ANNEX 4

PRODUCT SPECIFICATIONS AND TECHNICAL REQUIREMENTS FOR OXYGEN CONCENTRATORS AND RELATED SERVICES

This Annex provides offerors with the product(s) specifications and Technical Requirements for The Procurement of the commodities listed in the Annex 5-Price-Quotation and Capability Form under RFP-GHSC-PSM-TO1-O2-CONCENTRATORS.

1. Product Specifications

Please see the following technical specifications for both low pressure, low flow and high flow, high pressure oxygen concentrators, consumables, warranty and service agreement contract(s) for this procurement.

<table>
<thead>
<tr>
<th>1. Specific type or variation</th>
<th>Low flow, low pressure concentrator delivering a minimum of 10 LPM, with pressure of at least 10 psi. Vendors shall propose models capable of delivering a minimum of 10 LPM.</th>
<th>High flow, high pressure concentrator delivering a minimum of 10 LPM, with pressure of at least 50 psi. Vendors shall propose models capable of delivering from 10 LPM to 30 LPM.</th>
</tr>
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<tbody>
<tr>
<td>2. Definition</td>
<td>A stationary mains electricity (AC-powered) device designed to concentrate oxygen from ambient air and deliver the concentrated oxygen, typically through an attached nasal cannula (or prongs), to a patient requiring oxygen therapy. It processes the air through an internal filtration system (e.g. a molecular sieve [zeolite granules or membranes]), which has a large total surface area to concentrate oxygen from the air. It typically consists of an air compressor, filters, dual chambers, a reservoir and controls. The oxygen concentration is variable depending on the flow rate utilized. It is typically wheeled but is designed to be placed in one location (e.g. an institution or a home setting).</td>
<td>A stationary mains electricity (AC-powered) device designed to concentrate oxygen from ambient air and deliver the concentrated oxygen, typically through an attached nasal cannula (or prongs), to a patient requiring oxygen therapy. It processes the air through an internal filtration system (e.g. a molecular sieve [zeolite granules or membranes]), which has a large total surface area to concentrate oxygen from the air. It typically consists of an air compressor, filters, dual chambers, a reservoir and controls. The oxygen concentration is variable depending on the flow rate utilized. It is typically wheeled but is designed to be placed in one location (e.g. an institution or a home setting).</td>
</tr>
<tr>
<td>3. Detailed requirements</td>
<td>1. Provides a continuous low flow, low pressure of clean and concentrated oxygen, produced from air by molecular sieve process. Contains not less than 90.0 % V/V and not more than 96 % O2 V/V, the remainder consists of mostly argon and nitrogen. 2. Includes an oxygen monitor to measure % oxygen by volume and alarm for high or low oxygen concentrations. 3. Option for flow from one concentrator can be divided for at least two patients with (built-in or add-on)</td>
<td>1. Provides a continuous high flow, high pressure of clean and concentrated oxygen, produced from air by molecular sieve process. Contains not less than 90.0 % V/V and not more than 96 % O2 V/V, the remainder consists of mostly argon and nitrogen. 2. Includes an oxygen monitor to measure % oxygen by volume and alarm for high or low oxygen concentrations. 3. Option for flow from one concentrator can be divided for at least two patients with (built-in or add-on)</td>
</tr>
</tbody>
</table>
4. **Control panel / user interface**
   - Clearly visible, digital display, in English and/or Spanish, Portuguese, Tajik or French for at least:
     - Oxygen flow rate [on flowmeter]
     - Oxygen concentration [% by volume]
     - Output pressure
     - System status, including current maintenance need
     - Cumulative hours of operation (digital or analogue meter)
   - Audible and visual alarms with ability to be set by user for:
     - High temperature
     - Low/high pressure (ex., 0.1/0.23 Mpa)
     - Low oxygen concentration (<90%)
     - Occlusion (no flow)
     - Power failure; system failure

5. **Estimated lifespan**
   Indicate the estimated lifespan (hours of use) for models proposed.

6. **Power supply, (**voltage, frequency and plug variations across the countries**)
   
   **Electrical source requirements:** Frequency; Voltage; and Plug type based on country/setting of use as follows:

   ![](image)

7. **Storage and operational requirements**
   - Capable of being stored continuously in ambient temperature from 0 °C to 40 °C, RH from 15% to 95% and elevation from 0 to 3000 m.
   - Capable of operating continuously in ambient temperature from 10 to 40 °C, RH from 15% to 95%, simultaneously, and elevation from 0 to 3000 m.

Annex 5 requests pricing based on the operational requirements listed above, with the
understanding that operation and storage at differing elevations and/or above 40°C and/or relative humidity above 95% may require additional components within the relevant oxygen concentrator.

<table>
<thead>
<tr>
<th>8.</th>
<th>Product labelling</th>
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<tr>
<td>● Electrical power input requirements (voltage, frequency and socket type)</td>
<td></td>
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<tr>
<td>● Manufacturer serial number for tracking/inventory management</td>
<td></td>
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<tr>
<td>● Labelling as required to meet U.S./international safety standards for medical O2 systems</td>
<td></td>
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<tr>
<td>● Designating required environmental conditions for storage and operation (e.g. temperature, pressure, light, humidity)</td>
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<th>9.</th>
<th>Primary packaging</th>
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<td>Labelling on the primary packaging to include:</td>
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<tr>
<td>● Name and/or trademark of the manufacturer; model or product’s reference</td>
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<tr>
<td>● Information for storage conditions (temperature, pressure, light, humidity)</td>
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<th>10.</th>
<th>Risk classification</th>
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<tbody>
<tr>
<td>FDA Class II (USA); Class IIA (EU and Australia)</td>
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<tr>
<th>11.</th>
<th>Regulations</th>
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<td>US regulations:</td>
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<tr>
<td>21 CFR part 820 Quality System Regulation.</td>
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<tr>
<td>21 CFR section 868.5440 Portable oxygen generator.</td>
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<tr>
<td>EU regulations:</td>
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<tr>
<td>Medical Device Directive 93/42/EEC</td>
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| Consumables, spare parts, other accessories |

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<tr>
<th>12.</th>
<th>Consumables</th>
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<tbody>
<tr>
<td>Propose list of consumables for adult, child and infant use required for a one-year supply including any proprietary consumables. For each consumable, provide a brochure with specifications and image. If a brochure is not available, provide an image.</td>
<td></td>
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</table>

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<thead>
<tr>
<th>13.</th>
<th>Spare parts</th>
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<tbody>
<tr>
<td>Propose spare parts list per recommended preventative maintenance program clearly defined in a disaggregated list comprising part numbers, descriptions, and unit cost, as well as indicating manufacturer/brand/model specifics.</td>
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</table>

| Installation and Commissioning |

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<thead>
<tr>
<th>14.</th>
<th>Pre-installation requirements</th>
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<tr>
<td>Manufacturer must explicitly provide the minimum operating requirements within the following aspects of the health facility, including but not limited to:</td>
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<tr>
<td>● Acceptable mains capacity.</td>
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<td>● Appropriate connections/adaptors.</td>
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<tr>
<td>● Compliance with electrical standards and regulations.</td>
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<tr>
<td>● Power conditioner, voltage regulator, etc.</td>
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<tr>
<td>● Compatibility with back-up power supply (e.g. generator).</td>
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<tr>
<th>15.</th>
<th>Requirements for commissioning</th>
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<tbody>
<tr>
<td>● FCA 2020 INCOTERMS.</td>
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<tr>
<td>● Manufacturer’s local agent to note and report any signs of external or internal damage upon device delivery. Record the number of hours on the hour meter.</td>
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<tr>
<td>● Verify oxygen concentration level is within specifications when device is operated with all tubing and flowmeters installed.</td>
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<tr>
<td>● Verify operation of oxygen concentration, battery and power failure alarms.</td>
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<tr>
<td>● Additionally, any other standard manufacturer commissioning protocols.</td>
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</table>

| Warranty and maintenance |
16. **Warranty**

Provide standard warranty terms and conditions and exclusions.
Propose required parts for preventative maintenance during standard warranty.

17. **Maintenance tasks**

Provide guidelines that detail maintenance routines/tasks, checklists for those routines/tasks to be completed, their recommended frequency (for example, based on hours or use) in order to maintain continuity of warranty and the predetermined system for procuring spare parts that are brand/model related.

18. **User and maintenance training**

Manufacturer and/or authorized local service agent must explicitly indicate the following maintenance routines to match the dedicated staff capabilities within the health facility:
- Pre-trainings (before the device is implemented)
- Cleaning routines of the concentrator considering the electrical safety precautions.
- Cleaning routines for the filters, if applicable (i.e. reusable).
- Testing of alarms.
- Testing of operating pressures.
- Testing of oxygen concentration.
- Frequency of the recommended maintenance routines (e.g., minor service after X operating hours, major service after X operating hours).
- Safety precautions on management of oxygen.
- Maintenance tasks required to be carried out by the manufacturer’s authorized local agent.
- Additionally, any other standard manufacturer service routines not covered above.
- Provide details for annual trainings included free of charge separate from any service level agreement.

**Post Warranty**

19. **Type of service contract (post-warranty period)**

List extended warranty options/service level agreements that include technical support, spare parts, maintenance, repairs, etc. offered by the manufacturer and include a copy of the actual agreement(s). (Referencing Annex 5).

20. **Spare parts availability post-warranty**

List all spare parts for one year or 5000 hours and up to five years or 15 000 hours of use indicating whether parts are proprietary.

21. **Software/hardware upgrade availability**

Indicate if the equipment has any software that is used for maintenance and/or troubleshooting and if so, provide an upgrade schedule and associated costs, if any.

**2. Conformity with Quality and Products Standards**

Offerors and the products presented and delivered must fully comply with the following eligibility requirements:

- Manufacturer(s) shall conform to the quality standards set by the International Organization for Standardization and/or the US FDA Quality System Regulations or shall have a valid GMP certificate. Manufacturer must be quality assured with valid certifications like ISO 13485:2016 and other ISOs as described below. A copy of the manufacturer(s) certifications(s) must be provided.
Annex 4 – Product Specifications and Technical Requirements

- Product (or applicable components) shall have evidence of (a) US FDA Clearance (PMA/510K pre-market notification) and manufacturer shall provide evidence of medical device establishment registration with the US FDA or (b) CE Mark (USAID Recognized SRA)* Certificate. In case the aforementioned are not available, a clarification should be submitted by the offeror and a Free Sale Certificate (or equivalent) shall be provided.

- Product shall conform to the applicable conformance standards, or most updated equivalents:

  - ISO 18562-1 First edition 2017-03: Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
  - ISO 18562-4 First edition 2017-03: Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate
  - ISO 14971:2019 MEDICAL DEVICES — Application of risk management to medical devices
  - IEC 60601-1-8:2012 Medical electrical equipment – Part 1–8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.

*Recognized stringent regulatory authorities (SRA): U.S. Food and Drug administration (USFDA), Japanese Ministry of Health, Labor, and Welfare (MHLW), also represented by the Pharmaceuticals and Medical Devices Agency (PMDA); European Medicines Agency (EMA) and member states admitted to the European Union (EU) prior to 1996 Hague Convention (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands,
3. Lead Time

Please provide the estimated lead time

4. Post-Acceptance inspection

Each product delivered to GHSC-PSM shall comply with all product specifications and test procedures (when applicable) specified through the life cycle.

GHSC-PSM reserves the right to sample from and perform or cause to be performed any of the tests and inspections set forth in this purchase description to assure that supplies and services continue to conform to the prescribed requirements after product acceptance. In the event, products are determined to not be fully compliant, the Offeror shall be required to remedy any defects or faults.

5. Product documentation

Manufacturer shall provide documentation for all components, equipment, instrumentation and materials used in the entire oxygen 93 supply system, including but not limited to the following (see below). If some documentation is not available to be submitted with the proposal, the Supplier must identify such documentation and provide when the documentation would be available (e.g. ready for shipment, installation, etc.) for submission.

- Pressure testing certificates for all pressure equipment, in accordance with relevant standards and country regulations.
- Evidentiary documentation of current and valid Manufacturer QMS and ISO certification by internationally recognized standardization bodies
- Manufacturer’s product reference number and product description
- Certificate of conformance CE Mark (SRA), US FDA clearance (PMA/510K) or other when specified above in “Conformity with Quality and Product Standards”.
- Contact details of manufacturer, and authorized distributors (if applicable), and local service agent.
- Recommended storage and transportation conditions
- When applicable, country product registration or import permit to the country of destination.
- Certificate of quality, calibration and inspection (Printed and electronic copies, in English, and translated into French, Spanish, Tajik and Portuguese language)
- User manual, detailing (Printed and electronic copies, in English, and translated into French, Spanish, Tajik and Portuguese language):
  - Specific protocols for operation
  - List of equipment and procedures required for cleaning, disinfection
  - Troubleshooting, calibration, and routine maintenance
- Service manual (Printed and electronic copies, in English, and translated into French, Spanish, Tajik and Portuguese language).
- Certificate of cleaning for oxygen service in accordance with EIGA Doc 33 Cleaning of Equipment for Oxygen Service Guideline, or equivalent for the relevant equipment,
Annex 4 – Product Specifications and Technical Requirements

- Piping and instrumentation.
- Certificate of calibration for instrumentation including transmitters, analysers.
- Process and instrument diagram.
- Installation manual.
- Operating and maintenance manuals.
- Equipment specifications.
- Piping and fitting specifications.
- Pressure regulators and safety valve specifications.
  - Instrumentation specifications, including pressure and temperature gauges, temperature/flow/pressure transmitters, including oxygen analysers, carbon monoxide/carbon dioxide analysers, differential pressure analyser.
- Performance test of the concentrators including certificate and testing report.
- Hazard review.
- SDS - Safety data sheets for the material used.

6. Shipping Specifications

Please provide a Packing List with items, weights and dimensions per pallet (as applicable) as well as a Detailed Packing List with aggregate quantities per item, weights and dimensions as well as shipping conditions applicable to the items (i.e. temperature control, special instructions around loading, or hazardous goods declarations) and all batch numbers and quantities. A Detailed Packing List template may be provided to the Supplier. Supplier is required to comply with packaging and shipping instructions related to the INCOTERM.

The supplier will identify cargo with dangerous / hazardous characteristics and, if applicable, provide details around transportation limitations and packing requirements that suit the appropriate mode of transport. If air, this should be for passenger (PAX) aircraft as the base requirement except in the event the product quantity per package exceeds the allowable quantities and is only permitted to ship via cargo aircraft only (CAO). At this point, GHSC-PSM should be alerted for actions and or direction on next steps. The Safety Data Sheet (SDS) shall be provided for these commodities. Any products with hazardous/dangerous characteristics should be packaged / palletized separately so as not to impact the mode of shipment. Where applicable, suggestions should be offered to GHSC-PSM around packing and mode of transport. Combinations of dangerous goods should be packed in a fashion best suited to the correct mode of transport for the quantities or characteristics and to ensure that these are segregated as necessary on the shipping documentation and mode of transport e.g. where flammable solids and flammable liquids are ordered together, these should be split and assigned new packing lists wherein acceptable quantities should be further aligned.

7. Packaging and Packing

The products to be supplied under a contract resulting from this solicitation will be packed and protected to prevent damage or deterioration during transportation and storage. The box will be manufactured of a standard heavy-duty material appropriate for the destination countries where high heat and humidity is prevalent, that will withstand export handling and rough treatment, and help ensure the quality of the product. Individual boxes and shipping cartons (tertiary packaging) must be shrink wrapped on all sides in order to protect the goods from water damage during transit time. The supplier shall be required to remedy any defects or faults and Chemonics will not be responsible for any additional costs.
8. USAID Marking Requirements

Chemonics reserves the right to require USAID marking as below: The Manufacturer(s) will be responsible for ensuring that all export shipping cartons, whether shipped from the United States or from any other source country, carry the official USAID emblem.

Emblems will be affixed by metal plate, decal, stencil, label, tag, or other means, depending upon the type of commodity or export shipping carton and the nature of the surface to be marked. The emblem on each export-shipping carton will be affixed in a manner which assures that the emblem will remain legible until the carton reaches the consignee. The size of an emblem will vary depending upon the size of the commodity and the size of the package or export-shipping carton. The emblem will, in every case, be large enough to be clearly visible at a reasonable distance.

Emblems will conform in design and color to samples available from USAID and can be found at: http://www.usaid.gov/branding/.

Emblems will be obtained by the Manufacturer(s) at its expense in the quantity and type required. The Manufacturer(s) will be required to affix USAID emblems in accordance with the marking requirements stated above.

A list of the emblem suppliers can be found at: http://www.usaid.gov/branding/suppliers.

9. Innovation

- **Bar coding**
  Not applicable for this procurement.

- **EDI (Electronic Data Interchange)**
  Not applicable for this procurement.

- **Vendor Management Inventory**
  Not applicable for this procurement.

- **Global Trade Item Number (GTIN)**
  Please see the Global Standards Section of Annex 1 – Basic Ordering Agreement Template with Terms and Conditions for requirements.