

Medical Hyperbaric System for Oxygen Therapy



Introduction

Your body's tissues need an adequate supply of oxygen to function. When tissue is injured, it requires even more oxygen to survive. Hyperbaric oxygen therapy increases the amount of oxygen your blood can carry. An increase in blood oxygen temporarily restores normal levels of blood gases and tissue function to promote healing and fight infection.

Hyperbaric oxygen therapy involves breathing pure oxygen in a pressurized chamber; the air pressure is increased higher than normal air pressure. Under these conditions, lungs can gather more oxygen than would be possible breathing pure oxygen at normal air pressure following the basic gas physics laws. Your blood carries this oxygen throughout your body. This helps fight bacteria and stimulate metabolic activities.

Moreover, Hyperbaric oxygen therapy is a well-established treatment for emergency situations as decompression sickness, a hazard of scuba diving, arterial gas embolism and severe carbon monoxide poisoning.

#1

What is Drass Hot Series

Hyperbaric Medical System HOT Series for Oxygen Therapy is the most advanced solution in terms of safety, simplicity, and design. The therapeutic chamber design merges several smart solutions guaranteeing ergonomic efficiency and safe structure. Host bedridden people or wheelchairs will be no longer a problem thanks to rectangular doors in each lock and to the space available. The Therapy Management System guarantees a safe and perfect control of the therapy progress and oxygen dosing, amusing patients with music and video. Boredom will be easily forgotten and relaxation assured in a total safe way.



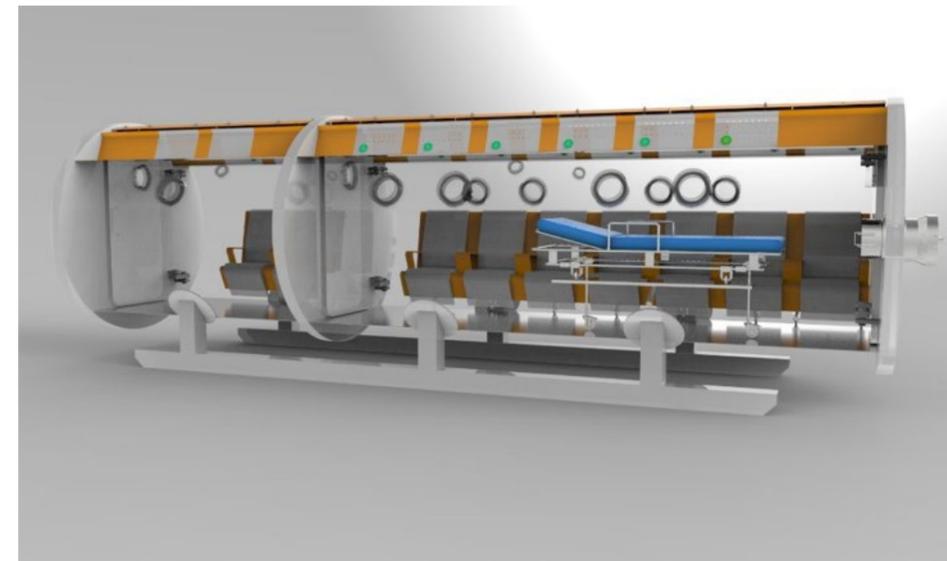
#2

How H0T Series is safe

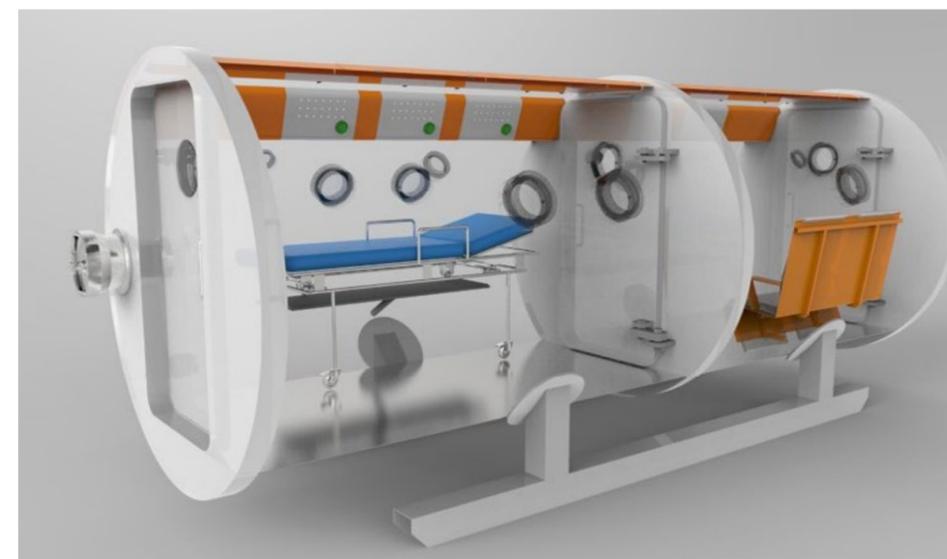
Drass risk assessment process is structured to identify and mitigate risks during the design phase of the project. The output of this process is reported in the "Hazard and Risk Analysis" which is developed on the base of the FMEA analysis. The FMEA analysis shall be developed in order to properly describe the fail safe philosophy, alarm management, redundancy and shall be included in the detailed design of the overall system.

Hyperbaric Medical Chamber

The chamber outfitting offers the highest level of comfort for the patients. Drass HOT Treatment Chambers (TC) are configured to accommodate from 6 up to 12 patients. The Therapeutic Chamber is configured with two locks: a Main Lock (ML) in order to accommodate up to 12 patients and a medical assistant and an Entry Lock (EL) to permit the access of 2 persons when the Main Lock is pressurized. The pressure vessel is available with 3 flat ends with rectangular door or 1 flat end and 2 circular doors. Drass Hyperbaric chambers are available in 4 different models:



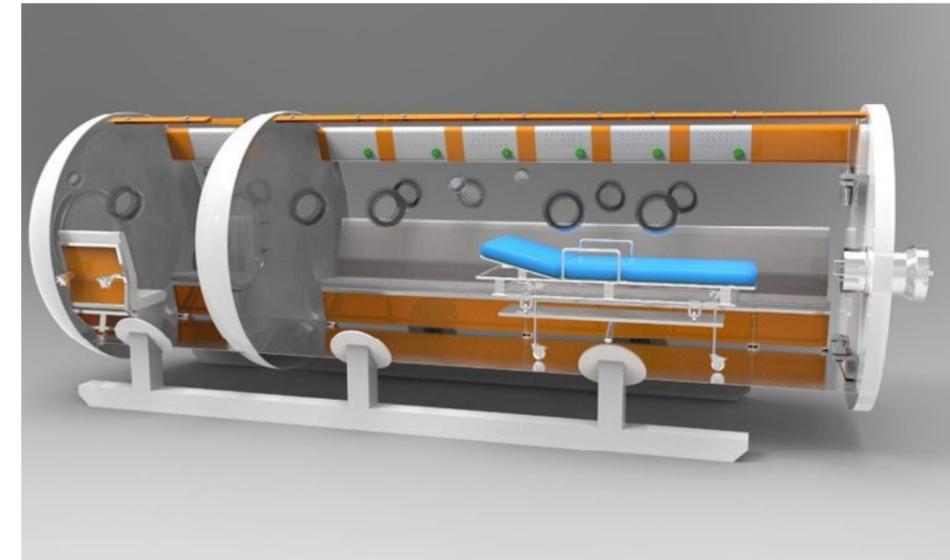
**12-man chamber
with 3 flat ends**



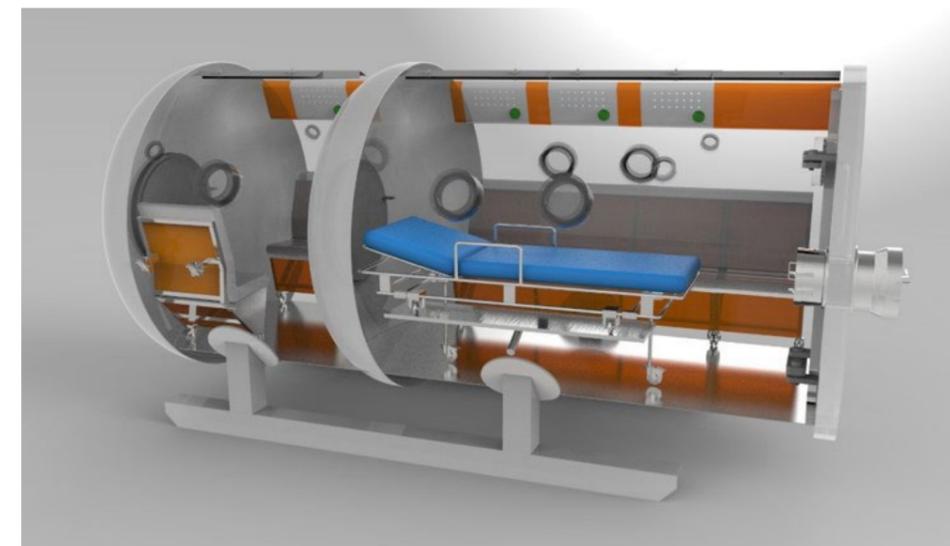
**6-man chamber
with 3 flat ends**

#3

Hyperbaric Medical Chamber



12-man chamber
with 1 flat end and 2
dished ends



6-man chamber
with 1 flat end and 2
dished ends

The availability of 3 flat ends allows the installation of 3 rectangular doors on the TC; through the rectangular doors it is possible to accommodate a stretcher from both the Entry Lock and the Main lock, making the overall operation of the TC more flexible and at the same time facilitating the passage of medical personnel through the entry lock, rather than the 800mm circular door of the dished ends.

#4

Hyperbaric Medical Chamber

A triple flat end makes the TC more compact for an easier installation in restricted spaces.

The TC floor is made of removable aluminium plates divided into sectors which permits an easy removal of floorboards for TC cleaning and maintenance.

The false ceiling inside the chamber is designed:

- to reduce the feeling of claustrophobia that chamber roundness may create in the patients.
- to allow an ideal installation of LED lamps which distribute light within the chamber perfectly.

All material and components installed in the hyperbaric environment of the TC are compliant with the existing regulations (compliant to EN 14931), tested to ensure that they are not dangerous for patients' health, easily washable and replaceable in case of dirt or damage. All fabric seat padding is made in anti-static material to prevent electrostatic sparks. Such technical choices make the internal environment more comfortable for patients.

In order to minimize more the sense of claustrophobia, the TC is equipped with several large viewports; each viewport is equipped with an additional acrylic anti-breaking device.

Oxygen supply to patients by masks and it is on demand and bulkhead spare plugs in the Main Lock and Entry Lock permit installation of medical devices inside the chamber such as: ECG, EEG etc.

Stretcher Features

Stretcher is necessary to transfer patient inside the hyperbaric chamber in order to provide him an oxygen hyperbaric treatment. Hyperbaric chamber is a cylinder with an inner diameter of 2300 mm made in carbon steel with a rectangular door large 960 mm and 1800 mm height,

Stretcher legs shall be folding in order to permit to store stretcher in a side of the hyperbaric chamber where the wall is rounded; mechanisms similar as shown below should be installed on the stretcher and the chamber wall, another type of mechanisms proposed can be accepted.

Stretcher mattress shall be suitable to a hyperbaric use, padding should be made in polyurethane with open cells and certified flame retardant as per EN 14931.

Stretcher is pressurized to 5 bar inside the hyperbaric chamber; use of pneumatic dumper in folding mechanism is not suggested, all parts of the stretcher shall be designed in order to avoid implosion during pressurization and explosion during decompression.

Stretcher mechanisms shall be without grease or with grease compatible with oxygen applications; this requirement shall be applicable also for stretcher wheels. It is preferable to use metallic materials in order to reduce flammable materials inside the hyperbaric chamber, all flammable material shall be certified flame retardant as per EN 14931.

All the metal parts shall be resistant to corrosion, preferably made of stainless steel or anodized aluminum.

Therapies Management System

Therapy Management System is based on two configurations:

- Conventional Manual Control (manual control panel)
- Automatic Control (manual Control Panel + Automatic Control Panel)

Conventional manual control configuration allows the operator to manage all therapy functions through valves on the Manual Control Panel (MCP); this panel is fitted with all the necessary instrumentation.



Automatic control configuration allows the operator to manage all therapy functions in normal mode via the HMI on the Automatic Control Panel (ACP); In emergency mode, the TC can be managed from the Manual Control Panel (MCP). Only one panel at a time can be active.

Using its vast experience in the manufacturing of hyperbaric chambers and our continuous improvement of the medical and diving automation system, Drass has developed the new automated TC based on PLC failsafe configuration with the scope of:

- keeping the automated system as simple as possible;
- automating only the main basic functions, avoiding any over-engineering of the system;
- using modularity as a reducing risk factor, splitting the validation of software and hardware between in house single module/equipment certification and on board overall system certification;
- implementing a robust star topology to transfer information from peripherals to the ACP.

The aim of the system is to integrate the control of all the units of a Standard Drass Medical Chamber System making it easier to manage and providing store and log functions for the main operations and Hyperbaric Oxygen Therapies, alarms and faults of the system.

Señor Frog

A water mist fire-fighting system has been selected so that in the case of activation, patients cannot be directly injured by the water spray. The water mist system generates extremely small water droplets which evaporate very quickly when landing on a hot surface or a flame, causing a quick decrease in room temperature. Moreover, whilst evaporating, the droplets increase their volume by 1000 times, diluting oxygen concentration locally and stopping the fire-reaction. This combined effect of cooling and dilution causes a rapid fire extinction with a small quantity of water. The Fire-Fighting system is realized in compliance with EN16081.

The system can be activated when both flame detectors have generated an alarm.

Automatic changeover of oxygen with breathable air on mask inlet is automatically activated to avoid an increase in oxygen content during fire-fighting operations.

Environmental Control and Gas Analysis

In normal operations, the inner hyperbaric chamber temperature increases during the compression phase and decreases during the decompression phase. To keep the patients in a comfortable environment, chambers are provided with an Environmental Control System (ECS) able to ensure a stable inner temperature during all the therapies.

Humidifiers are also installed to restore the humidity as integration of the dry compressed air. This solution is also a step forward in the ergonomics of the patient seats and a safety for oxygen stratification. O₂ and CO₂ Analyzers are installed in order check the stoichiometry of the environmental air and signal eventual high concentration of gases, that could be dangerous.

Multimedia Public Entertainment

Multimedia Public Entertainment is constituted by a single screen to be installed in the Main Compartment of the Chamber, in a position where it can be seen by all patients; the screen is integrated with touch functionality and completed with ambient microphone and loudspeaker, together with a webcam. External devices can be connected to the two USB and one MMC/SD ports.

The Multimedia Public Entertainment is a complete all-in- one touch PC, custom made to be suitable for hyperbaric installation. Multimedia Public Entertainment is intended mainly to watch movies or TV shows during therapy, anyway it can be connected to the web and used to surf the internet, or generally to do everything is possible to do with a PC.

Multimedia Private Entertainment

Multimedia Private Entertainment is constituted by a number of private touch screens, commonly one for each patient, to be used such as private tablets.

The screens are integrated with touch functionality (multi touch), and completed with headset connection (microphone and speaker), together with a webcam. External devices can be connected to the USB port.



Multimedia Private Entertainment

The Multimedia Private Entertainment is a complete all-in- one touch PC, custom made to be suitable for hyperbaric installation.

Multimedia Private Entertainment extends the possibility of the Public Entertainment by giving a private access to each patient; it can be connected to the web and used to surf the internet, or generally, to do everything is possible to do with a PC.

Audio Private Entertainment

In case the Multimedia Entertainment is not required, a simpler audio distribution system can be fitted in the system, capable to deliver entertainment music privately to each patient; it is expected a number of two stereo audio channels to be distributed to the patients, each one being able to freely choose the preferred one.

In the Control Console a panel will collect and distribute the two stereo audio sources from external devices.

#3

Connections and Interface supply for a Hyperbaric Center

In order to operate, the Hyperbaric Center requires the following external supplies and provisions:

- An electric distribution switchboard with total electric power rate of 15 KW - 230V -50Hz – monophase, with necessary automatic protection devices to feed the control panel and hyperbaric chamber.
- An Emergency Power supply (or UPS system) with the same electric power rating as the electric distribution switchboard and an endurance of at least 20 minutes, in order to feed the switchboard in case of emergency.
- An insulation transformer for medical use.
- An electric distribution switchboard installed in the technical room with total electric power rating of 150 KW - 400V - 50Hz – triphase, with necessary automatic protection devices to feed: air compressors, air filters, heater/chiller unit.
- Gas oxygen supply with a flow capacity of at least 4,50 NL/min at 12 bar with gas piping distribution system in order to provide oxygen to hyperbaric unit.
- Fresh water supply to refill Fire Fighting tanks (only for refilling purpose) with water piping distribution system to provide water directly to the tanks.
- Drainage line for water discharge connected to ML and EL drainage lines and Fire Fighting system tanks.

#4

Regulations

Rules	Description
EN 14931	Pressure vessels for human occupancy (PVHO). Multi-place pressure chambers for hyperbaric therapy. Performance, safety requirements and testing
EN 16081	Hyperbaric chambers. Specific requirements for fire extinguishing systems. Performance, installation and testing
IEC EN 62304	Medical Device - Software Life Cycle Processes
EN ISO 14971	Medical devices. Application of risk management to medical devices (British Standard)
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purpose
93/42/EEC (MDD)	Medical Device Directive (plus 07/47/MDD) - European Commission
97/23/EC (PED)	Pressure Equipment Directive - European Commission