Compressed Gas (Air) Supply System

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1. Executive summary:

The diversity of requirements adopted around the clinical hyperbaric operating world clearly shows that we have too often drawn on history, or adopted practices that have been researched and developed for other applications. It is considered opportune to review our knowledge of the standards for air quality and the quantity of air required to effect safe treatments, based on realistic and likely scenarios.

A significant amount of information exists in the scientific literature, as well as in national and industryregulated standards. In many cases, the information has been developed through practices and lessons learned. This data should be carefully heeded in the pursuit of extracting a single series of proposals for the road going forward.

Medical and industrial science, technology and experience have empowered us to better understand the effects of decisions, as well as providing us with better rationale behind making such decisions.

This paper represents a summary of the existing knowledge base, and then presents two proposals based on real or expected situations, rather than using either a best-guess or overly conservative speculative approach.

2. Objectives:

There is a need to review the currently available information and then to answer the following two questions:

(1) What is an appropriate standard for the quality of air provided to hyperbaric chamber occupants?

(Most hyperbaric air quality standards are based on occupational health or diving related applications, whereas we are essentially dealing with medical devices.)

(2) What is the appropriate quantity of air that should be available to hyperbaric chambers?

(Internationally accepted practices for ventilation and air storage vary greatly, and consistency based on realistic expectations is required.)

The final intended outcome of this discussion paper will be a proposal for suitable specifications for both the *quality* and the *quantity* of air provided to clinical hyperbaric chambers for use in Europe.

3. Introduction:

3.1 Background:

The technical realm of hyperbaric medicine has traditionally been driven by two main influencing forces, viz. (1) commercial and military diving practices and (2) clinical and hospital-engineering Compressed Gas Supply System September 2012 1

standards. The majority of our new and sector-specific standards and guidance documents have attempted to introduce technical specifications that are based on actual hyperbaric practice requirements, but there are some areas where the older, traditional methodologies have been incorporated without much change.

Medical investigative work has been performed to determine the human impact of common contaminants in breathing air and this has provided a rationale behind the stated carbon dioxide (CO₂) and carbon monoxide (CO) maximum levels in stored breathing gases.

Scientific analysis has been performed on CO_2 levels in closed environments, specifically for helmets and confined diving bells or habitat chambers. Suitable oxygen (O_2) levels in living environments have likewise been investigated, resulting in a degree of consensus regarding the requirements for sufficient air exchange based on these two gases.

Finally, other notable toxic or debilitating elements have found their way into breathing systems, including for example sulphur dioxide (SO₂), nitrous oxide (N₂O), nitrogen dioxide (NO₂), nitrous fumes (NO_x), methane (CH₄), non-volatile hydrocarbons and even more infrequent compounds such as xylene, toluene and various halogenated solvents (sometimes used in cleaning piping systems). Limits based primarily on health effects are published in occupational health regulations and specifications.

The contaminant elements that require specific consideration include oil and water, both in the form of vapour or condensed liquids. These 'contaminants', together with other biological hazards, require some discussion in order to consider suitable limits.

The combined processes of *elimination* and *air exchange* should provide a definitive guideline to quality as well as quantity of air required in the clinical hyperbaric environment.

3.2 Survey of international practices:

Before entering into sensible discussion, a survey is required of the existing practices and established standards that are in force in the various operating and geographical arenas.

Source data is available in standards, specifications, occupational health and clinical regulations, industry practices as well as in the original repositories of knowledge for breathing air (gas) systems, namely the 'rules' published by the international maritime classification societies.

The following two tables provide a summary of the available information on both air quality standards, as well as considerations for determining suitable quantities of air. Data is tabulated in the form needed to support the discussion on a suitable proposal and is thus by no means a comprehensive reflection of all the relevant data. Units are not always consistent with those published in the reference sources, as in some cases these needed to be converted to provide easier comparison. Also limits are as stated in the literature, with no corrections applied where approximation or interpretation have resulted in deviations from the actual values.

Region	Reference	CO2	со	H ₂ 0	Oil	Odour	Other
Europe	EN 12021 ^[1]	500 ppm _v	15 ppm_{v}	-11°C ^a	0.5 mg/m ³	NS ^b	С
	Ph Eur 1238 ^[2]	500 ppm _v	5 ppm_{v}	67 ppm _v	0.1 mg/m ³	NS ^d	-
USA	CGA Gr E ^[3]	1000 ppm _v	10 ppm _v	24 ppm _v ^e	5 mg/m ³	None	THC 25 ppm _v
	CGA Gr N ^[3]	500 ppm _v	10 ppm_{v}	None	None	None	-
	USP ^[2]	500 ppm_{v}	10 ppm_{v}	None ^f	None ^g	None	-
Canada	CZ275.1 ^[4]	500 ppm_{v}	5 ppm _v	26 ppm _v	1 mg/m ³	None	h
Australia	AS/NZS 2299.1 ^[5]	480 ppmv	10 ppm_v	62 ppm _v	0.5 mg/m ³	None	-
	AS 2568 ^[6]	500 ppm _v	5 ppm_{v}	1000 ppm _v	0.5 mg/m ³	NS ⁱ	THC 27.2 ppm _v
UK	HSE DVIS 9 ^[7]	500 ppm _v	3 ppm _v	31 ppmv ^j	0.5 mg/m ³	NS ^b	-
UK	LR 5-4 3.1 ^[8]	500 ppm _v	10 ppm_v	621 ppm _v	1 mg/m ³	None	-
International	ISO 8573-1 CI 2 ^[9]	-	-	-40°C ^k	0.1 mg/m ³	-	Partic. ¹ 1 mg/m ³
	ISO 10083 ^{[10]m}	300 ppm _v	5 ppm _v	67 ppm _v	0.1 mg/m ³	-	-
	RAG ^[11]	500 ppm _v	10 ppm_v	500 ppm _v ⁿ	5 mg/m ³	None	THC 25 ppm _v
	RAG ^[11]	500 ppm_{v}	10 ppm _v	500 ppm _v ⁿ	0.1 mg/m ³	None	THC 25 ppm _v

Table 1: Maximum limits of contaminating substances in breathing air^p

Notes to Table 1:

Shaded rows indicate medical air specifications; the clear rows indicate breathing air or other, similar specifications.

The list is not exhaustive and where countries like South Africa have followed specific ISO standards (published with local reference numbers), these standards have not been repeated.

Dew point temperatures are indicated as pressure dew point (PDP) temperatures in the table.

- a The requirement for stored air depends on circumstances: (1) Where conditions are unknown, a PDP limit of -11°C applies; or (2) PDP to be 5°C below the lowest likely temperature; or, at atmospheric pressure, the limits are (3) air stored between 40 to 200 bar, 50 mg/m³ (62 ppm_v), (4) air stored above 200 bar, 35 mg/m³ (44 ppm_v), & (5) air supplied to high pressure cylinders, 25 mg/m³ (31 ppm_v)
- b NS not significant
- c Free of any other harmful or toxic substances
- d NS not specified
- e Dew point (atmospheric) to be ±6°C below lowest likely temperature or -54°C for exposure of air in cold regions (24 ppm_v)
- f Determined through condensate on a mirror
- g Dew point (atmospheric) to be 5°C below lowest likely temperature and -53°C (26 ppm_v) for storage above 124 bar
- h ~ Volatile hydrocarbons 5 ppm_{v} and halogenated hydrocarbons 5 ppm_{v}
- i Dew point -20°C or less than minimum recorded temperature
- j Air stored between 40 to 200 bar, less than 50 mg/m³ (62 ppm_v); air stored above 200 bar, 35 mg/m³ (44 ppm_v); air supplied to high pressure cylinders, 25 mg/m³ (31 ppm_v)
- k Expressed as pressure dew point (PDP)
- I Maximum particle size 1 micron
- m ISO 10083 provides a specification for oxygen-enriched air, implying suitability for use in an oxygen pipeline or with oxygen-rated equipment. This provides good guidance where the breathing air is to be delivered via the oxygen breathing circuit.
- n Air supplied to patients and chamber need only meet the 500 mg/m³ requirement. Air stored at pressures up to 200 bar should contain less than 50 mg/m³ (62 ppm_v); air stored above 200 bar, is restricted to 35 mg/m³ (44 ppm_v).
- p Unless otherwise stated, the limits apply to air at standard temperature and pressure (STP) 0°C & 10⁵ Pa.

	Reference	Summarised interpreted minimum requirements	
1	EN 14931-2006 ^[12]	^a Pressurise treatment lock to 3 ATA plus 30 alpm per person for 150 minutes	
2	ECGP-2004 ^[13]	Refer to EN 14931	
3	NFPA-99: 2012 ^[14]	Ventilate at 85 alpm (3 acfm) per occupant not on mask at all stages of treatment.	
4	USN Dive Manual, Rev. 6 2008 ^[15]	1 pressurisation of treatment lock plus 2 pressurisations of transfer lock to 6 ATA plus 2 acfm per patient (at rest) plus 4 acfm per tender	
5	UHMS Manual: 2005 ^[16]	85 alpm (3 acfm)	
6	CSA: Z275.1-05 ^[4]	2 pressurisations of treatment lock to P _{max} ^b plus ventilation at 85 alpm (3 acfm)	
7	AS 4774.2-2002 ^[17]	Ventilate to ensure O_2 < 23.5% and CO_2 < 5000 ppm _v	
8	Nuckols, M.L. 1996 ^[18]	Ventilate to control CO_2 build-up and O_2 depletion. Minimum gas exchange required, per formula ^c , equates to 64 alpm (2.26 acfm) per person	
9	RAG 2010 ^[11]	1 pressurisation of treatment lock plus 2 pressurisations of transfer lock to P _{max} ^b plus 2 acfm per occupant for duration of treatment table	
	Maritime Classification Soc	ieties	
10	ABS-2002 ^[19]	Adequate capacity for intended operation plus O_2 & CO_2 monitoring	
11	DNV-OS-E402 (2010) ^[20]	Adequate capacity for intended operation plus O_2 & CO_2 monitoring	
12	GL-2009 ^[21]	1 pressurisation of treatment lock plus 2 pressurisations of transfer lock to 6 ATA plus 40 alpm per occupant for duration of operation	
13	LR-1989 ^[22]	Adequate capacity for intended operation plus O ₂ & CO ₂ monitoring	
14	NKK 12-480 2012 ^[23]	Adequate capacity for intended operation plus O_2 & CO_2 monitoring, plus scrubbing	
15	RINA-2011 ^[24]	Adequate capacity for intended operation plus $CO_2 < 5000 \text{ ppm}_v$	
16	RMRS-2004 ^[25]	As agreed with user, $O_2 \& CO_2$ monitored.	

Table 2: Air Capacity Requirements

Notes to Table 2:

In all cases above, the requirements apply where the occupant individual breathing gas systems are exhausted <u>outside</u> the chamber (commonly known as overboard dumping).

Flow rates indicated as alpm (actual litres per minute, meaning at pressure) or nlpm (normal litres per minute, meaning at normal temperature and pressure [NTP – 20°C and 101.325 kPa]).

The terms acfm and scfm similarly imply actual or standard cubic feet per minute. However there is a difference where standard temperature and pressure (STP) applies to metric versus imperial units. STP_{metric} is 0°C and 10⁵ Pa whereas $STP_{imperial}$ is 15.6°C and 101.325 kPa.

Only average values are assumed and no compensation for ambient pressures or temperature variations has been applied.

Where primary and back-up systems are required, the requirements for the primary case (the higher requirement) are assumed.

Some specifications provide capacity requirements, which may be reduced where active O_2 and CO_2 monitoring, and CO_2 scrubbing is performed. The requirements expressed remain those where actual capacities are specified.

- a This standard also requires continuous monitoring to ensure for $O_2 < 23.5\%$, $CO_2 < 5000$ ppm_v, organic compounds < 0.5 mg/m³ and RH 40 60%. This is noted as the only case of organic compounds requiring monitoring. No indication of how to do this is offered.
- $b P_{max} \ is assumed to be maximum intended treatment pressure as defined by the scope of services being offered.$
- c Nuckols et al derived a formula that allows a computation of the absolute minimum gas exchange required. This is detailed under the Discussion, section 4.2.4.

3.3 Practical considerations:

3.3.1 Quality assessment:

When establishing specifications for contaminants in air for use in hyperbaric facilities, consideration of the available analytical techniques is necessary to ensure that analysis can be done in practice. Clearly techniques that provide accuracy and resolution appropriate to the limits being imposed is necessary, but analyses that requires remote, expensive and elaborate testing methods are not going to provide practical solutions.

References [2] and [26] are examples where additional information has been provided as to how the analyses need to be done. Assuming the commercially available testing methods, the following data applies:

_		CO2	СО	H ₂ 0	Oil
Detection methods	Manual	Detector tube	Detector tube	Detector tube	Detector tube
	Electronic	Infrared sensor	Electro-chemical sensor	Dew-point meter	Gravimetry
Accuracy	Lower	± 15%	±15%	±20%	N/A ^a
	Higher	±2%	±5%	±0.2°C	±0.2% ^b
Lowest detection		100 ppm _v	5 ppm _v	5 mg/m ³	0.1 mg/m ³
Limit		50 ppm _v	0 ppm_{v}	±10 ppmv ^c	0.01mg/m ^{3b}

Table 3: Practical methods for air analysis

Notes to Table 3:

The lower values apply to the most commonly used method, i.e. the detector tube, while higher values are achieved using electronic (sensor-based) or laboratory-based instruments.

- a Oil-detection by detector tube or equivalent provides a simple pass or fail outcome only.
- b On-line oil detection requires highly sophisticated equipment, impractical to use in air-production plant. Gravimetric analysis in a testing laboratory provides greater accuracy for oil contaminant detection, but is not an on-line or real-time method.
- c The limits of detection expressed in ppm_v for a dew point meter reduces with temperature. The value shown is a rough indication that applies at the typical dew point temperatures that are required.

While there are a range of other toxic and debilitating compounds that have been detected in breathing air, it would be deemed impractical to demand analysis except where a risk assessment clearly shows that this is a likely hazard in a specific location or situation.

Theoretical concerns about microbiological or 'organic compound' contamination have been raised by concerned practitioners. In general, breathing gas supplied to a hyperbaric environment should be "unexposed" to human or animal environments, apart from any exposure prior to compression. In addition, compressed gases have pO_2 values that are toxic to most known pathogens. Microbiological contamination is thus unlikely in terms of 'unused' air. Organic compounds should be assessed by risk analysis and if a hazardous situation is likely to exist, there are analytical instruments commercially available to provide monitoring for these compounds.

3.3.2 Quantity assessment:

Appropriate means to assess the quantity of air required will be covered in the Discussion, section 4.2. As a general principle, the philosophy of "what is expected" and "what is likely" should be based on assessments of normal and emergency conditions or situations.

This has been the approach taken by the international maritime classification societies that need to accommodate situations that possibly contain even greater opportunities for mishaps when compared to a building on land, supplied by services that are generally always available.

The presiding reason for requiring a minimum specification should not be one of convenience or preference, but for a genuine emergency situation. One such example might be an injured diver requiring recompression therapy; another might be a critically-ill patient requiring immediate hyperbaric oxygen therapy; both presenting during a power outage. These two examples reveal that the worst case is thus not likely to be one of maximum occupancy at maximum pressure, except for a smaller hyperbaric chamber and in this case, the gas requirements are generally less. A realistic approach is needed.

3.4 Synopsis:

A range of options and approaches has developed over the past 50 or more years, systematically tempered through scientific advances, practical assessments and regulatory efforts.

It is an opportune time to review the standards based on improvements in compression and filtration techniques, advances and improved availability of analytical instruments, but also considering the extended history where incidents and accidents have been examined and assessed.

Air *quality* has traditionally been sub-divided into two distinct camps, viz. (1) air used to pressurise the hyperbaric environment, which has been heavily influenced by the diving industry, but also by the limiting practicalities of dedicated air compression plants; and (2) air provided to chamber occupants, primarily for therapeutic purposes.

The *quantity* of air required to ensure a safe and effective treatment is a product of the size and occupancy of the chamber, the pressure and duration of the intended treatment, and the accepted limits, in terms of contaminants such as CO_2 or excessive oxygen levels, that are introduced inside the hyperbaric environment. The changes over the past decades to offer larger therapeutic chambers, albeit at lower pressures, have perhaps moved the focus to considering ventilation rates on a per occupant basis. Guidelines for these computational variables would be of use to system designers, users and safety personnel.

The issue of suitable quality of air inside the chamber, apart from being an indication of the need to ventilate, is not considered a part of this discussion, and existing general limits for clinical facilities, viz. $CO_2 < 5000 \text{ ppm}_v$ and $O_2 < 23.5\%$, remain as the accepted norms for this industry.

4. Discussion:

While there is a cross-over between quality and quantity of air, the focus here is on unused air to be introduced into the chamber either for pressurisation and ventilation, or as an individual, therapeutic (or emergency) breathing gas.

The two subjects are thus discussed separately.

4.1 Quality of air:

4.1.1 General:

The three primary reasons for considering the assessment of air quality in clinical hyperbaric applications, listed in a normally accepted order of concern, include: (1) the risk to human health, (2) the risk of fire, and (3) the risk of equipment failure.

Contaminants can be divided into three levels that represent the likelihood of occurrence, namely: (1) those most commonly found in compressed air (CO₂, CO, H₂O, condensed oil, particles and odour), (2) those found in certain operational areas (volatile hydrocarbons and organic compounds, such as CH₄) and (3) relatively rare but reported toxic substances (for example vapours from cleaning products and halogenated solvents, emissions from motor vehicles, SO₂ and NO_x fumes).

The production process for compressed air can only introduce oil (vapourised or condensed), particulates, and some amounts of CO_2 and CO. All the other contaminants, including larger amounts of CO_2 and CO, must be available in the environment in order to be present in the final product.

As a general rule, occupational health practices require that we analyse environmental conditions in the vicinity where we are aware of potential hazards. Compressors used to produce air for chamber compression or for breathing air will require a thorough risk analysis prior to selection and purchase. Installation of the compressors, the compressed air lines, and all interface connections will require compliance with the applicable codes and standards governing the installation of gas systems. Site selection of the compressors' intake should also receive a careful risk analysis with consideration given to weather conditions, potential local toxic fumes and exhaust from buildings or internal combustion engines.

Lubricating oils for breathing air compressor are selected on the basis of their high temperature stability, inertness and acceptability to human exposure.

It remains an accepted fact that we do not monitor or analyse the air that we breathe unless we are have reason to be concerned.

These considerations are mentioned to provide a degree of pragmatism in any debate on the quality of air produced for hyperbaric facilities. In the ideal world, where all the correct selection criteria are applied, and where a thorough risk analysis is made of the operating area, these requirements for analysis and quality control could be reduced by design. Additionally, planned sampling could be limited to where changes or maintenance activities are known to have taken place.

However, the reality is that exposures to contaminants in compressed air have occurred due to a loss of controls, external influences and incidents, and where equipment has been neglected.

Finally, while it is possible to provide a consensus and even mandate of maximum exposure limits for all potential hazardous contaminants, the practicalities of on-line, real-time analysis, affordable measuring instruments, and the accuracy achievable in the field, have at the end a large determining influence on what can and should be required.

A discussion on air quality to derive safe, realistic, achievable and sustainable standards therefore needs to be done in the context of the imperfect world, but with a sensible dose of realism.

4.1.2 Main contaminants & detection: [27] [28]

Group 1: Contaminants always potentially present in compressed air

Compound:	Carbon dioxide (CO ₂)
Sources:	Ambient environment, internal combustion and cooking processes, human and animal respiration, microbial breakdown of organic matter, conversion of CO to CO ₂ in compressor filters and in motor vehicle exhaust systems.
Human safety:	Elevated levels stimulate respiratory centre, increasing rate of breathing; increase in depth increases respiratory risk; patients with high PaO_2 are at greater risk of oxygen-induced seizures with elevated $PaCO_2$; elevated levels lead to minor perceptive changes, discomfort, dizziness or stupor and finally to unconsciousness and even death.
Fire safety:	No concerns
Equipment:	No concerns
Detection methods:	Field detection through detector tube or on-line infra-red sensor. Laboratory measurement using GC-M-FID ¹ .
Compound:	Carbon monoxide (CO)
Sources:	Ambient environment, internal combustion processes, furnaces, gas burners, cigarette smoke or overheated compressor oils.
Human safety:	Decreases the carrying capacity of hemoglobin resulting in a decreased amount of oxygen available to the tissues leading to hypoxia. A highly toxic contaminant with environmental levels magnified by increased chamber pressure.
Fire safety:	No concerns
Equipment:	No concerns
Detection:	Field detection through detector tube or on-line electrochemical sensor cell. Laboratory detection using GC-M-FID ¹ .
Compound:	Moisture (H ₂ 0)
Sources:	Ambient environment (humidity), drying process (laundry), some combustion and other processes.
Human safety:	Elevated levels of moisture are desirable (comfort & reduced dehydration), whereas dry air inhibits growth of bacteria.
Fire safety:	Very dry conditions enhance production of static electricity.
Equipment:	Excessive moisture may cause regulators to freeze as adiabatic cooling takes place during pressure reduction. Regulators may fail open, causing downstream over-pressurisation of piping and equipment.
	Excessive moisture enhances corrosion and oxidation (rust) of air storage vessels. Excessive moisture causes filtration elements & chemicals to saturate, resulting in reduced
	filtration efficiency and effectiveness, as well as elevated pressure drops. Excessive moisture can interact with some ultra-fine carbon filtration units generating strong chemical odours and resulting in nausea and respiratory irritation.
Detection:	Field detection through detector tube or dew point meter (electronic hygrometer). Laboratory detection using GC-MS ² .
Compound:	Oil (condensed)
Sources:	Mostly compressor lubricating oil (introduced internally); but also: ambient evaporated oil from compressor oil leaks & surrounding equipment, motor vehicle exhaust fumes, pollens

	(introduced through the compressor intake) and even contaminated air pipes between the air processing plant and the chamber.
Human safety:	Larger condensed particles removed by body's clearance mechanisms; smaller particles are retained and may be hazardous depending on type and amount (symptoms include inflammation or even rupturing of alveoli) ^[28] .
Fire safety:	Significant fire concerns, irrespective of type of condensed oil.
Equipment:	No concerns at the levels usually controlled for. The maximum level of 5 mg/m ³ equates to a dew point temperature of -64°C, or 6 ppm_v ; significantly lower than the lowest required levels for H ₂ 0.
Detection:	Field detection through detector tube (Impactor ³).
	Laboratory detection using gravimetric analysis or GC-MS ² .
Compound:	Particles
Sources:	Ambient environment (micro-particles of dust & pollens); breakdown products in compressors, piping systems & filtration media; as well as post-construction debris in pipes and controls.
Human safety:	Particles smaller than 10 μ m have the potential to cause shortness of breath, especially in patients with respiratory conditions (e.g. asthma & bronchitis), as well as a reduction in the ability to resist infection.
Fire safety:	Large concentrations of particulates can serve as a source of ignitable fuel.
Equipment:	Larger particles are known causes of failures in pressure regulators, may cause valves not to seal when closed, and may erode valve seats, discs and seals.
Detection:	Field detection is not a practical option; however, filtration is highly effective where properly sized and located.
	Laboratory detection using gravimetric analysis. Particle size assessed using microscopy.
Compound:	Odour
Sources:	Ambient environment and cleaning compounds used on air supply systems.
Human safety:	Generally related to comfort levels only. Odours from volatile, toxic or otherwise harmful substances indicate potential safety issues related to these contaminants.
Fire safety:	No concerns from odour. Contaminants with fire risks (oils, VOC, etc.) are discussed under the relevant contaminant sections.
Equipment:	No concerns
Detection:	Field detection – subjectively through the human sense of smell.
	Laboratory detection for odours using an olfactometer. Identified odours assized using GC-MS ² .

Notes:

¹ GC-M-FID: Gas Chromatography - Methaniser - Flame Ionization Detection

² GC-MS: Gas Chromatography - Mass Spectrometry

³ Impactor is a Dräger Safety product enabling field detection of all oil types with reproducible results expressed in the ranges: <0.1 mg/m³, 0.1 to 0.5 mg/m³ and >1.0 mg/m³.

Group 2: Contaminants present in specific areas

This group may be significantly larger than discussed here, but the following analysis serves to indicate where potential hazards may exist for clinical hyperbaric facilities.

Volatile hydrocarbons include organic compounds. However, methane is the most commonly occurring of these compounds and is separated from the analysis.

Some standards require that all hydrocarbons be grouped as a total hydrocarbon (THC) limit. This does not allow for easy identification of potential sources.

Contaminant:	Volatile hydrocarbons and Volatile Organic Compounds (VOC) – include but are not limited to toluene, xylene, benzene, ethane, styrene and acetone.
Sources:	Ambient environment as a result of exposure to building materials, plastic materials, industrial chemicals & cleaning compounds, adhesives, furniture, flooring, heating & combustion processes. Overheating compressors reported as a potential source.
Human safety:	Generally hazardous in terms of carcinogens, neurological & narcotic effects, organ damage & general distress. Initial symptoms include fatigue, headaches, confusion, numbness, cardiac irritation & depression.
Fire safety:	Significant fire concerns in terms of low ignition temperature and low flashpoint fuels.
Equipment:	No significant concerns at the expected levels.
Detection:	Field detection – odour usually detected through the human sense of smell.
	Identified compounds measured using detector tubes or GC-MS ¹ .
Compound:	Methane (CH ₄)
Sources:	Ambient environment, especially prominent in certain geological areas as well as near decaying or fermenting organic matter, landfills, or domestic animals (cattle). CH_4 may permeate buildings and enter the compressor intake.
Human safety:	Not toxic (may be an asphyxiant where oxygen is reduced to below 16%)
Fire safety:	Significant fire concerns with CH ₄ being a highly flammable fuel.
Equipment:	No concerns
Detection:	Field detection through detector tube or on-line using infra-red sensors.
	Laboratory detection using GC-M-FID ² .
Notes	

Notes:

¹ GC-MS: Gas Chromatography - Mass Spectrometry

² GC-M-FID: Gas Chromatography - Methaniser - Flame Ionization Detection

Group 3: Rare but reported contaminants

This group is too diverse and extensive to discuss in a similar fashion to the previous two groups.

Typical contaminants include vapours from cleaning products or solvents not covered under Group 2 above, as well as environmental compounds including hydrogen sulphide (H_2S), SO_2 , NO, N_2O , NO_2 , NO_x fumes, ozone, lead compounds, asbestos and many others.

Each of these has specific deleterious effects on humans, but no significant fire or equipment issues – at least not in the concentrations expected in the air.

Nitrogen oxide products, loosely referred to as NOx, are associated with decreases in lung function, increased severity of respiratory problems, chronic inflammation and irreversible structural changes, amongst other related respiratory conditions and complications.

Most occupational health and safety regulations for any public enterprise provide regulations, limits and guidelines for identification and exclusion.

In terms of this discussion, we will exclude several of these from the requirements for acceptable air quality and accept that they will be controlled by occupation hazard identification and risk assessment (HIRA) practices.

4.1.3 Practical limits:

The following limits have been extracted from the literature based on the effect on human physiology, fire risks and risks to equipment.

Consistent units of measure have been used throughout the table as far as possible for easy of reading, but are not necessarily the units used by some measurement devices.

All human exposure limits are expressed as the surface equivalent value (SEV) and for the purposes of a discussion in clinical hyperbaric facilities, a maximum pressure of 6 ATA is assumed. Limits tabulated are generally stated as the "no-effect level", that is the dose with no known toxic or debilitating effects.

The exact conditions under which air quality analysis should be done are not discussed, but from a practical perspective, any analysis should be done such that the worst case can be detected. This will ensure that the actual air delivery conditions to the chamber, occupants or sensitive equipment are likely to be less severe.

	Human exposure	Fire risk	Equipment risk	Detection limit ¹	Achievable limit ²
CO2	5000 ppm _v for pO ₂ ≥ 3 ATA 15000 ppm _v for pO ₂ ≤ 1.6 ATA	Nil	Nil	100 ppm _v	< 350 ppm _v Normal air contains ±300 ⁺ ppm _v
СО	60 ppm _v ³	Nil	Nil	1 ppm _v	≤ 5 ppm _v
H ₂ 0	RH ⁴ : ≤ 50% – 60% Based on control of bacterial growth	RH ⁴ > 30% Dew point > 3°C	HP: Lowest ambient less 44°C LP: Lowest ambient less 6°C	Dew point -64°C based on 5 mg/m ³	-48°C or ≤ 35 mg/m³
Oil	≤ 5 mg/m ³	≤ 0.1 mg/m ³	None at ≤ 5 mg/m ³	0.1 mg/m ³	≤ 0.5 ⁵ mg/m ³
Particles	≤ 50 mg/m³ No particles ≤ 10 μm	≤ 5 mg/m³	No limits determined	0.01 mg Size 0.5 μm	0.5 mg/m ³ for particles > 5 μm
Odour	None	None detected	Nil	None	None
VOC	≤ 5 ppm _v	LEL ⁶ ≤ 1 % <i>Limit 1000 ppm</i> _v	Nil	5 ppm _v	≤ 5 ppm _v
CH₄	≤ 5% (5x10 ⁴ ppm _v)	$LEL^{6} \leq 5 \%$ Limit 5000 ppm _v	Nil	10 ppm_v	≤ 25 ppm _v
H ₂ S	≤ 50 ppm _v	Nil	>> Human limit	1 ppm _v	≤ 1 ppm _v
SO ₂	≤ 5 ppm _v	Nil	Nil	1 ppm _v	≤ 1 ppm _v
NO _x ⁷	≤ 10 ppmv	Nil	Nil	0.5 ppm _v	≤ 2 ppm _v

Table 4: Contaminant safe limits

Notes to Table 4:

- ¹ Limit applicable to what can be detected in the field using detector tubes or basic on-line analysers.
- ² Limit that can be realistically achieved based on current filtration, catalytic and elimination methods.
- 3 $\,$ A SEV value of 60 ppm_v at 6 ATA arises from a value of 10 ppm_v at 1 ATA.
- ⁴ RH: Relative humidity at normal temperature and pressure (20°C and 101.325 kPa).
- ⁵ Some equipment suppliers state the limit contained in EN 12021 ref. [1]. Using available and economically viable equipment, a limit of \leq 0.1 mg/m³ is realistically achievable.
- 6 LEL: Lower explosive limit fire codes usually recommend a limit of \leq 10% of LEL. 10% of 1% LEL = 0.1% or 1000 ppm_v.
- ⁷ NO_x represents all nitrogen oxide compounds.

4.2 Quantity of air:

4.2.1 General:

The primary criteria in determining a suitable quantity of air for the safe and effective treatment of clinical patients have been previously stated as (1) the size and occupancy of the chamber, (2) the pressure and duration of the intended treatment, and (3) the accepted limits in terms of contaminants introduced inside the hyperbaric environment (being primarily CO_2 and excessive O_2 levels).

The requirement for redundancy, due to the critical nature of some treatments, implies that this quantity of air shall be available with due regard to likely equipment failure, power failure or operator error.

Table 2 provides a summary of the air capacity requirements as stated in a variety of reference documents.

This discussion will endeavour to provide some rationale behind the process to determine a suitable quantity of air, based on actual requirements and the likely operational or clinical situations. This applies to both multiplace and air-driven monoplace chambers.

4.2.2 Criteria for determining air capacity:

The actual amount of air used during a treatment is the sum of the air required to:

- (1) pressurize the chamber to treatment pressure, plus
- (2) transfer staff, equipment and consumable products into the chamber, plus
- (3) ventilate the chamber during the treatment in order to condition the environment (reduce excess O₂ from equipment leakage, replenish consumed O₂, remove CO₂ build-up, cool-down and dehumidify the interior, and remove odours).

The first two parts of the computation are determined by chamber size and treatment pressure. The only relatively unknown factor is how many transfers under pressure (TUP) may be required.

Ventilation is more difficult to determine, as this is based on environmental conditions, actual occupancy, chamber type, equipment condition and fit, patient behaviour, potential dynamics of patients and tenders, and significantly, the type of treatment being provided.

In an ideal world, the chamber environment would be monitored for all possible situations of contamination or shortfall, equipment would not fail, power would always be maintained, and operators would not make errors. This would ensure that the lowest air capacity is required. The reality is not quite this simple, but any risk assessment would indicate that the converse is in fact a reality.

A logical approach would thus be a combination of decisions as to the most likely requirements, which would need to be critically re-evaluated in the event of an emergency, together with a realistic assessment of ventilation needs based on a scientific analysis.

4.2.3 Air requirements:

The following table indicates the air requirements, expressed as an operation rather than a value, and based on current regulated practices, together with a theoretical approach.

	Computation	Low regulation	High regulation	Scientific assumption
(1) Pressurisation	Tx chamber vol. x Tx pressure	1 Tx duration	1 Tx duration	1 Tx duration
(2) TUP	TUP vol. x Tx pressure	Not stated	2 TUP excursions	2 TUP excursions
(3) Ventilation	No. occupants x stated alpm x Tx pressure x Tx time	30 alpm per person for 150 minutes, or adjusted through monitoring of CO ₂ & O ₂ levels.	2 alpm per patient + 4 alpm per tender for longest Tx duration.	64 alpm per person for longest Tx duration, moderated by CO ₂ & O ₂ monitoring.

Table 5: Air capacity requirements for clinical treatments

Notes to Table 5:

- (1) Chamber volume (vol.) is the actual rated dimensional volume of a chamber, determined by computation or as stated by the manufacturer.
- (2) Treatment (Tx) pressure is the actual Tx pressure in absolute atmospheres (ATA) as required by the Tx protocol selected, but taken as the maximum pressure defined by the scope of services. If a 6 ATA Tx is offered in accordance with ref. [15] as a table 6A, then this pressure must be assumed in the worst case scenario planning.
- (3) TUP volume requires both locks used for transferring personnel as well as equipment or products to be used, and is the sum of the actual rated dimensional volumes as computed, or as stated by the manufacturer.
- (4) Ventilation capacity is computed as aclm x Tx pressure x numbers of occupants x total Tx duration in minutes. The Tx duration shall be the maximum duration offered under the scope of services.
- (5) The scientifically assumed ventilation rate is that as determined by ref. [18] and as explained below under section 4.2.4, based on the required air exchange.

4.2.3 Risk assessment:

In most cases, the requirements from the above table should be provided by both the primary as well as the secondary air supply systems.

This requires any low pressure compression packages to be capable of providing an achievable flow rate to pressurise both the treatment lock(s) and the TUP locks to the required pressure in a suitable time. Low pressure compression packages are not generally expected to provide excessive volumes of stored gases, implying that the required capacity is expressed simply in terms of a flow rate (in normal Ipm or normal m³/min).

High pressure compression packages general rely on a lower output flow rate and used to fill high pressure storage cylinders. In this case, the total volume of air required needs to be computed in terms of the amount of air (typically in m³) at NTP, and size and number of cylinders determined by this total volume requirement.

The actual risks envisaged in terms of air capacity are that the system is unable to continue with a treatment due to power failure, equipment failure or operator error.

Hospitals generally have electrical generator back-up systems, whereas free-standing facilities are not always expected to have this level of redundancy.

Secondary low pressure air supply systems are required to compensate for equipment failure, although careful attention is also required to ensure that piping and regulating systems have suitable redundancy and by-pass systems built-in.

Operator error should be mitigated through training, specifically for the management of fault or emergency situations.

The situation requiring a degree of consideration is the actual capability of the secondary or back-up system. This may be realistically considered as follows:

- (1) Where services are offered on a 24 hours per day, 7 days per week basis, and providing for emergency treatments, then the secondary system shall be capable of providing a full treatment as defined by the scope of services. This implies that any emergency treatment can be provided and concluded at all times, even in the event of equipment or power failures. (This would include the ability to commit to any emergency treatment where significant decompression times are part of the treatment profile.)
- (2) Where clinical treatments do not involve significant decompression times, such as for outpatients, non-emergency patients, non-diving patients or during working-hours, then treatments can be safely stopped at any stage, and the required capacity need only be determined by (a) the acceptable rate of pressurization, and (b) the flow rate required to ensure safe, effective ventilation and Tx termination.
- 4.2.4 Scientifically determined air exchange requirements:

Ref. [18] provides an evaluation for underwater habitats based on several factors, such as the likely O_2 consumption of individuals, CO_2 production, mixing within the environment and acceptable SEV values.

This is expressed in the formula: Q_{gas} (scfm) = (P_{TX} (ATA) x Q_{O2} (scfm) x RQ x F) ÷ (26.3 x [pCO₂])

Where: Q_{gas} is the required ventilation flow rate in scfm

 P_{TX} is the treatment pressure in ATA

 Q_{02} is the consumed oxygen, per person, in scfm

RQ is the respiratory quotient (ratio of the rates of CO_2 generation to O_2 consumption) used to compensate for the required rate of CO_2 elimination and generally accepted as 0.85 for underwater habitats^[18].

F is the mixing factor, generally accepted as 1 for well-designed (complete) mixing in the chamber.

26.3 is the conversion factor: slpm (metric, 0°C) to scfm (imperial, 15.6°C). (1 scfm equates to 26.3 slpm).

 pCO_2 is the difference between the maximum allowed limit (in ATA) and the expected input value (usually 280 ppm_v or 0.00028 ATA).

Substituting the values above provides a required ventilation flow rate of 64 actual slpm per person, determined at treatment pressure and limiting pCO_2 to less than 5000 ppm_v.

5. Proposal:

Based on the limited but focused literature survey, a discussion of limits in terms of what can be achieved in practice, and applying a clinical hyperbaric-specific risk assessment, the following two proposals are submitted:

Group 1 ¹ : Contaminants always potentially present should be limited to:				
CO ₂	Compressed air Hyperbaric chamber	1000 ppm _v 0.5% SEV (5000 ppm _v at 1 ATA)		
со	Compressed air	5 ppm _v		
H₂O	Compressed air Hyperbaric chamber	Produced < 15 bar: 402 mg/m^3 (500 ppm _v ; -27° C) Stored at 40 - 200 bar: 50 mg/m ³ (62 ppm _v) Stored above 200 bar: 35 mg/m ³ (44 ppm _v) Supplied to cylinders: 25 mg/m ³ (31 ppm _v) RH: Ideally maintained at 50% – 60%		
Oil	Pressurisation air ² Breathing air	0.5 mg/m ³ 0.1 mg/m ³		
Particles	Compressed air	0.5 mg/m ³ for particles > 5 μ m		
Odour	Compressed air	None		
Group 2 ³ : Con	taminants present in speci	fic areas should be limited to:		
voc	Compressed air Hyperbaric chamber	≤ 5 ppm _v LEL ≤ 0.1% (1000 ppm _v)		
CH₄	Compressed air Hyperbaric chamber	≤ 25 ppm _v LEL ≤ 0.5% (5000 ppm _v)		
Group 3 ³ : Rare but reported contaminants should be limited to:				
H₂S	Compressed air	≤ 1 ppm _v		
SO ₂	Compressed air	≤ 1 ppm _v		
NO _x ⁴	Compressed air	≤ 2 ppm _v		

5.1 Air quality requirements for clinical hyperbaric facilities

Table 6: Proposed Contaminant Limits for Compressed Air

Notes to Table 6:

¹ These contaminants should be monitored regularly (every 3 months) by means of either on-site or laboratory analysis.

 2 It is deemed preferable that all air meet the higher limit of 0.1 mg/m³.

³ A HIRA survey should be used to determine the likelihood of any of these or other potentially toxic elements being present in the environment during the air compression process.

⁴ NO_x includes all nitrogen oxides

5.2 Air capacity requirements for clinical hyperbaric facilities:

	Available 24/7 for emergency cases, including diving accidents:		Outpatient, non-emergency & no diving patients with suspected AGE:	
Activity	Primary Secondary		Primary	Secondary
Pressurisation	1 excursion to maximum Tx pressure	1 excursion to maximum Tx pressure	1 excursion to maximum Tx pressure	Nil
Lock transfer (TUP)	2 TUP to maximum Tx pressure	1 TUP to maximum Tx pressure	2 TUP to maximum Tx pressure	Nil
Ventilation ¹	64 alpm per person for longest Tx duration.	64 alpm per person for longest Tx duration.	64 alpm per person for longest Tx duration.	Nil

Table 7: Proposed Air Capacity Requirements for Hyperbaric Facilities

¹ Actual ventilation rate, or the amount of stored air to ensure venting, may be reduced through on-line CO₂ & O₂ monitoring.

Where the air supply for the primary chamber system is provided from stored gas banks (typically using 200 or 300 bar, 50 litre cylinders), it is not suggested that the air supply system requires dual redundancy in terms of available air.

Only one total air volume to provide a full, emergency treatment is required. A risk assessment should be performed to determine the actual, worst case scenario (treatment duration, pressure and number of occupants) and the total air volume requirement determined from this.

6. Concluding remarks:

The information presented in this paper has been extracted from available literature and combined with personal experiences in this industry. Medical effects stated are as presented in the scientific media and have not been based on any current human-based research.

It is not considered practical to base contaminant limits (or associated gas analysis), or capacity requirements only on incidents or accidents, unless these can be shown to occur with significant frequency. In some cases, the lack of reported accidents should not allow for the removal of, or reduction in a specific limit. Basic risk theory, where the actual risk is the product of the severity, the likelihood and the frequency of an accident, is a more suitable means of considering adjustment or even removal.

In specific regions, where local or other mandated regulations apply, these should always take precedence. It is likely that these are based on actual environmental conditions. Where the limits and requirements proposed exceed these, then it would be considered prudent to adopt the stricter levels.

In each and every case, there remains a place for specific risk assessments to be performed in order to accommodate individual and unique operational situations or requirements.

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