European Committee for Hyperbaric Medicine (ECHM)

&

European Underwater Baromedical Society (EUBS)

Joint position statement on the use of 'mild hyperbaric therapies' in humans

Introduction

Exposure of humans in hyperbaric treatment devices (hyperbaric chambers) up to 2.0 bar overpressure (equal to 20 meters depth of water) with the breathing of oxygen is known as hyperbaric oxygen therapy, HBO therapy or HBOT.

Due to tragic accidents with human fatalities in the past, different countries established safety regulations regarding technical and personnel standards for the performance of HBOT during the last decades. Within the European Union hyperbaric chambers are regarded as 'class IIb medical device' according to the Medical Devices Regulation (MDR) and have to meet strict safety standards to prevent harm to patients, caregivers, and third parties.

In the last years, different manufacturers presented new hyperbaric chamber devices using relatively low pressure e. g. up to 0.5 bar overpressure (equal to 5 meters depth in water). These devices are advertised e. g. as 'low-pressure hyperbaric chambers' for so-called 'mild hyperbaric oxygen therapies' or similar. The pressure exposures are claimed to be beneficial for a wide range of effects and wellness purposes.

With the arguments of different applications and low pressure compared to 'classical medical HBOT', some manufacturers claim to offer their chambers as wellness devices and not medical devices – with no need to meet the MDR standards mentioned above.

Looking at the physical principles, hyperbaric oxygen therapy depends a) on the breathing of enhanced oxygen concentrations and b) on the overpressure during the treatment. The combination of these two conditions is responsible for the treatment effects - for positive therapeutical effects as well as for possible side effects, and possible harm to exposed persons due to elevated oxygen pressure or effects of unplanned pressure changes.

In particular, the fire risk of enhanced oxygen concentrations and the barotrauma risk of unplanned pressure changes do not allow the definition of 'safe' thresholds regarding oxygen concentration or pressure in hyperbaric therapies. (4)

This is the basis for the European Committee for Hyperbaric Medicine (ECHM) and European Underwater Baromedical Society (EUBS) to publish this Joint Position Statement.

Statement 1

The administration of ~~a~~ breathing gas in a pressurized chamber, regardless of the construction materials, the pressure used and the concentration of oxygen in the breathing gas, is a medical procedure which carries a certain risk for complications, side effects as well as patient and staff safety issues.

Statement 2

So-called “mild HBOT chambers”, whether they are claimed to be used for the treatment of certain conditions or diseases, or for general claims of enhancing well-being (‘wellness’, ‘to increase energy’, ‘to rejuvenate’, or similar claims), are medical products that must comply with the regulations according to Class IIb Medical devices from the Medical Devices Regulation (Regulation EU 2017/745) of the European Parliament and Council (MDR). (1)(2)

Statement 3

The operating of devices that can be classified as Class IIb medical devices, if those devices have not been presented for evaluation to the Medical Devices Coordination Group (MDCG) (2), may be punishable by Law, according to Art 113 of the MDR.

National Authorities have adopted appropriate legislation to implement this Art 113. ECHM and EUBS urge hyperbaric experts from those countries that have not yet done so, to call upon their respective governments to implement this as soon as possible.

Statement 4

All hyperbaric chambers (multiplace or monoplace) must comply with European Norms EN14931 (European Standard for Multiplace Hyperbaric Chambers) (3) and EN16081 (Hyperbaric Chambers – specific requirements for fire extinguishing systems) (4) or DIN 13256-4 (Pressure vessels for human occupancy - Part 4: One-human pressure vessels for hyperbaric therapy; Safety requirements and testing) (5). Furthermore, the operation of these chambers should comply with the European Code of Good Clinical Practice in HBO therapy (6) (published by ECHM). Staff should be trained according to the ECHM-EDTC Educational and Training Standards for Physicians in Diving and Hyperbaric Medicine (7), and the EBAss-ECHM Resources Manual for hyperbaric technicians, nurses and operators (8).

Statement 5

As a consequence of the requirement to perform a risk-benefit assessment and the identification of possible alternative treatments to achieve the same intended goal, the use of any hyperbaric chamber or therapy should only be proposed for reasonable evidence-based indications. Care providers should have a system in place to monitor possible side effects and assess the efficacy of the treatment (Such obligation is also imposed on the manufacturers of hyperbaric chambers by MDR Annex XIV Part A Section I).

Conclusions

The ECHM and EUBS strongly advise against the use of pressure chambers that do not comply with, or have not been presented for evaluation according to the Medical Devices Regulation of the European Parliament and Council). The use of pressure chambers by any professional medical care provider or in ‘at-home’ settings not compliant with ECHM – EDTC – EBAss guidelines is not compliant with the Medical Devices Regulation and may be punishable by Law in European member states, according to local legislation.

The ECHM and EUBS do not endorse the use of ‘mild hyperbaric (oxygen) therapy’ outside the conditions of safety and indications as set forth by the MDR, the ECHM and EBAss.

The ECHM and EUBS strongly advise against the promotion and use of these devices for unverified claims such as ‘wellness’, ‘enhancing energy’ or the treatment of diseases for which insufficient clinical, peer-reviewed, scientific evidence exists.

Joint position statement issued on **20th December 2022**

On behalf of the EUBS:

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References

1. Medical Devices Regulation (MDR) [long name: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices], from April 5, 2017, valid from May 26, 2021 (link: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745&qid=1659852819647, accessed Dec 19, 2022)

2. Medical Device Coordination Group Document 2021-24 - Guidance on classification of medical devices (MDCG 2021-24) (link: https://health.ec.europa.eu/system/files/2021-10/mdcg_2021-24_en_0.pdf, accessed Dec 19, 2022)

3. EN 14931:2006 - Pressure vessels for human occupancy (PVHO) - Multi-place pressure chamber systems for hyperbaric therapy - Performance, safety requirements and testing (link: https://standards.iteh.ai/catalog/standards/cen/0b144b70-cf06-42e3-b94d-1b09f17ce2f2/en-14931-2006, accessed Dec 19, 2022)

4. EN 16081:2011 - Hyperbaric chambers – Specific requirements for fire extinguishing systems - Performance, installation and testing (link: EN 16081:2011+A1:2013 - Hyperbaric chambers - Specific requirements for fire extinguishing systems - Performance, installation and testing, accessed Dec 19, 2022)

5. DIN 13256-4 (Pressure vessels for human occupancy - Part 4: One-human pressure vessels for hyperbaric therapy; Safety requirements and testing (link: https://www.din.de/en/wdc-beuth:din21:47273966, accessed Dec 19, 2022)

6. ECHM. A European Code of Good Practice for Hyperbaric Oxygen Therapy, Revision 2022 (in press)

7. ECHM-EDTC Educational and training standards for physicians in diving and hyperbaric medicine 2011 (link: http://www.echm.org/documents/ECHM-EDTC%20Educational%20and%20Training%20Standards%20(2011).pdf, accessed Dec 19, 2022)

8. EBAss/ECHM Resources Manual - Education of nurses, operators and technicians in hyperbaric facilities in Europe, 2008 (link: http://www.echm.org/documents/EBAss-ECHM%20Education%20resources%20manual%20-%20Version%202008.pdf, accessed Dec 19, 2022)