MEDICAL OXYGEN SYSTEM AT HOSPITALS

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The second wave of COVID -19 pandemic highlighted need for robust oxygen generation and distribution systems in India. In response to the urgent need for amending oxygen supply chain systems, several govt agencies, corporates, NGOs or other social workers started to procure the required machinery and material related to medical grade oxygen generation and distribution from all available and possible sources, mostly sourced or imported from other countries. The oxygen support systems that were put up hastily for many of the emergency care facilities had no standard procedure or practice to conform to that could ensure maximum effectiveness with minimum wastage of this precious resource.

Technical acceptability and integration of all such systems in available hospital environment and compliance to the applicable standards was a challenge given the fact that very little information is available in a compiled form for understanding the technical requirements of all the components involved in integration of oxygen generating and piping distribution systems at hospitals.

This whitepaper is aimed at providing overview of the technical information on oxygen generation techniques and covers the recommended practices, guidelines on the design of oxygen distribution piping inside the hospitals. This document assimilates certified information available through various international standards and codes of practice and the guideline documents by organizations like World Health Organization (WHO), Asia Industrial Gases Association (AIGA), British Oxygen Company (BOC), British Compressed Gases Association (BCGA), Food and Drug Administration (FDA), United States Pharmacopeia and National Formulary (USP-NF). The guidelines collated in this document provides comprehensive information on oxygen system and sources, storage, distribution pipeline, devices for oxygen therapy and highlights current developments on standardization of medical equipment in India and practices for optimizing use of oxygen.

It is to be noted that the local regulatory requirements and prevailing design standard will always take a precedence over the guidelines discussed in this whitepaper.

Oxygen System

The overall infrastructure for medical oxygen is required at medical units at different levels of the health system:

a) Primary level – Home, Community care, Health centres
b) Secondary level – District Hospitals
c) Tertiary level – Regional facilities, Special hospitals, Special outpatient clinics

At all the levels, oxygen source and storage are the most important factors in the oxygen system required at the medical facility. Typical components of oxygen system across all healthcare system is shown in Figure 1 [(1)].

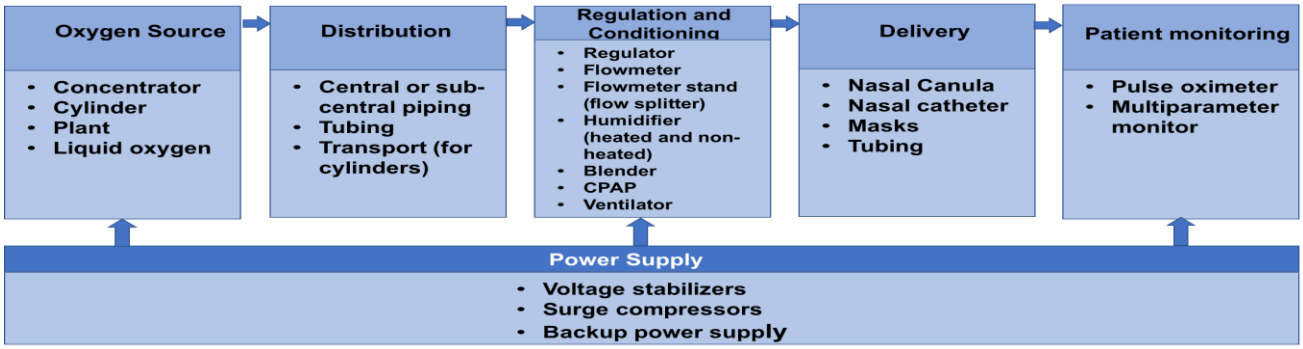

Figure 1: Components of Oxygen system

[1] WHO-UNICEF Technical Specifications and Guidance for Oxygen Therapy Devices; WHO | WHO-UNICEF technical specifications and guidance for oxygen therapy devices

Oxygen Therapy Devices

A comprehensive oxygen system consists of devices from source to patient monitoring along with support systems of power supply and maintenance. The system chosen for the facility is dependent on the source that is appropriate for the situation and the level of service for which the health unit is designed. The elements of the system especially at the patient connection end depend on the source chosen for the facility. The various elements and the guidelines for selection of appropriate system according to the level of the facility are shown in Figure 2 [(3)].

Depending on national policy and local capacity, the above figure may not be representative of all settings.

Back Up in Oxygen Supply Systems

Uninterrupted oxygen is the primary requirement in a medical facility [2]. BS EN 737-3: 2000 [3]

Devices required as part of a complete oxygen system, according to type of oxygen source (vertical) and level of the health system (horizontal)

	Oxygen sources		
	Concentrators	**Cylinders** (stand-alone or with manifold	**Oxygen plant** (with central piping)
Devices for distribution			
Primary level	• Tubing	• Tubing	(Plants may not be suitable as primary level oxygen source)
Secondary level and above (includes all primary level devices,		• Central or sub-central piping	• Central or sub-central piping
Devices for oxygen regulation and conditioning			
Primary level	• Flowmeter stand (Flow splitter)	• Flowmeter • Humidifier (non-heated)	(Plants may not be suitable as primary level oxygen source)
Secondary level and above (includes all primary level devices, plus…)		• Humidifier (Heated) • Blender • CPAP	• Flowmeter (wall mounted) • Humidifier (Non-heated) • Humidifier (Heated) • Blender • CPAP • Ventilator
Oxygen delivery devices			
Primary level	• Nasal cannula • Masks • Tubing	• Nasal cannula • Masks • Tubing	(Plants may not be suitable as primary level oxygen source)
Secondary level and above (includes all primary level devices, plus…)	• Nasal Catheter	• Nasal Catheter • High-low Nasal Cannula (HFNC)	• Nasal Cannula • Masks • Tubing • Nasal Catheter • HFNC
Pulse oximeters and patient monitoring devices			
Primary level	• Self Contained Fingertip • Handheld	• Self Contained Fingertip • Handheld	(Plants may not be suitable as primary level oxygen source)
Secondary level and above (includes all primary level devices, plus…)	• Tabletop	• Tabletop	• Self Contained Fingertip • Handheld • Tabletop • Multiparameter Devices
Devices for quality power supply and oxygen analysis			
Primary level	• Voltage Stabilizer • Surge Suppressor • Oxygen Analyzer • Backup Power Supply • Tools and Spare Parts.	• Oxygen Analyzer	(Plants may not be suitable as primary level oxygen source)
Secondary level and above (includes all primary level devices, plus…)			• Voltage Stabilizer • Surge Suppressor • Oxygen Analyzer • Backup Power Supply • Tools and Spare Parts.

Figure 2: Devices required for Oxygen system at various levels of healthcare units

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5885458/

[3] BS EN 737-3:2000, Medical gas pipeline systems. Pipelines for compressed medical gases and vacuum

(superseded by BS EN ISO 7396-1:2007+A3:2013) recommends the provision of three independent supply sources, primary, secondary and reserve sources. Each source should independently be adequate to meet the full demand in case of failure of supply from the other source(s). The manifold should have two banks of D-type cylinders with each bank having capacity equivalent to two days of consumption and connected to a fully automatic changeover control panel. Reserve capacity should suffice contingency consumption for three days[4].

Primary Supply

This is the main source of oxygen with permanent connection to the system for supplying medical oxygen. The design storage quantity should allow full usage of the healthcare facility between the regular refill intervals. The primary source of supply shall be permanently connected and shall be the main source of supply to the medical oxygen supply system. As a minimum[5], the primary supply should have usable quantity of product to meet expected usage between scheduled product deliveries. Primary supply is usually done by Oxygen Generator or Jumbo Gas Cylinder using manifold system or liquid tank.

Secondary Supply

This source also has permanent connection to the system with automatic switchover. The design capacity is adequate to meet the total oxygen requirement when the primary system malfunctions. Storage requirement should account for the regular replenishment period.

The secondary source of supply shall be[5] permanently connected, automatically supply the pipeline, and capable of providing the total oxygen flow requirement in the event of a primary supply failure. As a minimum, the secondary supply should[5] have usable quantity of product to meet expected usage between a request for product delivery and the delivery of the product.

Reserve Supply

The third and final tier of supply is designed to cater to requirement of patients in critical care units as minimum. It is connected to specific section of the distribution piping and operates when the supply from first two tiers fail. The storage quantity should account for the time between ordering and delivery of the product.

The reserve supply is the final source of supply to specific sections of the pipeline, capable of meeting the required demand in the event of failure of the primary and secondary supplies, or failure of the upstream distribution pipe work. As a minimum, the reserve supply should have usable quantity of product to meet critical patient care between a request for product delivery and the delivery of the product.

Under most conditions[5], compressed gas cylinders are the most appropriate method of providing a reserve source of supply.

The supply system can comprise of combinations of:

a) Gas cylinders or bundles of cylinders

b) Manifold with connected cylinders

c) Portable gas cylinders

d) Cryogenic tanks

e) Vacuum insulated evaporators (VIE)

Criteria for the selection of connections in the oxygen storage and pipeline system are provided in the documents AIGA 019[6] and AIGA 024[7].

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[4] Guideline to Medical Oxygen Supply System for Healthcare Facilities AIGA 049/17; Microsoft Word - Clean copy of AIGA 049_17 HealthCare Facility Bulk Medical O2 Supply Systems 10_05_17.doc (asiaiga.org)

[5] Medical Oxygen Guidelines – For District Level Hospitals – Uttar Pradesh Health System Strengthening Project - http://www.dgmhup.gov.in/Documents/Oxygen_Guidelines_and_Guidebook_Correction.pdf

[6] Connections for Portable Liquid Cylinders, AIGA 019/17; Microsoft Word - AIGA 019 Connections for portable liquid cylinders - Final 14-12-2017.doc (asiaiga.org)

[7] Connections for Transportable and Static Bulk Storage Tanks, AIGA 024/10; Microsoft Word - AIGA 024_10 Connections for transportable and bulk storage tanks_reformat Jan 12.doc (asiaiga.org)

Typical arrangement of oxygen source and connection to supply system is shown in 3 [(6)].

Cylinders of compressed gas are the most common source used as secondary and reserve supply. Reserve supply requirements and manifold locations for critical and high dependency units are identified through risk management process considering failure of the other medical oxygen systems.

Oxygen supply systems are detailed in Chapter 6 of the document HTM 02-01[19]; this covers the installation with bulk cryogenic tanks (VIE) and PSA oxygen plants. Typical plant installation schematics are shown in Figures 18 to 20 of this document that can be referred for planning of healthcare facilities.

- Locate master alarm in area with 24 hours attendance.

Alarm signals that are used to ensure functioning of the system are:

- Low level of liquid below minimum in the cryogenic storage tank as determined by the facility management and agreed with gas supplier
- Switching from primary to secondary source
- Low pressure below minimum in reserve source
- Deviation in pipeline operating pressure exceeds ± 20 % from the design value

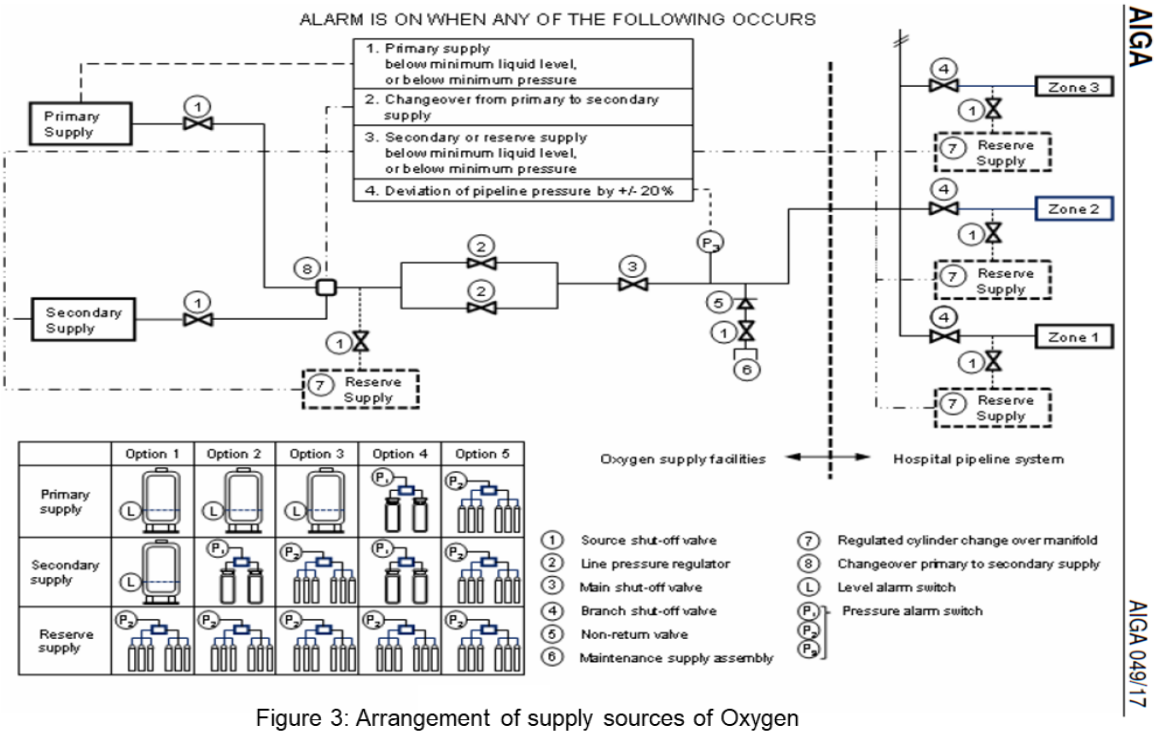


Figure 3: Arrangement of supply sources of Oxygen

Alarm System

The alarm systems[6] and its management protocol are based on risk evaluation of the medical oxygen supply system. Some important features of the alarm system are:

- System has both audible and visual alarms.
- Operator can override audible alarm for single condition only without impairing its functioning for new condition.
- Periodic maintenance of alarm system by equipment manufacturer.

Other Components

Other components[6] of the oxygen system include pressure reducing station, pressure relief valves, check valves and filters. The materials for the system components shall be compatible with oxygen use and system temperatures. Refer to EIGA IGC 73/08/E 'Design considerations to mitigate the potential risks of toxicity when using non-metallic materials in high pressure oxygen breathing systems' for detail requirements. All components are cleaned for oxygen service and commissioning tests

are carried out to meet safety and performance levels.

Sources of Oxygen

Industrial oxygen is used in numerous industries for running manufacturing processes. The procedure for generating medical and industrial oxygen is same. However, medical oxygen is generated with high purity and the oxygen system for generation of medical oxygen is fabricated with the highest quality standards. For production of medical oxygen, which is also listed as a drug on the WHO list of essential medicines, it is mandatory to have proper drug licenses and comply with standard operating systems. It is also necessary to comply with Indian Pharmacopeia standards for generating medical oxygen.

Medical grade oxygen is defined as follows:

- European Pharmacopoeia (Ph Eur) specification: Contains between 90.0%V/V and 96% V/V of O2. Remainder mainly consists of argon and nitrogen. This monograph applies to oxygen used on site where it is produced. It does not apply to individual concentrators.
- United States Pharmacopoeia (USP) specification: Oxygen produced from air by molecular sieve process. Contains not less than 90.0 % V/V and not more than 96 % O2 V/V, the remainder consists of mostly argon and nitrogen.
- The Indian Pharmacopeia 2018 laid down the following monograph pertaining to the quality of medical grade oxygen: Oxygen purity: 93 ± 3 vol%; CO: < 5 ppm; CO2: < 300 ppm; Water vapour: < 67 ppm; SO2: 0 ppm; NOx: 0 ppm

Oxygen therapy used as medical intervention uses medical oxygen generated by oil-free compressor and is free from contamination. Oxygen systems comprise a source or production unit and storage. The oxygen sources include oxygen generation plants, bulk liquid oxygen storage tanks, and oxygen concentrators. The most common storage system used in health-care facilities is a cylinder. Factors that affect the choice of appropriate oxygen source at the treatment unit include amount of oxygen required, infrastructure available, local supply chain, reliability of electric power, and availability of spare parts and maintenance service[8].

Liquid Oxygen

Liquid oxygen produced at offsite cryogenic facility is stored in tanks periodically filled from a tanker upon arrangement with the producer. The oxygen supply in the healthcare facility is through a central piping system where the gas is self-vaporized without external power. The system is suitable for larger installations with assured supply chain mechanisms and robust operating procedures for handling the high-pressure system. It is necessary to provide adequate insulation to avoid boil off and evaporation loss. The inventory must be continuously monitored. The system shall have back up in the form of cylinders. The capacity of back up cylinders must meet the uninterrupted supply condition based on logistics required to arrange fresh liquid oxygen quantity.

PSA Oxygen Units

Oxygen is generated from Compressed air by a separation process which uses the principle of selective adsorption. The air is passed through a bed of Zeolite Molecular Sieves (ZMS) which has a property of very high degree of affinity to nitrogen. The ZMS contains an infinite number of micropores and it retains the adsorbed nitrogen molecules in these pores. The dry & oil-free air from Air Dryer is stored in a Dry Air Receiver before it enters the PSA System. In this System, there are two adsorbers filled with ZMS, where nitrogen along with any traces of moisture are adsorbed and product gas (dry oxygen) comes out and passes to Oxygen Surge Vessel. In the Pressure Swing Adsorption (PSA) System, one adsorber is in production cycle while the other is regenerated (desorbed) by depressurization. The two adsorbers keep switching from adsorption to desorption automatically, through a sequence timer. The pressure in the adsorbers swings from atmospheric pressure to line pressure, which is why this process is known as Pressure Swing Adsorption.

[8] WHO – Oxygen sources and distribution for COVID-19 treatment centres; https://www.who.int/publications/i/item/oxygen-sources-and-distribution-for-covid-19-treatment-centres

PSA oxygen plants of required capacity can be located at the medical facility. The generated oxygen can be piped directly to patients and can be used through a booster compressor to refill cylinders. Oxygen plants require a reliable source of power and a back-up supply in the form of cylinders. When the PSA units are used for oxygen supply at hospitals, it must be provided with battery of pressurised oxygen cylinders as a back up. It is common to consider PSA oxygen plants with cylinder back up to be used as secondary source of oxygen supply at the hospitals. The PSA unit must be supplied with emergency power to the feed air compressor. In case of disruption in power supply, the system must be capable of auto switch over to the backup oxygen cylinder bank. The PSA plants may take significant time to re-stabilize after the power interruption/resumption cycle.

Technical specification for PSA plants is available in the WHO document "Technical specifications for Pressure Swing Adsorption (PSA) Oxygen Plants"[9].

Oxygen Concentrators

Oxygen concentrators are miniature PSA units; the technology is same as used in PSA plants. It has been successfully used as primary source of oxygen supply. It is robust, safe, efficient and reliable means of supply when built, tested and maintained as per international standards. As per Canadian publication[10] , the oxygen concentrators are used successfully as primary source of oxygen at hospitals. The primary supply must be sized to provide twice the average flow requirement and must have an appropriately sized storage tank to provide short duration peak flow rates [(10)]. The secondary and reserve supplies must be capable of supplying the anticipated peak flow requirement. It is intended that the secondary supply may provide the sustained high demand flows that are greater than the capacity of primary supply with its fixed flow capacity[10].

This is a portable unit running on electric power that is required to drive air compressor of the PSA unit. Emergency power back up is required for the compressor. When used as primary source of supply, it is recommended to use another oxygen concentrator as a backup. They can produce continuous supply of more than 90% concentrated oxygen but should not be used when the concentration falls below 90%. The flow rates normally available vary between 5 lt/ min to 20 lt/ min.

When used with a flowmeter stand for splitting flow, concentrators can provide a continuous supply of oxygen to multiple patients at the same time. Concentrators can provide a safe and cost-effective source of oxygen, but they do require a source of continuous and reliable power and regular preventive maintenance to ensure proper functioning. It is best practice to also have cylinders as a backup supply[9].

Oxygen Cylinders

Oxygen gas can be compressed and stored in cylinders. These cylinders are filled at a gas manufacturing plant, either via a cryogenic distillation or a PSA plant, and then transported to health facilities. Cylinders can be used in one of two ways. One, by installing them directly within patient areas or, similar to direct piping and two, by connecting them to sub-central manifold systems (groups of cylinders linked in parallel) at the facility. Thus, oxygen can be piped to specific areas of the health facility, even at the ward level. When cylinders are the only source of oxygen in a health facility, a strong supply-chain is required to ensure ongoing availability.

Once filled, cylinders themselves do not require electricity, but they do require several accessories and fittings to deliver oxygen, such as pressure gauges, regulators, flowmeters, and in some cases, humidifiers. Cylinders also require periodic maintenance, commonly provided by gas suppliers at the point of refilling. Cylinders can be used for all oxygen needs, including high-pressure supply and in facilities where power supply is intermittent or

[9] Technical specifications for Pressure Swing Adsorption(PSA) Oxygen Plants; https://www.who.int/publications-detail-redirect/WHO-2019-nCoV-PSA_Specifications-2020.1

[10] Friesen R.M., Raber M.B., Reimer D.H., "Oxygen Concentrators: a primary supply source", Candaian Journal of Anesth, 1999/ 46:12 / pp- 1185-1190

unreliable. Also used for ambulatory service or patient transport.

Additionally, storage or transportation of medical oxygen in cylinders must be done carefully and by trained personnel as the contents are under extreme pressure.

Specifications of Medical Oxygen Cylinders in India

Oxygen cylinders in India must comply to Indian standard IS: 7285. Different type of cylinders is mentioned as below.

A-Type Medical Oxygen Cylinder ISI Mark (20 CU.FT.)

- High pressure seamless cylinders for Medical Oxygen gas, cylinder is ISI Marked conforming to IS: 7285 part 2, certified by the Bureau of Indian standards (BIS) and approved by the chief controller of explosive (CCOE) Government of India.
- Cylinder made from Manganese Steel having 5 Ltr. Water capacity (20 CU.FT.)
- Valve made of Brass and Chrome Plated.
- Working pressure 150 Kg.f/cm^2 at 15deg.C; Hydraulic test pressure 250 Kg.f/cm^2.
- Colour code of the cylinder should as per IS 3933.
- Manufacturing certificate, ISI certificate & department of explosion Government of India to be provided for each specified cylinder separately at the time of supply.

B-Type Medical Oxygen Cylinder ISI Mark go CU.FT.)

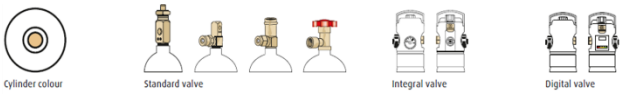
- B-type high pressure seamless cylinder for Medical Oxygen gas, cylinder is ISI marked conforming to IS: 7285 part 2, certified by the Bureau of Indian standards (BIS) and approved by the chief controller of explosive (CCOE) Government of India.
- Cylinder made from Manganese Steel; 10.2 Ltr. Water capacity (40 CU.FT.).
- Fitted with bull nose type valve as per IS: 3224, and neck cap.
- Valve made of Brass and Chrome Plated.
- Working pressure 150 Kg f/cm^2 at 15 deg. C. Hydraulic test pressure 250 Kg.f/cm^2.
- Colour code of the cylinder should be as per IS: 3933.
- Manufacturing certificate, ISI certificate & department of explosion Government of India to be provided for each specified cylinder separately at the time of supply.

D-Type Big size Medical Oxygen Cylinder ISI Mark (220 CU.FT.)

- D-Type high pressure seamless cylinder for medical oxygen gas, cylinder is ISI marked confirming to IS: 7285 part 2, certified by the Bureau of Indian Standards (BIS) and approved by the chief controller of explosive (CCOE) Government of India.
- Cylinder made from Manganese Steel. 46.7 Ltr. water capacity (220 CU.FT.).
- Fitted with bull nose type valve as per IS: 3224, and neck cap.
- Valve made of Brass and Chrome Plated.
- Working pressure 150 Kg.f/cm^2 at 15 deg. C. Hydraulic test pressure 250 Kg.f/cm^2.
- Colour code of the cylinder should as per IS 3933.
- Manufacturing certificate, ISI certificate & department of explosion Government of India to be provided for each specified cylinder separately at the time of supply.

In India, the fabrication of oxygen cylinders comply to the provisions of IS 7285: Specification for Refillable Steel Gas Cylinders – Part 1 (2018) and Part 2 (2017) for Normalized and Tempered & Quenched steel respectively. These standards cover details of material specification, design, manufacture, inspection, testing and approval, and certification for the cylinder body.

These standards have been aligned with corresponding parts of international standard ISO 9809 – 2010 for conformity to global requirements. The valve fittings for the cylinders comply to requirements of IS 3224: 2002 (which is based on BS 341), IS 3745: 2006 for yoke type valves for small



OXYGEN													
	ZA	AZ	CD	D	ZD	E	F	IQX	HX	ZX	G	J	W
CYLINDER CODE	101-ZA	298121-AZ	101-CD	101-D	101-ZD	101-E	101-F	101-IQX	101-HX	101-ZX	101-G	101-J	101-W
NOMINAL CONTENT (LITRES)	300	170	460	340	600	680	1360	2000	2300	3040	3400	6800	11300
NOMINAL PRESSURE (BAR)	300	137	230	137	300	137	137	200	230	300	137	137	230
NOMINAL OUTLET PRESSURE (BAR)	4	N/A	4	N/A	4	N?A	N/A	4	4	4	N/A	N/A	N/A
VALVE TYPE	INTEGRAL	STANDARD	INTEGRAL	STANDARD	INTEGRAL	STANDARD	STANDARD	DIGITAL INTEGRAL	INTEGRAL	INTEGRAL	STANDARD	STANDARD	STANDARD
VALVE OUTLET FLOW CONNECTION	6MM FIRTREE	PIN-INDEX ISO 407	6MM FIRTREE	PIN-INDEX ISO 407	6MM FIRTREE	PIN-INDEX ISO 407	5/8" BSP(F) BS 341 NO.3 BULLNOSE	6MM FIRTREE	6MM FIRTREE	6MM FIRTREE	5/8" BSP(F) BS 341 NO.3 BULLNOSE	PIN-INDEX ISO 407	ISO 5145 NO.5 (M)
VALVE OUTLET PRESSURE CONNECTION	N/A	N/A	OXYGEN SCHRADER (BS 5682)	N/A	OXYGEN SCHRADER (BS 5682)	N/A	N/A	OXYGEN SCHRADER (BS 5682)	OXYGEN SCHRADER (BS 5682)	OXYGEN SCHRADER (BS 5682)	N/A	SIDE SPINDLE	N/A
VALVE OPERATION	HANDWHEEL	KEY	HANDWHEEL	KEY	HANDWHEEL	KEY	KEY	HANDWHEEL	HANDWHEEL	HANDWHEEL	KEY	KEY	KEY
FLOW RATE (LITRES/MIN)	0.1-15	N/A	FIRTREE: 1-15 SCHRADER: 40	N/A	FIRTREE: 1-15 SCHRADER: 40	N/A	N/A	FIRTREE: 1-15 SCHRADER: 40	FIRTREE: 1-15 SCHRADER: 40	FIRTREE: 1-15 SCHRADER: 40	N/A	N/A	N/A
DIMENSIONS LXD (MM)	390 X 85	290 X 106	520 X 100	535 X 102	525 X 101	865 X 102	930 X 140	950 X 140	930 X 140	930 X 143	1320 X 178	1520 X 229	1540 X 230
WATER CAPACITY (LITRES)	1	1.2	2	2.3	2	4.7	9.4	10	10	10	23.6	47.2	46.6
NOMINAL FULL WEIGHT (KG)	1.6	2.5	3.5	3.9	4.1	6.2	17	18	19	14	39	78	85

Figure 4: Oxygen cylinder standard

medical gas cylinders (aligned with ISO 407: 1991) and IS 7302: 2018 for self-contained breathing apparatus (SCBA) units (based on ISO 13341: 2010).

Other Specifications of Medical Oxygen Cylinders

The general specification for oxygen cylinders for medical purposes are available in the document: WHO -UNICEF Technical Specifications and Guidance for Oxygen Therapy Devices[3]. These cover the aspects of pressure rating, construction, pressure regulator and safety release valve. However, variations in the end connections of valves exist among different countries and this can pose challenges in importing cylinders for use in a country different from the original manufacturer standards.

Data sheet for oxygen cylinders available in UK are specified in the document "Medical gas cylinder data chart" from British Oxygen Company (BOC)[11], are shown in Figure 4 and 5 [(12)].

The medical oxygen cylinders in UK are available in several sizes and their end connections are also different it should be noted that the end connections are also different. Suitable adjustments to the end connections would be required if the oxygen cylinders are imported from UK.

Oxygen cylinders must be handled in a safe manner. Some of the aspects of oxygen cylinder storage are as below.

It is recommended that the empty cylinder and full cylinder areas are segregated, identified by their service and well barricaded. The cylinders are not stacked one above other without proper stand or support structures. The cylinders must be positioned to stay upright and ensure that the valve protection

[11] Medical gas cylinder data chart by BOC; cylinder_data_med309965_2011_tcm409-54065.pdf (bochealthcare.co.uk)

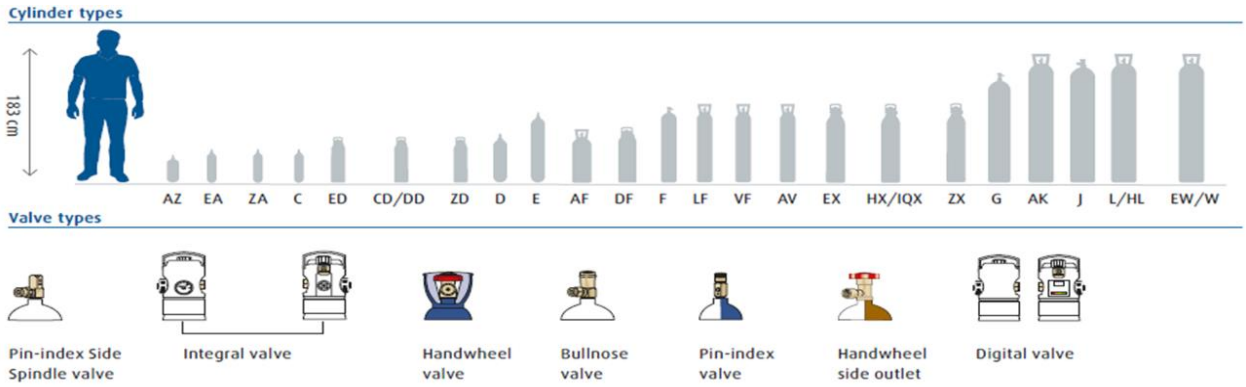


Figure 5: Oxygen cylinder types and Valves

caps, and valve outlet seals are not damaged during storage. The cylinder storage area must be well-ventilated and located away from combustible materials, if any. The storage area should have weather and rain protections.

Oxygen adds to the flammability and hence it is a good practice to maintain a minimum of 20 feet distance between any other cylinder storage and oxygen cylinder storage area. Preferred that oxygen storage area is separated, at a minimum, by a fire wall five feet high with a fire rating of 0.5 hours.

While handling the oxygen cylinders, the ‘’first-in, first-out’ inventory system concept can be used to prevent full containers from being stored for long

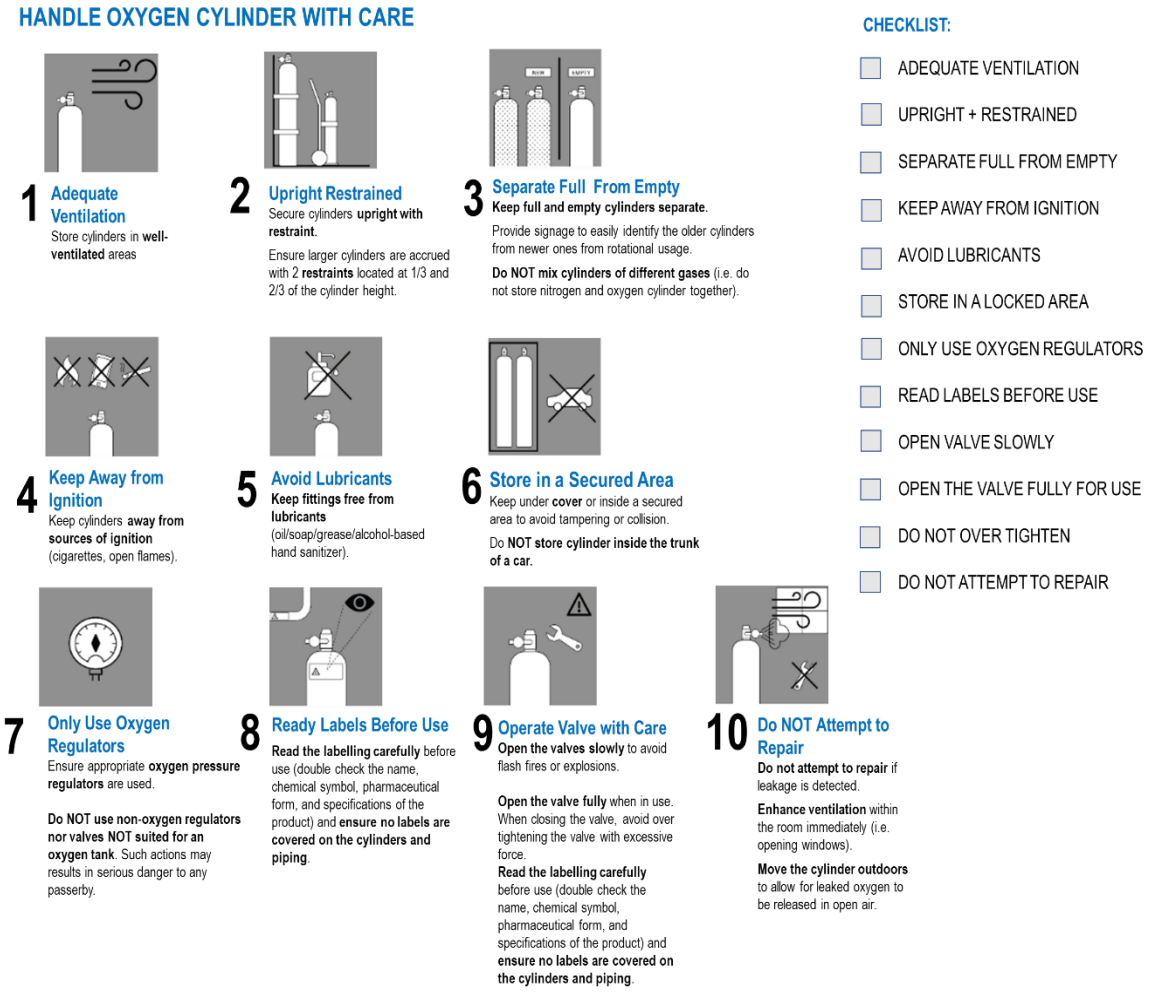


Figure 6: Oxygen cylinder information

periods of time. For better accessibility, all doors or gates giving direct access to the cylinder storage should open outwards and the cylinders should be stored away from the emergency exit areas. Oxygen cylinders must be inspected on a routine basis to check any indication of leakage.

Additional information on oxygen cylinders including basic data for design and selection, checklist for use and safety information are shown in Figure 6 [20]. To avoid any contamination from the cylinder valve, it is recommended to Inspect and purge the cylinder valve. Ensure that there are no loose pieces of plastic or any other material used for wrapping the cap.

It is also recommended to train the hospital staff on safety aspects of oxygen. Signage and visual instructions in the oxygen cylinder storage area would help the operators. The oxygen cylinders storage area should be marked as no smoking zone. The storage area must not be located on upper floors or below the ground level. It is important to note that the oil or grease or any other lubricating oils shall not be applied to the fittings or regulators of oxygen cylinders as it is a fire hazard. Refer to figure 7 [20] below for typical safety related signage and information.

Oxygen Cylinders End Connections

Comparative study of the valve details across different Asian countries is provided in subsequent section to highlight the varying standards. These need detail study before emergency import certification of complete cylinder units from other countries.

BCGA carried out a study to compare the different types of valves used for cylinders of medical gas across countries in Asia. The purpose of this study was to assess the differences in the valves used to highlight the variations that could affect interchangeability of the cylinders amongst these countries. Comparison of medical gas cylinder valves are shown in (18).

Table 1: Findings of survey on Medicinal Gas Cylinders in Asia

Country	Regulated	Industry Norm
China	Yes	15383-2011: Connection types and dimensions for gas cylinder valve outlets
Hong Kong	Yes	ISO 407 for pin index BS EN 850: 1997
India	Yes	IS 3224: 2002 Valve Fittings for Compressed Gas Cylinders Excluding Liquefied Petroleum Gas (LPG) Cylinders – Specification IS 7302: 1974 Specification for Valve Fittings for Gas Cylinder Valves for Use with Breathing Apparatus IS 3745: 2006 Specification for Yoke Type Valve Connection for Small Medical Gas Cylinders
Indonesia	Yes	BS 341 Transportable gas container valves
Japan	Yes	ISO 407 (Pin-index) for less than 10L medical gas cylinders, JIS B 8246
Korea	Yes	KS B 6214 Valve for High Pressure Cylinder (specifies inlet/ outlets and tests required)
Malaysia	Yes	MS ISO 407: 2004 Recommended Pin-index valves for medical gases ISO 5145 Cylinder valve outlets for gases and gas mixtures – Selection and dimensioning
Philippines	No	PNS 296: 1990 Standard Valve Outlets for High Pressure Permanent and Liquefiable Gases
Singapore	No	BS 341 Transportable gas container valves
Taiwan	Yes	CGA V-1 and JIS B 8246
Thailand	Yes	CGA V-1, TIS 1095 and TIS 255
Vietnam	No	BS 341 Transportable gas container valves

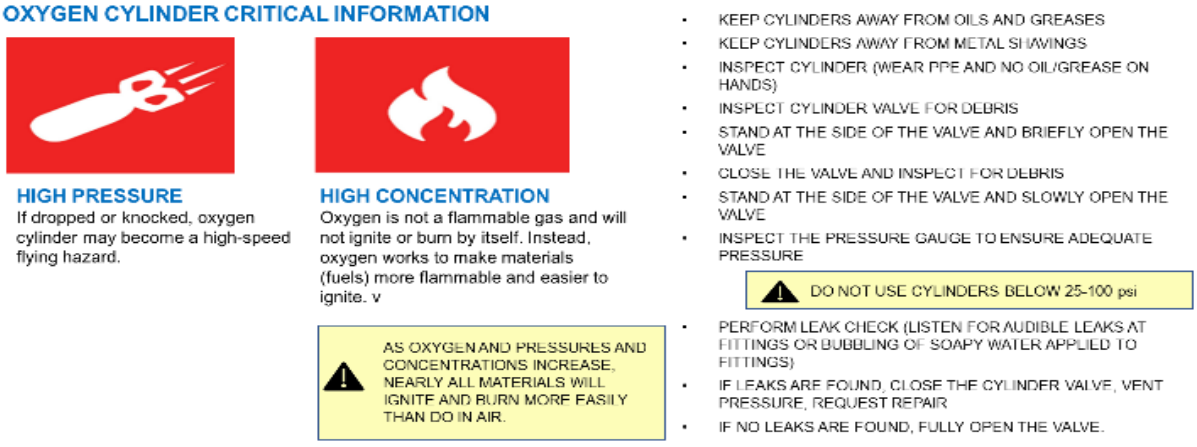


Figure 7: Oxygen cylinder safety information

- Technical Information Sheet 37 by British Compressed Gas Association (BCGA)[14]

CHARACTERISTIC	CYLINDERS	CONCENTRATORS (PSA)	OXYGEN PLANTS (PSA)	LIQUID OXYGEN
DESCRIPTION	A refillable cylindrical storage vessel used to store, and transport oxygen is compressed gas form. Cylinders are refilled at a gas generating plant and thus require transportation to and from the plant.	A sell-contained. Electrically powered medical device designed to concentrate oxygen from ambient air, using PSA technology.	An onsite oxygen generating system using PSA technology. Which supplies high-pressure oxygen throughout a facility via a central pipeline system, or via cylinders refilled by the plant.	Bulk liquid oxygen generated off-site and stored in a large tank and supplied throughout a health facility pipeline system. Tank requires refilling by liquid oxygen supplier.
CLINICAL APPLICATION AND/OR USE CASE	Can be used for all oxygen needs, including high-pressure supply and in facilities where power supply is intermittent or unreliable. Also used for ambulatory service or patient transport. Used as a backup for other systems.	Used to deliver oxygen at the bedside or within close proximity to patient areas. A single concentrator can service several beds with the use of a flowmeter stand to split output flow.	Can be used for all oxygen needs, including high-pressure supply.	Can be used for all oxygen needs, including high- pressure supply and in facilities where power supply is intermittent or unreliable.
DISTRIBUTION MECHANISM	Connected to manifold of central/sub-central pipeline distribution system, or directly connected to patient with flowmeter and tubing.	Direct to patient with tubing or through a flowmeter stand.	Central/ sub-central pipeline distribution system, or can be used to refill cylinders that can be connected to manifold system in the facility.	Central pipeline distribution system.
ELECTRICITY REQUIREMENT	NO	YES	YES	NO
MAINTENANCE REQUIREMENT	Limited maintenance required by trained technicians.	Moderate maintenance required. By trained technicians, who could be in-house	Significant maintenance of system and piping required by highly trained technicians and engineers, can be provided as part of contract.	Significant maintenance of system and piping required by highly trained technicians and engineers, can be provided as part of contract.
USER CARE	Moderate; regular checks of fittings and connections, regular checks of oxygen levels, cleaning exterior.	Moderate; cleaning of filters and device exterior.	Minimal; at terminal unit only	Minimal; at terminal unit only
MERITS	No power source	(1) continuous oxygen supply(if power available) at low running cost. (2) output flow cab be split among multiple patients.	(1) can be cost effective for large facilities. (2 continuous oxygen supply	(1) 99% oxygen obtained. (2) high oxygen output for small space requirement.
DRAWABACKS	(1) requires transport/supply chain. (2) exhaustible supply. (3) highly reliant upon supplier. (4) risk of gas leakage (5) risk of unwanted relocation.	(1) low pressure output, usually not suitable for CPAP or ventilators. (2) requires uninterrupted power. (3) requires backup cylinder supply. (4) requires maintenance.	(1) high capital investments (2) requires uninterrupted power (3) needs adequate infrastructure (4) high maintenance for piping system (5) requires backup cylinder supply (6) risk of gas leakage from piping system	(1) requires transport/ supply chain (2) exhaustible supply. (3) high maintenance for piping system (4) needs adequate infrastructure. (5) requires backup cylinder supply (6) risk of gas leakage from piping system

Figure 8: Comparison of oxygen sources

Guidelines for use of oxygen cylinders covering items of initial safety checks, preparing cylinder for use, leak tests, precautions during and after use, transport and storage of cylinders, area ventilation requirements, fire-fighting and accidental release mitigation measures, and disposal conditions are available in the document "Guidelines for Oxygen Cylinders"[12] based on safety data sheet by BOC.

Detail guidelines covering safe use of oxygen cylinders are provided in the following documents:

- Technical Information Sheet 22 by British Compressed Gas Association (BCGA)[13]
- Technical Information Sheet 21 by British Compressed Gas Association (BCGA)[15]
- Reference Guide on Medicinal Gas Cylinder Valves (AIGA 097/17)[16]

Comparison of Oxygen Sources

Description and comparison of oxygen sources and storage from the reference 7 is reproduced below. It is important to note that the oxygen concentrators can produce oxygen at low pressures and are not suitable for using oxygen requirements for patients on ventilators. The typical supply pressure required

[12] Guidelines for Oxygen Cylinders; SLSGB-New-Oxygen-Guidelines-2015.pdf

[13] Technical Information Sheet 22; BCGA LEAFLET L7: The Dangers of Industrial Gas Abuse

[14] Technical Information Sheet 37; BCGA TIS 37 - Revision 2 - 18-06-2019.pdf

[15] Technical Information Sheet 21; BCGA TIS 21 - Revision 2 - May 2019.pdf

[16] AIGA 097/17 - Reference Guide on Medicinal Gas Cylinder Valves; Microsoft Word - Final Ver of AIGA 096-17 Ref Guide on Medical Gases Cylinder Valves.doc (asiaiga.org)

for ventilators is in excess of 3.5 to 4 barg. The oxygen PSA units can be integrated with hospital piping and can deliver oxygen at about 3 barg pressure. The oxygen cylinders can meet the higher-pressure requirements. Figure 8 depicts the comparison of various oxygen sources.

Setting up Of Medical Oxygen Facility

For setting up of medical oxygen facility, one needs to obtain approvals mainly from following two government bodies.

A. Permission from Local Pollution Control Board:

- The applicant and operator of the medical oxygen facility must have an 'Establishment Registration License' from labor department of respective state government.
- Brief Project Report shall be submitted to local pollution control board authorities for obtaining a license for producing medical oxygen.
- Project report shall include (but not limited to:) - what are the raw materials used, Quantity per day/Month, Name plate capacity, etc. Any kind of hazardous material/or any other chemical used in the process must be highlighted. The report shall contain process description and Process brief of the manufacturing technology.

B. *Approval from PESO:*

Similar to any other chemical facility, engineering drawings such as plant Layouts, Area classification, etc shall be submitted for PESO approval.

No approvals are required for commissioning.

Certification:

No more certification is required for medical oxygen generation facility as govt has recently moved medical oxygen facilities into white category of manufacturing. White category is least polluting industrial sector.

As of now, no certification is required for product purity, but hospitals might require and demand it.

Central pollution control board classifies industries in four categories such as Red, Orange, Green and White. {example Red for Chemical and explosives and more polluting sectors).

Union Environment Ministry introduced a 'White' category - a colour code that meant 36 industry sectors may need no green clearance at all. {https://www.indiatoday.in/india/story/36-industries-white-category-central-pollution-control-board-967995-2017-03-28}

Other Requirements:

It is suggested to consult 'Liasioning dept' of the organization to confirm requirement of any other documents. This may include NOC from collector or district authority.

Pipeline Network

A central oxygen or pipeline, system uses pipes to provide oxygen to various locations within a health facility/hospital. These systems are typically economical in large hospitals that require a high volume of oxygen and can support the costs of the centralized pipeline infrastructure.

Intra-hospital pipe network has the advantage on ensuring controlled oxygen distribution with least manual intervention obviating requirement of handling cylinders and portable oxygen generators between patients which can become critical service for healthcare workers in emergency situations. However, setting up and maintaining this complex system with copper pipelines is less suitable for turn-key installations.

Centralized pipeline system comprises[5] a main source of supply (generally with a secondary and tertiary source to ensure continuity of service) connected via a permanent fixed pipeline system to appropriate terminal unit outlets in relevant locations across the site. Plant and system status are monitored continuously by a series of alarms which sound at designated locations to indicate faults or low pressure.

The manufacturer should comply [(18)] with BS EN ISO 9001:2000 for pipes and for all materials including fittings, terminal units etc. A complete specification is given in Model Engineering Specification C11 – 'Medical gases'. All pipes must be cleaned and degreased for oxygen service and be free of particulate matter and toxic residues.

Pressure sensors to provide the alarm function will need[(18)] to be fitted to pipeline distribution systems.

In all cases they should be installed in a location which is adequately ventilated and having access for maintenance.

Design of pipe network

The pipeline design, installation and testing are executed according to ISO 7396-1:2016[17] and HTM 02-01[18]. The provisions covered in these standards are related to the following aspects of pipeline design:

a) Maximum pipeline pressure

b) Distribution pressure

c) Distribution system (double stage system for each bed)

d) Shut-off valves

e) Terminal units, gas connectors, pressure regulators and pressure gauges

f) Pipeline installation requirements

g) Pipe supports and joints

h) Pipeline testing for leakages, mechanical integrity

i) Tests for shut-off valves (flow, obstruction and no cross-connection)

j) Checks at terminal units and connector for mechanical function, gas specificity and gas identification

k) System performance tests covering pressure-relief valves, supply sources, monitoring and alarm systems, particulate contamination, quality of oxygen-enriched air

l) Positive gas identification at terminal units

Pipeline Testing

Table 2: Pipeline testing requirements

Tests	Procedures
Blowdown	Lines are blown clear using oil-free dry nitrogen
Initial press test	System is subjected to 1.5 times working pressure to check leaks
Standing press test	System is subjected to 20% higher pressure for 24 h
Piping purge	Purging of each outlet until there is no discoloration of the white cloth held over it
Cross-connection test	One gas system at a time using O_2 analyser
Final tie-in test	Active vacuum pipeline joints are tested using an ultrasonic leak detector

Table 2 shows pipeline testing requirements.

Safety Checklists at Hospitals

The safety of a Medical Gas Piping System is dependent on four basic principles – Identity, Adequacy, Continuity and Quality of supply.

Identification is assured using gas-specific connections throughout the pipeline system, including terminal units, connectors etc, and by the adherence to strict testing and commissioning procedures of the system. Adequacy of supply depends on an accurate assessment of demands and the selection of plant appropriate to the clinical/medical demands on the system.

Continuity of supply is achieved by:

- the specification of a system that (except for liquid oxygen systems which may include a secondary vessel) has duplicate components;
- the provision of a third means of supply for all systems except vacuum;
- the provision of alarm systems; and

[17] ISO 7396-1: 2016, Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum

[18] Medical gases Health Technical Memorandum 02-01: Medical gas pipeline systems Part A: Design, installation, validation and verification; http://www.bcga.co.uk/assets/HTM_02-01_Part_A.pdf

- connection to the emergency power supply system.

Quality of supply is achieved using gases purchased to the appropriate Ph. Eur. requirements or produced by plant performing to specific standards, by the maintenance of cleanliness throughout the installation of the system, and by the implementation of the various testing and commissioning procedures.

The annexure F of ISO standard 7396 provides[17] extensive checklist of safety management systems in oxygen chain at hospitals. Some of the important elements of the checklist are reproduced below for ready reference and reading.

Continuity of Supply

The root causes include Partial or complete blockage of the pipeline, or Loss of supply from the source of supply in operation. Following measures can be considered.

- Flow and pressure drop tests at every terminal unit before use
- Ensure reserve and emergency sources of supply are included in the design of the supply system
- Ensure reserve and emergency sources of supply are included in the capacity and location of the supply sources
- Operational procedures established to supply cylinders for emergency situations to ensure continuity of supply
- Routine testing of the reserve and emergency sources of supply to ensure that they will function when primary source of supply fails
- Routine testing of the alarm system

Electricity Supply

Failure of operation of electrical components may potentially lead to loss of oxygen supply. Following measures are suggested as part of checklist.

- UPS or emergency electrical supply is available to ensure continuity of electrical system
- Check capacity of the emergency electrical supply
- Routine testing of the emergency electrical supply
- Check that reserve sources of supply can maintain gas supply during electrical supply failure (supplies from compressors)
- Procedures to ensure that all components are restored to an operational
- condition following reinstatement of the power supply
- Connect alarms to the emergency electrical supply to ensure continuity of alarm operation.

Piping Mechanical Integrity

Mechanical design failure of pipelines will cause leakages. It will lead to loss of supply of oxygen to patients. Following checklist can be followed for avoiding failure of piping systems.

- Design of pipework route to limit areas of high risk to the pipeline
- Design supply systems to prevent mechanical damage: Overpressure protection systems, Leak detection systems are installed.
- Corrosion: Design of pipework routing to limit pipeline corrosion, Earthing of pipeline system to limit electrolytic corrosion
- Support pipelines to provide adequate support/protection
- Identify location of pipeline routes: Use of markers above pipeline to indicate presence of pipeline in underground ducts, etc.
- Emergency plans for areas with high-dependency patients

Quality of gas

Meeting the required quality of oxygen is one of the most critical aspect of the safety checklists at hospitals. It is important that each oxygen supply systems are monitored continuously for the quality of the medical oxygen gas being supplied. Any drop-in quality would require switching off that particular source immediately. The oxygen generating, distributing and consuming equipments must comply to the statutory and codal requirements. Below are

some of the risk control measures to ensure quality of medical oxygen.

- Quality certificate for the oxygen gas is available.
- Check for correct connection of flexible connections to the manifold (gas specific connection where possible)

pandemic, the PSA oxygen plants are imported from other countries. As a backup, these plants were ordered with et of oxygen cylinders. It is necessary to follow the color code of cylinders followed in India. Therefore, whenever, the gas cylinders are imported, attention is required to change its colour code.

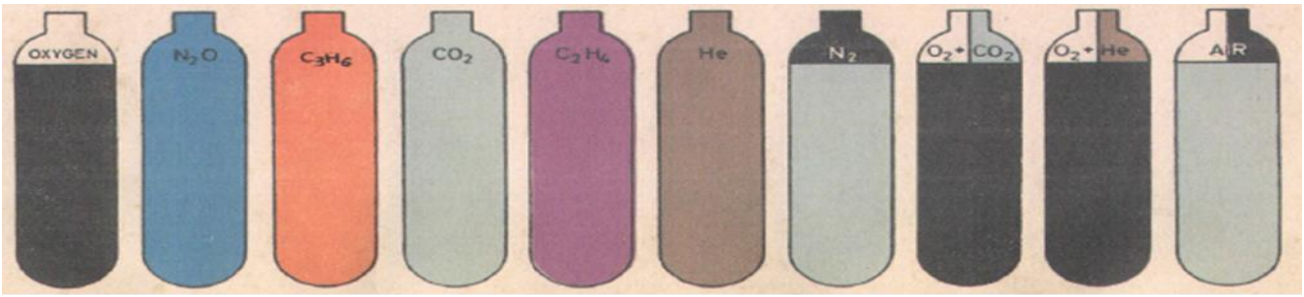


Figure 9: Colour Identification of Medical Gas Cylinders in India

- Check that the correct labels are fitted to terminal outlets and area shut-off valves. Check that the correct signs are fitted to manifold rooms, cryogenic tanks and medical gas cylinder stores
- Check pipelines are marked for the correct gas.
- Correct procedure to achieve the correct level of cleanliness to ensure proper cleaning and purging
- Operational and Maintenance Management Document
- Use components complying with the cleanliness requirements of ISO 7396
    - Correct location of air intake to compressor

Identification of Medical Gas in Hospitals

Typical medical gases used in hospitals are oxygen, Nitrogen, Nitrous oxides. These gases are used in cylinders and central pipelines. To ensure the correct use of medical gas standard colour codes are used globally. The colour coding used to identify these gases differs from country to country. During the

For gas cylinder - gas cylinder Rule 1981, static and mobile pressure vessels (unfired) rules 1981 and BIS Act 1986 is applicable. The Indian standard, BIS 3933:2021[19], "Colour Identification of Gas Cylinders and Related Equipment Intended for Medical Use" shall be followed. The colour coding standard for Europe can be found in "Additional Reference no. 21"

Colour Codes medical gas cylinders in India are shown in Figure 9 and given below.

- White shoulder and graphite black body contain medical oxygen.
- Blue shoulder and blue body contain nitrous oxide.
- Black shoulder and Grey body contain nitrogen.

The colour coding of medical gas piping as per BIS standard is shown in Table 3.

Table 3: Colour coding of medical gas piping as per BIS standard

Gas	Background	First Colour Band	Second Colour Band
Air	Sky Blue	White	Black
Oxygen	Canary Yellow	White	-
Nitrous Oxide	Canary Yellow	French Blue	Signal Red
Vacuum	Sky Blue	Black	Black

[19] Indian Standard, IS – 3933:2021, First Revision, Colour Identification of Gas Cylinders and Related Equipment Intended for Medical Use

Estimation of Oxygen demand

The dosage required for oxygen therapy for critical and severe Covid-19 patients as per WHO/ UNICEF recommendation are as follows[3, 9]:

- 1 – 2 lt/ min in children using nasal canula
- Starting flow at 5 lt/ min with nasal canula
- Moderate flow at 6 – 10 lt/ min with venturi mask
- High flow at 10 – 15 lt/ min using a mask with reservoir bag
- Very high flow up to 60 lt/ min using high flow nasal canula (HFNC) device
- Non-invasive ventilation (NIV) and invasive ventilation devices

HFNC and NIV use are associated with risk of aerosol generation and health worker using such items require protection from airborne transmission.

Oxygen Consumption at Hospitals

WHO provides a tool, Essential Supply Forecast Tool (ESFT), to estimate the oxygen flow that would be required at the COVID -19 treatment facility. Considering that 15-20% of total infected persons would be in severe or critical condition requiring hospitalization with oxygen support, the expected patient load can be estimated. Amongst the hospitalized Covid-19 patients, 75% can be considered as "severe" and 25% in "critical" condition. Typical calculation for required oxygen flow rates based on this assumed patient severity is shown in Table 4 [(9)].

Assisted ventilation is done through a mix of medical air and oxygen. The flow rate calculated above is an average estimate for the oxygen portion only of the total gas flow to reach the target therapeutic fraction of inspired oxygen (FiO2), the total % of oxygen in the lungs that takes part in gas exchange. The flow proportion is determined from

$$Target\ FiO_2 = \frac{O_2\ (lpm) + (air\ (lpm)\ x\ 21\%)}{Total\ flow, (lpm)}$$

Oxygen requirement for non-critical patients

Typical layouts of critical area units are shown in figures 4 and 5 in the document HTM 02-01[12]. Oxygen is used at a typical flow of 5–6 L/min. Each terminal unit should, however, be capable of passing 10 L/min (at standard temperature and pressure (STP)) at a supply pressure of 400 kPa (nominal), in case nebulizers or other respiratory equipment are used. Tables 12 and 13 of HTM 02-01[12] provide the details for oxygen requirements in various areas of a healthcare facility.

Manifolds for Gas cylinders

Typical manifold schematic in shown in Figure 10 and 11 of the document HTM 02-01[11]. Manifolds and control panels should be designed and certificated for use with 230 bar cylinders with J-size oxygen cylinders having nominal capacity of 6800 litres (usable capacity of 6540 litres at discharge to gauge pressure of 7 bar) at 137 bar.

Oxygen Delivery Devices[20]

After the supply of oxygen for is arranged, the proper distribution and delivery of oxygen to patients

Table 4: Sample oxygen flow planning for 100 bed facility

Hypothetical 100 Bed Covid-19 Treatment Facility				
Disease Severity	Avg O_2 Flow Rate		Size of Solutions of Scale*	
	Per Patient	Total	PSA Plant	Bulk Liquid
Severe 75 Patients	10 L/min	75*10*60=45,000 L/h	45 m^3/h	1.25 m^3/day
Critical 25 Patients	30 L/min	25*30*60=45,000 L/h	45 m^3/h	1.25 m^3/day
			90 m^3/h	2.5 m^3/day

[20] Practical procedures: oxygen therapy - https://www.nursingtimes.net/clinical-archive/respiratory-clinical-archive/practical-procedures-oxygen-therapy-11-01-2016/

requires deployment of various devices and technological systems at the healthcare unit. The correct choice of these equipment/ devices is critical for delivering the care and support to the patients. Detail information on the various components of the oxygen system in a healthcare facility are available in the document "WHO-UNICEF TECHNICAL SPECIFICATIONS AND GUIDANCE FOR OXYGEN THERAPY DEVICES"[3]. Description of equipment, operational requirements, maintenance and spare requirements, advantages and drawbacks for these items are available in this document which can be referred for guidance in procurement of the required devices for the proposed healthcare facility. Below are commonly used devices.

- Nasal cannula: It consists of a flexible tube that is placed under the nose. These devices are comfortable and well tolerated by most patients. They do not need to be removed when the patient is talking or eating. Oxygen is inhaled even when breathing through the mouth. Nasal cannula is useful for patients who are stable. They are commonly used to deliver oxygen in the home setting. Flow rates above 4 L/min can cause considerable drying of nasal mucosa and are more difficult to tolerate. Nasal cannula is not recommended for patients with unstable respiratory failure.
- Simple face mask: The simple, or "low flow" face mask is intended for short-term use, such as post-operative recovery. Oxygen is delivered at 2-10 L/min and supplemented with air drawn into the mask during breathing. Oxygen flow rates of < 5L/min may result in the patient rebreathing exhaled carbon dioxide, which may build up in the mask. Simple face masks should not be used for patients at risk of respiratory failure.
- Reservoir Mask: (Non- Rebreathing mask):
  A non-rebreather mask is a face mask that covers both the nose and mouth. It has two one-way valves. One valve is between the face mask and a plastic reservoir bag (typically 1 liter) that's attached to a supply of oxygen. The valve doesn't allow exhaled air or outside air from entering the bag, so only oxygen flows from the bag to the mask. The other valve allows exhaled air to flow into the atmosphere but doesn't allow the outside air to enter.

This mask is called "non-rebreather" because, when you're using it, you're unable to inhale anything you exhale. It allows you to breathe only pure oxygen

Oxygen at 10-15 L/min via a reservoir mask delivers oxygen to patients and is recommended for short-term use in patients who are critically ill. The reservoir bag must be filled with oxygen before use and the mask positioned to ensure a close fit on the patient's face. A one-way valve prevents exhaled air entering the bag. Oxygen via a reservoir mask cannot be humidified, and patients will be more comfortable if they can be maintained within target range on a humidified system once, they are more stable.

A simple face mask is usually used to deliver a low to moderate amount of oxygen. A simple mask

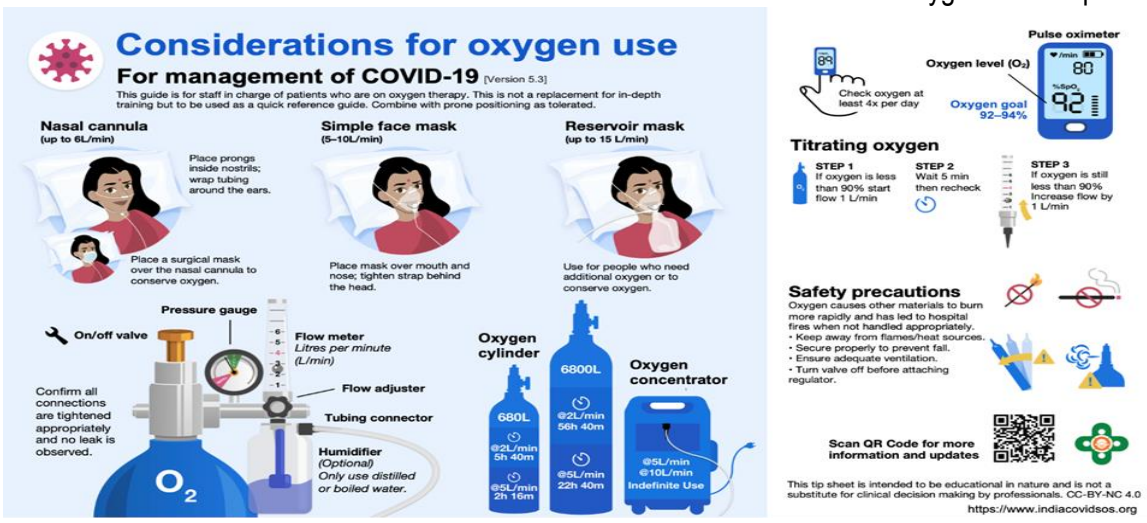


Figure 10: Oxygen management for Covid-19 patients

contains holes on the sides to let exhaled air through and to prevent suffocation in case of a blockage. It can deliver around 40 percent to 60 percent oxygen. A non-rebreather mask provides the highest concentration of oxygen. The use of the oxygen reservoir bag helps to increase the inspired oxygen concentration by preventing oxygen loss during inspiration.

An infographic guide showing the management of Covid-19 patients with oxygen therapy[21] using the various devices indicated in this section is shown in Figure 10 [(19)]. This diagram is designed to act as a quick reference for the treatment of patients with oxygen in a healthcare facility.

Oxygen Conservation

The shortage of oxygen for treatment of Covid-19 patients has led to development of devices for optimization of its use[19]. Designs for passive devices (operate without electricity) for use with high flow nasal cannula (HFNC) have been developed. In another concept, a device which stops or diverts the oxygen supply to a buffer storage when the patient is exhaling is being developed. This can reduce the total oxygen requirement using a pulse dosing system to two-thirds of the requirement in a continuous oxygen flow arrangement.

Use of non-rebreather masks[22] (NRB) in place of simple nasal canula can also help save oxygen by delivering high concentrations of oxygen (60% to 90%) to patients with very little effort from patients even at very high inspired flow rates of 50 lt/ min

Quality Standards

Specific standards for medical devices in India are currently under development based on international standards and India specific requirements.

- MHD 11 (17324) WC – Bureau of Indian Standards is now adopting several international standards. Presently there are no standards for oxygen concentrator design or certification in India. A new standard titled "Medical Electrical Equipment, Part 2: Particular Requirements for Basic Safety and Essential Performance, Section 69, Oxygen Concentrator Equipment Document" is being planned for release in mid-June 2021. This standard specifies requirements for the basic safety and essential performance of an oxygen concentrator along with its accessories for use in home or professional healthcare environment by a single patient or integrated into with other medical devices, ME equipment or ME systems.

  It is proposed that the draft of Indian Standard (Part 2/Sec 69) which is identical with ISO 80601-2-69 : 2020 'Medical electrical equipment — Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment' issued by the International Organization for Standardization (ISO) will be adopted by the Bureau of Indian Standards on the recommendation of the Anaesthetic, Resuscitation and Allied equipment Sectional Committee.

  and approval of the Medical Equipment and Hospital Planning Division Council.

- Association of Indian Medical Device Industry (AIMED) in collaboration with the Quality Council of India (QCI) and the National Accreditation Board for Certification Bodies (NABCB) established a voluntary quality certification scheme for medical devices in India, ICMED 13485.

  The program is based on the international harmonized quality management system standards with additional requirements specific to the India market.

  - ICMED 13485 – Based on the International Harmonized Standard (ISO 13485) "Quality Management Systems for Medical Devices" plus additional requirements specified under the scheme.
  - ICMED 9000 – Based on the International Harmonized Standard (ISO 9000:2008), "Quality Management Systems."

Indian medical device manufactures/ exporters, Local authorized representatives of medical device manufactures/ distributors can apply for the above. ICMED ISO 13485 registration would establish

[21] India Covid SOS; Oxygen — India Covid SOS

[22] Non-rebreather mask - Wikipedia

brand confidence of medical devices manufactured in India.

- IS 23485 - Medical Devices Quality Management Systems with Essential Principles of Safety and Performance: This Indian Standard specifies requirements for a quality management system that can be used by an organization involved in one or more stages of the life-cycle of a medical device, including design and development, production, storage and distribution, installation, servicing and final decommissioning and disposal of medical devices, and design and development, or provision of associated activities (for example, technical support).

  The requirements in this Indian Standard can also be used by suppliers or other external parties providing product (for example, raw materials, components, subassemblies, medical devices, sterilization services, calibration services, distribution services, maintenance services) to such organizations.

  This Indian Standard can also be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer and regulatory requirements applicable to the quality management system and the organization's own requirements. It is emphasized that the quality management system requirements specified in this Indian Standard are complementary to the technical requirements for product that are necessary to meet customer and applicable regulatory requirements for safety and performance.

- IS/ISO 13485 - Medical Devices Quality Management Systems (MDMS) Certification Scheme:

  This standard specifics requirements for a quality management: system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related service and supports essential requirements of directives on medical devices. It is the most accepted standard internationally for medical devices producers.

  ISO 13485 sustains the reduction of unexpected risks for companies that build, manufacture, or use medical products and services, both during the manufacturing process and after. The primary objective of ISO 13485 is to facilitate harmonization of medical devices regulatory requirements for medical devices with quality management system requirements.

Concluding Remarks

The severity of the effects of the second wave of Covid-19 pandemic in India has provided a strong pointer to bolster the medical facilities in the country. Amongst all the intervention measures required in the fight for human life against the virus, the need for oxygen therapy has been found to be of supreme importance. Tata Consulting Engineers (TCE) has taken up this initiative to help improve the information on technical requirements for oxygen chain at hospitals.

The information is compiled from several sources available in open literature and aimed to provide technical guidelines for setting up oxygen infrastructure at hospitals.

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