MARCHE ABRUZZO UMBRIA
CENTRO IPERBARICO MAU
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PUBLIC SERVICE CHARTER

Dear Customer,

I am pleased to present the Public Service Charter of the OTI M.A.U. Srl Hyperbaric Center of Porto Sant'Elpidio (FM).

We will hereby provide you with the information necessary for the knowledge of hyperbaric medicine and our structure, so that we can offer you a quality service aimed at a conscious and advantageous ability to use it.

Kind regards,

The Head of Hyperbaric Medicine

Dr. Edoardo Stagni

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INTRODUCTION

This Public Service Charter is a guide containing useful information for users who will use the OTI MAU facility as Customers and for Doctors who will send patients for hyperbaric treatments. The Charter clearly defines the technical aspects and organizational procedures, with the aim of promoting information and participation of customers. The aim is to activate forms of collaboration that tend to improve the quality of service and contribute to the knowledge of hyperbaric medicine. Finally, it gives information on the organization of the structure, the services, the types of therapies and their main indications, the professional figures operating and their tasks.

MISSION E VISION

Ethics is the foundation of the Centre's activity in the organization of the service, in the performance of services, in relations with patients and suppliers. The organization safeguards the dignity and privacy of people to create the best collaboration between the Center and the Patient and favoring the expectations and needs of the Patient himself.

The structure aims to provide a hyperbaric oxygen therapy service that can be used by everyone and especially by patients belonging to the Marche-Umbria-Abruzzo basin, from which the name MAU derives, with services carried out respecting the best standards of professionalism, safety and completeness: in this way it contributes to producing the best performance and optimizing the results for the exclusive benefit of Pazientand.

NOTES ON OXYGEN HYPERBARIC THERAPY

WHAT IS IT:

Bloodless administration of pure oxygen, which takes place inside special environments, the Hyperbaric Chambers, which are brought to a pressure higher than the atmospheric one by pressurization with compressed air, while the patient, inside, breathes pure oxygen, in a closed circuit, through masks, endotracheal tubes or helmets.

HOW IT WORKS:

In breathing in air, at atmospheric pressure, 98.5% of oxygen is transported by red blood cells, in the

which is present the hemoglobin with which the oxygen binds; therefore the presence of intact blood vessels, where the red blood cells pass, is necessary to facilitate the arrival of oxygen to the tissues. Exposure to high oxygen pressures results in an increase in the amount of oxygen transported in solution in the plasma and available for tissue respiration. At pressures between 2 and 3 ATA the amount of Oxygen transported, in this form, to the tissues can be even 15 times higher than normal, until it can fully satisfy the tissue needs. (ATA is the unit of measurement for gas pressure 1 ATA = 1 Absolute atmosphere. – The pressure gauges of the hyperbaric chambers are in meters of seawater; about 10 meters of water are equivalent to a pressure of 1 ATA, therefore 1.5 ATA correspond to 15 meters) .

WHAT IS IT FOR:

This increase in Oxygen, dissolved in physical form, in plasma involves the possibility of restoring oxygenation in areas where blood vessels are deficient or damaged and therefore hypoxic or hypoperfused areas, involves the resumption of oxygen-dependent tissue functions, the possibility of counteracting toxic effects that have implied tissue hypoxia. In addition to these effects, Hyperbaric Oxygen exerts a direct and indirect antibacterial action, has a vasoconstriction action with reduction of post-traumatic or post-surgical edema; has a stimulating effect on vascular neoformation.

HISTORY

For the first time used in therapy by Henshaw in 1662 for medical purposes, OTI (Hyperbaric Oxygen Therapy) was much later employed by Junot (1834) as "compressed air baths" in many European cities as a panacea for many infections.

In 1837 Pravez built, for that time, the largest hyperbaric chamber to treat many pathologies. However, only with studies of physics and physiology (Bert 1868; Haldane 1895; Cunningham 1921-28), you will begin to understand the beneficial and toxic effect of oxygen and this will pave the way for underwater activities. The alternating events of the OTI will arrive, however, with the studies of Boerema (1960) on clostridia infections, to safe results and will direct to the use of hyperbaric oxygen also in medical practice. If OTI was an evolution of Hyperbaric Therapy, originally used to treat decompression sickness (MDD), today it represents a medical therapy used worldwide. The possibility of being able to use it to treat different diseases, according to precise indications and strict protocols of use, make it a safe therapy and able to guarantee clinical results that are sometimes unthinkable.

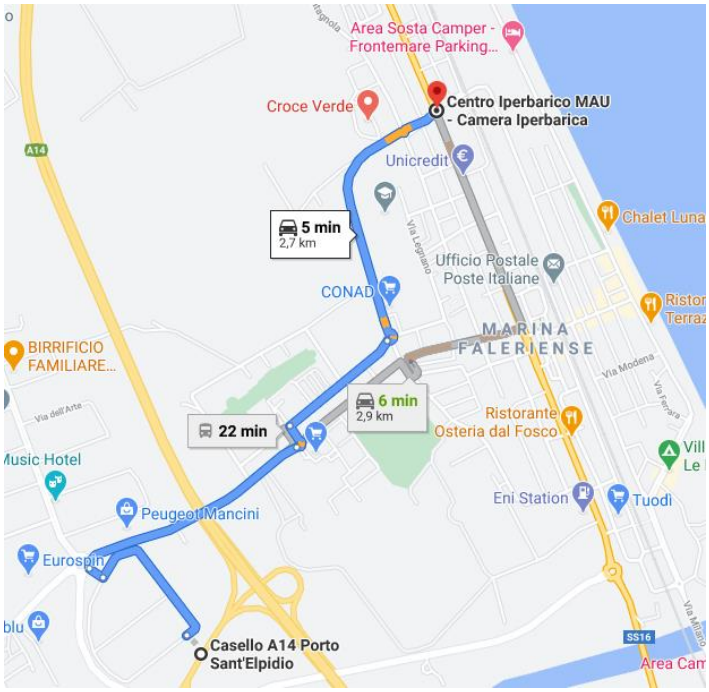
STRUCTURE AND ORGANIZATION

OTI MAU

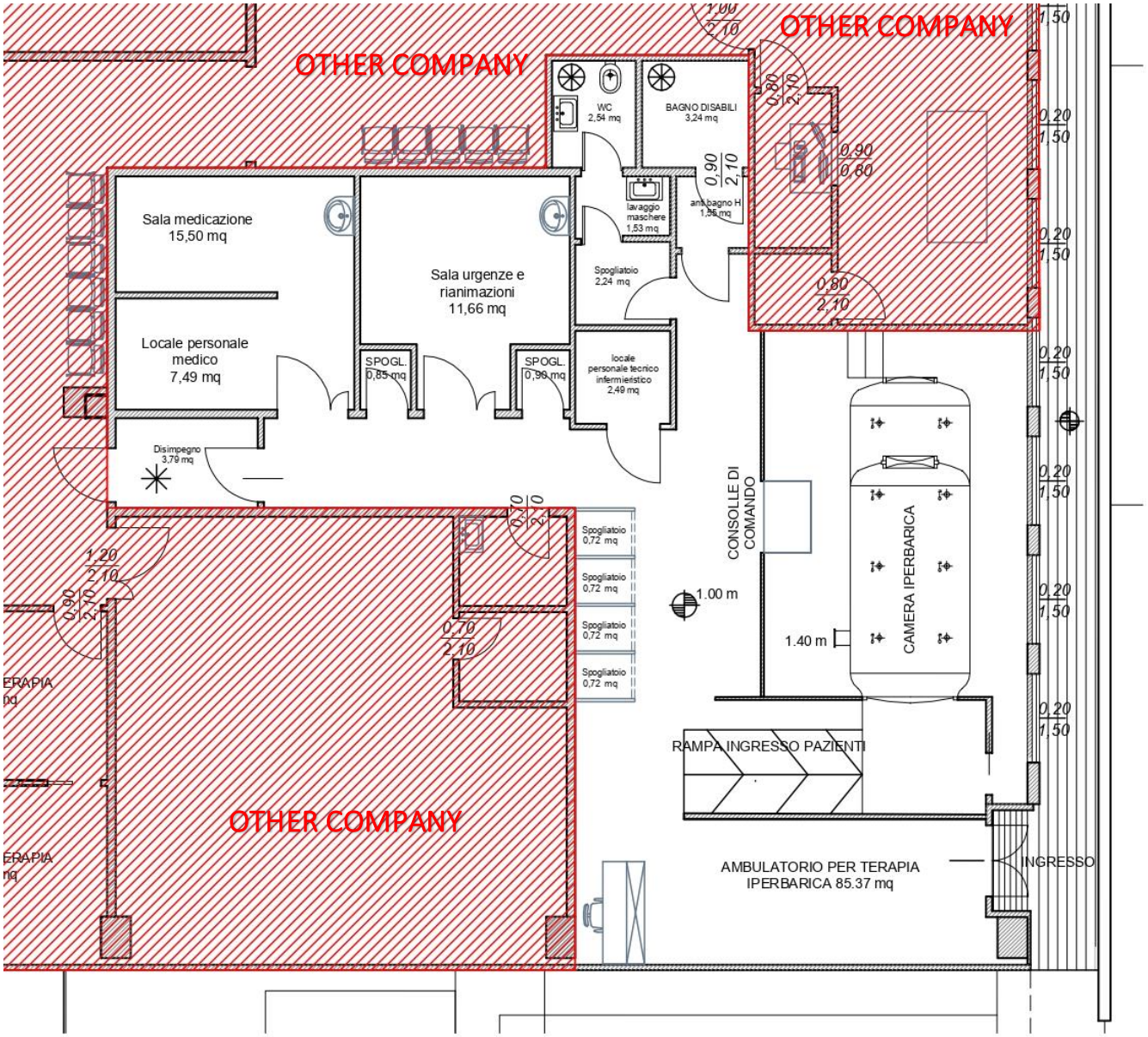
The structure, recently built, is located in Via Mazzini 12 in Porto Sant'Elpidio, just 5 minutes from the A14 Porto Sant'Elpidio exit and 2 minutes from the train station and is thereforeeasily accessible from the entire urban agglomeration.

It has a large parking lot in front and an internal one on the lower floor. Near the entrance there are parking spaces reserved for the disabled and emergency vehicles connected to the entrance by aslide for the disabled. The entire structure is air-conditioned and has automatic ventilation systems to maintain a correct and constant air recirculation. It is carried out thanks to a modern technology through ozone the disinfection of all environments.

Adjacent to our headquarters there is the La Fenice center with which we collaborate for all the services of diagnostic examinations, physiotherapy and specialist visits.

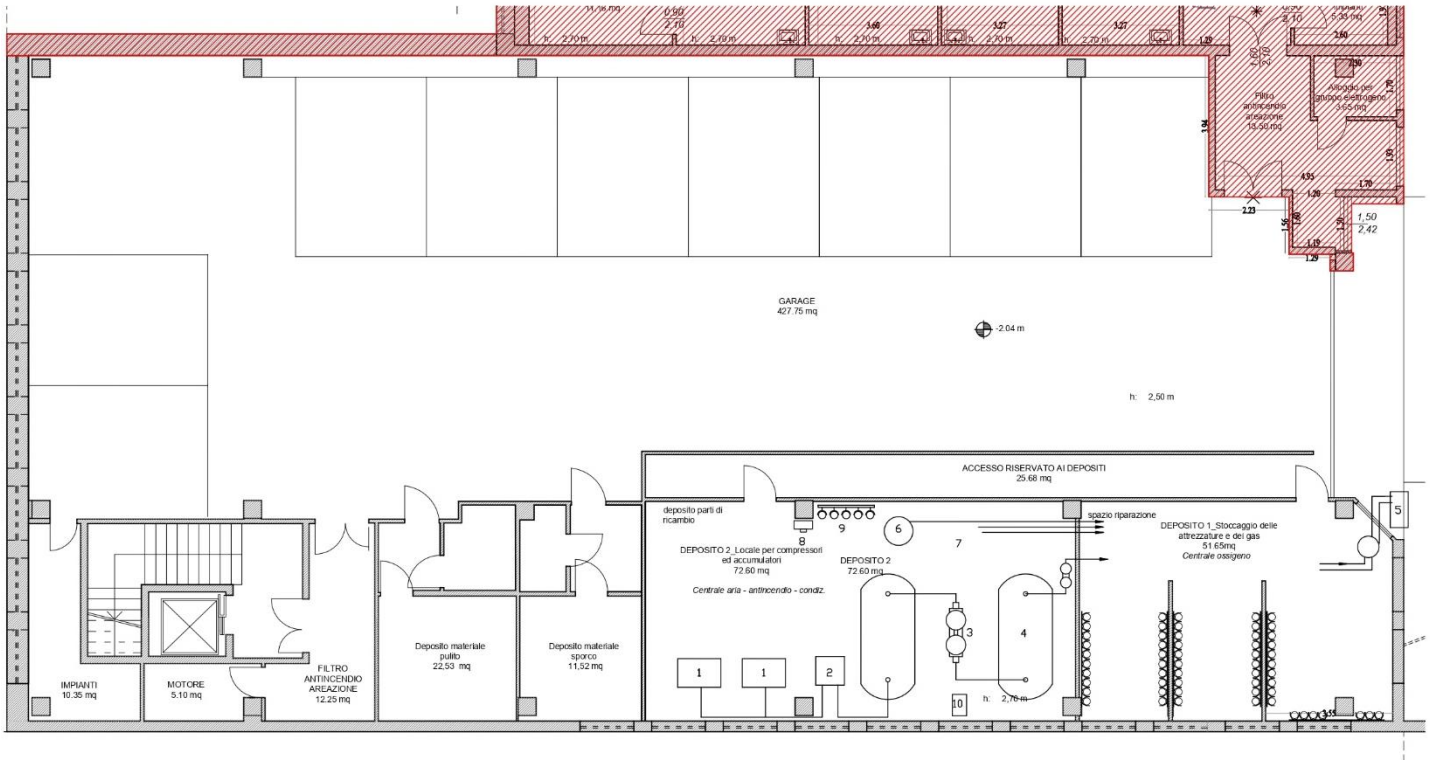


Below is the plan of the structure



GROUND FLOOR OTI MAU srl

DEPOSIT AREA



BASEMENTOTI MAU srl

DESCRIPTION OF THE HYPERBARIC CHAMBER

The hyperbaric chamber is a metal cylinder divided into two compartments where several users and a sanitary ware can take place at the same time.

The largest compartment, called "treatment chamber" is equipped with individual seats inside (the use of padding is not possible due to the rules imposed by the bodies responsible for the prevention and safety of the system), it is also equipped with circuits for breathing Oxygen according to the needs of the user.

The smaller compartment or "transfer chamber", also equipped with two individual seats and respiratory circuits, allows healthcare personnel or patients to enter or leave while therapy is in progress.

The hyperbaric chamber is put into operation via a control panel. The specializedtechnician is responsible for maneuvering and surveillance through special electronic instruments of control and audio/video communication with the inside of the chamber.

Inside the hyperbaric chamber, the pressure is increased relative to the outside with the introduction of compressed air.

The patient feels this difference in pressure only because he has to compensate for it at the level of the eardrums.

The hyperbaric chamber is equipped with all the control and safety mechanisms provided, perfectly efficient and periodically verified, such as to guarantee maximum safety during hyperbaric treatment. In case of need it is always possible for the staff to quickly enter and exit the hyperbaric chamber during the therapy, as well as the patient, who for particular reasons should require the interruption of the session (illness, pain in the ears, etc.), can be accompanied at any time outside within a few minutes.

OPENING HOURS AND BOOKING

The Centro OTI MAU s.r.l. is open from Monday to Friday from 08:30 am to 01:00 pm and from 2:30 pm to 6:30 pm. In case the hyperbaric chamber sessions take place during the lunch break, the structure will remain open continuously.

Reservations can be made:

1. By writing an email to info@centroiperbaricomau.it;
2. By calling 0734 904715;
3. By sending a booking request through our website www.centroiperbaricomau.it in the "info and reservations" section;

- Showing up in our structure during opening hours.

WAITING TIMES

One of our goals is to provide a service as quickly as possible so that the patient is put in a position to start therapy within 2-5 days of the suitability visit. Below, an indicative table of the average waiting times distinguished by service.

SERVICE PROVIDED	WAITING TIME
Provide the information necessary for access to hyperbaric oxygen therapy	1 h
Booking of fitness visit for OTI (if in possession of chest X-ray and ECG)	1-2 days
Dressing difficult wounds	7 days
Start of hyperbaric oxygen therapy cycle	1-4 days from the eligibility visit

RESPECT AND PROTECTION OF PRIVACY

The Center is committed to respecting privacy both from a structural point of view and for the collection, dissemination and storage of personal and sensitive data. All data are processed in compliance with current laws.

REPORTS AND COMPLAINTS

Any reports or complaints about inefficiencies that arose before, during and after the performance of the service, must be forwarded to the Quality Management Manager in a non-anonymous manner, using the appropriate forms available for acceptance. The Quality Management Manager together with the Management after having made the appropriate investigations, will respond to the patient within 5 days of receipt of the report. The Reports and Complaints Form is attached to this Service Charter.

PATIENT SATISFACTION SURVEYS

On a quarterly basis, the Quality Manager will analyze the answers to the questionnaires made by users, forwarding them to the Management which will provide for the solution of any sources of inefficiencies and dissatisfactions. The patient satisfaction questionnaire is attached to the presentand Service Charter and once completed must be delivered in acceptance.

PROFESSIONALS

The professional figures of reference are:

- MEDICAL DIRECTOR: Dr. Edoardo Stagni;
- MEDICAL MANAGER OF THE SERVICE: Dr. Edoardo Stagni;
- CONSULTANT FOR HYPERBARIC ACTIVITY IN URGENCY: Dr. Arturo Foca;
- HYPERBARIC DOCTORS: Dr. Edoardo Stagni, Dr. Arturo Foca;
- HEALTH PERSONNEL: Dr. Edoardo Stagni; Dr. Arturo Foca, Inf. Sara Ilari
- HYPERBARIC TECHNICIANS: personnel responsible for the management and maintenance of the hyperbaric plant, Paolo Mecozzi and Roberto Festa;
- PROFESSIONAL NURSES: staff who actively collaborate with doctors and other operators for the best protection of the quality of patients' health, Sara Ilari;
- ADMINISTRATIVE AND SECRETARIAL STAFF: staff who carry out the activities of office administration, acceptance, switchboard operator, provide information and deal with billing practices, Silvia Carletti.

TREATABLE PATHOLOGIES

Hyperoxygenation stimulates, strengthens and regenerates the ability of our body to react and heal from trauma and certain types of diseases. All this has a beneficial effect on the body such as accelerating the healing of skin wounds, burns or trauma wounds. In some situations breathing it at a very high concentration saves life and hyperbaric therapy, or the administration of pure oxygen at a pressure greater than that of the atmosphere, is an effective treatment in many diseases. Here is the complete list of pathologies with a brief description of its features and how hyperbaric therapy can improve the situation.

FIBROMYALGIA

Syndrome characterized by widespread muscle pain and stiffness, often associated with headache, asthenia, mood and sleep disorders. Recent studies confirm that this pathology is caused by the alteration of neurotransmitters that by sending wrong signals cause a continuous contraction of the muscles causing pain and stiffness. The high concentration of oxygen on the brain induces neuroplasticity phenomena and at the same time acts at the level of glial cells, reducing the hyperactivity of some regions and causing a decrease in pain.

Protocol: 2.2 –2.5 ATA [(12 mca, 223 kPa) -(15 mca; 253 kPa)] for at least 60 minutes (60') total of O2 at altitude, for 40 treatments.

Bibliography

Efrati S, Golan H, Bechor Y, Faran Y, Shir D T, Sekler G, Fishlev G, Ablin J N, Bergan J, Volkov O, Friedman M, Eshel BJ, Buskila D. *"Hyperbaric Oxygen Therapy Can Diminish Fibromyalgia Syndrome – Prospective Clinical Trial"*, 2015 (https://doi.org/10.1371/journal.pone.0127012)

BONE FRACTURES AT RISK – CRUSHING INJURIES AND COMPARTMENT SYNDROME

The first pathological condition contemplates all closed fractures of bones with terminal vascularization and exposed fractures in all other bones. In the first case the risk is that of aseptic osteonecrosis in fractures of the head and neck of the femur, the head of the humerus and the astragalus. Exposed fractures may result in septic complications or pseudoarthrosis.

In this type of fractures at risk, Hyperbaric Oxygen Therapy has an antibacterial action, stimulating fibroblastic repair and osteoblastic pposition, maintaining an optimal partial oxygen pressure and accelerating calcification.

Crushing lesions cause acute traumatic ischemia with necrosis of soft tissues and bone with more or less extensive areas of hypoxia that occurs when, following severe district trauma, there is an association of vascular damage and compartment syndrome.

The application of Hyperbaric Oxygen Therapy the more timely it is and the better the results will be that in a situation of compartmental suffering, increasing the partial pressure of tissue oxygen, manages to reduce vasogenic edema and to demarcate the vital areas from the non-viable ones, stimulating the macrophage reparative mechanism.

Protocol: pressure: ≥ 2.4 ATA (14 mca; 243 kPa), in the first 5-6 days in case of severe soft tissue suffering a bi-daily frequency is advisable. DURATION: 10-12 treatments with subsequent verification.

Bibliography

De Iaco G, Infascelli R M, Nasole E, Zanon V. *"SIMSI Guidelines (Italian Society of Underwater and Hyperbaric Medicine) on the indications to hyperbaric oxygen therapy"*, 2nd ed., 2015.

GANGRENE AND SKIN ULCERS IN DIABETIC PATIENT (DIABETIC FOOT)

One of the most serious complications caused by Diabetes is undoubtedly for severity the Gangrene and Skin Ulcer of the foot, called diabetic foot, caused by a macroangiopathy in the lower limbs. In high percentage, unfortunately, greater amputation must be used.

Hyperbaric Oxygen Therapy, by stimulating angiogenesis, is able to revascularize the ischemic tissues and demarcate the necrotic tissue from the ischemic one. In many studies carried out it appears that Hyperbaric Oxygen Therapy reduces the percentage of major amputations in people who have chronic ulcers as a result of diabetes.

Protocol: PRESSURE: 2.4 (14 mca; 243 kPa) 2.5 ATA (15 mca; 253 kPa) DURATION: at least 60 minutes (60') total of O2 at altitude, for 30-40 treatments.

Bibliography

De Iaco G, Infascelli R M, Nasole E, Zanon V. *"SIMSI Guidelines (Italian Society of Underwater and Hyperbaric Medicine) on the indications to hyperbaric oxygen therapy"*, 2nd ed., 2015.

SEVERE ISCHEMIC CONDITIONS OF ORGANS AND SYSTEMS

Ischemia is the interruption of blood flow to an organ, the consequences of which are the immediate deficiency of the elements indispensable for cellular metabolism (oxygen and glucose) to keep it alive, impossibility of eliminating waste substances, which will therefore tend to accumulate dangerously. The duration of ischemia determines the severity of the damage to the affected organ or tissue causing up to necrosis of the affected cells.

Hyperbaric Oxygen Therapy initiates the important process of angiogenesis in the tissues affected by the ischemic process, thanks to the production of stem cells and other adjuvant factors in this process of tissue repair and new vascularization.

Protocol: PRESSURE: 2.4 -2.5 ATA [(14 mca, 243 kPa) -(15 mca; 253 kPa)]; for at least 60 total minutes of O2 at high altitude, for 10-12 treatments.

Bibliography

De Iaco G, Infascelli R M, Nasole E, Zanon V. *"SIMSI Guidelines (Italian Society of Underwater and Hyperbaric Medicine) on the indications to hyperbaric oxygen therapy"*, 2nd ed., 2015.

SKIN GRAFTS AND FLAPS AT RISK

Skin grafts and musculocutaneous flaps in which a decrease in microcirculation has begun and a condition of hypoxia is establishing.

Hyperbaric Oxygen Therapy promotes angiogenesis with neoformation and stimulation of the microcirculation of the site receiving the graft or flap.

Protocol: PRESSURE: 2.4 -2.5 ATA [(14 mca, 243 kPa) -(15 mca; 253 kPa)]; for at least 60 minutes (60') total of O2 at altitude, for 5-10 treatments.

Bibliography

De Iaco G, Infascelli R M, Nasole E, Zanon V. *"SIMSI Guidelines (Italian Society of Underwater and Hyperbaric Medicine) on the indications to hyperbaric oxygen therapy"*, 2nd ed., 2015.

CARBON MONOXIDE POISONING

Exposure to Carbon Monoxide with inhalation, which involves the manifestation of a variable symptomatology (depending on the time of exposure and the concentration of gas in the respiratory mixture) that starts from nausea and vomiting and arrives at important neurological symptoms such as loss of consciousness, coma and death.
Shortening of the half-life of COHb, restoration of aerobic cellular metabolism.

Inclusion criteria and STATE OF SEVERITY

Patients **Grade 1** with COHb> 25% should be treated. Exception for pregnant patients who still need to be treated. For patients belonging to grade 1 with only headache and COHb<25%, and patients belonging to **grade 2** there is no specific indication for hyperbaric treatment, it is however advisable to evaluate each individual case, possibly after consultation with a hyperbaric center manager. Patients belonging to **grades 3-4** should always be treated.

Severity staging

1	Asymptomatic patient or with headache alone.
2	Patient with headache, dizziness, nausea, vomiting.
3	Patient may present mental confusion, slow ideation, blurred vision, weakness, ataxia, behavioral abnormalities, shallow breathing, dyspnea, tachypnea, tachycardia.
4	Patient with sleep, dullness of the sensory, previous loss of consciousness, state of coma, convulsions, syncope, disorientation, changes in brain CT or MRI, hypotension, chest pain, palpitations, arrhythmias, signs of ischemia on the ECG, pulmonary edema, decompensated metabolic acidosis, rhabdomyolysis, flittene.

Clinical Considerations (Outcome Assessment/Follow-up/Monitoring)

Keep in mind, where there are margins of exposure to possible Post-Interval Syndrome, the probability of having to carry out a subsequent re-evaluation of the case, with neurological examination and psycho-aptitude tests (to be programmed, in the case, about 30 days from intoxication). RmN, if any.

Protocol: The therapeutic times are variable but the pressure must be between 1.9 (9 mca; 193 kPa) and 2.8 ATA (18 mca; 284 kPa) (maximum in the first sessions). It is not considered useful to continue therapy beyond the fifth session.

Bibliography

De Iaco G, Infascelli R M, Nasole E, Zanon V. *"SIMSI Guidelines (Italian Society of Underwater and Hyperbaric Medicine) on the indications to hyperbaric oxygen therapy"*, 2nd ed., 2015.

SUDDEN HEARING LOSS OR DEAFNESS

Hearing loss is the decrease in hearing ability for any cause. Sudden deafness is a total loss of hearing of a total perceptual type that arises suddenly and usually affects only one ear. The causes can be different, including viral infections of the cochlea and the auditory nerve and of vascular origin due to ischemia of the cochlear vessels.

Hyperbaric Oxygen Therapy thanks to the high concentration of oxygen that reaches the liquids of the inner ear is able to stimulate the metabolism of cochlear and vestibular cells and performs an anti-edema and anti-inflammatory action.

Protocol: 2.2 –2.5 ATA [(12 mca; 223 kPa) -(15 mca; 253 kPa)] for at least 60 minutes (60') total of O2 at altitude, for 10-15 treatments.

Bibliography

De Iaco G, Infascelli R M, Nasole E, Zanon V. *"SIMSI Guidelines (Italian Society of Underwater and Hyperbaric Medicine) on the indications to hyperbaric oxygen therapy"*, 2nd ed., 2015.

POST-ACTINIC TISSUE LESIONS (RADIOTHERAPY)

Injuries to soft tissues or bones after radiation therapy. The most frequent clinical pictures are torpid skin ulcer, osteoradionecrosis of the jaw or other bone segments, enteritis, proctitis and post-actinic cystitis. In fact, radiation determines a situation of reduced vascularization, reduced cellular activity, tissue hypoxia, arrest of local reparative processes. Such pathological pictures can lead to amputation of limbs, demolition of the jaw, prosthetics of a joint and severe interventions on the bladder and intestines of the patient.

The angiogenic effect of hyperbaric therapy synergistically with the reparative stimulus and antibacterial activity, makes Hyperbaric Oxygen Therapy a very important indication for treatment in pathologies caused by radiation therapy.

Protocol: PRESSURE: 2.4 (14 mca; 243 kPa) –2.5 ATA (15 mca; 253 kPa); DURATION: Cycle of 40 -60 treatments, in cases of osteoradionecrosis of the jaw, radionecrotic ulcer, or post-actinic enteritis and cystitis; the cycle is reduced to 20 total treatments when it comes to preventive therapy, in the planned dental extraction in the patient with osteoradionecrosis in the irradiated jaw (in this case the sessions are distributed in a pre- and post-conditioning with OTI: 10 treatments before dental avulsion and 10 after the same).

Bibliography

De Iaco G, Infascelli R M, Nasole E, Zanon V. *"SIMSI Guidelines (Italian Society of Underwater and Hyperbaric Medicine) on the indications to hyperbaric oxygen therapy"*, 2nd ed., 2015.

DECOMPRESSION SICKNESS AND ARTERIAL GAS EMBOLISM

Decompression sickness or DCS is a syndrome with different clinical manifestations and different evolutions caused by the patient's transition from a relatively high pressure environment to a relatively low pressure. Such a reduction in pressure leads the inert gas that is in physical form in the tissues and vessels, to enter the gas phase: this can lead to an excessive formation of gas bubbles in the tissues, arteries and veins.

Arterial gas embolism is the accidental consequence of a medical procedure, which involved the penetration of gases into the circulation and can be classified into:

- venous embolism: when the point of penetration of the gas is located upstream of the pulmonary filter;
- arterial embolism: when the point of penetration of the gas is located downstream of the pulmonary filter;

• mixed embolism: crossed or paradoxical, when the embolus, generated in the venous circulation, manages to pass into the arterial circulation.

Protocol: The most serious accidents are treated with hyperoxygenated tables with moderate pressure (Table 6 US Navy) or high pressure (Comex CX30). Less serious accidents or painful forms can be treated with pure oxygen tables (Tab. 5 or 6 US Navy). The treatment protocol following the initial recompression (consolidation therapy) should provide for a maximum duration of 10 OTI sessions or continuation until stabilization of the clinical picture.

Bibliography

De Iaco G, Infascelli R M, Nasole E, Zanon V. *"SIMSI Guidelines (Italian Society of Underwater and Hyperbaric Medicine) on the indications to hyperbaric oxygen therapy"*, 2nd ed., 2015.

MÉNIÈRE'S DISEASE

Oto-vestibular syndrome characterized by: perceptual hearing loss (mainly unilateral), fluctuating and progressive, tinnitus or feeling of "fullness", subjective dizziness, with / without neurovegetative syndrome (duration from 20 minutes to a few hours; consists of recurrent vertiginous episodes, not loss of consciousness).

Protocol: PRESSURE: 2.5 ATA (15 mca; 253kPa), with masked breathing (FiO2 = 1) for a total of 80 minutes (80') of O2 at altitude; also in this case O2in mask is made to breathe also in the ascent from 2.5 ATA until the end of the session, here fixed at 1.3 ATA (3 mca, 132kPa). A single break in ambient air, at treatment altitude, lasting 5 minutes (5'). Pressurization/depressurization times: 1 meter in 40 seconds (i.e. 3 mca in 2 minutes). ---During the session, three 'jumps' are made from 2.5 ATA to 1.9 ATA (9 mca; 193kPa) with doubling in the speed of time taken in depressurization and subsequent repressurization (6 mca in 2 minutes). DURATION: 1st Cycle, 5 weekly sessions for 3 weeks (15 sessions); at the end of the first cycle stop of 30 days (tonal audiometric control examination and vestibular tests).

Bibliography

De Iaco G, Infascelli R M, Nasole E, Zanon V. *"SIMSI Guidelines (Italian Society of Underwater and Hyperbaric Medicine) on the indications to hyperbaric oxygen therapy"*, 2nd ed., 2015.

ASEPTIC BONE NECROSIS

Aseptic bone necrosis is a disease characterized by the resorption of the secondary bone structure due to a drastic reduction in oxygen supply. It mainly affects men aged 20 to 60 years. The most affected bones are those belonging to the joints of the hip, knee, shoulder,

ankle and the small bones of the hands and feet. The most frequent bone necrosis concerns the femoral head and femoral condyles.

Hyperbaric Oxygen Therapy represents for this pathology an important therapy to stop the process, supporting the osteogenesis necessary to replace the necrotic tissue in consideration that for the metabolism of both osteoclasts and osteoblasts a large amount of oxygen is indispensable. Therapy is implemented in the early stages of the disease, in which the joint retains its anatomical integrity.

Protocol: PRESSURE: 2.2 (12 mca; 223 kPa) 2. 5 ATA (15 mca; 253 kPa) DURATION: at least 60 minutes (60') total of O2 at altitude, for 60-90 treatments.

Bibliography

De Iaco G, Infascelli R M, Nasole E, Zanon V. *"SIMSI Guidelines (Italian Society of Underwater and Hyperbaric Medicine) on the indications to hyperbaric oxygen therapy"*, 2nd ed., 2015.

REFRACTORY CHRONIC OSTEOMYELITIS

Persistent bone infection caused by one or more pyogenic germs. The severity of the lesions is related to the involvement of the cortical and medullary bone and the extent of the infection; the vascular and immune condition of the patient is decisive.

Hyperbaric Oxygen Therapy enhances the functionality of antibiotics and increases the patient's non-specific defense capacity through a better functioning of cellular immunity. In addition, the capillary neoangiogenesis stimulated by Hyperbaric Oxygen Therapy is able to determine a lasting anatomical structural modification that allows to obtain higher and more stable partial pressure values of oxygen over time, a favorable osteoblastic action and the stimulus to the production of collagen by fibroblasts.

Protocol: PRESSURE: the treatments are carried out at a pressure of 2.4 (14 mca; 243kPa) –2.5 ATA (15 mca; 253kPa); for 30 -60 sessions. It is recommended that cleaning surgery, where possible, be carried out during the OTI treatment period (p.es.: 40 OTI sessions> intervention > 20 OTI sessions).

Bibliography

De Iaco G, Infascelli R M, Nasole E, Zanon V. *"SIMSI Guidelines (Italian Society of Underwater and Hyperbaric Medicine) on the indications to hyperbaric oxygen therapy"*, 2nd ed., 2015.

BYODONTOPATIA

Inflammation of the supporting tissues of the tooth such as gum, periodontal ligament, root cement and alveolar bone.

Hyperbaric Oxygen Therapy is indicated for severe chronic periodontitis, with a tendency to exacerbation even after dental therapy. The principle of operation for this pathology is the high antibacterial power of oxygen and the abilityto create new blood vessels in infected tissues.

Protocol: PRESSURE: 2.4 (14 mca; 243 kPa) –2.5 ATA (15 mca; 253 kPa); DURATION: 10 –16 treatments of 90 minutes (90') of O2.

Bibliography

De Iaco G, Infascelli R M, Nasole E, Zanon V. *"SIMSI Guidelines (Italian Society of Underwater and Hyperbaric Medicine) on the indications to hyperbaric oxygen therapy"*, 2nd ed., 2015.

RETINOPATHY

This pathology that affects the retina has several causes and according to these it is differentiated and classified.

Hyperbaric Oxygen Therapy is adjuvant to pharmacological therapies in retinitis pigmentosa and degenerative, where administering the right dose of oxygen has benefit.

Protocol: PRESSURE: 1.9 (9 mca; 193kPa) –2.2 ATA (12 mca; 223kPa); DURATION: 60 minutes (60') total of O2 at high altitude, for 20 treatments in the 1st month; these treatments will be followed by 5 sessions/month every 3-4 months.

Bibliography

De Iaco G, Infascelli R M, Nasole E, Zanon V. *"SIMSI Guidelines (Italian Society of Underwater and Hyperbaric Medicine) on the indications to hyperbaric oxygen therapy"*, 2nd ed., 2015.

ALGODYSTROPHIC SYNDROME AND ACUTE AND CHRONIC SOFT TISSUE INFECTIONS

Group of acute and chronic clinical pictures with infectious etiology that evolve into inflammation and necrosis of the skin, subcutaneous (progressive bacterial cellulitis) and fascia (necrotizing fasciitis). Acute forms are often associated with systemic septic impairment.

Hyperbaric Oxygen Therapy has a powerful bactericidal action even against difficult bacteria and antibiotic resistant.

Protocol: PRESSURE: 2.5 ATA (15 mca; 253 kPa) –2.2 ATA (12 mca; 223kPa) (first sessions at 2.5 and then 2.2); DURATION: at least 60 minutes (60') total of O2 at altitude, for 30-40 sessions, continuous or with interposed break.

Bibliography

De Iaco G, Infascelli R M, Nasole E, Zanon V. *"SIMSI Guidelines (Italian Society of Underwater and Hyperbaric Medicine) on the indications to hyperbaric oxygen therapy"*, 2nd ed., 2015.

RAYNAUD'S SYNDROME

The syndrome consists of a vasospasm of part of the hand, in response to cold or emotional stress, which causes painful sensation and reversible skin color variations (pallor, cyanosis, erythema or a combination of these) in one or more fingers. Occasionally, other acral areas (nose, tongue, etc.) are affected. The disorder can be primary or secondary. The diagnosis is clinical; diagnostic tests aim to discriminate primary from secondary pathology. Treatment of uncomplicated cases includes avoiding cold, psychological support (biofeedback), abolishing smoking and, as needed, taking vasodilating calcium channel blockers (e.g., nifedipine) or prazosin.

Protocol: although there is not yet a standard protocol for the treatment of this disease, Hyperbaric Oxygen Therapy by stimulating angiogenesis is able to revascularize the tissues and is therefore recommended to support a pharmacological, nutritional and psychological therapy.

CHRONIC SKIN ULCERS

Continuous cutaneous solution with various etiology not tending to healing.

OTI acts as a drug inducing indirect revascularization phenomena, for angiogenesis and vasculogenesis, mediated in the latter case by the release of medullary stem cells with endothelial differentiation. Hyperbaric Oxygen Therapy acts in fact as an accelerator or modulator of nitric oxide production thanks to the ability of the OTI to restore the picture of district tissue hypoxia, which usually prevents the functionality of eNOS (endothelial redoxystalline synthetase); the action of this synthetase can be expressed only at partial pressures of O2 > 30 mmHg.

Protocol: PRESSURE: 2.4 (14 mca; 243 kPa) –2.5 ATA (15 mca; 253 kPa); for at least 60 minutes (60') total of O2 at altitude, for 30-40 treatments.

Bibliography

De Iaco G, Infascelli R M, Nasole E, Zanon V. *"SIMSI Guidelines (Italian Society of Underwater and Hyperbaric Medicine) on the indications to hyperbaric oxygen therapy"*, 2nd ed., 2015.

PATHOLOGIES AFFILIATED WITH THE NHS

The pathologies affiliated by the National Health System for the Marche region are the following:

- Arterial gas embolism
- Decompression sickness
- Gas gangrene from clostridia
- Soft tissue infections by mixed bacterial flora
- Wet gangrene of the extremities in diabetics
- Intoxication with carbon monoxide, cyanides and methemoglobinizing substances
- Crushing syndrome
- Severe acute anemia
- Infections (osteoarthritis, osteomyelitis, infections at the site of prostheses)
- Turbid wounds or sores
- Skin transplants at risk
- Peripheral arterial insufficiencies
- Sudden hearing loss or deafness.

FORMS AND DOCUMENTS TO BE SUBMITTED

Here are the forms and documents to be presented to the competent offices of the Asur to which they belong:

1. Module "Provisions in favor of subjects undergoing Hyperbaric therapy L. R. N. 7/00 – Request for reimbursement of expenses incurred.
2. The Prescription of the general practitioner (family) or specialist requesting hyperbaric treatment
3. The invoices issued by the Hyperbaric center (in this case by the Hyperbaric center MAU) certifying the expenditure incurred.

HOW TO PREPARE FOR THE ELIGIBILITY VISIT

Access to therapy is preceded by a medical examination by the Doctors of the Hyperbaric Center, where the clinical conditions and the absence of absolute contraindications or related to the carrying out of Hyperbaric Therapy occur. The following examinations must be carried out before this visit:

1. Chest X-ray (recent or done at most three months before), in special cases the Doctor may request a chest CT scan;
2. Andlettrocardiogram (recent or done at most three months before);

The sending doctor will have to write a prescription where the reason for which the course of hyperbaric therapy is prescribed is specified.

Once in possession of the reports you can fix the visit with our hyperbaric doctor to which the above examinations and all the relevant documentation for the purposes of therapy must be brought. The visit lasts between 30 and 45 minutes and will be used to create the medical record.

If nothing prevents the therapy, the Secretariat will take care of the planning of the sessions.

N.B: FEMALE PATIENTS, OF CHILDBEARING AGE, MUST BE ABSOLUTELY SURE THAT THEY ARE NOT PREGNANT.

HOW TO GET READY TO ENTER THE ROOM

PERMITTED ITEMS and CLOTHING Inside the room you can bring:	**PROHIBITED ITEMS and CLOTHING** For safety reasons it is not allowed to bring the following objects into the hyperbaric chamber:
✓ dental prostheses of any kind ✓ eyeglasses of any kind ✓ 1 pencil ✓ 1 newspaper/magazine (NO newspapers) ✓ 1 book	⊗ LIGHTERS/MATCHES ⊗ MEDICAL ELECTRICAL EQUIPMENT (not certified for hyperbaric environment) ⊗ WEAPONS ⊗ ORTHOPEDIC AIDS (CRUTCHES ETC.) ⊗ SPRAY CANS (including asthma and rhinitis spray) ⊗ COMPUTERS/ PDAS ⊗ HERMETIC CONTAINERS ⊗ FLAME SOURCES ⊗ BATTERY/ELECTRIC TOYS ⊗ JEWELRY (excluding real wedding and fixed piercings) ⊗ NON-GAS PERMEABLE CONTACT LENSES ⊗ FLAMMABLE LIQUIDS ⊗ METAL OBJECTS OF ANY KIND (with the exception of the only key to the dressing room cabinet) ⊗ WATCHES (except for diver's watches with a metal strap) ⊗ MARKERS ⊗ FOUNTAIN PENS ⊗ NEWSPAPERS ⊗ RADIO/MP3/CD/DVD PLAYER ⊗ CIGARETTES/CIGARS/PIPES ⊗ MOBILE PHONES
They should be used, preferably **cotton clothing** that does not give rise to electrostatic charges. As for undergarments it is good to use COTTON.	**PROHIBITED CLOTHING:** ⊗ LYCRA ⊗ NYLON ⊗ PILE
	PROHIBITED COSMETICS: ⊗ ALCOHOL-BASED DEODORANTS ⊗ AFTERSHAVE ⊗ HAIR GEL ⊗ LACQUER

	⊗ OIL ⊗ PETROLEUM ⊗ PERFUMES ⊗ VASELINE

Fatty or otherwise flammable substances together with possible sources of flame or spark, such as electrical appliances or lighters, could cause particularly serious fire risks due to the greater ease of combustion secondary to the increase in pressure (more oxygen available) and also to the confined environment.
Other objects, while not inherently dangerous or a source of risk, can break or be damaged as a result of increased pressure. Heavy clothing or unsuitable materials should be avoided because they are unnecessary and bulky.
In case of need, a blanket must be requested from the staff.
Playing cards are not allowed, since during the games, with each movement of the players, the percentage of Oxygen in their masks is drastically reduced, making it almost useless to perform Hyperbaric Oxygen Therapy.

CONTACT LENSES

Patients with semi-rigid or soft contact lenses **should replace them with glasses.**

PERSONAL HYGIENE

Proper and effective personal hygiene must be maintained, respecting other patients, considering the narrowness of the environment in which the therapy takes place.

COLD

If the patient has caught a cold, if he feels very constipated, it **is better that he gives up a session so as not to risk damaging the eardrums**, otherwise he must consult with one of the Doctors of the Center, who will evaluate the patient's condition and give the appropriate therapeutic indications. It is important not to exceed in the use of these drugs, since side effects can develop, such as atrophy of the nasal mucosa, with unpleasant consequences.

SMOKERS

It is very important that smoking patients **completely stop or, at least, limit smoking as much as possible throughout the course of therapy, in** order not to nullify the beneficial effects of Hyperbaric Oxygen.
It is forbidden to smoke inside the Center.
After therapy, before smoking, wait at least 20 minutes and ventilate the clothes well.

DIABETIC PATIENTS

Diabetic patients, before therapy **, must have eaten**, to avoid experiencing hypoglycemia crises.

HOW DOES A SESSION OF HYPERBARIC OXYGEN THERAPY TAKE PLACE?

ARRIVAL AT THE CENTER AND PREPARATION

Patients should arrive earlier than the start time of the session to:

• leave their personal belongings in the appropriate lockers and place clothing and objects not allowed inside the room (it should be remembered to preferably use cotton clothing and to maintain proper personal hygiene, considering the narrowness of the environment where the therapy takes place);

•wear the supplementary clothing provided by the Centre, including a shirt and overshoes;

•undergo regular scheduled clinical evaluation or medication

BEHAVIOR IN THE ROOM

During the stay in the hyperbaric chamber, percussion of metal objects between them and on the walls must not be tampered with, the dispensers that spread the Oxygen and the other therapeutic and safety devices that are inside must not be tampered with.
For any problem, the doctor who attends the therapy should always be consulted and the instructions must be followed.

ENTRANCE TO THE ROOM

Patients are accompanied, by the staff of the O.T.I. Center in the hyperbaric chamber, to take a seat on the appropriate seats or in a wheelchair or stretcher according to the clinical situation, as well as according to the logistical needs, managed by the technical staff of the Center.

It should be remembered that the health and technical staff has the task of making the stay of patients inside the room as comfortable as possible, with the utmost respect, however, of the therapeutic needs and the safety and prevention rules, imposed by the bodies in charge. Therefore, any request, which does not fall within the established parameters, cannot be satisfied.

BEGINNING OF SITTING AND COMPRESSION

With the entrance of the sanitary in the room and the closing of the hatch begins the therapeutic session.

During the compression phase, inside the chamber, an increase in ambient temperature is felt, due to the increase in pressure. Throughout the session in the room there is a background noise that is generated by the introduction, inside, of clean air and by the exhaust, outside, of an amount of air equal to that entered.

TYMPANIC COMPENSATION

In this phase, which lasts about 15-20 minutes, it is necessary to perform the tympanic compensation maneuver, explained during the medical examination, to balance the pressure in the inner ear (close the nose with your fingers, then, with your mouth closed blow the air against the mouth, without letting it out, until you feel that the ears have "uncorked" or swallow the saliva with the mouth closed). It is very important to carry out this correctly

maneuver, so as not to damage the eardrums. Patients must warn the healthcare professional on duty, inside the chamber, of any compensation difficulties, which, neglected, can lead to inflammation of the eardrums and also to their perforation (these complications, depending on the severityà, interrupt hyperbaric therapy for more or less long times). The same applies if the patient during the compression phase should experience pain in the cheekbones and forehead.

START THERAPY

Once the therapeutic quota is reached, the mask is worn, always closing the supplied strap and checking that the mask is well adhered to the face; at this point the breathing in 100% Oxygen begins. Breathing can be done with the nose or mouth (better with the nose to avoid dryness of the throat), with natural frequency, rhythm and amplitude, without forcing.

END OF THERAPY AND BEGINNING OF DECOMPRESSION

At this point the decompression begins and we return to normal pressure (atmospheric pressure).

In the chamber you will hear a reduction in room temperature and some small sound in the ears, due to the leakage of air from the inner ear. It is not necessary to perform the compensation maneuver but only swallow to facilitate the rebalancing of the ear. If you find it difficult to compensate due to the difference in pressure (pain in the ears, cheekbones, forehead and teeth) you must immediately notify the operator present in the chamber, who will take appropriate measures. It can help open your mouth and emit the sound of the vowel "a" continuously. Under normal conditions, the duration of decompression is about 7 minutes; in emergency conditions the opening of the hatch can in any case take place in less than 3 minutes. During the decompression phase of the chamber, it is important to continue breathing normally, without ever holding your breath.

END OF SESSION

At the end of decompression the hatch is opened and it is possible to exit. Even if dry, a hyperbaric session is to be considered a diving in all respects; it is forbidden to refrain from ascents on high ground or from air flights up to 24 hours from the end of the sitting.

IN CASOR EMERGENCY SITUATIONS

ANDMERGENZA INSIDE THE ROOM

Remember to **KEEP THE MASK ON YOUR FACE** and **SIT IN YOUR SEAT**. In case of emergency in the hyperbaric chamber keep calm and carefully follow the instructions of the assistant staff: the room is a safe environment with a constant exchange of air and supervised by trained personnel, placed inside and outside.

EMERGENCY OUTSIDE THE CHAMBER - Evacuation of the Center

In the event of a disaster such as structural failure, earthquake, fire or other, the patient, warned by an acoustic signal or by voice by the staff of the Center who is part of the fire brigade, must start neatly and without running, towards the nearest emergency exit indicated by signs. Once outside you must go to the square in front of the Center, where you will receive further information.

SIDE EFFECTS OF OXYGEN HYPERBARIC THERAPY

The risks related to hyperbaric therapy are different and of different gravity and due to the increased pressure in force inside the hyperbaric chamber and to the breathing of oxygen at high pressure.

• **Inflammation or injury of the eardrum due to lack of compensation**:

- you can reduce the probability of it happening by performing the appropriate compensation maneuvers (close the nose with your fingers, then, with your mouth closed, blow the air against your mouth, without letting it out, until you feel that the ears have "uncorked" or swallow saliva with your mouth closed);
- the healthcare professional must be warned, inside the chamber, of any compensation difficulties.

• **Pain in the forehead or cheekbones due to difficulty balancing the pressure in the paranasal sinuses** (it can occur in case of cooling diseases, both in compression and in decompression): the probability that it will happen with the medical examination at the beginning of the cycle that excludes the presence of acute and chronic sinusitis or, in the presence of such pathologies, can be reduced, that prescribes adequate therapy.

• **Lung collapse and air entrapment in the pleural cavity (pneumothorax):this** can reduce the likelihood of it happening with the medical examination at the beginning of the cycle.

• **Convulsive crisis due to oxygen toxicity:** the probability of it happening with the medical examination at the beginning of the cycle can be reduced.

ASSESSMENT OF THE RISKS ASSOCIATED WITH THE INSTALLATION

It is necessary to reiterate that modern hyperbaric chambers, regularly checked and managed by trained technical personnel, able to drastically reduce any possible risk, are absolutely safe.

• **Fire risk**: the probability of it happening can be reduced by carrying out periodic checks and adequate maintenance of the system.
• **Fire extinguishing system:** The recently activated fire extinguishing system is a guarantee in the extinguishing of any fires inside the chamber, both as regards the flow rate and the diffusion of water. The operating values of the plant are higher than the specifications required by the US Agency (NFPA) and also those developed by the I.S.P.E.S.L. (Italian Agency for Safety at Work).
• **Safety systems:** There are two levels of control of the percentage of Oxygen in the chambers, which are activated when this percentage exceeds the established limits: the first system signals to the technician the increase in the amount of Oxygen in the atmosphere of the chamber; if the technician, for any reason, fails to block the increase in Oxygen, you get to the second control that switches the Oxygen, which is breathed in mask, in the air. Therefore the second value of the percentage of Oxygen in the atmosphere of the chamber, placed as a safe limit, can never be exceeded.

INFORMED CONSENT TO THERAPY

Access to therapy is linked to the issuance of the authorization to process your sensitive data by signing the appropriate form in the secretariat during acceptance. (D.Lgs. 30.6.2003 n. 196 "Codice Privacy" and Regulation UE n. 2016/679 - "GDPR"). In addition, the customer must express the "informed consent" to the performance of the therapy itself, which will be given only when the customer feels sufficiently informed by the doctor about the type of therapy he will have to carry out and the risks that may arise. The consent will be expressed by signing the appropriate form delivered and illustrated during the start-up visit, also containing the indication of the person or persons authorized to request information on their health conditions.

COMPLAINTS AND SUGGESTIONS FORM

Dear Patient, you can fill out this form to report any inefficiencies, problems, difficulties, or to send suggestions and advice.

The request for personal data (name, surname, address, e-mail) serves solely to ensure a personal response to the request submitted. The form can therefore also be filled in anonymously, in this case, however, the OTI MAU s. r. l. will not be able to guarantee the answer. We inform you that all completed forms can be sent to the e-mail address **info@centroiperbaricomau.it** or delivered directly to the acceptance. The forms will be sent to the Management and will be considered for the improvement of the service. We thank you in advance for your valuable cooperation.

NAME	
SURNAME	
ADDRESS	
CITY	
PHONE NUMBER	
E-MAIL	
DATA	

SUGGESTION / PROPOSAL ☐

COMPLAINT ☐

DESCRIPTION:_____

_____

_____

_____

_____

INFORMATION PURSUANT TO ART. 13 OF D.LGS. 30/06/2003 N. 196

"CODE REGARDING THE PROTECTION OF PERSONAL DATA"

The personal data provided to OTI MAU s.r.l. with this communication, are processed in full compliance with current legislation on the confidentiality of personal data. The indication of personal data in this communication is optional, but it is a condition for the user to receive the response relating to his complaint / suggestion. The use of the data is exclusively internal to OTI MAU s.r.l., for the sole purpose of giving effect to the user's communication. The data is not provided to third parties. The interested party has the right to have confirmation of the data concerning him, to delete them if collected unlawfully, to rectify or update them, to oppose any treatment outside the procedure for managing complaints / reports / suggestions. The data controller is OTI MAU s.r.l.. The Data Processor is the Administrator, with whom you can exercise at any time the rights provided for by art. 7 of the aforementioned Legislative Decree 196/2003.

Porto Sant'Elpidio, of _____ SIGNATURE

PATIENT SATISFACTION QUESTIONNAIRE

Dear Madam, Dear Sir, with the following Card the Centro OTI MAU s.r.l. intends to make available to its kind customers a new tool that will allow us to interact with you, listening to impressions, suggestions and advice for the improvement of our service. The questionnaire must remain anonymous. Once completed, it must be deposited at the reception.

How do you judge	Exceeds expectations	In line with expectations	Disappointed the expectations
Opening hours to the public			
Information received at the time of Acceptance			
The courtesy of the reception staff			
The courtesy of the Medical / Technical staff			
Waiting times and compliance with appointment times			
Suitability of the rooms and cleanliness of the premises			
In general, the quality of the services offered			
Compliance with the standards declared in the Charter of Services			
How likely are you to recommend our centre to a family member, friend or colleague? (give a judgment from 0 to 10)			
How would you define your current clinical picture compared to before starting hyperbaric oxygen therapy?	☐ improved ☐ unchanged ☐ worsened Reasons: _____ _____ _____ _____ _____		

How did you find out about our center:

☐ General Practitioner ☐ Word of Mouth ☐ internet ☐ Advertising

Suggestions:

_____
_____
_____

Porto Sant'Elpidio, of _____