

MEDICAL EQUIPMENT FOR MULTIPLACE HYPERBARIC CHAMBERS

Part I: Devices for Monitoring and Cardiac Support

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Kot J: Medical equipment for multiplace hyperbaric chambers. Part I: Devices for monitoring and cardiac support. *Europ J Underwater Hyperbaric Med* 2005, 6(4): 115-120. All medical devices introduced into the hyperbaric chamber should be of an appropriate design and fit for use in the hyperbaric environment and they should be certified by the manufacturer for hyperbaric conditions. However, until now only several medical devices are CE marked for usage in hyperbaric chambers. Therefore users often need to perform themselves checking of the medical equipment needed for continuation of intensive care during hyperbaric treatment. To make this task easier, this paper presents review of reports of usage of medical devices under increased pressure. Part 1 is concerning devices for monitoring and cardiac support. Part 2 will describe mechanical ventilators and Part 3 will be devoted to infusion pumps and syringes.

Hyperbaric Oxygen Therapy, Medical Equipment, CE Marking

INTRODUCTION

Hyperbaric chamber is an active medical device, which is potentially hazardous taking into accounts its application, and exposure of people inside to increased ambient pressure and increased partial pressure of oxygen. Therefore all hyperbaric systems have to be in accordance with the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (1). Moreover, according to this Directive all equipment which is introduced into the hyperbaric chamber should be should be certified by manufacturer for hyperbaric conditions and CE marked accordingly covering the hyperbaric environment conditions. Unfortunately, nowadays only several medical devices, which are needed, for continuation of intensive care inside the hyperbaric chamber are marked by manufacturers as compatible with hyperbaric conditions. Therefore users are still forced to perform some checking of devices before putting it into the chamber and usually this is done on the responsibility of the users. Equipment that does not belong to the internal equipment of the chamber and which is not a medical device, should be of an appropriate design and fit for use in the hyperbaric environment up to the maximum working pressure of the chamber it is used within (2).

The general recommendations for medical devices used in hyperbaric chamber systems are presented in the Annex B of the pr14931 "Pressure vessels for human occupancy (PVHO) – Multi-place pressure chamber systems for hyperbaric therapy – Performance, safety requirements and testing" (3), which describes the potential hazards which certain medical devices represent, the risks induced by medical devices likely to be used within hyperbaric chamber systems intended for hyperbaric oxygen therapy and the recommendations for manufacturers of medical devices and users of hyperbaric chamber systems, in order to achieve the highest possible level of safety of the patient and the attendants.

In cases when the medical devices need to be introduced into the hyperbaric environment and it is not certified by the manufacturer for the use in such conditions, the user (personnel of hyperbaric centres) has to check it before

installing. The structure of the device is checked from a point of view of raised pressure, of oxygen enriched atmosphere and of electrical supply. Furthermore, the function of the device is checked under hyperbaric conditions to verify the controls, the performances of the device's probes, the operating of the device's built-in electronics, the device's display and the flow rates, pressures and frequencies with which the device dispenses the medical products to the patients.

In case of any doubt, the installation of this medical device in hyperbaric chamber should be abandoned.

To guide medical users, the review of literature is presented here to report medical devices, which have been used under hyperbaric conditions. This is divided into three parts: the part 1 is concerning devices for monitoring and cardiac support, the part 2 will describe mechanical ventilators and the last part 3 will be devoted to infusion pumps and syringes.

MONITORING DEVICES

Monitoring of patophysiological parameters during HBO session strongly depends on severity of the illness and current status of the patient. The set of measured parameters can be as simple as only 3-leads electrocardiography (ECG) up to many critical points of measurement including for example pulmonary capillary wedge pressure (PCWP) or electroencephalography (EEG) (4).

For the safety reasons the optimal method of collecting measurements is to perform acquisition of signals under hyperbaric conditions, transfer it into the electrical signal of low voltage or current and to transfer it out of the chamber through the wall to the outside monitor to be displayed and recorded. The transfer of the signal from the inside to the outside of the chamber can be effectively performed via wire connection or telemetric transmission. The significant disadvantage of the wire connection through the chamber wall is a need for two additional connectors to switch the cable from inside to outside. This may result in decreasing the quality of signal being transmitted, especially with the low signal-to-noise ratio.

Transmission using telemetry ensures the continuous monitoring of the patient during all phases of the session including transportation of the patient to and from the chamber. The quality of the signals transmitted depends on the quality of the emitter and receiver, the position of the antenna and the thickness of the chamber wall. Unfortunately, such systems usually allow transmission of only some basic signals, like ECG, with no possibility to transmit more data collected from the patient.

The alternative method is to put the monitoring device under the hyperbaric conditions and to collect, display and record all signals at the patient bed inside the chamber. This solution is easier to be conducted and – in basic version - does not need to make any modification to the existing construction of the chamber. If the user needs, it is possible to collect data inside the hyperbaric chamber and then to send it out of the chamber (again via cable connection through electrical ports or using telemetry) to more sophisticated monitor located outside for further analysis. It is important to remember that introducing of the electrical device inside the chamber increases the risk of fire, and therefore its careful evaluation is obligatory.

The following methods and techniques have been reported to be used safely inside hyperbaric chambers.

Non-invasive monitoring

- A. **Electrocardiography.** This is the basic monitoring procedure for critically ill patients. The signal can be easily transferred outside the chamber to outside monitor or can be collected by internal one, eg. Propac Encore (5). It includes monitoring of heart rate, analysis of arrhythmias and ST levels, power spectrum analysis of heart rate variability, and tracing of respiration by monitoring the impedance variation between electrodes.
- B. **Pulse oximetry.** The value of the measurement is restricted to pulse frequency only, as breathing hyperbaric oxygen leads to full saturation of the haemoglobin with only few exception of serious cardiovascular deficiency (6).
- C. **Non-invasive blood pressure.** This can be done manually using method of auscultation of blood noises. On the other hand, automatic method based on oscillation analysis needs to place the electrical pump for inflation of the arm cuff inside the chamber to ensure working at the same pressure. It poses an additional hazard for fire and therefore careful examination of the mechanism is necessary prior to the usage inside the hyperbaric chamber, including a replacement of pump motor with brushless type in some cases, e.g. Propac Encore (5). Until now there is no reference in the literature about the influence of increased density of air used for inflation of the cuff on the accuracy of the blood pressure measurement or on the workload for the pumping systems.
- D. **Temperature.** It can be easily measured at any point by the electrical thermistors and signals can be sent to any device used for critical monitoring. The mercury thermometries must not be entered into the hyperbaric chambers due to the toxicity of mercury under hyperbaric conditions.
- E. **Transcutaneous partial pressure of the oxygen (TcPO₂).** It is used for evaluation of oxygenation of the local tissues as result of vascular system and efficacy of the hyperbaric therapy (7). Moreover, it can be used for quality assurance system giving independent measurement of the dose of oxygen absorbed by the patient leading to early detection of any leakage in breathing systems. Together with measurement of the transcutaneous partial pressure of the carbon dioxide (TcPCO₂) it is used for control of ventilation / perfusion status of the patient (8, 9). The sensors are connected to the patient skin and electrical signal from sensors is redirected to the internal or external display.
- F. **Electroencephalography (EEG).** It can be acquired safely using computerized multi-channel systems to avoid any artefacts (10, 11). Usually the signal obtained from head sensors is transferred out of the chamber to the external computer for further evaluation (eg. spectral analysis).
- G. **Evoked potentials (EP).** The usage of potentials evoked at a cortical and brainstem level by acoustic, visual and somatosensorial stimuli in humans during hyperbaric session have been described (10, 12) and it has been used for research purposes up to 62.5 ATA (13).
- H. **Laser-Doppler flowmetry (LDF).** It is used for assessment of peripheral microcirculation and is suitable for non-invasive monitoring of skin perfusion under hyperbaric conditions (14, 15).
- I. **Trans-thoracic bioimpedance.** It can be used for non-invasive estimation of cardiac output (CO) and extravascular lung water (ELW). Regardless of doubts arising for accuracy of this method in measurement of cardiac output in haemodynamically unstable patients, it has been validated in hyperbaric environment using the NNCCM3 Bohmed (16, 17, 18).
- J. **Echocardiography and Doppler studies.** It can serve for non-invasive monitoring of haemodynamic status of the patient (19). It can be performed under hyperbaric conditions with any equipment providing that signals from probes are directed outside the chamber through signal ports (20).
- K. **Transcranial Doppler.** The Doppler probe can be placed at the patient in the hyperbaric chamber and signal is transferred by wires to the outside of the chamber. This technique was used up to 4 ATA (8, 21).
- L. **Near infrared spectroscopy (NIRS).** It can be used for measurement of regional oxygenation of tissues. A transcranial regional cerebral oxygenation using INVOS 3100 cerebral oximeter (placed outside the chamber) has been reported to be measured under hyperbaric conditions up to 2.5 ATA with only sensor inside the chamber (22), as well as during pressurization in portable chamber at high altitude (23).
- M. **Spirometry and airway pressure.** Measurement of the airway pressure and the exhaled tidal volume (minute volume) is an absolute minimum set of monitoring of patients ventilation during artificial ventilation under hyperbaric conditions. The mechanical spirometers

are extensively used in hyperbaric chambers due to their simplicity. The electric spirometer Ohmeda 5420 has been used successfully up to 6 ATA (24).

- N. Breathing gas analysis. According to some authors to ensure that patient receives the correct dose of oxygen, breathing gas analysis should be performed continuously during every HBO session (25), with measurement of transcutaneous partial pressure of oxygen being an alternative (26, 27). The oxygen content in the breathing mixture can be measured at any point of the breathing system, including inspiratory line (27), space under mask or hood (25) or expiratory line (25, 28). The expired gas can be analysed for end tidal carbon dioxide partial pressure as a part of monitoring of the patient's ventilation (21). The mainstream determination is subjected to errors due to "pressure broadening effect" produced by the increased density of gas. As a result falsely high values of the patient's $ETCO_2$ are usually reported, which need to be corrected using mathematical equations (29, 30). Alternatively a side-stream analysis can be performed easily and reliably outside the chamber using decompressed expiratory gas. The usage of mass spectrometry for analysis of decompressed gas samples has been reported (31, 32, 33), however due to costly equipment it was mainly used for research purposes.

Invasive monitoring

- A. Blood pressure (BP). Blood pressure can be measured invasively in any blood vessel providing that transducer is placed under the hyperbaric conditions, correctly filled and calibrated (34). Using that method one can measure pressure in the central venous system (CVP), arterial system (ABP) and pulmonary arteries (PAP, PCWP). Regardless the clinical safety of the patient, the careful elimination of all gas bubble, which may collect at the diaphragm, is a must to ensure the stability of the pressure readout.
- B. Cardiac output (CO). Methodology and calculations for the cardiac output measurement by Swan-Ganz catheter using thermodilution is unchanged under hyperbaric conditions (16, 35, 36). The Edwards American Laboratories module for measurement of CO has been used in hyperbaric chamber (16).
- C. Intracranial pressure (ICP). It can be conducted using fluid-filled systems or tip transducer systems. Fluid-filled system is based on a catheter placed in the region of the brain being monitored and transducer located outside the skull similarly to the blood pressure measurement system (34, 37). In the tip transducer system the miniaturised pressure transducer is located just at the site of measurement and only the read-out signal is transferred outside the skull to the monitoring device (eg. via the fibre optic) (34). Whole system for fibre optic measurement of the ICP from Camino Laboratories (San Diego, CA, USA) has been used in hyperbaric chamber (34). Both systems for measurement of ICP can be used safely under hyperbaric conditions providing the general electrical safety for the monitoring device.
- D. Blood gas analysis (ABG). In order to receive the exact results of blood gas analysis it is necessary to measure it inside the hyperbaric chamber, as there are problems with accurate calibration of the blood gas analysers for gas tensions higher than ambient pressure (38). On the other hand, using some calculations, it is possible to get reliable results of normobaric blood gas measurement after decompression of the sample (39). The IL-813 and IL-1306 models (Instrumentation Laboratory Inc., USA) were used in the hyperbaric chamber with no technical problem under pressure of 2 and 3 ATA, respectively (40, 41). Also a portable blood gas analyser (StatPal II, PPG Industries, La Jolla, CA, USA) has been developed to operate under pressure and it has been successfully tested up to 2 ATA (42, 43).
- E. Venous saturation of the blood (SvO_2). It is method used to detect early onset of general or local ischaemia. The catheter equipped with the fiber optic to measure the saturation of the blood *in situ* can be placed in pulmonary artery or vena cava to measure global ischaemia or in jugular or hepatic vein to measure specific organ ischemia. Regardless of the electrical safety of the monitoring device inside the hyperbaric chamber, the main problem which exists with this method is calibration of the system under pressure (44).
- F. Tissue oxygenation. A multi-parameter sensor NeuroTrend (Codman, Johnson&Johnson Professional, Inc., MA, USA) can be used for a direct measurement of tissue oxygenation (45). The probe and a satellite monitor have been adapted for the hyperbaric conditions. It is designed for measurement of brain tissue oxygenation and it has been tested experimentally up to 3 ATA.
- G. Blood glucose level. The blood glucose level can be significantly decreased during the HBO session (46) and therefore its measurement is of critical value. Several models of glucometers using different methods of measurements have been tested under hyperbaric conditions: Chemstrips (47), Glucometer M+, Companion 2, HemoCue, OneTouch II, ExacTect Pen (48), Bayer Glucometer 4 (49). The general conclusion is that measurement of the glucose level is affected in the hyperbaric chamber giving falsely high readouts especially at low glucose levels.

CARDIAC SUPPORT

Defibrillation

Sudden cardiac death commonly results from ventricular tachycardia or fibrillation, and early defibrillation is the single most important determinant of survival for those patients (50). For every minute of sustained cardiac arrest, survival decreases by 10%. Therefore, the possibility to use defibrillation in hyperbaric environment is a logical consequence of treating critically ill patients in hyperbaric chambers. The procedure of defibrillation is inherently dangerous to use in hyperbaric chambers because of the danger of fire caused by electrical discharges and voltaic arc, which may be generated between the paddles. Therefore this procedure is absolutely contraindicated in

the pure oxygen atmosphere of the monoplace chamber (51). On the other hand, in multiplace chamber defibrillation can be performed relatively safely, if several precautions are taken:

1. The chamber is compressed with air and oxygen is kept below 21.5% (52).
2. Large surface adhesive plates are attached to the patient's chest (53, 54). The gel is applied to assure conductive bridge between the skin and the plates, and the area around the plates is kept free from flammable materials (55).
3. Transmission cable of wide diameter and low resistance passes through the chamber wall outside (54).
4. The defibrillator (including switches) is located outside (52, 53, 54, 55).
5. Three persons are needed to perform the operation: 1) medical attendant inside the chamber is responsible for attaching paddles; 2) an external defibrillator's operator is controlling the discharge unit located outside the chamber and 3) chamber operator is ready for immediate activation of water-deluge fire suppression system (52).

The data concerning the use of defibrillation in patients inside the hyperbaric chambers is scarce. The experiments of defibrillation were conducted with swine model of resuscitation in controlled environment up to 6 ATA without any incidents in 270 defibrillations (52, 56). Interestingly, luminous spark were seen in dark environment under the electrode plates during defibrillation with 200 to 360 joules at ambient pressure, while no spark was apparent under hyperbaric conditions, probably due to compression of endogenous gas in the electrode gel (57). When following presented rules the risk of fire is kept on the acceptable low level, so general opinion is that the defibrillation may be performed safely in the multiplace chamber (51, 52). If technically impossible to be conducted under hyperbaric conditions,

defibrillation is performed after emergency surfacing of patient from hyperbaric chamber to outside assuming that preoxygenation with hyperbaric oxygen gives few minutes more before brain death occurs.

External Pacing

Some temporary external pacemakers have been reported to malfunction under hyperbaric conditions (58, 59), some others have been shown to function satisfactorily up to 8.7 ATA (60). Therefore the use of untested external pacemakers should be avoided, and other alternatives should be used in case of need. One is to locate the pacemaker outside the chamber (55) and to transfer wires through the wall similarly to defibrillation described above. The other is to use permanent hermetically sealed pacemaker attached to the patient's temporary external leads (58) or to the catheter based wires.

Implanted Pacemakers

The number of patients with implanted pacemakers (PM) and automatic implanted cardiac defibrillators (AICD) treated inside hyperbaric chambers for other medical reasons is growing.

According to general opinion, internal cardiac pacemakers are unaffected by the hyperbaric environment (61), however – obviously – it can be true only for limited range of pressures. Most implanted devices are rated to at least 2.4 ATA (62, 63), but some authors reports that all pacemakers tested by them were adequate to treatment pressure below 3 ATA, and some even to 7 ATA (64). During the ISO-compatible ETO-standard sterilization process the pressure is up to 2.5 ATA, therefore all devices sterilized by this method are unintentionally tested for such overpressure (65).

Nevertheless, it is highly advisable to constantly monitor ECG of patients with implanted pacemakers and cardiac defibrillators during every HBO session.

The list of PMs and AICDs tested in hyperbaric chamber is presented in the Table 1.

Table 1. Pacemakers and automatic implanted cardiac defibrillators used in multiplace hyperbaric chambers.

Manufacturer	Device	Checking conditions
Biotronik GmbH	PM: All models developed until 1999	2.5 ATA, but not for 6.0 ATA (62, 65, 66)
Biotronik	PM: INOS CLS, INOS plus CLS	6.0 ATA (65, 66)
Biotronik	IS-1-Connector	6.0 ATA (67)
Biotronik	AICD: Phylax AV	6.0 ATA (66)
CPI	Pulse generator and AICD	2.36 ATA; anecdotally more (55)
CPI	PM: model 0503	7.9 ATA (58)
Intermedics	PM: Quantum (254-20), Nova II (281-05), Cornos (282-04), Relay (294-03)	5.78 ATA for 24 h (55)
Intermedics	PM: models 253-02, 259-01	7.9 ATA (58)
Medtronic, USA	PM: Legend TM, Legend II TM, Synergist II TM, Elite TM, Thera I, Prodigy, Eilte II	2.8 ATA (55)
Medtronic, USA	PM models: 5950, 5951, 5985, 5973, 5989	7.9 ATA (58)
Medtronic, Minneapolis, MN, USA	External PM: #5388	8.7 ATA (68)
Osypka		2.5 ATA (as declaration of manufacturer) (65)
Pacesetter	PM: All models developed until 1999	6.8 ATA (55, 65)
Pacesetter	PM: Synchrony III	6.8 ATA (65)
Pacesetter	PM: model Vivelith 5	7.9 ATA (58)

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