7 Hyperbaric Chambers: Equipment, Technique, and Safety

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Tremendous improvements have been made in hyperbaric chambers and ancillary equipment to provide a safe place for HBO treatments. The following main topics are discussed here:

Equipment Used in Hyperbaric Medicine

Introduction

The main facility required for hyperbaric medicine is of course the hyperbaric chamber itself. This is essentially a chamber constructed to withstand pressurization, so that oxygen can be administered inside at pressures greater than at sea level. The size, shape, and pressure capabilities of the designs chambers vary considerably. The technical details of each model now available are provided by the manufacturers, and a classification of various types of chambers is shown in Table 7.1.

Table 7.1
Types of Hyperbaric Chambers

1. Monoplace
2. Multiplace or "walk-in" chambers
3. Mobile or portable
   Monoplace: transportable by air, sea, or land
   Multiplace: chamber can be driven from place to place
4. Chambers for testing and training divers
5. Small hyperbaric chambers
   for neonates
   for animal experiments

Monoplace Chambers

Monoplace chambers are the most commonly used; in most of them the pressure cannot be raised over 3 ATA. The patient can be transferred into this chamber on a gurney, and the chamber is filled with oxygen under pressure. There are two types of oxygen flow mechanisms:

- Constant purging: This type has a fixed rate of oxygen flow through the chamber and out again to the external environment.
- Recycling: This type recycles all or a portion of the gases, which are used again after they are properly cleaned and unwanted CO_2 and water vapor are absorbed. Communication with the patient is through an intercom.

Advantages

The monoplace chamber has the following advantages:

1. Handling of patients individually; privacy and, in case of infection, isolation.
2. Ideal for intensive care; no transfer or interruption of medical treatment needed, patient can stay in chamber.
3. Face mask not required; no danger of oxygen leak; comfortable.
4. Ideal for patients confined to bed in acute stage of illness or injury, e.g., paraplegics.
5. Easy to observe patient.
6. No special decompression procedures required.
7. Economy of space and cost; can be easily moved and placed anywhere in hospital.
8. Fewer operators required.

Disadvantages

The disadvantages of monoplace chambers are:

- There is a potential fire hazard in an oxygen-filled environment.
- Direct access to the patient is very limited, except in the case of modified chambers with a side room for the attendant (Reneau dual compartment).
- Physical therapy cannot be carried out in the limited space.
- It is difficult to provide an "air brake" for a patient with decompression sickness unless the patient is conscious, cooperative, and able to put on a mask himself.

This design is ideal for the care of a patient who does not required the presence of medical personnel in the chamber. Most of the essential body functions can be monitored externally, and even the respirator can be controlled from outside the chamber.

A Sechrist monoplace chamber, in common use in the USA, is shown in Figure 7.1. The design of a monoplace chamber for an acute care facility or an intensive care unit is shown in Figure 7.2. An example of a small 1-man portable chamber is the Hyperlite folding hyperbaric chamber (SOS Ltd, London, UK) shown in Figure 7.3. It is made of modern lightweight material and can be easily pressurized on site and then transferred under pressure to and into virtually any therapeutic facility. It is suitable for diving complications, trauma and other emergency indications for HBO. It may be useful for the emergency treatment of acute stroke.

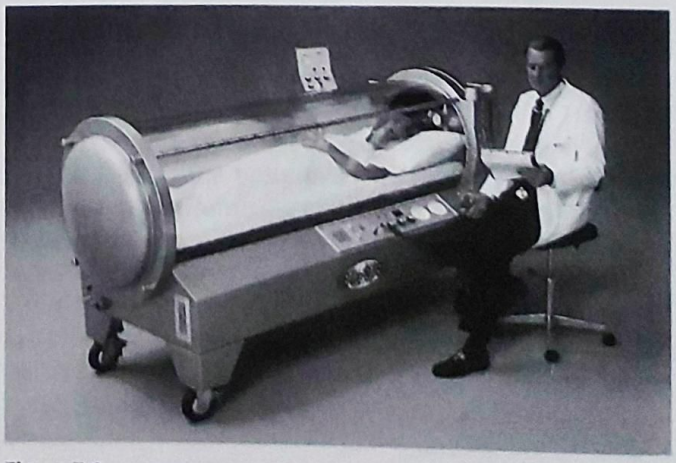

Figure 7.1
The Sechrist monoplace hyperbaric chamber.

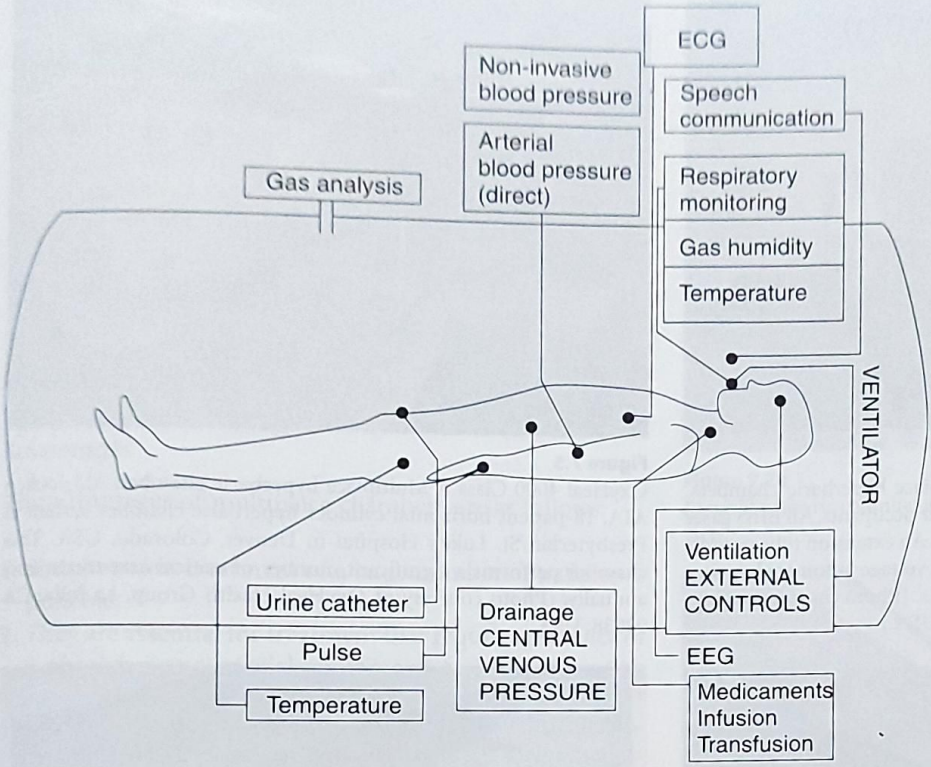

Figure 7.2
Monitoring and routine care functions for acute medical care in a monoplace chamber.

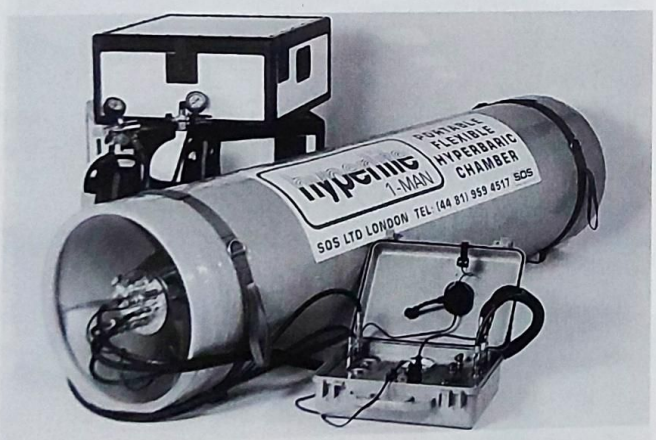

Figure 7.3a
The Hyperlite 1-man portable hyperbaric chamber (photos courtesy of SOS Ltd, London, UK).

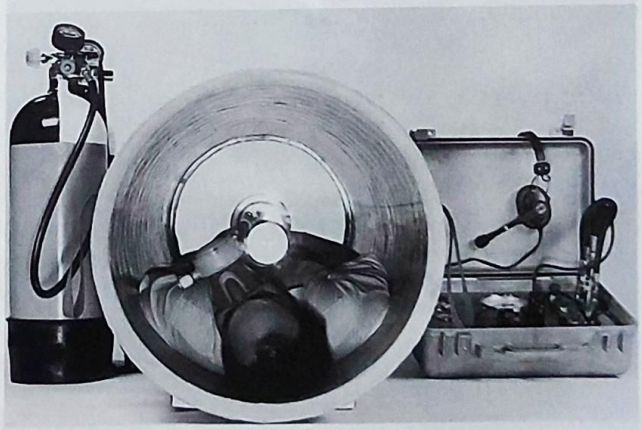

Figure 7.3b

Another transportable chamber which is in development is the Gamow bag which can be carried as a back pack and pressurized when required. It has been found to be useful for treating high altitude illness. The pressure limit of the original bag is set at 2 psi because of the fragility of the fabric. However, improvement of the hardware to make the bag capable of withstanding higher pressures has made it possible to perform standard HBO therapy with the newly devised portable chamber, the Chamberlite 15. In this study, the safety of the new bag was examined using healthy human volunteers, and the bag was shown to be usable in clinical emergency cases, such as CO intoxication and decompression sickness (Shimada *et al* 1996). The effectiveness of emergency hyperbaric oxygen therapy was also examined using the CO intoxication model of the rat. Evidence suggested that HBO was especially beneficial if applied during the first 30 min of rescue work. It was concluded that the transportable chamber was a promising emergency tool for CO intoxication. This bag can be considered for HBO treatment of acute stroke patients during transport to a medical center.

Figure 7.4
A pair of OxyHeal 2000 Class A multiplace hyperbaric chambers. These 3 ATA chambers accommodate four occupants. All BIBS gases can be controlled internally or externally. An extension tube permits the introduction of supine patients. Low voltage automated devices with manual back-ups control treatments. (Photo courtesy of OxyHeal Health Group, La Jolla, CA 92038, USA.)

Figure 7.5
OxyHeal 4000 Class A Multiplace hyperbaric chamber. A 3-lock, 6 ATA, 18-patient horizontal cylinder hyperbaric chamber system at Presbyterian/St. Luke's Hospital in Denver, Colorado, USA. This chamber performs a significant number of critical care treatments annually. (Photo courtesy of OxyHeal Health Group, La Jolla, CA 92038, USA.)

Figure 7.6a
OxyHeal 5000 Rectangular Chamber. The 3 ATA hyperbaric chamber complex adjoining the Regional Burn Center at the University Medical Center, Las Vegas, Nevada, USA. The complex consist of a large two-lock rectangular geometry Class A hyperbaric chamber designed to accommodate 12-patients and to perform critical care. The OxyHeal 2000, shown in the foreground, is used to enable routine hyperbaric treatments when the larger chamber is performing critical care treatments. The chamber complex Control Console operates both hyperbaric systems.

Figure 7.6b
OxyHeal 5000 Rectangular Chamber Interior. The view shows non-dedicated seating, large entertainment screen and floor level doors large enough to roll a hospital bed into. Underwater scene murals are applied in order to reduce patient anxiety. (Photo courtesy of OxyHeal Health Group, La Jolla, CA 92038, USA.)

Multiplace Chambers

Multiplace chambers are used for simultaneous treatment of a number of patients. The capacity varies from a few to as many as 20 patients. The chamber is filled with air and breathing is done via a mask covering the mouth and nose. Modern chambers of this type are fitted with a comprehensive gas supply and monitoring systems; the gas composition in the chamber is monitored and corrected, particularly if there are oxygen leaks from the masks. The atmosphere is air-conditioned for humidity as well as

temperature. Examples of multiplace hyperbaric chambers manufactured in the USA are:

- Dual OxyHeal 2000 Hyperbaric chamber (OxyHeal Health Group). A pair of Class A multiplace hyperbaric chambers accommodate four occupants (Figure 7.4).
- OxyHeal 4000 Multiplace hyperbaric chamber (OxyHeal Health Group). A 3-lock, 6 ATA, 18-patient horizontal cylinder Class A hyperbaric chamber system is used for critical care treatments (Figure 7.5).
- OxyHeal 5000 Rectangular Chamber (OxyHeal Health Group). The 3 ATA hyperbaric chamber complex Class A hyperbaric chamber is designed to accommodate 12-patients and to perform critical care (Figure 7.6).

Advantages

The advantages of multiplace chambers are as follows:

1. Simultaneous treatment of a large number of patients is possible.
2. They are essential for treatment that requires presence of a physician and special equipment, as in an operating room.
3. There is reduced fire hazard.
4. Physical therapy can be performed in the chamber.
5. Pressure can be raised to 6 ATA for special situations in air embolism and decompression sickness.

Multiplace hyperbaric chambers can be used to deliver patient care with enormous flexibility. Standard critical care techniques, such as mechanical ventilation, endotracheal suctioning, hemodynamic monitoring, blood gas measurement, and emergency therapy such as cardiopulmonary resuscitation, including defibrillation and cardioversion, can all be performed inside a multiplace chamber. The multiplace chamber can be considered an extension of the intensive care unit. This flexibility is accompanied by increased complexity of chamber operation. Defibrillation plays a crucial role in the resuscitation of patients from acute life-threatening cardiac dysrhythmias causing cardiac arrest. Concerns over safety and function of defibrillators under pressure have so far prevented their routine use in clinical hyperbaric chambers. Now increasing numbers of unstable and critically ill patients are being treated in such facilities.

Minor surgical procedures can be performed in the usual multiplace hyperbaric chamber, but major surgery such as heart surgery requires a specially designed chamber. There are many such chambers in existence in the USSR and Japan, but few in Europe (Graz & Amsterdam). The hyperbaric chamber with an operating room located at the University of Nagoya, Japan, is shown in Figure 7.7.

There are some technical problems of surgery in a hyperbaric chamber as some types of equipments cannot be operated in a chamber, e.g., electrocoagulation for hemostasis.

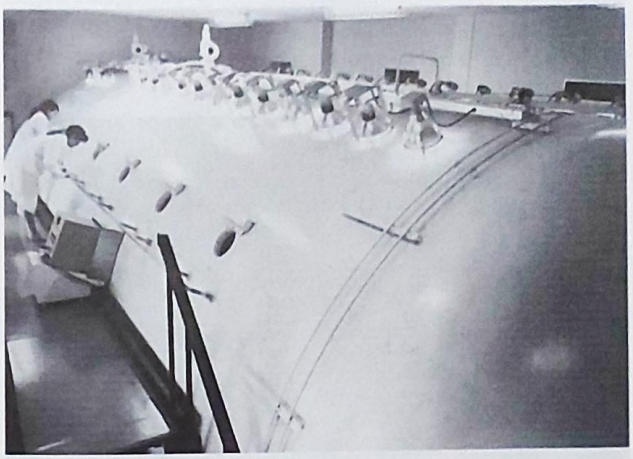

Figure 7.7a
Large hyperbaric chamber at the University of Nagoya, Japan, outside view.

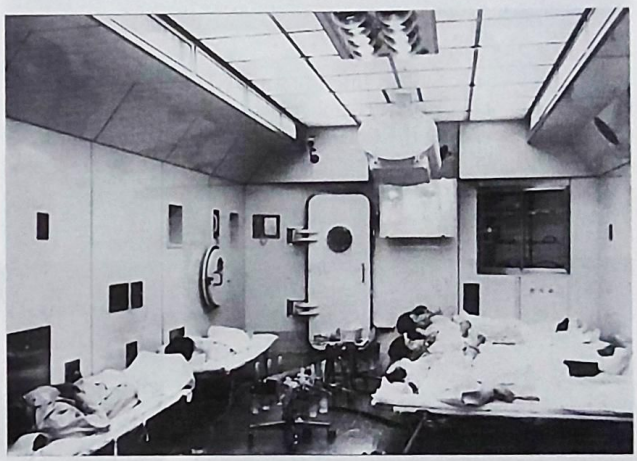

Figure 7.7b
Inside view. Operations can be carried out in this chamber.

Mobile Multiplace Hyperbaric Chambers

The first mobile multiplace chamber was constructed in the form of a bus in Nagoya, Japan, but it is no longer in use. Other mobile chambers are now available, in various locations throughout the world. An OxyHeal 4000 triple lock, 6 ATA, 18-patient mobile hyperbaric chamber (OxyHeal Health Group) resides within the over-the-road trailer. This chamber complex is now permanently installed on a roof of the Hermann Hospital in Houston, Texas, USA, where it has been in continuous operation since 1990. An OxyHeal 4000 dual lock, 6 ATA, 12-patient hyperbaric chamber (OxyHeal Health Group), shown in Figure 7.8 is placed next to the emergency department of Advocate/Lutheran General Hospital in Park Ridge, Illinois, USA. This was one of the first American hospitals to perform hyperbaric surgeries and the hyperbaric center there has been in continuous operation since the early 1960s.

Advantages

The advantages of the mobile chamber are:

Figure 7.8
Mobile Hyperbaric System Interior. An OxyHeal 4000 dual lock, 6 ATA, 12-patient hyperbaric chamber inside a 52' over-the-road trailer, installed adjoining the Emergency Room at Advocate/Lutheran General Hospital in Park Ridge, Illinois, USA. (Photo courtesy of OxyHeal Health Group, La Jolla, CA 92038, USA.)

- It can be moved where needed. It can function, for instance, in the parking lot of a hospital.
- It is comfortable and safe.
- It is ideal for clinical use as well as for research.
- It is suitable for use in military medicine. It can be moved to the base hospital in case of war. It can also be transported by air and sea.

Special Uses

The mobile chamber has various special uses:

- Sports physiology and physical therapy research. A treadmill is placed in the chamber and all the necessary investigations can be done while the patient exercises in the chamber.
- Treatment of patients with cerebrovascular insufficiency, myocardial ischemia, and peripheral vascular disease.
- "Brain jogging" mental exercises and psychological testing can be performed in the chamber during HBO administration or immediately afterward in the anteroom. This is useful in the treatment and assessment of patients with cognitive deficits.
- Emergency treatment of the patient can be carried out during long-distance transport in the chamber.

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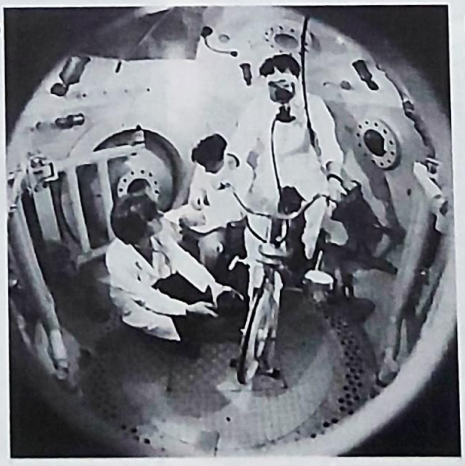

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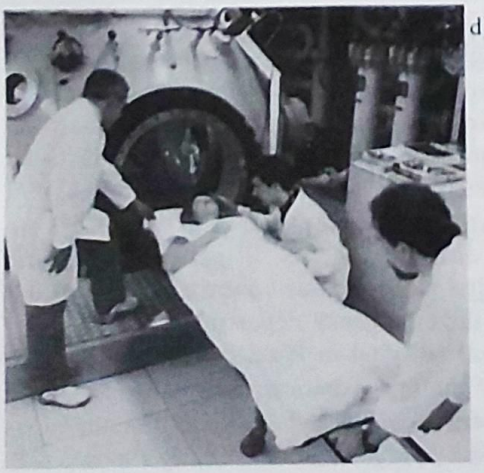

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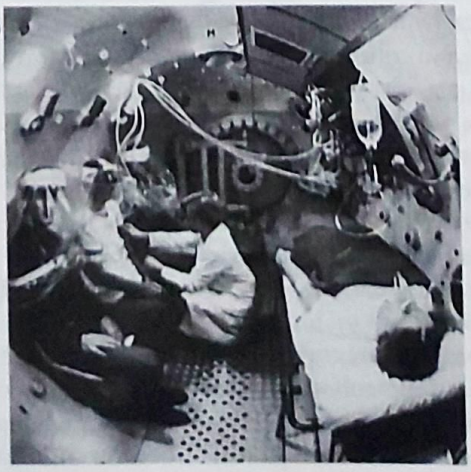

Figure 7.9a-e
Combined treatment and diver testing hyperbaric chamber at the University Hospital, Zurich, Switzerland (a) Diving testing; (b) exercise testing; (c) a patient being transferred into the chamber on a special device; (d) patients being treated inside the chamber – note the oxygen tents used by the patients; (e, next page) overall view. This chamber can be used for simulating dives to depths of 1000 m and high altitude simulation up to 10,000 m (Photos courtesy of Dr. B. Schenk, Head of Operations, Hyperbaric Laboratory, University Hospital, Zurich).

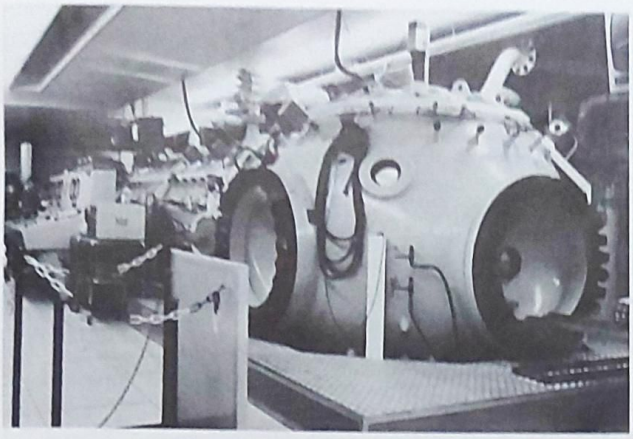

Figure 7.9e

Hyperbaric Chambers for Diving Medicine

Diving chambers are used for testing and training divers with simulated depths. These facilities can be combined with hyperbaric chambers for patient treatment in a hyperbaric center. An example of this is shown in Figure 7.9.

Small Hyperbaric Chambers

Hyperbaric chambers have been constructed for use in experiments with small animals. Small portable chambers are available for resuscitation of newborns. A specially designed chamber for animal experiments is shown in Figure 7.10. OxyCure 3000 Hyperbaric Cellular Incubator (OxyHeal Health Group) is a class C chamber with controls for the pressure, gases, temperature and humidity shown in Figure 7.11. It is used in cellular studies and to induce autologous stem cell replication.

Selection of a Hyperbaric Chamber

A classification of hyperbaric chambers according to pressure, size, and uses is shown in Table 7.2. Most of the indications (90%) can be covered by chambers of types I and II. Pressure up to 2.5 ATA is not only the upper limit for most applications, it is also the starting point for compulsory inspection by the technical inspection agency (TÜV) in Germany. This classification may help the manufacturer as well as the consumer to choose a chamber within a certain category. It would be uneconomical to make all the chambers capable of withstanding a pressure of 6 ATA. Two indications for which pressures of 6 ATA have been used in the past, i.e., decompression sickness and air embolism, are being reassessed. For both these conditions, the highest pressures required may not exceed 3 ATA, as discussed in Chapters 10 and 11.

The hyperbaric chamber is a durable piece of equipment

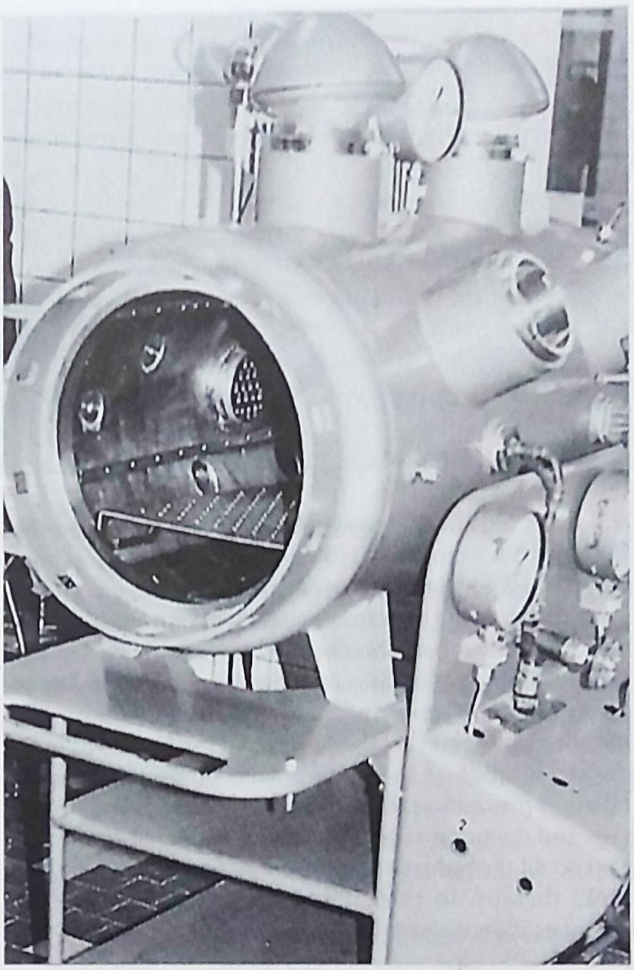

Figure 7.10
A hyperbaric chamber for animal experiments at the All Union Center for Surgical Research, Moscow.

Figure 7.11
OxyCure 3000 Hyperbaric Cellular Incubator for cellular studies. Acknowledgment: Photo courtesy of OxyHeal Health Group, La Jolla, CA 92038, USA.

Table 7.2
Classification of Hyperbaric Chambers According to Use and Pressure

Type	Pressure	Type	Typical indications
I	Up to 1.5 ATA	Mobile and multiplace	Ischemic disorders: cerebral, cardiac, peripheral-vascular: adjuvant to physical therapy and sports medicine; adjuvant to survival of skin flaps; acoustic trauma
II	Up to 2.5 ATA Up to 3.0 ATA	Monoplace and portable	Gas gangrene Burns Crush injuries of extremities Emergency treatment of decompression sickness
III	Up to 6.0 ATA	Multiplace	Air embolism Decompression sickness

and many old chambers are still performing well. The safety record has been good. However, as in any other technology, there is constant evolution and improvement. The latest addition to the hyperbaric chamber family is the mobile multiplace chamber. This chamber gives us an ideal opportunity to conduct further investigations in the field of rehabilitation and sports medicine. Another advantage of the mobile chamber is that the equipment can be moved to any desired location at short notice with no necessity for installation procedures. Hyperbaric chambers are still expensive, and the number of chambers available is not adequate to treat all the patients who would potentially benefit from HBO therapy. In this situation, the mobile hyperbaric chamber is an economical proposition.

Technique of Hyperbaric Oxygenation

The schedules of pressure for different diseases are listed in the appropriate chapters. We restrict ourselves here to some general comments about technique.

The hyperbaric technician follows the prescribed instructions from the hyperbaric physician about the pressure, duration, and frequency of treatment. Most of the treatments at our hyperbaric center are given at pressures between 1.5 and 2.5 ATA, and the usual duration of a hyperbaric session is 45 min. Of this 10 min are required for compression and 5 min for decompression if pressures of 1.5 ATA are used. Thus, the maximal oxygen saturation is maintained for about 0.5 h. In the case of infections, the treatment duration is doubled. The treatment sessions for most chronic conditions are given daily, including weekends. For the multiplace chamber, patients are grouped according to indications. For example, all stroke patients are grouped to go in the same session and are accompanied by a physiotherapist or a physician if a research project is involved. The technician keeps a complete log of the session and the data can be recorded and reproduced by computer. Compression and decompression are quite smooth, and if the patient complains of any discomfort such as ear pain, the procedure can be halted. In case of a more severe problem, the affected patient can be moved to the anteroom of the multiplace chamber and decompression started while the treatment of the remaining patients is continued in the main chamber with the door between the two chambers locked.

In the case of a monoplace chamber, oxygen is introduced into the chamber at the start while pressure is raised. In the multiplace chamber, oxygen masks are used and oxygen inhalation is started only when the chamber has been pressurized to the desired level.

Oxygen partial pressures are not measured routinely, but only for research purposes or in some special cases. Most of the measured values of paO_2 are around 1000 mmHg at 1.5 ATA.

Table 7.3
Ancillary Equipment for the Hyperbaric Chamber

1. Oxygen masks and hoods
2. Respirators and ventilators
3. Miscellaneous equipment for treatment
   - Cardiopulmonary resuscitation apparatus
   - Endotracheal tubes
   - Suction equipment
   - Intravenous infusions
4. Equipment for diagnosis
   - Basic medical examination tray
   - Transcutaneous oxygen measurement
   - EEG
   - ECG
   - Blood gases and hemorrheology equipment
   - Intracranial pressure and CSF oxygen tension monitors
   - Blood pressure measurement cuff
5. Neurological assessment equipment
   - Ophthalmoscope
   - Dynamometer to measure spasticity
6. Equipment for exercise: treadmill
7. Therapeutic equipment such as cervical traction for cervical spine injuries

Ancillary Equipment

Various types of ancillary equipment are listed in Table 7.3.

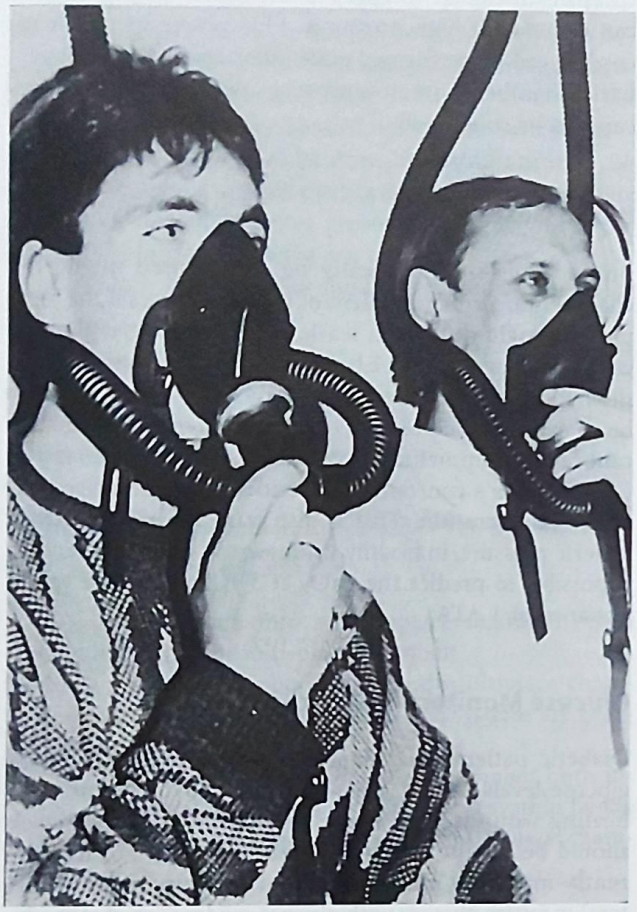

Figure 7.12
Oxygen masks for use in hyperbaric chambers.

Oxygen Masks and Hoods

Oxygen masks are required only in the multiplace hyperbaric chambers. The mask should fit tightly and not allow any leakage of oxygen. The US Air Force aviator's mask, when properly fitted, has end-inspired oxygen levels of 96.9–99%, and paO_2 of 1640 mmHg is reached at 2.4 ATA. One type of mask in common use is shown in Figure 7.12. The masks are made of rubber or silicon and can be cleaned and disinfected easily. Headbands of the masks can be placed easily. Oxygen hoods and oxygen tents have been used as an alternative to the masks and are particularly useful in patients with head and neck lesions.

Respirators and Ventilators

Various ventilators found to be effective in hyperbaric environments at pressures up to 6 ATA are:

- The Sechrist model 500A mechanical ventilator, shown in Figure 7.13, for use with the Sechrist monoplace chamber. Patients with respiratory failure can be placed in it and it will compensate for changes in pressure inside the chamber. Its specifications are shown in Table 7.4.
- The Penlon Oxford ventilator: this is a bellows type, volume-set, timed-cycle device and is used at some medical facilities.
- The Siemens Servo ventilators – sophisticated, volume-set, timed-cycle devices used in intensive care units.
- The Monaghan 225 ventilator is driven by compressed air rather than oxygen. At 1 ATA, this ventilator delivers between 35 and 40 l of the gas/min to the patient. Although this ventilator functions satisfactorily, gas delivery drops to 18 l/min, still adequate for the majority of patients.

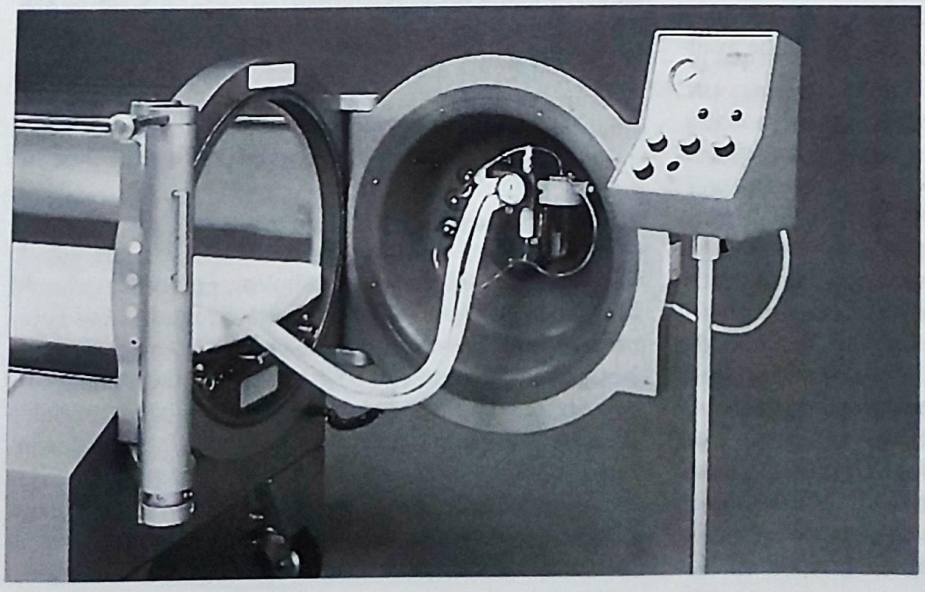

Figure 7.13
Sechrist Model 500A Mechanical Ventilator for the Sechrist monoplace hyperbaric system. (Photo courtesy of Sechrist Industries Inc, Anaheim, California.)

Table 7.4
Specifications of the Hyperbaric Ventilator, Model 500A (Sechrist)

Principals of function	Automatic adjustment of delivery pressure of ventilation to variations of pressure in the hyperbaric chamber
Regulating system	2 components: breathing circuit in the chamber and control module outside the chamber
Respiratory frequency	8–30 breaths/min
Respiratory minute vol.	0–15 l/min at 3 ATA
Tidal volume range	0–1.5 l at 3 ATA
Breathing time relationship (inspiration: expiration)	1:5–3.5:1
Respiratory flow range	0–100 l/min at ambient. 0–60 l/min at 3 ATA
Inspiratory pressure limit	20–80 cm water

The desirable features of a ventilator for hyperbaric environments are:

- No electrically driven components.
- Volume and rate remain stable with all changes in pressure.
- Low oxygen bleed into the chamber to prevent contamination of the air inside.
- Continuous flow in intermittent mandatory ventilation is superior to a demand valve, as it minimizes the inspiratory work and maintains a constant airway pressure.

Diagnostic Equipment

Basic medical diagnostic equipment such as reflex hammers, stethoscope, and ophthalmoscope should be available in the chamber.

Transcutaneous oxygen tension

Transcutaneous oxygen tension ($tcpO_2$) measurement is a noninvasive technique for measuring oxygen tension of the tissues by means of an electrode taped on the skin. It cannot be used in the monoplace chamber, as the electrodes are electrically heated and constitute a fire hazard. The results of measurements of $tcpO_2$ in volunteers breathing air and HBO up to 4 ATA show close correlation with pO_2 values measured directly in blood from arterial puncture inside the hyperbaric chamber. In patients with various degrees of peripheral vascular occlusive disease, the $tcpO_2$ are significantly lower than in control subjects.

ECG and EEG

ECG and EEG pose no special problems and should be standard in chambers for treating patients with cerebrovascular insufficiency. Changes in the signal quality of ECG can occur with high pressures. EEG power spectrum recording can be performed quite satisfactorily in the hyperbaric chamber. Somatosensory evoked potential studies can also be conducted.

Blood Gases

Blood gases should ideally be determined inside the chamber due to the problem of release of gases if the sample is brought outside to sea-level pressure. Several blood gas analysis systems have been modified to function inside the hyperbaric chamber. Blood samples of gases can also be analyzed at the pressure of measurement with specially calibrated equipment. The ratio of arterial to alveolar pO_2 (a/A ratio) is a constant, independent of the inspired oxygen concentration. This is also true at elevated atmospheric pressure, in healthy volunteers as well as patients. It is possible to predict the paO_2 at 3 ATA from the values obtained at 1 ATA.

Glucose Monitoring Devices

Diabetic patients may experience fluctuations in blood glucose levels during HBO treatment for ischemic nonhealing wounds. Therefore, whole blood glucose levels should be monitored during treatment. Most of the currently marketed glucose monitoring devices (glucometers) measure glucose with glucose oxidase- or glucose dehydrogenase-based methods. Glucose dehydrogenase methods do not utilize oxygen but inaccuracies have been reported between measurements at ground level and at 2.36 ATA (Price *et al* 1995). Glucose oxidase-impregnated reagent strips are are affected because both high and low pressures of oxygen interfere with enzymatic reactions involved which utilize oxygen.

Miscellaneous Medical Equipment

Basic cardiopulmonary resuscitation equipment should be available in the chamber. Endotracheal tubes and Foley catheter cuffs should be inflated with water or saline instead of air. Suction can be generated in the chamber by compressed air or made available from outside through a pressure reduction regulator. Special injection kits for intravenous infusion are available from the manufacturers for use in their chambers. In the case of monoplace chambers, special precautions are necessary when running an intravenous infusion because of the difference between

chamber pressure and external pressure. A treadmill motor can be placed under the hyperbaric chamber and the motion transmitted by a shaft through the floor of the chamber (Figure 7.10).

Pleural suction drainage systems can be dramatically affected by pressure change, but can be used safely in a hyperbaric environment provided that the following precautions are taken (Walker *et al* 2006):

- Suction should not be applied during pressurization.
- Pressurization needs to be slow, 10 kpa/min or less.
- Suction must be applied during depressurization if there is an air leak of 5/min or greater coming from the patient, otherwise suction is not essential.
- Hyperbaric compatibility should be tested before use.

Monitoring of Patients in the Hyperbaric Chamber

Patients and attendants in the chamber can be monitored by any of the following means:

- Visual. Direct view into a monoplace chamber; closed circuit TV in the multi-place chamber.
- Auditory. For both monoplace and multiplace chambers; several two-way communication systems are available for this purpose.
- Use of diagnostic and monitoring equipment both inside and outside the chamber; direct observation by the accompanying attendants in case of multiplace chambers.

The level of monitoring depends on the severity and type of illness. With critically ill patients, the routine monitoring in the ICU can be continued into the chamber. In patients not requiring medical attention by contact, most of the essential monitoring can be done in a suitably equipped hyperbaric chamber, such as the Dräger HTK 1200 monoplace chamber. Some of the problems of monitoring head-injured patients in the monoplace chamber are:

1. If the arterial blood pressure is monitored by an indwelling radial artery catheter, a pressure infuser should be used to keep the line flushed open with a heparinized solution. Any obstruction of the catheter during pressure changes may dampen the wave form or flatten it.
2. Central venous pressure can be measured by connecting the line to a transducer and a monitoring module.
3. Swan-Ganz catheter. Pulmonary artery pressures can be monitored during HBO therapy; satisfactory wave forms are obtained without significant changes in the pulmonary artery pressure.
4. For EEG monitoring, the electrodes should be attached prior to entry to the chamber, and the collodion should be allowed to dry because when wet, it is flammable. Properly placed electrodes can stay in position for up to 5 days.
5. The cuffs of the endotracheal tubes should be filled with sterile normal saline during HBO. After the treatment, the saline is removed and replaced by air.
6. Arterial blood gas analysis. Arterial blood gas samples can be aspirated from the arterial line for analysis during HBO treatment. Transcutaneous oxygen monitoring cannot be done in a monoplace chamber because the electrode presents a fire hazard.

Miscellaneous Special Diagnostic Procedures

Intracranial pressure monitoring is important in patients with head injuries and cerebral edema. The Richmond subarachnoid bolt system connected to a standard arterial pressure transducer located inside the chamber with electrical leads passing through the walls is satisfactory. Intracellular current passage and recording inside a hyperbaric chamber can be carried out without danger of fire by using using glass microelectrodes and micromanipulators.

The cerebrospinal fluid (CSF) reflects the oxygen tension of the brain. CSF examination by cistern puncture or after removal from an Ommaya CSF reservoir may give an idea of the state of oxygenation of the brain tissues. This is important, as there is no satisfactory practical method of measuring cerebral blood flow in the hyperbaric chamber.

Safety in the Hyperbaric Chamber

Operational Safety

Safety is a very important consideration in the construction of hyperbaric chambers. Loss of chamber structural integrity can result in rapid decompression and decompression sickness. Most chambers in the United States are constructed according to the requirements of the ASME Boiler and Pressure Vessels Code, as amplified by ANSI-ASME PUHO (Sect. VIII, Div. 1, American Society of Mechanical Engineers, New York). A chamber built according to these standards can be expected to give years of reliable service, if it is properly maintained.

The windows of a hyperbaric chamber are usually made of acrylic plastic because it is easily formed and gives ample warning of impending failure. These materials are subject to corrosion and alcohol-based solutions should not be used for cleaning windows. Acrylic is subject to damage by heat and nuclear radiation.

Essential controls and monitors for a hyperbaric chamber should be provided with an emergency power source

in the event of loss of power, and the transfer from normal to emergency power should be automatic.

Atmospheric Control

This refers to maintenance of a safe atmosphere inside the chamber. Contamination of the atmosphere is possible by products carried into the chamber. The hyperbaric chamber is pressurized by one of three methods:

- compressed gas directly from a compressor,
- compressed gas from a pressurized accumulator,
- gas from a cryogenic supply system through a suitable vaporizer.

Large multiplace chambers are pressurized by compressed air from an accumulator that acts as a buffer in the event of compressor failure or loss of electric power. Pressurized air, regardless of the source, should be checked periodically for composition and purity. Sufficiently clean air can be provided by locating the air intake away from sources of pollution and providing suitable absorbers for pollutants. Safety standards for the composition of chamber air are given in Table 7.5.

Table 7.5
Recommended Maximum Values for Contaminants in Hyperbaric Air (from Hamilton and Sheffield 1977, by permission)

- Oxygen: 20%–22% by volume
- Carbon dioxide: 1000 ppm by volume (0.10%)
- Carbon monoxide: 20 ppm by volume (0.002%)
- Gaseous hydrocarbons (methane, ethane, etc.): 25 ppm by volume (0.0025%)
- Halogenated solvents: 0.2 ppm by volume (0.00002%)
- Oil and particulate matter: 0.005 mg/l, weight/volume
- Total water: 0.3 mg/l, weight/volume
- Odor: None objectionable or unusual

Masks and Breathing Control System

The breathing control system is also referred to as BIBS (built in breathing system) in a multiplace chamber. It provides a safe and secure source of breathing gas in case of contamination of the chamber atmosphere. The masks for supplying oxygen are supplied by an overhead dumping system where the exhaled breath is directed out of the chamber. The masks should fit well. Oxygen leaking from the masks not only reduces the effectiveness of the treatment but also raises the oxygen concentration of the chamber air above accepted levels and should not exceed 23 vol%. The expired gases are removed directly by a so called "overboard dumping system." In the case of hoods, special attention is required to CO_2 removal and prevention of excessive humidity. The oxygen supply to the mask should be humidified to prevent the irritating effect of oxygen.

Fire Safety in the Chamber

Prior to 1970, there were no national fire safety standards for clinical hyperbaric chambers in the United States. Fire prevention was a matter left to common sense of the operators. Considering the widespread use of hyperbaric oxygen therapy, the record of fire safety in hyperbaric chambers has been good. The first hyperbaric chamber fire occurred in 1923 in Cunningham's chamber in in the United States (see Chapter 1). There have been a total of 25 fires in clinical hyperbaric chambers worldwide from 1923 to 1996 (Sheffield & Desautels 1997, 1998). The review by these authors was based on reports in the literature as well as the Chambers Experience and Mishap Database of the Undersea and Hyperbaric Medical Society. During the 73-year period reviewed, there were 91 human fatalities associated with 40 fires in pressure-related chambers of all types including diving bells, decompression chambers and pressurized Apollo Command Module. There were 60 deaths in 21 clinical hyperbaric chamber fires. No death occurred in clinical hyperbaric chambers in the United States. Most of the deaths prior to 1980 were associated with electrical ignition inside the chamber but after this period the reported source of ignition has usually been a prohibited source of ignition carried by an occupant inside the chamber. All fatal fires occurred in enriched oxygen environments and only reported survivors were in chambers pressurized with air.

The first fire in a clinical monoplace chamber was reported in Japan in 1967 and three more occurred in in the following years; all were initiated by hand warmers. Tobin (1978) reported an explosion due to static electricity while a patient was having cobalt irradiation under HBO at 3 ATA in a monoplace chamber. The patient developed a lung rupture due to explosive decompression but survived. From 1976 to 189, static electricity was considered to be the cause of seven fires resulting in five deaths in monoplace chambers filled with pure oxygen. Static charge stored in the fiberglass tray was considered to be the initiating factors and these trays were replaced with stainless steel trays. Strict guidelines to this effect as well as for grounding were laid down by the National Fire Protection Association of the United States and no such incidents have been reported since then.

Another accident occurred in 1987 in Naples, when a child died in a fire in a monoplace chamber. The child was playing with a toy pistol that may have caused the ignition. The accident was attributed to the laxity of the attendant in allowing the child to take a toy into the chamber. No prompt measures were taken to rescue the child, who was practically incinerated.

The first occurrence of a fire in a multiplace chamber was reported by Youn *et al* (1989). It was precipitated by an externally heated microwave blanket introduced through the safety lock. The fire was rapidly extinguished with a central deluge system. A second mishap occurred in Milan Italy in 1997 when a fatal explosion occurred in a multiplace chamber with 11 deaths. A gas operated hand warmer was the likely trigger and it is likely that the chamber was pressurized with oxygen rather than air as explosive fire would not occur in a chamber pressurized with air. There have been no fires reported in hyperbaric chambers during the past five years.

Fatal hyperbaric fires are usually caused by a combination of factors: abundance of combustible materials, high oxygen levels, faulty electrical components, inadequate fire extinguishing equipment and lack of vigilance for carriage of prohibited items into the chamber. Emphasis should be placed on the prevention, detection, and elimination of known and suspected fire hazards in a hyperbaric chamber. Fire is more of a hazard in a monoplace chamber because it is filled with 100% oxygen.

The following measures should be taken to prevent fire in a monoplace chamber:

- There should be no electrical equipment inside the chamber. All leads for diagnostic equipment should be connected to instruments outside the chamber. All ignition sources inside the chamber should be eliminated.
- There should be no nylon garments inside the chamber.
- The patient should not use an oil-based or volatile cosmetic (facial cream, body oil, or hair spray) before a hyperbaric session.
- In case of fire, prompt decompression should be performed and the chamber opened. Fire precautions should be continued outside the chamber until the oxygen soaked into the garment or the mattress under the patient has dissipated.

For multiplace hyperbaric chambers, guidelines of the U. S. National Fire Protection Association should be followed (NFPA-56D dealing with hyperbaric facilities, and NFPA-53M dealing with fire hazards in oxygen-enriched environments 1987). The standards include the following basic points:

- All equipment should be designed and tested to be intrinsically safe for hyperbaric conditions, i.e. it must be pressure tested and spark proof.
- All wiring and fixed electrical equipment must comply with NFPA-70, National Electrical Code, Article 500, Class I, Division I.
- All equipment, circuits included, must be waterproof, explosion proof, and from the chamber's sprinkler system.

The following additional measures should be taken in multiplace chambers:

1. No volatile or flammable liquid should be allowed inside the chamber.
2. Lubricants for mechanical devices inside the chamber should be of the halogenated polymer hydrocarbon type. All combustible lubricants should be avoided.
3. Electric motors should be replaced by air-driven or hydraulic motors.
4. Oxygen concentration in the chamber must be kept below 23%. If it goes over 25%, the oxygen supply should be shut off until the source of the leak is found.
5. Fire-detecting systems, manual or automatic, should be installed. The latter should have a safeguard for false alarms.
6. A fire extinguishing system should be provided. Pressurized water should be supplied by a built-in flooding system with additional hand-held hoses. Fire drill and escape procedures should be practiced periodically.

NFPA 99, Chapter 19, has specific guidance for fire extinguishing systems in class A (multiplace) chambers (National Fire Protection Association 1996). The important points are:

- Fire extinguishing systems must be capable of activation from inside or outside of chambers.
- Water is the extinguishing element of choice.
- Each member of the hyperbaric team should be trained in activating the chamber fire extinguishing system.
- NFPA has no guidelines on extinguishing fires in monoplace pure-oxygen chambers as fires in this atmosphere are not survivable.

Use of Portable Hyperbaric Chambers in Patient's Rooms

It is safe to use a portable hyperbaric chamber in a patient's room in a hospital provided all the precautions for an oxygen rich environment are observed and adequate technical supervision is provided.

Particular measures to be taken are:

1. All combustible material should be removed from the room
2. Electrical appliances should be placed at least 5 ft (1.5 m) away from areas where the oxygen concentration is greater than 23.5%.
3. All personal items likely to produce static discharges should be removed from the patient.

Regulatory Issues Relevant to Hyperbaric Medicine

There does not appear to be clearcut single authority for regulating hyperbaric medicine in any country. In the United States, the local fire marshal's office enforces the safety regulations of the National Fire Protection Association. The Food and Drug Administration (FDA), which is the main regulatory authority for pharmaceuticals and medical devices, had a rather background role in clinical hyperbaric medicine in the past but it is becoming more significant now. Oxygen is classified as a drug by the FDA. Therefore, both its application and the devices used to administer it fall under FDA's jurisdiction. Hyperbaric chambers are medical devices used for the administration of oxygen and are subject to FDA control which applies to all medical devices which entered into use since 1976. Hyperbaric chambers constructed prior to 1976 are not subject to FDA control.

Medical devices are divided by the FDA into three classes with differing levels of FDA involvement according to the class:

- **Class I:** General controls. These are simple devices where performance is not much of a concern, such as tongue depressors. Notification of intention to market the device is required under Section 510 (k) of the Safe Medical Device Amendments enacted in 1976. FDA clearance of the Premarket Notification (hence the term 510K) is required prior to marketing the device or placing it for commercial distribution.
- **Class II:** Special controls. These are complex devices where performance is a concern, but at a somewhat general level. Class II devices must comply with general controls and the requirement of some applicable standards. A 510K Pre-market Notification to the FDA is required. FDA clearance of the Pre-market Notification is required prior to marketing the device or placing it in commercial distribution.
- **Class III:** Pre-market approval. These are generally devices that are directly related to patient life support with a substantial risk of injury in the event of malfunction. An example is a cardiac pacemaker. Pre-market approval by the FDA is required. The resulting design and manufacturing controls are very strict.

Hyperbaric chambers are considered to be class II devices and the applicable industry standard is NFPA 99, Chapter 19 and "Safety Standard for Pressure Vessels for Human Occupancy (PVHO-1)" issued by the Safety Code Committee of the ASME.

All classes of medical devices are subject to the FDA's **Good Manufacturing Practice** (GMP) regulations. These are similar to the international quality assurance regulations (ISO 9000, ISO 9001, etc) that have come into widespread use in recent years. The main requirements are:

- As established design for the product (e.g., drawings) approved by some reasonable person.
- Production in accordance with the design
- Testing to confirm performance in accordance with design requirements
- Receipt control and inspections of incoming materials
- Established procedures for resolving problems and customer complaints
- Production documentation sufficient to maintain accountability and to confirm that the above requirements are being met.
- The manufacturing establishment and the product must be registered annually with the FDA.

Conformance with the FDA's rules as they apply to the manufacture of hyperbaric chambers is usually not difficult in a technical sense. However, it does require a commitment to procedural controls that can be difficult to maintain.

"**Labeling**" is interpreted by the FDA to mean just about everything the manufacturer says about what the device can be used for and how it can be used. In case of oxygen, the recognized claims are the indications recommended by the Undersea and Hyperbaric Medical Society.

Adultered devices are prohibited by the FDA. This term applies to devices that are:

- Built in an unregistered establishment
- Built without a cleared 510K Premarket Notification
- Altered or otherwise not built in accordance with the approved design

Avoidance of appearance of endorsement of products. Manufacturers are not permitted to refer to their FDA 510K Premarket notification nor resulting FDA clearance in advertising in any published literature. However, a manufacturer can respond to a request from a potential customer regarding whether or not a manufacturer has a cleared 510K Pre-market Notification for a specific device.

Regulation of hyperbaric chambers varies in other countries. A European code of good practice for hyperbaric oxygen therapy represents the harmonized European view on safety in therapeutic hyperbaric facilities and can be used as a reference document for European countries for guidelines, regulations, and standards in hyperbaric medicine (Kot *et al* 2004). One of the countries with very strict technical regulations is Germany where a certificate from an organization called TÜV (Technischer Überwachungsverein) is required before a hyperbaric chamber can be approved for use. Guidelines for quality control of laid down by GTÜM (Gesellschaft für Tauch- und Überdruckmedizin e.V.) which is an organization for diving and hyperbaric

medicine. Germany has an excellent record of safety in hyperbaric medicine and no mishaps have occurred in recent years. Currently all the hyperbaric chambers approved for use in Germany are multiplace and monoplace chambers are not allowed because of the fire hazard.

Staffing of Hyperbaric Facilities

All personnel employed in hyperbaric facilities should, of course, be properly trained, and familiar with all relevant safety precautions and decompression procedures.

Paramedical personnel are hyperbaric technicians and nurses. The technicians are mostly concerned with the operation and safety of the chamber but they should also have an elementary knowledge of hyperbaric medicine. Nurses are concerned mostly with the care of the patients before, during, and after HBO treatments. Although they are expected to have a fair medical knowledge of conditions treated by HBO, they should also be familiar with the operation of the hyperbaric chambers. The role of nurses in hyperbaric medicine has been reviewed elsewhere (Leifer 2001)

The occupational health and safety of hyperbaric attendants is an important issue for staff of hyperbaric medicine units. The reported incidence of DCI in attendants ranges from 0.01% to 1.3%. This is mostly related to depth of pressure exposure. DCI can be prevented by oxygen breathing and rotation of attendants. Ear trauma is a frequent complaint. No complaints have been reported from physical therapists carrying out treatments on patients at 1.5 ATA on a daily basis for several weeks. The health and safety record of hyperbaric chamber attendants has been very good with one death reported.

Conclusions

There is a great variety of hyperbaric chambers available and the hyperbaric physician has to choose the equipment best suited to the needs of his unit and according to the financial resources. The choice of ancillary equipment also depends upon the requirements. In general, the operation of hyperbaric chambers is safe if the safety precautions are followed. There is still room for improvement in the technical devices for monitoring the patients during hyperbaric treatment.

The basic technology for hyperbaric chambers is well established, though innovations continue to be made according to requirements. Gas supplies, the chamber hulls, control systems, monitoring equipment, and safety devices are constantly being adapted according to the most recent technical developments. Subtypes of hyperbaric chambers such as those for treatment or training or experimental use require different technical devices. Alarm as well as technical monitoring systems, fire-fighting equipment, and pressure locks are absolute requirements for any hyperbaric chamber. In chambers used for therapeutic purposes, facilities for invasive as well as noninvasive patient monitoring need to be ensured.