Technical specifications for Pressure Swing Adsorption (PSA) Oxygen Plants

Interim guidance

8 June 2020

World Health Organization

Oxygen is an essential medicine required at all levels of the health care system; only high quality, medical-grade oxygen should be given to patients. Pressure swing adsorption (PSA) oxygen generating plants are a source of medical-grade oxygen. This document provides technical specifications as the minimum requirements that a PSA Oxygen Plant must meet for use for the administration of medical-grade oxygen.

Medical grade oxygen 93 is defined as follows:

- Ph Eur: Contains between 90.0%V/V and 96% V/V of O_2. Remainder mainly consists of argon and nitrogen. This monograph applies to oxygen used on site where it is produced. It does not apply to individual concentrators.
- USP: Oxygen produced from air by molecular sieve process. Contains not less than 90.0 % V/V and not more than 96 % O_2 V/V, the remainder consists of mostly argon and nitrogen.

CAUTION:

Oxygen is not a flammable gas, but it easily supports combustion. All materials that are flammable in air will burn vigorously in oxygen. Some fuels, such as oil and grease, burn with almost explosive violence when combined with oxygen. Cylinders with fissures can be projected with force. All elements, except inert gases, in direct combination with oxygen, form oxides. Proper international signs and symbols for hazard management should be on the compress oxygen containers.

Pressure swing adsorption (PSA) is the process by which ambient air passes through an internal filtration system (e.g. a molecular sieve [zeolite granules or membranes]), which has a large enough total surface area to separate nitrogen (N_2) from the air, concentrating the remaining oxygen (O_2) to a known purity. It typically consists of an air compressor, dryer, filters, dual separation chambers, a reservoir, and controls.

PSA oxygen generator plant is a unit designed to concentrate oxygen from ambient air at scale, with output capacity varying according to calculated oxygen demand, typically ranging from 2 Nm^3/hr to 200 Nm^3/hr. For distribution of oxygen produced from PSA plants, oxygen can either be piped directly from the oxygen tank to wards, or further compressed to fill cylinders via a supplemental booster compressor and a cylinder filling ramp/manifold.

All medical PSA oxygen generator plants are sources of oxygen that can produce medical-grade oxygen, at scale, 24 hours a day, 7 days a week.

PSA plants themselves can be turn-key units complete with all the necessary equipment and supplies; however, the staff operating and maintaining them require specialized training. Strict maintenance schedules are needed to prevent malfunctions. Adequate supplies and spare parts are needed to allow operations for 5 years in resource-limited settings. A reliable supply chain is needed to meet any additional needs. Should repairs be required, these are often carried out by manufacturer or distributor staff.

Any facility with inpatients must ensure availability of continuous, high quality, medical-grade oxygen at all times

Abbreviations

% V/V	percent volume / volume
ASME	American Society of Mechanical Engineers
ASTM	American Society for Testing and Materials
FDA	Food and Drug Administration (USA)
FSC	free sales certificate
FSC	free sales certificate
GHTF	Global Harmonization Task Force
Hz	hertz
IMDRF	International Medical Device Regulators Forum
ISO	International Organization for Standardization
kPa	kilopascal
m	meter(s)
N_2	nitrogen
NFPA	National Fire Protection Association (USA)
Nm^3/h	normal meter cubed per hour
O_2	oxygen
PED	Pressure Equipment Directive
Ph Eur	European Pharmacopoeia
PSA	pressure swing adsorption
psi	pounds per square inch
psi	pounds per square inch absolute
UNICEF	UN Children's Fund
USP	United States pharmacopeia
VAC	volts, alternating current
VSD	variable speed drive
WHO	World Health Organization

Technical specifications for procurement

PSA oxygen generator plant		
1	Overview of functional requirements	• Uses pressure swing adsorption (PSA) technology to produce medical oxygen 93%±3 from ambient air. • 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). • optional: – remote monitoring feature. – soft start or variable speed drive (VSD) compressor.
2	Detailed requirements	• 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 • 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	Control panel / user interface	• Digital display, clearly visible in English and/or preferred language of destination country, for at least: – 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: – 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	• Air compressor with air dryer and pre-filters with automatic drains; • Filter assembly to include: – pre-filter (>5 micron); – coalescing filter (0.1 micron); and, – coal filter (coal tower, alternatively activated carbon filter), as applicable. • oxygen generator unit; • oxygen analyser for medical application; • oxygen tank (receiver/buffer tank) with bacterial outlet filter.
5	Spare parts (included)	• 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,	• Electrical source requirements must be locally compatible (frequency, voltage and plug type need to be specified); • VSD, optional

PSA oxygen generator plant		
	(*voltage, frequency and plug variations across the countries)	• Power requirements: plant operations: 380 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.
7	Documentation (included, minimum in English language)	Hard and soft copies, in English language as requirement and local language as preference, of: • life span of minimum 10 years; guaranteed by a letter from the manufacturer; • certificate of quality, calibration and inspection; • user manual, detailing: ▪ specific protocols for operation. ▪ list of equipment and procedures required for cleaning, disinfection, troubleshooting, calibration, and routine maintenance; • service manual; • contact details of manufacturer, and authorized distributors (if applicable), and local service agent.
8	Transportation, storage and operational requirements	• Plant to be either skid-mounted or containerized to facilitate rapid installation. • capable of supplying the specified oxygen concentration continuously in ambient temperature from 10–40 °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.
9	Product labelling	Electrical power input requirements (voltage, frequency and socket type); labelling for medical use according to standards.
10	Primary packaging	Labelling on the primary packaging to include: name and/or trademark of the manufacturer; model or product's reference. Information for storage conditions (temperature, pressure, light, humidity).
11	Risk classification	Class C (GHTF Rule 11); FDA Class II (USA); Class IIA (EU and Australia); Class II (Canada).
12	Standards, for the manufacturer	Certified Quality Management System for medical devices (e.g. ISO 13485, ISO 9001).
13	Standards, for the product performance	Free Sales Certificate (FSC) favourable, 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. ISO 7396-1: Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum. ISO 8573-1: Compressed air – Part 1: Contaminants and purity classes. ISO 8573-2: Compressed air – contaminant measurement – Part 2: Oil aerosol content. ISO 8573-4: Compressed air – contaminant measurement – Part 4: particle content. 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.
15	Warranty	Life span designed for minimum of 10 years; guaranteed by a letter from the manufacturer. Warranty 48 months, with option to extend. Agreements of terms of warranty and maintenance contract.

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 an dcorrective maintenance and spare parts for a period of a 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 authorised distributor). This guarantee ensures that the equipment and spare parts will not be discontinued during the 10 years after procurement.

Methodology and references

Technical specifications define the minimum requirements to ensure good quality, safety and efficacy of a product. The process to develop these specifications included conducting a broad landscape of products in the market that have Stringent Regulatory Authority approval from Regulatory Agencies of the five founding members of the International Medical Device Regulators Forum (IMDRF).

The following were used as references:

1) Clinical management of severe acute respiratory infection when COVID-19 is suspected – interim guidance. World Health Organization; 2020. (https://www.who.int/publications-detail/clinical-management-of-severe-acute-respiratory-infection-when-novel-coronavirus-(ncov)-infection-is-suspected).
2) Technical specifications and guidance for oxygen therapy devices. World Health Organization-UNICEF; 2019. (https://www.who.int/medical_devices/publications/tech_specs_oxygen_therapy_devices/en/).
3) ISO 7396-1:2016 Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum. International Standards Organization; 2016.
4) Health Facilities Code. NFPA 99; 2018.

Additionally, international experts have been consulted in the process (Martha Gartley, Clinton Health Access Initiative; Fetna Ramirez, Independent Consultant; and, Laura Alejandra Velez Ruiz Gaitan, WHO Consultant), and an open discussion was held with manufacturers to ensure and confirm non-bias.

WHO continues to monitor the situation closely for any changes that may affect this interim guidance. Should any factors change, WHO will issue a further update. Otherwise, this interim guidance document will expire 2 years after the date of publication.

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