Cumbria Hyperbaric – Hyperbaric Chamber Buyers Guide

Buyers Guide Part 2

The Risks of Non-Compliance

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HYPERBARICS FOR LIFE

Hayden Dunstan
CUMBRIA HYPERBARIC

Cumbria Hyperbaric – Buyers Guide Part 2
The Risks of Non-Compliance

The Risks and Consequences of Non-Compliance

Hyperbaric Chambers and the Reasons Construction Standards Exist.

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Introduction

Pursuant to the buyer's guide, recently prepared, the following text delves further into the reasons why some of these standards and regulations exist. This witing should be read in conjunction with the buyer's guide. Hyperbaric chambers, while fairly simple in technical design and operation, are not to be considered in the same light as other industrial equipment. A hyperbaric chamber is a life support system. Nothing less. When placing a human being inside a chamber, which is legally a pressure vessel, it becomes a pressure vessel for human occupancy. Formerly referred to as a "Manned Pressure Vessel". Whether it is for medical intent or not. It becomes a controlled confined space, controlled by an operator, not the occupant, and the laws of physics and physiology very much apply to the conditions and physiological responses of the body inside the chamber. [30]

The nature of these chambers is such that it would prevent an occupant from simply getting up and walking out. This constitutes a confined space which contains a person. The door cannot be opened under pressure and there is a time delay in egress. Add to that the nature of the controlled internal atmosphere in terms of temperature, oxygen content, CO2 content, humidity etc, and it becomes clear this equipment fills the definition of life support system. Meaning it is possible to get it wrong, and inadvertently create scenarios or conditions which may not be conducive to life.

The sourcing of materials and the manufacture of such a chamber is therefore regulated. Certain construction standards prevail in various geographic regions around the world for good reason.

The following text will examine in greater detail why these rules and construction standards exist and what can be some of the unintended consequences of ignoring them, from original materials sourcing to the construction, assembly, calibration and end use of such chambers.

UK Legislation

In the UK, the British Standards Institution (BSI) publishes product standards which must be followed and adhered to before putting a product to market. This is especially true for hyperbaric chambers and its allied equipment.

These standards are enforced by the Office for Product Safety and Standards (OPSS), which is part of the Department for Business and Trade.

The relevant standards in the UK for pressure vessels for human occupancy is standard; BS EN 14931 and the standard for compressed gasses for respiratory equipment for breathing purposes, or "breathing service" as its called is BS EN 12021. [1]

Manufacturers and distributors are legally required to comply with these standards. Failure to comply can lead to substandard equipment reaching the marketplace where it may cause harm to end users.

Included in this standard, and the American standard PVHO 1 – 2023, are specific items of compliance and construction methods, including materials used and what standard they must reach before being deemed suitable for use in a PVHO. Before a manufacturer is authorised to affix the mark "PVHO" to their chamber, along with the relevant standard it has been tested against, they must prove their design meets the standards. This can be done by employing the services of a classification society such as Lloyds, as discussed in the buyer's guide [20], to assess the design and prototype. The society then goes on to inspect future products during the manufacture and verification process. Sometimes, each and every chamber that is made requires inspection and certification.

For the purposes of this reading, the UK PVHO and the US PVHO are treated as near identical standards and minor differences between the standards are set aside for a discussion pertaining to the fine print of each standard. For the purposes of this discussion the standards are similar enough to be considered one and the same.

The following paragraphs highlight the risks, dangers and potential consequences of purchasing and operating non-compliant materials and equipment.

Off Gassing

The buyers guide refers to off gassing. Specifically, it focuses on the use of plastics and polymers, both natural and synthetic, in the production of equipment such as hoses, pipelines, claddings, masks, furnishings and so on.

Under pressure, plastics are inclined to release vapours. This can happen for a number of reasons including but not necessarily limited to: Incomplete bonding processes, the release of trapped gasses in the production process, sublimation (in the case of pressure related heating) and evaporation, desorption (as opposed to absorption) and gaseous products of slow chemical reaction left over from the manufacturing process. Many pressure related products are off gassed during their manufacture, meaning they are repeatedly pressurised to deliberately off gas the material until off gassing either stops, or is reduced to an acceptable level for breathing purposes.

Failure to ensure breathing apparatus such as masks, hoses and piping, and so on, can lead to toxic vapours being breathed into the lungs. This can cause permanent tissue damage and damage the lungs surfactant which plays a key role in breathing and oxygen transport across the alveolar membranes. Surfactant facilitates transport of oxygen into the blood and waste gasses and products out of the blood by reducing surface tension at the blood gas interface [31], and it can be eroded by toxic gas and fumes. A loss of surfactant is a serious condition which can become life threatening. Since surfactant aids in oxygen transport, it follows that erosion of surfactant will negatively impact oxygen transport essential for life. The use of inappropriate hoses and tubing, mask seals and faceplates, valve seats and seals and O-rings, as well as compressor parts and lubricants can cause serious lung injury. All components used to prepare and convey breathing gasses should be compliant with the standard BS EN 12021 and exhibit low off gassing characteristics. Some food grade hoses may be suitable, but it should not be assumed that food grade alone will be good enough. Use of plastics in food preparation seldomly involves increased pressure and these may not have been tested in a pressurised environment. Hoses made specifically for breathing service should be used.

Claddings found on a chambers internal surfaces are also subject to off gassing and claddings should be made to the same standard. They should be designed and tested for the hyperbaric environment.

Certain thread tapes are also unsuitable for use on oxygen breathing lines. Standard PTFE tape may not be used in oxygen systems.

Fire and Off Gassing

Ordinarily, when a joint is sealed with PTFE thread tape, the thread tape is wound around the male component of a few times. In most cases the tape will overlap and extend beyond the end of the threads. This leaves a small flap of tape in the flow inside the pipe or tube. Even well wrapped threads still have a portion of the sealing tape in contact with the gas within the system.

Common sources of heat inside a piping system include adiabatic compression, as well as high velocity particle impingement [39]. These 2 ignition sources can ignite this type of tape inside the piping system. Especially on corners where particles collide with the internal pipe walls and fitting bends creating micro heating and kindling events. PTFE contains fluorinated polymers which causes the tape, or membrane as referenced, to release PFAS (Perfluoroalkyl and Polyfluoroalkyl Substances) [34] which includes phosphine gas when burning [32][33]. Phosphine reacts with powerful oxidisers such as oxygen[35] and such release would deliver this toxic and lung damaging gas directly to the breathing circuit in this event. Phosphine is a known disperser of lubricating greases, and one can only imagine what it does to lung surfactant [36].

A further reason for not using standard PTFE tape is that when the resin used to manufacture PTFE thread tape is mixed , it is mixed with a small amount of solvent. If this solvent is not removed it can react with oxygen and cause an explosion. [2]Only oxygen compatible tapes should be used. These are often pigmented green so as to be easily identifiable as oxygen compatible however there are some variants available that are white and that look the same as standard PTFE. Always ask for evidence that the correct tapes have been used.

Rubber seals and O-rings are usually suitable for use with air, however standard rubber may not be suitable for use on oxygen systems. For similar reasons stated above, the production of these rubbers may include the use of combustible components which could react with the oxygen causing an explosion. Even in less severe events, toxic fumes may be produced.

Regarding fire, even though these components are small, they can be responsible for something known as a “kindling chain” which can be the cause of ignition of surrounding materials including metals. Yes, metals burn in an oxygen rich atmosphere [37]. It is not uncommon for oxygen fires to burn metals such as stainless steel as fuel. Materials deemed safe for use with oxygen and pressure are those deemed to have an acceptably low ignition probability or in other words, good ignition tolerance properties. They must also be capable of dissipating micro heating and kindling chain heat easily. Stainless steel for example is not good at doing this. Copper and Tungum are preferred for their ability to dissipate heat quickly in a system. Details of these materials can be found in the testing criteria published by ASTM Global[3]. Formerly the American Society for Testing of Materials. Oxygen compatible test standards may include:

Category of Test	ASTM Standard	Test Objective	ISO Equivalent Test Methods
Flammability	G125 [4]	Oxygen Index (OI)	No Equivalent ISO Test (ASTM Test is referenced by BAM)
Ignition Sensitivity	G72 [5]	Autogenous Ignition Temperature (AIT)	ISO 21010 Annex B, Test for Spontaneous Ignition Temperature Determination
	G74 [6]	Gaseous Fluid Impact Sensitifity (GFIS)	ISO 21010 Annex C, Pressure Surge Test (A new ISO pressure surge test standard is currently in development)
	G86 [7]	Mechanical Impact Sensitivity in LOX or GOX (MI)	ISO 21010 Mechanical Impact in Ambient LOX
Damage Potential	D4809 [8]	Heat of Combustion (HoC)	No ISO Equivalent Test (ASTM Test is referenced by BAM)
	No ASTM Equivalent	Flange Kindling	Testing of Flange Gaskets in gaseous oxygen performed by BAM
LOX = Liquid Oxygen; GOX = Gaseous Oxygen			

Source: [4]

In short though, compatible materials for use with oxygen and pressure include materials such as nylon 66, certain types of Teflon, Non-PTFE tapes such as PCTFE (Polychlorotrifluoroethylene), Viton®, butyl rubber and some silicones. One of many sources in the reference section. [5]

Paint and Painting

Internal paint requires a special mention. External paint is a little less serious when selection is considered provided it is neutral when cured and reasonably fireproof suitable for an oxygen facility. Usually, a 2-part epoxy neutral cure paint can be used.

Inside the chamber however is a different story.

Internal paint must have a neutral cure as well, but it must also have a low ignition probability or, good ignition tolerance. For this, it must have as low a solvent content as possible, solvent free if possible. In other words, it must have a high ignition temperature. Meaning the temperature needs to be considerably higher than normal ignition temperatures for paints, for it to ignite.

All materials have an auto ignition temperature at which they will combust. Owing to the surface area internal paint covers, it is understandingly undesirable to have this paint be a potential source of ignition and kindling chain. Most paints are highly flammable even in their dry or cured state. One cannot simply use any old paint. It must be designed for the hyperbaric environment. Furthermore, in the event it does burn, the fumes or steam it produces should be non-toxic and not harmful. It is for this reason that many chambers take on an industrial look with tread plate floor plates and metallic internal surfaces. It's safer and is one less point to consider. Notwithstanding that, it is acceptable to soft clad internal surfaces provided the materials used are compatible with the hyperbaric and potentially oxygen rich environment.

Painting processes typically involve applying a base or priming coat following sand blasting. This is usually zinc-epoxy paint which provides corrosion protection. This is followed by an intermediate coat of 2-part epoxy paint. This is finished with certain polyurethane paints for chambers or epoxy paint for bells [6]. Hempel® [7] is common brand of fireproof internal paint. Further reading is recommended on paint for HBOT chambers at the references. [8][9] Paint must also have low off gassing characteristics. In the same way plastic and polymers off gas, so does paint do.

Needless to say, a paint-based fire in a chamber leaves slim chance of survival. It's not so much the paint itself that's the entire danger on its own, but rather the chain reaction a relatively small ignition point can trigger as well as potential fumes produced by the wrong kinds of paint. Surrounding material will easily burn in the presence of oxygen, and a catastrophic fire can be triggered by the smallest of kindling events. In the event of a fire inside the chamber, pressure will increase in accordance with Charlse's Law [10], making it very difficult to decompress the chamber as quickly as may be needed. This, along with fumes and heat, make survival unlikely in the event of a significant chamber fire.

Without the ability for gas to expand with heating, the pressure will increase making decompression difficult. Fire suppression systems may not be adequate to extinguish a significant or catastrophic fire, meaning that the fire will only extinguish once all the oxygen has been used up. This is providing the system can isolate the oxygen flow going into the chamber. This is a key requirement of oxygen systems. It must be able to be switched to air to avoid adding oxygen to a fire and to give occupants an uncontaminated breathing source through their masks.

At some point, either the fire will go out for lack of oxygen, or the chamber will explode. Either way, survival is unlikely. Always make sure the chamber is fitted with appropriate fireproof fittings and paints.

Pipelines

Metallic and non-metallic pipelines must be constructed from breathing service materials. In many cases a combination of flexible and non-flexible pipelines may be in use. Just because a pipe is constructed from copper or tungum, both suitable for breathing and oxygen service, it doesn't mean the internal lining is appropriate. The materials used to line hoses and pipelines must also be breathing service and for use with oxygen if required. Failure to adhere to this can result in excessive toxic off gassing and potential fires inside pipelines. Pipelines should also be oxygen clean to remove traces of hydrocarbons left over from the manufacturing process when being used to convey oxygen or oxygen rich mixes.

Woven Fabrics

Woven fabrics should be given the same consideration as plastic and polymers above. Large surface areas of woven fabrics, constituting the pressure barrier in flexible chambers, are subject to potentially toxic off gassing if the wrong materials are used. Toxicology reports should detail the origins of the materials used and confirm safe levels of potentially toxic off gassing under pressure. These reports should also detail all compounds present in the materials.

Ordinarily a woven fabric may be lined with a secondary pressure barrier which too must be made to the same standard. It's important to note that even though it covers the primary pressure barrier, they must both be suitable for human occupancy and breathing service. The use of incorrect or unsuitable materials can lead to irreparable lung damage over time. Also worth remembering is that the skin is also an organ. It absorbs compounds in its own right and generalised toxic response and allergic reaction is possible if non-hypoallergenic and unsuitable materials are used.

Valves and Viewports

Valves and safety relief devices/valves (SRV's) must be constructed and tested against the PVHO standard [11]. In the event a subpar quality safety relief valves fails, and the chamber compression becomes uncontrolled, the chamber could in theory explode as pressure exceeds test pressure. While catastrophic explosion is less likely, it is not uncommon for fittings and other parts to blow off poorly made systems. These become high velocity projectiles more than capable of injuring or killing a bystander. In any event, the over pressurization of a chamber owing to a failed relief valve would invalidate its pressure test nullifying most insurance policies. The financial impact of this cannot be

understated. Neither can the potential criminal liability. Properly constructed and tested SRV's are legally required equipment on pressure vessels. These should never be tampered with either.

Additionally, over pressurising an occupant could prove to be a serious health hazard and could give rise to decompression illness when breathing air, either in the form of bubble formation in tissues and blood, or gas embolism from disbaric injury [12]. Both very serious, potentially life-threatening diving diseases. Uncontrolled and excessive compression may also expose occupants to oxygen toxicity if they were to continue breathing oxygen at pressures exceeding safe limits.

While oxygen toxicity is not life threatening and generally leaves no sequalae, both of these decompression related illnesses can be life threatening. Chambers are legally required to have a safety relief valves set to around 10% higher than maximum allowable working pressure (MAWP). This test and calibration should return a calibration and test certificate to be included in the data file for the chamber.

Malfunctioning valves can result in compression or decompression rates which are not suitable for safety. Rapid compression or decompression can lead to serious pressure related injuries or barotrauma [13]as it's called. This can involve simple air spaces such as the middle ear, or it can involve more serious air spaces such the lungs. Some injuries of this nature can be life threatening. Valves and safety relief features must comply with construction standards to avoid potential serious injury.

Flexible and plastic viewports must comply with testing criteria and construction standards. Poorly made viewports, and those which have not undergone the prerequisite testing and approval are dangerous and subject to failure. PVHO 1 details the testing required to have a viewport design approved. For acrylic viewports this is at least 10 000 hours of testing as well as having approved designs for such viewports. Flexible chambers make use of transparent plastic viewports, and these must have the same pressure tolerance as the primary hull.

A failed viewport would result in uncontrolled decompression of the PVHO leading to serious barotrauma explained above. Barotrauma involving the lungs can lead to life threatening injuries such as arterial gas embolism. [14] It cannot be stressed enough the risk to life serious pulmonary barotrauma [15] presents. Chambers must be so designed to avoid potential catastrophic failure of any part of the primary pressure barrier (hull), including fittings and especially penetrations. Penetrations should enter the chamber through an area of hull thickening know as a penetrator plate, or "pen-plate". This reduces the chances of splitting or cracking of the pressure barrier where it has been drilled and tapped.

Welds and Welding

This brings into focus the topic of welds. Various materials, including metals and non-metallic materials such as plastics, are often welded to create a permanent joint. Chamber hulls fabricated from metallic materials will be made of spun or rolled metals which are welded together in sections to form the basic geometry of the primary pressure barrier. These welds must be full thickness welds. IE: they must penetrate all the way through the material. They must also be tested ultrasonically (or other accepted NDT method) and certified as compliant on every chamber build. Failure to ensure welds are adequate can result in catastrophic failure of the pressure barrier explained above. Not only is this expensive to remedy, but it can be dangerous as well.

Plastic welds can also be tested in a similar NDT (non-destructive testing) manner to ensure they have been constructed appropriately to promote the integrity of the pressure barrier. Failure of the pressure barrier can lead to catastrophic decompression explained above.

Furnishings and Bedding

Furnishings and beddings must comply with certain fire retardancy limits. Similar considerations should be given to bedding and furnishings as paints above. Chamber fires are very serious and flammable bedding is unacceptable. In a chamber fire involving plastic and polymer bedding materials, these burning materials would stick to an occupant and continue to burn. An incomprehensible thought. Materials under pressure will ignite at lower temperatures[38], and in the presence of oxygen, burn more fiercely and in a much hotter manner. Oxygen vigorously supports combustion, and fires are far more severe in the presence of oxygen.

One cannot place just any furniture inside a chamber. It must be specifically designed for the environment and must be constructed from non-flammable, non-toxic materials in accordance with the ASTM testing standards for non-flammable and non-toxic materials [16] [17]

Furthermore, drapes and fabrics used in the chamber must conform to the NFPA 99 Chapter 14 as well, in terms of fire retardancy and flame progression to avoid potentially lethal fires inside the chamber. [18][19]

BIBS (Built in Breathing System) and Masks

Masks and hoses supplying masks with oxygen should be built from quality materials and sub-assemblies to ensure proper operation. Cheaper masks tend to use cheaper demand valve mechanisms which are prone to failure and restriction of gas flow. While not a life-threatening emergency, this is still an inconvenience warranting a refund for clients or patients. When a patient/client/occupant in the chamber feels like they cannot breathe this can lead to panic very quickly. Dealing with a panicked occupant can turn serious, but even if not, it's likely to put that occupant off for good. Its's a sure-fire way to loose repeat clients/patients and it gives the whole discipline a bad name. BIBS masks and their mechanisms, larynx hoses, overboard dump and exhaust circuits should comply with PVHO design criteria. [11] Additionally, they should be built around quality demand valve mechanisms which are not prone to failure. Brands such as Scott Drager and Vaks are all good quality. Other masks are available, and quality masks are not limited to these few mentioned here. Research the product you intend to buy. When your chamber is supplied to you, along with all the other documentation, the chamber file should contain details of what make and model the BIBS masks and regulators are.

Verification Agencies and Classification Societies

Mentioned at some length in the buyer's guide,[20] these are agencies or societies that verify that a design meets an approved standard of construction. Details of the particular points of compliance can be found in the standards themselves however for the purposes of this material, its prudent to consider the consequence of non-compliance.

When a chamber is manufactured in a factory and then put to market, it must be deemed safe. It must have certain features and functions included in its design which make it safer to use. For example, occupants must be able to end a session in an emergency and achieve egress themselves without the assistance of an outside attendant or operator. This, among many other features are detailed in the construction standards and the classification society verifying the chamber will inspect it and test it against the relevant standard.

Companies offering hyperbaric chamber services are required to purchase various types of insurance. This can include personal liability, business liability, other public liability as well as actual contents insurance. IE: the chamber and its equipment itself. In many cases the value of the chamber and its allied equipment can reach into the hundreds of thousands of pounds/dollars. More so, in a litigious society such the UK or the USA for example, liability claims from clients or patients and compensation claims can reach into the millions. In the event a patient or client suffers and injury, which is entirely possible even when doing everything right, and it can be shown to be related to your chamber, and that chamber is then investigated and found to be non-compliant with a required standard, it is likely the legal consequence would devastate the business and its owners. Not to mention what it would do the reputation of the modality on the whole. In serious cases of deliberate noncompliance and flouting of regulations and product safety standards, criminal liabilities may apply.

The HSE and other statutory bodies mandated with enforcing regulations take their mandates very seriously and an investigation which returns a finding of an inadequately built chamber would have grave consequences indeed. It's not worth the risk to save perhaps 25% on the purchase price.

The Risks of Non-Compliance

There is a reason properly built products are the price they are. You won't get good for cheap, and if it's cheap it won't likely be good.

The onus is on the manufacturer to produce equipment that is compliant, but very often the manufacturers aren't even aware of the regulatory requirements themselves. You as a buyer must ensure your chamber is compliant to minimise and mitigate legal consequence. You as the operator will be held ultimately responsible for the chamber and its effects on its occupants. In the same way a driver is held liable for the condition of a vehicle they drive, even if it's a company vehicle. In every case, it's the operator that is liable, then the business and its owners. The manufacturer will unlikely voluntarily accept liability in the event of serious issues. And if it's a manufacturer or distributor from outside the UK/USA/EU the task of holding them accountable is made that much more difficult. If you

can, deal with a distributor or manufacturer who has a proper base in the UK or your other country as the case may be. You as an operator should not agree to operate a chamber of which its pedigree cannot be evidenced by a solid trail of documentation, test data, construction and design documents, and certificates of compliance.

In addition to PVHO and NFPA 99 compliance, In the USA you should also determine if the chamber is FDA compliant. If its being used for human occupancy and it is having a physiological response in the human body, then it is likely it will be classed as a medical device.[21]

In the UK it is probably a good idea to determine if your chamber may be considered a medical device under the medical device regulations. [22]

These medical devices regulations are enforced by the Medicines & Healthcare products Regulatory Agency (MHRA) [23], and they too take their mandate very seriously. Falling foul of regulations and coming out of an investigation on the wrong side of the finding will have life changing consequences. Not all chambers are medical, granted, for example diving chambers. However, for the wellness market, it is likely they would be deemed medical or at the very least therapeutic. In any event, it’s the human occupancy that matters more. IE PVHO. In addition to PVHO there is also a requirement to have products meet all required UKCA and EU quality measures for these regions. This can include electrical compliance, Electromagnetic interference compliance, toxicology compliance and so on. Legal consequence applies for noncompliance.

An easy way to tell if your chamber is compliant, as a purchaser, is to inspect the data plate attached to the chamber. This plate will be accompanied by a file of all documents relating to the pedigree of the chamber. This will include test certificates, certificates of compliance, materials certificates of origin, manufacturing processes and most importantly the test pressure, working pressure rating, the design standard, the manufacturers name and address and the date of manufacture as well as UKCA and EU marking as required. If it doesn't have one, you may be inadvertently assuming responsibility for non-compliance by choosing to use the chamber anyway.

Pressure Testing

Pressure testing is a means of determining if the pressure vessel is safe to be compressed with compressed air or other gas. Some suppliers have been noted saying, "It's meant to do

2 atmospheres absolute, but it's fine to go up to 3". User beware! This is not the case and may incur liability.

The test pressure determines maximum allowable working pressure, (MAWP) and the overpressure test itself is normally conducted at 25% over the MAWP. Exceeding this pressure rating is not only potentially unlawful, but ill-advised and dangerous as it could lead to catastrophic failure of the pressure barrier. IE the chamber could crack, deform and even explode. If there is no data plate with a pressure test, and a test certificate, that means there is no evidence it meets a PVHO standards. Even those chambers not strictly requiring PVHO compliance, IE those under 1,5 atmospheres absolute (ATA), should still have a stated MAWP for safe operation and test pressure exceeding MAWP by at least 25%. Without this data it's anyone's guess if the chamber will fail under pressure or not. Pressure testing also extends to point of failure testing which will determine at which point the pressure barrier will fail. Without such data available, there is no way of telling where the chamber will fail.

Gauges and manometers should also be as accurate as possible. An acceptable 3 to 5% variation for low pressure barochambers for wellness applications is acceptable, however, gauges should read within 1% of real pressure in an ideal world and certainly in medical treatments of divers this is the case. Gauges should be calibrated during manufacture and have these calibration certificates included in the chamber data file.

Pressure barrier failure can lead to serious barotrauma, usually in the pulmonary system and can also seriously injure the operator and bystanders. As gas escapes a ruptured pressure vessel it expands in accordance with Boyle's Law [24] in the same way an exploding bomb does. This type of failure can result in flying debris in the form of fittings, pipes, hoses, pieces of chamber, poorly fitted viewports etc. All pipework must also be rated for the same MAWP as the chamber and tested accordingly. Certificates should be forthcoming. Cheaply made piping and tubing systems as well as fittings are prone to failure and common causes of pressure barrier failure in poorly constructed chambers. A poorly cut tube or hose can lead to this type of failure as well. Manufacture methods are important too. For flexible hose for example, simply remove the hose from the push fit or other fittings and inspect its end. If it not cut perfectly straight, as in it has a kink in the cut or has an angled cut, it could fail. Fittings works best with accurately cut and fitted tubing and pipework. For rigid pipe, remove the fitting and inspect the pipe flare on the end of the pipe if it has one. Make sure it's not cracked, and it is evenly flared, check that threads match each other etc. Even something as simple as over-tightening a fitting can deform the pipe/fitting/tube and make the joint probe to failure.

Electrical Compliance

Mentioned above is the need to be compliant in terms of UKCA and EU electrical safety regulations. [25] This includes electromagnetic interference limits, as well as grounding and earthing of electrical equipment. Note: Chambers may not have high voltage AC (alternating current) in or on the chamber. It must all be 12- or 24-volt direct current (DC). DC does not travel "everywhere" like alternating current does. Its path of travel is limited to the shortest route between positive and negative. It is much less likely to cause electrocution in this application, especially for low power applications. Low voltage is also less likely to generate arcing which can be a source of ignition and kindling chain mentioned above in matters pertaining to fires.

The Risks of Non-Compliance

The key takeaway for electrical safety is that occupants are subject to electrocution from stray fault current on the chamber hull or its pipework. Safety standards contain details pertaining to design and necessary fusing of unavoidable high current and the need for low voltage equipment made for the hyperbaric environment. Failure to ensure your chamber is compliant could lead to legal consequence in the event of an electrical accident such as electrocution.

This also extends to installation. Electrical systems in the building should be robust enough to supply adequate power to equipment without overheating or excessive wear on RCB devices. Usually, breakers for motor applications such as compressors, require more robust D curve RCB's as opposed to the standard C and B curve breakers. Not all sellers of chambers will provide buyers with an installation or installation advice service.

Equipment must also be RoHS compliant to avoid liabilities related to substances included in electrical constructions which may be harmful to animal and human health and even possibly environment.

Warranty

Briefly covered here as well as in the buyer's guide, compare warranties. More importantly compare the likelihood a supplier can actually live up to their warranty. It's easy to offer a 5-year warranty but it is worthless if the seller cannot live up to their obligations.

Buyers are investing considerable funds into buying a chamber. Don' be caught short by a sellers failure to honour their warranty obligations.

It's a good idea to familiarise yourself with the conditions laid out in the Consumer Rights Act 2015. [27] The regulations establish minimum warranty periods that must be offered and the terms on which goods are bought and sold as they pertain to the existence of a contract between seller and buyer. International suppliers may not be familiar with all of these rules.

Training

You must be adequately trained to operate your chamber safely. Failure to ensure you or your staff are well enough trained to understand the risks and cautions associated with hyperbaric chambers could land you in hot water in the event of an accident. Some suppliers offer training as an add on product and some do not. At the very least you should receive operational instruction on how the chamber actually works with further training highly recommended. Independent training is also available from independent specialists not directly employed by sellers. [28] (Other training providers are available).

In the event of accident, the operator and owner of a chamber will need to satisfy investigators that they are well enough trained to identify hazards and risks in order to avoid them. Failure to prove competence could lead to legal liability in the event of an incident or accident.

See the buyer's guide for other commentary [20]

Conclusion

The intention of this document at the outset was to highlight the potential consequences of buying and operating less than compliant equipment of which there is plenty to be found in the hyperbaric wellness industry. Equally, there is no shortage of high-end equipment as well.

Contrary to statements made by leading researchers, this is not an entirely unregulated industry. It's plenty regulated.

With many products hitting the market without adequate safety built into the designs, without accreditation and without the required designs and testing, it's only a matter of time before we see a serious failure or accident which will bring with it regulatory crackdowns that will inhibit most small businesses from operating.

This will make elective complementary therapy so expensive it will put it out of reach of the average person. HBOT will once again become a fashion statement for the rich and famous.

No one wants that. Most of those involved with this modality strive daily to bring it to a wider audience. And this includes suppliers who provide quality, tested and approved equipment.

Anything less is criminal and will ultimately stifle the industry to the detriment of many.

The bottom line is, a chamber is a pressure vessel, and it's a manned pressure vessel which makes it a PVHO, a Pressure Vessel for Human Occupancy. It doesn't matter the reason for that occupancy when it comes to construction standards.

Failure to comply with design, construction and testing regulations to ensure equipment meets the required standards can, and most likely will lead to serious consequences including, but not necessarily limited to:

- Legal liability
- Serious Injury to Occupants
- Property Damage
- Equipment Damage
- Injury to Bystanders and Operators
- Nullification and Voiding of Insurance
- Financial Liability
- Criminal Liability and even
- Death in worst case scenarios

It isn’t worth the risk of buying something cheaply made, which may not be compliant. Compliance by manufacturers costs money. Rather a lot of money. This is why some chambers are twice the price of others. The price includes the prior testing of designs and compliance with regulations and construction codes.

If it’s too good to be true, it probably isn’t true. Further, affordable and cheap are different concepts. There are affordable chambers available that meet compliance requirements. However, if its dirt cheap, or exceptionally below the market price norm, alarm bells should be ringing. Make very sure it complies with all the requirements to be sold as a PVHO, if PVHO is required, to avoid serious complications down the line. If the pressure rating is sub PVHO IE below 1,5 ATA, ask for the design document. It should detail all of the mentioned testing protocols and design standards mentioned here.

If there is any doubt as to the seriousness of the matter, just ask the surviving CEO of Ocean Gate. The owners of the Titan, a submersible PVHO covered by the design standard ASME PVHO 1 Section 7 -Submersibles. [20]

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