



TECHNICAL OFFER

MONOPLACE HYPERBARIC CHAMBER FOR MEDICAL TREATMENTS MODEL: OXICAB MO-13



Supplied by

HYPERBARIC S.A.C. LIMA. PERÚ.

www.hyperbaricsac.com

hyperbaric@hyperbaricsac.com

***The images and illustration included are in some cases for reference. There may be changes.





CONTENT OF THE PRESENTATION:

- 1. Description, dimensions and measures
- 2. Technical features
- 3. Medical oxygen system
- 4. Operation of the hyperbaric chamber
- 5. Documents and certifications
- 6. Spare parts
- 7. Optional equipment, systems and services







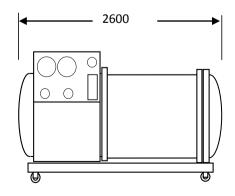
1.- DESCRIPTION DIMENSIONS AND VOLUMES

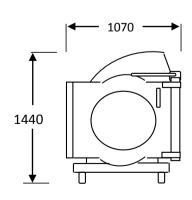
1.1 DESCRIPTION

- The Hyperbaric Chamber OXICAB MO-13 is a chamber of the monoplace type, designed for medical treatments (therapies) of hyperbaric oxygenation in controlled conditions, in an atmosphere of medical oxygen at pressures up to 3 ATA.
- The Hyperbaric Chamber OXICAB MO-13 is a pressure vessel made of special steel, with horizontal cylindrical structure, with transparent acrylic tube section of 1,300 mm long and 900 mm. diameter, made of one single piece without seams or glue that allows the patient full visibility to the outside, reducing the feeling of confinement and providing comfort for its interior space.
- All the equipment, parts and pieces used in the manufacturing process are designated, certified and approved for its use especially in a hyperbaric atmosphere.
- Upon request of the customer, this model can be made with pressurization system with compressed breathing air and oxygen supply by mask.

1.2 DIMENTIONS AND MEASURES

- Material: Special Steel according to the ASME PVHO standard.
- Maximum treatment pressure: 3 ATA
- Pressurization with oxygen
- Material: Two sections, one of special steel and other acrylic tube.
- Exterior Diameter: 950 mm.
- Interior Diameter: 840 mm.
- Length of the acrylic tube section: 1300 mm.
- Length of the Steel section: 1,060 mm.
- Overall exterior length: 2,600 mm.
- Total height: 1,440 mm.
- Total width: 1,070 mm.
- Total volume: 1.6 m^3 .
- Approximated weight: 1,300 kg.
- Maximum working pressure: 3 ATA.
- Width of the stretcher: 750 mm.
- Length of the stretcher: 2,130 Mts.





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2.- TECHNICAL FEATURES

- 2.1. The Hyperbaric Chamber OXICAB MO-13 is designed to attend one single patient.
- 2.2 Considering the amplitude of the stretcher width, in this chamber model, is feasible to treat a child accompanied by a parent, comfortably.
- 2.3 The control panel of the equipment is installed laterally, attached to the steel structure of the chamber.
- 2.4 This panel contains all the equipment commands, gauges, operation valves, emergency valves, intercom, etc... for the full operation of the equipment.
- 2.5 The control panels can be placed either to the left or right side of the steel tank according to the needs of the customer, allowing in the case of a clinic or hospital to have two chambers for example, requested one with left and the other with right panel, so that one single person can operate the two chambers simultaneously.
- 2.6 The patient enters into the chamber in a comfortable telescopic and reclining stretcher of 750 mm wide.
- 2.7 This stretcher comes completely out of the chamber and allows the patients to enter very comfortable to the hyperbaric chamber.
- 2.8 Being telescopic, once the patient is lying on the stretcher, it softly slide and get inside of the chamber through a special telescopic system. This allows the stretcher to be always stored inside the chamber and doesn't take up any extra space in the barosala.
- 2.9 When the patient enters into the hyperbaric chamber, a special antistatic bracelet is placed in his wrist to give more security regarding the static charges in cities of dry weather.
- 2.10 Special medical penetrators are installed in the door of the chamber to allow the customer to put hyperbaric medical equipment in an optional way.
- 2.11 A special penetrator T-COM type of 1 inch is also placed in the door of the chamber to allow the placement of a transcutaneous oxygen monitor.
- 2.12 In the door of the monoplace hyperbaric chamber there is installed a security system for oxygen blockage, which doesn't allow this gas to enter to the pressurization system while the door of the chamber remains open.
- 2.13 This way we make sure that the oxygen doesn't contaminate the barosala because of a bad operation of the commands of the chamber while the door is open.
- 2.14 Double security device (One pneumatic and one mechanic) is also installed in the chamber door to block the opening while the chamber is pressurized.
- 2.15 A communication system (hands-free) between the patient and the operator of the chamber is supplied with the equipment to allow the constant communication with the patient.
- 2.16 A security or relief valve comes installed in the equipment and is automatically activated in the case of a not allowed overpressure inside the chamber.





- 2.17 An indicator of the internal temperature and humidity is installed in the control panel to continuously measure these two parameters.
- 2.18 An indicator of treatment time (Timer) is installed in the control panel to control the treatment time of the patients.
- 2.19 A special connection for the equipment grounding is installed on the back leg of the support system of the equipment.
- 2.20 A special holder or external arm is installed on the upper steel turnbuckles bars of the equipment to allow placement of a flat screen TV to entertain patients.
- 2.21 The exterior paint of the chamber is polyurethane type and includes anticorrosive scheme.
- 2.22 The interior paint of the chamber is a special fireproof paint and food grade for human use called Jet Pox 2000 of CPP.
- 2.23 Efficient noise reducers (Silencers) for the pressurization and depressurization are located inside the chamber avoiding annoying sounds for the patients.
- 2.24 The Certifying Authority of our hyperbaric chambers is the International Company INSPECTORATE, from the BUERAU VERITAS group.









3. MEDICAL OXYGEN SYSTEM

- 3.1 Our Monoplace Hyperbaric Chamber MO-13 is pressurized with breathable medical oxygen for human use.
- 3.2 This allows the patients breathe pure oxygen during the whole treatment without any mask.
- 3.3 The cylinders and the whole system of oxygen supply external to the chamber must be provided by the customer with a local supplier of this gas.
- 3.4 We recommend, for this chamber model, a group of six (6) medical oxygen cylinders divided in two (2) groups of three (3) cylinders.
- 3.5 The oxygen cylinders must be 50 liters capacity and 200 bar of pressure.







4. OPERATION OF THE HYPERBARIC CHAMBER

- 4.1 Our Monoplace Hyperbaric Chambers are manufactured with automatic systems for the pressurization, the ventilation and the depressurization for medical treatments up to 3 ATA.
- 4.2 In this sense has keypads able to perform the following functions automatically:
 - Programming of the desired pressure level for each session of hyperbaric oxygen therapy.
 - Programming of the required speed to reach the programmed pressure.
 - Automatic changes of pressure during treatment.
 - Automatic programming of the chamber ventilation during the whole treatment.
 - Emergency depressurization if it is required to remove a patient from the chamber quickly.
 - Automatic depressurization.
- 4.3 These systems allow the chamber operator to do the following:
 - Regulate for each session the treatment pressure indicated by the doctor.
 - Regulate for each session, according to the easiness of the patients to clear their ears, the pressurization speed.
 - With a single button ON / OFF starts the pressurization session according to the programmed speed up to reach the selected pressurization level.
 - From the beginning of the pressurization, to obtain automatically a minimum ventilation system of 50 liters per minute.
 - Regulate the ventilation of the chamber from 50 to 300 liters per minute, as desired.
 - Automatically maintain the pressurization level of the chamber even making changes in ventilation.
 - Perform during the treatment, pressure variations with the regulating knob; the hyperbaric chamber will
 modify automatically its pressure to the new one selected.
 - Depressurize the chamber automatically putting the command knob in the OFF position.
 - Depressurize the chamber quickly, when a patient is requiring emergency evacuation (180 seconds from 3 ATA).





5. DOCUMENTS AND CERTIFICATIONS

- 5.1 At the time of shipment of the equipment, our company will send the customer directly or through the banking system, according to the payment way chosen by him, the following documents:
 - COMMERCIAL INVOICE OF THE EQUIPMENT
 - DETAILED PACKING LIST
 - BILL OF LADING OF THE SHIPPING COMPANY
 - CERTIFICATE OF MANUFACTURING ORIGIN
 - MECHANICAL GUIDES FOR THE BAROSALA
 - USER MANUAL
 - MANUALS OF THE EQUIPMENT AND ACCESORIES
 - CERTIFICATE OF DELIVERY AND RECEPTION
 - CERTIFICATE OF GUARANTEE OF THE EQUIPMENT
 - INTERNATIONAL CERTIFICATIONS
 - DVD FOR PRESENTATION TO THE PATIENTS BEFORE STARTING A SESSION.
- 5.2 The international certifications that we deliver in original to the customers at the time of delivery of the chamber are the following:
 - ASME (American Society of Mechanical Engineers)Boiler and Pressure Vessel Code, Section VIII, Division 1 Pressure Vessels
 - ASME Boiler and Pressure Vessel Code, Section IX Welding Qualifications and Procedures.
 - ASME PVHO-1-2007, Safety Standard for Pressure Vessels for human occupancy.
 - NFPA-99
 - FDA (Food and Drug Administration) The requirements of the Good Manufacturing Practices (GMPs) as defined by the U.S. Food and Drug Administration (FDA) in Code of Federal Regulations (CFR). 21 code, Chapter 1, Part 820 for class II medical devices. Quality System Regulation.
 - ISO 9001
 - ISO 13485







ORGANISMO DE CERTIFICACIÓN DE PRODUCTOS ACREDITADO POR EL ORGANISMO PERUANO DE ACREDITACIÓN INDECOPI-SNA CON **REGISTRO No OCP-012**



Nº 035640

S/T IND 3763

CERTIFICATE OF UNDER WITH VALUE OFFCIAL Nº 7131

Callao, June 14, 2013

Pág. 1 de 3

GENERAL DATA

1.1 CLIENT:

HYPERBARIC S.A.C.

ADDRESS:

STREET SOLIDARITY NO. 140, INDUSTRIAL PARK - VILLA THE SAVIOR - LIMA - PERU.

1.2 PURPOSE OF THE CERTIFICATION OF UNDER:

Evaluate the steel Hyperbaric Chamber described in the item 2, meet the compliance requirements of manufacture of the agreement code ASME section VIII, Division 1-2010 in the items relevant to the product: a) Base Material of Body and Caps (UG-5 Plates), b) Design "minumum thickness of Body and Caps" (U6-27, UG-32) c) Radiographic testing (UW-51, Appendix 4). Hydrostatic pressure test (UG-99), d) Welding and Welders Inspections (UW-47, UW-48). The ASME PVHO-1 code in the relevant articles of the material manufacturing of the acrylic cylinder component of the Hyperbaric Chamber (Article-3). NFPA 99 norm in the relevant articles of the materials of the Hyperbaric Chamber (Article-19).

1.3 SCHEME OF CERTIFICATION:

System No 1B of the guide ISO/IEC 67

2 PRODUCT DATA (DECLARED)

01 monoplace hyperbaric chamber for occupation of human.

Nº of Series CH-MO-13-13-03 Chamber Type Monoplace Maximun Patient Capacity : 01 human Overall Width : 1.07 mt (42"). Overall Height 1.45 mt (57") 900 mm (35.5") Exterior Diameter Interior Diameter 840 mm (33") Overall Volume : 1.4 m3 Approximate Weight. : 1 300 Kg. Nominal Thickness of the body 6.35 mm Nominal Thickness Heads 6.35 mm

RX circunf linear welding. Maximum Working Pressure Neumatic Pressure Test **Body Material** Cap Material

Year of Manufacture

ASTM A 516 Gr 70 ASTM A 516 Gr 70 2013 Manufacturing Code ASME SECCIÓN VIII Div. 1 Manufacturer HYPERBARIC S.A.C.

PLACE AND DATE OF INSPECTION



Manufacturing Plant of Hyperbaric Street Solidarity No. 140, Industrial Park, Villa the Savior. from of January 28, 2013 to April 09, 2013

100 %

29.4 PSI (2.11 Kg / cm²)

32.3 PSI (2.25 Kg / cm2)

Av. Elmer Faucett Nº 444 Callao - Perú / Central: (511) 613-8080 Fax : (511) 628-9016 www.inspectorate.com.pe







ORGANISMO DE CERTIFICACIÓN DE PRODUCTOS ACREDITADO POR EL ORGANISMO PERUANO DE ACREDITACIÓN INDECOPI-SNA CON **REGISTRO No OCP-012**



Nº 035643

S/T IND 3763

CERTIFICATE OF UNDER WITH VALUE OFFCIAL Nº 7131

Callao, June 14, 2013

Pág. 2 de 3

DOCUMENT LEGAL

ASME SECC VIII, Div.1: 2010: Rules for construction of pressure vessels. ASME SECC II, Part A: 2010: Ferrous material specifications

ASME SECC II, Part D: 2010: Properties.
ASME PVHO -1: 2002: Safety Standard for Pressure Vessels for Human Occupancy.

NFPA 99: Chapter 19 Hyperbaric Facilities.

METODO: CODIGO ASME SECC. V- 2010: Nondestructive Examination.

NFPA 99: Visual Inspection.

RESULTS

The results of the This Certification is details to below in the following records:

5.1 REVIEW OF DESIGN

- Map N° MD-900-00-MO-13
- Certificate of Quality of Material Nº 629726
- Certificate of Quality of Material Nº 573372
- Certificate of Quality of Material Nº 628403
- Memory of Calculation Hyperbaric Chamber (Monoplace)
- **Technical Specification**

5.2 INSPECTION

5.2.1. DURING THE FORMING PROCESS

- Welding Procedure Specification (WPS) N

 WPS-MQMET-09-11
- Procedure Qualification Record Welding (PQR) № PQR-MQMET-09-11
- Welder Qualification Record WPQ, Welder name: Gabriel Gamonal Cangana Nº DNI: 41180575 (WPS-MQMET-09-11)

5.2.2. FORMING PROCESS IS COMPLETE

- Visual Inspection Record
- Physical Inspection and Operating Record

Nº 7135

Nº 7132

5.3 TESTS: FORMING PROCESS IS COMPLETE

- Radiographic Inspection Report Nº 101/MQ-01-2013(01 Pág.)
- Ultrasonic Examination Report Form Nº 001-01-UT/13 (01 Pág.)
- Test Inspection Report Neumatic Nº 7134
- Test Inspection Report Hydrostatic Nº 7133

Painting Procedure Nº MO-13

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Nº 035638

S/T IND 3763

CERTIFICATE OF UNDER WITH VALUE OFFCIAL Nº 7131

Callao, June 14, 2013

Pág. 3 de 3

6. REVISION (EVALUATION)

It evaluated the Hyperbaric Chamber described in the Item 2 This document, in Based on the results indicated in the Itm 5. It can be concluded with the approval of the evaluated.

The results of this certificate have been developed based on the documentation submitted by the manufacturer whose veracity was concerned.

7. DECISION ON THE CERTIFICATION

The chamber described in Item 2 of this document meets the requirements of ASME PVHO -1, NFPA 99 and ASME VIII, Div 1 SECC - 2010, on items relevant to the product, so we conclude with the issuance of certified.

8. CONDITIONS OF THE CERTIFICATE

This certificate is valid only for the purpose stated in item 1.2, the product described in Item 2, and the results shown in Item 5 of this certificate, no conclusion can be extended to other units other than certified.

9. VALIDITY OF THE CERTIFICATE

This certificate is valid only in its original paper for the product mentioned in item 2 and the conditions outlined in this document. The validity of the certificate of conformity is **05 years**, provided that the hyperbaric chamber has no modifications, repairs or any change in its forming.

flat

License Nº 010 date granted 18/04/2013 a 18/04/2015, valid for 02 years.

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THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

IQNet and ICONTEC Hereby certify that the organization

HYPERBARIC SAC

Calle Solidaridad Mz. B1 Lt. 7 Parque Industrial Villa El Salvador, Lima, Perú

For the following field of activities:

Diseño, fabricación, comercialización, instalación y servicio post venta de cámaras hiperbáricas

Design, manufacture, commercialization, installation and after-sales service of hyperbaric chambers

Has implemented and maintains a

Quality Management System

which fulfills the requirements of the following standard

ISO 9001:2008

Issued on: 2015 03 06 Validity date: 2018 03 05

Registration Number: CO-SC-CER375728

President of IONet

Mónica Vivas Conformity Assessment Director of ICONTEC

IQNet Partners*:

IQNet Partners*:

AENOR Spain AFNOR Certification France AIB-Vincotte International Belgium ANCE-SIGE Mexico APCER Portugal CCC Cyprus CISQ Italy CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany DS Denmark FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia IMNC Mexico INNORPI Tunisia Inspecta Certification Finland IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com









ICONTEC Certifica que el Sistema de Gestión de: ICONTEC Certifies that the Management System of:

HYPERBARIC SAC

Calle Solidaridad Mz. B1 Lt. 7 Parque Industrial Villa El Salvador, Lima, Lima, Perú

Ha sido evaluado y aprobado con respecto a los requisitos especificados en: Has been assessed and approved based on the specified requirements of:

ISO 9001:2008

Este Certificado es aplicable a las siguientes actividades: This certificate is applicable to the following activities:

Diseño, fabricación, comercialización, instalación y servicio post venta de cámaras hiperbáricas

Design, manufacture, commercialization, installation and after-sales service of hyperbaric chambers

Esta aprobación está sujeta a que el sistema de gestión se mantenga de acuerdo con los requisitos especificados, lo cual será verificado por ICONTEC This approval is subject to the maintenance of the management system according to the specified requirements, which will be verified by ICONTEC

> Certificado: SC-CER375728 Certificate

Fecha de Aprobación: 2015 03 06

Approval Date:

Fecha Última Modificación: Last Modification Date

Fecha de Vencimiento: 2018 03 05

Expiration Date





Directora Evaluación de la Conformidad de ICONTEC Conformity Assessment Director of ICONTEC

ES-P-S0-01-F-012 Versión 02

Casa narralizado es propiedad de ICONTEC y debe ser devuelto cuando sea so

ICONTEC INTERNACIONAL carrera 37 nro. 52 - 95. Boootá D.C., Colombia

Aprobado 2013-04-26







THE INTERNATIONAL CERTIFICATION NETWORK

IQNet and ICONTEC Hereby certify that the organization

HYPERBARIC SAC

Calle Solidaridad Mz. B1 Lt. 7 Parque Industrial Villa El Salvador, Lima, Perú For the following field of activities:

Diseño, fabricación, comercialización, instalación y servicio post venta de cámaras hiperbáricas

Design, manufacture, commercialization, installation and after-sales service of hyperbaric chambers

Has implemented and maintains a

Quality Management System

which fulfills the requirements of the following standard

ISO 13485:2003

Issued on: 2015 03 06 Validity date: 2018 03 05

Registration Number: CO-DM - CER375726

Michael Drechsel President of IQNet

Mónica Vivas Conformity Assessment Director of ICONTEC

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ICONTEC Certifica que el Sistema de Gestión de: ICONTEC Certifies that the Management System of:

HYPERBARIC SAC

Calle Solidaridad Mz. B1 Lt. 7 Parque Industrial Villa El Salvador, Lima, Perú

Ha sido evaluado y aprobado con respecto a los requisitos especificados en: Has been assessed and approved based on the specified requirements of:

ISO 13485:2003

Este Certificado es aplicable a las siguientes actividades: This certificate is applicable to the following activities:

Diseño, fabricación, comercialización, instalación y servicio post venta de cámaras hiperbáricas

Design, manufacture, commercialization, installation and after-sales service of hyperbaric chambers

Esta aprobación está sujeta a que el sistema de gestión se mantenga de acuerdo con los requisitos especificados, lo cual será verificado por ICONTEC This approval is subject to the maintenance of the management system according to the specified requirements, which will be verified by ICONTEC

> Certificado: DM - CER375726 Certificate

Fecha de Aprobación: 2015 03 06 Approval Date:

Fecha Última Modificación: Last Modification Date

Fecha de Vencimiento: 2018 03 05

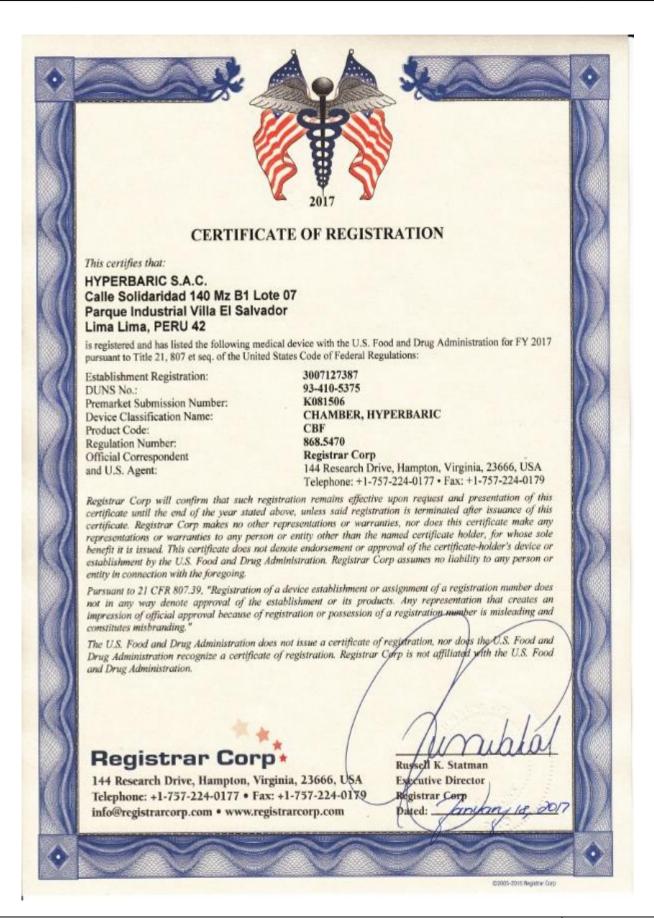
Expiration Date

Directora Evaluación de la Conformidad de ICONTEC Conformity Assessment Director of ICONTEC

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6. SPARE PARTS

- 6.1 At the time of shipping the chamber, the following spare parts are included inside the packaging of the equipment:
 - Door gasket (1)
 - Fireproof grease (1)
 - Allen wrench for the security system of door
 - Protective cover







7. OPTIONAL EQUIPMENT, SYSTEMS AND SERVICES

7.1 INSTALLATION, STARTING AND TRAINNING

- Our company provides advice to the customers in the different stages of the equipment supply, such as project elaboration, constructive norms, adjustments and requirements of the barosala, complete installation of the hyperbaric chamber with its accessories
- The customer shall arrange the necessary works in his facilities to guarantee the conditions for our company to perform the installation and starting of the hyperbaric chamber. This way the customer will be responsible for the unloading and transfer operations of the equipment to the installation site.
- Is essential that in the moment in that the Customer decides to acquire the Hyperbaric Chamber and before beginning the works of conditioning of the Barosala, receive our specialists' advice on important aspects as for example:
 - Where to place the Hyperbaric Chamber?
 - Condition, requirements and constructive aspects of the local for the installation.
 - Norms of security for the installation, etc.
- Regarding the training service to the staff that will be in charge of the operation of the hyperbaric chamber, as well as the small maintenance, our company will provide it simultaneously with the installation and starting of the equipment in the same place of the customer.
- The training in the operation of the equipment will have a maximum duration of 3 days and will be taught in Spanish. Maximum four people.
- The training is based on the following Program and it will consist on qualifying the personnel in the following operations:
 - Information and Operations of Work. Compression and Decompression.
 - Information, operation and regulation of the gases systems. Medical Oxygen.
 - Operation of the equipment and elements of the Hyperbaric System.
 - Security Measures
 - Cleaning and revisions of the Hyperbaric System.
 - Appropriate manipulation of the equipment to supply medical oxygen to the patients inside the Chamber.
- It is also included the training of Engineers and maintenance Technicians for the technical team designated by the Customer to give support to the Hyperbaric System.
- The training for the maintenance will have a maximum duration of 2 days and will be carried out in the facilities
 of the customer.
- The language of the maintenance training will be Spanish and for maximum 3 people.





- The training is based on the daily and periodic maintenance of the Hyperbaric Chamber and its systems and solution of problems.
- If for reasons beyond **HYPERBARIC S.A.C.** the training extends beyond the maximum time stated by us, the Customer shall bear the costs and expenses resulting for this extended time of our stay at their facility.
- To guarantee the not occurrence of problems and the safe operation, we insist in the periodic maintenance and in the opportune checkup of the Chamber and its systems.
- The specialized annual maintenances will be carried out only and exclusively by our Company in order to continue guaranteeing the correct operation of the Hyperbaric equipment.

7.2 HYPERBARIC MEDICAL EQUIPMENT

- Upon request of our Customers, we can quote the following Hyperbaric Medical Equipment included their installation in anyone of the models of our Hyperbaric Chambers:
 - Hyperbaric Ventilator.
 - Hyperbaric Infusion pump.
 - Hyperbaric vital signs monitor.
 - Transcutaneous Oxygen Monitor.