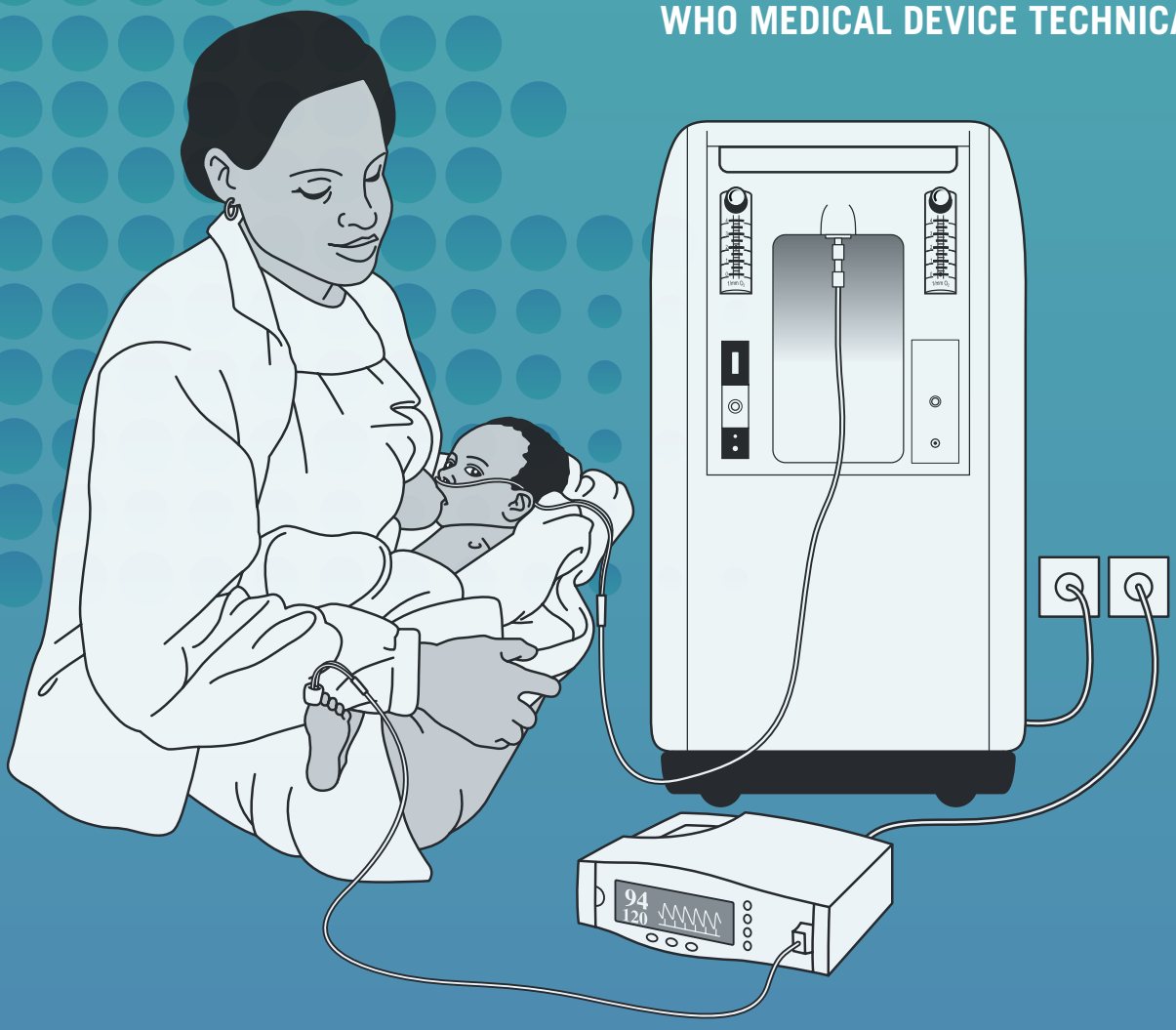
World Health Organization

TECHNICAL SPECIFICATIONS FOR OXYGEN CONCENTRATORS

WHO MEDICAL DEVICE TECHNICAL SERIES



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Technical specifications for oxygen concentrators

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Contents

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Due to the concern over the lack of oxygen supplies in low- and middle-income countries, especially in regards to the treatment of childhood pneumonia, the development of this document was initiated. This document was prepared in line with other similar WHO medical device publications.

Grace Wu (PATH consultant) drafted the technical specifications document under the supervision and guidance of Adriana Velazquez Berumen of the World Health Organization (WHO) Department of Essential Medicines and Health Products, with additional input from Meena Cherian (WHO Department of Service Delivery and Safety), Shamim Qazi (WHO Department of Maternal, Newborn, Child and Adolescent Health [MCA]) and Wilson Were (WHO MCA). Additional preparation and draft-editing were provided by: Jaclyn Delarosa (PATH), Gene Saxon (PATH), Alec Wollen (PATH), Fay Venegas (PATH), John Ballenot (PATH), Glenn Austin (PATH), Stephen Himley (PATH consultant), Amy Ginsburg (PATH) and Darin Zehrung (PATH).

This document builds primarily on the outcomes of a meeting of subject-matter experts in oxygen concentrators, organized by PATH and the Bill & Melinda Gates Foundation in Seattle on 13–14 August 2014. The goal of this expert advisory group meeting was to build consensus on approaches to improve oxygen concentrators to treat paediatric patients with hypoxaemia or severe respiratory distress in low-resource settings (LRS). The meeting identified several key issues related to technical specifications for oxygen concentrator equipment, including procurement, performance and maintenance.

A result of this meeting was a first draft of oxygen concentrator technical specifications aimed to guide the development, purchase, utilization and maintenance of oxygen concentrators for use in low-resource settings. Members of the group included: Mike Eisenstein (PATH), Keith Klugman (Bill & Melinda Gates Foundation), David Mukanga (Bill & Melinda Gates Foundation) and Muhammad Zaman (Boston University). In addition, WHO expresses its appreciation to members of this expert advisory group meeting that also provided feedback throughout the development of this document: Glenn Austin (PATH), Jim Black (University of Melbourne), Jaclyn Delarosa (PATH), Trevor Duke (University of Melbourne), Penny Enarson (International Union Against Tuberculosis and Lung Disease), Mike English (Kenya Medical Research Institute – Wellcome Trust Research Programme), Amy Ginsburg (PATH), Stephen Howie (Medical Research Council), Rasa Izadnegahdar (Bill & Melinda Gates Foundation), Robert Jacobson (Consultant), David Peel (Ashdown Consultants), Shamim Qazi (WHO MCA), Gene Saxon (PATH), Alec Wollen (PATH) and Grace Wu (PATH consultant).

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Abbreviations

AC	alternating current
AIDS	acquired immunodeficiency syndrome
BMGF	Bill & Melinda Gates Foundation
°C	degree(s) Celsius
CE	Conformité Européenne/European Conformity
CFR	Code of Federal Regulations
CPAP	continuous positive airway pressure
dB(A)	decibel(s) attenuated
EN	European Norm
EU	European Union
FDA	United States Food and Drug Administration
HEPA	high-efficiency particulate arrestance
HIV	human immunodeficiency virus
Hz	hertz
IEC	International Electrotechnical Commission
IMDRF	International Medical Device Regulators Forum
ISO	International Organization for Standardization
kg	kilogram(s)
kPa	kilopascal(s)
LPM	litre(s) per minute
LRS	low-resource settings
m	metre(s)
mm	millimetre(s)
N2	nitrogen
NHSRC	National Health Systems Resource Centre
O2	oxygen
PCB	printed circuit board
RH	relative humidity
STPD	standard temperature and pressure, dry
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
UPS	uninterruptible power source/supply
US or USA	United States of America
USAID	United States Agency for International Development
USD	United States dollar
V	volt(s)
VAC	volts of alternating current
W	watt(s)
Wh	watt-hour(s)
WHO	World Health Organization

Executive summary

Oxygen concentrators are a suitable and favourable option for administering point-of-care oxygen in developing-country settings, especially where cylinders and piped systems are inappropriate or unavailable. Even where oxygen supplies are available at health facilities, patient access may be limited due to missing accessories, inadequate electricity and a shortage of trained staff. Management of hypoxaemia, or low blood oxygen saturation, is a critical component of World Health Organization (WHO) standards and guidelines for newborn illnesses and complications, childhood pneumonia, surgery, anaesthesia, trauma, emergency triage, obstetric care and other serious conditions that are commonly associated with morbidity and mortality in developing countries. Hypoxaemia is easily treated with oxygen, which is included in the WHO *Model list of essential medicines* and is perhaps the only medicine with no alternative agent. Having a reliable oxygen supply is necessary for the care of seriously ill patients to improve the probability of survival. It is important to ensure that potentially life-saving oxygen equipment is available and included in health planning budgets.

Oxygen concentrators provide a sustainable and cost-effective source of medical oxygen to health facilities with reliable power. An oxygen concentrator is a medical device that draws in air from the environment and passes it through molecular sieve beds to concentrate room oxygen to therapeutic levels for delivery to the patient. Oxygen therapy for the treatment of hypoxaemia involves the delivery of concentrated oxygen to the patient to improve and stabilize blood oxygen saturation levels. It is critical to understand the indications and clinical use for oxygen. Guidelines for the safe administration of oxygen differ across broad applications; the required flow rate and concentration of oxygen delivered vary depending on the patient's age and condition. Pulse oximetry should be used in conjunction with the oxygen concentrator to identify hypoxaemic patients and monitor oxygen therapy to promote the efficient and safe use of oxygen.

Despite the evidence of the importance of oxygen and the existence of appropriate oxygen supply technologies, utilization has been limited by inadequate maintenance, training, selection and procurement of high-quality devices. Many hypoxaemic patients in low-resource settings (LRS) still do not receive oxygen, thus improving access to oxygen therapy should be a priority. Recognizing the need to increase the availability of appropriate, safe and reliable oxygen concentrators in LRS, WHO collaborated with PATH to mobilize technical advisors, clinicians, clinical engineers and manufacturers to prepare this guidance document for the appropriate selection, procurement, utilization and maintenance of oxygen concentrators. This document also focuses on guidance for the appropriate use and maintenance of oxygen concentrators in an effort to increase the availability, management and quality of oxygen concentrators and, ultimately, to improve health outcomes in LRS. This document is intended to serve as a resource for the planning and provision of local and national oxygen concentrator systems for use by administrators, clinicians and technicians who are interested in improving access to oxygen therapy and reducing global mortality associated with hypoxaemia.

1. Introduction

1.1 The role of oxygen concentrators

Oxygen is included on the World Health Organization (WHO) list of essential medicines, yet it is still not widely available in developing-country settings that bear the greatest mortality burden of seriously ill newborns, children and adults *(1)*. Reasons for low oxygen availability are often associated with cost and lack of infrastructure to install and maintain reliable oxygen supply. Even where oxygen supplies are available, patient access may be limited due to missing accessories, inadequate electricity and/or shortage of trained staff *(2–4)*.

Fortunately, there is compelling evidence that oxygen concentrators are a feasible and cost-effective strategy for the administration of oxygen therapy, especially where oxygen cylinders and piped oxygen systems are inappropriate or unavailable *(5–8)*. Good-quality oxygen concentrators can provide a sustainable and reliable source of oxygen to multiple patients. Oxygen concentrators operate by drawing air from the environment to deliver continuous, clean and concentrated oxygen. They may run for up to five years or more, with minimal service and maintenance (see Section 4.6).

There is strong evidence on the use and effectiveness of oxygen concentrators to increase access to life-saving oxygen and improve the overall quality of health care in low-resource settings (LRS). Studies conducted in Egypt *(9)*, Gambia *(6)*, Malawi *(3,10)*, Nepal *(11)*, Nigeria *(8)* and Papua New Guinea *(12,13)* have demonstrated the utilization of oxygen concentrators to expand the availability of oxygen in health facilities in resource-limited settings. These studies show that oxygen concentrators have been successfully used in developing-country settings to supply oxygen in paediatric and operating wards *(1,5,8)*.

The advantages of oxygen concentrators have been discussed in the technical literature; they include high reliability and low cost compared with oxygen cylinders and piped oxygen supply systems (Table 1) *(6,14)*. Disadvantages of oxygen concentrators include the need for regular, although minimal, maintenance and a reliable power supply – both of which can be addressed with effective programme planning and training. Capacity-building and collaboration among management personnel, clinicians and technicians are necessary to ensure effective implementation and timely maintenance of oxygen concentrators. Oxygen concentrators are important medical devices, and systematic approaches to ensure their quality and maintenance are vital to achieving reductions in mortality associated with hypoxaemia.

Table 1. Comparison of oxygen cylinders and concentrators as the basis for oxygen systems

System	Central oxygen (pipeline system)	Oxygen cylinders	Oxygen concentrators
Power source required	No	No	Yes, continuously (100–600 W, depending on model)
Transport requirement	Those associated with cylinders	Regularly; heavy and costly to transport	Only at time of installation
Exhaustible supply	Yes, if pipes are refilled from an offsite supply facility	Yes, depending on the size, storage pressure and patient needs	No, continuous supply as long as power remains uninterrupted
Initial costs[a]	Significant: generator and cylinders (US$ 20 000), piping system (US$ 10 000+), installation, commissioning and training	Moderate: cylinder, oxygen flowmeter and regulator per cylinder (~US$ 200)[b]	Moderate: concentrator (US$ 300–3400)[b], spares, installation, commissioning and training
Operational costs[a]	Small to moderate: maintenance, continuous refill of pipeline by bank or tanks	High: cylinder refills and transport from refilling station to hospital	Small: electricity and maintenance
User care	Minimal	Minimal: regular checking, minimizes fire hazard (no grease or flammables)	Moderate: cleaning of filters and device exterior, and minimizes fire hazard
Maintenance	Moderate: check for pressure leaks with manometer Maintenance of oxygen pipelines to prevent leaks and oxygen wastage Significant: if supply facility is onsite	Moderate: check for pressure leaks with gauge	Moderate: check for low oxygen output with analyser
Cost per 1000 litres oxygen[c]	Data not available	US$ 10–30/kilolitre varying with estimated oxygen requirement and power availability	US$ 2–8/kilolitre (greater depending on cost of power source), varying with estimated oxygen requirement and power availability

Note: All costs are approximations and not guaranteed.
a See literature for region-specific cost breakdowns *(3,6,12)*.
b Based on current market prices for June 2015.
c Includes initial capital and operational costs, based on cost modelling performed in Gambia *(6)*.

1.2 Hypoxaemia and the need for oxygen therapy

Oxygen is a basic requirement in order to save the lives of seriously ill patients. Oxygen therapy is a highly effective intervention for reducing global mortality. WHO guidelines emphasize the importance of oxygen and its broad indications for neonates *(15)*, paediatrics *(1–8)*, obstetrics *(14)*, internal medicine *(16)*, emergency care *(14,17)*, triage *(18)*, anaesthesia *(14)*, surgery, trauma, survival services, and pandemic preparedness *(19)* and treatment of other common medical conditions and illnesses affecting patients of all ages *(5)*.

Hypoxaemia, or low blood oxygen saturation, is a common complication of a range of clinical conditions. Oxygen is essential for the treatment of hypoxaemia and should be

given to the patient to improve and stabilize blood oxygen saturation levels. The current standard of care for oxygen therapy includes proper monitoring and training of clinical staff regarding when and how to administer therapy. Pulse oximeters are an important low-cost technology and the accepted standard for detecting hypoxaemia and monitoring oxygen therapy. When combined with an appropriate oxygen supply, pulse oximetry can promote the efficient use of oxygen.

Oxygen is critical to the treatment of hypoxaemia associated with serious conditions contributing to the global burden of maternal, newborn and child mortality. Hypoxaemia is the major fatal complication of pneumonia; the leading infectious cause of death in children under 5 years of age worldwide. In 2013, pneumonia killed 935 000 children – about 2600 children every day – and accounted for more childhood deaths than HIV/AIDS and malaria combined *(20)*. In addition, paediatric deaths that result from other common serious conditions such as birth asphyxia, low birth weight, meningitis, sepsis, acute asthma and malaria add to the substantial burden of hypoxaemia. Increasing the availability of supplemental oxygen promises to improve health outcomes and survival. Nonetheless, many hypoxaemic children in LRS still lack access to oxygen therapy *(2–4)*. Oxygen is often unavailable in primary health clinics or smaller remote hospitals and is often lacking in district hospitals *(1,21)*.

1.3 Background and scope of technical specifications

The WHO technical specifications for oxygen concentrators that are outlined in this document both comply with relevant International Standards Organization (ISO) requirements (based on ISO 80601-2-69:2014, which supersedes EN ISO 8359:2009/A1:2012) and list *additional essential requirements* necessary for acceptance and operation of oxygen concentrators in LRS. Harsh, hot and humid environments as well as intermittent and unstable power in LRS present challenging operating conditions that often cause premature failure of oxygen concentrators. Exacerbating this problem is the lack of trained technicians to provide corrective and preventive maintenance and access to spare parts, which result in device underutilization or failure.

The guidance in this document were established in an effort to address the barriers to access of oxygen concentrators and potential causes of oxygen concentrator failure in LRS. This document outlines key performance and technological aspects of concentrators that are essential for successful operation in LRS.

1.4 Purpose of the document

This document provides an overview of oxygen concentrators and technical specifications to aid in the selection, procurement and quality assurance of these devices for the treatment of hypoxaemia in developing-country settings. Recognizing the need to increase the quality, accessibility and availability of oxygen concentrators in LRS, this document highlights the minimum performance requirements and technical characteristics for oxygen concentrators and related equipment that are suitable for the use scenarios and climates in LRS. If oxygen concentrators are manufactured in accordance with ISO standards and properly procured using the proposed specifications

and appropriate supply chain, then these actions will help to ensure that the end user receives a high-quality product. Other resources needed for safe use, cleaning and maintenance are highlighted as important considerations for implementation. It should be noted that this document does not replace published international standards, manufacturer instructions and maintenance manuals, which are informative materials that should be obtained and referenced. Additional information on WHO technical specifications for medical devices is available at www.who.int/medical_devices/en/.

1.5 Intended audience for this document

This document is intended for administrators, including policy-makers, programme managers, hospital personnel, procurement officers, logisticians and biomedical/clinical engineers in facilities with the responsibility of planning and supplying local, national or international oxygen concentrator systems in LRS. Global procurement agencies and national health products regulatory authorities may refer to this in preparation for the regulatory clearance, procurement, management and effective supply of oxygen concentrators to treat hypoxaemia. Manufacturers should comply with these specifications to produce safe, high-quality and affordable oxygen concentrators that are appropriate for use in LRS. Others may also benefit from this resource, including health workers, clinical staff, technicians, nongovernmental agencies, academia and those interested in defining the oxygen supply resources for reducing mortality associated with hypoxaemia. This document also highlights areas of future work to address current knowledge gaps regarding oxygen concentrators in LRS that may be helpful for researchers, manufacturers and organizations.

2. Technical specifications for oxygen concentrators

2.1 Description

An oxygen concentrator is a self-contained, electrically powered medical device designed to concentrate oxygen from ambient air. Utilizing a process known as pressure swing adsorption, an oxygen concentrator produces up to 95.5% concentrated oxygen. Atmospheric air is drawn through a gross particle and intake filter before moving through a compressor. The pressurized air passes through a heat exchanger to reduce the temperature before entering sieve beds that contain zeolite, a mineral material that preferentially adsorbs nitrogen gas (N_2) at high pressures. As each sieve bed is depressurized, N_2 is released. Valves open to deliver concentrated oxygen into a reservoir where it accumulates, and from which a flowmeter can be used for measured and continuous release of oxygen to the patient at a specified flow rate. A process flow diagram of a typical oxygen concentrator is illustrated in Figure 1. In general, there are two types of oxygen concentrators: stationary and portable.

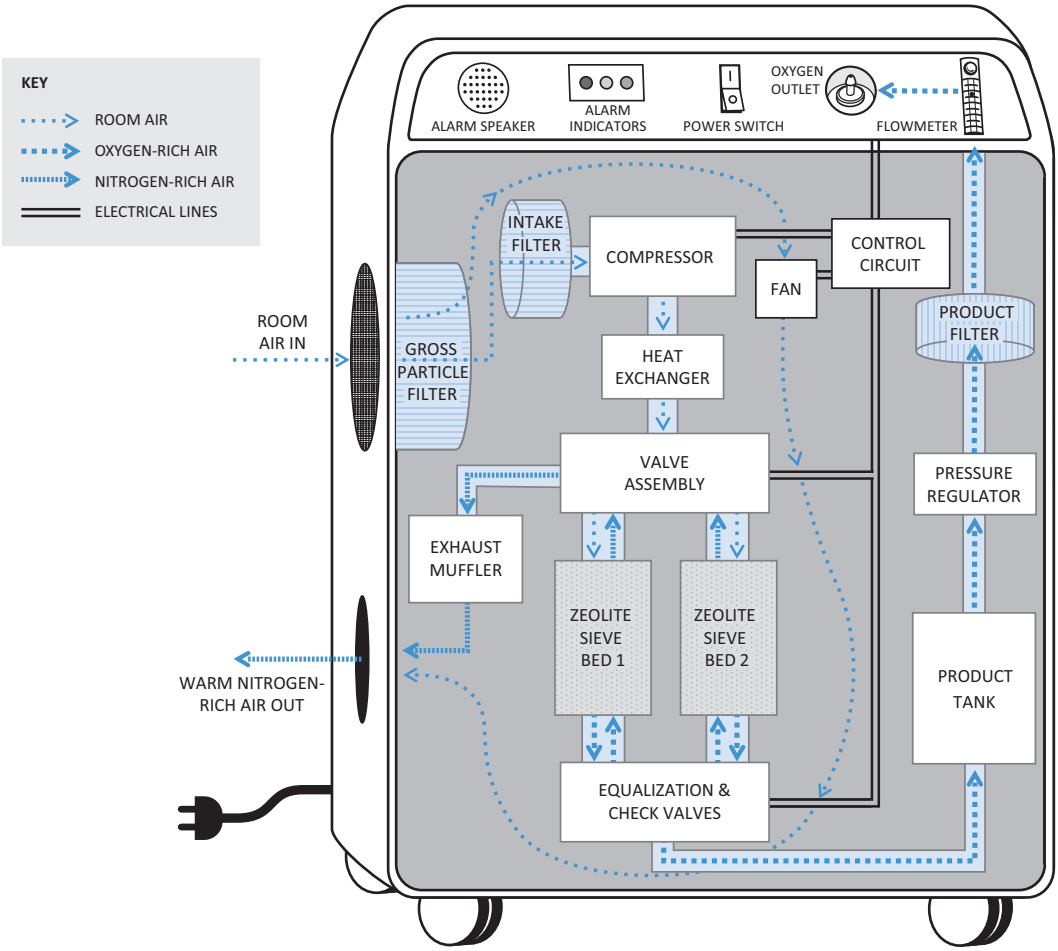
Most stationary oxygen concentrators weigh less than 27 kg and have wheels so that they are easily movable by the user. They are self-contained devices that supply an economical, continuous stream of oxygen at flow rates up to 10 litres per minute (LPM). Very low flows, down to 0.1 LPM, may be delivered via the built-in flowmeter or with additional accessories (see Section 3.4). Most concentrators that are appropriate for health facilities can deliver at least 5 LPM and operate on alternating current (AC) electricity, and consume approximately 280–600 watts (W), depending on the model (see Annex 2). Separate models for 110–120 V of alternating current (VAC) (typically 60 Hz) and 220–240 VAC (typically 50 Hz) are generally available from the manufacturer to match the voltage and frequency of the local grid power.

In general, portable oxygen concentrators have a lower output capacity (3 LPM or less), consume less power than their stationary counterparts (approximately 40–130 W) and are used by individual patients as ambulatory oxygen systems. Many contain batteries capable of operating on direct current (DC). Due to their low flow capacity, they are not suitable for simultaneous use by multiple patients. In addition, many portable devices contain a mechanism that allows oxygen delivery only during inspiration. This type of flow, known as pulsed-dose or intermittent flow, conserves oxygen and battery power. It is important to note that some infants and young children may not generate enough negative pressure during inspiration to reliably trigger oxygen flow. Nonetheless, a subset of portable concentrators are capable of both continuous and intermittent flow.

Concentrators are designed for continuous operation and can produce oxygen 24 hours per day, 7 days per week, for up to 5 years or more. These devices can be used at any level of health facility to provide oxygen therapy, as long as there is a continuous

source of reliable power and a system for regular cleaning and maintenance by users and technical personnel alike. While most oxygen concentrators operate by the same principles, spare parts are not interchangeable between different models. The typical component names of oxygen concentrators and their functions are described in Figure 1. Models also often differ in user interface features, such as device settings alarm indicators and maintenance components.

Figure 1. Process flow and components of a typical oxygen concentrator



Source: Provided by PATH (2015).

Table 2. Typical components and their function within an oxygen concentrator

Component	Other names	Function
Enclosure	Cabinet, interior	Encases internal components of concentrator
Gross particle filter	Cabinet filter, air intake filter, coarse filter	Filters coarse particulates to extend intake filter life
Compressor intake filter	Inlet filter, intake filter, compressor	Filters fine particles to protect compressor and/or valves
Compressor	Not applicable	Pressurizes and pumps air into the system
Fan	Cooling fan	Circulates cabinet air and cools the compressor
Heat exchanger	Aluminium pipe, coil, pipe	Dissipates heat created by gas compression
Control circuit	PCB, printed circuit assembly	Analyses the system state and controls the valves and compressor
Valve assemblies	Solenoid, check, rotary valves	Controls the flow processes for the sieve and exhaust
Sieve beds	Sieve columns, zeolite	Separates gases as air is moved in and out
Exhaust muffler	N_2 exhaust muffler, muffler	Expels and quiets the N_2-rich air released back into the room
Product tank	Reservoir tank, accumulator tank, mixing tank, product tank	Gas accumulator for providing a steady and continuous flow
Flowmeter	Flow selector	Controls the delivered flow rate
Product filter	Outlet, output filter, final filter	Removes particulates from the product stream
Humidifier	Bubble humidifier, bubbler	Humidifies the delivered gas before inhalation
Oxygen monitor	Low oxygen alarm, oxygen concentration status indicator	Signals an alarm when oxygen concentration is below a preset level

2.2 Technical specifications

The following specifications define requirements for stationary oxygen concentrators that are appropriate for the treatment of hypoxaemia in developing countries (summarized in Annex 1). It should be noted that these specifications are intended to be used in conjunction with the current standard for oxygen concentrators, ISO 80601-2-69:2014 of the Medical Electrical Equipment – Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment (see Section 5.6). Unless otherwise noted, the following is specified at standard temperature and pressure, dry (STPD). STPD is defined as 101.3 kPa at an operating temperature of 20 °C, dry.

For the purposes of these specifications, "shall" means that compliance with a requirement or a test is mandatory; "should" means that compliance with a requirement or a test is recommended, but is not mandatory; "may" is used to describe a permissible way to achieve compliance with a requirement or test; "particular standard" refers to the requirements for oxygen concentrators (ISO 80601-2-69:2014).

2.2.1 Oxygen concentration

- The oxygen concentrator shall be capable of delivering a continuous flow at a concentration of oxygen greater than 82%.

  NOTE: Oxygen concentration may also be referred to as oxygen purity.

  NOTE: Most concentrators currently available produce an oxygen concentration between 82% and 96% volume fraction when operated within manufacturer specifications. Subclause 201.12.4.102 of the particular standard requires that oxygen concentrators must activate at least a low priority technical alarm condition with an alarm signal if producing an oxygen concentration less than 82% volume fraction.

- The minimum oxygen concentration shall be maintained at the maximum rated flow rate, at 40 °C, 95% relative humidity (RH) and atmospheric pressure representing an altitude of 2000 m above sea level.

  NOTE: Testing at the rated RH and temperature *simultaneously* is particularly important for oxygen concentrators since the concentration of oxygen can be significantly reduced by high RH such as those encountered in non-air-conditioned environments. Subclause 201.12.1.103 of the particular standard requires that oxygen concentrators be tested under the least favourable working conditions, as specified in the instructions for use. Check compliance with testing specified in subclause 201.12.1.103 of the particular standard.

  NOTE: In contrast to ISO 80601-2-1:2014, ISO 8359:2009/A1:2012 (hereinafter referred to as ISO 8359) did not require that concentrators be tested under *simultaneous* temperature and RH conditions. An independent study evaluated the performance of several ISO 8359 devices under these conditions and found that performance decreased with increasing heat and humidity *(22)*.

2.2.2 Flow control

- The oxygen concentrator shall be equipped with at least one built-in flowmeter with flow-rate control. If the oxygen concentrator is equipped with more than one flowmeter, each shall incorporate independent flow-rate control.

- For paediatric use, the flowmeter shall be capable of providing a minimum flow rate of at least 0.5 LPM. The maximum rated flow should depend on the oxygen needs (for examples, see Section 2.3.1).

  NOTE: Some 8 or 10 LPM units may only provide flow down to 2 LPM. In this case, if there is a clinical need for lower flow rates, such as for paediatrics, additional accessories are required (see Section 3.4).

- The oxygen concentrator shall be prevented from providing a flow rate greater than the maximum rated flow rate.

NOTE: Drawing a higher flow rate than intended by the manufacturer can reduce sieve-bed performance with resultant oxygen concentration dropping too low. It can also result in an earlier than usual replacement of sieve beds, which will need to be performed by trained technical personnel.

- The flowmeter shall provide continuous flow-rate control, with markings from 0 LPM to the maximum rated flow-rate, at a minimum of 0.5 LPM intervals.

- The oxygen concentrator shall be capable of generating at least 55 kPa at all flows, up to the maximum rated flow.

  NOTE: This is to overcome pressure drops due to long oxygen delivery tubing. In clinical practice, back pressure is added when accessories such as flow splitters and oxygen administration tubing accessories are connected to the oxygen concentrator outlet.

2.2.3 Indicators and alarms

- The oxygen monitor shall indicate when the oxygen concentration is less than 82%.

  NOTE: An oxygen monitor helps indicate when service or maintenance is needed. Faulty oxygen concentrators are sometimes still able to produce oxygen concentration greater than room air, although not greater than 82%.

- The oxygen concentrator shall incorporate alarms for alerting the user of fault conditions such as:
  - low oxygen concentration (<82%)
  - no flow
  - high/low pressure
  - low battery
  - power supply failure
  - high temperature.

  NOTE: The above alarms help indicate when service or maintenance is needed. These alarms may indicate the type of service needed, including changing of the gross particle filter or blocked flow. Troubleshooting information should be included in the manufacturer's user manual.

  NOTE: Different models may use alternative names for the same functional component (see Table 2).

- The oxygen concentrator shall incorporate a time meter that records the cumulative hours of device operation.

2.2.4 Outlets

- The oxygen concentrator shall have at least one oxygen outlet for direct attachment of oxygen delivery tubing.

- The outlets shall be barbed fittings and should be recessed or made out of materials that will not be easily bent or broken to avoid damage.

  NOTE: When moving concentrators across or between rooms, the device can be bumped or caught on other objects, which causes weak plastic or protruding outlets to break quickly.

  NOTE: Good oxygen outlet designs are critical to the safe and effective use of medical devices. Considering available resources in developing countries, barbed fittings are preferred to prevent tubing misconnections.

2.2.5 Enclosure

- The oxygen concentrator shall incorporate gross particle filters to prevent dust and grime from entering the enclosure and air inlet.

- All user-removable filters shall be cleanable. Cleaning instructions for filters shall be included in the instructions for use.

- The enclosure shall have wheels to allow for movement of the oxygen concentrator between rooms.

  NOTE: A lightweight device, weighing less than 27 kg, is recommended based on the average weight of current devices. Brakes are also ideal to prevent free rolls.

- The oxygen concentrator shall produce no more than 50 dB(A) of noise when operating.

  NOTE: Subclause 201.9.6.2.1.101 of the particular standard provides instruction for measuring sound pressure levels, based on methods from ISO 3744. It is essential that the noise level be related to patient acceptability and comfort. It is desirable to reduce the noise level as far as possible for devices that interfere with sleeping. It is recognized that oxygen concentrators may have both a steady sound level and a peak sound level. The peak sound level is considered to be more likely to be obtrusive to the patient during continuous machine performance.

2.2.6 Power

- The oxygen concentrator shall have a power efficiency of ≤70 W/LPM.

  NOTE: Stationary oxygen concentrators consume a significant amount of power, ranging from about 300–600 W. This amounts to significant energy demands if the concentrator is used continuously over several days or even weeks.

- The oxygen concentrator shall have an electrical plug that is compatible with the power outlets of the clinical facility and country where it will be installed.

  NOTE: Electrical input requirements should be labelled on the device since concentrators are available for different ranges of voltage and frequency. Procurement-related documents should also specify these requirements, including the voltage, frequency and type of plug needed.

2.2.7 Documentation and compliance

- The oxygen concentrator shall be supplied with an appropriate user manual (see Section 5.8).

- The oxygen concentrator shall be supplied with an appropriate service manual with full details of advanced maintenance and a list of spare parts (see Section 5.8).

- The oxygen concentrator shall comply with the ISO 80601-2-69:2014 (which supersedes ISO 8359), or its equivalent (see Section 5.6).

  NOTE: Devices compliant with ISO 80601-2-69:2014 are not expected to enter the market until 2017 or later. The requirements specified in this document must still be applied to existing concentrators, as of June 2015, which comply with ISO 8359. With careful selection and planning, existing models of concentrators can be sustainably implemented in LRS *(7,22–26)*.

- The oxygen concentrator shall be approved by a national regulatory authority. Stringent regulatory processes include clearance by the United States Food and Drug Administration (FDA), Conformité Européenne/European Conformity (CE) marking or appropriate national regulatory clearance from other members of the International Medical Device Regulators Forum (IMDRF) (see Section 5.7 for full documentation requirements to demonstrate this compliance).

  NOTE: The IMDRF is an international effort to harmonize medical device regulation; in 2015, members include Australia, Brazil, Canada, China, the European Union (EU), Japan, the Russian Federation and the United States. More information can be found at http://www.imdrf.org/.

2.3 Context-dependent considerations

The following context-dependent guidance is based on WHO guidelines on oxygen therapy and must be adjusted appropriately based on an oxygen needs assessment (see Section 5.1).

2.3.1 Maximum flow output

Oxygen concentrators are available as 3, 5, 8 and 10 LPM units. An oxygen needs assessment is critical to determining the maximum flow that an oxygen concentrator should deliver. In general, a 5 LPM or more unit is able to support at least two paediatric patients with hypoxic acute respiratory illness simultaneously. This assumes that each child receives at most 2 LPM of un-humidified air, as long as nasal prongs or nasal catheters are used (16). A 5 LPM machine may also support adults and older children. An 8 or 10 LPM device may be capable of use for indications with other supporting equipment (see Section 3.6) or sufficient to support up to four paediatric patients. An oxygen concentrator unit that delivers between 1 and 10 LPM would be the most versatile for surgical care applications based on current WHO guidelines *(14)*.

2.3.2 Oxygen concentration output at higher altitudes

At altitudes higher than 2000 metres above sea level, device performance requirements at high temperature and humidity need not be as stringent as described in previous sections. At these altitudes, environmental conditions rarely reach up to 40 °C and 95% RH simultaneously (i.e. temperature and humidity tend to decrease at higher altitudes). However, oxygen partial pressures in the atmosphere are lower at higher altitudes. Therefore, patients at facilities in higher altitudes may require higher flow rates for longer duration for adequate therapy compared to patients at sea level.

2.3.3 Humidification

Consult clinical guidelines to determine if humidification is needed. Per WHO guidelines, humidification is not required when oxygen is used at low flow rates up to 2 LPM with nasal prongs or nasal catheters in children under 5 years of age *(16)*. Furthermore, humidification may not be necessary when oxygen is delivered in tropical climates by a concentrator rather than a cylinder, since concentrators provide oxygen at room temperature whereas cylinders deliver cold oxygen.

Humidification may be required for high-flow oxygen needs greater than 2 LPM or if oxygen bypasses the nose, such as when nasopharyngeal catheters or tracheal tubes are used *(23)*. In this case, a humidification bottle provided by the manufacturer must be connected between the concentrator and the patient-breathing circuit. Humidifiers typically have threads for direct attachment to concentrators with threaded outputs or require a humidifier adapter for concentrators with oxygen barbs. The water in the bottle must be changed regularly in order to prevent contamination, and flow to patient checked at every change to detect humidifier-related oxygen leaks.

2.3.4 Blended oxygen gas

Per WHO guidelines on neonatal resuscitation, premature infants and neonates may require 30% oxygen in order to prevent oxygen toxicity. If no source of blended oxygen is available, in the case of premature infants, it is better instead to use room air with normal 21% oxygen.

To provide 30% oxygen from a near-100% oxygen source, an air-oxygen blender device may be used. However, most oxygen concentrators cannot be used with air-oxygen blenders because they do not provide sufficient pressure. This is because air-oxygen blenders usually require a high-pressure oxygen source (typically 300–450 kPa), which is not usually available in LRS. High-pressure oxygen is available from cylinders and piped oxygen systems, but not from oxygen concentrators (<140 kPa).

Alternatively, blended oxygen can be delivered by some continuous positive airway pressure (CPAP), anaesthesia and mechanical ventilator devices. In particular, concentrators with an air outlet can be made into a source of blended oxygen gas in the form of bubble CPAP (see Section 3.6.2) and are commercially available.

3. Guidance regarding oxygen concentrator consumables, accessories and other related equipment

This section highlights the other important medical equipment that is needed in conjunction with the oxygen concentrator to safely provide oxygen therapy.

3.1 Importance of pulse oximetry

Hypoxaemia can be detected by monitoring the oxygen saturation of the patient with a pulse oximeter (Figure 2). Monitoring oxygen saturation is important to determine whether oxygen treatment is effective and to prevent overtreatment. While a blood gas analyser can be used to determine the partial pressure of oxygen in blood, a simpler, inexpensive and non-invasive method is pulse oximetry. Pulse oximetry is the preferred method to measure the oxygen saturation in arterial blood *(16)*. In one study, the combination of pulse oximetry and oxygen was associated with a reduced death rate of 35% in children admitted with pneumonia (24). When pulse oximetry is not available, the necessity of oxygen therapy should be guided by clinical signs, even though they are less reliable *(16)*.

Various pulse oximeters are available in the market. Either bench-top (AC-powered) or hand-held pulse oximeters can be used, depending on the financial, electrical and staff resources available. Hand-held oximeters are cheaper than their larger counterparts, but most hand-held oximeters have batteries that require replacement, which could be very easily lost, stolen or unavailable in certain LRS. Where theft or loss of hospital equipment is a major risk, it may be sensible to secure the oximeter in one location within the ward, within reach of the sickest patients. An alternative is to have a locked chain securing the oximeter to a bracket on a wall or bench, with the key kept by the nurse in charge of each shift.

Oximeter accessories include batteries, battery chargers and the sensor probe. It is suggested that the sensor probe be reusable, not disposable and specified for long life if at all possible. The lifespan of sensor probes can be problematic in LRS and suggestions for improving their design have been discussed *(25)*. Reusable probes are generally designed to clip onto the end of a patient's finger, but some are designed to clip onto the ear lobe. The fingertip clip probes are available in adult and paediatric sizes and can be used on a finger, a toe, an earlobe or even across an infant's foot, depending on a patient's size and the signal achieved from peripheral blood flow at the particular anatomic location.

For additional information, refer to WHO resources on pulse oximetry, including medical device technical specifications (http://www.who.int/medical_devices/management_use/mde_tech_spec/en) and training manuals (http://www.who.int/patientsafety/safesurgery/pulse_oximetry/tr_material/en) *(26–28).*

Figure 2. Setup of a typical oxygen concentrator, pulse oximeter and connection to the patient

Source: Illustration by David Woodroffe. Adapted with permission of the International Union Against Tuberculosis and Lung Disease, from Duke et al. *(5)*. Copyright © The Union.

3.2 Patient delivery accessories

To deliver oxygen from the concentrator to the patient, oxygen outlet adaptors and oxygen delivery tubing are necessary in addition to replaceable nasal prongs and/or catheters (Figure 3). The concentrator oxygen outlet(s) should have a ¼-inch barbed fitting (or equivalent) for direct attachment of oxygen tubing to the patient. Oxygen tubing should be kink resistant and kink free and have standard connectors.

3.3 Patient delivery consumables

Therapeutic levels of oxygen are delivered to the patient via oxygen tubing and a breathing device such as nasal prongs, nasal catheters or oxygen masks. Nasal prongs and nasal catheters are consumables that are not recommended for reuse between patients by the manufacturer. If nasal prongs are to be reused, cleaning and disinfection protocols must be followed (see Section 4.5).

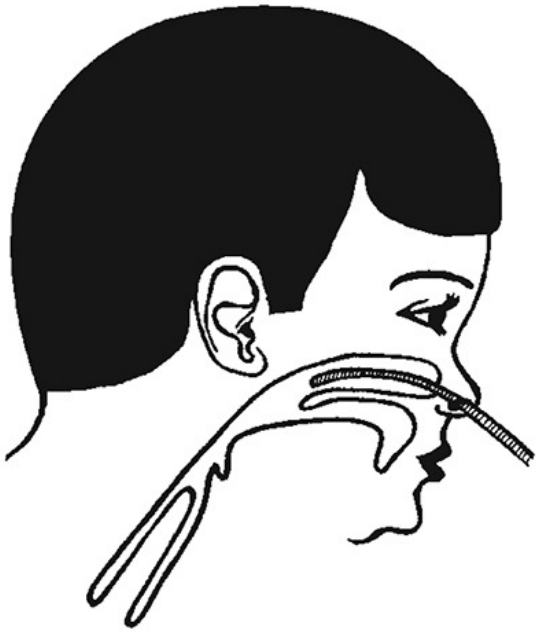
In children with hypoxic respiratory illness, it is recommended that nasal prongs are used *(16)*. The distal prong diameter should fit well into the nostril (1 mm for premature infants; 2 mm for neonates up to 10 kg).

Figure 3. Nasal prongs

Source: World Health Organization (2013) *(16)*.

Nasal prongs are preferred, however, nasal catheters can also be used (Figure 4) *(16)*. If nasal catheters are used, French size 6 or 8 can be used in neonates and infants *(16)*.

Figure 4. Nasal catheters



Source: World Health Organization (2013) *(16)*.

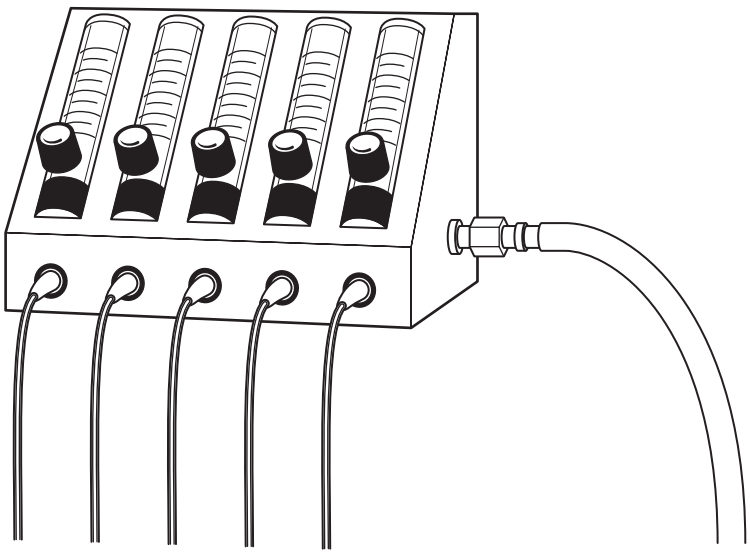
Due to their relative inefficiency and low patient acceptance, oxygen masks are not ideal in locations where oxygen is scarce or for patients that require prolonged oxygen therapy. Oxygen masks require higher flows than nasal prongs or catheters to achieve similar inspired oxygen concentrations, and if lower flows are used, carbon dioxide (CO_2) builds up in the mask and the patient will re-breath their exhaled CO_2.

3.4 Accessories to divide flow to multiple patients

The flow rate of delivered oxygen must be continuously adjustable by the user. This is necessary because oxygen flow needs require adjustment over the course of treatment and is particularly important for premature newborns in whom excessive oxygen therapy causes harm *(29)*. Furthermore, patients are started at different flow rates depending on their age, clinical condition and the type of breathing device used *(30–33)*.

While ISO 80601-2-69:2014 specifies oxygen concentrator performance and safety requirements for single patient-use, concentrators can be used with multiple patients. The options for dividing flow to multiple patients are as follows. First, some concentrators have two built-in flowmeters, with two corresponding oxygen outlets, to treat two patients simultaneously. This method avoids the need for additional user assembly, but is also limited to a maximum of two patients that can be treated at the same time. Only some concentrators designated as paediatric have built-in flowmeters capable of titrating oxygen to very low flows (0.1–0.2 LPM; see Annex 2). Second, flowmeter stands consisting of from two to five mounted meters can be used (see Figure 5). This has the advantage of being more familiar to clinical staff who are used to using flowmeters on cylinders and allows precise titration of flow to each individual patient (including down to 0.1 LPM).

Figure 5. Example flowmeter stand



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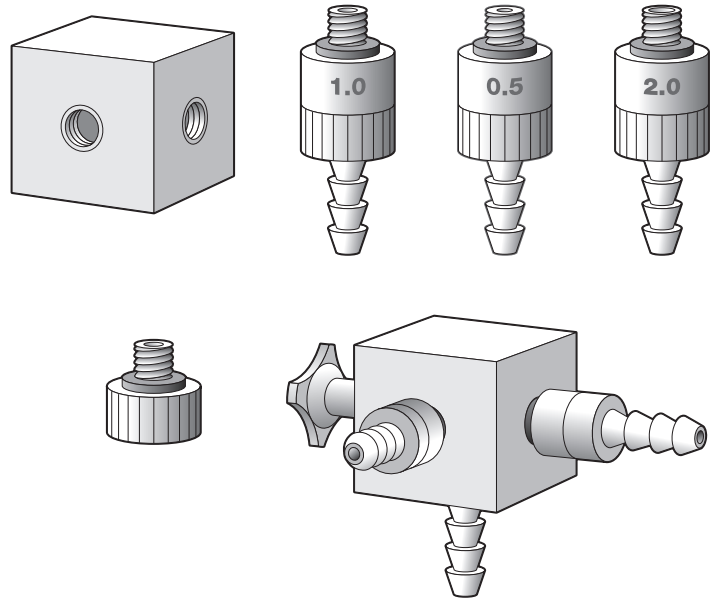
A four-way flow splitter assembly has been used as a method to split flow. It consists of a four-way flow splitter block, nozzles for 0.5, 1 and 2 LPM and blanking plugs (Figure 6). Flow splitters are less preferred than flowmeter stands or built-in paediatric flowmeters, since the corresponding blanking plugs are very easily lost or misplaced. Moreover, flow splitters use nozzles that deliver oxygen at a single fixed rate.

Figure 6. Example flow splitter, nozzles and blanking plugs



Source: Illustration by David Woodroffe. Adapted from World Health Organization (1993) *(46)*.

3.5 Supporting equipment during power failure

3.5.1 Oxygen cylinders

In the event that all available power sources fail or when the concentrator has been sent for repair, a back-up oxygen cylinder is essential to ensure continuity of oxygen treatment. The cylinder must be safely secured on a wheeled trolley and have a prefitted oxygen flow regulator and cylinder contents gauge. If local cylinders do not have hand-actuated valves, an oxygen cylinder valve key chain secured to the trolley is needed.

Oxygen cylinders must be regularly checked to make sure that they are full and immediately ready for clinical service at every staff shift change. In addition, cylinders usually need to be transported to and from the bulk supply depot for refilling.

3.5.2 Power supplies and conditioning

Operation of oxygen concentrators depends on a reliable and continuous AC electricity power supply. It is also important that the concentrator is protected from voltage fluctuations, including power sags and surges/spikes. While ISO-compliant devices include basic power protection, repeated exposure to such poor-quality power can cause shut down, underperformance or permanent damage that requires repair by a skilled technician earlier than expected. Therefore, it is recommended that back-up power

supplies, such as an uninterruptible power supply (UPS) and/or battery bank systems, are also considered during the procurement of oxygen concentrators.

At a minimum, a voltage stabilizer and surge protector are recommended to counter the poor-quality power that causes cumulative damage to the device over time. The voltage stabilizer should accept a minimum range of voltage that is ± 20% of the rated input. The surge protector usually has a visual indicator to signal its status, such as a green light for "protection present", and is certified to International Electrotechnical Commission (IEC) standard 61643-11 or its substantial equivalent (e.g. Underwriters Laboratories standard 1449).

Where mains power[1] failures are common, back-up generators can provide back-up power for hours, even days. However, in practice generators are problematic due to insufficient (and expensive) fuel supply. Where there are relatively brief failures of mains electricity, a UPS can be more appropriate. A UPS is a packaged unit consisting of a battery (or batteries), charger, surge protector, inverter and control circuitry that automatically switches between the grid and batteries. Some high-end models include an additional voltage stabilizer to accept a wide input range of voltage before switching to battery power. Because a concentrator has a starting wattage that is two or three times greater than its rated operating wattage, a UPS should be sized to meet that starting wattage. The internal batteries in a UPS generally only last for a few minutes to half an hour at most, so a UPS is not appropriate where the mains power supply is interrupted for longer periods of time.

To provide back-up power of 30 minutes or longer, a battery bank system can be used. A battery bank typically consists of batteries, a charge controller and an inverter *(34)*. The batteries can be charged via mains electricity. Two parameters dictate the hours of backup provided: the total energy stored by the batteries, measured in watt-hours (Wh), and the operating wattage of the concentrator. Each component must be adequately sized for the concentrator; therefore, it is useful to work with a trained battery technician prior to setting up a battery bank. An example of how to calculate the back-up energy requirements for an oxygen concentrator is shown in Annex 3.

The number of batteries needed depends on the characteristics of the concentrator and the average duration of power outages. For example, in Gambia, a battery bank system was developed to provide continuous operation for a 350 W concentrator with as little as four hours of mains electricity available per day. Their system utilized eight lead-acid batteries (6 V sealed, maintenance-free, deep-cycle lead-acid) with a 50-A (ampere) charger on mains electricity *(34)*. All components were designed to last five years, but the battery cells may wear out sooner depending on power cycles and ambient conditions.

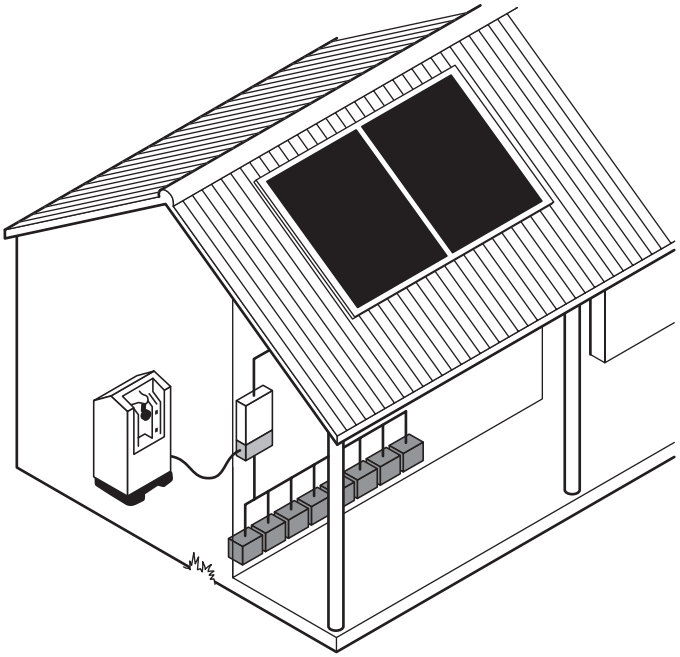
In areas with especially unreliable or unavailable mains electricity, solar panels can be used to charge battery banks (Figure 7). This has been demonstrated as a cost-effective solution that offers continuous power, even during mains electricity outages of 30 minutes or longer *(34,35)*. To set up these alternative power systems, the power requirements must be determined in the setting of use and an adequate support system for installation, training and maintenance must be defined. This should be done by local engineers and local suppliers of alternative power sources. The economics of these

1 Also known by various terms, including mains electricity, AC power line, grid power, and grid electricity.

systems, including sizing, costing and payment is usually discussed with manufacturers and local suppliers of alternative power sources.

Further field experience of such systems will provide an even better idea of the level of specification required to make them sufficiently robust over the expected lifetime of the system. For additional guidance and training on sustainable energy technology options, specifications, training and maintenance, see http://www.poweringhealth.org/index.php/topics/technology/design-and-installation.

Figure 7. Oxygen concentrators can be powered with solar-powered battery banks



Source: Illustration by David Woodroffe.

3.6 Optional equipment for other applications of oxygen concentrators

Some oxygen concentrators can be used for other medical applications besides oxygen therapy. While some applications are possible through built-in features, other applications require additional equipment. The appropriate clinical guidelines and technical recommendations should be referred to, if available.

3.6.1 Anaesthesia

Oxygen concentrators can be used in some, but not all, anaesthesia machines. There are two different systems available for delivering anaesthetic gases and vapours to the patient, with which oxygen concentrators have been used: draw-over and continuous flow. In draw-over systems, volatile agents or compressed medical gases are added to an air stream that is delivered to the patient. The air is driven by the patient "drawing" in air through the system, rather than by a source of compressed oxygen, as is used in continuous flow anaesthesia systems. Therefore, oxygen concentrators can be used in

draw-over systems. In contrast, not all continuous flow anaesthesia machines can work with oxygen concentrators since most concentrators do not produce sufficient pressure. Nonetheless, some continuous flow anaesthesia machines are designed to operate with oxygen concentrators *(36)*.

Overall, if oxygen concentrators are used as the primary oxygen source for anaesthesia, there must be a back-up power supply (such as a generator or UPS) or cylinder supply present to continue delivery in the event of a power failure. Furthermore, it is important to determine whether the concentrator can deliver oxygen at the necessary concentration and pressure required by the type of anaesthesia system used. For additional information, refer to the WHO manual *Surgical care at the district hospital (14)*, available at http://www.who.int/surgery/publications/en/SCDH.pdf and *Integrated management for emergency and essential surgical care toolkit (17)*, available at http://www.who.int/surgery/publications/imeesc/en.

3.6.2 Bubble CPAP

CPAP is a respiratory technique to provide airway support in the form of positive pressure, primarily for premature babies with respiratory distress syndrome. Bubble CPAP is a simple and inexpensive form of CPAP that can be made using standard nasal prongs and an oxygen concentrator *(23)*. However, in premature neonates less than 32 weeks of gestational age, blended gas is required as it is not safe to administer high oxygen concentration due to the risks of oxygen toxicity, including retinopathy of prematurity, brain damage and chronic lung injury. As a result, oxygen concentrators without blending functionality are not suitable for CPAP in premature infants since concentrators do not generate enough pressure to be used with an air-oxygen blender (see Section 2.3.4). However, certain concentrator-based bubble-CPAP systems have been designed to provide blended oxygen gas, having been demonstrated in neonatal wards *(37)*. For additional information, refer to the WHO *Manual on clinical use of oxygen therapy in children* (in preparation) for clinical guidelines *(23)* and the WHO *Technical specifications for medical devices* for related equipment *(26)*.

3.6.3 Nebulizers

A nebulizer is a device that entrains aerosolized liquid medication into inhaled air in order to deliver medication to the lungs. Examples of drugs that have been aerosolized and delivered orally or intra-nasally are surfactants, steroids, anti-inflammatory drugs, antibiotics and vaccines. There are three types of nebulizers currently available: jet nebulizers; ultrasonic nebulizers; and vibrating mesh membrane nebulizers.

If jet nebulizers are used, then concentrators with a built-in nebulizer function or that can provide high enough oxygen outlet pressure to power a nebulizer can be used. Some concentrators have an additional air outlet to supply pressurized air for a nebulizer (see Annex 2). Such concentrators may reduce the need for other dedicated equipment and infrastructure to provide pressurized air.

4. Guidance for handling oxygen concentrators

This section highlights key considerations when installing, using and maintaining oxygen concentrators. This section does not intend to replace manuals provided by the manufacturer, which are the primary sources of information and must be referenced. General procedures are described to exemplify the maintenance resources required to ensure the proper functioning of oxygen concentrators.

The WHO template for medical device technical specifications always requests that service and operating manuals be delivered with the equipment. User and maintenance manuals must be obtained when purchasing, and are essential learning, training and troubleshooting materials.

It is important to carefully read and refer to the user manual instructions for proper operation of the oxygen concentrator. These manuals contain information on general operation and indications for use as well as instructions for safety, cleaning, care and routine maintenance. It is important to make arrangements to translate the user manual into the local language.

4.1 Potential hazards

Oxygen concentrators produce a high concentration of oxygen, which increases the danger of fire for other objects, causing them to burn more readily. Manufacturers must comply with international safety standards that require mechanical safeguards and warnings to address these fire hazards. The following fire safety and hazard precautions are highlighted and should be addressed during installation and training of clinical and technical staff:

- immediately replace damaged electrical cables or plugs;
- utilize firebreak connectors to stop the oxygen flow in the event of fire;
- set the concentrator power switch to “off” when is not in use;
- when not in use, do not leave nasal catheters or prongs in contact with bed sheets or blankets – this is an infection control hazard as well as a fire hazard if the concentrator is turned on, as the oxygen will make the bedding material much more flammable;
- keep anything that might create a spark or flame, such as cigarettes, candles, lanterns, portable heaters, stoves and electrical appliances, well away from concentrators, cylinders and tubing;
- do not use oil, grease or petroleum-based products on or near the unit, as these increase the risk of explosion and fire;
- place the concentrator on a flat surface to prevent inadvertent rolling or damage to the compressor.

4.2 Installation

Prior to installation, manufacturer operating manuals and documents must be read and understood. The following is a non-exhaustive list of key procedures to perform for installation of the oxygen concentrator:

- note and report any signs of external or internal damage;
- avoid placing the unit in a confined area – place the unit so that all sides are at least 30 centimetres away from a wall or other obstruction to ensure adequate airflow to the device and heat dissipation;
- avoid placing the unit in direct sunlight;
- position the unit away from all potential fire hazards, including curtains or drapes, hot air registers, heaters and fireplaces;
- record the number of hours on the hour meter;
- verify that the electrical plug is compatible with the socket to be used;
- verify that the oxygen concentration level is within specifications when the device is operated with all accessories connected at maximum flow;
- verify that all specified alarms, including power failure and battery alarms, are operational (see Section 2.2).

While an oxygen concentrator is easily movable by an individual, oxygen concentrator units may be installed in a fixed position to prevent damage, loss or removal to another room. The concentrator can be located some distance from the flowmeter assembly. The flowmeter assembly should be located conveniently on the wall near the nurse's station. A conduit to fix oxygen tubing against the wall can be installed to deliver oxygen to the individual patient beds (Figure 8).

Figure 8. Example setup of an oxygen concentrator in a paediatric ward

Source: Illustration by David Woodroffe.

4.3 Training

High staff turnover and lack of training could translate to impeding oxygen concentrators from receiving the preventive maintenance required to function properly. A system for training clinical and technical staff is essential, especially since high staff turnover can disrupt safe and effective device use *(24)*.

Clinical users, including nurses and doctors, should be instructed and trained to perform the following:

- identify when and which patients need oxygen therapy;
- give the appropriate amount of oxygen, in the correct manner, according to clinical oxygen therapy guidelines;
- determine device use, both individual and multiple-patient use;
- manage day-to-day user maintenance and care of equipment;
- check that oxygen flows through the nasal prongs with a bubble test (Section 4.4).

Technicians and engineers (e.g. hospital, clinical and biomedical) should be trained by the manufacturer, supplier and/or experienced users. Note that in addition to information, some manufacturers may have useful instructional videos available online. Training for technicians and engineers performing regular maintenance and service checks should include:

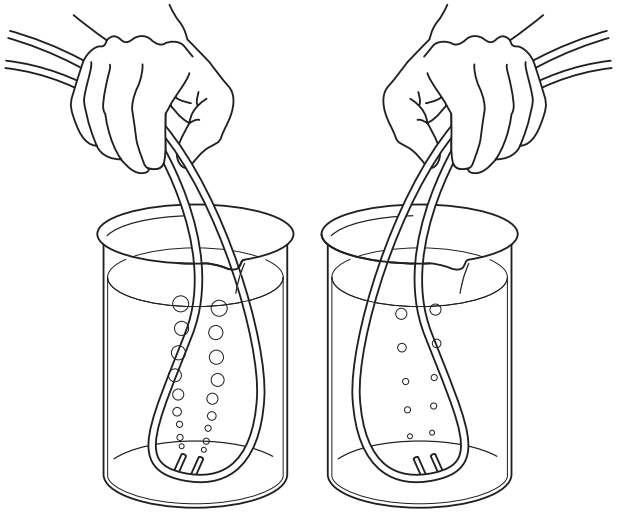
- name and function of all components;
- regular maintenance and service checks;
- device operation and safety;
- routine monitoring of oxygen concentration and outlet pressure;
- performance verification and troubleshooting;
- repair and management of spare parts.

4.4 Handling and use

Prior to use, an understanding of both the clinical guidelines and appropriate equipment is necessary (see Section 1). In general, concentrated oxygen is delivered to the patient such that their oxygen saturation stabilizes and is maintained within normal ranges. Exposure to too much or too little oxygen can harm patients, especially neonates *(23)*. To monitor oxygen therapy, pulse oximetry should be used (see Section 3.1).

The bubble test is a simple method to quickly check for gross leaks in the oxygen connections to the patient *(23)*. All users of oxygen concentrators should be trained to conduct this test. To perform this test, the distal end of the nasal prongs or catheters is submerged into a beaker of clean water (see Figure 9). Bubbles will appear if gas is flowing through the nasal prongs. If not, all oxygen delivery connections should be checked. Note that the bubble test does not indicate whether the oxygen purity meets specifications; oxygen purity can be verified by the oxygen monitor or an oxygen analyser.

Figure 9. Bubble test to check for gross leaks



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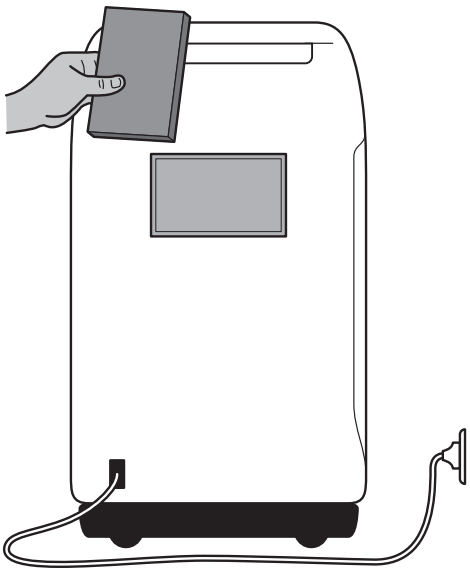
4.5 Cleaning and decontamination

Cleaning and decontamination procedures should be followed according to manufacturer recommendations and standard clinical practice. Cleaning can be done easily by the user, including nurses or assistants. No special training is required to clean the oxygen concentrator; the user only needs to be shown how to correctly remove, wash, dry and replace the gross particle filter of the oxygen concentrator (see Figure 10). If the environment is particularly dusty or dirty, then the gross particle filter and device exterior must be cleaned more frequently, at least twice per week and following every dust storm (see Table 2 for alternative names that manufacturers use for these filters).

Figure 10. The gross particle filter on a concentrator must be removed and cleaned weekly or more often if in a dusty or dirty environment



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In general, the filter can be cleaned with a mild detergent, rinsed with clean water, dried and replaced. A spare filter is inserted if the concentrator is being used during cleaning. The gross particle filter may be reused after each cleaning but should be replaced if visible degradation occurs. Users should refer to the manufacturer for cleaning and replacement protocols.

Similarly, the exterior of the oxygen concentrator should be wiped according to the manufacturer's instructions, disconnected from the power supply. Manufacturers generally recommend cleaning using a mild detergent or cleaning agent. Allow the solution to remain on the surface for 10 minutes and then rinse off and dry.

Manufacturer recommendations are that nasal prongs are not to be reused. However, this may not be practical in some settings and efforts to publish standard protocols for safe reuse are under way *(23)*. Cleaning and disinfection protocols should always be followed if nasal prongs are reused, and requires: cleaning with soap and water; soaking in dilute bleach solution; rinsing in clean water; and allowing to dry in room air *(23)*. An effective cleaning solution can be created by mixing undiluted bleach (from 5% to 5.25% sodium hypochlorite) to water in a ratio between 1 : 100 and 1 : 10.

When humidifiers are used, they should have clean water replaced daily and be soaked in dilute bleach for 15 minutes weekly (and between patients), and then dried *(23)*.

4.6 Maintenance

Regular maintenance and specified service are vital to the long-term operation and proper functioning of oxygen concentrators. Keep in mind that concentrators are designed to run continuously for days. While the compressor is the primary moving component and most subject to wear over time, it may be repaired or replaced if available from the manufacturer (see Section 5.5). An analysis of an oxygen concentrator fleet in Gambian hospitals demonstrated that the useful lifetime of concentrators can be up to seven years or more with proper maintenance and repair *(4,38)*.

To maintain optimal performance over time, regular maintenance by both clinical and technical staff alike is required. In addition, maintenance should be scheduled, performed and documented by a trained technician at least once per year (ideally every three to four months). The frequency of maintenance checks varies by model, use and environment, but should be done at least annually or every 5000 hours of use (see Section 5.5). More frequent maintenance is needed for hot, humid and/or dusty operating environments. Training in basic concentrator maintenance, including how each component functions, should be provided by an experienced technician or by a service representative from the manufacturer. Maintenance can be performed by a trained technician, but a manufacturer may request that the device be submitted for specialized repair if a problem cannot be addressed. Instructions for advanced maintenance tasks should be detailed in the manual provided by the manufacturer.

Regular maintenance checks on the oxygen concentration output with a calibrated oxygen analyser is essential and must be carried out by a trained technician at least once per year, and every three to four months if possible. During these checks, it should be verified if the oxygen concentration is within operating range. This can be done with a calibrated oxygen analyser. As necessary, the pressure output is checked with a pressure gauge. These pressures may include output delivery pressure, pressure in the product tank and pressures in the sieve-bed ends at various points of the pressure cycle. The bubble test may also be performed as a quick check of connections for gross leaks (see Section 4.4).

Performance outside the normal range indicates that internal components may need replacing. A spare oxygen concentrator should be available for exchange, so that the faulty oxygen concentrator can be examined. The sounds produced by the concentrator also provide information about performance status. If the compressor is particularly loud, it likely needs servicing. Additional troubleshooting and repair tasks may involve disassembling the equipment and replacing components. The general components of oxygen concentrators are illustrated and described in Figure 1 and Table 2. An understanding of each of these components and their function greatly enhances the technician's ability to properly maintain, diagnose and repair a concentrator.

It is indispensable that the procurement document indicates that equipment be delivered by the manufacturer along with a service manual in addition to the user manual (see Section 5.8). Furthermore, the manuals should be made available in the local language to facilitate use. The service manual should include troubleshooting as part of corrective maintenance. It is important that information on the manufacturer's technical support department is attached to or on a sticker on the equipment in case something is not working properly or to request spare parts. Information on local distributors who should have spare parts and/or technical personnel that can provide maintenance support should also be provided. All this contact information is obtained at the time of purchase and should be available where the equipment is used. If contact can be established via email, it will allow the user to receive updates on equipment and service manuals. In addition, technical support should offer troubleshooting assistance and recommends spare-parts inventories. A sample troubleshooting guide to some of the more common problems found with oxygen concentrators is provided in Table 3.

Table 3. Sample troubleshooting guide for hospital engineers and service technicians

Problem	Probable cause(s) and solution(s)
The concentrator does not turn on	No mains power. Inspect and check power cord, electrical connections, circuit breaker (if equipped), internal fuse (if equipped; sometimes located on the PCB), on/off switch, PCB.
The concentrator operates, but the compressor shuts down intermittently	Check gross particle filter, cabinet fan, capacitor for the compressor, cabinet thermal switch (if equipped), valve(s), PCB. Compressor may have a faulty internal switch.
The concentrator's compressor does not turn on	Inspect and check electrical connections to the compressor, capacitor and PCB.
The concentration is within specifications, but flow fluctuates	Check all filters and replace if necessary. Pressure regulator needs to be adjusted, repaired or replaced.
The concentration is within specifications, but the oxygen monitor indicates low concentration	Tubing to oxygen monitor is kinked or oxygen monitor is faulty. Repair tubing or replace sensor.
The concentrator runs, but oxygen concentration is low	Check all filters and replace if necessary. Check compressor pressure and flow output; replace or rebuild if necessary. Sieve beds may be faulty and require replacement.
The concentrator overheats	Check ventilation fan operation; replace if necessary. Inspect and wash gross particle filter. Power may be in an overvoltage or undervoltage condition, check the UPS (if installed).
Oxygen does not flow out of the concentrator	Check system power. Inspect oxygen tubing and cannula for kinks or plugs. Check all filters and replace if necessary. Check internal tubing and fittings for leaks or kinks. Check compressor pressure and flow output; replace or rebuild if necessary.

PCB, printed circuit board; UPS, uninterruptible power supply
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5. Procurement guidance for oxygen concentrators

Improving health outcomes through the implementation and utilization of oxygen concentrators is possible with time and planning. Oxygen systems will be optimally effective if they are planned as part of an overall approach to improve quality of care within a hospital and a ward. A team approach is necessary, involving clinical staff, hospital administrators, engineers and trainers. Choosing the location, establishing a high-dependency area that is integrated within the ward and ensuring that there is sufficient technical expertise for day-to-day care, regular maintenance and safety of equipment are all crucial to increasing the availability of oxygen and having a positive impact on patient outcomes.

The following section outlines the key steps and considerations required in the procurement process to guide the selection of appropriate high-quality concentrators. An overview of existing manufacturers and models of stationary oxygen concentrators and their specifications are listed in Annex 2. These existing devices (June 2015) have FDA clearance and/or a Declaration of Conformity to ISO 8359 (refer to Section 5.5 for essential information regarding selection of appropriate concentrators).

This document draws upon certain aspects of the procurement process outlined in the *Procurement capacity toolkit: tools and resources for procurement of reproductive health supplies,* which was published by PATH in 2009 *(39),* and from *The TCu380A intrauterine contraceptive device (IUD): specification, prequalification and guidelines for procurement*, which was published by WHO in 2010 *(40)*.

Additional information on WHO guidelines for procurement is available at http://whqlibdoc.who.int/publications/2011/9789241501378_eng.pdf?ua=1. Procurement guidance specific to medical devices is available at http://www.who.int/medical_devices/management_use/en.

5.1 Needs assessment

Prior to procurement, an oxygen needs assessment must be performed to identify the appropriate equipment for a particular ward or hospital and to define the power supply requirements. Assessing and defining power supply requirements for oxygen concentrator devices and related equipment will depend on several factors that should be discussed with all parties involved in the usage, procurement and distribution of oxygen concentrator devices. For additional procurement guidance, including information on conducting needs assessments, refer to *Needs assessment for medical devices* at http://www.who.int/medical_devices/management_use/en *(41)*.

5.1.1 Define programme context

Before forecasting and quantifying product requirements, it is important to understand the needs of the end users and the country policies and guidelines. Country policies and guidelines will determine the appropriate clinical applications for oxygen therapy, placement within the health system and appropriate personnel to be trained and

approved to use oxygen concentrator devices. The top priority usually lies in providing oxygen to sick neonates and young children. Availability of funds is the usual limiting factor to providing oxygen to other areas.

5.1.2 Forecast programme requirements

Before the procurement process can begin, it is important to forecast the requirements of each type of device. Conducting an oxygen needs assessment is essential to determine the number of oxygen concentrators that should be available. This number depends on the total number of beds, the number of annual admissions, the estimated proportion of patients admitted who have hypoxaemia, the average duration of hypoxaemia and the need to accommodate higher hypoxaemic admissions in the peak season(s). These data are not always available and do not address other system and capacity factors that can affect utilization. A short audit to assess the current situation, including using pulse oximetry to assess the prevalence of hypoxaemia and/or reviewing basic admission data for children, may be necessary.

As a rough guide, oxygen concentrators are often used in neonatal units, paediatric wards and operating theatres. If needed in these areas, at least one concentrator per room is recommended to prevent removal. At a minimum, planning should be done to ensure that oxygen is available for all critical unit beds in the neonatal wards and for a sufficient percentage of beds in the paediatric wards. In hospitals where acute respiratory infection is the most common condition, it has been found that 9–38% of admitted children with pneumonia will have hypoxaemia *(42)*. The average duration of hypoxaemia in children with pneumonia is about two–three days, although some studies, particularly in hospitals at higher altitudes, have found an average duration of up to five days *(29,43,44)*. A sample equipment list is provided in Table 4. These quantities must be adjusted based on the oxygen needs assessment as appropriate.

5.1.3 Customize the specifications

One of the more important responsibilities of a purchaser is to ensure that each oxygen concentrator device specification is accurate, detailed, clear and consistent. The purchaser should review the WHO specifications in this guide to fully understand the different levels of requirements and to identify which requirements can be adapted by the purchaser to address specific programme needs and which requirements must be left unaltered so as not to jeopardize the integrity and quality of the product. See Annex 1 for an overview of procurement specifications, Section 2.2 for the minimum specification requirements and Section 2.3 for guidance on customizing the specifications.

5.2 Programme planning

It is important to note the minimum resources that should be available when considering the implementation of oxygen concentrators:

- pulse oximetry;
- capacity for technically trained staff;
- source of reliable power;
- availability of consumables, spare parts and maintenance tools;
- physical space to place the concentrator (see Section 4.2).

At a minimum, the following should be included as part of an oxygen concentrator procurement plan:

- oxygen concentrators that can deliver a continuous flow of concentrated oxygen (>82%);
- reusable pulse oximeter with a guaranteed supply of sensor probes – it is recommended that a five-year supply be considered;
- adequate yearly supply of appropriate patient delivery consumables and accessories – it is recommended that a five-year supply be considered;
- availability of spare concentrators and back-up supplies (e.g. back-up power supplies and oxygen cylinders) in case of power failure.

5.3 Procurement planning

Prior to procuring oxygen concentrators, it is important to establish a procurement plan that includes the following:

- Confirmation of budget allocations and timing for the availability of funds.
- Technical specification review ensuring the following (see Annex 1):
  - the general performance and design description is complete;
  - regulatory requirements are clearly stated;
  - packing, labelling and marking requirements are included;
  - sampling, inspection and testing protocols are included where necessary.
- Confirmation of the required delivery date, location and mode of transport.
- Knowledge of specific country requirements and national regulatory procedures that need to be taken into account; e.g. many countries have special regulations covering the importation of medical devices. Procurers involved in the procurement of oxygen concentrator devices need to be aware of any rules and regulations. Questions concerning specific requirements that should be answered include:
  - Is there a mandatory national quality standard with which the oxygen concentrator devices must comply?
  - How are the standards applied?
  - What other requirements are there, such as import taxes and duties, certification, required shipping documents?
  - Is there a requirement for registration prior to importation?
  - Is there an in-country requirement for confirmatory testing and/or pre-inspection (physical and/or shipping documents)?

Information can be obtained from the national regulatory authority and/or the Bureau of Standards of each country.

5.4 Assessment of procurement options and procurement method

In preparing for the procurement of oxygen concentrators, the purchaser must determine which procurement method would be most appropriate for the particular circumstances of the country and the programme needs.

The process of assessing the options for procurement is intended to:

- identify the procurement options that are possible;
- consider what is practical under the circumstances;

- look at who can/will do the work;
- examine cost implications;
- evaluate the options and select the most appropriate option or procurement method for the procurement.

There are a number of options for obtaining oxygen concentrators for LRS, depending on the agreements made in low-income countries. Options include:

- direct from manufacturers depending on country programme and needs;
- government agencies; e.g. the United Nations Children's Fund (UNICEF) Supply Division, the United Nations Population Fund (UNFPA) or the United Nations Office for Project Services (UNOPS);
- international procurement agents such as those approved by national governments;
- manufacturer-approved distributors may also exist for some products (contact the manufacturer to obtain information on an authorized distributor in the region where the products are being procured);
- rental contracts that are sometimes available from third-party distributors;
- donations.

Product offerings and catalogues offered through government agencies or approved international procurement agents are intended to assist in the planning, procurement, supply and/or delivery of essential commodities. An understanding of all the available procurement options for oxygen concentrators is critical for selecting a procurement method that is suitable and economically feasible for the destination country.

5.5 Manufacturers and warranties

There are many oxygen concentrators on the market, but not all are of high quality or appropriate for effective use in LRS. Independent testing of seven 5 LPM concentrators found that most concentrators did not meet the manufacturer's specifications (22). From this study, operation at simultaneous high temperature and RH was a common problem. Therefore, independent verification of a device's performance under the maximum specified temperature and RH is ideal.

Overall, the manufacturer and model of concentrators should be selected based on the specifications outlined in Section 2.2, contexts of use outlined in Section 2.3 and the documentation outlined in Section 5.7. Current models of concentrators (June 2015) comply with ISO 8359. An overview of manufacturers, current models with clearance from the FDA and/or CE conformity to ISO 8359 and their performance specifications are listed in Annex 2. Future devices will be expected to comply with ISO 80601-2-69:2014 (which supersedes ISO 8359) following ratification.

Because new models of oxygen concentrators appear every year, consistently procuring concentrators from one or two manufacturers is critical to the bidding and procurement process to help ensure continuation of services and uniformity of spare parts, maintenance and training. A country may or may not have special requirements or registration processes for medical devices. Regardless, it is important to select manufacturers and devices that fit quality assurance needs and requirements.

Warranties should always be requested during the procurement process, and service contracts are usually established after the warranty expires. The original manufacturer and/or a third-party provider may offer additional warranties and service contracts.

It is important to clearly understand what the contract includes, such as cost, transportation, services and replacement components. Additionally, it is essential to identify who will perform the installation, training, repair and maintenance. Ideally, the manufacturer and/or the service provider should be responsible for providing technical support, regular maintenance and repair for the duration of the warranty. The procurer defines the time of the warranty. It is recommended that the warranty should be at least two years, and longer if possible, with a prepaid service contract that ensures that the equipment will be available and operating for several years after acquisition.

It is important to have an understanding of what is already in good working order in health facilities as well as an estimate of each device's average lifespan. While there is no standard method for reporting lifespan, the useful life of oxygen concentrators can reasonably span several years with proper maintenance and repair (see Section 4.6). The compressor is subject to the most wear, but can be repaired or replaced if available from the manufacturer. Many the manufacturers quantify the lifetime of components as hours under normal conditions of use (i.e. with regular cleaning, dust-free environment and reliable power). As a guide, one year of use ranges from 5000 hours (moderate use) to 8000 hours (nearly continuous use year round). Expected lifetimes may differ between manufacturers and will decrease if the equipment is poorly maintained and/or in hot, dusty and sooty environments.

Warranty options are not always possible, such as when equipment is donated or the cost and time required to return equipment to the manufacturer are beyond capacity. In such cases, a system and budget for maintenance and repair would need to be set up independently *(3,38)*. This requires training of local engineering departments and setting up a spare-parts inventory, which should form part of the donation. Contact with the original manufacturer is required to determine if the following services are provided: continuing technical support; troubleshooting assistance; recommendations to maintain spare-parts inventories pertaining to those particular models that are donated; and technical training either at their facility or onsite.

5.6 Safety standards and regulatory approvals

Oxygen concentrators are medical devices, and many countries have special regulations covering the importation and distribution of medical devices. Most national regulatory authorities require that a product comply with appropriate international or national standards before it can be marketed. These standards establish minimum safety, performance and quality requirements for a wide range of products, including oxygen concentrators. The principal international standards authority is the ISO, the worldwide federation of national standards bodies.

Oxygen concentrators that meet minimum specifications for quality and safety must comply with the ISO standards for oxygen concentrators and IEC 60601-1 (current version edition 3.1 2012-08) or their equivalent. The current ISO standard for existing

oxygen concentrators, as of June 2015, is ISO 8359. Future concentrators will be expected to comply with ISO 80601-2-69:2014 following ratification (note that these are not expected to enter the market until 2017 or later).

ISO has also created ISO 13485, a standard for ensuring high-quality manufacturing of medical devices. ISO 13485 prescribes the documentation, procedures and structures to follow to facilitate the production of devices of consistent quality and standards. Manufacturers must demonstrate compliance with ISO 13485, or equivalent good manufacturing practices.

ISO standards are updated from time to time and current editions can be purchased from national standards organizations or directly from ISO at http://www.iso.org/iso/home.htm. Direct ISO certification is typically conducted by third-party services and documentation of compliance can be requested from the manufacturer. It is important to request the most current documentation of compliance as well as all necessary regulatory approval(s) for countries for which oxygen concentrators will be procured and distributed (see below for further information).

Oxygen concentrators fall under the purview of various regulatory authorities that license drugs and medical devices for use in a particular country or region. However, regulatory authorities depend on the stated specifications from manufacturers and may not require independent testing protocols to verify the quality of the oxygen concentrator before they are shipped to the country.

Two well-established regulatory procedures for oxygen concentrators are the FDA 510(k) pre-market clearance procedure and the European Union (EU) CE marking scheme.

In the United States, oxygen concentrators are regulated as Class II medical devices. To receive clearance for sale of a Class II medical device in the United States, a manufacturer must submit a 510(k) pre-market notification to the FDA with information demonstrating device safety and effectiveness. The 510(k) process requires that the manufacturer demonstrate equivalence to a predicate device, which would be an oxygen concentrator that has already received 510(k) market clearance.

In the EU, oxygen concentrators are regulated as Class IIa, according to classification Rule 11 of the European Medical Device Directive (93/42/EEC as amended). Prior to sale in the European market, a manufacturer of a Class IIa device must obtain certification from an EU-accredited Notified Body, which assesses conformity to the Medical Device Directive of the manufacturer's technical file and quality system. After the Notified Body validates conformance, the manufacturer affixes the CE mark to the device and issues a Declaration of Conformity.

If devices that are not approved in the United States or EU are used, they should have an equivalent internationally recognized regulatory approval, such as those from members of the IMDRF. The IMDRF includes Australia, Brazil, Canada, China, the EU, Japan, the Russian Federation and the United States. Most countries have their own regulatory procedures, which should cite published standards. The regulatory process for medical devices in countries outside the United States and EU must conform to equivalent quality management systems: US 21 CFR part 820 Quality System Regulation; EU

Medical Device Directive 93/42/EEC; and ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes.

5.7 Documentation

The following relevant documentation can be requested to help ensure high-quality oxygen concentrators:

- ISO certificates;
- letter of FDA clearance, Declaration of Conformity for the CE mark or other regulatory body approval documentation;
- certificate of registration in the country to be shipped or import waiver, if applicable;
- documentation showing conformance with the manufacturer's performance specification for oxygen concentration at maximum flow and simultaneous maximum operating temperature and maximum RH (see Section 2.2).

Documentation of conformance with the ISO standard for oxygen concentrators and necessary regulatory approval(s) should always be requested from the manufacturer (see Section 5.6).

Other information that may be important to request in a tender/request for quotation includes:

- lead time from receipt of contract/purchase order;
- delivery date;
- method of shipment;
- shipping route;
- freight and insurance costs;
- International Commercial Terms (Incoterms®) ensure that it is clear who is paying customs clearance charges, import duties and taxes, final delivery costs, etc.;
- shipment/delivery costs;
- handling fees;
- warranty information, if applicable;
- service contract information, if applicable;
- training information, if applicable;
- weights and dimensions of shipment (of particular importance if procurement is done on an ex works basis and this information is needed for a freight forwarder or shipping line/airline to provide a freight quotation);
- validity of quotation;
- payment terms;
- general and any special terms and conditions that will appear on the contract and/or the purchase order.

5.8 Manufacturer user and maintenance manuals

User and service manuals are indispensable sources of information for installation, maintenance and training purposes. Electronic and/or paper copies should always be supplied and:

- available in English, French and Spanish (ideally in the local language);

- provide instructions for cleaning and use;
- provide instructions for all preventive maintenance and replacement procedures;
- include the contact information of the manufacturer and/or the local supplier;
- detail all spare or replacement parts, their expected lifetime under normal use and costs, ideally for five years of use;
- include a troubleshooting guide (see example in Table 3);
- some manufacturers may have useful instructional videos available online.

5.9 Consumables and spare parts

A system to replenish consumables and maintain an inventory of spare parts is essential, as concentrators are likely to fail prematurely without regular maintenance and replacement parts. Furthermore, replacement parts can be in scarce supply and a supply and maintenance infrastructure is rarely in place, which results in device underutilization or failure. Therefore, it is important that a continuous supply of consumables and replacement parts is identified and arranged at the time of initial purchase since oxygen concentrators are unsustainable without the regular procurement of spare parts. It is recommended that a minimum five-year supply be considered. Consumables and spare parts must be continually sourced from the manufacturer, as local suppliers may not have these supplies.

The primary consumables and spare parts include the patient delivery accessories, such as nasal prongs and catheters and gross particle filters. Note that gross particle filters may also be referred to as air (intake) filters, or coarse filters (see Table 2). Filters must be regularly cleaned and users should follow the appropriate clinical or manufacturer guidelines on cleaning and replacement (see Sections 4.4 and 4.5). Procurers should purchase an initial set of replacements for at least one year of use (ideally five) in the initial purchase contract.

While oxygen demand varies between hospitals and regions, a rough guide to the amount of consumables, supporting equipment and spare parts needed is provided in Table 4. Detailed studies conducted in LRS regarding oxygen concentrator spare parts replacement frequency and cost are described in the literature *(3,38)*.

The inventory of spare parts should contain components that wear out quickly and most, if not all, electrical components. Items to consider include compressors, compressor mounts, sieve beds, valves, printed circuit boards (PCBs), on/off power switches, power cords, hour meters, circuit breakers, fuses, motor capacitors, fans, tubing, fittings and wheels. This inventory of parts should be adjusted according to the number of concentrators being supported.

Table 4. Sample equipment list for the administration of oxygen for up to two paediatric patients from one oxygen concentrator; adjust per oxygen needs assessment, manufacturer specifications and device model

Equipment	Minimum quantity for use	Example quantity for one year[a]	Example quantity for five years[a,b]
Oxygen concentrator			
Oxygen concentrator, 5 LPM	1	1	1
Gross particle filter	Varies	3	15
Intake, product filters	Varies	1 each	5 each
Circuit breaker, PCB, sieve beds, compressor, valves, fans, service kits	Varies	As needed	As needed[b]
Oxygen delivery devices			
Kink-resistant plastic oxygen delivery tubing, up to 15 m each	2	12	60
Oxygen outlet adaptor(s), if applicable	1	3	15
Nasal prongs	2 x each size	26 x each size	130 x each size
Four-way flow splitter or flowmeter stand	1	1	1
Nozzles of 0.5, 1 and 2 LPM, if using flow splitter	4 each	4 each	8 each
Blanking plugs, if using flow splitter	4	4	8
Other equipment			
Pulse oximeter[c]	1	1	1
Pulse oximeter probes	2 x each size	2 x each size	4 x each size
Back-up cylinder with regulator and flow controller	1	Depends on power availability	Depends on power availability
Surge protector	1	1	1
Firebreak device	1	1	1
Voltage stabilizer, if applicable	1	1	1

LPM, litre(s) per minute; PCB, printed circuit board

[a] Assuming regular use, one set of spares (if lost or broken) and one set for replacement (once per month for breathing apparatuses, once every two months for oxygen tubing, once per year for oxygen adaptors, and once every five years for nozzles, blanking plugs, and pulse oximeter probes).

[b] See study by Bradley et al. (2015) for additional information *(38)*.

[c] One pulse oximeter is desirable per patient, but a single one may be used to spot-check each patient throughout treatment.

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6. Areas for future research

Technical specifications play a vital role in the selection, procurement and implementation of affordable and high-quality oxygen concentrator supply systems. In the development of this guidance, several technology and knowledge gaps were identified. Stakeholder collaboration to address these gaps may help to improve the availability and sustainability of oxygen supply systems in LRS.

Increase availability of affordable and cost-saving accessories and devices:

- Flowmeter stands allow multiple paediatric patients to be treated with one machine. Current flowmeter stands are difficult to find and cost nearly the same as the concentrator.
- Devices with dual outlets, higher oxygen outlet pressure and nebulizing functions are valuable in neonatal and paediatric wards, and some devices currently have this feature (but publications regarding their performance in LRS have not yet been found).
- Some device features that may be useful to end users and purchasers may not be readily specified in manufacturer specification sheets. This includes stating whether the device has flow limiters to prevent the user from overdrawing oxygen and damaging the devices.

Establish international standards and clinical guidelines for life-saving essential health technologies, some of which may expand the use of oxygen concentrators:

- There is a lack of technical specifications for pulse oximeters and sensor probes appropriate for LRS. Recent research evaluating their quality and affordability must also be taken into consideration.
- No comprehensive clinical guidelines currently exist for the sizes of patient delivery consumables and accessories. The absence of internationally agreed standard sizes may leave room for confusion during procurement.
- There is a lack of clinical guidelines for bubble CPAP, a life-saving treatment for infants for which an oxygen concentrator could be easily repurposed. This is an evolving field; more evidence-based literature is needed to support the development of technical specifications on the use of oxygen concentrators for this application.

Develop unbiased optimal recommendations without sacrificing affordability, quality and availability:

- While current oxygen concentrators are suitable for implementation in most health facilities in LRS, further design improvements to reduce the burden of maintenance on clinical staff would be highly valued. More data are needed concerning the reliability and sustainability of both older and new models, such as those that comply with either ISO 8359 or ISO 80601-1-2:2014.
- While a system of procuring spare parts may seem costly, but necessary; a retrospective analysis of oxygen concentrator needs and costs in Gambia showed that most repairs within a seven-year period were low cost and required a low level of technical experience to complete. More studies such as this are needed to demonstrate the cost-effectiveness and simplicity of oxygen concentrator-based systems.

- Many current oxygen concentrators lack features that could increase the usability and/or utility in LRS. These features include the ability to operate at below 0 °C or above 40 °C, larger diameter wheels and decals affixed to a unit that illustrate minimum user operation instructions.

Improve research and knowledge-sharing on life-saving essential health technologies:

- There is limited knowledge of the power quality among the different health systems in developing countries. Quantitative information on voltage fluctuations could help inform procurement needs and specification development for manufacturers and standards organizations to produce oxygen concentrators and other electrical medical devices better suited for these countries.
- There is limited evidence-based research on the widespread clinical and economic impact of oxygen concentrators and oxygen therapy in LRS. More studies are necessary to improve awareness, increase procurement efficiency and motivate stakeholders to prioritize oxygen availability in LRS.

Annex 1 Oxygen concentrator technical specifications

Table A1.1 summarizes technical specifications to guide the procurement and acquisition of oxygen concentrators of high quality, safety and efficacy as well as other considerations for implementation, functioning and decommissioning. Similar specification sheets for other critical medical devices are available from the World Health Organization (WHO). The template used to produce this table was developed by WHO and can be found at http://www.who.int/medical_devices/management_use/mde_tech_spec/en.

Table A1.1 Oxygen concentrator technical specifications

Medical device specification *(where relevant/appropriate, including information on but not limited to the following)*		
i	Version number	
ii	Date of initial version	2012
iii	Date of last modification	June 2015
iv	Date of publication	September 2015
v	Completed/submitted by	WHO, PATH
Name, category and coding		
1	*WHO category/code*	
2	Generic name	Oxygen concentrator.
3	Specific type or variation (optional)	Stationary oxygen concentrator.
4	GMDN term name	Stationary oxygen concentrator.
5	GMDN code	12873
6	GMDN category	02 Anaesthetic and respiratory devices, 04 Electro mechanical medical devices, 11 Assistive products for persons with disability.
7	UMDNS™ name	Oxygen concentrators.
8	UMDNS™ code	12873
9	UNSPSC® code (optional)	42271702
10	Alternative name/s (optional)	Concentrator, oxygen concentrator, oxygen enricher, stationary concentrator, bedside concentrator.
11	Alternative code/s (optional)	CAW (FDA)
12	Keywords (optional)	Hypoxaemia, oxygen therapy.
13	GMDN/UMDNS™ definition (optional)	A stationary mains electricity (AC-powered) device designed to concentrate oxygen from ambient air and deliver the concentrated oxygen, typically through an attached nasal cannula (or prongs), to a patient requiring oxygen therapy. It processes the air through an internal filtration system (e.g. a molecular sieve [zeolite granules or membranes]), which has a large total surface area to separate N_2 from the air. It typically consists of an air compressor, filters, dual chambers, a reservoir and controls. The oxygen concentration is variable depending on the flow rate utilized. It is typically wheeled, but is designed to be placed in one location (e.g. an institution or a home setting).

Purpose of use		
14	Clinical or other purpose	Delivery of low-flow, continuous, clean and concentrated oxygen (>82%) from room air (21%). With appropriate accessories, two or more hypoxaemic patients can be treated with one concentrator.
15	Level of use (if relevant)	Health centre, general hospital, district hospital, provincial hospital, regional hospital, specialized hospital.
16	Clinical department/ ward (if relevant)	Paediatric ward, surgical operating theatre.
17	Overview of functional requirements	1. Provides a continuous flow of concentrated oxygen (>82%) from room air through one or two oxygen outlets. 2. Contains oxygen monitor to verify concentration. 3. Delivers oxygen through a nasal prongs or nasal catheter. 4. Flow from one concentrator can be divided for at least two paediatric patients with (built-in or add-on) flowmeters that allow continuous flow rate control. 5. Requires continuous AC power source to operate, such as solar power, battery or mains electricity ± backup (e.g. generator, UPS or battery). (Maximum flow is chosen based on the expected patient load at any given time. Oxygen needs vary per by patient and application. In general, up to 2 LPM per patient under 5 years of age is needed.)
Technical characteristics		
18	Detailed requirements	1. One or two oxygen outlets. 2. Audible and/or visual alarms for low oxygen concentration (<82%), low battery and power supply failure. 3. Audible and/or visual alarms for high temperature, low/high/no-flow rate and/or low/high pressure. 4. Power efficiency <70 W/LPM. 5. User interface to be easy to operate; numbers and displays to be clearly visible. 6. Digital or analogue meter that displays cumulative hours of device operation. 7. Oxygen outlet(s) with 6 mm (¼-inch) barbed fitting, or equivalent. 8. Flowmeter minimum flow rate of 0.5 LPM or less. 9. Flowmeter continuously adjustable, with minimum markings at 0.5 LPM intervals (or lower for paediatrics). 10. Oxygen monitor for signalling when concentration is below 82%. 11. Noise level <50 dB(A).
19	Displayed parameters	Oxygen flow rate (on flowmeter). Cumulative hours of operation.
20	User adjustable settings	Oxygen flow rate.
Physical/chemical characteristics		
21	Components (if relevant)	Case to be hard, easy to wipe clean and safe to transport. Oxygen outlet to be not easily broken or bent. Contains flow limiter to prevent overdrawing oxygen flow beyond rated maximum flow rate.
22	Mobility, portability (if relevant)	Whole unit to be easily movable by a single person (<27 kg). Castor wheels.
23	Raw materials (if relevant)	Water, detergent and/or mild cleaning solution to clean device exterior and gross particle filter (if applicable).
Utility requirements		
24	Electrical, water and/or gas supply (if relevant)	Electrical source requirements: Amperage: _____; Voltage: _____; Plug type: _____ (based on country/setting of use). Voltage corrector/stabilizer to allow operation at ± 20% of local rated voltage. Protections against overvoltage and overcurrent line conditions. Electrical protection by resettable circuit breakers or replaceable fuses, fitted in both neutral and live lines. Compliance with _____ electrical standards and regulations. Surge protector.
Accessories, consumables, spare parts, other components		
25	Accessories (if relevant)	For two or more simultaneous paediatric patients: • 1 x flowmeter stand with minimum range from 0 to 2 LPM; or • 1 x four-way flow splitter with 0.5, 1, 2 LPM nozzles and blanking plugs. Kink-resistant oxygen tubing with standard connectors (15 m each).

26	Sterilization process for accessories (if relevant)	Disinfection for nasal prongs.
27	Consumables/reagents (if relevant)	Five-year supply recommended. One-year supply (adjust quantities per patient load and usage frequency): • nasal prongs or nasal catheters (each size for adult, child, infant); • child nasal prongs: distal diameter: 1–2 mm: › child/infant catheters: 6 or 8 French gauge.
28	Spare parts (if relevant)	Five-year supply recommended. One-year supply (adjust quantities per manufacturer specifications and model design): • 3 x gross particle filters • 1 x intake filters • 1 x product filters • 3 x oxygen outlet connectors • blanking plugs and nozzles, if using flow-splitter. Other spares that may be needed: circuit breaker, printed circuit board, sieve beds, compressor service kit, valves, wheels, motor capacitor, flowmeters and fan. (Spare parts are not interchangeable between devices of different brands and models, and can vary in their design and lifetime. Medical units to select spare parts ensuring compatibility with the brand and model of the equipment.)
29	Other components (if relevant)	NA
Packaging		
30	Sterility status on delivery (if relevant)	NA
31	Shelf life (if relevant)	NA
32	Transportation and storage (if relevant)	Keep away from oil, grease and petroleum-based or flammable products as well as smoking or open flames.
33	Labelling (if relevant)	Electrical power input requirements (voltage, frequency and socket type).
Environmental requirements		
34	Context-dependent requirements	Capable of being stored continuously in ambient temperature from 0 °C to 40 °C, RH from 15% to 95% and elevation from 0 to 2000 m. Capable of operating continuously in ambient temperature from 10 to 40 °C, RH from 15% to 95%, simultaneously, and elevation from 0 to 2000 m. (For operation at elevations higher than 2000 m, environmental requirements may be less stringent due to milder conditions.)
Training, installation and utilization		
35	Pre-installation requirements (if relevant)	Verify plug electrical requirements with socket to be used. Clinical and staff training on device use. System for procuring spare parts.
36	Requirements for commissioning (if relevant)	Note and report any signs of external or internal damage upon device delivery. Record the number of hours on the hour meter. Verify oxygen concentration level is within specifications when device is operated with all tubing and flowmeters installed. Verify operation of oxygen concentration, battery and power failure alarms. Spare parts for one year or 5000 hours (five years or 15 000 hours ideally) of use are arranged.
37	Training of user/s (if relevant)	Clinical staff training in oxygen therapy guidelines, device use and multiple-patient use. Technical staff training in device operation, safety and maintenance provided by manufacturer, supplier or experienced users. Advanced maintenance tasks required shall be documented.
38	User care (if relevant)	Device exterior to be wiped effectively with a mild solution of detergent or cleaning agent (weekly), without connection to mains power. Gross particle filter to be cleaned effectively when removed and washed with soap and water (weekly). Do not clean with alcohol. (User care needed more often in very dusty environments.)
Warranty and maintenance		
39	Warranty	Two years or more (five years ideally) to cover lifespan of equipment. Manufacturer/supplier ideally responsible for all costs for repairs and replacement covered under the warranty. Extended warranty options specified by manufacturer.

40	Maintenance tasks	Test power failure alarms. Measure operating pressure with pressure test gauge. Measure oxygen concentration with a calibrated oxygen analyser. Repair internal components as needed. Maintain spare-parts inventory.
41	Type of service contract	Service contract is recommended and includes technical support, spare parts, maintenance and repairs. Pricing for service contracts should be negotiated before the system is purchased.
42	Spare parts availability post-warranty	Less than four weeks after warranty end. Five years of spare parts should be organized at the time of purchase and replaced when used.
43	Software/hardware upgrade availability	NA
Documentation		
44	Documentation requirements	User, technical and maintenance manuals to be supplied in _____ language. Procedures for cleaning and disinfection/sterilization. Contact details of manufacturer, supplier and local service agent. List of all spare or replacement parts, their lifetime and costs for five years of operation. Troubleshooting guide.
Decommissioning		
45	Estimated lifespan	Seven years; this can vary between brands.
Safety and standards		
46	Risk classification	Class C (GHTF Rule 11); FDA Class II (USA); Class IIA (EU and Australia); Class II (Canada).
47	Regulatory clearance/ certification	CE mark (EU); FDA 510k clearance (USA).
48	International standards	ISO 80601-2-69:2014 Medical electrical equipment – Part 2–69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment. IEC 60601-1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. IEC 60601-1-2:2014 Medical electrical equipment – Part 1–2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests. IEC 60601-1-6:2013 Medical electrical equipment – Part 1–6: General requirements for basic safety and essential performance – Collateral standard: Usability. IEC 60601-1-8:2012 Medical electrical equipment – Part 1–8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems. IEC 60601-1-9:2013 Medical electrical equipment – Part 1–9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design. IEC 60601-1-11:2010 Medical electrical equipment – Part 1–11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home health-care environment. ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes (Australia, Canada and EU). ISO 14971:2007 Medical devices – Application of risk management to medical devices.
49	Regional/local standards	NA
50	Regulations	**US regulations:** 21 CFR part 820 Quality System Regulation. 21 CFR section 868.5440 Portable oxygen generator. **Japan regulations:** MHLW Ministerial Ordinance No.169 Standards for Manufacturing Control and Quality Control for Medical Devices and In-Vitro Diagnostic Reagents. **EU regulations:** Medical Device Directive 93/42/EEC.

AC, alternating current; CE, Conformité Européenne/European Conformity; CFR, Code of Federal Regulations; dB(A), decibel(s) attenuated; EU, European Union; FDA, United States Food and Drug Administration; GHTF, Global Harmonization Task Force; GMDN, Global Medical Device Nomenclature; IEC, International Electrotechnical Commission; ISO, International Organization for Standardization; kg, kilogram(s); LPM, litre(s) per minute; m, metre(s); mm, millimetre(s); N2, nitrogen; NA, not applicable; RH, relative humidity; UMDNS, Universal Medical Device Nomenclature System; UNSPSC, United Nations Standard Products and Services Code; UPS, uninterruptible power supply; US or USA, United States of America; W, watt(s); WHO, World Health Organization

Annex 2 Manufacturers of oxygen concentrators

Table A2.1 Examples of oxygen concentrator manufacturers[a]

[a] This table lists oxygen concentrator manufacturers, models with clearance from the United States Food and Drug Administration (FDA) and/or the Conformité Européenne/European Conformity (CE) mark via the Declaration of Conformity (to ISO 8359) and performance specifications. In addition, all devices are continuous flow units, have low oxygen alarms that are already included or can be optionally added, provide a user manual and have a minimum three-year warranty. Devices with additional air outlets or nebulizing features are denoted by (*). Disclaimer: This list is not intended to be inclusive and was based on available information from manufacturers (including specification sheets and compliance documentation) and the ECRI Institute (June 2015). Some of these concentrators were evaluated in an independent study, including for their performance at simultaneous high temperature and high relative humidity (RH) *(22)*.

Manufacturer	Device family	Power (W)	Power efficiency (W/LPM)	Min O2 output (LPM)	Max O2 output (LPM)	Flow outlet	Outlet pressure (kPa)	Power input options (VAC /Hz)	Operating conditions	Manufacturer warranty (years)	Marketed	Contact details
AirSep	NewLife® Elite*	350	70	0.125	5	Single	45–60	120/60, 220–240/50, 220/60	10–40 °C; 95% RH; 3048 m	5	Worldwide	USA www.airsep.com
AirSep	NewLife® Intensity	410	52	0.125	8	Single or dual	135	120/60, 220–240/50, 220–240/60,	5–40 °C; 95% RH; 3048 m	5	Worldwide	USA www.airsep.com
AirSep	NewLife® Intensity	590	59	0.125	10	Single or dual	135	120/60, 220–240/50,	5–40 °C; 95% RH; 3048 m	5	Worldwide	USA www.airsep.com
AirSep	VisionAire™ *	290	58	0.125	2–5	Single	30	115/60, 220–240/50, 230/60	5–40.5 °C; 95% RH; 3048 m	5	Worldwide	USA www.airsep.com
Caire Medical	Companion®	250–350	53–117	0.5	5	Single	30	120/60, 230/50	5–40 °C; <95% RH; 3010 m	3	Worldwide	USA www.airsep.com
Canta Medical Tech. Co., Ltd	HG Series*	350–530	60–117	1.0	3–10	Single	40–80	220/50	10–40 °C; 30–85% RH	3	Worldwide	China en.canta.com.cn +86-0-24-8672-2700

Manufacturer	Device family	Power (W)	Power efficiency (W/LPM)	Min O2 output (LPM)	Max O2 output (LPM)	Flow outlet	Outlet pressure (kPa)	Power input options (VAC /Hz)	Operating conditions	Manufacturer warranty (years)	Marketed	Contact details
Chart SeQual Technologies	eQuinox™ Eclipse®	110	37	0.5	3	Single	35	100–240/50–60	10–40 °C; 10–95% RH; 4000 m	3–5	Worldwide	USA www.sequal.com
DeVilbiss	525	310	67	0.5	5	Single or dual	60	115/60, 230/50, 230/60	5–40 °C; 95% RH; 3962 m	3	Worldwide	USA www.devilbisshealthcare.com
DeVilbiss	iGo®	NA	NA	1.0	3	Single	30–40	115/60, 230/50, 230/60	5–40 °C; 10–95% RH; 4000 m	3 (1 year for battery)	Unknown	USA www.devilbisshealthcare.com
Inova Labs, Inc.	Activox DUO2®	372	75	Unknown	5	Single	60	110/60, 230/50	10–35 °C; ≤95% RH; 4000 m	Not specified	Unknown	USA www.inovalabs.com
Invacare®	PerfectO2™	280–325	65	0.5	5	Single	35	120/60	10–35 °C; 20–60% RH; 1828 m	3	Unknown	USA www.invacare.com
Invacare®	Platinum™ XL	585	59	0.5	10	Single	35–60	120/60	10–35 °C; 60% RH; 1219 m	5	Unknown	USA www.invacare.com
Kröber	Aeroplus	295	59	0.5	5	Single	70	230/50, 115/60	10–40 °C; 3200 m	5	Europe, Far East	Germany www.kroeber.de +49-0-2607-94040
Kröber	Kröber	280–350	56–58	1.0	5–6	Single	70	230/50, 115/60	5–40 °C; 93% RH; 3200 m	5	Europe	Germany www.kroeber.de +49-0-2607-94040
Nidek Medical	Nuvo Lite	300–330	60–66	0.125	5	Single	50	115/60, 230/50–60	10–38 °C; 95% RH; 2286 m	3	Worldwide	USA www.nidekmedical.com

Manufacturer	Device family	Power (W)	Power efficiency (W/LPM)	Min O2 output (LPM)	Max O2 output (LPM)	Flow outlet	Outlet pressure (kPa)	Power input options (VAC /Hz)	Operating conditions	Manufacturer warranty (years)	Marketed	Contact details
Nidek Medical	Nuvo 8	490	61	2.0	8	Single	115	115/60, 230/50–60	10–38 °C; 95% RH; 2286 m	3	Worldwide	USA www.nidekmedical.com
O2 Concepts	Oxlife	NA	NA	0.5	3	Single	30–40	100–240/50–60	10–40 °C; 10–95% RH; 4000 m	5 (1 year for battery)	Unknown	USA www.o2-concepts.com
Philips Respironics	EverFlo	350	70	0.5	5	Single	40	120/60, 230/50–60	13–32 °C; 95% RH; 2286 m	3	Worldwide	USA www.respironics.com
Precision Medical, Inc.	EasyFlow5	350	70	0.5	5	Single	55	115/60	10–35 °C; 95% RH; 3048 m	3 (1.5 year for compressor)	USA	USA www.precisionmedical.com

°C, degree Celsius; Hz, hertz; LPM, litre(s) per minute; m, metre(s); NA, not applicable; O2, oxygen; RH, relative humidity; USA, United States of America; VAC, volts of alternating current; W, watt(s)

Annex 3 Sample calculation of back-up energy requirement for an oxygen concentrator

Variable	Notes	Example value
Concentrator power consumption (A)	100–600 W, depending on the model	400 W
Average duration of power outage per day (B)	Varies from facility to facility	4 hours
Additional compensation for losses (C)	Batteries will lose capacity and require replacement over time	10%
Battery depth-of-discharge (D)	10–70% depending on the battery type; batteries should not be depleted beyond the rated depth-of-discharge, in order to maintain the battery's optimal lifetime	50%
Calculations		
Total concentrator back-up energy requirement per day (E)	A x B x (1 + C/100)	400 W x 4 h x (1 + 0.1) = 1760 Wh = 1.76 kWh
Total back-up battery bank energy requirements	E x (100/D)	1760 Wh x (100/50) = 3520 Wh = 3.52 kWh[a]

Ah, ampere hour; kWh, kilowatt hour; Wh, watt hour

[a] Note that batteries are generally rated by both their V and Ah. The total energy stored in a battery bank (in Wh) is equal to: total number of batteries x V x Ah.

For additional guidance and training on sustainable energy technology options, specifications, training and maintenance, see http://www.poweringhealth.org/index.php/topics/technology/design-and-installation.

Annex 4 Glossary

Continuous flow: The most common method of delivering oxygen that uses a constant flow rate. Flow can be divided as necessary to deliver gas to multiple patients. The other flow type is pulsed-dose flow.

Filter, gross particle: Also known as cabinet, air intake or coarse filter. Filters large particulates from entrained air. This filter is generally a foam mesh located at the air inlet of the device for easy cleaning. It blocks the majority of dust from entering the case, protecting the fan, heat exchanger and intake filter. It should be cleaned weekly or more frequently depending on air quality and particle accumulation in the filter. Dirty and blocked filters will reduce airflow throughout the device. These filters can deteriorate over time and may require replacement after approximately 10 000 hours of use.

Filter, high-efficiency particulate arrestance (HEPA): This is a specification for air filters that are rated to remove very fine particulates as well as bacteria from gas streams. These types of filters are often used as product filters as well as intake filters.

Filter, intake: Also known as inlet, compressor or compressor intake filter. Protects the compressor and valves from particulates in the air. It is generally a paper filter and is replaced every one–two years depending on the environment, but also can be designed to last the entire device lifetime. Dirty and blocked filters will reduce airflow into the compressor.

Filter, product: Also known as bacteria, high-efficiency particulate arrestance (HEPA), final, final stage or output filter. Removes particulates from the product gas.

Flowmeter: Maintains a specified and steady flow rate, usually measured in standard litre(s) per minute (LPM). Most machines have one or two integrated flowmeters.

Intermittent flow: A method of delivering flow that is not continuous, but provided as boluses of concentrated oxygen. In portable oxygen concentrators, the inhalation pressure of the patient is monitored so that the boluses are delivered at the start of every breath. For this reason, flow cannot be easily divided to multiple patients. Also known as pulsatile or pulsed-dose flow.

International Organization for Standardization (ISO) standards: These standards require manufacturers to disclose the performance of their devices, including specifications, electromagnetic emissions and electrical immunity. Direct certification is done by third-party services.

Oxygen concentrator, portable: A medical device that provides a continuous or pulsed-dose flow of therapeutic oxygen.

Oxygen concentrator, stationary: A medical device that provides a continuous and clean flow of therapeutic oxygen.

Pressure swing adsorption: Process by which oxygen concentrators generate concentrated oxygen from room air.

Annex 5 Research on access to oxygen therapy in low-resource settings (LRS) for the treatment of childhood pneumonia

Hypoxaemia, or low blood oxygen saturation, is a common complication of pneumonia, the leading infectious cause of morbidity and mortality among children under 5 years of age *(20)*. Although pneumonia affects children worldwide, hypoxaemia is much more common in LRS than in wealthy regions, and hypoxaemia is a strong indicator of pneumonia mortality *(24)*. In 2013, pneumonia killed 935 000 children – about 2600 children every day – and accounted for more childhood deaths than HIV/AIDS, malaria and tuberculosis combined *(20)*.

Delivering oxygen for treatment of hypoxaemia in children with pneumonia is essential *(3,45)*. A systematic review of hospital admissions in developing regions from 2009 revealed that the average prevalence of hypoxaemia in children with pneumonia was 13.3% and ranged from 9.3% to 37.5% *(42)*. In recognition of the critical role of oxygen in child health care, the World Health Organization (WHO) currently is preparing the *Manual on clinical use of oxygen therapy in children (23)* to complement current clinical guidelines for child health care *(16,46)*.

Management of hypoxaemia is also a critical component of WHO guidelines for neonatal resuscitation *(15)*, anaesthesia *(14)*, emergency care *(14,17)*, triage *(18)* and treatment of other common medical conditions and illnesses affecting neonates, children and adults in developing countries *(5)*. In neonates, common conditions requiring oxygen therapy include respiratory distress syndrome, birth asphyxia and transient tachypnoea. Neonates affected by prematurity, sepsis, seizures or hypoglycaemia can be prone to apnoea, leading to hypoxaemia *(5)*. Oxygen therapy is most commonly needed for adults with chronic obstructive pulmonary disease, acute asthma, pneumonia and trauma *(2)*. Meningitis and malaria are hypoxaemia-related diseases affecting all age groups. Hypoxaemia occurs frequently in trauma and obstetric and perioperative emergencies *(14)*. The WHO *Integrated management for emergency and essential surgical care toolkit* contains recommendations for the minimum standards for quality and safety of emergency, surgical, trauma and obstetric care, and anaesthesia at first-referral level health-care facilities *(17)*.

Hypoxaemia can be easily treated with oxygen. Oxygen therapy for the treatment of hypoxaemia involves the delivery of concentrated oxygen to the patient to stabilize blood oxygen saturation levels to above 90%. Oxygen is typically provided from an oxygen concentrator or oxygen cylinder, each providing an oxygen concentration of greater than 85% or near 100%, respectively. WHO clinical guidelines recommend the delivery of oxygen to infants and children with hypoxic respiratory illness using flow rates up to 2.0 standard litres per minute (LPM) *(16)*. It is important to note that guidelines for the safe administration of oxygen differ, including required flow rate and concentration of oxygen delivered, depending on the patient's age and condition. Oxygen therapy for

other patient populations and medical conditions can require flow rates up to 10 LPM *(14)*. Newborns, particularly preterm infants, are prone to oxygen toxicity and thus require less concentrated oxygen *(15)*.

Oxygen is a cost-effective and essential medicine included in the *WHO Model list of essential medicines for children (47)*. A prospective study across five hospitals in Papua New Guinea observed a 35% reduction in the risk of child mortality from pneumonia 27 months after oxygen concentrators and a monitoring system were implemented *(24,48)*. The Child Lung Health Programme in Malawi installed oxygen concentrators in all district hospitals more than a decade ago to support case management of childhood pneumonia. The programme demonstrated a reduction in the case fatality rate of infants and children with severe pneumonia *(3,4,16)*.

Oxygen concentrators provide a good source of immediately available and cost-effective oxygen, where oxygen cylinders and piped oxygen systems are inappropriate or unavailable. First, oxygen concentrators have significant advantages in reliability and cost over other oxygen supply systems (see Table 1). Analyses performed in Egypt *(13)*, Nepal *(11)*, Nigeria *(8)* and Papua New Guinea *(12)* demonstrated the potential of oxygen concentrators to expand the availability of oxygen in LRS. In Gambia, the cost savings, as compared to use of oxygen cylinders, depended on oxygen demand and power availability *(4)*. The settings of these studies included areas that were remote, high altitude or pertinent to paediatric wards.

Second, programmes in rural and district-level hospitals in Malawi and Papua New Guinea have been successful in spite of high staff turnover *(3,24,45,49)*. These programmes have emphasized that robust training and maintenance systems are critical to the success of oxygen concentrators. While these programmes were implemented for childhood pneumonia, they can also provide the basis for implementation with other common serious conditions requiring oxygen therapy, including trauma and obstetric and perioperative emergencies *(17)*.

Despite the evidence and existence of appropriate oxygen supply technologies, many hypoxaemic patients in LRS still do not receive oxygen. Overall, oxygen is usually not available in primary health clinics or smaller remote hospitals, and often is lacking in district hospitals *(1,21)*. Studies in Gambia, Malawi and Papua New Guinea showed that oxygen supplies were poor and often unavailable for admitted children who were hypoxaemic *(2–4)*.

Even where oxygen supplies are available at a hospital, patient access may be limited due to a lack of accessories, inadequate electricity and a shortage of trained staff. For example, pulse oximeters and devices to connect the patient to the oxygen supply (e.g. oxygen tubing, nasal cannulas or face masks) are often reported missing or underused due to a lack of awareness and knowledge by staff *(21,50,51)*. Oxygen supply is also frequently interrupted due to shortages of mains power and the scarcity of fuel to run back-up generators *(50)*. It is not uncommon to find oxygen concentrators being moved from paediatric wards to operating theatres or vice versa *(52)*. As a result, it is not unusual to encounter the following situations:

- oxygen supplies are available, but difficult to use because there are no accessories, consumables or instructions;

- oxygen devices are available, but broken because there are no maintenance staff or replacement parts;
- oxygen is unavailable because demand and supply were unevenly matched, so some patients are not given oxygen;
- oxygen is unavailable due to power outages and a lack of back-up power supplies;
- oxygen supplies are taken from paediatric wards or operating theatres.

As a result of oxygen shortages, patients often do not receive this critical therapy when needed. There is a need to increase the availability of supplemental oxygen in LRS to improve patient outcomes and survival.

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