WHO Technical specifications for health facility based medical oxygen systems

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Cover picture, hand in glove turns the valve on the gas cylinder. ©AdobeStock/sudok1

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Acknowledgements

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Abbreviations and acronyms

AC	alternating current
ASME	American Society of Mechanical Engineers
AVSU	area valve service unit
BCGA	British Compressed Gases Association
BOQ	bill of quantities
BPVC	Boiler Pressure and Vessel Code
CE	Conformité Européenne
CFR	Code of Federal Regulations (USA)
CGA	Compressed Gas Association (USA)
CMMS	Computerized Maintenance Management System
CSC	container safety certificate
DC	direct current
DISS	diameter index safety system
EIGA	European Industrial Gases Association
EMDN	European Medical Device Nomenclature
EN	*Europäische Norm* (European Standards)
EU	European Union
EWG	Expert Working Group
FDA	Food and Drug Administration (USA)
FSC	free sales certificate
GHTF	Global Harmonized Task Force
GMDN	Global Medical Device Nomenclature
hr	hour
HVAC	heating, ventilation and air conditioning
IEC	International Electrical Commission
IMDRF	International Medical Device Regulators Forum
ISO	International Organization for Standardization
kPa	kilopascal
LOX	liquid oxygen
LPM	litres per minute
LVA	line valve assembly
LVD	Low Voltage Directive (EU)
MAOP	maximum allowable operating pressure
MAWP	maximum allowable working pressure
MGPS	medical gas pipeline system
NFPA	National Fire Protection Association (USA)
NGO	nongovernmental organization
NRA	national regulatory agency/authority
PBU	pressure build-up
PED	Pressure Equipment Directive (EU)
PLC	program logic controller
PPE	personal protective equipment

PSA	pressure swing adsorption
psi	pounds-per-square-inch (unit of pressure)
P&ID	piping and instrumentation diagram
SCFH	standard cubic feet per hour
SLA	service level agreement
SOP	standard operating procedure
S/N	serial number
TPED	transportable pressure equipment directive
TU	terminal unit
UNICEF	United Nations Children's Fund
UNSPS	United Nations Standard Products and Services (code)
UPS	uninterrupted power supply
VIE	vacuum insulated evaporator
VIPR	valve integrated pressure regulator
VPSA	vacuum pressure swing adsorption
VSA	vacuum swing adsorption
VSD	variable speed drive
V/V	volume per volume
WHO	World Health Organization

Introduction

Medical oxygen is a life-saving essential medicine *(1)* with no substitute. It is used for the management of hypoxaemia across both communicable and noncommunicable diseases such as pneumonia, tuberculosis and chronic obstructive pulmonary disease, and the treatment of some acute HIV-, tuberculosis-, cancer-, cardiovascular- and malaria-related conditions. Oxygen needs are ever present and span all levels of care. Medical oxygen is essential for safe surgery and for stabilizing patients in critical care and trauma wards. Access to medical oxygen is critical for pregnant women during and after delivery and for supporting newborns in respiratory distress. Other vulnerable groups that often require medical oxygen include young children and older adults.

In many low-resource settings not all health facilities have uninterrupted access to adequate volumes of medical oxygen – a shortcoming that contributes to preventable deaths. These already taxed systems were further stressed during the COVID-19 pandemic when the need for medical oxygen grew beyond existing capacities. As a result, there have been global efforts to scale up and increase access to medical oxygen. On 26 May 2023, at the Seventy-sixth World Health Assembly (WHA), Resolution WHA 76.3 on Increasing access to medical oxygen[1] *(2)* was unanimously adopted by 194 WHO Member State governments. This resolution highlights the need for continued prioritization and focus on capital and operational investments that facilitate oxygen therapy.

Background to medical oxygen systems

Medical oxygen systems are complex. They constitute various highly interdependent components including medical devices, pressure vessels and specialized ancillary equipment which interact with and rely on one another and require infrastructure and human resources to ensure safe operations to continuously provide quality medical oxygen. Increasing the accessibility of medical oxygen requires tackling the whole oxygen ecosystem and, when acquiring new technologies, a comprehensive planning process followed by meticulous implementation, which must consider ongoing operations, maintenance and monitoring.

In late 2020, WHO-hosted a technical consultation on oxygen access scale-up for COVID-19 across four sessions *(3).* Three areas were noted as gaps requiring further action:

- Collaboration across actors to build technical resources for and operational guidance on all aspects within medical oxygen systems, inclusive of strategies for planning, procurement, commissioning, operations and maintenance of oxygen systems.
- Development of a global oxygen data platform (mapping).
- Incorporation of medical oxygen systems into health system strengthening efforts, including but not limited to access across various levels of care (including transport/referral), capacity building of all cadres in the health workforce, emergency preparedness and sustainability.

While there are some technical resources that are publicly available that support access and scale-up (see Annex 4), there remains a noted gap for generic technical specifications for the products that make up medical oxygen systems within health facilities:

- facility-scale oxygen source equipment (source);
- equipment for storing oxygen (storage); and
- components for the distribution of oxygen up to the point of, but not including, patient delivery (distribution).

[1] The resolution was drafted and submitted by the Uganda Ministry of Health and co-sponsored by 33 Member States.

Purpose

The purpose of this document is to present a comprehensive package of technical specifications for medical oxygen system products and components: source, storage and distribution. These specifications detail technical characteristics, performance requirements, safety features and quality requirements of medical oxygen systems that can help to ensure that products will be effective and safe in their use through their lifespan.

Scope

This document covers the technical specifications of the following products that make up health facility based medical oxygen systems:

- Oxygen source-related:
  - oxygen generator plants (molecular sieve/swing adsorption technologies);
  - cylinder filling station (from on-site oxygen generator plants);
  - containerized housing for oxygen generator plants.
- Oxygen storage:
  - high-pressure oxygen cylinders (inclusive of shells and primary valves);
  - vacuum insulated evaporator (VIE) systems: cryogenic storage tanks, vaporizers, control panel (pressure control manifold);
  - cryogenic liquid oxygen (LOX) cylinders.
- Oxygen distribution:
  - oxygen distribution manifolds;
  - medical gas pipeline system (MGPS) components for medical oxygen (alarms, valves and their assemblies, piping and fittings, terminal units).

These technical specifications stipulate the minimum criteria that prospective buyers can use when planning for and procuring medical oxygen systems – the equipment or components in part or as an assembly. Applying these specifications will require additional inputs to ensure that contextual needs are met. Any project scope will depend on a need-gap assessment, funding and other resources availability, environmental conditions and other factors.

Distinction between medicinal oxygen and medical oxygen system equipment or components

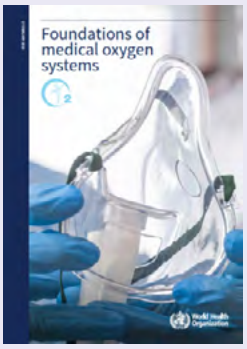
Medicinal oxygen is a medicine and should be regulated as such. This document does not cover requirements for the production, acquisition or patient delivery of medical oxygen.

Medical oxygen system equipment or components that, in part or as an assembly, make up medical oxygen systems are predominantly medical devices, pressure equipment and/or accessories. Each must meet their respective regulatory requirements to guarantee safety, efficiency and quality during design, manufacture, operation and maintenance.

Aspects not covered in this document

Note that this resource document does not cover the following:

- Detailed explanations or principles of use and/or operations of each product or component.
- Technical guidance related to:
  - system design: selection, sizing and configuration;
  - system installation, testing and commissioning;
  - operations and maintenance; and
  - system decommissioning.



These activities are part of broader project implementation and must be considered ahead of any procurement process, especially with regard to technologies requiring high capital investments. These activities should be conducted by qualified and experienced technical personnel.

WHO's *Foundations of medical oxygen systems (4)* provides an overview on the system design activities listed above, as well as general information on medical oxygen systems.

The following products are not covered in this document as current technical specifications exist:

- bedside oxygen concentrators;
- oxygen therapy medical devices used for the delivery of medical oxygen.

Specifications for these products can be found in the *WHO-UNICEF Technical specifications and guidance for oxygen therapy devices (5)* and in WHO's *Priority medical devices list for the COVID-19 response and associated technical specifications (6).*

Other related equipment not covered in this document:

- Dewar tanks (not used for medical oxygen);
- ISOtainers/ISOtanks;
- hyperbaric chambers; and
- products specific to other medical gases.

Note: Any additional specifications or regulations required for transport and use of compressed gases in aviation are also not covered here.

Complementary guidance specific to the procurement of medical oxygen generation plants can be found in WHO's *Foundations of medical oxygen systems – web annex A: technical considerations for the procurement of oxygen generator plants (7).*

Target audience

These technical specifications are intended to support more technical cadres of the workforce such as procurement officers, planning officers, clinical/biomedical engineers/technicians and civil/mechanical/electrical engineers/technicians to assess, select and/or procure safe, appropriate oxygen systems for medical application. Pharmacists or other personnel who bear responsibility regarding medical oxygen would also benefit from this document.

This document may be used by other personnel involved in oxygen systems development and/or implementation including health facility administrators and management, clinical decision-makers, health care workers, logisticians and supply chain personnel, policy-makers, academics/researchers, development agencies, NGOs and device manufacturers and distributors. Additionally, this document may be used by government ministries, for example, health and industry, and by standards institutes and regulators.

Methodology for development

These technical specifications have been developed by WHO, with inputs from several experts in oxygen production, storage and distribution technologies, using the methodology indicated in Fig. 1.

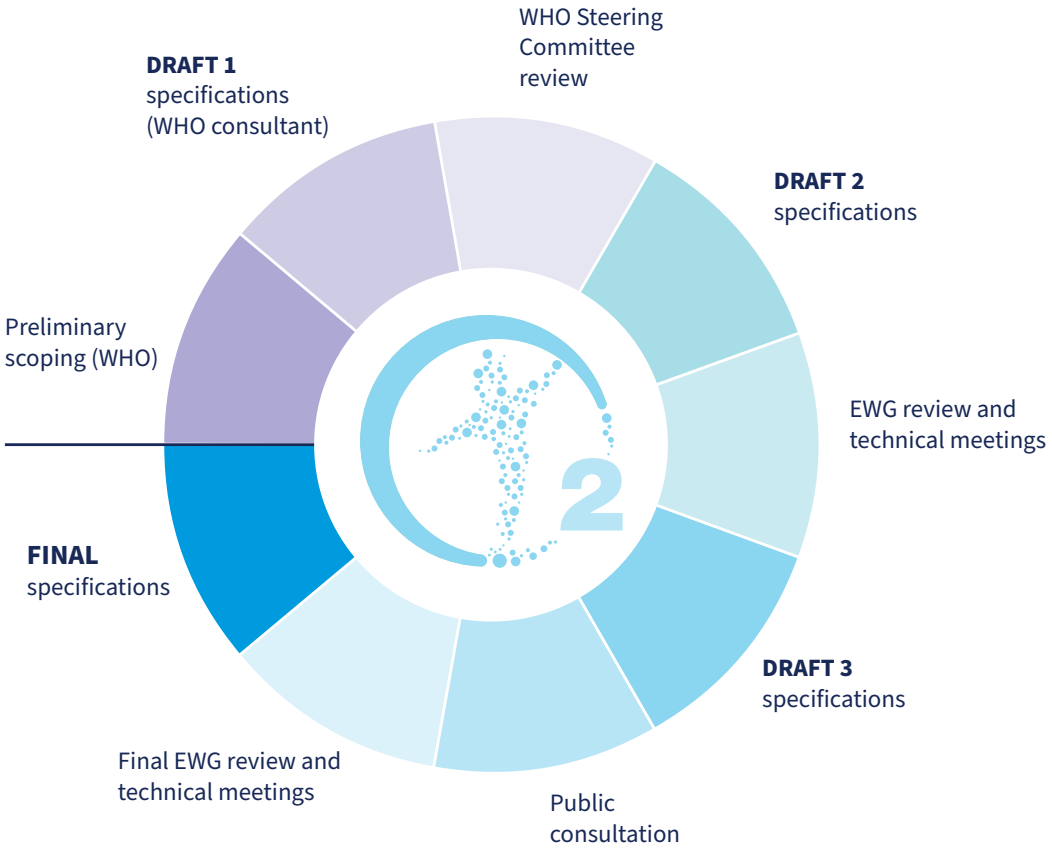


Fig. 1. Methodology for development

A preliminary scoping exercise was conducted by WHO biomedical engineers and the WHO Steering Committee convened to formally establish scope, intended audience and the following methodology:

- Existing and publicly available technical specifications used in the procurement of medical oxygen system components relating to source, storage and distribution were reviewed for completeness and clarity, and to identify any gaps.
- Additional potential sources of evidence to close noted gaps were identified as:
  - Pre-existing (including interim) technical specifications and guidance related to medical oxygen supply systems.
  - Requirements of regulatory agencies that apply stringent standards of quality, safety and efficacy in their reviews of medicines, vaccines, medical devices and pressure equipment in applications for marketing authorization. Specific examples include the United States Code of Federal Regulations (CFR) and various directives of the European Union (EU).
  - Standards established by international bodies such as the International Organization for Standardization (ISO), American Society of Mechanical Engineers (ASME), ASTM[2] and International Electrotechnical Commission (IEC), all of which have been developed via international cross-sectoral technical committees.
  - Existing, relevant normative guidance resources (e.g. United Kingdom HTM-02-01 *(8),* United States NFPA 99 *(9)*).
  - Guidelines and technical briefs from association bodies (e.g. European Industrial Gases Association [EIGA], Compressed Gas Association [CGA] and British Compressed Gases Association [BCGA]).

The collected evidence was analysed and synthesized to develop draft technical specifications which were then cross-checked with openly available user and service manuals of commercially available products from an array of manufacturers. Applicable references are compiled under each product or component category and can also be found in the References.

The draft was reviewed by the WHO Steering Committee, then by members of the EWG, which comprised an interdisciplinary group of expert clinicians, engineers and technicians, programme managers and academics working with medical oxygen systems (see Annex 1). Both groups served to review and refine the draft technical specifications by providing feedback on content, clarity and completeness, and shared relevant implementation experiences, where applicable, relating to procurement and installation, system errors and other appropriate lessons learned or resolutions realized. The EWG convened twice during this process (13 November 2023 and 15 December 2023). See Annex 1 for EWG details.

A public consultation on the draft technical specifications was held via posting an article on WHO's online newsroom platform, and amplified through working networks with input collected between 6 February and 15 March 2024. Voluntary participation from government officials, civil society organizations, international organizations, research institutions, interested citizens and stakeholders globally enhanced the document's development by gathering opinions, collecting information and enabling identification of unintended consequences or technical issues and, lastly, helping to check the relevance and accuracy of the draft document in terms of technical details, performance requirements, safety features and quality requirements. All inputs collected during the public consultation were considered in the revision of the document, many of which were reflected in the final draft. See Annex 2 for an overview of feedback from all consultations.

The final draft underwent peer review for clarity and relevance with regard to scope. Peer reviewers were selected based on subject matter familiarity and geographic representation was also taken into consideration. All peer reviewers indicated that the document was clear and relevant. The notable feedback from the peer review group was to ensure use of this document in conjunction with a comprehensive plan for the installation, testing, commissioning, day-to-day operation and maintenance and repair of these systems.

The format of these technical specifications is an adaptation of the WHO technical specification format for medical devices and in vitro diagnostics. These technical specifications should be reviewed after 5 years. These specifications do not preclude appropriate upcoming related health products and/or technologies, in which case WHO will consider whether additional specifications are to be drafted.

[2] ASTM International was formerly known as American Society for Testing and Materials.

How to use these technical specifications

In this context, technical specifications serve to improve access to quality, safe and efficient products or components that make up facility-level medical oxygen systems. These minimum requirements facilitate streamlined planning and allow for better management of different resources that will enable system implementation, including financial, human and infrastructural.

These technical specifications have been organized in three sections:

1. Oxygen source equipment (three products);
2. Oxygen storage equipment (three products); and
3. Oxygen distribution components (two sets).

There are eight technical specification tables in total.

For each technology, the specifications are outlined in a table. Each table contains: name, category and coding; purpose of use; technical characteristics; physical characteristics; utility requirements; accessories, consumables, spares and other components; packaging; environmental requirements; training, installation and utilization; warranty and maintenance; decommissioning; safety and standards; and, lastly, documentation.

These specifications have been developed as generic minimum requirements of products and components in a standard format. They will require further adaptation to meet project-specific requirements[3] to ensure alignment in each unique setting. Therefore, some ranges and/or optional features should be adapted, and these can be identified as follows:

- [x] boxes are to be "checked" to include an option or ensure choices between options are specified; and/or
- **[Specify...]** indicates where text is to be added/modified as per suggestion/instruction noted.

When preparing specifications to meet your needs, please download Adobe Acrobat or use Acrobat online and use "edit" function to add your specifications where [Specify...] is indicated.

The user is encouraged to include a explanation to this effect if these specifications are used for a tender.

Clear project-specific technical specifications enable a comprehensive evaluation of products or components offered by vendors and facilitate comparison between offers to make a recommendation regarding an appropriate solution from a technical perspective.

These specifications are to be used within broader system planning. In the case of procurement for medical oxygen systems for health facilities, the use of these technical specifications can only commence after a needs assessment and a feasibility study have been completed, and when project financing has been secured (see Fig. 2).

[3] Context-specific requirements may include, but are not limited to, considerations of geography and environment, national regulations, norms and/or standards, electrical power grid, transportation, logistical capacity, available personnel.

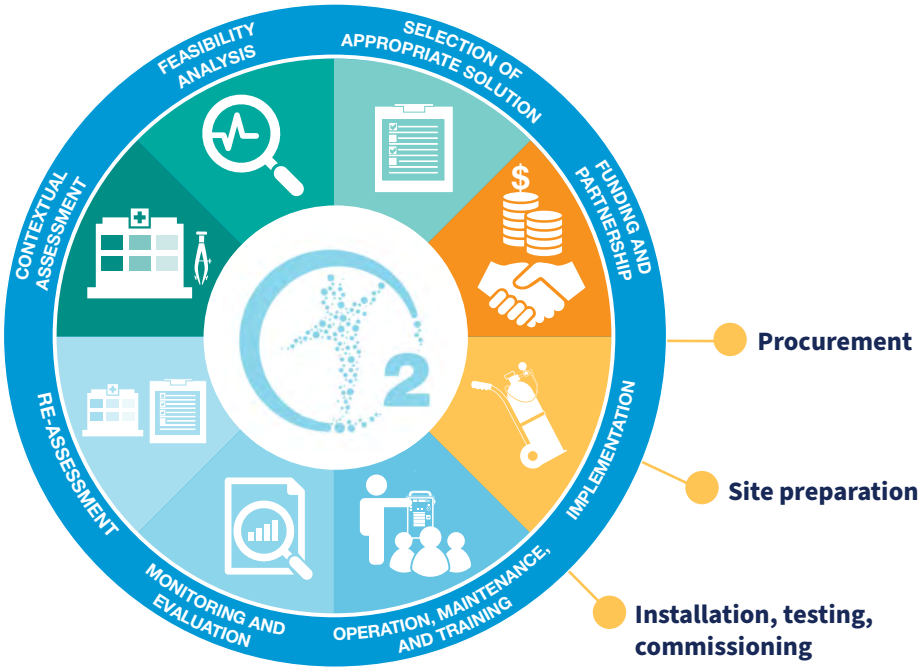


Fig. 2. Procurement as part of implementation within the broader life cycle of oxygen systems
Note: Adapted from *Foundations of medical oxygen systems*, WHO *(4)*.

Complementary products, components or activities

Each product specification is followed by two subsections:

- Other system requirements: these are activities or components that will be necessary to ensure functionality of the component specified.
- Other system considerations: these are activities or components that are not mandatory but can work to complement or enhance the component specified.

All the activities related to service provision during installation (including testing and commissioning), for operations, or maintenance of oxygen systems, should be adapted based on the project scope.

The user may need to combine different product or component specifications depending on need. For instance, an oxygen storage system can be linked to an oxygen distribution system and so on.

Consulting broader members of the workforce

All relevant cadres of the workforce should be consulted for proper adaptation of the specifications to ensure all project needs are met, including but not limited to:

- clinical personnel, namely health care providers, pharmacists, data managers;
- technical teams:
  - civil/structural, mechanical and electrical engineers/technicians for all infrastructure;
  - biomedical engineers and technicians for all health care technology;
- administrative personnel, including facility management and finance managers;
- quality and regulatory personnel, including national regulatory agency/authority (NRA) personnel and others involved in norms and standards.

Precedent of national standards and regulations

These specifications detail a variety of internationally recognized performance, quality and safety standards for the products themselves as well as for the manufacturer/distributor, where applicable. Each of these should be reviewed, and compliance to each (or an equivalent) may be necessary in whole or in part and may vary from one context to another depending on the availability of national and/or regional standards, which will take precedent over international standards.

In any jurisdiction, products are to be classified and regulated by an NRA, which is also responsible for market authorization. In the absence of an NRA, government bodies under relevant ministries can oversee regulatory aspects of products under their jurisdiction. In medical oxygen systems, equipment and accessories used in production, storage and distribution are components, in part or as an assembly, are often regulated under different authorities (e.g. pressure equipment, electrical equipment). These specifications outline established regulatory frameworks, such as the European Union Conformité Européenne (EU CE) or the United States Code of Federal Regulations (CFR) across various product categories, which can be used as a reference.

All standards and regulations listed in the specifications are summarized in Annex 3.

Continuous training for operators and service providers

Ongoing operations and maintenance are critical aspects for the sustainability of medical oxygen systems. Introductory training versus establishing competency must be considered. Thus, planning and resourcing for quality and ongoing training of the human resources involved in the operation and/or maintenance will be necessary.

In the case of service contracts, certifications of trainers by the original manufacturer, details of content and modality of delivery should be agreed on by all parties prior to engaging in a contract.

These specifications emphasize the training needs, but do not outline the details. To develop proper training packages, the following should be considered:

- Assessing workforce competency prior to implementation of new products or components of medical oxygen systems, as minimum needs will vary greatly.
- Determining preferred training modality, and whether training is to take place on-site, virtually or hybrid. If resources permit, visiting other sites (e.g. manufacturing site or a centre of excellence) can add depth and breadth to trainees' knowledge base.
- Requesting a sample training package as part of documentation in a tender. Doing so can indicate how comprehensive and varied the curriculum will be.
- Trainers should be recognized by the product or component manufacturer/supplier and should also be qualified or certified as trainers. Teams who install, test and commission are not necessarily suitable for or qualified to conduct training.

Warranty

The term "warranty" used in these specifications refers to guarantee of product and/or components from the time of commissioning and encompasses any manufacture-related issues or defects. It does not refer to coverage for or provision of any after-sales service such as operations, preventive maintenance and/or repair resulting from operational wear and tear.

Coverage under any warranty will vary between products, components, context and vendors. The responsibility lies between the parties to establish what is covered under warranty, the duration of warranty and all associated costs. Thus:

- Terms and conditions, inclusive of warranty, will vary from one purchase order contract to the next. Terms and conditions can be negotiated.
- Buyers must closely examine the warranty on offer to clearly understand what will and will not be covered in the event of premature product or component error and/or failure.
- Expectations of provision of any service must be clearly indicated, including explicit details regarding the responsibilities of the parties.

Spare parts

Spares are vital for ongoing operations of any health facility based medical oxygen system; delayed or skipped intervals due to lack of access to spares may temporarily affect system functionality and may also cause permanent damage, rendering large initial investments a waste. **Planning for access to an affordable and reliable supply chain of spare parts will be compulsory to safely sustain any facility based medical oxygen system product.**

Spare parts include replacement components necessary during scheduled maintenance intervals (planned preventive maintenance) as well as those needed for repair during system failure, in whole or in part (curative maintenance). Manufacturer recommendations should be followed when acquiring spares, and all quality standards specific to each must be met.

There are multiple avenues and approaches for acquisition of spares. Any buyer shall closely examine the terms and conditions of any contract for any details related to inclusion, acquisition (e.g. availability of generic or brand specific) or access to spares both during and after warranty.

Complementary to making arrangements for sourcing spares, access to tools and resources for maintenance (whether preventive or curative) shall also be considered. More remote contexts may not have easy access to lifting equipment or specialized measurement tools or calibration equipment, which must also be planned for.

Contracting

These generic technical specifications should be adapted to the project needs before being considered as binding. If a vendor offer differs or deviates from the requested technical solution, the vendor must provide justification, and the solution must be agreed upon on by all parties. National or organizational procurement guidance should be followed – an example of this is the United Nations Department of Operational Support *United Nations procurement manual (10)*.

For a list of tools and resources that can help in system planning and implementation, see Annex 4.

The content in these specifications focuses on commercially available technologies; however, they have been written with the understanding that innovations in manufacturing, products, infrastructure and clinical practice will advance the field of oxygen production, supply and delivery.

These specifications do not preclude appropriate upcoming products and/or technologies.

Technical specifications for health facility based medical oxygen system products

Reducer with pressure gauge on the oxygen cylinder.
©AdobeStock/rostovdriver

These specifications have been developed as generic minimum requirements of products and components in a standard format. They will require further adaptation to meet project-specific requirements to ensure alignment in each unique setting. These can be identified as follows:

- ☒ **boxes** are to be "checked" to include an option or ensure choices between options are specified; and/or
- **[Specify…]** indicates where text is to be added/modified as per suggestion/instruction noted.

Compressed air preparation. Nitrogen and oxygen stations and air dryers.

1. Oxygen source equipment

1.1 Oxygen generator plants (PSA, VSA, VPSA)

Oxygen generator plants – pressure swing adsorption (PSA), vacuum swing adsorption (VSA), vacuum pressure swing adsorption (VPSA) – are described in detail in WHO's *Foundations of medical oxygen systems* (see comprehensive overview pp. 21–23).

These specifications describe the minimum requirements (unless otherwise specified) and components assembled for a single system.

Note: This specification supersedes WHO's *Technical specifications for pressure swing adsorption (PSA) oxygen plants: interim guidance* (2020).

Name, category and coding		
1	WHO category/code	(under development)
2	Generic name	Oxygen generator plant
3	Specific type or variation	Pressure swing adsorption (PSA) oxygen generator plant Vacuum swing adsorption (VSA) oxygen generator plant Vacuum pressure swing adsorption (VPSA) oxygen generator plant
4	UNSPS code (optional)	42271700 (oxygen therapy delivery systems and devices)
5	EMDN name	
6	EMDN code	
7	GMDN name	Bulk oxygen concentration system © GMDN Agency 2005-2024[4]
8	GMDN code	57850
9	Alternative name/s (optional)	
10	Alternative code/s (optional)	
11	Keywords	PSA, VSA, VPSA, Pressure swing adsorption, Vacuum swing adsorption, Vacuum-pressure swing adsorption, Oxygen generator plant, Oxygen plant, Oxygen generator, Oxygen supply system, Oxygen source, Oxygen supply, Medical oxygen
12	Product definition	An oxygen generator plant is an assembly of components which collectively produces medical oxygen of at least 93 ±3% purity volume per volume (V/V) from ambient air *(11)*. A secondary adsorption phase is also available, which can be used to achieve higher oxygen concentrations (oxygen 98%, which contains not less than 96% of oxygen *(12)* using double stage adsorption). These plants all rely on molecular sieve technology (zeolites) to selectively adsorb and discharge nitrogen, allowing for oxygen to concentrate for downstream use. There are a few variations of oxygen generator plants (e.g. PSA, modular PSA, VSA, VPSA); however, in general, all plants operate on the principle of pushing pressurized air through a molecular sieve bed for nitrogen removal. Sizing an oxygen generator-based medical oxygen system is dependent on a rigorous analysis of context-specific needs; however, a single production unit for medical application will typically range 10–60 Nm^3/h, and there are many configurations for achieving ultimate desired outputs to ensure continuous medical oxygen supply.

[4] Global Medical Devices Nomenclature. GMDN Agency; 2024.

ⓘ **☒ boxes** are to be "checked" to include an option or ensure choices between options are specified; and/or **[Specify...]** indicates where text is to be added/modified as per suggestion/instruction noted.

Purpose of use		
13	Intended use	Oxygen generator plants can be used to generate medical oxygen in health facilities, which is then piped directly to patients' bedsides, and/or can be further compressed to fill high-pressure gas cylinders.
14	Service delivery platforms/health care levels	• First-level (district) hospital services. • Second-level and third-level hospital services and specialized outpatient services.
15	Clinical department/ ward	N/A; however, unit generates medical oxygen that can be used across any clinical department/medical ward where oxygen therapy/respiratory support is indicated.
16	Overview of functional requirements	The oxygen generator plant will: • Use molecular sieve technology (zeolites) to concentrate oxygen from ambient air. • Continuously and reliably produce medical oxygen according to the purity specification. • Display parameters of operations (digital display bearing numerical and graphical values of operation preferred, not mandatory). • Have in-built monitoring to ensure oxygen output is of acceptable purity. • Have alarms (audible and visual) to indicate any output non-conformance or system anomaly. • For installation: components can be shipped for on-site assembly, can come pre-assembled (skid-mounted), or come pre-assembled and pre-housed in a fit-for-purpose container (containerized). • Be suitable for direct connection or "tie-in" to a facility MGPS, where required.
Technical characteristics		
17	Components	• Air feed pressure generator (compressor for PSA or blower for VSA). • Dryer. • Filtration assembly. • Condensate drain assembly. • Compressed air tank. • Molecular sieve beds (dual separation chambers) with automatic changeover. • Product tank/reservoir. • Oxygen analyser. • Outlet filter (bacteria filter or "sterile" filter) and odour filter. • Control panel for system operations inclusive of instruments for monitoring and alarms. • Hoses/piping/connections. • Electrical panel and wiring between relevant components.
18	Detailed requirements	• Air feed – pressure generator. – To be sized to accommodate for output capacity of generator (minimum 5x expected output + required accommodation for elevation, see line 35). – Type: ☐ For PSA, a compressor, which can be: • filtered oil-injected/oil-lubricated: ☐ rotary screw type; **or** ☐ rotary vane type; **or** • oil-free technology: ☐ reciprocating piston type (oil-free); **or** ☐ rotary screw/scroll type (oil-free). ☐ For VSA, a blower, oil-free. – Energy saving components: ☐ Variable speed drive (VSD)/variable frequency drive (VFD). (*Note:* Soft-starter also required if downstream filling station compressor in use.) ☐ Soft-starter feature to reduce load upon start-up. – Output air pressure > 750 kPa (7.5 bar, 108 psi) (except for modular units, provided product output pressure is met). – Maximum noise 80 dBa (additional soundproofing if greater power required).

Technical characteristics *(continued)*		

18	Detailed requirements *(continued)*	– Exhaust duct to ventilate hot air, insulated:
		  • Proven reduction in thermal transfer.
		  • Dimensions to be determined in coordination with supplier at time of installation to ensure fit.
		• Air dryer:
		– Type, size and/or configuration[5] to be justified by supplier based on context's environmental conditions, can be:
		  • Refrigerant dryer.
		  • Desiccant/adsorption dryer.[6]
		– Capable of managing compressor/blower output.
		– Capable of producing output with pressure dew point ≤ 3 °C.
		– Condensate purge, automatic.
		• Filters:
		– Air preparation, minimum filtration assembly (class and values as per ISO 8573-1, or equivalent):
		  • Pre-filter: removal of particulates as per "Class 3" or better.
		  • Coalescing filter: removal of particulates as per "Class 1", maximum 0.1 mg/m³ oil carry over as per "Class 2".
		  • Oil-vapour filter (activated carbon tower): maximum 0.003 mg/m³ oil vapour carry-over, "Class 0" (can be optional in the case that the air feed unit is oil-free: a vacuum or an oil-free reciprocating piston compressor; otherwise, mandatory).
		  • Pressure drop across any filter in the air preparation assembly must not be greater than 0.1 bar (1.45 psi).
		  • Other filters as per manufacture recommendation.
		  • Automatic drain valve(s) on filtration assembly.
		– Outlet filter (bacteria filter or "sterile" filter), downstream of product tank, removal particulates as per "Class 1".
		• Tanks, pressure vessels:
		– Compressed air tank, ≥ 1000 kPa maximum allowable working pressure (10 bar, 145 psi).
		– Oxygen product tank, tested to 1000 kPa (10 bar, 145 psi).
		– Each bearing an analogue pressure gauge, displayed in kPa (or bar or psi).
		– Each fitted with a safety relief valve.
		• Oxygen generator:
		– Twin towers (*Note:* only one for VSA) with zeolite molecular sieve beds.
		– Nitrogen by-product outlet, silenced (a duct hose for nitrogen exhaust should be included. Length: [Specify estimated length required for installation.]
		• Control panel:
		– System controls and operations.
		– Alarm panel.
		– Display:
		  • Oxygen product requirements (and displayed at a minimum).
		  • Purity of concentrated oxygen at least 93 ±3% V/V:
		  – paramagnetic **or** zirconia analyser technology;
		  – measured with ± 1% accuracy.
		  • Temperature ≤ 40 °C (104 °F).
		  ☐ Carbon monoxide (≤ 5 ppm V/V) (specify if applicable).
		  ☐ Carbon dioxide (≤ 300 ppm V/V) (specify if applicable).
		  • Output pressure: 500–800 kPa (5–8 bar, 73–116 psi). (*Note:* If connected to MGPS, select to align with applicable standard and specific system design.)
		  • Use of differential colour scheme to indicate system or operation status (e.g. green "normal", red "alarm").

[5] Size of refrigerant dryer dependent on ambient temperature and relative humidity of context; desiccant/adsorption dryer to be considered for colder environments or for contexts with noted elevation.

[6] Consider use for colder climates or those at elevation, where temperatures drop below 10 °C.

Technical characteristics *(continued)*		
18	Detailed requirements *(continued)*	• Product and other safety features: – Water-oil separating unit, reusable, to safely manage and dispose of condensate from filtration assembly. – Condensate drain tubing, adequate lengths for installation, for: • Filtration assembly, including connecting to water-oil separator unit. • Air compressor/dryer. • Compressed air tank. – Product tank purge function for low-concentration oxygen (automatic, solenoid valve). – Automatic shut-off for: • Event of non-conformance (factory set for oxygen < 90%) with manual override. • Overheating of air feed unit (compressor/blower) when air-end discharge > 110 °C (230 °F). – Standby mode (when no demand on system). • Piping/hoses: – Compatible for use with oxygen according to ISO 15001 (or equivalent, vendor to supply details accordingly) for any piping within and downstream of oxygen generator. – Fitted with isolation valves: • After compressor. • Before and after air tank. • Before and after product tank. • On sample line. • On product line. • On cylinder fill line (if applicable). • Electrical (see supply requirements in line 26): – Standby mode when no system demand. – Safe mode comprising an uninterruptible power supply feature built into control panel (to prevent system damage and data loss resulting from micro-current cuts). – All electrical components to be pre-wired, with cables sufficiently housed to avoid tampering; protective trunking to be used for connections direct to the skid and/or container flooring. – Additional wiring provided for connections if more than one skid/component for configuration. – Electrical cable length, armoured, for main connection to power supply (length and section sized accordingly). – All requisite safety features (e.g. fuses/breakers, grounding). • Assembly, components are to be delivered: ☐ Disassembled, for on-site assembly; **or** ☐ Pre-assembled and skid-mounted; **or** ☐ Pre-assembled and pre-housed in a fit-for-purpose container ("containerized plant"). ***Where any of these criteria cannot be met exactly, vendor to provide justification or evidence that proposed system, components or subcomponent meets or exceeds the intended specifications herein.***
19	Size(s)	Size indicated by output capacity, in flow: • Required output: [Specify for based on demand, also specify units: Nm^3/hr or LPM or SCFH] for medical application. • Air and product tanks to be sized accordingly for system capacity and function (pressure balance),[7] vendor to size in L (gal).

[7] Tanks are not intended for storage – they serve to balance pressure across the oxygen generator system. Oversized tanks will result in operational lags, undersized tanks can render the system overly sensitive to downstream pressure fluctuations. Rule-of-thumb for external tanks: plant capacity (in Nm^3/hr) x 50, round up to nearest 500 L (e.g. 15 Nm^3/hr x 50 = 750, so 1000 L).

Technical characteristics *(continued)*		
20	Control panel/user interface	Program logic controller (PLC) system: • Digital display: – Preferred language of destination country and/or English. – Colour. – Display in SI units. ☐ Touchscreen *(optional).* ☐ Remote monitoring *(optional);* [specify need for integration into Computerized Maintenance Management System (CMMS) if applicable]. • Data export functionality (e.g. USB port, SD card, Bluetooth).
21	Displayed parameters	• Oxygen generator plant control panel to display: – Oxygen production, trending continuous: • Product purity, % (***purity should be always explicitly visible***). ☐ Flow, Nm^3/hr (or LPM or SCFH) (optional, recommended). • Sieve bed pressure, kPa (or bar or psi). • Output pressure, kPa (or bar or psi). ☐ Product impurities (specify if applicable). – System status, indication if: • Standby (online) mode. • Maintenance needed. – Cumulative hours of operation (digital or analogue). • Air compressor and dryer. – Dew point. – Temperature. – Oil level (suggested). ☐ Automatic purge kit display panel (if applicable). – Line pressure, kPa (or bar or psi). – Cumulative flow, Nm^3. – Purity, %. ☐ Other display parameters as per specific features and/or configuration: ☐ Impurity monitoring. ☐ Secondary oxygen generation plant. ☐ Oxygen system operations. ☐ Other: [specify].
22	Alarms	• Audible and visual alarms for: – High temperature, > 40 °C (104 °F). – Low or high pressure, < 5 bar (73 psi) or > 8 bar (116 psi). [Specify otherwise to align with applicable standard and specific system design.] – Low oxygen concentration (< 90%). ☐ High carbon monoxide (> 5 ppm V/V) (specify if applicable). ☐ High carbon dioxide (> 300 ppm V/V) (specify if applicable). – Power failure; system failure. – Secondary/reserve source activation (e.g. plant in duplex configuration [secondary] or cylinders from distribution manifold [secondary or reserve]). – Air dryer pressure dew point (> 3 °C). ☐ Ambient oxygen monitoring system for plant room (optional, recommended): – Audible and visual alarms if ambient air above 23.5% or below 19.5%.
23	User adjustable settings	N/A; however, pressure setpoints can be adjusted if necessary.

Physical characteristics		
24	Configuration	• Plant output is to be connected to at least one of the following: – Cylinder filling station, requiring: a booster compressor, a filling ramp/ manifold, a purge vacuum, cylinders and cylinder transport trolleys. – MGPS, comprising piping and associated fittings, alarms, line valve assemblies, area valve service units, an emergency supply inlet port and bedside wall outlets. • Consideration to be given to allow for redundancy of components through duplex/multiplex configurations to enhance supply security and enable maintenance activities such as for: – Air compressors/blowers. – Product tank for continuous dual application (feeding MGPS and filling high-pressure gas cylinders). – Complete oxygen generating plant. ***The whole system configuration must continuously meet anticipated oxygen needs of a facility and consider a secondary/back-up supply. This could be achieved by employing redundant systems, or a combination of different technologies.***
25	Mobility, portability	N/A.
Utility requirements		
26	Electrical, water and/ or gas supply	Power supply requirements: • Air compressor/blower: 380 ±15% V AC, 3-phase [specify otherwise]. – Frequency: ☐ 50 Hz; **or** ☐ 60 Hz. • Controls/PLC: – Voltage ☐ 220 ±15% V AC, single phase. ☐ 110 ±15% V AC, single phase. – Frequency ☐ 50 Hz; **or** ☐ 60 Hz. • Ensure voltage, frequency and plug type (if applicable) are locally compatible. • Appropriately sized and rated electrical protection via resettable circuit breakers or replaceable fuses in panel. For the products on offer, vendor to indicate estimated: • Total power consumption of product(s); indicate back-up power supply size requirements. • Peak current during start-up.
Accessories, consumables, spare parts and other components		
27	Accessories	• Cylinder filling station (inclusive of booster compressor and cylinder filling ramp).
28	Consumables/ reagents	Vendor to detail anticipated replacement frequency requirements for [specify climatic conditions and variations thereto]: • Inlet filter assembly. • Bacteria filter/outlet filter. • Oil.

Accessories, consumables, spare parts and other components *(continued)*		
29	Spare parts	• Toolkit necessary for daily checks, planned maintenance and basic troubleshooting, as per the manufacturer training and recommendations. • Vendor to detail all spares required for at least the first [16 000 hour of operation, specify longer if needed to align with SLA] for each component of the oxygen generator plant as follows: – Disaggregated list as per service interval. – Detail: ◦ Brand/model, part number, description and shelf life (if applicable) as per catalogue for manufacture reference. ◦ Unit cost. – Highlight a critical spares list to facilitate curative maintenance. *Note:* All spares and components that will have contact with air and/or product stream shall be intended for application with medical oxygen generator plants and come: • Sealed in individual packages (for fittings). • Capped at both ends (for any piping/hose).
30	Other components	[Specify needs or refer to additional specifications, see Section 1.1.1.]
Packaging		
31	Cleaning requirements	Entire system shall be cleaned for use in oxygen-enriched environments, conforming to the following (e.g. ISO 15001, or equivalent): • Not have a level of hydrocarbon contamination greater than 550 mg/m^2.
32	Shelf life	Manufacturer to indicate pre-installation shelf life of unit(s) on offer, inclusive of details for sieve beds and instrument sensors.
33	Transportation and storage	• Plant shall be protectively packed in a full enclosure for safe onward shipping. – All connection points on tanks and piping ends to be sealed. – If to be assembled on-site, components to be securely crated. – If skid-mounted, ensure that a shipping crate encases the skid or that there is a barrier for access to components. • Information for the following to be provided for product on offer: – Transportation condition requirements (temperature, pressure, light humidity). – Storage condition requirements (temperature, pressure, light, humidity, etc.), to be indicated on the packaging/container. – Storage procedure for long periods of storage and any associated implications for commercial conditions (if applicable). – Approximate gross weight and dimensions of each crate, skidded crate or containerized plant.
34	Labelling	Permanent, embossed nameplates shall be affixed to components, and include the following (where applicable): • Name and/or trademark of the manufacturer. • Manufacturer's product reference, serial number (S/N). • Type of product and main characteristics (e.g. voltage and frequency requirements). • Indication that the product is for medical application. • Regulatory markings. • Date of manufacture. • Origin of manufacture. There shall be signage and labelling on container or plant unit indicating "no oil" and "no sources of ignition".

Environmental requirements		
35	Context-dependent requirements	• Continuous operations within specification in ambient temperature of at least 5–40 °C (41–104 °F), concurrent with relative humidity from 15–95%. • Elevation: [specify in m or ft above sea level[8]] ***Many components of these plants are sensitive to environmental conditions. Where the operating environment is out of this range, vendor to propose accommodating measures to protect equipment and facilitate continuous operation.***
Training, installation and utilization		
36	Pre-installation requirements	Manufacturer to specify the following to ensure context and infrastructure compatibility: • Comprehensive site readiness pre-installation checklist to facilitate optimum installation. • Dimensioned drawings of system to facilitate installation of all components, indicating: – Dimensions: height of all components and total footprint. – Pneumatic diagram. – Electrical drawings (inclusive of panel configuration). – Drainage requirements. • Housing (if not containerized) and shelter requirements (if containerized) to ensure cover to protect from the elements, security, access, etc. • Floor mass resistance requirements. • Heating, ventilation and air conditioning (HVAC) (if applicable). • Equipment to transport and lift equipment from point of reception to point for installation (e.g. forklift, crane, sling).
37	Requirements for installation, testing and commissioning	Manufacturer to provide detailed requirements for installation, testing and commissioning of all components. The following are requirements prior to and inclusive of manufacturer-recommended commissioning: • Contractor must position and interconnect all components (if/where applicable), and connect the entire system to the power supply. • All equipment to be grounded/earthed as per national regulations in [Specify country. In absence of national regulations, international standard IEC 60364-5-54 or equivalent can apply.] • "Tie-in" to facility MGPS (including secondary/emergency supply) and/or to the cylinder filling station. • There shall be clear signage and labelling on the plant room room depicting hazards and noting safety requirements. • Tests should be conducted and documented in accordance with the established protocols of the manufacturer. Results to be cross-checked with pre-shipment inspection. • Verify functionality of automatic switch-over to secondary/reserve oxygen supply. • A minimum of 72 hours of continuous operations to test/simulate the entire system should be performed prior to commissioning. All analysers and alarms, inclusive of power failure, should be checked.
38	Training of user/s	On-site training in preferred language of destination country and/or English to include, but not be limited to: • Safety: general, oxygen-specific and operations of the plant. • Operational overview: – Theoretical overview of plant. – Functionality of each component. – Plant performance indicators. – Risk management.

[8] Every 300 m (985 ft) of variance in elevation could have an impact on performance and efficiency of the unit under consideration.

Training, installation and utilization *(continued)*		
38	Training of user/s *(continued)*	• Cleaning requirements of the site/plant room, of the unit. • Daily operations, inclusive of record keeping and data management. • Periodic testing of user setpoints and alarms (both visual and audible). • Planned preventive maintenance standard operating procedures (SOP) and work instructions. • Troubleshooting approach and corrective maintenance SOPs and work instructions if they can be carried out by user. • Discussion of what tasks or procedures may need to be carried out by (manufacturer certified/authorized) third-party technician. ***Consideration to include "continuous development" training programme to be paired alongside service level agreement (SLA) activities.***
39	User care	Provide instructions and checklists in preferred language of destination country and/or English for, but not limited to: • Cleaning of the site/plant room, of the unit. • Daily operations, inclusive of record keeping and data management. • Planned preventive maintenance according to manufacture SOPs and work instructions, and agreement in line with SLA (see lines 41 and 42).
Warranty and maintenance		
40	Warranty *(see p. 9)*	1 year from date of commissioning, minimum: • 24 hours/day, 7 days/week remote support for manufacturer defect. • Clear terms and conditions inclusive of details of time-to-response for on-site intervention. • Contact details of manufacturer, supplier and local service agent to be provided.
41	Maintenance tasks	Maintenance should be conducted by a qualified party. The following shall be provided from the manufacturer: • A comprehensive, manufacturer-recommended preventive maintenance schedule, inclusive of calibration requirements, according to clearly established frequency (e.g. operating hours or months lapsed). • A list of all associated spares for each maintenance interval (see line 29).
42	After-sales service contract	An SLA is suggested with a qualified provider authorized by the manufacturer of the equipment and should detail: • Terms and conditions, including duration of SLA. • Level of responsibility clearly delineated to-the-task, inclusive of requisite sourcing, within: ☐ Planned preventive maintenance (incl. required calibration); **or** ☐ Planned preventive maintenance, troubleshooting and curative maintenance; **or** ☐ Troubleshooting and curative maintenance. • Costs, itemized in terms of labour, travel, lodging and all parts. • Time-to-response for remote support **and** for on-site intervention. • Timeline for critical spares to reach point of intervention. • Burden of responsibility of emergency oxygen supply if stock-out/rupture occurs. • Requirements of record keeping of all activities.
43	Spare parts availability post-warranty	Minimum 10 years, from time of acceptance of product.
44	Software/hardware upgrade availability	Original equipment manufacturer (OEM) for PLC to provide guaranteed period of support post-warranty to facilitate any necessary software and firmware updates. Details to be provided by vendor.

Decommissioning		
45	Lifespan	10 years minimum, guaranteed by manufacturer.
Safety and standards		
46	Regulations	Regulated as per NRA of intended market. In the absence of NRA requirements, suggest using alternative, such as (but not limited to): Oxygen generator plant classified as a **medical device:** • EU: MDR (No. 2017/745). • US: 21 CFR § 820 – Quality System Regulation (medical devices). • Air and product tanks are classified as **pressure equipment:** – EU: Pressure Equipment Directive (PED) 2014/68/EU. – US: 46 CFR § 54 – Pressure vessels. • All electrical components for **electrical safety:** – EU: Low Voltage Directive (LVD) (No. 2014/35/EU). – US: 29 CFR § 1910 – Occupational safety and Health Standards. • Other: – US: 21 CFR § 801 – Labeling. – US: 21 CFR § 803 – Medical Device Reporting.
47	Risk/hazard classification	Classified as per NRA of intended market. In the absence of NRA classification of this product, suggested alternatives: Oxygen generator plants are classified as **medical devices:** • Class II (US Food and Drug Administration [FDA]), Class B (Global Harmonized Task Force [GHTF] Rule 6), Class II b (EU, Australia), Class II (Japan, Canada). Air and product tanks are classified as **pressure equipment:** • EC PED: Category 1. • US: Class II.
48	Regulatory approval/ certification	Compliance (where applicable, but not limited) to: • NRA requirements of intended market. • Approval by NRA and regulatory body of country of manufacturer. In the absence of classification or regulation by the NRA, suggest regulatory clearance/approval and certification by a conformity assessment body from a well-regulated market such as (but not limited to): • United States regulations: – US FDA: Device Class II for Medical Devices. – ASME U-stamp for pressure vessels. • EU regulations: – CE marking for medical devices (with notified body indicated). – PED certified pressure equipment (with notified body indicated). • Other: Equivalent approvals from a regulatory body in an International Medical Device Regulators Forum (IMDRF)/GHTF founding member country such as Australia, Canada or Japan.
49	International standards for manufacturer	Compliance to (where applicable, but not limited to) and last available version or equivalent of: • ISO 9001: Quality management systems – Requirements. • ISO 13485: Medical devices – Quality management system – Requirements for regulatory purposes.

Safety and standards		
50	International standards for product performance	Compliance to the latest available version of the following international standards or to regional or national equivalent, including technical tests for safety and performance from an accredited laboratory or third party (where applicable, but not limited to): • Electrical component: – IEC 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. – IEC 60601-1-8: 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. • Filter output: – 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 8573-5: Compressed air – Part 5: Test methods for oil vapour and organic solvent content. – Filters for compressed air – Test methods – Part 1: Oil aerosols. – Filters for compressed air – Test methods – Part 2: Oil vapours. – Filters for compressed air – Test methods – Part 3: Particulates. • Piping/hoses/connections: – ISO 5359: Anaesthetic and respiratory equipment – low-pressure hose assemblies for use with medical gases. – ISO 7396-1: Medical gas pipeline systems – Part 1: Pipeline systems for compressed medical gases and vacuum. • Air and product tanks: – Design, test, performance: • ISO 16528-1: Boilers and pressure vessels – Part 1: Performance requirements. • ASME BPVC Section VIII – Rules for Construction of Pressure Vessels Division 1. – ISO 15001: Anaesthetic and respiratory equipment – Compatibility with oxygen. – ASTM G93/G93M-19: Standard guide for cleanliness levels and cleaning methods for materials and equipment used in oxygen-enriched environments.
51	Regional/local standards	• Country-specific and regional standards may take precedent. • Registered in country of import (if applicable).
Documentation		
52	Documentation requirements	Hard and soft copies, to be supplied in preferred language of destination country and/or English of all the following: • Company profile. • Product catalogue/commercial brochure. • Letter of authorization for distribution agent (if applicable). • User manual, detailing for each component: – Protocols for start-up and operations. – Preventive maintenance requirements including: • Frequency schedule (in terms of operating hours). • Calibration requirements. – Troubleshooting and curative maintenance procedures. – System schematics. – List of equipment and procedures required for cleaning.

Documentation *(continued)*		
52	Documentation requirements *(continued)*	• Maintenance/service manual (*if details listed above are not covered in the user manual*). – Spares list (see line 29). • Layout design considering environmental, infrastructural and electrical requirements as indicated. • Pre-shipment inspection report, inclusive of all certificates of analysis of product output, technical tests and calibration and other documentation proving safety and efficacy of all components of the oxygen generator plant. • Evidence of valid regulatory approval (see line 48). • Evidence of valid standards compliance for: – Manufacture requirements (line 49). – Product-specific requirements (line 50). • As-built drawings (after installation, see line 36). • Certificate to guarantee of lifespan, minimum of 10 years. • Free sales certificate (FSC) (where applicable). • Installation, testing and commissioning reports (to be provided at time of completion).

1.1.1 Other system requirements

Procurement of an oxygen generator plant will rarely take place in isolation. The following are products or components that are necessary to facilitate safe, continued operations of an oxygen generator plant and should be considered during planning and procurement.

- Hand-held oxygen analyser (stand-alone) for quality control of product.
- Housing (containerized or purpose-built), inclusive of appropriate footings and shelter, complete with all requisite HVAC, drainage, safety and security measures.
- Secondary back-up oxygen supply: redundant generator plant or other secondary source (see *Foundations of medical oxygen systems* p. 51 for details).
- Changeover to secondary source (preferably automatic).
- Dedicated continuous, quality power supply: voltage stabilization and surge suppression when on mains, back-up power source (e.g. diesel-based electricity generator or photovoltaic/battery system).
- Heavy equipment for installation (e.g. forklift and/or crane).
- Personal protective equipment (PPE) for operators such as: coverall (loose, natural fibres, no cuffs), ear defenders, safety goggles, steel-toed boots, high-visibility "hi-vis" vest.
- Fire safety measures (e.g. signage, fire alarm, fire extinguisher, evacuation routes).

1.1.2 Other system considerations

The following activity/product should be considered during planning and/or procurement to extend, enhance or complement an oxygen generator plant.

- Means to conduct quality control tests using methods such as semi-quantitative indicator tubes.
- Ambient oxygen monitoring system for plant room safety (19.5–23.5%).

1.1.3 References and resources

- European Industrial Gases Association (EIGA):
  - DOC 33/18: Cleaning of equipment for oxygen service *(13)*.
  - DOC 149/22: Safe installation and operation of PSA and membrane oxygen and nitrogen generators *(14)*.
  - DOC 195/20: Safe design and operation of on-site generation of oxygen 93% for medicinal use *(15)*.
- *How to plan and budget for your healthcare technology,* 'How to Manage' Series for Healthcare Technology, Guide 2 *(16)*.
- UNICEF Supply Division: Supply catalogue, 12 "Plant in a box" packages/configurations *(17)*.
- US Code of Federal Regulations: Title 46 Part 54 – Pressure vessels *(18)*.
- WHO *Foundations of medical oxygen systems (4)*.
- WHO *Technical specifications for pressure swing adsorption (PSA) oxygen plants: interim guidance (19)*.
- Commercialized product landscape review:
  - AirSep® Corporation: *PSA oxygen generator models AS-20–1000: instruction manual (20)*.
  - Atlas Copco: e-book on compressed air dryers *(21)*.
  - CHAI and PATH: *Respiratory care equipment market report (22)*.
  - Ozcan Kardesler: *Medical oxygen plant with filling station service and operation manual (23)*.
  - PCI Gases: On-site oxygen solutions medical catalogue *(24)*.
- WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices *(25)*.

1.2 Cylinder filling station (from on-site oxygen generator plants)

Cylinder filling stations are described in detail in WHO's *Foundations of medical oxygen systems* (see comprehensive overview pp. 30–31).

Name, category and coding		
1	WHO category/code	(under development)
2	Generic name	Cylinder filling station, medical oxygen
3	Specific type or variation	
4	UNSPS code (optional)	
5	EMDN name	Not a medical device
6	EMDN code	Not a medical device
7	GMDN name	Not a medical device
8	GMDN code	Not a medical device
9	Alternative name/s (optional)	
10	Alternative code/s (optional)	
11	Keywords	Oxygen cylinders, Oxygen generator plant, Filling station, Cylinder filling, Medical oxygen, Booster compressor, Medical oxygen gas, Cylinder purge vacuum, Purge vacuum, Cylinder vacuum pump
12	Product definition	Filling station for high-pressure gas (oxygen) cylinders.
Purpose of use		
13	Intended use	Filling stations for oxygen cylinders can be used on-site where oxygen generator plants have been installed to optimize the plant output and to safely store oxygen produced, which can then be used at another time or transported and used at another location.
14	Service delivery platforms/health care levels	• First-level (district) hospital services. • Second-level and third-level hospital services and specialized outpatient services.
15	Clinical department/ ward	Cylinders filled with medical oxygen can be used across any clinical department/ medical ward where oxygen therapy/respiratory support is indicated provided appropriate safety measures are applied.
16	Overview of functional requirements	Filling stations comprise a booster compressor and a filling manifold (also known as a filling ramp) where medical oxygen is compressed from between 5–8 bar (73–116 psi) into dedicated high-pressure gas cylinders to a final set pressure, typically ~150 bar (~2175 psi).
Technical characteristics		
17	Components	• Booster compressor (reciprocating piston type, rated for use with oxygen). • Filling manifold comprising: rack, header, pressure indicators, cylinder connection points and safety chains. • Purge vacuum.
18	Detailed requirements	• Booster compressor: – Capable of filling medical oxygen cylinders: ☐ up to 150 bar. ☐ up to 200 bar. ☐ up to [specify other]. – Vendor to indicate compressor efficiency: inlet flow versus outlet flow. • Capable of continuous operations (24 hours/day, 7 days/week), without affecting stated efficiency for at least 1500 hours of operations.

Technical characteristics *(continued)*		
18	Detailed requirements *(continued)*	– Adjustable pressure setpoint: • Factory set automatic shut-off: ☐ 150 bar. ☐ Other: [Specify otherwise, based on context.] – Pressure gauges displaying pressure for each stage of compression, kPa (or bar or psi). – Oxygen inlet assembly comprising a pressure regulator and valve. – Throughput capacity range: [insert capacity in Nm^3/hr or LPM or SCFH]. (*Note:* Consider only oxygen generator plant capacity to be dedicated for cylinder filling.) • Vendor to indicate suction pressure range and compatibility and efficiency with oxygen generator plant. – Reciprocating type, oxygen side oil-free. – Cooling (*Note:* Consider water cooled for warmer climates and throughput capacity greater than ~15 m^3/hr.) ☐ Air cooled; **or** ☐ Water cooled. – Safety features: • Safety relief valves at each stage of compression. • Automatic shut-off at pre-set fill pressure. ☐ Automatic shut-off for breach of any stage temperature reference point (optional, recommended). • Cylinder filling manifold: – Cylinder rack with chains to ensure that cylinders remain in place during purge/fill. – Flexible hoses or metallic pigtails intended for high-pressure oxygen filling. – Check-valve for each cylinder connection point (recommended safety feature; however, please see line 24). – Connection type for cylinder compatibility: ☐ Bull-nose: ☐ 5/8 inch BSP (F)/BS 341 #3 valve; **or** ☐ CGA 540; **or** ☐ DIN 9; **or** ☐ NF ‘F’; **or** ☐ NEN Ri2. ☐ Pin-index: ISO 407/BS 850/CGA 870 valve. • Purge/vacuum pump (compressor). – Throughput capacity: ≥ 40m^3/hr. – Vacuum achieved: 0.5 mbar. • Piping to/from booster compressor to manifold header to be oxygen compatible as per ISO 15001 (or equivalent). • Assembly, components are to be delivered: ☐ Disassembled, for on-site assembly; **or** ☐ Pre-assembled and skid-mounted; **or** ☐ Pre-assembled and pre-housed in a fit-for-purpose container (e.g. alongside a generator plant).
19	Size(s)	• Throughput capacity range for booster compressor: [insert capacity in Nm^3/hr or LPM or SCFH]. (*Note:* Consider only oxygen generator plant capacity to be dedicated for cylinder filling.) • Number of cylinders to be filled simultaneously: [Specify number of connections for fill ramp considering duration of fill interval and staffing structure for shifts]. ***Note:* If expressing capacity in # cylinders/day, cylinder size and fill pressure must be indicated.**

Technical characteristics *(continued)*		
20	Control panel/user interface	• Power button. • Start button. • Stop button (for emergency use). • Function switch (automatic/manual).
21	Displayed parameters	• Gauges on the booster compressor to display: – Input pressure (suction). – Pressure of each stage of compression. • Cumulative hours of operation (digital or analogue). ☐ Operating temperature of each stage (optional).
22	Alarms	• Automatic shut-off when maximum temperature of 204 °C (400 °F) is exceeded. • Visual alarm for abnormal temperature rise (recommended).
23	User adjustable settings	Function for operations: automatic and manual start-up.
Physical characteristics		
24	Configuration	• Cylinder filling station to be connected to outlet of an oxygen generator plant. • Consideration to be given to allow for redundancy of components through duplex/multiplex configurations to enhance supply security and enable maintenance activities for booster compressor. ***If filling ramps are to be configured for use as a temporary source for MGPS, an expert in system design is to be consulted to ensure appropriate safety features are applied for continuous gas supply. Consider applicable regulatory requirements for medical devices and see ISO 7396-1 for further details.***
25	Mobility, portability	N/A.
Utility requirements		
26	Electrical, water and/or gas supply	Power supply requirements: • Booster compressor: 380 ±15% V AC, 3-phase. [Specify otherwise; note there are circumstances where booster compressors may only require single phase]. – Frequency: ☐ 50 Hz; **or** ☐ 60 Hz. • Purge vacuum: – Voltage ☐ 220 ±15% V AC, single phase. ☐ 110 ±15% V AC, single phase. – Frequency ☐ 50 Hz; **or** ☐ 60 Hz. – Max. 1.5 kW power consumption (vendor to indicate otherwise). • Vendor to indicate estimated total power consumption of product(s) on offer. • Ensure voltage, frequency and plug type will be locally compatible. • Appropriately sized and rated electrical protection (e.g. via resettable circuit breakers).
Accessories, consumables, spare parts and other components		
27	Accessories	• Cylinders (dedicated for medical oxygen application). • Key to open valve (for cylinders with no hand spindle). • Cylinder transport trolleys.
28	Consumables/ reagents	• Replacement filters. • Lubricant (for crank drive).

Accessories, consumables, spare parts and other components *(continued)*		

29	Spare parts	• Toolkit necessary for daily checks, planned maintenance and basic troubleshooting, as per the manufacturer training and recommendations.
		• Vendor to detail all spares required for the first [10 000 hour of operation, specify longer if needed to align with SLA] for each component of the cylinder filling station as follows:
		– Disaggregated list as per service interval.
		– Detail:
		  • Brand/model, part number and description as per catalogue for manufacture reference.
		  • Unit cost.
		– Items to include (not limiting): valve assemblies, piston assemblies, fast-moving spares such as O-rings and sealing rings.
		– Spare hose lengths (for critical connections) *(if applicable)*.
		– Flexible connections.

30	Other components	[Specify needs or refer to additional specifications, see Section 1.2.1.]
Packaging		
31	Cleaning requirements	Entire system shall be cleaned for use in oxygen-enriched environments, conforming to the following (ISO 15001 or equivalent): • Not have a level of hydrocarbon contamination greater than 220 mg/m^2. • Have no particulates greater than 100 microns in diameter.
32	Shelf life	N/A.
33	Transportation and storage	• Fill stations shall be protectively packed in a full enclosure for safe onward shipping. – All connection points and piping ends to be sealed. – If to be assembled on-site, components to be securely crated. – If skid-mounted, ensure that a shipping crate encases the skid or that there is a barrier for access to components. • Information for the following to be provided for products on offer: – Storage condition requirements (temperature, pressure, light, humidity, etc.), to be indicated on the packaging/container. – Approximate gross weight and dimensions of each crate or skidded crate.
34	Labelling	Permanent, embossed nameplates shall be affixed to components, and include the following (where applicable): • Name and/or trademark of the manufacturer. • Manufacturer's product reference (S/N). • Type of product and main characteristics (e.g. voltage and frequency requirements). • Indication that the product is for medical application. • Regulatory markings. • Date of manufacture. • Origin of manufacture. There shall be signage and labelling on unit indicating "no oil" and "no sources of ignition".
Environmental requirements		
35	Context-dependent requirements	• Continuous operations within specification in ambient temperature of at least 5–40 °C (41–104 °F), concurrent with relative humidity from 15–95%. • Elevation above sea level: [specify in m or ft.] ***Components of filling stations are very sensitive to environmental conditions. Where the operating environment is out of this range, vendor to propose accommodating measures to protect equipment and facilitate continuous operation.***

Training, installation and utilization		
36	Pre-installation requirements	• All planning to align with national guidelines and consider safe distance from hazards (see WHO's *Foundations of medical oxygen systems (4),* p. 52). • Manufacturer to specify the following to ensure context and infrastructure compatibility: – Total footprint to determine space requirements. – HVAC requirements (if applicable). – Accessibility ramp and/or loading dock (context dependent) to facilitate trolleys to transport full/empty cylinders (no lips, no steps). – Storage: well-ventilated area dedicated for the safe, segregated storage of oxygen cylinders according to status (e.g. "to check", "to fill", "full", "fail/rejected", etc.).
37	Requirements for installation, testing and commissioning	The following are requirements prior to and inclusive of commissioning: • All equipment to be grounded/earthed as per national regulations in [Specify country. In absence of national regulations, international standard IEC 60364-5-54 or equivalent can apply.] • On-site training for installation, testing and commissioning shall be provided.
38	Training of user/s	On-site training in preferred language of destination country and/or English to include, but not be limited to: • Safety: general, oxygen-specific and operations of the cylinder filling station. • Operations: theoretical overview of cylinder filling station and functionality of each component. • Cleaning of the unit. • Daily operations, inclusive of record keeping and data management. • Planned preventive maintenance SOPs and work instructions (inclusive of calibration requirements). • Troubleshooting approach and corrective maintenance SOPs and work instructions if they can be carried out by user. • Discussion of what tasks or procedures may need to be carried out by (manufacturer certified/authorized) third-party technician. ***Consideration to include "continuous development" training programme to be paired alongside SLA activities.***
39	User care	Provide instructions and checklists in preferred language of destination country and/or English for, but not limited to: • Cleaning: of the filling station area, of the unit. • Daily operations, inclusive of: – Cylinder checks prior to fill/transport events. – Cylinder purge. – Record keeping and data management. • Planned preventive maintenance according to manufacture SOPs and work instructions, and agreement in line with SLA (see lines 41 and 42).
Warranty and maintenance		
40	Warranty *(see p. 9)*	1 year from date of commissioning, minimum. • 24 hours/day, 7 days/week remote support for manufacturer defect. • Clear terms and conditions inclusive of details of time-to-response for on-site intervention. • Contact details of manufacturer, supplier and local service agent to be provided.
41	Maintenance tasks	Maintenance should be conducted by a qualified party. The following shall be provided from the manufacturer: • A comprehensive, manufacturer-recommended preventive maintenance schedule, according to operating hours. • A list of all associated spares for each maintenance interval (see line 29).

Warranty and maintenance *(continued)*		
42	After-sales service contract	An SLA is suggested with a qualified provider authorized by the manufacturer of the equipment and should detail: • Level of responsibility: ☐ Planned preventive maintenance (including required calibration); **or** ☐ Planned preventive maintenance, troubleshooting and curative maintenance; **or** ☐ Troubleshooting and curative maintenance. • Costs, itemized in terms of labour, travel, lodging and all parts. • Time-to-response for remote support **and** for on-site intervention. • Timeline for critical spares to reach point of intervention. • Burden of responsibility of emergency oxygen supply if stock-out/rupture occurs. • Requirements of record keeping of all activities.
43	Spare parts availability post-warranty	Minimum 10 years, from time of acceptance of product.
44	Software/hardware upgrade availability	N/A.
Decommissioning		
45	Lifespan	10 years minimum, guaranteed by manufacturer.
Safety and standards		
46	Regulations	Regulated as per NRA of intended market. In the absence of NRA requirements, suggest using alternative, such as (but not limited to): • EU: LVD (No. 2014/35/EU).
47	Risk/hazard classification	Classified as per NRA of intended market. In the absence of NRA classification of this product, suggested alternative (but not limited to): • EU: LVD (No. 2014/35/EU).
48	Regulatory approval/ certification	Compliance (where applicable, but not limited) to: • NRA requirements of intended market. • Approval by NRA and regulatory body of country of manufacturer. In the absence of classification or regulation by the NRA, suggest regulatory clearance/approval and certification by a conformity assessment body from a well-regulated market such as (but not limited to): • EU CE certified as compliant to the Low Voltage Directive (LVD) by a conformity assessment body (with notified body indicated).
49	International standards for manufacturer	Compliance to (where applicable, but not limited to) last available version or equivalent of: • ISO 9001: Quality Management Systems – Requirements.
50	International standards for product performance	Compliance to the latest available version of the following international standards or to regional or national equivalent, including technical tests for safety and performance from an accredited laboratory or third party (where applicable, but not limited to): • Piping/hoses/connections: – ISO 7396-1: Medical gas pipeline systems – Part 1: Pipeline systems for compressed medical gases and vacuum. • Booster compressor: – IEC 60204: Safety of machinery – Electrical equipment of machines – ALL PARTS. – IEC 61000-4: Electromagnetic compatibility (EMC) – Part 4: Testing and measurement techniques, *sub-parts 4-2, 4-3, 4-4, 4-5, 4-6, 4-8, 4-11.* – IEC 61000-6-4: Electromagnetic compatibility (EMC) – Part 6-4: Generic standards – Emission standard for industrial environments. – IEC 61010-1: Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements.

Safety and standards *(continued)*		
51	Regional/local standards	• Country-specific and regional standards may apply. • Registered in country of import (if applicable).
Documentation		
52	Documentation requirements	Hard and soft copies, to be supplied in preferred language of destination country and/or English of all the following: • User manual, detailing: – Protocols for start-up and operations. – Preventive maintenance requirements, including calibration where necessary. – System schematics. – Troubleshooting and curative maintenance procedures. – List of equipment and procedures required for cleaning. • Maintenance manual (if details listed above are not covered in the user manual). – Spares list (see line 29). • Evidence of regulatory approval (see line 48). • Evidence of standards compliance for: – Manufacture requirements (line 49). – Product specific requirements (line 50). • Certificates for: – Calibration and inspection prior to shipment. – Guarantee of lifespan, minimum of 10 years. • FSC (where applicable).

1.2.1 Other system requirements

Procurement of a cylinder filling station will rarely take place in isolation. The following are products or components that are necessary to facilitate safe, continued operations of a cylinder filling station and should be considered during planning and procurement.

- An oxygen generator plant to serve as the oxygen source.
- Dedicated continuous, quality power supply: voltage stabilization and surge suppression when on mains, and back-up power source (e.g. diesel-based electricity generator, photovoltaic/battery system).
- Housing (containerized or purpose-built), inclusive of appropriate footings and shelter, complete with all requisite HVAC, drainage, safety and security measures, which will be the same or adjacent to the oxygen generator plant.
- Storage for cylinders, separate from that of the oxygen generator plant and filling station, including space for management and segregation of cylinders (e.g. "to check", "to fill", "full", "fail/rejected", etc.).
- Accessibility ramp and/or loading dock (context dependent) to facilitate trolleys and vehicles to transport full/empty cylinders (no lips, no steps).
- Cylinder transportation vehicles (i.e. trolleys, forklifts) with safety apparatus (i.e. chain).
- PPE for operating teams, as a minimum: hard hat, coverall (loose, natural fibres, no cuffs), ear defenders, safety goggles, steel-toed boots, high-visibility "hi-vis" vest.
- Fire safety equipment (e.g. fire alarm, fire extinguisher).

1.2.2 Other system considerations

The following are activities or products that should be considered during planning and/or procurement to extend, enhance, or complement a cylinder filling station.

- Ambient oxygen monitoring system for safety of filling station room (19.5–23.5%) optional, recommended.
- Transport truck/lorry for broader cylinder distribution.
- Cylinder tracking system (e.g. QR coding/bar coding) inclusive of data management software.
- Valve sealing system with safety shrink bands and heat-gun.

1.2.3 References and resources

- European Industrial Gases Association (EIGA): DOC 33/18: Cleaning of equipment for oxygen service *(13).*
- *How to plan and budget for your healthcare technology*, 'How to Manage' Series for Healthcare Technology, Guide 2 *(16).*
- Supplier landscaping:
  - Filling station inclusive of booster compressor:
    - AirSep® Corporation: O_2 cylinder refilling systems *(26).*
    - AmcareMed: High pressure oxygen booster compressor product details *(27).*
    - Ozcan Kardesler: *Medical oxygen plant with filling station service and operation manual (23).*
    - Mil's: Station de remplissage d'oxygène HP technical sheet *(28).*
  - Vacuum pump:
    - General Europe: Pump type GP/GPM 45E-65E *(29).*
    - Leybold: Innovative vacuum pumps, systems and components for diverse application *(30).*

1.3 Container housing for oxygen systems

The following specification is to be used in the case of a pre-ordered, bespoke container housing for oxygen generator plants (and cylinder filling stations, where applicable). There are alternative approaches to achieving safe, effective and quality housing for oxygen generator plants. Decisions on what is appropriate and how to go about achieving this will vary from context to context, and will be dependent on space, technical capacity and financial resources. Considerations regarding this are discussed in WHO's *Foundations of medical oxygen systems* (see p. 28 for an example of a containerized oxygen generator plant).

Name, category and coding		
1	WHO category/code	(under development)
2	Generic name	Container for housing medical oxygen system
3	Specific type or variation	
4	UNSPS code (optional)	
5	EMDN name	Not a medical device
6	EMDN code	Not a medical device
7	GMDN name	Not a medical device
8	GMDN code	Not a medical device
9	Alternative name/s (optional)	
10	Alternative code/s (optional)	
11	Keywords	Containerized plant, Modified shipping container
12	Product definition	Standard shipping container modified to safely and securely house oxygen generator plants to facilitate optimal installation and continued operations.
Purpose of use		
13	Intended use	A containerized oxygen generator plant can minimize additional on-ground civil works and facilitate installations of oxygen generator plants in lieu of building a permanent structure, or to use where space for structures/housing is limited.
14	Service delivery platforms/health care levels	• First-level (district) hospital services. • Second-level and third-level hospital services and specialized outpatient services.
15	Clinical department/ ward	N/A.
16	Overview of functional requirements	Containerized oxygen generator plants (and potentially cylinder filling stations too) serve to function as a means to more quickly install an oxygen supply solution where all components of the units are laid out and affixed as well as plumbed and wired, ready for placement on level footings/slab and for connection to external power supply (mains or electrical generator), as well as to an MGPS if applicable.

Technical characteristics		
17	Components	N/A.
18	Detailed requirements	• Steel frame construction: – Walls and roof made of steel plates. • Flooring: – Able to withstand loading and mechanical operations of medical oxygen system housed over lifespan of container with context in consideration. – Rodent-proof. – Material: • If steel, ≥ 4 mm thick. • If wood: – treated with fire retardant; – treated to prevent rot and withstand indicated humidity. • Insulation to be considered in design of container (pre-insulated “reefer” container acceptable if following conditions met): – Fibreglass or mineral wool: • Fire-resistant. • Acoustic insultation, minimum 10 dBa reduction. • Thermal insulation to accommodate: [Specify based on local climate conditions, refer to EN 14308.] ☐ Underfloor insulation. *(Optional, specify for colder climates.)* – Insulation material to be between inner and outer wall of container. • Access doors: – End access: double-door. – Side-door access: double doors along container length. – All doors enhanced with seal for water-tightness. – All doors to have external locking capability. • Painting: – Exterior to be painted white (to reflect direct sunlight). – Interior: painted in a light colour to enhance visibility. • Paint shall conform to ISO 12944 (or equivalent) and shall be washable. • Floor coating/finishing to be resistant to continuous wear and tear. • Lighting, protected to standard IEC 60529 (or equivalent): – Bulkhead fixtures. – Minimum 200 LUX. • HVAC: – System designed according to the local climate conditions to ensure: • Temperature maintained between 10–40 °C (50–104 °F). • Ventilation mechanism to be proposed, and minimum resulting rate of air changes/hour to be expressed by vendor. – Air conditioning: wall-mounted inverter type. – Ventilation: exhaust fans with stabilizers (to prevent excess vibrations and shaking). – All vents/louvres/outlets to be covered with screen to prevent entry of insects, rodents and birds. • Equipped with the following features: – Ambient oxygen monitoring system to facilitate safe operating conditions (19.5–23.5%). – Fire extinguisher (select whichever can be filled locally): ☐ CO_2. ☐ Powder. – Drainage conduits for filter condensate.

Technical characteristics *(continued)*		
18	Detailed requirements *(continued)*	• Installation: – Plant components (including those which are skid-mounted) shall be securely affixed to the container floor. – Stabilizers to be used for any mechanical equipment to prevent excess vibration. – All components pre-plumbed to one another and wired to the electrical distribution panel. – Trunking shall be used to cover cabling to avoid any tripping or snags. – Air compressor shall have dedicated heat dissipation duct outlet. – Nitrogen by-product outlet pre-plumbed. Additional requirements IF filling station is a feature of the containerized solution: • The filling ramp shall face outward (e.g. be installed at the end double-doors) with a physical barrier (e.g. a wall) separating high-pressure filling from other plant components. • Booster compressor must be stabilized.
19	Size(s)	Common dimensions for containerized plants are (ISO 668): ☐ "1AA", Forty-foot (40'): – Length, L = 40' (12.2 m). – Width, W = 8' (2.44 m). – Height, H = 8'6" (2.59 m). – Tare weight: max. 3610 kg. ☐ "1CC", Twenty-foot (20'): – Length, L = 20' (6.1 m). – Width, W = 8" (2.4 m). – Height, H = 8'6" (2.59 m). – Tare weight: max. 2280 kg. ***Note: Size chosen must ensure allowance between components of plant assembly for operations and maintenance.***
20	Control panel/user interface	The container itself has no control panel, but the plant within will and should be permanently affixed in appropriate location relative to the oxygen generator plant and for user access.
21	Displayed parameters	N/A.
22	Alarms	Audible and visual alarms if ambient conditions within container are above 23.5% or below 19.5%.
23	User adjustable settings	N/A.
Physical characteristics		
24	Configuration	Select container size and door configuration based on type of oxygen generating plant configuration and cylinder filling station (if applicable).
25	Mobility, portability	Containers are intended for mobility over long distances and require compliance to internationally recognized standards (e.g. ISO 668) to be able to be lifted and stacked for shipment. However, when used as housing for oxygen generator plants and/or filling stations, it is not recommended to move the container (inclusive of contents) once commissioned.
Utility requirements		
26	Electrical, water and/or gas supply	Connection between nearby power source to contents of container will be necessary (see specifications for oxygen generator plants and cylinder filling station where applicable).

Accessories, consumables, spare parts and other components		
27	Accessories	N/A.
28	Consumables/ reagents	N/A.
29	Spare parts	N/A.
30	Other components	[Specify needs or refer to additional specifications, see Section 1.3.1.]
Packaging		
31	Cleaning requirements	To be cleaned of any grease or oil-based products before use.
32	Shelf life	N/A.
33	Transportation and storage	N/A.
34	Labelling	Exterior must bear coding according to ISO 6346 for international shipment. Information shall include (directly onto container, duplicated on a permanent, embossed nameplate): • Owner prefix. • Equipment category identifier. • Serial number. • Check digit. • ISO-code (container size/type). • Weight markings: max. gross, tare and net weights. • Maximum cargo volume. • Manufacture logo. The following signage is necessary on the outside of the container post shipment, once installed, visible to all: • Symbols for: oxidizer/oxidizing substance, non-flammable gas (from the globally harmonized system of classification and labelling of chemicals). • “No smoking” and “No open flames”. • “Authorized personnel only”.
Environmental requirements		
35	Context-dependent requirements	Appropriate insulation for convective heat transfer: • Into the container because of hot environs; **and/or** • From the container because of cold climates.
Training, installation and utilization		
36	Pre-installation requirements	Civil works, site-specific design, to include at a minimum (and as indicated by supplier): • Footings/slab. • Roof/shelter. • Electrical hook-ups (in line with oxygen generator plant requirements). • Access ramp (preferable, mandatory if cylinder filling station present).
37	Requirements for commissioning	N/A.
38	Training of user/s	N/A.
39	User care	Ensure that the supplier provides instructions, particularly around cleaning, to prolong the life of the container material.

Warranty and maintenance		
40	Warranty *(see p. 9)*	1 year warranty from date of acceptance, minimum. *Unit is not intended for further transport once installed.*
41	Maintenance tasks	Ensure that instructions are provided for inspection requirements to avoid accelerated degradation from exposure to elements.
42	After-sales service contract	N/A.
43	Spare parts availability post-warranty	N/A.
44	Software/hardware upgrade availability	N/A.
Decommissioning		
45	Lifespan	25 years minimum, guaranteed by manufacturer (may differ from the lifespan of equipment contained therein).
Safety and standards		
46	Regulations	Regulated as per NRA of intended market.
47	Risk/hazard classification	Classified as per NRA of intended market.
48	Regulatory approval/ certification	Compliance (where applicable, but not limited) to: • NRA requirements of intended market. • Approval by NRA and regulatory body of country of manufacturer, including: – Container safety certificate (CSC) issued by a certified inspector.
49	International standards for manufacturer	Compliance to (where applicable, but not limited to) last available version or equivalent of: • ISO 9001: Quality management systems – Requirements.
50	International standards for product performance	Compliance to the latest available version of the following international standards or to regional or national equivalent, including technical tests for safety and performance from an accredited laboratory or third party (where applicable, but not limited to): • ISO 668: Series 1 freight containers – Classification, dimensions and ratings. • ISO 1161: Series 1 freight containers – Corner and intermediate fittings – Specifications. • ISO 1496-1: Series 1 freight containers – Specification and testing – Part 1: General cargo containers for general purposes. • ISO 6346: Freight containers – Coding, identification and marking. • ISO 12944-4: Paints and varnishes – Corrosion protection of steel structures by protective paint systems – Part 4: Types of surface and surface preparation. • ISO 12944-5: Paints and varnishes – Corrosion protection of steel structures by protective paint systems – Part 5: Protective paint systems. • EN 14308 Thermal insulation products for building equipment and industrial installations – Factory made rigid polyurethane foam (PUR) and polyisocyanurate (PIR) products – Specification. • IEC 60529: Degrees of protection provided by enclosures (IP Code).
51	Regional/local standards	Country-specific and regional standards may apply. Registered in country of import (if applicable).

Documentation		
52	Documentation requirements	Hard and soft copies, to be supplied in preferred language of destination country and/or English of the following: • CSC issued by a certified inspector. • Drawings in line with specifications for oxygen generator plant (and filling station if applicable): – Piping and instrumentation diagram (P&ID). – Electrical schematic. • Instructions for use, including cleaning, and maintenance should be provided. • Pre-installation checklist from supplier (needs for safe and rapid installation such as footings/slab, cranage requirements, shelter, electrical hook-ups, etc.). All other documentation and certificates required for oxygen generator plant and filling station (where applicable).

1.3.1 Other system requirements

Procurement of a container for housing an oxygen generator plant will rarely take place in isolation. The following are products or components that are necessary to facilitate the use of container housing for an oxygen plant.

- Oxygen generator plant.
- Dedicated continuous, quality power supply: voltage stabilization and surge suppression when on mains, back-up power source (e.g. diesel-based electricity generator or photovoltaic/battery system).
- Concrete pad or footings to ensure stability of unit on local soil conditions.
- Shelter to protect container and its inlets/outlets from weather.
- Lip-less ramp to facilitate cylinder access (if applicable).
- Fire safety equipment (e.g. fire alarm, fire extinguisher).

1.3.2 Other system considerations

The following activity/product should be considered during planning and/or procurement to extend, enhance or complement a container housing an oxygen generator plant.

- Cylinder filling station, if applicable.

1.3.3 References and resources

- European Industrial Gases Association (EIGA): DOC 195/20: Safe design and operation of on-site generation of oxygen 93% for medicinal use *(15)*.
- GlobalSpec: ISO containers information *(31)*.
- Rodrigue J-P: Container identification system *(32)*.
- UK NHS: HTM 02-01: Medical gas pipeline systems, Part A: Design, installation, validation and verification *(8)*. Housing guidance translated from section “14 Accommodation” for container modification.
- Commercialized product landscape review:
  - W&K Container Inc.: ISO shipping container specifications *(33)*.

These specifications have been developed as generic minimum requirements of products and components in a standard format. They will require further adaptation to meet project-specific requirements to ensure alignment in each unique setting. These can be identified as follows:

- ☒ **boxes** are to be "checked" to include an option or ensure choices between options are specified; and/or
- **[Specify…]** indicates where text is to be added/modified as per suggestion/instruction noted.

Bulk liguide oxygen, nitrogen storage tank.
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2. Oxygen storage equipment

This section covers vessels that are used to store oxygen range from very large cryogenic tanks, which store bulk LOX, to smaller LOX cylinders, to the ubiquitous high-pressure gas cylinders. These products are typically regulated as pressure vessels.

2.1 Medical oxygen cylinders (high-pressure gas cylinders)

High-pressure gas cylinders used for oxygen may seem simple in concept, but as reusable container/closure systems for a medicine, there are context-specific criteria to ensure technical compatibility in broader oxygen systems and quality of product for continued, safe use.

High-pressure gas cylinders are described in detail in WHO's *Foundations of medical oxygen systems* (see comprehensive overview pp. 33–37). Additionally, WHO has published an *oxygen cylinder safety* poster which should be shared with health workers and other relevant personnel who use or manage medical oxygen cylinders.

Note: This specification supersedes the *cylinder (shell and valve) specifications* only from the following previously published documents:

- *WHO-UNICEF technical specifications and guidance for oxygen therapy devices*; and
- WHO's *Priority medical devices list for the COVID-19 response and associated technical specifications: interim guidance*.

Name, category and coding		
1	WHO category/code	(Under development)
2	Generic name	Medical oxygen cylinder
3	Specific type or variation	
4	UNSPS code (optional)	42271701 (medical gas cylinders or related devices)
5	EMDN name	
6	EMDN code	
7	GMDN name	Oxygen refillable cylinder © GMDN Agency 2005-2024[9]
8	GMDN code	47225
9	Alternative name/s (optional)	Oxygen cylinder, Oxygen bottle, Medical oxygen bottle, High-pressure gas cylinder
10	Alternative code/s (optional)	
11	Keywords	Cylinder, Medical oxygen, Compressed oxygen, Gaseous oxygen, Valve, Respiratory care, MGPS, High-pressure gas cylinder
12	Product definition	High-pressure gas cylinders are used to safely store and transport compressed medical gases under varying pressures, up to 200 bar (2900 psi) for medical oxygen (O_2). Medical gas cylinders comprise a shell, a valve stem and a valve. They are available in a variety of sizes and are typically made of molybdenum steel but can also be made of aluminium or composite construction.

[9] Global Medical Devices Nomenclature. GMDN Agency; 2024.

Purpose of use		
13	Intended use	High-pressure gas cylinders are refillable vessels that behave as container-closure systems for gases; in the case of medical oxygen, they shall be dedicated to a specific gas and only used for medical application. They can store medical oxygen pressurized up to 200 bar (2900 psi) but are more typically used at 150 bar (2175 psi) for standard valve cylinders. To safely use the contents at lower pressures needed for patient care, they can be: • Used directly bedside, to one or two patients simultaneously, with a pressure regulator and flowmeter accessory set; **or** • Connected to a distribution manifold, where the gas is distributed to the patient via an MGPS. • Smaller sized cylinders can be used in patient transport.
14	Service delivery platforms/health care levels	• Community services for primary care. • General outpatient and outreach services for primary care (health post, health centre). • Pre-hospital emergency service. • First-level (district) hospital services. • Second-level and third-level hospital services and specialized outpatient services.
15	Clinical department/ ward	Where available, high-pressure gas cylinders containing medical oxygen can be used across any clinical department/medical ward where oxygen therapy/ respiratory support is indicated provided appropriate safety measures are applied. Cylinders can also be used in emergency vehicles and for home care.
16	Overview of functional requirements	Medical oxygen cylinders shall be: • Capable of safely storing medical oxygen to the indicated nominal working pressure, typically 150 bar (2175 psi), to a maximum of 200 bar (2900 psi) for standard valve cylinders. • Made of steel, aluminium, or composite according to internationally recognized standards. • Dedicated for medical oxygen use. • Fitted with valves suitable for context. • Transported and stored with a valve protection feature (either a valve guard or valve cap). • Colour-coded to align with contextual norms and/or standards. • Hard-stamped with design standards, manufacturing details and regulatory markings.
Technical characteristics		
17	Components	High-pressure gas cylinders used for medical oxygen comprise: • Shell (cylinder body). • Valve (valve stem, opening/closing, outlet, spindle). • Valve protection: ☐ Cylinder valve guard (preferable); **or** ☐ Cylinder valve cap.
18	Detailed requirements	• Shell: – Material: ☐ Steel (molybdenum steel, 37Mn); **or** ☐ Aluminium alloy (typically only if MR conditional required needed); **or** ☐ Composite construction (typically carbon fibre, and note fragility of material prior to consideration). – Construction: • Material dependent. • See test and drawing requirements in line 52 – documentation requirements.

Technical characteristics *(continued)*		

18	Detailed requirements *(continued)*	– Pressure requirements:
		  • Nominal working pressure (WP): minimum 150 bar (2175 psi).
		  • Hydraulic test pressure (TP): minimum 250 bar (3625 psi).
		• Valve:
		– Copper alloy.
		☐ Residual pressure device (specify if required).
		– Valve connection type (ensure compatibility with manifold/regulation assemblies used):
		☐ Bull-nose:
		– top or side connection;
		– operated with a standard valve handle. If key-operated, tools must be supplied;
		– connection type:
		☐ 5/8 inch BSP (F)/BS 341#3 valve; **or**
		☐ CGA 540; **or**
		☐ DIN 9; **or**
		☐ NF 'F'; **or**
		☐ NEN Ri2; **or**
		☐ JIS B 8246.
		☐ Pin-index: ISO 407/BS 850/CGA 870 valve.
		☐ Integral valves (valve integrated pressure regulator [VIPR]).
		– Colour:
		☐ Black cylinder, white shoulder (ISO).
		☐ All white cylinder (ISO).
		☐ All green cylinder (USA).
		☐ Other: [Specify to which standard used locally].
		• Valve protection:
		☐ Cylinder valve guard. (*Note:* Already inbuilt for VIPR.)
		☐ Cylinder valve cap.

19	Size(s)	Size(s) – quantity of each size(s) based on what is used/required locally: ☐ "D" – 2.3 L *(in US: 'D' or M15);* Quantity: [Specify]. ☐ "E" – 4.7 L *(in US: 'E' or M24);* Quantity: [Specify]. ☐ "F" – 9.4 L*;* Quantity: [Specify]. ☐ "G" – 23.6 L *(in US: M or MM, or M122);* Quantity: [Specify]. ☐ "J" – 47.2 L *(in US: 'H' or M250);* Quantity: [Specify]. ☐ "B" – 50 L*;* Quantity: [Specify]. *Note:* In the above sizes, litres (L) is the cylinder volume expressed in litres of water capacity.
20	Control panel/user interface	• Bullnose or pin-index valves: open/close valve using spindle or key. • Integral valve cylinders: open/close by turning flowmeter to desired flowrate.
21	Displayed parameters	For cylinders with integral valves (VIPR): • Pressure: [Specify unit, bar or kPa or psi].
22	Alarms	N/A.
23	User adjustable settings	N/A.
Physical characteristics		
24	Configuration	Can be used: • On their own (with a pressure and flow regulation accessory set). • Connected in parallel to a manifold for distribution into an MGPS. • Bundled on a pallet to a common outlet to also be connected to an MGPS.
25	Mobility, portability	Portable; however, use of fit-for-purpose trolleys (with safety chain) are recommended.

Utility requirements		
26	Electrical, water and/or gas supply	N/A.
Accessories, consumables, spare parts and other components		
27	Accessories	• Key to open valve (if no hand spindle). • Pressure regulator and flowmeter accessory set (with or without oxygen conserver device), where applicable, and specific for the medical application (e.g. standard low-pressure or higher-pressure for ventilatory support). • Tubing, type specific to application (low pressure or high pressure).
28	Consumables/reagents	N/A.
29	Spare parts	Valve protection: cylinder valve guards (preferable) or cylinder valve caps.
30	Other components	[Specify needs or refer to additional specifications, see Section 2.1.1.]
Packaging		
31	Cleaning requirements	Cylinders and valves shall be cleaned for use in oxygen-enriched environments, conforming to the following (ISO 15001 or equivalent): • Not have a level of hydrocarbon contamination greater than 220 mg/m^2. • Have no particulates greater than 100 microns in diameter.
32	Shelf life	N/A.
33	Transportation and storage	• Valves to be protected. • Shipped cylinders must be depressurized (especially if shipped by air).
34	Labelling	Shoulder of the cylinder must bear the following information hard-stamped as a minimum (adapted from ISO 13769): • Nominal and test pressures. • Cylinder capacity (expressed in litres of water). • Tare weight (kg). • International transport rating (UN stamp Ⓗn) • Regulatory: include pi "π" mark, DOT 3AL / DOT 3AA, or marking per NRA for transportable pressure equipment (where applicable). • Inspection agency stamp for regulatory. • Name and origin of manufacturer. • Date of manufacture. • Serial number.
Environmental requirements		
35	Context-dependent requirements	• Capable of being stored in ambient temperature of at least 0–50 °C, relative humidity of at least 15–95% non-condensing. • Suitable for continuous operation in ambient temperature of at least 5–45 °C, relative humidity of at least 15–90% non-condensing.
Training, installation and utilization		
36	Pre-installation requirements	• Dedicated, well-ventilated area for safe storage, with space to segregate oxygen cylinders according to status, e.g. "awaiting checking," "awaiting filling," "full," "prepared deliveries," "fail/rejected" or similar type of organization. • Ensure that oxygen cylinders are procured only if an accredited or quality-assured oxygen supplier and/or source and cylinder filling station is available for refilling.
37	Requirements for commissioning	As best practice, it is recommended to fill to low pressure (e.g. 5 bar [73 psi]) and release gas to ensure no particulates remain.

Training, installation and utilization *(continued)*		
38	Training of user/s	Training in preferred language of destination country and/or English of: • Users in safe handling and operations, including making proper connections. • Technical staff in: – Safe transport, handling and operations (including for adverse events). – Conducting checks and determining fitness for use. – Cleaning cylinders in a safe manner without any oil-containing products.
39	User care	Provide instructions and checklists in preferred language of destination country and/or English for, but not limited to: • Protecting valves during transport and when not in use (even if cylinder is empty). • Safe transport and handling of cylinders including immobilization to avoid bodily harm by falling cylinders. • Safe, effective connections to manifold header or pressure regulator: – Recommended torque, not to force. – How to avoid cross-threading. • Connections to manifold header or pressure regulator are hand tightened, never forced. • Cylinder check prior to use (sealing ring intact or no obvious damage). • Cylinders remain clean to avoid any potential for particulate contamination. Other procedures may apply, according to the use and the manufacturer's instructions.
Warranty and maintenance		
40	Warranty *(see p. 9)*	1 year from date of acceptance, minimum.
41	Maintenance tasks	Maintenance should be conducted by a qualified party. • Visual checks required at each fill interval. • [Re] painting as needed. • Pressure testing (also known as hydrostatic testing) at a predetermined interval. • Corrosion testing (e.g. weight test) at a predetermined interval.
42	After-sales service contract	N/A.
43	Spare parts availability post-warranty	For 8 years from date of acceptance.
44	Software/hardware upgrade availability	N/A.
Decommissioning		
45	Lifespan	20 years minimum, guaranteed by manufacturer.
Safety and standards		
46	Regulations	Regulated as per NRA of intended market. In the absence of NRA requirements, suggest using alternative, such as (but not limited to): • EU: Directive 2010/35/EU – Transportable Pressure Equipment Directive (TPED). • US: 49 CFR § 178 Specifications for packagings (and 49 CFR § 180 Continuing qualification and maintenance of packagings).
47	Risk/hazard classification	Classified as per NRA of intended market. In the absence of NRA classification of this product, suggested alternative (but not limited to): UN: Class 2.2, UN1072 (when cylinders are filled with compressed oxygen gas).

Safety and standards *(continued)*		
48	Regulatory approval/ certification	For **both** cylinder shell and valve assembly, compliance to (where applicable, but not limited to): • NRA requirements of intended market for transportable pressure equipment. • Approval by NRA and regulatory body of country of manufacturer (if applicable). In the absence of classification or regulation by the NRA, suggest regulatory clearance/approval and certification by a conformity assessment body for **both** cylinder shell and valve assembly from a well-regulated market such as (but not limited to): • EU: TPED conformance indicated with a pi "π" mark. • US: CFR conformance indicated with: – DOT 3AA for seamless steel. – DOT 3AL for aluminium alloy. • Canada: US requirements apply. AND for the cylinder to bear a UN marking, Ⓗ, per international transport requirements.
49	International standards for manufacturer	Compliance to (where applicable, but not limited to) last available version or equivalent of: • ISO 9001: Quality management systems – Requirements.
50	International standards for product performance	Compliance to the latest available version of the following international standards or to regional or national equivalent, including technical tests for safety and performance from an accredited laboratory or third party (where applicable, but not limited to): **For all cylinders**, compliance to the following (or equivalent): • ISO 32: Gas cylinders for medical use – Marking for identification of content. • ISO 5145 Gas cylinders – Cylinder valve outlets for gases and gas mixtures – Selection and dimensioning. • ISO 7225 Gas cylinders – Precautionary labels. • ISO 10297: Gas cylinders – Cylinder valves – Specification and type testing. • ISO 11114: Gas cylinders – Compatibility of cylinder and valve materials with gas contents. • ISO 11117: Gas cylinders – Valve protection caps and valve guards – Design, construction and tests. • ISO 11363-1: Gas cylinders – 17E and 25E taper threads for connection of valves to gas cylinders – Part 1: Specifications. • ISO 13341: Gas cylinders – Fitting of valves to gas cylinders. • ISO 13769: Gas cylinders – Stamp marking. • ISO 14246: Gas cylinders – Cylinder valves – Manufacturing tests and examinations. • ISO 15001: Anaesthetic and respiratory equipment – Compatibility with oxygen. • ISO 18119: Gas cylinders – Seamless steel and seamless aluminium-alloy gas cylinders and tubes – Periodic inspection and testing. **Additionally:** **If seamless steel cylinders are specified**, compliance to the following (or equivalent): • ISO 9809-1: Gas cylinders – Design, construction and testing of refillable seamless steel gas cylinders and tubes – Part 1: Quenched and tempered steel cylinders and tubes with tensile strength less than 1100 MPa. **If aluminium alloy cylinders specified**, compliance to the following (or equivalent): • ISO 7866: Gas cylinders – Refillable seamless aluminium alloy gas cylinders – Design, construction and testing.

Safety and standards *(continued)*		
50	International standards for product performance *(continued)*	**If composite cylinders specified**, compliance to the following (or equivalent): • ISO 11119: Gas cylinders – Design, construction and testing of refillable composite gas cylinders and tubes. • ISO 11623: Gas cylinders – Composite construction – Periodic inspection and testing. **If residual pressure valves are specified**, compliance to the following (or equivalent): • ISO 15996: Gas cylinders – Residual pressure valves – Specification and type testing of cylinder valves incorporating residual pressure devices. **If pin-index valves specified**, compliance to the following: • ISO 407: Small medical gas cylinders – Pin-index yoke-type valve connections. **If integral valves specified**, compliance to the following (or equivalent): • ISO 10524-3: Pressure regulators for use with medical gases – Part 3: Pressure regulators integrated with cylinder valves (VIPRs). • ISO 22435: Gas cylinders – Cylinder valves with integrated pressure regulators – Specifications and type testing.
51	Regional/local standards	• Country-specific and regional standards may apply. • Registered in country of import (if applicable).
Documentation		
52	Documentation requirements	Prior to shipment, the following is to be provided: • Evidence of regulatory approval (see line 48). • Evidence of standards compliance for: – Manufacture requirements (line 49). – Product specific requirements (line 50). • Batch testing: Post manufacture, all test documentation detailing ultrasonic, hardness, pressure (hydrostatic) and leak testing as per ISO detailing design, construction and testing (cylinder material dependent, e.g. ISO 9809-1 for seamless steel) and signed off by a conformity assessment body (e.g. notified body). • Cleaning: Evidence of compliance to cleaning standards (ISO 15001 or equivalent) shall be provided by the manufacturer upon request. (*Note:* check with receiving jurisdiction to see if provision of certification by a conformity assessment body, e.g. notified body, is required.) • Drawings for cylinder design (cylinder material dependent). • Design standard certification (e.g. ISO 9809-1 for seamless steel), batch specific (this also allows the conformity assessment body, e.g. notified body) to affix their marking as part of the required shoulder hard-stamp. • Certificate to guarantee of lifespan, minimum of 20 years.

2.1.1 Other requirements

Procurement of high-pressure gas cylinders will rarely take place in isolation. The following are activities, products or components that are necessary to facilitate safe, continued use of high-pressure gas cylinders and should be considered during planning and procurement.

- Oxygen cylinder filling station or supplier capable of filling high-pressure gas cylinders with medical oxygen.
- Distribution manifold and MGPS and/or pressure and flow regulation accessory sets.
- Cylinder transportation vehicles (i.e. trolleys, forklifts, trucks) with safety apparatus (i.e. chain).
- Facility or service for 10-year hydrostatic testing *(34).*
- Dedicated storage area large enough to safely facilitate segregation and manoeuvring.
- Fire safety measures:
  - **Storage room:** signage, fire extinguisher, fire alarm and evacuation route.
  - **Transport vehicle:** signage, fire extinguisher.

2.1.2 Other system considerations

The following are activities or products that should be considered during planning and/or procurement to extend, enhance, or complement high-pressure gas cylinder use.

- Means to conduct quality control tests using methods such as semi quantitative indicator tubes.
- Cylinder tracking system (e.g. QR coding/bar coding) inclusive of data management software.
- Neck ring to facilitate tracking/record of hydrostatic testing cycle.

2.1.3 References and resources

- European Union Directive 2010/35/EU on transportable pressure equipment *(35).*
- European Industrial Gases Association (EIGA): DOC 33/18: Cleaning of equipment for oxygen service *(13).*
- *How to plan and budget for your healthcare technology*, 'How to Manage' Series for Healthcare Technology, Guide 2 *(16).*
- United Nations: *Recommendations on the transport of dangerous goods: model regulations (vol. 1) (36).*
- US Code of Federal Regulations:
  - Title 49 Part 173.301 – General requirements for shipment of compressed gases and other hazardous materials in cylinders, UN pressure receptacles and spherical pressure vessels *(37).*
  - Title 49 Part 178 Subpart C – Specifications for cylinders *(38).*
- *WHO-UNICEF technical specifications and guidance for oxygen therapy devices (5).*
- WHO's *Foundations of medical oxygen systems (4).*
- WHO's *Priority medical devices list for the COVID-19 response and associated technical specifications (6).*
- Commercialized product landscape review:
  - Applied Home Healthcare Equipment: Oxygen cylinder sizes and info *(39).*
  - BOC: Medical gas cylinder data chart *(40).*
  - CHAI and PATH: *Respiratory care equipment market report (22).*

2.2 Vacuum insulated evaporator systems

VIE are described in detail in WHO's *Foundations of medical oxygen systems* (see comprehensive overview pp. 42–43).

Before procuring a VIE system, it is imperative to discuss with prospective LOX vendor(s)/supplier(s) to understand their operational and safety directives as these will inform some of the criteria in the specification template herein.

Name, category and coding		
1	WHO category/code	(under development)
2	Generic name	Vacuum insulated evaporator (VIE) system
3	Specific type or variation	
4	UNSPS code (optional)	
5	EMDN name	Not a medical device
6	EMDN code	Not a medical device
7	GMDN name	Not a medical device
8	GMDN code	Not a medical device
9	Alternative name/s (optional)	
10	Alternative code/s (optional)	
11	Keywords	Vacuum insulated evaporator, LOX, Cryogenic storage tank, Bulk LOX tank, MicroBulk LOX tank, Liquid oxygen
12	Product definition	A VIE system is a set of specialized components that allow for LOX to flow from where it is stored, in a vacuum-insulated cryogenic "bulk" storage tank, through an ambient-heated (passive) vaporizer, where the LOX changes state from liquid to gas, and finally through a control panel comprising pressure and flow regulation devices to ensure that the oxygen can be safely applied in patient care. These systems work pneumatically, where aggregated demands downstream in the MGPS will cause changes in pressure that will trigger the pre-set points on the VIE system control panel pressure and flow regulation assembly.
Purpose of use		
13	Intended use	VIE systems can be used for medical oxygen supply for health facilities where LOX suppliers are available to provide medical oxygen. They function to store LOX and to convert it to gaseous oxygen to a safe, usable pressure.
14	Service delivery platforms/health care levels	• First-level (district) hospital services. • Second-level and third-level hospital services and specialized outpatient services.
15	Clinical department/ ward	These units store LOX and convert it to gaseous medical oxygen that can be distributed across any piped clinical department/medical ward where oxygen therapy/respiratory support is indicated.
16	Overview of functional requirements	VIE systems shall: • Store LOX at a stable temperature and pressure. • Minimize product loss through its pressure build-up (PBU) system. • Convert the LOX to gaseous oxygen via a passive (ambient-heated) vaporizer. • Be capable of meeting estimated peak flow demands of health care facility. • Manage the gaseous oxygen pressure via two-stage regulator to safely deliver oxygen through the MGPS and on to the patient's bedside.

Technical characteristics		
17	Components	A VIE system comprises: • Cryogenic storage tank. • Vaporizer (passive). • Control panel (pressure regulation/control manifold).
18	Detailed requirements	**Cryogenic storage tank (stationary):** • Tank construction: – Cylindrical structure, vertical. – Stainless steel or carbon steel "jacket"/outer shell. • Surface painted white after appropriate surface preparation. – Stainless steel (aluminium free) inner vessel. – Minimum 3 steel section legs. – Lifting lugs affixed to top of tank and legs. • Annular space (between outer and inner vessels): – Perlite-filled. – Established vacuum of at least 0.05 mbar. • Operational requirements and components: – Temperature, inner vessel: -196 °C to +20 °C (-320 °F to +70 °F). – Established maximum allowable working pressure (MAWP) such as 18 bar (261 psi) controlled by: • PBU/blow-down assembly. • Pressure regulator (allowing setpoints for tank operating between minimum operating pressure [MOP] and maximum allowable operating pressure [MAOP]). • Filling components: – Fill coupling for LOX: [align with LOX supplier to specify type.] – Bottom-fill and top-fill lines fitted with secondary isolation valves. – Fill-line drain valve. • Monitoring instruments: – Pressure gauge. – Liquid level gauge. ☐ Liquid level transmitter for telemetry capability (recommended to improve system efficiency, consider aligning with LOX supplier.) • Designed for outdoor use: ☐ IP55; **or** ☐ NEMA 4 rated. • Bracket for mounting (with anti-theft feature). • Offtakes: – Liquid offtake line. – Gas offtake from pressure blow-down (economizer circuit/line). • Safety components: – Trycock vent valve. – Thermal relief valve. – Safety valves: • Primary safety valves, set for when MAOP such as 16 bar (232 psi) is exceeded. • Secondary safety feature set for when MAWP such as 18 bar (261 psi) is exceeded: ☐ Secondary safety valves; **or** ☐ Bursting discs. (*Notes:* 1. Bursting discs can only be considered if supply chain allows for immediate replacement; and, 2. There are LOX suppliers who will not fill tanks with bursting discs! Check before specifying "bursting discs".) • Tank vacuum safety features: – over-pressurization relief device; – vacuum pump-down valve.

Technical characteristics *(continued)*		
18	Detailed requirements *(continued)*	• Vendor to indicate in offer: – Discharge capacity. – Boil-off/evaporation rate. – Thermal conductivity. **Vaporizer (passive, ambient-heated):** • Aluminium construction. • Operating temperature: -196 °C to +50 °C (-320 °F to +122 °F). • Nominal working pressure: ≥ 36 bar (522 psi). • Fin gap to ensure minimum 500 hours continuous operation. • Flange connections: – Inlet: ☐ ASME B16.5; **or** ☐ BS PR C1; **or** ☐ EN 1092; **or** ☐ M40x2 thread; **or** ☐ DIN 2635. – Outlet: ☐ ASME B16.5; **or** ☐ BS PR C1; **or** ☐ EN 1092; **or** ☐ M40x2 thread; **or** ☐ DIN 2635. ☐ Vaporizer heating device (optional, to select depending on context[10]). **Control panel (pressure control manifold):** • Dual-stage pressure regulation assembly, rated outlet pressure: [Specify to align with applicable standard and specific facility system design]. • Duplexed regulation assembly for redundancy. • Alarm system connectivity: – Tank liquid level. – MGPS (hospital side) high- or low-pressure events. **Plumbing, capable of withstanding unit design temperature and pressure:** • Piping: stainless steel. • Fittings, valves: copper alloy or stainless steel.
19	Size(s)	**Cryogenic storage tanks for use at a medical facility:** • Size: [Insert tank size in volume, in L of LOX or in weight, tonnes of LOX. Sizes typically range between 3–20 tonnes for direct offtake for a medical facility's MGPS and is informed by demand and established refill frequency (to be discussed with LOX supplier).] • Supplier to indicate maximum fill ratio as % of tank volume. **Vaporizer:** • Nominal capacity: [Specify in m^3/hr, suggested to be 2x estimated peak demand to ensure flow continuity under abnormal surge conditions. Sizes typically range from 50 m^3/hr to over 700 m^3/hr.]
20	Control panel/user interface	N/A.
21	Displayed parameters	Cryogenic storage tank: • Tank pressure. • Liquid level in tank. Pressure control manifold: • Pressure of gaseous oxygen exiting the vaporizer. • Pressure of gaseous oxygen entering MGPS.

[10] Consider use for colder climates or those at elevation, where temperatures drop below 10 °C.

Technical characteristics *(continued)*		
22	Alarms	Connected to facility MGPS master alarm and/or supplier alarm panel.
23	User adjustable settings	N/A.
Physical characteristics		
24	Configuration	A standard VIE comprises a cryogenic storage tank, a vaporizer and a control panel (pressure manifold assembly). • Consideration to be given to twinning the vaporizer to enhance facility supply security.
25	Mobility, portability	N/A.
Utility requirements		
26	Electrical, water and/or gas supply	Power supply requirements: • To support LOX pump for transfilling, if applicable: – Voltage: 380 ±15% V AC, 3-phase [specify otherwise]. – Frequency: ☐ 50 Hz; **or** ☐ 60 Hz. – Ensure appropriate plug connection, e.g. 63 Ampco. • For telemetry (transmitter and GSM/CDMA, TCP/IP), where applicable: – Voltage ☐ 220 ±15% V AC, single phase (option for DC where available). ☐ 110 ±15% V AC, single phase (option for DC where available). – Frequency ☐ 50 Hz; **or** ☐ 60 Hz. Water supply and hose for installation and de-icing the VIE system.
Accessories, consumables, spare parts and other components		
27	Accessories	MGPS, inclusive of flowmeter, for distribution of the gaseous product.
28	Consumables/ reagents	N/A.
29	Spare parts	Bursting discs (if applicable).
30	Other components	[Specify needs or refer to additional specifications, see Section 2.2.1.]
Packaging		
31	Cleaning requirements	Cleaned to ISO 23208 (for oxygen) or equivalent. • Maximum acceptable hydrocarbon contamination of 500 mg/m^2.
32	Shelf life	N/A.
33	Transportation and storage	• Tank delivered pressurized to slightly over ambient pressure (either with dry medical air or nitrogen, check import requirements) to avoid ingress of moisture and other contaminants prior to commissioning. • All openings to be capped/sealed. • All piping and valves to be protected during packing/shipping. Supplier to provide the following information prior to shipment: • Drawings indicating how units are packed, all dimensions clearly marked. • Dry weight (kg) of units.

Packaging *(continued)*		
34	Labelling	Permanent, embossed nameplate on all components bearing: • Manufacturer's name. • Serial number. • Country of manufacture. • Date of manufacture. • Standards/code to which vessels have been manufactured (i.e. EN 13485, ASME BPVC SEC.VIII DIV.I). • Regulatory stamp and stamp of a conformity assessment body (i.e. notified body). • Maximum allowable working pressure. • Minimum and maximum design temperature.
Environmental requirements		
35	Context-dependent requirements	Capable of operating in ambient conditions between -30 °C to +50 °C.
Training, installation and utilization		
36	Pre-installation requirements	• All planning to align with national guidelines and consider safe distance from hazards (e.g. NFPA 99 *(9),* BCGA CP36 *(41)*). • Civil infrastructure: – Load-bearing concrete slab for VIE (unique to each context, to consider geotechnical conditions). – Utility connections. – Fencing for security/to limit access. – Clear, unobstructed access (including adequate turning radius) for LOX lorry truck during deliveries. – Delivery apron. • Equipment to transport and lift equipment from point of reception to point for installation (e.g. forklifts, cranes, slings).
37	Requirements for installation, testing and commissioning	The following are requirements prior to and inclusive of commissioning: • Physical anchoring of equipment to slab. • All equipment to be grounded/earthed as per national regulations in [Specify country. In absence of national regulations, international standard IEC 60364-5-54 or equivalent can apply.] • On-site training for installation, testing, commissioning shall be provided. • A VIE system purge. • Functionality checks of all instruments. • Pressure and leak testing. • "First fill" procedure will be necessary to safely lower the temperature of the vessel from ambient conditions to operational (cryogenic) temperature. • "Tie-in" to facility MGPS. • Prominent signage depicting hazards and noting safety requirements. • Qualified third party to provide technical audit to verify system status and functionality to finalize for commissioning.
38	Training of user/s	• All facility staff to be trained in safety related to LOX in preferred language of destination country and/or English. • On-site training for technical staff at the facility in preferred language of destination country and/or English for: – Operations: theoretical overview of VIE system operations and functionality of each component (including telemetry, if applicable.) – Daily safety checks of the equipment and surrounding environment. – Daily operational checks including system pressure and liquid levels. ***Consideration to include "continuous development" training programme to be paired alongside SLA activities.***

Training, installation and utilization *(continued)*		
39	User care	Provide instructions and checklists in preferred language of destination country and/or English for, but not limited to: • Daily operational and safety checks. • De-icing if any tank component freezes up, contact supplier if/when persistent. • De-icing on vaporizer when excessive.
Warranty and maintenance		
40	Warranty *(see p. 9)*	1 year from date of commissioning, minimum. • 24 hours/day, 7 days/week remote support for manufacturer defect. • Clear terms and conditions inclusive of details of time-to-response for on-site intervention. • Contact details of manufacturer, supplier and local service agent to be provided.
41	Maintenance tasks	Maintenance should be conducted by a qualified party.
42	After-sales service contract	An SLA is suggested with a qualified provider authorized by the manufacturer of the equipment and should detail: • Level of responsibility: ☐ Planned preventive maintenance (incl. required calibration); **or** ☐ Planned preventive maintenance, troubleshooting and curative maintenance; **or** ☐ Troubleshooting and curative maintenance. • Costs, itemized in terms of labour, travel, lodging and all parts. • 24-hour emergency support contact number. • Time-to-response for remote support **and** for on-site intervention. • Timeline for critical spares to reach point of intervention. • Burden of responsibility of emergency oxygen supply if stock-out/rupture occurs because of hardware malfunction. • Requirements of record keeping of all activities.
43	Spare parts availability post-warranty	The supplier must ensure availability of spare parts for 10 years from date of acceptance.
44	Software/hardware upgrade availability	• Telemetry (if applicable). • Data connectivity and subscription (if applicable, and GSM or CDMA).
Decommissioning		
45	Lifespan	20 years minimum, guaranteed by manufacturer.
Safety and standards		
46	Regulations	Regulated as per NRA of intended market. In the absence of NRA requirements, suggest using alternative, such as (but not limited to): • EU: Pressure equipment directive 2014/68/EU. • US: 46 CFR § 54 – Pressure vessels.
47	Risk/hazard classification	Classified as per NRA of intended market. In the absence of NRA classification of this product, suggested alternatives: • EU: Hazard category 1 (oxidizing gases). • US: Class I-L.
48	Regulatory approval/ certification	Compliance (where applicable, but not limited) to: • NRA requirements of intended market. • Approval by NRA and regulatory body of country of manufacturer.

Safety and standards *(continued)*		
48	Regulatory approval/ certification *(continued)*	In the absence of classification or regulation by the NRA, suggest regulatory clearance/approval and certification by a conformity assessment body from a well-regulated market such as (but not limited to): For cryogenic tank assembly (inclusive of PBU assembly, valves, piping and safety devices) AND control panel (pressure control manifold comprising regulators and ball valves): • EU: PED (with notified body indicated). • US: ASME "U" stamp. For vaporizer: • EU: PED (with notified body indicated). • US: ASME "U" stamp preferable but not mandatory.
49	International standards for manufacturer	Compliance to (where applicable, but not limited to) last available version or equivalent of: • ISO 9001: Quality Management Systems – Requirements.
50	International standards for product performance	Compliance to the latest available version of the following international standards or to regional or national equivalent, including technical tests for safety and performance from an accredited laboratory or third party (where applicable, but not limited to): General design standards (latest available version or equivalent): **For storage tanks:** • EN 13458-1: Cryogenic vessels – Static vacuum insulated vessels – Part 1: Fundamental requirements; **or** • ASME BPVC Section VIII – Rules for Construction of Pressure Vessels Division 1. **For vaporizers:** • ASME B31.3 – Process Piping. (*Note:* Heat exchangers fall outside the scope of this standard; however, it is advisable that this standard or an equivalent is used as a general design standard for this component.) **Additional standards:** • ISO 8501-1: Preparation of steel substrates before application of paints and related products – Visual assessment of surface cleanliness – Part 1: Rust grades and preparation grades of uncoated steel substrates and of steel substrates after overall removal of previous coatings. • ISO 8504-2: Preparation of steel substrates before application of paints and related products – Surface preparation methods – Part 2: Abrasive blast-cleaning. • ISO 12944-4: Paints and varnishes – Corrosion protection of steel structures by protective paint systems – Part 4: Types of surface and surface preparation. • ISO 12944-5: Paints and varnishes – Corrosion protection of steel structures by protective paint systems – Part 5: Protective paint systems. • ISO 21009-1: Cryogenic vessels – Static vacuum-insulated vessels – Part 1: Design, fabrication, inspection and tests. • ISO 21009-2: Cryogenic vessels – Static vacuum-insulated vessels – Part 2: Operational requirements. • ISO 21010: Cryogenic vessels – Gas/material compatibility. • ISO 21011: Cryogenic vessels – Valves for cryogenic service. • ISO 21013-1: Cryogenic vessels – Pressure-relief accessories for cryogenic service – Part 1: Reclosable pressure-relief valves. • ISO 21013-3: Cryogenic vessels – Pressure-relief accessories for cryogenic service – Part 3: Sizing and capacity determination.

Safety and standards *(continued)*		
50	International standards for product performance *(continued)*	• ISO 21028-1: Cryogenic vessels – Toughness requirements for materials at cryogenic temperature – Part 1: Temperatures below -80 °C. • ISO 23208: Cryogenic vessels – Cleanliness for cryogenic service (specify for LOX service).
51	Regional/local standards	• Country-specific and regional standards may apply. • Registered in country of import (if applicable).
Documentation		
52	Documentation requirements	Hard and soft copies, to be supplied in preferred language of destination country and/or English for: Cryogenic storage tank, “databook”, comprising: • Conformity – manufacturer’s declaration and third-party certification for: – Tank. – Safety valves. • Technical documentation/engineering: – Piping and instrumentation diagram (P&ID). – Materials: composition, preparation, testing (including but not limited to X-ray, pressure test, vacuum test). – Stress and loading calculations. – Cleaning. • Manual for commissioning, operations and maintenance. Vaporizer: • Conformity to regulatory requirements (e.g. PED or ASME “U” stamp). • Technical documentation/engineering: – P&ID. – Materials: composition, preparation, testing. – Stress and loading calculations. – Cleaning. • Manual for commissioning, operations and maintenance. Pressure control manifold: • Conformity – manufacturer’s declaration and third-party certification for pressure regulators. • P&ID. • Manual for commissioning, operations and maintenance. General: • Cleaning: Evidence of compliance with cleaning according to ISO 23208 (oxygen) or equivalent shall be provided by the manufacturer upon request.

2.2.1 Other system requirements

Procurement of a VIE system will rarely take place in isolation. The following are activities or products that are necessary to facilitate safe, continued operations of a VIE system and should be considered during planning and procurement.

- All civil engineering work for site preparation inclusive of geotechnical study.
- MGPS inclusive of a "tie-in" or connection.
- 3-phase power connection nearby to facilitate transfilling (with plug adaptor compatible with LOX supplier's pump).
- Reliable water supply and hose.
- Reliable year-round access roads for installation and for ongoing supply of LOX.
- Site to be maintained in clean, clear condition at all times. It is not to be used as a storage area.
- Heavy equipment for installation (e.g. forklift and/or crane).
- PPE for operating teams (minimum): hard hat, coverall (loose, natural fibres, no cuffs, clean), ear defenders, safety glasses and face shield, steel-toed boots, high-visibility "hi-vis" vest.
- Fire safety equipment (e.g. fire alarm, fire extinguisher).

2.2.2 Other system considerations

The following are activities or products that should be considered during planning and/or procurement to extend, enhance, or complement a VIE system:

- Secondary back-up oxygen supply such as a PSA plant or high-pressure gas cylinders.
- Understanding of LOX supplier landscape to track price fluctuations and ensure supply stability.
- Safety shower (may be considered a requirement in some jurisdictions).

2.2.3 References and resources

- BCGA code of practice: CP36 Cryogenic liquid storage at users' premises *(41)*.
- European Industrial Gases Association (EIGA): DOC 224/20: Static vacuum insulated cryogenic vessels operations and inspection *(42)*.
- European Union Directive 2014/68/EU on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment *(43)*.
- *How to plan and budget for your healthcare technology*, 'How to Manage' Series for Healthcare Technology, Guide 2 *(16)*.
- US Code of Federal Regulations:
  - Title 46 Part 54 – Pressure vessels *(18)*.
  - Title 46 Part 58 – Main and auxiliary machinery and related systems *(44)*.
- Commercialized product landscape review:
  - CHART product manual: VS and HS storage systems *(45)*.
  - Thermax® CHART vaporizers (global markets): Thermafin Supergap™ product datasheets (US-made) *(46);* Thermafin Supergap™ product datasheet (EU-made) *(47)*; and VRV cryogenic division product datasheet (India-made) *(48)*.
  - Linde: LITS – F2 Leading international cryogenic tank standards *(49)*.
  - BeaconMedaes®: VIE control panel specification *(50)*.
  - Herose: Product range cryogenic services *(51)*.

2.3 Liquid oxygen cylinders

LOX cylinders are described in WHO's *Foundations of medical oxygen systems* (see p. 43).

Before procuring LOX cylinders, it is imperative to discuss with prospective LOX vendor(s) and transportation companies to understand their operational and safety directives as these could inform some of the variables in the specification template herein.

The use-case for LOX cylinders in medical oxygen system under consideration should be examined prior to procurement. It is important to note their limitations if being considered for direct offtake from cylinder to patient or to medical apparatus. While their initial flow rate can range from 150–300 L/min, continuous high-flow offtake cannot be maintained and will deplete tank pressure at a rate far greater than can be accommodated by the in-built vaporizer coils. This will result in a reduced flow capacity to as low as 45 L/min *(52)*. Additionally, intra-facility movement will be very challenging as LOX cylinders are very heavy (weight is size dependent, but average ~300 kg when full). These limitations are mitigated when connected to a manifold for distribution to the MGPS.

Name, category and coding		
1	WHO category/code	(under development)
2	Generic name	Liquid oxygen cylinder
3	Specific type or variation	
4	UNSPS code (optional)	
5	EMDN name	Not a medical device
6	EMDN code	Not a medical device
7	GMDN name	Not a medical device
8	GMDN code	Not a medical device
9	Alternative name/s (optional)	
10	Alternative code/s (optional)	
11	Keywords	LOX cylinder, Cryogenic cylinder, LOX cryotank, LOX reservoir, Liquid oxygen
12	Product definition	Liquid oxygen (LOX) cylinders are smaller capacity LOX storage tanks that can supply LOX in either liquid or gaseous form.
Purpose of use		
13	Intended use	LOX cylinders require an inbuilt vaporizer coil which will facilitate the vaporization of LOX from its liquid to gas state. When used directly, LOX cylinders are only intended for shorter bursts of use. For continued use, LOX cylinders can be connected to a distribution manifold configured for LOX cylinders to supply an MGPS. They are typically filled in-situ due to the weight of filled units and to maximize usable product.
14	Service delivery platforms/health care levels	• General outpatient and outreach services for primary care. • Pre-hospital emergency services. • First-level (district) hospital services. • Second-level and third-level hospital services and specialized outpatient services.
15	Clinical department/ ward	These units store LOX and convert it to gaseous medical oxygen that can be distributed across any clinical department/medical ward where oxygen therapy/ respiratory support is indicated.

Purpose of use *(continued)*		
16	Overview of functional requirements	LOX cylinders shall: • Store LOX at a stable temperature. • Minimize product loss: – By balancing temperature and pressure. – Through the use of an economizer setting. • Convert the LOX to gaseous oxygen directly via an in-built vaporizer.
Technical characteristics		
17	Components	N/A.
18	Detailed requirements	• Tank construction: – Vertical, cylindrical structure. – Outer shell: Stainless steel or aluminium. – Inner vessel: Stainless steel. – Annular space support frame: Stainless steel. – Handling ring at the top with holes or lifting lugs to facilitate cranage. – Foot ring and wheels (optional, rugged and lockable) to facilitate transport. • Annular space: – Multi-layer insultation (“MLI”). – Established vacuum of at least 0.05 mbar. • Operational requirements and components: – Temperature, inner vessel: -196 °C to +20 °C. – MAWP: [Specify, such as 16 bar (232 psi).] • Pressure build-up via in-built vaporizer coil in the annular space. • Pressure regulator (allowing setpoints so tank operates below MAWP). – Gas flow rate: [Specify LPM or SCFH.] • Filling components: – LOX fitting on liquid fill line (align with LOX supplier for specification, if applicable): ☐ CGA-440; **or** ☐ 3/8” NPT female. – Spray head on vent valve to facilitate top-fill via pump transfer. • Monitoring instruments: – Pressure gauge. – Liquid level gauge. • Offtakes: – Gas: ☐ ISO 5145; **or** ☐ M24 ISO; **or** ☐ CGA 1340 female. – Liquid (align with LOX supplier for specification, if applicable): ☐ CGA-440; **or** ☐ 3/8” NPT female. – Economizer line. • Safety components: – Thermal relief vent valve. – Safety pressure relief valve set to MAWP. – Bursting discs. – Outer-shell relief device (for vacuum integrity). • Vendor to indicate in offer: – Discharge capacity. – Boil-off-rate. – Thermal conductivity.
19	Size(s)	Size: [Insert tank size in volume, in L of LOX. Typical LOX cylinders range between 160–265 L.]

Technical characteristics *(continued)*		
20	Control panel/user interface	N/A.
21	Displayed parameters	• LOX level. • Tank pressure.
22	Alarms	N/A.
23	User adjustable settings	N/A.
Physical characteristics		
24	Configuration	Can be configured as follows: • Stand-alone use for direct gas offtake (though for short periods of time only to avoid drops in pressure and therefore available flow). • Connected to a manifold with multiple LOX cylinders in parallel for distribution into an MGPS.
25	Mobility, portability	Transportable; however, advisable to fill in-situ at point of connection for use.
Utility requirements		
26	Electrical, water and/or gas supply	N/A.
Accessories, consumables, spare parts and other components		
27	Accessories	• Distribution manifold and MGPS. • Line gas regulator for direct gas offtake (if applicable).
28	Consumables/ reagents	N/A.
29	Spare parts	Replacement bursting discs.
30	Other components	[Specify needs or refer to additional specifications, see Section 2.3.1.]
Packaging		
31	Cleaning requirements	Cleaned to ISO 23208 (for oxygen) or equivalent.
32	Shelf life	N/A.
33	Transportation and storage	• Tank delivered slightly pressurized (either dry medical air or nitrogen, check import requirements) to slightly over ambient pressure to avoid ingress of moisture and other contaminants between leaving the point of manufacture up until commissioning. • All openings to be capped/sealed. • All piping and valves are to be protected during packing/shipping. Supplier to provide the following information prior to shipment: • Drawings indicating how units are packed, all dimensions clearly marked. • Tare weight (kg) of units.
34	Labelling	Permanent, embossed nameplate unique to the tank bearing: • Manufacturer's name. • Serial number. • Country of manufacture. • Date of manufacturer. • Standards/code to which vessels have been manufactured (i.e. EN 1251-1, ISO 21029-1, or equivalent).

Packaging *(continued)*		
34	Labelling *(continued)*	• Regulatory: include pi "π" mark, DOT 4L, or marking per NRA for transportable pressure equipment (where applicable). • Stamp of a conformity assessment body (i.e. notified body). • Maximum allowable working pressure. • Minimum and maximum design temperature. • Vessel volume. • Tare weight.
Environmental requirements		
35	Context-dependent requirements	Capable of operating in ambient conditions between -30 °C to +50 °C.
Training, installation and utilization		
36	Pre-installation requirements	• A dedicated manifold room appropriately designed with: – Adequate ventilation. – Access to the LOX cylinders to facilitate safe loading/offloading and transfilling. • Technical staff at the facility adequately trained to ensure daily safety and operational checks of the hardware and of the LOX levels.
37	Requirements for commissioning	The following are requirements prior to and inclusive of commissioning: • On-site training for installation, testing and commissioning shall be provided. • LOX cylinder operations shall be tested; functionality with the distribution manifold shall be tested (in line with MGPS commissioning protocol).
38	Training of user/s	• All facility staff to be trained in safety related to LOX in preferred language of destination country and/or English. • On-site training for technical staff at the facility in preferred language of destination country and/or English for: – Operations: theoretical overview of LOX cylinders and functionality of each component. – Daily safety checks of the equipment and surrounding environment. – Daily operational checks including system pressure and liquid levels. ***Consideration to include "continuous development" training programme to be paired alongside SLA activities.***
39	User care	Provide instructions and checklists in preferred language of destination country and/or English for, but not limited to: • Daily operational and safety checks.
Warranty and maintenance		
40	Warranty *(see p. 9)*	1 year from date of commissioning, minimum. • 24 hours/day, 7 days/week remote support for manufacturer defect. • Clear terms and conditions inclusive of details of time-to-response for on-site intervention. • Contact details of manufacturer, supplier and local service agent to be provided.
41	Maintenance tasks	Maintenance should be conducted by a qualified party.
42	After-sales service contract	An SLA is suggested with a qualified provider authorized by the manufacturer of the equipment and should detail: • Level of responsibility: ☐ Planned preventive maintenance (incl. required calibration); **or** ☐ Planned preventive maintenance, troubleshooting and curative maintenance; **or** ☐ Troubleshooting and curative maintenance.

Warranty and maintenance *(continued)*		
42	After-sales service contract *(continued)*	• Costs, itemized in terms of labour, travel, lodging and all parts. • Time-to-response for remote support **and** for on-site intervention. • Timeline for critical spares to reach point of intervention. • Burden of responsibility of emergency oxygen supply if stock-out/rupture occurs because of hardware malfunction. • Requirements of record keeping of all activities.
43	Spare parts availability post-warranty	The supplier must ensure availability of spare parts for 10 years from date of acceptance.
44	Software/hardware upgrade availability	N/A.
Decommissioning		
45	Lifespan	20 years minimum, guaranteed by manufacturer.
Safety and standards		
46	Regulations	Regulated as per NRA of intended market. In the absence of NRA requirements, suggest using alternatives, such as (but not limited to): • EU TPED. • US: – 49 CFR § 173.316 – Cryogenic liquids in cylinders. – 49 CFR § 173.320 – Cryogenic liquids; exceptions. – 49 CFR § 178.57 – Specification 4L welded insulated cylinders (and 49 CFR § 180 – Continuing qualification and maintenance of packagings, where applicable).
47	Risk/hazard classification	Classified as per NRA of intended market. In the absence of NRA classification of this product, suggested alternative (but not limited to): • UN: Class 2.2, UN1073 (when cylinders are filled with LOX).
48	Regulatory approval/ certification	Compliance (where applicable, but not limited) to: • NRA requirements of intended market. • Approval by NRA and regulatory body of country of manufacturer. In the absence of classification or regulation by the NRA, suggest regulatory clearance/approval and certification by a conformity assessment body from a well-regulated market such as (but not limited to): • EU: TPED conformance indicated with a pi "π" mark (with notified body indicated). • US: CFR conformance indicated with "DOT 4L".
49	International standards for manufacturer	Compliance to (where applicable, but not limited to) last available version or equivalent of: • ISO 9001: Quality Management Systems – Requirements.
50	International standards for product performance	Compliance to the latest available version of the following international standards or to regional or national equivalent, including technical tests for safety and performance from an accredited laboratory or third party (where applicable, but not limited to): **General design standards** (one of the following or equivalent): • EN 1251-1: Cryogenic vessels – Transportable vacuum insulated vessels of not more than 1000 litres volume – Part 1: Fundamental requirements. • ISO 21029-1: Cryogenic vessels – Transportable vacuum insulated vessels of not more than 1000 litres volume – Part 1: Design, fabrication, inspection and tests. • US DOT 4L specifications (49 CFR § 178.57). • CGA C-3: Standards for welding on thin-walled, steel cylinders.

Safety and standards *(continued)*		
50	International standards for product performance *(continued)*	**Additional standards:** • EN 1626: Cryogenic vessels – Valves for cryogenic service. • CGA S-1.2: Pressure Relief Device Standards – Part 2: Portable containers for compressed gases. • ISO 21029-2: Cryogenic vessels – Transportable vacuum insulated vessels of not more than 1000 litres volume – Part 2: Operational requirements. • ISO 21010: Cryogenic vessels – Gas/material compatibility. • ISO 21013-2: Cryogenic vessels – Pressure-relief accessories for cryogenic service – Part 2: Non-reclosable pressure-relief devices. • ISO 23208: Cryogenic vessels – Cleanliness for cryogenic service (specify for LOX service).
51	Regional/local standards	• Country-specific and regional standards may apply. • Registered in country of import (if applicable).
Documentation		
52	Documentation requirements	• Manual for commissioning, operations and maintenance in hard and soft copies, to be supplied in preferred language of destination country and/or English. • Conformity – manufacturer's declaration and third-party certification for: – Tank. – Safety valves. • Tank filling weight chart. • Cleaning: Evidence of compliance with cleaning according to ISO 23208 (oxygen) or equivalent shall be provided by the manufacturer upon request.

2.3.1 Other system requirements

Procurement of LOX cylinders will rarely take place in isolation. The following are activities, products or components that are necessary to facilitate safe, continued operations of LOX cylinders and should be considered during planning and procurement.

- Ambient oxygen monitoring system for manifold room safety (19.5–23.5%).
- Scale to measure LOX cylinder weight for safe transfilling.
- Heavy-duty trolly or forklift for safe handling of LOX cylinders.
- Manifold room to be maintained in clean, clear condition at all times. It is not to be used as a storage area.
- Fire safety equipment (e.g. fire alarm, fire extinguisher).

2.3.2 Other system considerations

The following are activities or products that should be considered during planning and/or procurement to extend, enhance or complement liquid oxygen cylinders.

- Secondary back-up oxygen supply (if used as primary supply) such as high-pressure gas cylinders.
- Understanding of LOX supplier landscape to track price fluctuations and ensure supply stability.

2.3.3 References and resources

- BCGA code of practice: CP27 Transportable vacuum insulated containers of not more than 1000 L volume *(53)*.
- *How to plan and budget for your healthcare technology*, 'How to Manage' Series for Healthcare Technology, Guide 2 *(16)*.
- UK NHS: Performance of healthcare cryogenic liquid oxygen systems *(52)*.
- UK NHS: HTM 02-01: Medical gas pipeline systems, Part A: Design, installation, validation and verification *(8)*.
- US Code of Federal Regulations:
  - Title 49 Part 173.316 – Cryogenic liquids in cylinders *(54)*.
  - Title 49 Part 173.320 – Cryogenic liquids; exceptions, where low-pressure liquid cylinders are considered *(55)*.
  - Title 49 Part 178.57 – Specification 4L welded insulated cylinders *(56)*.
- Commercialized product landscape review:
  - Air Products: Safetygram 6: Liquid oxygen *(57)*; Safetygram 27: Cryogenic liquid containers *(58)*.
  - CHART: Product manual: liquid cylinders *(59)*.

A large steel vessel for the cryogenic and chemical industry, a container for carbon dioxide CO_2 and oxygen O_2
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These specifications have been developed as generic minimum requirements of products and components in a standard format. They will require further adaptation to meet project-specific requirements to ensure alignment in each unique setting. These can be identified as follows:

- ☒ **boxes** are to be "checked" to include an option or ensure choices between options are specified; and/or
- **[Specify…]** indicates where text is to be added/modified as per suggestion/instruction noted.

Medical oxygen cylinders. Close up shot of oxygen breathing cylinder.
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3. Oxygen distribution components

3.1 Distribution manifolds

Distribution manifolds are described in detail in WHO's *Foundations of medical oxygen systems* (as ramps) (see comprehensive overview pp. 31–32).

Name, category and coding		
1	WHO category/code	(under development)
2	Generic name	Distribution manifold
3	Specific type or variation	Automatic Semi-automatic Manual
4	UNSPS code (optional)	42191706 (medical gas manifold)
5	EMDN name	Medical/medicinal gas pipeline systems and related accessories[11]
6	EMDN code	Z120309
7	GMDN name	Medical gas pipeline system pressure reduction manifold © GMDN Agency 2005-2024[12]
8	GMDN code	47560
9	Alternative name/s (optional)	
10	Alternative code/s (optional)	
11	Keywords	Manifold, Distribution manifold, MGPS
12	Product definition	A distribution manifold mechanically combines the output of multiple cylinders (gas or LOX) as a bank in parallel, along a header, into a single stream of gas regulated to a pre-set pressure to feed into an MGPS. These banks operate one-at a time, as a "duty bank", to provide supply to the MGPS, enabling replacement of empty cylinders on the depleted bank. Engagement of a manifold as supply source can be automatic or manual, and the change-over from the duty to the standby bank can also be automatic or manual; combining these functionalities describe distribution manifold type: automatic, semi-automatic or manual.
Purpose of use		
13	Intended use	Oxygen distribution manifolds have the following use-cases: • Primary supply to wards in stand-alone buildings. • Secondary supply of medical oxygen to an MGPS that relies on either an oxygen generator plant or a bulk LOX VIE system. • Emergency back-up to any oxygen supply.
14	Service delivery platforms/health care levels	• First-level (district) hospital services. • Second-level and third-level hospital services and specialized outpatient services.
15	Clinical department/ ward	These units facilitate the distribution of gaseous medical oxygen across piped clinical department/medical ward where oxygen therapy/respiratory support is indicated.

[11] European Medical Devices Nomenclature (EMDN). European Commission; 2024.
[12] Global Medical Devices Nomenclature. GMDN Agency; 2024.

ⓘ ☒ boxes are to be "checked" to include an option or ensure choices between options are specified; and/or [Specify...] indicates where text is to be added/modified as per suggestion/instruction noted.

Purpose of use *(continued)*		
16	Overview of functional requirements	Distribution manifolds shall: • Supply medical gas at constant pressure into the MGPS. • Comprise at least two banks of cylinders to ensure supply continuity. • Alert users of need to either change bank and/or swap out cylinders that are empty. • Have safety features to ensure that supply will continue in the event of a single-fault condition (e.g. power failure).
Technical characteristics		
17	Components	• Manifold: – Bank header valves (high-pressure for gas). – Bank header pressure regulators & gauges (high-pressure for gas). – Cylinder connection with: • Flexible hoses. • Safety check valves. • Changeover (between manifold banks): – Lever to control/indicate “duty” bank (depending on manual, semi-automatic or automatic). • Line outlet pressure regulator and gauge. • Line pressure release valve and exhaust line. • Test point valve (to test for purity and to exhaust gas for maintenance). • Lockable line isolation valve. • Alarm panel with visual and audible alarm (located where someone will see/hear 24 hours/day, 7 days/week, e.g. nursing station), connected via pressure transducers.
18	Detailed requirements	Manifold header, one per bank, inclusive of: • Pressure regulator (primary): – Sensor and gauge (pressure displayed in bar and psi). – Sintered brass filter (25 microns) at inlet. • Primary pressure relief valve, capable of withstanding the following nominal pressure: ☐ Gas: 230 bar (3335 psi); **or** ☐ LOX: 27.5 bar (399 psi). • Flexible “pigtail” connections with: – Non-return valves (check valves). – Copper alloy adaptors for cylinder valve connection: • High-pressure gas cylinders: ☐ Bull-nose: ☐ 5/8 inch BSP (F)/BS 341 valve; **or** ☐ CGA 540; **or** ☐ DIN 9; **or** ☐ NF ‘F’; **or** ☐ NEN Ri2. ☐ Pin-index: ISO 407/BS 850/CGA 870 valve. • LOX cylinders: ☐ CGA-440; **or** ☐ 3/8” NPT. • Mounting: – Each bank to have a rack to support cylinders (either stainless, galvanized, painted or powder coated steel). – Rack to be capable of wall mounting or to be affixed to the floor. – Safety chains (zinc plated), to be used to secure cylinders in use.

Technical characteristics *(continued)*		
18	Detailed requirements *(continued)*	Bank changeover: • Type: ☐ Manual. ☐ Semi-automatic (automatically changes between banks without fluctuation, manual override). ☐ Automatic (manifold engages automatically as secondary supply, automatically changes between banks without fluctuation, manual override). • Housed in an enclosure: – Back bracket for wall mounting. – Enabling outdoor installations: ☐ IP55; **or** ☐ NEMA 4 rated. • Functions: – Pressure display in each header: • Displayed in analogue on the gauge (can be digital on automatic). • Colour coded bank status (see “displayed parameters”). – High- and low-pressure alarm status (adjustable). – Additional features depending on change-over type (see “displayed parameters” and “alarms”). – Semi-automatic and automatic manifolds to default to both banks engaged in complete power failure. ☐ Include economizer hardware for configurations using LOX cylinders (if applicable). Electrical requirements (where applicable, for semi-automatic and automatic): • Max. 45 W power consumption (vendor to indicate otherwise). • Voltage inside the panel shall not exceed 24 V DC (setting of solenoid valves). Distribution line: • Secondary pressure regulation assembly: – Pressure regulator and gauge (pressure displayed in bar and psi). – Pressure reference points to be clearly indicated: • High [Specify unit, e.g. bar or psi.] • Low [Specify unit, e.g. bar or psi.] – Line pressure transducer. • Line pressure relief/safety relief assembly: – Safety relief valve (15 mm or 1/2” NPT). – Exhaust vent line (copper piping, diameter > main line diameter). • Supply isolation valve. • Test outlet (maintenance purge). • Line diameter: [Specify, to accommodate facility-specific demand-based design.] ***Note:* “Multistage” regulators are NOT acceptable.**
19	Size(s)	Number of cylinders per bank: [Insert number based on use-case, facility demand and system planning; typically ranging from 1 to 14 cylinders/per bank.]
20	Control panel/user interface	Preferred language of destination country and/or English. ☐ Manual — • Manual switch-over. ☐ Semi-automatic and automatic — • Adjustable manual or automatic operations: – Automatic microprocessor-based printed circuit board (PCB) with plug and socket connectors. • “Service mode” – engaging allows for user to deactivate alarms during commissioning, testing and maintenance. ☐ Remote monitoring *(optional);* [Specify need for integration into CMMS if applicable].

Technical characteristics *(continued)*			
21	Displayed parameters	☐ Manual	• Pressure displayed by analogue gauges: – One for each manifold header. – One for the distribution line. • Alarms (see line 22): – High- and low-pressure on each bank. – When bank change needed.
		☐ Semi-automatic	• Pressure – bank status via LED indicator: – Green = "in-use". – Amber/yellow = "bank ready/on standby". – Red = "bank empty". • Pressure – line status, analogue gauge (minimum). • Alarms (see line 22): – High- and low-pressure on each bank. – When "standby" bank activated. – Signal to indicate need for preventive maintenance.
		☐ Automatic	• Pressure – bank status via LED indicator: – Green = "in-use". – Amber/yellow = "bank ready/on standby". – Red = "bank empty". • Pressure – line status, analogue gauge (minimum). • Backlit LCD display, touchscreen (*optional*): – System status: ◦ Pressure in each bank. ◦ Volume in each bank. ◦ Trending data: volume used/time. ◦ Distribution line pressure (including fault). – Energy efficient: ◦ Full brightness during use and alarm events. ◦ Screensaver when not in use. • Alarms (see line 22): – High- and low-pressure on each bank. – When "standby" bank activated. – Signal to indicate need for preventive maintenance.
		Note: No digital display feature will override display on an analogue gauge.	
22	Alarms	To be integrated into the control panel:	
		☐ Manual	• Audible (horn, bell, or similar – min 80 dB at 1 m) and visual (strobe, beacon, or similar) in-built alarms. • Option to install pressure transducers to inform a remote alarm (e.g. to nurses' station) – *recommended.*
		☐ Semi-automatic and automatic	In-built alarms: • Audible (horn, bell, or similar – min 80 dB at 1 m); and, • Visual (strobe, beacon or similar).
23	User adjustable settings	• Adjustable alarm/warning levels for high- and low-line pressure. • Automatic manifold systems (when applicable) to have restricted "setup mode" or "configuration mode" to allow: – Change in measurement units. – Selection of type of alarm output (online, external).	
Physical characteristics			
24	Configuration	Manifold configurations are as follows: • "Cylinder by cylinder": high-pressure gas cylinders on each bank. • "Liquid by liquid": LOX cylinders on each bank.[13] • "Liquid by cylinder by cylinder": LOX on primary bank, standby high-pressure gas, with an emergency reserve bank of high-pressure gas.	

[13] Considering drawdown can occur simultaneously from both banks on "liquid by liquid" configurations, an additional back-up/emergency reserve source should be planned for.

Physical characteristics *(continued)*		
24	Configuration *(continued)*	Sub-configurations for high-pressure cylinders where the header should accommodate manifold room layouts: ☐ Standard (line, straight along the wall). ☐ "L" shaped (around a corner). ☐ "U" shaped (cylinders contained centrally between headers). ☐ Crossover (cylinders on the back and front of a header). ☐ Staggered (like standard, but adding an offset row in front).
25	Mobility, portability	N/A.
Utility requirements		
26	Electrical, water and/or gas supply	Where applicable (semi-automatic and automatic changeover), electrical components shall be in an enclosure to limit dust, water penetration and simplify electrical connection with alarms (see line 18). • 120–240 V AC, 50–60 Hz. • Dedicated continuous, quality power supply (e.g. voltage stabilization and surge suppression when on mains, uninterruptible power supply [UPS] in the event of power failure).
Accessories, consumables, spare parts and other components		
27	Accessories	• Cylinders. • Cylinder carts/trolleys.
28	Consumables/reagents	N/A.
29	Spare parts	• Flexible connectors. • Pressure regulator and gauge. • Pressure sensors.
30	Other components	• MGPS. [Specify needs or refer to additional specifications, see Section 3.1.1.]
Packaging		
31	Cleaning requirements	All components shall be cleaned for use in oxygen-enriched environments, conforming to the following (e.g. ISO 15001 or equivalent): • Not have a level of hydrocarbon contamination greater than 220 mg/m^2. • Have no particulates greater than 100 microns in diameter.
32	Shelf life	N/A.
33	Transportation and storage	• Information for storage conditions (temperature, pressure, light, humidity, etc.) to be indicated prior to shipping; any particulars to be indicated on the packaging/container.
34	Labelling	Permanent, embossed nameplates shall be affixed to bank changeover unit and include the following (where applicable): • Name and/or trademark of the manufacturer. • Manufacturer's product reference (S/N). • Type of product and main characteristics (e.g. voltage and frequency requirements). • Indication that the product is for medical application. • Regulatory markings. • Date of manufacture. • Origin of manufacture.

Environmental requirements		
35	Context-dependent requirements	Capable of storage, installation and continuous operation in ambient temperatures between -15 °C to 50 °C and with relative humidity of at least 15–90% non-condensing. ***Oxygen system components are sensitive to environmental conditions. Where these criteria cannot be met and or maintained during operations, vendor to propose accommodating measures to protect equipment.***
Training, installation and utilization		
36	Pre-installation requirements	• MGPS installation to facilitate use of manifold. • Primary oxygen source (if/where applicable). • Near to on-site cylinder supply. • Floor surface to: – Consider mass resistance requirements of medical gas cylinders. – Be completely flat. – Be prepared to withstand wear and tear from 'rolling' cylinders into place on their base rim. • Rack and safety chains to keep cylinders upright and in place during use. • Shelter, well-ventilated, designed with necessary fire-retardant materials or barriers: ☐ Dedicated manifold room; **or** ☐ Weather protection/awning (from snow or direct sunlight) if placed in an open location. ☐ Continuous availability of 45 W power (for automatic and semi-automatic).
37	Requirements for installation, testing and commissioning	The following are requirements prior to and inclusive of commissioning: • All equipment to be grounded/earthed as per national regulations in [Specify country. In absence of national regulations, international standard IEC 60364-5-54 or equivalent can apply.] • Functionality in the complete oxygen system (whether it is primary or secondary supply) including associated changeovers and alarms. • "Tie-in" to facility MGPS. • On-site training for installation, testing and commissioning shall be provided. • There shall be clear signage and labelling on unit/in manifold room indicating "no oil" and "no sources of ignition". • Third-party technical audit to verify and certify manifold in the MGPS as final step of commissioning.
38	Training of user/s	On-site training in preferred language of destination country and/or English to include, but not be limited to: • Safety: General, oxygen-specific, cylinder management and operations of the distribution manifold. • Operations: Theoretical overview of distribution manifolds and their functionality. • Cleaning of the unit. • Daily operations, inclusive of record keeping and data management. • Planned preventive maintenance SOPs and work instructions. • Troubleshooting approach and corrective maintenance SOPs and work instructions if they can be carried out by user. ***Consideration to include "continuous development" training programme to be paired alongside SLA activities.***
39	User care	Provide instructions and checklists in preferred language of destination country and/or English for, but not limited to: • Cleaning of the manifold room, of the unit. • Daily operations, inclusive of record keeping and data management. • Planned preventive maintenance according to manufacture SOPs and work instructions, and agreement in line with SLA (see lines 41 and 42).

Warranty and maintenance		
40	Warranty *(see p. 9)*	1 year from date of commissioning, minimum. • 24 hours/day, 7 days/week remote support for manufacturer defect. • Clear terms and conditions inclusive of details of time-to-response for on-site intervention. • Contact details of manufacturer, supplier and local service agent to be provided.
41	Maintenance tasks	Maintenance should be conducted by a qualified party. The following shall be provided from the manufacturer: • A comprehensive, manufacturer-recommended preventive maintenance schedule. • A list of all associated spares (where applicable) for each maintenance interval.
42	After-sales service contract	An SLA is suggested with a qualified provider authorized by the manufacturer of the equipment and should detail: • Level of responsibility: ☐ Planned preventive maintenance (incl. required calibration); **or** ☐ Planned preventive maintenance, troubleshooting and curative maintenance; **or** ☐ Troubleshooting and curative maintenance. • Costs, itemized in terms of labour, travel, lodging and all parts. • Time-to-response for remote support **and** for on-site intervention. • Timeline for critical spares to reach point of intervention. • Requirements of record keeping of all activities.
43	Spare parts availability post-warranty	Minimum 10 years, from time of acceptance of product.
44	Software/hardware upgrade availability	N/A.
Decommissioning		
45	Lifespan	20 years minimum, guaranteed by manufacturer.
Safety and standards		
46	Regulations	Regulated as per NRA of intended market. In the absence of NRA requirements, suggest using alternative, such as (but not limited to): • EU: European Commission Regulation EU MDR (No. 2017/745). • US: 42 CFR § 482.41 – Condition of Participation: Physical Environment (Basic hospital functions).
47	Risk/hazard Classification	Classified as per NRA of intended market. In the absence of NRA classification of this product, suggested alternatives (but not limited to): • EU: Class II a medical device. • Other: Class A (GHTF Rule 6).
48	Regulatory approval/ certification	Compliance (where applicable, but not limited) to: • NRA requirements of intended market. • Approval by NRA and regulatory body of country of manufacturer (if applicable). In the absence of classification or regulation by the NRA, suggest regulatory clearance/approval and certification by a conformity assessment body from a well-regulated market such as (but not limited to): • European-marketed products: CE marking (certificate specifying product, and notified body indicated). • US-marketed products: Distribution manifolds must comply with NFPA and CGA requirements as per 42 CFR § 482.41. • Other: Equivalent approvals from a regulatory body in an IMDRF/GHTF founding member country such as Australia, Canada or Japan.

Safety and standards *(continued)*		
49	International standards for manufacturer	Compliance to (where applicable, but not limited to) last available version or equivalent of: • ISO 9001: Quality management systems – Requirements. • ISO 13485: Medical devices – Quality management systems – Requirements for regulatory purposes.
50	International standards for product performance	Compliance to the latest available version of the following international standards or to regional or national equivalent, including technical tests for safety and performance from an accredited laboratory or third party (where applicable, but not limited to): • ISO 7396-1: Medical gas pipeline systems – Part 1: Pipeline systems for compressed medical gases and vacuum. • ISO 10524-2: Pressure regulators for use with medical gases – Part 2: Manifold and line pressure regulators. • ISO 15001: Anaesthetic and respiratory equipment – Compatibility with oxygen. • ISO 21969: High-pressure flexible connections for use with medical gas systems. • Electrical component: – IEC 60529: Degrees of protection provided by enclosures (IP Code). – IEC 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. – IEC 60601-1-2: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests. – IEC 60601-1-8: 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.
51	Regional/local standards	• Country-specific and regional standards may apply. • Registered in country of import (if applicable).
Documentation		
52	Documentation requirements	Hard and soft copies, to be supplied in preferred language of destination country and/or English of all the following: • User manual, detailing: – Protocols for start-up and operations. – Preventive maintenance requirements, including calibration where necessary. – System schematics. – Troubleshooting and curative maintenance procedures. – List of equipment and procedures required for cleaning. • Maintenance manual (*if details listed above are not covered in the user manual*). • Evidence of regulatory approval (see line 48). • Evidence of standards compliance for: – Manufacture requirements (line 49). – Product specific requirements (line 50). • Certificates for calibration and inspection prior to shipment. • Cleaning: evidence of compliance cleaning according to ISO 15001 or equivalent shall be provided upon request (*Note:* Check with receiving jurisdiction if provision of certification by a conformity assessment body, e.g. notified body is required for aforementioned documents).

3.1.1 Other system requirements

Procurement of an oxygen distribution manifold will rarely take place in isolation. The following are products or components that are necessary to facilitate safe, continued operations of an oxygen distribution manifold and should be considered during planning and procurement.

- Housing/shelter for distribution manifold.
- Source of oxygen cylinders (high-pressure gas or LOX).
- Storage facilities (for cylinders).
- MGPS inclusive of a "tie-in" or connection.
- Ambient oxygen monitoring system for manifold room safety (19.5–23.5%).
- Dedicated continuous, quality power supply: voltage stabilization and surge suppression when on mains, back-up power source (e.g. diesel-based electricity generator or photovoltaic/battery system) and configured with UPS.
- Fire safety equipment (e.g. fire alarm, fire extinguisher).

3.1.2 Other system considerations

The following activity/product should be considered during planning and/or procurement to extend, enhance, or complement a distribution manifold.

- Secondary back-up oxygen supply (if used as primary supply).

3.1.3 References and resources

- European Industrial Gases Association (EIGA): DOC 33/18: Cleaning of equipment for oxygen service *(13).*
- *How to plan and budget for your healthcare technology*, 'How to Manage' Series for Healthcare Technology, Guide 2 *(16).*
- ISO 7396-1: Medical gas pipeline systems – Part 1: Pipeline systems for compressed medical gases and vacuum *(60).*
- National Fire Protection Association: NFPA 99: Health care facilities code *(9).*
- UK NHS: HTM 02-01: Medical gas pipeline systems, Part A: Design, installation, validation and verification *(8)*.
- US Code of Federal Regulations: Title 42 Part 482.41 – Condition of participation: physical environment *(61).*
- WHO's *Foundations of medical oxygen systems (4).*
- Commercialized product landscape review:
  - Tri-Tech Medical Inc.: Medical gas manifold system *(62).*
  - BeaconMedaes®: Manifold control systems (HTM/ISO) *(63)* and Lifeline manifolds (NFPA) *(64).*
  - Amico: Downloads – repository of brochures, specifications, drawings and manuals *(65).*
  - Genstar Technologies: Medical pipeline – repository of brochures, specifications and manuals *(66).*
- WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices *(25).*

3.2 Medical gas pipeline system components

An MGPS and its components are described in detail in WHO's *Foundations of medical oxygen systems* (see comprehensive overview pp. 39–41).

This specification format is for components and not for quantities thereof; a stand-alone solicitation should not be made for the components of an MGPS. The components should be reflected in a bill of quantities (BOQ) for a proposed MGPS, where the system has been designed by an engineer according to one of the following normative guidance documents (or equivalent):

- HTM 02-01 *(8).*
- NFPA 99 *(9).*

Name, category and coding		
1	WHO category/code	(under development)
2	Generic name	Medical gas pipeline system
3	Specific type or variation	
4	UNSPS code (optional)	
5	EMDN name	Medical/medicinal gas pipeline systems and related accessories[14]
6	EMDN code	Z120309
7	GMDN name	Medical gas pipeline system © GMDN Agency 2005-2024[15]
8	GMDN code	44807
9	Alternative name/s (optional)	
10	Alternative code/s (optional)	
11	Keywords	Oxygen piping, Medical gas piping, Reticulated oxygen system, Reticulated gas system, Piping network.
12	Product definition	An MGPS is an assembly of devices installed in health facilities that is designed to deliver compressed medical gases (e.g. oxygen, medical air) from a central source through to a delivery point such as the patient bedside. These systems typically comprise the gas source (e.g. oxygen generator plant, compressed gas cylinders, bulk cryogenic oxygen), a pipework system that includes various components for regulation of pressure, valves for isolation, alarms to indicate system status and bedside terminal units. MGPS shall accommodate emergency back-up gas supply.
Purpose of use		
13	Intended use	These MGPS components, combined and installed according to a facility specific design and standard, will enable the continuous and uninterrupted distribution of medical oxygen at required pressure and flows in an "on-demand" fashion, including under peak flow scenarios, to administer to patients when and where medical oxygen is clinically indicated.
14	Service delivery platforms/health care levels	• First-level (district) hospital services. • Second-level and third-level hospital services and specialized outpatient services.

[14] European Medical Devices Nomenclature (EMDN). European Commission; 2024.
[15] Global Medical Devices Nomenclature. GMDN Agency; 2024.

Purpose of use *(continued)*		
15	Clinical department/ ward	All clinical departments/medical wards where oxygen therapy/respiratory support is indicated.
16	Overview of functional requirements	Each component of an MGPS plays an integral role into the broader MGPS system. Appropriate functionality is dependent on an effectively designed network of pipes, valves, and regulating and monitoring devices.
Technical characteristics		
17	Components	Alarms, line valve assemblies, area valve service units, emergency inlet port, wall outlets/bedside outlets/terminal units, piping and associated fittings.
18	Detailed requirements	**Vendor to indicate unit quantities and connection sizes for each component herein, based off preliminary design, and present in a clearly tabulated BOQ.** Piping and associated fittings: • Piping: – Copper **or** Monel® **or** other ignition-resistant alloy acceptable as per ISO 15001 or equivalent. – For ceiling mounted outlets, non-metal flexible connections are permissible as per ISO 15001 and ISO 5359 or equivalent. – Specify pipe outer diameter(s), required wall thickness, # of lengths of each diameter according to applicable standards (e.g. EN 1057, EN 13348 or ASTM B819 or equivalent). • Fittings: – Material: Copper alloy, nickel-plated if threaded. – Type: Couplings, check valves, reducers, tees, elbows. – Dimensions: As per piping requirements, alignment with standards. • Joinery: – Suitable to a minimum of 2 070 kPa (300 psi). – Permanent in nature. – Mode: • Brazing: use of brazing filler material as per ISO 17672 or equivalent *(Vendor must indicate gas(s) to be used for brazing and* shielding); **or** • Press-fitting/mechanical fitting (which can be swaged): – connection must have equivalent sealing integrity of a brazed joint; – sealing ring must have proven oxygen compatibility (see line 31). ***Elastomeric materials are not acceptable unless they have been explicitly tested for application with medical oxygen and are shielded from direct exposure to medical oxygen.*** • MGPS components: ☐ Flowmeter, laminar mass flow technology (suggested): – Range: [Specify flow to align with maximum system capacity] m^3/hr. – Accuracy: ±1%. – Repeatability: ±0.2%. – Pressure: 10 bar (145 psi). ☐ Temperature sensor (optional). • Alarm, wall-mounted panel: – Function: [Specify master and/or local alarm, and specify area(s) of service/zone(s)]. – Indication of gas (oxygen as a minimum) supply parameters: • Pressure (displayed in bar and psi). • System status. – In-built up-stream pressure switch. – Audible and visual alarms for notification and/or fault conditions (see line 22). – Alarm to remain active until condition resolved. – Temporary “mute” function. ☐ Remote monitoring capability (optional).

Technical characteristics *(continued)*		
18	Detailed requirements *(continued)*	• Line valve assembly (LVA)/Isolation valve: – Ball valve type. – Forged copper alloy body, chrome plated ball. – Lever handle, ¼ turn (90°), lockable in both open and closed positions. – Pneumatically tested to 2x system working pressure (typically 800 kPa/ 116 psi). • Line pressure regulator (if applicable): – Stem type seat mechanism. – Delivery range: 10–200 psi. – Maximum inlet pressure: 350 psi. – In-built relief valve. – Copper alloy. • Area valve service unit (AVSU)/zone valve box: – Contained in a panel-type box. – Pressure sensor and analogue gauge to be installed downstream to indicate line pressure (in bar and psi). – At least one LVA (for oxygen). ☐ Upstream pressure switch where department/ward has alternate circuit (where applicable). – Copper alloy. ☐ Pressure switch – additional [Select to include if/where:] ☐ AVSU has no upstream pressure switch and an alternate circuit is present. ☐ Secondary source such as a reserve manifold. – Factory set: • Low: 370 kPa (53 psi). • High: 500 kPa (73 psi). – Adjustable range: 3.5–550 kPa (0.5–80 psi), tested to 2x maximum pressure. – Inclusive of pressure transmitter. • Wall outlets/bedside outlets/terminal units (TUs): – Spring operated. – Copper alloy terminal block. – Non-return valve. – Type: ☐ Afnor NF S 90-16 (French); **or** ☐ AFROX/SANS 1409 (South Africa); **or** ☐ BS 5682 (British); **or** ☐ Chemetron®; **or** ☐ DIN 13260-2 (German); **or** ☐ DISS Hex; **or** ☐ DISS Handwheel; **or** ☐ ENV 737- 6 (European); **or** ☐ JIS T7101 (Japanese); **or** ☐ NIST EN 739 (International); **or** ☐ Ohmeda®; **or** ☐ Puritan-Bennett®; **or** ☐ SIS AS2896 (Australian); **or** ☐ UNI (Italian). – Braised copper stub pipe. • Emergency inlet port: – Encased in a panel-type box (surface or recess mounting). – Connection, plugged to prevent ingress of particulates or contaminants: ☐ Female NPT; **or** ☐ 22 mm. – Pressure gauge for emergency supply (displayed in bar and psi). – Isolation valve. – Connection to be indicated.

19	Size(s)	Various, to be based off of detailed design and resulting BOQ.
Technical characteristics *(continued)*		
20	Control panel/user interface	(See line 18, Detailed requirements, "Alarm, wall-mounted panel".)
21	Displayed parameters	• AVSUs: pressure displayed on gauges. • Alarm panel: displaying line pressure, fault conditions (purity drop, flow cessation), alerting for bank changeover (where relevant), indication of activation of secondary/emergency reserve source(s).
22	Alarms	Alarms (audible and visual) for notification and/or fault conditions for: • High- and low-pressure events. • Oxygen purity drop below 90%. • Cessation of flow. • Need for bank changeover on manifold (where relevant). • Initiation of secondary/emergency oxygen supply.
23	User adjustable settings	N/A.
Physical characteristics		
24	Configuration	Installation of these components will be unique for each healthcare facility-based design.
25	Mobility, portability	N/A.
Utility requirements		
26	Electrical, water and/or gas supply	Power supply for alarm panel and pressure switches (if applicable): • Voltage: ☐ 110 V AC; **or** ☐ 220 V AC. • Frequency: ☐ 60 Hz; **or** ☐ 50 Hz.
Accessories, consumables, spare parts and other components		
27	Accessories	• Flowmeters, with inlet connections compatible with terminal units. • Tubing, type specific to application (low-pressure or high-pressure).
28	Consumables/ reagents	N/A.
29	Spare parts	• Maintenance kits for terminal units. • Springs for terminal units. • Back-up LVAs. • Any other spare listed by vendor as per maintenance requirement.
30	Other components	[Specify needs or refer to additional specifications, see Section 3.2.1.]
Packaging		
31	Cleaning requirements	• Terminal units, AVSUs, LVAs: – ≤ 550 mg/m^2 hydrocarbon contamination ISO 15001; **or** – ≤ 500 mg/m^2 hydrocarbon contamination CGA G-4.1; **or** – Other equivalent standard. • All other components which come into contact with oxygen (copper piping, fittings), shall not have residues greater than 0.020 g/m^2 residues (EN 13348 test methods or equivalent).
32	Shelf life	N/A.

Packaging *(continued)*		
33	Transportation and storage	To minimize potential for contamination after cleaning for oxygen service (see line 31): • All MGPS components shall come sealed in individual packages. • All pipeline fittings shall come sealed in individual packages. • Pipes shall be shipped/delivered with both ends capped.
34	Labelling	• Colour: – Terminal units, labelled "oxygen": ☐ Green (USA); **or** ☐ White (international). – Piping, label with the word "oxygen" clearly visible: ☐ Green (USA); **or** ☐ White (internationa)l. • "For oxygen service" clearly indicated on all valves and pressure regulators. • The product manufacturer's name and registered trademark shall be marked on each component. Other details include (from EN 13348): – Specification. – Traceable batch number or production date.
Environmental requirements		
35	Context-dependent requirements	N/A.
Training, installation and utilization		
36	Pre-installation requirements	• Comprehensive system planning and design, including but not limited to: – Site assessment. – Detailed drawings (facility layout with MGPS overlay). • Oxygen supply.
37	Requirements for installation, testing and commissioning	• Provision of comprehensive installation plan, including preparation and staging if installation in an already operational facility, to be submitted in a "permit to work" format (if applicable). • "Tie-in" to oxygen source (oxygen generator plant, VIE, and/or distribution manifold). ***Note: All other commissioning requirements are in line with installation guidance and will include, but not be limited to, protecting components from the environment, labelling and marking of all components including for gas identity and flow direction (and appropriate colour where applicable), and comprehensive system testing: leak tests, standing pressure test, testing for system pressure drops or shocks and final technical audit.***
38	Training of user/s	*Note:* All training requirements are to accompany system installation, testing and commissioning. On-site training in preferred language of destination country and/or English to include, but not be limited to: • Safety: General, oxygen-specific, isolation protocols. • Operations: Theoretical overview of MGPS and its functionality. • Cleaning of components (where applicable). • Daily operations, inclusive of record keeping and data management. • Planned preventive maintenance SOPs and work instructions. • Troubleshooting approach and corrective maintenance SOPs and work instructions if they can be carried out by user. ***Consideration to include "continuous development" training programme to be paired alongside SLA activities.***

Training, installation and utilization *(continued)*		
39	User care	Supplier to provide detailed user care instructions in preferred language of destination country and/or English including but not limited to: • Requirements for the technical team to ensure smooth daily operations. • Requirements of the clinical care team to ensure that equipment is properly used and cared for. • Cleaning requirements.
Warranty and maintenance		
40	Warranty *(see p. 9)*	1 year from date of commissioning, minimum.
41	Maintenance tasks	Maintenance is to be conducted by a qualified party under broader MGPS system operations. The following following shall be provided from manufacturer: • A comprehensive, manufacturer-recommended preventive maintenance schedule for each component, including but not limited to: – Regular system leakage tests. – Sensor accuracy testing and re-calibration. • A list of all associated spares (where applicable) for each component at each maintenance interval.
42	After-sales service contract	As part of installation of MGPS, if applicable, an SLA is suggested and should detail: • Level of responsibility: ☐ Planned preventive maintenance (incl. required calibration); **or** ☐ Planned preventive maintenance, troubleshooting and curative maintenance; **or** ☐ Troubleshooting and curative maintenance. • Costs, itemized in terms of labour, travel, lodging and all parts. • Time-to-response for remote support **and** for on-site intervention. • Timeline for critical spares to reach point of intervention. • Requirements of record keeping of all activities.
43	Spare parts availability post-warranty	Minimum 8 years, from time of installation.
44	Software/hardware upgrade availability	N/A.
Decommissioning		
45	Lifespan	20 years from date of commissioning, minimum, guaranteed by manufacturer.
Safety and standards		
46	Regulations	Regulated as per NRA of intended market. In the absence of NRA requirements, suggest using alternative, such as (but not limited to): • EU: all components of MGPS are medical devices – EU MDR (No. 2017/745) applies. • US: – 21 CFR § 820 Quality System Regulation (for medical devices, terminal units). – 42 CFR § 482.41 Condition of Participation: Physical Environment (Basic hospital functions, for all remaining MGPS components).
47	Risk/hazard classification	Classified as per NRA of intended market. In the absence of NRA classification of this product, suggested alternative (but not limited to): • MGPS components, as medical devices, are Class B (GHTF Rule 6), Class II a (EU, Australia), Class II (Japan, Canada). • Wall units/bedside units/terminal units, as medical devices, are Class II (US FDA).

Safety and standards *(continued)*		
48	Regulatory approval/ certification	Compliance (where applicable, but not limited) to: • NRA requirements of intended market. • Approval by NRA and regulatory body of country of manufacturer. In the absence of classification or regulation by the NRA, suggest regulatory clearance/approval and certification by a conformity assessment body from a well-regulated market such as (but not limited to): • United States regulations: – US FDA: Device Class II for medical devices (terminal units). – For remaining components, compliance to NFPA and CGA requirements as per 42 CFR § 482.41. • EU regulations: – CE marking under EU MDR clearly indicating components covered. • Other: Equivalent approvals from a regulatory body in an IMDRF/GHTF founding member country such as Australia, Canada or Japan.
49	International standards for manufacturer	Compliance to (where applicable, but not limited to) last available version or equivalent of: • ISO 9001: Quality management systems – Requirements (with relevant scope clearly indicated). • ISO 13485: Medical devices – Quality management systems – Requirements for regulatory purposes *(for terminal units only).*
50	International standards for product performance	Compliance to the latest available version of the following international standards or to regional or national equivalent, including technical tests for safety and performance from an accredited laboratory or third party (where applicable, but not limited to): **All:** • ISO 7396-1: Medical gas pipeline systems. • CGA G-4.1 – Cleaning of equipment for oxygen service. **Specific components:** • ISO 5359: Anaesthetic and respiratory equipment – Low-pressure hose assemblies for use with medical gases. • ISO 9170-1: Terminal units for medical gas pipeline systems – Part 1: Terminal units for use with compressed medical gases and vacuum. • ISO 10524-2: Pressure regulators for use with medical gases – Part 2: Manifold and line pressure regulators. • ISO 15001: Anaesthetic and respiratory equipment – Compatibility with oxygen. **Piping:** • ISO 17672: Brazing – filler metals. • EN 1057: Copper and copper alloys. Seamless, round copper tubes for water and gas in sanitary and heating applications. (*Note*: This standard is used for dimensioning of piping as per HTM-02-01.) • EN 1254-1: Copper and copper alloys – Plumbing fittings – Part 1: Capillary fittings for soldering or brazing to copper tubes. • EN 1254-4: Copper and copper alloys – Plumbing fittings – Part 4: Threaded fittings. • EN 1412: Copper and copper alloys – European numbering system. • EN 13348: Copper and coppery alloys. Seamless, round copper tubes for medical gases or vacuum or equivalent. • ASME B16.50 Wrought copper and copper alloy braze-joint pressure fittings. • ANSI/AWS A5.8 Specification for filler metals for brazing and braze welding. • ASME B1.20.1 – Pipe threads, general purpose. • ASTM B819-19 – Standard specification for seamless copper tube for medical gas systems.

Safety and standards *(continued)*		
51	Regional/local Standards	• Country-specific and regional standards may apply. • Registered in country of import (if applicable).
Documentation		
52	Documentation requirements	Hard and soft copies, to be supplied in preferred language of destination country and/or English for all functional components of MGPS (alarm panels, AVSUs, LVAs, TUs inclusive of sample port): • User and maintenance manual, detailing: – Operational requirements, inclusive of preventive maintenance procedures. – Troubleshooting and curative maintenance procedures. – List of equipment and procedures required for operations, maintenance, repair and cleaning. • Maintenance manual (if details listed above are not covered in the user manual). • Evidence of regulatory approval (see line 48). • Evidence of standards compliance for: – Manufacture requirements (see line 49). – Product specific requirements (line 50). Prior to shipment: • Certificates of calibration for all pressure sensors/gauges. • Certificates of analysis for: – Composition for copper pipes. – Composition of pipeline fittings. • Evidence of conformance for all cleaning requirements (see line 31) (*Note:* Check with receiving jurisdiction if provision of certification by a conformity assessment body, e.g. a notified body is required). • FSC (where applicable).

3.2.1 Other system requirements

Procurement of components for an MGPS must be done so only after the detailed design phase of the pipeline system, must be informed by and done so only after the detailed design phase of the pipeline system. The following are products or components that are necessary to facilitate safe, continued operations of an MGPS and should be considered during planning and procurement.

- MGPS design (including calculations and drawings).
- Oxygen source (oxygen generator plant, VIE system) inclusive of a “tie-in” or connection.
- Distribution manifold and cylinder supply.
- Dedicated continuous, quality power supply: voltage stabilization and surge suppression when on mains, back-up power source (e.g. diesel-based electricity generator or photovoltaic/battery system) and configured with UPS.

3.2.2 Other system considerations

MGPS typically include other gases and services, such as medical air and vacuum. Given the complexity and costs associated with system installation, it would be more effective to include the design and installation of additional gas services at once.

3.2.3 References and resources

- European Industrial Gases Association (EIGA):
  - DOC 13/20: Oxygen pipeline and piping systems *(67).*
  - DOC 33/18: Cleaning of equipment for oxygen service *(13).*
- *How to plan and budget for your healthcare technology*, 'How to Manage' Series for Healthcare Technology, Guide 2 *(16).*
- National Fire Protection Association: NFPA 99: Health care facilities code *(9).*
- UK NHS: HTM 02-01: Medical gas pipeline systems, Part A: Design, installation, validation and verification (Appendix G, Table A1 pipe diameter and thickness) *(8).*
- US Code of Federal Regulations: Title 42 Part 482.41 – Condition of participation: physical environment *(61).*
- Commercialized product landscape review:
  - Amico: Downloads – repository of brochures, specifications, drawings and manuals (*65).*
  - Genstar Technologies: Medical pipeline – repository of brochures, specifications and manuals *(66).*
  - Medlock®: Documents – brochures, specifications, installation briefs *(68).*
  - Omega Sensing Solutions: FMA1600-Series Mass and volumetric flowmeters *(69).*
- Chou T, Fiedorowicz A. Oxygen Compatibility of Polymers Including TFE-Teflon®, Kel-F® 81, Vespel® SP-21, Viton® A, Viton® A-500, Fluorel®, Neoprene®, EPDM, Buna-N, and Nylon 6,6 *(70)*.
- WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices *(25).*

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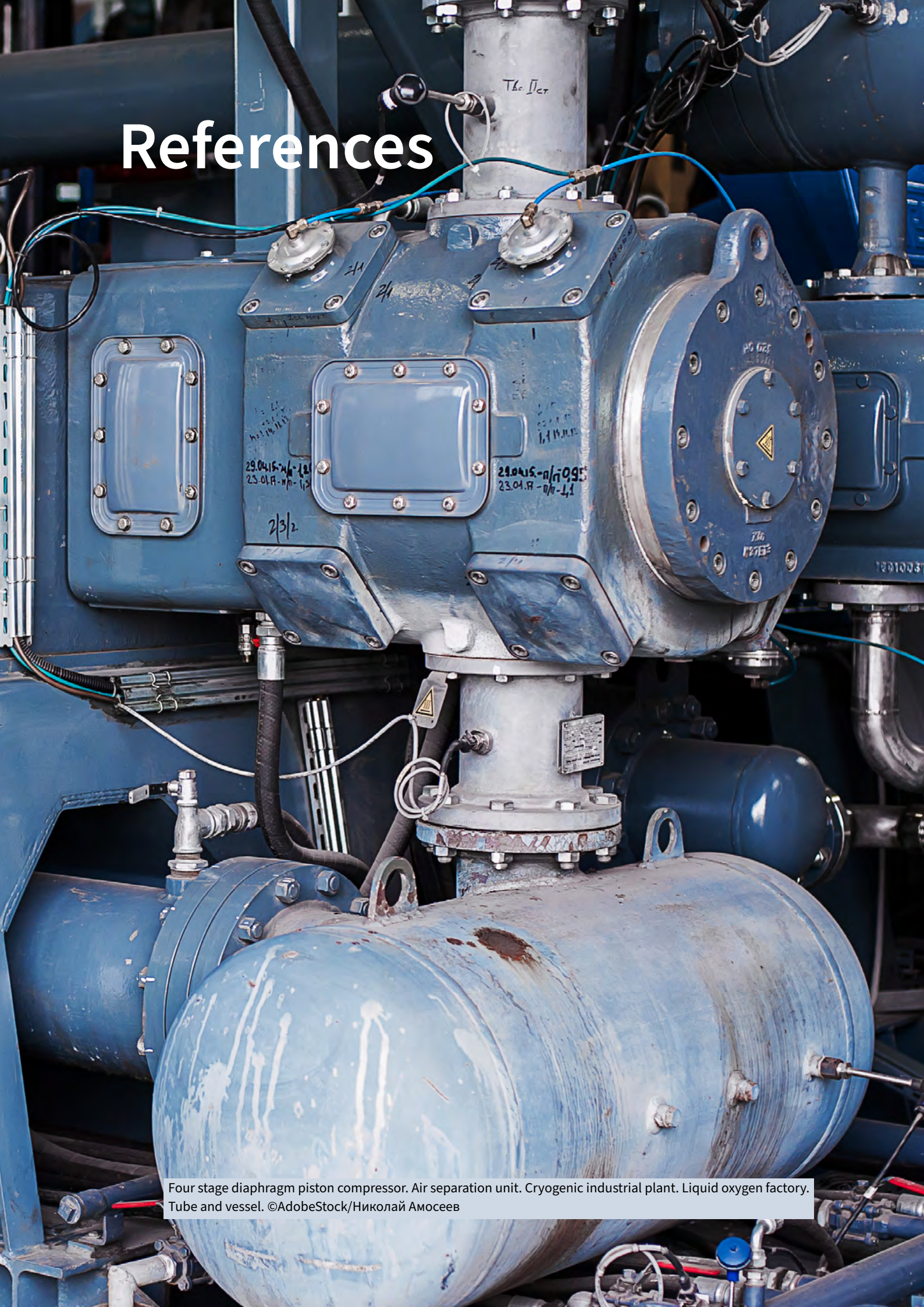

Four stage diaphragm piston compressor. Air separation unit. Cryogenic industrial plant. Liquid oxygen factory. Tube and vessel. ©AdobeStock/Николай Амосеев

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4. Foundations of medical oxygen systems. Geneva: World Health Organization; 2023 (https://apps.who.int/iris/handle/10665/366149).

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Annexes

Compressed gas cylinders being stored vertically secured by a metal chain and a metal cap.
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Annex 1: Expert Working Group details

Name	Role	Organization	Country
Wisal Alahab	Regional Medical Equipment Specialist	International Federation of the Red Cross	Jordan
Jim Ansara	Co-Founder and Managing Director	Build Health International	USA
Andrew Argent	Professor, Medical Director Paediatric Intensive Care	University of Cape Town	South Africa
Beverly Bradley	Technical Specialist, Oxygen Therapy	UNICEF Supply Division	Denmark
Hilda Bugingo	Technical Lead	FREO2 Foundation	Uganda
Frank Chirowa	Regional Strategic Information Lead	Right to Care International	South Africa
Harish Hande	CEO	SELCO Foundation	India
Noah Hudelson	Mechanical Engineer	Build Health International	USA
Atalawoe Kossivi Kumedjro	Biomedical Engineer	Freelance consultant	Togo
Ingrid Lara	Technical Specialist	UNICEF Supply Division	Denmark
Michael Lipnick	Professor, Anesthesia and Critical Care	University of California San Francisco	USA
Gabriela Jimenez Moyao	Lead Biomedical Engineer	UNOPS	Senegal
Alex Rothkopf	Supply Chain Management and Data Science Advisor	PATH	USA
Paul Sonenthal	Director, Inpatient Medicine and Critical Care	Partners In Health	USA
James Stunkel	Vice President/Director Program Operations	Assist International	USA
Francine Umutesi	Medical Technology Division Manager	Rwanda Biomedical Centre	Rwanda
Umberto Vitale	Medical Devices Advisor	UNOPS	Denmark

Notes: Details current at time of EWG engagement. All members of the EWG submitted declarations of interest, which were reviewed and analysed for any potential conflicts of interest; none were identified.

Organizations serving as observers to the EWG

Organization	Country	Representative(s)	Role
Clinton Health Access Initiative (CHAI)[a]	USA	Omileye Toyobo and Jonas Twizeyimana	Senior Manager Senior Technical Associate
Family Health International (FHI360)[a]	USA	Tadesse Gamessa	Technical Advisor
International Committee of the Red Cross	Switzerland	Morgane Pladys	Biomedical Engineer Lead Buyer
International Federation for Medical and Biological Engineering[a]	Ethiopia	Ashenafi Hussein Ababu	Interim Chair, Africa Region
The Global Fund	Switzerland	Nicholas Furtado	Senior Medical Advisor, Oxygen and Respiratory Care

Notes: [a] Organizations in official relations with WHO in line with the Framework of Engagement with Non-State Actors. The remaining observers submitted declarations of interest, which were reviewed and analysed for any potential conflicts of interest; none were identified.

Annex 2: Overview on feedback from consultations

Expert working group consultation

The EWG, comprising 17 individuals, was an interdisciplinary group of expert clinicians, engineers and technicians, programme managers and academics working with medical oxygen systems. Additionally, there were five contributing observers to the EWG, who were representatives of entities which fell within the WHO Framework of Engagement with non-State Actors.

The EWG and observers had a month to review the draft specifications and specific section(s) for content, clarity and completeness, and were welcome to share relevant implementation experiences, where applicable, relating to procurement and installation, system errors and other appropriate lessons learned, or resolutions realized.

Fig. 3 illustrates the distribution of the 310 content-related comments across the specification document.

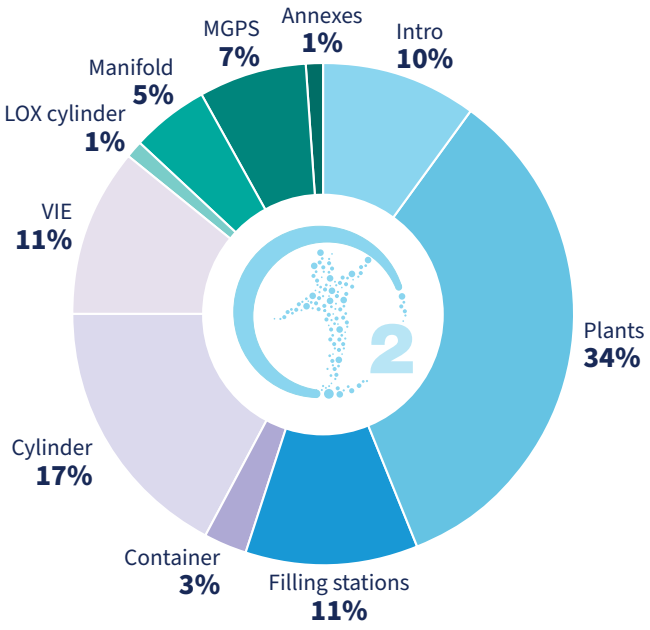

Fig. 3. Proportion of comments across all specifications, EWG and observers

These comments were managed as follows:

- ~16% suggestions N/A:
  - comments were either operational guidance or altogether out of scope.
- ~22% comments necessitated minor, straightforward language adjustments:
  - comments which did not change meaning/intent;
  - comments which did not warrant any further discussion.
- ~40% of the comments resulted in clarifications/additions/deletions to the document which:
  - enhanced the specifications;
  - did not warrant broad discussion or consensus.
- ~23% of the comments warranted discussion with the broad EWG to find a resolution or reach consensus, relating to:
  - previously unresolved/outstanding topics;
  - significant change in intent.

The second EWG meeting, held on 15 December 2023, lasted several hours and allowed for discussion of all of these topics. Where any question remained, the item was explicitly called to the attention of the public reviewers, soliciting targeted input.

Public consultation

A public consultation of the draft technical specifications was held via posting an article on the WHO online newsroom platform. Voluntary participation from a total of 21 individuals comprising government officials, civil society organizations, international organizations, research institutions and interested citizens resulted in an additional 292 comments across the specifications, distributed as shown in Fig. 4.

All inputs collected during the public consultation were considered in the revision of the document, and many were reflected in the final draft.

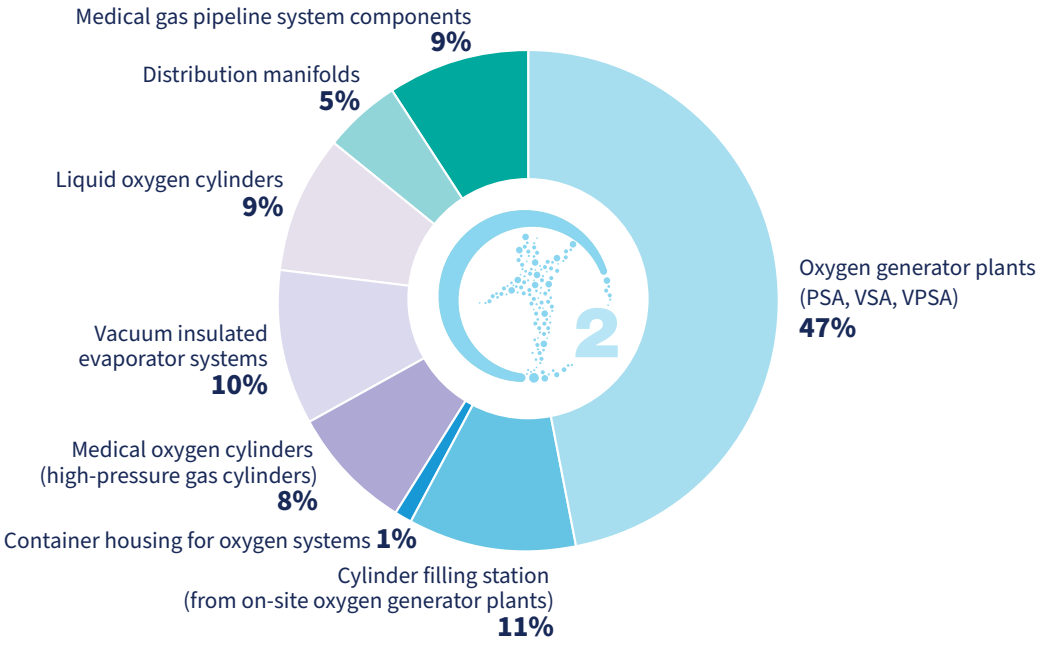

Fig. 4. Proportion of comments across all specifications, public consultation

These comments were managed as follows:

- ~43% suggestions N/A:
  - comments were either operational guidance or altogether out of scope.
- ~4% comments necessitated minor, straightforward language adjustments:
  - comments which did not change meaning/intent;
  - comments which did not warrant any further discussion.
- ~47% of the comments resulted in clarifications/additions/deletions to the document, which:
  - enhanced the specifications;
  - did not warrant broad discussion or consensus.
- ~6% warranted discussion as the comments related to:
  - previously unresolved/outstanding topics;
  - significant change in intent.

To address the 6% of comments warranting further discussion, a third and final meeting was held with the EWG and all the outstanding topics were discussed and a resolution was found.

Annex 3: Standards and regulations

The following lists all standards and regulations, by topic, found throughout this document.

The requirements of an NRA of the intended market will take precedent. In the absence of classification or regulation by the NRA, suggest regulatory clearance/approval and certification by a conformity assessment body from a well-regulated market, examples of which are provided.

Note: Compliance to the latest available version of applicable standards (or to regional or national equivalent), including technical tests for safety and performance from an accredited laboratory or third party, will help to ensure safety, efficiency and quality of device, equipment or accessory during design, manufacture, operation and maintenance.

Topic	Standard/regulation reference	Standard title
Air preparation (filtration)	ISO 12500-1	Filters for compressed air – Test methods – Part 1: Oil aerosols
Air preparation (filtration)	ISO 12500-2	Filters for compressed air – Test methods – Part 2: Oil vapours
Air preparation (filtration)	ISO 12500-3	Filters for compressed air – Test methods – Part 3: Particulates
Air preparation (filtration)	ISO 8573-1	Compressed air – Part 1: Contaminants and purity classes
Air preparation (filtration)	ISO 8573-2	Compressed air – Contaminant measurement – Part 2: Oil aerosol content
Air preparation (filtration)	ISO 8573-4	Compressed air – Contaminant measurement – Part 4: Particle content
Air preparation (filtration)	ISO 8573-5	Compressed air – Part 5: Test methods for oil vapour and organic solvent content.
Cleaning	ASTM G93-03	Standard guide for cleanliness levels and cleaning methods for materials and equipment used in oxygen-enriched environments
Cleaning	CGA G-4.1	Cleaning of equipment for oxygen service
Cleaning	ISO 15001	Anaesthetic and respiratory equipment – Compatibility with oxygen
Cleaning	ISO 23208	Cryogenic vessels – cleanliness for cryogenic service
Containers (housing)	EN 14308	Thermal insulation products for building equipment and industrial installations – Factory made rigid polyurethane foam (PUR) and polyisocyanurate (PIR) products – Specification
Containers (housing)	ISO 1161	Series 1 freight containers – Corner and intermediate fittings – Specifications
Containers (housing)	ISO 1496-1	Series 1 freight containers – Specification and testing – Part 1: General cargo containers for general purposes
Containers (housing)	ISO 6346	Freight containers – Coding, identification and marking
Containers (housing)	ISO 668	Series 1 freight containers – Classification, dimensions and ratings
Cryogenic vessels	US: 49 CFR § 180	Continuing qualification and maintenance of packagings
Cryogenic vessels	US: 49 CFR § 178.57	Specification 4L welded insulated cylinders
Cryogenic vessels	US: 49 CFR § 173.316	Cryogenic liquids in cylinders
Cryogenic vessels	US: 49 CFR § 173.320	Cryogenic liquids; exceptions
Cryogenic vessels	US: 49 CFR § 178.57	Specification 4L welded insulated cylinders inclusive of safety valves
Cryogenic vessels	ASME BPVC Section VIII	Rules for construction of pressure vessels division 1

Topic	Standard/regulation reference	Standard title
Cryogenic vessels	CGA C-3	Standards for welding on thin-walled, steel cylinders
Cryogenic vessels	CGA S-1.2	Pressure Relief Device Standards – Part 2: Portable containers for compressed gases
Cryogenic vessels	EN 1251-1	Cryogenic vessels – Transportable vacuum insulated vessels of not more than 1000 litres volume – Part 1: Fundamental requirements
Cryogenic vessels	EN 13458-1	Cryogenic vessels – Static vacuum-insulated vessels – Part 1: Fundamental requirements
Cryogenic vessels	EN 1626	Cryogenic vessels – Valves for cryogenic service
Cryogenic vessels	ISO 16528-1	Boilers and pressure vessels – Part 1: Performance requirements
Cryogenic vessels	ISO 21009-1	Cryogenic vessels – Static vacuum-insulated vessels – Part 1: Design, fabrication, inspection and tests
Cryogenic vessels	ISO 21009-2	Cryogenic vessels – Static vacuum insulated vessels – Part 2: Operational requirements
Cryogenic vessels	ISO 21010	Cryogenic vessels – Gas/material compatibility
Cryogenic vessels	ISO 21011	Cryogenic vessels – Valves for cryogenic service
Cryogenic vessels	ISO 21013-1	Cryogenic vessels – Pressure-relief accessories for cryogenic service – Part 1: Reclosable pressure-relief valves
Cryogenic vessels	ISO 21013-2	Cryogenic vessels – Pressure-relief accessories for cryogenic service – Part 2: Non-reclosable pressure-relief devices
Cryogenic vessels	ISO 21013-3	Cryogenic vessels – Pressure-relief accessories for cryogenic service – Part 3: Sizing and capacity determination
Cryogenic vessels	ISO 21028-1	Cryogenic vessels – Toughness requirements for materials at cryogenic temperature – Part 1: Temperatures below -80 °C
Cryogenic vessels	ISO 21029-1	Cryogenic vessels – Transportable vacuum insulated vessels of not more than 1000 litres volume – Part 1: Design, fabrication, inspection and tests
Cryogenic vessels	ISO 21029-2	Cryogenic vessels – Transportable vacuum insulated vessels of not more than 1000 litres volume – Part 2: Operational requirements
Cryogenic vessels	ISO 23208	Cryogenic vessels – Cleanliness for cryogenic service (specify for LOX service)
Documentation	US: 21 CFR § 801	Labeling
Documentation	US: 21 CFR § 803	Medical device reporting
Electrical	EU: LVD (No. 2014/35/EU)	European Union: Low Voltage Directive
Electrical	IEC 60204	Safety of machinery – Electrical equipment of machines – ALL PARTS
Electrical	IEC 60529	Degrees of protection provided by enclosures (IP Code)
Electrical	IEC 60601-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
Electrical	IEC 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – requirements and tests

Topic	Standard/regulation reference	Standard title
Electrical	IEC 60601-1-8	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
Electrical	IEC 61000-4	Electromagnetic compatibility (EMC) – Part 4: Testing and measurement techniques, *sub-parts 4-2, 4-3, 4-4, 4-5, 4-6, 4-8, 4-11*
Electrical	IEC 61000-6-4	Electromagnetic compatibility (EMC) – Part 6-4: Generic standards – Emission standard for industrial environments
Electrical	IEC 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements
Electrical	US: 29 CFR § 1910	Design safety standards for electrical systems
Gas cylinders	ISO 10297	Gas cylinders – Cylinder valves – Specification and type testing
Gas cylinders	ISO 10524-3	Pressure regulators for use with medical gases – Part 3: Pressure regulators integrated with cylinder valves (VIPRs)
Gas cylinders	ISO 11114	Gas cylinders – Compatibility of cylinder and valve materials with gas contents
Gas cylinders	ISO 11117	Gas cylinders – Valve protection caps and valve guards – Design, construction and tests
Gas cylinders	ISO 11119	Gas cylinders – Design, construction and testing of refillable gas cylinders and tubes
Gas cylinders	ISO 11363-1	Gas cylinders – 17E and 25E taper threads for connection of valves to gas cylinders – Part 1: Specifications
Gas cylinders	ISO 11623	Gas cylinders – Composite construction – Periodic inspection and testing
Gas cylinders	ISO 13341	Gas cylinders – Fitting of valves to gas cylinders
Gas cylinders	ISO 13769	Gas cylinders – Stamp marking
Gas cylinders	ISO 14246	Gas cylinders – Cylinder valves – Manufacturing tests and examinations
Gas cylinders	ISO 15996	Gas cylinders – Residual pressure valves – Specification and type testing of cylinder valves incorporating residual pressure devices
Gas cylinders	ISO 18119	Gas cylinders – Seamless steel and seamless aluminium-alloy gas cylinders and tubes – Periodic inspection and testing
Gas cylinders	ISO 22435	Gas cylinders – Cylinder valves with integrated pressure regulators – Specification and type testing
Gas cylinders	ISO 32	Gas cylinders for medical use – Marking for identification of content
Gas cylinders	ISO 407	Small medical gas cylinders – Pin-index yoke-type valve connections
Gas cylinders	ISO 5145	Gas cylinders – Cylinder valve outlets for gases and gas mixtures – Selection and dimensioning
Gas cylinders	ISO 7225	Gas cylinders – Precautionary labels
Gas cylinders	ISO 7866	Gas cylinders – Refillable seamless aluminium alloy gas cylinders – Design, construction and testing

Topic	Standard/regulation reference	Standard title
Gas cylinders	ISO 9809-1	Gas cylinders – Design, construction and testing of refillable seamless steel gas cylinders and tubes – Part 1: Quenched and tempered steel cylinders and tubes with tensile strength less than 1100 MPa
Medical Devices Regulation	EU: MDR (No. 2017/745)	European Union Medical Devices Regulation
Painting	ISO 12944-4	Paints and varnishes – Corrosion protection of steel structures by protective paint systems – Part 4: Types of surface and surface preparation
Painting	ISO 12944-5	Paints and varnishes – Corrosion protection of steel structures by protective paint systems – Part 5: Protective paint systems
Painting	ISO 8501-1	Preparation of steel substrates before application of paints and related products – Visual assessment of surface cleanliness – Part 1: Rust grades and preparation grades of uncoated steel substrates and of steel substrates after overall removal of previous coatings
Painting	ISO 8504-2	Preparation of steel substrates before application of paints and related products – Surface preparation methods – Part 2: Abrasive blast-cleaning
Piping	US: 42 CFR § 482.41	Condition of participation: physical environment
Piping	ANSI/AWS A5.8	Specification for filler metals for brazing and braze welding
Piping	ASME B1.20.1	Pipe threads, general purpose
Piping	ASME B16.50	Wrought copper and copper alloy braze-joint pressure fittings
Piping	ASTM B819-19	Standard specification for seamless copper tube for medical gas systems
Piping	EN 1057	Copper and copper alloys. Seamless, round copper tubes for water and gas in sanitary and heating applications
Piping	EN 1254-1	Copper and copper alloys – Plumbing fittings – Part 1: Capillary fittings for soldering or brazing to copper tubes
Piping	EN 1254-4	Copper and copper alloys – Plumbing fittings – Part 4: Threaded fittings
Piping	EN 13348	Copper and copper alloys – Seamless, round copper tubes for medical gases or vacuum
Piping	EN 1412	Copper and copper alloys – European numbering system
Piping	ISO 17672	Brazing – filler metals
Piping	ISO 21969	High-pressure flexible connections for use with medical gas systems
Piping	ISO 5359	Anaesthetic and respiratory equipment – Low-pressure hose assemblies for use with medical gases
Piping	ISO 7396-1	Medical gas pipeline systems – Part 1: Pipeline systems for compressed medical gases and vacuum
Piping	ISO 9170-1	Terminal units for medical gas pipeline systems – Part 1: Terminal units for use with compressed medical gases and vacuum
Piping	ISO 10524-2	Pressure regulators for use with medical gases – Part 2: Manifold and line pressure regulators
Pressure equipment	EU: (PED) 2014/68/EU	European Union: Pressure Equipment Directive

Topic	Standard/regulation reference	Standard title
Pressure equipment	US: 46 CFR § 54	Pressure vessels
Pressure equipment	ASME B31.3	Process piping
Quality management system	ISO 13485	Medical devices – Quality management system – Requirements for regulatory purposes
Quality management system	ISO 9001	Quality management systems – Requirements
Quality management system	US: 21 CFR § 820	Quality system regulation (medical devices)

Annex 4: Complementary tools and resources

Resource	Description
FHI360 https://www.fhi360.org/wp-content/uploads/drupal/documents/epic-oxygen-assessment-tools.pdf	**Assessing the medical oxygen ecosystem: tools from national to primary health care levels** This collection of tools is a resource to support meaningful assessments and better target effective interventions for those who are building the oxygen ecosystem. A key element of this work is partnership across sectors and groups to optimize opportunities for collaboration, and a recognition that oxygen by itself does not save lives, without knowledge and additional capacity. The tools collected here can be used individually for specific areas or together, as the first section focuses on liquid oxygen at the national level, then an assessment at the hospital level and, finally, the primary care level. By improving the understanding of the gaps and resources related to medical oxygen supply and effective delivery, the goal is for more patients to receive the treatment they need.
Open Critical Care – resource hub https://opencriticalcare.org/	**Open Critical Care Project – a hub for oxygen and critical care tools** OpenCriticalCare.org was launched in August 2020 as a repository for reliable, open-access critical care learning tools with relevance to resource-variable settings. Many tools are focused on COVID-19 or oxygen and are included in a Resource Library, as well as a dedicated Oxygen Encyclopedia. The project also created an online tool for estimating oxygen supply and demand (OxygenCalculator.com) and Oxygen FAQ, a library of pulse oximeter performance data OpenOximetry.org and Oxygen Image Library and Clinical Quick References for oxygen therapy. The resource library includes curated and original content that can be used for training at various levels and multiple health care cadres.
Open Critical Care – supply and demand calculator https://www.oxygencalculator.com/oxygen/o2supply	**Open Critical Care Project – OxygenCalculator.com** The OxygenCalculator.com tool allows users to estimate facility level supply and demand for all oxygen supply sources and all oxygen delivery devices. Users can save and track data over time. The tool also helps users estimate cylinder size or cylinder duration. The tool is available in five languages and can be used without an Internet connection. *Note:* At time of publishing, this tool remains unvalidated.
WHO https://www.who.int/publications/i/item/WHO-2019-nCoV-MedDev-TS-O2T.V2	**Priority medical devices list for the COVID-19 response and associated technical specifications** This document describes the medical devices required for the clinical management of COVID-19, selected and prioritized according to the latest available evidence and interim guidelines. This includes: oxygen therapy, pulse oximeters, patient monitors, thermometers, infusion and suction pumps, X-ray, ultrasound and CT scanners as well as PPE. In order to facilitate access to quality assured priority medical devices, the document also includes technical and performance characteristics, related standards, accessories and consumables. It is intended for policy-makers and planning officers in ministries of health, procurement and regulatory agencies, intergovernmental and international agencies as well as the medical device industry.
UNICEF https://www.unicef.org/innovation/oxygen-system-planning-tool	**Oxygen System Planning Tool (OSPT)** The Oxygen System Planning Tool (OSPT) can be used to support high-level health care budgeting and planning needs related to oxygen, including health and procurement specialists and oxygen technology stakeholders. The tool uses health facility level input data and customizable country input parameters to calculate oxygen needs. With the relevant data from users, the OSPT recommends an oxygen source to meet those needs, can help users develop multiple scenarios of oxygen infrastructure to compare capital expenditure/operating expenditure cost, demand, resource re-allocation, and other key outcomes. *Note:* At time of publishing, this tool remains unvalidated.

Resource	Description
UNICEF https://www.unicef.org/innovation/oxygen-therapy	**Oxygen Market Dashboard** The UNICEF Oxygen Market Dashboard showcases information on the global medical oxygen market. It is designed to inform decision-making for planning, procuring and building durable, strategic and accessible oxygen supply chains and it expressly addresses the gaps exposed during the COVID-19 pandemic. Beyond oxygen procurement, the oxygen ecosystem requires complex components across diverse programmatic and supply dimensions. This dashboard highlights such elements so that users can understand a holistic supply chain via many component pieces, from oxygen production to patient delivery. With this dashboard, UNICEF supports governments and partners to tailor oxygen solution ecosystems that reflect and respect unique country contexts.
USAID MTaPS Program https://www.mtapsprogram.org/wp-content/uploads/2023/07/Quality-Assurance-of-Oxygen-QA-MTaPS-30-June-2023-final.pdf	**Quality assurance practices for medical oxygen systems: technical resource for distribution- and facility-level medical oxygen systems** This USAID MTaPS technical resource document for ensuring the quality of medical oxygen, whether produced on-site or outsourced, aims to serve as a reference and includes tools for practical application in its annex. It can be used by any stakeholder working in the oxygen space (public or private sector, multilateral or not-for-profit), with an emphasis on in-country application to establish and/or implement and adhere to quality assurance practices along the medical oxygen supply chain – sourcing and/or producing medical oxygen on-site, and its storage and distribution so that patients receive oxygen that is safe, reliable, continuous and of acceptable quality.
WHO https://iris.who.int/handle/10665/366149?search-result=true&query=foundations+of+medical+oxygen&scope=&rpp=10&sort_by=score&order=desc	**Foundations of medical oxygen systems** This publication has been complied to capture definitions, technical requirements, tools and resources related to medical oxygen systems based on information available in January 2023. It aims to make relevant and practical material accessible for Member States, policy-makers, implementing partners, practitioners, biomedical engineers and technicians.
WHO-UNICEF https://iris.who.int/handle/10665/329874	**Technical specifications and guidance for oxygen therapy devices** In order to meet the growing demand from countries to increase the availability of good quality, affordable, safe and appropriate oxygen therapy systems, the purpose of this interagency publication is to provide harmonized product specifications for a wide range of oxygen products, and to give guidance on the selection, procurement, use and maintenance of these products.
PATH https://www.path.org/who-we-are/programs/market-dynamics/oxygen-delivery-toolkit/	**The oxygen delivery toolkit** provides materials to help decision-makers, implementers and advocates plan, manage and communicate the value of scaling up oxygen delivery systems and access to oxygen and pulse oximetry. **The oxygen business models brief** introduces the oxygen ecosystem that business models operate within and then outlines four types of business models: bulk supply agreements, cash-and-carry filling stations, direct equipment purchases and equipment leasing. **The oxygen generation and storage brief** is intended to be a concise primer for decision-makers who govern, lead, support or manage health systems and their associated facilities. Providing an overview of the key elements that define each technology – as well as key considerations related to COVID-19 – it can establish a starting point for understanding the solutions available to meet a health system's need for medical oxygen and its delivery. It should serve alongside a broader suite of planning and analytical requirements necessary for the implementation of medical oxygen solutions.
UK NHS MGPS Series https://www.england.nhs.uk/wp-content/uploads/2021/05/HTM_02-01_Part_A.pdf	This guidance applies to all medical gas pipeline systems installed in health care premises. It is aimed at health care estates services to help them ensure medical gas pipeline systems are managed effectively. The guidance contains: • HTM 02-01: Medical gas pipeline systems, Part A: Design, installation, validation and verification; and • HTM 02-01: Medical gas pipeline systems, Part B: Operational management.

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