



Emergency Life Support Equipment for Commercial Diving Operations

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Guidance Note

Table of Contents		Page
1	Background	4
1.1	Commercial Diving Techniques	4
1.2	Problems with Medical Equipment for Diving Operations	6
1.3	Clinical Hyperbaric Medicine Equipment	8
1.4	Prior Efforts to Improve Diving Medicine Equipment Availability.....	8
1.5	The Population at Risk	9
1.6	Next Steps.....	9
1.7	Images.....	10
2	Diving Chambers - The Physical Environment.....	11
2.1	Images.....	12
3	Operating Conditions for Equipment.....	12
3.1	Introduction.....	12
3.2	Physical Environmental Conditions	12
3.3	The Ambient Gas Environment.....	15
3.4	Breathing Gas Delivered by Masks or Ventilators	16
3.5	Other Atmospheric Environmental Considerations	17
3.6	Operational Considerations.....	18
3.7	Images.....	21
4	Medical Equipment Requirements.....	21
4.1	Introduction.....	21
4.2	Images.....	25
5	Electrical and Electronic Issues.....	25
5.1	Introduction.....	25
5.2	Fire Risk in Diving Chambers	26
5.3	Power Supply Inside Chambers.....	27
5.4	Notes on the Different Options for Electrical Power	28
6	Relevant Regulatory Processes	32
6.1	Generic Overview of Medical Device Regulations	32
7	Existing Standards, Codes and Guideline Documents	37
7.1	International Medical Device Standards of a 'Top Level' Nature.....	38
7.2	European Medical Device and Diving Chamber References	38
7.3	Classification and Certification Societies	38
7.4	Industry Association Guidelines.....	39
7.5	US and North American Reference Materials.....	39
7.6	Australia New Zealand Reference Materials.....	40
7.7	Others.....	40
7.8	Outcomes of Testing.....	40
8	Existing Testing Processes and Centres of Expertise	41
9	Glossary	43

Appendix A: Process Flow Chart 46

Appendix B: Conversion Tables..... 47

Appendix C: Summary of Recommendations 48

Scope of Report

This Guideline identifies the requirements for emergency life support and medical treatment equipment for site use in supporting commercial diving operations.

For those unfamiliar with this subject, a description of the typical environments is provided along with a summary of current problems in sourcing appropriate equipment that faces industry.

In order to assist industry address the problems identified, this document aims to action the following objectives;

1. To identify and to collate under a single document, all relevant current industry standards, testing and approval processes to;
 - Ensure that manufacturers of medical equipment can gain easier access to such information.
 - Enable them to understand the required testing processes and rationale behind processes.
2. To identify and collate other existing literature and informal guidelines that may be useful so as to provide a degree of methodology and a recommended approach to the challenges in rendering medical equipment suitable and safe for use in a commercial diving hyperbaric environment.
3. To identify the gaps between what is currently available and suggest a suitable means of addressing this.
4. To make recommendations that will guide the next steps towards realising appropriate medical equipment that has been robustly tested and approved for use in commercial diving and associated pressurised environments.
5. This document is neither a “standard” nor an audit tool. It is intended to provide guidance, applicable reference materials, and to educate the manufacturer and user as to hyperbaric-specific requirements.

The document focuses on commercial diving applications but is equally applicable to other, similar working environments, such as in tunneling chambers – where hyperbaric work is also conducted, aerospace habitats, and any confined environment where similar restrictions, hazards and requirements are found.

The terms *diving* or *hyperbaric* will be used to signify such environmental conditions.

1 Background

1.1 Commercial Diving Techniques

The purpose of this section is to provide an overview for manufacturers and testing organisations that are unfamiliar with the commercial diving workplace.

Commercial diving operations play an important role in supporting the construction, maintenance and repair of infrastructure wherever water is present, in particular in the offshore energy sector, water supply industry, ports and harbours.

Whilst some shallow water diving is undertaken with techniques little different from simple recreational SCUBA diving, most commercial diving is undertaken with much more complex equipment in order to manage the risks that would otherwise arise from the types of water conditions, the nature of the work involved and the surrounding physical and industrial environment.

A key feature of commercial diving is the connection of the diver to the surface with an ‘umbilical’ which supplies breathing gas, hot water (if needed), continuous communications to and from the diver's helmet, depth monitoring and supervision by a surface based Supervisor. The umbilical also supports rescue if needed.

For all surface-orientated diving operations, local legislations / regulations and Industry Best Practices require an hyperbaric chamber to be immediately available on the vessel / worksite, for enabling immediate therapeutic recompression & decompression if needed. In certain risk assessed circumstances local regulation may allow a nominated Hyperbaric chamber to be within a certain time limit from the dive site, provided detailed plans are in place to cope with an emergency.

In these operations, the diver is only placed in the decompression chamber if there is an emergency – usually the development of decompression illness.

In cases of severe decompression illness, the diver may require various medical interventions inside such a chamber for a number of hours, including intravenous fluids, urinary catheterisation, and in extreme cases, artificial ventilation.

Another use for decompression chambers is to enable 'surface decompression using oxygen', a technique where a diver avoids a prolonged period of decompression in the water by relocating to the interior of a pressurized decompression chamber. The diver must omit several in-water stops that he should have performed during a standard in-water decompression, then exit the water and be successfully re-compressed to depth in the chamber within a surface interval as brief as possible as there is a high risk of severe decompression sickness if there is any delay or failure in the surface decompression procedure.

Surface decompression methods have been developed by the military diving teams for enabling them to bring the divers back on board the ships more quickly. In commercial diving. The benefit of surface decompression using oxygen is that prolonged decompression can occur in the dry and controlled environment of the decompression chamber, whenever the diving supervisor assesses that an in-water decompression could become unsafe because of adverse environmental conditions or emergency situation.

Should any injury occur underwater, however, the management of that injury must take place inside the surface decompression chamber as it is highly dangerous to abort the scheduled decompression.

The use of surface decompression has become more infrequent in the more highly regulated UK offshore energy sector in recent years but it is still used elsewhere in the world. The time a diver must spend undergoing surface decompression can range from minutes to hours in duration.

Nitrogen becomes anesthetic / narcotic when its partial pressure increases. This effect starts at a depth around 30 msw. The UK Health & Safety Executive (HSE) limits exposure depth at 50 msw for diving operations using compressed air, and also exposure duration. (Reference: UK HSE Diving information Sheet No 5).

So helium / oxygen mixtures ('heliox') are used, or much less frequently helium, nitrogen, oxygen ('trimix'). These 'mixed gases' are supplied to the diver, via an umbilical, from cylinders or gas mixing systems.

Decompression chambers are routinely used in this type of diving both for emergency treatment of decompression illness, and in some cases for surface decompression. There are regulations surrounding these issues built on 'lessons learned' over many years.

These are implemented / regulated in the UK by the HSE whilst other countries have their own similar Regulators in place.

For extended intervention work below 50 metres depth, a more complex system of saturation diving is used as the shallow safe work durations available become insufficient for the tasks required.

Saturation diving involves teams of divers living under pressure in an advanced version of a decompression chamber – a saturation diving complex made of a number of interlinked compartments in which there are provisions for sleeping, eating, hygiene and changing in and out of diving suits and helmets on the way to and from underwater work.

These saturation chamber systems are usually located on barges, platforms or most commonly on 'diving support vessels'. Transport of divers to and from the underwater worksite is provided by 'transfer under pressure' in a small submersible chamber often referred to as a 'diving bell' which is lowered to the appropriate depth at which the working divers exit into the water with a colleague remaining in the 'bell' to manage the divers umbilical and as a monitoring and rescue capability.

Teams of divers live and work under pressure in these systems for periods of days to weeks at the end of which the safest decompression duration can range from as short as 2-3 days, up to some weeks for the deepest of dives.

Exit from the saturation facility is not possible before safe decompression without the risk of severe or fatal decompression illness; such risk may be enhanced by illness or injury. Any injury or medical emergency occurring in saturation conditions must therefore, be managed in the existing saturation environment, until safe decompression is achieved.

Saturation diving thus creates the highest demands for medical contingency planning and medical treatment equipment. The saturation dive environment is in many ways as remote or perhaps more so than that applying to astronauts in space.

The inherent hazards & potential risks of the subsea hyperbaric environment, combined with the implicit trust which divers place in their surface teams; require that the prevention (primary,

secondary and tertiary), is designed in a more stringent way than the equivalent for workers who have to execute the same type of task in a normobaric environment. This is about due diligence and duty of care. These two essential principles justify the contents of this document its publication and its implementation across the Industry.

In addition to the location and lack of ability to exit the system, the physical gas environment inside the saturation complex is of necessity at high pressure (4 – 30 ATA) predominantly constituted of helium with low levels of oxygen, almost always humid and of necessity very warm.

There is a preference by many Operators and Contractors to use Saturation diving methods at depths shallower than 50.0 m for extended work.

Experience shows it to be potentially safer, more efficient and cost effective than surface supplied diving in the depth ranges 30.0 m to 50.0 m.

During the early pioneering years of saturation diving it was felt that this technique introduced long term health issues of working at significant depth for extended periods of time.

However, medical research now suggests that the single blow-down and recompression back to surface in saturation diving may be less severe on the human body than the frequent and repetitive pressurisations of surface supplied diving.

As a contingency against fire or sinking of the host vessel or platform, it is now an expectation that there will be some form of 'hyperbaric lifeboat' in which saturation divers may be evacuated from the vessel or platform whilst remaining under pressure.

In order to provide a planned destination for such evacuations, there are also now a number of 'hyperbaric reception facilities' (HRFs), or emergency saturation facilities at a safe location to which hyperbaric lifeboats could in principle be taken to allow divers under pressure to transfer to a safe and medically equipped facility.

The hyperbaric lifeboats and certainly the HRF's therefore require suitable medical care equipment.

All of these conditions expose divers to a range of physical and physiological hazards inherent to underwater and pressurised environments as well as the risk of injury involved in the particular work that is being undertaken.

These diving techniques are also used to a limited extent by military, emergency services and scientific agencies, whilst variations of these techniques may be used in pressurised tunneling work in wet or unstable ground.

Employers are therefore required to put in place specialised medical support arrangements to cope with those potential injuries and medical illnesses that can and do occur in these special environments which are often, in addition, geographically remote.

The most extreme challenges apply when emergency care must be provided in the saturation diving environment, requiring specially trained personnel and medical and communications equipment that will work in high pressure saturation diving chambers for many days.

1.2 Problems with Medical Equipment for Diving Operations

A guideline as to what medical support arrangements are considered appropriate for saturation diving is published by the Diving Medical Advisory Committee (DMAC) as DMAC 28.

DMAC is supported by the International Marine Contractors Association (IMCA) who supply the Secretariat.

DMAC 28 cross-references DMAC 15, a recommended medical equipment and drug list for the commercial diving industry.

Although IMCA is an industry group, it is widely respected and utilised as source of guidance, especially for work in the offshore energy sector.

DMAC 15 and 28 are therefore good guidance as to what is expected and seen as reasonable. Where national Regulations and codes exist and have requirements for medical support these are generally similar to the DMAC guidelines.

Unfortunately, it is not at present, possible for all contractors to fully comply with these recommendations nor to provide optimal medical care in decompression or saturation chambers as a result of a series of interacting factors.

Medical equipment items such as ventilators, monitors, suction and infusion devices that were chosen for use in saturation and surface supplied deck decompression chambers in the 1970s, were simple mechanical units, less affected by the humid, high pressure helium environments in saturation chambers or the potentially high oxygen partial pressures in the deck decompression chambers.

Some items were informally tested and deemed safe to use as sold, whereas others needed modification or even custom manufacture. The resulting relatively crude equipment served its purpose in a manner consistent with healthcare expectations at the time.

This legacy equipment has remained in use in the saturation diving field well past what would normally be considered its 'use by date'. However, much of this equipment has now either failed or is failing, and is no longer able to be maintained or replaced with similar items.

More modern monitoring, diagnostic and therapeutic equipment often have electronic, touch screen or battery technologies that are incompatible with pressure environments.

Those items that might potentially be compatible have no certification for hyperbaric and/or saturation use, putting contractors and medical advisors in a difficult position regarding whether any specific item is suitable, safe or legally appropriate.

There are many commercial diving industry codes, standards and specifications which cover matters like pressurised gases, electrical or electronic systems, radio-frequency emissions, environmental robustness and the construction and fit-out of hyperbaric chambers.

Medical authorities and regulatory agencies have a strong preference or in some cases legal requirements to only provide medical care with items of equipment that are registered as 'approved Medical Devices' by bodies such as the FDA in the USA, TGA in Australia or via CE marking in the EU.

There are few specific guidelines within any of these schemes for diving industry hyperbaric use of medical devices.

Medical equipment develops and changes on a constant basis. Older models are withdrawn and no longer supported, hence there is a need to renew or replace equipment on a regular basis, as is customary for the medical equipment field.

There has been a concentration of ownership and increased internationalisation in the medical device marketplace resulting in larger companies that seem more risk-averse with respect to involvement in small market segments such as the hyperbaric sector.

This problem applies equally to the hospital based hyperbaric medical sector, although there are some significant technical differences between the saturation diving and hyperbaric medicine fields, in addition to which, the diving medical equipment field is smaller.

Overall, medical equipment manufacturers seem reluctant to make special efforts, presumably due to very limited potential sales volumes, the complexity of meeting the requirements of the arduous operating environment, the high costs of medical equipment certification and a general concern for product liability where used outside of the environment that they know and are comfortable with.

In some cases, equipment has worked by trial and error, resulting in the equipment being put into use outside of its design environment presumably voiding product warranties, and possibly even affecting life insurance issues.

Rigorous equipment assessment projects have been undertaken by some of the smaller life-support equipment manufacturers and by some operators.

In some cases this knowledge has been disseminated into the medical literature, however often this is not the case and there is no easy way to access performance or safety testing information, or to evaluate how rigorous the assessment process has been.

In other cases equipment has been modified without the original manufacturers' involvement or even custom-manufactured and in such cases liability clearly passes to the parties who have undertaken the modifications, testing and therapeutic use of the item.

The primary certification authorities for offshore, ship and marine applications are the marine classification societies, and these organisations have their rules for hyperbaric function, safety and maintenance compliance.

However, these rules do not provide a specific certification avenue for medical devices.

The engineering standards and guidance documents for pressure vessels for human occupancy do in some cases include provisions applicable to medical equipment, especially when it is permanently installed or powered inside the chamber.

1.3 Clinical Hyperbaric Medicine Equipment

Hyperbaric oxygen therapy is increasingly utilised in mainstream medicine and many hospitals worldwide have hyperbaric chambers. Although hyperbaric chambers are conceptually similar to diving chambers in being 'pressure vessels for human occupancy', there are some significant differences.

Hyperbaric chambers are designed for clinical use in healthcare facilities and operate at lower pressures than diving chambers – typically 2 – 3 ATA only.

The requirement for medical equipment for this field is larger than applies for occupational diving, and significantly, the requirement is for routine use in a hospital environment, rather than as a rarely used contingency plan for (remote) emergencies.

There are some medical devices that have been specifically approved for clinical hyperbaric chamber use via European and US approval avenues, although the applications are limited to a maximum of 6 ATA, or more often, only 3 ATA.

Such equipment may be of 'some use' in the lower pressure chambers used as emergency support for onshore and surface supply diving, but equipment only tested to 3 ATA may not be suitable for use beyond that pressure and thus is limited in use, in practice.

This pressure range is also significantly below the requirements for more complex commercial saturation diving which may involve pressures up to 30 ATA or more.

It is important to note however, that some medical equipment is considered unsuitable for clinical hyperbaric chamber use on fire safety grounds based upon the concern that batteries or electrical components might initiate a fire in an oxygen-rich pressurised environment.

Very conservative electronic and fire safety criteria are therefore utilised for clinical hyperbaric medical equipment and these criteria are almost certainly excessive for those deeper water saturation diving operations where 100% oxygen use is rare, and the chamber environment usually involves low percentages of oxygen.

High percentages of oxygen are generally only used in a saturation diving situation for the treatment of suspected DCI at shallow depths.

1.4 Prior Efforts to Improve Diving Medicine Equipment Availability

In the past, the diving industry's medical advisory body 'DMAC' tried to stimulate the industry into providing finance and impetus towards relevant equipment testing and certification for medical equipment for use in the diving environment.

DMAC Guidance Note 28 is the current top level advisory document (available from the DMAC website: www.dmac-diving.org) and this was initially published in 1997 superseding prior documents.

This document is limited to advising what sort of equipment and capabilities are needed without specifics as to suitable brands or types of equipment, nor the details necessary for testing and certification.

This subject has been discussed over many years, with papers presented at industry meetings, but in general no significant progress has been made towards a suitable solution.

A very small number of individual equipment item projects have been undertaken by medical, military and industry teams, in many cases proving that a desired equipment item did not work under high pressure.

Meanwhile, the medical field has both expanded its capabilities as well as made progress in ensuring the availability of advanced care for injured workers in complex and remote environments, unfortunately the same advances have not been made with respect to having suitable equipment for the hyperbaric environment.

Telemedicine in particular has made great strides with equipment and bandwidth availability that can now provide a shore-based medical consultant with first-hand, real-time encrypted patient information that can enhance treatment and intervention decisions and guide paramedics on scene.

These technologies are now available for hyperbaric use but progress is restricted by the limited range of equipment suitable for the high pressure diving chamber environment.

1.5 The Population at Risk

Meanwhile, the average age of commercial divers has been increasing and this brings with it an increased risk of incidental medical problems occurring under pressure in addition to the risks of physical injury and pressure related pathology.

It is not uncommon to find 50 - 60 year old saturation divers still in regular employment, working for up to a total of 6 months in the year within a saturation diving environment.

Despite the medical screening requirements for all divers, provision for medical care needs to be made for both injuries as well as incidental medical issues.

1.6 Next Steps

For the diving industry to be able to comply with the medical intervention equipment requirements as suggested by DMAC 28 and DMAC 15, an appropriate testing and certification path needs to be developed and made available so that;

- Manufacturers can be convinced to test and certify their existing equipment or even custom manufacture with proper guidance. However sales volumes will always be very limited, even without the excessive costs related to formal medical industry compliance.
- Dive equipment owners and contractors will have the means to meet their client, regulatory and classification society requirements, knowing that their emergency medical equipment is tested and suitable for use under pressure.
- They will also have the assurance that any interfaces with diving related pressure vessels and any other critical plant and equipment are safe and compliant.
- Certification authorities have an independent, common template to guide their processes of review, surveillance and approval of equipment, and ensure that different authorities do not have different procedures and standards.
- A guideline exists which allows inventors and innovative companies to understand the unique requirements posed by deeper pressure excursions, changed gas content and densities, humidity, electronic interference and confined space in sufficient detail that they can develop new hyperbaric medical technology with safety adequately addressed.

The processes for developing an internationally implementable testing and certification guideline via existing medical device authorities or via existing Standards agencies such as ISO, CE etc. are too slow and uncertain to expect any useful outcome for many years.

The various international and regional diving medical societies have discussed these problems continually with respect to medical hyperbaric chamber equipment without any real progress, this includes anything specific to commercial diving.

The few military and civil agencies, companies and individuals with any real expertise (including those listed in this proposal) have made informal contacts and published academic papers on this subject without any consistency, formal linkages or usable outcomes for the medical device industry or for commercial diving operators.

It is hoped, therefore, that this document will facilitate some progress.

An illustration of the process of rendering the required equipment to determine suitability, safety, effective function and regulatory approval is shown in Appendix A.

1.7 Images



A Surface Supplied Diver with helmet and dry suit.



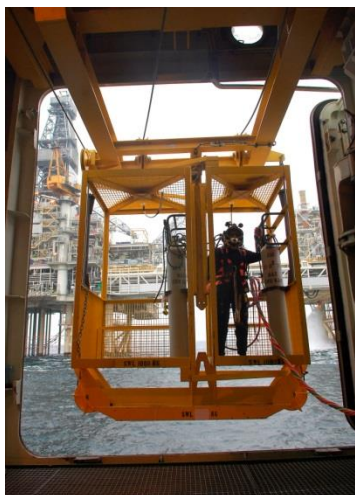
A basic mobile skid mounted twin lock Deck Decompression Chamber (DDC)



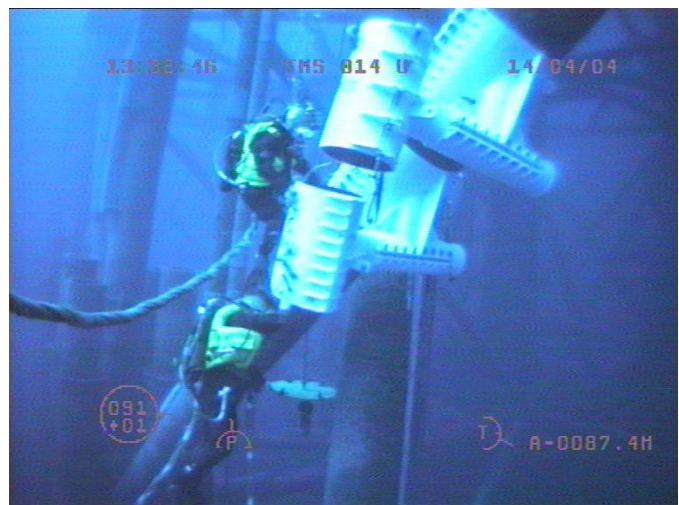
A typical construction Diving Support Vessel (DSV)



A portable Saturation Diving system in operation



A Surface Supplied Diver about to be lowered into the water in a Launch And Recovery System (LARS)



Saturation Divers at work.

2 Diving Chambers - The Physical Environment

The environments relevant to this Report are most commonly found in the onshore and offshore commercial diving industry with a particular focus on diving in support of the oil and gas industry.

Whilst emergency life support and medical care may be required in the relatively 'normal' outdoor industrial waterside environment of the dive site, the principal focus of this Report is on the various types of Pressure Vessels for Human Occupancy (PVHO) used in the commercial diving industry.

PVHOs used in diving include:

- surface supply diving deck decompression chambers (DDC)
- mixed gas diving decompression chambers (Saturation Systems)
- undersea habitats i.e. for hyperbaric welding
- Submersible Decompression Chambers (Diving Bells)
- hyperbaric lifeboats
- hyperbaric reception facilities
- transfer under pressure submarine rescue facilities

Note: there are some semantics around the use of the terms 'compression', 'decompression', 'recompression' or 'hyperbaric' when these terms are used to qualify the word 'chamber'. Regardless of which term is used, the phrase refers to pressure vessels for human occupancy used in the diving industry and for the purposes of this document, these terms may be considered interchangeable.

As a useful generalisation for targeting design of emergency medical equipment the most common diving industry PVHO types are;

Deck Decompression Chambers (DDCs) which usually have a maximum operating pressure of 6 ATA and a normal maximum occupancy duration of 5-8 hours.

DDCs are usually comparatively stand-alone devices that are portable and sometimes containerised but in other cases are permanently installed on vessels or in buildings adjacent to major marine works locations.

In order to operate they require supply with compressed air from cylinders or compressors (divers breathing gas quality) and *medical* quality oxygen. They are operated by a dive supervisor or appointed chamber operator.

They have lights and heaters/coolers but availability of medical locks, internal scrubbers and sanitary facilities will very much depend upon contractor and location.

Saturation Systems involving multiple connected chamber compartments in which divers live and work at operating pressures up to 30 ATA and in some cases significantly higher for periods of up to four weeks or more.

Saturation systems usually involve more than one interconnected chamber and the 'diving bell' plus all of its handling equipment. These are much more complex and usually permanently or semi-permanently installed on floating or fixed assets.

There will be a formal diving safety management system for operations, with a minimum 24 hour manned level including separate diving supervisors and life support technicians who control and manage the 'living chambers'.

There is a complex infrastructure of gas supplies predominantly heliox, usually with gas reclamation and recycling, given the high cost and relative rarity of this gas.





Saturation systems have internal environmental control including temperature and humidity management and carbon dioxide scrubbing.

PVHOs are in themselves both life support devices and sources of significant worksite hazards. The key over-riding safety principle is that any medical device taken into the diving chamber must not increase risk or degrade the safety of the chamber.

In addition the environment of the diving chamber must not degrade the safety of any medical device which needs to be used.

Section 3 which follows, details the many abnormal physical environment parameters that are intrinsic to diving chambers and which need to be considered in assessing compatibility of medical devices for use inside such chambers.

2.1 Images

	
<p>Internal view of a saturation chamber's "wet pot" for toileting and washing etc...</p>	<p>Internal view of Saturation System living conditions.</p>
	
<p>Submersible Decompression Chambers (Diving Bells)</p>	<p>Hyperbaric Lifeboat Reception Facility (HRF) and Self Propelled Hyperbaric Lifeboat</p>

3 Operating Conditions for Equipment

3.1 Introduction

This section details the various physical and operating aspects of the commercial diving chamber environment with which any successful medical equipment item must be compatible.

3.2 Physical Environmental Conditions

3.2.1 Operating Pressure:

Equipment required to operate inside diving pressure chambers needs to function at increased ambient pressure. This is the primary source of problems, challenges and limitations.

Appendix B contains the needed conversion formula or tables in order to use either Imperial or SI units.

Note on units of measurement:

Divers often refer to pressures in terms of the depth of sea water at which the pressure applies – metres depth sea water (MSW) or in some US influenced sectors, feet sea water (FSW). The acronym 'ATA' is also often used, referring to Atmospheres Absolute, usually given to one decimal place, approximated by dividing the depth equivalent in MSW by 10 and adding 1.0 to make the measurement an 'absolute' pressure – the pressure in excess of a complete vacuum, rather than a 'gauge' pressure which is the relative pressure in excess of the external ambient sea level pressure. The units used in this paper are thus either ATA to describe pressure or atm (atmosphere) to describe a gauge or rate-of-change pressure unit.

For medical equipment to be useful in the PVHO environment, it needs to be tolerant of minimum ambient pressures as follows:

- (a) Hyperbaric medicine chambers and surface supply diving chambers when used only for emergency treatment of mild to moderate decompression sickness at least 2.8 ATA.
- (b) Unrestricted use in general (surface supply) diving support and emergency chambers as well as chambers used for surface decompression with oxygen at least 6 ATA.
- (c) Saturation diving chambers: 21 ATA will be adequate to make the equipment suitable for use in the bulk of saturation diving operations, but 31 ATA is preferred as this is the maximum pressure applicable to maximum anticipated depths of current and future diving projects. The deepest diving operations undertaken to date have involved 46-51ATA whilst the maximum human pressure exposures ever were undertaken in specialist environmental research facilities and these involved pressures up to 71 ATA.
- (d) Hyperbaric lifeboats and hyperbaric reception facilities – pressures of at least 21 ATA but preferably 31 ATA as for saturation.

Recommendation: *Diving medical equipment should be functional at pressures of 6 ATA for surface supplied diving use, and 31 ATA for saturation diving.*

3.2.2 Pressure change rates

In many cases, there will be limitations on the safe rate of pressure change for a particular item of medical equipment, usually because in-built venting of gaseous spaces is insufficient to cope with rapid compression or decompression.

The pressure change tolerance of equipment needs to match the potential scenarios in which the equipment may be used, as described below;

Equipment transfer or medical locks

When equipment held externally to the diving chamber is required inside, it will usually be compressed fairly rapidly in a small 'transfer-lock' (also sometimes referred to as a 'medical lock' or the slightly larger 'equipment lock') which is typically built into the side of habitable chambers.

Such medical or equipment transfer compartments are intended to allow routine transfer of small items of food, drink, waste, medical or other equipment into or out of the living or working chamber in which a diver is pressurised.

It is therefore highly desirable that items of medical equipment can be transferred via such medical or equipment transfer locks if needed, however it should be noted that the pressurisation rates involved can be very rapid as these transfer compartments are of small volume with only simple valving arrangements allowing limited control.

In addition to the rate of pressure change, equipment will also be exposed to a short but often significant temperature rise as a consequence of the pressure rise going of the chamber.

Similarly, there is a significant temperature drop with the potential for condensation and even 'icing' when items are transferred out of the chamber as a consequence of the pressure reduction.

If equipment cannot cope with such rapid pressure and/or temperature changes, it will need to be clearly labelled with the maximum allowable pressure change rate so that the chamber operator can appropriately slow the pressure change by utilising one of the larger equipment locks.

Alternatively items of equipment that are too large for transfer locks will inherently have to cope with the slower and more controlled pressurisation rates of chamber or transfer compartments designed for human occupancy.

Note, however, that equipment will not be required to be operating during compression or decompression in an equipment transfer lock. The equipment needs to be functional on arrival at the intended pressure when brought into the manned chamber.

It is highly desirable however that equipment is capable of operating normally during slower compressions or decompressions in case a patient on life support needs compression or decompression.

Pressurisation (compression) rates:

(a) Unmanned (equipment transfer or medical lock):

DDCs: The pressurisation rate is often not controllable and items may be pressurised by 2.8 ATA in 5-10 seconds – i.e. at rates up to 20 atm per minute.

Saturation diving chambers: From a clinical care perspective, it will be impractical to wait more than 10 minutes to get equipment down to the pressure of the diver. The slowest useful pressurisation tolerance rate for medical equipment is thus probably around 3 - 5 atm/minute.

As many equipment transfer locks can pressurise very quickly, much higher pressurisation tolerance is a safer option, given some uncontrolled pressurisations could occur at rates of 20 ATM per minute as for DDCs.

In emergency medical situations, it is critical to get the equipment to the diver as quickly as possible. Very rapid pressure change will clearly affect most equipment, hence this characteristic needs to be determined and clearly documented for all equipment.

Note that rapid pressure changes are associated with significant temperature changes – see subsequent section.

Recommendation: *Medical equipment should be tolerant of extremely high compression rates when in a non-operating condition.*

(b) Manned Chambers:

DDCs are typically pressured at 0.6 atm/min but some are capable of pressurisation at up to 1.8 atm/min.

Saturation chambers are of a larger volume and may be initially pressurised at rates as fast as 0.9 - 1.8 atm/min but are subsequently pressurised much more slowly, to avoid undesirable physiological consequences for the divers. Final pressurisation rates to 'storage depth' can in some cases be as slow as approximately 0.015 atm/min or 1.0 atm/hour.

Recommendation: *Medical equipment should at a minimum be tolerant of 2 atm/min pressurisation and should be functional during such compressions.*

Depressurisation (decompression) rates

(a) Unmanned (equipment transfer or medical lock):

The potential maximum depressurisation rates possible vary with the engineering of each diving chamber and with the 'depth' to which the chamber is pressurised, as a rule, equipment is usually 'locked out' rapidly, implying depressurisation rates can be as high as 20 atm/min.

In addition to the physical challenges created by such rapidly dropping pressure and thus expanding gas, significant cooling and condensing conditions will be created, albeit briefly. This is a major challenge for any item of electrical equipment or any equipment with gaseous spaces, even if it is electrically isolated during depressurisation.

Although used equipment will usually be slowly depressurised with the injured or ill diver, it is possible that some items might need to be depressurised in the equipment transfer lock, for instance to allow recharging of a battery.

Recommendation: *Medical equipment should be tolerant of extremely high decompression rates when in a non-operating condition, from either saturation or compressed air environments.*

If an item of diving medical equipment is completely intolerant of very rapid depressurisation, the limitation on depressurisation applicable will need to be clearly stated by the manufacturer.

(b) Manned Chambers:

Occupied DDCs are typically decompressed at 0.03 atm/min when being used for therapeutic purposes during which time equipment could need to be operating. If medical equipment is held

in a chamber during normal diving operations, decompressions may occur much faster for example in a medical emergency, but rarely faster than 1 atm/min.

In a saturation chamber, decompression typically proceeds very slowly. Current Industry advice suggests decompression rates in the range of only 0.09 to 0.18 atm/hour. (e.g. safe human decompression from 30 atm may take up to 14 days).

Recommendation: *It is important for medical equipment to continue to function and operate safely during and after manned emergency decompressions at rates up to 2atm/min.*

Recommendation: *The function of the equipment should meet normal medical device specifications at decompression rates of up to 0.1atm/min.*

(c) Helium Venting:

There is a particular problem associated with sealed gas spaces in equipment transferred out of a chamber after spending time at pressure in a helium environment. Helium is so diffusible that over time, it will penetrate most seals, and many container materials, including even thin glass.

As a result, a 'closed' gas space intended to remain at surface pressure will accumulate helium and pressure within it. On decompression, this can result in the container 'exploding' or more usually venting via bursting of seals intended to resist external pressure, but not internal pressure.

This phenomenon commonly affects 'waterproof' and 'pressure resistant' items like diver's watches and the solution is to build in a helium vent valve that will allow internal gas to vent during decompression.

Recommendation: *Any item of equipment intended for use in a saturation chamber environment shall be assessed and approved for helium venting – including practical testing involving time at pressure, followed by decompression and then inspection for dysfunction or damage. Although devices at risk of helium decompression damage could be designated as 'single use', this is obviously undesirable and unsustainable.*

3.3 The Ambient Gas Environment

It is normally assumed that the ambient gas environment in which medical equipment will be used is normobaric atmospheric air, although in some cases, tolerance or intolerance of anaesthetic gases and/or explosive vapours may be listed.

For diving medicine use, it is necessary for equipment to tolerate gaseous environments which can be very different from the usual situations of natural air at between sea level and modest altitudes.

3.3.1 Oxygen Levels in DDCs:

DDCs are pressurised and ventilated with compressed atmospheric air. Whilst air normally contains around 21% oxygen, 79% nitrogen and only traces of other gases, the air inside an occupied PVHO can be enriched by extra oxygen.

Within the chamber, divers use masks to breath 100% oxygen or other gas mixtures, to support decompression or as a treatment mix for decompression sickness. If a diver is unconscious and not breathing, the resuscitator or ventilator in use will be required to deliver the same high oxygen content breathing gas (treatment mix).

The exhaust of such oxygen breathing systems should be vented to the exterior of the chamber and open air/upper deck so that it does not excessively enrich the interior ambient atmosphere, raising the fire and oxygen toxicity risk. Some leakage from breathing gas systems often occurs but normal chamber operating procedures should keep ambient oxygen levels from exceeding 23.5%.

Chamber interior levels of 25% are not unknown however, and any medical equipment that may be used near to where oxygen is being delivered to a diver may be exposed to local pockets of more oxygen-enriched gas. This is a significant fire risk. It is thus critical that equipment does not have operating temperatures, failure modes or have potential ignition sources that could trigger fire in an oxygen-enriched environment.

Recommendation: *Diving medical equipment must be safe for normal use in pressurised environments containing 25% oxygen and it is highly desirable that the equipment does not present a safety hazard if accidentally exposed to higher concentrations of oxygen, including up to 100% oxygen at ambient pressures below 2 atm.*

3.3.2 Diving Air Quality:

The air supply to chambers should be of the same quality as that breathed by divers and should always be well filtered, clean, dry and analysed. The specifications for the quality and testing of divers' air vary slightly between various jurisdictions but all require very low levels of carbon monoxide, oil and water vapour and other contaminants.

As oil lubricated compressors are still used, it is possible for there to be some contamination of the environment, although normal filtering and air testing procedures should minimise this.

Whenever a chamber is occupied, there will be some elevation of carbon dioxide levels as a result of the occupants' exhaled breath which will be higher if the chamber is inadequately ventilated / flushed through.

In most cases the air inside diving chambers also becomes quite humid due to exhaled breath, evaporation of wet equipment and / or perspiration.

3.3.3 The Saturation Chamber Gas Environment

When saturation chambers are pressurised, the initial pressure increment is often achieved with compressed air, resulting in there being some nitrogen present in the final mix within the chamber.

The bulk of the gas used however is helium, so that the final gas mixture is predominantly helium, sometimes with a small amount of nitrogen and always with a proportion of oxygen that is controlled to levels that are physiologically safe for the diver living at pressure.

This requires the oxygen level to be maintained at a partial pressure above that applying in a normal atmosphere (0.2 ATA), but below the level at which oxygen becomes toxic to the lungs (around 0.5 ATA).

The partial pressure chosen is usually around 0.4 atm, which can be achieved by breathing 40% oxygen at the surface, or, as an example, by breathing 4% oxygen in a saturation chamber environment at 9 atm pressure (10 ATA) as saturation techniques are usually used for depths in excess of 40 MSW, oxygen levels inside saturation chambers are virtually always below 10%, except in the final hours of decompression.

As helium is a rare and expensive gas, saturation diving systems always use closed or near closed circuit environmental control systems which recirculate the heliox environment with chemical 'scrubbers' to absorb carbon dioxide and filters or absorbents to capture other contaminants. Oxygen is added as needed to replace the metabolic oxygen consumed by the chamber occupants.

Equipment for use in saturation systems will thus be required to operate in a helium rich environment that can come close to pure helium at higher pressures/deeper depths.

The oxygen levels will usually be well below those applying at atmospheric pressure, and fire risk is therefore usually diminished.

Recommendation: *It is desirable for saturation diving medical equipment to also be safe to use in the oxygen rich treatment environments that can be present in DDCs and during the final lower pressure phases of saturation decompression.*

3.3.4 Saturation Diving Gas Contaminants

The saturation diving chamber environment will always have a somewhat raised carbon dioxide (CO₂) level as a result of CO₂ exhaled by the occupants. This is usually maintained at 500ppm or less (0.05%) but can climb higher than this during emergency situations with compartment crowding or sub-systems failures.

The saturation diving environment is a closed living space where food, waste and body odours are normal. In contaminated waters, divers returning to the saturation living chambers may introduce contaminants on their equipment such as hydrocarbons, although significant effort goes into minimising this risk.

Contaminants may also be introduced as a result of the off-gassing of materials introduced into the chamber. Gases and vapours may result from the exposure of materials to elevated operating pressures, temperatures and oxygen enriched environments.

Recommendation: *Verification of all new materials prior to introduction into the chamber should be carried out in accordance with an accepted technique, valid for the offshore environment.*

3.4 Breathing Gas Delivered by Masks or Ventilators

Saturation divers working at the deepest depths may require as little as 1% oxygen in the breathing gas within their living chambers and the gas delivered to their diving helmets.

When a diver in saturation needs treatment for illness or injury, or if more rapid decompression is indicated, the diver may be directed to breath a gas mixture with a higher partial pressure - potentially up to a partial pressure of 2.8 ATA or rarely a little more.

The therapeutic breathing gas in these situations is delivered through a demand mask, hood tent or for an unconscious non-breathing diver (patient) a ventilator, and the proportion of oxygen needs to be controlled accurately to ensure the right partial pressure is achieved for the particular ambient chamber pressure involved.

Oxygen is usually 5-100% of such therapeutic gas mixes, with the balance being helium. This is usually achieved in practice by external life support technicians supplying the required mixture to a gas connection point inside the chamber, with no gas blending or mixture control occurring within the respiratory devices inside the chamber.

For medical ventilators, any gas mix is likely to be selected from the appropriate therapeutic mixes available. Further consideration of these issues is included in the relevant equipment specific sections that follow.

As a result of the above considerations, it could be concluded that it might be acceptable for saturation diving emergency resuscitation devices to be designed for 21% oxygen and lower only, whilst therapeutic respiratory devices for general saturation diving use would only need to deliver 50% oxygen or less.

This would be valid only if the equipment was not intended to also be of use in other types of diving chambers.

From a fire safety point of view, in most cases the potential for exposure to an oxygen enriched environment of >23.5% oxygen is unlikely.

This is undesirable however as any such equipment with limited oxygen tolerance would need prominent warning labels and systems preventing connection or use in high oxygen environments.

As saturation diving systems are often co-located with one or more surface supplied DDCs, it will be safer and generally preferable if equipment can be oxygen safe and tolerant.

For apparatus specifically designed to deliver breathing gas - i.e. masks, hoods and ventilators - these should definitely be safely capable of delivering up to 100% oxygen as the breathing gas as this may be required during the final stages of emergency decompressions.

A specific example of a fire safety issue is the presence of Quarter turn valves. Quarter turn valves have been identified as being responsible for the causation of fires in lines / pipe work carrying hyperbaric oxygen in the past. These Quarter turn valves have now been universally replaced by needle valves which control acceleration of gases when opened more efficiently.

Any device intended to be used in saturation, will be used through-out the decompression stages.

Recommendation: Medical equipment specifically designed to deliver breathing gas should be capable of delivering 100% oxygen. ***(This does not include the existing divers breathing apparatus already installed in the chambers.)***

3.5 Other Atmospheric Environmental Considerations

(a) Temperature

Diving equipment is often stored in a non air-conditioned environment and can thus be exposed to the full range of environmental temperatures. Surface supplied DDCs may not always have heating or cooling equipment and will operate at close to the environmental temperature.

During rapid pressure changes, temperature will rise during pressurisation and fall with depressurisation. This is most notable in air chambers and in medical/equipment transfer locks where pressure changes more rapidly.

Due to the very high thermal conductivity of helium at pressure, the saturation diving chamber environment must be actively maintained by environmental conditioning systems to within a small, relatively warm range in order to prevent divers being endangered by hypothermia or excessive heat stress.

Saturation chambers are generally maintained at 29° - 34°C at operating pressure, reducing to 21°C ± 2°C during the final stages of decompression.

During equipment pressurization in the medical/equipment transfer lock, temperatures commonly reach 50°C and can rise higher - although not usually beyond 60°C.

During equipment depressurization in the medical/equipment transfer lock, temperature will fall to near freezing point and in extreme cases, sub-freezing temperatures may occur briefly.

Note: Significant temperature variations that can occur in medical/equipment transfer locks are for relatively short periods only and the equipment will not be required to be operational during transfer.

Note: As the temperature change occurs as a result of pressure change, the thermal load is generated by the compartment gas itself, and thus occurs within gas containing equipment as well as external to the equipment.

As the thermal capacity of gas is low compared with the steel walls of the medical/equipment transfer lock and potentially of the equipment item components, the rise or fall of the gas temperature due to pressure change is rapidly modulated back towards the starting temperature of the equipment and the lock.

There are also many diving operations taking place in tropical and arctic conditions making the transport of medical equipment to and from the dive site and its storage a potential challenge which needs to be accounted for.

Additionally should the medical equipment be deployed in the event of an SPHL and / or an HRC launch, it may be exposed to raised levels of temperature and humidity for considerable periods

Recommendation: Equipment for diving use should have an operating temperature range of 0 – 50°C as this is a common temperature design range for diving chambers.

Recommendation: Equipment for diving use should have non-operating tolerances of below freezing conditions and of temperatures in excess of 60°C when being stored, transported to and from the diving site or passed into or out of chambers via equipment transfer locks.

Recommendation: Equipment for use in Arctic conditions should be specifically designed and rated for such use.

(b) Humidity

DDCs will commence pressurisation with ambient air humidity but are then usually fairly dry initially, as almost moisture-free compressed air is used to initially pressurise. With occupancy, humidity can rise significantly as a result of exhaled breath humidity and evaporation from wet diver equipment and bodies.

When air chambers are being used for therapeutic decompression, relative humidity is usually between 20-50%

Saturation diving chambers

- (1) Normally controlled in the range 30 – 80% RH.
- (2) Ideally maintained in the range 50 – 70%RH.
- (3) May be close to zero during pressurization and close to 100% in extreme cases.

Recommendation: Equipment for diving use should as a minimum be tolerant of operating in humidities between 0 and 100%. Equipment should be tolerant of exposures to near 100% Relative Humidity (RH) when not operating, and should ideally be tolerant of brief exposures to condensing atmospheres in case the item is depressurised rapidly.

3.6 Operational Considerations

(a) Ship-board operating environment

Diving operations are commonly conducted from 'diving support vessels' and other seagoing mobile units. Equipment must therefore be capable of operating normally during the movement involved.

The vessel accelerations due to heave, pitch, yaw and roll, require that simultaneous dynamic acceleration loads of 1G should be allowed for in each direction.

The vertical static (gravitational) acceleration of 1 G must be added to the vertical load, implying that a minimum worst case scenario of 2 G vertical, 1 G transverse and 1 G longitudinal be used in load computations.

Clients might specify higher loading due to expected sea state, but as a general rule, portable equipment is required to meet the above simultaneous conditions.

Permanently installed equipment may also allow the consideration of reduced loads.

(b) Manual handling and drop testing

The operating environment is much less controlled than any normal clinical environment, however it is difficult to provide specific parameters as chambers vary greatly in size and ergonomics.

Equipment will be moved often and must be robust enough for transport in off-road vehicles, helicopters, light aircraft as well as small and large vessels at sea.

If equipment has robustness and packaging suitable for helicopter or land-based rescue service or for use in a military operating environment, then it should be suitable for diving operations.

(c) Availability of electrical power

Medical or multi-purpose electrical power outlets are not generally available inside hyperbaric chambers with most electrical power specifically installed to supply a particular piece of equipment. Such power supplies will most commonly be 12 or 24 volt DC, ungrounded, with dedicated waterproof wiring and connectors.

Saturation diving chambers usually have individual 'bunk lights' in the sleeping compartments and in some cases these have been modified to allow connection of other low voltage, low power equipment such as personal electronic communications, music or games technology.

This document calls for operators of diving chambers to make available 12 volt electrical power for medical equipment but at present, this may not be universally available. When low voltage power is considered there will be a need for more widely accepted standards for voltage range and stability, amperage and connector types in the wiring rules and safety systems followed.

It will be preferable at this stage, therefore, that equipment has the option of being self-contained and where necessary, battery powered with hyperbaric-compatible batteries.

In order to enable suitable functional duration, devices will need to have changeable batteries or the ability to connect external power, noting that this is subject to the safety considerations around electrical and electronic devices discussed in greater detail in Section 4.

The availability of electrical power external to the chamber will vary with the host vessel or worksite and if AC power is required for charging batteries then allowance should be made for the full range of options found internationally, from 100 – 250 volt, 50 or 60 Hz.

(d) Illumination

Lighting is often poor by clinical standards and any control panels and displays should be legible in poor light or preferably be illuminated.

(e) Water, dust and contaminants

Delicate or sensitive equipment items should have storage containers that protect the equipment from contamination or damage during storage and transport.

During emergency use inside chambers and around dive sites, equipment may be operated by persons with wet hands and clothes.

There may be other contaminants present, so it is therefore highly desirable that the exterior of equipment is tolerant of contamination with water, dirt and grease, and easily cleanable.

Note: It is important that any manufacturer considers carefully the potential application, operational requirements, and use of their individual equipment. Each of the requirements mentioned above may or may not be applicable to a specific piece of equipment, depending on the nature of the equipment or the expected operating conditions.

For example, relatively inexpensive and simple items of medical equipment such as a thermometer, might remain in an occupied saturation chamber throughout the compression, working and then the decompression phases of the 'dive' and hence would never require to be compressed or decompressed faster than the occupants. Some items of emergency equipment might need to be compressed quickly in an emergency e.g. a defibrillator, whereas others might be only used when compressed with a medical attendant.

Manufacturers should also ensure there are clear markings on the equipment outlining what conditions it has been tested as safe and functional in.

3.7 Images



Telemedic sensors attached to patient and to transmitter. Well Enhancer DMAC 28 drills



HRF chamber set up for the care of the injured diver in Baku



Signals from patient sensors transmitted to outside via bulkhead penetrator. Well Enhancer DMAC 28 drills



Inside the BP Baku HRF saturation control cabin with the Supervisor communicating with and watching the divers inside the HRF.



A penlon ventilator and hyperbaric syringe pumps. Inside the BP Baku HRF



A Diver working in Arctic conditions

4 Medical Equipment Requirements

4.1 Introduction

Safe commercial diving operations require contingency arrangements for the management of any trauma or medical emergencies that may occur in the diving workplace – an environment that can be very remote, both physically and as a result of the multi-day decompression requirements for saturation diving.

Diving contractors therefore employ diving medical technicians (DMT's) who are Divers that have been trained to meet the challenges of providing care inside the pressurised and confined environment of decompression chambers.

Professional medical advisory and support services are provided by a very small number of sub-specialist diving medicine advisors with expertise in the physiology and practicalities of the commercial diving industry and saturation diving in particular.

When emergencies do occur, there are a very limited number of emergency medical teams with the skills and resources to respond either by delivering remote support telephonically or by deploying into the field.

Any of these medical and paramedical personnel who may have to manage medical emergencies require appropriate healthcare equipment and this may be variously held by industry at dive sites and at the hospitals and private bases from which medical teams may respond.

Medical equipment required to support saturation diving operations includes items that form part of the emergency kit for the dive bell, the medical kit available on site for use in the saturation chambers, specialist medical items that might be brought to the site by an emergency medical response team, and items for use during transfer or transport.

The scope of equipment encompasses everything needed to look after an ill or injured diver for a period of at least 3 days and potentially up to a week or more, as necessitated by the decompression times associated with the depth of dive operations.

The range of equipment categories includes basic health and hygiene care items, nursing care requisites, first aid, minor surgery, critical care and monitoring equipment, diagnostic items plus IT, telemetry and communications equipment.

The Diving Medical Advisory Committee (DMAC) publish guidelines covering various medical aspects of diving operations, including DMAC 28 and DMAC 15. These are published on their website:

www.dmac-diving.org

The equipment listed in DMAC 15 – Medical Equipment to be Held at the Site of an Offshore Diving Operation, presents only a few problems as this Guideline lists the drugs and advanced first aid supplies, most of which are compatible with use under pressure in the diving chamber.

One problematic item is the Self Inflating Bag Resuscitator. Standard models of this common item of advanced first aid equipment cannot be assumed to work at extreme pressures – experience has shown that the elastic recoil of some bags may be insufficient for it to refill properly.

In addition, the resuscitator must be supplied with gas via an adapter to a divers Built-in Breathing System (BIBS) mask or from a dedicated regulator.

The unit also requires (ideally) exhaust gas capture and connections to dump this to the exterior of the chamber. There are thought to be many resuscitators in the field that have not been tested at pressure and which might fail to work in an emergency.

DMAC 28, 'The provision of emergency medical care for divers in saturation', provides an overview of the higher level care systems that are required to support commercial diving operations.

This includes adequate equipment for a DMT or a doctor to provide makeshift but functional critical care for several days whilst decompression is affected. The most problematic items where deficiencies exist in the availability or suitability of medical equipment are identified in 4.1.1.

4.1.1 Intravenous infusion pumps

These are required to control the flow of intravenous fluids and/or drugs into the patient. A number of syringe drivers exist which have battery power and which appear to work under pressure. Few, if any, have been formally tested to saturation diving pressures. For multi-day operations, a system to enable extended duration operation is essential as most devices have battery run times of a few hours only at best.

It is not ideal to pass infusion pumps in and out of the chamber repetitively for charging, as this can risk damaging the device requiring frequent change of pump, resulting in discontinuity of drug delivery and the risk of error.

Options include the availability of external hard wired power, 'hot swappable' batteries or extension battery packs but each of these has particular safety and practicality issues that are discussed in more detail in the following Section.

4.1.2 Ventilators

This is the most critical deficiency at present for use by diving medical physicians. It is very challenging to make any ventilator work under pressure but the industry has, in the past, had access to one very simple, robust, volume cycle ventilator that has a proven track record at pressure – the 'Oxford Penlon'.

This has not been manufactured for many years, but the Penlon Company is understood to still have the design documents and modern manufacturing techniques may enable a small production run to be possible if there are sufficient guaranteed sales or a specific grant.

There are few alternatives, although another legacy ventilator, the Manley, is also pressure compatible.

It is not in principle impossible to design and manufacture a new ventilator for the saturation diving pressure range, but it is unlikely that any existing modern ventilator design will be adaptable – almost certainly a new design will be needed.

4.1.3 Electrophysiological monitoring equipment

(ECG, Blood Pressure, Oxygen Saturation, End tidal carbon dioxide)

There are a number of portable multi-parameter medical monitoring systems that may be pressure compatible, however information is scant regarding testing results.

There is a need for detailed testing and promulgation of the details of those systems that are most suitable.

These should ideally be equipped with Wi-Fi, Bluetooth or an alternative wireless data-out capacity, so that the monitored waveforms and parameters can be also seen by external personnel on a slave monitor or preferably a computer, from which the data could be re-transmitted to a remote medical facility.

4.1.4 Telemetry for above

Telemetry systems are required to relay medical data to remote medical personnel in a secure and reliable fashion.

There are a number of commercial solutions for this but the offshore commercial diving industry should consider standardising on one or a small number of preferred systems, to ensure the widest usability.

This technology is not necessarily diving specific and suitable systems should be able to be sourced from the wider telemedicine technology field, although the inputs from inside the chamber will need to be from pressure compatible devices with data transmission systems that work through the chamber pressure boundary (wired or wireless).

4.1.5 Audio-visual communications from chamber interior to remote support

(Including consumer electronics such as Skype via tablet devices)

As for telemetry above, audio-visual linkage is critical. Most emergencies managed in saturation diving chambers to date have had to rely on relayed audio communication only, often with many intermediaries.

Modern video-conferencing solutions offer much improved supervision and direction of care but the devices to be taken into the chamber need formal testing. This should include the consumer tablets that are not infrequently taken into chambers.

A good head-mounted camera for the DMT would be a great advantage. The ideal system should have multi-channel feeds from the site of the emergency – perhaps a general view inside the chamber as well as a head mounted camera with an external camera for support personnel to appear on the conference feed.

4.1.6 Semi-automatic defibrillators

With an ageing diver workforce, it would be preferable to have a pressure tolerant semi-automatic or fully automatic defibrillator available. Most standard models tested to date do not function at higher pressures.

This piece of equipment is required by both DMAC 28 and DMAC 15. Defibrillation capability can be provided by a through-hull electrical penetrator selected and wired to connect an external defibrillator with internal defibrillation pads.

As such wiring would ideally be needed in all chamber compartments and is rarely installed at present. It would be preferable for there to be development of self-contained pressure tolerant defibrillators.

4.1.7 Portable ultrasound equipment

The diagnosis of many emergency conditions can be greatly assisted by portable ultrasound. Some tests have apparently been successful in clinical hyperbaric chambers at low pressures. This work needs extending to include saturation dive pressures/depths.

4.1.8 Blood glucose monitoring equipment

The accurate measurement of blood glucose is potentially important in an aging diving population that spends many months in saturation should they develop any unexplained illnesses.

4.1.9 Suction systems

DMAC 28 specifies foot power suction, these such units are readily available and alternatives are possible. Suction systems can be installed, with suitable back pressure regulation and it would theoretically be possible to use BIBS overboard dump connectors to operate a suction unit.

If suitable battery powered units were available, these could provide a very functional and flexible alternative.

4.1.10 Intra-osseous infusion insertion systems

Spring loaded and manual systems are hyperbaric compatible however it is possible that a battery powered drill type system could also be made hyperbaric compatible.

4.1.11 Stethoscope

Traditional stethoscopes function poorly under pressure. A suitable electronic unit would be ideal but would require digital signal processing to correct for the altered acoustics in heliox at pressure.

4.1.12 Portable lighting

Modern battery powered LED lights are improving and units designed for camping and emergency lighting will probably be suitable. Magnet mounts are useful for chamber internals.

4.1.13 Humidifier

Simple heat exchange humidity retention systems may be used but can increase work of breathing at higher pressures.

It would be useful to be able to use humidification that did not create breathing resistance, perhaps using ultrasonic nebulisation.

4.1.14 Nebuliser

Nebulisers for aerosolised drugs for bronchoconstriction need testing at pressure.

4.1.15 X-ray equipment

In the past, lightweight, portable capacitor discharge X-Ray units have been available to take to the dive chamber site enabling an X-Ray to be taken through a porthole and then sent for processing.

With most radiology now digital capacitor discharge portable X-Ray units are no longer approved for human use, there is a need to identify suitable units to replace them.

These do not necessarily need to be pressure compatible and military and disaster team technology may be able to be used.

4.1.16 Volumeter / Flowmeter

The adequacy of artificial ventilation at pressure should be monitored by both End Tidal CO₂ and by measuring the volumes delivered either as breath by breath volumes, minute volume, or ideally flow/time volume measurement capable of displaying as real time waveforms and measurements. To date, simple volumeters only have been available.

The confirmed falling price of ultrasonic flow measurement and pressure sensors should enable a more advanced solution.

This would greatly enhance quality of ventilation and patient outcomes, given that seems likely that the ventilators themselves will probably remain crude for the foreseeable future.

Any electronic volumeter should ideally have data out capability to enable the ventilation data to be transmitted via the medical telemetry system.

4.1.17 Video otoscope

Ear problems are common and diagnosis would be easier with video out otoscopy. This is commercially available for normal clinical use but would require testing and perhaps modification for chamber use.

4.1.18 Decision support aides

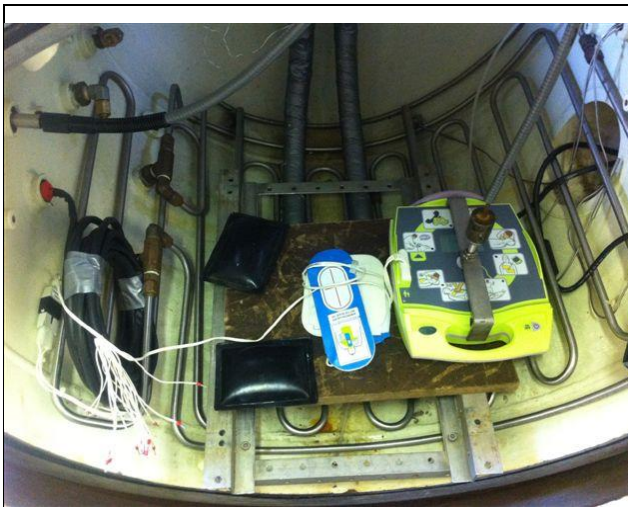
(Paper or electronic guidelines for when communications with remote support is limited or absent)

There are some very simple guidelines on medical emergency management in diving texts and diving manuals.

Advanced computer based systems are under development for military, remote area and space travel use.

It would be useful to have such aids developed for the diving specific environment and conditions needing remote treatment.

4.2 Images



A Defibrillator undergoing hyperbaric testing.



Defibrillator testing equipment.



AED External chamber connections for testing



A test chamber in closed and clamped condition

5 Electrical and Electronic Issues

5.1 Introduction

Many items of modern medical and telecommunications equipment are electrically powered and/or electronically controlled.

This section aims to introduce the newcomer to this field to some of the specific issues that arise when electrically powered devices enter the pressurised diving chamber environment.

Electrical and electronic medical devices involve the most complex regulatory and standards issues. This section addresses general principles without reference to specific regulations and standards.

Most of these regulatory and required documents assume sea level pressure operation and do not have provisions for operation at pressure which can create a compliance problem if compliance with a particular requirement is in conflict with what is needed to allow function under pressure.

There are some documents that have been prepared with provisions for pressurised operations but most of these related to low pressure medical hyperbaric chamber operations.

The most well known of these is the US based National Fire Prevention Association (NFPA) healthcare standard NFPA 99, which has a chapter on hyperbaric chamber safety which includes a number of requirements around electrical power.

In the offshore resources diving sector, there are a number of guidelines around the safe use of electricity in diving and pressurised environments and the shipboard or platform environment from which diving is undertaken is covered by many electrical safety provisions.

Currently there are no comprehensive and specific recommendations for electrical safety of medical devices used in saturation diving environments, and this is therefore an important sub-section of what the authors have tried to include in this report.

It is hoped that this section will provide some preliminary guidance but it is recommended that a significant and specific effort is put into further developing recommendations and some degree of standardisation so as to facilitate the necessary functional operation during extended duration medical emergencies in saturation diving chambers.

One issue that may be problematic is that some standards, codes and regulations have tried to ensure electrical safety by setting simple voltage and current or power limits.

It should be noted that this does not automatically provide safety – for example, it is possible to create a fire igniting spark with very low voltages, whilst very high powered and high voltage equipment can be safely operated in hazardous locations such as offshore oil and gas production platforms, subject to highly engineered safety systems.

Ideally, rigorous and expert risk assessment would be undertaken on all components of any electrical system in normal operation, under stress, and in failure modes. This is however, a very specialised field with few centres of expertise.

Some general information is supplied on regulatory and standards issues in the following section but the detail is beyond the scope of this report.

Useful guidance is included in the IMCA publication Code of Practice for Safe Use of Electricity Underwater - IMCA D 045.

5.2 Fire Risk in Diving Chambers

One of the major concerns with electricity is to avoid the risk of fire ignition inside a sealed space in close proximity to human occupants.

The ease with which fire is ignitable rises greatly with increasing oxygen percentages and is thus highest in clinical single person hyperbaric chambers which are pressurised purely with oxygen.

Ignition risk is moderately increased in air pressurised clinical chambers and DDCs with the risk highest when there is oxygen leakage from breathing masks or ventilators which contaminates the chamber environment without being adequately flushed away by a high rate of fresh air exchange.

Particularly stringent electrical safety precautions are thus necessary in these types of chambers to guarantee that devices cannot provide an ignition source.

For any given percentage of oxygen, there will be increased availability of oxygen if the chamber is at higher pressure (a higher 'partial pressure') and fire can therefore burn hotter and faster if it is ignited, and materials that are not flammable at lower levels of oxygen may become flammable.

As heat is produced by the combustion process, the pressure inside a sealed chamber will rise unless the chamber is immediately vented.

The heat, pressure, fumes and toxic gases produced by combustion all combine to create a significant hazard to the lives of the occupants with hopes of survival dependent upon whether the fire can be immediately suppressed by a high capacity hyperbaric fire-fighting system with concurrent rapid decompression of the chamber.

The oxygen percentage in a saturation diving chamber at pressure is normally maintained at a much lower than in normal air.

Typically, the partial pressure is maintained at 1.5 – 2 times normal atmospheric levels as a safety factor against oxygen deficiency without risking the biological toxicity associated with oxygen at higher levels.

Achieving the optimal oxygen partial pressure can call for an oxygen percentage inside the chamber that is as low as 2 – 5% only.

As a result of this, the fire flashpoint will be much lower than normal during most of the time a saturation chamber is at pressure however there is still oxygen available to support combustion if it is ignited.

100% oxygen breathing may be used via a mask, hood or ventilator for therapy or decompression purposes during the final phases of decompression, however, for some of the time the same risks apply as for an air chamber.

Most of the electrical safety discussion that follows in this report is built around avoiding any fire ignition risk as a result of either normal operation or any failure modes of electrical and electronic devices with their associated batteries and power supplies.

All medical devices are subject to many safety requirements aimed at avoiding electrocution risk.

These issues are generally well covered by standard design features within the devices and within power supply safety systems, such as line insulation monitoring and using ungrounded power supplies.

Very detailed guidance is available which is not further discussed here other than to note that any modifications needed for hyperbaric operations must not compromise the patient or user safety of the device.

The principal international standards specifically applicable to medical device electrical risks are published by the International Electro-technical Commission – most notably the IEC60601 series of standards. These do not, however, have specific diving or hyperbaric provisions.

5.3 Power Supply Inside Chambers

With respect to electrical power inside diving chambers, it is generally considered unsafe to have mains power outlets (high voltage AC) available in any pressure vessels for human occupancy and any medical devices incorporating electrical and electronic elements will therefore be required to operate from low voltage power or battery.

This has the diver and patient safety advantage that many risks of electrocution are mitigated by the absence of mains voltage AC power.

Most electrical equipment potentially called for inside diving chambers will not be permanently installed inside the chamber or even kept within the chamber – it is more likely that these complex and expensive devices will be taken into the chamber when an emergency arises.

The power supply therefore needs to be either part of the emergency response kit or installed in the chamber according to a standard that ensures the power is available and usable by the device in question.

For DDCs, either hardwire or battery power can be used subject to power supply duration being adequate – it is recommended that at least 8 hours run-time will be required.

For saturation diving chamber use, any of the items of equipment that are electrically powered will require a means of providing power for extended use over many days.

Some devices specifically designed and approved for clinical hyperbaric medical chambers in Europe are supplied purely from hard-wired low voltage DC sources but it is unlikely that such equipment will be included in the permanent configuration of diving chambers.

Many devices that might be taken into chambers are designed with a DC power-in connection, and this is most commonly 12 volt DC in order to enable automotive vehicle power to be used.

The most commonly used alternative power supply inputs for medical devices are 24 volt DC, (as used in many truck, bus, marine and industrial environments) 28 volt DC (aircraft) and the more recent but almost ubiquitous 5 volt DC USB power outlet. Many other inputs exist, however, with specific power supplies or plug-packs often supplied with the device.

It would be very useful for medical device manufacturers to have standard methodologies specified for medical device power supply into chambers.

USB power can readily be supplied via a suitable voltage converter supplied from a 12 or 24 volt source and installed USB power does not, therefore seem an absolute necessity.

Recommendation: *It is recommended that a suitable group be commissioned to prepare and circulate improved and more specific guidance regarding the installation of low voltage power in diving chambers specifically for medical devices.*

***Note:** Although consultation would be needed with the medical device industry it should be noted that any such guidance would, primarily, be aimed at the diving industry and chamber manufacturers who would need to install such systems into their chambers.*

Hardwired electrical power with interchangeable connectors inside the chamber is a problematic concept, particularly in terms of ensuring safety.

The power requirement for multiple simultaneously operating critical care medical devices is likely to exceed what is recommended in some clinical hyperbaric chamber guidelines such as the US based NFPA 99 standard.

If 12 volt DC power supplies were chosen, these might need to have a 10 amp total current capacity in order to provide for devices with a power capacity up to 100 watts. The selection of 24 volts would, of course, halve this current requirement.

Any medical power specification would need to include specifications for methods of safe installation and operation. Consideration of how to address the power safety issue once the chamber nears surface pressure with the associated increased fire hazard if high fractions of oxygen are used.

The reliability and redundancy of the power supply should be specified with the aim of ensuring continuity of supply in critical care situations.

If guidance was created regarding low voltage medical power supplies, it would be useful if a standard connector could also be specified which was of a type readily available from multiple suppliers.

This would preferably be environmentally sealed as well as electrically insulated when connected. The connector should incorporate design features that prevent inadvertent disconnection of the power when current is flowing and the chamber is at pressure.

The seal of any connector should not expose the connection pins and sockets to the chamber gas environment until power carrying conductors are separated sufficiently that sparking cannot occur.

Two approaches would be possible with respect to supplying power from outside the chamber.

Either there could be standardised power supplies installed into all saturation chambers for use by compatible medical devices, or there could be wiring only, with the responsibility for supplying medical power held by the supplier of the medical device using connectors compatible with the specified pre-installed medical wiring cable.

The latter would seem more attractive to the diving industry, especially for existing chambers.

Whichever approach were chosen, it would be useful for bodies that specify diving medical equipment (such as DMAC) to publish a complementary Guidance Note or updated guidelines to help users select equipment that would be compatible with any future diving industry standard medical power supply system.

5.4 Notes on the Different Options for Electrical Power

5.4.1 Hardwired Power Reliability

The main clinical safety issue here is the reliability and redundancy of the power supply. If the device is critical to patient safety, then the power supply must be guaranteed throughout the care period, without fluctuations or interruption that might interrupt the function of the device.

Externally this can be addressed by using dual medical grade power supplies powered from a guaranteed mains power supply or UPS, with either manual or automatic switching and suitable monitoring displays.

A more common alternative is a high grade primary external power supply with a battery backup that is permanently connected and normally on continuous trickle charge.

5.4.2 Hardwired Power Safety

Whilst hardwired power supplies are external to the chamber this does not obviate all electrical safety concerns as there will be a risk of sparking with an associated fire risk if the power connectors inside the chamber are disconnected during use.

This is usually best addressed by utilising connectors that cannot be easily or inadvertently disconnected such as connectors with a screw lock.

There are widely available industrial connectors that offer protection against disconnection sparking risks including Explosion Proof designs and many types of underwater power, aerospace and hyperbaric chamber specific connectors.

If hyperbaric devices are designed for hardwired power use only, it is usual for one or other type of 'disconnection safe' power connector to be incorporated, there are many variations and no common standard.

For the more common devices that are also used for patient transport, and for most consumer electronics, the plugs used are readily disconnectable during use. This is probably not a major risk in the case of 5 volt USB power but devices supplied with 12 volts from high capacity power supplies could easily spark during disconnection.

If hardwired power supplies with standardised connectors become routinely available in chambers as we recommend, many, if not most devices will require a change of power input connector or an adapter lead or plug.

For adapter leads or plugs to fulfil the safety aim of preventing disconnection under load, the 'unsafe' original device connector will need to be secured suitably (for instance with glue, a locking screw, cover etc.) so that in-chamber connection and disconnection is only via the pressure safe connector.

5.4.3 Power Supply Switching

The modern generation of semi-conductor or hermetically sealed switches should make safe in-chamber power supply switching possible.

It would be possible to have a single medical device with multiple power inputs and one power output to the device, with LED's to indicate power from the supply.

Perhaps this could be based on a set voltage so that it can also indicate condition of charge and then a switch to connect to the medical device. This would allow safe disconnection of battery or hardwired power source, with supply switching to an alternative.

The same technology could also be used in the reverse manner – that is, a high capacity single power supply could have switchable outlets to power more than one medical device.

Either of these technologies could add flexibility and facilitate the use of multiple devices over prolonged periods since selection of suitable technology, customisation for diving chamber medical applications and rigorous safety testing is lacking at present.

(There are a few examples of such systems that have been engineered to enable consumer electronics to be charged from saturation divers bunk light power supplies.)

External power supplies must also be controlled and protected against over-voltage or excess current flow with suitable fuses and/or circuit breakers.

Hyperbaric chambers are fabricated from steel and whilst this is usually painted there is often exposed stainless steel or aluminium and moisture or sea water present.

Low voltage power systems need to be designed to prevent electrical shorts to such conductive surfaces. This will involve insulation, suitably robust cables routed and secured to minimise risk of damage and connectors that do not expose powered conductors. The low voltage side of the power supplies should not be earthed. ('Ungrounded power')

5.4.4 Low Voltage Supply and Battery Charging

Most relevant medical devices incorporate rechargeable batteries and circuitry that automatically charges these batteries when the external power is connected.

This unfortunately creates safety risks for pressurised operations as it is under charge conditions that batteries most commonly fail in a dangerous manner.

Dangerous failure during charging is probably most relevant for lithium batteries as discussed below. The other issue with charging batteries under pressure is that some battery types release hydrogen during charging creating a potent fire and explosion risk in a confined space.

When a device is being simultaneously operated and is connected to external power because batteries are flat, the power input will be greatest.

This readily foreseeable scenario is the time of greatest risk of overheating power circuitry inside the device and overloading of supply wiring.

Overheating in connectors with corroded conductors with reduced but not absent conductivity within the connector is also possible.

There are potential solutions to all of the above problems but many solutions will involve modifications to standard designs.

- For devices fitted with internal, rechargeable batteries, the internal charging circuitry shall be deactivated when the device is powered using external power. Battery charging shall only take place outside the chamber.
- Batteries could be removed during chamber use, although this is a human and probably very fallible precaution and the device will revert to being a hardwired device only, requiring suitably reliable low voltage power.
- Battery charging could be disabled manually via a suitable switch or in theory automatically via some sort of analog or electronic pressure interlock.

5.4.5 Exchangeable Batteries

Some medical devices incorporate removable batteries (either single use or rechargeable and sometimes the option exists to use either.)

This may be a good option provided the device is of a type that does not require continuous operation. Safe battery exchange usually involves powering down the device which may not be clinically acceptable.

A safety evaluation is needed for all the potential risks of this type of practice including the risks of battery damage during pressure change, of shorting a removed battery to metal surfaces or via wet hands, and how to ensure the device is powered down when the batteries are changed, so as to prevent battery removal or insertion under electrical load.

It is a known fact that standard, non-rechargeable, sealed dry cells may shrink on compression. This may lead to contact being broken with the battery (ies) and a subsequent power loss. The manufacturer shall test for this condition and apply a modification to ensure that power cannot be lost at a depth of $\pm 20\%$ deeper than the rated depth.

5.4.5.1 Hot Swappable Batteries

Some medical transport devices incorporate 'hot-swappable' batteries which enable one or more batteries to be removed and replaced whilst the device continues to operate on other batteries.

One model of clinical hyperbaric intensive care ventilator (Maquet Servo-i) has this feature as a legacy of its intensive care parent, however the manufacturer required battery removal prior to pressurisation and operation on low voltage power only in order to avoid fire risks

5.4.6 Generic Battery Supplied Power Units

It should be simple to manufacture extension battery packs for hyperbaric use that are able to be charged outside the chamber then transferred in for use with the relevant device and connected via the external low voltage power-in connector.

Free standing power supplies are generally seen as undesirable as they introduce a potentially large and relatively uncontrolled energy source into the chamber.

They also carry the same safety hazards that exist around the interface between any external power pack and the device its power supplies, often without the expected safety systems that are usual with externally powered, permanently wired systems.

It should be possible to engineer safety into such power packs, and the principles of portable, universally usable and long duration power packs are attractive. (The authors of this report are not aware of any suitable systems presently on the market.)

5.4.7 Battery Types

Ideally, each individual model of battery considered for diving chamber use would undergo failure modes and effects analysis (FMEA) as well functional testing of multiple samples for pressure tolerance.

In practice, the safety of various battery types are most commonly discussed as if the issues are the same for all models of battery within any one chemistry type.

This is probably inadequate, as within each generic category of battery chemistry, there are usually many different constructions, as well as widely varying quality, embodied energy and safety components.

Risk should generally be low with low voltage single use '*dry cell*' batteries such as *alkaline batteries*. Small single use *lithium 'button' batteries* and *time-clock batteries* incorporated into devices should also usually be very low risk. There are however, specific risks associated with all of the commonly used rechargeable batteries.

Lead acid batteries with liquid acid should not be used in chambers as a result of the consequences of acid spillage.

'Spill-proof' sealed gel cells and **glass fibre mat absorbed cells** may be pressure safe but will need individual assessment and testing. **Lead acid batteries** release hydrogen when being charged and should not be charged under pressure.

Nickel cadmium (NiCad) batteries have become relatively uncommon in recent years due to the availability of **nickel metal hydride (NiMH) and lithium batteries** with superior performance characteristics.

Cadmium is an extremely toxic metal and the increased risk of damage under pressure makes this chemistry undesirable for hyperbaric use.

NiMH batteries are perhaps the most suitable chemistry rechargeable battery type presently in use.

The components of these batteries are non-toxic and they are used in a range of medical devices.

In many cases, it is possible to obtain **NiMH batteries** in a configuration that enables replacement of **NiCad or Li-Ion batteries**.

The most common battery type incorporated into modern devices is generically labelled as '**Lithium Ion**' (**Li-Ion**), or in some cases, '**Lithium Polymer**' (**LiPo**) although LiPo is really just a sub-category of Li-Ion.

Most authorities have concerns about the hazard inherent in any form of lithium chemistry battery when used in the hyperbaric environment given that pressure exposure may increase failure risk and many lithium battery types are capable of failing in a high-temperature 'melt down' mode.

Destructive heat production is most usually the result of the concentrated discharge of the high amount of embodied electrical energy, but some Li-Ion types are also probably capable of a runaway chemical fire fed by the lithium component and oxidants inherent within the device.

Such electrical heat discharge or chemical heat production produces very high temperatures that can ignite many other materials, melt metal, and continue even when immersed in water.

There are, in fact, multiple different lithium battery chemistries, some being less prone to failure than others and some construction methods and geometries more robust and/or pressure tolerant.

In LiPo cells, the lithium chemistry is incorporated into polymer sheets, resulting in a thin, flat battery form that ideally suits mobile telephones and tablet devices. Very high capacity LiPo cells have been used in power batteries for submersibles exposed to very high pressures underwater, supporting the opinion that LiPo cells may be safer than the common cylindrical Li-Ion cells that are fabricated from long strips of anode, cathode and separating membrane, wound up into a cylinder.

Quality control of construction of Li-Ion cells is critical as hot-spots and failure can originate at the sites of breaches in the membrane between anode and cathode.

This can occur as a result of manufacturing variability, perhaps brought to a critical point by damage to the cell, possibly by repetitive pressurisations and depressurisations.

The safety of modern Li-Ion cells is also in significant part brought about by 'add-on' safety components built into the battery container.

These can include electronics that limit charging rates and prevent excessive discharge, temperature cut-outs and mechanical vents that ensure that gas pressure cannot build up inside the cell.

These safety systems are critical to preventing dangerous battery failure, yet the tolerance of these systems to pressure remains unproven at present.

There are examples of manufacturers who have released clinical hyperbaric medical devices to market with Li-Ion batteries (e.g. the Corpuls Hyperbaric Defibrillator).

Such manufacturers will have undertaken significant testing in house and by third parties to ensure that their device's batteries are safe.

Testing has not extended to the higher pressure range required for diving chamber use, however, and a question remains as to whether battery safety will be maintained over time, as battery ageing, and repetitive pressurisation may degrade safety.

5.4.7.1 Alternative approaches to battery safety

Batteries can be rendered safe for hyperbaric use if they are fully encapsulated in a pressure proof housing, which protects the battery from pressure and which would contain the battery in case of any problem. Helium Venting issues mentioned above, need to be considered here.

An alternative that could be explored includes heat dissipation cases or phase change material cases.

These provide significant heat absorption and protection from over-temperature conditions, as long as the quantity of phase change material used is sufficient to absorb the energy available.

6 Relevant Regulatory Processes

6.1 Generic Overview of Medical Device Regulations

Medical devices are an essential part of the provision of healthcare and there are a range of laws, regulations, standards and licensing requirements in every country to ensure that medical devices remain safe and effective.

Globally, the definition of what qualifies as a medical device varies but the principles remain the same – anything that is specifically designed and marketed for use in caring for a patient.

Generally, regulation is getting stricter and this trend sees some equipment that was not historically defined as a medical device now clearly covered by regulation in many jurisdictions.

Hyperbaric oxygen therapy chambers are now considered as regulated medical devices in many countries.

Fortunately, however, operators of occupational diving support chambers are not faced with the requirement for the chamber itself to be a 'Medical Device' – it is just the environmental setting inside which the relevant medical devices must work.

The rigour of medical device processes varies with the degree of risk associated with any particular type of device. Medical devices are most commonly categorized into one of three classes, as defined in following text (see below for definitions).

The most rigorously regulated class 3 devices are mostly those that are surgically implanted and these are unlikely to be relevant to emergency care in the diving workplace.

Most of the devices which have diving environment specific requirements fall into the Class 2a and 2b categories.

6.1.1 Trans-national issues

A special problem for international operators in the commercial diving industry is determining what jurisdictions are relevant – in some cases diving vessels or platforms are in international waters. It is common for there to be multiple nationalities responsible for different aspects of a project e.g.

- The port of origin of a vessel
- The physical location of the works
- The nationality of the medic or ship's captain responsible for drugs and medical devices
- The location and registration of the supervising medical officer (who may be on the other side of the world)
- The nationalities of the primarily responsible employer, the operator and, of course the patient.

In practice, this is mainly a problem with respect to who takes responsibility for patient care and for ownership of 'dangerous drugs'.

To date it has been rare for questions to be raised about the source of common items of first aid and medical emergency equipment.

The responsibility for supplying legal and appropriate equipment is generally accepted by the company who supplies the kit – most commonly a diving contractor – and the suppliers, purchasing officers, medics, nurses and/or doctors involved will have to work with what is made available.

Sometimes this situation brings with it problems with compatibility of power supplies, radio spectrum or language of labels and instructions.

The diving contractor will often be contracted to an Oil Operator and there may be requirements set by the Client and/or by officers of the jurisdiction where the works are being undertaken.

Again, the most frequently asked questions relate to what drugs are legal in the relevant jurisdiction.

It is theoretically possible but not common, for questions to be asked about medical devices, however unlike 'dangerous drugs' most of the medical devices needed for support of diving operations do not require specific prescription or 'physician only use', and even where such rules do apply, there are usually pathways open to allow a locally licensed physician to take responsibility and 'authorize' medics or a ship's captain to hold and if needed use such equipment.

6.1.2 Medical Device Regulation¹

The most significant internationalised medical device regulatory system operates in Europe. There are several main European Community Directives that guide the medical device regulatory environment within Europe and the United Kingdom.

As with many EC Directives, these Directives have a primary aim of creating open and competitive markets in addition to the patient safety aims of such regulation.

Compliance with these directives requires member countries to have legislation and administrative systems in place to enable approval of medical devices by a 'Competent Authority' which can then approve 'CE Marking' to allow use with patients across Europe. CE marking is the most widely recognized medical device approval system in the world although many other jurisdictions have robust systems, with the United States and Japan being notable developers and manufacturers of medical devices under their own regulatory systems.

Council Directive 93/42/EEC is the primary ruling for members of the European Community and its provisions have been taken up into legislation in each country, albeit with some important differences in how oversight of the medical device market is provided.

It provides the overarching principles for medical device approvals, the classification matrix and is harmonized with the critical European and ISO Standards that cover medical devices. Critical international standards for medical devices include ISO 14971 - Application of risk management to medical devices and ISO 13485 Quality management standard for medical devices.

This latter standard is harmonized with the more generic ISO 9000 series of quality standards. Another set of critical documents with much more specific information about various types of devices is the International Electro-technical Commission IEC 60601 series of standards.

The practical implementation of these Directives is administered slightly differently in different countries.

In some, the regulatory authority has its own inspectorate that directly examines the design and manufacture of devices and then provides medical device approval if warranted. Others, by contrast, use private, third party agencies to assess the competence of the manufacturer to design and manufacture a medical device.

¹ A good source of overview information on medical device regulation is the website of the UK's Competent Authority, the Medicines and Healthcare products Regulatory Agency (MHRA) which publishes Bulletins which explain the requirements and clarify various issues in straightforward language.

It should, of course, be remembered that the MHRA advice represents the UK legal situation and both law and its interpretation will be somewhat different in other jurisdictions, despite harmonisation.

Readers should note the above section attempts to summarise some general principles from the point of view of the authors who do not have legal training.

The legal position applying in each reader's jurisdiction will depend upon the jurisdiction's relevant laws and any Standards and Codes called up, as well as local interpretation and the administration processes of the relevant authorities.

Acknowledging that the greatest expertise in medical device engineering often resides within the manufacturer's company, a substantial focus is on audit of quality assurance systems including quality assurance over company management as well as device design, safety testing and manufacture.

Once approval is received by a company under such quality based arrangements, it is often possible for the company to manufacture new devices which are declared as 'substantially similar' and therefore able to be CE marked and marketed using an existing approval, rather than having to undergo a new inspection.

This pathway for development is an attractive one for hyperbaric compatible medical devices, as it avoids much of the cost of gaining approval for a new device. It is, however, only applicable if there is a 'parent device' which is sufficiently suitable for hyperbaric use that only relatively minor changes are required.

Any manufacturer using this pathway will have to have sufficient expertise in house to understand the challenges and requirements of making a device hyperbaric compatible and in most cases, external validation by a suitable third party testing agency would be wise if not required.

Medical devices are categorised according to the perceived risks associated with the device. The categorisation rules are complex and are as follows;

- **Class I Medical Devices** are typically non-invasive devices that do not deliver drugs and this class includes passive objects like chairs and bedpans.

Most relevant Class I devices are relatively simple items for which there are no operating limitations specified, and where the device is clearly an inert item that is obviously inert to pressure change, such as a simple plastic splint, a bandage and similar items, although some caution is necessary as saturation diving pressures may be sufficient to deform items made of foamed plastics for instance.

- **Class IIa Medical Devices** include most surgical instruments, infusion pumps and equipment that can act physically upon the body but in a non-hazardous way.
- **Class IIb Medical Devices** include lower risk implantable devices and all devices which can deliver potentially dangerous energy to the body or modify physiology or drug actions.
- **Class III Medical Devices** are those categorized as carrying the highest risk, such as implantable pacemakers and invasive neuro-monitoring equipment. (Note that when hyperbaric chambers are sold for hospital or clinic based medical therapeutic purposes, they are classified as Class IIb devices, however this is not considered to apply to the sale of diving chambers)

In recent years, there have been many developments in the regulation of medical devices. New ISO standards have been developed, often originating from previous Euro-Norms.

There are a number of ISO committees working on international standards to replace previously varying country by country standards.

One such important committee is ISO TC121 – Anaesthetic and respiratory equipment, where a debate has been initiated as to whether hyperbaric medicine deserves a specific subcommittee within this Technical Committee.

There have also been significant revisions and developments with respect to the IEC 60601 series of standards, which provide the most detailed template for the design, manufacture and safety testing of medical devices involving electrical components.

Most medical device regulatory authorities and most countries' laws call for compliance with IEC 60601, although in some cases only older versions or specific parts are called up at this time.

Much work remains necessary with respect to international harmonisation, given that the market for most medical devices is worldwide and it is presently difficult for manufacturers to gain approval in multiple markets, given so many different and often complex, slow and expensive administrative pathways.

Most companies with a new medical device will engage specialists to help assemble the paperwork or to provide the auditing required to gain approval to 'go to market'.

6.1.3 Multi-component and modified devices

'Composite' medical devices have created challenges for regulators in recent years – especially when consumer devices are used as part of the operation of a medical device.

An example might be a physiological monitor which has a laptop computer and printer connected, all powered from a small computer UPS, connected with 'off the shelf' power leads.

From a patient safety point of view, the whole assembly needs to be considered as one system but the monitor manufacturer has only provided one part of the system – the final responsibility for patient safety rests with the persons who purchased the items, assembled them into a complete working system and then put the finished system into service.

In this setting, the person who assembled the system can be considered to have become 'The Manufacturer' from a legal point of view unless the monitor manufacturer has specifically identified that the selection and connection of each of the ancillary components is part of the design for which they gained approval.

Similar considerations come in to play whenever a modification is made to a medical device, for instance to make it compatible with the hyperbaric environment.

If work is conducted on the device by a manufacturer trained technician and according to the technical manual, then this could in some cases be considered normal practice that does not void the device's warranty or its medical device approval and CE marking.

This could even be the case when the modification is made by a biomedical engineer independent of the manufacturer but who has been trained and approved by the manufacturer for the maintenance of a particular device.

As discussed earlier, it can be allowable for a manufacturer to approve modifications in accordance with their own internal approval and quality assurance processes, with the resulting modified device falling under the same medical device registration as the original 'parent' item of equipment.

In contrast to the above, if a significant change is made to the device in any way that is not approved by the original manufacturer, the employer of the engineer making the modification can be considered to be the new 'Manufacturer' who is now legally responsible for the device.

When the modifier is also the user, this is not too complicated, but if there is any consideration of selling or distributing the modified device to other users, all of the requirements associated with registering a new medical device will probably come into play, along with potential conflict with the original manufacturer.

Just what is 'significant' is open to some debate, but non-significant changes would usually be considered to be limited to those that are listed within the device's operating instructions, environmental specifications, technical manual or service manual as published by the original manufacturer.

There are provisions that may allow hospitals (but probably not other parties) to avoid the cost, delays and paperwork involved in seeking medical device registration themselves for such modifications or for assembly of composite device systems. Medical device regulation primarily controls the 'marketing' of medical devices.

If there is no 'marketing' then the regulations may not apply, and this can be considered the case when a hospital's biomedical engineering department manufactures or modifies a device for use in the hyperbaric chamber.

Note, however, that supplying a successful custom made device to another hospital would be considered 'marketing' in most jurisdictions, whether payment is made or not. Also important to note is that general safety and liability provisions of law always continue to apply – it is only the registration and CE marking component of law that can be avoided.

The pathway of an individual hospital manufacturing or modifying a medical device for saturation diving use might thus have potential to deliver specific equipment items to a specific medical response team, but it is clearly not an answer to the problem faced by the diving industry in sourcing functional and compliant devices.

6.1.4 Off Label Use

A legal principle that does offer some wider flexibility to manufacturers of devices that might be useful for the diving industry relates to the 'labelling' of medical devices. Labelling refers to the methods of use and the indications for use that the Manufacturer identifies for the device in the operating manual or on the 'label'.

The information submitted by the Manufacturer to the medical device regulatory agency will define what is 'on-label' versus 'off-label' use. Included in the manufacturer's documentation will be the environmental

operating conditions that are allowed and this will only rarely include hyperbaric pressure. In some cases there may be a reference to hyperbaric use being either allowed or specifically not recommended.

Off-label use is usually considered to be use for an indication other than recommended by the manufacturer but the term can also be considered to apply to use of the device in an environment that falls outside the manufacturers specific 'operating environment', for instance at pressure inside a hyperbaric chamber.

In at least one recent instance, these different 'label' considerations were not in alignment – the Cardinal Alaris modular infusion pump system used to have its operating conditions specified as including pressures of 0 – 6000hPa (full vacuum to 6 ATA) but it was specifically not approved for hyperbaric oxygen chamber use.

Presumably the warranty was not voided by having the pumps used in the chamber but any use on patients would have been clearly 'off-label'. (This has since changed and Cardinal now do support hyperbaric chamber use).

It would in principle be possible, therefore, for a manufacturer to test one of their products against the environmental parameters set down in this document and extend the device's environmental operating conditions in response to this without specifically changing the devices "Intended Use" to include the diving chamber environment.

In such cases, the device would have to be used "off-label" by the relevant healthcare provider, but only off-label in an environmental sense and not in terms of the clinical indications or therapeutic aims of use.

The consequences of off-label use vary somewhat in different jurisdictions but as a general principle, a physician is entitled to use a device "off-label" in several circumstances.

In an emergency, the physician (and his or her employer if relevant) can take responsibility for off-label use.

Off-label use may also be permitted for "special" or "compassionate" purposes. Such off-label use will usually require a special application or at least notification to the medical device authority – in some jurisdictions for every case where the device is used.

It is this principle that will most usually apply to more complex medical devices used inside diving chambers, unless the manufacturer has specified that the Device is for saturation diving chamber use.

6.1.5 Non-Medical Devices and Accessories

There is significant potential for the development and testing of devices which are not medical devices, but which will be able to significantly assist in medical care in diving chambers.

Any such devices need to be safe and functional within themselves, and also need to not degrade the safety of other devices, but they should not need approved via medical device regulatory pathways.

There are probably two categories of such devices, devices which are non-medical but which have an incidental value in healthcare and devices which might be accessories, mounting or power supply components or modifications to the chamber.

The first category involves no direct connection or interaction with any medical device and would include items such as LED headlamps and IT and communications equipment that simply transmits audio-visual content.

The second category covers items which connect to or interact with a medical device in some way, but without being part of the medical device and thus subject to the 'composite device' concept that sees the person assembling the final system become the 'manufacturer'.

This category can include things like power supplies, cabinets and cases, mounting brackets, gas supplies and gas exhausts, and in some cases remote displays that enable viewing of video-out.

In order to avoid the 'composite device' complications, such accessories or installation hardware needs to be either approved by the manufacturer (e.g. 'this video out port can be connected to any analogue video display unit capable of receiving a VGA or higher resolution signal' or 'VESA mounts are supplied for mounting the device') or else it must be external to some defined 'boundary' of the device and if it supplies energy or gas, the supply must meet the manufacturers requirements.

Examples of this would include the gas supplies for ventilators, exhaust scavenge systems and power supplies which connect into the standard external power socket of a device.

Storage cases would clearly be considered as accessories not impacting on the use of a medical device, but a pressure proof case to enable a device to be used in a chamber would be more arguable, with issues such as ventilation, temperature and any changes to patient connectors needing to be considered.

7 Existing Standards, Codes and Guideline Documents

The following existing documents provide mandatory, guidance or ancillary requirements for a manufacturer to follow in the design, production, testing and certification of appropriate medical devices or equipment.

Many of the documents are not specific to the commercial diving industry.

The existing overall regulatory processes have been summarised in section (6) above.

The first list contains the traditionally 'international' documents, being those that are usually referred to. Thereafter, region-specific documents are listed to specifically contain hyperbaric or commercial-diving reference materials.

The focus is on existing, regional-specific documents so that manufactures can obtain the appropriate focus; however, they can then obtain guidance elsewhere where their region may contain insufficient documented requirements or guidance.

The codes, standards, guidelines and reference materials mentioned below are provided **as guidance only**. Certain jurisdictions might specify compliance with applicable documents; classification societies may waiver national compliance for offshore applications; but it remains the responsibility of the manufacturer to comply with the needed and applicable documents.

7.1 International Medical Device Standards of a ‘Top Level’ Nature

Reference	Type	Description
ISO 14971	Standard	Establishes the requirements of risk management for ensuring the safety and reliability of medical devices.
IEC 60601-1	Standard	Identifies required safety standards and essential performance for electro-medical equipment.
ISO/TR 80002	Guidance document	Validation of software used for the production and service of medical devices. Applies the risk management requirements of ISO 14971 to medical device software.
IEC 62304	Standard	Defines software life-cycle requirements for medical devices to establish a framework for software development and maintenance.

7.2 European Medical Device and Diving Chamber References

Reference	Type	Description
93/42/EEC 2007/47/EC	Directive	Establishes requirements & standards for the design & manufacture of medical devices, primarily to ensure safety & reliability. Devices classified according to risk (4 classes).
EN 14931 (PVHO)	Standard	Provides performance & safety requirements (including test methods) for medical multi-place pressure chamber systems. Note Annex B: Recommendations for medical devices.

7.3 Classification and Certification Societies

Reference	Type	Description
DNV-OS-E402	Offshore Standard	Provides criteria for design, fabrication, testing & commissioning of diving systems. Includes guidance on life-support equipment.
GL-2009 I Part 5	Certification Rules	Provides rules for the design and construction of all forms of manned pressure vessels. Includes guidance on life-support equipment.
Lloyd’s Register of Shipping	Certification Rules	Provides rules for the design and construction of diving systems, including life-support systems.

7.4 Industry Association Guidelines

Reference	Type	Description
IMCA D034	Regulatory Guidance	Norway/UK joint guidance document incorporating NPD & UK HSE regulations; Norsok standards; IMCA guidance; IMO codes; DMAC guidance: Specifies medical personnel & equipment requirements.
DMAC 015	Guidance note	Specifies medical equipment to be available on site for offshore diving.
DMAC 028	Guidance note	Specifies the requirements for emergency medical care for divers in saturation.
IMCA D039	Guide	FMEA (Failure Modes & Effects Analyses) for diving systems, including aspects of life support for divers.
IMCA D052	Guide	Guidance on Hyperbaric Evacuation Systems.
British Hyperbaric Association	Guide	Provides guidelines for medical electrical equipment standards for hyperbaric treatment chambers.
EIGA 152/11	Guide	Comparison of required gas quality levels for Europe, the US and Japan.

7.5 US and North American Reference Materials

Reference	Type	Description
FDA: Various	Legal acts & various regulations	Food & Drug Administration: Lists the requirements for registration with the authority prior to medical equipment being marketed for medical application in the USA.
FDA 21 CFR Part 11	Legal	US law (Code of Federal Regulations) which allows for the implementation of computer systems, but ensures that any software used to develop and manufacture medical devices meets the standards for data security and integrity.
NFPA 99 Cpt 14: 2012 edition	Code	Health Facilities Code: Specifically provides requirements for new equipment to be provided for use in hyperbaric facilities.
NFPA 70 NEC	Code	National Electrical Code providing specific requirements for electrical safeguards.
ASME PVHO-1	Standard	Provides the requirements for any structural changes to the pressure vessel for installing medical equipment (penetrations, supports). Covers diving and clinical hyperbaric chambers.
American Bureau of Shipping	Rules	Provides rules for the design and manufacture of diving & hyperbaric facilities, including life-support and safety considerations.
ASTM	Standard Guide	G63-99: Evaluating non-metallic materials for oxygen service. G 88-90: Designing systems for oxygen service. G 93-96: Cleaning methods and cleanliness levels for materials and equipment used in oxygen-enriched environments. G 94-92: Evaluating metals for oxygen service.
CSA Z275.1-93	Standard	Provides requirements for the design and construction of hyperbaric facilities.
ASME STP-PT-047	Guidelines	Provides safety & performance guidelines for regulatory submission of medical hyperbaric chambers.

Reference	Type	Description
CGA	Handbook	Compressed gas handbook containing specification on types of connections for different gases - to ensure appropriate connection safety, quality of gases and gas storage vessels.

7.6 Australia New Zealand Reference Materials

Reference	Type	Description
TGA: Various	Regulation	Therapeutic Goods Administration: Lists requirements for registration of medical equipment prior to sale into Australia.
TGA ARGMID	Regulatory Guidelines	Provides guidance for manufacturers of medical devices to comply with Australian legal requirements.
AS/NZS 2299.1	Standard	Requirement for equipment and procedures for occupational underwater operations up to 50.0 m.
AS 4774.2	Standard	Requirements for the design & construction of PVHO but excluding underwater diving equipment.
NOPSEMA (Australia)	Diving Guidelines	General requirements for diving activities in the offshore resources and greenhouse gas storage sector.
Occupational Diving (NZ)	Guidelines	General requirements for occupational diving activities to comply with HSE regulations.
AS/NZS 3200	Standard	Requirements for medical electrical equipment.
AS/NZS 3551	Standard	Requirements for the development of medical equipment management programs.

7.7 Others

Each nation has its own medical device regulatory system with detailed compliance systems. The most relevant are those of the nations that manufacture the most commonly used medical devices.

These are Europe, the USA and Japan. European nations follow processes that are generally very similar utilising the ISO, IEC and EU standards and regulatory processes leading to CE marking.

Items manufactured for sale only in the US must primarily meet FDA requirements but if sold internationally will have complied with the relevant ISO codes and the specific requirements for registration in each relevant jurisdiction. To date, the authors of this report have not identified any nation that publishes diving medical equipment specific requirements.

7.8 Outcomes of Testing

Ideally, medical devices would be manufactured that are suitable for commercial diving chamber use and are fully approved by the regulatory authorities in the country of manufacture at least. Third party validation testing would have been performed by a reputable and suitably experienced organisation and the device would function completely normally at pressure.

This may not always be possible for various technical or market reasons so it would be desirable for medical devices to also be available if any of the following outcomes were achieved;

- The device functions satisfactorily, but requires non-standard accessories or special gas or power supplies in order to enable this function.
- The device functions with limitations compared to its normal functioning. The device functions with limitations that make it fail to reach published standards. The device functions sufficiently to provide a useful clinical efficacy that would be better than not having the device.
- The device requires modification in the way it is used at pressure. These modifications could involve a physical change, such as removing a battery or other part, or non-standard user interactions with the controls, or changes to normally used settings.
- The device has had to be modified from its original form, in either hardware or software to enable it to be used in the hyperbaric environment.

8 Existing Testing Processes and Centres of expertise

At present, there do not appear to be any specific centres of expertise in the testing of equipment for the saturation diving environment. Likewise, there does not appear to be any best practice document as to how to proceed with such testing.

A useful reference for hyperbaric equipment testing is Burman F, Sheffield R, Posey K. Decision process to assess medical equipment for hyperbaric use. *Undersea Hyperb Med.* 2009 36 (2): 136-44.

One of the other authors of this report (Millar) and his colleagues have also published a general flow chart process and the details of testing undertaken for a number of items of electronic and non-electronic equipment, again this is limited to looking at suitability for low pressure hyperbaric oxygen chamber environment.

Internationally, there are a number of hospital based hyperbaric medicine units with an interest and some demonstrated expertise in testing medical equipment for hyperbaric purposes, these have to date each used their own processes.

These centres have published reports on the testing of various individual items of equipment, with varying degrees of rigour involved.

Any of these could potentially pursue testing into the saturation diving pressure range, were they to have access to a higher pressure mixed gas test chamber.

A number of individual diving contractors have taken an interest in this field, trialing individual equipment items in the saturation diving pressure range

There are understood to be a number of individuals with an interest and varying levels of official support within the Navies of a number of nations, including the US Navy and the Navies of a number of European nations.

There are significant efforts underway to improve international cooperation and capabilities for responding to sunken submarines. This would require pressurisable equipment similar to that discussed here, although it is most likely that only low pressures would be involved in any survivable situation.

To date, it is understood that little progress has been made with respect to equipment, with most efforts focused on transfer under pressure rescue systems.

In the United Kingdom, the equipment related research and testing activities of the former Royal Navy Physiological Laboratory have been transferred to the private entity, Quinetic, which has substantial capability, were it to be tasked and funded.

It is known that a group within this company are currently working on the whole issue of battery safety and other such issues with using battery driven electrical equipment in diving chambers.

This work is likely to be a valuable contribution to our knowledge base and should help move some of the issues, mentioned above, forwards.

With respect to third party verification and certification testing, there is one notable group with experience in this field and their own processes, the diving and hyperbaric group within the Det Norske Veritas - Germanischer Lloyd group of companies.

A wide variety of government, military and commercial groups in most countries have expertise in specific testing processes and could be utilised for various aspects of testing, such as flammability, off-gassing, physical properties, electrical hazard ratings etc. however this would require funding and in each case, specifications to be provided as to what needed testing and against what criteria.

A number of space agencies, including NASA and ESA are understood to be trialing a variety of high level medical care equipment systems for potential use during long duration space flight and/or future Moon and Mars habitation.

Although the space vehicle environment does not present the pressure tolerance challenges of diving chambers, there is much potential value in the combination of software guided systems with remote video telemetry for both diagnostic and therapeutic purposes, should such equipment go to market.

Amongst other fields, ultrasound, endoscopy and robotic surgery are understood to be under investigation. Testing for diving chamber suitability would be required but the technology groups involved might prove to be useful resources if they could be engaged.

Finally, remote monitoring, especially with the use of video links and increased data transfer requirements, may require significant data transfer rates. The use of compression data compression or bit-rate reduction should be considered to reduce transmission requirements (also referred to as bandwidth requirements).

9 Glossary

CE	Conformité Européene: previously EC. Mandatory conformity marking for certain products sold within the European Economic Area.
CO ₂	Carbon dioxide: a by-product of human breathing as well as a contaminant produced by internal combustion (engines), combustion (fires) and cooking.
DDC	Deck Decompression Chamber, a hyperbaric chamber usually used to the limit of air diving, or 50 MSW.
DCI	Decompression illness, any residual tissue gas condition that causes a diver to suffer medical issues. Decompression sickness is one such issue, commonly referred to as "the bends".
DMAC	Diving Medical Advisory Committee, an independent body providing guidance to medical practitioners and industry as to how to prepare for, avoid and manage diving illnesses and injuries in the commercial diving industry.
DMT	Dive Medical Technician, a formal qualification obtained to allow a support person to manage injured or ill divers.
DNV-GL	Det Norske Veritas (Norway) – Germanischer Lloyd (Germany). Previously two separate classification societies providing certification services for diving support vessels and equipment; now one organisation.
ESA	European Space Agency
FMEA	Failure Mode and Effects Analysis: a systematic analysis and pro-active technique for determining causes for and predicting failures.
FDA	Federal Drug Administration: a USA-based approval authority issuing pre-marketing clearance for the sale, in this case, of medical equipment.
G	In terms of sea-state, 1 g = 9.81 ms ⁻² , or the acceleration equating to the gravity induced by the earth. In terms of pressure, g refers to a gauge pressure, which is a relative measure of pressure with respect to the immediate environment.
Heliox	A suitable and predetermined mixture of helium and oxygen.
HRF	Hyperbaric Reception Facility, the pressurized living environment that a hyperbaric life raft would connect to once rescued from the ocean.
HSE	Health and Safety Executive, a UK statutory organisation tasked with the responsibility for the health and safety of people at work.
Hyperbaric	In the context of this document, and where coupled with the word treatment, refers to the treatment of any injured person using oxygen under pressure as the medicinal agent.
IMCA	International Maritime Contractors Association, an international trade organisation representing business providing diving and other offshore services.
Intra-osseus	Using the context of infusion: the injection of fluids directly in the marrow of the human bone to provide a non-collapsible point of entry into the venous system.
IT	Information Technology, the transmission, retrieval, storage and manipulation of electronic data.
LED	Light-Emitting Diode, used here in the context of either indicators or lighting used inside the pressurized chamber. An electronic device that produces light when activated.
MHRA	Medicines & Healthcare products Regulatory Agency, similar to the FDA and the UK regulating authority for medicines and medical equipment.
NASA	North American Space Agency
Nebuliser	(Also nebulizer) is a drug delivery device that is used to administer medication in the form of a mist inhaled directly into the lungs.
NFPA	National Fire Protection Association (USA), a body that creates and maintains standards and codes for use in the prevention of fires and which may be adopted by local governments or other parties.
Quarter turn	Quarter turn valves, also referred to as ball valves or quick-acting valves. General used to isolate gas lines using a 90° rotation between fully closed and fully open.
RH	Relative Humidity, the amount of water vapour present in air expressed as a percentage of the amount needed for saturation at the same temperature. In essence an indication of the humidity in the air, with 100% being the maximum.
Saturation	Saturation diving: the absorption by the diver's tissues of the maximum partial pressure of gas possible for a specific depth due to the diver being exposed to breathing gas at that pressure for prolonged period. A technique used to maximize the diver's ability to work under pressure without endangering their health due to decompression sickness.

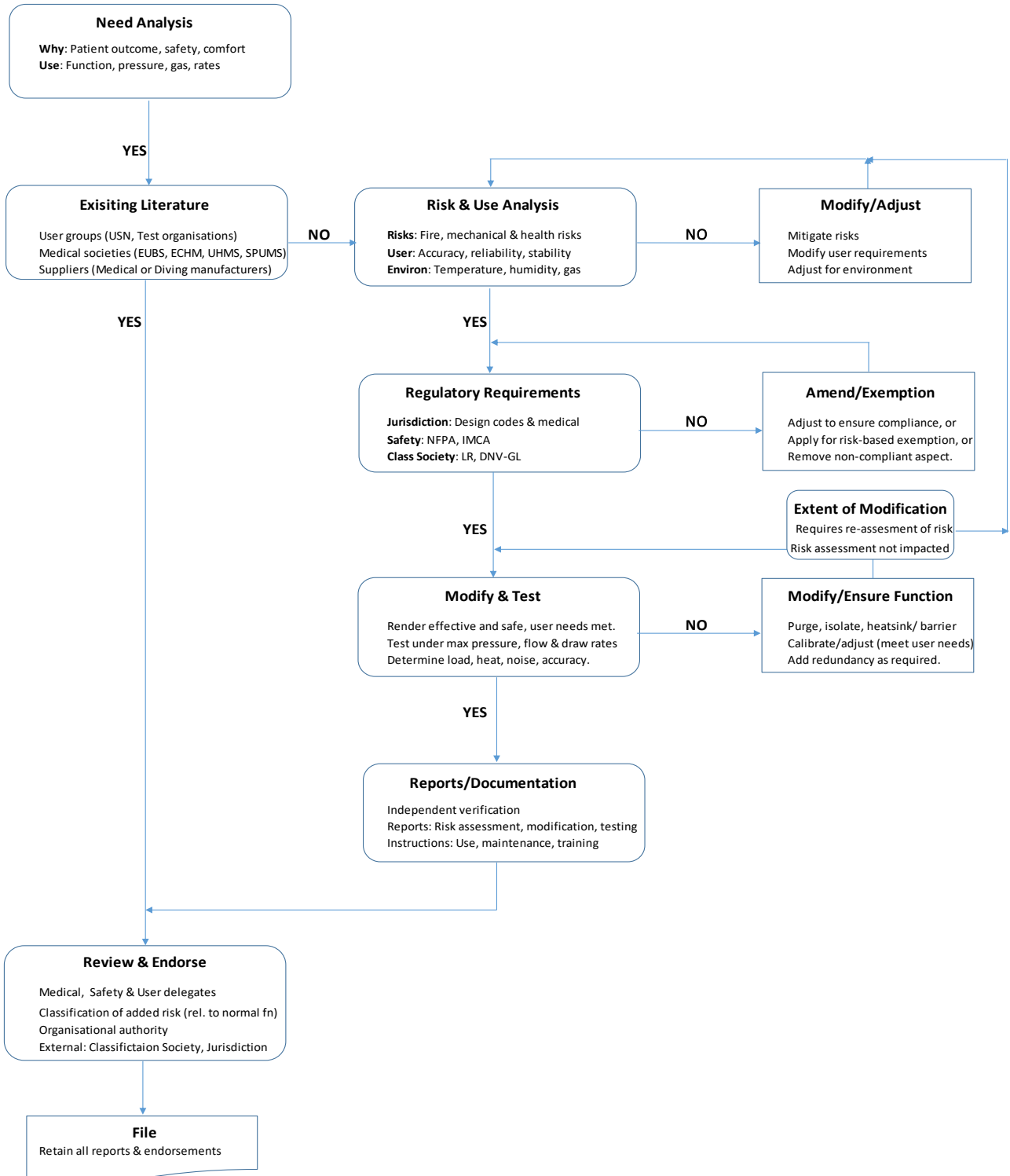
SCUBA	Self Contained Underwater Breathing Apparatus, equipment that provides breathing gas to the diver but allows them to operate independently of the surface support vessels for shallow water areas. Generally prohibited for commercial diving operations, and replaced by a mobile or portable surface supplied diving system which aims to provide the flexibility of SCUBA without the safety limitations. The system may be moved to different locations on an installation or mounted on a small boat operating from a support vessel.
TGA	Therapeutic Goods Administration, Australia: similar to the MHRA and FDA above. The Australian regulatory authority that controls the marketing and sale of medicines and medical equipment.
Telemetry	An automated communications process used to transmit data from a measuring device to a remote point where the data can be processed.
Trimix	A mixture of oxygen, nitrogen and helium to provide a suitable breathing gas at depths beyond which air is no longer a feasible option.
Umbilical	A bundle of tether hose & cables between the diving support vessel and/or the diving bell and the diver, providing breathing gas, hot water and electronic communications (voice, video and other sensors) as well as removing exhaled gas back to the vessel.
USB	Universal Serial Bus, a standard data connection that is used to provide power and data in both directions.
VESA	Video Electronics Standards Association, generally referring to a standard video connector.
VGA	Video Graphics Array, specifically referring to the display screen coupled to a computer, camera(s) or other data outputting instruments, generally outdated and replaced with LED screens.

Appendix A: Process Flow Chart

An illustrative view of the process of rendering medical devices safe & fit for use in commercial diving chambers.

Notes to the reader:

This flow chart is intended to provide an illustrative overview of the process a manufacturer might take to prepare a medical device for the safe & effective use inside a pressurized chamber. It follows the scope and intent of the information paper to which it is attached, but is not intended to replace the information paper, only to illustrate the process. The flow chart intentionally does not list all the applicable criteria, parameters, restrictions, cautions or regulatory or reference documents. The details included are simply examples, provided to show context. These will vary per jurisdiction, per type of product and per operating environment that the manufacturer shall define in their equipment (user) specification. Each manufacturer will thus be required to populate the flow process with their own relevant details, the applicable information gleaned from the regulatory environment, and the specified testing & certification requirements of the inspection or classification authority appointed to endorse the final product. As such, much of this information would be proprietary (IP) and thus not necessarily be shared with the broader commercial diving community. However, using this flow chart in conjunction with the information paper should ensure a more efficient process to achieve the desired outcome, avoiding missing essential steps, ensuring a clearer understanding of both the operating environment together with the associated risks, and proving any authorized authorities with a clear process against which to evaluate the devices.



Appendix B: Conversion Tables

To Convert from one unit to another, multiply by the number to the right.

For example, to convert litres to US gallons, multiply by 0.264. To convert US gallons to litres, multiply by 3.79.

Although a conversion factor is given below, for most practical purposes, one bar can be considered equal to one atmosphere.

Unit	Conversion	Unit	Conversion	Unit
m	3.281	ft	0.305	m
metres/sec	1.944	knot	0.514	metres/sec
metres/sec	2.237	mph	0.447	metres/sec
m ²	10.765	ft ²	0.093	m ²
m ³	35.310	ft ³	0.02832	m ³
litre	0.035	ft ³	28.32	litre
litre	0.220	UK gal	4.546	litre
litre	0.264	US gal	3.79	litre
UK gal	1.201	US gal	0.833	UK gal
kg	2.204	lbs	0.454	kg
kg	0.000984	UK ton	1.017	kg
kg	0.0011	US ton	909	Kg
tonne	2.205	lbs	0.000454	tonne
tonne	0.984	UK ton	1.017	tonne
tonne	1.1	US ton	0.907	tonne
UK ton	0.893	US ton	1.12	UK ton
bar	0.987	atm	1.013	bar
bar	14.509	psi	0.069	bar
msw	3.3	fsw	0.303	msw
joule	0.000948	Btu	1,055.06	joule
°C	$\times 1.8 + 32$	°F	-32×0.556	°C

This table has been gratefully copied from the IMCA Guidance DO22 rev 1: Guidance for Diving Supervisors.

Appendix C: Summary of Recommendations

1. Diving medical equipment should be functional at pressures of 6 ATA for surface supplied diving use, and 31 ATA for saturation diving (page 13).
2. Medical equipment should be tolerant of extremely high compression rates when in a non-operating condition (page 14).
3. Medical equipment should at a minimum be tolerant of 2 atm/min pressurisation and should be functional during such compressions (page 14).
4. Medical equipment should be tolerant of extremely high decompression rates when in a non-operating condition, from either saturation or compressed air environments (page 14).
5. If an item of diving medical equipment is completely intolerant of very rapid depressurisation, the limitation on depressurisation applicable will need to be clearly stated by the manufacturer (Page 14).
6. It is important for medical equipment to continue to function and operate safely during and after manned emergency decompressions at rates up to 2atm/min (page 15) .
7. The function of the equipment should meet normal medical device specifications at decompression rates of up to 0.1atm/min (page 15).
8. Any item of equipment intended for use in a saturation chamber environment shall be assessed and approved for helium venting – including practical testing involving time at pressure, followed by decompression and then inspection for dysfunction or damage. Although devices at risk of helium decompression damage could be designated as ‘single use’, this is obviously undesirable and unsustainable (page 15).
9. Diving medical equipment must be safe for normal use in pressurised environments containing 25% oxygen and it is highly desirable that the equipment does not present a safety hazard if accidentally exposed to higher concentrations of oxygen, including up to 100% oxygen at ambient pressures below 2 atm (page 15).
10. It is desirable for saturation diving medical equipment to also be safe to use in the oxygen rich treatment environments that can be present in DDCs and during the final lower pressure phases of saturation decompression (page 16).
11. Verification of all new materials prior to introduction into the chamber should be carried out in accordance with an accepted technique, valid for the offshore environment (page 16).
12. Medical equipment specifically designed to deliver breathing gas should be capable of delivering 100% oxygen (page 17).
13. Equipment for diving use should have an operating temperature range of 0 – 50°C as this is a common temperature design range for diving chambers (page 18).
14. Equipment for diving use should have non-operating tolerances of below freezing conditions and of temperatures in excess of 60°C when being stored, transported to and from the diving site or passed into or out of chambers via equipment transfer locks (page 18).
15. Equipment for use in Arctic conditions should be specifically designed and rated for such use (page 18).
16. Equipment for diving use should as a minimum be tolerant of operating in humidities between 0 and 100%. Equipment should be tolerant of exposures to near 100% Relative Humidity (RH) when not operating, and should ideally be tolerant of brief exposures to condensing atmospheres in case the item is depressurised rapidly (page 18).
17. It is recommended that a suitable group be commissioned to prepare and circulate improved and more specific guidance regarding the installation of low voltage power in diving chambers specifically for medical devices (page 28).