

## **Portable Mild Hyperbaric Chambers**

# **Operating and Reference Guide**

PORTABLE MILD HYPERBARIC CHAMBERS

## **Operating and Reference Manual**

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### Chapter One



## Introduction

Portable chambers feature safety, ease and flexibility

his manual explains functional aspects and operation of the PORTABLE MILD HYPERBARIC CHAMBERS. It is designed to take you step by step through Chamber Space Preparation, and Initial Setup, Occupant Treatment Preparation, Chamber Operation, and Safety Considerations and Contraindications for Chamber usage.

The revolutionary design of the Mild Hyperbaric chambers offers a safe and effective means of providing mild hyperbaria. Its unique design allows the mild hyperbaric chamber to easily fit in the office, the clinic, and even a home.

## Chapter Two

# 2

# Product Descriptions and Specifications

Portable chambers in a variety of styles to suit your needs



#### SOLACE 210 PERSONAL SYSTEM

#### Main Body (the bladder)

- Durable double-sided 44 oz. urethane coated polyester
- Not compromised by temperature extremes
- Portable—folds for transport in carry bag
- Dual-redundant steel air-exchange/regulator valves
- External pass-through port—1/8" NPT
- Air Pressurization/ depressurization Valve accessible internally and externally
- Reinforced zipper assembly accommodates higher operation pressure



#### Occupant observation

- Three windows incorporated into urethane shell
- Room light illuminates chamber interior
- o Direct audible communication with patient

#### **Operational Specifications**

- Time to Inflate: 3-5 minutes
- Maximum operating pressure 4 PSI

WEIGHTS	LBS	KG
BLADDER	27.0	12.2
COMPRESSOR	27.5	12.4
BOLSTERS	11.5	5.4
MATTRESS	11.0	5.2
FRAME	18.0	8.2

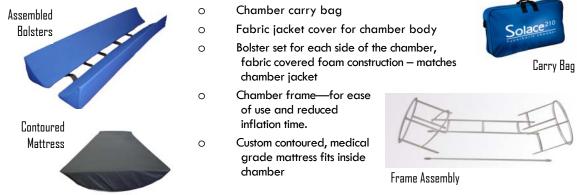
DIMENSIONS		
CHAMBER INFLATED	INCHES	METERS
LENGTH	92.0	2.33
DIAMETER	22.0	0.56
CIRCUMFERENCE	70.0	1.80
VOLUME	<b>81</b> FT <sup>3</sup>	2.3 M <sup>3</sup>

#### Peripheral equipment



- 10 ft. medical grade hose; quick disconnect valve
- Analog pressure gauge
- High efficiency inline air filtration system—filters air down to 0.01 microns
- Double head oil-less 1/4 hp compressor with dual air-intake filters

#### Accessories



## 4 PSI HEAVY DUTY 21"

#### RESPIRO 270 PROFESSIONAL SYSTEM

#### 4 PSI HEAVY DUTY 21"

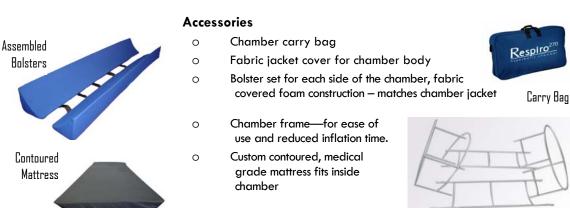
#### Main Body (the bladder)

- Durable double-sided 44 oz. urethane coated polyester
- Not compromised by temperature extremes
- Portable—folds for transport in carry bag
- Dual-redundant steel air-exchange/regulator valves
- External pass-through port—1/8"-3/8" NPT
- Air Pressurization/ depressurization Valve accessible internally and externally
- Reinforced zipper assembly accommodates higher operation pressure
- Large opening for patient placement

#### **Operational Specifications**

- Time to Inflate: 4-6 minutes
- Maximum operating pressure 4 PSI
- Recommended operating temperature: 72° F

WEIGHTS	LBS	KG
Bladder	29.5	13.4
COMPRESSOR	27.5	12.4
BOLSTERS	11.5	5.4
MATTRESS	12.5	5.6
Frame	24.5	11.2
DIMENSIONS		
CHAMBER INFLATED	INCHES	METERS
LENGTH	89.0	2.25
DIAMETER	27.0	0.69
CIRCUMFERENCE	87.0	2.10
VOLUME	119 FT <sup>3</sup>	3.38 M <sup>3</sup>



Frame Assembly

#### **Occupant observation**

- Three windows incorporated into urethane shell
- o Room light illuminates chamber interior
- Direct audible communication with patient
- Large Head Window



#### **Peripheral equipment**



- 10 ft. medical grade hose; quick disconnect valve
- Analog pressure gauge
- High efficiency inline air filtration system—filters air down to 0.01 microns
- Double head oil-less 1/4 hp compressor with dual air-intake filters

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#### VITAERIS 320 CLINICAL SYSTEM

Large Top

Window

#### Main Body (the bladder)

- Durable double sided 44 oz. urethane coated polyester
- Not compromised by temperature extremes
- Portable—folds for transport in carry bag
- Dual-redundant steel airexchange/regulator valves
- Reinforced zipper assembly accommodates higher pressure
- Air Pressurization/ depressurization Valve accessible internally and
- External pass-through port—3/8" NPT

#### Pressurization

- Time to Inflate: 5 8 minutes
- Maximum operating pressure 4 PSI

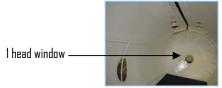
WEIGHTS	LBS	KG
BLADDER	38.0	17.4
COMPRESSORS	55	24.8
BOLSTERS	12.5	5.6
MATTRESS	11.0	5.2
FRAME	29.0	13.2
DIMENSIONS		
CHAMBER INFLATED	INCHES	METERS
Length	93	2.36
DIAMETER	33.5	0.85
	107	2.72
Volume	190 FT <sup>3</sup>	5.43 M <sup>3</sup>

## Occupant observation

 Four windows incorporated into urethane shell



- Room light illuminates 2 side windows chamber interior
- o Direct audible communication with patient



#### **Peripheral equipment**



- 10 ft. medical grade dual pump hose; quick disconnect valve
- Analog pressure gauge
- High efficiency inline air filtration. Filters air down to 0.01 microns
- 2 Double head oil-less 1/4 hp compressors with dual air intake filters

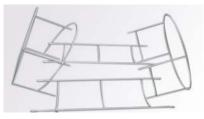
Assembled Bolsters Contoured Mattress

#### Accessories

- Chamber carry bag
- Fabric jacket cover for chamber body
- Bolster set for each side of the chamber, fabric covered foam construction – matches chamber jacket
- Chamber frame—for ease of use and reduced inflation time.
- Custom contoured, medical grade mattress fits inside chamber

Carry Bag





Frame Assembly

#### 4 PSI HEAVY DUTY 32"

## **Specifications—All Chambers**

#### **Relief Valves (Air Exchange Valves)**

The chamber is equipped with two, stainless steel RELIEF VALVES – one as a regulator and the other as a redundant backup. Fresh air is constantly pumped into the chamber while 'old' air is exhausted via these RELIEF VALVES (AIR EXCHANGE VALVES) to eliminate  $CO_2$ 

buildup. These valves also regulate (limit) the

pressure in the chamber. Both relief valves will begin to release air at approximately 4 PSI and will continue to release air during operation. In previous models, white protection caps are installed on top of the valves



Previous model, white caps shown above

for safety and must be in place at all times when the chamber is in operation. It is imperative that these caps not be removed by anyone. Furthermore, the release valves under these caps are not to be tampered with. Valves are pre-set at the factory and are calibrated with the provided compressor system.

> Warning: Do not tamper with relief valves or the covers. Improper use can result in serious injury to the user or occupant and irreversible damage to the chamber bladder. If the white covers are damaged or missing, stop using the chamber and contact your distributor for replacements.

#### Pressure Gauge



The chamber is equipped with an ANALOG PRESSURE GAUGE that monitors the internal pressure of the chamber. This gauge is calibrated in PSIG (pounds per square inch - gauge). Ambient pressure will be displayed as 0 PSIG.

The chart below shows the conversion from the gauge pressure (PSIG) to various units of measurement commonly referred to in the diving/Hyperbaric industry.

Pressu	r <b>e Table</b> Psi	g (gauge press	ure)		Altitud	e	Depth- S	ea water
PSIG Pounds /Square Inch	ATA Atmospheres Absolute	atm Atmospheres	Hg MmHg	Millibar <sup>mbar</sup>	Feet/ / Ft	Meters m	Feet / fsw	Meters msw
0	1.00	0.00	760	1014	0	0	0.0	0.00
1	1.07	0.07	812	1083	-1598	-487	2.3	0.69
2	1.14	0.14	864	1151	-3094	-943	4.5	1.37
3	1.20	0.20	915	1220	-4511	-1375	6.8	2.06
4	1.27	0.27	967	1289	-5843	-1781	9.0	2.74

\*Altitude calculated using Atmospheric Pressure Formulae from http://www.physics.usyd.edu.au/~mar/gurps/science/pressure.html

#### **Dual Zipper Sealing System**

The chamber is equipped with a patented "ZIPPER SEAL" SYSTEM. Two nylon zippers used in conjunction with an AIR-SEALING GASKET create a unique seal that allows the chamber to hold pressure safely while providing easy entry/egress for the user. Each zipper has a double-sided head that allows the user to zip or unzip the chamber even from the inside. With the proper training, a user can easily give 'self treatments' a feature that no other hyperbaric chamber can offer.







sealing gasket

Air sealing gasket

#### **Quick Disconnect Valves**



"Chamber end" (above left). Compressor end" (above right)

Each chamber system comes with a 10-foot medical grade AIR SUPPLY HOSE that connects the pump to the chamber bladder. QUICK-DISCONNECT VALVES couple the units to the hose.

There are two types of quick-disconnect valves at opposite ends of the air hose. The CROSSHAIRS-

THROATED VALVE will attach to the chamber, and the NIPPLE-THROATED VALVE will attach to the compressor. The hose ends will also be labeled 'Chamber End' and 'Compressor End' to visually aid the user.

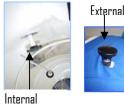


Nipple-type

**Note:** For chambers manufactured after September 2002, there is only one type of QUICK-DISCONNECT VAVLE-the CROSSHAIRS THROATED TYPE (shown above, right), on both ends

of the hose. Either end of the hose may them be connected to the COMPRESSOR or to the CHAMBER. There is no special labeling for the hose ends.

#### Pressurization/Depressurization Valve





Turn clockwise or counterclockwise



The PRESSURIZATION/DEPRESSURIZATION VALVE is located near the large view window for easy access by the occupant. It extends internally and externally. By simply turning the knob clockwise, this valve can be used by the occupant inside the chamber to depressurize and deflate the chamber for ease in exiting.

To depressurize the chamber from outside, turn counter-clockwise. Remember to do this slowly when someone is inside the chamber. This value is also used to decrease the pressure to a lower PSI (POUNDS PER SQUARE INCH), if necessary, by slightly opening the valve. Watch the pressure gauge until the pressure reaches the desired lower PSI.

To pressurize from outside the chamber, turn clockwise until closed. To pressurize from the inside, turn counter-clockwise.

#### Air Supply Hose

The air supply hose is a medical grade hose. It is attached to the quick disconnect valves, which will attach to the outflow side of the HIGH EFFICIENCY AIR FILTER and to the air intake site of the chamber, as described in the "QUICK DISCONNECT VALVES" section above.



#### Compressor



Gast OIL-LESS DUAL COMPRESSOR for medical use, with dual intake filters. 1/4 hp., model DAA-P103EB (9C303A) with quick-start capacitor.

Do not use any other COMPRESSOR or PUMP with this hyperbaric system—may cause injury.

#### Air Filtration System

**COALESCING** HIGH-EFFICIENCY AIR FILTER attached to compressor outflow.

Filters and removes particulates from the compressed air flowing into the chamber down to 0.01 microns. Takes out smoke, smog and other pollutants.

This exceeds the ratings of the HEPA media rated at 99.9% efficiency at 0.3 microns. Consider that 0.3 micron is 1 /75 of an inch, or 1/300 the diameter of the human hair. It traps micro particles and vapors.



#### Carry Bag

Yes! The chamber fits inside a durable, NYLON-CONSTRUCTION CARRY BAG, which is provided for convenient chamber transport.



Mattress



A CONTOURED MATTRESS, which fits the length of the chamber, provides a comfortable surface inside the chamber. It is easy to clean and folds for convenient storage.

#### Frame

An optional, HEAVY-GAUGE, METAL FRAME is also available for easy entry into and egress from the chamber. Four pieces comprise the frame assembly for

portability and storage. It assembles in minutes with the 'allen wrench' provided, and will provide a further convenience during treatment. The use of a frame is highly recommended, especially with the larger chambers.



M	Th
HA	TH
4	TI

21" chamber frame, shown above

32" chamber frame, shown to the left

#### **Chamber Jackets**

CHAMBER JACKETS cover the outer urethane body (bladder) of the chamber. They come in royal and navy blue gabardine, and may be machine laundered as necessary.

#### **Bolsters**

Each system comes with TWO FABRIC-COVERED FOAM BOLSTERS, which cradle the chamber and prevent it



from rolling. The bolsters attach to each other via Velcro closures, forming a support for the chamber. When the chamber is not in use, the bolsters may be folded in half and stored. The gabardine covers match the chamber jackets, and may also be machine laundered.

### Chapter Three

# 3

# Preparation for Chamber Operation

Easy to place and operate



Above: 27" chamber on elevated platform



Above: 21" chamber on massage table

## The chamber may be set up and operated:

- On a table—such as a treatment or massage table—low enough for the person to easily and comfortably access the chamber. The 21" chamber is best suited for this location.
- On a bed or cot
- On the floor—preferably with a cover or mat beneath the chamber. The 32" and 27" chambers are best suited for this location.
- On a permanent structure constructed of wood, for example, with a recessed top to hold a cushioned pad as the base for the chamber and a high enough platform to allow a lift system.
- □ In an emergency setting
- Note: Consider setting up the chamber in a cool location or near an air-conditioning vent, as pressure changes will increase the temperature inside the chamber by about 3 to 5 degrees Fahrenheit.

**Note:** No specialized training is required to operate the portable mild hyperbaric chamber. However, please follow the "INITIAL CHAMBER SETUP" procedure before administering treatment.

There are no known usage hazards associated with these portable mild hyperbaric chambers. Please refer to the "SAFETY CONSIDERATIONS, PRECAUTIONS AND CONTRAINDICATIONS" section for more information.

#### **Chapter Four**

# 4

## **Initial Chamber Setup**

This Setup Procedure is a MUST!

The chamber should initially be set up, pressurized and run for about two hours **before any treatments are** given (i.e. without human occupancy). This permits full testing of the chamber for proper setup.

The chamber should be set up in an air-conditioned or well-ventilated room, depending on the ambient room temperature. Remember that the temperature inside the chamber will be a little higher than the temperature in the room. This will become important later with an occupant inside the chamber.

You may also want to set up the compressor as far away from the chamber as possible in order to reduce its sound within the chamber.

## HOW TO SETUP:

Your chamber comes in three to four boxes—one for the chamber and compressor, one for the bolsters, one for the mattress and frame (if included), and one for the frame straight supports (if included).

#### **BOLSTER SETUP**:

Set up the FABRIC-COVERED FOAM BOLSTERS first. They ship folded in half, with the covers open. Straighten the two foam sections of each bolster so that they form one long piece and close the Velcro cover over them. Separate the two covered



bolsters and place them on the space you have prepared (Chapter 3), with the curved sides facing inside and upward.

Notice that there are five (5) connecting straps, each with a

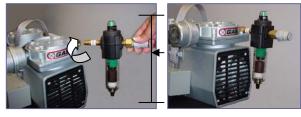
long Velcro patch. Evenly connect all five straps at the inside-most portion of the Velcro patch for the 21" SOLACE, toward the middle for the 27" RESPIRO, and at the end of

the Velcro patch for the VITAERIS 32" chamber. The chamber will later be placed snugly, face-up between the bolsters, as shown.



You may choose a level surface such as a platform or massage table

#### PUMP SETUP FOR SOLACE 210 AND RESPIRO 270:



Turn clockwise into place, fig. 1 Filter attac

Filter attached vertically, fig. 2

- First: Attach the HIGH-EFFICIENCY AIR FILTER to the compressor connection at the site labeled "ATTACH FILTER HERE". Turn the filter clockwise to tighten. The filter should remain in a vertical position, as shown in figure 2.
- Attach the hose to the filter at the connector end labeled "COMPRESSOR END." In lieu of



a label, look inside the QUICK-RELEASE VALVE for the NIPPLE-THROATED CONNECTOR HEAD. **Note:** for chambers manufactured after September 2002, all quick release valves are only crosshairs throated. No special labeling exists. Simply attach one side of the hose to the pump.

□ Find a power outlet that will not be disturbed during the time of treatment and plug in the COMPRESSOR POWER CORD for the pump.

#### PUMP SETUP FOR VITAERIS 320:

**First:** Attach the two HIGH-EFFICIENCY AIR FILTERS to their respective compressor connections



at the sites labeled "ATTACH FILTER HERE". As shown above, turn the filters clockwise to tighten. Both filters

should remain in vertical positions, as shown in figure 2 above.



Attach both short ends of the "Y-SHAPED" HOSE to each filter at the connector ends labeled "COMPRESSOR END." In lieu of a label, look inside the QUICK-RELEASE VALVE for the NIPPLE-THROATED CONNECTOR HEAD.

**Note:** for chambers manufactured after September 2002, the QUICK-RELEASE VALVES on all 3 ends of the hose are the CROSS-HAIRS THROATED CONNECTOR types. No special labeling exists. Simply attach the short ends of the Y-SHAPED HOSE to the COMPRESSORS.

□ Find a power outlet that will not be disturbed during the time of treatment and plug in the COMPRESSOR POWER CORDS for each pump.

#### CHAMBER SETUP

- Unfold the PORTABLE MILD HYPERBARIC CHAMBER and lay it on the prepared surface with the zipper and top window area facing up.
- Note: Optional FRAMES should not be inserted into the chamber now, since the chamber must first stretch out to accommodate the FRAME STRUCTURES.



Attach the other end of the hose, which has a QUICK-RELEASE CONNECTOR HEAD labeled "CHAMBER END," to the chamber. In lieu of a label, look inside the QUICK-RELEASE VALVE for the CROSSHAIRS-THROATED CONNECTOR HEAD. The chamber QUICK-DISCONNECT, AIR-INTAKE RECEPTOR VALVE is located at the top of the chamber near the zippers and the large view window.

Note: for chambers manufactured after September 2002, all QUICK-DISCONNECT VALVES are CROSSHAIRS-THROATED. No special labeling exists. Simply attach the other end of the hose to the chamber.



The COMPRESSOR must be "on" and hooked up to the chamber before Note: human occupancy in the chamber; it must remain on until the person completely exits the chamber.

These mild chambers have been designed and calibrated for use with the compressors provided. Do not attempt to use any other pump to pressurize these chambers.

### CHAMBER PRESSURIZATION TEST

#### **CLOSE CHAMBER**

With the COMPRESSOR(S) "ON", close the INNER ZIPPER of the chamber first, ensuring complete closure by lifting up the GASKET and pushing the ZIPPER SLIDER all the way to the end. The ZIPPER HEAD should be laid flat in order to avoid buckles in the gasket.



Inner zipper closes from the inside and outside

Lay the two (2) GASKET FLAPS flat (one at a time) and tuck them under the



Tip: keep gasket flap flat into crease

WHITE OUTER ZIPPER FLAP at the crease between the TOP ZIPPER FLAP and the chamber body. Make sure that there are no buckles in the GASKET to ensure a proper seal. Carefully smooth out any wrinkles in the RUBBER AIR-SEALING GASKET by using a massaging motion with the hands over the GASKET FLAPS. Then close the OUTER ZIPPER a few inches at a time to make sure the GASKET is completely smooth and flat. Again, massage the WHITE OUTER ZIPPER FLAP over the GASKET and INNER

ZIPPER to ensure a tight seal.

Note: Failure to close both zippers completely will decrease the effectiveness of the chamber by not allowing it to attain or maintain full pressure.







From outside the chamber, turn the PRESSURIZATION/DEPRESSURIZATION VALVE clockwise until it stops turning. If this valve is not screwed tightly enough, the chamber will not attain or maintain full pressure. Be careful not to screw the valve too tightly as this will strip or break the THREADING.

Turn valve clockwise to close



As the chamber inflates, constantly massage the ZIPPER to smooth out the GASKET SEAL.





When the chamber reaches a SEMI-HARD STAGE, apply pressure directly to the ZIPPER by pressing with the palm of your hand. This may be necessary at the front and/or the end of the ZIPPER TRACK. Then, lean on the CHAMBER ZIPPER with your crossed arms and upper body weight evenly on the zipper. You will feel the pressure building beneath your body weight. Keep this pressure until the chamber goes from SEMI-HARD TO HARD (1/2 TO 1 POUND PER SQUARE INCH -PSI) and then release.



The patented zipper system seals and works only under pressure. Therefore, leaning on the chamber creates this pressure that seals the zipper—allowing it to build its own pressure.



Watch the PRESSURE GAUGE on top of the chamber to assure the indicator reaches 3 - 4 PSI and remains at or near 3- 4 PSI (depending on the style of chamber you have).

## DEPRESSURIZE

Once you have taken the chamber to its maximum pressure, you may depressurize by turning the PRESSURIZATION/DEPRESSURIZATION VALVE counterclockwise. You may do this quickly since there is no occupant inside the chamber. When sufficient air has gone out of the chamber—there is considerable slack in the zipper and throughout the chamber—you may open the zippers and the chamber.



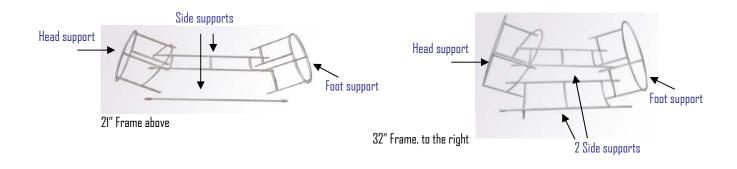
#### Familiarize yourself with this entire procedure before treating patients.

You should be able to reach the desired pressure with ease before attempting to occupy the chamber. If necessary, practice the INITIAL CHAMBER SETUP PROCEDURE until you are comfortable enough with your ability to operate the chamber. If additional help is needed, please call your distributor. Qualified staff will be happy to assist you. See also, the TROUBLESHOOTING section of this manual.

#### FRAME INSTALLATION (OPTIONAL)

Once the chamber has been inflated, stretched out through the pressurization procedure, and depressurized again, you may install the chamber frame.

The frame comes in four pieces: A head support, a foot support and two side supports. As their names suggest, they support the sections of the chamber body.



**To install the frame**, you will need to open the chamber zipper and wiggle the foot support of the frame into the foot end of the chamber. This will take some manipulation.



Foot support installed at foot of chamber

Next, you will need to install the head support into the viewing-window end of the chamber. To aid with the orientation of the head support, it will come labled "top". It is also helpful to note that the shape of the head support is wide at the top and allows the view window to remain unobstructed by the frame. As in the foot support installation, you will need to wiggle the head support into place.

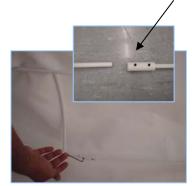


Head support inserted through chamber opening

Finally, you need to install both side supports, one at a time by aligning the couplings of the side support to the open ends of the foot and head supports. **Note:** Make sure each rod is *fully* inserted into its coupling. Use the 'allen wrench' provided to lock the couplings into their respective positions.



Side support being inserted into chamber opening





'Side support tightened into place

**Note:** The 21" chamber, being smaller and shorter has one triple-H side support and one single bar support. The single bar support should face the side into which patients will be entering the chamber. The lowered bar makes it feasible to locate the chamber on a massage table with a step stool to facilitate entry into the chamber.

'Allen wrench' being used to tighten

side support into place

The 32" chamber, being larger and thus taller, has two triple-H side supports, over which patients will step when they enter the chamber. This 'easy-to-step-into' feature makes it feasible to locate the chamber on a mat on the floor.

**Installation Hint**: It may be easier to install the 32" frame from inside the chamber. To do this, simply open the chamber, insert the four frame supports into their general locations, climb in, and pressurize the chamber. When the chamber inflates, you will have sufficient room to manueover the chamber supports into place. **Again**, make sure the rods are *fully* inserted into the couplings. Lock the pieces into place with the 'allen wrench' provided.

#### **Chapter Five**

# 5

# Preparing the Person for Hyperbaric Therapy

A comfortable experience: Mind and Body

Introduce the chamber in its inflated form to first-time patients. This shows how "roomy" the chamber will be once it has expanded with pressure. Then, deflate the chamber in front of the patient and open the zippers. This will also give them insight into the process of exiting the chamber.



Also, ask the person in advance about any ear problems they may have. Determine if they have problems in an airplane equalizing the air pressure on their eardrums, or if they have problems going up in an elevator. If they are aware of any prior problems, pay close attention as the chamber starts to pressurize.

If they experience ear pain (otic barotrauma) at the time of treatment, take the pressure back down slowly (by slightly opening the DEPRESSURIZATION VALVE) until their ears are comfortable again, and then gradually increase the pressure until you reach the optimal pressure. Some people at first may require a lesser treatment pressure.

The "VALSALVA MANEUVER" (closing the mouth, pinching the nostrils and blowing) will help to equalize the pressure on the eardrums. In the alternative, yawning—unlocking the lower mandible—often stretches the muscles around the ears enough to allow the eardrums to equalize.

**Reminder:** Pressurizing, even though mild, may cause ear discomfort (much like that experienced in an airplane). Often, lowering the pressure, for about a minute, to point where the person does not feel discomfort will enable the patient to equalize their ears. The pressure may then be increased incrementally, over several minutes, until full pressure is achieved.

If the patient experiences excruciating pain, it may be a sign of other existing medical problems, and the patient's physician should be consulted. Hyperbaric treatment may be resumed upon the advice of the medical counselor.

### Considerations before Treatment:

#### NECESSITIES



 To make the HYPERBARIC TREATMENT experience more pleasant: The person should get as comfortable as possible. That means taking care of restroom breaks and/or drinking water before getting into the chamber.

#### CLOTHING

- The person may go into the chamber fully clothed. Women should remove nylon stockings. Clothing should be loose. A treatment gown or shorts and tee shirt work well.
- Shoes, jewelry, or any sharp objects that could damage the chamber should be removed.
- Disposable feet and hair covers may be used for increased sanitation.

#### BREATHING NORMALLY

- Explain to the person, that the air inside the chamber will be continually exchanged, and that they should have no difficulty breathing.
- The person should be advised to relax and breathe normally.



Fig. 3 Comfort factor: regulating the pressure from the inside

#### SAFETY AND REASSURANCE

 Show the person the white depressurization /air release valve which extends inside the chamber and is located near the large view window. Let them turn the valve so they can

see how easy it is to depressurize the chamber from inside (fig 3.). This increases their comfort level and removes any anxiety for first time users.

• Also point out the double zippers that unzip from inside (fig 4).



Fig. 4 Reassurance: Double zippers

#### CHAMBER PRESSURIZATION

- Make sure that the person knows that the chamber will take a few minutes to fully pressurize. It should be stressed that the chamber will not inflate instantly. *This is normal*.
- Pressurization time varies (usually from 3 to 8 minutes), according to the style chamber you have. Refer to the PRODUCT DESCRIPTIONS AND SPECIFICATIONS Chapter.

#### COMMUNICATION

- The person may communicate with the outside attendant, more clearly when the attendant is standing by and looking into the chamber window.
- A two-way communication system may also be used during chamber operation.

All persons treated in the hyperbaric chamber must be informed that, in the highly unlikely event of a rapid decompression, they must EXHALE. (See PULMONARY HYPEREXPANSION under the SAFETY CONSIDERATIONS Chapter for more details).

### **Chapter Six**

# 6

## Claustrophobia

How to overcome claustrophobia

Nature of Claustrophobia: The most important problem for a claustrophobic is the feeling of "being trapped" in an enclosure.



There is an initial feeling of anxiety for some people when they first see the chamber. Face it, the chamber is a new "space age" looking device, and they may be fearful. However, fears about something viewed as "unfamiliar" will generally be ameliorated by examining the chamber thoroughly and becoming acquainted with its various safety features and healthpromoting benefits.



**Remedies**: We have found that only about 10% of those who say they are claustrophobic, actually are. The most important treatment is the very first treatment. After that, the person is familiar and comfortable with the process. For this reason we recommend that everyone be treated as a claustrophobic for their very first treatment.

Fig. 5 An inflated chamber is key



- Ask the person if they have any problems going into an elevator.
- Always let the person first see the chamber under pressure (fig. 5). This means, always having the chamber inflated when not in use. This gives the chamber a more substantial and attractive appearance to anyone coming in for a treatment. To do this, pressurize the chamber to the point just before the AIR EXCHANGE VALVES activate (about 2 PSI) Shut off the compressor. The chamber then stays inflated.
- If you have access to chamber frames, make use of them. Frames reduce pressurization time and keep the chamber walls distended, thus limiting the feeling of enclosure.

Always show the AIR PRESSURIZATION/ DEPRESSURIZATION VALVE to the person before they enter the chamber (fig.6). Show them that it goes through to the inside, and that it turns from the inside as well as from the outside. Explain that they may release the pressure at any time from the inside and that they may let themselves out if necessary. Let

them turn the valve to see how easily it works. Fig. 6 Air Valve and zipper are



Also show them the ZIPPER ASSEMBLYthat each zipper has an INNER AND PULL—which, if OUTER necessary, enables them to exit the chamber (at any time) without external help from you or any other individual.

The person being treated first needs to be reminded to focus on the reason they need and want to have the treatments. This is a major psychological tool in overcoming claustrophobia.

Assure them that you are not going to leave them and that they can hear you speak to them when they are inside the chamber (fig. 7). Also. assure them that you are not going to zip up the chamber until they are comfortable, and that they will help you finish closing the INNER ZIPPER.



Fig 8. Use hands to support

When they get into the chamber ask the

patient to move up under the WIDE VIEW WINDOW-while keeping the chamber wide open-and to see how much visibility there is. Make sure the window stays in a domed position. The patient may put their arms up to help assure that the deflated chamber stays up and away from their face (fig. 8). The person may then come back out of the chamber to a sitting position and breathe deeply.

Tell the person that they may go into and back out again a few more times if they wish. After their examination of the chamber, inform them that it is time for their treatment and that you will remain within eye contact.

- Some doctors have advised that a hand-held fan blowing air into the person's face is effective in reducing the feeling of not being able to breathe. Also, it may be helpful for the person to sit or lay directly under the AIR INTAKE VALVE, which blows air directly into the chamber. Remember: the AIR EXCHANGE VALVES on the chamber automatically start to exchange air circulation as soon as the COMPRESSOR is turned on. The COMPRESSOR should be on at all times during a treatment session.
- Follow all other steps in this manual, especially the sections covering "INITIAL CHAMBER SETUP," "PREPARING THE PERSON FOR TREATMENT," "OPERATING THE CHAMBER," and "EXITING THE CHAMBER."

### Summary:

The key to overcoming claustrophobia is "PATIENCE". It may require repeating some of the above steps to make the person feel comfortable with the chamber. As already mentioned, a calm-setting precedence should be established with the first therapy session. Sometimes a claustrophobic patient may end the first treatment session early. With subsequent treatments he or she will be able to remain inside for a longer periods of time, until the person becomes accustomed to the full treatment time. Reaching new milestones with each treatment, the patient will soon be able to reap the benefits of hyperbaric therapy.

### **No Surprises!**

Advise the person of the complete process. The person is giving you control of their environment, so it is crucial that there are no surprises.

Fig. 7 Visual contact allays fears



## Chapter Seven

# 7

## Treatments

A versatile chamber: Doctor and Patient

Consult with the prescribing doctor for individual protocols. In most cases, each therapy session will be 60 minutes long and will be considered as 1 dose.

Your medical advisor may recommend 1 dose every other day or 1 dose daily, and in some cases 2 doses per day.

Caution: We recommend that an attendant be present during the entire time someone is inside the chamber due to any unforeseen emergency involving the patient's condition that is unrelated to the hyperbaric chamber treatment.

### **Chapter Eight**

# 8

## **Operating the Chamber**

A few quick steps and a breath of fresh air

### 1 st PREPARE EQUIPMENT

You should have already followed the INITIAL SET UP procedure in Chapter 4. Set up the COMPRESSOR(s) by attaching all the components—FILTER(S) AND HOSE CONNECTOR(S). Find a power source and insert the POWER CORD into an appropriate power outlet.





"to compressor."

Make sure the INTAKE HOSE is connected securely to the INTAKE VALVE. Turn "on" the COMPRESSOR and leave "on" for the duration of the treatment. Securely push in the 'QUICK-DISCONNECT VALVES' to their respective attachment sites ("to chamber" and "to compressor"). Note: on chambers manufactured after September 2002, there is only one type of QUICK DISCONNECT VALVE, and it is not



Quick-disconnect valve "to chamber."

labeled. Simply attach one end of the hose to the chamber. For two pump systems, attach the short ends of the Y-shaped hose to the pumps and the long end to the chamber.

There should be no air leak from the QUICK DISCONNECT VALVES.



Chamber shown on massage table supported by bolsters

#### 2<sup>nd</sup> OPEN THE CHAMBER

The chamber should already be in its designated place (See Chapter 4). The chamber with BOLSTER ASSEMBLY may be placed on a massage table or on a pad on the floor. Depressurize, if necessary.

Open both ZIPPERS all the way. Spread the CHAMBER APERTURE open to allow entry.



Always use zipper fly when opening or closing chamber





Fig. 9 Optional internal frame holds up chamber walls for ease of entry

## 3<sup>rd</sup> ENTRY

Ask the person to step into the chamber, supporting the CHAMBER OPENING (Fig. 9). INTERNAL FRAMES are available.

## The person should enter the chamber carefully to avoid putting too much stress on the ZIPPERS.

Ask the patient to assume a sitting position at the center area of the DEFLATED CHAMBER. They should tuck their

legs into the chamber and scoot down facing the foot end of the chamber, so as to make room behind them to lay down into the chamber. Holding the zippers apart, the occupant may now lay down into the chamber. In the alternative, it may be easier to sit on your knees at the end opposite the VIEW WINDOW, so that the person may support themselves on their hands as they tuck their head (face down), shoulders and body into position under the ZIPPER FLAPS (fig. 10).



Fig. 10 A sitting position will facilitate your entry

As the person enters, they should turn and face up, with legs bent and arms supporting the chamber

Move toward domed window



away from the face, so that they may then scoot upward toward the LARGE VIEWING WINDOW. They should be able to easily see the attendant through the window. If necessary, they may use their hands to temporarily keep the window area in a domed position.



### 4<sup>th</sup> CLOSE THE CHAMBER

Hold the UPPER ZIPPER AREA up to keep the chamber off of the upper body as much as possible. Make sure the window area remains in a domed position away from the face (fig. 11).

Fig 11. A domed position relieves stress about being inside

Close the INNER ZIPPER first, ensuring complete closure by lifting up the GASKET and pushing the ZIPPER SLIDER all the way to the end. The ZIPPER HEAD should be laid flat in order to avoid buckles in the



Inner zipper closes from the inside and outside

GASKET. Both persons inside and outside the chamber should assist the completion of the closure inside to assure that it is airtight.



Fig. 12a-c

Lay the two (2) GASKET FLAPS flat (one at a time) and tuck them under the WHITE OUTER ZIPPER FLAP at the CREASE between the TOP ZIPPER FLAP and the CHAMBER BODY (fig 12a-c). Make sure that there are no bumps or buckles in the GASKET to ensure a proper seal. Carefully smooth out

any wrinkles in the RUBBER AIR-SEALING GASKET by using a massaging motion with the hands over the GASKET FLAPS. Then close the OUTER ZIPPER a few inches at a time to make sure the

GASKET is completely smooth and flat.

Again, massage the GASKET FLAPS over the INNER ZIPPER to ensure a tight seal.

Remember, if you are sealing the chamber from the inside, you must start from the outside -in.

Note: Failure to close both ZIPPERS completely will decrease the effectiveness of the chamber by not allowing it to attain or maintain full pressure.

## 5<sup>th</sup> PRESSURIZATION



From outside the chamber, turn the PRESSURIZATION/DEPRESSURIZATION VALVE clockwise until it stops turning. If this valve is not screwed tightly enough, the chamber will not attain or maintain full pressure. Be careful not to screw the valve too tightly as this will strip or break the THREADING.

Fig. 13

Turn valve clockwise to close

#### 6<sup>th</sup> CHAMBER MANIPULATION

As the chamber inflates, constantly massage the ZIPPER to smooth out the GASKET SEAL. When the chamber reaches a SEMI-HARD STAGE, apply pressure directly to the ZIPPER by pressing with the

palms of your hands (fig 13). This may be necessary at the front and/or the end of the zipper track. Then, lean on the TOP CHAMBER ZIPPER with your crossed arms and upper body weight evenly on the zipper (fig 14). You will feel the pressure building beneath your body weight. Keep this pressure until the chamber goes from semi-hard to hard (1/2 to 1 pound per square inch -PSI) and then release. For self-treatments apply pressure from the inside by pushing up.





Gauge at ½ PSI

Gauge at 4 PSI

Watch the PRESSURE GAUGE on top of the chamber to assure the indicator reaches 3 - 4 PSI and remains at or near 3- 4 PSI (depending on the style of chamber you have).



<sup>th</sup> OBSERVE

Set a clock or timer for the prescribed treatment period. Reassure the person inside that the attendant will remain with them during the entire treatment and will be regularly checking on them.

Note: If the chamber gets too warm during treatment, the PRESSURIZATION/ DEPRESSURIZATION VALVE may be slightly opened to allow the warm air to cool as the pressure drops. Close the valve again to resume treatment.

As discussed in Chapter 3 "PREPARATION FOR CHAMBER OPERATION," the chamber may initially be set up near an air-conditioning vent or other cool air source.

### **Chapter Nine**

# 9

# **Exiting the Chamber**

One, two!



Fig. 15 Turn counter-clockwise from outside to release

Turn the AIR PRESSURIZATION/ DEPRESSURIZATION VALVE counter-clockwise, slowly releasing pressure (fig. 15).

**From Inside:** Turn the AIR PRESSURIZATION/DEPRESSURIZATION VALVE clockwise, slowly releasing the pressure (fig. 16).



Fig. 16 Turn clockwise from inside to release pressure

The rate of deflation will depend upon the ear comfort of the person, but should not be less than 3 minutes. Depressurize slowly until GAUGE reaches 1 PSI, at which point the chamber may be depressurized more quickly. Take your depressurization-rate cues from the person inside the chamber.



Once the chamber has been depressurized enough to eliminate any stress on the zippers—i.e., there should be some slack in the CHAMBER ZIPPER AREA when you press down—open the zippers and exit the chamber.

#### **Reminders**:

- Depressurizing too rapidly may cause ear pain. As in the pressurizing procedure, the person may need to equalize the pressure on their eardrums by using the VALSALVA MANEUVER (closing the mouth, pinching the nostrils and blowing). In the alternative, flexing the jaw muscles, for example by yawning, may also help to relieve ear pressure.
- The person inside the chamber may easily exit unassisted, if necessary, by first turning the AIR PRESSURIZATION/RELEASE VALUE clockwise from inside to release the pressure, and thus deflating the chamber. Since the zippers have TWO-WAY PULLS, they may be unzipped from inside. First unzip the INNER ZIPPER. Then pull down on the URETHANE GASKET STRIP to view the OUTER ZIPPER and unzip the OUTER ZIPPER.
- Caution: Do not attempt to open zippers while the chamber is under pressure as this will damage the integrity of the zippers.

# Chapter Ten

## **Cleansing and Disinfecting**

Simplicity is more



#### MAIN CHAMBER:

The chamber can easily be wiped inside and outside with a cloth and cleaned with mild hypoallergenic soap and water. Do not use any bleach or harsh chemicals on the chamber bladder. A mild non-toxic disinfectant spray may be used, such as a little hydrogen peroxide mixed with distilled or purified water. Do make sure that the inside bladder is wiped dry.



There are many good non-toxic and non-caustic disinfectant sprays on the market. Keep in mind, however, that traces of the scents from the disinfectant will also linger inside the chamber. Less is best. Simplicity is key.



#### CHAMBER COVERS:

Any covers on the chamber may be machine-laundered as you would any other gabardine cloth—warm wash with mild detergent, no bleach; dry medium to low; low iron, if necessary.

# Chapter Eleven

# Safety Considerations: Precautions and Contraindications

Safety comes first

# Below, aspects of the following conditions and dangers are discussed in detail:



- Otic Barotrauma
- Decompression Sickness
- Pulmonary Hyper-expansion
- Excessive Carbon Dioxide Exposure

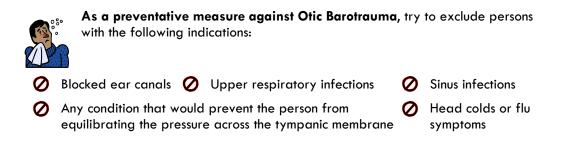
#### OTIC BAROTRAUMA



**Definition:** "Increased (non-equilibrating) pressure on the tympanic membrane causing rupture."

If the ear canal were blocked, the increase in pressure would not equilibrate across the tympanic membrane, causing an increase in ear pain as the pressure increases. A continued pressure increase under these conditions could rupture the tympanic membrane.

However, *rupture is very rare* when using the mild hyperbaric chamber. Pay attention to the patient's body signals. Pain usually alerts the person long before any rupture can occur.



Note: if pain or discomfort persists, stop inflating the hyperbaric chamber immediately. DO NOT continue treatment.

#### DECOMPRESSION SICKNESS



**Definition:** "A disorder occurring in divers; caused by a release of nitrogen bubbles into the blood due to a rapid decrease in pressure."

This is a problem usually experienced by divers after ascending too rapidly from a dive.

Note: At the low pressure that these mild hyperbaric chambers use, decompression sickness does **NOT** occur at any rate of ascent (removal of pressure).

#### PULMONARY HYPEREXPANSION



**Definition**: "Uncontrolled expansion of a volume of air in the lungs that is caused by a rapid pressure drop."

In order for this to happen the person would have had to completely fill their lungs with air, and be holding their breath at the time of decompression. Doing this would cause the air in the lungs to expand, and possibly cause damage.

Fortunately, breath holding is not a usual response during rapid decompression in a hyperbaric chamber, since the expanding air tends to stimulate exhalation.

However, because breath holding is a natural tendency while under water, divers have reported the most cases of pulmonary hyperexpansion.

In any case, do your best to breathe normally while giving or taking treatments.

Keeping this in mind, all persons treated in the mild hyperbaric chamber must be informed that, in the *unlikely* event of a rapid decompression, they must EXHALE.

#### EXCESSIVE CARBON DIOXIDE EXPOSURE



Definition: "A disorder caused by excessive carbon dioxide inhalation."

The person inside of the mild hyperbaric chamber is in an enclosed structure and is expiring carbon dioxide. This carbon dioxide is concentrated to a level that is determined by the rate at which fresh air is pumped into the chamber and released through the two air release valves.

Acceptable levels for exposure to carbon dioxide have been determined based on time of exposure as described in the following table:

Duration (Hours)	Carbon Dioxide Level (Percent)
1	3
24	1

As long as the CHAMBER COMPRESSOR is "ON" and running, fresh air will be introduced into the chamber and the equilibrium value for carbon dioxide concentration will remain at **less than one percent (1%)** 

#### OTHER PRECAUTIONS AND CONTRAINDICATIONS

- o Never use the chamber while suffering head cold or flu symptoms
- Never use the chamber if ear canals are blocked for any reason
- Never use the chamber if any alcohol has been consumed

Note: These are the same precautions one would take before traveling in an airplane

#### Further considerations:



Food consumption:

To avoid discomfort, it is best to wait a while before taking a treatment after consuming a large meal.

#### Temperature increase:



To alleviate excessive warm air that may build up inside the chamber, slightly open the air pressurization/depressurization valve to release the pressure and warm air, (since reducing the pressure reduces air temperature) and then resume pressurization by closing the valve.

It is possible that while under pressure and individual may perspire profusely and the chamber view window may fog due to excessive heat generation. While this is an uncommon occurrence, should such an event occur, the chamber may be depressurized, and the person may exit.

## FDA 510(K) CLEARANCE

The Portable Mild Hyperbaric Chambers are Class II Medical Devices. They are cleared by the FDA 510(k). The approved indications for the chamber are High Altitude Sickness (also known as AMS) and its associated mild symptoms. The chambers are cleared for sale to or on the order of a licensed practitioner.

This product has been manufactured, tested, and inspected with procedures conforming to Good Manufacturing Practices, and to Government Spec Mil-I-45208A. These chambers do not have ASME PVHO approvals at this time.

# Chapter Twelve

# Troubleshooting and Chamber Operation

## Things to check

While the operation of the chamber is relatively simple, some details should not be overlooked. Most often, careful scrutiny of chamber openings will reveal an easy solution to your concern. It is best to familiarize yourself with the chamber, its CLOSURES and SEALING GASKETS, its PRESSURE VALVES and HOSE CONNECTION VALVES. A little care will save you lost time.

That said, the two most common problems are listed below:



PROBLEM:

CHAMBER DOES NOT INFLATE PROPERLY

PRESSURE DOES NOT GO TO OR HOLD AT PROPER PSI



#### CAUSE:

If the chamber does not fully inflate or hold pressure, a momentary escape of air from one or more areas is probably the cause. Each chamber is unique, and its pressuresealing characteristics vary according to the individual construction of the SEALING GASKETS and ZIPPERS. Thus, some manipulation of the GASKETS and ZIPPERS may be required to ensure a proper seal. (Refer to Chapters 4 and 8 for details on chamber manipulation.)



## TROUBLESHOOTING:

- Move your hand close to (not touching) all connections and along the zipper, to detect any areas from which air escapes.
- Make sure the PRESSURIZATION/ DEPRESSURIZATION VALVE is in the closed position. Note: When turning valves, make sure you do not screw in too tightly and strip the housings.
- □ Check AIR EXCHANGE VALVES to verify they are screwed in tightly enough.
- The ZIPPERS should be pushed completely up toward the VIEW WINDOW, leaving as little space as possible. You may need to use one finger to push the zipper up the last centimeter of the ZIPPER TRACK. The fly of zipper should be placed flat against the zipper track, to minimize unnecessary buckles in the seal.

In order to create a tight seal, the DOUBLE GASKET between the zippers must lay completely smooth and flat, with the top flap of the GRAY GASKET tucked into the fold between the OUTER AND INNER WHITE ZIPPER FOLDS. Failure to do so will result in an excessive amount of air being released through the zippers.

- **Both** ZIPPERS must be completely closed to their utmost closed positions.
- □ Check the INTAKE HOSE fitting. Make sure the proper ends of the HOSE CONNECTORS are attached to their respective places. The QUICK-DISCONNECT VALVES are labeled before shipping, according to where they need be attached: "CHAMBER END" and "PUMP END."

In lieu of these labels, you may ascertain the CONNECTOR TYPE by simply looking into the mouth of the QUICK-DISCONNECT VALVE to see either a CROSSHAIRS-TYPE or NIPPLE-TYPE inside the connector head (See the "PRODUCT DESCRIPTIONS" chapter for more detail). The CROSSHAIRS CONNECTOR attaches to the chamber; the NIPPLE CONNECTOR attaches to the pump. Ensure that no air is escaping from these fittings by pressing them firmly into position.

- Check the HOSE ASSEMBLY and IN-LINE AIR FILTER, to insure tight seal. The filter should remain in a tightened and vertical position (See Chapter 4, "INITIAL CHAMBER SETUP" for details).
- Check the PRESSURE GAUGE to verify that it is screwed in tightly.

**Chapter Thirteen** 

13

## Warranty

#### What you need to know

All Portable Mild Hyperbaric Chambers come with a one-year manufacturer's warranty (parts and labor) from the date of purchase, by Oxy-Health Corporation, for any manufacturer defects. This warranty does not cover shipping costs to and from Oxy-Health Corporation, and is void if the chamber is used in any manner that is not construed as "NORMAL USAGE." Damage caused by the transportation of the chamber assembly is not covered by this warranty and any such claims should be directed to the carrier.

The compressor unit (including filtration system) has a one-year warranty from the date of purchase, by Oxy-Health Corporation, covering any manufacturer defects. Consumable parts (filters) are to be replaced regularly by the owner and are not covered by this warranty.

#### Limited Warranty

Oxy-Health Corporation warrants to the original purchaser the chamber to be free from defects in material and workmanship under use and operation in strict accordance with the instructions and specifications in the Oxy-Health Corporation "Portable Mild Hyperbaric Chambers: Operating and Reference Manual." Our obligation under this Warranty shall be limited to the repair or replacement of any part or parts which may be found to be defective under use and operation in strict accordance with the instructions and specifications in the Oxy-Health Corporation "Portable Mild Hyperbaric Chambers: Operating and Reference Manual." WITHIN ONE (1) YEAR FROM THE DATE OF PURCHASE, and which our examinations shall disclose to our satisfaction to be thus defective, free of charge, F.O.B. point of manufacture, provided that notice of defect is sent to Oxy Health Corporation as specified herein. Parts and components such as compressors, pumps, filters, valves, etc., furnished by Oxy-Health Corporation, but not manufactured by us, will carry the warranty of the manufacturer. Purchaser must notify us by registered or certified mail, return-receipt requested, of a breach of warranty within 30 days after discovery thereof, but not later than the warranty period; otherwise, such claims shall be deemed waived. No allowance will be granted for any repairs or alterations made by Purchaser without our prior written consent. This shall be the limit of Oxy-Health Corporation's liability for breach of warranty.

Oxy-Health Corporation does not warrant this product to meet the requirements of any safety code of any state, municipality, or other jurisdiction, and Purchaser assumes all risk and liability whatsoever resulting from the use thereof, whether used singly or in combination with other machines or apparatus. Oxy-Health Corporation shall not be liable for any loss resulting, directly or indirectly, from the use or loss of use of the Mild Hyperbaric Chambers. Without limiting the generality of the foregoing, this exclusion from liability embraces the Purchaser's expenses from downtime or for making up downtime, damages for which the Purchaser may be liable to other persons, damages to property, and injury to or death of any persons. This warranty shall not apply to any Oxy-Health Corporation product, or parts thereof, which has been repaired or altered, without our prior written consent, outside of our factory or altered in ay any way so as in our judgment, to affect adversely the stability or reliability of the Mild Hyperbaric Chambers, or has been subject to misuse, negligence or accident, or has not been operated with the Oxy-Health Corporation "Portable Mild Hyperbaric Chambers: Operating and Reference Manual", or has been operated under conditions more sever than, or otherwise exceeding those set forth in the operating instructions and specifications of the Mild Hyperbaric Chambers. This warranty shall not apply to any Oxy-Health Corporation product, which has been sold, rented, leased or otherwise conveyed by the Purchaser to another individual or entity.

This Limited Warranty is deemed to have been made in the State of California and shall be construed and interpreted in accordance with California Law. All judicial actions, suits or proceedings brought with respect to any matter under or arising out of or in connections with this Limited Warranty shall be brought in any state or federal court of competent jurisdiction in the State of California. If any term or provision of this Limited Warranty, or the application thereof to any person or circumstance, shall, at any time or to any extent, be invalid or unenforceable, the remainder of this Limited Warranty, or so much hereof that has not been deemed invalid or unenforceable, shall be valid and enforced to the fullest extent permitted by law.

This sale is made on the express understanding that there is no implied warranty that the goods shall be merchantable or an implied warranty that the goods shall be fit for any particular purpose. The buyer acknowledges that he is not relying on the skill of judgment of Oxy-Health Corporation to select or furnish goods suitable for any particular purpose and that there are no warranties which extend beyond the face thereof.

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#### FDA Warning

Caution: Federal law restricts this device to sale by or on the order of a physician.

Increasing the percentage of oxygen content in the air delivery is considered the same as administering a drug under FDA regulations. This device is intended for use with ambient air and is not to be inflated with enriched oxygen.

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