UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION
OFFICE OF THE MINISTER

الإمارات العربية المتحدة
وزارة الصحة ووقاية المجتمع
مكتب الوزير

MIO-MOD/2024/156

ر/ط-5232

قرار وزاري رقم (١٦٧) لسنة 2024 م
بشأن اعتماد المعايير الوطنية للعلاج بالأوكسجين عالي الضغط

وزير الصحة ووقاية المجتمع:

بعد الاطلاع:

- على القانون الاتحادي رقم (1) لسنة 1972 م بشأن اختصاصات الوزارات وصلاحيات الوزراء وتعديلاته،
- وعلى القانون الاتحادي رقم (4) لسنة 2015 م في شأن المنشآت الصحية الخاصة وتعديلاته ولائحته التنفيذية،
- وعلى القانون الاتحادي رقم (5) لسنة 2019 م في شأن تنظيم مزاولة مهنة الطب البشري ولائحته التنفيذية،
- وعلى القانون الاتحادي رقم (6) لسنة 2023 م بشأن مزاولة غير الأطباء والصيادلة لبعض المهن الصحية،
- وعلى المرسوم بقانون اتحادي رقم (4) لسنة 2016 م بشأن المسؤولية الطبية، وتعديلاته ولائحته التنفيذية،
- وعلى قرار مجلس الوزراء رقم (20) لسنة 2017 م باعتماد المعايير الموحدة لترخيص مزاولي المهن الصحية على مستوى الدولة وتعديلاته،
- وعلى قرار مجلس الوزراء رقم (11) لسنة 2021 م في شأن الهيكل التنظيمي لوزارة الصحة ووقاية المجتمع.

وبناء على مقتضيات المصلحة العامة،،،

ص.ب. 848 . أبوظبي، الإمارات العربية المتحدة ABU DHABI, UNITED ARAB EMAIRATES . فاكس FAX +971 2 6217722 . هاتف TEL +971 2 6520500
ص.ب. 1853 . دبي، الإمارات العربية المتحدة DUBAI, UNITED ARAB EMAIRATES . فاكس FAX +971 4 2392949 . هاتف TEL +971 4 2301000
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قـــــرّر ما يلي:

المادة (1): تعتمد المعايير الوطنية للعلاج بالأوكسجين عالي الضغط الواردة بمرفق هذا القرار.

المادة (2): ينشر هذا القرار في الجريدة الرسمية ويعمل به اعتباراً من اليوم التالي لتاريخ نشره.

عبدالرحمن بن محمد العويس
وزير الصحة ووقاية المجتمع

صدر بتاريخ:
04/09/2024

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مرفق القرار الوزاري رقم (١٦٦) لسنة 2024 م
بشأن اعتماد المعايير الوطنية للعلاج بالأوكسجين عالي الضغط

National Standard of Hyperbaric Oxygen Therapy

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PURPOSE:

To promote the provision of safe, high quality and appropriate hyperbaric medical care for patients with conditions likely to benefit from hyperbaric oxygen treatment.

SCOPE:

This standard applies to:

- All licensed healthcare providing or seeking to provide Hyperbaric Oxygen Therapy.
- Licensed Healthcare Professionals engaged in the provision of Hyperbaric Oxygen Therapy in healthcare facilities.

DEFINITIONS AND ABBREVIATIONS:

Chamber Operator: The person responsible for operating the chamber.

Healthcare Facility: An establishment at which healthcare services are provided and falls within a category named by concerned health authorities in a Healthcare Facility Definition.

Healthcare Professional: are healthcare personal working in healthcare facilities and required to be licensed as per the applicable laws in United Arab Emirates.

Healthcare Worker: is an individual employed by the hospital, (whether directly, by contract with another entity), provide direct or indirect patient care, this includes but not

limited, healthcare professionals, medical and nursing students, administrative staff and contract employees who either work at or come to the hospital site.

Hyperbaric Oxygen Therapy (HBOT): is a treatment in which the patient is placed in a chamber and breathes 100% oxygen at pressure higher than local atmospheric pressure.

Hyperbaric therapeutic chamber: is a pressure vessel capable of accommodating one or more persons with the purpose of providing medical treatment.

Incompetent Patient: is a patient who either lack the full legal capacity or have the full capacity, but unable to provide an Informed Consent.

Informed Consent: is an agreement or permission accompanied by full information on the nature, risks and alternatives of a surgical or interventional procedure before the physician begins the procedure/treatment. Accordingly, the patient either consents to or refuses treatment.

Inside Attendant (IA): is a licensed Healthcare Professional who is assessed physically and mentally and declared medically fit to provide direct care and observation in a HBOT chamber during the treatment.

Legal guardian: is a person appointed by the law to consent in place of an incompetent patient based on UAE federal laws and/ or local regulation, when the patient is unable to provide Informed Consent due to an illness or incompetency.

Licensure: is a process of issuing an official permission to operate a health facility to an individual, government, corporation, partnership, Limited Liability Company (LLC), or other form of business operation that is legally responsible for the facility's operation.

Mono-place chamber: a stand-alone, single compartment hyperbaric chamber designed for occupancy by one person without an attendant. The entire chamber is pressurized with 100% oxygen or air, and the patient breathes the ambient chamber oxygen directly or breathing the o2 through a mask.

Multi-place chamber: A hyperbaric chamber with more than one compartment that is designed for occupancy by more than one person at a time with an inside attendant. This chamber is pressurized with compressed air while the patients' breath 100% oxygen via masks, head hoods or endotracheal tubes and it allows entrance or exit whilst the treatment compartment remains under pressure.

OHM: is the electric unit of resistance.

Patient: is any individual undergoing hyperbaric oxygen therapy for elective, medical or investigational exposure.

Undersea and Hyperbaric Medicine: is a discipline that deals with the prevention of injury and illness due to exposure to environments in which the ambient pressure is increased, such as in diving or hyperbaric chamber exposure, and the therapeutic use of high environmental pressure and the delivery of oxygen under high pressure to treat disease.

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ACLS: Advanced Cardiac Life Support

ARTG: Australian Register of Therapeutic Goods

ASME: American Society of Mechanical Engineers

BLS: Basic Life Support.

CE: Conformité Européenne

FDA: Food and Drug Administration

HBOT: Hyperbaric Oxygen Therapy

IV: Intravenous

MITI: Ministry of International Trade and Industry

MOHAP: Ministry of Health and Prevention

NEBOSH: National Examination Board in Occupational Safety and Health

NFPA: National Fire Protection Association.

O2: Oxygen

OSHA: Occupational Safety and Health Administration

PALS: Pediatric Advanced Life Support

PVHO: Pressure Vehicles for Human Occupancy

RN: Registered Nurse

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STOP: Safety Time Out and Pause

UAE: United Arab Emirates

UHMS: Undersea & Hyperbaric Medicine Society.

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1. REGISTRATION AND LICENSURE REQUIREMENTS:

Health care facility to provide HBOT service should:

1.1. Comply with facility licensing requirements and regulations available on the concerned Health Authorities website.

1.2. Submit a request of adding service under the existing licensed facility.

1.3. HBOT service can be provided in:

1.3.1. Hospital

1.3.2. Day Surgical Centre

1.3.3. Medical Centre

2. GENERAL REQUIREMENTS:

Multiplace chamber is a hyperbaric chamber with one or more compartments that is designed for occupancy by more than one person at a time. This chamber is pressurized with compressed air while the patient's breath 100% oxygen via masks, head hoods or endotracheal tubes and it allows entrance or exit via an airlock whilst the treatment compartment remains under pressure.

There are three classes of hyperbaric chamber:

- Class A "Walk in" for multiple patients (Human – Multiplace Chamber).
- Class B for single patients (Human – Monoplace Chamber).
- Class C for animal (nonhuman).

HBOT Healthcare facilities should:

2.1. Not be located in a mall or an industrial area.

2.2. Class A (multi-place chambers) shall be used only in hospitals and shall be located on the ground floor.

2.3. Class B (Mono-place chambers) shall be used in approved health facilities.

2.4. Class C chambers shall not be used in health facilities.

2.5. Have appropriate equipment and trained healthcare professionals to manage critical and emergency cases.

2.6. Develop Standard Operating Procedures for therapeutic hyperbaric facilities, which should document the presence of guidelines or facility policy for the referrals, reception, consultation, assessment, treatment, and discharge of patients in the facility.

2.7. The health facility should develop and maintain the following policies and procedure:

2.7.1. Emergency action plan

2.7.2. Fire safety and evacuation

2.7.3. Incident reporting

2.7.4. Infection control measures

2.7.5. Management of Pediatric Patients (if applicable)

2.7.6. Management of Critically ill patients

2.7.7. Management of patients with known infections

2.7.8. Medication management

2.7.9. Patient education and Informed consent

2.7.10. Patient acceptance criteria

2.7.11. Patient health record

2.7.12. Patient privacy and confidentiality

2.7.13. Patient discharge/transfer

2.7.14. Staffing.

2.8. Develop a quality assurance program that follows international evidence-based guidelines and recommendations.

2.9. Provide documented evidence of contracts for the following:

2.9.1. Contract with a nearby hospital (in case not located in a hospital) in case of any complication or emergency.

2.9.2. Clinical laboratory services

2.9.3. Equipment maintenance with manufacturing company or an authorized dealer

2.9.4. Housekeeping services

2.9.5. Laundry services

2.9.6. Medical waste management as per Health Authorities requirements

2.10. Have in place a written plan for monitoring equipment for electrical and mechanical safety, with monthly visual inspections for apparent defects.

2.11. Relocation of the HBOT chamber shall be possible only with Health Authorities approval.

2.12. Maintain a record of HBOT chamber:

2.12.1. Installation checklist

2.12.2. Assessment checklist

2.12.3. Operational checklist

2.12.4. Cleaning checklist

2.12.5. Maintenance log including the calibration dates.

2.12.6. Log of use of the chamber.

2.13. Apply the following basic safety requirements:

2.13.1. Accurate measurement and control of the chamber pressures

2.13.2. Accurate time pieces and time keeping

2.13.3. Periodic testing to ensure the purity and composition of compressed breathing gases.

2.13.4. Control and monitoring of chamber environmental conditions.

2.13.5. Reliable equipment

3. STAFFING REQUIREMENTS:

HBOT Healthcare facilities should:

3.1. Employ a sufficient number of certified and experienced licensed healthcare professionals as per each type of used chamber in the facility and the patient's condition by meeting the minimum staffing requirement available in appendix (5) to satisfy the functional program of the health facility.

3.2. Ensure that HBOT multi-disciplinary team includes:

3.2.1. Director/chief of HBOT service

3.2.2. HBOT Consultant/Specialist Physician

3.2.3. HBOT chamber Operator (HBOT Technician)

3.2.4. Inside Attendant (IA)

3.2.5. Outside Attendant

3.2.6. Registered Nurses

3.2.7. Safety Officer

3.2.8. Fire Marshal

3.3. Ensure that employed staff meets the qualification and training requirements available in Appendix (5).

3.4. All healthcare professionals shall be trained in HBOT and have Basic Life support (BLS) and Advanced Cardiac Life Support (ACLS).

3.5. Valid certificate of Pediatric Advanced Life Support (PALS) when applicable.

3.6. All staff should be medically checked for fitness to be involved in HBOT. The medical check-up shall be conducted annually and in a third party facility.

3.7. All personnel shall complete equipment – specific training for the system which they will be operating.

4. HEALTH FACILITY DESIGN REQUIREMENTS:

4.1. General Design Requirements:

4.1.1. A HBOT facility shall have an emergency exit with visible signs directing patients in case of an emergency.

4.1.2. The health facility shall ensure easy access to the health facility and treatment areas for all patient groups.

4.1.3. HBOT Facility/service area shall include but not limited to:

4.1.3.1. Reception and waiting area (Separate for Male and Female).

4.1.3.2. Consultation/ Examination room (s).

4.1.3.3. Holding area for inpatients. (If applicable)

4.1.3.4. Patient changing area (Separate for Male and Female).

4.1.4. HBOT treatment room:

4.1.4.1. Should be away from kitchen or generator.

4.1.4.2. Have an antistatic, impervious, fireproof, monolithic, joint free and washable flooring, with no carpets or wooden flooring.

4.1.4.3. Have window(s) with an outside view.

4.1.4.4. Be adequately ventilated with a smoke evacuator.

4.1.4.5. Have easy access for wheelchairs.

4.1.4.6. Have access to toilets.

4.1.4.7. Be provided by approved sprinkler heads equipped with fusible and temperature elements that have ratings as low as possible.

4.1.4.8. Have "No smoking" signs visibly displayed.

4.1.4.9. Preferably provide a metal detector at the entrance of the HBOT treatment room to ensure that the patient do not carry any form of metal into the chamber.

4.1.5. Gas cylinder storage room.

4.1.6. Compressor room.

4.1.7. Gurney/ Stretcher storage.

4.1.8. Clinical and non-clinical storage.

4.1.9. Clean and Dirty utility.

4.1.10. Administrative activities area.

4.1.11. Ensure that the floor can support the weight of the pressure vessels and all associated equipment, both when moving the chamber into place and under operating conditions.

4.1.12. Antistatic floor, fireproof, joint free and washable flooring, no carpets or wooden flooring

4.1.13. Chamber room should have enough space for the chamber, patient support and staff activities.

4.1.14. Chamber placement within the room should ensure adequate space for chamber operations, patient loading and support equipment.

4.1.15. If the chamber is placed near a wall, it shall not obstruct the controls or viewports of the chamber.

4.1.16. Provide emergency communication device inside chamber room.

4.2. Class A (Multiplace) treatment room requirements (Appendix 8):

4.2.1. Class A facilities shall be designed not to obstruct flow of patients and staff. The rapid or emergency removal of a patients or healthcare professional from one chamber shall not restrict the orderly, rapid and simultaneous removal of patients or healthcare professional from other chambers.

4.2.2. A minimum of two (2) exits shall be provided for the treatment room unless a single exit opens directly to a primary evacuation route.

4.2.3. Doorways of exit shall have a minimum opening of one (1) meter.

4.2.4. The Class A chamber room should have a minimum clearance of 2.5 meters in front of a chamber entry door, that is intended for gurney/stretcher access.

4.2.5. There shall be a minimum of 0.9-meter clearance around any part of the chamber system that defines an exit pathway.

4.2.6. If the chamber control console is immediately adjacent to the chamber, there should be a minimum clearance of 0.9 meter between the control console and any obstruction.

4.2.7. There should be a minimum clearance of 0.6 meters in a pathway that allows access to valves used in chamber operation.

4.2.8. There should be a minimum clearance of 0.6 meters in a pathway that allows access to areas of the chamber that require cleaning or maintenance.

4.2.9. Entries designed for wheelchairs or wheeled gurneys should have access ramps. A ramp should be a minimum width of 1.14 meter, a maximum of height of 0.75 meters, have a maximum slope of 1 in 12, and have handrails on both sides. These ramp specifications are not necessary if the slope of the ramp is no steeper than 1 in 20.

4.2.10. The chamber shall have breathing equipment for all occupants, and an extra spare one.

4.2.11. All material inside the chamber shall be fire resistant and HBOT environment compatible.

4.2.12. Multi-place Chambers shall be located on the ground floor.

4.3. Class B (Monoplace) treatment room requirements (Appendix 9):

4.3.1. The health facility housing a Class B chamber shall be designed not to obstruct flow of patients and staff.

4.3.2. In the case of multiple Class B chambers installed in a single setting, the rapid or emergency removal of a patient from one chamber shall not restrict in any way the rapid and simultaneous removal of patients from other chambers.

4.3.3. Exit doorways of egress shall have a minimum opening of one (1.1) meter.

4.3.4. The space required to house Class B chambers and supporting equipment shall not be less than eighteen (18) sq. meters to host one (1) monoplace hyperbaric chamber and patient-transfer gurney.

4.3.5. There shall be a minimum clearance of 0.9 meters around any part of the chamber system that defines an exit pathway.

4.3.6. If the chamber control console is integrated into or immediately adjacent to the chamber, there shall be a minimum clearance of 0.9 meters between the control console and any obstruction.

4.3.7. There shall be a minimum clearance of 0.6 meters in a pathway that allows access to valves or controls used in chamber operation. If the chamber has

a patient-loading device, this clearance shall be maintained when the patient loading device is extended out of the chamber.

4.3.8. Any part of the chamber that must be accessed shall be at least 0.3 meters away from any obstruction, unless the chamber is fitted with wheelchairs.

4.3.9. There shall be an O2 shut-off valve for each chamber, which is accessible to the chamber operator.

4.3.10. Any electrical service outlets located within three (3) meters of the Class B chamber entrance shall be located no less than 0.9 meters above floor level.

4.3.11. Lighting over the Class B chamber shall be incandescent, preferably with dimmer control.

4.3.12. Fluorescent lighting installed in rooms housing Class B chambers shall not be located directly over the chambers.

4.3.13. If the room housing Class B chambers has windows, the chambers should be protected from direct exposure to sunlight.

4.3.14. There shall be screens between chambers to ensure patient privacy.

4.3.15. There shall be a 0.3 meters clearance at the foot of the chamber for unobstructed gas connection at the foot of the chamber.

4.3.16. O2 detector of sensor to detect any O2 leak.

4.4. Class B (Monoplace Chambers), it shall:

4.4.1. Not be located in direct sunlight or close to a heat source.

4.4.2. Be easily accessible to the patient and staff.

4.4.3. Be free of cracks internally or externally.

4.4.4. Be free of corrosion, damage, dents, gouges or other damage internally and externally.

4.4.5. Have an atmosphere free of toxic or flammable gases.

4.4.6. Have alarms for low-pressure and high-pressure gas monitoring panel, which are tested and maintained routinely.

4.4.7. Be equipped with audible and visual alarms.

4.4.8. Have a warning sign displaying prohibited material inside the hyperbaric chamber, which shall be posted at the chamber entrance Appendix 4.

4.4.9. Have an external breathing air source in case of emergency evacuation from the chamber.

4.4.10. Have acrylic windows with certification such as a "U"/a partial "U2" ASME stamp, with PVHO-1 or an equivalent certification.

4.4.11. Have viewing ports if not completely transparent.

4.4.12. Have a manual access for the operating controls for pressurization, depressurization, parameter condition monitoring and safety interlocking.

4.4.13. Have external exhaust termination with the pipe elbow facing down.

4.4.14. Have a dedicated vent line to release the O2 after treatment.

4.4.15. Have earth grounding system with a regular documented maintenance.

4.4.16. Be grounded to a common building (pipe/steel) or true earth ground.

4.4.17. Have the resistance between the grounded chamber hull and electrical ground not exceeding one (1) Ohm (DO NOT use the building electrical panel or wall outlet ground to ground the chamber).

4.4.18. Have a quick release access door.

4.4.19. Have all openings leading from the chamber to external fittings or controls and shall be free from obstruction.

5. FIRE SAFETY:

5.1. The risk of fire is a major concern in the hyperbaric environment. The potential for accidental ignition of flammable materials is increased in the hyperbaric environment and their burning rate is markedly enhanced by a raised percentage or raised partial pressure of O2.

5.2. The facility shall exclude flammable material or other sources of ignition from the treatment room by a rigorously enforced "Contraband Policy".

5.3. Patients when undergoing HBOT treatment should wear only 100% cotton or other hyperbaric compatible materials.

5.4. All the linen used inside the hyperbaric chamber shall be 100% cotton.

5.5. The facility should comply Civil Defense and NFPA 99.

5.6. There should be evacuation maps posted in the facility to indicate current locations marked with "You are here" to provide information regarding escape routes, fire exits and fire extinguishers.

5.7. All fire exit doors shall be unobstructed and in proper working condition with exit points marked correctly.

5.8. There shall be "No Smoking" signs visibly displayed all around the facility.

5.9. The facility shall establish a fire safety plan for early detection, confining, extinguishment, rescue, evacuation and alerting the Civil Defense.

5.10. The facility shall maintain fire extinguishers, smoke alarms, sprinkler system and other fire protection equipment and devices as per the Civil Defense requirements.

5.11. Fire extinguishers shall be properly and accessibly located. They must be fixed securely on the wall with safety pins fitted, seals intact, charged and current service record available.

5.12. The facility shall have trained staff as fire marshals and at least one (1) fire marshal shall be present on the premises during working hours.

5.13. Staff shall have fire and safety training to respond to fire events in the building. Orientation on the fire safety measures must be included in new staff induction program.

5.14. All staff shall be aware of the following:

5.14.1. Location and use of fire hose reel/cabinets/blankets

5.14.2. Assembly points

5.14.3. Fire alarms/call points break glass/pull station

5.15. Fire evacuation drill should be conducted and documented at least two (2) times a year.

5.16. Fire in the facility buildings and evacuation procedures including removing patients from the chamber should be documented.

5.17. The installation of additional electrical equipment should be limited only for devices, which comply with hyperbaric conditions.

5.18. Gas cylinder storage room shall:

5.18.1. Be large enough able to store enough (H) cylinders and manifolds for the reserve breathing gases required for chamber operations.

5.18.2. Have a minimum of six (6) medical O2 tanks.

5.18.3. Have a minimum of one (1) 400-liter liquid O2 tank with vaporizer.

5.18.4. Be designed to comply with NFPA 99 requirements.

5.18.5. Have explosion proof electrical fittings.

5.18.6. Have an external exhaust ventilation provided outside the building area.

5.18.7. Have an automatic gas manifold monitored by alarm.

5.18.8. Maintain an alarm that monitors the high and low gas pressure.

5.18.9. Maintain documentation of staff training in emergency procedures in the event of any incident related to gas pressure release.

5.18.10. Have a concrete or tiled flooring.

5.18.11. Have a visibly displayed "No smoking" sign in this room.

5.18.12. Provide a door to the room with door vents for O2 to pass in case of leakage from cylinders.

5.18.13. Provide access for a truck to refill the O2 in case the health facility uses liquid O2 for the treatment.

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6. HBOT MEDICAL EQUIPMENT REQUIREMENTS:

Medical equipment used for the provision of HBOT should be:

6.1. Approved by minimum of two of the following authorities:

6.1.1. Food and Drug Administration (FDA)

6.1.2. Health Canada.

6.1.3. Conformité Européenne (CE)

6.1.4. Australian Register of Therapeutic Goods (ARTG).

6.1.5. Japans Ministry of International Trade and Industry (MITI).

6.2. Installed and operated according to the manufacturing specifications and concerned Health Authorities requirement.

6.3. Regularly maintained and all necessary parts shall be changed as per equipment manufacturers' recommendation.

6.4. Inflatable, collapsible or portable chambers shall not be used in any health facility as they are NOT recognized medical devices for hyperbaric oxygen treatment by the FDA and no supporting clinical studies validate their effectiveness.

6.5. The multi-place equipment shall be continuously and accurately monitored for the following:

6.5.1. Oxygen Concentration

6.5.2. Carbon di Oxide Concentration

6.5.3. Humidity

6.5.4. Temperature

6.5.5. Pressure.

6.6. All HBOT facilities shall have the following equipment:

6.6.1. Oxygen resuscitation equipment, which can supply 100% oxygen to a nonbreathing patient.

6.6.2. Equipment to allow intubation and ventilation of a patient with close to 100% oxygen.

6.6.3. A set of apparatus to enable pleurocentesis to be performed.

6.6.4. A system to call the doctor in case of an emergency. This call device shall be simple to operate with an uninterruptable path to the doctor who is required to respond within five minutes.

6.6.5. Therapeutic equipment such as cervical traction for cervical spine injuries.

6.6.6. Gas analysis system should be installed and verified according to the manufacturer's instructions and calibrated by ISO/IEC 17025 accredited calibration laboratory by national accreditation body that is recognized by ILAC MRA

6.7. For multi-chamber facilities, the facility shall have available and maintain some of the equipment inside as well as outside the chambers. This includes but is not limited to:

6.7.1. Apparatus to measure blood pressure with an appropriately sized cuff.

6.7.2. Equipment for electrocardiographic monitoring.

6.7.3. IV supplies and accessory equipment such as syringes, needles, tape, etc.

6.7.4. Emergency drugs and supplies/crash cart with procedures to review expiry date. ر/ط5232

7. PATIENT'S CARE:

HBOT Healthcare facilities should:

7.1. Assess and advise each patient prior to commencing a program of HBOT to ensure that:

7.1.1. The patient has an approved medical condition that is likely to benefit from HBOT.

7.1.2. There are no absolute contra-indications to HBOT and that any relative contra-indications have been considered and appropriately managed.

7.1.3. The patient's medical conditions are optimized to the best practical extent.

7.1.4. Other anticipated or potential risks are considered and a plan is in place to ameliorate these if necessary.

7.2. Educate patients on the treatment and associated procedures, including the risks and benefits of Hyperbaric Oxygen Therapy, the likelihood of success, and any potential pre and post interventions.

7.3. Obtain prior written consent and this should conform to hospital / health authority policies and should include discussion of the risks, benefits and procedures involved in HBOT. If the age of the patient is below eighteen (18) years or is incapacitated, the parents or legal guardian shall fill and sign the consent form.

8. MANAGEMENT OF HBOT:

8.1. HBOT is available for the treatment of patients who meets the following criteria:

8.1.1. Have medical conditions with the indications included in Appendix 1.

8.1.2. HBOT Services should be immediately available for patients with emergency conditions where HBOT is considered as the first line treatment.

8.1.3. Where HBOT is not considered as first line treatment, Patient assessment should be carried out by physician every 10 session to assess for improvement, treatment can be terminated as per physician advise if no improvement after 10 or 20 sessions according to diagnosis and treatment protocol

8.2. Patient is referred by a physician, or dentist.

8.3. All referrals shall be assessed by a physician with privileges in the facility for the appropriateness of and fitness for HBOT and according to the patients' medical status and history.

8.4. Avoid HBOT treatment for patients with the international recognized contraindications including but not limited contraindications mentioned in Appendix 2.

8.5. HBOT on critically ill or unstable patients shall be carried out only in hospital-based facilities unless, subject to a determination that is made by both the referring and HBOT physician that the risk of treatment at a HBOT medical

center is less than the risk of delays associated with the transfer of the patient to a hospital-based facility.

8.6. Pediatric cases considered for hyperbaric treatment should be:

8.6.1. Carefully reviewed and discussed with the referring pediatrician prior to commencement of hyperbaric oxygen therapy.

8.6.2. Reviewed by an ENT and bilateral myringotomy (+/ - tympanostomy tubes) should be considered (especially in the case of a child with an emergency indication for hyperbaric oxygen treatment).

8.6.3. All pediatric cases need EEG before start of hyperbaric therapy.

8.7. If needed, pediatric cases considered for hyperbaric can be accompanied by adult with a non-rebreathing, reservoir facemask to deliver air or oxygen.

8.7.1. The accompanying adult should be evaluated and found suitable to be exposed to hyperbaric air and oxygen.

8.8. Prior of HBOT treatment ensure the following:

8.8.1. Perform a Safety Time Out and Pause (STOP) prior to every HBOT. STOP shall include the following:

8.8.1.1. Verifying "Right patient, Right Treatment and Right Safety".

8.8.1.2. Checking the patient ground (monoplace).

8.8.1.3. Ensuring all prohibited items are removed from the chamber (both monoplace and multiplace).

8.9. The treatment profile and staffing plan should be confirmed and the completed STOP checklist dated and signed by two staff members prior to closing the door of the chamber.

8.10. Patient has had a shower to ensure that the patient is free of any makeup or other flammable lotions or balms.

8.11. Patient wears cotton scrubs without pockets that are provided by the health facility.

8.12. Patient wears a grounding device in case of Monoplace chamber

8.13. After HBOT all patient shall:

8.13.1. Avoid flying (24hours)

8.13.2. Avoid climbing altitude more than 300 meter (Burj Khalifa included)

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APPENDIX 1: APPROVED MEDICAL CONDITIONS FOR HBOT:

1) Air or Gas Embolism
2) Carbon Monoxide Poisoning Carbon Monoxide Poisoning Complicated by Cyanide Poisoning
3) Clostridial Myositis and Myonecrosis (Gas Gangrene)
4) Crush Injury, Compartment Syndrome and Other Acute Traumatic Ischemia's
5) Decompression Sickness
6) Arterial Insufficiencies: Central Retinal Artery Occlusion
7) Enhancement of Healing in Selected Problem Wounds
8) Severe Anemia
9) Intracranial Abscess
10) Necrotizing Soft Tissue Infections
11) Osteomyelitis (Refractory)
12) Delayed Radiation Injury (Soft Tissue and Bony Necrosis)
13) Compromised Grafts and Flaps
14) Acute Thermal Burn Injury
15) Idiopathic Sudden Sensorineural Hearing Loss
16) Cases to be considered for research process.
17) Wounds
18) Avascular osteonecrosis

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APPENDIX 2: SIDE EFFECT OF HBOT:

1) Fatigue.
2) Damage to the lungs (Barotrauma)
3) Rupturing of middle ear (Barotrauma to the ears)
4) Damage sinuses
5) Changes in vision (Myopia).
6) Oxygen Toxicity (ling or CNS

APPENDIX 3: CONTRAINDICATIONS TO HBOT FOR PATIENTS AND ATTENDANT:

Contraindications	Absolute Contraindications	Relative Contraindications
1. Contraindications to Hyperbaric Oxygen Therapy (for Patients)	• Unvented pneumothorax • Acute sever bronchospasm • Concomitant treatment with doxorubicin • Usage the following medication: Bleomycin, Doxorubicin, Cis-Platinum, and Disulfiram and Mafenide Acetate (Sulfamylin).	• Upper airway infection • Allergic rhinitis • Chronic sinusitis and otitis Chronic obstructive pulmonary disease with emphysema • History of pneumothorax or thoracic surgery • History of ear, nose and throat surgery • Epilepsy

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Contraindications	Absolute Contraindications	Relative Contraindications
		• Optic neuritis • Arterial hypertension (uncontrolled) • Heart failure (uncontrolled) • Claustrophobia • Dangerous behavior.
2. Contraindications to Serving as an Inside Attendant in a Clinical Multi-place Hyperbaric Chamber (for attendant)	• Seizure disorder • History of spontaneous pneumothorax • Significant hearing loss • Active chronic obstructive pulmonary disease or asthma • Residual of decompression illness • Current or impending pregnancy • Psychiatric disorder • Congestive heart failure	• Difficulty equalizing middle ear pressure. • Previous unexplained decompression illness. • Diabetes with frequent hypoglycemia.

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Contraindications	Absolute Contraindications	Relative Contraindications
	• Lung bullae or cysts	

APPENDIX 4: POSTER AT THE ENTRANCE OF THE HBOT CHAMBER:

- The following is allowed inside the hyperbaric chamber:

1. Yourself; free of hair products, make-up, perfume/cologne, hearing aid, anything on the list below "List of Prohibited Items"
2. Undergarments: Only when permitted on an as needed basis. If permitted, please wear 100% cotton undergarments. (Do not wear Lycra or spandex brassier or underpants)
3. Center issued scrubs or gown
4. Water bottle provided by your chamber technician

- List of Prohibited Items- The letter(s) beside each item indicates the general reason for prohibiting it, the coding is elaborated below)

1. Adhesives (F)

2. Aerosols (D, E, F)
3. Aftershave (D, F)
4. Alcohol (D, F, P)
5. Batteries with unprotected leads (F)
6. Chemical cleaners, e.g.; trichloroethylene, 'Freon', etc. (D)
7. Cigarettes, cigars, tobacco of all kinds (F, M)
8. Cleansing powder (C, F, P)
9. Clothing, bedding included blankets, sheets, pillows, mattresses, etc. (F)
10. Drugs, non-prescribed (P)
11. Electrical equipment including tape recorders, radios, etc. (F)
12. Explosives (F)
13. Glass thermometers, including batteries containing mercury (C, D, P)
14. Ink pens (M)
15. Lighters, matches (F)
16. Newspaper (F)
17. Non-diving watches (L, M)
18. Petroleum based lubricants, grease, fluids (F)
19. Sugar and fine powders and other flammable food stuffs (E, F)
20. Thermos flasks (L, P)

• C - possibility of damaging the fabric of the chamber

• L - could be broken or damaged by pressure

- D - contamination of the environment
- E - explosion risk
- F - fire source (including static charges) or a combustible substance
- M - will possibly cause a mess
- P - affects ability of diver

APPENDIX 5: HBOT STAFF REQUIREMENTS AND RESPONSIBILITIES:

Staff	Requirements
Chief or Director of HBOT services	Director of HBOT services should: a) Have a minimum of 1year experience in hyperbaric center b) Responsible on ensuring safe and ethical care of patients, developing proper facility's structure, procedures and equipment, supervises the provided services and HBOT personnel. c) Ensure healthcare workers in the facility are qualified and competent to perform their duties and knowledgeable of the risks and hazards. d) Ensure policy and procedure manuals for the administration of the HBOT facility, the operation of equipment, and the management of patients are prepared, maintained and readily accessible to staff.

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Staff	Requirements
1) HBOT Physician	Physician of HBOT services should: a) licensed as consultant/ specialists in Undersea and Hyperbaric Oxygen Medicine. b) Prescribe and supervise the safe provision of HBOT services. c) Be responsible for the overall medical care of the patient receiving the service. d) Be responsible for the quality assurance of the HBOT service. e) Be responsible for patients follow up after the hyperbaric treatment. f) Define the protocol, procedures for the treatment and ensure they are adhered to. g) Assess the suitability and the fitness of the patient for HBOT. h) Determine the risk benefit profile. i) Interpret any related diagnostic testing. j) Generate a therapeutic dosing profile. k) Evaluate subsequent clinical course. l) Manage any related side effects and complications. m) Be present at the premises and immediately available at all times that the chamber is occupied and promptly respond and manage any critical events. n) Ensure the safe and ethical care of patients.

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Staff	Requirements
3) HBOT Chamber Operator	HBOT chamber operator should: a) Be licensed by MOHAP as registered nurse. b) To be initially and annually privileged by MOHAP if i. Have a completed a minimum of 40 hours course in hyperbaric approved by a recognized international body and undersea technology with 6 months experience in hyperbaric chambers. ii. Maintain a current certificate in Advanced Cardiac Life Support (ACLS). iii. Pass MOHAP Exam c) The Chamber Operator shall be trained to safely implement prescribed therapy. d) Since the Chamber Operator is in-charge of operating the multi-place or mono-place hyperbaric chamber(s), his/her presence is essential during the working hours of the health facility providing HBOT services. e) There shall be one (1) chamber operator for every two (2) mono-place chambers during all working hours of the health facility providing HBOT services. f) At least one additional staff, preferably the Physician responsible for HBOT in addition to the Chamber Operator must be present during the treatment.

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Staff	Requirements
	g) There shall be two (2) Chamber Operators for every multi-place chamber during all working hours of the facility. h) The Chamber Operator should i. Conduct a general check-up of the patient, including vital signs and the initial assessment and file this in the medical records. ii. Maintain visual and audio contact with patient during their treatment iii. Notify the physician immediately in case a patient complains or shows signs suggesting an unanticipated change in status. iv. Not assume any of the responsibilities of the Hyperbaric Physician v. Not carry out hyperbaric treatment without patient-specific hyperbaric physician signed medical orders. vi. In case of a multi-place chamber, i. Shall be present inside the multi-place chamber during treatment to monitor patients. ii. Operate the internal and external devices of the chamber in-between sessions iii. Control and operate the mechanisms for compression and decompression and deliver gas mixtures and O2. iv. Control and application of the safety regulations concerning prevention of fire and O2 toxicity.

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Staff	Requirements
4) HBOT Inside Attendant	HBOT Inside Attendant should be: a) Be licensed by MOHAP as either registered nurse, respiratory therapist b) To be initially privileged by MOHAP if a. Have completed at a minimum, a 40-hour course approved by a recognized international body. A record of completion of the course of training shall be kept on file in the facility. b. Pass MOHAP exam c. Maintain a current certificate in Basic Life Support. c) and/or HBOT Technician who is mentally and physically fit to work in a Class A multi-place chamber with compressed air. The minimum patient to IA ratio for optimal operational safety should typically be as follows: a. For uncomplicated ambulatory patients, minimum patient to IA ratio of 6:1. b. For complicated patients requiring increased level of personal care, minimal patient to IA ratio of 4:1. c. For critical care patient, minimum patient to IA ratio of 1:1 (ventilated patients may require 2-staff per patient). i. When critical care patients are treated along with either uncomplicated or complicated patients, staffing ratios for non-

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Staff	Requirements
	critical patients remain as above, regardless of the number of staff necessary to safely and effectively treat critical patients. d. For critically ill patients or intubated patients it is recommended that a RN experienced with hyperbaric medicine be present inside the chamber with the patient at all times. The patient: IA ratio should be 1:1. d) The IA shall be exposed to a maximum of ninety (90) minutes in the chamber per day and the time gap between two sessions shall be at least 8-10 hours. e) The IA is recommended medical examinations as mentioned below: a. Before starting work as an IA. b. Periodic physical examination every five (5) years. c. A re-examination after a hyperbaric related injury or illness such as a known decompression sickness, arterial gas embolism, audio-vestibular illness, central nervous system dysfunction, when there is a change on the annual self-report, or as needed to determine fitness to work in hyperbaric conditions. A person should not be allowed to return to work after any significant injury or illness in hyperbaric conditions until released by the hyperbaric specialist to do so. d. The physician responsible for the HBOT shall provide a written fitness for duty report outlining the IAs medical condition and fitness

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Staff	Requirements
	to work in a compressed air environment or other hyperbaric activities and should indicate any restrictions that would apply to the IA's work activity in the report.
Outside Attendant	a) This could be a RN or any health care professional with proper training available to provide technical or patient support as needed. b) The Outside Attendant shall remain in the room at all times when the chamber is pressurized so that the Chamber Operator has no additional responsibilities other than operating the chamber
Registered Nurse (RN)	a) The ratio of the RN to the physician shall be 1:1. b) The RN shall conduct the general check-up of the patient, such as vital signs, initial assessment etc. and document it in the health records. c) The RN shall be trained and responsible for going through a checklist before placing the patient inside the chamber. d) In case of a multi-place chamber, the RN could be the IA during treatment to monitor patients. e) The RN shall be responsible to manage any medical emergencies that may arise when the patient is in the health facility.
5) Safety officer	a) Any healthcare worker employed in the HBOT facility could be nominated as the safety officer.

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Staff	Requirements
	b) The facility should assure that the safety officer has a formal and comprehensive training in the safety aspects of hyperbaric medicine and related technology from international or national organization such as National Examination Board in Occupational Safety and Health (NEBOSH) or Occupational Safety and Health Administration (OSHA). c) The safety officer shall develop, maintain and manage a safety program based upon compliance with recognized standards, which shall demonstrate effective elements of hazard mitigation, while employing recognized risk management concepts.
6) Fire Marshal	a) Any healthcare worker employed in the HBOT facility could be nominated as the fire marshal. b) The facility shall ensure that these fire marshals are formally trained and at least one (1) fire marshal shall be present on the premises during working hours. c) The fire marshal shall orient, train the staff on fire safety measures and response to fire events in the facility.

Note: staffing requirements can be adjusted in accordance with the Concerned Health Authorities' clinical privileging policy.

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APPENDIX 6: MEDICAL TESTS FOR INSIDE ATTENDANT (IA) FITNESS TO WORK IN CLINICAL HYPERBARIC CHAMBER:

Test	Initial	Periodic	Comments	
Medical History	Yes	Annually	Include predisposition to loss of consciousness, vomiting, cardiac history, low O2 saturation, CO2 retention, serious blood loss, or anything that in the opinion of the licensed practitioner would interfere with work in hyperbaric conditions	
Physical Examination	Yes	Every 5 years and as deemed necessary	Include predisposition to loss of consciousness, vomiting, cardiac history, low O2 saturation, CO2 retention, serious blood loss, or anything that in the opinion of the licensed practitioner would	

Test	Initial	Periodic	Comments	
			interfere with work in hyperbaric conditions	
Pulmonary Function	Yes	As medically indicated	To include FEV1, FVC, PEF, FEF25-75.	
Audiogram	Yes	As per OSHA or institutional policy, or as medically indicated	Pure tone audiology	
Routine Urinalysis	Yes	As medically indicated		
Haematocrit, Haemoglobin, WBC	Yes	As medically indicated		
Chest x ray	Yes	As medically indicated	PA and LAT	
EKG: Standard (12 lead)	Yes	As medically indicated	Required initially to establish baseline	
EEG	As medically indicated	As medically indicated		

Test	Initial	Periodic	Comments	
Visual acuity	Yes	As medically indicated	Vision, near & distant, uncorrected and corrected, to include colour	
Toxicology Screen	According to institutional policy	According to institutional policy		

APPENDIX 7: STAFFING MATRIX FOR CLASS A AND CLASS B CHAMBERS:

Class A Multiplace HBOT Chamber				
Patient Characteristics	**Stable**	**Intermediate**	**Complex**	**Critical**
Patient Complexity Level	1 – 2	2 – 3	4	5
HBOT Type	Elective	Elective/ Urgent/ Emergency	Elective/ Urgent/ Emergency	Elective/ Urgent
Facility Level	1 – 3	1 – 3	1 – 2	1 – 2
HBOT Physician	1 present, may act as outside attendant	1 present, may act as	1 present	1 (consider additional physician if

		outside attendant		needed inside chamber but not mandatory)
Chamber Operator (HBOT Technician)	1	1	1	1
Safety Director	1 for the facility, need not be present unless acting as supervisor	1 for the facility, need not be present unless acting as supervisor	1 for the facility, need not be present unless acting as supervisor	1 for the facility, need not be present unless acting as supervisor
Inside Patient Attendant	1 for a maximum of 8 stable patients			
Outside Patient Attendant	1 required, but may be the hyperbaric physician	1 required, but may be the hyperbaric physician	1 required	1 required, additional personnel recommended

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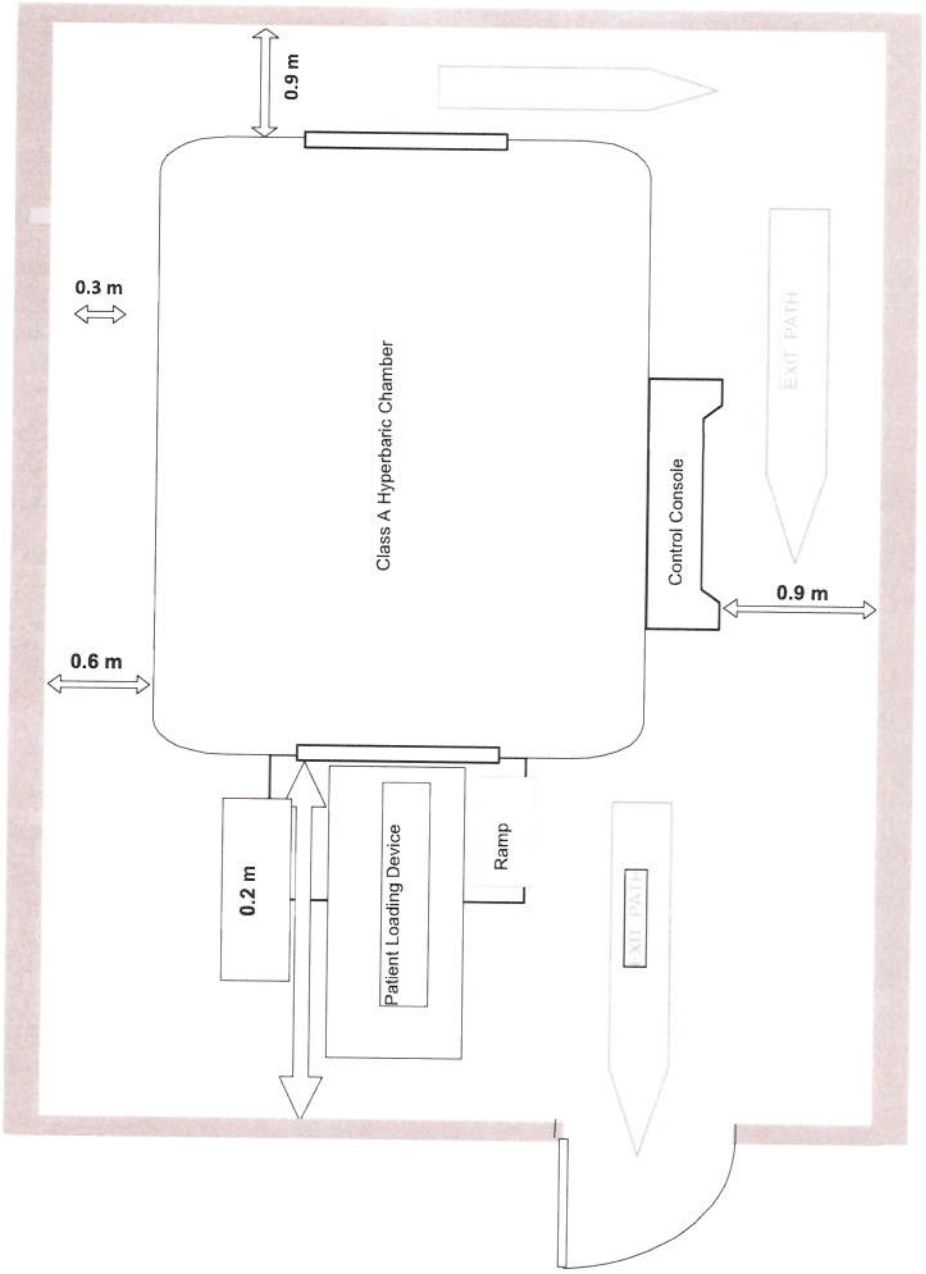
Class B Monoplace HBOT Chamber				
Patient Characteristics	**Stable**	**Intermediate**	**Complex**	**Critical**
Patient Complexity Level	1 – 2	2 – 3	4	5
HBOT Type	Elective	Elective/ Urgent/ Emergency	Elective/ Urgent/ Emergency	Emergency/ Urgent
Facility Level	1 – 3	1 – 3	1 – 2	1 – 2
HBOT Physician	1	1	1	1
Chamber Operator (HBOT Technician)	1 operator for a maximum of 3 simultaneous chambers with staggered start/stop times	1 operator for a maximum of 3 simultaneous chambers with staggered start/stop times	1 operator for a maximum of 2 simultaneous chambers, if both patients complex	1 operator for each chamber and patient
Safety Director	1 for the facility, need not be present	1 for the facility, need not be present	1 for the facility, need not be present	1 for the facility, need not be present

	unless acting as supervisor	unless acting as supervisor	unless acting as supervisor	unless acting as supervisor
Inside Patient Attendant	N/A	N/A	N/A	N/A
Outside Patient Attendant	Not required	Not required	1 recommended	1 required, 2 recommended for ventilated patients

APPENDIX 8: EXAMPLE OF A TYPICAL (CLASS A) HYPERBARIC FACILITY:



APPENDIX 9: EXAMPLE OF A TYPICAL FACILITY WITH TWO (CLASS B) CHAMBERS: