

Technical Specifications

مستشفى الولادة امدرمان

PSA Oxygen Generator Plant		Fill your Specifications
1	<p>Overview of functional requirements</p> <ul style="list-style-type: none"> · To be used for patients in hospital · Fully automated system Microprocessor based oxygen concentrator module, duplex process valve system with PSA (Pressure Swing Adsorption) Technology. · Complete Oxygen PSA Production Plant 60 m3/hr Capacity · Uses pressure swing adsorption (PSA) technology to produce medical oxygen 93%±3 from ambient air. · The oxygen should be of medical grade and shall be supplied through oxygen outlet at minimum pressure of 4.2 bar (61 psi) at all times of operations of the generator · Easy to install: preassembled and skid-mounted, or containerised. · Oxygen production monitoring. · Control panel / user interface, with numerical and graphical values, as applicable. · On-site training for installation, use, and maintenance preferable. · Remote support for installation, use and maintenance. · Life span of a minimum of 10 years; guaranteed by a letter from the manufacturer. · Alarm for low oxygen concentration. · Alarm when automatic back-up engaged, as configured (e.g. secondary plant in duplexed parallel system or reserve cylinders from ancillary manifold). - Remote monitoring feature. - Soft start or variable speed drive (VSD) compressor. 	
2	<p>Detailed requirements</p> <ul style="list-style-type: none"> · Oxygen concentration monitor with +/- 1% accuracy; · continuous display of the oxygen concentration and pressure; · alarm when an oxygen concentration is lower than 90%; · function of purge of low concentration of oxygen, optional · Automatic shut off valve should be installed to control the medical oxygen purity and pressure · The oxygen concentrator system shall have PSA sieve beds with screen display of size not less than 5" for constant quality control by measuring oxygen purity, outlet pressure, instruction manual, curves of oxygen pressure, basic setting, alarm facility for process a cycle failure, low oxygen pressure, maintenance alerts, process overview with valve operation and an analogue values · In case of valve malfunctioning, the panel shall have diagnostic tool to pin point exact values in question for fast service <p>Oxygen Purity 93% +/- 3% CO < 5 ppm CO2 < 300 ppm Water Vapour (< 67 ppm)</p> <p>Maintenance Free self-lubricating, heavy duty valve section, angle seat pneumatic valve technology for constant availability of pure oxygen. The inlet pressure sensor shall be included in the scope of the contract</p> <p>The oxygen concentrator should have built in Zirconium/Ultrasonic type oxygen sensor with Oxygen Analyzer with digital display having automatic backup control system also fitted with Medical sterile and bacterial filter</p> <p>All the Certifications should be provided by Original Equipment Manufacturer:</p> <ul style="list-style-type: none"> • It should have ISO9001:2008 certification – for organization • Oxygen Generator must have US FDA (United States, Food and Drug Administration) or CE (Conformity Europeenne) / EC (European certificate) of the Original Equipment Manufacturer • ISO 13485: 2016 certification – for design of medical systems • ISO 10083, EN ISO 7396-1, EN 737-3 European Standards and should be in accordance with medical device directives 93/42/EEC or Medical use international standard regarding the supply of oxygen via oxygen generators for a use in medical gases distribution networks. <p>Filtration system for the compressed Air:</p> <p>Feed air quality of the oxygen concentrator should be conforming to ISO 8573 Class 4 and is of filtration grade of 0.01 micron. The filtration system should include both inlet filtration comprising of micro filter and active carbon filter as well as outlet filtration comprising dust fine filter. Type of filters to be specified in terms of Prefilter, Fine filters and activated carbon Filter</p> <p>Air Receiver:</p> <p>The system should be provided with an Air vertical receiver tanks of 3000 ltrs capacity having the specific capacity and should be designed in such a way to sustain pressure of 8 bars. The air receiver should be fabricated as per ASME Sec VIII Div.1 or IS 2825 code and fitted with 2 Nos. auto drain-out moisture filters. Tank should have auto drain valve with timer to be provided as a safety valve.</p> <p>Oxygen Surge Tank:</p>	

	<p>Oxygen vertical receiver tanks of 3000 ltrs capacity fitted with Auto Drain Valves to drain out the moisture and the tank is designed to sustain a pressure three times the normal working pressure of 7 bars.</p>	
	<p>Main Electrical Panel: The Main electrical control Panel should be compatible with Oxygen plant and allied equipments and should be flame proof. The Panel should have automatic starter, overload protection, single phase preventer, timer assemblies, emergency stop buttons and indication lamps etc. for successful operation of all the components of the Oxygen plant Charging of the panel to me included in the scope of work(This requires Cable lying, electrification work from the main panel and earthing works).The entire cabling from the mains to the panel should be armoured cable up to 30 mtrs only.</p>	
	<p>Automatic change over Panel: The automatic change over panel shall be compatible with oxygen Plant. The Cover of Panel shall be made of SS/MS duly powder coated. The Change Over should consist of 02 no. of Solenoid Valve, 09 no. of Ball Valve, 01 no. of Pressure Switch, 01 no. pressure Gauge, 01 no. AC/DC Converter, 03 nos. Indicators, 01 no. Pressure Regulator, Inlet and outlet for Oxygen with copper tubing of 28 mm dia.</p>	
	<p>Alarm System: Providing and fitting of Main Alarm Panel to indicate any abnormality of gas pressure and other failures of the system. Job includes providing of Medical Gas Alarm System for 01 services viz. oxygen. The Alarm System consists of an isolation valve box, pressure sensors , circuit plate with LED colour indicators for visual indications. The Gas Alarm system is sensitive to detect any pressure drop in the supply pipelines. The Alarm System is fitted with electronic hotter/ audio siren for audio indications of pressure drop. The alarm is provided with the manual pressure gauge for indication of pressure in services. It shall have anti-microbial coating labels for touch control. The alarm system shall be complete with digital display, sensor module and power supply. The alarm system shall be complete with all indication controls, wirings, accessories etc as required.</p>	
	<p>Servo Voltage stabilizer: Servo voltage stabilizer of suitable capacity for oxygen plant and allied equipment's with input voltage range 300V-480V & output voltage 415+1% rating 3 phase 50Hz, micro processed based digital display suitable for unbalanced / balanced supply and unbalanced/balanced load copper wound with bypass switch, MCCB, selector switches, complete in all respect.</p>	
	<p>High speed oxygen cylinder filling system with filling ramp for six cylinders: The system should be with high speed high pressure oil free compressor. The compressor compresses & fills the low pressure oxygen generated from oxygen generator into different size of cylinders at high pressure, pressure 150 bar. The fastest filling time of 960L in 12 Hrs. Compact size & high mobility: system must be mobile. Weight should not more than 50 to 53 Kg Low power consumption & energy saving: The average power consumption should be 0.5 KW. Suction oxygen pressure: 6-20 PSI Oxygen Product Flow rate: 5-10 LPM (The Minimum product flow should be at least 15 LPM & The maximum capacity of booster should not exceed 20 LPM) Filling ramp for 6 cylinders</p>	
	<p>Oxygen analyser with digital display. Environmental factors The unit shall be capable of being stored continuously in ambient temperature of 0 -55deg C and relative humidity of 15-90% The unit shall be capable of operating in ambient temperature of 20-50 deg C and relative humidity of 80%</p>	
	<ul style="list-style-type: none"> · continuous output flow to cover 100% of the oxygen demand; · Continuous output pressure of 300-600 kPa / 3 – 6 bars / 44-87 psi. A gauge or sensor located between the source and the line pressure control to monitor the output pressure; · alarm when the output pressure is < 3 bar / 44 psi; · feed air compressor, either oil-free or filtered oil-injected or oil-lubricated rotary screw type: minimum 750 kPa / 7.5 bars / 108 psi; · External air dryer with capacity sized to manage compressor output. 	
3	<p>Control panel / user interface</p> <ul style="list-style-type: none"> · Digital display, clearly visible in English and/or preferred language of destination country, for at least: <ul style="list-style-type: none"> - oxygen concentration [%] - oxygen production trending [Nm3/hour] - output pressure - system status, including current maintenance need - cumulative hours of operation (digital or analogue meter). · Audible and visual alarms for: <ul style="list-style-type: none"> - high temperature; - low/high pressure; - Low oxygen concentration (<90%); - power failure; system failure; - second/reserve source active; 	

	- air dryer pressure dew point (>3°C)	
4	Components <ul style="list-style-type: none"> · Air compressor with air dryer and pre-filters with automatic drains; · Filter assembly to include: <ul style="list-style-type: none"> - pre-filter (>5 micron); - coalescing filter (0.1 micron); and, - Coal filter (coal tower, alternatively activated carbon filter), as applicable. · oxygen generator unit; · oxygen analyzer for medical application; · Oxygen and Air tank (receiver/buffer tanks) with bacterial outlet filter. 	
5	Spare parts (included) <ul style="list-style-type: none"> · 3-year spare parts kit as per recommended preventive maintenance programme clearly defined in a disaggregated list comprising part numbers, descriptions, and unit cost, as well as indicating brand/model specifics (e.g. for circuit breaker, printed circuit board, sieve beds, compressor components, valves, wheels, motor capacitor, analyser, etc.) by the manufacturer. · Set of inlet filters and outlet bacteria filter for 3-years operation. 	
6	Power supply <ul style="list-style-type: none"> · Electrical source requirements must be locally compatible (frequency, voltage and plug type need to be specified); · VSD (variable speed drive) 	
7	PSA oxygen generator plant (*voltage, frequency and plug variations across the countries) <ul style="list-style-type: none"> · Power requirements: Plant operations: 415 VAC ± 15% - 3 phase / 50 Hz. Control system operations: 220 VAC ± 15% - 1 phase / 50 Hz. · Equipment must be connected to a reliable and continuous source of energy. · Electrical protection by resettable circuit breakers or replaceable fuses, fitted in both neutral and live lines. 	
8	Vacuum system (60 m3/h duplex: <ul style="list-style-type: none"> ☑ The package shall include lubricated rotary vane vacuum pumps and associated equipment, one horizontal ASME tank and one control panel. ☑ The only field connections required would be system intake, exhaust and power connection at the control panel. ☑ All components shall be completely pre-piped and pre-wired to single-point service connections. ☑ All interconnecting piping and wiring shall be completed and operationally tested prior to shipment. ☑ Provide liquid tight conduit, fittings and junction boxes for all control and power wiring. ☑ The medical vacuum pumps shall be of the rotary vane air-cooled design with integral, fully recirculating oil supply with sight gauge to indicate oil level. ☑ The oil separation system shall be integral and shall consist of no less than four stages of internally installed oil and smoke eliminators. ☑ This system shall be capable of removing 99.9% of oil and smoke particles from the exhaust. ☑ Each pump shall include a built-in anti-suck-back valve mounted at the pump inlet; and each pump shall be equipped with three non-asbestos vanes, each having a minimum life of 30,000 to 40,000 hours. ☑ The system shall include the following accessories for each pump: inlet check valve, inlet isolation valve, vacuum control switch, oil temperature gauge, thermal malfunction switch and vacuum control switch. ☑ Provide flexible connectors on inlet and exhaust of each pump exhaust tee with union, drip-leg with cock valve as well as copper tubing with shut-off cock for gauge and vacuum switches. ☑ The system shall include a 750 liter vacuum storage tank of ASME construction. ☑ The tank shall be rated for full vacuum service and shall be equipped with a valve by-pass, vacuum gauge and manual tank drain. ☑ The inside of the tank shall be coated for rust protection with a two component coating which provides a hard, durable lining. ☑ Provide vibration mounting as per NFPA 99. ☑ The system shall include a UL listed control panel in a NEMA 12 enclosure with the following accessories for each pump: <ul style="list-style-type: none"> ☑ Externally operable fusible disconnect with door interlock, control circuit transformer with fused primary and secondary coils, H-O-A switch, magnetic starter with 3 leg overload protection, hour meter, motor running light and minimum run timer to prevent short cycle operation. ☑ Provide the panel with a plug-in type programmable controller with removable terminals to allow quick and easy replacement in the field. ☑ The system must be designed to function even if the programmable controller fails. ☑ If one of the pumps is out of service the system control shall omit the pump from the alternating cycle, automatically alternating between the remaining pumps only. 	

	<p>☒ The system shall revert to normal alternation automatically when the condition is corrected. In addition to standard automatic alternation, the system shall be equipped with forced time alternation in the event that the pump is unable to satisfy the demand in 30 minutes.</p>	
	<p>☒ The system shall be equipped with a flashing light pump failure alarm/shutdown at any of the following conditions: motor overload tripped, main disconnect is off, blown fuse, control transformer failure, starter coil failure, H-O-A is off.</p>	
	<p>☒ Provide audible and visual local alarm (complete with indicating lights and individual sets of auxiliary contacts wired to the terminal strip for remote alarm indication) for the following: vacuum pump thermal malfunction and reserve vacuum pump in use.</p>	
	<p>☒ Provide manual reset for thermal malfunction shut-down. All control and alarm functions shall remain energized while any vacuum pump in the system remains electrically on-line.</p>	
	<p>☒ The lag vacuum pump shall be able to start automatically if the lead vacuum pump fails to operate.</p>	
	<p>☒ An additional Vacuum reservoir with bypass arrangement (optional)</p>	
9	<p>Air Compressors system 100 m³/h duplex:</p>	
	<p>☒ The entire system including the receiver shall be mounted on a common structural steel stack base.</p>	
	<p>☒ The only field connections required would be system intake, exhaust and power connection at the control panel.</p>	
	<p>☒ All components shall be completely pre-piped and pre-wired to single-point service connections.</p>	
	<p>☒ All interconnecting piping and wiring shall be completed and operationally tested prior to shipment.</p>	
	<p>☒ The medical air compressors shall be of the totally oil-less reciprocating aircooled design.</p>	
	<p>☒ Connecting rod and bearings shall be packed with lifetime lubrication and sealed.</p>	
	<p>☒ Each compressor shall be 3 phase, 50 cycle, 415volt, ODP NEMA construction motor.</p>	
	<p>☒ Slide bases for convenient belt tension adjustment and totally enclosed OSHA approved belt guards shall be provided.</p>	
	<p>☒ The system shall include individual compressor inline intake filters, discharge check valves of bronze construction, safety relief valves, bronze intake and discharge flexible connectors, solenoid unloaders, isolation valves, air cooled after coolers for each compressor, high discharge temperature shut down switches on each cylinder, pressure control switches, as well as copper tubing with shut-off cock for gauge and switches.</p>	
	<p>☒ The system shall include a 1000 liter pressure storage tank of ASME construction rated for 200-PSI MWP service.</p>	
	<p>☒ The tank shall be equipped with a pressure gauge, safety relief valve, 3-way bypass; gauge glass and automatic electronic tank drain with manual override.</p>	
	<p>☒ The inside of the tank shall be coated for rust protection with a two component coating which provides a hard, durable lining.</p>	
	<p>☒ Provide spring vibration isolators for each compressor.</p>	
	<p>☒ The system shall include a UL listed control panel in a NEMA 12 enclosure with the following accessories for each pump:</p>	
	<p>☒ Externally operable fusible disconnect with door interlock, control circuit transformer with fused primary and secondary coils, H-O-A switch, magnetic starter with 3 leg overload protection, hour meter and motor running light.</p>	
	<p>☒ Provide the panel with a multiple position selector switch for selection of normal operation (automatic alternation) or manual selection of lead and lag pumps if one of the pumps is taken out of service due to scheduled maintenance.</p>	
	<p>☒ Provide audible and visual local alarm (complete with indicating lights and individual sets of auxiliary contacts wired to the terminal strip for remote alarm indication) for the following: compressor temperature malfunctions and reserve compressor in use. Provide manual reset for thermal malfunction shutdown.</p>	
	<p>☒ All control and alarm functions shall remain energized while any compressor in the system remains electrically on-line.</p>	
	<p>☒ The lag compressor shall be able to start automatically if the lead compressor fails to operate.</p>	
	<p>☒ Dual desiccant air dryers, dual 0.5 micron pre-filters, dual 0.5 micron afterfilters, line pressure regulating valves, dew point monitor, CO monitor and other accessories required to meet and exceed the current code requirements shall be mounted on the compressor system base.</p>	
	<p>☒ All components shall be completely pre-piped and pre-wired to single-point service connections as per latest international standards.</p>	
	<p>☒ There shall be two identical banks of air treatment equipment, piped in parallel and provided with valves to by-pass either filter set for element replacement, maintenance and repair work on one of the sets while still treating medical compressed air through the other set without any sacrifice in air quality.</p>	
	<p>☒ Each bank must consist of three stages of treatment.</p>	
	<p>☒ The first stage is a prime efficiency coalescer with particle removal down to 0.5 micron with 99.9999% retention. This filter removes aerosols and solid particles.</p>	
	<p>☒ The filter is equipped with electronic drain and element change indicator.</p>	

	<p>☒ The second stage is a desiccant heatless air dryer, equipped with purge control. Built-in purge saver control will automatically minimize and adjust the amount of purge air to match the variable airflow.</p>	
	<p>☒ The dry compressed air is discharged from the "on line" tower into the third stage.</p>	
	<p>☒ The third stage is a prime efficiency particulate after filter with particle removal down to 0.5 micron. The after filter element provides high particle retention, low pressure drop and long element life.</p>	
	<p>☒ Downstream pressure regulators will maintain constant discharge pressure of 55 PSIG (field adjustable).</p>	
	<p>☒ Digital dew point and CO monitors with alarm set points at +390F and 10 PPM are provided with dry contacts for connection to remote alarm panels.</p>	
	<p>☒ A "demand check" for maintenance must as per current code requirements of latest international standards.</p>	
10	<p>Alarm System:</p>	
	<p>☒ The master and area alarms as per required locations</p>	
	<p>☒ Alarm shall be microprocessor based with individual microprocessors on each area display and sensor board.</p>	
	<p>☒ The sensors shall be capable of local or remote mounting.</p>	
	<p>☒ Each area display module/sensor unit shall be gas specific, with an error message display for an incorrect connection.</p>	
	<p>☒ The alarms shall be field expandable with the addition of extra modules.</p>	
	<p>☒ Each specific service shall be provided with an LED digital read out comprising of 0-250 psi for positive pressure and 0-30 inch Hg for vacuum.</p>	
	<p>☒ The digital readout shall provide a constant indication of each service being measured.</p>	
	<p>☒ A bar graph trend indicator shall be provided for each service indicating a green "NORMAL", yellow "CAUTION" and a red "HIGH" or "LOW" alarm condition.</p>	
	<p>☒ Under normal operation the bar graph display shall move up and down in the green range depending on service usage.</p>	
	<p>☒ If an alarm occurs, the "RED" alarm light will flash and the audible alarm will sound.</p>	
	<p>☒ Pushing the "ALARM SILENCE" button will cancel the audible alarm but the unit will remain in the alarm condition until the problem is rectified.</p>	
	<p>☒ The default set points shall be +/- 20% variation from normal condition.</p>	
	<p>☒ In the calibration mode the following parameters shall be field adjustable:</p> <ul style="list-style-type: none"> • High/Low set points • imperial/Metric Units • Repeat alarm enable/disable 	
	<p>☒ Set points shall be adjustable by two on board push buttons.</p>	
	<p>☒ In addition "PUSH TO TEST" & "ALARM SILENCE" buttons shall be easily accessible to operate and test the unit.</p>	
	<p>☒ Combination master/area alarms shall have no moving parts and shall require no maintenance after initial installation.</p>	
11	<p>Valve Boxes:</p>	
	<p>☒ Each recessed zone valve box shall consist of the following components: A steel valve box which can house single or multiple shut-off ball valves with tube extensions, a three piece design Valve, an aluminium frame, and a pull-out removable window.</p>	
	<p>☒ The valve box shall be constructed of 18 gauge steel complete with a baked enamel finish.</p>	
	<p>☒ The doorframe assembly shall be constructed of anodised aluminium and shall be mounted to the back box assembly by screws as provided.</p>	
	<p>☒ The removable front shall consist of a clear window with a pull out ring premounted to the centre of the window.</p>	
	<p>☒ Access to the zone shut-off valves shall be by merely pulling the ring assembly to remove the window from the doorframe.</p>	
	<p>☒ The window can be reinstalled without the use of tools only after the valve handles have been returned to the open position.</p>	
	<p>☒ The window shall be marked with the following:</p>	
12	<p>Electrical Panel:</p>	
	<p>Panel shall be wall mounted and fabricated from 16/14 SWG CRCA Sheet duly powder coated. Panel shall incorporate isolators for the following equipment.</p>	
	<p>☒ Isolator for Medical Compressed air system.</p>	
	<p>☒ Isolator for Medical Vacuum System</p>	
	<p>Panel shall have following instrumentations for easy monitoring purpose:-</p>	
	<p>☒ Incoming power supply indications of each Phase</p>	
	<p>☒ Mains indication for mains supply on for each Phase.</p>	
	<p>☒ Mains shall have digital metering.</p>	
	<p>☒ Each circuit shall have digital meter.</p>	
	<p>☒ Mains and each circuit shall be with MCCB only.</p>	
13	<p>Accessories, spares and consumables</p>	
	<p>Flow meter with Humidifier - Imported Back Pressure Compensated flow meter will be of accurate gas flow measurement with following features:</p>	
	<p>☒ Control within a range of 0 – 15 Lpm.</p>	
	<p>☒ It will meet strict precision and durability standard.</p>	

	<p>☒ The flow meter body must be made of brass chrome plated materials.</p> <p>☒ The flow tube and shroud components must be made of clear, impact resistant polycarbonate.</p> <p>☒ Inlet filter of stainless steel wire mesh to prevent entry of foreign particles.</p> <p>☒ The humidifier bottle is made of unbreakable & Reusable of polycarbonate material and autoclaveable at 134 degree centigrade.</p> <p>Ward Vacuum Units (Imported)</p> <p>☒ Ward vacuum Unit shall be wall mounted and shall consists of the following with same make:</p> <p>☒ Suction Controller/ Regulator</p> <p>☒ Collection bottle 1000ml with mounting arrangement.</p> <p>☒ The vacuum regulator will be step-less adjustable and have large vacuum gauge providing digital indication of the suction supplied by the regulator.</p> <p>☒ Safety trap shall be provided inside the jar to safeguard the regulator from overflowing. Different colour options must be available.</p> <p>☒ The unit will be consisting of reusable 1000 ml shatter resistant bottle, each made up of poly carbonate material and fully autoclaveable at 134 degree centigrade.</p> <p>Theatre Vacuum Units:</p> <p>☒ The vacuum regulator will be step-less adjustable and have large vacuum gauge providing digital indication of the suction supplied by the regulator.</p> <p>☒ Safety trap will be provided inside the jar to safeguard the regulator from overflowing.</p> <p>☒ Different colour options must be available.</p> <p>☒ The unit will be consisting of two reusable 2000 ml shatter resistant bottle, each made up of poly carbonate material and fully autoclaveable at 134 degree centigrade.</p> <p>All the above items must be mounted on a Trolley having free moving castor wheels.</p> <p>All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer. Bidders must specify the quantity of every item included in their offer (including items not specified above).</p>	
14	<p>Maintenance Service During Warranty Period</p> <p>During the warranty period supplier must ensure planned preventive maintenance (PPM) along with corrective/breakdown maintenance whenever required.</p>	
15	<p>Documentation (included, minimum in English language)</p> <p>Hard and soft copies, in English language as requirement and local language as preference, of:</p> <ul style="list-style-type: none"> · life span of minimum 10 years; guaranteed by a letter from the manufacturer; · certificate of quality, calibration and inspection; · user manual, detailing: <p>§ Specific protocols for operation.</p> <p>§ list of equipment and procedures required for cleaning, disinfection, troubleshooting, calibration, and routine maintenance;</p> <ul style="list-style-type: none"> · service manual; · Contact details of manufacturer, and authorized distributors (if applicable), and local service agent. 	
16	<p>Transportation, storage and operational requirements</p> <ul style="list-style-type: none"> · Plant to be either skid-mounted or containerized to facilitate rapid installation. · capable of supplying the specified oxygen concentration continuously in ambient temperature from 20–50 °C, relative humidity from 15-95%, preferably simultaneously, and elevation from 0 to 1000 m, minimum. · Capable of being stored continuously in ambient temperature from 10–40 °C, relative humidity from 15–95%, and elevation from 0 to 1000 m, minimum. 	
17	<p>Product labelling</p> <p>Electrical power input requirements (voltage, frequency and socket type); labelling for medical use according to standards.</p>	
18	<p>Primary packaging</p> <p>Labelling on the primary packaging to include: name and/or trademark of the manufacturer; model or product's reference.</p> <p>Information for storage conditions (temperature, pressure, light, humidity).</p>	
19	<p>Risk classification</p> <p>Class C (GHTF Rule 11); FDA Class II (USA); Class IIA (EU and Australia); Class II (Canada).</p>	
20	<p>Standards, for the manufacturer</p> <p>Certified Quality Management System for medical devices (e.g. ISO 13485, ISO 9001).</p>	
21	<p>Standards, for the product performance</p> <p>Free Sales Certificate (FSC) favorable, provided by any of the following countries: Australia, Canada, Japan, USA and European Community (e.g. FDA and/or CE certificate given by a third certified party for the specific medical devices proposed).</p> <p>ISO 7396-1: Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum.</p> <p>ISO 8573-1: Compressed air – Part 1: Contaminants and purity classes.</p> <p>ISO 8573-2: Compressed air – contaminant measurement – Part 2: Oil aerosol content. ISO 8573-4: Compressed air – contaminant measurement – Part 4: particle content.</p>	

	ISO 5011: Inlet air cleaning equipment for internal combustion engines and compressors – performance testing.	
	ISO 21969: High pressure flexible connections for use with medical gas systems. All pressurized vessels to be:	
	· designed according to PED or ASME VIII, or equivalent;	
	· certified PED or ASME III, or equivalent;	
	· Cleaned according to ISO 15001, ASTM G93, or equivalent.	
22	Warranty Life span designed for minimum of 2 years; guaranteed by a letter from the manufacturer. Warranty 48 months, with option to extend. Agreements of terms of warranty and maintenance contract.	
23	Service agreement conform contract	
1	Pre-installation requirements Manufacturer must indicate explicitly the following aspects to match infrastructure capabilities within the health facility:	
	· acceptable mains capacity;	
	· appropriate connections/adaptors;	
	· compatibility with back-up power supply (e.g. generator);	
	· compatibility with housing for the plant;	
	· infrastructure requirements for operation e.g. roofing, ventilation, air conditioning, room requirements without oil, grease and petroleum-based or other flammable products;	
2	Requirements for commissioning	
	· Delivery of shipment direct from factory.	
	· Note and report any signs of external or internal damage upon device delivery.	
	· Verify oxygen concentration and pressure level meets specifications when device is operational.	
	· Verify operation of oxygen analyser and all alarms, including power failure alarms.	
	· Verify automatic switch to secondary supply when failure, if applicable	
	· Conformity of installation shall be verified by a certified third party.	
3	User and Maintenance training Manufacturer must indicate explicitly the following maintenance routines to match the dedicated staff capabilities within the health facility:	
	· Cleaning routines of the PSA plant 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.	
	· Safety precautions on management of oxygen.	
	· Advanced maintenance tasks required that shall be carried out by a third-party trained technician authorized by the manufacturer.	
4	Maintenance agreement during warranty period Preventative maintenance parts and kits during warranty period must be included. The system should establish the costs for preventative and corrective maintenance and spare parts for a period of at least 3 years from date of installation. Manufacturer must propose the maintenance routines and the predetermined system for procuring spare parts that are brand/model related.	
5	Life span – Guarantee of obsolescence Life span designed for a minimum of 10 years; guaranteed by a letter from the manufacturer (not only from the authorized distributor). This guarantee ensures that the equipment and spare parts will not be discontinued during the 10 years after procurement.	