Oxygen Delivery Toolkit
Resources to plan and scale medical oxygen

Procurement Guide

Assisting stakeholders in planning for, procuring, and sustaining oxygen delivery systems

For use by:



Decision-makers



Implementers

July 2020

This resource is part of the **Oxygen Delivery Toolkit: Resources to plan and scale medical oxygen.** The materials provided within the toolkit can be used together or separately, as needed. The complete Oxygen Delivery Toolkit includes the following resources:

- *Oxygen is Essential: A Policy and Advocacy Primer*
- *Health Facility Standards Guide*
- *Baseline Assessment Manual*
- *Consumption Tracking Tool*
- *Procurement Guide*
- *Quantification and Costing Tools*
- *Reference Pricing Guide*
- *Electricity Planning Guide*
- *Asset Management Guide*
- *Global Financing Facility Medical Oxygen Investment Guide*

The toolkit is available at www.path.org/oxygen-delivery-toolkit.

Acknowledgments

Oxygen Delivery Toolkit: Resources to plan and scale medical oxygen was developed by PATH, in collaboration with international and national maternal, newborn, and child health and industry partners, as well as the ministries of health in India, Indonesia, Kenya, Malawi, and Senegal. The authors are grateful to each contributor for their insightful feedback and support on the development of the toolkit components.

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Abbreviations

CAPEX	capital expenditures
EML	essential medicines list
OPEX	operational expenditures
PPP	procurement product profile
PSA	pressure swing adsorption
TPP	target product profile
UNICEF	United Nations Children's Fund
WHO	World Health Organization

1. Introduction

The *Procurement Guide* has been developed as a resource to help effectively plan, procure, and sustain oxygen delivery devices* for health care facilities. Information provided in this guide can be incorporated into existing procurement processes, and is intended to help procuring personnel:

- Understand the sequence of critical decisions that need to be made to support effective identification, selection, procurement, and introduction of oxygen delivery devices.
- Outline links between the analytical tools and resources in the Oxygen Delivery Toolkit with integrated decision-making in procurement of oxygen delivery devices.

The guide covers the selection and procurement of the different components of an oxygen delivery system, including cylinders, oxygen concentrators, oxygen-generation plants, pulse oximeters, and the required accessories, such as oxygen blenders and flowmeters, consumables such as nasal cannula and oxygen tubing, and spare and replacement parts such as filters for oxygen concentrators and batteries for pulse oximeters. A brief description of the components of an oxygen delivery system can be found in Annex A. The guide does not provide information on other respiratory devices, such as resuscitation devices, mechanical ventilators, continuous positive airway pressure devices, and anesthesia machines.

The *Procurement Guide* is a component of the Oxygen Delivery Toolkit—a set of broader resources to plan and scale medical oxygen.

*For the purposes of this guide, the term "oxygen delivery devices" is defined as appropriate technologies and supplies necessary for safe and effective provision of oxygen therapy, including medical oxygen supplies and pulse oximetry devices.

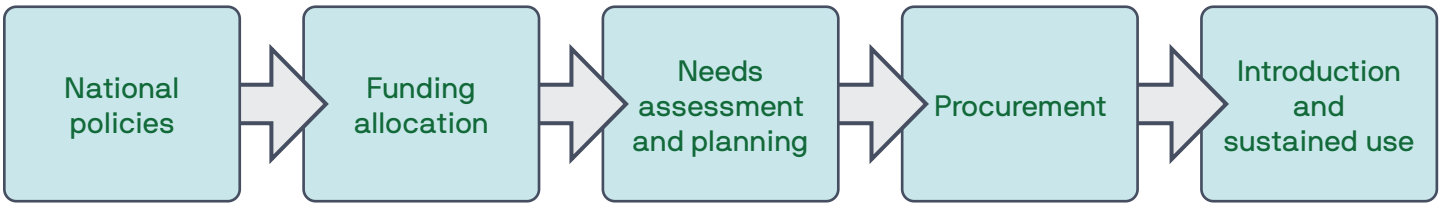
2. The role of procurement in improving access to oxygen

Multiple factors contribute to and support national and subnational efforts to expand access to oxygen therapy (See Figure 1). Within that overall objective, the procurement process plays an important role in ensuring that a cost-effective and efficient selection and award process is conducted to obtain appropriate and sustainable technologies and supplies to support the health facility's oxygen therapy needs.

For the procurement process to achieve this objective, an **integrated approach** should be adopted—one that engages key stakeholders (i.e. end users, program personnel, procurement personnel, and biomedical engineers/technicians) in the appropriate planning and procurement activities (i.e. assessment, quantification, determining total cost of ownership, and technical specification development). Such an approach helps to ensure that an effective process to identify, procure, and sustain oxygen delivery devices is conducted.

This guide incorporates references to relevant tools and resources developed as part of the Oxygen Delivery Toolkit, as well as other helpful guidance from international agencies and normative bodies.[1]

Figure 1. Factors contributing to sustainable oxygen supply.



3. Challenges encountered when procuring medical equipment

It is important to recognize that public-sector procurement of any health commodity can be challenging due to the administrative processing requirements, the multiple parties engaged in the procurement process, and the policy and regulatory environment in which procurement takes place. These general factors are often referred to as **procurement process challenges**.

Procurement of medical equipment, including oxygen delivery devices, faces these same process challenges. It can also encounter additional **equipment procurement challenges** based on the extra requirements that medical equipment generates, such as the need for appropriate infrastructure, identification and support of the total cost of ownership, operator training, and equipment maintenance. When procuring medical equipment, including oxygen delivery devices, it is important that both procurement process challenges and equipment procurement challenges are carefully considered and addressed for every procurement transaction. These challenges are briefly highlighted below.

a. Procurement process challenges

i. Integrity and transparency

Ensuring integrity and transparency in the procurement process is a challenge that crosses all product categories, including health commodities. When suppliers perceive there is a lack of integrity and transparency in the procurement process, and that contract awards are made on an arbitrary basis, they have less incentive to participate in the process and submit competitive bids. When suppliers decide not to participate in a procurement system, the number of suppliers submitting bids decreases—and as competition decreases, prices generally tend to increase.

ii. Communication and coordination

Procurement can be a complex process that requires communication with multiple parties. To prevent delays and/or misunderstandings in the procurement process, clear and complete information regarding procurement requirements should be developed through a multidisciplinary, integrated process that engages relevant key stakeholders.

iii. Timelines

There are several steps in the procurement process and some will require review and approval of different stakeholders, which can take time. Any implementation issues that could impact the timeline for conducting the procurement process should be identified as early as possible. An adequate buffer should be built into the timeline as needed.

iv. Regulations

Countries have different regulations and registration requirements for medical equipment. When procuring oxygen delivery devices, it is important to confirm that the device complies with the regulatory and registration requirements of the responsible national regulatory agency.

b. Equipment procurement challenges

i. Quantification of requirements

It is important to accurately quantify the amount of medical equipment that will be required to meet a health care facility's need. A shortage of oxygen from inaccurate quantification of health facility need can result in unreliable access for patients. A surplus of oxygen equipment can result in low equipment utilization rates and higher facility costs.

To help quantify the requirements for oxygen therapy, the Oxygen Delivery Toolkit includes the *Baseline Assessment Manual*, *Consumption Tracking Tool*, and *Quantification and Costing Tools*. More information on these tools and their use in quantifying the need for oxygen is presented in the "Procurement planning activities" section of this guide.

ii. Technical specifications

One of the biggest challenges in procuring medical equipment is developing a comprehensive technical specification. A comprehensive technical specification is one that is accurate, complete, and fair and that provides

all the necessary information a supplier will need to deliver a product that meets the technical specification requirements. Developing a comprehensive technical specification for more complex medical equipment requires an integrated and multidisciplinary approach that engages end users, biomedical engineers/technical experts, and procurement personnel. Information on developing a comprehensive technical specification, and references to the technical specifications for oxygen delivery devices developed by the World Health Organization (WHO) and United Nations Children's Fund (UNICEF), are presented in the "Procurement product profile" section of this guide.

iii. Accurate budgets

Developing a reasonable budget estimate for medical equipment, including oxygen delivery devices, can be challenging, as the budget estimate should not be based solely on the initial equipment purchase price but should also include estimates for operational costs over the anticipated life cycle of the equipment. This is referred to as the total cost of ownership concept. The *Quantification and Costing Tools* incorporate the total cost of ownership concept when producing cost estimates for oxygen delivery sources and pulse oximetry devices. More information on these tools and their use is presented in the "Identify oxygen delivery device options and their associated total cost" section of this guide.

iv. Infrastructure requirements

When planning to procure medical equipment, including oxygen delivery devices, the supporting infrastructure where the equipment will be used must be taken into consideration. Factors such as availability and reliability of electrical supply and physical space can have an impact on the equipment specifications and, ultimately, the total cost of the procurement. The Oxygen Delivery Toolkit provides an *Electricity Planning Guide* to help decision-makers plan for effective deployment of medical devices in areas of intermittent electrical access.

v. Training

When procuring medical equipment, including oxygen delivery devices, it is important to understand the level of staff training that will be required to effectively operate the equipment. Some medical equipment, such as laboratory equipment, can be very sophisticated and complex, requiring specialized training of the operator to ensure the equipment can be run properly and can produce accurate and reliable results. If proper operator training is not identified and provided, then the medical equipment runs the risk of not being effectively used and the investment made in the medical equipment is not fully realized. For oxygen delivery devices (oxygen cylinders, concentrators, and oxygen-generation plants) training requirements will range from a minimal level for oxygen cylinders (primarily inventory management and maintenance training), some training required for an oxygen concentrator, to more training required for an oxygen-generation plant.

vi. Maintenance

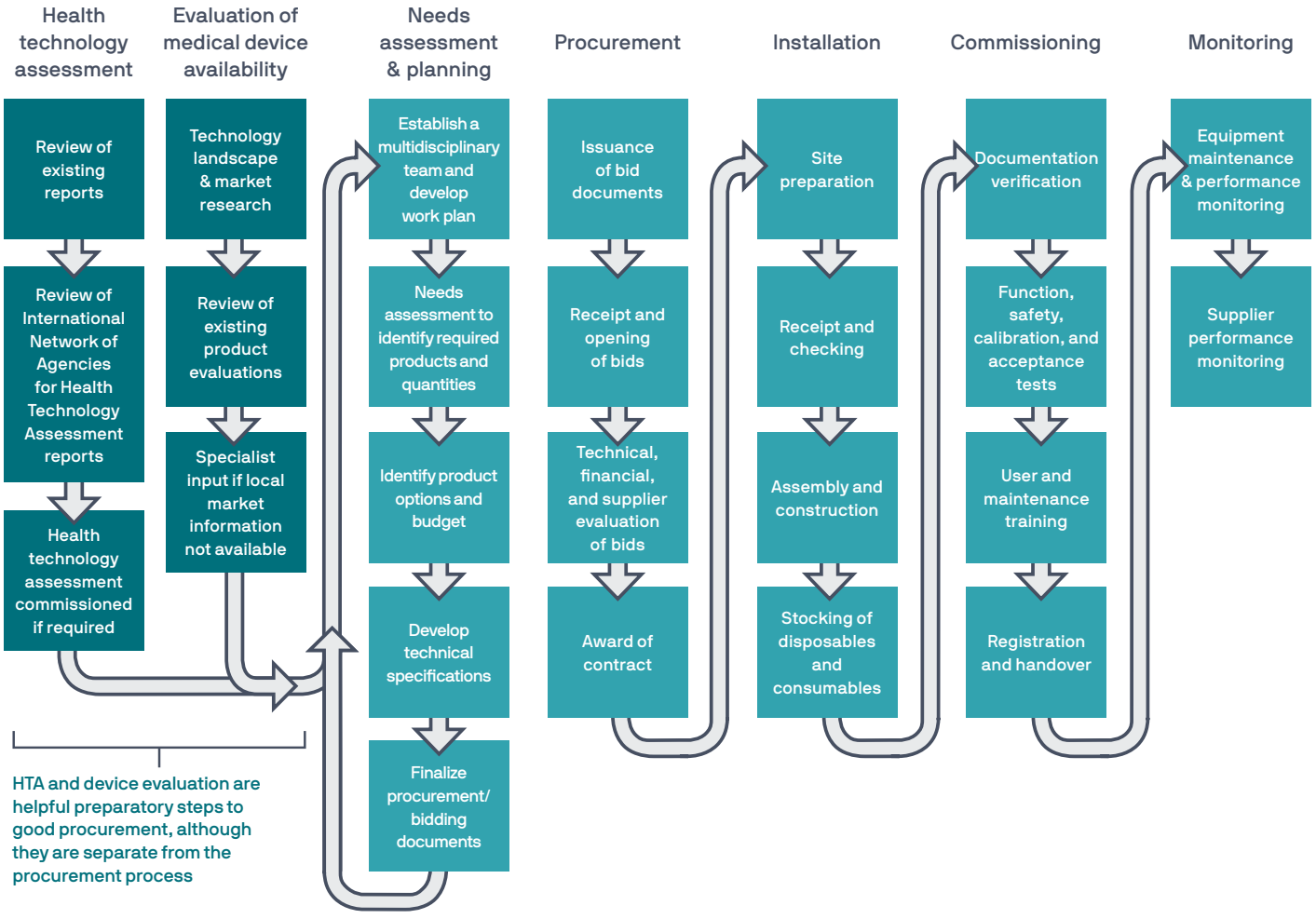
A properly functioning oxygen delivery device is an important component in ensuring a health care facility has the ability to effectively support patients' oxygen needs and thereby improve population health. If an oxygen delivery device is not operational due to equipment failure resulting from lack of maintenance, it limits the health facility's ability to achieve this objective. When procuring medical equipment, such as oxygen delivery devices, it is important to plan for and provide the level of maintenance that is required to keep the equipment functioning properly and continuously. For oxygen delivery devices, maintenance requirements will range from a minimal level for the oxygen cylinders to more thorough maintenance requirements for an oxygen-generation plant.

4. Using a multistep process for procuring medical devices and equipment

To help ensure that the equipment procurement challenges mentioned above are properly addressed so that the oxygen delivery devices procured meet end users' needs and fit the environment where they will be used, an integrated multistep process should be followed that identifies overall gaps and needs, clarifies requirements, prioritizes technology options, and supports an effective procurement and introduction process.

While each country will have its own procedures for medical equipment procurement, Figure 2 provides a flowchart of a multistep procurement process that is generally followed when planning for and procuring medical equipment, including oxygen delivery devices.

Figure 2. Summary flowchart of integrated procurement process.[2]



Note: HTA, health technology assessment.

The *Procurement Guide* is structured to provide general information on the two preliminary activities identified in Figure 2, health technology assessment and evaluation of medical device availability, that may precede the procurement process, depending upon the health technology being procured. The guide provides more specific information on the other procurement process steps identified in Figure 2—needs assessment, planning, and procurement. It also provides general guidance on installation, commissioning, and monitoring.

5. Preliminary activities that can support the procurement process

a. Health technology assessment

A health technology assessment can be an important activity to support an effective procurement process for a new or complex health commodity, and should be performed prior to actual procurement. The primary purpose of a health technology assessment for a medical device is to evaluate the properties, effects, and impacts of the technology so that health care policymakers can be better informed in establishing policies that will support the adoption and use of cost-effective health technologies, and prevent the adoption and use of health technologies that are of questionable value for the health care system.[3] The assessment will look at the clinical effectiveness of the technology, the cost-effectiveness, and how use of the device would maximize the positive impact on population health.[4]

One of the challenges in conducting a health technology assessment for medical devices, including oxygen delivery devices that are used to treat several different health indications, is **difficulty in obtaining accurate cost-effectiveness data for the device**. While some information on device operational costs may be obtained from manufacturers, suppliers, and health facilities currently using the device, additional effort and resources will be needed to address the current gap in cost-effectiveness data for medical devices.

In countries with national policies that include oxygen on their list of essential medicines, a health technology assessment should not be needed when planning for and procuring an oxygen delivery device. Countries may also have a national standards or norms document that recommends the type of medical devices that should be available at each health facility level.

For countries that do not currently include oxygen on their national essential medicines list (EML),[5] or do not have a standards and norms document for medical device recommendations by health facility level, the procurement entity must identify and comply with the country's requirements for obtaining authorization to proceed with planning for and procuring of oxygen delivery devices.

Global resources that document the clinical effectiveness of oxygen therapy, which can be considered to support obtaining authorization to proceed with planning and procurement of oxygen delivery devices, include:

- *The WHO Model List of Essential Medicines* (2017) and the *WHO Model List of Essential Medicines for Children* (2017). Oxygen appears on the core lists of both documents, which identify the most efficacious, safe, and cost-effective medicines for high-priority conditions. High-priority conditions are selected based on the current and future public health relevance and potential for safe and cost-effective treatment.[6]
- Existing health technology assessment reports available through the International Network of Agencies for Health Technology Assessment. The International Network of Agencies for Health Technology Assessment is a network of 50 health technology assessment agencies in 31 countries that cooperate and share information on producing and disseminating health technology assessment reports.[a]

If oxygen is currently not included on the national EML, adding it should be considered an important policy priority, as inclusion in the EML can facilitate the procurement process for oxygen delivery devices. The Oxygen Delivery Toolkit includes *Oxygen is Essential: A Policy and Advocacy Primer* to support advocacy efforts to add oxygen to the EML.

For the same reason, oxygen delivery devices and pulse oximeters should be included in the national medical device list or national standard, if a country has established a national medical device list or national standard. If the national device list or national standard for health facilities does not include oxygen delivery devices and/or pulse oximeters at appropriate health facility levels, the toolkit's *Health Facility Standards Guide* provides information on how to assess and update national standards to address the omission.

b. Evaluation of medical device availability

Prior to procuring medical devices and equipment, such as oxygen delivery devices, another step that can be beneficial to the overall procurement process is to perform a preliminary technology landscape and market review of the medical devices or equipment being considered to:

- Identify the types and range of the devices that are currently available in the country and/or might be available in the near future.

[a] For more information on the International Network of Agencies for Health Technology Assessment and the services they provide, see http://www.inahta.org.

- Obtain information on the performance and features of the medical devices.
- Obtain information on the suppliers and distributors of the medical devices and their service support capabilities.

i. Technology landscape

To identify the medical devices or equipment that are available for procurement now or in the near future, it is common to conduct a technology landscape of the market. A technology landscape can draw upon multiple sources to understand medical device supply including:

- Local suppliers and distributors.
- Other in-country health facilities that provide similar health care services.
- Internet search.
- Tender results and electronic catalog information from other countries.
- In-country public agency responsible for physical assets management (e.g., the National Health Systems Resource Centre in India).
- Literature reviews (e.g., PubMed Central®, Medicine, etc.).
- Conferences and trade shows.
- Free or paid access to industry reports.

The above resources can be used for a broad range of medical devices and equipment. A technology landscape for oxygen delivery devices looks at a more focused range of options, including cylinders, oxygen concentrators, oxygen plants, pulse oximeters, and supporting accessories and consumables. Most countries conducting a technology landscape for these items can draw upon information from manufacturers and their distributors, ask health facilities (public, private, and faith based) with similar health care services what oxygen delivery systems they are using, and conduct internet searches.

Review of existing product function and performance information

In addition to identifying the types of oxygen delivery devices that are available now or in the near future on the local market, the technology landscape should also gather general information on the function and performance of the oxygen delivery devices. For an oxygen concentrator, this could include basic information such as:

- Oxygen equipment manufacturer and model.
- Oxygen output in liters per minute.
- Output pressure in pounds per square inch gauge (psig).
- Minimum oxygen concentration level.
- Maximum number of adult beds that can be serviced simultaneously.
- Maximum number of pediatric beds that can be serviced simultaneously.
- Power source.
- Power consumption in watts.
- External equipment required.

Annex B provides an example of a detailed global technology landscape of oxygen concentrators, conducted by PATH in 2016, that includes function and performance information.

Function and performance information for an oxygen cylinder could include basic information[7] such as:

- Cubic meter capacity.
- Valve type.
- Built-in regulator.
- Minimum oxygen concentration level.

Function and performance information for an oxygen-generation plant could include the same basic information as gathered for an oxygen concentrator, as well as:

- Pipeline system requirements.
- Production capacity in m^3/hour.
- Energy usage.
- Redundant system backups.
- Additional generation plant.
- Manifold oxygen cylinder bank.
- Cylinder-filling high-pressure compressor.
- Plant telemetry monitoring.
- Facility requirements, including:
  - Square footage.
  - Clean air requirements.
  - Backup power supply.

ii. Market review

A market review can be conducted in conjunction with the technology landscape. Not only would a market review identify manufacturers and distributors that are able to provide oxygen delivery devices and accessories, it also would obtain information on the range of oxygen delivery devices they provide; the number of years they have been providing the devices; their service support capabilities, including lead time for service repairs and spare parts; the number of trained technicians available to provide service support; and the type of acquisition options that they offer for the oxygen delivery devices (purchase, lease, managed equipment services).

The information from the technology landscape and market review will set the parameters on the types and range of oxygen delivery devices and accessories that are available to meet the identified procurement needs for oxygen therapy. The product information obtained in the technology landscape will also be helpful when finalizing the technical specifications for the oxygen delivery devices being procured, as it will allow comparison of the technical specification requirements to existing products to help ensure the specifications are compatible with existing products available on the market.

c. Specialist input if local market information is not available

For more complex medical devices and equipment, and in situations where product information may be limited because the product recently commercialized, it may be helpful to hire a consultant to conduct the technology landscape and market review. This approach is likely not needed for oxygen delivery devices, since such devices have been in existence for some time and the resources mentioned above (manufacturers and distributors, health facilities, internet) should be sufficient in most cases to gather information on the availability, function, and performance of oxygen delivery devices along with the service support capabilities of suppliers and distributors.

6. Procurement planning activities

a. Establish a multidisciplinary team and develop a work plan

An effective planning and procurement process for oxygen delivery devices, and medical equipment in general, should include the following activities:

- Identify the overall gaps that the oxygen system will need to address (needs assessment).
- Prioritize technology options (budgeting and total cost of ownership evaluation).
- Define appropriate requirements for the oxygen delivery device to ensure it addresses the identified needs (product specification development).
- Plan for and conduct the procurement.
- Effectively introduce, maintain, and monitor the oxygen delivery device.

To help implement these planning and procurement activities, it is important to engage a multidisciplinary team that can contribute:

- Their understanding of the clinical needs the device must address.
- Their technical knowledge of the device performance and features.
- Their experience in budgeting and procurement.
- Their experience in equipment maintenance and support.

The multidisciplinary team should include key stakeholders such as end users (doctors, nurses, and other health care professionals), program personnel, procurement staff, finance personnel, biomedical engineers, and technical staff. Once the multidisciplinary team members have been identified, they should develop a general work plan that outlines the major activities in the overall planning and procurement process and the stakeholders that should be engaged in each of these activities.

Table 1 provides an example of a work plan outline for planning for and procuring a moderately complex medical device, such as an oxygen concentrator, that identifies key stakeholders and the stages of the planning and procurement process in which they should be engaged. The work plan and engagement of key stakeholders will vary depending upon the complexity and value of the oxygen delivery device and supporting accessories being procured, as well as upon the national, subnational, or health facility processes for managing medical equipment procurement.

Table 1. Key stakeholders to engage for a multidisciplinary planning and procurement process for a moderately complex medical device.

Needs assessment & planning	End users	Program staff	Procurement staff	Finance staff	Biomedical engineers	Technical staff
Establish multidisciplinary team & work plan	X	X	X	X	X	X
Identify required products & quantities	X	X			X	X
Budgeting & funding		X	X	X		
Develop technical specification	X	X	X		X	X
Develop procurement bidding document			X			
Procurement						
Receive & open bids			X			
Evaluate technical, financial, & supplier qualifications	X		X		X	X
Award contract			X			
Installation						
Prepare site & receive goods	X	X			X	X
Stock disposables & consumables	X	X	X			X
Commissioning						
Verify documentation		X	X		X	X
Conduct function, safety, calibration, & acceptance tests	X				X	X
Conduct user & maintenance training	X					X
Conduct registration & handover	X	X	X			X
Monitoring						
Monitor equipment & supplier performance	X		X			X

b. Conduct an assessment to quantify the need for oxygen

One of the first steps in supporting an effective procurement process is to conduct an assessment to quantify the need for oxygen. In general, for oxygen therapy, such an assessment will identify what is required to fully address the projected need for oxygen at a health facility, regional, or national level and what is currently available and functional in supporting oxygen therapy. The difference between these two figures is the existing, overall gap in oxygen needed for oxygen therapy. This identified gap drives the process of evaluating different technical options and their estimated cost, enabling stakeholders to select the appropriate oxygen delivery device, or combination of devices, that meets the identified oxygen need in the designated catchment area and aligns with their available financial resources.

Different approaches are used to conduct need assessments depending upon the product being assessed and the country context.[8] The Oxygen Delivery Toolkit includes three planning tools to assess and identify the overall gap in the need for oxygen.

i. Baseline Assessment Manual

The *Baseline Assessment Manual* is used to conduct health facility assessments to identify what is currently available in terms of delivery systems for oxygen therapy, the related infrastructure to support the oxygen delivery system, and the functional condition of the existing oxygen delivery system. The *Baseline Assessment Manual* includes the baseline assessment survey, an Excel-based tool to collect facility-level data on the availability of oxygen at one point in time. The tool collects data on all types of oxygen sources (oxygen cylinders, concentrators, oxygen plants, liquid oxygen cylinders) at all levels of the health system and all wards of a hospital.

ii. Consumption Tracking Tool

The *Consumption Tracking Tool* is used to track daily oxygen use in health facilities. The tool tracks patient information metrics and metrics related to the volume of oxygen use across multiple device types in order to understand how much oxygen is currently being used within a facility. The information generated can be used to both monitor current oxygen use and estimate future oxygen need (once the facility is meeting its current demand).

iii. Quantification and Costing Tools

The *Quantification and Costing Tools* provide a holistic view of both device need and total costs for oxygen delivery sources (in one tool) and pulse oximetry devices (in a second tool). These tools help quantify total device need and determine appropriate device mixes across all levels of the health care system where oxygen and pulse oximetry are required. They may be used for planning in a single facility or a group of facilities.

The benefits of using a total cost of ownership approach are discussed in the "Procurement planning activities" section of this guide. An example of applying the *Quantification and Costing Tool: Oxygen Delivery Sources* to three common health care system scenarios to help quantify the need for oxygen delivery sources is presented in Annex C.

c. Identify oxygen delivery device options and their associated total cost

Once the projected need for oxygen to support the health system has been quantified through the above assessment processes, the next steps are to identify the different oxygen delivery devices (or combination of devices) that would best meet the health facility or health system needs and to estimate the projected total cost of the different options so that a reasonable budget for the oxygen delivery device options can be established. The *Quantification and Costing Tools* generate the estimated total cost of ownership for oxygen delivery sources and pulse oximetry devices, using either a single device type or a custom device mix.

i. Benefits of using a total cost of ownership approach for medical equipment budgeting

Often, when budgets are developed for medical equipment, only the estimated initial purchase price of the equipment is included. However, using the estimated initial purchase price for budgeting does not accurately capture other costs that are incurred over the life cycle of the equipment, such as regular service and maintenance, repairs and spare parts, or energy costs to operate the equipment.

The benefits of using a total cost of ownership approach when planning and budgeting for oxygen delivery devices, or other medical equipment, include that it:

- Provides a complete picture of the total costs required to support the sustainable use of the oxygen delivery devices.
- Supports appropriate budgeting for the oxygen delivery devices over time.

- Supports planning for the effective installation, long-term use, and maintenance of the oxygen delivery devices.

ii. *Quantification and Costing Tool: Oxygen Delivery Sources*

After being used to quantify the oxygen need and number of oxygen sources that could be used to meet that need at the health facility, regional, or national level, the *Quantification and Costing Tool: Oxygen Delivery Sources* calculates the total cost of meeting that need. It applies baseline reference prices (which can be adjusted by the user) to each of the cost components[d] (See Figure 3) that occur over the life cycle of the oxygen delivery source and calculates the total cost of ownership for each oxygen delivery source option (oxygen cylinder, oxygen concentrator, oxygen plant, and/or liquid oxygen) over a selected period of time.

iii. *Quantification and Costing Tool: Pulse Oximetry Devices*

The *Quantification and Costing Tool: Pulse Oximetry Devices* uses inputs on the recommended number of pulse oximeters that should be available for each bed type across all health facility levels, incorporates pricing and consumable costs, and provides total cost of ownership projections based on the health facility or health system needs.

iv. Factors to consider when selecting oxygen delivery system options

While applying the *Quantification and Costing Tools* will help to identify the total cost of the different oxygen delivery sources and pulse oximetry device options being considered for procurement, additional measures need to be taken to evaluate the feasibility and appropriateness of each oxygen delivery device being evaluated for the health facility or health care system.

For example, when considering oxygen cylinders as a source of oxygen, factors need to be taken into consideration, such as the frequency of cylinder refills that will be needed, the distance to the refill site and time required to travel that distance, and whether road conditions are impacted by seasonal weather conditions, which could impact cylinder delivery times. When considering oxygen concentrators as the source of oxygen supply, the availability and reliability of electrical power need to be considered. In situations where electrical power is inconsistent or subject to fluctuations, then other measures, such as procuring a voltage stabilizer and surge protector, need to be planned and included in the budget.

These and other factors should be taken into account when selecting an oxygen delivery device to help ensure the selected device or combination of devices is best suited for the operating environment in which it will be used. Engaging a multidisciplinary team in the planning process can help to

Figure 3. Components of the total cost of ownership tool.



Abbreviations: CAPEX, capital expenditures; OPEX, operating expenditures.

[d] Note: Costs not included in the *Quantification and Costing Tool: Oxygen Delivery Sources* calculations are consumable supplies, like tubing or cannulas, that should be used regardless of the oxygen delivery source, backup supply of spare parts, and distributor service plans.

identify the important factors that will need to be addressed for each oxygen delivery device and ensure requirements to address these factors are incorporated into the technical and procurement specifications for the oxygen delivery device as appropriate.

v. Budget reconciliation

Once the preferred oxygen delivery device option, or a combination of options, has been selected and the total estimated cost has been determined, that amount can be compared to the available budget for oxygen delivery systems. If sufficient budget funds are available to support procurement of the projected quantity of devices required to meet the assessed need for oxygen, that quantity would be placed into the request for quotation/proposal that will later be released to suppliers.

If sufficient budget funds are not available, then the Plan and Budget tab in the *Quantification and Costing Tools* can be used to adjust the quantity and mix of oxygen delivery devices to identify other options that could be considered to meet the need and align with the available budget. That quantity of oxygen delivery devices would then be used in the request for quotation/proposal.

The next step in the procurement planning process is to develop technical and procurement specifications for medical devices and equipment, including oxygen delivery devices, which is discussed in the following section.

d. Develop technical and procurement specifications

Developing technical and procurement specifications for medical devices and equipment, including oxygen delivery devices, takes time and resources. It is, however, an important step to help ensure that the medical equipment being procured provides the performance and functional features needed to meet the end user's needs and is suitable for the environment in which it will be used.

To ensure that the final procurement specification for an oxygen delivery device that is issued to bidders addresses these requirements, it is recommended that the following three sequential steps be conducted:

1. Develop the procurement product profile (PPP) for the oxygen delivery device.
2. Develop the technical specification for the oxygen delivery device.
3. Develop the procurement specification for the oxygen delivery device.

Key stakeholders need to be engaged when conducting each of these activities to ensure the process captures all relevant information that should be included in the PPP, the technical specification, and the procurement specification. Figure 4 illustrates the key stakeholders that should be considered for each of the three activities.

i. Procurement product profile

The PPP concept has been adapted from the Target Product Profile (TPP) process that is used by medicine and medical technology. A TPP is an organized "wish list" of characteristics, features, and attributes—basically, a list of preferred product characteristics that one would like to see in a newly developed medical product once it reaches the market.[9] This would often include collecting primary data in the field for the reference population under consideration to help determine the most appropriate level of sensitivity and specificity for the design of the medical technology.

The PPP concept has been adapted from the TPP process to provide medical device and equipment end users, health care program staff, biomedical engineers, and technical experts with a tool to help identify the use case, needs, and constraints for the medical device and the broad performance

Figure 4. Key stakeholders engaged in the development of the procurement product profile and specifications.



requirements it must meet.[e] The following sections provide information on the key components of a PPP and how to obtain information to complete each PPP component. Additionally, using an oxygen concentrator as an example, samples of completed PPP components are provided.

Key components of a procurement product profile

The key components of a PPP development process are:

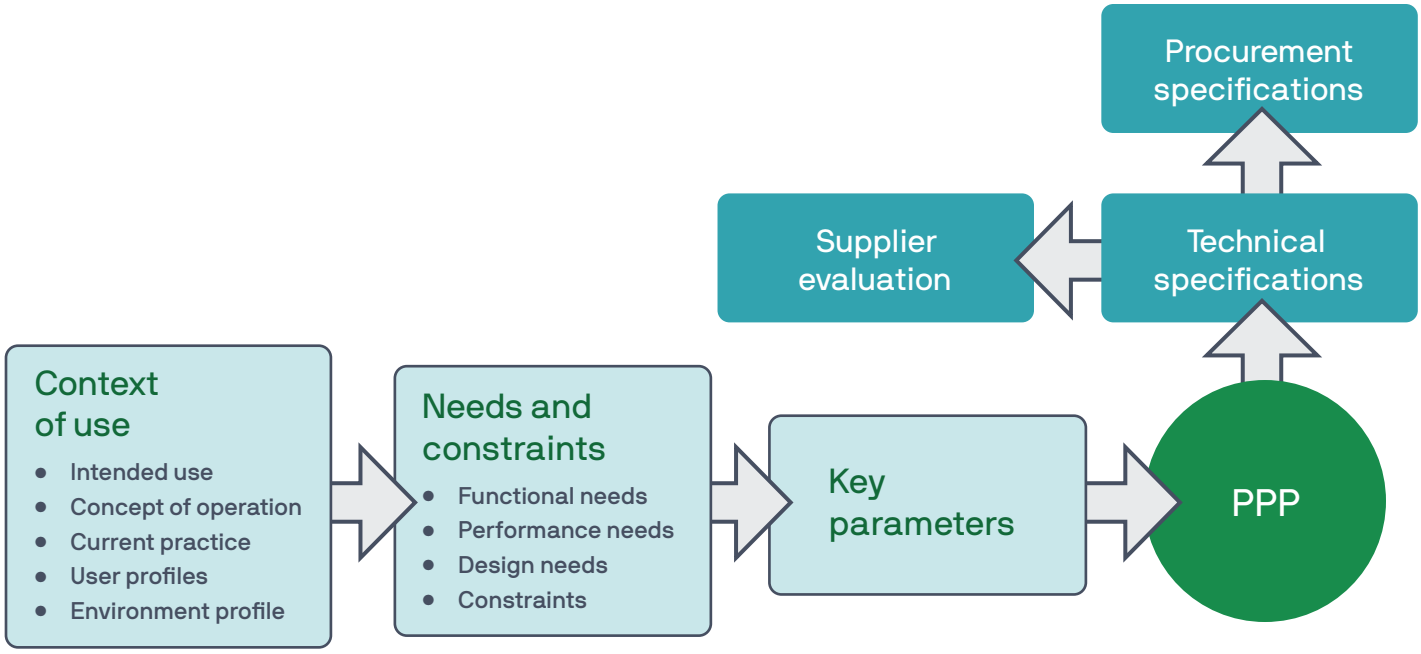
- The context of use scenario.
- The needs and constraints scenario.

Information to complete these components is obtained by engaging key stakeholders in the PPP development process. These identified preferred requirements then inform the development of the technical specification, which is included in the procurement specification. Figure 5 illustrates the relationship of these key components in the PPP and specification development process.

Developing the context of use

Developing the context of use for a medical device or equipment, including oxygen delivery devices, is a multidisciplinary process that should engage end users of the device, program staff, biomedical engineers, and technical experts to ensure the PPP correctly captures information on the purpose of the medical device or equipment, how it will be used, when it will be used, who will use it, and where it will be used. This information is commonly assembled through an interactive working group process, with the key members mentioned above

Figure 5. Components of the procurement product profile process.



Note: PPP, procurement product profile.

[e] PPPs generally benefit the procurement process when the medical equipment being procured is more complex. For oxygen therapy devices, when procuring devices with limited technical features and functions, such as an oxygen cylinder, conducting a PPP would not be of significant benefit to the procurement process. In contrast, conducting a PPP for an oxygen concentrator and oxygen plant would be beneficial.

providing information for the categories of the context of use identified in Figure 6.

The process of obtaining information for the context of use categories can be facilitated by asking the working group the questions indicated in Table 2, and similar questions, for each of the context of use categories.

Using an oxygen concentrator as an example, Table 3 (next page) illustrates the potential information and requirements that might be identified by convening a multidisciplinary working group to discuss the context of use for an oxygen concentrator.

Assembling such information on the context of use categories for the medical device, or oxygen delivery device, helps to ensure that the end users' needs for the device are clearly identified. It also will support the development of the technical specification.

Figure 6. Context of use categories.

Intended use:	Defines the problem and how the device is expected to address it
Concept of operation:	Describes the clinical setting and processes in which the device is intended for use
Current practice:	Describes the current processes and treatments used to address the problem
User profiles:	Describe the intended users, including their level of training, skills, and qualifications
Environment profile:	Describes the climate and physical areas of use and storage

Table 2. Context of use questions by category.

Context of use categories	Category questions
Intended use	• What is the target population? • What is the number of patients that are affected or at risk? • What is the current disease prevalence rate? • What periphery equipment will be required to support the device?
Concept of operation	• How does the device fit in the clinical system/process/package of care? • Are there existing guidelines for the use of the device?
Current practice	• What devices are currently available for treating the problem? • What are the current treatment practices?
User profiles	• Who will be operating the device? • Who will be administering the treatment? • Who will be responsible for maintenance and repair?
Environment profile	• What is the level of the facility where the device will be used? • What is the common temperature range where the device will be used? • What is the common humidity range where the device will be used? • At what elevation will the device be used? • What is the level of dust that occurs where the device will be used?

Table 3. Context of use: Example for an oxygen concentrator.

Context of use categories	Information
Intended use	• Semirural health facility. • Performs 3 births per week. • 1 trauma case per week (road accident). • High prevalence of pediatric pneumonia. • 7 beds: 2 pediatric, 3 maternal (1 delivery, 2 recovery), 2 male. • Open 24 hours. • Inpatient capability, but generally referrals to other facilities.
Concept of operation	• Guidelines call for oxygen in maternity, pediatric, and emergency wards. • Oxygen source will be used to provide oxygen to patients and to operate periphery equipment [air/oxygen blender, continuous positive airway pressure (CPAP) machine].
Current practice	• Doctors prescribe oxygen using clinical signs. • Oxygen source is cylinders. • Replace one 6 m^3 cylinder every week. • Refill costs US$12, not including transport. • Frequent stockouts. • Oxygen mainly used for deliveries, pediatric pneumonia, and trauma.
User profiles	• Oxygen is administered and monitored by nurses. • Nurses are clinically trained but may have limited experience with medical devices. • High turnover results in limited training opportunities.
Environment profile	• Generally 8 hours of main electricity per day. • Backup generator used when necessary. • Temperatures reach above 40°C. • Humidity can reach 90% during rainy season. • Dusty conditions during dry season. • Elevation is below 2,000 m.

Identifying needs and constraints

The other important component in developing a PPP is to identify the needs and constraints for the medical device or equipment. This information is also assembled through an interactive process with the multidisciplinary working group, which would provide information for the needs and constraints categories identified in Figure 7.

As was suggested for obtaining information for the context of use categories, the discussion to identify information to complete the needs and constraints categories can also be initiated by asking the working group the questions indicated in Table 4, and similar questions, for each of the needs and constraints categories.

Again using an oxygen concentrator as an example, Table 5 illustrates the potential information and requirements that might be identified by convening a multidisciplinary working group to discuss needs and constraints for an oxygen concentrator.

Figure 7. Needs and constraints categories.

Functional needs:	Needs related to the functionality of the device (i.e., the functions that the device should have to meet the needs of the operators and to enable the device to achieve its intended use)
Performance needs:	Needs related to the performance of the device (e.g., how well the device needs to perform)
Design needs:	Needs attributed to the design of the device (e.g., needs related to the user interface and shape, and other needs not related to the functionality or performance of the device)
Constraints:	Describes the requirements the device must meet to address context-specific needs

Table 4. Needs and constraints questions by key category.

Needs and constraints categories	Category questions
Functional needs	• Is the device a single- or multiple-use device? • What is the level of user involvement in the operation of the device? • What are the display requirements for the device? • What are the requirements for periphery devices or consumables?
Performance needs	• What is the level of required throughput for the device? • What is the level of accuracy required?
Design needs	• What is the need for mobility for the device? • Are there size limitations for the device? • Does the device require electricity or other utilities? • What is the need for calibration, repair, and maintenance?
Constraints	• What level of quality assurance of the device is required? • What is the operational life of the device? • Are there language requirements for the information and publications for the device? • What is the availability of spare parts in a timely manner and for the life cycle of the device?

Table 5. Needs and constraints: Example for an oxygen concentrator.

Needs and constraints categories	Category questions
Functional needs	• Must be able to provide oxygen for 1 surgery, 1 adult, and 2 pediatric beds simultaneously. • Must be appropriate for use with adult, child, and neonatal patient populations. • Must be able to operate continuous positive airway pressure (CPAP) machine and air/oxygen blender.
Performance needs	• Must provide sufficient pressure to operate medical equipment. • Must be able to reduce oxygen flow for pediatric patients. • Must be able to operate at high temperatures. • Must be able to operate in high humidity. • Must be able to handle electricity spikes and sags.
Design needs	• Must have clear operating controls. • Operation must be intuitive. • Regular maintenance must be simple. • Must have simple repair procedures. • Must be able to move easily between wards.
Constraints	• Must be registered with a stringent regulatory authority (e.g., European Commission, US Food and Drug Administration). • Must come with operation manual and controls in appropriate language. • Must come with sufficient consumables for 1 year. • Must have an operational life of 5 years.

Identifying and prioritizing key parameters

Once the needs and constraints exercise has been completed, the multidisciplinary team should review the needs and constraints to identify the key parameters that they believe should be considered when selecting the medical device. Following the identification of the key parameters, each parameter should then be reviewed and prioritized to identify which are most important to consider. This activity could help inform the budgeting process, as it is important to think about what parameters or functions might offer best value for money.

Continuing with the oxygen concentrator as an example, Figure 8 illustrates the potential key parameters that might be identified by the multidisciplinary working group and their prioritization. Upon completion of the discussions on the context of use, needs and constraints requirements, and prioritization of the key parameters for a given device, the PPP is finalized. The key parameters in the PPP will help guide the biomedical engineers and technical experts in the next step of the procurement process: developing the technical specification.[f]

[f] In some cases, there may still be some gaps in information that need to be filled. If that is the case, the working group should develop an agreed upon action plan to fill the identified information gaps and complete the procurement product profile.

Figure 8. Key parameters for oxygen concentrator identified and prioritized.

Needs and constraints categories	Key parameters
Functional needs	• Provides oxygen for **1 surgery, 1 adult, and 2 pediatric beds simultaneously.** • Appropriate for use with **adult, child, and neonatal** patient populations. • Able to **operate continuous positive airway pressure (CPAP) machine and air/oxygen blender.**
Performance needs	• Provides **sufficient pressure** to operate medical equipment. • Operates at high **temperatures.** • Operates in high **humidity.** • Able to **handle electricity spikes and sags.**
Design needs	• Clear operating controls. • **Intuitive** operation. • Simple regular maintenance. • Simple repair procedures. • Easily moved.
Constraints	• Registered with a **stringent regulatory** authority (e.g., European Commission, US Food and Drug Administration). • Operation manual and controls in **appropriate language.** • Comes with sufficient **consumables** for 1 year. • **Operational life** of 5 years.

Prioritization process

- Registered with a **stringent regulatory authority.**
- Operates in high **humidity.**
- Operates at high **temperatures.**
- Simple regular maintenance.
- **Simple repair procedures.**
- **Intuitive** operation.
- Provides **sufficient pressure** to operate medical equipment.
- **Easily moved** between wards.
- Provides oxygen for **1 surgery, 1 adult, and 2 pediatric beds simultaneously.**
- Appropriate for use with **adult, child, and neonatal** patient populations.
- Able to **handle electricity spikes and sags.**
- **Operational life** of 5 years

ii. Technical specifications

There is a range of general types of specifications that is often used when procuring different goods and services, including:

- Standards—industry standards, national standards, or international standards can be used to identify the product requirements.
- Technical specifications—identify physical characteristics, design details, production method, operational requirements, quantity, training requirements, and delivery schedule.
- Composition specifications—primarily used to identify the components of the materials.
- Performance and functional specifications—identify the functions to be performed, level of output required, quality level, and operating environment.

While each of the above specification types serves a purpose, when procuring medical equipment, including an oxygen delivery device, the best practice is to develop a comprehensive technical specification that includes components of the standards and performance and functional specification types mentioned above.

Developing a comprehensive technical specification provides the following benefits:

- Helps ensure the quality of the medical equipment procured by identifying the quality standards with which the equipment must comply.
- Helps ensure the medical equipment meets user needs by identifying performance and functional requirements with which the equipment must comply.
- Provides suppliers with an accurate and complete technical description of the equipment to be supplied, including other important services that may be required, such as operator training.
- Serves as the benchmark against which the purchaser will evaluate supplier proposals to verify the equipment's

compliance with the quality standards, specifications, and performance requirements identified in the technical specification.

Use a comprehensive technical specification format

When developing a technical specification for medical equipment, including oxygen delivery sources or pulse oximetry devices, it is important to use a comprehensive format that identifies all of the key equipment requirement categories that should be included, such as purpose of use, technical requirements, physical requirements, utility requirements, accessories, environmental requirements, training requirements, warranty, etc.

A comprehensive format that identifies the key categories of information to include in a technical specification for medical equipment provides the following benefits:

- Ensures the specification is comprehensive by identifying all key requirement categories.
- Facilitates gathering input from biomedical engineers and technical experts by providing a standard format that they can add specific equipment requirements to, and also advise if any other important information is missing and should be added.
- Clearly identifies equipment requirements to suppliers so that they address all requirements in their response.

WHO has developed a comprehensive technical specification format that includes all of the important requirement categories that should be considered when developing a technical specification for medical devices and equipment. This comprehensive format can be found in the *User Guide: WHO Technical Specification for Medical Devices*.[10] In addition to identifying the key requirement categories that should be included in a medical equipment technical specification, the document also provides general advice on the type of information that should be included in each requirement category.

Existing technical specifications for oxygen delivery devices and accessories

In 2019, WHO and UNICEF published the *WHO-UNICEF Technical Specifications and Guidance for Oxygen Therapy Devices*[1] as part of the WHO Medical Device Technical Series of publications. The document provides technical specifications, using the WHO comprehensive technical specification format, for an extensive range of oxygen delivery devices and supporting accessories. In 2020, WHO published the *WHO Technical Specifications for Pressure Swing Absorption (PSA) Oxygen Plants*[11] to support the procurement of oxygen plants. Table 6 provides a complete list of the oxygen delivery devices for which WHO has published technical specifications.

Given the detailed information provided and use of the WHO comprehensive technical specification format, the *WHO-UNICEF Technical Specifications and Guidance for Oxygen Therapy Devices and the WHO Technical specifications for Pressure Swing Adsorption (PSA) Oxygen Plants* should be used when planning to procure these devices. Any additional information that may need to be included, such as specific installation or training requirements, can be added to the technical specification or the procurement specification/bidding documents. The technical specification for an oxygen concentrator is provided in Annex D to illustrate the level of detail that is provided in the technical specification. The WHO-UNICEF technical specifications for oxygen delivery devices identified in Table 6 can be found in the annexes of the *WHO-UNICEF Technical Specifications and Guidance for Oxygen Therapy Devices*.

The *WHO-UNICEF Technical Specifications and Guidance for Oxygen Therapy Devices* document also provides technical guidance on oxygen delivery devices and accessories, including for example, a comparison of oxygen sources, comparison of the merits and drawbacks of the different pulse oximeter models, and information on installation and maintenance for the devices. This should be reviewed as part of the procurement planning process for oxygen delivery devices.

Oxygen-generating plant

An oxygen plant is an on-site oxygen-generating system that supplies oxygen through pressure swing adsorption (PSA) technology or cryogenic distillation.[9] An oxygen plant can be constructed, using a central pipeline distribution system, to deliver oxygen directly to the units or wards to facilitate patient access to oxygen. An oxygen plant can also be designed to refill oxygen cylinders that can then be connected to existing manifold systems in the health facility, or can be filled and delivered to nearby heath facilities.

The cost of an oxygen plant, the installation costs for a central pipeline system to deliver high-pressure oxygen, and the associated maintenance costs make the option of installing an oxygen plant less feasible for lower-level health facilities.[12]

Liquid oxygen tanks

Providing liquid oxygen to a health facility is done through installation of a large, bulk liquid oxygen tank that is refilled as needed by a local supplier that generates the liquid oxygen off-site and delivers it via truck to the health facility. A central pipeline system is required to deliver the liquid oxygen, which vaporizes during the pipeline delivery process, directly to the health facility units or wards. Given the need for maintenance of the pipeline and the

[9] Other oxygen generation technologies, namely, vacuum pressure swing adsorption (VPSA/VSA) plant are not reviewed in detail in this guide, but are available supply alternatives.

Table 6. List of oxygen delivery devices with World Health Organization technical specifications.[13]

Product category	Product	Technical specifications
Oxygen sources	Oxygen cylinders	Yes
	Oxygen concentrator	Yes
	Oxygen-generating plant	Yes[11]
Devices for oxygen regulation and conditioning	Flowmeter: Thorpe tube	Yes
	Flowmeter: Bourdon gauge	No
	Flowmeter: Dial click	No
	Flowmeter stand (flow splitter)	Yes
	Humidifier: Unheated, bubble bottle	Yes
	Humidifier: Heated	No
Oxygen delivery devices	Nasal cannula	Yes
	Nasal catheter	Yes
	Non-invasive (e.g., mask)	No
	Tubing	Yes
Pulse oximetry	Pulse oximeter: Self-contained fingertip	Yes
	Pulse oximeter: Handheld	Yes
	Pulse oximeter: Tabletop	Yes
Devices for high-quality power supply	Voltage stabilizer: Solid state	Yes
	Voltage stabilizer: Servo-electronic	No
	Surge suppressor	Yes
Biomedical tools	Oxygen analyzer: Galvanic cell	Yes
	Oxygen analyzer: Ultrasonic	Yes

environmental requirements for well-ventilated space and minimal exposure to extreme temperatures or humidity, liquid oxygen is generally considered less feasible for lower-level health facilities.[14]

An example of technical specifications for liquid oxygen cylinders, manufactured by Chart Inc., can be found in Section 6 of *Liquid Cylinder: Operating Manual*.[15] This section provides information on the physical characteristics, the normal operating pressure, storage capacity, and gas delivery rates for the identified liquid oxygen cylinders.

Technical specifications for medical devices and equipment

For the majority of oxygen delivery devices and accessories, as noted above, the detailed and thorough technical specifications developed by WHO and UNICEF should be used when procuring these devices. Any specific information needed can be added as appropriate.

For an oxygen delivery device or other medical device that does not have a technical specification, this section provides a brief summary of the major steps that can be

followed to develop technical specifications. It begins from the point of the completed PPP and leads to the development of the procurement specifications. The relationships between the key components in developing a technical specification are illustrated in Figure 9.

Personnel resources for developing a technical specification for medical equipment

It is important to have the right personnel engaged in developing a technical specification. For medical equipment, the parties in this multidisciplinary approach would be biomedical engineers and technical experts familiar with the equipment being procured.

As seen in the development of the PPP, end users bring the valuable perspective of what they need the equipment to do by identifying the general function and performance needs of the equipment in the environment where it will be used. Biomedical engineers and technical experts use that information and, drawing upon their technical background, convert the key parameters of the PPP to specific technical requirements for the equipment to ensure the technical requirements align with industry standards and norms, and the technical requirements are feasible in terms of there being existing medical equipment on the market that can comply with the technical specifications.

Developing a technical specification

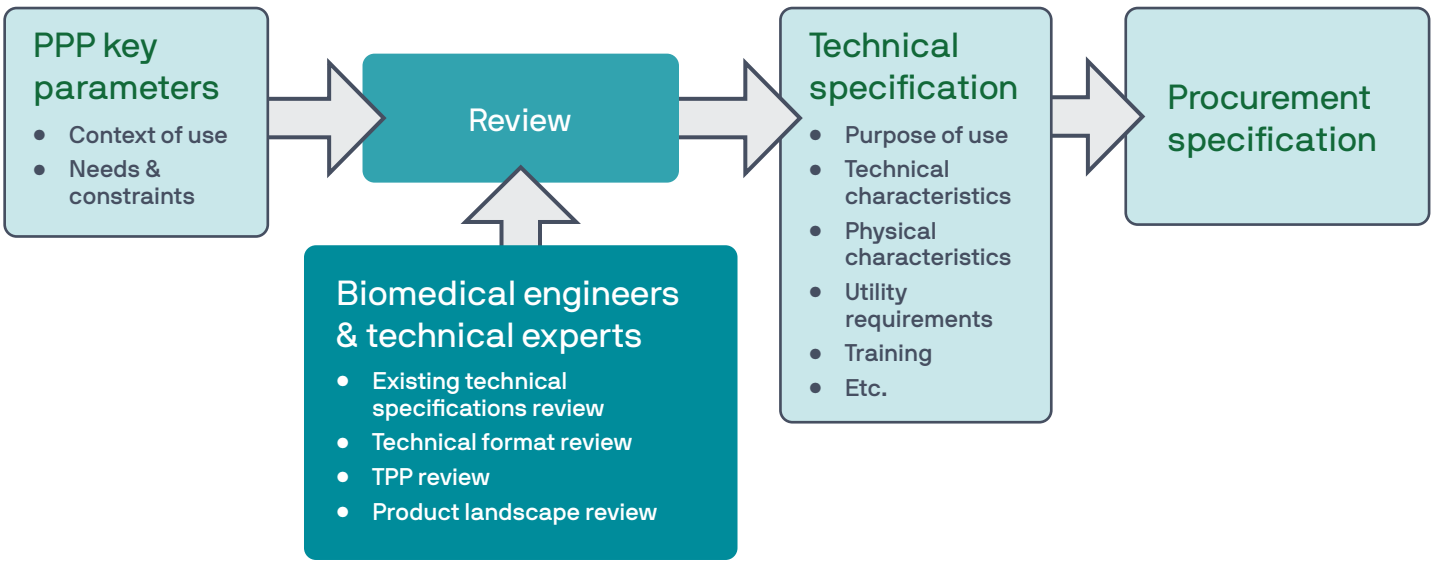
In developing technical specifications for medical devices and equipment, biomedical engineers and technical experts convene to identify the minimal performance, operational and technical requirements, international and national standards, and other requirements with which the medical device or equipment must comply.

The process will generally consist of the following steps:

1. Review national documents to identify any existing technical specifications for the medical equipment being procured, and select the technical specification that most closely aligns with the equipment being procured.

   If national technical specifications for the medical equipment are not are available, a procurement agency can often access technical specifications for medical equipment on international and other country websites. For example, WHO has developed technical specifications for 61 medical devices using their comprehensive technical specification format.[16] The National Health Systems Resource Centre in India has developed medical device technical specifications for neonatal and pediatric intensive care units[17] and for emergency response systems.[18] The Ethiopian Food, Medicine and Health Care Administration and Control Authority has developed minimum technical specifications for medical instruments.[19]
2. Review the selected technical specification format against the WHO technical specification format for medical devices to identify any requirement categories that should be added to the technical specification, and include identified requirements in the finalized technical specification format.
3. Review the key parameters of the PPP (context of use and needs and constraints requirements) and convert them as needed to specifically identify the minimum performance and functional requirements for the

Figure 9. Components of a technical specification development process.



Note: PPP, procurement product profile.

equipment. Incorporate the requirements into the technical specification in the appropriate requirement category.

For example, a key parameter from the needs and constraints performance section of a PPP exercise for an oxygen concentrator is likely to have general statements, such as "must provide sufficient pressure to operate medical equipment" and "must be able to reduce oxygen flow for pediatric patients." Biomedical engineers and technical experts will need to take information such as this and convert it into more specific technical performance requirements, such as "should provide a continuous flow of clean and concentrated oxygen (> 82 percent) up to 15 liters per minute" and "should include a flowmeter with a minimum range of 0 to 2 liters per minute for pediatric patients."

4. Review and complete the specification requirement categories that are not addressed in a PPP exercise. PPPs provide basic functional and performance information but do not address all of the requirement categories in a comprehensive technical specification for medical equipment.

   For example, the PPP exercise will likely not address the WHO requirement category 44 (Documentation requirements) or requirement category 48 (International standards). Biomedical engineers and technical experts must review and complete these and other requirement categories of the technical specification that are relevant to the equipment, as needed, with the understanding that, for some medical equipment, there will be requirement categories that are not applicable.

5. Identify accessories that may be needed. Other accessories and consumables may be required to support the operational performance of the medical equipment being procured. For example, oxygen cylinders, in general, should be equipped with a pressure regulator, flowmeter, and a humidifier. Other accessories that could be considered would be a flow splitter and a rolling cart to transport the cylinder. Other consumables that would be considered for low-flow oxygen therapy include nasal cannula and tubing extensions. The specific accessories and consumables that should be purchased for medical equipment will depend on the final configuration and performance requirements of the medical equipment. Once the accessories and any consumables needed for the medical equipment have been identified, they should be included in the technical specification in WHO requirement category 25 (Accessories) and WHO requirement category 27 (Consumables/reagents), as appropriate.

6. Include information on installation, training, and maintenance requirements in the technical specification as needed. These requirements are often briefly defined in the technical specification and expanded upon in more detail in the special conditions of the contract in the procurement specification. Installation, training, and maintenance requirements will be discussed further in the "Procurement product profile" section of this guide.

7. After the initial technical specification development process has been completed, it is often a good practice to review the specification's technical performance and functional requirements against the stated performance and functional capacity of existing comparable medical equipment on the market to ensure that the technical specification requirements have not been so narrowly or tightly defined that they preclude any existing product from meeting the technical specification requirements. The product information gathered during the technology landscape activity discussed earlier in the *Procurement Guide* can be used to assess whether the technical specification is sufficiently drafted to encourage competition for the medical equipment. If a review of the technology landscape product information determines that there are no products on the market that meet the drafted technical specifications, then the working group will need to reevaluate and adjust technical requirements, as needed, to ensure product availability.

Upon completion of the technical specification, the next step is to finalize the procurement specification.

iii. Procurement specification/bidding document

The procurement specification, which is commonly referred to as the bidding document, is the package of assembled information on the medical equipment requirements to which the interested suppliers will need to respond. Preparing a complete and comprehensive procurement specification/bidding document for the proposed procurement provides the following benefits:

- Comprehensive procurement specifications/bidding documents provide clear instructions to suppliers on what to submit and how to submit their bids. They also can reduce errors in suppliers' bids, which can often create problems during the evaluation of supplier bids and award of the contract.
- Comprehensive procurement specifications/bidding documents can help protect against acquiring substandard and poor-quality medical equipment.
- Comprehensive procurement specifications/bidding documents establish the rules and expectations for any supplier performance requirements under the contract.

Personnel resources for developing procurement specifications/bidding documents for medical equipment

The key parties involved in developing procurement specifications/bidding documents for medical equipment, including oxygen delivery devices, are procurement personnel, who assemble the components of the procurement specifications/bidding documents discussed in the next section, and technical experts, who can provide any additional technical information that may be needed on issues such as equipment installation, training, maintenance, etc.

Procurement specifications/bidding document components

All national governments traditionally have existing standard bidding document components that are used by procurement personnel when requesting bids from suppliers. These standard bidding document key components, and the actions needed to complete them, are briefly discussed below.

Instructions to suppliers/bidders

Instructions to suppliers/bidders identify all the requirements, procedures, and other information deemed necessary to aid bidders in submitting their bids, such as how to submit the bid, where to submit the bid, when to submit the bid, the validity period required for the bid, when the bid will be opened, whether a performance security check is required, and any other documentation that is required to support the bid. This information is prepared by procurement personnel.

Technical specifications

Technical specifications have been completed at this point in the procurement planning process and are included in the bidding document package by procurement personnel.

Schedule of requirements

The schedule of requirements identifies the quantity of each medical device required, which was previously determined through the quantification processes discussed earlier in the *Procurement Guide*. It also identifies the requested delivery date for the medical device(s) and the final delivery destination for the medical device(s). This information is completed by procurement personnel.

Supplier qualification criteria

Supplier qualification criteria identify the documentation the supplier should submit to verify that it meets the required qualification criteria. Such criteria can include:

- The supplier has verifiable business and financial stability.
- The supplier has adequate production/supply capacity.
- The supplier has verifiable technical support capability.
- The supplier has a verifiable history of successful performance.

This information is assembled by procurement personnel.

Bid evaluation and award criteria

Bid evaluation and award criteria identify the criteria against which a supplier's bid will be evaluated and a contract award decision will be made. In public-sector procurement, the traditional bid evaluation components are:

- Preliminary examination—reviews suppliers' compliance with the general administrative requirements of the bidding documents.
- Technical evaluation—reviews the medical equipment's compliance with the technical specifications.
- Financial evaluation—reviews the total cost of the supplier's bid to determine best value for money.
- Evaluation of supplier qualifications—reviews the supplier's documentation to confirm it meets the identified qualification criteria.

Information on the bid evaluation process and award criteria is assembled by the procurement personnel.

General conditions of the contract

These are standard contract terms and conditions that include the warranty. General terms and conditions are not changed from contract to contract and are included in the bidding document package by the procurement personnel.

Special conditions of the contract

Special conditions of the contract provide the opportunity to add more detailed information on requirements that may appear in the technical specification, such as installation, training, and maintenance requirements.

The special conditions also provide an opportunity to request additional information from the supplier on issues such as total cost of ownership for the medical equipment proposed and information on different ownership model (buy, lease, rent) costs for the medical equipment, if relevant to the medical equipment being procured. Additional information on addressing these special condition considerations in the procurement specification/bidding document is presented below.

iv. Special conditions: Installation, training, and maintenance requirements

While the technical specification process will develop specific details on equipment performance and function

requirements, for other requirements such as installation, training, and maintenance, the technical specification requirement may be more general in scope and may require additional clarification in the special conditions clause to ensure the requirement is both clear and enforceable.

The *WHO-UNICEF Technical Specifications and Guidance for Oxygen Therapy Devices* provides helpful information on the following areas for oxygen delivery devices and should be reviewed when preparing special conditions to address these requirements:

- Installation.
- Safety and handling.
- User care and preventive maintenance.
- Troubleshooting and corrective maintenance.

In some cases, the language in the national government's standard bidding documents for installation, training, and maintenance requirements may not be specific enough to capture all of the issues that should be considered for medical equipment procurement and introduction. To help address this issue, procurement staff can refer to Annex 5 of the *User Guide: WHO Technical Specifications for Medical Devices*,[20] which provides suggested special conditions clauses that address the multiple aspects that should be considered when installation, training, maintenance, and other medical equipment–specific services are required. A copy of Annex 5 from the WHO *User Guide* is included in the *Procurement Guide* as Annex E.

To help determine how best to support equipment maintenance, the complexity of the equipment and the critical role the equipment plays in addressing the health facility's need must be taken into consideration. Another factor that should be considered when determining the optimal maintenance plan for the equipment is the ownership model for the equipment. This topic will be discussed in the section titled "Special conditions: Requesting medical device ownership model costs."

For an example of using Annex 5 of the *User Guide: WHO Technical Specifications for Medical Devices* to help provide more specific language and information for finalizing the special conditions, look at category 37 (Training) in the WHO technical specifications for oxygen concentrators, which states the following specification: "Technical staff training in device operation, safety and maintenance provided by manufacturer, supplier or experienced users." Using the special condition clause on training requirements provided in Annex 5 of the *User Guide*, this requirement can be defined further to identify more specific requirements, such as the number of staff to be trained, the topics of the training, the duration of the training, and the materials to use for the training.

Annex F of this document is an example of adapting the special condition clause on training from Annex 5 of the WHO *User Guide* to provide more specific information on the equipment training that the supplier must provide for an oxygen concentrator. Procurement personnel discuss and finalize these additional requirements with the technical experts to ensure the requirements accurately identify the specific installation, training, and maintenance needs of the medical equipment being procured.

Special conditions: Requesting total cost of ownership information

Depending upon the oxygen delivery device being procured, an additional requirement to consider for the special conditions of the bidding document would be for suppliers to provide information on the proposed oxygen delivery device's total cost of ownership.

The *Quantification and Costing Tools* provide estimated total cost of ownership for different oxygen delivery device options (gas cylinders, liquid oxygen cylinders, concentrators, PSA oxygen-generating plants), as well as pulse oximetry. As previously noted, the reference cost data used for the tools were based on multiple interviews with manufacturers and distributors who provided cost information on their products, as well as personnel from ministries of health, country procurement agencies, and partner nongovernmental organizations who shared general estimates that informed the tools' calculations. Since circumstances will vary by facility location, the cost figures presented in the tool are considered general costs for a given oxygen delivery device type.

To obtain what would likely be a more accurate projection of the total cost of ownership, a requirement can be added to the special conditions of the bidding document for the supplier to provide information on the total cost of ownership for the oxygen delivery device they are proposing. Based on their experience with the performance of their oxygen delivery device, suppliers should be able to provide information on the CAPEX and OPEX costs for the device over a projected period of time. To ensure that the total cost of ownership information provided by suppliers is consistent, and suppliers' device costs can be properly compared to one another, the bidding documents should include a total cost of ownership template that each supplier would complete and submit with its bid.

A sample template that can be used to request total cost of ownership costs from suppliers for the oxygen delivery device they are proposing is provided in Annex G. Documentation that supports the validity of the total cost of ownership components submitted should also be requested from the supplier.

Special conditions: Requesting medical device ownership model costs

The total cost of ownership information is used to better understand what the total life cycle cost of the medical device would be if the device were to be directly purchased. There are other ownership models besides direct purchase that can be considered; these include leasing and renting the medical equipment.

Each ownership model has its advantages and disadvantages. Determining the optimal ownership model requires taking several factors into consideration, such as:

- How quickly the technology is changing.
- Expected device life span.
- Frequency of device operation.
- Frequency of device failures.
- Overall cost of the device.

These factors and their role in helping to determine the optimal medical device ownership model (buy, lease, rent) are summarized in Table 7.

When considering the optimal ownership model for a medical device, one should also look to identify the type of maintenance service approach that is best suited for the device, as doing so provides the opportunity to effectively align the maintenance service approach with the ownership model. To help determine the appropriate maintenance service approach for the device being considered, the device should be evaluated against the key factors identified in Figure 10.

The results of applying this evaluation approach can be used to help prioritize a medical device's maintenance needs and inform the decision on whether maintenance should be insourced or outsourced. This, in turn, can inform the appropriate contracting approach for the medical device.

Table 7. Determining the optimal medical device ownership model.[21]

Key questions	Buying	Leasing		Renting
		Capital	Operational	
How quickly is the technology changing?	Low to medium	Low to medium	High	Not applicable
	Devices with rapidly changing technology are not purchased or capital leased, as the buyer might end up owning an obsolete device		Short- to medium-term nature provides choice to switch to upgraded devices	Not applicable
What is the expected device life span?	Long term	Long term	Short to medium term	Short term
	Device with usage for more than 3 years		Up to 3 years	Less than a year
How often is the device in operation?	Medium to high	Medium to high	Medium to high	Less
	Device that is used every day or every week on a continuous basis			Occasional usage based on ad hoc requirement
How often do device failures take place?	High	High	Medium	Low
	Provide both standard and customized services		Provide only standard services	Provide only basic maintenance services
What is the overall cost of the device?	Low to medium	High	High	Not applicable
	Buying is manageable within budget	For high-cost devices and limited budget, leasing allows access to the device with the option to switch to upgraded devices		Not applicable

Figure 10. Maintenance evaluation process for medical devices.

Market attributes: Rate of technological innovation, level of competition, device price range, device quality level

Criticality: Level of importance of device use to mission

Cost: Technical specificity and complexity of device maintenance

Constraints: Describes the requirements the device must meet to address context-specific needs

Life span: Frequency of device failures and total life span

Table 8. Illustrative maintenance evaluation process for oxygen delivery devices.

Key attributes in LMIC markets	Pulse oximeters	Oxygen concentrators	PSA oxygen-generation plants
Market attributes	Mature market with: • Limited core technological innovation year over year • High competition • Low prices • Variable quality	Mature market with: • Limited core technological innovation year over year • High competition • Moderate prices • Variable quality	Relatively mature market with: • Ongoing technological innovation in product substitutes • Moderate competition • High prices • Highly customizable product offerings
Device criticality	Not life sustaining	Mission critical with product substitutes (e.g., oxygen cylinders)	Mission critical with product substitutes (e.g., oxygen concentrators and cylinders)
Complexity of technology	Low complexity	Moderate complexity	High complexity
Cost of spares and repairs	Not significant	Not significant	Variable, typically higher in cost
Product life cycle	5- to 7-year device life cycle; 1- to 3-year probe life cycle	5-year device life cycle	Dependent upon the model; up to 20 years
Recommended ownership model	Own	Own	Lease or own
Recommended maintenance approach	Purchase probes as needed; replace device when broken	Insource routine maintenance; contract complex repairs from outsourced resource—distributor or third-party provider	Contract routine maintenance and repairs from the manufacturer, distributor, or third-party provider

Note: LMIC, low- and middle-income countries; PSA, pressure swing adsorption.

Table 8 provides an example of applying the medical device maintenance evaluation process to oxygen delivery devices to identify the recommended maintenance approach for pulse oximeters, oxygen concentrators, and PSA oxygen-generating plants.

Managed equipment services

Another contracting model considered for some medical equipment is a managed equipment services contract. Under a managed equipment services contract, all aspects of the medical equipment are outsourced to a third party that specializes in providing the type of equipment. The contracted third party will procure and install the equipment, train the equipment users, and maintain the equipment. Managed equipment service contracts can include service-level agreements with established performance levels and agreed upon availability and uptime for the equipment. The managed equipment services provider will usually own the equipment and provide all necessary elements to support the use of the equipment over a long-term basis, ranging from 5 to 25 years.

While a managed equipment services contract can be considered for different medical equipment, it is generally more cost-effective for larger, more expensive, and technically complex medical equipment—such as radiology, pathology, and radiotherapy—where payments for the high cost of the equipment can be averaged out over an extended period of time. A managed equipment services contract would not be suitable for pulse oximeters or oxygen concentrators, but depending upon the situation, it might be considered for a large, high-capacity PSA oxygen-generating plant or series of PSA oxygen-generating plants. Determining the suitability of a managed equipment services contract would require clearly identifying the full scope of the contract, the equipment that will be provided, and the service improvements that will be achieved. It should also include accurately identifying the total costs for the current service and the benefits and cost savings that would be realized through a managed equipment services contract.

Finalizing procurement specifications/bidding documents

Once the procurement specification/bidding document components discussed above have been completed, procurement personnel submit the bidding document package for review and approval by the designated procurement authority in accordance with national procurement policy and procedure requirements.

7. Procurement activities

a. Issuance of request for proposal

Upon approval of the bidding documents by the procurement authority, the request for quotation/request for proposal announcement and the bidding documents are posted on the procurement agency's website and in national papers or other sites, in accordance with procurement policy requirements.

b. Supplier bid opening

At the time and place identified in the instruction to bidders that is included in the bidding document, the bids submitted by suppliers are opened. Procurement personnel publicly share specific information on the suppliers' bids in accordance with the national procurement policy.

c. Bid evaluation and supplier selection

The bid evaluation and supplier selection process is a comprehensive, transparent, and multiple-step process that reviews suppliers' bids against the stated technical and procurement requirements to ensure that the medical equipment selected meets its intended purpose and end users' needs, is considered fit for purpose, and provides best overall value for money. Bids are evaluated following national procurement policy procedures for bid evaluation. In many countries, supplier bid evaluation is traditionally a four-step process, as illustrated in Figure 11.

i. Preliminary examination

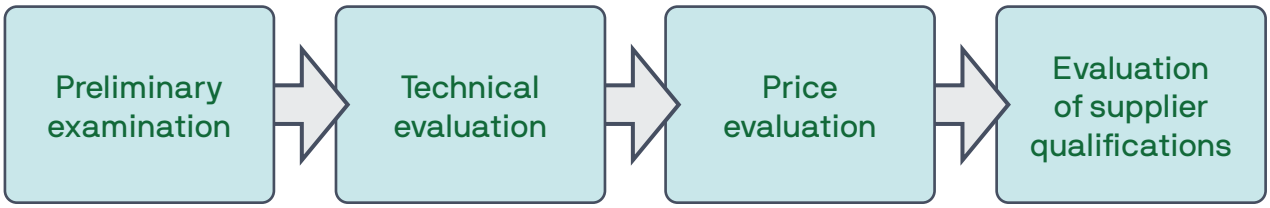
The first step in bid evaluation is to review the suppliers' compliance with the general administrative requirements of the bidding document. Suppliers' bids should include all required information, documents, and certifications identified in the bidding document. For example, if the bidding document requires documentation that the medical device is properly registered in the country, such documentation should be provided in the supplier's bid. Supplier-provided documents should be complete and, where required, properly signed. Any calculation errors should be appropriately corrected. Under most national procurement policies, if a supplier's bid does not comply with the general administrative requirements identified in the bidding documents, it can be removed from further evaluation.

ii. Technical evaluation

Following preliminary examination, supplier bids are reviewed for compliance with the technical specifications. Supplier bids should include written documentation that validates that the proposed medical device meets the minimum technical specification requirements identified in the bidding document. The technical evaluation is a generally systematic process where all of the requirement categories for the technical specification, and any additional requirements identified in the special conditions of the bidding document, are reviewed and confirmed compliant.

Given the complex technical features of some oxygen delivery devices, in addition to the procurement personnel and end user, a biomedical engineer and a technical

Figure 11. Supplier bid evaluation process.



expert should be included in the bid evaluation process to determine if the supplier's equipment complies with the technical specification and special conditions requirements.

If a supplier's equipment **does not** meet the minimum technical specification and special conditions requirements identified in the bidding document, then the supplier's bid is not considered for further evaluation. If the supplier's equipment **does** meet minimum technical requirements and special conditions requirements, the bid is put forward for price evaluation.

iii. Price evaluation

In evaluating a supplier's bid and selecting a supplier, one of the procurement best practices is to use a value for money approach. The World Bank defines value for money as follows: "The principle of value for money means the effective, efficient, and economic use of resources, which requires an evaluation of relevant costs and benefits, along with an assessment of risks, and non-price attributes and/or life cycle costs as appropriate. Price alone may not necessarily represent value for money."[22]

Applying a total cost of ownership approach to the price evaluation process considers this principle and ultimately ensures value for money over the lifetime of the equipment.

Conducting the price evaluation using a total cost of ownership approach

1. Take the total cost of ownership costs provided by each supplier in their bid response and place the information in a table by cost component category for comparison.
2. Review the sum of the total cost of ownership for each supplier and identify the supplier submitting the lowest total cost of ownership.
3. Review the prices submitted by the selected supplier and compare them to available reference price information. If the price review indicates the proposed prices are higher than comparable device reference prices, contact the supplier to negotiate more reasonable pricing.

Following identification of the supplier bid that provides the lowest total cost of ownership and confirmation of price reasonableness, or following negotiation with the supplier to agree upon a reasonable price, review the supplier bid against the following considerations:

- End user's current level of experience and training (for example, the user could have a shorter learning curve if an existing supplier were selected).
- Ease of integration with an existing system.
- Availability of local service support.
- Reduced cost through standardization with existing equipment.

These and other similar considerations can be factored into the supplier selection process to help ensure that selection is based not only on total cost of ownership but considers other use conditions. This supports achieving overall value for money in the procurement.

After a preferred supplier is identified following the above process, the next step is to evaluate the supplier's compliance with the required supplier qualifications.

Effective procurement policy for medical device procurement

In some countries, the national procurement policy criteria for price evaluation and supplier selection are based on the lowest price submitted. Often, the price being evaluated only considers the initial purchase price for the medical device and shipping charges, and does not consider the full costs of operating the medical device over its life cycle—the total cost of ownership. A contract award decision based only on the initial purchase price runs the risk of additional operating costs, such as maintenance and spare parts, not being fully budgeted for, which can result in increased medical device downtime and a reduced device utilization rate. In such situations, the procurement policy should be updated to allow the use of the total cost of ownership in supplier bid evaluation and selection, so that cost-effective use of government financial resources can be realized.

iv. Evaluation of supplier qualifications

A supplier should provide all written documentation needed to validate that it meets the supplier qualification criteria identified in the bidding documents. Such criteria can include:

- The supplier has verifiable business and financial stability.
- The supplier has adequate production/supply delivery capacity.
- The supplier has verifiable technical support capability.
- The supplier has a verifiable history of successful performance.

The supplier's submitted qualification documentation is reviewed; if compliant, the supplier is selected for contract recommendation. If the supplier does not meet the qualification criteria, the suppliers' bid is not further considered. The bid evaluation committee then reviews the bid of the supplier submitting the next lowest total cost of ownership proposal.

d. Supplier recommendation

Upon completing the evaluation of the suppliers' bids and selection of a supplier, the bid evaluation committee then recommends the selected supplier for contact award. The recommendation is usually based upon the supplier that meets all of the following criteria:

- Supplier's medical device meets all stated technical specifications and special conditions requirements.
- Supplier's medical device provides best value for money and the lowest total cost of ownership among supplier bids that meet technical specification requirements.
- Supplier meets all stated supplier qualification criteria.

e. Contract award

Depending upon national procurement policy requirements, the supplier recommendation is submitted to the appropriate procurement committee with designated authority to approve the recommendation. Upon approval by the procurement committee, the contract is awarded to the recommended supplier.

The above procurement process describes the public-sector competitive bidding process that is traditionally used for high-value procurements. Each country has its own procurement rules and procedures; generally, other procurement methods, such as issuing requests for quotes or documenting fair market value for the commodity to be procured, are allowed for lower-value commodity purchases. For example, a health facility purchasing a single pulse oximeter would most likely use one of the less stringent procurement processes allowed by the national government's procurement policy, based on the relatively low value of the procurement. Procurement personnel must always confirm the required procurement process for the goods to be procured.

8. Procurement implementation

Once the contract has been awarded to the supplier, the health facility receiving the medical device needs to make the necessary arrangements to ensure the device can be fully and properly used. Depending upon the technical complexity and use of the medical device, these arrangements can include device installation, commissioning, operator training, and maintenance support. The supplier requirements for these activities have been identified in the technical specifications and special conditions of the contract, but the health facility also has responsibilities in these areas to ensure they are prepared to receive and effectively use the medical device.

As mentioned, the technical complexity of the medical device will determine, to a large extent, the level of preparation a health facility needs to have to receive and use the device. Using selected oxygen delivery devices with different levels of technical complexity as an example, Table 9 illustrates the level of site preparation and training requirements that will be needed for pulse oximeters, oxygen concentrators, and PSA oxygen-generation plants.

Table 9. Installation, commissioning, and training requirements for oxygen delivery devices.

	Pulse oximeters	Oxygen concentrators	PSA oxygen-generation plants
Complexity of technology	Low complexity	Moderate complexity	High complexity
Installation	Not applicable	Minimal requirements—electrical power source	High requirements—site infrastructure preparation, possible manifold construction, electrical power
Commissioning	Minimal requirements—verification of proper functioning	Moderate requirements—verification of oxygen concentration level, operation, and alarms	High requirements—verification of oxygen output and concentration, integrity of manifold construction, cylinder connections, safety alarms
Training, operational	Minimal requirements—reading output, connecting probes	Moderate requirements—training in device use and multiple patient use	Moderate to high requirements—monitor power, piping connections, gas leakage
Training, maintenance	Minimal requirements—battery replacement, cleaning and disinfection	Moderate requirements—testing of pressure, measuring of oxygen concentration, testing of alarms	High requirements—maintenance of system and piping requires highly trained technicians/engineers

Note: PSA, pressure swing adsorption.

The following sections provide general guidance on measures that can be taken when preparing for medical device installation, commissioning, and training. Their application should be adjusted in accordance with the technical complexity, use, and size of the medical device.

a. Installation preparation

- Ensure that a person with the correct technical knowledge is available to receive the medical device and supervise the installation.
- Ensure the installations are performed in accordance with requirements as defined in the medical device manual.
- Ensure the warranty commences upon completion of installation.[h]

Prior to delivery of large medical devices, conduct a facility needs assessment to determine if the proposed physical space can support the device:

- Is there space to store and install the medical device?
- Are doors, stairwells, or elevators large enough for device entry?
- Are floors strong enough to support heavy medical devices?
- Is there appropriate ventilation, water, and/or power available for the medical device?

Ensure that the findings from the facility needs assessment are implemented prior to delivery of the medical device. Annex H provides additional information on the arrangements that can be made to prepare for and support medical device installation.

b. Commissioning

Commissioning is the process of conducting calibration and performance tests to confirm the medical device performs in accordance with technical specifications and safety requirements. Prior to commissioning the medical device, the device and all accessories should be inspected to confirm that everything ordered has been received. The contract and technical specifications can serve as a checklist to inspect and verify receipt of all goods ordered. Steps that are usually taken in the commissioning process include:

- Reviewing medical device documentation.
- Preparing the medical device for use.
- Conducting safety tests.
- Calibrating the medical device.
- Conducting functional/performance tests.
- Documenting the results of the tests.

Annex I provides additional information on the key steps that can be taken for the medical device commissioning and validation process.

c. Training

- Identify end users and, as applicable, maintenance technicians requiring training; set training schedule well in advance of medical device installation.
- Begin training with a baseline assessment of current knowledge; ensure training includes a post assessment to inform ongoing training needs.
- Ensure availability of a sufficient quantity of consumables, if necessary, to support training.
- Ensure training includes operational use.
- Ensure training includes routine and preventive maintenance. Maintenance instructions from the manufacturer should:
  - Be well designed and easy to understand.
  - Clearly explain every step in the procedure.
  - Explain what test equipment is required, if needed.
  - Explain the frequency of each preventive maintenance activity.
  - Show how to replace parts.
- Identify expert trainers to ensure sustainability and continuity of training for new users.
- Repeat user and maintenance training as often as needed based on complexity of the equipment.
- Ensure training is performed in accordance with requirements as defined in the medical device operational manual.

See Annex J for more information on the arrangements to be made for initial training on the medical device.

d. Medical device asset management

Upon completion of the installation, commissioning, and training requirements, the medical device is ready to be put into operation and used effectively to meet the health facility's needs. To help support the sustainable operation of the medical device, it is important to have an asset management plan for the medical device in place. An asset

[h] When considering purchasing an extended warranty for medical equipment, the procurement team—in consultation with members of the multidisciplinary team who helped develop the technical specifications, such as end users and biomedical engineers—should review the terms of the warranty to ensure that there are no equipment warranty requirements that could be invalidated through the planned use of the equipment or the environmental conditions under which the medical equipment will be used. For example, an environment with high dust particulates or high temperatures might negatively impact the equipment performance and render the extended warranty coverage invalid.

management plan provides current information on the status of available inventory, such as spare parts, that are needed to maintain the functionality of the medical device. The Oxygen Delivery Toolkit includes an *Asset Management Guide* that provides information on current asset management systems being used and identifies the factors to consider in establishing an asset management system at the health facility level up to the national health system level.

e. Monitoring supplier performance

Monitoring supplier performance over the course of the contract is an important activity that documents the ability of the supplier, and the medical device it has provided, to meet the contract requirements. Standard performance indicators that can be used for medical devices, including oxygen delivery devices, are:

- Medical device is delivered on time.
- Medical device is delivered in good condition.
- Required quantities were provided.
- Medical device was installed properly and commissioned.
- Medical device is operational and maintenance training was provided.
- Medical device meets operational and performance requirements.
- Medical device service support and spare parts are available when needed.

i. Monitoring service contract performance

If a service contract was issued as part of the procurement of the medical device, performance indicators could include:

- Are supplier's responses to service calls for medical device repairs completed promptly and effectively?
- If preventive maintenance is provided by the supplier, is it provided according to scheduled maintenance requirements?

The supplier's performance against the established service performance indicators should be reviewed on a regular, scheduled basis to confirm that the supplier continues to provide the contracted services at the agreed upon level.

If a review of the supplier's performance finds that the supplier is deviating from and not meeting performance requirements for medical device service support, the following actions can be taken:

- Meet with the supplier to develop an improvement plan that will address the areas where lack of performance has been identified.
- Schedule meetings as needed to monitor the supplier's performance in implementing the improvement plan. If continued shortfalls are identified, request the supplier to take prompt corrective actions to resolve the shortcomings in performance.

9. Medical device donations

When properly planned for, donated medical devices can be a valuable asset for a health facility. In situations where funds to procure oxygen delivery devices to meet the facility's need may be limited, a donation of medical devices, such as oxygen concentrators or pulse oximeters, can support the health facility's objective to provide oxygen to meet all patients' needs.

Unfortunately, there are also situations when donations of medical devices can become a liability for the health facility. This occurs when medical device donations do not meet a health facility's requirements and become unused surplus property; when there are not sufficient funds to cover the operational costs of the medical device and consumables, spare parts, and repairs; and when technical support, either at the health facility or through a local medical device supplier, is not available to support operator training and medical device repair and maintenance.

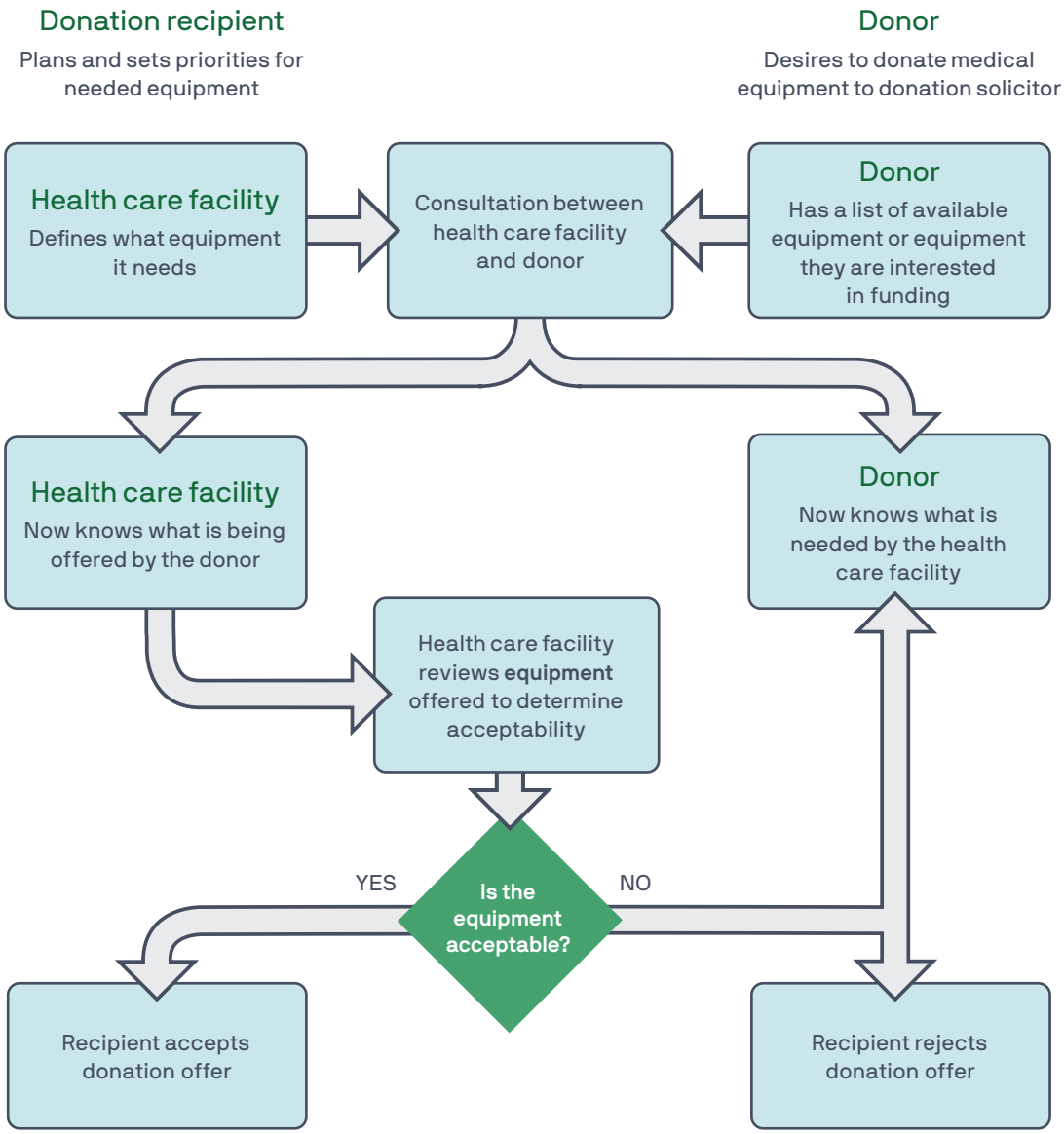
a. Ensure medical device donations are suitable and acceptable to the health facility

To avoid these problems and ensure that donated medical devices will meet health facility needs, it is important to follow an administrative process that is similar to the process conducted when planning for and procuring medical devices. This would include conducting a needs assessment, identifying the criteria for accepting or rejecting a medical device donation, identifying how device life cycle operational costs will be covered, identifying technical resources needed for medical device operation and maintenance, and evaluating the donation offer to determine whether it should be accepted or declined. These device donation activities are briefly reviewed in Annex K.

b. Coordinate communication between the donor and the recipient

Another important component of the donation process is for the recipient of the donation and the donor to be in communication throughout the process to help ensure the intended donation meets the recipient's needs and requirements. Figure 12, adapted from the WHO document *Medical Device Donations: Considerations for Solicitation and Provision*, provides an overview of the communication process that can be followed to help coordinate and manage the medical device donation process.

Figure 12. Process for requesting and offering donations of medical equipment.[23]



c. Evaluate the donation offer to determine whether it should be accepted or declined

After receiving information from the donor on the medical device to be donated, the recipient then reviews the donation offer against the medical device technical specifications and other identified requirements it has established. Upon completion of the review of the medical device donation offer, the recipient determines whether the medical equipment donation meets its requirements, in which case it can accept the donation offer.

If the proposed medical device donation does not meet requirements, the recipient can notify the donor of the shortcomings and discuss how they can be addressed. If the donor agrees to resolve the shortcomings to the recipient's satisfaction, the recipient can choose to accept the donation offer. If the shortcomings cannot be resolved, the recipient should then reject the donation offer.

As noted by WHO, "The most important pre-requisite for a successful donation is that the potential recipient truly needs the equipment being requested and has the expertise and means to operate and provide maintenance for it."[24]

10. Closing

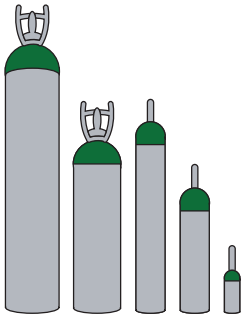
Medical devices, including oxygen delivery devices, are integral components of a health care system—essential to effectively meet its patients' health care needs. Given their critical role, it is important that the process used to identify and acquire medical devices ensures their ultimate performance and functions, as well as suitability for the local environment.

An integrated process to effectively plan for, procure, and sustain medical devices for health care facilities is key to meeting the identified patient needs. From the initial stages of needs assessment and requirements identification—including developing PPPs and technical and procurement specifications—through device installation, commissioning, and user and maintenance training, such comprehensive, multidisciplinary and multi-step process will help improve access to oxygen therapy and, ultimately, save lives.

Annex A. Technologies and supplies for oxygen delivery[5]

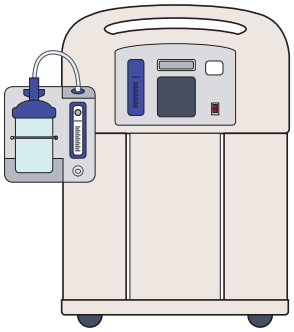
Oxygen cylinders

Oxygen cylinders or tanks contain set amounts of liquid or pressured gas. They require continuous refills and are thus most useful where central refilling and transportation infrastructure are reliable and affordable.



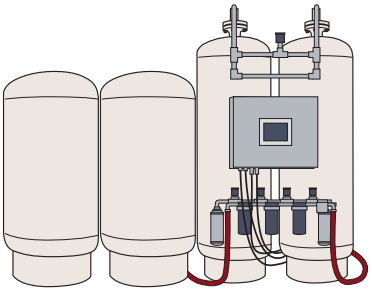
Oxygen concentrators

Oxygen concentrators draw air from the environment to provide a continuous supply of concentrated oxygen. They require a consistent supply of electricity and routine maintenance. When power supplies are inadequate or susceptible to voltage fluctuations, power stabilizers or uninterruptible power supply may be needed.



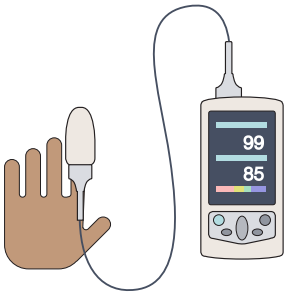
Central oxygen or pipeline system

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



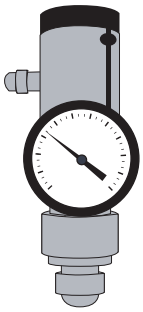
Pulse oximeter

A pulse oximeter is a simple, noninvasive device used to measure the oxygen level (oxygen saturation) of blood. The standard of care for detecting hypoxemia, a pulse oximeter should be used to determine the need for oxygen therapy and to closely monitor the required concentration of oxygen.



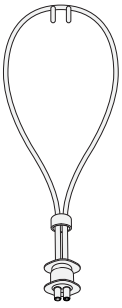
Accessories

Accessories, such as flowmeters, flow splitters, and oxygen blenders, are used to adjust the flow rate and concentration of oxygen therapy. They are used to prevent the risk of improperly delivered oxygen therapy, especially for newborns, and to allow multiple patients to be treated at the same time. During high-flow oxygen therapy, oxygen humidifiers may be required. Pressure regulators and gauges are accessories required for oxygen cylinders.



Consumables

Consumables, including airway interfaces such as nasal cannula and oxygen tubing, should be appropriately sized. They are intended for single use to deliver oxygen to the patient. Nasal prongs are the preferred method for delivering oxygen to infants and children younger than five years.



Spare and replacement parts

Spare and replacement parts, such as probes and batteries for pulse oximeters and internal filters for oxygen concentrators, are key to proper maintenance. They can vary in design and life expectancy, can require regular replacement, and usually are not interchangeable between different brands and models.

Oxygen analyzing systems

Oxygen analyzing systems are instruments that measure the flow rate, oxygen concentration, and outlet pressure from oxygen technologies, verifying the devices are functioning properly and signaling when maintenance is needed. They should be used to periodically monitor the performance of oxygen technologies.

Annex B. Technology landscape for oxygen concentrators

Manufacturer	Alvi Medtech	Beijing North Star Yaao SciTech	CAIRE Inc.*
Location	India	China	United States
Device type	Stationary	Stationary	Stationary
Devices	Mountain Air 	FY3 FY4 FY5 FY8 FY10 	Companion 5 
Release date	In development	April 2011	May 2, 2012
Retail price	Unknown	Unknown	Unknown
Noise (dBA)	55	40–56	40
Average power consumption (W)	450	380–480	250 @ 2 LPM 350 @ 5 LPM
Power efficiency (W/LPM)	90	48–127	125 @ 2 LPM 70 @ 5 LPM
Min oxygen output flow rate	1.0	0.5	0.5
Max oxygen output capacity (SLPM)	5	3–10	5
Output pressure (psig)	7.3	5.8–8.7	4.6
Oxygen concentration (%)	88.0–96.0	≥90.0	87.0–95.5
Oxygen sensor	Not specified	Optional	Optional
Oxygen alarm range(s)	Not specified	Not specified	Below normal: 70%–85% Abnormal: < 70%
Alarms	Power failure Performance	High temperature Low O_2 High/low pressure Power failure	Power failure High/low flow Malfunction Low O_2
Width (inches)	14.8 (37.5 cm)	11.4–15.0 (29.0–38.1 cm)	12.5 (31.8 cm)
Height (inches)	25.8 (65.5 cm)	19.7–23.6 (50.0–60 cm)	21.5 (54.6 cm)
Weight	52.8 lb (24 kg)	46.3–66.1 lb (21.0–30 kg)	36.0 lb (16.3 kg)
Battery life (hours)	NA	NA	NA
Battery recharge time (hours)	NA	NA	NA
Circuit breaker and/or fuse?	Not specified	Not specified	Fuse
Filters and time until replacement	Not specified	Air filter core: time not specified	Intake filter: 2 years Product filter: 2 years
Operating temperature	41°F–104°F (5°C–40°C)	104°F (max) (40°C)	41°F–104°F (5°C–40°C)
Operating humidity (RH%)	95	85	< 95
Operating level	3,281 ft (1,000 m)	Not specified	9,878 ft (3,010 m)
Standard warranty (yrs)	Not specified	1.5	3.0
Certification	ISO 8359	ISO 8359, ISO 9000, CE, CMD, ISO 9001:2000	FDA K121167, CE
Continuous or pulse flow	Continuous	Continuous	Continuous
Manufacturer Website	http://alvimedtech.com/alvi/	N/A	https://www.caireinc.com/

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Manufacturer	CAIRE Inc.*	CAIRE Inc.*	CAIRE Inc.*
Location	United States	United States	United States
Device type	Portable	Portable	Portable
Devices	eQuinox Eclipse 5 Eclipse 3 	Focus 	FreeStyle Freestyle 5 
Release date	March 14, 2014	March 2011	July 2013 (Freestyle 5)
Retail price	$4,850 (eQuinox) $2,850 (Eclipse 5)	$2,850	$2,850
Noise (dBA)	37–47	45	38–44
Average power consumption (W)	110	28	< 120
Power efficiency (W/LPM)	37	70	NA
Min oxygen output flow rate	0.5	2.00 (continuous equivalent)	1.00 (continuous equivalent)
Max oxygen output capacity (SLPM)	3.0	2.0 (continuous equivalent) 0.4 LPM (based on freestyle)	3.0, 5.0 (continuous equivalent) 1.0 LPM continuous
Output pressure (psig)	5.0	NA	NA
Oxygen concentration (%)	87–93	87.0–95.6	87.0–95.5
Oxygen sensor	Standard	no	no
Oxygen alarm range(s)	Below normal (yellow): 70%–85% Abnormal (red): < 70%	Not specified	Not specified
Alarms	Power failure Low O_2 Malfunction	Power failure High/low flow Malfunction	Power failure High/low flow Malfunction
Width (inches)	10.9–11.4 (27.7–29.0 cm)	4.8 (12.2 cm)	6.1–6.6 (15.5–16.8 cm)
Height (inches)	14.0–17.9 (35.6–45.5 cm)	6.5 (16.3 cm)	8.6–10.7 (21.8–27.2 cm)
Weight	14.0–18.0 lb (6.4–8.2 kg)	1.8 lb (0.8 kg)	4.4–6.2 lb (2.0–2.8 kg)
Battery life (hours)	2.8 – 5.0	3.0	1.0–3.5
Battery recharge time (hours)	1.5–3.5 for 80%	4.0	3.25
Circuit breaker and/or fuse?	Neither	Neither	Neither
Filters and time until replacement	Coarse filter: wash weekly, replace 1 year Inlet filter: 1 year Product filter: 1 year	Felt compressor filter: 5,000 hours Filter in product tank: no required service	Gross particle filter: weekly cleaning Product filter: 10,000 hours Felt filter: 5,000 hours
Operating temperature	50°F–104°F (10°C–40°C)	41°F–104°F (5°C–40°C)	41°F–104°F (5°C–40°C)
Operating humidity (RH%)	10–95	10–95	< 95
Operating level	13,123 ft (4,000 m)	10,000 ft (3,048 m)	12,000 ft (3,658 m)
Standard warranty (yrs)	3 (5 optional)	3 (1 for battery)	3 (1 for battery)
Certification	FAA, FDA K120785, CE 0459	FAA, FDA	CE 0459, ISO 9001:2008, ISO 13485:2003, FDA, FAA
Continuous or pulse flow	Both	Pulse	Pulse
Manufacturer Website	https://www.caireinc.com/commercial/	https://www.caireinc.com/commercial/	https://www.caireinc.com/commercial/

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Manufacturer	CAIRE Inc.*	CAIRE Inc.*	Canta Medical Tech Co., Ltd.
Location	United States	United States	China
Device type	Stationary	Stationary	Stationary
Devices	VisionAire 2 VisionAire 3 VisionAire 5 	9620 9621 9622 6323A 	HG3 HG5 HG8 HG10 
Release date	October 2010	September 10, 2004	Unknown
Retail price	$750 (VisionAire 5)	$1,385	$315–$527
Noise (dBA)	40	60	45–50
Average power consumption (W)	290	575	350–530
Power efficiency (W/LPM)	58	58	53–117
Min oxygen output flow rate	0.13	1.00	1.00
Max oxygen output capacity (SLPM)	5.0	10.0	3.0–10.0
Output pressure (psig)	4.5	7.5; 7.0, max 11.0	5.8–11.6
Oxygen concentration (%)	87.0–95.5	88–94	90–96
Oxygen sensor	optional	Optional	Optional
Oxygen alarm range(s)	< 82%	Below normal (yellow): 70%–85% Abnormal (red): < 70%	Not specified
Alarms	High temperature High/low pressure Power failure Low O_2 Low flow	Power failure High/low pressure Low O_2	High temperature Power failure Low O_2 High/low pressure
Width (inches)	14.1 (35.8 cm)	14.7 (37.3 cm)	15.7 (39.9 cm)
Height (inches)	20.8 (52.8 cm)	26.0 (66.0 cm)	25.6 (65.0 cm)
Weight	30.0 lb (13.6 kg)	57.0 lb (25.9 kg)	59.5–68.3 lb (27.0–31.0 kg)
Battery life (hours)	NA	NA	NA
Battery recharge time (hours)	NA	NA	NA
Circuit breaker and/or fuse?	Circuit breaker	Circuit breaker	Circuit breaker
Filters and time until replacement	Felt inlet filter: no required service Filter in product tank: no required service	Compressor inlet filter: 10,000 hours Cabinet filter: Weekly cleaning HEPA filter	Noise filter Sponge paper filter Second grade filter
Operating temperature	41°F–105°F (5°C–40.5°C)	50°F–104°F (10°C–40°C)	50°F–104°F (10°C–40°C)
Operating humidity (RH%)	95	95	30–85
Operating level	10,000 ft (3,048 m)	9,000 ft (2,743 m)	Not specified
Standard warranty (yrs)	5	5	3
Certification	ISO 8359, FDA, CE 0459, ISO 9001	CE, FDA K042262, ISO 8359	CE; ISO13485; FDA K081508
Continuous or pulse flow	Continuous	Continuous	Continuous
Manufacturer Website	https://www.caireinc.com/commercial/	https://www.caireinc.com/commercial/	http://www.cantamedical.com/

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Manufacturer	**Canta Medical Tech Co., Ltd.**	**Canta Medical Tech Co., Ltd.**	**Delphi***
Location	China	China	United States
Device type	Stationary	Portable	Portable, assembled
Devices	V3 V5 V8 	M2 	RS-00400 
Release date	Unknown	Unknown	January 3, 2008
Retail price	$338–$556	$389	$4,495
Noise (dBA)	40–45	40	43
Average power consumption (W)	350–480	90	120 (max while charging)
Power efficiency (W/LPM)	60–117	90	NA
Min oxygen output flow rate	1	1 (continuous equivalent)	0.2
Max oxygen output capacity (SLPM)	3.0–8.0	5.0 (continuous equivalent)	0.9
Output pressure (psig)	7.3–11.6	NA	17.0
Oxygen concentration (%)	90–96	90–96	87–93
Oxygen sensor	Optional	Not specified	standard
Oxygen alarm range(s)	Not specified	NA	Warning: < 82%
Alarms	High temperature Power failure Low O_2 High/low pressure Valve failure	Not specified	Low O_2 Power failure
Width (inches)	15.4 (39.1 cm)	7.8 (19.9 cm)	7.4 (18.8 cm)
Height (inches)	24.4 (62.0 cm)	12.8 (32.4 cm)	11.6 (29.5 cm)
Weight	46.3–52.9 lb (21.0–24.0 kg)	13.2 (6.0 kg)	9.8 lb (4.5 kg)
Battery life (hours)	NA	NA	3.0–4.0 @ setting 2
Battery recharge time (hours)	NA	NA	3.0
Circuit breaker and/or fuse?	Circuit breaker	Not specified	Neither
Filters and time until replacement	Coarse filter Paper filter (intake) Bacteria filter	Dust filter Inner filter	Input filter: wash periodically Patient filter: change as indicated by device Compressor filter: change as indicated by device
Operating temperature	50°F–104°F (10°C–40°C)	Not specified	41°F–104°F (5°C–40°C)
Operating humidity (RH%)	30–85	Not specified	5–95
Operating level	Not specified	Not specified	8,000 ft (2,438.4 m)
Standard warranty (yrs)	3	Not specified	3
Certification	CE; ISO13485	CE; ISO13485	FAA, FDA K073242
Continuous or pulse flow	Continuous	Pulse	Not specified
Manufacturer Website	http://www.cantamedical.com/	http://www.cantamedical.com/	https://www.oxygenconcentratorinc.com/centralair.htm

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Manufacturer	**DeVilbiss**	**DeVilbiss**	**Diamedica***
Location	United States	United States	United Kingdom
Device type	Stationary	Portable	Stationary, Assembled
Devices	525DS 525KS 525PS 	306DS 	Oxygen Concentrator 
Release date	March 2008	2009	Unknown
Retail price	$585	$2,689	Unknown
Noise (dBA)	48	48 (typical); 55 (max)	Not specified
Average power consumption (W)	310	< 120	430
Power efficiency (W/LPM)	62	NA	54
Min oxygen output flow rate	0.5	1.0	2.0
Max oxygen output capacity (SLPM)	5.0	3.0	8.0
Output pressure (psig)	8.5	4.0–6.0 (max 15.0)	20.0
Oxygen concentration (%)	90–96	88–94	Not specified
Oxygen sensor	Standard	Standard	Not specified
Oxygen alarm range(s)	Yellow: < 84% ± 2% Red: < 60%	Low O_2 Light: 75%–85% Service required light (red) Audible alert: < 75%	NA
Alarms	High/low pressure Power failure Low O_2 Low flow	Power failure High/low flow High temperature Low O_2 Malfunction	High temperature High/low pressure Power failure Low O_2 Battery test
Width (inches)	13.5 (34.3 cm)	11.0 (27.9 cm)	16.5 (42.0 cm)
Height (inches)	24.5 (62.2 cm)	15.0 (38.1 cm)	27.6 (70.0 cm)
Weight	36.0 lb (16.3 kg)	19.0 lb (8.6 kg)	53.9 lb (24.5 kg)
Battery life (hours)	NA	1.6–5.4	NA
Battery recharge time (hours)	NA	3.0 (w/external charger)	NA
Circuit breaker and/or fuse?	Circuit breaker and fuse	Neither	Circuit breaker
Filters and time until replacement	Coarse filter: wash weekly Intake filter: 2 years Bacteria filter: 3 years Compressor filter: 5 years	Dust filter: wash weekly	Gross particle filter: daily to weekly cleaning depending on dust Product filter: 25,000 hours Optional felt filter: 5,000 hours
Operating temperature	41°F–104°F (5°C–40°C)	41°F–104°F (5°C–40°C)	Not specified
Operating humidity (RH%)	95	10–95	Not specified
Operating level	13,000 ft (3,962.0 m)	13,123 ft (4,000 m)	Not specified
Standard warranty (yrs)	3	3 (1 for battery)	Not specified
Certification	ISO 8359, FDA K071397, CE	FAA, ISO 8359, FDA K081468, CE–0044	CE ISO 8359:1996, ISO 9001
Continuous or pulse flow	Continuous	Both	Continuous
Manufacturer Website	http://www.devilbisshealthcare.com/	http://www.devilbisshealthcare.com/	http://www.diamedica.co.uk/english/

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Manufacturer	Drive Medical*	Drive Medical	Inogen
Location	United States	United States	United States
Device type	Portable	Stationary	Stationary
Devices	NA 	Pure 	Inogen At Home 
Release date	Unknown	April 16, 2015	June 20, 2014
Retail price	$2,395	$1,099	$1,495
Noise (dBA)	43	45	Not specified
Average power consumption (W)	120 (max while charging)	360–390	275
Power efficiency (W/LPM)	NA	72–78	50–55
Min oxygen output flow rate	0.2	0.5	1.0
Max oxygen output capacity (SLPM)	0.9	5.0	5.0
Output pressure (psig)	17.0	5.0–6.0	4.9–25.9
Oxygen concentration (%)	87–96	87–96	87–96
Oxygen sensor	Standard	Optional	Standard
Oxygen alarm range(s)	Warning: < 82%	Warning: 72%–81% Alarm: < 72%	Oxygen low Oxygen error O_2 sensor failure alarm
Alarms	Power failure Low O_2 Maintenance Low flow	Low O_2 Low flow Power failure High temperature	Sieve failure; Low O_2 Malfunction; Sensor failure; Low flow; High/low temp; Smoke detected; Power failure
Width (inches)	7.6 (19.3 cm)	16.8 (42.5 cm)	13.0 (33.0 cm)
Height (inches)	11.9 (30.2 cm)	24.5 (62.2 cm)	16.5 (41.9 cm)
Weight	9.9 lb (4.5 kg)	35.0 lb (15.9 kg)	18.0 lb (8.2 kg)
Battery life (hours)	3.0–4.0 @ setting 2	NA	NA
Battery recharge time (hours)	3.0	NA	NA
Circuit breaker and/or fuse?	Neither	Not specified	Neither
Filters and time until replacement	Input filter: wash periodically Patient filter: change as indicated by device Compressor filter: change as indicated by device	Compressor inlet Foam intake: wash as needed HEPA intake: Replace yearly or as needed	Gross particle filter: weekly cleaning; Product filter: Between patients; Intake filter: No PM stated
Operating temperature	41°F–104°F (5°C–40°C)	41°F–104°F (5°C–40°C)	41°F–104°F (5°C–40°C)
Operating humidity (RH%)	5–95	20–60	15–95
Operating level	8,000 ft (2,438 m)	13,123 ft (4,000 m)	8,000 ft (2,438 m)
Standard warranty (yrs)	3	3	3
Certification	FAA, FDA K073242, CE	Likely FDA (US manufacturer)	FDA K132489, ISO 8359, IEC 60601-1
Continuous or pulse flow	Continuous	Continuous	Continuous
Manufacturer Website	https://www.drivemedical.com/us/en	https://www.drivemedical.com/us/en	https://www.inogen.com/

Manufacturer	**Inogen**	**Inova Labs Inc.**	**Inova Labs Inc.**
Location	United States	United States	United States
Device type	Portable	Portable	Stationary
Devices	G2 G3 	Activox Pro Activox Sport 	DUO2 
Release date	May 13, 2004	December 28, 2011	March 2015
Retail price	$2,495	$3,895–$3,995	Unknown
Noise (dBA)	38–42	41–46	45
Average power consumption (W)	85–90	40	372
Power efficiency (W/LPM)	65–69	NA	74
Min oxygen output flow rate	0.2	10.9 ml (pulse)	1.0
Max oxygen output capacity (SLPM)	1.3	30.0 ml (pulse)	5.0
Output pressure (psig)	NA	19	8
Oxygen concentration (%)	87.0–96.0	87.0–93.0	90.0–96.0
Oxygen sensor	Standard	Standard	Standard
Oxygen alarm range(s)	Oxygen low: < 82% Oxygen error: < 50% O_2 sensor failure alarm	O_2 sensor alarm: < 85%	Warning: < 82%
Alarms	Power failure High/low temperature Internal error Low O_2 High/low pressure	Low O_2; Low flow; Power failure; Malfunction	Low O_2; Low flow; Power failure; Malfunction
Width (inches)	3.0–3.9 (7.62–9.9 cm)	9.1 (23.1 cm)	14.2 (36.0 cm)
Height (inches)	7.25–9.5 (18.4–24.1 cm)	7.9 (20.1 cm)	24.8 (63.0 cm)
Weight	4.8–7.0 lb (2.2–3.2 kg)	4.8 lb (2.2 kg)	37.5 (17.0 kg)
Battery life (hours)	4.5–10.0	5.0–15.0	NA
Battery recharge time (hours)	2.25–8.0	4.0–7.0	NA
Circuit breaker and/or fuse?	Neither	Neither	Circuit breaker
Filters and time until replacement	Product filter	Intake grill: clean w/ dry cotton swab monthly	Cabinet filter Air intake filter: replace yearly Product filter
Operating temperature	41°F–104°F (5°C–40°C)	41°F–104°F (5°C–40°C)	50°F–95°F (10°C–35°C)
Operating humidity (RH%)	0–95	≤ 95	≤ 95
Operating level	10,000 ft (3,048 m)	10,000 ft (3,048 m)	13,000 ft (4,000 m)
Standard warranty (yrs)	3	3 (1 for battery / seive)	Not specified
Certification	CE, CSA, FDA K032818, FAA	FAA, FDA K113317, CE	FDA K132205, CE
Continuous or pulse flow	Continuous	Pulse	Continuous
Manufacturer Website	https://www.inogen.com/	https://www.resmed.com/en-us/portable-oxygen/	https://www.resmed.com/en-us/portable-oxygen/

Manufacturer	**Invacare**	**Invacare**	**Invacare**
Location	United States	United States	United States
Device type	Stationary	Stationary	Portable
Devices	Perfecto2 Perfecto2 V Perfecto2 W 	Platinum XL Platinum 5 Platinum 9 Platinum 10 	TPO100 TPO100B XPO100 XPO100B 
Release date	August 31, 2009	July 2, 2002	August 2008 (XPO2)
Retail price	$836	$1,913	$3,148
Noise (dBA)	43	50	45
Average power consumption (W)	280–325	585	36
Power efficiency (W/LPM)	65	59	45
Min oxygen output flow rate	0.5	0.5	0.3
Max oxygen output capacity (SLPM)	5.0	10.0	0.8
Output pressure (psig)	5	5–9	NA
Oxygen concentration (%)	87.0–95.6	87.0–94.0	87.0–95.6
Oxygen sensor	Optional	Optional	Not specified
Oxygen alarm range(s)	Sieve-GARD compressor shutdown: < 73% Purity warning: 73%–85%	Compressor shutdown: < 73% Purity warning: 73%–85%	NA
Alarms	High temperature; Power failure; Low flow; Low O_2	High temperature; Power failure; Low flow; Low O_2	Power failure; Malfunction; High/low flow; High/low temperature
Width (inches)	15.0 (38.1 cm)	18.4 (46.7 cm)	7.0 (17.8 cm)
Height (inches)	23.0 (58.4 cm)	26.4 (67.0 cm)	10.0 (25.4 cm)
Weight	40.0–45.0lb (18.1–20.4kg)	54.0 lb (24.5 kg)	6.0 lb (2.7kg) –7.3 lb (3.3kg)
Battery life (hours)	NA	NA	1.0–7.0
Battery recharge time (hours)	NA	NA	4.0
Circuit breaker and/or fuse?	Circuit breaker	Circuit breaker	Neither
Filters and time until replacement	Cabinet: Clean weekly Inlet: Inspect annually Product filter: Inspect annually All: replace as needed	Cabinet: clean weekly Inlet: inspect annually Product filter: inspect annually All: replace as needed	Coarse filter: clean regularly Inlet filter: replace yearly
Operating temperature	50°F–95°F (10°C–35°C)	50°F–95°F (10°C–35°C)	41°F–95°F (5°C–35°C)
Operating humidity (RH%)	20–60	60	15–60
Operating level	6,000 ft (1,828 m); < 90%: 6,000–13,129 ft (1,828–4,000 m)	4,000 ft (1,219 m)	10,000 ft (3,048 m)
Standard warranty (yrs)	3	5	3 (concentrator) 2 (compressor) 1 (battery)
Certification	UL1431, UL1097 ETL CSA C22.2 No. 68 FDA K020386, CE, ISO 8359	FDA K020386, CE	FAA, FDA K083751, CE
Continuous or pulse flow	Continuous	Continuous	Pulse
Manufacturer Website	http://www.invacare.com/cgi-bin/imhqprd/default.jsp	http://www.invacare.com/cgi-bin/imhqprd/default.jsp	http://www.invacare.com/cgi-bin/imhqprd/default.jsp

Manufacturer	Kare Medical	Kare Medical	Kröber
Location	Turkey	Turkey	Germany
Device type	Stationary	Stationary	Stationary
Devices	OxyBreath 10L 	Mini 3 Mini 5 	aeroplus 5 
Release date	2013	2013	Unknown
Retail price	$950	$620	1,000 €
Noise (dBA)	Not specified	Not specified	< 40
Average power consumption (W)	550	165 (Mini 3); 330 (Mini 5)	295
Power efficiency (W/LPM)	55	55–66	59
Min oxygen output flow rate	1.0	0.5	0.5
Max oxygen output capacity (SLPM)	10.0	3.0 (Mini 3) 5.0 (Mini 5)	5.0
Output pressure (psig)	13–19	Not specified	10
Oxygen concentration (%)	89.0–95.0 (1–9 LPM) 87.0–93.0 (10 LPM)	90–96	82–95
Oxygen sensor	Optional	Optional	Standard
Oxygen alarm range(s)	Not specified	Low oxygen: < 82% Service required: < 70%	Warning: 60%–82% Alarm: < 60%
Alarms	Not specified	Low O_2	High temperature Power failure Low O_2 System malfunction Low pressure
Width (inches)	Not specified	Not specified	11.4 (29.0 cm)
Height (inches)	Not specified	Not specified	23.6 (59.9 cm)
Weight	47.7 lb (21.7 kg)	26.4 lb (12.0 kg) (Mini 3) 33.2 lb (15.1 kg) (Mini 5)	33.1 lb (15.0 kg)
Battery life (hours)	NA	NA	NA
Battery recharge time (hours)	NA	NA	NA
Circuit breaker and/or fuse?	Not specified	Not specified	Fuse (x2)
Filters and time until replacement	2 filters—one labeled as "dust filter"	Cabinet filter Inlet filter	Coarse filter: replace every 4 weeks Intake filter: yearly/5,000 hours Bacteria filter
Operating temperature	41°F–104°F (5°C–40°C)	41°F–104°F (5°C–40°C)	50°F–104°F (10°C–40°C)
Operating humidity (RH%)	Not specified	Not specified	No rating
Operating level	Not specified	Not specified	10,500 ft (3,200 m)
Standard warranty (yrs)	Not specified	Not specified	5
Certification	CE	CE	ISO 8359, CE 0197 DOC
Continuous or pulse flow	Continuous	Continuous	Continuous
Manufacturer Website	http://www.karemedical.eu/en/	http://www.karemedical.eu/en/	https://www.kroeber.de/site/home_d.asp

Manufacturer	**Kröber**	**Kröber**	**Legend Medical**
Location	Germany	Germany	China
Device type	Portable	Stationary	Portable
Devices	aeroplus m 	O2 4.0 	LoveGo 
Release date	Unknown	Unknown	Unknown
Retail price	2,990 €	1,200 € (4.0); 1,100 € (O_2)	$1,299
Noise (dBA)	40	31 (4.0); 35 (O_2)	38
Average power consumption (W)	max 100	280 (4.0); 350 (O_2)	90
Power efficiency (W/LPM)	125	56 (4.0); 58 (O_2)	72
Min oxygen output flow rate	0.2	1.0	1.0
Max oxygen output capacity (SLPM)	0.8	5.0 (4.0) 6.0 (O_2)	5.0 @ 40% (1.25 LPM)
Output pressure (psig)	NA	10.0	5.8–8.7
Oxygen concentration (%)	> 90	82–95 (4.0); 72–95 (O2)	40–93
Oxygen sensor	Standard	Standard	No
Oxygen alarm range(s)	Not specified	Warning: 60%–82% Alarm: < 60%	NA
Alarms	High temperature Power failure Low O_2 Malfunction	High temperature; System malfunction; Power failure; Low O_2; Low flow	Power failure; High temperature; High/low pressure
Width (inches)	6.1 (15.5 cm)	8.0 (20.3 cm)	9.6 (24.4 cm)
Height (inches)	9.1 (23.1 cm)	20.5 (52.1 cm)	14.3 (36.3 cm)
Weight	8.0 lb (3.6 kg)	35.3 lb, 16.0 kg (4.0) 43.7 lb, 20.0 kg (O2)	11.9 lb (5.4 kg)
Battery life (hours)	2.0–4.0	NA	1.3 (estimated)
Battery recharge time (hours)	Not specified	NA	Not specified
Circuit breaker and/or fuse?	Neither	Fuse (x3)	Not specified
Filters and time until replacement	Coarse filter: replace every 4 weeks Intake filter: yearly/5,000 hours	Coarse filter: replace every 4 weeks Intake filter: yearly/5,000 hours Bacteria filter	Air filter
Operating temperature	41°F–104°F (5°C–40°C)	41°F–104°F (5°C–40°C)	Not specified
Operating humidity (RH%)	15–93	93	Not specified
Operating level	10,500 ft (3,200 m)	10,500 ft (3,200 m)	12,000 ft (3,658 m)
Standard warranty (yrs)	2 (1 battery)	5	7
Certification	ISO 8359, CE	ISO 8359, CE 0197 DOC	Not specified
Continuous or pulse flow	Pulse, quasi-continuous	Continuous	Continuous
Manufacturer Website	https://www.kroeber.de/site/home_d.asp	https://www.kroeber.de/site/home_d.asp	https://www.legendmedical.us/

Manufacturer	Longfei	Longfian Scitech	Longfian Scitech
Location	China	China	China
Device type	Stationary	Portable	Stationary
Devices	LFY–I–3A,B,F,G LFY–I–4A,B LFY–I–5A,B,F LFY–I–8A,B 	1P 3P 5P 	JAY–3 JAY–5 JAY–8 JAY–10 
Release date	October 18, 2005	Unknown	Unknown
Retail price	$460–$785	$569	$340 (JAY–5); $520 (JAY–10)
Noise (dBA)	< 48–62	45	43–50
Average power consumption (W)	300–520	75	280–550
Power efficiency (W/LPM)	90–104	NA	55–93
Min oxygen output flow rate	1	1.00	0.13
Max oxygen output capacity (SLPM)	3–8	5* (probably not 90% O_2)	3–10
Output pressure (psig)	4.4–10.2	4.4–10.2	5.8–10.2
Oxygen concentration (%)	90–96	30–90	88–96
Oxygen sensor	Optional	Not specified	Standard
Oxygen alarm range(s)	Yellow: 70%–73% – 85%–90% Red: < 70%–73%	NA	Red: < 82%
Alarms	Power failure High/low pressure	Power failure	High temperature; Maintenance; High/low pressure; Power failure; Low O_2
Width (inches)	18.9 (48.0 cm)	7.5 (19.1 cm)	14.8 (37.6 cm)
Height (inches)	28.7 (73.0 cm)	12.6 (32.0 cm)	23.6 (59.9 cm)
Weight	44.0–62.7 lb (20.0–28.5 kg)	13.2 lb (6.0 kg)	30.8–66.1 lb (14.0–30.0kg)
Battery life (hours)	NA	NA	NA
Battery recharge time (hours)	NA	NA	NA
Circuit breaker and/or fuse?	Fuse	Not specified	Fuse
Filters and time until replacement	"Coarse filter: monthly cleaning Intake filter: check every 3 months, yearly replacement"	Not specified	Filter intake cloth
Operating temperature	32°F–104°F (0°C–40°C)	50°F–104°F (10°C–40°C)	104°F (max); (40°C)
Operating humidity (RH%)	< 80	30–85	85
Operating level	4,468 ft (1,360 m)	10,500 ft (3,200 m)	NA
Standard warranty (yrs)	Lifetime (parts only)	NA	1.25
Certification	CE, ISO 13485, FDA K033405	CE & ISO	ISO 8359, FDA K131968, CE
Continuous or pulse flow	Continuous	Not specified	Continuous
Manufacturer Website	http://www.longfei.com/eng/main.asp	http://www.longfian.com/en/	http://www.longfian.com/en/

* indicates that the listed supplier of the concentrator is not the original equipment manufacturer.

Manufacturer	medicap	Merits Health Products*	Metran
Location	Germany	United States	Japan
Device type	Stationary	Stationary, Assembled	Portable
Devices	P 6000 P 6000 S 	M520 M525 	KM–X3L 
Release date	2001	August 4, 2005	Unknown
Retail price	Unknown	$1,875(M520); $2,125 (M525)	Unknown
Noise (dBA)	39	40	33
Average power consumption (W)	< 460 (2.0 A rating) 330 and 350 claimed by distributors	310	45
Power efficiency (W/LPM)	77	62	45
Min oxygen output flow rate	0.10	0.13	Not specified
Max oxygen output capacity (SLPM)	5 6 (S model)	5	1
Output pressure (psig)	4.4–5.1	7	NA
Oxygen concentration (%)	77–95	87–96	87–93
Oxygen sensor	Standard (M designation)	Optional	Not specified
Oxygen alarm range(s)	Low: < 82%; Service (compressor shutdown): < 72%	Warning: < 85% ± 3% (82% ± 2% for 50 Hz)	NA
Alarms	High temperature; High/low pressure; Low O_2; Power failure	Power failure; High/low pressure; Operating fault; Low O_2	Not specified
Width (inches)	8.5 (21.5 cm)	14.0 (35.6 cm)	10.6 (26.9 cm)
Height (inches)	21.7 (55.0 cm)	23.0 (58.4 cm)	12.6 (32.0 cm)
Weight	46.2 lb (21.0 kg)	30.0 (13.6 kg)	12.8 lb (5.8 kg)
Battery life (hours)	NA	NA	2.0
Battery recharge time (hours)	NA	NA	Not specified
Circuit breaker and/or fuse?	Fuse	Circuit breaker	Not specified
Filters and time until replacement	Coarse dust filter: weekly cleaning; Fine filter: 6 months or 2,000 hours; Microfilter: 6 months or 2,000 hours; Patient bacteria filter: exchange during inspection	Coarse filter: weekly cleaning Inlet filter: replace every 2 years or sooner Product filter: replace with compressor service	Not specified
Operating temperature	50°F–104°F (10°C–40°C)	50°F–104°F (10°C–40°C)	Not specified
Operating humidity (RH%)	Not specified	15–95	Not specified
Operating level	Not specified	Not specified	Not specified
Standard warranty (yrs)	1.00	1	Not specified
Certification	ISO 13485, ISO 8359, CE DoC	FDA K053230, CE	JIS–T–7209 (Japan)
Continuous or pulse flow	Continuous	Continuous	Both
Manufacturer Website	https://www.medicap.com/	http://www.meritsusa.com/page/index.html	http://www.metran.co.jp/en/

* indicates that the listed supplier of the concentrator is not the original equipment manufacturer.

Manufacturer	Nidek	O2 Concepts	Philips Respironics
Location	United States	United States	United States
Device type	Stationary	Portable	Stationary
Devices	Nuvo Lite Nuvo 8 	NA 	EverFlo EverFlo Q 
Release date	April 29, 2004	April 16, 2008	November 15, 2006
Retail price	$719 (Lite); $1,120 (8)	$2,399	$1,852–$2,395
Noise (dBA)	40, 48	41–44	40
Average power consumption (W)	350, 500	NA	350
Power efficiency (W/LPM)	70, 63	NA	70
Min oxygen output flow rate	0.5	0.5	0.5
Max oxygen output capacity (SLPM)	5, 8	3	5
Output pressure (psig)	7.0, 17.0	4.0–6.0	5.7
Oxygen concentration (%)	87.0–95.0	87.0–95.6	90.0–96.0
Oxygen sensor	Optional	Standard	Optional
Oxygen alarm range(s)	Warning: < 85% (60Hz), 83% (50 Hz)	Alert: < 85% Alarm: < 72%	Low O_2 (yellow): 70%–82% Very low O_2 (red): < 70%
Alarms	Power failure; High/low pressure; System malfunction; High temperature; Low flow	Power failure; Low O_2; Low flow; High temperature; Maintenance	Power failure; System malfunction; Low flow; Low O_2
Width (inches)	15.6 (39.6 cm)	8.0 (20.3 cm)	15.0 (38.1 cm)
Height (inches)	27.8 (70.6 cm)	12.0 (30.5 cm)	23.0 (58.4 cm)
Weight	32.0 lb, 14.5 kg (lite) 55.5 lb, 25.2 kg (8)	16.7 lb (42.4 kg)	31.0 lb (14.1 kg)
Battery life (hours)	NA	2.5–5.8	NA
Battery recharge time (hours)	NA	1.5 (single) 2.5 (double)	NA
Circuit breaker and/or fuse?	Circuit breaker	Neither	Fuse
Filters and time until replacement	Coarse filter: weekly cleaning Inlet filter: replace annually or sooner Product filter: replace with compressor service	Air inlet filter: weekly cleaning	Inlet filter: 2 years Micro-disk (bacteria) filter: as necessary
Operating temperature	50°F–100°F (10°C–38°C)	50°F–104°F (10°C–40°C)	55°F–90°F (13°C–32°C)
Operating humidity (RH%)	95	10–95	95
Operating level	7,500 ft (2,286 m)	13,123 ft (4,000 m)	7,500 ft (2,286 m)
Standard warranty (yrs)	3	5 (battery 1)	3
Certification	FDA K123738 (lite) K093308 (8), ISO 13485:2003, ISO 8359, CE 0413	FAA, FDA K080082, CE	CE, US/Canada, FDA K061261
Continuous or pulse flow	Continuous	Both	Continuous
Manufacturer Website	https://www.nidekmedical.com/	http://www.o2-concepts.com/	https://www.usa.philips.com/

Manufacturer	**Philips Respironics**	**Philips Respironics**
Location	United States	United States
Device type	Portable	Stationary
Devices	SimplyGo SimplyFlo 	Millennium M10 
Release date	April 22, 2012 (Go)	February 11, 2005
Retail price	$2,995 (Go); $1,995 (Flo)	$1,130
Noise (dBA)	43	50
Average power consumption (W)	120	600
Power efficiency (W/LPM)	60	60
Min oxygen output flow rate	0.5	1.0
Max oxygen output capacity (SLPM)	2	10.0
Output pressure (psig)	3.0 (Go), 6.4 (Flo)	10–30
Oxygen concentration (%)	87.0–96.0	88–96
Oxygen sensor	Standard	Optional
Oxygen alarm range(s)	Not specified	Low O_2 (yellow): 70%–82% Very low O_2 (red): < 70%
Alarms	Power failure; Low O_2; Low flow; Malfunction; No breath; High breath rate	High/low pressure; Power failure; Low O_2; Low flow
Width (inches)	11.5 (29.2 cm)	19.0 (48.3 cm)
Height (inches)	10.0 (25.4 cm)	27.0 (68.6 cm)
Weight	10.0 lb, 4.5 kg (SimplyGo) 8.5 lb, 3.8 kg (SimplyFlo)	53.0 lb (24.1 kg)
Battery life (hours)	0.9–3.0	NA
Battery recharge time (hours)	2.0–3.0	NA
Circuit breaker and/or fuse?	Not specified	Fuse
Filters and time until replacement	Air inlet filter: weekly cleaning Internal bacteria filter	Coarse filter: wash weekly; HEPA Inlet: 1–3 years; Optional pre-inlet filter: replace when worn; Felt; Micro-disk
Operating temperature	41°F–104°F (5°C–40°C)	55°F–90°F (13°C–32°C)
Operating humidity (RH%)	15–95	95
Operating level	10,000 ft (3,048 m)	7,500 ft (2,286 m)
Standard warranty (yrs)	2–5	1.0 (2.0 optional)
Certification	FAA, FDA K111885, CE	FDA K043006, CE 0459,
Continuous or pulse flow	Pulse	Continuous
Manufacturer Website	https://www.usa.philips.com/	https://www.usa.philips.com/

Manufacturer	**Precision Medical**	**Precision Medical**
Location	United States	United States
Device type	Stationary	Portable
Devices	PM4350 PM4351 	POC 
Release date	October 27, 2008	July 1, 2011
Retail price	$699	$3,995
Noise (dBA)	53	44
Average power consumption (W)	350	< 60
Power efficiency (W/LPM)	70	75
Min oxygen output flow rate	0.5	0.2
Max oxygen output capacity (SLPM)	5.0	0.8
Output pressure (psig)	8	NA
Oxygen concentration (%)	87–95 (<6,500') 85–90 (6,501'–10,000')	87–95
Oxygen sensor	Optional	No
Oxygen alarm range(s)	Low O_2 (yellow) Very low O_2 (red)	NA
Alarms	High temperature; Occluded flow; Power failure; Low O_2; System malfunction	Power failure; High/low flow; malfunction; High temperature; Service needed
Width (inches)	12.3 (31.2 cm)	6.5 (16.5 cm)
Height (inches)	17.0 (43.2 cm)	10.1 (25.7 cm)
Weight	29.6 lb (13.4 kg)	6.8 lb (3.1 kg)
Battery life (hours)	NA	1.5–4.5
Battery recharge time (hours)	NA	Not specified
Circuit breaker and/or fuse?	Automatic restart**	Neither
Filters and time until replacement	Intake muffler/filter: Washable; Product filter: Never needs replacement	Inlet filter: washable
Operating temperature	50°F–95°F (10°C–35°C)	41°F–104°F (5°C–40°C)
Operating humidity (RH%)	95	Up to 95
Operating level	10,000 ft (3,048 m)	9,000 ft (2,743 m)
Standard warranty (yrs)	3.0—concentrator 1.5—compressor	3.0 (device) 0.5 (battery)
Certification	ISO 8359, ISO 13485; FDA K072348	ISO 8359, FDA K103563, CE
Continuous or pulse flow	Continuous	Pulse
Links	https://www.precisionmedical.com/	https://www.precisionmedical.com/

Note: CMD, ; CSA, ; FAA, ; FDA, US Food and Drug Administration; HEPA, high-efficiency particulate air; ISO, International Organization for Standardization; Max, maximum; Min, minimum; NA, not applicable; PM, ; yrs, years.

Annex C. Common health care scenarios for application of the oxygen quantification tools

Oxygen quantification needs assessment—Scenario 1

1	Assessment focus	Single health facility (community health center, district hospital, regional/reference hospital)
2	Oxygen status	Currently meeting patient oxygen needs
3	Tools to use	*Consumption Tracking Tool*, *Baseline Assessment Manual*
4	Responsible parties	Health facility management
5	Output	Estimated future oxygen need
6	Use/application	Supports costing and selection of oxygen delivery device options to address identified oxygen need

For an assessment to quantify future oxygen needs of a single health facility that is currently meeting patients' oxygen needs, the primary tools to use would be the *Consumption Tracking Tool* and the *Baseline Assessment Manual*.

Consumption Tracking Tool: This tool tracks the volume of oxygen used for all oxygen delivery devices in use at the health facility (oxygen cylinders, oxygen concentrators, oxygen plant, liquid oxygen) over a designated period of time. The tool also collects patient metrics, such as the number and type of beds at the health care facility, number of inpatients admitted, average length of inpatient stay, number of births, etc. This information can be used to understand the relationship between number of patients and oxygen usage, and thus project future oxygen needs and the budget required to meet those needs.

Baseline Assessment Manual: This tool identifies the availability and functionality of all oxygen sources at the facility at a designated point in time. The information from the baseline assessment, which identifies the reduced capacity created by nonfunctioning oxygen sources, can be used to adjust and further refine the estimate of the health facility's future oxygen needs, as determined through the *Consumption Tracking Tool*.

Oxygen quantification needs assessment—Scenario 2

1	Assessment focus	Single health facility (community health center, district hospital, regional/reference hospital)
2	Oxygen status	Not meeting patient oxygen needs
3	Tools to use	*Quantification and Costing Tools*, *Consumption Tracking Tool*, *Baseline Assessment Manual*
4	Responsible parties	Health facility management
5	Output	Quantified estimated future oxygen need
6	Use/application	Supports costing and selection of oxygen delivery device options to address identified oxygen need

For an assessment to quantify future oxygen needs of a single health facility that is not meeting patients' oxygen needs, the tools to use would be the *Quantification and Costing Tools*, *Consumption Tracking Tool*, and *Baseline Assessment Manual*.

The *Quantification and Costing Tools* can be used to estimate the amount of oxygen the facility should be using, using data on the number of beds by type (general, beds with added services, and critical care beds), the bed occupancy rates by type, and the average required oxygen flow rate (liters per minute) by type. The result of this calculation is an ideal oxygen capacity for the health care facility, which should be compared to data gathered from the *Consumption Tracking Tool* (on current oxygen use) to understand the gap in the current availability of oxygen. Data from the *Baseline Assessment Manual* can also be used to further adjust and refine the projected estimated need for oxygen for the health facility.

Oxygen quantification needs assessment—Scenario 3

1 Assessment focus	Regional, national levels
2 Oxygen status	Undetermined
3 Tools to use	*Quantification and Costing Tools*
4 Responsible parties	Health facility management
5 Output	Estimated ideal future oxygen capacity
6 Use/application	Supports costing and selection of oxygen delivery device to address projected oxygen capacity need

Since quantifying oxygen delivery device needs on a regional or national basis using the *Consumption Tracking Tool* can incur additional costs due to the resources and time required to collect data across multiple health facilities, the *Quantification and Costing Tools* are the preferred tools when planning for oxygen use across a regional or national catchment area of facilities. These tools estimate the ideal amount of oxygen needed for a group of health facilities, based on number of beds by type, bed occupancy rates, and estimated oxygen flow rates. If data are not available on the actual number of bed in the catchment area, it may be possible to use health facility standards documents on bed type requirements per health facility level as proxy data. If data on current oxygen use (for facilities already meeting their full oxygen need) are available from any health facility assessments using the *Consumption Tracking Tool* and/or the *Baseline Assessment Manual*, these data may be used to refine the ideal oxygen capacity that should be provided, which is projected by the *Quantification and Costing Tools*.

These tools are part of the Oxygen Delivery Toolkit, which can be accessed here: www.path.org/oxygen-delivery-toolkit.

Annex D. World Health Organization oxygen concentrator technical specification[25]

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.

Purpose of use, continued		
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 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.

Note: 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); N_2, 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 E. World Health Organization's *User Guide: WHO Technical Specifications for Medical Devices*[26]

Annex 5. Related services to be considered for tendering, purchasing technology and local conditions purposes

1. Delivery at Place
   b. Specify required certifications for Supplier and Manufacturer (ISO 9001 and ISO13485 suggested) to be included in the Bidding documents.
   c. Specify Delivery Incoterms and Delivery Place.
   d. Specify if there is the possibility for a temporary storage.
   e. The Supplier shall deliver the original software license, in the name of the final Beneficiary, where applicable, together with the equipment.
   f. The Supplier shall make available to the Purchaser all the consumables, measurement and calibration instruments used during commissioning operations.
   g. The Supplier shall provide together with the goods the didactic material for maintenance and user training courses. The didactic material will be in specify language without any exception. The didactic material shall be approved by the Purchaser.
   h. The Supplier shall deliver together with the equipment one hard or one CD/DVD copy of the operation manual and maintenance manual in specify language with each unit provided. If the above required language version of the manual is not available the English shall be delivered along with a translation into the above required language signed by the technical manager of the Supplier.
   i. All the labels and indications on the equipment as well as the software included with the equipment shall be in specify language and exceptionally some English label may be used providing the translation in the above mentioned language during training.
2. Preliminary acceptance
   a. The Purchaser will inspect the delivered good checking their quantities and their integrity.
   b. In case that the installation is not included in the contract the Purchaser will install, directly or by a third part, and check the quality of the goods in this phase and will preliminary accept the goods according with the result of the check.
   c. The Supplier can be present to the above mentioned phases. If the Supplier is not present he will accept any decision taken by the Purchaser.
   d. The Supplier shall supply to the Purchaser all the consumables, measurement and calibration instruments used during official commissioning operations. All the expenses necessary for the official testing and commissioning procedure shall be responsibility of the Contractor.
   e. The Purchaser shall evaluate, item by item, the consistency of the goods and the services supplied respecting the contract conditions and the technical specifications.
   f. The Supplier shall be invited by the Purchaser to assist with the measurement operations during official commissioning for provisional acceptance. At the end of the operations the Purchaser shall prepare minutes of the results and make it available to the Supplier.
   g. Each item shall be declared as compliant, not-compliant or revisable.
   h. The official testing and commissioning is declared successful when all the items of a Lot are declared compliant.
   i. The Supplier shall substitute all not-compliant items with compliant ones at its own cost.
   j. An item is declared revisable only if it has minor defects or is not perfectly compliant. In these cases, only when the Supplier has substituted the item or has solved the defects, he can ask for a new official testing and commissioning.
   k. The not-compliant or revisable items shall be substituted or modified without any break of safety and Manufacturer rules, any cost for the Purchaser or any extension to the contractual deadlines. Any delay due to not-compliant or revisable items is responsibility of the Supplier, thus liquidated damages are applicable.
3. Installation
   a. Specify installation requirements in terms of civil works, data network, electricity, hot and cold water, special treated water, drainage medical gases, steam, air conditioning etc. required to the Supplier.
   b. Specify availability of installations in terms of data network, electricity, hot and cold water, special

treated water, drainage, medical gases, steam, air conditioning, etc.: technical characteristics and position.

c. The Supplier/Installer shall transport the equipment inside the hospital to the installation site, open the packages and install it according with the installation requirements.

d. The Supplier/Installer shall clean up the site of any packaging/shipping material after installation and after requesting the Purchaser whether or not the original boxes must be left with the Purchaser;

e. The Supplier/Installer shall install the equipment taking into consideration the construction characteristics of the hospital receiving the equipment.

f. The Supplier/Installer is responsible to install the equipment "ready to start" for testing and commissioning.

g. Any damage to hospital structures or finishing caused by the supplier personnel during the installation will be repaired by the supplier within 2 weeks using the same construction materials of the damaged areas.

4. Supplier testing and commissioning

a. The Supplier/Installer shall test, calibrate and commission the goods as appropriate in a way that, on installation completion, they are fully operational and can be used. The Purchaser reserves the right to witness the Supplier/Installer's testing and commissioning without thereby relieving the Supplier/Installer of his obligation to provide goods in a fully operable condition.

b. A complete set of commissioning forms with the entire set of tests run and the results obtained will be given to the Purchaser after the final reception of the equipment.

c. When the Purchaser will proceed with the commissioning, the successful Bidder will make available to Final beneficiary the use of all consumables, measurement and calibration instruments used during the commissioning.

5. Training to the maintenance personnel

a. The Supplier/Installer shall train technicians made available by the Purchaser/final Beneficiary in the most frequent problems that could occur during equipment utilization and that are under maintenance technicians' competencies.

b. The training course for maintenance technicians shall be theoretical and practical, using the equipment in the configuration offered and simulators. The Supplier must supply simulators where and when it is needed. The simulator is a property of the Supplier who will keep it after the course is completed.

c. The Supplier shall provide the didactic material. The didactic material will be in Specify language without any exception.

d. The training course for maintenance technicians shall be organized for a minimum of 1 person to a maximum of 5 persons.

e. The location of the training course delivery for maintenance technicians shall [be] the place where the equipment is delivered and installed.

f. The trainers shall be qualified experts belonging to the Manufacturer Company and/or representatives in the country/region of the Supplier/Installer and/or by qualified experts certified by the Manufacturer. The course will be held in Specify language.

g. The training course for maintenance technicians shall focus at least on the following topics:

- presentation and contacts of the reference technicians;
- general equipment functions, specific technical characteristics and alarm signals;
- main electrical and functional schemes;
- calibrations (if requested) and daily maintenance in order to assure the longest equipment life;
- preventive maintenance and its regular recurrence;
- corrective maintenance (to solve the most frequent problems);
- equipment safety controls.

h. The average duration of the training course will be not less than 2 hours per item.

i. A final test administered by the trainees shall be organized at the end of the training course in order to verify the know-how acquired. The results shall be delivered to the Purchaser before commissioning.

6. Training to the equipment users

a. The Supplier/Installer shall train the users in the equipment maintenance and correct utilization.

b. The training course for users shall be theoretical and practical, using the equipment in the offered configuration and planning simulations of all possible mistakes occurring during equipment utilization.

c. The Supplier shall provide the didactic material. The didactic material will be in Specify language without any exception.

d. The training course shall be organized for at least 2 users for each equipment item installed.

e. The location of the training course delivery shall [be] the place where the equipment is delivered and installed.

f. The trainers shall be qualified experts belonging to the Manufacturer Company and/or representatives

in the country of the Supplier/Installer and/or by qualified experts certified by the Manufacturer. The training will be held in Specify language.

g. The training course for users shall focus on least on the following topics:
   - presentation and contacts of the reference technicians;
   - general equipment functions in the offered configuration, alarm signals and error signals showing all the possible equipment functionalities;
   - calibrations (if requested), daily cleaning and maintenance operations in order to assure the longest equipment life;
   - correct equipment utilization and related possible risks for users and patients;

h. The average duration of the course shall be not less than 2 hours for each item.

i. The evaluation of the know-how acquired will be done through two tests: one entrance test at the beginning of the course and one final test at the end. The trainees shall certify that the received training is satisfactory.

7. Provisional equipment handing over
   a. Official testing and commissioning will be carried out by Lot when all items and services of the Lot have been supplied.
   b. The Supplier/Installer shall apply by written notice to the Purchaser for an Official Testing and Commissioning not earlier than 10 days before the date when, in the Supplier/Installer's opinion, the delivery of the goods and services of one Lot will be complete and ready for Provisional Taking Over.
   c. Upon receipt of the above mentioned note and within 15 days after the receipt of the goods and the Services according to the specified requirements, the Purchaser shall conclude the Official Testing and Commissioning procedure.
   d. If the Purchaser fails to conclude the Official Testing and Commissioning procedure within the aforementioned term he shall be deemed to have issued the preliminary Taking-Over Certificate on the last day of that period.
   e. The Purchaser shall evaluate, item by item, the consistency of the goods and the services supplied respecting the contract conditions and the technical specifications after the installation phase.
   f. The Supplier shall be invited by the Purchaser to assist with the measurement operations. At the end of the operations the Purchaser shall prepare minutes of the results and make it available to the Supplier.
   g. Each item shall be declared as compliant, not-compliant or revisable.
   h. The official testing and commissioning is declared successful when all the items of a Lot are declared compliant.
   i. The Supplier shall substitute all not-compliant items with compliant ones at its own cost.
   j. An item is declared revisable only if it has minor defects or is not perfectly compliant. In these cases, only when the Supplier has substituted the item or has solved the defects, he can ask for a new official testing and commissioning.
   k. The not-compliant or revisable items shall be substituted or modified without any break of safety and Manufacturer rules, any cost for the Purchaser or any extension to the contractual deadlines. Any delay due to not-compliant or revisable items is [the] responsibility of the Supplier, thus liquidated damages are applicable.
   l. The Goods are taken over by the Purchaser once they have been supplied together with the services in accordance with the Contract. Within two weeks after successful official testing and commissioning of all the items of one Lot and of one Hospital the Purchaser shall deliver to the Supplier the Preliminary Taking Over Certification. This Certificate shall be deemed to signify the Purchaser's satisfaction with the supplied Goods and Services and therefore the completion of the Supplier's obligations under Contract for the said Hospital.
   m. The warranty period shall commence on the date of Preliminary Taking Over stated in the Preliminary Taking-Over Certificate.

8. Manufacturer Warranty
   a. The manufacturer warranty certificate will be in the name of the final Beneficiary.
   b. The warranty period will be not less than specify manufacturer warranty duration starting from the date of issuance of the preliminary acceptance (before installation).
   c. The warranty will cover the entire machine including any and all component parts, spare parts, software modules, accessories and consumables thereof. The warranty coverage will be applied fully and without any cost to Beneficiary and to the users whatsoever, including but not limited to the cost of visits, labor, spare parts, and shall be valid for unlimited consultations within the warranty period save in cases of proven misuse, intentional damage, or force majeure.
   d. If in the opinion of the Supplier, Goods were subject to misuse, intentional damage or force majeure; therefore, not covered by warranty, the Supplier should present indubitable proof of such misuse, intentional damage or force majeure.

e. The Manufacturer warranty will be carried out at manufacturer premise, being all the travel and transport cost covered by the Supplier.

9. Supplier/installer additional Warranty
   a. The supplier warranty integrates the manufacturer warranty both for coverage and duration.
   b. The supplier warranty certificate will be in the name of the final Beneficiary.
   c. The warranty period will be not less specify supplier warranty duration starting from the date of provisional taking over (after installation and commissioning).
   d. The Supplier/Installer additional warranty will be at delivery place, being any cost of equipment transport or technician travelling at Supplier/Installer charge and included in the offered price.
   e. At least 95% of one single year of full functioning, i.e. 347 days out of 365/366 days, will be guaranteed by the Supplier within the warranty period. In the event that the equipment supplied has been malfunctioning for more than five percent (5%) of one single year of the warranty period, i.e. more than 18 natural days in one single year, the Supplier shall extend the warranty period for a duration of six times of the time duration when the equipment was malfunctioning.
   f. The time elapsed between the communication about the broken equipment and the intervention on site will be, inside the warranty period, not longer than 5 business days.
   g. During the warranty validity period the programmed on-site maintenance and calibration visits will be at least 2 per year. The schedule of the visit will be presented before the taking preliminary taking over certification. During the visits a concise additional training will be provided to the users and to the maintenance personnel.
   h. During on-site maintenance and calibration visits a short user training update will be carried out by the Supplier/Installer.

10. Final Taking Over Certificate
    a. Within one month after expiration of the Warranty Period for the Goods or any part and in case the Supplier has fulfilled all his obligations under Contract, the Purchaser's shall issue and send to the Supplier a Final Taking-Over Certificate.
    b. Before issuing the Final Taking-Over Certificate, the Purchaser shall receive from the Supplier a written warranty that the manufacturer will continue to grant the availability spare parts and Support Services for the Goods for Specify duration for spare parts availability.

Annex F. Special condition clause on equipment training requirements

Supplier will provide the following training services.

1. Training for equipment users.
   a. The Supplier/Installer shall train the users on the correct operation of the equipment.
   b. The training course for users shall be theoretical and practical, using the equipment in the offered configuration and planning simulations of all possible mistakes occurring during equipment utilization. The trainees will serve as trainers to other equipment users.
   c. The training course shall be organized for at least five trainees.
   d. The location of the training course for equipment users shall be at a location designated by the Purchaser.
   e. The Supplier shall provide the training material. The training material will be in the English language and should include materials and resources that will support the trainees in their role as trainers.
   f. The trainers shall be qualified experts belonging to the Manufacturer Company and/or manufacturer representatives in Tanzania and/or by qualified experts certified by the Manufacturer. The course will be held in the English language.
   g. The training course for users shall focus on at least the following topics:
      - Presentation and contacts of the reference technicians.
      - General equipment functions in the offered configuration, alarm signals, and error signals showing all the possible equipment functionalities.
      - Calibrations, daily cleaning, and maintenance operations.
      - Correct equipment utilization and related possible risks for users and patients.
   h. The average duration of the training course will be not less than 4 hours per each unique equipment.
   i. The evaluation of the know-how acquired will be done through two tests: one entrance test at the beginning of the course and one final test at the end. The trainees shall confirm that the received training is satisfactory.
2. Training for maintenance personnel.
   a. The Supplier shall train technicians made available by the Purchaser in the most frequent problems that could occur during equipment utilization and that are under maintenance technicians' competencies.
   b. The training course for maintenance technicians shall be both theoretical and practical, using the equipment in the configuration as purchased. The trainees will serve as trainers to other maintenance technicians.
   c. The Supplier shall provide the training material. The training material will be in the English language and should include materials and resources that will support the trainees in their role as trainers.
   d. The training course for maintenance technicians shall be organized for a minimum of three persons to a maximum of [provide the maximum number of persons for the training] persons.
   e. The location of the training course for maintenance technicians shall be in Tanzania at a location designated by the Purchaser.
   f. The trainers shall be qualified experts belonging to the Manufacturer Company and/or manufacturer representatives in Tanzania and/or qualified experts certified by the Manufacturer. The course will be held in the English language.
   g. The training course for maintenance technicians shall focus at least on the following topics:
      - Presentation and contacts of the reference technicians.
      - General equipment functions, specific technical characteristics, and alarm signals.
      - Main electrical and functional schemes.
      - Calibrations and daily maintenance in order to ensure the longest equipment life.
      - Corrective maintenance (to solve the most frequent problems).
      - Equipment safety controls.
      - Preventive maintenance and its regular reoccurrence.
      - Corrective maintenance to solve the most frequent problems.
   h. The average duration of the training course will be not less than 4 hours per unique equipment.
   i. A pre- and posttest of the trainees shall be organized in order to verify the know-how acquired. The results shall be delivered to the Purchaser before commissioning.

All expenses associated with the Supplier's provision of trainers and training material for the above trainings will be at the Supplier's expense.

Annex G. Template for supplier total cost of ownership costs

Expenses			Total cost	
COST CATEGORY 1	COST ITEMS	UNIT COST	QTY YRS	SUBTOTAL COSTS
All initial costs on purchase (one-off)	Unit price			
	Accessories			
	Packaging			
	Delivery costs			
	Taxes			
	Installation/integration/ engineering/calibration costs			
	Training costs			
	Subtotal			
COST CATEGORY 2	COST ITEMS	UNIT COST	QTY YRS	SUBTOTAL COSTS
Regular ongoing operational costs (per annum)	Annual licenses			
	Consumables 1 (e.g., disposables)			
	Consumables 2 (e.g., cleaning products)			
	Consumables 3 (e.g., health and safety equipment)			
	Consumables 4 (e.g., paper)			
	Software and hardware upgrades			
	Staff training			
	Subtotal			
COST CATEGORY 3	COST ITEMS	UNIT COST	QTY YRS	SUBTOTAL COSTS
Regular service and maintenance (per annum)	Annual maintenance—service contract			
	Preventative maintenance—service contract			
	Labor only			
	Other maintenance			
	Spare parts			
	Hire of replacement equipment during downtime			
	Costs associated with additional work requested			
	Overtime costs			
	Equipment refresh—evergreen programs			
	Supplier travel and accommodation costs			
	Subtotal			

COST CATEGORY 4	COST ITEMS	UNIT COST	QTY YRS	SUBTOTAL COSTS
Fuel/energy costs (per annum)	Electricity			
	Water			
	Gas			
	Subtotal			
COST CATEGORY 5	**COST ITEMS**	**UNIT COST**	**QTY YRS**	**SUBTOTAL COSTS**
Anticipated downtime (per annum)	Planned maintenance outages—additional costs			
	Unplanned outages—additional costs			
	Unplanned outages—lost revenue			
	Subtotal			
COST CATEGORY 6	**COST ITEMS**	**UNIT COST**	**QTY YRS**	**SUBTOTAL COSTS**
Disposal costs (one-off not per annum)	Decommissioning/ deconstruction costs			
	Cost of transportation of equipment from site			
	Disposal costs (e.g., reagents, hazardous items)			
	Restoration of site to original state			
	Write-off			
	Subtotal			
Total expenses costs	**Total of cost categories 1 to 6**			
INCOME		**UNIT COST**	**QTY YRS**	**SUBTOTAL COSTS**
Income on disposal (one-off not per annum)	Trade-in value			
	Resale/salvage value of equipment			
	Resale/salvage value of parts			
	Resale/salvage value of operational items (e.g., consumables)			
	Subtotal			
Total operating cost	**Total expenses costs minus income**			

Note: For the supplier to provide an approximate trade-in value for the equipment, the purchaser should provide the supplier with the expected number of years after which the equipment will be traded in.

Annex H. Arrangements for installation of medical equipment[27]

STEP	ARRANGEMENTS
Ensure the work site is ready	• Ensure all site preparation work is complete. • Ensure lifting equipment is available if necessary.
Identify staff to learn from and monitor the work	• Draw up lists of: – the user staff to observe and learn from the installation and commissioning work. – suitable maintenance staff to learn from and monitor the installation and commissioning work. • Ensure they attend at the correct time and place.
Liaise with the in-house/ visiting installation team	Discover: • how the installation and commissioning will be provided. • any needs they have. • whether initial training will take place at the same time or at a later date.
Provide the necessary inputs	Organize (as necessary): • overnight accommodation for the installation team. • travel and subsistence for the installation team (for local staff and those from abroad). • any materials for installation that you are responsible for providing (such as cable, plugs, piping). • any materials for checking operation that you are responsible for providing (such as consumables used whilst ensuring equipment is performing correctly).
Ensure you know what you are doing	• Gather together the necessary assembly, installation, commissioning, and safety testing instructions. • If these are not in the manuals/videos that came with the equipment, liaise with the equipment manufacturer/supplier.
Provide the necessary working space	Organize: • a secure room which can act as a store for the installation team's materials and instruments. • suitable access for the installation team to the user department when large/heavy equipment is being installed and commissioned in situ. • a suitable work room for the installation team when portable equipment is being assembled and commissioned, which: – is secure, but has adequate fire exits and fire extinguishers. – has sufficient workbenches. – has access to proper power and water supplies, and gas cylinders. – is clean and dust-free.

Annex I. Key steps in the equipment commissioning process[27]

STEP	ARRANGEMENTS
Check the documentation	• make sure all the relevant documentation is available (for example, manuals, instructions). • place it where staff can easily gain access to it during commissioning. • during commissioning check that everything that is mentioned in the documentation is available and functioning on the machine.
Prepare the equipment for use	• fit the correct mains plug to the mains lead. • attach any accessories. • carry out any relevant warm-up processes (for example, with a boiler, ensure electrodes are activated, and carry out pre-burn runs, burn runs, blow throughs, etc.). • where applicable, allow the equipment to go through any built-in self-check or test programmes on start up (such as infant resuscitation tables, bench-top autoclaves, diathermy units). • where applicable, place the equipment 'on-charge' (such as defibrillators).
Undertake safety tests	• ensure all electrical equipment is tested for adequate insulation and earth connections. • ensure all electro-medical equipment is tested for compliance with IEC 60101 electrical and medical safety standards to guarantee patient and operator safety. This is particularly important if there has been a significant time lapse since installation. • consider mechanical safety aspects, visually inspect the equipment, and study drawings. • if harmful radiation is produced (β, γ or X-rays), carry out tests to ensure correct calibration and safe use.
Initial calibration	• adjust the equipment to prevailing conditions (climate, electricity supply, altitude, etc.) so the readings are true. For example: – adjust laboratory counters to give reliable readings. – adjust air conditioners to the right setting for cooling rooms. – provide X-ray units with sufficient power output to provide the required dosage to patients.
Calibration	• ensure that the equipment provides dependable and accurate results. If calibration is not done, the equipment may not function properly. For instance, an autoclave could go through its operational cycle without reaching the correct temperature to sterilize. • ongoing re-calibration is required throughout the life of the equipment to ensure that it is in a proper, accurate working condition. These tasks could eventually be carried out by users and maintenance technicians, depending on the equipment model type and its sophistication.
Function tests	• for larger or complex equipment like autoclaves, laboratory analysers or X-ray machines, run the manufacturer's recommended methods/protocols on phantoms or known samples to ensure the method is adequate and the results are acceptable and stable over time. • process a few control samples, or samples of known value, to make sure the equipment is functioning properly. • both maintenance staff and operators should cooperate in performing such tests.
Record the results	• keep records of all test results in the Equipment File. • note and record any technical issues in the Equipment File. • fill in the relevant sections of the Acceptance Test Logsheet, when the work has been completed satisfactorily and all tests have been passed.

Annex J. Arrangements for initial equipment training[27]

STEP	ARRANGEMENTS
Identify the trainees to be present at the initial training sessions	• Draw up lists of: – the user staff to obtain skills in handling, operation, application, cleaning, safety, user PPM, etc. – the maintenance staff to obtain skills in operation, cleaning, safety, PPM, repair, etc. – any staff that can be trained as trainers. • Ensure they attend at the correct time and place, and record that they do so. • Decide whether to run several training sessions to cover staff on different shifts, or make use of follow-up training (see below).
Liaise with the in-house/ visiting training team	Discuss: • The types of training required and how it should be pitched to suit the skill base of the staff. • How the training will be provided. • Whether initial training will take place at the same time as commissioning or at a later time. • How long the different types of training sessions will take.
Confirm your booking at the training site	This might be: • At the manufacturer's factory or at their local representative's workplace. • At your health facility or at a central location for training. • In a special training room and/or around the equipment in situ.
Identify the numbers to be trained	Decide: • how many staff need training at each site. • how many times the training sessions should be run.
Provide the necessary inputs	Organize (as necessary): • room hire. • overnight accommodation for the trainees or trainers. • travel and subsistence for the trainees or trainers (for local staff and those from abroad). • trainers' fees (if not in the purchase contract). • visual aids and teaching equipment. • training materials (hand-outs) for the trainees.
Organize follow-up training	Decide: • how many additional staff, who did not attend the initial training sessions, require training. • which trainer or previously trained staff can train them. • how many times the training sessions should be run. • when they should take place.

Annex K. Needs assessment and acceptance criteria for medical device donations

a. Needs assessment (using oxygen as an example)

If a needs assessment, as discussed earlier in the *Procurement Guide*, has been conducted to quantify the need for oxygen, then the overall gap in meeting the health facility's oxygen needs has been identified. As part of the procurement planning process, that identified gap would have been compared to the funding available for procuring oxygen delivery devices to meet the health facility needs. If available funding is not sufficient to procure 100 percent of the identified oxygen delivery needs, then a gap still remains in meeting the health facility's oxygen therapy needs. This remaining gap could be addressed by soliciting appropriate donations of oxygen delivery devices from donors. If a needs assessment has not been conducted, then it is important to do so to quantify the oxygen therapy gap that would be addressed through a donation process.

b. Identify the criteria for accepting or rejecting a medical device donation

To ensure that the donated oxygen delivery device will be sufficient to meet the health facility's oxygen needs, it is important for the recipient to identify to the donor the criteria with which the donated oxygen delivery device must comply. Here again is an opportunity to draw upon work performed during the procurement planning process—the development of technical specifications. If technical specifications have been developed, then the performance and other technical criteria for the oxygen delivery device have been identified and the health facility can submit the technical specifications to the potential donor to establish the requirements for an oxygen delivery device donation that meets the health facility's needs. The technical specifications should identify the safety requirements for the equipment, and accessories and spare parts needed to keep the equipment operational.

It is also good practice for the recipient to request the following information from the donor:

- Confirmation that the donated medical device complies with national donation policies (if such policies exist) and is registered in accordance with national registration requirements.
- Confirmation that the donated medical device is fully operational and functional at all system levels.
- Confirmation that manufacturer's sales and service support will be available for a minimum of two years, and preferably four years.
- Confirmation of the operational requirements that need to be addressed to ensure functional use of the medical device, such as operational training needed, and any necessary consumables that are required to operate the equipment.
- Confirmation of the installation requirements for the medical device, such as space and electrical power, if installation is required.
- Confirmation of the maintenance requirements, such as technical training and preventive maintenance materials that are needed to ensure the sustainable operation of the donated medical device.[28]

The health facility also has the responsibility to ensure that it is fully prepared to effectively use and sustain the operation of any medical device that it accepts as a donation. To do so, the health facility should undertake the following measures.

- Identify how the life cycle operational costs for the donated medical device will be supported.
  - Using a total cost of ownership approach, identify the operational costs that will be required to sustain the functional performance of the donated medical device on an annual basis. Confirm that a secure source of funding is available to support the total operational costs. If it is determined that sufficient funds are not available to support the projected operational costs, the recipient can initiate discussion with the donor on the possibility of the donor also donating additional items, such as consumables, to reduce the funding the recipient would need to secure to support the total cost of ownership for the donated medical device.
- Identify how the technical resources needed for medical device operation and maintenance will be supported.
- Confirm that staff will be available to both operate the donated medical device and perform repairs and maintenance on the device as needed. This requires confirmation that the donor will provide training to the health facility staff to perform these functions. If the donated medical device is technically complex and health facility staff do not have the necessary background to be trained to repair and maintain the medical device, then local service support needs to be confirmed and the cost for such support included in the total operational cost projection discussed above.[29]

References

1. *WHO-UNICEF Technical Specifications and Guidance for Oxygen Therapy Devices*. Geneva: World Health Organization and the United Nations Children's Fund (UNICEF); 2019. WHO Medical Device Technical Series. Licence: CC BY-NC-SA 3.0 IGO. https://apps.who.int/iris/bitstream/handle/10665/329874/9789241516914-eng.pdf?ua=1.

2. Adapted from: World Health Organization (WHO). *Procurement Process Resource Guide*. Geneva: WHO; 2011: 13. WHO Medical Device Technical Series. https://apps.who.int/iris/bitstream/handle/10665/44563/9789241501378_eng.pdf?sequence=1.

3. World Health Organization (WHO). *Health Technology Assessment of Medical Devices*. Geneva: WHO; 2011:8. WHO Medical Device Technical Series.

4. An example of applying a heath technology assessment process can be found in: National Health Systems Resource Centre India, World Health Organization (WHO). *Compendium of Health Technology Assessments: An Evidence Based Approach to Technology-Related Policy Making in Health Care*. Geneva: WHO; 2014. http://nhsrcindia.org/sites/default/files/practice_file/Health%20Technology%20Assessments.pdf. This document illustrates how a heath technology assessment process was used to assess 12 health care technologies, including an oxygen concentrators to treat chronic obstructive pulmonary disease, to identify the clinical benefits and cost-effectiveness of the technologies, and the ethical and regulatory issues that need to be considered.

5. A survey conducted by PATH in 2016 found that of 105 country national essential medicines lists, more than 30 percent did not include oxygen and approximately half listed oxygen only for anesthesia. See: PATH. ***Oxygen is Essential: A Policy and Advocacy Primer***. Seattle: PATH; 2017. https://www.path.org/resources/oxygen-is-essential-a-policy-and-advocacy-primer/.

6. World Health Organization (WHO). *WHO Model List of Essential Medicines: 20th List (March 2017)*. Geneva: WHO; 2017. http://apps.who.int/iris/bitstream/handle/10665/273826/EML-20-eng.pdf?ua=1; World Health Organization (WHO). ***WHO Model List of Essential Medicines for Children: 6th List (March 2017)***. Geneva: WHO; 2017. http://apps.who.int/iris/bitstream/handle/10665/273825/EMLc-6-eng.pdf?ua=1.

7. Additional information on oxygen cylinders—such as cylinder sizes, filling, and maintenance requirements—can be found in: Bland H, Borton C, Jafri S. The supply of anaesthetic and other medical gasses. *ClinicalGate*. February 27, 2015. https://clinicalgate.com/the-supply-of-anaesthetic-and-other-medical-gasses.

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For more information

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