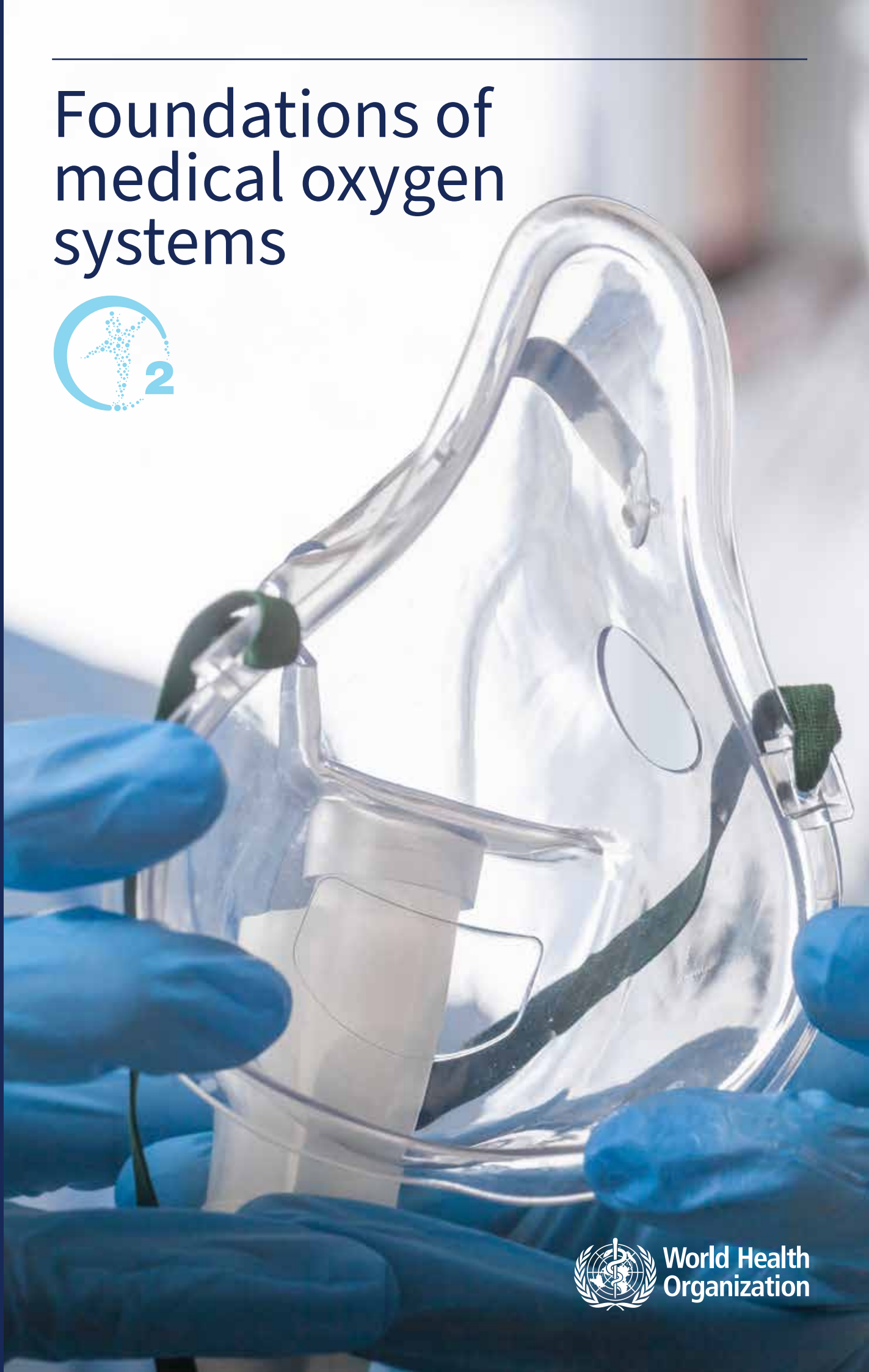
17 FEBRUARY 2023

Foundations of medical oxygen systems



World Health Organization

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Abbreviations

AFNOR	Association Française de Normalisation
AGA	American Gas Association
ALIMA	Alliance for International Medical Action
ASME	American Society of Mechanical Engineers
ASU	air separation unit
AVR	automatic voltage regulator
BPAP	bilevel positive airway pressure
BP	British Pharmacopoeia
BS	British Standard
CGE	Compressed Gas Association (USA)
CHAI	Clinton Health Access Initiative
COA	certificate of analysis
CPAP	continuous positive airway pressure
DIN	Deutsche Industrial Norms
DISS	Diameter Index Safety System
DOT	Department of Transport (USA)
EBC	Every Breath Counts Coalition (public-private partnership)
ESFT	Essential Supplies Forecasting Tool (WHO)
Eur Ph	European Pharmacopoeia
FiO_2	fraction of inspired oxygen
FSC	Free Sales Certificate
GB	Guo Biao (national standards, People's Republic of China)
GDP	good distribution practices
GMP	good manufacturing practices
GOX	gaseous oxygen
HFNC	high-flow nasal cannula
HFNO	high-flow nasal oxygen
HHHF	heated humidified high flow
HTM	Health Technical Memorandum (NHS)
HVAC	heating, ventilation, air conditioning
ICU	intensive care unit
IPC	infection prevention and control
ISO	International Organization for Standardization
JIS	Japanese Institute of Standards
kPa	kilopascal (unit of pressure, metric) (SI)
KPI	key performance indicator
LCC	life cycle cost
L/min	litres per minute

LMIC	low- and middle-income countries
LOX	liquid oxygen
MGPS	medical gas pipeline system
NFPA	National Fire Protection Association (USA)
NHS	National Health Service (United Kingdom)
NIV	Non-Invasive Ventilators
Nm^3/hr	normal cubic metres per hour
NTP	normal temperature and pressure
OEM	original equipment manufacturing
OSPT	Oxygen System Planning Tool (UNICEF)
O_2	oxygen (molecule)
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PMP	preventive maintenance programme
PPE	personal protective equipment
PPM	planned preventive maintenance
PSA	pressure swing adsorption
PSI	pounds per square inch (unit of pressure, imperial)
PSIG	PSI gauge
QA	quality assurance
QC	quality control
RPV	residual pressure valve
SaO_2	arterial oxygen saturation
SARI	severe acute respiratory infection
SI	International System of Units
SLA	service level agreement
Sm^3/hr	standard cubic metres per hour
SPD	surge protection device
SpO_2	peripheral capillary oxygen saturation
STP	standard temperature and pressure
TCO	total cost of ownership
TPED	Transportable Pressure Equipment Directive (European Union)
UNDSS	United Nations Department for Safety and Security
UNICEF	United Nations Children's Fund
USP	United States Pharmacopoeia
VIE	vacuum-insulated evaporator
VPSA	vacuum pressure swing adsorption
VSA	vacuum swing adsorption
VSD	variable speed drive
WFSA	World Federation of Societies of Anaesthesiologists
WHO	World Health Organization
% v/v	percentage volume per volume

Introduction

Oxygen – an element present in the atmosphere – is the second largest component after nitrogen, comprising 20.8% of air by volume. It is the most common medicinal gas used in health facilities.

Medical oxygen is lifesaving and an essential medicine used to ensure safe surgical, emergency and critical care services. It is used at all levels of the health care system and is crucial for the treatment of COVID-19 and other life-threatening conditions such as severe pneumonia, severe malaria, sepsis caused by a wide variety of pathogens, trauma and complications of pregnancy or birth. Unlike many medicines, it has no substitute. Although much work has been undertaken in the oxygen ecosystem over the years, especially in relation to its clinical use, access and availability remain limited in many countries. The COVID-19 pandemic has highlighted this gap. Only collaborative action can truly scale up access to and availability of medical oxygen.

Foundations of medical oxygen systems has been compiled to capture definitions, technical requirements, tools and resources related to medical oxygen systems based on information available as of January 2023. The purpose of this effort is to make relevant and practical material accessible for national authorities, policy-makers, donors, implementing partners, practitioners, biomedical engineers and anyone interested in medical oxygen systems.

This document references key WHO products, which are the result of multidisciplinary efforts related to medical oxygen; its safe use and quality system's implementation. A major gap regarding medical oxygen systems concerns publicly available technical guidance *(1)*, and this document focuses on providing definitions related to medical oxygen systems and the technical and engineering aspects requiring contextualized assessment, implementation and operation. Relevant external resources are outlined, acknowledging the recent enhanced global collaboration made to close the identified gaps which have started to be addressed since the beginning of the COVID-19 pandemic.

Structure

The document has five main sections:

1. Oxygen history, ecosystem and related systems: This section provides definitions, gives a history of the use of medical oxygen, outlines the oxygen ecosystem and describes the different components of oxygen systems.

2. Health facility oxygen systems: This section presents an overview of the onsite technologies for the production, distribution and storage of medical oxygen.

3. Operationalization of oxygen systems: Key operational topics and main concerns related to the design, implementation and use of oxygen systems are covered in this section.

4. Offsite oxygen production: This section provides a brief appraisal of general topics related to the value chain of offsite liquid oxygen (LOX) production.

5. Tools and resources: Here various WHO practical tools, studies and platforms are outlined and links to external relevant resources, all related to oxygen ecosystem.

Method

The contents of this introduction document were developed by WHO collaborators from the Health Care Readiness Department, under the Clinical Pillar led by Janet Diaz, and written by Laura Alejandra Velez with further contributions from Hugues Gaertner. The document is based on information available as of September 2022, and refers to available WHO guidelines and guidance, and ongoing work related to oxygen across a number of WHO units. The WHO technical tools contained in the annexes were developed together with consultants Florestan Boualame, Edgardo Diaz and Ingrid Lara. These tools have been tested via country and regional support in collaboration with WHO biomedical engineers and oxygen focal points. Appropriate WHO confidentiality undertakings were signed and submitted by all individual consultants.

This document contains links to multidisciplinary WHO oxygen-related resources, such as normative products, clinical guidelines, platforms, dashboards, calculators and other publications. Relevant external resources produced by recognized partners belonging to the Oxygen Task Force are outlined. The entities were consulted to approve inclusion of the external resources. WHO is not responsible for the development or use of those tools and simply refers to them as available resources.

The draft document was sent for review to selected internationally recognized entities with technical expertise of the subject matter and which are part of the Oxygen Task Force. The content was reviewed for readability, technical accuracy and usability.

Note: Further information about the Oxygen Task Force can be found at: https://www.who.int/news/item/25-02-2021-covid-19-oxygen-emergency-impacting-more-than-half-a-million-people-in-low--and-middle-income-countries-every-day-as-demand-surges

Confidentiality and Declarations of Interest

The selection of internal WHO participants was based on their involvement in oxygen-related work. The selection of entities, which participated in the external review, was based on their technical expertise of the subject matter. Each entity appointed representatives to undertake content review. The necessary measures to avoid conflicts of interest and to follow the Framework of Engagement with Non-State Actors rules were assessed by the WHO technical unit in consultation with the legal unit, and no conflicts were identified. Appropriate WHO confidentiality undertakings were signed and submitted by all individual consultants of the participating entities.

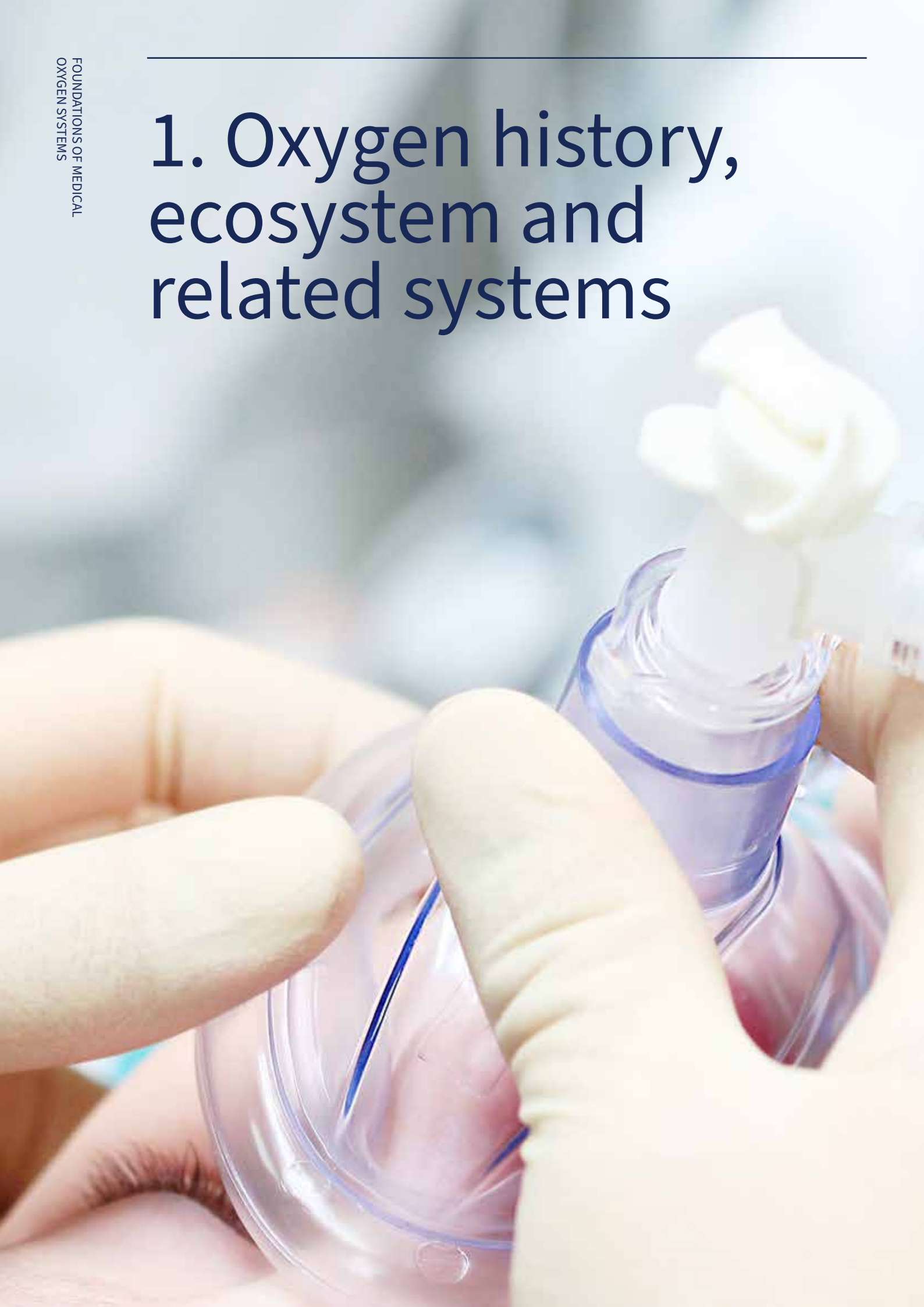
A note on pressure units

This document refers to units derived from the International System of Units (SI). Therefore, references to pressure are expressed in pascal (Pa). However, the units most commonly used by manufacturers are bar or pounds per square inch (psi). To facilitate understanding, pressure values are expressed in kPa with bar and psi conversions provided in the present document. Additional conversion equivalences are shown in Table 1.

Table 1. Pressure unit value equivalents

	kg/cm^2	atm	bar	psi (libra/pulg^2)	kPa	mm hg
1 kg/cm^2		0.968	0.980	14.2	98	736
1 atm	1.033		1.013	14.7	101.3	760
1 bar	1.020	0.987		14.5	100	750
1 psi (libra/pulg^2)	0.070	0.068	0.069		6.894	51.7
1 kPa	0.010	0.010	0.010	0.145		7.50
1000 mm hg	1.360	1.316	1.333	19.33	133.3	

1. Oxygen history, ecosystem and related systems



1. Oxygen history, ecosystem and related systems

1. Oxygen history, ecosystem and systems

This section provides definitions, gives a history of the use of medical oxygen, outlines the oxygen ecosystem and describes the different components of oxygen systems.

1.1 An essential medicine

Oxygen is an essential medicine – lifesaving for many pathologies involving respiratory distress of the patient. Health care professionals use oxygen for respiratory support [1.3] to treat illnesses such as COVID-19, pneumonia, severe malaria and sepsis. It is also essential in ensuring safe surgical, emergency and critical care services.

Access to medical oxygen must be ensured across all levels of care to treat diseases in all patient groups, especially the vulnerable such as older people, pregnant women and newborns. Unlike many medicines, oxygen has no substitute.

The International Pharmacopoeia (2) regional pharmacopoeias (e.g. European Pharmacopoeia [Ph Eur]), and national pharmacopoeias (e.g. United States Pharmacopeia [USP], British Pharmacopoeia [BP]), establish the threshold values and requirements for testing concentration and impurities of oxygen considered for medical applications. As with any other medicine, oxygen production, distribution [1.6] and delivery must be strictly regulated. Recommendations to guarantee the identity, adequacy, continuity and quality of the oxygen for medical use can be found in *WHO Good manufacturing practices for medicinal gases (3).*

In 1979 oxygen was added to *The Selection of Essential Drugs (4)* and although much work has been undertaken in the medical oxygen ecosystem [1.4] since then, especially in its safe clinical use, access, availability and the regulatory framework remain limited in many countries *(1).*

1.2 History of medical oxygen

The history of the use of oxygen in medicine began in the 1770s, when Swedish pharmacist Karl Scheele and British scientist Joseph Priestley independently isolated oxygen gas. It was first administered to a patient in 1890, when Dr Alfred Blodgett used it to treat pneumonia *(5).* Over the years, clinical and technical guidance has been developed for use in many different populations and settings, most recently in the treatment of COVID-19 patients.

Key milestones (Fig. 1.1 and Fig. 1.2):

- In 1971 the first pharmacopoeia monograph on oxygen was published in the *European Pharmacopoeia (6)*.
- In 1979 oxygen was added to the WHO Model List of Essential Medicines, under sections 1. Anaesthetic and 1.1 General anaesthetics and oxygen – only considered for use in anaesthesia *(4).*
- In 1979 the monograph on oxygen was included in *The International Pharmacopoeia.*
- In 2006 technical guidance for system design, installation, validation and verification of oxygen as a medicinal gas was released by the United Kingdom of Great Britain and Northern Ireland's National Health Service (NHS) *(7).*
- In 2017 oxygen was added to the WHO Model List of Essential Medicines for treating hypoxaemia *(8).*
- In 2019 the *WHO-UNICEF technical specifications and guidance for oxygen therapy devices* was published *(9).*
- In 2020 WHO published the *Technical specifications for pressure swing adsorption (PSA) oxygen generator plants (10)*.
- In 2021 WHO revised the monograph on oxygen in *The International Pharmacopoeia (11)* and on good manufacturing practices (GMP) for medicinal gases *(3).*

Key resources

The International Pharmacopeia: https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/norms-and-standards-for-pharmaceuticals/pharmacopoeia
Good manufacturing practices for medicinal gases: https://www.who.int/publications/m/item/trs1044-annex5
WHO Model Lists of Essential Medicines: https://www.who.int/groups/expert-committee-on-selection-and-use-of-essential-medicines/essential-medicines-lists
WHO Oxygen Access Scale Up Initiative: https://www.who.int/initiatives/oxygen-access-scale-up
WHO health topics – oxygen: https://www.who.int/health-topics/oxygen#tab=tab_1
WHO health topics – medical devices: https://www.who.int/health-topics/medical-devices#tab=tab_1

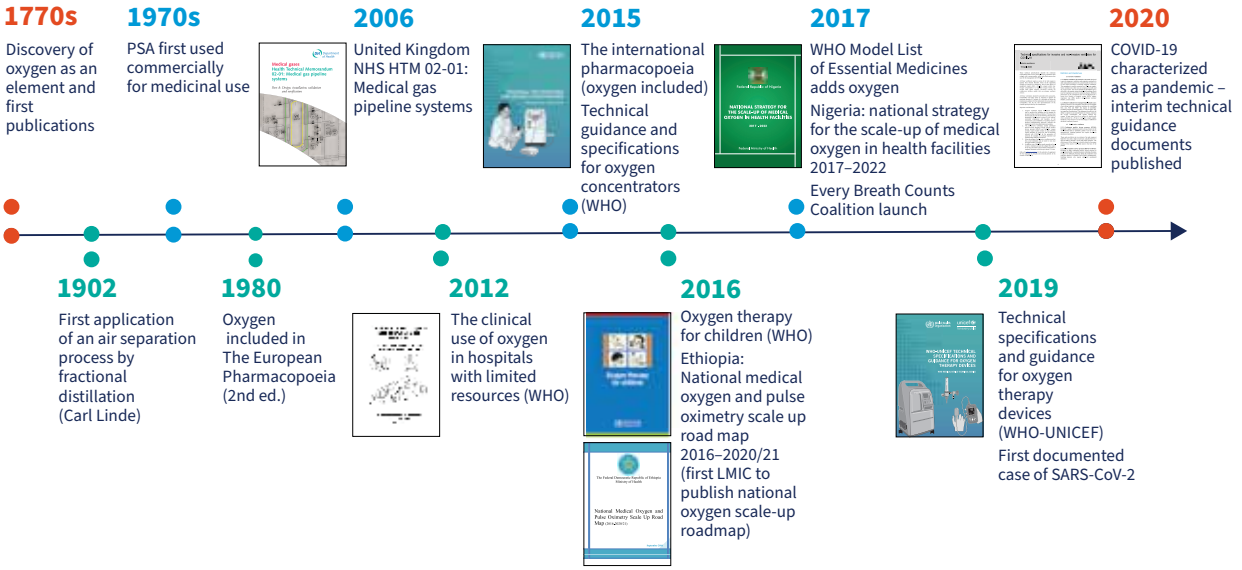


Fig. 1.1 Oxygen history: identifying technical guidance for low- and middle-income countries

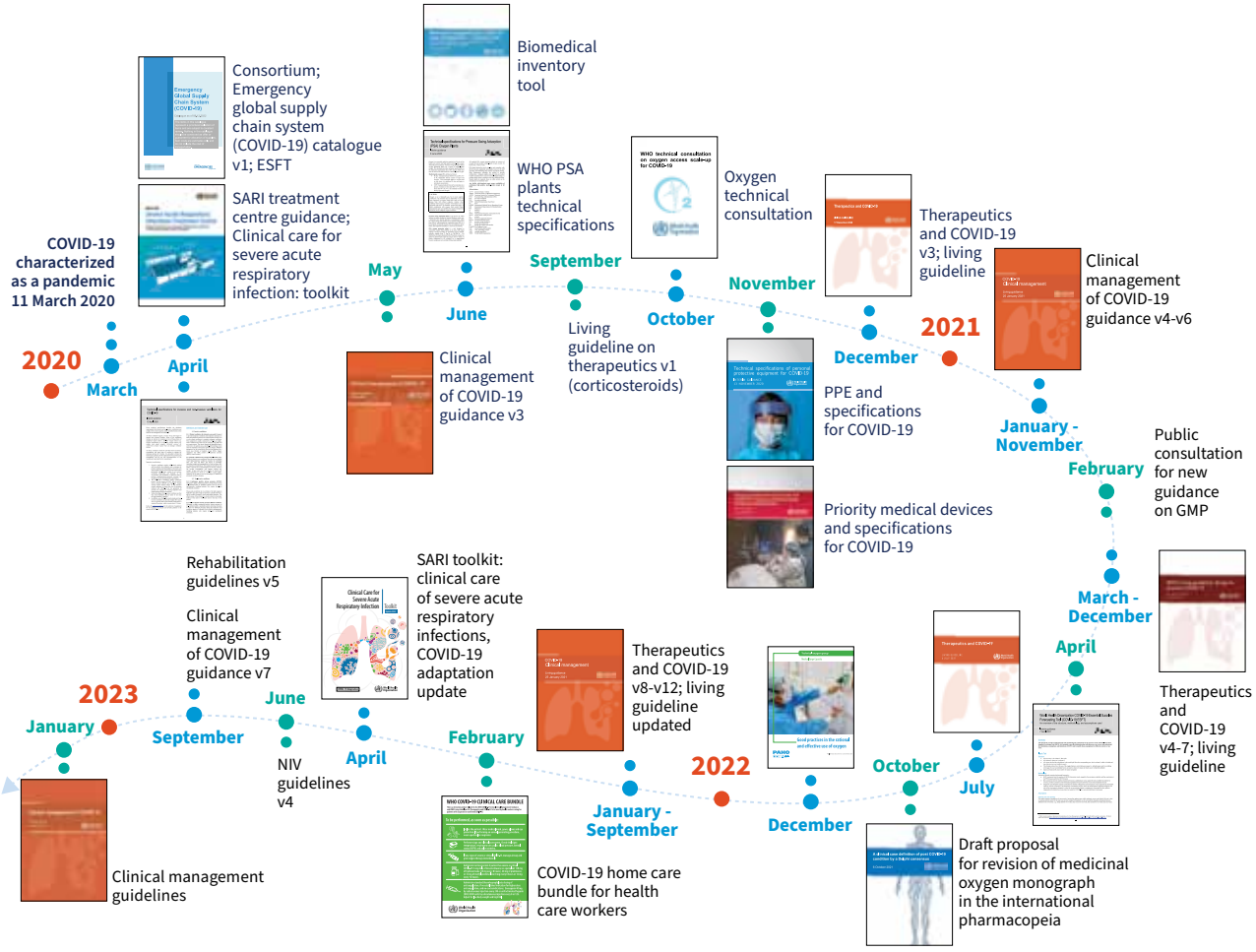


Fig. 1.2 Oxygen history: clinical and technical guidance triggered by COVID-19

1.3 Oxygen therapy and respiratory support: key concepts

Oxygen therapy is the administration of medical oxygen by any means that improves oxygen delivery to the tissues by increasing oxygen content in the blood of hypoxaemic patients. Hypoxaemia is a clinical condition which indicates low oxygen levels in the blood *(12).*

Oxygen therapy is delivered either through an open respiratory circuit (low-flow oxygen therapy such as nasal cannula or a mask) where the fraction of inspired oxygen (FiO_2) is variable, or in a closed circuit (i.e. when on ventilatory support) where FiO_2 is more accurately controlled.

As with any other medicine, delivering medical oxygen to a patient must follow the prescription and instructions of a health worker. These instructions involve providing a clear description outlining how, when, for how long, how much, and the monitoring actions. Specific medical conditions require specific delivery equipment and devices [1.7]. Further information on oxygen therapy can be found in various WHO clinical treatment guidelines [5.1]. Moreover, the clinical treatment guidelines are considered the baseline information to estimate oxygen demand [3.1] for a given health facility.

An overview of key terminology (Fig. 1.3) concerning oxygen administration to the patient follows; however, this is not intended as an in-depth exploration of clinical practice and recommendations.

1.3.1 Oxygen concentration (% O_2)

Medical oxygen is acquired from ambient air by a concentration method that varies depending on the production source. Independent of the production method, resulting in either gas or liquid oxygen (LOX), medical oxygen is always delivered to the patient in gas form which is without colour, odour and taste.

Oxygen concentration (% O_2) – or oxygen purity – is the amount on oxygen present in the final product, which can range depending on the source. *The International Pharmacopoeia (2)* establishes that when produced cryogenically, "oxygen contains not less than 99.5% v/v of O_2". However, when produced by means of oxygen generator plants through molecular sieves (i.e. no liquification), then the minimum standard for medical grade is 93% (90–96%).

The International Organization for Standardization (ISO) 80601-2-69:2020 *(13)* covers the specific requirements for the safety and essential performance of bedside concentrators [1.6.1], and stipulates that oxygen purity should typically be 82–96%. *WHO-UNICEF technical specifications and guidance for oxygen therapy devices (9)* state the production of oxygen by bedside concentrator devices must attain a concentration of > 82% and trigger an alarm if the level falls below this level.

1.3.2 Fraction of inspired oxygen (% FiO_2)

The FiO_2 is the percentage of oxygen concentration participating in gas exchange in the alveoli.

FiO_2 depends on:

- oxygen flow rate;
- delivery interface;
- patient's minute ventilation (which is related to respiratory rate and tidal volume); and
- entrainment of ambient gas by the patient during each spontaneous inspiration (when applicable).

Regardless of the delivery device (non-invasive or invasive) during respiratory support, the patient is continuously receiving a mixture of medicinal air and oxygen. The application of 100% oxygen for long periods of time could be toxic for the patient.

1.3.3 Measured oxygen levels in the blood (% SpO_2)

Arterial blood oxygen saturation (SaO_2) is usually determined by blood gas analysis. Peripheral capillary blood oxygen saturation (SpO_2) is measured non-invasively using pulse oximetry.

- % SpO_2 is used to determine whether patients are hypoxaemic (usually < 90%) and require oxygen therapy.
- % SpO_2 is the ratio of red light not absorbed by deoxygenated haemoglobin (the coloured substance in blood which carries oxygen) to infrared light not absorbed by the oxygenated haemoglobin.

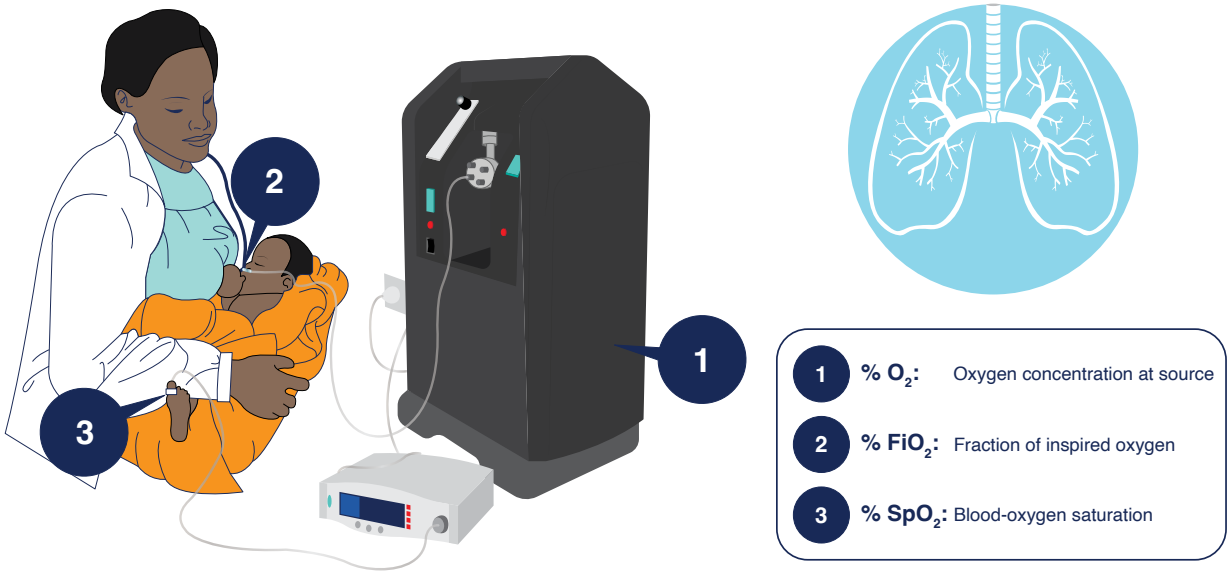


Fig. 1.3 Key terminology: % O_2, % FiO_2 and % SpO_2

Source: Technical specifications for oxygen concentrators (WHO, 2015) *(14).*

1.4 Elements of the oxygen ecosystem

The oxygen ecosystem (Fig. 1.4) refers to holistic efforts, initiatives and resources across health systems, that are required for an optimal and sustainable implementation of oxygen systems [1.5]. To accomplish this, stakeholders must have the ability to incorporate, adopt, operationalize and sustain investments into health systems at the country and facility level by providing policies and health system frameworks, health financing, multidisciplinary guidelines, country roadmaps, qualified and appropriately robust multidisciplinary teams, physician engagement initiatives, patient safety and quality of care programmes, biomedical engineering strengthening, and other structural and non-structural actions. All these aspects take part in the interdependent activities for ensuring a reliable and continuous cycle of provision of quality and safe medical oxygen, which ultimately will reach the patient.

1.5 Oxygen systems

The oxygen systems for medical use include, but are not limited to, oxygen production, storage, distribution [1.6] and delivery supplies, as well as various items for flow regulation, conditioning [1.9], quality assurance (QA), quality control (QC) and safety, that are embedded into the dynamics of the oxygen ecosystem [1.4]. It is important to contextualize and regularly evaluate the implementation and functioning of oxygen systems, together with re-assessing the environment in which they operate and ultimately impact the patient (Fig. 1.5). The long-term sustainability of oxygen systems requires a holistic approach and a resource ecosystem focused not only on oxygen production but also on distribution and delivery, ongoing maintenance and upkeep.

Oxygen systems are affected by both internal and external factors:

- Internal factors include human and material resources allocated to implement the oxygen systems, from assessing the need, decision-making on solutions and their implementation, training of staff in correct use and maintenance, up to allocation of financial resources for installation, running and maintenance costs.
- External factors cover the environmental and contextual conditions, such as geographical location, product and service providers, technical and clinical availability and capacities, partnerships, financial and donor entities, policy-makers, health systems planners and technological upgrades.

Fig. 1.4 Oxygen ecosystem

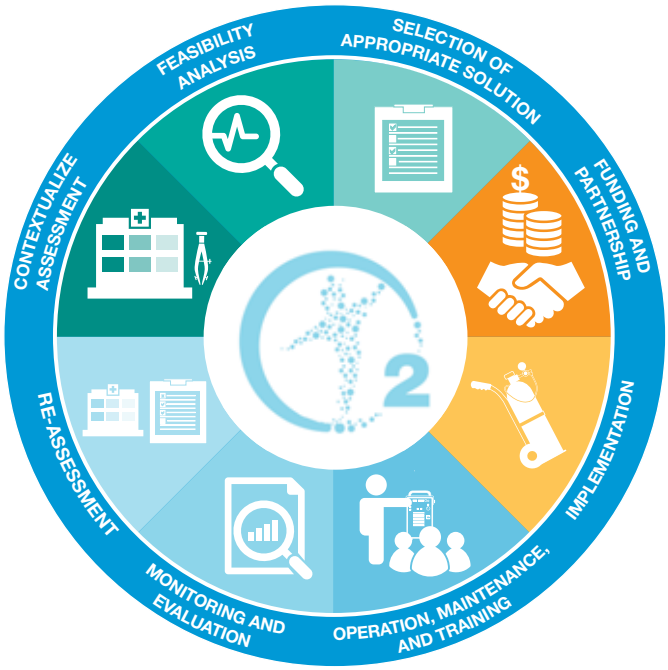


Fig. 1.5 Life cycle of oxygen systems

To enable access to high-quality, safe and continuous oxygen systems the following are required:

- sustained financial resources;
- appropriate policy and regulatory frameworks;
- regular needs and feasibility assessment;
- available, appropriate, trained clinical and technical workforce;
- available, appropriate, affordable and well-maintained source, storage, distribution and delivery systems; and
- system monitoring: reporting and tracking key performance indicators (KPI).

The appropriate choice of oxygen systems is multifactorial. It is based on the need-gap assessment and the absorptive capacity of the health facility, which includes available technical workforce, infrastructure, reliability of power supply [3.5.3], access to maintenance services and spare parts, among others. Unfortunately, an important standard procedure of preparing backup plans *(15)* to ensure continuous access to oxygen, even in case of emergency, is often disregarded due to budget availability and structural design.

1.6 Oxygen production, storage and distribution

The production of medical oxygen can either take place onsite in health facilities, or offsite at manufacturing sites. Even if different standards apply to each production method and site, the process to concentrate, store and transport medical oxygen must follow strict regulations for QA and verifications for QC conducted by certified specialized laboratories.

The concentration of medical oxygen is possible because of air separation units (ASU), which separate nitrogen and oxygen, and sometimes also argon and other rare inert gases, from atmospheric air. The different separation methods to obtain concentrated oxygen are:

- cryogenic fractional distillation [1.6.3], which generates a liquid oxygen (LOX);
- pressure swing adsorption (PSA) [2.1], which generates a gas oxygen product;
- vacuum swing adsorption (VSA) [2.1], which also generates a gas product; and
- vacuum pressure swing absorption (VPSA) [2.1] – a mixed technology, which combines engineering systems of pressure variations from positive (PSA) to negative (VSA) at different stages of the overall process to concentrate oxygen.

Further to quality requirements, understanding the relation between pressure and flow depending on the product form is crucial to properly design systems for storage, transport and distribution; namely high-pressure gas cylinders [2.8], bulk tanks [2.10.1], cryogenic cylinder [2.10.2] and pipeline networks [2.9]. Temperature and pressure will affect the flow of concentrated oxygen depending on whether it is in liquid or gas form.

In a health facility, there will normally be a primary and secondary source and, it is important to consider the preparation for backup supply [3.4.4], via redundancy (duplication of the system) or a combination of different technologies, for example, high-pressure gas cylinder stocking. If applicable, where there are existing medical gas pipeline systems (MGPS) [2.9], each of the sources will be interconnected through a pneumatic changeover system [2.7] to ensure uninterrupted supply.

1.6.1 Bedside concentrators: oxygen production and delivery

A bedside oxygen concentrator (or oxygen extractor) is a self-contained medical device normally designed and manufactured for the sole purpose of home care *(9).* However, WHO acknowledges this solution remains a vital resource for many outreach settings in low- and middle-income countries (LMIC). Further information can be found in the *WHO technical specifications for oxygen concentrators (14).*

This portable “plug and play” medical equipment uses PSA technology to generate flow rates of, typically, 5, 8 or 10 L/min. Currently in the market, there are “oxygen concentrators” with higher production capacity (flow rate capacity up to 30 L/min) intended to be used for health care facilities with little or no access to medical oxygen, especially those which have operating theatres and intensive care units (ICUs), as they can offer an output pressure of around 345 kPa (3.45 bar or 50 psi). To date, technical data on the quality and cost-effectiveness of this solution are still relatively poor.

This equipment is situated onsite, generally at the bedside, and the oxygen generated is directly supplied to patients through non-invasive delivery devices [1.7.1].

1.6.2 Oxygen generator plants: oxygen production, storage and distribution

PSA, VSA or VPSA plants [2.1] are an assembly of different equipment often situated onsite, at facility level. The plants are sized to produce different flow rates ranging from 2–200 Nm^3/hr depending on the capacity of their air compressor. Further information about PSA plants is described in technical requirements [2.2], sizing and configuring [2.3] and PSA system costs [2.4].

The oxygen concentrated in gas form by these plants will be distributed directly to the medical gas pipeline system (MGPS)[2.9], or through high-pressure gas cylinders [2.8] filled at a cylinder filling station [2.5] (composed of a booster compressor and filling ramp). The high-pressure cylinders serve to store the gas product, which is then transported to the patient's bedside with proper conditioning and regulation devices [1.9] or connected to a distribution ramp [2.6]. This distribution ramp is always connected to a MGPS. In some countries bedside use of high-pressure cylinders is prohibited for safety reasons.

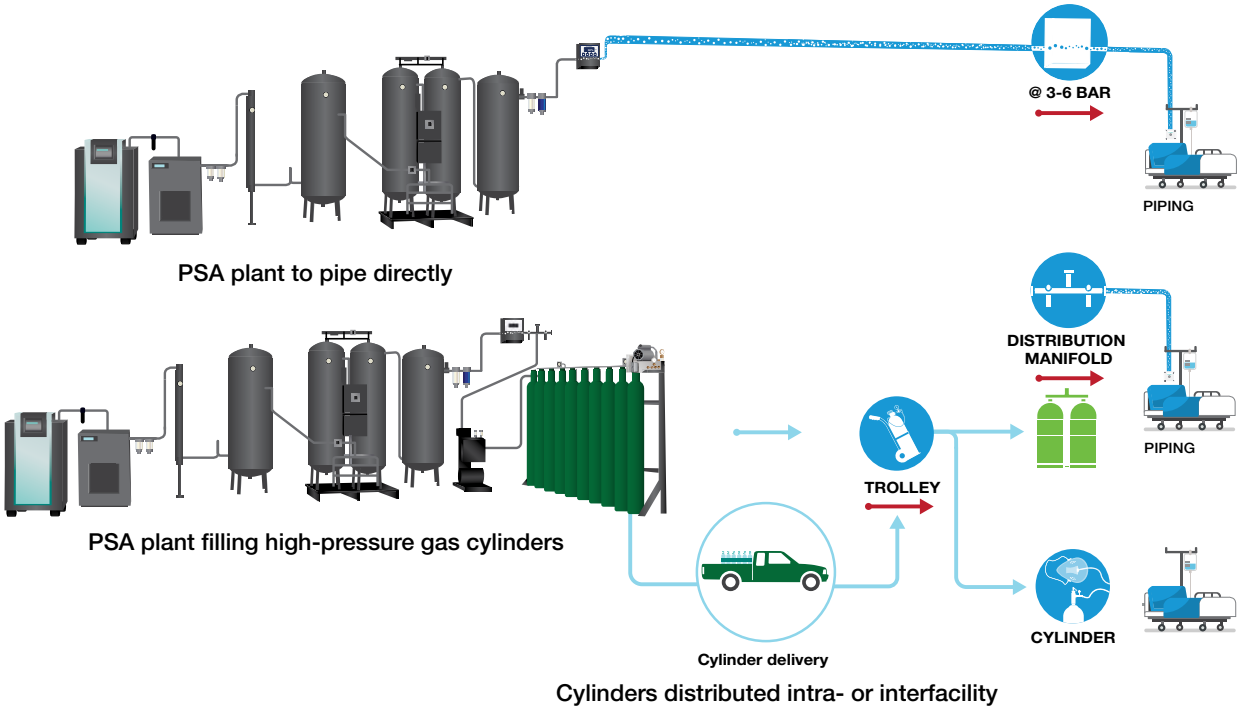


Fig. 1.6 Distribution of oxygen produced by a primary line coming from a PSA plant

1.6.3 Cryogenic fractional distillation plants: liquid oxygen (LOX) production, storage and distribution

Oxygen in liquid form is less bulky and less costly to transport than the equivalent capacity of high-pressure gaseous storage. One litre of liquid oxygen is equivalent to 798 L gas at Normal Temperature and Pressure (NTP), or 861 L at Standard Temperature Pressure (STP). In Table 1.1 are shown the definitions of normal and standard temperature and pressure conditions.

Table 1.1 Definitions of temperature and pressure conditions *(16)*

	NTP (normal temperature and pressure)	STP (standard temperature and pressure)
Pressure	101.3 kPa (1.013 bar or 14.7 psi)	100 kPa (1 bar or 14.5 psi)
Temperature	20 °C	0 °C

Air separation unit (ASU) plants for production and bulk LOX storage are situated offsite and typically managed by private companies who are responsible for the entire value chain [4.1]. Such production serves for industrial and medical sectors [4.1], in which the latter have more stringent requirements on the compliance with GMP and good distribution practices (GDP). The distribution sites where large bulk storage tanks with specialized high-pressure vaporizer and cryopump are installed to transform the LOX into gas oxygen (GOX) before distribution to health facilities are normally subsidiaries of the same third-party manufacturing company.

The distribution pathway is very variable, as oxygen can be supplied from the production or distribution site to health facilities, either in liquid or gas form as depicted in Fig. 1.7. The transportation of LOX must comply with strict international and/or national regulations for handling of cryogenic pressure vessels. These containers can vary their capacity from litres to many tonnes. Since heat leak (ingress) and surface evaporation are always present, vaporization is continuously taking place, creating waste product. The loss factor is sensitive to the size and isolation technology of the tank and ambient conditions – it can be as much as ~5% loss per day. This should be reviewed on a case-by-case basis with manufacturers' specifications at the design stage.

Table 1.2 depicts the main oxygen production sources with additional considerations.

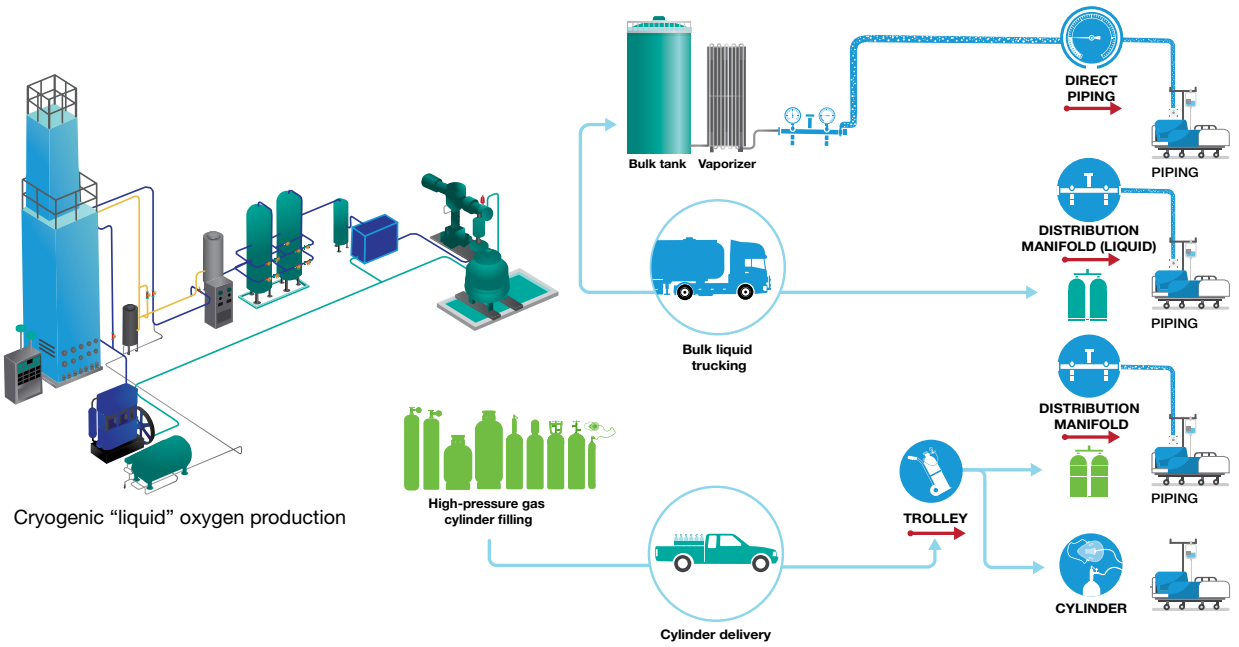
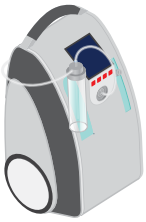
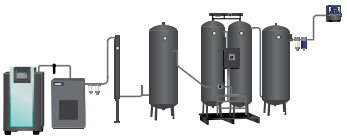
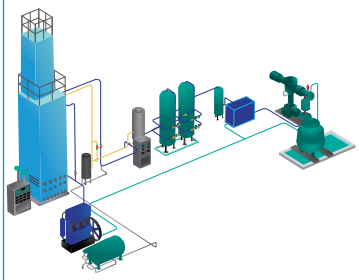


Fig. 1.7 Distribution of cryogenically produced oxygen (liquid and gas)

Table 1.2 Oxygen production

Oxygen production sources	**PSA bedside concentrator** (gas O_2 generator) 	**PSA, VSA, VPSA plant** (gas O_2 generator) 	**Cryogenic fractional distillation plant** (liquid O_2 generator) 
Additional considerations	• Continuous and reliable electrical source is required during operations. • Device-specific spare parts need. • Timely technical maintenance need. • Need to follow infection prevention control (IPC) measures as situated bedside. • Inefficient for large-scale provision. • Flow could be split among patients, depending on oxygen therapy [1.3] needs and available mandatory ancillary devices (e.g. flow splitter). • Low-pressure output and limited flow output. So, usually not suitable for higher flow or higher pressure needs (e.g. patient ventilators.	• Continuous and reliable electrical source is required during plant and booster operations. • Device-specific spare parts need. • Timely specialized technical maintenance need. • Detailed financial planning for long-term operations required (~20 years). • Various own/operate models. • Need trained technicians to ensure continuous operations and regular maintenance.	• Typically, the recipient facilities will engage with contracts with the third party. • Detailed financial planning for long-term operations required (~20 years). • Need trained technicians to ensure continuous operations and regular maintenance.

Note: Complementary details about these sources can be found in *WHO-UNICEF technical specifications and guidance for oxygen therapy devices (9).*

1.7 Delivery equipment and devices

The oxygen systems [1.5] also include medical devices for delivering oxygen to patients, as well as patient monitoring devices [1.8], such as pulse oximeters, which are also required for measuring patient oxygen saturation levels (SpO_2) [1.3.3] to detect hypoxaemia [1.3] (Fig. 1.8).

Delivery equipment and devices serve as an interface to provide oxygen to the patient. The appropriate selection of these devices depends on the specific medical condition and treatment needs of the patient. Refer to WHO clinical treatment guidelines [5.1] and recommendations for the right selection and use of medical devices for the administration of oxygen.

The *Priority medical devices list for the COVID-19 response and associated technical specifications: interim guidance (17)* includes the minimum technical specifications to ensure the safety and quality of the medical devices required for administering medical oxygen. Some of these specifications have been adapted from *WHO-UNICEF technical specifications and guidance for oxygen therapy devices (9).*

The technologies classified as medical devices must follow specific regulations to guarantee safety, efficiency and quality during design, manufacture, operation and maintenance.

The selection, adaptation and adoption of the technical specifications for procurement are always context related and should consider the life cycle and total cost of ownership (TCO) of the equipment.

Adequate installation, use and maintenance of medical devices must be in accordance with manufacturers' recommendations.

Infection prevention and control (IPC) measures, such as cleaning, disinfection, and/or sterilization methods for reusable medical devices, must be followed *(18) (19).* Likewise, IPC measures while using reusable medical equipment and accessories, must be implemented *(20) (21).* This includes adequate selection of personal protective equipment (PPE) to minimize the risk of infections in health care providers.

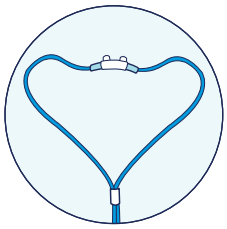
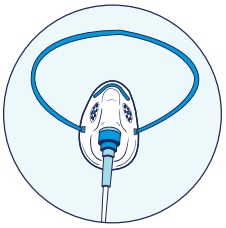
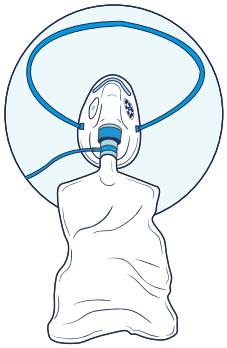
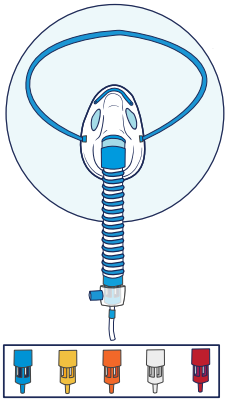
For more information about medical devices and innovative technologies for LMIC see WHO *Medical devices (22)* and *WHO compendium of innovative health technologies for low-resource settings (23).*

1. **Monitor:** The screen displays vital signs parameters such as such as blood pressure measurements and heart rate. An alarm is activated when abnormal vital signs develop.
2. **Suction device:** Excess secretions are regularly removed from the airways using suction.
3. **Oxygen supply:** Every bed area should have an oxygen supply available at all times.
4. **Pulse oximeter sensor:** The level of oxygen saturation in the blood (SpO_2) is measured painlessly with probe on the finger or earlobe.
5. **Ventilator tubing and face mask:** These consumables are the interface between equipment and patient.
6. **Ventilator:** This equipment provides respiratory support by inflating the lungs with a mixture of oxygen and air.

Fig. 1.8 Medical devices related to oxygen therapy used in an intensive care unit

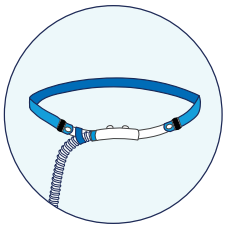
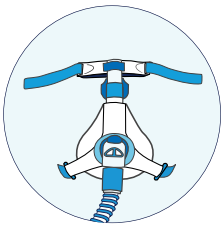
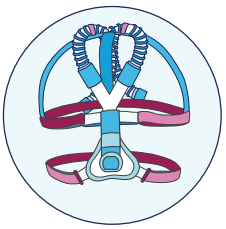
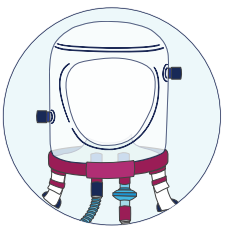
1.7.1 Non-invasive delivery devices

Non-invasive devices (Fig. 1.9) are connected directly to the output of a conditioning device [1.9], which in turn is connected to either a bedside oxygen concentrator [1.6.1], wall outlet [2.9.2] or to a high-pressure gas cylinder [2.8]. Most of these are intended for single-patient use. However, more advanced non-invasive devices (Fig. 1.10) are commonly connected to patient ventilators and frequently designed to be reusable – following reutilization measures and lifespan recommended by the manufacturer.

Non-invasive O_2 delivery devices			
Nasal cannula	**Face mask**	**Face mask reservoir bag**	**Venturi face mask**
			
O_2 flow 1-5 L/min	O_2 flow 5-10 L/min	O_2 flow 10-15 L/min	O_2 flow 2-15 L/min
FiO_2 0.23-0.35*	FiO_2 0.30-0.50*	FiO_2 0.24-0.60*	FiO_2 0.50-0.85*

* Delivered O_2 concentration depends on multiple factors including the concentration of the oxygen source and the patient's respiratory pattern (e.g. peak inspiratory flow and minute ventilation).
O_2 flow ranges differ for neonates, children and adults.

Fig. 1.9 Non-invasive delivery devices

Advanced non-invasive O_2 delivery devices				
High-flow nasal oxygen	**BPAP/CPAP**			
				
	Oronasal	**Nasal**	**Full face**	**Helmet**
O_2 flow 10-60 L/min	O_2 flow ~10-80** L/min			
FiO_2 0.23-1.00*	FiO_2 0.21-1.00*			

* Delivered O_2 concentration depends on multiple factors including the concentration of the oxygen source and the patient's respiratory pattern (e.g. peak inspiratory flow and minute ventilation).
** O_2 consumption for BPAP/CPAP is widely variable depending on device used and the leak of the system.
O_2 flow ranges differ for neonates, children and adults.

Fig. 1.10 Advanced non-invasive delivery devices

1.7.2 Patient ventilators: non-invasive and invasive

Non-invasive respiratory support is provided by Non-Invasive Ventilators (NIV), high-flow nasal cannula (HFNC), heated humidified high-flow (HHHF) therapy or high-flow nasal oxygen (HFNO). This equipment is used in the escalation of respiratory support [1.3] in adults and children during the titration of oxygen for pneumonia *(12)*. Continuous positive airway pressure (CPAP) is not considered as non-invasive ventilator but is an equipment sometimes used for respiratory support. Table 1.3 shows the equipment used for advanced non-invasive respiratory support.

Table 1.3 Advanced non-invasive respiratory equipment and intended use

Non-invasive respiratory equipment	Intended use
NIV (e.g. BPAP)	Allows clinicians to adjust pressures for inspiratory and expiratory phases of a breath to non-intubated adult or paediatric patients.
HFNC, HHHF, HFNO	Allows clinicians to deliver high flow rates with heated humidification to non-intubated adult or paediatric patients.

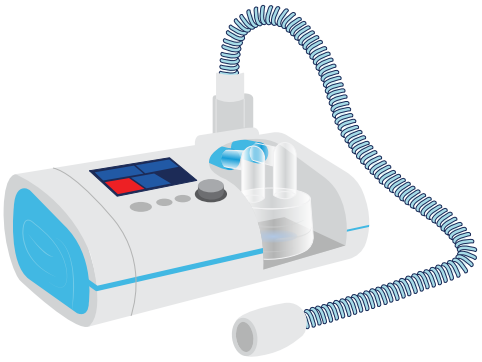


Fig. 1.11 Non-invasive ventilator

Invasive ventilators are mainly used in ICUs for long-term respiratory support. Certain modes of operation require highly trained medical staff to perform intubation and to set the pressure and/or volume settings, controls and alarms. The FiO_2 [1.3.2] can be adjusted according to the concentration of oxygen prescribed by the physician up to 100% of medical oxygen. Table 1.4 shows the equipment used for invasive respiratory support.

Table 1.4 Invasive respiratory equipment and intended use

Invasive respiratory equipment	Intended use
ICU	To provide temporary ventilatory and respiratory assistance to adult and paediatric intensive care patients.
Transport	To provide temporary ventilatory assistance with a full degree of portability (weight and manageability).
Subacute care	To provide mainly non-invasive ventilation, but in case of an emergency, it can also provide temporary invasive ventilation to patients who cannot breathe on their own or who require assistance to maintain ventilation.

The ICU ventilators require weekly calibration of the integrated oxygen cell with the supply of ~100% oxygen concentration. This can be achieved by using a high-pressure cylinder with appropriate regulator temporarily connected to the inlet to allow calibration of the ventilator between 21–100% values.

Fig. 1.12 Patient ventilator for intensive care unit

1.7.3 Flow and pressure parameters per delivery equipment and devices

The delivery equipment (i.e. patient ventilators) may require a source of medical air and/or medical oxygen to operate.

For instance, the most commonly used invasive ventilators require high-pressure medical oxygen and air to operate. Some of them can have an in-built air compressor, and a few models can operate with low-pressure oxygen coming from bedside oxygen concentrators [1.6.1].

When required, the stream of high-pressure medical oxygen could be supplied by an oxygen generator plant [2.1], high-pressure gas cylinders [2.8], or cryogenic vessels [2.10], as long as the source has been certified for medical use.

On the other hand, non-invasive ventilators mostly operate with air only, sometimes integrating an in-built air compressor or turbine unit. However, certain equipment like the HFNC can generate a high flow of mixed air and medical oxygen, allowing the user to control the administration of oxygen in L/min but not the level of FiO_2 [1.3.2].

Regardless of the needs for high- or low-pressure medical gases at the inlet of the delivery equipment, the oxygen will be delivered to the patient with low pressure (regulated by a pressure regulator) and variable flow by an independent or integrated flowmeter *(9)*.

Table 1.5 presents a variety of delivery equipment with the different user interfaces devices, showing variable outputs of flow and pressure before reaching the patient.

Table 1.5 Oxygen delivery: flow and pressure considerations for various combinations of delivery equipment and devices

Flow/pressure at the output		Delivery device						
		Bedside concentrator	**High-pressure cylinder**	**Wall outlet**	**Non-invasive ventilator**	**HFNC**	**Invasive ventilator *(21)*: non-invasive mode**	**Invasive ventilator *(21)*: invasive mode**
User interface	**Non-invasive delivery devices: nasal cannula, face mask, venturi face mask, face mask with reservoir bag**	Low-flow (device dependant) and low pressure	Variable flow (0–70 L/min *(22)*) and regulation to low pressure	Variable flow (0–70 L/min *(22)*) and regulation to low pressure	*Not applicable*	*Not applicable*	*Not applicable*	*Not applicable*
	Advanced non-invasive devices: high-flow nasal oxygen	*Not applicable*	*Not applicable*	*Not applicable*	*Not applicable*	Variable flow (from 10–60 L/min) and regulation to low pressure by the ventilator	Variable flow (10–60 L/min) and regulation to low pressure by the ventilator	*Not applicable*
	Advanced non-invasive devices: oronasal, nasal, full face, helmet	*Not applicable*	*Not applicable*	*Not applicable*	Variable flow (from 10–80 L/min) and regulation to low pressure by the ventilator	*Not applicable*	Variable flow (from 10–80 L/min) and regulation to low pressure by the ventilator	*Not applicable*
	Closed breathing circuits with endotracheal or tracheostomy interface	*Not applicable*	*Not applicable*	*Not applicable*	*Not applicable*	*Not applicable*	*Not applicable*	Variable flow (0–120 L/min) and regulation to low pressure by the ventilator

1.8 Patient monitoring

Equipment for vital sign patient monitoring (e.g., heart rate, blood pressure, respiratory rate,temperature and oxygen saturation) is used widely at all levels of the health system. Patient monitoring is essential when providing oxygen therapy [1.3]. The research community is continuously refining the regulation around qualified and accurate medical devices for this purpose.

Pulse oximeter (Fig. 1.13): A pulse oximeter is a medical device designed for non-invasive monitoring of haemoglobin oxygen saturation (SpO_2) [1.3.3], by comparing the absorbance of light of different wavelengths across a translucent part of the body.

Pulse oximetry is accepted globally as the most reliable, accurate, affordable way for health care workers to continuously and/or spot measure blood SpO_2.

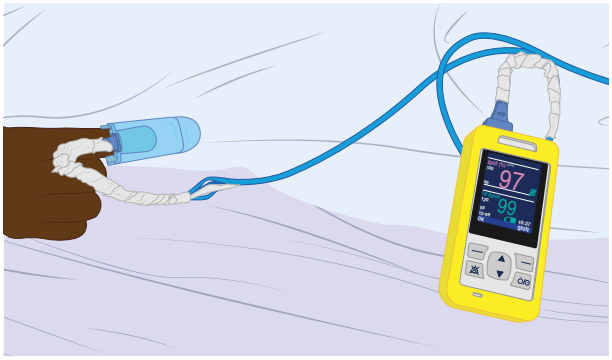


Fig. 1.13 Pulse oximeter

Patient monitor (Fig. 1.14): Patient monitors are designed to measure vital signs and, in some cases, other physiological parameters of a patient. Depending on the number of parameters, monitors are classified as basic, intermediary or advanced. When used in oxygen therapy, patient monitors must include the SpO_2 [1.3.3] parameter and sensor *(16).*

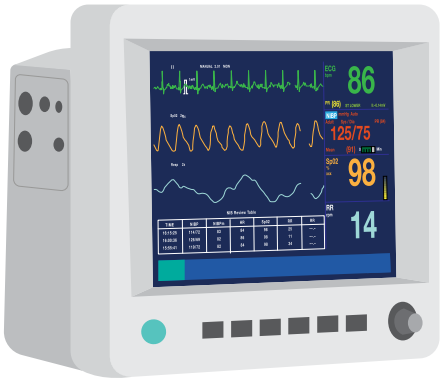


Fig. 1.14 Multiparameter monitor

1.9 Conditioning, regulation and testing devices

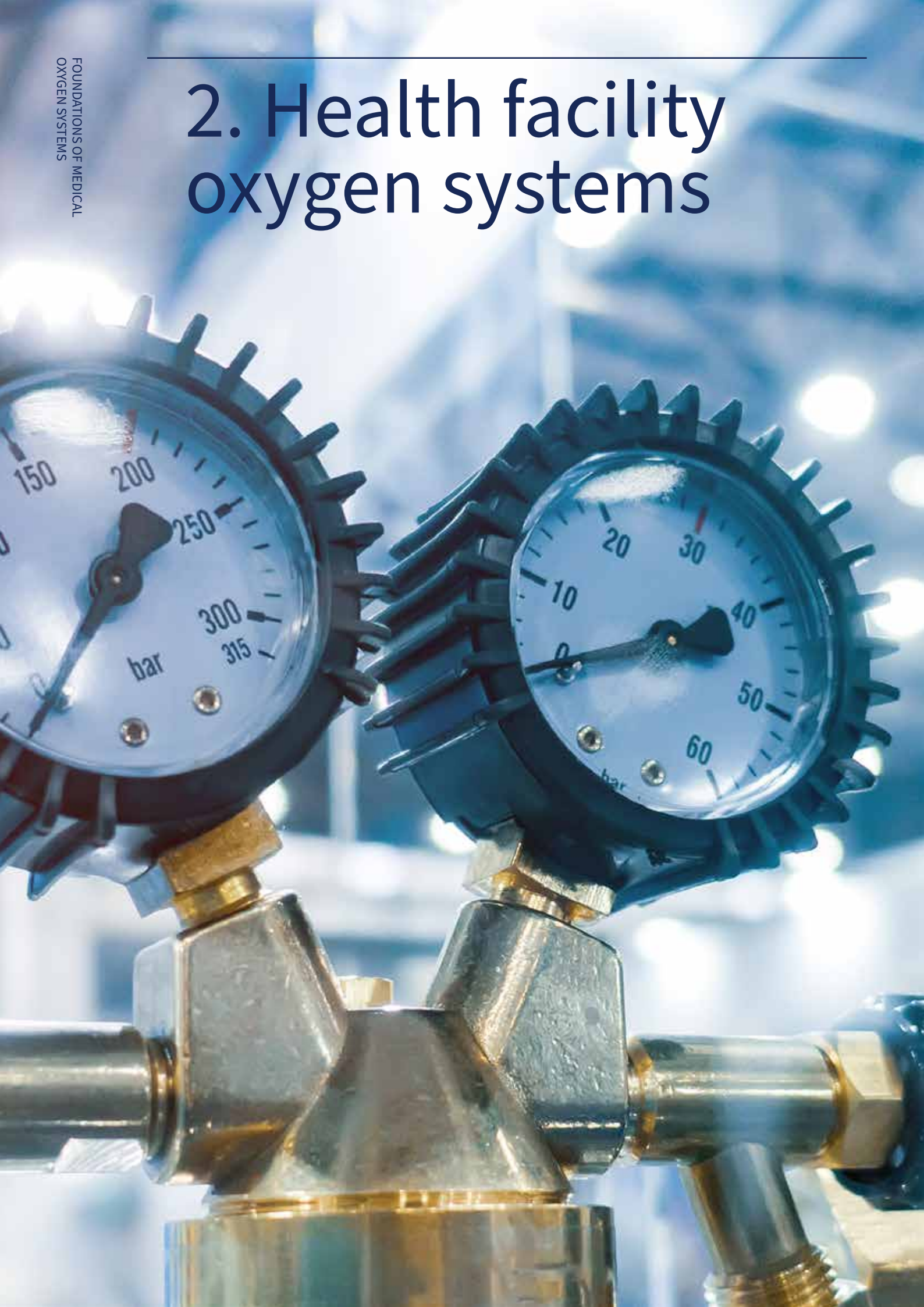
Across storage, distribution and delivery of oxygen, different equipment is used to control pressure, flow, humidity and concentration of the oxygen. Some of these devices include pressure regulators, flowmeters, valves, flow splitters, humidifiers and oxygen analysers (see Fig. 1.16).

Fig. 1.15 Oxygen outlet: conditioning and regulation using a flowmeter

Fig. 1.16 Oxygen analyser

Note: Further specifications can be found in *WHO-UNICEF technical specifications and guidance for oxygen therapy devices (9).*

2. Health facility oxygen systems



2. Health facility oxygen systems

2. Health facility oxygen systems

This section presents an overview of the onsite technologies for the production, distribution and storage of medical oxygen.

2.1 Onsite production technologies: PSA, VSA and VPSA

Although there is extensive and detailed available information on bedside oxygen concentrators [1.6.1], there are considerable gaps in publicly available technical material related to at scale onsite production sources [1.6.2] (i.e. oxygen generator plants) *(24)*. The following informations cover at scale technologies only.

Oxygen generator plants are an assembly of different equipment. The two existing technologies to perform this process are PSA and VSA (Fig. 2.1). Depending on the technology, PSA or VSA, the assembly will comprise an air compressor or blower, always followed by a dryer, filters, a compressed air tank, dual separation chambers (sieve beds), a product tank/reservoir and controls and alarms. Along the assembly there are copper pipes and hoses that are specific and certified for high-pressure gases. The whole assembly should be certified for medical application.

The process of oxygen concentration begins by compressing ambient air. This air then passes through a filtration assembly to remove any particulate matter and remaining moisture. Afterwards, it goes through a molecular sieve containing zeolites that adsorb or retain almost all the nitrogen molecules, while the oxygen, along with a few other elements, passes through resulting in a concentrated oxygen product. The purity of the concentrated oxygen should be 93% ±3% *(2)*. The oxygen production capacity varies depending on the model, typically ranging from 2–200+ Nm^3/hr, which has a reference condition of temperature at 0°C for an absolute pressure 101.3 kPa [1.013 bar or 14.7 psi]. Sometimes the production capacity will be expressed in Sm^3/hr which means that the flow rate is based on standard reference conditions (temperature 20 °C and absolute pressure 101.3 kPa [1.013 bar or 14.7 psi]. Therefore, depending on the measurement units used this will determine the actual gas volume produced.

It is useful to distinguish the key differences between PSA and the newer VSA technologies, starting with the technology used to create the gas flow:

- PSA plants use a compressor to push the gas by pressure through the sieve beds.
- VSA plants use a vacuum system to suck the gas into the production equipment.

Additionally, for VSA the main operating differences from PSA are:

- Oil-free blower – results in lower requirements for filtration and eliminates the risk of oil carry over downstream of the oxygen system [1.5].
- Higher efficiency in humid environments due to lack of need of the air dryer component.
- Operation is less affected by altitude above the sea level.
- In certain cases, VSA minimizes the potential for water condensation, by cooling the feed gas for the molecular sieve beds to within 10 °C of the prevailing ambient temperature.
- VSA sieve beds have a longer projected lifespan and require less maintenance than those for PSA.
- Lower output pressure, after the molecular sieve beds, ranges from 130–420 kPa (1.3–4.2 bar or 18.85–60.89 psi). As this is below the common requirements for pipeline networks, this generally adds the need for an oil-free booster compressor [2.5] to attain 689 kPa (6.89 bar or 100 psi).
- Regarding electrical consumption and costs: the absence of an air dryer may lower overall consumption; however, the addition of a booster may increase it.

Key resources

WHO-UNICEF technical specifications and guidance for oxygen therapy devices: https://apps.who.int/iris/handle/10665/329874

WHO technical specifications for oxygen concentrators: https://apps.who.int/iris/handle/10665/199326

Technical specifications for pressure swing adsorption (PSA) oxygen plants: https://apps.who.int/iris/handle/10665/332313

In terms of capital expenditure, VSA plants are approximately 15% higher than PSA plants because of the additional booster compressor. Nevertheless, when the units are generating > 100 Nm^3/hr, this margin drops off and VSA affordability falls more in line with PSA.

A hybrid system exists which consists of a combination of the two technologies, called vacuum pressure swing adsorption (VPSA). These systems apply pressurized gas to the separation process as well as a vacuum to purge gas. This technology is generally preferred when oxygen need is higher than normal and large-scale production is required, because it combines the benefits from VSA and PSA systems. However, it involves some complexity in the configuration of the equipment which makes VPSA a significant cost investment.

In general, VSA technology is restricted in availability due to the low number of manufacturers and suppliers worldwide marketing the technology for medical application. However, several major PSA manufacturers offer VSA and PSA technologies, and some of them even include VPSA hybrid designs. Regardless of the technology, training on these oxygen generation systems should be generic in nature, to empower the workforce to be appropriately skilled to operate and maintain any of the systems.

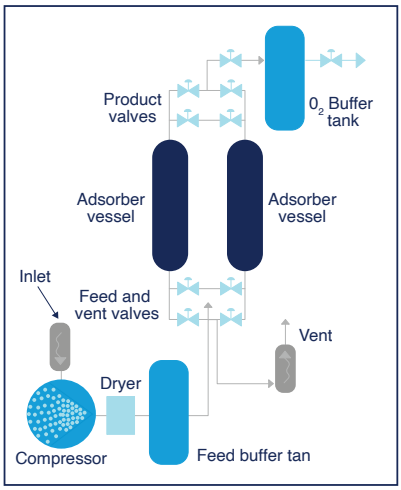
2.2 Technical requirements for PSA oxygen generator plants

Currently, PSA technologies are more commonly available in the market, thus the focus in this document is on them. However, many of the technical requirements apply to PSA, VSA and VPSA.

2.2.1 General overview

- PSA plants (Fig. 2.2) should be designed according to the oxygen need-gap assessment and the context in which they will be implemented. They are typically manufactured to operate non-stop.
- PSA plants can be built onsite, skid-mounted or containerized. They can be delivered as turn-key units with all the necessary equipment to operate. A typical PSA configuration is shown in Fig. 2.2.
- PSA plants must be compliant with the technical specifications *(10).* These generic specifications provide comprehensive interim guidance; however, contextualized details for the goods and services acquired may prevail over the generic specifications. Detailed guidance for procurement is outlined in Web annex A. Technical considerations for the procurement of oxygen generator plants.

PSA schematic



VSA schematic

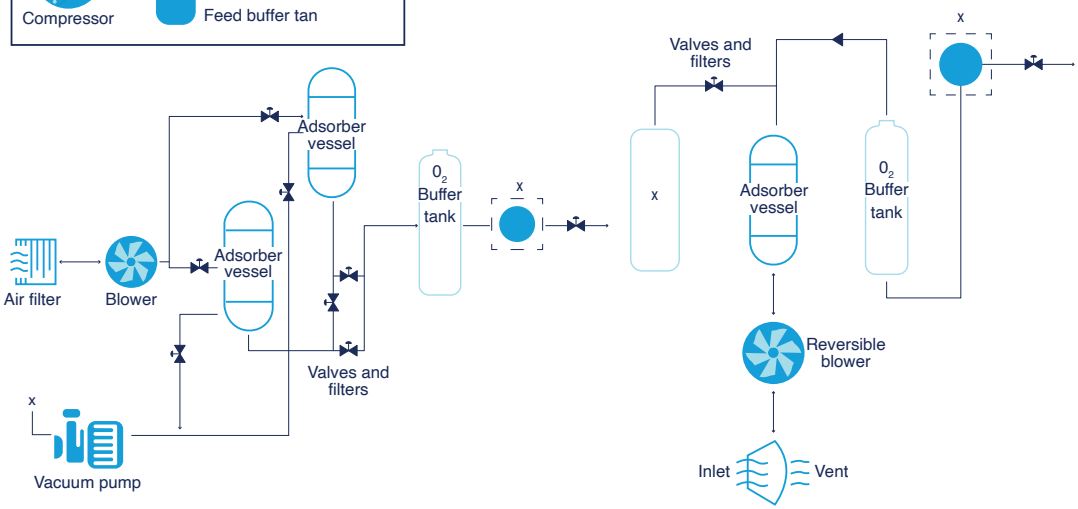
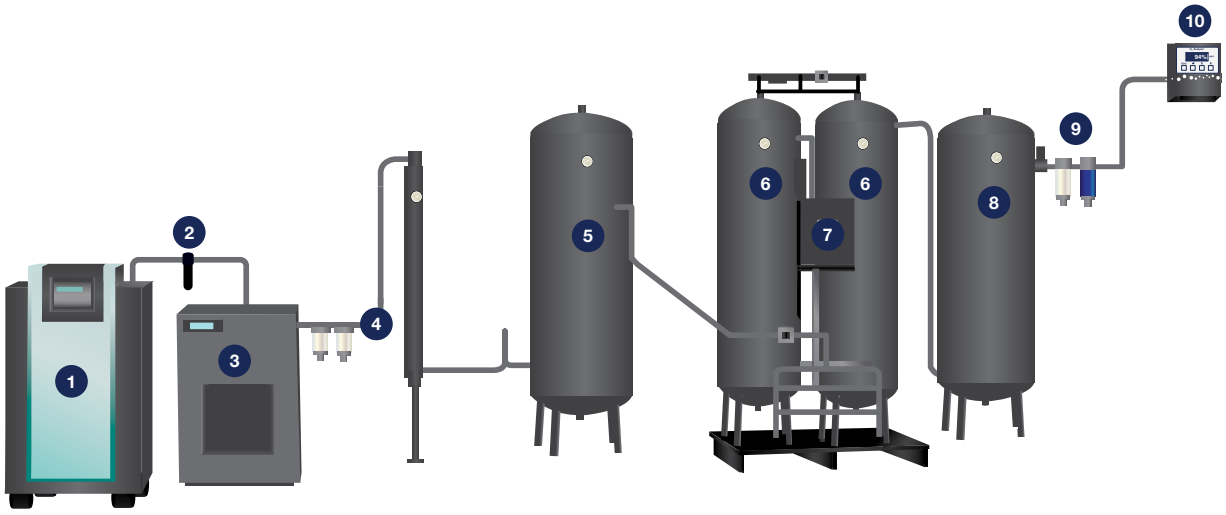


Fig. 2.1 Main components of PSA and VSA plants

- The oxygen concentrator element must have a regulatory certification for medical use that shows a risk classification (e.g. Class C [GHTF Rule 11]; FDA Class II [United States]; Class IIB [European Union]; Class IIA [Australia]; Class II [Canada]).
- For regulatory approval of PSA plants, there are two main considerations: quality of design and quality of the supplier. For design, the manufacturer should hold a design dossier or technical file that contains all the information about the design and development of the plant, verification test reports (e.g. mechanical, electrical), risk management files, post-market surveillance and monitoring procedures and records. For supplier evaluation, generally the manufacturer needs to be ISO 13485 certified. ISO 13485 ensures the manufacturer's company operates consistently, and covers a wide range of topics from senior management, staff training, documentation control, production, internal audit, post-market reporting and complaint handling.
- During the design phase, site-specific environmental considerations should be addressed, such as elevation above sea level, temperature, humidity, dust. Likewise, the system output and configuration [2.3] should be specified.
- During the procurement phase, besides a proper design of the PSA plant, the vendor is expected to provide information that will allow site preparation (Web annex B: Site evaluation for oxygen generator plants) and readiness (Web annex C: Site readiness for oxygen generator plants) to implement the project. This includes but is not limited to:
  - Precise power requirements of the main components and the whole system: acceptable mains capacity, appropriate electrical connections/adaptors, and compatibility with primary power supply [3.5.3] (e.g. diesel generator and electrical grid).
  - Safety and structural requirements [3.5.1] needed to ensure that the building and placement of equipment is to standard. This includes appropriate room dimensions, door and window location and size, ventilation (amount and specific location), air extractors and extra copper piping. The supplier should provide a final drawing/layout indicating the placement of the components.
  - Other tests and reports such as pre-shipment inspection report, running test to reach nominal performance (minimum time for continuously running is 3 days), alarm testing, commissioning report (Web annex D: Commissioning report for oxygen generator plants), user and service manual and training package.



1 Air compressor
2 Water trap
3 Refrigeration or adsorption dryer
4 Filtration assembly:
- pre-filter (> 5 micron),
- coalescing filter (0.1 micron)
- coal filter or coal tower, alternatively activated carbon filter

5 Compressed air tank
6 PSA – O_2 generator
7 Control panel
8 Product/buffer tank
9 Bacteria/sterile filter
10 Oxygen analyser

Fig. 2.2 Configuration of typical PSA plant

2.2.2 Maintenance service

- Rigorous preventive maintenance programmes (PMP) are needed to prevent malfunctions in accordance with manufacturer's recommendations. Some maintenance tasks should be performed periodically even if the plant is not continuously operational for external reasons (e.g. lower oxygen demand, lack of power supply [3.5.3], scarce number of operators).
- Availability of spare part kits should be guaranteed during the lifespan of the plant.
- Spare parts kits for preventive maintenance service, as recommended by the PMP, should be clearly defined in a list comprising part numbers and descriptions, quantity per kit and per maintenance activity, as well as indicating brand/model specifics and expiration dates.
- Maintenance toolkit with oxygen analyser, other testing and mechanical tools, and complementary PPE (e.g. gloves, protective glasses, hearing protectors) should be available for the operators of the plant.
- If a service level agreement (SLA) with the vendor is available, the corrective maintenance terms and conditions may specify estimated times for response, including: lead time for reception of any necessary spare parts; location of stockpiles and warehouses to access in case of distribution of spare parts; capabilities for remote support; and, availability of local agent.

2.2.3 Electrical requirements

- The PSA plant must be connected to a reliable and continuous source of energy for all intended hours of operations. Power supply [3.5.3] includes main and backup sources.
- The energy efficiency of PSA plants is largely determined by the feed air compressor.
- Peak power demand is determined by both the inflow current and voltage of the feed air compressors. To minimize the requirement for peak power, some brands offer feed air compressors fitted with variable speed drives (VSDs). Careful assessment of the power supply reliability must be done before choosing this option.
- The plant must be supplied with electrical cables for the power connection of each component as applicable (e.g. air compressor, air dryer, desiccant dryer, oxygen generator, booster compressor), power cabinet with surge and earth protection, and inbuilt phase controller for 3-phase devices.
- The electrical requirements chart for the different components in the plant configuration should be provided by the supplier (including the starting current, minimum protection current and load curve) to determine total power needs and ability to configure the power source (e.g. diesel generator, voltage stabilizer, electrical grid with transformer, circuit breaker and medium voltage module). The power load differs depending on the PSA plant configuration [2.3] (single/multiplex, with or without cylinder filling station [2.5]).
- The primary and secondary power supply must be connected to the power cabinet through a transfer switch system. An automatic transfer switch is ideal as it reduces the transfer time delay. However, a manual transfer switch requires less maintenance activities.
- Voltage fluctuation will cause damage to the unit. Power should be supplied to the unit from an armoured grounded electrical outlet with a three-prong plug and earth cable.
- Electrical elements must be compatible with the power source (frequency, voltage and plug type need to be specified).
- If diesel generators are installed, they must be properly chosen and provided with spare part kits and a maintenance service. Certain type of specifications and diesel consumption may impact capital expenditure and operational costs. Preferably, the engine should be electronically controlled and, if the diesel generator will be used as a primary source (prime mode) instead of backup source (standby mode), the preferred specifications may comprise, for example, a shunt excitation system (also called "self-excited") and an integrated automatic voltage regulator (AVR).
- If diesel generators are installed, they should be installed in a weatherproofed and sound-attenuated enclosure. They should be positioned so that air intake cannot be obstructed and the exhaust points away from nearby oxygen sources or pedestrian walkaways. The installation should be accessible to accommodate refuelling. The access to this equipment should be restricted to authorized personnel.

2.2.4 Infrastructure requirements

- During the project design phase, it is important to properly define the location where the PSA plant will be installed. Considerations include distance to the MGPS [2.9] to prevent pressure drop in the wall outlets [2.9.2] and safety distance [3.5.2] to crowded areas and least polluted areas.
- As for all medical gases, the oxygen production system must be located under a covered structure, allowing protection from environmental factors such as atmospheric precipitation, wind or dust; protection from external mechanical damage; and assuring noise reduction during operation.
- The structural elements [3.5.1] of housing should be built considering the local environmental conditions and available isolation materials (for heat management and fire prevention). If, for example, a roofing system with a metallic structure and corrugated sheets represents a potential risk for room overheating, then adding a more performant mechanical ventilation system will be needed.
- The entrance doors should have external protective shutters, which only authorized personnel can access; and appropriate signage for medicinal gases and fire safety [3.6.2].
- Adequate ventilation should be provided to ensure that oxygen-depleted air is rapidly replaced. To monitor the oxygen-enriched atmosphere, items such as oxygen depletion sensors should be installed in the plant room.
- The floor finish and material (e.g. concrete) must be flat and smooth to facilitate movement in the area and ease of cleaning, sustain the heavy weight of the components and reduce equipment vibration.
- The underground rooms, pits, vessels, ducts and trenches may represent a risk for oxygen accumulation.
- The plant room should have ducts for discharge water coming from the water separator and necessary openings for exhaust ventilation and the introduction of cables and pipelines.
- The nitrogen discharge duct should be vented to the atmosphere. It is suggested that the exhaust should terminate at least 3 m clear of any door/window that can be opened, or other ventilation/air intake; it should have its end turned downward to prevent the ingress of dirt and moisture.
- The plant room should be equipped with appropriate continuous lighting. LED lighting reduces fire risks.
- The dimensions of the housing should match manufacturer's layout recommendations, should allow space for servicing the equipment and will be dependent on the plant configuration [2.3]. In some cases, the plant room may be larger than 6 x 6 x 5 m.
- The colour the structure should be specified to match the existing hospital colour.
- Pipelines, pipe fittings and coupling connections must be designed, manufactured, assembled and tested in accordance with applicable national or international regulations.
- Interconnecting pipelines with the existing pipeline network should be made of stainless steel or reinforced rubber with a silicone coating on the inner surface.
- If high-pressure gas cylinders [2.8] are available, a separate cylinder storage room must be defined with sufficient space to keep cylinders apart and for manoeuvring of full and empty cylinders. A ramp (6–8% slope) should facilitate movement of cylinders in and out of the room.

Fig. 2.3 depicts the typical layout of an onsite oxygen generation plant, showing the cross-ventilation and separation from the production room, with ambient air enriched with nitrogen, from the cylinder's storage room, and separation of empty and full cylinders.

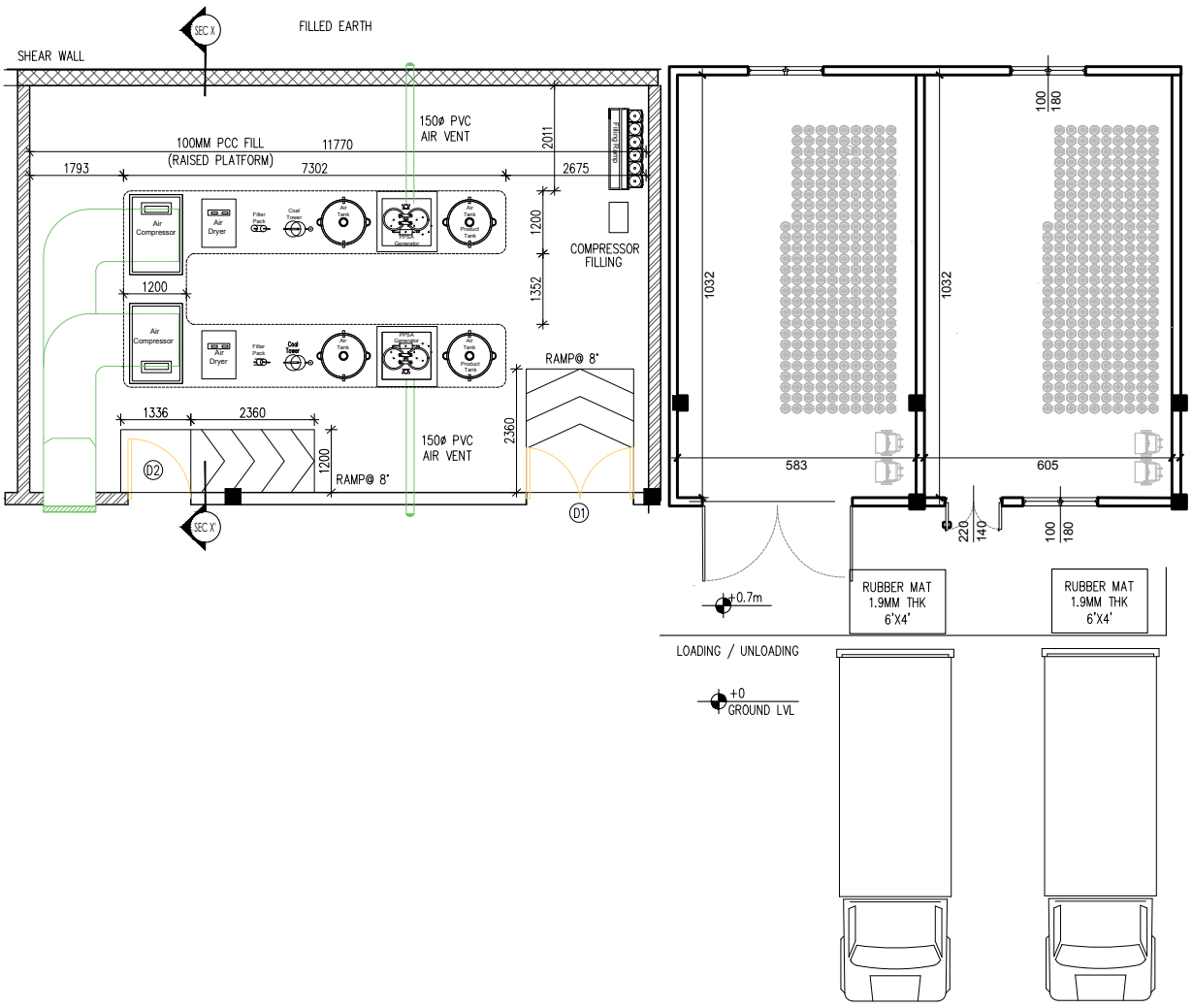


Fig. 2.3 Typical layout of an onsite oxygen generation plant

2.2.5 Human resources requirements

- PSA plants require trained personnel [3.4.2] for operation and maintenance. The training plan for local operators should indicate content, number of days and persons to be trained. The trainers should be certified by the manufacturer.
- The personnel (operators and drivers) dedicated for cylinder management and handling, onsite and/or offsite, must be trained in safety and mitigation measures [3.6] to prevent accidents and fire.
- When managing the cylinder's fleet, consideration should be given to the workload of personnel and the distance for distribution (onsite and/or offsite).
- If diesel generators are installed, they also require trained personnel for operation and maintenance.

2.3 Sizing and configuring of PSA oxygen generator plants

The production capacity of an oxygen generator plant can range from 2–200 Nm^3/hr. It's important to note that not all plants existing in the market are certified for medical application, especially when they are above 100 Nm^3/hr.

Plants must be sized and configured based on facility needs and estimated oxygen demand [3.1]. Different configurations can allow a combination of more than one plant (e.g. single, duplex or multiplex plants) to reach the expected oxygen output, or to alternate usage and scheduled maintenance. While this has the advantage of mitigating risk in case of malfunctioning of one of the plants, it will require higher maintenance resources.

The configuration should also consider the distribution system that will be implemented, either direct connection to the MGPS [2.9], and/or to the cylinder filling station [2.5] composed of a booster compressor and filling ramp. In Figs 2.4 to 2.7 several possible configurations for an identical estimated oxygen demand of 30 Nm^3/hr are shown.

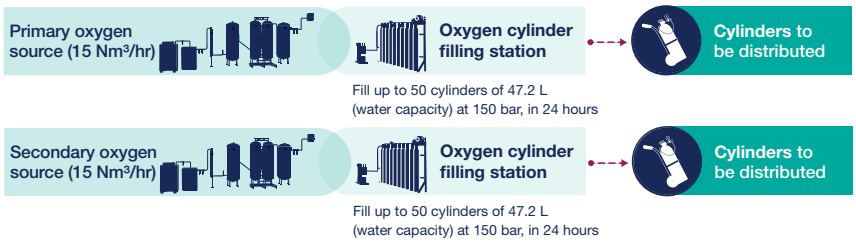


Fig. 2.4 Redundant production source used to fill cylinders

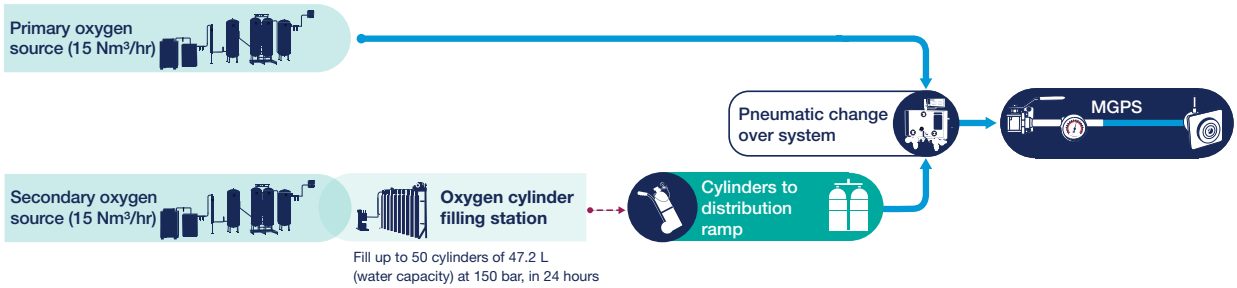


Fig. 2.5 Primary source connected to MGPS and secondary source used to fill cylinders

Fig. 2.6 Duplex system connected to MGPS

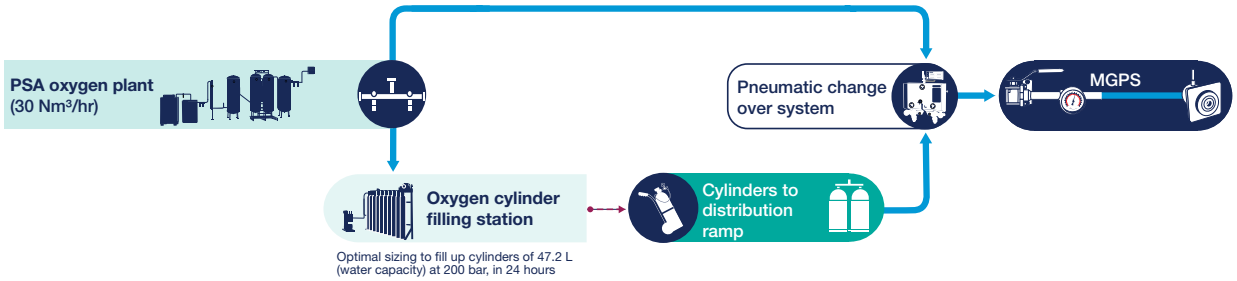


Fig. 2.7 Single system connected to MGPS and alternating to fill cylinders when oxygen demand is low

The sizing of the plant will also depend on whether the system will be used as main, secondary or backup oxygen supply. At facility level, it is important to consider the provision of a backup supply [3.4.4], via a secondary supply source and/or cylinder stocking.

An additional factor to consider is if the plant will be assembled onsite (Fig. 2.8), containerized (Fig. 2.9 and Fig. 2.10) or skid-mounted (Fig. 2.11). Though the last two solutions facilitate smoother installation, they are not feasible for bigger sizes, typically above 30 Nm^3/hr production capacity.

Fig. 2.8 PSA oxygen generator plant assembled onsite

Fig. 2.9 Containerized PSA plant

Fig. 2.10 Containerized PSA plant

Fig. 2.11 "Skid-mounted" PSA generator

2.4 PSA system costs

The estimated cost for acquisition of a PSA system varies significantly depending on:

- size and configuration [2.3] of the assembly;
- whether built onsite, skid-mounted or containerized;
- whether spare parts kits for PMP are included;
- interconnection to the selected distribution system;
- country of origin;
- shipping methods (type of transport), insurance and trade terms (e.g. Incoterms); and
- other associated costs for the implementation and operation [3.4], such as housing and/or shelter, ventilation, air conditioning and heating equipment, diesel generator, high-pressure cylinders, cylinder accessories and trolleys, vehicles to transport cylinders offsite, SLA, staff recruitment to operate and maintain the systems.

In 2020, the *Respiratory care equipment market report (25)* produced information on different suppliers in the United States, Europe and China. In 2021, UNICEF offered in its supplies catalogue an "oxygen plant-in-a-box" solution *(26)* with some reference costs. However, since then, the market landscape and pricing continue to change considerably.

Implementing and scaling up oxygen solutions should consider a project stepwise approach, starting with technical assessment, followed by procurement and operationalization. Technical experts should be involved throughout the entire process, from initial decision-making to final set up of contextualized and holistic solutions that are also aligned to budget availability for long-term operations.

Web annex A. Technical considerations for the procurement of oxygen generator plants, outlines best procurement practices and how stakeholders can raise awareness of the hidden costs and factors that need to be considered for long-term operation of oxygen systems [1.5] at scale. As far as possible, these high-value investments should include long-term SLA to ensure continued, safe and successful operation of the oxygen systems.

2.5 Cylinder filling station: booster compressor and filling ramp

The booster compressor (Fig. 2.12), also known as a "high-pressure compressor", must be an oil-free compressor. Such compressors represent one of the most expensive components of the PSA plant assembly [2.1], due to their capital cost, electrical requirements and associated maintenance needs.

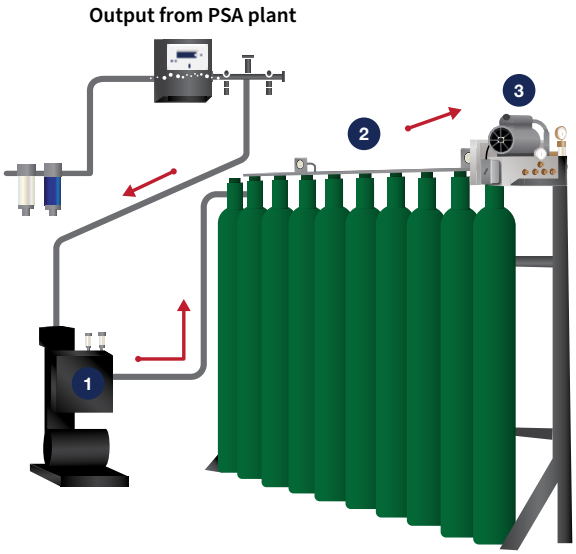
Fig. 2.12 Booster compressor

Fig. 2.13 Booster compressor connected to the filling ramp of eight high-pressure cylinders

The filling capacity of the booster compressor is stated in a range of Nm^3/hr and must be optimal in relation to the production capacity of the plant and the expected number and size of high-pressure gas cylinders [2.8] to be filled. Once, the specific flow rate is settled, the configuration must be kept unchanged.

The booster compressor is connected to a filling cylinder ramp with flexible pigtails, regulators and valves compatible with the existing cylinders (Fig. 2.13). Additionally, a vacuum pump needs to be located close to the filling ramps to be used for purging cylinders before refilling.

In Fig 2.14, note that the flow of gas is from the plant to the fill in cylinders, illustrating that the direction of flow in a filling ramp is opposite to the flow in a distribution ramp [2.6].



1 Booster compressor
2 Cylinder filling ramp
3 Vacuum pump

Fig. 2.14 Gas flow from PSA plant to cylinder filling station

Table 2.1 shows the approximate number of cylinders per day that can be filled by different booster compressor capacities, assuming that the PSA system is running at full capacity, 24 hours a day and that ~50 L (water capacity) cylinders are filled to 15 000 kPa (150 bar or 2175.6 psi).

Table 2.1 Booster compressor capacity

Booster compressor capacity	No. of cylinders/day
3 Nm^3/hr (50 L/min)	< 10
6 Nm^3/hr (101 L/min)	< 20
12 Nm^3/hr (200 L/min)	< 35
16 Nm^3/hr (266 L/min)	~50
32 Nm^3/hr (533 L/min)	~100

2.6 Distribution ramp

A standalone distribution ramp consists of a ramp with flexible pigtails, regulators and valves compatible with the existing high-pressure gas cylinders [2.8]. The main and backup ramps are interconnected through a pneumatic changeover system [2.7], which in turn is connected to a MGPS [2.9] allowing the continuous supply of medicinal gas at constant pressure in the wall outlets [2.9.2]. The whole system is also called the "cylinder bank".

The cylinders are filled with medical grade oxygen [1.3.1] produced by an oxygen generator plant, or by a LOX source, after passing through the vaporization stage. Having a mixture of cylinders filled by different sources has not demonstrated any risk to the patient, or to the MGPS, as long as the quality is ensured in the whole supply chain and GMP *(3)* and GDP *(27)* are strictly followed.

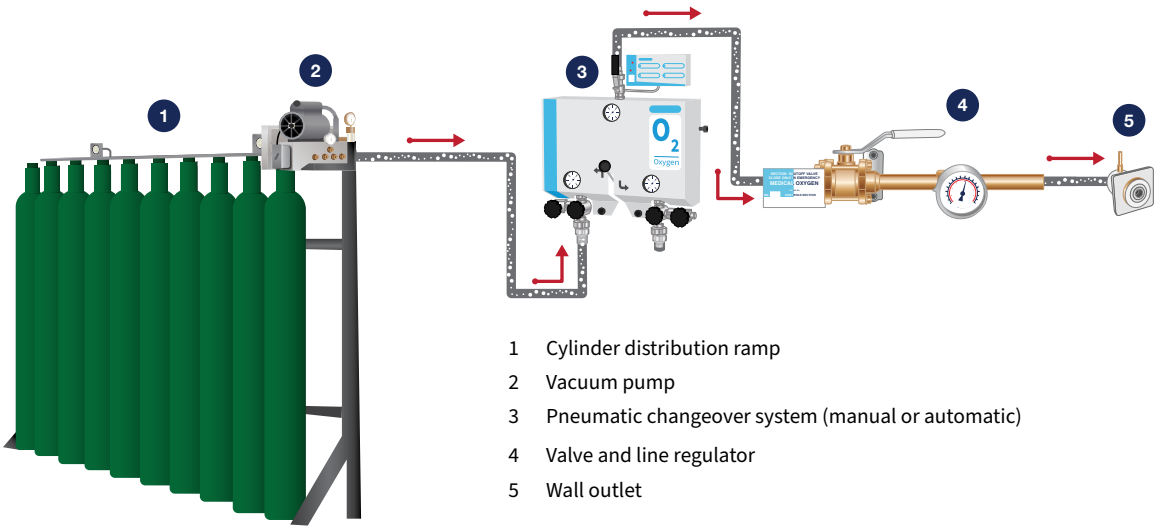
In Fig. 2.15, note that the flow of gas is from the cylinder bank to the MGPS, illustrating that the direction of flow in a distribution ramp is opposite to the flow in a filling ramp [2.5].

2.7 Pneumatic changeover system: automatic/manual

Pneumatic changeover systems ("manifold" or "pneumatic manifold") are designed to ensure continuous supply from two or more onsite oxygen sources (Fig. 2.18). The onsite oxygen sources could be an oxygen generator plant [1.6.2], VIE system [2.10.1], cryogenic cylinder [2.10.2], high-pressure gas cylinders [2.8], or a combination, as long as all sources are certified for medical application.

Depending on the design, one source will be considered primary and the other secondary. A typical configuration will use two different production methods in case one fails or presents constraints. For example, a combination of a LOX source with a cylinder bank; or two redundant oxygen generator plants.

The changeover systems consist of multiple selection valves which work manually (Fig. 2.16) or are programmed to automatically adjust and switch when pressure and demands change in the pipeline network (Fig. 2.17). These systems also include controls that serve to measure and regulate the pressure between the entry point (higher pressure) and the output of the pipeline network (lower pressure). Additionally, alarms will activate when the working pressure diminishes, for example when it reduces by more than 25%. The whole system requires maintenance, cleaning, and testing of the specific medicinal gas following relevant national and international standards. The schematic in Fig. 2.18 illustrates the detailed components of changeover systems.



1 Cylinder distribution ramp
2 Vacuum pump
3 Pneumatic changeover system (manual or automatic)
4 Valve and line regulator
5 Wall outlet

Fig. 2.15 Gas flow from distribution ramp to MGPS

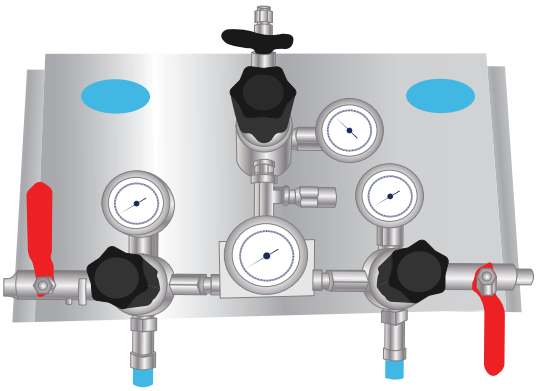


Fig. 2.16 Changeover system: manual

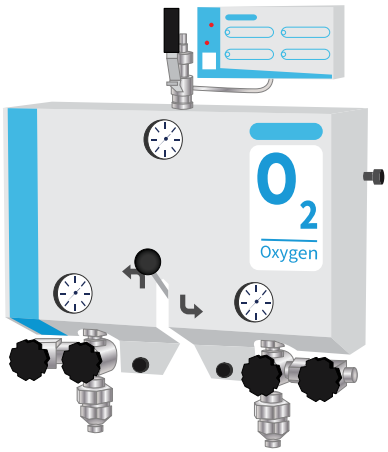
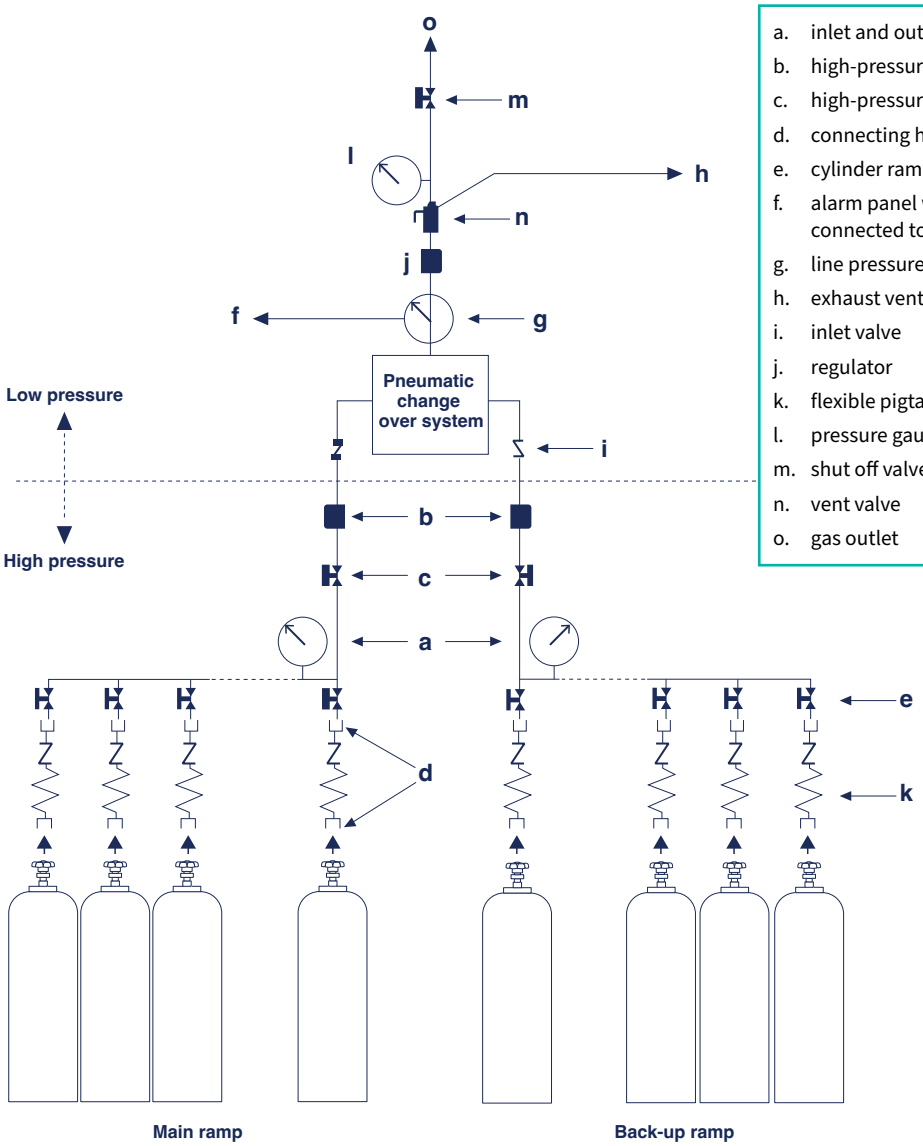


Fig. 2.17 Changeover system: automatic



a. inlet and outlet pressure gauges
b. high-pressure regulators
c. high-pressure valves
d. connecting hoses (NF, DIN, BS, CGA etc.)
e. cylinder ramps and safety valves
f. alarm panel with visual and audible alarm, connected to pressure switch (optional)
g. line pressure gauge
h. exhaust vent
i. inlet valve
j. regulator
k. flexible pigtails with check valves
l. pressure gauge
m. shut off valve
n. vent valve
o. gas outlet

Fig. 2.18 Schematic of a pneumatic changeover system

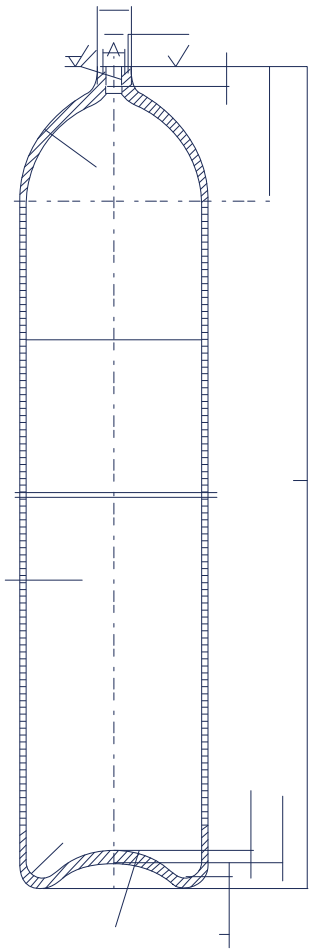
2.8 High-pressure gas cylinders

High-pressure gas cylinders are used to store compressed medical gases under varying pressures. The main components of high-pressure cylinders are depicted in Fig. 2.20. They are available in a variety of sizes and most often made from molybdenum steel, but can also be made of aluminium or carbon fibre *(28)*. Even though cylinders and the associated residual pressure valves (RPV) are not manufactured by the gas supplier, the entity responsible for refilling the medical gas must oversee proper maintenance every 5 years. The maintenance involves, as a minimum, a hydrostatic test, weight loss test (> 5%) and corrosion test. The cylinders must pass strict verification procedures and be cleaned after every use. Only cylinders tested following QA for medical application should be used for medical oxygen. At facility level, users must conduct frequent visual and leakage checks of the cylinders.

These cylinders are typically regulated as pressure vessels and not considered under the medical device regulatory framework. However, ascertaining the quality of these "container closure systems" when carrying a medicinal gas is vital; they should follow GDP for medical products *(27).* The manufacturer must be able to provide a technical data sheet for the production batch outlining relevant information (Fig. 2.19).

Following best practices for procurement, refilling and management [3.6] may mitigate the risks associated with pressurized contents and maintain the purity of the gas contained.

There are several applicable quality and safety standards for these devices, including the Transportable Pressure Equipment Directive (TPED) in the European Union, which requires cylinders to have a "π" mark stamped on their shoulder; and the Code of Federal Regulations of the Department of Transportation (DOT) in the United States, which requires them to have a "DOT3AA" stamp. Another indicator of an appropriate vessel is if it bears a United Nations packaging symbol stamp next to ISO 9809-1.



Technical requirements

1. Manufacture standard: ISO 9809-1
2. Manufacture process
3. Working pressure
4. Hydraulic testing pressure
5. Minimum burst pressure
6. Material, including chemical composition (%)
7. Heat treatment process
8. Mechanical properties
9. Thread specification
10. Specification of the cylinder:
    - Capacity (L) +5%
    - Length (mm) ±10
    - Weight (kg)

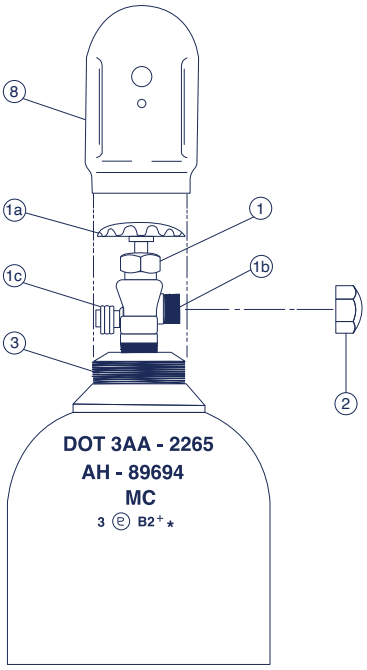
Fig. 2.19 Information outlined in a technical datasheet for cylinder conformity

2.8.1 Distinguishing different types of high-pressure cylinders

It is crucial to distinguish between the different high-pressure cylinders containing different medicinal gases (e.g. oxygen, air, nitrous oxide) to avoid a potentially lethal situation of administering the wrong gas to a patient. Different standards for colour coding, labelling and connections are applicable in different countries. Also, each type of medicinal gas has a specific colour, nomenclature and connection system across the national standards. The following sections describe the characteristics applicable to oxygen cylinders.

2.8.2 Cylinder labelling

In absence to an existing national regulation, the labelling, including the content of the label (Fig. 2.21), must respect the requirements for identification of the content and warn of principal hazards stated on ISO 7225 *(29)*. Likewise, the ISO 13769 (*30*) indicates the requirements for permanent marking applied to cylinders by hard metal stamping, engraving, casting or other method.



No.	Description
1	Cylinder valve body
1a	Handwheel
1b	Gas outlet / connection (CGA 540)
1c	Security valve (pressure relief device)
2	Security stopple
3	Thread for head cover
8	Security head cover

Fig. 2.20 Cylinder components

No.	Description
A	Hazards and precautions notice
B	Name of the product
C	Hazard diamond
D	Filling pressure
E	Gross weight
F	Cylinder size
G	Manufacturer brand name and contact
H	Serial number

Fig. 2.21 Cylinder labelling

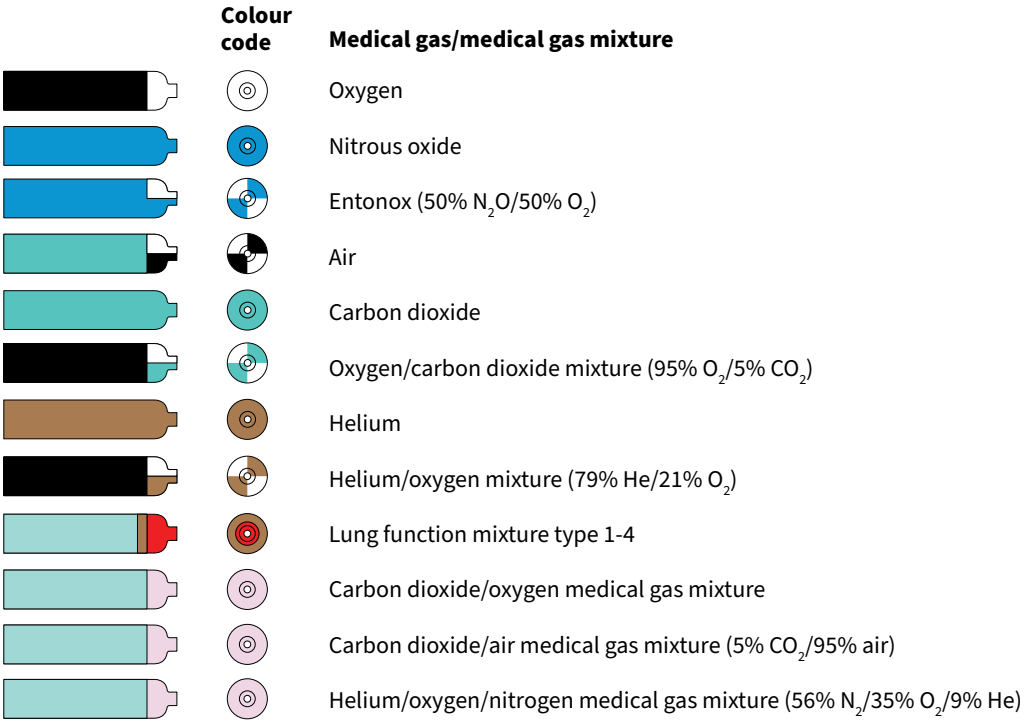


Fig. 2.22 ISO cylinder colour coding for different gases

2.8.3 Colour coding

Currently, there are two predominant tank colouring systems: ISO (Fig. 2.22) and that used in the United States. In ISO standards, the oxygen cylinder body is black, but the shoulders have different colours depending on the gases contained. In the case of oxygen cylinders, they should have a white top or "white shoulder". In contrast, in the United States, oxygen cylinders should be completely green.

2.8.4 Valve outlet connection

The primary valve of cylinders must be compatible with the fitting element, which is either the pressure regulator, filling ramp [2.5] output or distribution ramp [2.6] input. Valves are made of steel/plated brass/aluminium casing and support the specified nominal inlet pressure.

The cylinder valves models will change according to the national standard applied and to the use type, industrial vs medicinal (e.g. United States and Canada standard CGA 580 for industrial use vs standards CGA 540 and 810 for medical use).

Some cylinder valves require a metal protection cap, also called a valve guard, to be used during the transport of cylinders. This cap protects the valve from tearing off if the cylinder falls over.

There are three main types of cylinder valves (Fig. 2.23):

Bullnose valves: Cylinder valves with a bullnose connection have threaded outlets that use specific non-interchangeable screw thread systems for different medical gases to prevent a wrong connection. These are the most common valves on larger cylinders. When the regulator is fitted to a cylinder with a bullnose valve, the nut allows for the nipple to seal against the valve outlet, which then allows the gas to pass through.

Pin-index valves: Cylinder valves with a pin-index connection prohibit interchanging cylinders for different medical or non-medical gases as only the correct pressure regulator (with the correct pin) fits the associated cylinder.

Integral valves: These are more common on smaller cylinders. They have inbuilt pressure regulators and flowmeters. While these are the most expensive, they require the least amount of maintenance.

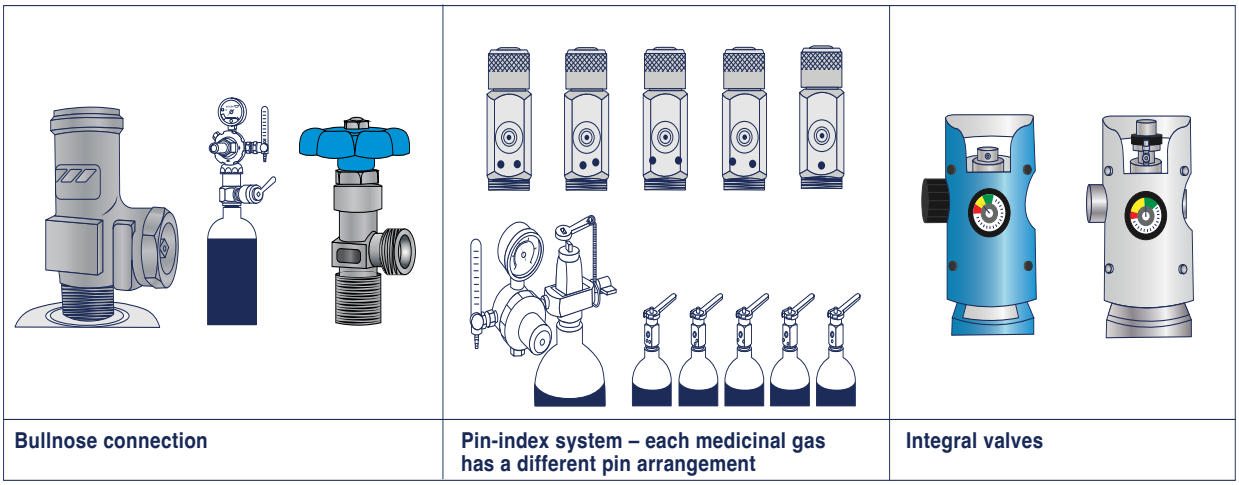


Fig. 2.23 Cylinder valve types and depiction of the connection with pressure regulator and flowmeter

2.8.5 Size and denomination

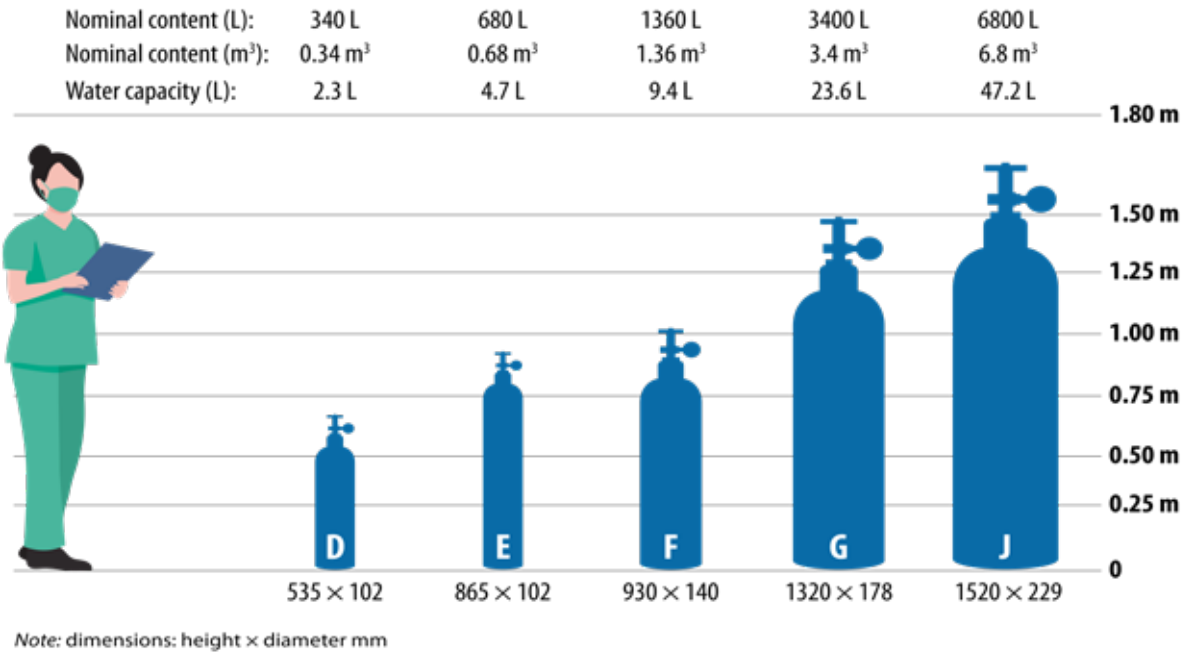
There is no internationally harmonized standard, nevertheless there are two common systems used to name and differentiate oxygen cylinder sizes. In the United States, the naming system begins with the letter "M," for "medical," followed by a number signifying the volume (in cubic feet) of gas that can be compressed into the cylinder. The British naming system (letters) is more widely used (Fig. 2.24).

Manufacturers typically offer a range of sizes from 1.2 to 50 L water capacity (i.e. capacity to hold litres of water). However, it is the pressure to which the gas is compressed that dictates the quantity of gas contained in a cylinder. Cylinders have rated working or nominal pressure, which is defined as the maximum pressure to which a cylinder can be filled. This varies according to manufacturer, but typically ranges from 13 700–15 000 kPa (137–150 bar or 1987–2175 psi) .

When a booster compressor [2.5] is used to fill gas into a cylinder, the pressure inside the cylinder increases proportionately with the volume of gas introduced. The following is a rule-of-thumb relationship, simplified formula which gives an approximate estimation at STP to determine cylinder content:

Pressure (bar) × Cylinder water volume (L)= Total gas volume (L)

Table 2.2 shows the example of a 47.2 L water capacity cylinder contents at different filling pressures.



Note: dimensions: height × diameter mm

Fig. 2.24 Cylinder dimensions and nominal content at a pressure of 150 bar

Source: Adapted from *WHO-UNICEF technical specifications and guidance for oxygen therapy devices (9).*

Table 2.2 Volume of gas in a 47.2 L water capacity cylinder at different pressures

Gauge pressure (kPa)	Gauge pressure (bar)	Gauge pressure (psi)	Gas amount (approx. L)
100	1	14.5	47.2
1000	10	145	472
10 000	100	1450.4	4720
13 700	137	1987	6466.4
15 000	150	2175.6	7080

Larger cylinders are typically suited for use in distribution ramps [2.6] but can also be brought to the bedside of patients. The smallest cylinders (i.e. type D or E) are typically used for anaesthesia machines, for ambulances and for patient intrahospital transportation.

Regardless of the size of the cylinder, they are often filled at 15 000 kPa (150 bar or 2175 psi) and removed from use with a retained minimum pressure of 200 kPa (2 bar or 29 psi). This pressure remains in the cylinder to prevent the ingress of any contaminants, including moisture.

2.8.6 Cylinder accessories

All cylinder accessories, pressure regulators, flowmeters and humidifiers are described in detail in the *WHO-UNICEF technical specifications and guidance for oxygen therapy devices (9).* The key cylinder accessories are outlined below.

Pressure regulator: A pressure regulator reduces the pressure of highly compressed gas in an oxygen cylinder to lower usable pressure for medical application. The regulator allows the outlet pressure to be kept stable, regardless of the fill-level of the cylinder and the flow demanded.

A pressure regulator can have a single gauge with a set pressure, showing the pressure of the contents. This is generally used in direct delivery to a patient using a flowmeter and, optionally, a humidifier.

There are also regulators with two gauges (Fig. 2.25), one showing the contents' pressure – the inlet gauge (which corresponds to the amount of gas in the cylinder) and the other showing the reduced outlet pressure, which can be adjustable with a knob or screw. These are used to provide oxygen to specific medical equipment (e.g. invasive ventilator).

When purchasing a new regulator, ensure:

- The outlet pressure is within the required range, i.e. sized for achievable flow rate, clearly indicating half-full and maximum values.
- The connection thread fits to the cylinder.
- It is suitable for use with the specified medicinal gas.

When the cylinder is directly connected to a patient ventilator, an additional adaptor is needed to fit the connection requirements between the pressure regulator outlet and patient ventilator inlet. This connection is illustrated in Fig. 2.26.

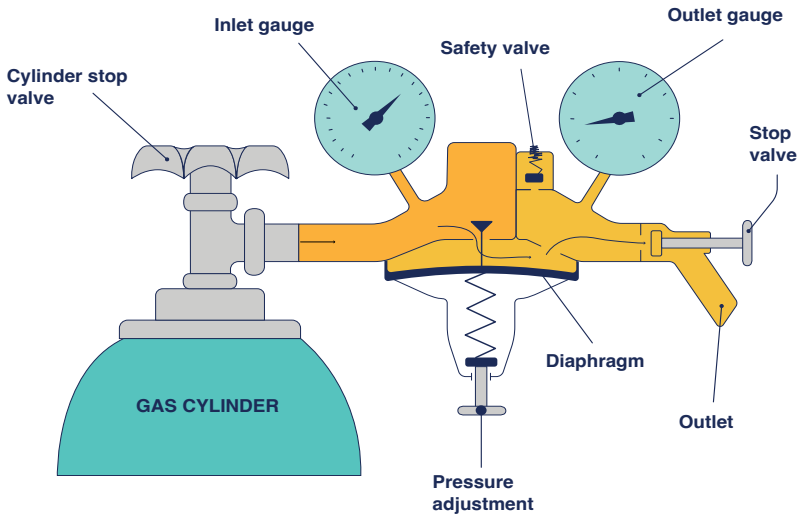


Fig. 2.25 Depiction of a two-gauge pressure regulator connected to a cylinder

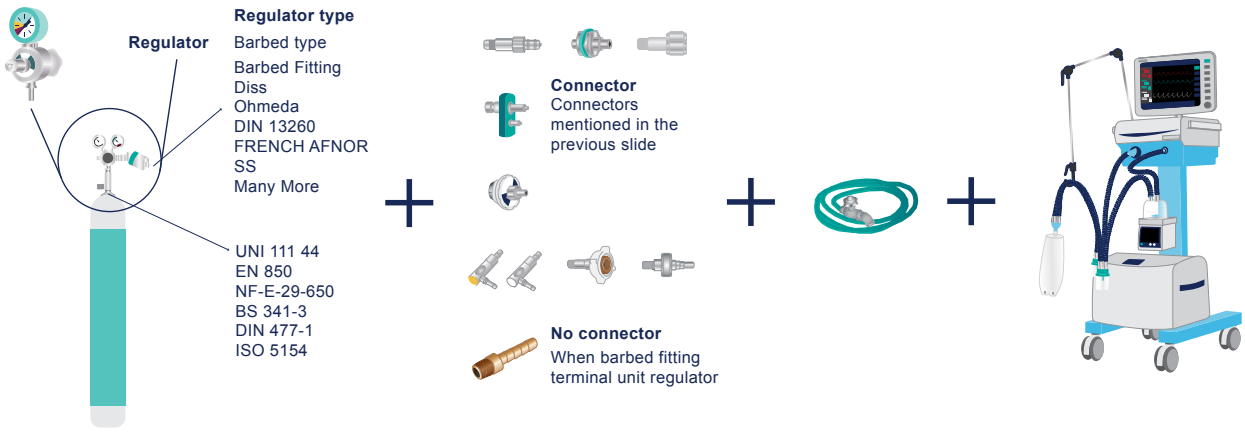


Fig. 2.26 Oxygen cylinder in direct supply to patient ventilator

Flowmeter (flow regulator): Flow regulators are connected between the patient and gas supply to deliver controlled flow rates according to the therapy (Fig. 2.27). There are three types of flowmeters: Thorpe tube, dial-click and Bourdon gauge.

Fig. 2.27 Cylinder with flowmeter (dial-click left; Thorpe tube right) and attached humidifier

The most common type of flowmeter used in oxygen therapy [1.3] is a Thorpe tube a transparent plastic tube with a scale. Inside this tube there is a small floating ball. The height of the ball indicates the flow of the oxygen to the patient. The flow of oxygen can be adjusted using the knob at the bottom of the tube. It is important to know if the Thorpe tube is pressure compensated.

A pressure-compensated flowmeter has a float that is upstream from the valve so that the float is in contact with the source pressure rather than atmospheric pressure. This offers the advantage that if pressure is applied distally to the tube, e.g. flow-restricting equipment or kinked tubing, it will have no effect on the flowmeter's performance. The flow displayed is accurate in the face of an obstruction downstream. As the flow is restricted, the flowmeter will display lower and lower flows, down to zero if there is a complete blockage. If the resistance is removed, the flow will increase.

Non-heated bubble humidifier: Humidifier bottles are fitted to the outlet end of flowmeters. They are used, when prescribed by the clinician, in administrating oxygen to the patient. The oxygen passes through distilled water to prevent dryness of the upper respiratory track reducing discomfort of the patient.

2.8.7 Key considerations for storage, transport and handling of high-pressure cylinders

To prevent accidents when managing these pressurized vessels containing oxygen, which is an oxidating agent, safety and mitigations measures [3.6] must be followed, including:

- A dedicated, well-ventilated and sizable space must be designated to store cylinders ("cylinders storage station").
- Separated areas to differentiate full and empty cylinders must be clearly identified.
- Only trained personnel should transfer and transport cylinders, with an appropriate trolley, and keeping cylinders chained.
- Appropriate vehicles to transport cylinders should be considered if distribution offsite is required.
- Never change a cylinder's contents from that intended.

- Never repaint a cylinder.
- Never change a cylinder's markings or identification.
- Never refill a cylinder from another one; especially big containers to smaller ones.
- Tighten the regulator inlet nut securely with a spanner.
- Use appropriate wrench.

2.9 Medical gas pipeline systems

The MGPS consists of a network of pipelines, fittings for connections, line valve assemblies and isolation valves, regulators, alarms and control panels and wall outlets (bedside terminal units) (Fig. 2.29). The design, installation and upkeep of MGPS are complex undertakings and require expert consultation and overview. All MGPS designs are facility-specific; there is no one-size-fits-all solution. For design alone, there is no straightforward methodology or approach because each facility's configuration will differ. A design engineer will follow a logical approach, apply theories of fluid dynamics, and draw from previous experience for each situation to find the "best fit" solution. The length and number of branches of the network, and/or manufacturers' technical requirements for specific medical equipment which need oxygen provision, will typically require the gas output pressure from the source to be between 300–600 kPa (3–6 bar or 43.5–87 psi).

There are three reference standards widely used in the design MGPS, namely ISO 7396-1 *(31),* the Health Technical Memorandum (HTM 02-01) *(7)* and National Fire Protection Association (NFPA) 99 *(32)*. Still, national authorities will indicate the applicable local standard (e.g. Guo Biao [GB] standards for the People's Republic of China). There are also certified agencies that will establish testing procedures for some components of the MGPS, e.g. American Society of Mechanical Engineers (ASME) B31.3 *(33)* and Compressed Gas Association (CGA) *(34).*

2.9.1 Dual-line regulators assembly

An important aspect to be considered when designing the MGPS is the gas working pressure. It is essential to guarantee a minimum pressure at every wall outlet [2.9.2] terminal, from the one closest to the central source, to the farthest one at the other side of the health facility site. For example, NFPA 99 *(32)* standards recommend a gas working pressure at the wall outlets of 345–380 kPa (3.45–3.8 bar or 50–55 psi). Today, medical equipment is designed to operate at lower pressures than in the past and this may impact their oxygen usage.

Considering the physical laws of fluid dynamics, the initial pressure provided by the source of medical oxygen will drop along the distribution system depending on various factors such as the section of the tube, the length of the network, the number of branches to wall outlets [2.9.2].

Dual-line regulators (Fig. 2.28) control the oxygen pressure, allowing it to be supplied at the average value defined during the design phase. This assembly includes a relief pressure valve. The maximum flow and relief pressure settings are manufacturer set.

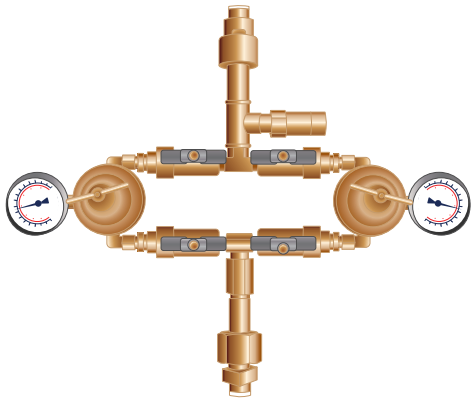


Fig. 2.28 Dual-line regulator assembly

2.9.2 Wall outlet

Wall outlet terminals are the endpoint of the MGPS and are placed at each patient bed. They must clearly distinguish between the different medical gases (e.g. oxygen, air, nitrous oxide) and vacuum line, to avoid life-threatening situations. To ensure this differentiation, there are two combined methods, colour coding and shape/fitting of the connectors.

Colour code: Using the same colour code [2.8.3] as for high-pressure cylinders, the front cover of the terminal displays the colours of the medical gas distributed. Local and international standards may vary.

Shape/fitting of the connectors: Wall outlet [2.9.2] terminals used for health purposes must have a "foolproof" system, which makes it impossible to connect a hose from one medical gas or for a vacuum, with a wall outlet terminal of another medical gases or vacuum.

There are several styles of connector patterns, including the DISS (Diameter Index Safety System), Ohmeda, Puritan, Chemetron (NCG), AFNOR (Association Française de Normalisation), DIN (Deutsche Industrial Norms), BS (British Standard), JIS (Japanese Institute of Standards), AS (Australian Standard) or AGA (American Gas Association). Each of these styles establishes a standard for non-interchangeable indexing which acts in a key-like fashion, so that the fittings within the gas service

group will connect only with their own type. Fig. 2.29 illustrates some examples of these types of wall outlets.

A “foolproof” system supplements but does not replace:

- any of the means for medical gas identification currently in use;
- pin-index safety system;
- existing threaded outlet standards for cylinder valves; or,
- automatic quick coupler valves that also provide non-interchangeable connections for medical gases and suction equipment.

2.9.3 Safety (isolation) valves

Safety valves aim to stop the flow of medical gases in the MGPS when necessary and in pre-defined areas or wards. The reasons for this can range from simple maintenance procedures to a first responder needing to stop the flow of gas during an emergency situation. The two use types are defined according to their purpose, distinguishing between main and zone isolation valves.

The **main isolation valve** is located directly downstream of the source system. This single valve effectively isolates the source of supply from the rest of the pipeline network. This valve is rarely closed. This valve would only be closed in a major emergency or if the entire system was compromised and deemed not to be used.

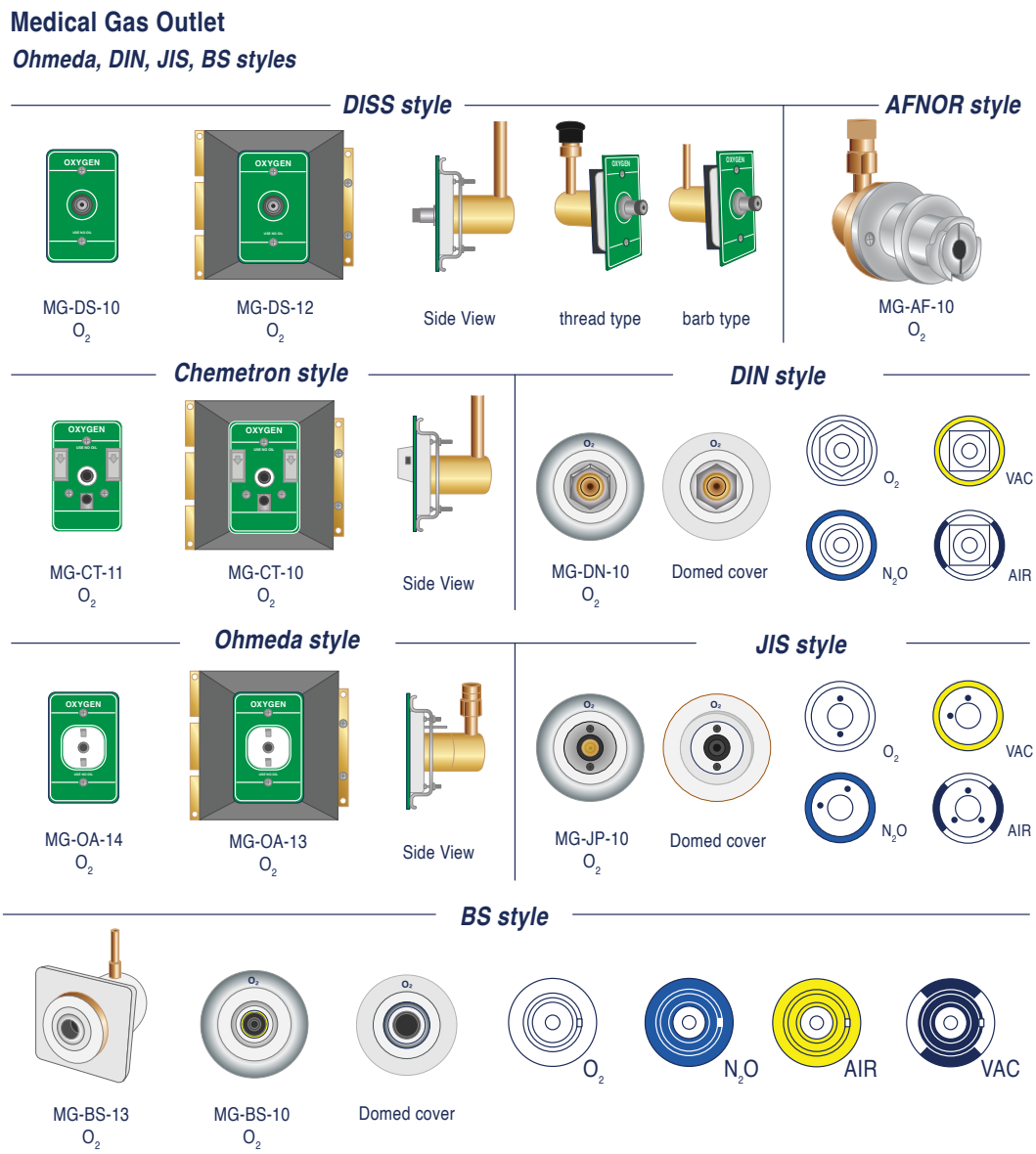


Fig. 2.29 Examples of medical gas wall outlet types

The MGPS also contains **zone isolation valves** installed in a number of locations. Strategic locations are decided during the design phase of the network, as a common agreement between the key manager of the health facility and providers. In most cases, they are close to the ceiling line, with the objective of being operated only by authorized personnel. However, some may be accessible to other medical staff. These valves are meant to assist if medical gas needs to be shut off immediately. They may have a safety feature which makes it extremely visible to nearby staff if a valve is open or closed.

For both types, the only acceptable isolation valve style is a quarter turn ball valve (Fig. 2.30) *(7).* It consists of a ball assembly inside the body of the valve which has a hole from one side to the other, lined up with the inlet and outlet part of the body. When the handle is turned a quarter rotation, the ball moves and effectively closes the direction in which the gas travels. This is an easy-to-use configuration and allows for quick opening and closing.

For MGPS, valves are used fully open or fully closed, i.e. they are not meant to act as a flow control mechanism. Valves should be installed in such a way as they are secured during normal use, i.e. it should take a specific act to move the handle beyond how it is orientated. Securing the assembly in the proper position prevents the valve from being mistakenly closed by accident. On the other hand, the operationality of the valve must be facilitated, with clear access to the valve and no obstacle to performing the full quarter turn movement of the valve.

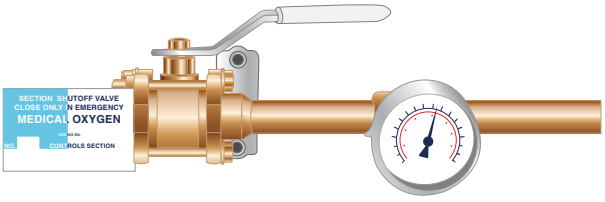


Fig. 2.30 Quarter turn isolation valve for medical oxygen

The combination of valves allocated to different medical gases in an enclosure is referred to as the **zone valve box** (Fig. 2.31). In a valve box, butterfly style valves are not appropriate, regardless of the medical gas piped. Each valve in the box has a label to identify the medical gas and the locations it serves. A gauge is usually present to indicate the pressure downstream of the valve. In an emergency (e.g. fire outbreak), first responders can open the glass-door and close the valve, providing there is a gauge that can identify how much pressure is left in the line.

2.9.4 Alarms and sensors system

The pressure of oxygen gas in the pipeline network between the source system and the patient must be monitored. Specific alarm sensors and displays are located along the MGPS to detect if the pressure drops or rises. The alarm panels are constantly monitored by authorized personnel (Fig. 2.31). The two types – master and zone alarms – are defined according to their purpose.

Master alarm: While the source systems have their own alarms, which are a combination of pressure sensing, electrical failure, device failure, or other specific functions; to monitor pressure in the pipeline network, the most common alarm device is a pressure switch, which sends a low-voltage signal to the supply system panel if the level in the pipeline exceeds or drops below set values. This master alarm is normally located in the operator's room.

Zone alarms: Zone alarms are installed downstream of the zone valve box. These panels not only sense pressure but also display the actual pressure contained in the pipeline. Should the level drop below or rise above the set point, an audible and visual alarm is initiated. They are all hardwired, via low-voltage wiring, to the master alarm.

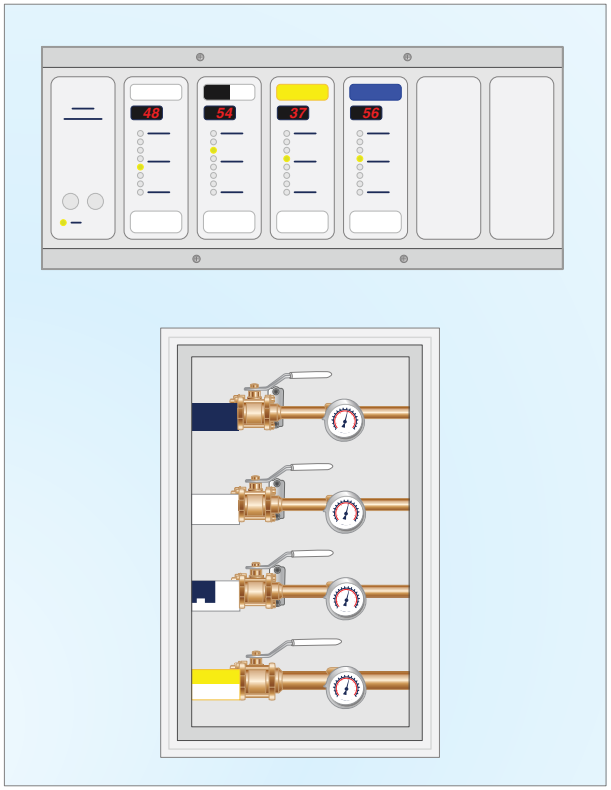


Fig. 2.31 Zone valve box and alarm panels

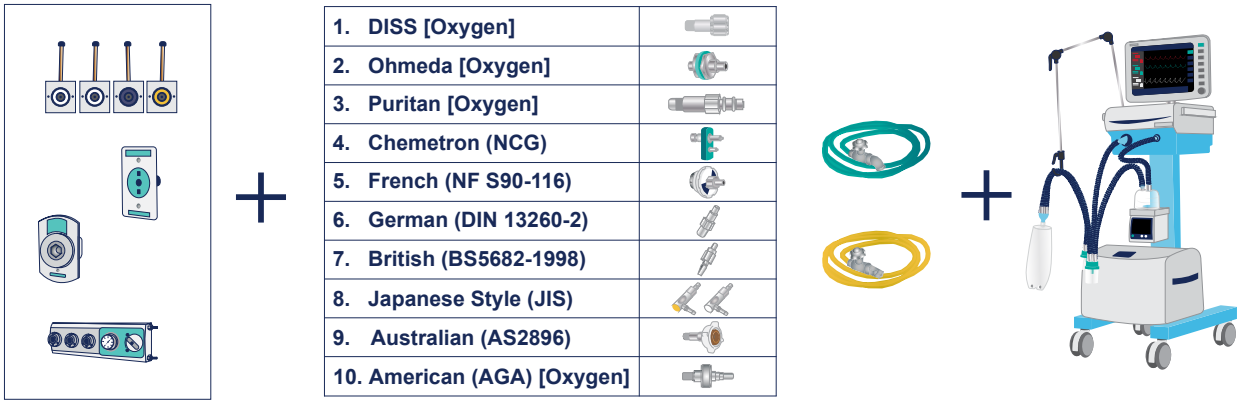


Fig. 2.32 Connection between oxygen wall outlet and patient ventilator

2.9.5 Other accessories at delivery level

In connecting medical equipment (such as a patient ventilator [1.7.2] to the pipeline network, it is necessary to adjust fitting connectors (adaptors) between the wall outlet terminal and the specific hoses used in the medical equipment (as illustrated in Fig. 2.32).

It is highly recommended to follow a colour-coded system in accordance with the colour code used for the high-pressure cylinders based on national or international regulations.

2.10 Onsite liquid oxygen storage

As outlined in cryogenic fractional distillation plants producing liquid oxygen (LOX) [1.6.3], bulk LOX is produced by specialized and certified companies outside health facility premises. After production it follows a strict supply chain [4.1] to reach health facilities in liquid or gas form. This section describes the LOX storage [1.6.3] set up and conditions at facility level. In the facility, LOX is always transformed by passive means to gas before entering the MGPS [2.9].

Fig. 2.33 External vaporizer in a VIE system

Selecting the adequate size for the LOX storage must consider various factors such as:

- Maximum and average oxygen demand, anticipating potential surges.
- Pipeline network diversification.
- Distance of the health facility from source of LOX (either distribution hub or point of production).
- Logistics to establish a regular refiling schedule; for instance, trucking capacity, both size of and total number of trucks in circulation; and environmental constraints (e.g. snow or rainy season) that may affect roads, are critical factors.
- Financial resources.

The sizing of the source will also depend on if the system will be used as a main, secondary or backup oxygen supply. At facility level, it is important to consider the backup supply [3.4.4], via a secondary source of supply, and/or cylinder stocking.

2.10.1 Vacuum-insulated evaporator systems for bulk LOX storage

The key advantage of LOX bulk storage over other systems is more evident when high demand exists. The pre-installed vacuum-insulated evaporator (VIE) system consists of a cylindrical cryogenic pressure vessel (bulk tank) with a pressure regulation assembly connected to an external vaporizer (Fig. 2.33).

Bulk tanks vary in size, typical volumes being 2, 3, 5, 10 and 20 m^3 (Fig. 2.34, Fig. 2.35). The size selection should consider the average oxygen demand in the facility (unlike PSA plants, which are sized based on peak flows) to allow oxygen flow at working pressure and prevent excessive icing in the external vaporizer. Over-sizing the bulk tank can result in future excess pressure build-up and off-gassing (wastage). Whereas under-sizing can result in the need for greater frequency of refills and could run the risk of LOX stock out.

In addition, the shape, design and sizing of the external vaporizer, which conditions the oxygen from liquid to gaseous form, is also relevant. The external vaporization is a passive process. The maximum quantified flow rates should determine vaporizer size. An undersized vaporizer would mean that the demand would exceed the possible output flow rates of the vaporizer, and this would result in icing up, eventually damaging material and parts. While there are measures to thaw pipes, if not noticed early, system blockages could occur. When in doubt, safe practice for a vaporizer would be to oversize, not undersize.

The pressure control manifold manages and monitors the product fill, pressure build-up, pressure relief, product withdrawal and tank vacuum. The pressure is reduced from 1050 to 420 kPag (10.5 to 4.2 barg or 152.3 to 60.9 psig) to enter the pipeline network. The pressure is expressed as gauge pressure, meaning it is measured against the local site atmospheric pressure instead of 1 standard atmosphere. The whole system should incorporate an alarm mechanism.

Fig. 2.34 VIE system [2 m³] mounted on a skid

Fig. 2.35 Installation of LOX bulk tank [20 m³]

2.10.2 Cryogenic LOX cylinders with in-built vaporization

These cylinders are insulated, vacuum-jacketed pressure vessels, equipped with pressure relief valves and bursting discs to protect the cylinders from pressure build-up (Fig. 2.36). The working pressure is up to 2413.2 kPag (2.4 barg or 350 psig). The typical volumes are 185, 260, 300 and 500 L of LOX, although there are other sizes on the market.

Cryogenic LOX cylinders are more sensitive to small shocks and inertia, which occur during transportation, leading to small escapes of gas. Moreover, as a result of static losses, only around two thirds of the volume is ever usable. Thus it is crucial to reinforce proper sizing that considers estimation of volume usability and secondary sources available at the facility (e.g. cylinder bank).

Fig. 2.36 Cryogenic LOX cylinder

2.10.3 Key implementation, managerial and operational considerations for LOX implementation

Acquiring this type of hardware can be done through lease agreements with LOX providers, where the provider will be the ultimate owner of the asset and responsible for all preventive and curative maintenance. An alternative, is third-party ownership, including by the client themselves. However, in this case it is imperative that the tank intended for use adheres to both the operational and safety directives of the intended LOX supplier.

Regardless of the ownership model, installation of LOX equipment should be sited away from boilers and other sources of naked lights, fuel stores, paint stores and other volatile flammable materials. Warning notices prohibiting smoking and naked lights must be posted clearly in the vessel storage area. The emergency services should be advised of the location of the vessel store and this location must have appropriate signs for medicinal gases and fire safety [3.6.2].

Installing VIE systems [2.10.1] requires some specialized civil engineering works to ensure safe, secure, lasting placement (Fig. 2.37). This is high-pressure equipment with many associated risks, and ownership comes with high responsibility.

Firstly, a site must be dedicated for siting a VIE system. At a minimum, a 5 x 5 m footprint will be required, sited at least 8 m away from the facility. This area must be fenced, unobstructed and accessible by the LOX tanker truck for refilling and safely turning around. Preferably, no parking or user area should be in the nearby area.

Secondly, prior to installation and physical anchoring, a slab is needed. A full tank bears a significant tonnage (dependent on size of tank but can be up to 30 tonnes). A formal geotechnical assessment is essential to ensure appropriate slab design, which should be cast accord to specifications (this will require a water supply). A crane is needed for installation.

Fig. 2.37 Installation with cranes of onsite LOX bulk tank

Finally, operations of the VIE system will entail limited electrical supply for instrumentation and alarms (e.g. 12 V) , and the availability of 63 A industrial plug. Ongoing maintenance and upkeep are imperative to ensure both continued operations and safety, and this will require regular checks, as well as third-party inspection at predetermined intervals to ensure that the unit is and will continue to operate safely.

For cryogenic cylinders [2.10.2], key considerations include:

- Stored in a covered, dry and clean, well-ventilated area not subjected to extremes of heat, and away from stocks of combustible material.
- Stored separately from other medical cylinders and other non-medical cylinders.
- Stored to maintain separation between full and empty cylinders.
- Stored in a secure and upright position to avoid spilling of the liquid.
- Stored without a cover or material over the vessel.
- Used in strict rotation so that cylinders with the earliest filling date are used first.

3. Operationalization of oxygen systems

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This section covers key operational topics and main concerns related to the design, implementation and use of oxygen systems.

3.1 Estimation of oxygen demand

There are different methods for estimating oxygen demand at facility level, or to capture needs across a broader catchment when the intention is to establish oxygen distribution hubs. Regardless of the methodology applied, oxygen demand estimation and procurement planning are key first steps for sustaining a long-term oxygen ecosystem [1.4]. Spreading the required costs over time to meet the required demand can ensure the financial means for long-term maintenance and may impact government and donor cost estimations. Depending on the context – emergency or long-term oxygen needs – scenarios may need to be evaluated repeatedly over time to model changes in clinical need.

It is important to point out, oxygen demand estimation may not always be equal to oxygen usage; particularly where there are other ecosystem barriers, e.g. weak value chain, poorly maintained equipment, or lack of clinical staff trained on provision of oxygen therapy [1.3] on the subject matter. For instance, if the overall availability of oxygen increases but there is not enough medical equipment to diagnose and/or treat hypoxaemia, there will be a discrepancy between oxygen forecasted and consumed.

Three most used methods to calculate estimated need are based on:

- number of beds per type of wards/per health facility;
- number of gas wall outlets [2.9.2] per bed in each type of ward, if any; or
- historical consumption, e.g. additional cylinders consumed per day (indicating size), if any.

With the above information, the calculation method will apply assorted usage factors. Common usage factors are: annual inpatient admissions, facility bed occupancy rate, estimated hypoxaemia [1.3] rate per type of ward, and average flow rates per ward. It is suggested not to use more than two usage factors together to prevent undersizing the oxygen system [1.5]. Likewise, not using any of them could lead to oversizing the system, which could also represent technical and financial risks.

Once the oxygen demand is calculated, the following must be considered in order to arrive at an appropriate contextualized technical solution:

- Existing and planned oxygen production, storage and distribution systems [1.6]: location, distance and accessibility of those sites.
- The ability to incorporate, adopt, assimilate and operationalize investments at country and facility level. This includes but is not limited to the actual operating conditions, available operators, available medical staff to provide oxygen therapy, working hours and power supply [3.5.3].
- Financial sustainability to pay local vendors for oxygen delivery, provision and maintenance.
- Other project risks that may affect the sustainability of the different technical solutions, such as political or environmental factors.

Key resources

Good practices in the rational and effective use of oxygen (PAHO): https://iris.paho.org/handle/10665.2/55735

Medical oxygen fire risk – mitigation measures: https://www.who.int/publications/m/item/medical-oxygen-fire-risk-mitigation-measures

Medical gas piping systems safety: https://www.who.int/publications/m/item/medical-gas-piping-systems-safety

Oxygen cylinder safety: https://www.who.int/publications/m/item/oxygen-cylinder-safety

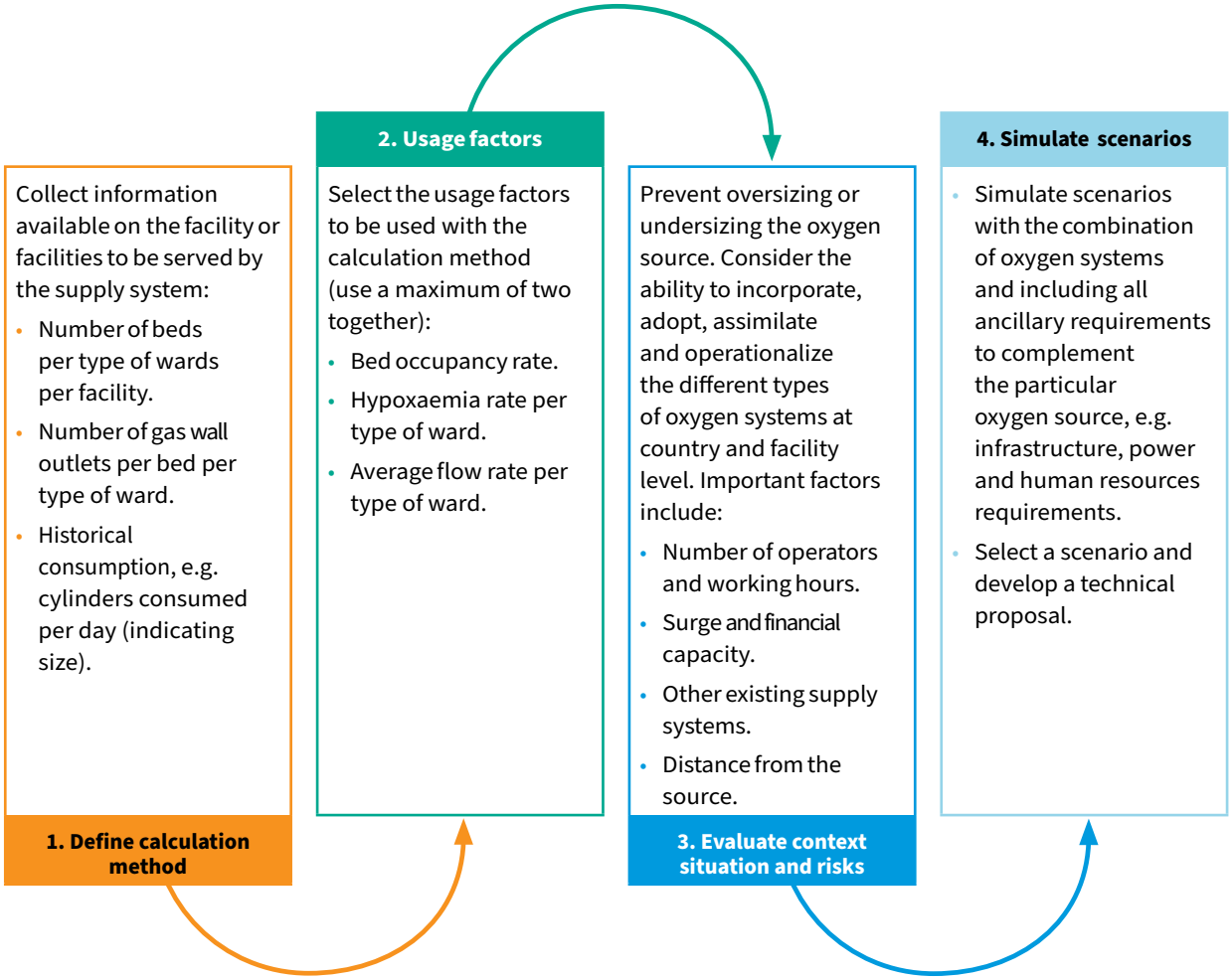


Fig. 3.1 Estimation of oxygen demand

3.2 Calculation methods for estimating oxygen demand

Depending on the calculation method used (Fig.3.1), there are various caveats to consider in arriving at the final estimation. Below are the pros and cons related to each of the three calculation methods.

3.2.1 Considerations when assessing by number of beds per type of wards/ per health facility

Once the clinical wards and number of beds per ward have been identified, this method analyses each type of bed to suggest how many patients will be treated with oxygen therapy [1.3]. The flow rates and beds in need of oxygen therapy vary according to the type of ward, as well as for each patient along their treatment course. Flow and hypoxaemia rates are usage factors that have reference values based on literature *(35–40)*. See Table 3.1 for pros and drawbacks of this method.

Table 3.1 Pros and drawbacks of calculations based on bed capacity

Pros	Drawbacks
Quantity of beds for each purpose is obtained quickly in hospitals.	Bed type definitions can vary according to each context.
Use of bed is defined.	Surge capacity is limited by the defined type of bed.
Calculation is not affected by distribution system (i.e. pipeline network or cylinders).	If MGPS is installed, it is possible that two or more wall terminal outlets per bed are available. In case of surged need, all wall terminal outlets could be used suddenly increasing the oxygen usage and surpassing the estimated production.
Average hypoxaemia and flow rates are based on clinical guidelines.	Average hypoxaemia and flow rates may not represent the real clinical practice in the facility.

3.2.2 Considerations when assessing by number of wall outlets per bed/per type of ward

This method only applies when there is an existing pipeline network. Based on the total number of wall terminal outlets in each ward, the calculation is done considering either an average or a maximum flow rate per ward. Prior to the calculation, it must be ensured the pipeline network design has been properly planned. See Table 3.2 for the pros and drawbacks of this method.

Table 3.2 Pros and drawbacks of calculations based on wall outlets

Pros	Drawbacks
Defined maximum or average flow rates of each outlet station.	Is limited to facilities with pipeline network.
As it considers 100% of stations, when there are two or more stations per bed, it allows preparation for surge demand.	By considering 100% of the stations in use and maximum flow, the source can be easily oversized.
Calculation considers different flow rates allowing more versatile scenarios.	It is complex to simulate and analyse the different scenarios because it needs detailed consumption per medical equipment or historical averages of consumption per outlet, that are commonly unknown.

3.2.3 Considerations when assessing by using historical consumption

This method can be used only when there are existing oxygen systems [1.4] implemented in the health facility from which historical consumption has been recorded. In general, to prevent underestimating the demand, careful understanding of potential external factors that have affected the registered consumption should be considered. For example, lack of funds to refill LOX or high-pressure gas cylinders [2.8], uncertainty of the size of cylinders, scarce suppliers in the area, difficult road access, lack of trained staff to provide oxygen therapy [1.3], deficient system to keep records, are common restrictions that can affect the baseline information. Consequently, this method is best used as complementary to the two previous methods. See Table 3.3 for pros and drawbacks of this method.

Table 3.3 Pros and drawbacks of calculations based on historical consumption

Pros	Drawbacks
When information is clear, legible and complete, it is easy to aggregate the historical consumption of cylinders per size per period of time, or LOX bulk tank refilling per period of time.	Historical records can be unrealistic due to several external factors.
Appropriate for modular facilities and/or without piped distribution systems.	Surge capacity is limited by historical consumption and existent storage space.

3.3 Tips for rational use of oxygen

The gap in oxygen access is multifactorial. It should not only be focused on one topic like production capacity, availability of supply or needs assessment. Improving access to oxygen also means using the oxygen available efficiently. Rational use of oxygen can be addressed through different strategies:

3.3.1 Management

- Periodically monitor and register the consumption of oxygen at the health facility to detect critical changes timely.
- Monitor and, when possible, diminish the working pressure of pipeline network.

3.3.2 Medical equipment usage

- If possible, use bedside concentrators [1.6.1] when patient needs lower flow (< 10 L/min) oxygen therapy.
- Disconnect patient ventilator [1.7.2] from the oxygen source when not in use.
- Close valves and pressure regulators when high-pressure gas cylinders [2.8] are not in use.
- Make sure that flowmeters are of good quality supplied by approved manufacturers.
- Check for leakages along the MGPS [2.9], from the source downstream to the medical wards.
- Be aware of any alarm activated on the MGPS or medical equipment in use.
- Select appropriate conditioning, regulation [1.9] and delivery devices [1.7].
- Enable effective monitoring with properly fitted pulse oximeters [1.8] probe. Remove nail polish if applicable and if possible.
- Make sure that pulse oximeters comply with quality and safety standards for medical devices and properly selected for the patient's demographic.

3.3.3 Health care worker: provision of oxygen therapy

- Provide continued and repeated training in oxygen therapy [1.3] for clinical staff, on delivering and weaning at different levels of care.
- Ensure that patients are properly diagnosed with hypoxaemia [1.3] before administering oxygen.
- Periodically monitor patient [1.8] status and adjust flow rates as needed for treating hypoxaemia to avoid under- or overuse of oxygen *(12).* For HFNC, HHHF, HFNO [1.7.1], the additional benefit at flow rates of < 30 L/min is minimal. Consider stepping down to face mask.
- Weaning *(12)* during the phase of "continuous monitoring and reassess" to reduce flow as tolerated, if patient is on nasal prongs, face mask or non-rebreathing mask.

3.4 System implementation, operation and maintenance

This section outlines basic considerations for the operationalization and maintenance of health facility oxygen systems [1.5].

3.4.1 Implementation

Depending on the system, the installation tasks may include but are not limited to:

- use of equipment for positioning the system onsite, e.g. forklifts, cranes, slings, rigging gear;
- connecting reliable and continuous source of power;
- interconnecting primary and/or secondary supply with the available distribution system [2.6];
- designing and installing the MGPS [2.9] (including pipeline, wall terminal outlets, alarms and valves);
- building or improving the existing housing;
- increasing the number of technical workers dedicated to operate and maintain the oxygen systems;
- training on safety management of oxygen;
- operator training by the supplier's certified trainers;
- handover of documentation, tests and reports from the supplier;
- verification by third parties (e.g. auditors, certified laboratories, technical experts);
- establishment of long-term SLA to ensure continued, safe, successful operation of the oxygen systems;
- ensuring available financial resources for operational costs (e.g. staffing, training, spares and repairs, SLA, power supply [3.5.3] and offsite distribution);
- if cylinders are transported offsite, appropriate access for dedicated and appropriate vehicles must be guaranteed, along with fuel and resources to maintain said vehicle.

3.4.2 Human resources

Besides the clinical staff, skilled and dedicated staff are necessary for successful operation and maintenance of oxygen systems.

Oxygen generator plants [1.6.2] (depending on facility/catchment area):

- operator(s) required onsite 24/7;
- qualified technician(s), required on call 24/7;
- manager of operations, dayshift (if operations are large).

Note: Repurposing guards or otherwise allocated staff is not appropriate.

Bedside oxygen concentrators [1.6.1] (depending on level of facility):

- dedicated technical staff may not be necessary 24/7, but on-call technician allows for quick support.

Note: Otherwise, having functional replacement concentrators available so that users can easily swap with non-functioning units during non-working hours can avoid treatment interruptions.

Note: Clinical staff must carry out basic weekly tasks to ensure proper functioning and to clean and disinfect the equipment.

LOX storage [1.6.3] (depending on facility/catchment size):

- operator(s) required onsite 24/7, even if not dedicated only for the medicinal gases station, to communicate with service provider when something is amiss.

High-pressure gas cylinders [2.8]**:**

- minimum team, to be scaled to accommodate operations, comprising:
  - order management staff,
  - book-keeping,
  - trained manoeuvring for loading/offloading;
- trained personnel for onsite distribution (at distribution ramp and/or in medical wards) required on call 24/7;
- drivers, if offsite distribution available.

3.4.3 Equipment management

Proper management of capital equipment, including a functional inventory and forecasting of spare parts and consumables, is crucial for sustainability of the oxygen systems [1.5]. The procurement and storing of spare parts and consumables must consider the shelf life of the parts (even if they don't expire, dust and other environmental conditions can damage their useful life). The warehouses and/or workshops for storing parts should be secured and covered to reduce environmental damage.

Proper maintenance tasks are related to inspection, and preventive and corrective servicing of the oxygen systems *(41)*. Tasks are executed with the aim that the systems should operate safely, performing as specified by manufacturers' standards of quality and continuously for the sake of patient needs. Such maintenance tasks can be performed by dedicated and qualified staff at the facility, and/or they can be outsourced via an SLA. If an SLA with the vendor is available, logbooks to keep records of maintenance and parts exchanged should be in place. The SLA should specify: warranty terms and conditions; response times; time schedules for reception of any necessary spare parts; location of stockpiles and warehouses; capabilities for remote support; and availability of local agent. Currently, some technologies, such as PSA oxygen generator plants [2.1], allow vendors to do remote monitoring. Where feasible, this hardware feature enables live reporting and tracking of systems' dysfunctions.

The PMP must be diligently performed according to manufacturers' specifications. For instance, the equipment maintenance schedule may relate to the number of hours operated. For example, air and booster compressors [2.5] may need servicing after 2000 hours or 6 months of operations. In general, daily or very frequent, visual and audible inspections are recommended to be followed by operators or final users, as applicable.

3.4.4 Backup supply

A backup strategy is a safety net that should be considered essential to guarantee continuity of distribution of medical oxygen to patients. A backup plan should include comprehensive risk analysis and mitigation measures, emergency response time, resource availability, among other contextualized factors, to allow preparation for security of supply. System security means that the primary source has two additional fallbacks at any time to ensure continuity of supply: the secondary system and the reserve supply. The secondary system and reserve supply could be redundant systems, or a combination of different technologies. The Hospital Safety Index (designed to improve preparedness for emergency and disaster situations) recommends having a backup supply [3.4.4] for continued oxygen delivery of at least 72 hours *(42)*.

Unfortunately, budgetary implications mean that this safety net is often deprioritized.

Fig. 3.2 Building for housing an oxygen plant

3.5 Structural and electrical requirements for onsite oxygen systems

3.5.1 Structural elements and general considerations

The structural elements of health facilities such as location, design and buildings (Fig. 3.2), are context related and oxygen system dependent. The following structural considerations are not applicable to all designs and implementation. For example, for most VIE systems, it is endorsed to rely on natural ventilation and install the hardware in an open-air space. In contrast, PSA oxygen generator plants require a dedicated housing conditioned to maintain the inside ambient temperature between an operational range of 5–35 °C. In this case, the decision of adding mechanical ventilation will also take into consideration the capacity to deplete the oxygen-enriched atmosphere inside the room. Therefore, the considerations below are intended as guidance only, further consultation with civil engineers, architects and other experts must be performed.

- As a general rule, the medicinal gas room must be protected from environmental factors such as atmospheric precipitation, wind or dust; external mechanical damage; unauthorized personnel; and must ensure noise reduction during operation and appropriate signage for medicinal gases and fire safety [3.6.2].
- It is the responsibility of the implementor to assess all the different information for the setup of new oxygen systems, and to refer to vendor's recommendations.

- The implementor should consider:
  - Hospital ground conditions (e.g. flood during high tide, storm surges).
  - Other context-important requirements (e.g. strong winds or earthquakes).
  - Infrastructure requirements for operation (e.g. roofing, flooring, ventilation, air conditioning, ducting, water drains, room requirements without oil, grease and petroleum-based or other flammable products).
  - Compatibility with existing structure (e.g. container or tent field hospital).
  - Locally available construction materials.
  - Colour context sensitivities.
  - Truck pathway and parking (e.g. for transportation of high-pressure cylinders [2.8], LOX refilling).
  - Storage area for fuel/diesel tanks.
  - Power supply [3.5.3] in the facility: location and distance.
  - Distance and requirements for interconnection with existing MGPS [2.9].
  - In general, no water service is required for the operations of onsite oxygen systems [1.5]. However, a VIE system requires a water point to perform de-icing maintenance.
  - In general, no sanitary sewer or storm sewer systems are needed in relation to oxygen systems.
  - Local regulations for civil works related to new and refurbishing health facilities.
- As required, some architectural elements include:
  - A security wire mesh to enclose the perimeter of the canopy. The enclosure should be painted and galvanized to prevent rusting; and of gauge 16 wire or thicker.
  - Structural steel trusses that are efficient and simple to erect. Spacing should be sufficient and uniform. All steel framing should be hot dipped galvanized or coated with a high-performing paint to reduce potential corrosion.
  - A secure sliding gate on a roller system located above the gate. The gate should be made of a tubular steel frame and security mesh, with a locking mechanism provided.
  - Concrete slabs that should be designed considering the load of the equipment (in kg/m^2) and be broom finished with non-slip finish.
  - Concrete main entry ramps that should meet local accessibility requirements or 1:12 maximum slope, whichever is more stringent. Doors that should be wide enough to allow the passage of equipment.
  - Prime and paint all steel with a high-performance coating or acceptable marine grade paint.
  - Finishes that should be easy to clean and kept dust free. In order to keep the room as clean as possible installing grids/nets in the openings (i.e. windows) is suggested.
  - Provision of a concrete pad for the heavy equipment such as generators. Consult size and anchoraging recommendations from the equipment manufacturer; engineer the depth based on the equipment load.
  - Anchorage systems to the foundations that should resist sliding or overturning as a result of cyclones or earthquakes and be located as prescribed by the vendor.
- For systems that will require roofing and/or an enclosed building structure, the design should consider the indoor temperature to be maintained in the specific environmental conditions. These conditions should include worst case outdoor conditions, including maximum expected temperature and maximum expected enthalpy. Temperature control influences architectural strategies, roofing shape and building materials. If local climate conditions do not allow the temperature to be kept within the required operational range, mechanical ventilation (air conditioning and/or heating) should be considered. The ventilation system should be designed in an efficient manner, locating the air inlet opposite to the air outlet. In addition, adequate ducting systems should be designed to maintain acceptable indoor conditions.
- The medicinal gases station should have proper exterior and interior lighting during the whole day. As applicable, provide exterior lights on the underside of new awning structures; exterior LED flood lights at three corners of the new structure to provide site lighting near the secured entrance; control exterior lights with photocells to illuminate from dusk to dawn; and install surface-mounted interior LED lights, controlled with manual switches at the entrance to each enclosed building and equipped with a timer switch.

3.5.2 Safety distances to implement a medical gas room

The location of the onsite oxygen system [1.5] must consider:

- Firstly, due to fire risk, a minimum safe distance from flammable and combustible sources must be respected. The distance will depend on the type of materials nearby.
- Secondly, due to the close source of contaminated air (e.g. gas exhaust from a diesel generator, or waste zone incinerator) performance of onsite production technologies [2.1] may be affected. Thus, the distances endorsed by the manufacturer to aid good quality of oxygen production and to reduce degrading of parts (e.g. filters, sieve beds etc.) should be followed.

Local regulations must be consulted to determine the safety distances recommended regarding the location of the medical gas room, including VIE systems [2.10.1] (Fig. 3.3) and the distribution ramps [2.6] (Fig. 3.4). Table 3.4 charts the safety distances established by the British Compressed Gases Association (BCGA) CP36 for VIE systems *(43).*

In contrast, the Table 3.5 list the safety distance from exposure to VIE systems available in another standard named NFPA 99 *(32).*

Table 3.4 Safety distance from exposure to VIE systems (BCGA CP36)

Safety distances from:	Oxygen vessel up to 2000 litres water capacity (m)	Oxygen vessel 2000–20 000 litres water capacity (m)	Oxygen vessel above 20 000 litres water capacity (m)
Large wooden structures, timber yards, etc.	5	15	15
Areas where open flames/smoking permitted	3	5	8
Small stocks of combustible materials, site huts, etc.	3	5	8
Non-flammable gas cylinder storage	1	1	1
Liquefied petroleum gas storage vessels (up to 4 tonnes).	7.5	7.5	7.5
Bulk flammable liquid storage vessels (up to 4 tonnes)	7.5	7.5	7.5
Flammable gas cylinder storage (up to 4 tonnes)	5	8	8
Flanges, unions in flammable gas pipelines	6	6	6
Continuous sections of flammable gas pipelines	1	5	6
Pits, ducts, surface water drains	4	5	8
Vehicle parking areas (other than authorized)	3	5	8
Property boundaries	3	5	8
Public roads	3	5	8
Railways	3	10	15
Places of public assembly	5	10	15
Openings, windows and escape routes from buildings	5	7	8
medium voltage and high voltage sub-stations	4	5	8
Process equipment and machinery which is not part of the storage installation	4	5	8
Fuel gas vent pipes	5	5	8
Compressor, ventilator and air conditioning intakes	5	7	8
Offices, canteens and areas of occupancy	5	7	8

Table 3.5 NFPA 99 recommendations for location of LOX cylinders – safety distances

Exposure	Minimum distance (m)	Minimum distance (ft)
Building exits	3.1	10
Wall openings	0.3	1
Air intakes	3.1	10
Property lines	1.5	5
Room or area exits	0.9	3
Combustible materials (e.g. paper, leaves, weeds, dry grass, debris)	4.5	15
Incompatible hazardous materials	6.1	20

Source: NFPA 99 (NFPA, 2021:126) *(32).*

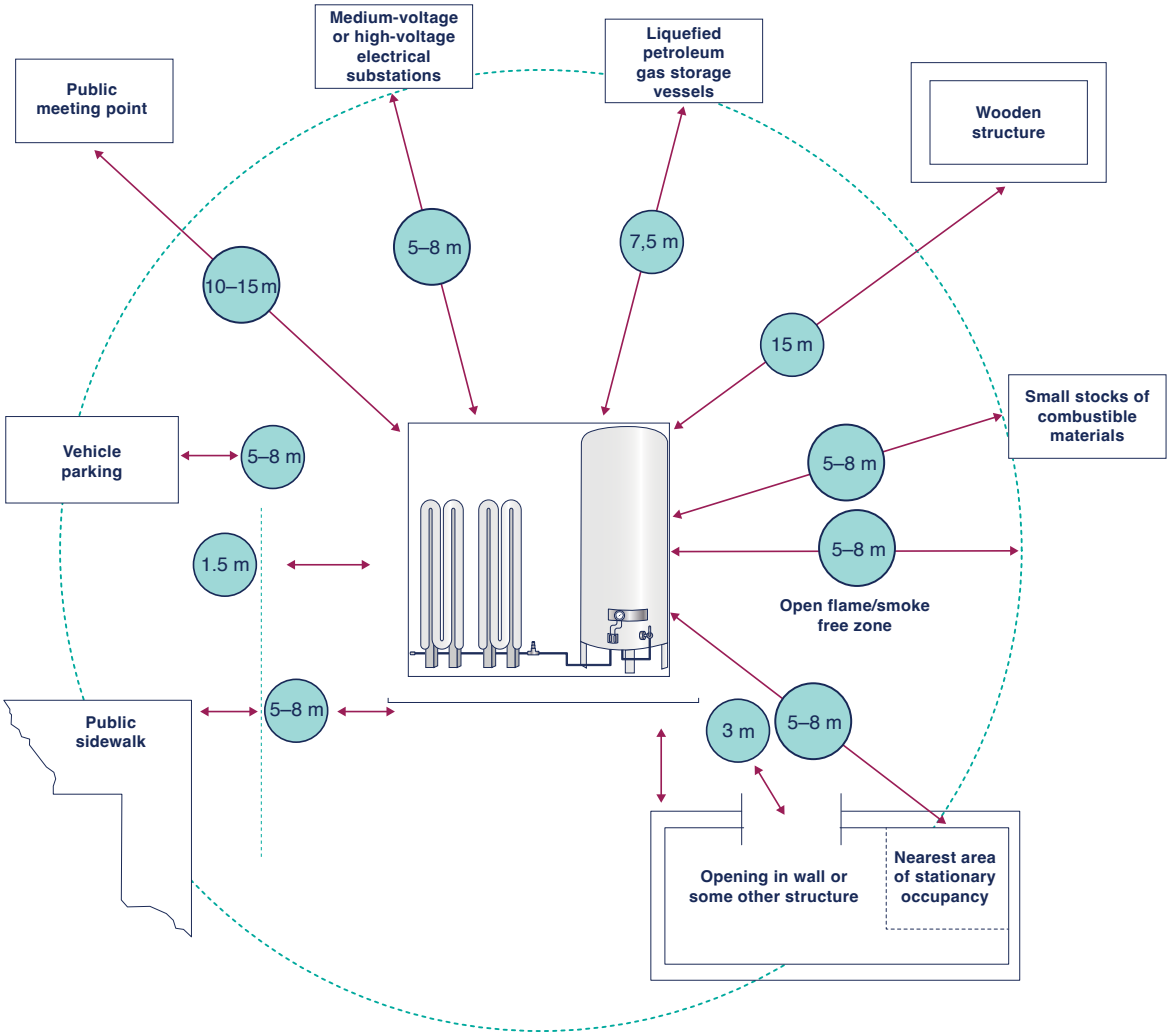


Fig. 3.3 Location of VIE system: safety distances

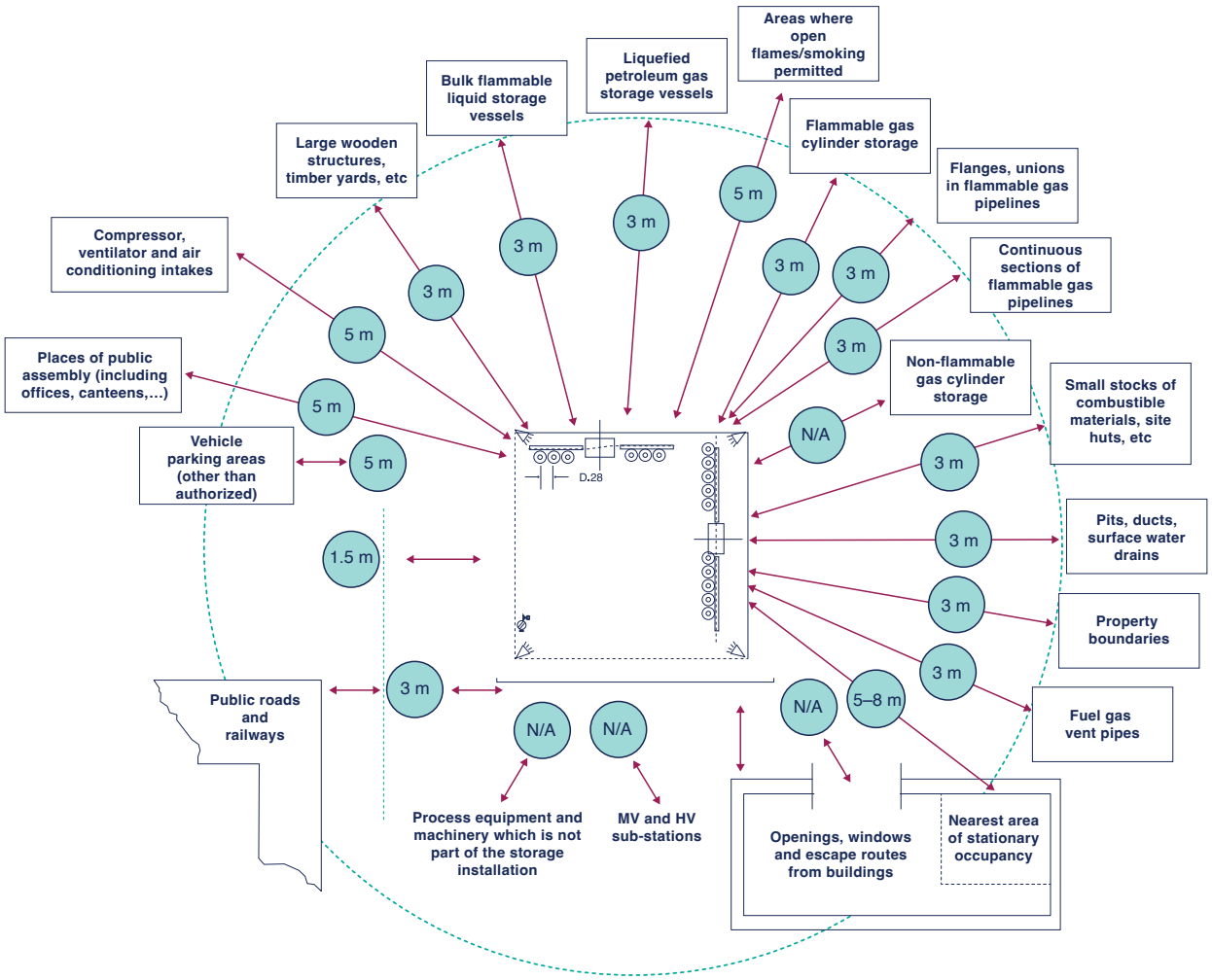


Fig. 3.4 Location of main and backup distribution ramps: safety distances

3.5.3 Power supply

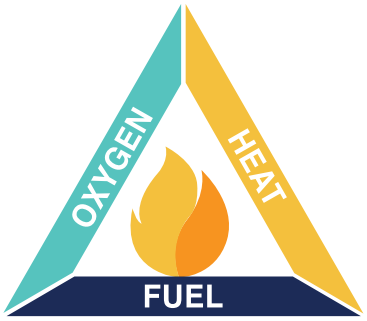
The following considerations are intended to give guidance, but further consultation with electrical engineers, electricians and other experts must be performed.

- The power supply in health facilities must be continuous, reliable and stable. Voltage fluctuation causes equipment damage. If needed, additional to the electrical grid, voltage stabilizers and/or diesel generators with stable voltage can be installed.
- The supplier of the oxygen system [1.5] should specify the total power needs for the system, including the starting current, minimum protection current, and load curve to determine power supply needed.
- Power should be supplied to the unit from an armoured grounded electrical outlet with a three-prong plug and earth cable.
- The configuration of the power supply must consider the primary and secondary sources and could have a combination of elements, such as diesel generator, voltage stabilizer, electrical grid with transformer, circuit breaker and medium voltage module. Electrical elements must be compatible with the power source (frequency, voltage and plug type need to be specified).
- Ideally, an automatic transfer switch between the main and backup sources allows the transfer time delay to be minimized. However, a manual transfer switch can be less maintenance dependent.
- If diesel generators (Fig. 3.5) are installed, they must be properly chosen and provided with spare part kits and a maintenance service. The specifications and diesel consumption may impact the capital expenditure and operational costs. Preferably, the engine of the diesel generator should be electronically controlled and, if it is to be used as primary source (prime mode) rather than a backup source (standby mode), the preferred specifications may comprise, for example, a shunt excitation system (also called “self-excited”) and an integrated AVR.
- Alternative sources of energy could be assessed for cost-effectiveness (e.g. solar power plant).

Fig. 3.5 Diesel generator

3.6 Safety and mitigation measures

Pure oxygen does not burn itself, but it is an oxidizing agent and therefore, it facilitates combustion (i.e. it makes fires burn faster and hotter than in normal air) *(44) (45)*. Fig. 3.6 depicts the three elements fires require to start and expand – heat, or an ignition source; fuel; and oxygen. This is typically referred to as the "fire triangle" (Fig. 3.6) *(45) (46).*



- **Fuel** is any combustible material that can be used as the source of ignition of the fire, as well as to keep it burning.
- **Oxygen** is an oxidizing agent which reacts with the fuel to start and continue the fire. Lower concentrations of oxygen result in slower fuel combustion.
- **Heat**: Fires require oxygen and fuel reacting with each other at a temperature exceeding a threshold temperature, referred to as the "flash point." Different materials and chemicals have different flash points. The lower the flash point temperature of a compound, the more easily the compound ignites.

Fig. 3.6 The fire triangle

Oxygen, contained at high pressure, such as inside high-pressure gas cylinders [2.8], can react violently with flammable materials such as oil and grease. Leakages from damaged hoses, flexible pigtails, pipes, valves and poor connections are common causes of oxygen fires and explosions in health facilities *(44).* A gas leakage in a poorly ventilated room or confined space can quickly increase the oxygen concentration in the ambient atmosphere to a dangerous level. Even a small increase in the oxygen level in the air (from 21% to 24%) can be hazardous as some materials become self-combustible. Oxygen-enriched air in combination with a fuel source (i.e. combustible materials such as paper, clothing, flammable liquids) and heat source (i.e. an item that emits a spark or flame such as torches, matchbox) can cause a fire.

3.6.1 Fire risk mitigation essentials

1. Medical gases should be handled by qualified personnel.
2. Oxygen systems [1.5] should be maintained in good condition, well secured and protected, with a good quality anchorage system to withstand major hazards *(32).*
3. Careless operation, misuse and unnecessary storage of oxygen must be always avoided.
4. Oxygen, where stored or used, must be in a well-ventilated area, away from any source of heat or fuel.
5. Adequate ventilation should ensure that oxygen-depleted air is rapidly replaced. To monitor the oxygen-enriched atmosphere, items such as oxygen depletion sensors are installed in the room.
6. Ventilation can be provided with a natural or mechanical exhaust. To define the ventilation requirement, the volume of stored oxygen in the largest single vessel or the entire volume of connected vessels on a common manifold, whichever is greater, needs to be considered.

   If natural ventilation, this must consist of two non-closable louvred openings (to allow "cross ventilation"). These openings have the following requirements:

   – each opening must have an open area of at least 155 cm^2 per 28 m^3 of stored oxygen. The total surface of cumulative openings should not be less than 464 cm^2;
   – one opening must be located within 30 cm of the floor, and one must be within 30 cm of the ceiling;
   – openings need to be located to ensure cross ventilation; and
   – openings have to be direct to the outside atmosphere without ductwork.

7. Newly assembled equipment should be leak checked. All related equipment and hose connections must be properly fitted.
8. High-pressure gas cylinders should be handled and transported with care, securing with racks or chains, and protecting them against being knocked or dropped. Requirements for the storage of medical high-pressure gas cylinders depend on the total volume of gas contained: the greater the volume, the more stringent the requirements for the cylinder storage station.
9. Cylinder valves must be turned off when not in use.
10. Where oxygen systems [1.5] require maintenance, only tools and substances recommended by the manufacturer should be used. Oil and grease can ignite and burn in oxygen-enriched air and must not be used on oxygen equipment. Only lubricants and tapes made specifically for oxygen service should be used.
11. Fire brigades should be constituted at hospital level, and fire extinguishing equipment should be available in strategic places. Local regulations may specify extinguishers available for enriched-oxygen areas.
12. New facilities should be designed using building codes and guidelines for fire prevention, and the materials used should have adequate fire resistance ratings. These ratings refer to the duration, usually in hours, that a given material can withstand a fire at a specific maximum temperature before losing its integrity, including its strength and insulation capabilities. In the case of both structural and non-structural components, fire resistance ratings/durations can vary from 30 minutes to over 4 hours.
13. As-built drawings or plans for existing facilities are required to determine the fire-retardant retrofitting needs of the facility. As-built drawings should also be produced for new facilities for future reference, for example in the case of renovation or refurbishment. These drawings should be submitted to the fire service so that, in the event of an emergency at the medical facility, first responders will have a good knowledge of the layout and location of emergency exits, fire compartments, and so forth, allowing for a more efficient response in saving lives.
14. Consider prohibiting the use of combustible structural (e.g. floors, walls, roofs, stairwells, fire escapes) and non-structural (e.g. doors, windows, ceilings, fixtures, façades, insulation, mechanical and electrical conduits) components in the medical gas room. Some examples of materials that emit toxic fumes during a fire and should be avoided: polystyrene (for example, polystyrene decorative mouldings), insulation spray foams, polyurethane and isocyanate foams in newly built facilities. Design engineers should account for the required fire rating of the structural components of the building, guided by Building Code Standards. Building codes differ depending on the country.
15. Materials used in the design and construction of hospitals must be non-combustible/non-flammable, must have adequate fire-resistance ratings, and should not emit toxic gases/smoke during a fire. Fire-resistance ratings are usually dependent on the layout, occupancy and usage of the facility. For example, walls and floors with 1-hour fire-resistance rating, and other openings with 45-minutes fire protection rating (if indoors).
16. Appropriate safety signage (Figs 3.7, 3.8 and 3.9) must be in the medical gas room *(47)*.

3.6.2 Signage for mitigation measures

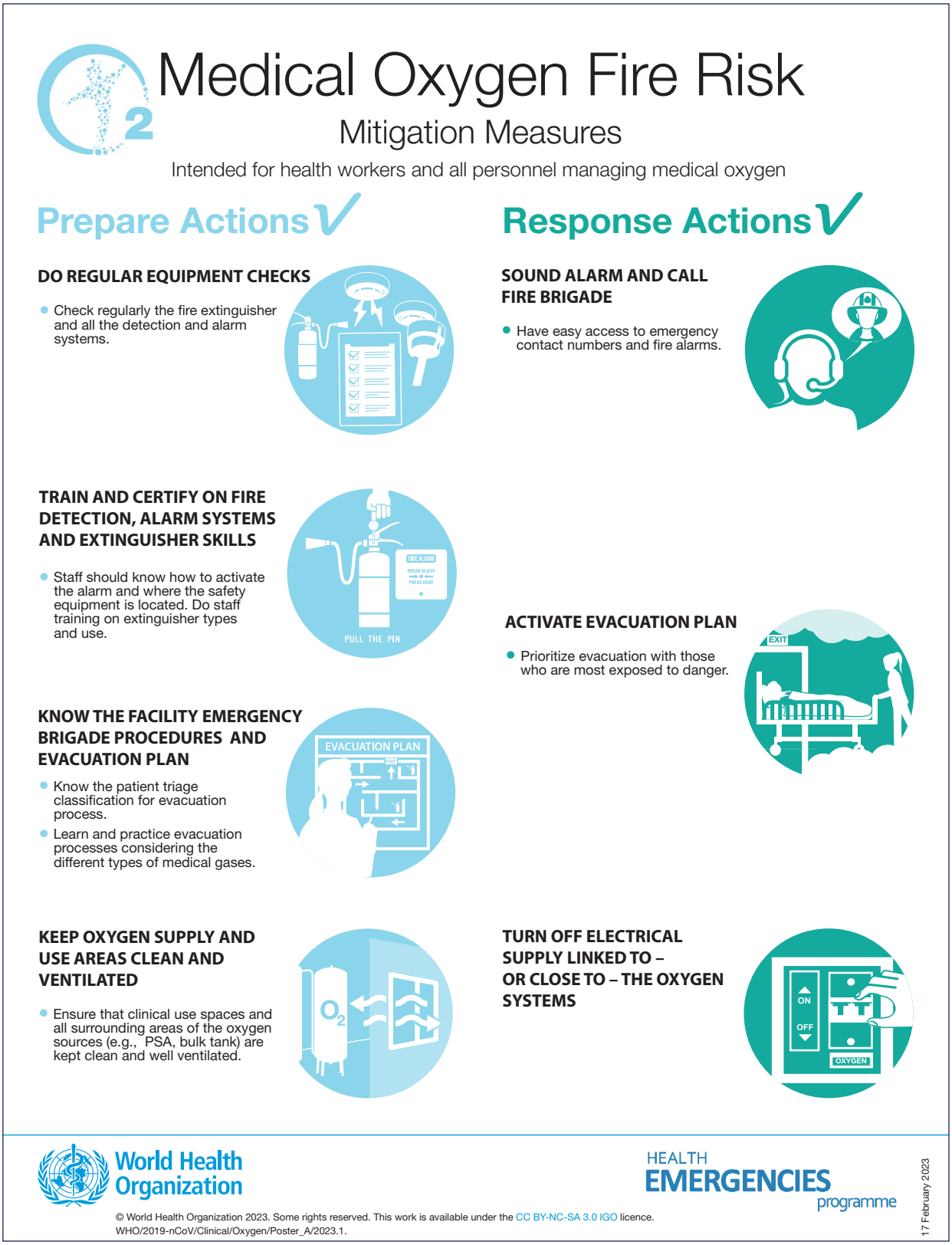


Fig. 3.7 Signage for medical oxygen fire risk
https://apps.who.int/iris/bitstream/handle/10665/366139/WHO-2019-nCoV-Clinical-Oxygen-Poster-A-2023.1-eng.pdf

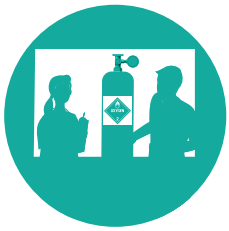
Oxygen Cylinder Safety

Intended for health workers and all personnel managing medical oxygen

Do ✓

DO LEARN PROPER MEDICAL CYLINDER SAFETY HANDLING

- Read and follow the cylinder labelling instructions.

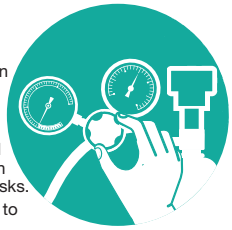


DO TRANSPORT CYLINDERS CORRECTLY

- Use personal protective equipment and mechanical assistance when handling cylinders (e.g. trolleys).
- Ensure cylinder (regardless of size) is firmly secured by a strong chain or strap, capable of preventing the cylinder from falling or being knocked over.
- Ensure valve guards or caps are fitted when cylinders are not in use or when being transported for delivery.

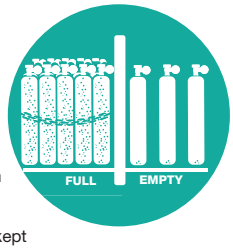
DO SET UP CYLINDERS FOR CLINICAL USE AT A SAFE DISTANCE FROM THE PATIENT

- Ensure that the gas is only turned on when it is required. Adequate valves, pressure regulators and flowmeters should be placed to control the desired rates.
- Oxygen cylinder valves should be opened smoothly to avoid (adiabatic) compression and heat generation and associated fire risks.
- Ensure adequate ventilation on the wards to reduce the risk of fire.



DO STORE CYLINDERS CORRECTLY

- Always physically separate full and empty medical cylinders.
- Store all oxygen cylinders in upright position and nesting, with three points of contact.
- Ensure that the storage room is well ventilated, clean and not exposed to extremes of temperature and humidity.
- Keep oxygen sources several metres from ignition sources (for example, acetylene used in maintenance).
- Ensure appropriate fire extinguishers are kept nearby and are regularly inspected.



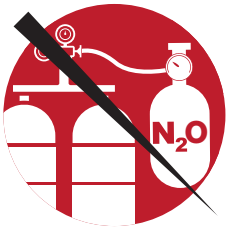
Do not ✗

DO NOT ALTER, TRANSPORT OR HANDLE CYLINDERS INCORRECTLY

- **Do not** change the labelling or repaint a cylinder.
- **Do not** transport gas cylinders in the passenger compartment of a vehicle.
- **Do not** handle more than one cylinder at a time, or roll cylinders along the ground, except on carts designed for handling gas cylinder.

DO NOT USE UNCERTIFIED MEDICAL OXYGEN CYLINDERS

- **Do not** refill cylinders that are not meant for medical oxygen (e.g. cylinders used for other industrial gases) and that have not passed a quality test by a specialist.



DO NOT USE OIL, LUBRICANTS OR ALCOHOL-BASED HAND SANITIZER ON CYLINDER'S FITTINGS

DO NOT ATTEMPT TO REPAIR A CYLINDER OR A VALVE IF LEAKAGE IS DETECTED

- Replacement of damaged components is suggested.

Sources: WHO-UNICEF Technical Specifications and Guidance for oxygen therapy devices. https://www.who.int/medical_devices/publications/tech_specs_oxygen_therapy_devices/en/
GOV.UK Department of Health, Medical gases – Health Technical Memorandum 02-01: Medical gas pipeline systems. Part B: Operational Management. Department of Health libraries, House of Commons library, 2006. https://www.cganet.com/resources/safety-posters/

World Health Organization

HEALTH EMERGENCIES programme

WHO/2019-nCoV/Clinical/Oxygen/Poster_B/2023.1.

17 February 2023

Fig. 3.8 Signage for medical oxygen cylinder safety
https://apps.who.int/iris/bitstream/handle/10665/366140/WHO-2019-nCoV-Clinical-Oxygen-Poster-B-2023.1-eng.pdf

Medical Gas Piping Systems Safety

Intended for health workers and all personnel managing medical oxygen

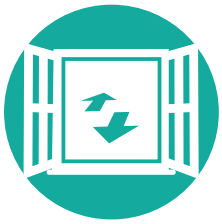
Do ✓

DO REPORT ANY GAS LEAKS AS SOON AS DETECTED

- Report if any noise of leaking gas is detected to maintenance department for urgent action.
- Set off medical gas escape alarm.

DO ENHANCE VENTILATION IF A LEAK IS DETECTED

- Open windows and doors to lower the gas concentration in the air.



DO REGULAR CHECKS TO THE PIPING

- Check for damage, especially serious abrasion, corrosion, leakages, flattening or mechanical damage of pipelines.

Do not ✗

DO NOT STAY NEARBY THE GAS LEAKAGES

- **Do not** stay in the vicinity of the gas leakage because of the possibility of gas saturation in the air, asphyxiation, explosion, fire.

DO NOT COVER PIPING LINEMAKERS AND SIGNAGE

- **Do not** paint over piping networks to cover labeling, identification, flow direction arrows, valve box labels, etc.

DO NOT USE OILY-SOAP SOLUTIONS TO CHECK FOR LEAKS

- **Do not** use water solutions with soap that contains oil and/or animal fat. The animal fats may burn easily in an oxygen enriched atmosphere.

References:
Medical Gases, Health Technical Memorandum 02-01: Medical gas pipeline systems. Part B: Operational management. Department of Health, UK.
http://www.bcga.co.uk/assets/HTM_02-01_Part_B.pdf

World Health Organization

HEALTH EMERGENCIES programme

WHO/2019-nCoV/Clinical/Oxygen/Poster_C/2023.1

17 February 2023

Fig. 3.9 Signage for medical gas piping systems safety
https://apps.who.int/iris/bitstream/handle/10665/366141/WHO-2019-nCoV-Clinical-Oxygen-Poster-C-2023.1-eng.pdf

4. Offsite oxygen production

4. Offsite oxygen production

4. Offsite oxygen production

This section provides a brief appraisal of general topics related to the value chain of offsite liquid oxygen (LOX) production.

4.1 Value chain of liquid oxygen

The value chain is the model describing the full range of activities needed to bring a product or service from its production site through the subsequent supply chain until it reaches the user. In this case, the focus is production of medical oxygen and its distribution for the health sector.

Typically, industrial plants manufacture different gases at the same site (e.g. oxygen, nitrogen, argon, helium, carbon dioxide, hydrogen). Depending on the site location and distribution network, the gases are transported using cryogenic vessels or, in some cases, through industrial pipelines. The industrial applications of these gases are diverse, including the energy sector, mining, production of metals, aerospace, petrochemicals, food preservation, and ripening of fruits and vegetables. The main medical applications include use in hyperbaric chambers and cryopreservation, oxygen therapy [1.3] and mechanical ventilation, diagnosis and treatment of obstructive sleep apnoea, aerosol therapy, laser surgery and cryosurgery.

Oxygen is produced in liquid form by an ASU through a method of cryogenic fractional distillation. It can have different purity levels (Table 4.1). It is pale blue in colour and has a boiling point of -183 °C (-297 °F). Its production, handling and storage require special technologies to keep it insulated from the surrounding environmental heat. These technologies can be capital intensive. Cryogenic fractional distillation plants produce LOX in large quantities: 300–5500 tonnes/day (equivalent to 8750–160 370 Nm^3/hr of gas at NTP). Production requires significant energy input; at scale cost-effective LOX production consumes around ~0.3 kW per m^3 produced.

Table 4.1 Oxygen products and purity levels

Products	% purity	Purity level
Oxygen gas	99.5	2.5
Liquid oxygen (LOX)	99.95	3.5
Extra-dry oxygen	99.5	2.5
Ultra-high purity zero oxygen	99.8	2.8
Ultra-pure carry oxygen	99.98	3.8
Oxygen research	99.999	5.0

LOX produced at industrial scale in fractional distillation plants can serve either industrial or medicinal purposes, depending on whether or not GMP *(3)* and GDP *(27)* have been applied during production. Manufacturers and distributors of medical oxygen, as for any other medicine, must comply with local regulations and standards, and, when applicable, with international regulations. Two publicly available and relevant reference guides are GDP *(27)* and the Pharmaceutical Inspection Co-operation Scheme (PIC/S) *(48).* These guidelines establish specific steps for testing medical gas along the value chain. Fig. 4.1 depicts an extended LOX value chain.

Key resources

The International Pharmacopoeia: https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/norms-and-standards-for-pharmaceuticals/pharmacopoeia

GMP – Good manufacturing practices for medicinal gases: https://www.who.int/publications/m/item/trs1044-annex5

GDP – Good storage and distribution practices for medical products (TRS 1025 Annex 7): https://www.who.int/publications/m/item/trs-1025-annex-7-gdp-medical-products

Oxygen Task Force: https://www.who.int/news/item/25-02-2021-covid-19-oxygen-emergency-impacting-more-than-half-a-million-people-in-low--and-middle-income-countries-every-day-as-demand-surges

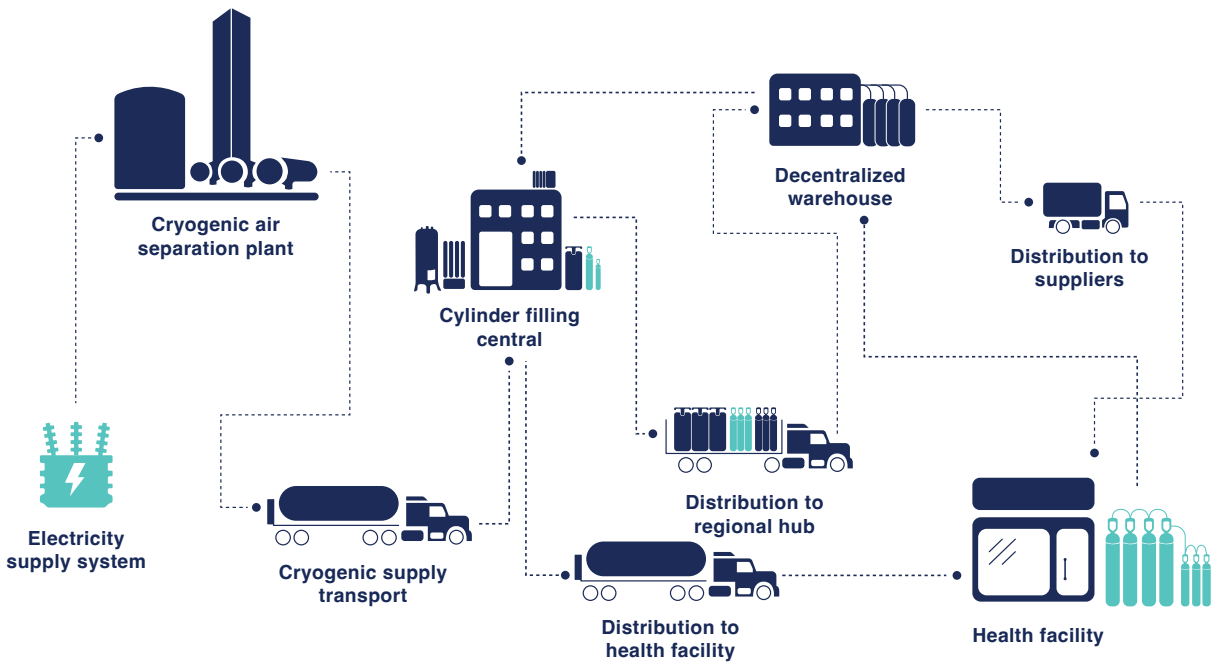


Fig. 4.1 LOX production and distribution value chain

A proper assessment for oxygen suppliers ensures:

- Production capacity of medical oxygen is guaranteed to cope with the oxygen demand of the targeted health facilities (Web annex E: Oxygen supplier's mapping).
- Chain of custody of bulk tanks and/or high-pressure cylinders is always maintained.
- That there is no cross-over with equipment intended for industrial application (e.g. welding) as this could result in cross-contamination. For instance, before unloading the LOX from the cryogenic supply transporter truck into storage tanks of the central cylinder filling station, the contents of each pipe should be analysed and approved for compliance with quality standards.
- That before filling bulk tanks [2.10.1], cryogenic cylinders [2.10.2] and/or high-pressure gas cylinders [2.8], product sampling should be performed once more and sent to a laboratory. The resulting analysis must again fulfil reference pharmacopoeia requirements for both purity levels and remaining impurities. Details found on the certificate of analysis (COA) (Fig. 4.2) should align with a reference pharmacopoeia: International Pharmacopoeia (WHO), United States Pharmacopeia (USP), British Pharmacopoeia (BP) and European Pharmacopoeia (Ph Eur) and/or national regulations. Only then should the production batch be made available for distribution to health facilities.
- Labelling must also comply with standards applicable for medicines.

Only medical oxygen that has been tested to meet authorized specifications for its identity, purity and content and that was produced, stored and distributed following appropriate practices for medicinal use should reach the patient. Uncertainties regarding the content of oxygen intended for industrial purpose, due to the possible occurrence of particulate and microbial contamination, can result in unacceptable risks for patients.

4.2 Liquid oxygen availability

LOX availability is extensive, though not in all LMIC. Understanding where LOX is produced, and whether it is accessible and affordable, as well as whether it is an option for medical applications are important considerations. There are a few global multinational producers of LOX with a handful of subsidiaries, often regionally or nationally branded – at least two of these do not claim to produce medical grade oxygen.

Historical barriers to additional companies entering the sector are the perceived high costs for the medical LOX value chain, operational costs related to common business models (needing deposits and/or leases for expensive requisite hardware), and no sense of ownership by the end user. Since the onset of the COVID-19 pandemic, global partnerships have been established to reduce these costs and strategically increase LOX availability, especially for LMIC *(49)*.

Certificate of Analysis

Product: Oxygen [gas]

Date			
Facility Name			
Facility Address			
Lot #		**Batch #**	
Sampling method			

Final analysis results

Component	Unit (V/V)	Ph. Eur. Method	Analytical Device	Measured	Requirement Ph. Eur
O_2	%	Ph Eur IX 2.5.27 2017	LH-02-45-1	99.86	> 99.5
CO_2	ppm	Ph Eur IX 2.5.24 2017	LH-02-26-1	0.1	< 300
CO	ppm	Ph Eur IX 2.5.25 2017	LH-02-26-2	0.1	< 5
H_2O	ppm	Ph Eur IX 2.5.28 2017	LH-02-37	1.22	< 67
Odour	–	None	N/A	–	N/A

- This product was manufactured by air liquification.
- The equipment used for analysis has been calibrated. Validation certificates can be requested to the oxygen supplier.

Conclusion

The analysed gas complies with the requirements of current version of the European Pharmacopoeia for oxygen for medical use.

Analyst	Date
Quality Reviewer	**Date**

Fig. 4.2 Certificate of analysis of gas stored in high-pressure cylinder

5. Tools and resources

5. Tools and resources

5. Tools and resources

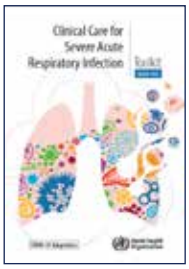
Various WHO practical tools, studies, and platforms are outlined here together with links to external relevant resources, all related to oxygen ecosystem.

5.1 WHO clinical treatment guidelines

The following list of WHO clinical treatment guidelines, concerning delivery of oxygen to a patient, is not exhaustive – further and up-to-date references can be found on the WHO website (https://www.who.int/publications/who-guidelines, https://www.who.int/teams/health-care-readiness/covid-19).

Clinical management of COVID-19: living guideline 2023.
https://apps.who.int/iris/handle/10665/365580

WHO guidelines for safe surgery 2009: safe surgery saves lives.
https://apps.who.int/iris/handle/10665/44185



Clinical care for severe acute respiratory infection: toolkit (COVID-19 adaptation, update 2022).
https://apps.who.int/iris/handle/10665/352851

Guidelines for essential trauma care, 2004.
https://apps.who.int/iris/handle/10665/42565

Oxygen therapy for children: a manual for health workers, 2016.
https://apps.who.int/iris/handle/10665/204584

Paediatric emergency triage, assessment and treatment: care of critically ill children (updated version), 2016.
https://apps.who.int/iris/bitstream/handle/10665/204463/9789241510219_eng.pdf

Therapeutics and COVID-19: living guideline, January 2023.
https://www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2023.1

5.2 WHO Emergency Response Framework

At the onset of the COVID-19 pandemic, the WHO **Emergency Response Framework** established a multidisciplinary team to integrate the clinical management and operations emergency response regarding medical oxygen. The team comprised expertise in supply chain, markets, clinical management, biomedical engineering, architecture, logistics, data management and pharmaceuticals, with the objective of scaling up access and availability of medical oxygen across the globe, especially in LMIC. Initial tools developed to establish the need-gap at national or subnational level include the **WHO COVID-19 Essential Supplies Forecasting Tool (ESFT)** and the **Medical Equipment for COVID-19 Case Management Inventory Tool.**

- Emergency Response Framework (ERF), 2nd edition. Geneva: World Health Organization; 2017 (https://apps.who.int/iris/handle/10665/258604).

5.3 WHO COVID-19 Essential Supplies Forecasting Tool (ESFT)

There are various case method estimations within the ESFT, which provide a forecast of anticipated cases over time. Considerations when choosing a case estimation method include the length of the forecast and availability of country-level data. The estimated cases are applied to a variety of inputs and ratios to estimate the equipment needed to manage the anticipated cases. This tool includes capital equipment, as well as accessories and consumables, and covers PPE, IPC, diagnostics and therapeutics in addition to medical equipment and oxygen estimation in cubic metres per day at national level. The tool has been updated as more data became available to better reflect evolution of the understanding of treatment, for example, through changing ratios needed for invasive or non-invasive ventilation for ICU patients. These ratios impact the equipment, infrastructure and market-shaping requirements of what needs to be mobilized to allow scale-up access to respiratory care.

- WHO COVID-19 Essential Supplies Forecasting Tool (COVID-ESFT), v 4.1. Geneva: World Health Organization; 2022 (https://apps.who.int/iris/handle/10665/352028).

5.4 Medical Equipment for COVID-19 Case Management Inventory Tool

The Biomedical Equipment for COVID-19 Case Management Inventory Tool was developed rapidly in response to the pandemic to determine medical equipment availability and management, and facility and operational readiness. With this resource, countries can assess the existing functional capacity at facility level regarding equipment and forecast procurement needs.

- Biomedical Equipment for COVID-19 Case Management Inventory Tool. Geneva: World Health Organization; 2020 (https://apps.who.int/iris/handle/10665/332777).

5.5 WHO Global Clinical Platform for COVID-19

To characterize the clinical presentation of COVID-19 among hospitalized individuals globally, including the need for oxygen therapy and respiratory support, in April 2020 WHO launched the **WHO Global Clinical Platform for COVID-19**. Anonymized individual patient level data contributed to the platform are pooled and regularly analysed to inform public health interventions and clinical management guidelines.

- WHO Global Clinical Platform for COVID-19. Geneva: World Health Organization; 2021 (https://www.who.int/teams/health-care-readiness/covid-19/data-platform).

5.6 WHO technical consultation on oxygen access scale-up for COVID-19

At the end of 2020, WHO convened a consultation, held over four meetings, with groups with proven experience in implementing oxygen scale-up activities. This consultation identified gaps and further actions needed to scale up access to medical oxygen. The consultation facilitated the understanding of the critical challenges of oxygen systems and highlighted the need for operational guidance to scale up, in an efficient, transparent and sustainable manner in the short term, for the COVID-19 surge, but with a long-term vision beyond the current emergency response.

- WHO technical consultation on oxygen access scale-up for COVID-19; 2021 (https://apps.who.int/iris/handle/10665/342817).

5.7 O2CoV2 study

Due to the need to understand the requirements for oxygen at both the patient and facility level, the WHO Clinical Characterization and Management Working Group developed a protocol for the observational study **O2CoV2:** Oxygen requirements and approaches to respiratory support in patients with COVID-19 in LMIC.

The study's primary objective is to inform an upcoming multidomain randomized clinical trial to test the ability of a variety of non-invasive respiratory approaches to reduce mortality and the need for intubation and mechanical ventilation. In mid-2021, LMIC sites with a diverse range of resources and experience were encouraged to participate in O2CoV2. Over 175 expressions of interest from principal investigators from over 50 LMIC were received, of which 40 principal investigators from 30 countries were invited to implement the study, across all WHO regions.

- O2CoV2 terms of reference (International Study Steering Committee).
- WHO respiratory support research (https://www.who.int/news-room/articles-detail/who-respiratory-support-research-group).

5.8 External resources

Partners of the Oxygen Task Force have made collective efforts to enhance the resources available in relation to the oxygen ecosystem.

Country coordinating mechanisms:

- *Assessing the medical oxygen ecosystem: tools from national to primary health care levels (a compilation of resources).* USAID and EpiC; March 2022 (https://pdf.usaid.gov/pdf_docs/PA00Z9ZB.pdf).
- Every Breath Counts (EBC): (https://stoppneumonia.org/about-us/).
- *Improving oxygen delivery: country progress in the time of COVID-19*. PATH; 2022 (https://www.path.org/programs/market-dynamics/improving-oxygen-delivery-country-progress-time-covid-19/).
- Operational recommendations resource package (C19RM). Partners in Health; 2021 (https://www.pih.org/sites/default/files/2021-04/GF_C19RM_MASTER_V8.pdf).
- *Oxygen delivery toolkit: resources to plan and scale medical oxygen*. PATH; 2022 (https://www.path.org/programs/market-dynamics/oxygen-delivery-toolkit/).

Rapid oxygen and respiratory care equipment gap assessment for designated, planned and/or potential COVID-19 treatment centres:

- World Federation of Societies of Anaesthesiologists (WFSA) Oxygen Supply & Demand Calculator
- UNICEF Oxygen System Planning Tool (https://www.unicef.org/innovation/oxygen-system-planning-tool)
- EBC Oxygen Plant Find & Fix Map
- Open Critical Care – The hub for critical care education tools (https://opencriticalcare.org/)

Develop high-level supply landscape overview:

- PATH/CHAI distributor data collector
- PATH/CHAI Respiratory care equipment market report
- EBC coalition members matrix

Develop robust procurement requests:

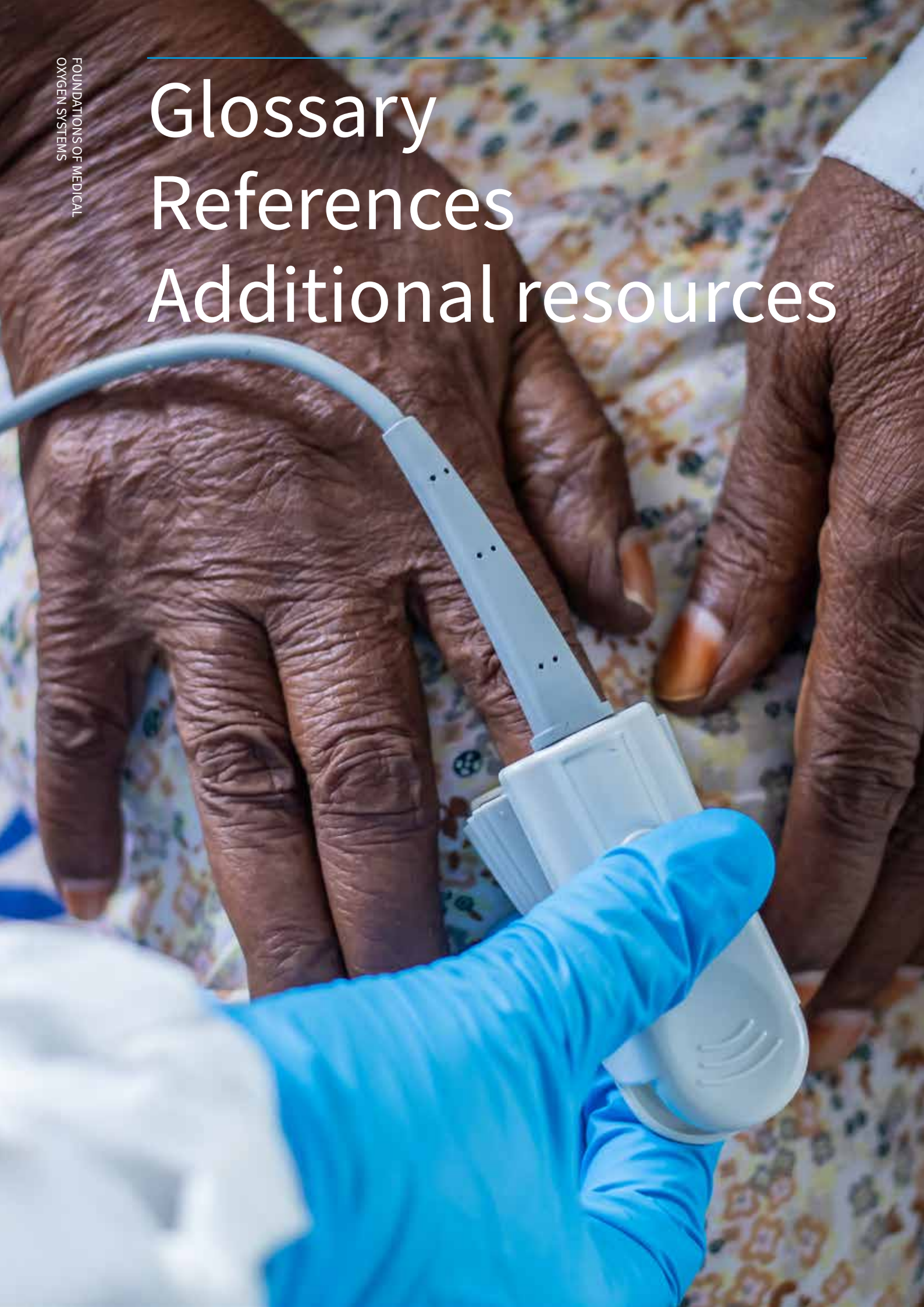
- UNICEF Supply Division procurement services

Develop targeted training plans:

- Project ECHO webinar series from Assist International

  Build Health International: training and repair packages https://buildhealthinternational.org/oxygen/

Glossary
References
Additional resources



Glossary

Air separation unit (ASU): Through different separation methods, this system separates mainly nitrogen and oxygen from atmospheric air; sometimes also argon and other rare inert gases.

Bilevel positive airway pressure (BPAP): Medical device for the delivery of a two levels airway pressure providing a constant flow of air/oxygen to the patient at a preselected pressure, thereby imposing a small positive pressure within the lungs which assists with gas exchange. This function is typically found in advanced patient ventilators; however, it can also be a standalone device and used in several treatment settings.

Booster compressor or high-pressure booster: Device connected to the output of an oxygen generator plant enabling the pressure of the gas to be increased – from 3 to 6 bars – before filling high-pressure gas cylinders (up to 200 bars).

Cryogenic fractional distillation: Process of air separation into its constituents. The separation method involves first liquifying the air at low temperature and high pressure, and then increasing the temperature at different degrees, which correspond to the boiling points of the various desired constituents.

Cylinder bank, or cylinder row: Arrangement of high-pressure cylinders in a line.

Cylinder filling station: Assembly of a booster compressor and a cylinder filling ramp.

Cylinder storage station: The main area where all cylinders (segregated into full, empty or faulty) on a site are stored, excluding those cylinders in, or for immediate use in, the medical gas room, at the patient bedside or for transport (ambulances or stretchers).

Dewpoint: Temperature to which air must be cooled in order to reach saturation with respect to water vapour at its instant pressure. In medical air compressors, dewpoints are quoted as if the air were at atmospheric pressure; even though the air comes out from the dryer columns with high pressure.

Diesel generator: A standalone, diesel-fuelled, power generator, or electricity generator, which converts mechanical energy into electricity. The electrical output is alternating current (AC) and can typically range from 7 to 7000 kVA.

Distribution ramp: A cylinder ramp with pressure regulators, one-way valves and flexible pigtails. This assembly allows the supply from high-pressure gas cylinders connected into the rack to feed into the pipeline network at constant pressure. Before entering the medical gas pipeline system, the gas will typically pass through a pneumatic changeover system which itself is connected to a gas source. The length of the ramp is variable and typically has space for 4, 8 or 10 cylinders.

Filling ramp: A cylinder ramp with pressure regulators, one-way valves and flexible pigtails. This assembly allows the supply of high-pressure gas coming from the booster compressor to fill the high-pressure cylinders at constant pressure. The length of the ramp is variable, typically has space for 4, 8 or 10 cylinders.

Flexible pigtails: Pigtails are hoses used to connect to a cylinder ramp with high-pressure gas cylinders.

Flow: Steady and continuous movement in a stream commonly used for liquid, air or gas.

Health facilities: Includes facilities at different levels of care. Primary level refers to health centres, rural, community and general hospitals. Secondary level refers to regional and provincial hospitals, and some general hospitals with above five clinical specialties. Tertiary level refers to highly specialized facilities with above 300 beds, including national, central and university or teaching hospitals.

Hypoxaemia: Low oxygen in the blood.

Hypoxia: Low oxygen at cellular level.

International Organization for Standardization (ISO): An independent, nongovernmental standard-setting body to facilitate the international coordination and unification of proprietary, industrial and commercial standards. ISO standards are of relevance to manufacturers, sellers, buyers, customers, trade associations, users and regulators.

Maintenance: Includes tasks related to inspection, preventive maintenance and corrective maintenance (i.e. troubleshooting and repairs).

Medical device: An article, instrument, apparatus or machine used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means.

Medical equipment: Medical devices requiring calibration, maintenance, repair, user training and decommissioning – activities usually managed by biomedical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable or other piece of medical equipment. Medical equipment excludes implantable, disposable or single-use medical devices.

Medical gas pipeline system (MGPS): Assembly of different elements (fixed medical gases pipeline networks, warning and alarm systems, sets of valves and pressure regulators, and wall outlets) to safely bring a medical gas from the generator or bulk storage system to the patient bedside. Medical gases can include provision of medicinal oxygen, medical compressed air, anaesthetic gas scavenging systems (AGSS) and medical vacuum installations.

Medical gas room or medical gas central station: Structural element hosting the medical gases (e.g. oxygen, air, vacuum) and comprising generator plants, compressors and/or pumps and/or storage systems.

Molecular sieve beds: Components of PSA systems containing zeolite crystals, which separate gases as air moves in and out. For oxygen production, the zeolites in the sieve beds are designed particularly for nitrogen adsorption so that oxygen can pass through for use, whilst the nitrogen is selectively adsorbed.

Monograph: In this context – a detailed written study of a single medicine, its composition, allowable impurities, methods of analysis and other relevant information contained in a pharmacopoeia; detailing essential standards to ensure the quality of medicines, thus contributing to their safe and efficacious use.

Non-structural: Non-structural elements of a health facility include architectural elements (such as ceilings, windows and doors), medical and laboratory equipment, lifelines (mechanical, electrical and plumbing installations) and safety and security issues. These elements are necessary for the daily operation of health facilities.

Oxygen (O_2): O_2 molecule. Oxygen is critical to sustain human life (and other animals). Oxygen is used by cells to release energy from food. The primary role of the respiratory system is to take in oxygen from the air into the blood, and to expel carbon dioxide from blood into the air. If there is insufficient oxygen in the cells they die. This is especially important in vital organs such as the brain.

Oxygen analyser: An oxygen analyser (also known as an oxygen meter) is a device used to determine the percentage or concentration of oxygen being delivered. There are different types of oxygen analysers: hand-held devices with a digital display and external oxygen sensor; or sensors installed inside a source of oxygen (e.g. bedside concentrator or oxygen generator plant).

Oxygen delivery: Includes reusable and single-use medical devices used to administer oxygen to the patient; covers the capital equipment as well as accessories and consumables related to it (e.g. invasive and non-invasive patient ventilators, breathing circuits, nasal cannulas, face masks).

Oxygen ecosystem: Refers to the multisystemic efforts, initiatives and resources required for an optimal and sustainable implementation of oxygen systems, including policy, guidelines and roadmaps, physician engagement initiatives, patient safety and quality of care programmes, structural and non-structural investments.

Oxygen generator plant: An assembly of different equipment, consisting, at minimum, of an air compressor, air dryer, filtration unit, air tank (or vessel), control panel, oxygen generator (element that separates the oxygen from atmospheric air through molecular absorption) and product tank (or vessel).

Oxygen production sources: Includes bedside oxygen concentrators, oxygen generator plants (PSA, VSA, PSA/VSA) and cryogenic liquid plants.

Oxygen storage and distribution: Includes, but is not limited to, high-pressure gas cylinders, vessels, pipeline networks and other supplies for storage and distribution of medical oxygen.

Oxygen system: Includes, but is not limited to, oxygen production sources, storage, distribution and delivery supplies.

Oxygen therapy: Administration of medical oxygen by any means that improves oxygen delivery to the tissues, increasing oxygen content in the blood.

Pipeline network: Interconnected tubes of typically non-arsenical copper that is treated for medical use, with potentially several branches, allowing to connect the medical gas to the wall outlets that reach the patient bedside. It is part of the MGPS.

Pharmacopoeia: Reference book providing specifications, test methods and a scientific basis for quality control during the entire life cycle of medicines. It supports building trust in the supply of safe, quality medicines people rely on for health.

Pneumatic changeover system, or manifold: A device that allows interconnection and alternation between different medical gas supply systems (e.g. distribution ramp, oxygen generator plant, VIE system) within a medical gas pipeline network. It comprises a control panel which regulate the working pressure and has alarm indicators. It can be automatized, semi-automatized or mechanical.

Power supply, or electrical supply: Refers to the provision of electrical energy from an electricity source.

Pressure: The pressure is the force exerted by molecules in a specific area.

Pulse oximetry: Non-invasive method to measure the oxygen saturation (SpO_2) of the blood cells.

Quality assurance and quality control (QA & QC): Quality assurance focuses on systemic activities implemented within a quality system; quality control focuses on the testing of a product to ensure it meets the specifications required. QA and QC are complementary activities; strong QA and QC programmes are critical in manufacturing high-quality products.

Relative humidity (RH): Ratio of the current absolute humidity to the highest possible absolute humidity, which is the mass of water vapour divided by the mass of dry air in a volume of air at a given temperature.

Service level agreement (SLA): A contract between a service provider and its customers which defines the services (e.g. maintenance activities) and goods (e.g. spares parts) that the provider is required to offer in accordance with the terms, standards and duration established.

Structural: Construction and building elements of health facilities.

Vacuum-insulated evaporator (VIE): A pressure vessel that allows the bulk storage of cryogenic liquids including oxygen, nitrogen and argon for industrial processes and medical applications. The purpose of the vacuum insulation is to prevent heat transfer between the inner shell, which holds the liquid, and the surrounding atmosphere.

Value chain: A term used relating to the supply chain to describe the series of processes involved to deliver a service or create a product. It involves the full life cycle from production to delivery the customer.

Valve: Device for controlling the passage of fluid or air through a pipe, duct, etc., and allowing movement in one direction only.

Wall outlets: Terminals at the endpoint of the medical gas pipeline network and placed at the patient bedside to deliver a given medical gas.

Zeolite: Microporous crystalline aluminosilicate materials commonly used as commercial adsorbents and catalysts. Because of its unique porous properties, its main use is in the separation and removal of gases and solvents.

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WHO and ESICM developed the C19_SPACE interactive programme C19 Skills Preparation Course (C19_SPACE) to orientate and supplement clinical learning for nurses and doctors not regularly or newly engaged in intensive care units (ICUs). C19_SPACE provides the most recent evidence-based information, video lectures and clinical case videos delivered by critical care experts to continue supporting the healthcare community worldwide. (https://www.esicm.org/who-covid-19-skills-preparation-course, accessed 5 January 2023).

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