Division of Governmental Medical Center

Ministry of Health

Public tender no. 12399378

For purchase, delivery, installation of a Hyperbaric chamber for the hyperbaric oxygen therapy

Deadline for submitting proposals:
Date: 26/10/23
Time: 11:00
Place: Sheba Medical Center, pavilion 65, at the Tender Department.

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Invitation to public tender no. 12399378

1. Introduction:

The Division of governmental medical centers in the ministry of health (Hereinafter: "The Division") presents an invitation for the submission of proposals for the Purchase, Delivery, Installation and Maintenance of Two Multi - place Hyperbaric Chambers at Sheba Medical Center and Ziv Medical Center, all as detailed in the public tender documents.

All the documents attached to this tender (Hereinafter: "The Tender documents") are an integral part of it and must be seen as supplementing each other.

Corporations may submit bids for the tender (in accordance with the tender conditions below) that meet the tender requirements and conditions and are able to provide the performance of the services as stated in the tender documents.

Project Class: Turnkey project. (TKP)

General condition for the tender

1.1 It is hereby clarified that the purchase of the Hyperbaric chamber is conditional and subject to receiving all permits required by law for installation and operation according to all applicable Israeli laws.

1.2 The Applicant must carefully review all the Tender's documents and submit them in accordance with the instructions contained therein. The Applicant shall be deemed to have received appropriate advice for the purpose of his participation in the tender and submission of his Proposal. All relevant details in the Tender's documents must be fully filled, and the documents must be signed, each page signed with initials. All the Tender's required documents and/or approvals and/or permits must be attached.

1.3 One winner will be selected in the public tender, according to the criteria detailed in the public tender. The commissioning entity does not undertake to accept the cheapest bid or any given bid. The commissioning entity may cancel or broaden or reduce the scope of the public tender, due to budgetary and/or other reasons, of its discretion.

1.4 Do not add or include any stipulations, omissions, additions and/or changes to the terms or requirements in the Tender's documents.

1.5 **Timetable for this tender**:

Date of issuance of the tender: 21/8/23
Deadline for submitting questions for clarifications: 19/9/23
Deadline for submitting proposals:26/10/23

In the event of discrepancies between the schedule specified in this table and other dates specified in the Tender itself, or its appendices, the schedule specified in this chart is the determining schedule. It is understood that any missing data shall not be construed as a discrepancy. The division may update, change or reject the said timetables at its discretion.

1.6. Definitions

In general, and in the absence of any other meaning explicitly laid out, the terms and conditions in this Tender shall have the same meaning as they have in the Mandatory Tenders Regulations, 5753-1993 (Hereinafter: "**The Regulations**")

1.6.1. "Winner" of tender will be chosen and declared by the Tender Committee of the Division as the winning bid and will be accepted by the division, as stated in the invitation.

1.6.2. "The Commissioner" or " division": The Division of governmental medical centers in the ministry of health

1.6.3. "Tender" or "Invitation" or "Tender Documents": This document, including any document or appendix attached to it, and as updated or amended from time to time.

1.6.4. "Applicant" - A person who has submitted an offer in response to the Invitation.

1.7. **Tender Documents**:

The following appendices are attached to the invitation as an integral part thereof:

Appendix name	Description
Appendix A	Sample of Tender Guaranty to ensure the Proposal is upheld
Appendix B	Price Quote
Appendix C	Demands for computer and Cyber Security
Appendix D	Questionnaire for receiving new equipment
Appendix E	list of disinfectants

1.8. Priority between documents

1.8.1. The Tender documents shall be interpreted as one entity and in a complementary manner.

1.8.2. In case of contradiction or discrepancy between the Invitation and the technical appendix, preference shall be given to the technical appendix. In case of contradiction or discrepancy between the Invitation and the non-technical appendix, the Invitation will be given priority. During the course of the proceedings, and in case of clarifications given by the Tender Committee, the later version shall prevail over the earlier.

Threshold conditions

1. General Conditions

1.1 If the Applicant is an Israeli Legal registered entity to provide permits and licenses as required by the Public Entities Transactions Law, 5736-1976, as follows:

1.2 Permits for authorized businesses for VAT authorities ("Ossek Murshe" in Israel), valid as of the date of submission of the offer.

1.3 An approval from an assessor or CPA for managing accounts as required by Law, in accordance with the Income Tax Ordinance, valid as of the date of submitting the proposal.

1.4 Project manager: The applicant will must agree to designate a professional project manager, who will accompany the project on vendor's behalf as from signing date of the agreement and through the entire period of the contract (including the period of service and maintenance). The applicant will attach the project Manager's cv to his proposal. The applicant shall be entitled to replace the Project manager only with the prior written approval of the division.

2. Professional threshold condition

An Applicant who meets all the threshold conditions detailed in this section below may participate in this Tender:

2.1 The manufacturer of Hyperbaric Oxygen Therapy Institution stipulated in the Proposal (hereinafter: "The Manufacturer ") shall have experience in installation, operation and maintenance of at least 3 similar projects in the world during the past 10 years. The Applicant shall specify the active sites and the starting date of each project (with contact names and details for communicating with them).

2.2 In case of discrepancies in Proposals the Applicant shall fulfill the following conditions:

If it is not explicitly stated otherwise, all the threshold conditions must be met by the Applicants themselves. However, the Manufacturer may decide that the Proposal will be submitted by the authorized representative of the Manufacturer in Israel, in which case both the Applicant and the Manufacturer are bound by all of the Applicant's undertakings, as defined in the Tender Documents, and the Applicant must attach to his Proposal a Letter of Commitment on behalf of the Manufacturer as specified below:

If the Applicant is a local representative of the Manufacturer, then the Applicant will attach to its Proposal a Letter of Commitment from the Manufacturer (hereinafter: "Letter of Commitment"), according to which the Manufacturer accepts all the undertakings and declarations of the Applicant pursuant to the Invitation, the accompanying documents and the signed agreement (hereinafter collectively: "the Applicant's Obligations"). The Letter of Commitment shall include a commitment by the Manufacturer to undertake all the commitments of the Applicant, jointly and severally. The Letter of Commitment will be duly

signed by the authorized signatories on behalf of the Manufacturer and will include an attorney's validation that the letter was duly signed by the authorized parties on the Manufacturer's behalf and obligates the Manufacturer for all intents and purposes according to Law. The Letter of Commitment will constitute a condition for signing the agreement with the Winner. The Tender Board reserves the right to demand addendums to the Letter of Commitment.

2.3 The Applicant has attached to their bid a Tender Guaranty, as detailed and required in section ___4_____ hereunder.

3. Clarification questions

3.1 All inquiries should be addressed until the date indicated in section 1.5, to Keren Deutcher Roffe, at the e-mail addresses listed below:

Keren.DeutcherRoffe@sheba.health.gov.il

No questions will be accepted after 19/9/23.

3.2 All inquiries must include the name of the Applicant, the identity of the person asking on his behalf if applicable, and contact details.

3.3 Only answers given in writing by the tender Committee will be binding for the commissioning Entity. The commissioning Entity reserves the right to issue amendments and clarifications on the Tender's documents, even after answers to the clarification questions were published, either on its own initiative or in response to any of the Applicants. Such amendments and clarifications shall be sent to all Applicants.

4.Bank guarantee

The applicant shall submit a bank guarantee linked to the Tender in the amount of 200,000 NIS valid until 6 months after the final date of submitting proposals. The Winner of the Tender will extend the validity of the guarantee and transfer it into an Operative Indemnification that will be valid until the supply and installation the Hyperbaric chamber is completed. Upon commencement of the operation of the Hyperbaric chamber, the applicant shall in increase the amount of the guarantee to 10% of the total amount of the order and extend its validity so it shall be in force 6 months after the contractual period.

The guarantees required under this section shall be autonomous, unconditional and unrestricted and should be in the name of the Applicant only and solely for the benefit of the Commissioning Entity.

4.1 In its discretion, the Commissioning Entity reserves the right to demand the applicants extend the guarantee periods, subject to written notice.

4.2 The Commissioning Entity reserves the right to require the applicants to amend the letter of guarantee that was submitted, insofar as the guarantee was granted and the error in the guarantee does not apply to either the amount stipulated therein, the duration of its validity, its autonomy, its being unconditional and without restrictions.

4.3 An Applicant who is required to amend the Letter of Guarantee will do so by presenting an amended Letter of Guarantee at the time requested, and only after that will he be entitled to receive back the Letter of Guarantee which had the error that was corrected.

4.4 Forfeiture of the Guarantee:

The Tender Committee will be entitled, after giving the Applicant the opportunity to state his defense, to either partially or fully forfeit the guaranty for the Proposal submitted by the Applicant if the Applicant is found to have committed, inter alia, one of the following:

4.4.1 Any ploys or schemes or lack of integrity and/or providing the Tenders Committee with misleading information or essential information that is inaccurate either during the process of the Tender and/or the work itself.

4.4.2 The Applicant retracted his Proposal after the last deadline for the submission of Proposals had elapsed, but before the end of the date of validity of the Proposal and/or after he received notice of his winning the Tender, and did not comply with the provisions set out in the Tender's documents, which are prerequisites for entering into a contract with the winner of the Tender (including, but not limited to: signing the contract, providing the Operative Indemnification, providing a confirmation form of possession of the relevant insurances, permits etc.).

5. Price Quote and selection of winner

The full system configuration and all accompanying components according to the tender's conditions detailed in this document.

Including but not limited to the following components: accessories, machinery, control systems, first supply of all disposables, installation, regulation, quality control etc.

The price quote is attached as an appendix "**B**".

Pay attention to fill out a quote for option A, option B and option C separately.

Each item to be named, detailed and priced.

***The currency rate will be calculated according to the time the envelopes are opened.

Attached to the quote will be the following documents and materials:

1. Document attesting to the compliance of the experience condition including a detailed list of past projects and contact detail.
2. Document specifying all data for all relevant devices and equipment according to the Tender conditions. Particularly for Technical Specifications and according to the clauses of the public tender. The document should be conformed to the requirements, dated signed and to be accompanied by reference material (manufacturer data, regulation documentation etc.)
3. The appropriate and full system configuration including catalogue numbers, description and quantity.
4. A full characterization of facility and infrastructure the system requires for installation, operation, control and safety, based on system specification and manufacturer instructions. Construction (load and dimensions), air conditioning system, compressors and relevant infrastructure, water and sewerage, power and all other system requirements.
5. A detailed maintenance plan for all proposed components separately and from a high level perspective. The maintenance plan will include specified actions required, details on the executing parties, frequency and prices. Since the manufacturer's instructions vary over large periods of time, the plan will be presented for the first 10 years of operation on a yearly basis.
6. A service contract quote for 10 years.
7. The quote will include:
    a. All covered systems, components and devices
    b. SLA
    c. Maximum system down time in case of a malfunction or scheduled service
    d. For local execution of service – please specify the number of local personals certified by the manufacturer, extent of local inventory and response time throw-out the work week and weekends.
    e. Specify which action items are performed by the manufacturer
    f. First year warranty period.
    g. include all medical devices and an independent maintenance plan (periodic service, calibration etc) as instructed. In addition, attach a breakdown of the maintenance plan including parts, work and needed technical equipment.

Bid review and selection process:

Without derogating from the Commissioning Entity ’s discretion, choosing the winning bid will be done in three stages:

Stage A - each vendor will receive a score in a 0-100 range based on the following parameters. This score will embody 30% of the final total score to be determined in stage B.

1.Quality and Service			30%
1.1.The Manufacturer ’s Experience:		4%	
1.1.1. Number of installations globally (1% - over five medical application installations) and the number of years of activity in manufacturing hyperbaric chambers for medical needs (1% - over 10 years).	2%		
1.1.2. Proven experience in Israel in operating and maintaining hyperbaric chambers for medical therapy. To be added to the score if the sites (1 or more) are operational and the supplier receives a positive evaluation by the site's management.	2%		
1.2. Technological and Operational Evaluation		20%	
1.2.1. The complexity of the infrastructures that the Commissioning Entity must prepare to install the system And operate it.	5%		
1.2.2. The System’s Reliability - downtime for the purpose of maintenance and malfunction (as reported by vendor + customers reports)	5%		

1.2.3. Operating Convenience. To be scored by the site operational and clinical team.	5%		
1.2.4. Technology - quality and innovation	5%		
1.3. Service Provider's Evaluation		6%	
1.3.1. Knowledge, professional experience and human resources	2%		
1.3.2. Response times to handle faults (as reported by vendor + customers reports)	2%		
1.3.3. Performance Level of regular maintenance (past experience + customers reports)	2%		

Stage B - A final score will be comprised of the stage A evaluation, the price and the:

1) The comprehensive score the Bidder received in Stage A - 30%
2) Price - 65%
3) Delivery time - 5%

The price will be calculated according to the overall system cost and the Maintenance cost for a period of 10 years.

The delivery time will include the installation of a working device. Will be calculated according the delivery time from the moment of the order. The maximum score will be given to a supplier with supply availability of up to 5 months from the moment of the order.

only a Bidder who receives a weighted score of 85 and over in stage A will progress to Stage B

Stage C - up to three Bidders receiving the highest score according to the criteria detailed above in Stage B, pursuant to the Commissioning Entity 's determination, will progress to Stage C, within the framework of which an additional competitive procedure will be conducted between the Bidders including negotiations over the price and the option

of submitting corrected bids advantageous to the Commissioning Entity (including but not limited to the price), to receive a higher score than they received in Stage B.

It is clarified that the Commissioning Entity of its absolute discretion may waive stage C and/or have less than three Bidders progress to Stage C, if it thinks that this will be beneficial to the Commissioning Entity and/or to determine a winner at the end of Stage B including but not limited to the Bidder thinking that conducting an additional procedure will delay the project and/or will lead to less favorable bids and/or for any other reason.

The Bidders waive any argument and/or demand from the Commissioning Entity if and insofar as it decides on an additional procedure and/or if it is decided not to conduct an additional procedure including a reliance argument and/or any other argument.

It is agreed that upon the fulfillment of one of the following cases, the Commissioning Entity may terminate the engagement with the Bidder of the bid and/or the winner of the Public Tender:

a. A winding up application was filed or a receiver against the Bidder and/or the Equipment Manufacturer.

b. Liens or charges were imposed over the Bidder's assets likely to prejudice the Bidder's functioning.

c. The government ministries, Standards Institute, Ministry of Health or the Ministry of Industry and Trade approvals were revoked.

d. The Bidder did not establish a service structure as detailed in the agreement.

The Commissioning Entity will not bear any liability for any expense and/or damage the Bidder sustains in connection with preparing the bid and/or submitting its bid, and in particular, and without derogating from the generality of the above, for damages and/or expenses sustained due to its bid not being accepted, or accepted in part and/or the Public Tender being cancelled, whether fully or partially.

8. The rights of the customer

a. The division reserves the right to choose the offer that gives her the most advantages according to the amount determined in the tender documents, but is not obligated to choose the cheapest offer, the offer that the winner may decide not to contract at all, for budgetary or other reasons.
b. The division may expand or reduce the scope of the tender and/or projects or cancel it for organizational, budgetary or other reasons, and this also after the winner of the tender has been announced, without the need to justify her decision, without prior notice and without any compensation. In this case, an appropriate notice will be given to the bidders.
c. The division reserves the right to contact the bidder during the inspection to obtain clarifications, subject to the tender obligation law -1993, and the regulations established pursuant to it, to visit the bidder's facilities and/or to call for an additional interview which of the bidders he deems appropriate according to her sole discretion.
d. The rules of contracting and the execution of the tender are clarified and the ordering party is conditioned on maintaining a budget. The ordering party reserves the right to cancel the tender and/or the contract as soon as the budget for the tender is not approved, without any compensation.
e. The division reserves the right to hold negotiations with each of the bidders, including regarding the rate and other conditions.

9. Insurance

The supplier undertakes to arrange and maintain suitable insurances related to the services/works supplied/conducted by him for the State of Israel - The Ministry of Health, Sheba Medical Center and Ziv Medical Center (hereinafter under this section: "the Client"), to the extent that is acceptable in the field of his activity; [according to the matter: workers compensation, Employers' Liability Insurance, Third-Party Liability Insurance, Umbrella Liability Insurance, Property Insurance, Marine ("door to door, as per Institute Cargo Clause A include, inter alia, cover against war risks, riots, strikes and civil commotion") , CAR Insurance, and Products Liability Insurance, etc.] with reasonable limits of liability in accordance with the nature and scope of the services/ products supplied by him. As long as subcontractors are employed by the supplier must ensure that his insurances include coverage for his liability.

In regards to their activities as well as demand, them to arrange insurances covering their direct liability as required under this section or, alternatively, shall include coverage for their direct liability and activities in his insurances. For avoidance of any doubt, The Supplier shall be solely responsible to pay all premiums, and the deductibles, and be accountable for all conditions imposed (if at all) by the Insurers.

The supplier shall ensure that all his insurances shall include the Client as additional insureds subject to an indemnity extension as accepted in each insurance type. The Car insurance shall extended to include contractors and sub-Contractors and the Client as additional insureds.

The supplier shall ensure that all his insurances shall include a waiver of subrogation clause in favor of the Client and Its employees (this waiver of subrogation shall not apply for the benefit of a person that has caused willful damage).

The insurances also shall be primary and apply prior and without contribution to any other insurance arranged by or on behalf of the Client.

The Client reserves itself the right to receive from the supplier a certificate of insurance or copies of the insurance policies, from time to time, by demand.

Law, Jurisdiction, and Territorial Limits in all the supplier's insurances shall include the state of Israel.

Additional insurance requirements shall be agreed and detailed in the Agreement

Technical specifications and special requirements

System overview.

Project class: **Turnkey project**. (TKP)

5 Special requirements:

5.1 Planning, infrastructure design and construction for a complete and operational Hyperbaric Oxygen Therapy institute.
5.2 All necessary planning and coordination required for the delivery, lift an installment of the chamber and all other systems.
5.3 All supporting technical systems including a designated technical site and control consoles.
5.4 All required safety systems and a compatible fire extinguishing system.
5.5 A Multi-place hyperbaric chamber with a full inner design including structural characteristics according to the configuration and all seats, beds and equipment required for all relevant clinical applications.
5.6 Additional devices and equipment such as oxygen masks, medical devices, monitoring and audio systems etc.
5.7 All other relevant facilities included in the site: Reception, waiting room, changing rooms, bathrooms, physician's office and staff room.
5.8 Comprehensive plans for the following issues:
5.9 A 10-year maintenance and operation plan
5.10 Procedures and documentation to meet regulation and safety requirements
5.11 Gas supply quality control
5.12 controls and safety measures for all technical supporting systems
5.13 A 10-year service plan and quote.

6 Submission format and conditions:

Each item included in the two following sections, technical characteristics and regulation, requires a written response. The vendor will specify any technical details needed to provide a comprehensive response to the requirements and will attach supporting materials (marked manufactures materials, sketches, quotes etc.). In the technical specifications section, the vendor will use the table to provide a written response. The vendor may add any additional materials as they see fit, all materials will be marked and referred to.

The Division may disqualify a bid if all the documents detailed below and/or some of them are not attached to it. According to the division discretion.

7 General technical characteristics:	
Atmospheric pressure:	
The bidders will submit quotes for a hyperbaric chamber with the following working pressures: 3, 5, 6 atm (absolute). Each option priced separately and each for the purchase of two hyperbaric oxygen therapy sites.	
Each quote will provide the appropriate pricing for each one of the above pressure ATA goals.	
The commissioning Entity may select any offers most suitable with the determined clinical applications at each location.	
Chamber design and dimensions:	
A large chamber designed to treat, simultaneously, multiple patients according to the needs of each patient.	
An overall operation of high pressure supply, pressure comparison and oxygen supply.	
The chamber will be pressurized with compressed air and oxygen supply. Treatments will be performed through masks or hyperbaric hoods.	
Wheelchair compatible - convenient and safe wheelchair entry. Provide detailed sketches for both passage and chamber and specifications for a designated wheelchair compatible with hyperbaric conditions.	
Entry points - Each department will have an entry point. Provide marked schemas displaying location and measurements of all entrances. For each one detail the lock mechanism and the materials the doors are made from.	

Additional airlock doors for the insertion of equipment - if there are any additional openings (not including main doors) please specify. Mark placement and measurements in the chamber schema. Functional airlock doors are an advantage.	
Observation windows - Specify quantity and mark placement and measurements in the chamber schema.	
Oxygen regulation - the system will include oxygen supply, regulators and means of consumption (mouthpiece / hood). Specify the regulation resolution – seat / Compartment / Section / chamber.	
Configuration:	
Option A:	
Two main compartments designed to service 12 patients each (14 seats) with a passage/transition section (2 seats).	
External dimensions - to be provided by the bidder based on the technical specifications in this document and actual measurements taken at the site.	
Angular orientation for the specified configuration (linear/angular) will be determined based on measurements taken on site and must be approved by the authorized constructor.	
Compartments will be independently pressurized.	
Option B:	
Two main compartments designed to service 12 and 6 patients (14 and 8 seats respectively) with a passage/transition section (2 seats).	

External dimensions - to be provided by the bidder based on the technical specifications in this document and actual measurements taken at the site.	
Angular orientation for the specified configuration (linear/angular) will be determined based on measurements taken on site and must be approved by the authorized constructor.	
Compartments will be independently pressurized.	
Option C:	
Two main compartments designed to service 12 and 6 patients (14 and 8 seats respectively) with a passage/transition section (2 seats). In this option, the second 6 patient compartment will be designed as a future add-on section.	
The initial configuration for a 12 patient compartment and a 2 seat transition section will be fully operational.	
All supporting systems, designated technical sites, control consoles and all other aspects of infrastructure and construction will be planned, purchased and installed to support the full final configuration. All plans will include space reservation (fuse box, room space, control consoles etc.)	
How many years after the initiation of the project will we have to realize the final portion	
External dimensions - to be provided by the bidder based on the technical specifications in this document and actual measurements taken at the site.	
Angular orientation for the specified configuration (linear/angular) will be determined based on measurements taken on site and must be approved by the authorized constructor.	

Compartments will be independently pressurized.	
Submissions:	
The vendor will submit an offer and full specifications for all 3 configurations. All other technical specifications and conditions in this document apply to all 3 options.	
The commissioning entity reserves the right to select and acquire any configuration based on budgetary/clinical considerations as it sees fit.	
Planning - structure and construction:	
Design and construction is to be approved by the attending architect and institutional constructor.	
All bidders will be scheduled to tour the premises to examine the site and infrastructure.	
Stage A: The bidder will submit a plan for transportation, lift, installment and support to be examined and approved.	
Stage B: Project hand off will be finalized at the conclusion of construction, supply, and installation and only after the approval of said authority.	
For stage A, please make sure to detail the following information in addition to any other aspects regarding the submitted plan:	
Specify detailed Transporting Requirements	
How the system is transported - in its entirety or assembled. If it's the latter, please specify the disassembly resolution, dimensions of largest parts and when and how assembly will accrue.	
How will the system be inserted into its permanent place? Description of the Method and route taking into account the site location and accessibility.	

The system will be compatible with the Israeli electrical grid. Provide data concerning the system's Electrical feed. Electric panel (fuse box) or existing equipment interface. To be approved by the relevant authority.	
Supply and installment of constructive supports	
All lifting, transportation and final positioning will accommodate all loading scenarios.	
The vendor will submit BIM plans (/similar tools)	
The vendor will provide structural specifications (and will approve!) for all loading scenarios, emergencies and earthquake readiness. In accordance with the ministry of health guidelines for Nonstructural systems https://mapi.gov.il/earthquake/documents/hanlecele.pdf	
The vendor will document and store all confirmation and testing for a period of 10 years.	
Backup:	
The system requires uninterrupted power supply to ensure a continuous and safe operation. The vendor will provide electrical specifications for the infrastructure and systems in place.	
This also includes backup communication systems.	
Internal specifications:	
Materials:	

The materials comprising the inner chamber including walls and panels should be anti-bacterial and washable.	
Colors used internally should be fire resistant, shade should be bright and compatible with a clinical environment.	
The floor will be made of non-slip materials and surfaces.	
Seats:	
Materials - smooth and washable	
Easy dismantling and disassembly - provide instructions and sketches.	
Grounded (electricity)	
Any pads (mattresses, pillows) will be made out of fire resistance materials	
Equipment and devices:	
The quote will include the following attached, connotative items:	
Seats - In accordance with the general specifications, the chambers will include seats in two compartments. Specify the dimensions of a single seat and gaps. Can be submitted for each configuration.	
Beds - the proposal will include 2 treatment beds. Please specify: the instructions to make use of said beds and any disassembly steps required, the number	

of remaining usable seats when a bed is inserted with a marked schema.	
Compatible wheelchair.	
Oxygen masks and hoods in an adequate initial amount.	
Control units - Electronic and pneumatic.	
Entertainment system – provide a quote and specifications with supporting images. Acquisition for the consideration of the Commissioning Entity.	
Audio system – to be used for clinical instruction and two-way communication.	
Patient monitoring systems:	
Close circuit video system	
Coverage - a full view of all patients in the chamber and entry points.	
External monitoring and observation option	
For clinical monitoring see the medical devices section	
Lighting systems in the chamber and the entire facility.	
Fire prevention apparatus in the chamber.	

Administration of gas mixtures Nitrox 50 and Heliox 50 - To be specified and priced as an option (not a threshold requirement). Provide details on the relevant procedure required for administration.	
Specify any perishables/disposables required to operate the system and how those are to be supplied.	
External specification:	
The Commissioning Entity will be able to select a custom graphic design for the chamber's exterior.	
Cleaning and disinfections:	
Attached is information regarding cleaning materials used by the medical centers to clean and sterilize medical devices and equipment in the patients' area, specify if those materials are approved to be used for all relevant system components. If not, provide manufactures cleaning instructions. The response will not be accepted if it will not include a specific reference to the materials in use.	
Additional Facilities:	
Designated technical site:	
Will include technical equipment supporting the operation of the hyperbaric chamber or supporting systems such as but not limited to compressors, containers and tanks, climate control systems, filtering systems, fire equipment, control consoles etc.	
Operations and requirements:	

The quote will include a detailed list of all equipment and machines required for a full system operation	
An initial supply of gas tanks. The quote will also include pricing for all relevant tanks and containers needed for a full operation.	
Will be located in proximity to the chamber without interfering with clinical operations at the institution (safety, noise, ventilation etc.).	
Water and oil drainage systems	
exhaust pipe output will be located outside the institution. Mark on schema.	
Submit a plan for: A. Controls and alerts. B. Maintenance plan. C. Safety systems.	
Safety systems - what protection measures are in place in case of hypertension, sudden pressure drops, fast escape, fire etc.	
Bathrooms*:Standard and clean	
Changing rooms with lockers*	
Reception and waiting room*	
Physician and staff rooms*	
Clarifications:	

The vendor is obligated to include any other facilities essential or recommended for the institution's full and optimal operation.	
Quantity of facilities and rooms can be submitted for approval based on configuration and site inspection prior to finalizing a construction plan.	
Air supply and control systems:	
The system will include: All machines, components and supplies required for a fully functioning air and gas supply system.	
The vendor will include details and images for the system components in addition to the following items:	
Humidifier and Humidity control	
Compressor suitable with producing breathing air	
Sampling - specify the procedure and frequency	
Air purity testing - specify protocol and equipment	
Compressor entrance point will be located in a non-contaminated site with a low levels of CO2	
Air storage systems to be compatible with chamber volume according to the submitted configuration.	
Clarifications:	
Steps will be taken to ensure limited noise levels. Please specify the predicted decibel level.	

Fire systems:		
The facility will include a designated fire detection and extinguishing systems compatible with hyperbaric conditions.		
This section will include: planning, adjusting to site, installment and implementation.		
The plans will be submitted to the commissioning authority's fire department for approval.		
Computerization Requirements		
The vendor will produce detailed Computerization Requirements for the system or any components of it as needed to be reviewed and approved by the commissioning authority information systems department.		
Any component that should or can be connected to the medical center's internal network (by wifi or otherwise) must be examined and approved. For this process, fill and submit the attached Demands for computer and Cyber Security appendix. This will include all proposed medical devices.		
Medical devices:		
The vendor will only include medical devices and technologies for which he is able to provide technical and clinical support and that are in full compliance with the conditions below.		
Acquisition based on commissioning entity's discretion, according to available devices, clinical assessment and need.		
For each item, please submit a written response supported by marked manufacturer's materials and regulatory documents. All service related conditions require a written and signed obligation.		

The quote will include any of the following medical devices, priced individually:	
Medical device:	Specify: model, manufacture, Basic functionality and any clinical/technical relevant notes.
Monitoring system (patient monitor and central station). Will provide the following parameters: 3 leads, pulse, temp, saturation, EtCO2 (modular/integral), blood pressure, Arterial blood pressure (modular/integral).	
Ventilator	
Administration systems – syringe and volumetric pumps	
Pulse Oximeter	
Blood pressure monitor (including temp and SpO2)	
ECG	
Defibrillator monitor	
Medical suction	
Transcutaneous oxygen pressure (TcPO2) - noninvasive measurements. *Indicative for diabetic HBOT treatments, 1-2 units will be acquired.	
Requirements for all items (Provide a written response to each proposed medical devise):	

Compatible with hyperbaric conditions. To be specified by AMAR and FDA/CE regulation documents.	
The items will have valid AMAR (Medical Device Division, Ministry of Health) approval.	
Provide full technical specifications and brochures (digital) for each item.	
Each item will be technically and functionally inspected by the Bio-Medical engineering department and demonstrated to the clinical authority	
Include a quote for all relevant disposable for a complete system operation	
Attached is information regarding disinfectant materials used by the medical centers, specify if those materials are approved to be used for all system components. If not, provide manufactures cleaning instructions. This will be submitted for each medical device. The response will not be accepted if it will not include a specific reference to the materials in use.	
The vendor will hold a local inventory of replacement and backup components and devices. Quantity should be sufficient as to insure a non-interrupted system operation.	
Technical literature will be supplied in a digital format (operation and service manuals)	
Full implementation support will be given for each device as needed.	
To ensure safe and efficient maintenance, medical devices are an inherent part of the system management and as such, included in the 10-year service agreement. We ask that for backup purposes,	

two technological personnel from the ordering entity will receive technical certification provided by the manufacturer.	
Implementation and training:	
In the two-weeks following installment, an application personal will be available on the site daily.	
Training will be held for all levels of operation (technicians, operators, nursing staff and physicians). Unlimited training sessions to the satisfaction of each medical center.	
In addition, a representative from the vendor will design and implement protocols based on clinical guidelines.	
Finally, Application personals will be available for all inquiries – 1-day response time for a remote response and 3-day response time for on-site response.	

8 Regulation and Standardization:

Planning, construction, installment, operation and documentation with compliance to relevant regulation as detailed at all stages of service.

- Installment and operation based on manufacturer instructions
- The equipment has valid CE approval and/or FDA approval
- The equipment will have valid AMAR (Medical Device Division, Ministry of Health) approval.
- The chamber will be manufactured and installed according to 14931:2006EN and ASME PVHO-1
- The manufacture has IQ, OQ, PQ processes in place according to FDA/CE regulations
- The Equipment Manufacturer has valid approval for Standard ISO 9001 and ISO 13485 to assure quality management of the medical equipment.
- The Equipment Manufacturer has valid approval that the hyperbaric chamber conforms to Standard EN13445.
- The Equipment Manufacturer has valid approval that the hyperbaric chamber and conforms to Standard EN13480.
- The Equipment Manufacturer has valid approval that all fire systems including the fire-mist spraying system conforms to Standard EN16081.
- The Equipment Manufacturer has valid approval that the system responsible for the patient's breathing in the hyperbaric chamber conforms to Standard EN-14931 and G-01 (Israeli ministry of health).
- Details on Documentation Methods - please specify the methods, frequency and executor of documentation related to operation, safety and quality.
- In addition to the proposed systems and equipment conforming to the relevant standards, all plans, construction and specifications submitted will conform as well.