Diving Centre’s Hyperbaric Complex Modernization for Medical Recovery and Treatment Throughout Hyperbaric Oxygen Therapy

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Abstract: The main objective of the hereby research-development study is the modernization of the Diving Centre’s hyperbaric complex facilities so as to carry out, in accordance with the current European standards, medical recovery and treatment procedures by means of hyperbaric oxygen therapy (HBOT). The present study proposes setting up a hyperbaric chamber, pleasantly monitored and appropriately equipped, able to completely meet the provisions of the European Standard EN 14931-2006, adopted and confirmed by the Romanian Standardizing Society (ASRO), thus becoming SR EN 14931 of 2006. The research laboratory is presented in this work in order to build a consortium of institutions which are interested in launching a project on structural funds with regard to the compatibility of the hyperbaric complex, available within the base, with its modern HBOT centres established over the last twenty years in the developed states of the contemporary world.

1. Overview
The department of research, training and divers formation (SCAS) presents this work in order to develop a consortium of institutions interested in starting a cooperation with the Diving Center so as to improve the activity of the hyperbaric equipment existing in our unit. The Hyperbaric laboratory was built by the French firm COMEX in collaboration with Romanian specialists, and it can provide, if needed, good medical services of therapy with hyperbaric oxygen.

The theme supposes a monitored hyperbaric chamber able to meet the provisions of the European standard EN 14931-2006, adopted by the method of confirmation of ASRO which became SR EN 14931 of 2006 (Hyperbaric Chambers for Human Use, Hyperbaric Chambers with More Places, for Therapeutic Use, Performance, Safety Requirements, Testing).

The complex will meet hyperbaric made compatible with good performance parameters and missions referred to in this document.

2. Analysis of system requirements
The increased number of possibilities which man have developed to work underwater revealed new physiological and pathological aspects of immersion and life in hyperbaric conditions, which have made us consider that the information contained in this paper is up-to-date, not only in terms of heuristic, but also of medical and engineering practice. Hyperbaric medicine has come a long way, deriving from the history of diving activities, dating back to ancient times.
The history of hyperbaric therapeutics was closely connected with the development of technology and advanced underwater activities with the accumulation of knowledge about the physical and physiological mechanisms of breathing oxygen at pressures greater than atmospheric pressure. The use of hyperbaric oxygen therapy (HBO) has been addressed mainly in France as the practice of hyperbaric medicine on scientific basis. HBO effects on vessels and anaerobic bacteria can be used as a defense against infection and helps heal wounds. The indications for HBO were established more precisely, especially for treatment of chronic diseases, and only for those that have been validated clinically based on the criteria (EBM). During the recent years, the United States have drawn predominant indications for surgery, wound healing, traumatology and plastic surgery, mandibular osteonecrosis, and so on. In Italy, the most commonly used application was in the field of anaesthesia / intensive care. In Spain, within the domain of internal medicine, some specialists have initiated hyperbaric medicine. The indications for HBO were agreed at the ECHM Consensus Conference in Lille in September 1994 and updated 10 years later, also in Lille in December 2004. In order to be considered acceptable, any indication had to be based on experiments and clinical trials conducted with strict methodology and demonstration of significant positive results. The jury has issued recommendations using a three-tier scale of recommendations: Type 1 – recommended with demonstrated certainty, Type 2 - recommended with probable certainty, Type 3 - recommended with optional certainty. Considering the basic missions of the Diving Centre hyperbaric complex, such as treating of diving accidents, carrying out oxygen and narcosis tests, training the divers within a dry and wet environment, as well as the mission covered by the present HBO study, the system will have to meet the following conditions cumulatively:

- the existence of equipment to ensure an optimal environment for the development of specific activities, according to current diving technologies and to divers training and testing programs,
- rigorous monitoring of all technical and medical parameters at the level of life and work,
- monitoring, analyzing, maintaining or regenerating the diving parameters provided within the unitary saturation technology and saturation, through modern equipments that provide:
  - measuring, adjusting and monitoring the following parameters:
    - The concentration of CO₂ in the respiratory gases (ppm);
    - The concentration of O₂ in the respiratory gases;
    - Humidity in the respiratory gases;
    - Pressure (m water column);
    - The temperature of water and air.
- tracking medical parameters: pulse, voltage,
- permanent monitoring of the activities in the Chamber and of the diving activity in the simulator,
- recording and processing the parameters of the hyperbaric environment at the life and work level,
- conditioning the atmosphere within the Chamber,
- rapid analysis of the respiratory mix used during diving and the possibility of changing it as needed,
- meeting the SR EN 14971 requirements regarding the automated fire extinguishing system or the fire extinguishing means which are to be used within hyperbaric environment.

The capabilities limitations of the existing equipment are listed below. These operational limitations are due to:

- the insufficient number of pressure transducers depending on the depth;
- the need for redundant measurements regarding temperature, dew point (humidity), CO₂ and O₂ concentrations. It is also necessary to equip all watertight compartments with independent measurement capability of all physical sizes;
- air conditioning of the hyperbaric areas throughout the diving process (compression – bottom time with life level – decompression);
- the lack of continuous monitoring possibility of essential physiological parameters (pulse, voltage, ppO₂);
- the oral-nasal masks and obsolete spills;
- the fact that there is no data acquisition and recording system;
- the fact that there is no centralized and managed monitoring through software tools;
- the fact that it is necessary to complete the video monitoring system with equipment that should be related to each hyperbaric compartment;
- the need for rigorous gas analysis.

The regulations applied to manufacturers of hyperbaric therapeutic equipment are severe. A hyperbaric therapeutic chamber is considered to be a medical device in accordance with the European Council Directive 93/42 “medical products”.

The design, test and safety requirements of new therapeutic systems must be in accordance with the new European standards EN 14931 CEN TF 127.

All new chambers will be marked with “CE” and those existing should reach the same safety level.

A risk assessment in accordance with the European standards EN 14971 must be carried out before bringing medical equipment into the chamber. To avoid treating a critically ill patient and a chronic outpatient in the same chamber, it is useful to have a series of chambers connected to each other with airlocks. A chamber is kept for emergencies and intensive care and another or others are scheduled for treatments of chronic illness. Ideal for a hyperbaric system would be to have separate compartments with specific equipment to perform the test function of divers, of workers in the hyperbaric environment or HBO patients.

The jury strongly recommends that through the European Code of Good Practice for Hyperbaric Oxygen Therapy (ECGP) minimum requirements should be met by the European hyperbaric centres, as established by consensus among internationally recognized European experts.

3. Main Performances

3.1. Performance Parameters

Operational performance parameters are represented by environmental factors. These are the essential vectors of respirable atmosphere within the hyperbaric chambers.

| No. | Performance parameter                                      | Objective’s Value | Threshold Value | Obs.                          |
|-----|------------------------------------------------------------|-------------------|----------------|-------------------------------|
| 1.  | Pressure measurement precision in hyperbaric compartments | ± 0.15% full scale| ± 0.25% full scale|                               |
| 2.  | Temperature measurement precision                          | 1°C               | 1°C            |                               |
| 3.  | Accuracy of ambient temperature control in stable pressure mode (level). | ± 2°C | ± 2°C | With a precision of ± 2°C |
| 4.  | Value range for water temperature adjustment               | 0°C and 25°C      | 4°C and 25°C   |                               |
| 5.  | Moisture regulation precision                              | ± 5%              | ± 5%           | For the air lock when not using the sanitary group |
### 3.2. Functional Performances

The functional performances are provided by the brief technical environment in which the essential equipment, along with relevant technologies and trained responsible personnel, carry out missions during the planned time with minimal risk of accidents.

### 4. Current technical status. International Trends. The situation at internal level. Comparative analysis of main similar existing achievements.

#### 4.1. Current technical status and international trends

The hyperbaric therapeutic equipment has developed and evolved a lot, being able to meet cumulative requirements for ergonomics, performance and efficiency. Specialized technical and medical training is well regulated and provided by the professional associations, materializing in skills and certifications regarding the exploitation of systems, technologies as well as the provision of specific medical assistance.

#### 4.2. The internally situation

Situated in the centre of Constanta, “S.C. Eurohiperbar S.R.L.” possesses one of the most modern pressure rooms in Europe, equipped with the most modern computerized monitoring systems of treatment and patients at the level of the German therapy standards. The “Hawar Starmed 2200” Chamber has the option of simultaneous treatment of 13 patients plus an attendant or up to 4 stretchers. Each treatment site has separate oxygen supply. The Chamber has the ability to perform hyperbaric treatments up to 50m deep / 6bar (absolute scale), 5bar (relative scale). The creation of the Association of Romanian Hyperbaric Medicine is currently being undertaken at the initiative of the Hyperbaric Medicine Centre in Constanta.

|   | The max. compression and decompression speed in the room and in the air lock is 25 m/min | 25 m/min | 20 m/min |
|---|---------------------------------|----------|----------|
| 6. | max. domain of measurement: 0…100% oxygen; | max. domain of measurement: 0…100% oxygen; |
| 7. | min. domain of measurement: 0…10% oxygen; | min. domain of measurement: 0…10% oxygen; |
|  | measurement precision (general use): ±0,2% oxygen; | measurement precision (general use): ±0,2% oxygen; |
|  | measurement precision (constant environment): ±0,1% oxygen | measurement precision (constant environment): ±0,1% oxygen |
| 8. | area: 0-5.000ppm | area: 0-5.000ppm |
|  | resolution: 1 ppm | resolution: 1 ppm |
|  | precision: ±3% or ±50 ppm | precision: ±3% or ±50 ppm |
| 9. | Monitoring potential of all parameters, independently for each compartment | A set of switchable sensors for a compartment plus the adjacent air lock. |
The present configuration of the Diving Centre’s Hyperbaric Laboratory, which covers the range of missions listed in Chapter 2, namely, treating of those involved in diving accidents, carrying out oxygen and narcosis tests, training the divers in a dry and wet environment, previously regarding unitary and saturation diving activities, comprises: a central hall, a compressor compartment, regeneration assembly and gas storage, a compartment for various groups of power and water supply.

- **The central Hall** contains (see figure 1 and 2): 

The ASS 500 Hyperbaric Complex. This consists of:

- a humid chamber disposed as a symmetry between two identical decompression chambers. The wet chamber is positioned vertically, thus offering the possibility of flooding in the lower half (water column about 3000 mm). The dry side of the room is equipped with standard turret material. The compression and decompression speed in this room is 25 m/min (2.5 bar/min). In the dry part, the adjustment accuracy of the ambient temperature is ± 2°C. This precision is only valid under the constant pressure mode (level). Humidity is not constant. Water can be cooled for diving activities in which warm water suits are used. A refrigeration group allows the water temperature to be set between 0°C and 25°C with an accuracy of ± 2°C. When hot water diving suits are used, raising the water temperature in the Chamber will be around 4°C in one hour and the return time to the starting temperature between 0°C and 25°C will be around 4 hours. This data is calculated for 2 divers. The detachable bridging, between the wet and dry side allows only dry use when required. Permanent communications are possible between the divers from the dry side, the wet one and the assisted personnel due to an intercom system with a decoder. Visualization can be done through portholes or through the permanently functioning TV system.

- the decompression chambers. These are two chambers that allow for two separate dive programs. Each room has two parts: an enclosure with sanitary equipment (outer lock or toilet and shower room) and a chamber (room) for 4 divers. The maximum compression and decompression speed in the room and in the enclosure is 25 m/min. The accuracy of ambient temperature control is 1°C. This precision is only valid under a constant pressure regime (level). The accuracy of humidity adjustment is ±5%. This precision will not be met in the enclosure when using the sanitary group. Permanent communications are possible between divers and support staff due to an intercom system with a decoder. Visualization is done either through portholes or through a permanently functioning TV system.

- free climbing room. It is a vertical chamber, usually of 2300 mm in diameter and height, placed under the wet chamber. This room allows submarine staff training in the “free ascent” rescue technique. Training is done at simulated depths between 0 and 200 m. For pressure value convergence, the chamber is designed to allow homogeneity with other chambers in case of a different use (wet side to wet chamber extension, hydraulic tests of some equipment, etc.). The “free ascent” procedure is as follows: The wet room is half filled with water, and pressurized with air between 0 and 200 m meters. The training staff enters the “free ascent” room through the side gate. The room is filled with water. The staff breathes in the gas volume at the top of the room. This is rapidly pressurized at the pressure of the wet room. At the pressure equalization, the lower access door in the wet room is opened and the personnel climb to the top of the wet room that is immediately decompressed to simulate the surface climb. The compression speed of this room is 250m/min (25 bar/min) when free climbing. Water can be cooled if the wet room extension is used. Visualization is done through portholes and a permanently functioning TV system.
**Figure 1.** The Hyperbaric Complex

(consisting of 2 Decompression Chambers (Inner Lock), 2 vertical Simulation Rooms - one for diving training & one for the training of the people working on submarine, Medical Lock, Porter etc.)

*The control panel:*
- a four-section gas control panel, each section being the responsibility of a compartment, with pressure gauges and valves that allow compression and decompression management;
- a control panel for electrical circuits, communications, television;
- an analysis panel.

**Figure 2.** The Hyperbaric Complex. Side View

**Figure 3.** Gas storage racks
The gas conditioning and storage compartment (see figure 3) contains:

*Regeneration and storage of gases:*
- racks or spheres for gas storage;
- regeneration units (soda lime, silica gel, reheater) to keep CO₂, humidity and temperature of the gas in the room at a certain level.

*Compressor room:*
- 1 compressor for gas transfer;
- 1 O₂ compressor;
- 1 vacuum pump (to remove the air from the Chamber before the He pressurization);
- flexible storage tank;
- a panel that allows distribution and control of the mixtures.

The compartment for different groups of electricity and water supply contains:

*Boiler* (for warm water diving suits). It is used to heat water (up to 40°C) in warm water diving suits, and the circulation is carried out via a pressure changer (50 bar).

*The cold group.* It allows water to be held in the simulation room between 0°C and 25°C when divers use warm water suits (water heating will be of 4°C in one hour for 2 divers).

*Boiler* (room heating). Each decompression room is heated by an individual electric boiler.

*The water circulation pump in the rooms.*

*The emergency generator.* It is an automatic generator of at least 40 KVA, which will automatically be switched on when electricity is disconnected from the national grid.

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5 Case study

We will further explore the current configuration of the system Pressure chamber ASS 500 Center divers in terms of compliance with SR EN 14931: 2006.

After the analysis that laid the foundation of the current R & D study, numerous conformities have been identified and the technical limitations of the pressure chamber owned by the hiperbar laboratory system are being presented, according to SR EN 14931 standard (annex 2). This standards applicable field is: hyperbaric chamber for general human use, hyperbaric chamber with several therapeutic uses and performance analysis, security requirements and testing mode of said requirements SR EN 14931:2006.

Identified Shortcomings

Presentation of the non-conformities according to the standard SR EN 14931:2006:

- the materials inside must be antistatic according to EN ISO 6941 or similar;
- the materials inside must be hardly combustible according to EN ISO 6941 or similar;
- each compartment must be equipped with fire extinguishing materials (ISO standard was developed after the adoption of this) or a special extinguishers pressure chamber;
- the existence on the outside of the pressure chamber of a breathable sources of air;
- control manometer of the inside pressure with 1% precision on the entire measuring scale;
• posting the no flammable or non-approved materials signs in visible spots ;
• an independent emergency illumination system from the main system with a illumination capacity of min. 90 lx,
• the inside electrical installation can not go over 42 V, fitted with a safety system;
• the existence of a calibrated safety decompression system allowing decompression of 2 bar. to Ambient in max. 2 min.;
• compressed air purity according to STANAG 1458. The existence ballots analysis.
• conditioning system inside the hyperbaric atmosphere.
• monitoring and analysis data storage system with the possibility of analyzing at the last 3 h;
• visual and audible alarm system for when the O₂ % is exceeded inside the pressure chamber;
• at least two timers;
• additional power supply, source type UPS monitoring equipment.

As presented above, cutting-edge achievements do not reflect changes regarding the basic principles or structure. Built on a different scale, the systems retained the same functional framework. The hereby study elaborated by the Centre’s specialists presents also the theoretical training module for the specialized technical and medical personnel.

6. System / cost efficiency analysis. Comparison of possible solutions, conclusions on their efficiency and economy.

From the analysis carried out on the types of versions, it was established that the principle of efficiency and the technical-economic principle are optimized by using the II nd version above-studied.

7. Conclusions, proposals

The ASS 500 hyperbaric assembly provided by the Diving Centre is technically and constructively compliant with the SR EN 14931: 2006 standard which accounts for 90% of the endowment conditions necessary for its use according to the designation for which it was intended, in a safe mode.

Considering the fact that the Diving Centre, through the hyperbaric laboratory, broadly owns the necessary infrastructure for putting this kind of therapy into practice, it clearly shows it’s potential to become one of the oxygen-specific areal entities.

In conclusion the idea of modernization revolves around “common sense” interventions.

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