs through the high-pressure cylinders pack, 200–220 bar stored on specially crafted storage tanks and led to low working pressure via a pressure reducer.

WHAT YOU CAN AND WHAT YOU SHOULD NOT INTRODUCE IN THE ROOM

Hyperbaric chambers are pressurized with compressed air environments and oxygen is supplied by an independent circuit, thus keeping the oxygen percentage values between 20.9%–22%. The fire risk is controlled, not completely cancelled. To increase security, it is forbidden to introduce a series of potentially dangerous elements

FIGURE 6. Control Panel of a modern hyperbaric chamber (hyperbaric chamber at ATIP, Padova, Italy).

inside the room. Here is a list of these materials or equipment that are absolutely prohibited:

- lighters and matches (for possibility of open flames)
- gas hand warmers (for possibility of open flames)
- battery-powered equipment, e.g., phones, remote controls, music players (for possibility of sparks)
- fully synthetic clothing (for possibility of electrostatic discharge sparks)
- uncertified equipment and medical equipment not tested by the physician in charge of the hyperbaric chamber
- furnishings (pillows, blankets, mattresses) not certified for hyperbaric environments (flame retardant and antistatic) to minimize the danger of fire
- cosmetics on the patient's face, directly in contact with 100% oxygen mask used in the environment
- newspapers (usually these papers are impregnated with oil products in the ink to write)
- Inside the room one can take the following items:
- magazine or book
- eyeshades of any material
- pencil to write (pens are not dangerous but may stain for excessive leakage of ink due to pressure changes)
- implanted medical devices (pacemakers or cardiac defibrillators) if they are hyperbaric eligible; if they were not tested, these could have serious consequences for the patient due to malfunctions
- soft contact lenses

HYPERBARIC CHAMBER ATTENDANT

Personnel providing assistance – technical assistance, nursing staff, or a physician – depending on the needs of the patient are permitted inside the multiplace chamber during therapeutic activities. When the chamber is under pressure, these assistants breathe compressed air at the pressure of treatment. The therapies vary depending on the pathology of the disease being treated from 2.0 to 2.8 ATA, for a total time varying from 95 to 115 minutes. In case of therapy for a decompression sickness accident, depth and time of exposure increase substantially (see Table 6 U.S. Navy, and Table 6A U.S. Navy). It is important to adopt procedures to protect the hyperbaric chamber attendant to avoid incurring a decompression accident.

The most straightforward method is to adopt no-decompression limits shown in the U.S. Navy tables for the depths reached in the chambers during therapy. After that time limit, the assistant will not breathe compressed air but will don a mask breathing oxygen (Figure 7).

This procedure, in addition to limiting the further accumulation of nitrogen in the tissues, accelerates nitrogen washout while breathing oxygen at pressure.

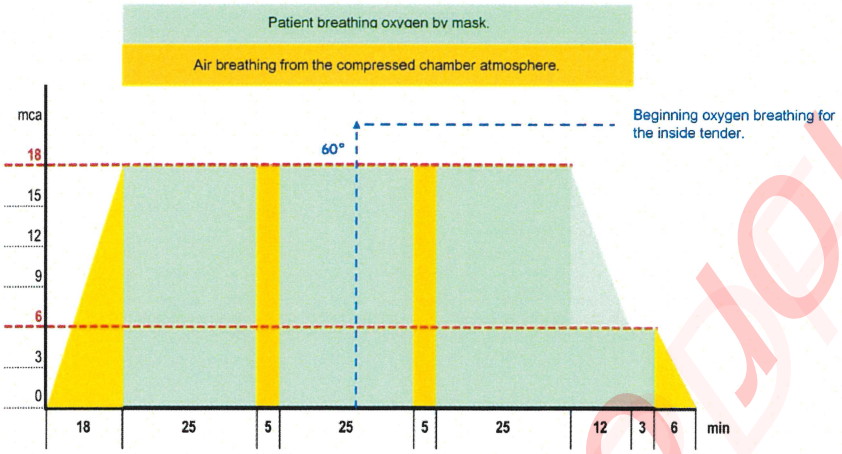

FIGURE 7. Example of therapy to 2.8 ata (60 feet). The chamber attendant starts breathing oxygen after 60 minutes. No decompression limits at a given altitude exist according to the U.S. Navy tables.

MEDICAL DEVICES

Medical electrical equipment involves intensive patient care within the hyperbaric chamber during the session and should have the same characteristics as those that are used for monitoring in the intensive care unit.

The hyperbaric environment is a particular environment, both for the increase in air pressure inside the chamber (a factor that can alter the parameters set at atmospheric pressure) and for environmental safety regulations (power supply and fire risk), factors that severely limit the usability of the equipment normally and make it difficult to find suitable material.[6]

In the selection of medical equipment for use within hyperbaric chambers, one must first seek material the use of which is certified in a hyperbaric oxygen–enriched environment. Clinical parameters to be monitored will be corrected at various pressures of therapy because technicians at designated time will have taken into account the possible environmental variations by affixing corrections.

If certified material is not available, the doctor of the hyperbaric chamber is directly responsible for what is used for monitoring:

- Must be certain that the clinical parameters measured, fluids injected, and ventilation mode set are kept constant, even by changing to the ambient pressure, with the basal setting
- Should ensure that even under pressure, equipment does not lose its functions, but retains the ability to change parameters at any time during the therapy
- Should ensure that the exercise is far superior to the duration of the therapy session
- Lower alert thresholds and in response to the increase of oxygen in the room, check the relative humidity in the room by increasing the percentage over the values normally used thus reducing the possibility of electrostatic current and increasing environmental safety

- Must reduce the number of people in the chamber to just the physician and single patient
- Monitor vital signs
  - ECG/HR: 35 leads are sufficient.
  - IBP/NIBP: IBP, always present in patients from ICU. More widespread use of NIBP, even in situations of unstable pressure supported by pharmacologic means. The small compressor for inflating the cuff is running on battery power, and its repeated use significantly reduces the duration of battery power. Must be taken into account in the choice of monitor. The newer models and compatibles use compressed air to inflate the cuff: does not affect the battery life and is safer as there are no moving parts in compression.
  - SpO_2: this parameter is not required in treating a normal patient but becomes very important in a critical patient. The sensor shows the saturation of the hemoglobin in the blood that normally takes values close to 100% in room air, and therefore does not detect the significant increase of oxygen dissolved plasma by hyperbarism. In critical patients, assisted breathing can be a sensitive index of ineffective ventilation and therefore poor oxygenation of the blood.

CONTINUOUS INFUSION PUMPS

Continuous infusion pumps are necessary for the continuity of drug therapy in the ICU.

To ensure safety of the subject, equipment must be designed in a manner that allows for the changing of parameters at any time during the session. Furthermore, working autonomy of at least 1.5 the duration of therapy must be maintained (practicing 50% more safety than required.

HYPERBARIC VENTILATORS

We analyze the following characteristics that a ventilator must have when used inside a hyperbaric chamber:

- Maintain a steady gas flow despite different pressures inside the chamber
- Maintenance of a constant ventilator rate at different pressures
- The ability to provide different types of ventilation (volume-controlled, SIMV, pressure-controlled, pressure-assisted ventilation
- Ability to set PEEP (positive end-expiratory pressure)
- if battery operated, there should be sufficient electrical power for the length of the given treatment

The environment at higher pressure than the atmospheric alters volumes, due to the increase of the ambient pressure and increasing resistance to increased density of gases. This is reflected with hypoventilation and increasing work of breathing.

There can be both types of ventilators in use: constant volume ventilators and constant pressure ventilators. In constant volume ventilators (VCV), the density of the gas increases with increasing pressure, causing a decreased flow which results in

a decrease of tidal breathing volume at different pressures. These ventilators require continuous adjustments to tidal volume at different pressures.

In pressure-controlled ventilation (PCV), the pressure values to be reached are constant over time, and the ratio of inspiration to expiration (I-E ratio) is kept constant. In this case, the tidal volume may vary in different breaths. Every reduction of flow induced by an increase in ambient pressure is recorded by transducers of the volume expired by the patients and is compensated and offset by a stability control algorithm of pressure, and thus the tidal volume remains almost constant.

REFERENCES

1. BS EN 14931:2006 Pressure vessels for human occupancy (PVHO). Multi-place pressure chambers for hyperbaric therapy – performance, safety requirements and testing. British Standards Institution; 2008 Jul.
2. Citti P, Delogu M. Studio di un approccio operativo integrato al progetto e sviluppo delle attrezzature a pressione a fronte dell'entrata in vigore della direttiva 97/23/CE: "PED." In: Convegno, A.T.T.I. SAFAP 2016. 2016. Italian.
3. Direttiva ONDR. 93/42/CEE e successiva modifica 2007/47/CE. Dispositivo medico classe II a. (2005). Italian.
4. European Commission. Classification of medical devices (MEDDEV 2.4/1 Rev. 9) [Internet]. 2010 Jun. Available from: http://ec.europa.eu/consumers/sectors/medicaldevices/files/meddev/2_4_1_rev_9_classification_en.pdf
5. National Fire Protection Association. NFPA 14 Standard for Installation of Standpipe and Hose Systems. 2010.
6. Workman WT. Hyperbaric facility safety: a practical guide. Best Publishing Co.; 1999.