

# HBOT2017 New Orleans 11<sup>th</sup> Annual International Symposium for Hyperbaric Medicine

## Hyperbaric Oxygen Therapy – *Scope Of Practise – Tiered System*

Malcolm R. Hooper  
Clinical Director  
OXYMED Australia ©



# Australian regulatory guidelines for medical devices (ARGMD)

Version 1.1, May 2011

**TGA** Health Safety  
Regulation



## About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- ➔ • The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <[www.tga.gov.au](http://www.tga.gov.au)>.



## Australia – Therapeutic Goods Administration (TGA)

### Medical Device - Class 1

- The Portable Altitude Chamber (PAC) is a low pressure hyperbaric chamber constructed of flexible reinforced PVC fabric. **It is designed for the treatment of high altitude sickness**, especially the life threatening acute cerebral and pulmonary oedemas. It is only used in **remote wilderness conditions of high altitude** (trekking above 2500m) where conventional medical services are not readily available.

#### Specific Conditions:

- **No specific conditions included on record.**

### Medical Devices - Class 2b

- Hyperbaric Chamber is to administer 100% Oxygen at pressures greater than ambient, up to 3 atmosphere absolute (30psi) of pressure.

#### Specific Conditions:

- **No specific conditions included on record.**



## Public Summary

**Summary for ARTG Entry:** 279723 C E Bartlett - Chamber, patient, hyperbaric

**ARTG entry for** Medical Device Included (Export Only) Class 1  
**Sponsor** C E Bartlett  
**Postal Address** PO Box 49, WENDOUREE, VIC, 3355  
 Australia  
**ARTG Start Date** 29/08/2016  
**Product category** Medical Device Class 1  
**Status** Active  
**Approval area** Medical Devices

### Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

### Manufacturers

#### Name

C E Bartlett

#### Address

172 Ring Road  
 WENDOUREE, VIC, 3355  
 Australia

### Products

#### 1. Chamber, patient, hyperbaric

Product Type	Medical device system	Effective date	29/08/2016
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**GMDN** 12061 Chamber, patient, hyperbaric

**Intended purpose** The Portable Altitude Chamber (PAC) is a low pressure, hyperbaric chamber constructed of flexible, reinforced PVC fabric. It is designed for the treatment of high altitude illness, especially the life threatening, acute cerebral and pulmonary oedemas. It is only used in remote wilderness conditions at high altitude (trekking above 2500m) where conventional medical services are not readily available.

### Specific Conditions

No Specific Conditions included on Record



## Public Summary

**Summary for ARTG Entry:** 148448 Fink Engineering Pty Ltd - Chamber, patient, hyperbaric

**ARTG entry for** Medical Device Included Class IIb  
**Sponsor** Fink Engineering Pty Ltd  
**Postal Address** 30 Premier Circuit, WARANA, QLD, 4575  
Australia  
**ARTG Start Date** 13/12/2007  
**Product category** Medical Device Class IIb  
**Status** Active  
**Approval area** Medical Devices

### Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

### Manufacturers

#### Name

Sechrist Industries Inc

#### Address

4225 East La Palma Avenue  
ANAHEIM, CALIFORNIA, 92807  
United States Of America

### Products

#### 1. Chamber, patient, hyperbaric

Product Type	Single Device Product	Effective date	13/12/2007
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**GMDN** 12061 Chamber, patient, hyperbaric

**Intended purpose** The Sechrist Model 3300E/ER Hyperbaric Chamber is to administer 100% oxygen at pressure greater than ambient, up to 3 atmospheres absolute (30 psi) of pressure.

#### Specific Conditions

No Specific Conditions included on Record



## Public Summary

**Summary for ARTG Entry:** 147142 Hyperbaric Oxygen Therapy Systems Aust- Chamber, patient, hyperbaric

**ARTG entry for** Medical Device Included Class IIb  
**Sponsor** Hyperbaric Oxygen Therapy Systems Aust  
**Postal Address** PO Box 1110, INDOOROOPIILLY, QLD, 4068  
Australia  
**ARTG Start Date** 8/11/2007  
**Product category** Medical Device Class IIb  
**Status** Active  
**Approval area** Medical Devices

### Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

### Manufacturers

#### Name

Divex Ltd

#### Address

Enterprise Drive  
Westhill, Aberdeen, AB326TQ UK  
United Kingdom

### Products

#### 1. Chamber, patient, hyperbaric

**Product Type** Medical device system **Effective date** 8/11/2007

**GMDN** 12081 Chamber, patient, hyperbaric

**Intended purpose** To provide hyperbaric oxygen to patients via a sealed mask for therapeutic purposes

#### Specific Conditions

No Specific Conditions included on Record



## Medical Devices Safety Update

<https://www.tga.gov.au/publication/medical-devices-safety-update> ✓

Joint registry data offers insight into Australian orthopaedic implants; Reports highlight reprocessing issues; 'Mild' **hyperbaric** chambers cancelled; Recent safety alerts.



## Medical Devices Safety Update, Volume 3, Number 6, November 2015

<https://www.tga.gov.au/publication-issue/medical-devices-safety-update-volume-3-number-6-november-2015>



1 Nov 2015: Mild' **hyperbaric** chambers cancelled after advertising complaints. Public complaints about therapeutic goods advertising triggered a TGA investigation that led to the cancellation of three portable 'mild' **hyperbaric** chambers from the Australian







# Medical Devices Safety Update

Volume 3, Number 6, November 2015

## 'Mild' hyperbaric chambers cancelled

Public complaints about therapeutic goods advertising triggered a TGA investigation that led to the cancellation of three portable 'mild' hyperbaric chambers from the Australian Register of Therapeutic Goods.

The TGA's Medical Devices Branch recently completed a post-market review of portable 'mild' hyperbaric chambers after receiving complaints regarding the large range of therapeutic claims being advertised in relation to these devices.

'Mild' hyperbaric chambers are soft-sided enclosed units into which a patient is placed and subjected to higher-than-normal air pressure.

The term 'mild' differentiates them from similar hard-bodied units which operate at higher pressures and are used to treat certain illnesses, such as decompression sickness in divers.

The TGA identified three devices listed on the Australian Register of Therapeutic Goods (ARTG) for review and each of these made therapeutic claims.

In all three cases, clinical evidence could not be provided by the sponsors to substantiate the therapeutic claims made in relation to the devices.

Two of the ARTG entries were subsequently cancelled by the TGA and one by the sponsor.



## Hypo2 Australia Pty Ltd

**Product name/ARTG reference:** Chamber, patient, hyperbaric

**ARTG No:** 204982

**Type of regulatory action:**

Cancelled from the ARTG  
under s.41GN(1)(b)

**Date of effect:** 01/10/2015

[+ Grounds for cancellation](#)

## Melbourne Hyperbaric Oxygen Therapies

**Product name/ARTG reference:** Chamber, patient, hyperbaric

**ARTG No:** 225150

**Type of regulatory action:**

Cancelled from the ARTG  
under s.41GN(1)(b)

**Date of effect:** 19/08/2015

[+ Grounds for cancellation](#)

## Public Summary

Summary for ARTG Entry: 279723 C E Bartlett - Chamber, patient, hyperbaric

ARTG entry for	Medical Device Included (Export Only) Class 1
Sponsor	C E Bartlett
Postal Address	PO Box 49, WENDOUREE, VIC, 3355 Australia
ARTG Start Date	29/08/2016
Product category	Medical Device Class 1
Status	Active
Approval area	Medical Devices



## Hyperbaric Chamber Melbourne - Hyperbaric Chambers

[www.hyperbaricchambers.com.au/](http://www.hyperbaricchambers.com.au/) ▼

**Hyperbaric Chambers** is proud to present the finest & most affordable portable ... All of our portable hyperbaric models available in **Australia** are customised to your .... warranty and simply want the best chamber money can **buy**, look no further.

PORTABLE  
HYPERBARIC  
CHAMBERS  
Australia

☎ 1300 661 653



FAQ's

Contact





Mild hyperbaric therapy or mHBOT has also shown significant health benefits and administers 95% oxygen in a small range of 1.3 to 1.4 atmospheric pressure. Providing incredible health benefits, mHBOT is a much more affordable treatment option.

## Benefits of Hyperbaric Oxygen Therapy

HBOT can benefit any patient who is healing from a condition triggered by inflammation in the body. The healing process can be improved using HBOT to deliver a higher rate of oxygen to damaged tissue. In fact, oxygen controls more than 8,000 genes and is one of the most natural forms of antibiotics. Twenty sessions of therapy improves the function of stem cells by eightfold.

HBOT has also been shown to help with the following:

- Stimulates new blood vessel growth and increase blood flow
- Elevates the body's natural immune defenses to fight infection and bacteria
- Reduces swelling that may occur around damaged areas
- Speeds up healing by increasing tissue oxygen levels to areas in the body where they are reduced due to injury or illness
- ➡ Boosts the supply of circulating stem cells
- Promotes the growth of new capillaries and blood vessels
- Promotes new nerve growth in the brain
- Reduces radiation and inflammation in tissue and bones
- Stimulates oxygenation
- Support faster wound healing.

### How can I learn about the HBOT?

The most comprehensive book about HBOT is The Oxygen Revolution by Paul Harch, M.D. This book is geared toward consumers who would like to learn more about how HBOT works and what conditions it treats. The book explores the science behind HBOT, as well as case histories of patients who have benefited from HBOT.

### Can I use the chambers without supervision?

The Salus36 Portable Hyperbaric Chamber is easy to use without the need for any supervision or specialised training. Pressure gauges and pressure release valves come standard in the interior of the chamber, and the zipper is double sided for easy and fast exiting if required.





## Hyperbaric Oxygen Therapy - Humanergetic Therapies

[www.humanergetics.com.au/hyperbaric.php](http://www.humanergetics.com.au/hyperbaric.php) ▼

Mild hyperbaric oxygen therapy activates the white blood cells to fight infection, promoting ...

**Hyperbaric chambers for sale** Enhance your business ... Humanergetic Therapies are **Qld** distributors of the Hypo2 Mild **Hyperbaric Oxygen** Chamber ...





## Why would I need oxygen therapy?

Because oxygen deficiency is often overlooked, it's not seen as being a cause for symptoms or diseases. Symptoms that may result from an imbalanced oxygen flow include:

- premature ageing
- depression
- anger
- fatigue
- dullness and a general feeling of sluggishness.

If the imbalance is chronic, the immune system is weakened and we are left more susceptible to germs and viruses and therefore, diseases.

## What are the benefits?

There are several benefits to mild hyperbaric oxygen, including:

- improves strength, energy and endurance
- relieves tension and stress
- improves concentration and memory
- detoxifies the blood
- promotes healing and counters ageing
- strengthens heart and lungs
- natural remedy for headaches and migraines
- improves metabolism and aids digestion
- reduces fatigue and improves sleeping patterns
- relieves muscle stiffness
- improves skin conditions





## Commonly 'Advertised' Benefits of HBOT

Source: [www.ihmf.org](http://www.ihmf.org) ....

- Preconditioning against injury
- Shortens recovery time after extreme exercise, injury or surgery
- Revitalizes by improving blood flow and oxygen to all organs
- Regenerates small blood vessels (capillaries), nerves and bones
- Improved performance
- Increased strength
- Enhanced endurance
- Energy boost preventing exhaustion
- Reducing inflammation, swelling, pain
- Reducing fatigue and recovery time
- Speeding up healing of muscles, ligaments and fractured bones
- Rejuvenates by releasing stem cells from bone marrow for tissue repair
- Reducing and preventing infection
- Reducing scar tissue formation
- Cleansing blood from toxins and toxic substances
- Maintaining general health

# Court action

23 December 2016

Section 61(5A) of the *Therapeutic Goods Act 1989* provides that the Secretary may release to the public therapeutic goods information relating to any decision or action taken under this Act or the regulations. It is TGA practice to publish details of regulatory compliance decisions and actions on its website.

The TGA collects intelligence in relation to alleged breaches of the *Therapeutic Goods Act 1989* and Regulations and undertakes:

- ➡ • criminal prosecutions (in association with the Commonwealth Director of Public Prosecutions) and
- civil litigation for the recovery of civil penalties where appropriate.

## 2016

### Conviction for criminal charges for dealing with unapproved and counterfeit medicines

## 2015

### Conviction for criminal charges for dealing with unapproved therapeutic goods

On **3 December 2015**, a Melbourne man appeared in the Ringwood Magistrates Court, Victoria on 8 criminal charges relating to dealing with unapproved therapeutic goods:

- ➡ • 6 counts of importing therapeutic goods not included in the Australian Register of Therapeutic Goods (ARTG) contrary to section 19B(4) of the *Therapeutic Goods Act 1989* (Cth) (the Act)
- 1 count of supplying therapeutic goods not included in the ARTG contrary to section 19B(4) of the Act
- 1 count of supplying counterfeit therapeutic goods contrary to section 42E of the Act.

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## New Laws To Crack Down On Dodgy Health Providers

Minister for Health

9 February 2016

Health

Media Release

- Victoria's health complaints watchdog will be given greater powers to **name and shame dodgy health service providers and practitioners**, and protect the public by banning them from practising.
- The Andrews Labor Government will today introduce the *Health Complaints Bill 2016* into Parliament, to establish a tough new complaints system **to crack down on dangerous unregistered health practitioners**.
- Under the proposed new laws, the existing Health Services Commissioner will be replaced by a **new watchdog, the Health Complaints Commissioner**, creating a more comprehensive health complaints system that better protects the public and providers of health services.
- **The new Commissioner will receive beefed up powers to take action against dangerous and unethical health providers** who are **not registered** under national health practitioner regulation law.





- In a major change, the Bill will **allow anyone to make a complaint, rather than just the person who received the health service.**
- The Commissioner will also have the **power to instigate an investigation even when no complaint is lodged**, for example, if the media have uncovered an **unscrupulous unregistered provider making fake or harmful claims.**
- The new Commissioner would have the powers to **investigate and crack down on high profile cases** such as the blogger who faked cancer to profit from her wellness app, the fake gynaecologist performing 'fertility treatments' on women for a decade, or the unregistered 'dodgy' dentists, and ban them from providing these **unethical and dangerous treatments.**
- Other examples include a formerly registered dentist who claimed '**ozone therapy**' could cure cancer, or people purporting to be able to '**convert**' **gay people through medical or therapeutic means.**
- Individuals who breach the Commissioner's ruling would **face up to two years in prison.** The Commissioner will be able to issue **public warnings and name and shame providers in the media in order to protect the public.**
- *"We're taking action to crack down on dangerous and health practitioners who **take advantage of vulnerable** Victorians."*
- *"Our tough new laws will give the Health Complaints Commissioner the power to **name and shame** and put these dodgy health providers out of business for good."*
- *"We're closing loopholes in the existing legislation to make sure Victorians receive the health care protection they need."*



# Health Professional Australia Reform Association - HPARA

Melbourne April 2017

**HPARA is the peak body for healthcare regulation reform in Australia.**



HPARA  
Seeking Health Reform



## Health Professional Australia Reform Association - HPARA

### Road to Reform

- **'The bullying and harassment of medical and allied health professionals has become so widespread that it recently became the subject of no less than two Senate Inquiries into the Medical Complaints process in Australia.'**
- Despite the hard questions being asked by the Inquiry the answers from AHPRA were typically evasive and have done little to change the current state of affairs that continue to see **Healthcare Professionals being unfairly treated by a regularity system that is allowing bullying and anti-competitive behaviour.**

### HPARA

- HPARA is an organisation dedicated to the reform of health care regulation in order to best support the delivery of great health care for all. **We represent the health and well-being of all regulated health care practitioners.**
- The targeting of health care workers and doctors is in itself abhorrent, but the impacts for patients and the broader community are equally substantial because in a **culture where bullying is rife no true advancement and innovation can occur.**
- HPARA and its members are not prepared to sit back and allow this to occur.
- Our push for a **Royal Commission** will continue until reform is fully achieved.



- We advocate for a **system that supports practitioners to grow and evolve**, with the knowing that being a health care professional is a **life long learning**. We understand that mistakes can be made, and all efforts should be made to support our practitioners to grow and learn and not to mark and shame and put a black mark against their name.
- We equally understand that the **current system is designed to support false, misleading and vexatious complaints**.
- **Our current system operates under the presumption of guilty until proven innocent**. This is not a system that supports anyone.

### What do we stand for?

Health care regulation that holds practitioners and patients/clients in equal respect with complainants and practitioners having **equal rights and accountability**.

- The upholding of all **human rights for all in all investigative processes**.
- **A culture of care equal** for practitioners and patients/clients.
- **A culture of support** equal for practitioners and patients/clients.
- We hold as a foundational tenet that both practitioners and clients/patients are **united by a common humanity**.
- We are all people with the same **foundational human rights and deserving of equal respect and consideration in all matters**.
- It is important in all systems that the **principle of truth is honoured, and all who are engaged in the process have an equal accountability and responsibility**. (Model Litigant Obligations)



- **At present the current system is set up with a bias in favour of complainants with no accountability for those who are making unfounded, invented or malicious and vexatious complaints.**
- This does not hold everyone in equal respect or accountability.
- Regulation is needed to ensure that the **public is protected from harmful practitioners**, as nobody deserves to be harmed by another, **but equally we need a system that ensures that practitioners are equally held in respect from the harm that comes from unfounded or malicious complaints.**
- The impact of **false complaints and the repercussions that ensue from protracted investigative and review processes** are wide and far reaching and can lead to the inappropriate withdrawal of practice licenses and profound personal impacts for practitioners that are pursued. **Financial loss, immense personal suffering and high rates of burnout, depression, anxiety and even suicide can result.**

There is a responsibility and **duty of care to all people** to be upheld in the health care regulation system.

- Vexatious complaints can also lead to the removal from society of caring, qualified and highly sought after practitioners performing much needed service and care in their communities. **These people cannot be replaced.**





## Hyperbaric Global

### USA

#### Soft Hyperbaric - Hyperbaric 'Air' Therapy (HBAT)

- Allied Health Care and Medical Clinics.
- Low Pressure 1.1-1.3 ATA using **pressurized ambient air - HBAT.**
- USA FDA requires "medical doctor script referral for use or purchase of a soft HBO".
- USA FDA - It is ~~'illegal'~~ to fit a oxygen concentration to a soft chamber
- USA FDA - It is 'prohibited safety fire risk' to take inside a soft chamber any lithium battery operated device ie mobile phone, notebook, i-pad etc.
- **This is NOT the situation around the globe. Soft HBOT is provided using O2 concentrators and with no consideration to prohibition items.**

#### Hard Hyperbaric - 'off-label'

- Medical Clinics.
- Mid Range Pressure 1.4 - 2.4 ATA using up to and including 100% O2

#### FDA Approved Hyperbaric - High Pressure >2.4 ATA using 100% O2

- Reimbursement in hospital and no hospital medical clinics.



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## CFR - Code of Federal Regulations Title 21

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**The information on this page is current as of April 1 2016.**

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[Code of Federal Regulations]  
[Title 21, Volume 8]  
[Revised as of April 1, 2016]  
[CITE: 21CFR868.5470]



TITLE 21--FOOD AND DRUGS  
CHAPTER I--FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
SUBCHAPTER H--MEDICAL DEVICES

PART 868 -- ANESTHESIOLOGY DEVICES

Subpart F--Therapeutic Devices

Sec. 868.5470 Hyperbaric chamber.

(a) *Identification.* A hyperbaric chamber is a device that is intended to increase the environmental oxygen pressure to promote the movement of oxygen from the environment to a patient's tissue by means of pressurization that is greater than atmospheric pressure. This device does not include topical oxygen chambers for extremities (878.5650).

(b) *Classification.* Class II (performance standards).

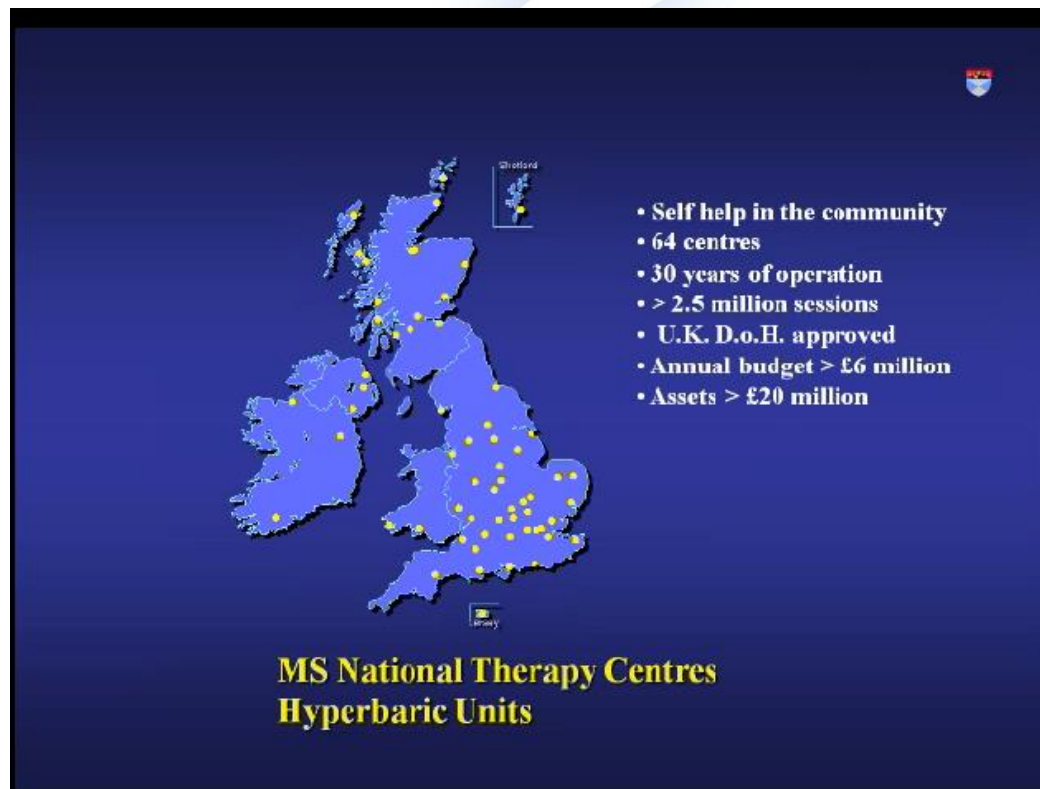


## Australia

- Non Hospital HBO is largely – **‘unregulated profession’**.
- Any registered or unregistered ‘Health Care Professional’ can provide HBOT without medical supervision or referral.
- **Australian TGA cancelled all soft hyperbaric chambers**, however ‘therapists’ continue to provide soft HBOT using O2 concentrators – 92%.
- Hard HBOT – the barrier to entry is cost.
- Hospital HBOT are UHMS controlled with **Medicare Reimbursed restricted to only hospital based HBOT**.
- Medicare reimbursement is limited to **6 – conditions**.

## England

- UK NHS covers **3-approved conditions**.
- Hospital are tightly controlled under UHMS.
- Non hospitals are largely **unregulated**
- 64 - MS HBOT Centres under Prof Phillip James. Centres run on donations and a 'not for profit' business model. Over 30 years in operation with estimated in excess of 2.5million separate HBO sessions provided.



## England

- 2008 UK Legislation

### Deregulation of Type 3 Hyperbaric Oxygen Chambers.

HBOT clinics are only required to meet 'fire and O2 safety standards'.

**Type 3** HBO clinic – **"stable neurologic patient"** does NOT require Medical Supervision or referral to attend for HBOT.

### Deregulation of Type 3 hyperbaric oxygen chambers

3.2 At present all types of hyperbaric oxygen therapy (HBOT) are prescribed as listed services in regulation 3(1)(e) of the PVH Regulations. The Department categorises hyperbaric oxygen chambers into three types, depending on the level of critical care management provided. While Type 1 and 2 chambers are primarily used for patients who need critical care and whose treatment is supervised by a medical professional, Type 3 chambers are mainly used for the treatment of patients with neurological disorders for which hyperbaric treatment on the NHS is not clinically indicated, and this treatment does not take place under medical supervision. All three types of chamber were regulated due to the perceived risks of fire and oxygen toxicity.

3.5 Subject to this consultation, we propose to achieve this aim through amending regulation 3(1)(e) of the PVH regulations to provide for HBOT carried out under the supervision of a medical professional to remain in regulation, while removing all other types of HBOT from the category of listed services.





## China

'HBOT in China' : Yan et al. Medical Gas Research (2015) 5:3.

The current HBOT indications and contraindications were released at the 22nd academic meeting held in Qingdao in 2013 and approved on the 1st of November 2013.

- The new indications include diseases that were **directly or indirectly caused by hypoxia and/or ischemia or a series of conditions that are related to hypoxia and/ or ischemia in the evolution of the disease process.**

### Google search:

- **Soft HBOT** (HBAT and HBOT) market appears to be popular but largely an **'unregulated' market.**
- **Hard HBOT** appear to be **restricted to hospitals with 100+ beds.**



## Middle East

### New Healthcare Regulations in Dubai May 2016

#### Hyperbaric Oxygen Therapy Service Standards

- This new standard applies to healthcare facilities providing hyperbaric oxygen therapy (“HBOT” and “HBOT Standard”) services. HBOT treatment is defined under the HBOT Standard as “a treatment in which the patient is placed in a chamber and breathes near 100% oxygen or special mixed gases at higher than local atmospheric pressure”.
- **The demand for this treatment has grown as the prevalence of diabetes as increased in the Emirate. The provision of HBOT services is limited to hospitals, day surgical centres, and outpatient care facilities with certain specialities.**
- As with other healthcare services, **the provision of HBOT services is subject to licensure by the DHA.** In addition to governing the delivery of HBOT services, the HBOT Standard stipulates the requirements of licensure, professionals carrying out the HBOT care, facility location and configuration, and patient care delivery.
- **These requirements apply to semi-governmental and private healthcare facilities, as well as those operating in free zone areas, except facilities regulated by the Dubai Healthcare City Authority.**



## **IHMF - Vision for the Future**

### **IHMF 'Peak Body' - Training & Certification**

- **IHMF endorsed 'global standard' - training and certification for a recognised schedule of conditions based on the service providers qualifications and country national standards.**
- **IHMF accredited - Continuing Professional Development Credits.**

### **Tiered System – Scope of Practise**

- **Tier 1 – Allied Health Care Practitioners & Medical Doctors**
- **Tier 2 – Allied Health Care Practitioners with Speciality & Medical Doctors**
- **Tier3 – Medical Doctors/Hospital**
- **Home Chambers – purchase requires independent medical (clinical) examination and suitability for HBOT.**
- **IHMF approved installation to include: safety, training and certification.**



*The human frame is Oxygen dependent.  
We all require Oxygen to survive, enhance our  
performance, accelerate our recovery and to  
promote our vision of the future*



Hyperbaric Oxygen Therapy (HBOT) is the combined benefit of both increased Pressure and increased Oxygen – pO<sub>2</sub>  
Tier 1 & 2 - Adjunctive Use, Non-emergency HBOT : Lower Pressures < 2.4 ATA  
Tier 3 – Emergency Use HBOT : Higher Pressures > 2.4 ATA

## TIER 1

### Low Pressure HBO (1.1 to 1.5 ATA)

- Protocols – HBOT 60-minutes daily, initially to 20-40 hours
- Well Being, Anti-Aging, Sports Recovery & Performance
- Mild Neurologic disorders: Autism Spectrum, Cerebral Palsy, Mild Traumatic Brain Injury, Post-Traumatic Stress Disorders, Shock Blast injuries

## TIER 2

### Mid Range Pressure HBO (1.5 to 2.4 ATA)

- Protocols – HBOT 60-120 minutes once to twice daily, initially to 80-100 hours
- The 'non-emergency' HBOT where 'hypoxia is associated with the condition or the evolution of disease process'. The objective of HBOT is to 'ameliorate' the patient suffering through biologic mechanisms enhancing immune modulation; 'upregulating' stem cell mobilization, growth factors and cytokine gene expressions.

1. Acute Respiratory Distress Syndrome 2. Angioneurotic Headache 3. Aseptic Osteonecrosis 4. Bronchial Asthma 5. Burns 6. Carbon Monoxide Poisoning or Other Toxic Encephalopathy 7. Central Retinal Inflammation 8. Cerebral Hemorrhage Recovery 9. Cerebral Palsy 10. Chronic Skin Ulcer (Arterial Blood Supply Obstacles, Venous Congestion, Bedsores) 11. Coronary Atherosclerotic Heart Disease (Angina and Myocardial Infarction) 12. Craniocerebral Injury (Concussion, Post-Traumatic Stress, Traumatic Brain Injury, Cerebral Contusion of Intracranial Hematoma Removal Surgery, Brain Stem Injury) 13. Diabetes and Diabetic Foot 14. Facial Paralysis 15. Fatigue Syndrome 16. Fetal Developmental Delays 17. Frostbite 18. Guillain-Barre Syndrome 19. Infectious Hepatitis 20. Intracranial Benign Tumor Surgery 21. Ischemic Cerebrovascular Disease (Cerebral Arteriosclerosis, Transient Ischemic Attack, Cerebral Thrombosis, Cerebral Infarction) 22. Lyme and Tick Born Illness 23. Malignant Tumors (with Radiotherapy or Chemotherapy) 24. Multiple Sclerosis 25. Myocarditis 26. Osteomyelitis 27. Otic Nerve Injury 28. Paralytic Ileus 29. Peptic Ulcer 30. Periodontal Disease 31. Peripheral Nerve Injury (Reflex Sympathetic Dystrophy, Complex Regional Pain Syndrome) 32. Peripheral Vascular Disease, Vasculitis - Raynaud's, Deep Vein Thrombosis, etc. 33. Pityriasis rosea 34. Plastic Surgery Pre and Post Recovery 35. Plateau Adaptation Insufficiency Syndrome 36. Poor Healing Fractures 37. Psoriasis 38. Pustular 39. Radioactive Damage (Bone and Soft Tissue, Cystitis, Etc.) 40. Rapidly Arrhythmia (Atrial Fibrillation, Premature Beat, Tachycardia) 41. Recurrent Oral Ulcer 42. Skin Grafting 43. Spinal Cord Injury (Acute, Chronic) 44. Spinal Disc Prolapse & Degeneration 45. Sports Injuries 46. Sudden Deafness 47. Ulcerative Colitis 48. Vegetative State 49. Vertigo 50. Viral Encephalitis;

## TIER 3

### High Range Pressure HBO (> 2.4 ATA) – Medicare Reimbursement

- Protocols – HBOT 90-120 minutes once to multiple daily, initially to 60 hours
- FDA approved - 'Emergency' HBOT
- Air or gas embolism, Carbon monoxide poisoning, Clostridial myositis and myonecrosis (gas gangrene), Crush injury, compartment syndrome, and other acute traumatic ischemias, Decompression sickness, Enhanced healing of selected problem wounds, Exceptional blood loss anemia, Necrotizing soft tissue infections, Osteomyelitis (refractory), Delayed radiation injury (soft tissue and bony necrosis), Skin grafts and flaps (compromised), Thermal burns, Intracranial abscess



Hyperbaric Oxygen Therapy (HBOT) is the combined benefit of both increased Pressure and increased Oxygen – pO<sub>2</sub>

Tier 1 & 2 - Adjunctive Use, Non-emergency HBOT : Lower Pressures < 2.4 ATA

Tier 3 – Emergency Use HBOT : Higher Pressures > 2.4 ATA

## TIER 1

### Low Pressure HBO (1.1 to 1.5 ATA)

- Protocols – HBOT 60-minutes daily, initially to 20-40 hours
- Well Being, Anti-Aging, Sports Recovery & Performance
- Mild Neurologic disorders: Autism Spectrum, Cerebral Palsy, Mild Traumatic Brain Injury, Post-Traumatic Stress Disorders, Shock Blast injuries

**Tier 1 – Non Emergency, Adjunctive Use Low Pressure HBO**

**Tier 2 – Non Emergency, Adjunctive Mid Range Pressure Use HBO**

**Tier 3 – Emergency Use High Pressure HBO**

**Tier 1 - Low Pressure HBO (1.1 to 1.4 ATA)**

- **‘Non Emergency, Adjunctive HBO’**
- Protocols – HBO 60-minutes - initially to 40-hours.
- General Well Being, Anti-Aging, Sports Recovery & Performance. Mild Neurologic disorders: Autism Spectrum, Cerebral Palsy, Mild Traumatic Brain Injury, Post Traumatic Stress Disorders, Shock Blast injuries.

## TIER 2

### Mid Range Pressure HBO (1.5 to 2.4 ATA)

- Protocols – HBOT 60-120 minutes once to twice daily, initially to 80-100 hours
- The 'non-emergency' HBOT where 'hypoxia is associated with the condition or the evolution of disease process'. The objective of HBOT is to 'ameliorate' the patient suffering through biologic mechanisms enhancing immune modulation; 'upregulating' stem cell mobilization, growth factors and cytokine gene expressions.

1. Acute Respiratory Distress Syndrome 2. Angioneurotic Headache 3. Aseptic Osteonecrosis 4. Bronchial Asthma 5. Burns 6. Carbon Monoxide Poisoning or Other Toxic Encephalopathy 7. Central Retinal Inflammation 8. Cerebral Hemorrhage Recovery 9. Cerebral Palsy 10. Chronic Skin Ulcer (Arterial Blood Supply Obstacles, Venous Congestion, Bedsores) 11. Coronary Atherosclerotic Heart Disease (Angina and Myocardial Infarction) 12. Craniocerebral Injury (Concussion, Post-Traumatic Stress, Traumatic Brain Injury, Cerebral Contusion of Intracranial Hematoma Removal Surgery, Brain Stem Injury) 13. Diabetes and Diabetic Foot 14. Facial Paralysis 15. Fatigue Syndrome 16. Fetal Developmental Delays 17. Frostbite 18. Guillain-Barre Syndrome 19. Infectious Hepatitis 20. Intracranial Benign Tumor Surgery 21. Ischemic Cerebrovascular Disease (Cerebral Arteriosclerosis, Transient Ischemic Attack, Cerebral Thrombosis, Cerebral Infarction) 22. Lyme and Tick Born Illness 23. Malignant Tumors (with Radiotherapy or Chemotherapy) 24. Multiple Sclerosis 25. Myocarditis 26. Osteomyelitis 27. Otic Nerve Injury 28. Paralytic Ileus 29. Peptic Ulcer 30. Periodontal Disease 31. Peripheral Nerve Injury (Reflex Sympathetic Dystrophy, Complex Regional Pain Syndrome) 32. Peripheral Vascular Disease, Vasculitis - Raynaud's, Deep Vein Thrombosis, etc. 33. Pityriasis rosea 34. Plastic Surgery Pre and Post Recovery 35. Plateau Adaptation Insufficiency Syndrome 36. Poor Healing Fractures 37. Psoriasis 38. Pustular 39. Radioactive Damage (Bone and Soft Tissue, Cystitis, Etc.) 40. Rapidly Arrhythmia (Atrial Fibrillation, Premature Beat, Tachycardia) 41. Recurrent Oral Ulcer 42. Skin Grafting 43. Spinal Cord Injury (Acute, Chronic) 44. Spinal Disc Prolapse & Degeneration 45. Sports Injuries 46. Sudden Deafness 47. Ulcerative Colitis 48. Vegetative State 49. Vertigo 50. Viral Encephalitis;





## **Tier 2 - Mid Range Pressure HBO (1.5 to 2.4 ATA)**

- Non Emergency, Adjunctive HBO
- **Protocols – HBO 60-120 minutes**
- **Conditions where ‘hypoxia is associated with the condition or evolution of the disease process’ (HBOT in China 2015).**
- **The treatment objective is to ‘ameliorate’ the patient suffering through biologic mechanisms enhancing immune modulation; ‘upregulating’ stem cell mobilization, growth factors and cytokine gene expression. (Harch 2015).**
- **Over 50-conditions including:**
  - Vascular induced hypoxic injuries: Traumatic ischemia (ABI, TBI), Stroke (all stages), Neurodegenerative i.e. Multiple Sclerosis, Parkinson’s, Vascular Dementia, Spinal Cord Injury (Paraplegia, Quadriplegia).**
  - Autoimmune disorders: Cancer (adjunctive to Chemotherapy & Radiation), Fibromyalgia, Chronic Pain Syndromes, Disc Prolapse, Ulcerative Colitis, Lyme and Lyme Like Chronic Fatigue Illness**
- **Reference: ‘HBOT in China’ : Yan et al. Medical Gas Research (2015) 5:3.**



## **Hyperbaric Oxygen Therapy in China (2015)**

**Currently, there are more than 5000 hyperbaric oxygen chambers in China [4].**

This number is the highest in the world, and significantly contributes to the amount of global HBOT research [4].

In China, HBOT has been adapted to treat a wide variety of diseases.

**Emergency indications** are diseases where HBOT should be administered as soon as possible.

- (1) acute carbon monoxide poisoning and other harmful gas poisoning;**
- (2) gas gangrene, tetanus and other anaerobic bacteria infections;**
- (3) decompression sickness;**
- (4) air embolism syndrome;**
- (5) after cardiopulmonary resuscitation (CPR) due to a variety of risks for acute brain dysfunction;**
- (6) aid in the treatment of shock;**
- (7) brain edema;**
- (8) pulmonary edema (except cardiac pulmonary edema);**
- (9) crush syndrome;**
- (10) limb (finger, toe) and the blood supply after skin transplantation;**
- (11) drug and chemical poisoning;**
- (12) acute ischemia anoxic encephalopathy.**



## Hyperbaric Oxygen Therapy in China (2015)

The current HBOT indications and contraindications were released at the **22nd academic meeting held in Qingdao in 2013 and approved on the 1st of November 2013.**

- **The new indications include diseases that were directly or indirectly caused by hypoxia and/or ischemia or a series of conditions that are related to hypoxia and/ or ischemia in the evolution of the disease process.**

Additionally, the following **non-emergency indications** approved for use:

- (1) **carbon monoxide poisoning or other toxic encephalopathy;**
- (2) **sudden deafness;**
- (3) **ischemic cerebrovascular disease (cerebral arteriosclerosis, transient ischemic attack, cerebral thrombosis, cerebral infarction);**
- (4) **craniocerebral injury (concussion, cerebral contusion of intracranial hematoma removal surgery, brain stem injury);**
- (5) **cerebral hemorrhage recovery;**
- (6) **poor healing fractures;**
- (7) **central serous retinal inflammation;**
- (8) **vegetative state;**
- (9) **plateau adaptation insufficiency syndrome;**
- (10) **peripheral nerve injury;**
- (11) **intracranial benign tumor surgery;**



- (12) periodontal disease;**
- (13) viral encephalitis;**
- (14) facial paralysis;**
- (15) osteomyelitis;**
- (16) aseptic osteonecrosis;**
- (17) cerebral palsy;**
- (18) fetal developmental delays;**
- (19) diabetes and diabetic foot;**
- (20) coronary atherosclerotic heart disease (angina and myocardial infarction);**
- (21) rapidity arrhythmia (atrial fibrillation, premature beat, tachycardia);**
- (22) myocarditis;**
- (23) peripheral vascular disease, vasculitis, e.g., Raynaud's, deep vein thrombosis,**
- (24) vertigo;**
- (25) chronic skin ulcer (arterial blood supply obstacles, venous congestion, bed sore);**
- (26) spinal cord injury (acute, chronic);**
- (27) peptic ulcer;**
- (28) ulcerative colitis;**
- (29) infectious hepatitis (use the special chamber of infectious disease);**
- (30) burns;**
- (31) frostbite;**
- (32) plastic surgery;**

- (33) skin grafting;**
- (34) sports injuries;**
- (35) radioactive damage (bone and soft tissue, cystitis, etc.);**
- (36) malignant tumors (with radiotherapy or chemotherapy);**
- (37) otic nerve injury;**
- (38) fatigue syndrome;**
- (39) angioneurotic headache;**
- (40) pustular;**
- (41) psoriasis;**
- (42) pityriasis rosea;**
- (43) multiple sclerosis;**
- (44) acute Guillain-Barre syndrome;**
- (45) recurrent oral ulcer;**
- (46) paralytic ileus;**
- (47) bronchial asthma; and**
- (48) acute respiratory distress syndrome.**

- **‘HBOT in China’ : Yan et al. Medical Gas Research (2015) 5:3.**

## TIER 3

### High Range Pressure HBO (> 2.4 ATA) – Medicare Reimbursement

- Protocols – HBOT 90-120 minutes once to multiple daily, initially to 60 hours
- FDA approved - 'Emergency' HBOT
- Air or gas embolism, Carbon monoxide poisoning, Clostridial myositis and myonecrosis (gas gangrene), Crush injury, compartment syndrome, and other acute traumatic ischemias, Decompression sickness, Enhanced healing of selected problem wounds, Exceptional blood loss anemia, Necrotizing soft tissue infections, Osteomyelitis (refractory), Delayed radiation injury (soft tissue and bony necrosis), Skin grafts and flaps (compromised), Thermal burns, Intracranial abscess

Reference as supported by The International Hyperbaric Medicine Foundation (IHMF).

'HBOT effects on Traumatic Brain Injury: Oxygen, Pressure & Gene Therapy' : Harch et al. Medical Gas Research (2015).

'HBOT in China' : Yan et al. Medical Gas Research (2015) 5:3.

### **Tier 3 - High Range Pressure HBO (> 2.4 ATA) – Medicare Reimbursement**

- Protocols – HBO 90-120 minutes once to multiple daily, initially to 60 hours
- **FDA Approved - Emergency HBO**

**Air or gas embolism, Carbon monoxide poisoning, Clostridial myositis and myonecrosis (gas gangrene), Crush injury, compartment syndrome, and other acute traumatic ischemias, Decompression sickness, Enhanced healing of selected problem wounds, Exceptional blood loss anemia, Necrotizing soft tissue infections, Osteomyelitis (refractory), Delayed radiation injury (soft tissue and bony necrosis), Skin grafts and flaps (compromised), Thermal burns, Intracranial abscess**