




Cumbria Hyperbaric – Hyperbaric Chamber Buyers Guide



Complementary Therapy and Wellness Hyperbaric Chamber Buyers Guide Part 1 August 2024

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Introduction

In recent years, specifically in the “wellness” sector of the market, it has become obvious that many unscrupulous manufacturers and sellers of hyperbaric chambers have come to the fore. This has occurred as a result of the well know de-regulation of 2008 in which hyperbaric chamber services were removed from the list of regulated services in terms of the Care Quality Commission, formerly the Healthcare Commission. Unfortunately, one undesirable consequence of this, is that when subpar manufacturers and purveyors of chambers release subpar equipment into the marketplace, it reflects badly on all of us. Even the ones who sell quality, tested and proven equipment. It brings the whole industry down.

How to tell the difference between the good, the bad, and the downright ugly, is key. The intention of this buyers guide is to help educate customers and purchasers of hyperbaric chambers in the wellness field and highlight potential pitfalls when outlaying what amounts to considerable funding when acquiring a

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chamber. Much of the information disseminated here is applicable to wellness chambers as well as hospital based so called, “medical grade” chambers because as you will see in terms of construction standards there is little difference.

This document is intended to be un-biased and favours no particular chamber provider but rather seeks to safeguard to pioneering work done by Professor Philip James and Sir David Downie when they campaigned for deregulation in terms of CQC registration in 2008. It would be a shame to see that work undermined and compromised by those seeking to make a quick buck, shut up shop, and re-emerge to trade again under a different name. And believe me, there are many of them around.

It’s also important to learn to determine as a buyer, if you’re being lied to, or if your potential supplier actually knows what they are talking about. It has become common practice to weave a single thread of truth into a fabric of tall tales and hope the customer doesn’t notice. This happens a lot with the technical nature of hyperbarics. On the face of it certain claims seem to be legitimate because they are built around some element

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of truth. Look for the common thread between stories and sales pitches. That will enable you to separate sales pitch from fact. Also endeavour to understand the terminology used by marketing departments. Very often this terminology will be erroneously applied and with a discerning eye, it's not difficult to separate the wheat from the chaff. Being a scientific discipline it can be confusing and certainly difficult to differentiate between truth and beautifully described garbage.

“Experts” are a dime a dozen in today’s world. Everyone is a “**S**ubject **M**atter **E**xpert”. It’s important to quiz these experts on their credentials and discover for yourself if they are justified in assuming the title “SME” (subject matter expert). Personally, I’ve never liked the

term “expert”. To me and expert is someone way older than I with 50 years’ plus experience behind them. I prefer the term specialist. I know only a handful of these true experts. they’re who I call when I don’t have an answer to a question. Anyone who claims they have all the answers to all the questions is deceiving you. Buyer beware!

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I call myself a specialist. And you can investigate my credentials here: <https://cumbria-hyperbaric.org/about-us/> I am the face behind the Cumbria Hyperbaric Brand and its ideals as they relate to charitable provision of HBOT.

In an effort to keep this document short enough to complete in a quick read, we will touch on subjects such as construction standards, materials compliance and testing including the potential toxicity of plastics under pressure, the 2008 deregulation, Pressure testing and verification, certificates of compliance, training, quality management, and after sales support, among others.

Hopefully by the time you, the reader, has completed this reading, you should have a better understanding on what goes into actually building a chamber that is safe for human use and one which will last for the intended life span of the product.

You will then understand that it simply isn't possible to make a new chamber that sells for £5k or £10k and have it comply with everything it should comply with.

Let's dive right in.

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Cumbria Hyperbaric – Hyperbaric Chamber Buyers Guide **Regulations – Health and safety**

UK Legislation

Contrary to popular belief, and contrary to statements from leading researchers to the contrary, the wellness market is not completely un-regulated. All standard health and safety regulations apply. In the UK this includes but is not necessarily limited to:

- PVHO (Pressure Vessels for Human Occupancy) regulations and construction standards (including ASME and the European Pressure Equipment Directive of 2014/38/EU and EN 14931 / BS EN 14931).
- Pressure vessels construction codes
- The Control of noise at work regulation 2005
- Use of Oxygen in the Workplace Guidance 2013
- Compressed Air at Work Regulations 1996
- COSHH and RIDDOR (Control of substances hazardous to health & Reporting of Injuries,

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Diseases and Dangerous Occurrences Regulations) 2002 & 2013

- Elements of the Diving at work regulations 1997
- Elements of the Care standards act 2000
- Elements of the Private and voluntary healthcare regulations 2001
- Elements of the Medical devices and pipeline regulations 2002
- The provisions of Health and safety at work regulations 1974
- Lifting Operations and Lifting Equipment Regulations 1998 (LOLER)
- Any patient handling regulation prevailing in your region.
- Manual Handling Operations Regulations 1992 (MHOR) (as amended 2002)

The above list is not exhaustive by any measure, but it's a good place to start when considering what your health and safety policy may need to contain. Keen readers will notice that I refer to the diving at work regulations and highlight that elements of these regulations may apply. As a strict rule, diving regulations are expressly stated as

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not applicable to non-diving activities. It says as much in the paragraph on scope in the legislation itself. Similar can be said for mining and tunnelling regulations which are specifically targeted at those activities and operations and specifically exclude hospital or clinic-based chambers.

However, there isn't a separate set of regulations written for the wellness market to guide its members. The reason I mention these two specific sets of regulations is that they contain much about hyperbaric working conditions and chamber management. After all, it's in

diving that hyperbaric chambers originate, and it makes sense that good practice can be derived from any source whether legally applicable or not. What is expected of users of chambers is to conduct their own due diligence and just because a set of regulations cannot be directly applied, it doesn't mean an investigation would dismiss them entirely. And that's where the diving and mining regulations can help. One can extrapolate a set of rules to work by, from these

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regulations by excluding diving and mining specific references.

The same can be said for a document published by the International Marine Contractors Association (IMCA) named IMCA D023. This document establishes best practice and rules for air diving systems, of which hyperbaric chambers form an integral part. It's where many of the safety protocols come from. We in the diving industry have modified it to be applicable to both the medical and wellness hyperbaric therapy market.

Most importantly listed above is first on the list. PVHO. This discussed in a paragraph on its own below.

The important thing to understand is that the wellness market is not unregulated. Far from it. if you believe a potential supplier when they claim it is not regulated you are setting yourself up for a fall that they will shy away from when it happens. They will not be in your corner. Regulations still apply.

Deregulation

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Mentioned above is the deregulation of 2008. A little background to this event will help.

Prior to 2008 ALL hyperbaric chamber services were considered as “listed Services” with the Care Quality Commission (CQC). At around that time an organisation called the “Multiple Sclerosis National Therapy Centres” (MSNTC) network of centres was offering hyperbaric oxygen therapy (HBOT) as one of its therapies to those suffering from MS. It was argued by Professor Phillip James and his colleague Sir David Downie, that subjecting these units to onerous registration requirements wasn’t necessary due to the safety of the therapy and the reduced pressures they employed. They also viewed the treatments as self-administered by the patients/clients themselves.

Incidentally, Sir David is the only ever recipient of an MBE for services to hyperbaric medicine and he himself managed the Isle of Man Centre for over 40 years. Professor Phillip James is a professor of hyperbaric medicine and lead the Wolfson Hyperbaric Unit at the University of Dundee for most of his career. He is a published author of numerous papers and books on the subject.

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There argument was successful. In 2008, the Private and Voluntary Healthcare Regulations of 2001 were amended to remove what was from then designated as “type 3” hyperbaric chamber services, from the description of “listed services” and also from the definition of day hospital or private clinic. The Department of Health memorandum on this is readily

available online which explains it in greater detail. It is also evident in reading the amendment to the regulations itself that this is what it means.

This removal, and subsequent removal of the requirement to register with the CQC became applicable to HBOT therapy which was administered by a non-medical professional. The regulations only called for HBOT therapy administered, supervised, or overseen by a medical professional to be captured by the scope of registration for the CQC. Treatment not administered, supervised, or overseen by a medical professional was from this point on, considered complementary therapy or alternative therapy and therefore no longer qualified for registration. Medical professionals offering HBOT as

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private medical services still need to include their HBOT treatments in their registration with the CQC.

This made it possible for the MS centres to operate a little more freely and not have to pay the substantial annual fee to the CQC and hire medical directors at great expense.

In order to maintain standards, the organisation adopted a document entitled “A Code of Construction and Working Practice for Low Pressure Barochambers”. That document remains in force in the organisation to this day. It is also the basis of their internal training program.

This document has been built on, by me, to include the construction of flexible as well as rigid chambers which fall below the critical 1,5 atmosphere absolute threshold for requiring PVHO compliance. PVHO is discussed under its own heading below.

Unfortunately for the industry, the deregulation brought forth a sea of cowboy operators and fly-by-night manufacturers who specialise of cheap and nasty chambers. These operators commonly sell cheap chambers and then fail to honour warranties and even

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place unsafe equipment into the market. Equipment which can cause harm.

The danger is that when, not if, these chambers start to cause accidents and harm, a rapid return to regulations will be forthcoming. And no one wants that for the wellness market. Its unnecessary provided the industry polices itself regarding quality compliance and best practice.

That brings us to materials and what needs to be considered when selecting a chamber for purchase.

HB

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Chamber Buyers Guide
**Materials ASTM, Steel,
Aluminium, Flexible Woven
Fabrics – Biocompatibility, Toxic
Off-Gassing**

A crucial element of chamber design comes down to the individual materials used to build the chamber. These materials include but are not necessarily limited to:

- Metallic components forming the hull or pressure barrier
- Acrylics which most viewports are made from
- Rubber or nylon seals and gaskets which help seal doors and viewports
- Flooring
- Wall claddings
- Internal and external paint
- Metallic or plastic pipes and tubes

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- Fixed metallic or flexible pipelines
- Linings of pressure vessels, tubing and pipelines
- Gas filters
- Compressors
- Oxygen generators
- High- and low-pressure gas storage
- Communications systems
- Woven fabrics used in the manufacture of flexible chambers
- Valves and safety relief devices
- Flexible plastics and viewports
- Welding materials such as welding rods (plastic or metallic)
- Furnishing and bedding used inside the chamber
- Masks and oxygen lines
- Oxygen service and oxygen clean components

And the list can go on and on depending on your specific design, however the above list covers most of the main materials involved in building a chamber. For more comprehensive lists of materials consult the design document for your chamber. Your supplier should be happy to at least show you this document. They may not want random copies of it floating around

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the internet, but you should be able to at least view this document at a sales meeting. The design document will list all materials used and what testing protocols were followed when determine their safe use in a pressure vessel for human occupancy, (a PVHO).

Materials science is a huge and very complex discipline in its own right. It is up there with the high sciences and usually this industry is populated by accomplished scientists. It isn't necessary for a buyer to remember all that is involved with materials testing. It is however, a little more so for manufacturers.

It is reasonable though to have a basic understanding of the requirement itself to ensure materials are safe for their intended use.

The short version of this is, one cannot simply select any materials for use in a hyperbaric environment. Not all metals are suitable and certainly not all plastics are suitable.

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All materials used in the production of a chamber must be traceable. Right back to source to comply with most regulations around the world. If it's a steel hulled chamber the steel must be traceable back to the foundry that made it. There must also be a foundry certificate issued for the very steel, (or batch of steel), used to make the hull. The same is true for aluminium and other alloys. Sometimes chambers will be made of stainless steel too and the same is true.

If a chamber is made from a non-metallic material such as carbon fibre or a woven fabric, then there must be a certificate issued for the material which is based on its testing as it relates to pressure tolerance, toxicity, biocompatibility, age related decline, cracking, repeated pressure cycling, drop testing etc. The manufacturer who makes the base material must provide all this data to the chamber manufacturers when supplying a chamber. It should then be passed on to the chamber buyer included with all other certificates of compliance and calibration certificates in the chambers data file. If there's no file, don't buy it. You have no idea what it's made of and as the operator, you will be held responsible for any adverse effects on its occupants.

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This would include all plastics-based seals, zippers, door locking mechanism, and so on.

Plastics are of particular concern because when plastic is pressurised it releases gas from its structure. Its referred to as off-gassing. In many cases these gasses can be toxic to breathe. Certainly, plastics that may contain substances such as benzene, polyvinyl chloride, solvents used in coatings, colourants, etc, must be traceable to source and there must be adequate documentary evidence provided that they meet construction standards. Not all plastics are suitable. For instance, a hose for breathing service cannot be simple PU (polyurethane) hose. It must be lined with, or made entirely from, a food grade plastic that is not susceptible to excessive off gassing. It also cannot be used for oxygen service. Oxygen service hoses must be made from, or lined with Nylon 66, certain types of Teflon and certain types of nitrile rubber. ASTM International publish a list of compatible plastics for use with oxygen. They absolutely must be oxygen compatible and oxygen clean, together we call them “oxygen service”.

Similar is true for thread tapes and sealants. They too will off gas and the correct thread tapes must be used

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for air and oxygen applications. For example, standard PTFE tape used

on an oxygen system can burn. Where a little flap of tape on the inside of the piping system burns off, phosphene gas is produced and thus would be directed straight into the breathing circuit. All of this should be detailed in the chambers data file. Phosphene gas is highly toxic to breathe. Accordingly standard thread tape may not be used on oxygen system joints.

So, the question arises, how is the layman supposed to know how plastics and other material conform to biocompatibility and toxicity standards.

The answer is the “ASTM number”. Formerly known as the American Society for the Testing of Materials, the organisation now known as ASTM International publishes standards to which materials must conform and be suitable and appropriate for their intended use.
<https://www.astm.org/>

Every plastic and piece of something that a chamber is made up of, will have an ASTM number.

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For example, the following materials are used in the production of a flexible chamber and should meet the associated ASTM standards for that specific material.

- Woven nylon fabrics should comply with provisions laid down in ASTM – D751 B
- bending characteristics (low and high temperature) - ASTM S2136
- Fracture characteristics – ASTM D 751
- High temperature adhesion – ASTM D 751
- tear strength – ASTM D751 B
- Low temperature resistance – ASTM D2136
- Abrasion resistance – ASTM – D3389
- cracking strength – ASTM – D751
- flame retardant ability. – FM MVSS302 – iso 3795
- Nylon twist – EN 1773, EN 12127 or equivalent
- breaking force – ISO 13934 - 1
- tear force ISO – 13937 – 2

The above is included as an example of what is meant by the ASTM number. A prospective buyer must demand from the prospective supplier of a chamber,

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the details of compliance with materials testing requirements to ensure that nontoxic and low off gassing materials have been used. We usually refer to these as “breathing service” materials and special attention should be paid to the linings of hoses supplying gas which will be breathed in the chamber. Either from the chamber atmosphere or from a mask. In the EU, air for breathing applications must also comply with standard EN12021. This is harmonised with the British standard BS EN 12021 and details the standard for breathing gasses in the EU and the UK.

There will be an equivalent US standard included in PVHO 1 - 2019. The equipment being purchased must comply with this standard. And it should be evidenced.

When a plastic is new it will generally off-gas a lot. As it is pressurised repeatedly the amount of gas it releases should reduce to an acceptable level. For this purpose, many materials are subjected to a “running-in” type of process in the factory. They are deliberately pressurised many times to get rid of the off-gassing, or at least bring

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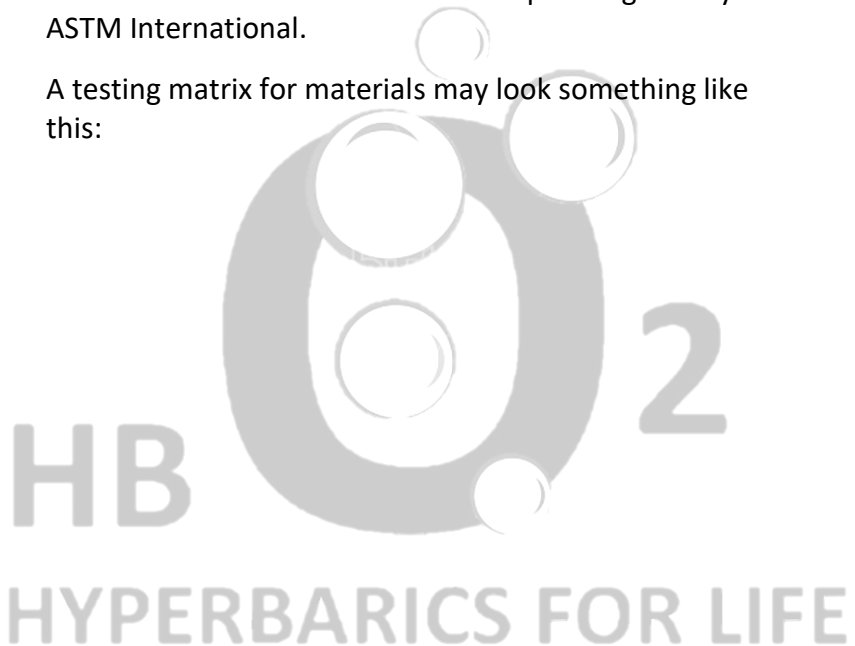
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it within limits established by ASTM International. Most countries subscribe to the standards promulgated by ASTM International.

A testing matrix for materials may look something like this:



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- TPU mesh cloth
- TPU + Polyester Fiber (PET) Composite
- Base cloth description : 1500D*1500D
- 15*16/cm
- Tensile Strength (Longitudinal) 323KGF ASTM-D751 B
- Tensile Strength (Latitude) 280KGF ASTM-D751 B
- Weld peeling 200N/5cm ASTM-D751
- Low temperature bending (static) No cracks ASTM-D2136
- Fracture elongation (longitudinal) 37% ASTM- D751
- Fracture elongation (latitudinal) 49% ASTM- D751
- High temperature adhesion 71°C No precipitation ASTM- D751
- Tear strength 110 lbs ASTM-D751 B
- Low temperature resistance (dynamic) No crack ASTM- D2136
- Abrasion (>3000 rpm) Non-leaking base cloth ASTM- D3389
- Cracking Strength Loss after Thermal Aging <7% ASTM- D751
- Flame retardant 102mm/min FM MVSS302*
- TUP Transparency Sheet (Polyester) Hardness 95 Shore A ASTM D2240
- Thickness 2.04mm ASTM D3767
- Density 1.22g/cm ASTM D297
- Color Transparent /
- Tensile strength (MPa) CD:37.92 MD:35.12 ASTM D412/Die C
- 100% Tensile modulus (MPa) CD:10.04 MD:11.91 ASTM D412/Die C
- 300% Tensile modulus (MPa) CD:17.86 MD:21.24 ASTM D412/Die C
- Fracture Tensile Rate (%) CD:616 MD:526 ASTM D412/Die C
- Tear strength Note 1 (KN/m) CD:150.6 MD:150.16 ASTM D624
- Melting point (°C) 175 DSC
- Dain value (dyn/cm) 34 Dyne Test Pen
- Yellowing resistant grade Grade ASTM D1148
- Nylon 100%NYLON TWIST Cuttable width (cm) 148 EN 1773
- OXFORD 840D*840D/60T Total weight (g/m²) 282 279 282 EN12127
- Breaking force (N) warp 2493.4 2233 2547 EN ISO 13934-1
- Breaking force (N) weft 1911.6 2305.8 2173.4 EN ISO 13934-1
- Elongation at break warp (N) 88.95 76.78 82.96 EN ISO 13934-1
- Elongation at break weft (N) 85.68 95.39 80.01 EN ISO 13934-1
- Tear force (N) warp 142.17 153.64 136.51 ISO 13937-2
- Tear force (N) weft 138.93 137.27 128.13 ISO 13937-2
- Ultra-high molecular weight polyethylene strand elongation at break (%) 3.5 GB/T 3916

In a materials report there would be lists and lists of all compounds and chemicals in the plastics and their relative standard as laid out by ASTM International.

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Toxicology

In addition to the above paragraph on materials, toxicology is also an important point to consider.

All materials used in the production of a hyperbaric chamber must be non-toxic, or at the very least, any toxic components must have the level of toxicity fall within prescribed limits.

These limits are generally also determined by ASTM International.

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A separate toxicology report must be commissioned by the manufacturer as part of the production and verification process of new designs. All chemical constituents of materials must be listed and what their toxic effects on physiology may be and at what level they are considered to become toxic. This might be measured in parts per million (PPM), percentage, molar mass or any of the scientific measures commonly used.

Various chemical components used in the production of even standard plastic parts can be toxic to humans, especially under pressure. Where they may be inert under normal conditions, they may release toxins under pressure, and this must be established prior to sale, through testing against the published standards for each material. Usually, the manufacturer would find a testing house that specialises in the types of materials in use. Testing can include toxic response, allergies, intolerance and more. Some of the regulations involved may be as follows but not necessarily limited to these.

- Biological compatibility: ISO10993-5:2009 in vitro cytotoxicity test MTT
- (Method)/type test + report/ISO10993-10:201 Skin Sensitization (bipolar)/type test + report/ISO10993-10:201 Skin irritation (bipolar)”
- “ISO 18562-1/-2/-3”
- “Biocompatibility evaluation of breathing gas access devices: ISO 18562-1:1700 /
- Biological Assessment Report /ISO 18562-2:1700 / Emissions of particulate matter

HB O₂
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And an excerpt from a toxicology report may look something like this:

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4.4 Results

VOCs identified and quantified with maximum concentration are provided in Table 2. In addition, carcinogenicity and reproductive toxicity for each VOC were also classified. And Table 2 and 3 is the results for toxicological evaluation with maximum concentration and TE

Table 2 VOCs with Maximum Concentration

No.	VOCs	CAS	Maximum Concentration ($\mu\text{g}/\text{m}^3$)	POD	TI ($\mu\text{g}/\text{m}^3$)	MOS	Carcinogenicity or reproduction/developmental toxicity
1	n-Hexane	110-54-3	11.26	1760 mg/m^3 [1]	2933	260.48	Yes (R)
2	Silanol, trimethyl-	1066-40-6	22.63	2213.5 mg/m^3 [2]	11067.5	489.06	No
3	Ethyl Acetate	141-78-6	47.89	350 ppm (1.28 mg/L) [3]	6400	133.64	No
4	Benzene	71-43-2	7.75	20.9 $\mu\text{g}/\text{m}^3$ [4]	20.9	2.70	Yes (C)
5	Heptane	142-82-5	3.86	12470 mg/m^3 [5]	62350	16152.85	No
6	1-Butanol	71-36-3	2.60	1.5 mg/L [6]	7500	2884.62	No
7	Cyclohexane, methyl-	108-87-2	2.66	1600 mg/m^3 [7]	16000	6015.04	No
8	n-Propyl acetate	109-60-4	2.13	6.4783 mg/L [8]	21594.3	10138.17	No
9	Toluene	108-88-3	6.07	1131 mg/m^3 [9]	11310	1863.26	Yes (R)
10	Ethylbenzene	100-41-4	18.46	9464 $\mu\text{g}/\text{m}^3$ [10]	9464	512.68	Yes (C)
11	Benzene, 1,3-dimethyl-	108-38-3	41.72	236.6 $\mu\text{g}/\text{m}^3$ [11]	236.6	3.18*	No
12	o-Xylene	95-47-6	32.66	236.6 $\mu\text{g}/\text{m}^3$ [11]	236.6		No

The above is an example excerpt from a toxicology report for a flexible hyperbaric chamber. The total document reads 86 pages of similar details for every chemical component involved in the production of the chamber. Buyers are advised to ask about this when speaking with a sales team. This is information that you are entitled to know. If they don't have it, don't buy it.

When a new design comes about, this is the process employed to bring it to market. If the seller doesn't have direct access to this information, they should be able to get it from the factory that makes the chamber or the manufacturer that makes the base materials. It will be on file somewhere as part of the process of bringing the chamber to market. In the EU and UK any product sold must have a data sheet. The data sheet will detail the materials testing ASTM number and any cautions.

In some instances, where established materials are used such as paints which cure inert for use in rigid chambers, it may not be necessary to have a separate assessment done per design, but your supplier should at least be able to provide the data sheets for the paints and primers used for example.



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The example which can be found on the ink is a 19-page data sheet for red oxide primer which is commonly used to prime metallic hulls prior to painting. It is not included owing to its length but can be read to give an idea of what a data sheet should look like.

https://msp.images.akzonobel.com/prd/dh/eukexp/documents/548_dulux_trade_drywall_primer_sealer_06-2013.pdf

Acrylic Viewports and Windows

Brief mention of compliance for viewports and windows is warranted.

If a view port is made from glass, it doesn't have the limited life span that acrylics viewports do.

However, glass will generally be a lot thicker than acrylic. This is what makes using acrylic attractive. It allows for thinner metals to be used in the production of the hull which reduces overall weight and costs of production. Glass essentially lasts as long as the chamber exists if it isn't damaged. But it does require bigger and more robust void seats which house each individual circular pane of glass. The word "pane" is used rather liberally, they aren't in fact flat panes but are more of conical frustrum shaped or convex pieces of glass made to fit the opening or void in the chamber hull. Some curve outward and are flat on the inside and are called "nemo windows" while others may be flat on both sides and called "flat disk" windows. In any event, if they are glass, they will be very thick indeed. Usually, they're conical frustrum with a convex outside surface. Each viewport should be serialised with a laser etched unique serial number which should traceable back to source as with above comments. There should a certificate of compliance (COC) for each individual viewport. The manufacturer of the glass window should provide all the necessary geometry information on the viewport design as well as the test data supporting the design in compliance with PVHO 1 - 2019 in the USA or EN 14931 in the EU and BS EN 14931 harmonised in the UK. In some cases, this can amount to up to 10 000 hours of testing data with accelerated testing being permitted.

Acrylic viewports are far more attractive to manufacturers as they are able to be made flat on both sides and can be considerably thinner. Acrylic viewports are made from "Poly Methyl Methacrylate" or "PMMA", a very strong engineered and transparent thermoplastic. Although a chamber pressurized 2 atmospheres absolute will still have view ports and inch or possibly thicker, due to the forces being applied to them.

For a differential of 1 atmosphere between the inside and outside of a chamber pressurised to 2 atmospheres absolute, there is 1kg per centimetre squared of force pushing on the

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view port. Calculate the area of the viewport or door in CM², then multiply that by 1 kilogram per CM². A one square meter door has 10 000CM² which translates to 10 000 kg of force applied to that door. Hence the requirements for extensive testing and design data for viewports. Acrylics that form part of the hull fall under permitted materials for hatchways and hull materials and can also be found in PVHO- 1 & 2 - 2019 or the UK and EU BS EN 14931 standards.

Acrylics should also be serialised with unique number correlating to the certificates of compliance issue by the manufacturer. Acrylics also have a limited life span of 10 000 pressurisations or 10 years whichever comes first or 40 000 hours as per PVHO 1-2019 for specific designs, at which time they must be scrapped and replaced. Extending their life span is possible with application during the design and testing phase. They cannot be re-lifed. This is the main set back of using acrylics. Especially if your business plans to pressurise multiple times a day, for example 6 treatments a day. 6 Treatments a day roughly converts to 4 and a half year of use before the requirement to replace acrylics kicks in. (calculated for a 365-day year.) That would also line up with the abovementioned 40 000 hours if extended life is not applied for.

Flexible transparent viewports used in the production of flexible chambers should comply with the above-mentioned ASTM numbers relevant for transparent polypropylene or other such material they may be made of. These would be stitched and glued, or heat welded in place as opposed to sitting in a seat or “void seat” as they are known. They form part of the primary pressure barrier.

Verification Agencies

It's one thing to cite standards and recall various legislation and its references, but without verification it all amounts to very little. Internal verification is technical legal, and in some cases internal certificates of compliance will be suitable, however for general compliance to design standards and materials compliance it is customary for a manufacturer to employ the services of a classification society or verification agency as they are known. This is called third party verification and when a design standard such as that for a hyperbaric chamber is being assessed the agency or society, it will assess the design and test it against an established standard. For hyperbaric chambers that standard is called the “Pressure Vessel for Human Occupancy” standard.

There are plenty of them about and most countries have their own, but the key well-known names include but are not limited to: Lloyds Register, Det Norske Veritas(DNV), Bureau Veritas (BV), RINA among others. A Google search will turn up no shortage of choice.

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It is the legal duty of the manufacturer or distributor to ensure the PVHO they are selling meets the prevailing standard for their territory being sold into. If a chamber does not meet your local PVHO design standard and regulatory requirements, it is being sold illegally. This is explained further below. This isn't a choice thing; it is compulsory and all pressure vessels that will have a human occupant are captured by these regulations and requirements. Just the same way standard boiler and pressure vessels are captured by regulations specific to their design. Whether its for medical grade use or not.

This is what makes well-built quality chambers so expensive. It isn't a cheap process. It is also the reason many companies will only sell chamber which can be pressurised to 1,49 ata (atmospheres absolute) or less. The requirement for PVHO compliance falls way for chambers below 1,5 ata. It's a tactic less scrupulous companies employ to circumvent the need for PVHO approval. More reputable company may sell flexible chambers which have a maximum working pressure of less than 1,5 ata, and then also sell a range of PVHO approved chamber which operate above this threshold. If the supplier you are dealing with cannot provide evidence that your chamber meets and complies with some kind of PVHO standard then do not buy it. If they have achieved this compliance and it has been recognized, they will have certificates to prove it and they would yell it from the rooftops as it is a considerable selling point.

Flexible chambers under 1,5 ata work a little differently.

Buyer beware: Many companies will show you a legitimate CE marking certificate or a UKCA certificate allowing them to use these marks on their equipment. Make sure you know what the mark is for. What aspect of the chamber is approved for this mark? A hyperbaric chamber set-up is a system of integrative parts and machines rather than a single thing that gets verified. In most cases it is only for electrical compliance. You may also see a RoHS certificate. These certificates are for electromagnetic compliance only, and don't usually validate anything to do with pressure, medical devices or biocompatibility and toxicology. The chamber could still be a dangerous cheap and nasty, even with a CE or UKCA mark. In the USA, ask if it is FDA approved or not. If not FDA, then it must still be ASME PVHO -1 – 2019 compliant.

Also check its compliance with fire safety via the document, NFPA 99 chapter 14. This a document published by the National Fire protection Association in America. It has become a global standard recognised in most countries. Internal statements of conformity are common for this point. As long as you have their internal verification of compliance you should be ok. Internal verification such as this amounts to a written commitment that the product is compliant. If it were ever to be found to be non-compliant, the responsibility for this would be squarely on the manufacturer. It is important to ask about it though.

The takeaway from this heading is that the design standard for your chamber must be a recognised one for your region, and the chamber must be tested against such a standard before it may be sold in your region. Usually this is PVHO for one of the main countries



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mentioned. Many countries recognise the American standard the PVHO 1 - 2019 for the chamber and PVHO 2 - 2019 for acrylic viewports and repairs.

There will be documentary evidence in the way of verification agency certificates confirming the design. There will also be a design document detailing design, welds, geometry, maximum working pressure, forces exerted on the chamber and so on. You are within your rights to see this material before purchasing. The verification agency will also stamp the chamber hull itself. This will leave a permanent stamp in the metal of the hull conforming it has been inspected by them. This is stamped into the metals somewhere on the hull and is not removeable.

Construction Standards – PVHO And Sub PVHO Designs – Flexible Chambers – Pressure Vessels.

In the preceding paragraphs and sections, the term “PVHO” has been used a fair amount with some description of what it is.

PVHO stands for “Pressure Vessel for Human Occupancy”.

A hyperbaric chamber, or barochamber, or whatever name its given, is a pressure vessel. It is deemed a pressure vessel in regulations because of its size and volume and that it contains pressurised gas or fluid. Typically, vessels under half a litre don't require a pressure test. Chambers are way above this volumetric measure and therefore they must be tested in line with the design standard, and the test results marked on the chamber to display maximum working pressure and test pressure. It's part of requirements to get a design approved and tested against a PVHO standard.

When we talk about design standards, we are talking about details of the design being tested. The geometry, the pressure tolerance, the pipework design details etc. These standards in America are published by the American Society of Mechanical Engineers (ASME). They produce standards for a great many things including pressure vessels and boiler construction codes. A chamber for human occupancy is referred to as a PVHO.

In the EU and UK, we have our own standards which are modelled on the ASME standards. These are EN 14931 for Europe and BS EN 14931 for the UK. They are harmonised following Brexit.

The standards detail how a chamber must be built, what kinds of welds are acceptable, what thickness steel must be depending on pressure, what design the acrylic view ports must follow etc.

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Generally speaking, ASME will not provide a standard for chambers which are rated for 1,49 atmospheres absolute (ata) and below. They typically only provide standards for 1,5 ata and above.

Verifications agencies, discussed above, will then use these standards to assess a design, and if it is found to be compliant, they will inspect a prototype and verify that the design meets the standard. The manufacturer may then affix the mark that designates the standard to the chamber. Usually this is stamped onto a data plate which is permanently fixed to the chamber itself. This is the single most important part of the chamber, the data plate which details the design standard, the manufacturer, the verification society/agency, the test pressure and maximum working pressure.

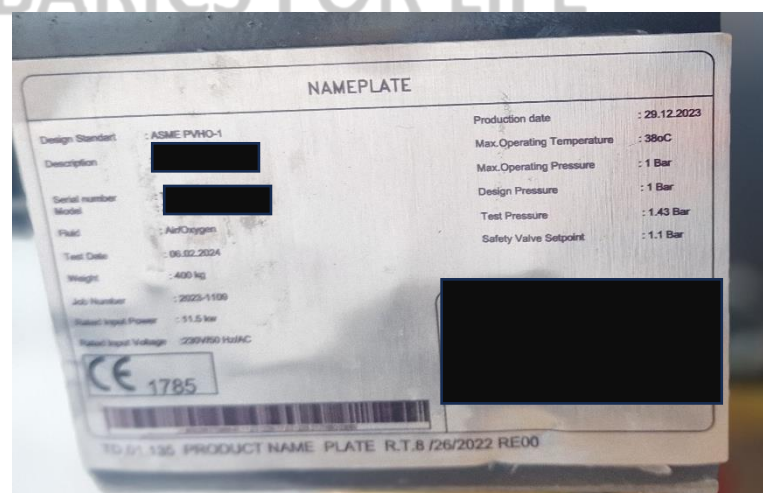
IF A CHAMBER HAS NO DATA PLATE EITHER ENSURE ONE EXISTS AND CAN BE FITTED OR DO NOT BUY THE CHAMBER. THE PLATE IS EVIDENCE THAT ALL THE NECESRAY TESTS AND APPROVALS HAVE TAKEN PLACE.

The data plate will be accompanied by a stamp from the verification society or agency as described above. It will be stamped into the material of the hull and will be non removeable.

A Lloyds stamp looks like this:



And a Data Plate Look like this:



Details of the manufacturer and serial numbers have been obscured in the interests of neutrality.



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If your supplier does not fit a data plate or claims it doesn't need one, walk away. The chamber will have zero resale value anywhere that requires construction standards. The value is in the certification plates and stamp. Some suppliers claim the chamber doesn't need a plate and doesn't need to comply with PVHO requirements if it's a non-medical chamber. This is untrue. It has nothing to do with whether the chamber is medical or not, it has to do with human occupancy. They all need a plate, and they all need to be compliant.

For chambers under 1,5 ata it can become a little tricky to establish quality of design. As already mentioned, PVHO is generally not required for less than 1,5 ata working pressure. This is usually where most flexible chambers operate. For this reason, the vast majority of flexible chambers do not have PVHO recognition. If the salesperson claims their 1,4 ata chamber is PVHO compliant they are not being entirely truthful. No 1,4ata flexible has been tested against PHVO regulations because the standard don't provide for this. At least none I know of.

Furthermore, there are precious few above 1,5 ata that have been tested against PVHO. I only know of 2 manufacturers globally that meet the standard. This is the reason most suppliers will only supply flexibles up to 1,49 ata. For pressures above that, reputable suppliers will switch to rigid chambers which are more easily tested against the standard. There are some in the market up to 1,7ata which claim to be PVHO approved but I haven't seen the data. Ask them for the data to back up the claim. If they have it, great. If not, walk away.

Designs which operate under 1,5 ata are dubbed Sub PVHO. For these chambers you are within your rights as a customer to ask to see the design document, the ASTM details, any and all testing data, toxicology reports, biocompatibility reports, certificates of compliance, statements of conformity, calibration certificates for gauges etc, as well as full operations manuals detailing all of the above.

Many suppliers actually market rigid chambers that only operate below 1,5ata. These chambers successfully skirt around the requirement to acquire PVHO accreditation. You would be potentially unnecessarily limiting yourself buying such a chamber. It would cost not much more to simply buy a 2 ata PVHO accredited design. It's quite normal to operate a 2 ata chamber at 1,5 ata or less. The difference being you cannot go as high as 2 ata with a 1,5 ata chamber but you can always operate at reduced pressure in a 2 ata.

Notwithstanding that there is a place in the market for 1,5ata monoplace chambers. Usually for home use. just ensure they have a design document and all the testing data mentioned above. Not everyone wants a 2 ata chamber, and the saving on costs may be material to buyers of these chambers. The disadvantage is that very often without the PVHO testing, many of these come into the market subpar standard and don't last as long and could even have biocompatibility issues.



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When reading the PVHO 1 – 2019 document, it becomes clear that it isn't a single document that determines standard. The PVHO 1 - 2019 refers to the ASME "Boiler and Pressure Vessel Code" (BPVC). The latest version is 2023. In fact, PVHO 1 was due to have a new version in 2023 also. PVHO also refers to NFPA 99 mentioned above. It's important to ensure your chamber design meets ALL of the standards it needs to.

Pressure Testing

Pressure testing is mentioned more than once above and briefly explained is the process by which the chamber is pressure tested to approximately 1,25 times its rated working pressure. Maximum Working Pressure, or "MWP", is the pressure the chamber would routinely be, and is certified to be compressed to on a day-to-day basis.

Some manufacturers will say, "yes it can do 3 ata, but we only test to 2 ata." This should raise your eyebrows. What they are advocating is exceeding its rated working pressure and this can be extremely dangerous. Don't fall for it.

Test pressure must exceed MWP by a factor of 1,25 and then held at that pressure for a prescribed time. During this time the chamber is observed for any obvious distortion and deformity or crazing and cracking of the view ports.

In many cases a hydrostatic test is completed. This involves filling the chamber with water and pressurising it. Then measuring with precision equipment, any change in shape or any distortion of the pressure vessel. Naturally this done before adding any furnishing's or electronic equipment. Similar testing is done at 5-year intervals for diving cylinders. Cylinders for surface use only need only be tested every 10 years unless some event occurs which invalidates the previous test. Events can include fire, impact, drilling etc. The 10-year interval coincides nicely with the life span of the acrylic view ports. We usually re-life chambers at 10 year intervals.

Non-metallic chambers may be subject to more frequent intervals but typically chambers are "lived" for 10 years from test date.

When you buy a chamber. Make sure it is still "In test" and has a reasonable time left to run on the test validity. Especially when buying second hand chambers. Chambers which are "Out of test" can often be bought cheaply and then re-tested but there is no guarantee they will pass a pressure test. A lot of buyers opt for this option with retired diving chambers which may not pass a diving pressure test at a greater pressure but will pass a test at a lower pressure and are essentially downgraded for use as a wellness chamber. This is a good way to get a more affordable chamber. But check the test dates, or likelihood of getting a valid test done, you may just be buying scrap metal. If this is something you wish to do,



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Maybe employ the services of an expert who can view the chamber with you and learn about its history and also evaluate the viewports discussed above.

During manufacture and commissioning a pressure drop test will also be conducted. Also known as a pressure hold test. The chamber will be pressurised to maximum working pressure and held for an hour while isolated from the pressurising gas. If the chamber loses more than 1% of its pressure it will fail, and it must be determined why the chamber is losing pressure. Usually, it is simply a bad seal or O-ring on the door. Either way it should be repaired and retested. Pressure hold test can also be done at regular intervals as part of preventative maintenance.

Certification – COC's – Calibration Certificate,

Accreditation, CE and UKCA Marking, ISO, PVHO

Already discussed at some length however revisited to simply add that all certifications, calibration certificates, certificates of compliance (COC's), statements of conformity, verifications, and other testing data as well as the full life cycle of the product and its materials should be included in a master chamber data file which holds all of the information. It is worth noting that insurance companies will want to see all of this data.

NFPAA 99 Ch 14 Bedding and Clothing

All furnishings and bedding that is to be used inside the chamber must meet exacting fire safety standards as laid out in the aforementioned document the NFPAA 99. Chapter 14 deals with hyperbaric facilities. Most of NFPAA 99 deals with the premises, however there are details regarding fire retardancy of bedding and fabrics used in the chamber. Not just any furniture and fabrics, including sponge fillers and foam, can be used. They must be specially fire retardant for use in hyperbaric environments.



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Electrical Equipment

All electrical equipment used in, or on a chamber must be 12- or 24-volt DC (direct current) only. In general, no high voltage is permitted on or in the chamber to avoid electrocution from potential fault current on the hull. Lower DC voltage also minimises the risk of electrical arc which can be a source of ignition and fire. If it is absolutely necessary to mount 230/240 VAC (alternating current) on the hull it must be double insulated and must be either double fused on the live and neutral lines, or there must be a residual current device/breaker (RCD or RCB) installed on the chamber which will detect fault current and trip. They should be in the region of 30mA and 30 milliseconds in break times and sensitivity to reduce the likelihood of fibrillation across the heart in the case of electrocution. Any lighting that is 230/240 VAC must be encased in a pressure proof housing and double insulated from the hull and be protected as above. See our document on electrical and fire safety.

Quality Management

When buying a chamber don't be afraid to ask for evidence of ISO compliance for management and quality systems.

Suppliers who have this will be only too happy to offer it up.

Check for:

- ISO 9001 for quality management systems.
- ISO 13485 Medical devices — Quality management systems — Requirements for regulatory purposes.
- ISO 45001 for Occupational Health & Safety Management.

There are more as well. However smaller companies may not have these accreditations. If they don't, you are within your rights to ask for details of their quality management system and quality assurance procedures. QA (quality assurance) is vital in manufacturing of chambers. Usually, companies selling them are bigger than "mom and pop" businesses and in theory should have all their ISO compliance in order.

QA systems should include but is not limited to tracking of all parts, materials, assemblies, sub-assemblies, materials, paints and coating, lubricants and seals, and tools used in the fabrication and assembly of the chamber. Manufacturers should have all of this detailed in tabulated matrices for customers to have a look at. They should also detail weld procedure



Cumbria Hyperbaric – Hyperbaric Chamber Buyers Guide and types as well as weld testing procedure such as Xray, ultrasonic, magnetic particle testing, and any other non-destructive testing methods they may use (NDT), and fabrication methods. Origins of metallic and non-metallic materials etc.

Warranty

Your chamber must absolutely come with a written warranty and should be around 3 years. In the UK it is only compulsory to offer a 12-month warranty on materials and workmanship, but this can sometimes be as long as 3 years depending on the product. A review of consumer law might be a good suggestion.

No warranty? Don't buy it.

Your supplier should also offer ongoing maintenance contracts and plans for matters such as annual or bi-annual servicing and annual recertifying. A chamber needs re-certifying every year. While it's main test remains in date for 10 years or 10k pressurization cycles, all gauges need to be calibrated annually, as well things like oxygen purity needs to be tested and verified. Hoses, seals and O-rings and filters need to be inspected and recertified or replaced. Compressors require servicing as do chillers and oxygen generators. There's quite a lot that goes into a PMS (Planned Maintenance System). Taking out an optional service contract is a good idea.

Training – Operational and Extended Training

I've witnessed, in person, some training amounts to no more than a half hour telephone conversation. This is unacceptable.

A chamber system is just that. A complex system of machines and essentially, it's a **life support system**. Operators must be shown how to safely operate the system. Manufacturers have a duty of care to provide this operational training as part of the purchase price. Further training should also be achievable with your supplier. They may contract it out, but they should be able to connect you with training providers that can train in aspects of the therapy itself, health and safety, staff management, system management etc.

Operational training often takes all day. IE 6 to 8 hours to complete depending on the number of attendees. It involves the thorough demonstration of the systems functions as well as detailed explanations of how things work. The do's and don'ts, emergency

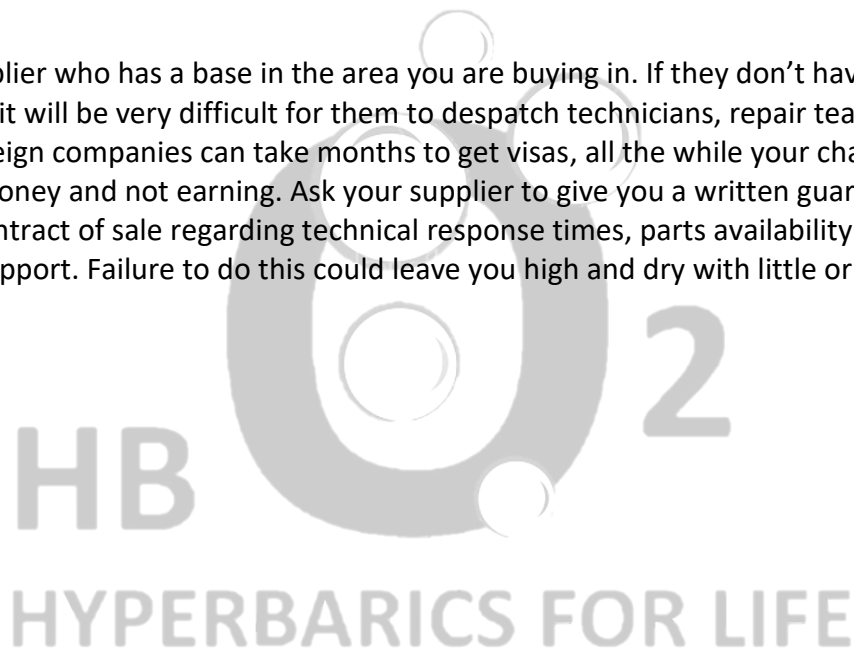


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procedures, who is and isn't suitable for treatment and so on. It should be documented and signed off by the trainer as the basis for the health and safety system. Inductees receiving training must physically demonstrate competence in the use of the system. Every single inductee must demonstrate this.

Suppliers who offer none of this may not be the best ones to go with. Once they have your money you'll likely not hear much from them again.

After Sales Support

Choose a supplier who has a base in the area you are buying in. If they don't have a base in your country, it will be very difficult for them to despatch technicians, repair teams, trainers etc. Some foreign companies can take months to get visas, all the while your chamber is costing you money and not earning. Ask your supplier to give you a written guarantee as part of the contract of sale regarding technical response times, parts availability and remote and on-site support. Failure to do this could leave you high and dry with little or no assistance.



Conclusion

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I'll circle back to some of my first comments at the beginning of this document. No, it's not a free for all as some world leading researchers and authorities may state and think. It is still highly regulated in terms of construction standards, normal health and safety rules and regulations, fire regulations, etc. There is no shortage of regulation in the UK and abroad that control the wellness market. If not by direct regulations and requirements for registration, then by controlling the standard to which a chamber must be built before being made available for sale.

The only deregulation was to remove type 3 HBOT services from listed services in terms of CQC registration. And it was a necessary deregulation which I will continue to support. The chamber itself and its construction and sale is still regulated.

However, customers do need to educate themselves as to these regulations, to which your supplier must adhere.

Hopefully this document sheds a little light on what you should expect from your supplier when buying a chamber. There is much to know. Unfortunately, many of the existing suppliers don't know much of this themselves. Unfortunately, as well, in the event of an accident or investigation, it's you, the operator, that is responsible. It's a good idea to study the comments contained herein and try remembering them when you deal with the sales teams. When they ask why a competitor is half the price, now you know why. If they tell you it doesn't need to comply with ABC regulation, or XYZ rule, know they're misleading you.

You will never get quality for cheap, and if you want cheap you cannot expect quality. Then there are the compliance regulation which all countries have. Running afoul of these can get an owner into hot water with authorities.

BUYER BEWARE!!!

Indeed. The sharks have been circling this past few years and customers need to be better informed. Some of the quality and construction standards I have witnessed have been no less than shocking and as an industry we don't want accidents. That will bring massive regulation which will end the wellness market. We absolutely have to self-police our own standards. Manufacturers, it's time to step up and comply. Customers it's time to get educated so you can identify the non-compliant at a glance.

Do your due diligence, and if you cannot find the answer get in touch. I'm happy to help at no cost for a quick call or email.

Hayden.

END