SUPPLY INTELLIGENCE



December 2020

Acknowledgments

The Respiratory Care Equipment Market Report was developed by PATH and the Clinton Health Access Initiative (CHAI) as part of the COVID-19 Respiratory Care Response Coordination project—a partnership between PATH, CHAI, and the Every Breath Counts coalition to support country decision-makers in the development and execution of a comprehensive respiratory care plan to meet the demands of COVID-19. The project is also pursuing strategies to help prioritize and improve access to oxygen therapy and other essential equipment involved in respiratory care as an integral part of health systems strengthening, beyond the pandemic response. For information: oxygen@path.org.

The report was written by PATH staff Evan Spark-DePass and CHAI staff Jason Houdek and Marissa Wu. Data compiled in this report were collected by PATH China Hub staff, led by Guang Gao and Junchen Li, and by CHAI staff Cynthia Liao, Max Wang, Sheldon Xie, and Yizi Yang.

The authors would like to thank the following individuals and organizations for their insightful feedback and support: Audrey Battu (CHAI), Adriana Velazquez Berumen (World Health Organization [WHO]), Janet Diaz (WHO), Martha Gartley (CHAI), Michael Griffin (WHO), Zachary Katz (CHAI), Felix Lam (CHAI), Lisa Smith (PATH), and Laura Alejandra Velez (WHO).

Finally, the authors would like to thank all of the manufacturers who provided information on their products and services to make this report possible. While a prioritized list appears in this report, PATH and CHAI are grateful to over 200 manufacturers who contributed detailed market intelligence as part of this effort.

Table of contents

Abbreviations	ii
Document guide	
Objective	1
Section guide	2
Considerations for product deployment	
Considerations for product selection	
Identified suppliers	3
Aggregated price range	3
Concentrator supplier landscape	4
Considerations for product deployment	4
Considerations for product selection	4
Identified suppliers	5
Aggregated price range	6
Cylinder supplier landscape	7
Considerations for product deployment	
Considerations for product selection	
Identified suppliers	
Aggregated price range	
Delivery interface supplier landscape	10
Considerations for product deployment	
Considerations for product selection	
Identified suppliers	11
Aggregated price range	
Handheld pulse oximeter supplier landscape	14
Considerations for product deployment	
Considerations for product selection	
Identified suppliers	
Aggregated price range	
Patient monitor supplier landscape	17
Considerations for product deployment	
Considerations for product selection	
Identified suppliers	
Aggregated price range	
Vacuum/pressure swing adsorption plant supplier landscape	21
Considerations for product deployment	
Considerations for product selection	
Identified suppliers	
Aggregated price range	
References	

Abbreviations

ANSI American National Standards Institute

BS British Standards

BSP British Standard Pipe

CE Conformité Européenne [European Conformity]

CFS Commodity Flow Survey

CGA Compressed Gas Association

DISS Diameter-Index Safety System

DOT Department of Transportation

EN European standards

EU European Union

FDA Food and Drug Administration

ICU intensive care unit

IEC International Electrotechnical Commission

IP Ingress Protection

ISO International Organization for Standardization

L liter

LMIC low- and middle-income countries

LPM liters per minute

m⁽³⁾ (cubic) meter

PSA pressure swing adsorption

SpO₂ oxygen saturation

SRA stringent regulatory authority

TPED Transportable Pressure Equipment Directive

TUV Technischer Überwachungsverein [Technical Inspection Association]

WHO World Health Organization

Document guide

Objective

The primary objective of this document is to provide a preliminary guide to available suppliers with capacity to provide equipment for respiratory care. This document is intended to help buyers conduct an initial assessment of the supplier landscape for each product of interest. For each product, a list of suppliers, a brief overview of critical technical specifications to consider, and a product price range is included.

While this report was motivated by an anticipated increase in demand for oxygen and respiratory care products due to the COVID-19 pandemic, all of the products covered in this report are relevant for non-COVID-19 clinical oxygen provision, as well. The report covers oxygen concentrators, cylinders, delivery interfaces, handheld pulse oximeters, patient monitors, and vacuum / pressure swing adsorption (PSA) plants.

Buyers who may find this report useful include government purchasers, such as ministries of health; regional procurement platforms; and global procurers, such as multilateral agencies. Buyers can use the information in this report to help inform considerations around product selection and deployment, better understand product offerings and pricing, and access supplier-specific information, such as quality and production capacity.

Audiences that may also benefit from the market report are distributors and wholesalers who work closely with suppliers, as well as suppliers themselves, who can derive a deeper understanding of the competitive landscape for their products through review of this report.

This market report is focused primarily on Chinese manufacturers of respiratory equipment, as partner organizations and governments expressed the most uncertainty about potential suppliers from this market at the outset of the pandemic. The only exception is the PSA section, which is based on a globally representative sample. Future iterations of this report will expand the geographic scope across product areas to reflect suppliers located in a broader range of countries. The information included in this document was originally gathered between March and August 2020 and will be periodically updated as new information is made available, without routine data collection from any specific set of suppliers. Any information should be taken as indicative only and confirmed directly with individual suppliers by the buyer at a relevant stage in the procurement process.

Further, this information should be evaluated in the context of anticipated peak oxygen demand from epidemiological modeling and other available oxygen supply sources, which will inform the volume and type of respiratory care products needed.

For additional references on developing procurement criteria, the latest guidelines from the World Health Organization for purchasing oxygen therapy devices can be found here.

Last updated December 2020

¹ The date indicating when information was most recently gathered is indicated at the bottom of each product's landscape section.

Section guide

This guide provides an overview of the information in each product-specific landscape included in this report. Each product landscape follows the same structure, with four primary headers: (1) considerations for product deployment; (2) considerations for product selection; (3) identified suppliers; and (4) aggregated price range.

Considerations for product deployment

For each technology, we outline what the potential uses are for a product and how the product fits into the continuum of respiratory care.

Generally, when considering how a product will be deployed, it is critical to consider the context into which it will be introduced. Buyers should carefully devise required product specifications and options based on the intended use of each product and the requirements of existing diagnostic and treatment delivery systems, as well as require suppliers to provide documentation of conformity.

We also encourage buyers to plan for how the product will be used in a post-pandemic setting, particularly for those technologies with long life spans.

Considerations for product selection

For each technology, we establish criteria for selection according to five categories: (1) quality, (2) ability to service the market, (3) functional requirements, (4) operational requirements, and (5) price. While these categories remain consistent across the range of products in the report, the selection criteria in each section is tailored to each product specifically.

Buyers are advised to review the criteria as a starting point, determine those most relevant to their context, and then require confirmation and specific documentation from suppliers to show that product models selected meet those specifications. This process can be undertaken at the Expression of Interest or bid phase of the process.

In general, many parameters could be considered "optional configurations" to base models by manufacturers. Thus, as the buyer proceeds with purchase orders, care should be taken to ensure the correct parameters are requested in the bid process and final purchase order.

Moreover, many suppliers may not have completed testing to the requested specifications because the markets and customers they typically serve do not require them. In these cases, suppliers are unlikely to claim meeting compliance with these specifications but may be able to do so if suitable testing can be arranged. We recommend that, where thresholds for individual specifications cannot be adjusted and mitigation strategies are not available, suppliers whose products come close to meeting requested specifications be engaged to assess the feasibility of rapidly performing additional testing.

In some cases, particularly with features or quality characteristics considered essential, buyers may wish to consider third-party testing. Sometimes separate distributors of a particular product model will make different claims about specific technical features.

In this report, "high-quality suppliers" are defined as those having the capacity to deliver models which have the critical features for their target use and meet recognized quality assurance criteria. This can be determined by gathering detailed technical and quality certification documents and reviewing these against World Health Organization specifications and/or a set of internal technical specifications.

Identified suppliers

For each technology, prioritized suppliers are presented according to quality standards, production capacity, and, in some cases, product design and specification considerations. As future iterations of the market report are developed, we will expand these sections to cover a broader range of geographies.

Aggregated price range

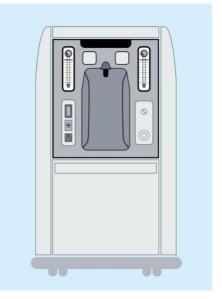
For each technology, we provide anonymized price ranges for the identified suppliers. Where possible, comparisons are made according to product features.

Prices should be taken as indicative only and may be highly variable depending on the urgency of the order, volumes required, requirements for various international regulatory specifications or certifications, and other contextual factors. In individual scenarios, there may be significant room to maximize value for money and adjust an initial quote from a supplier depending on these factors. It is also important to note that, for every product other than PSAs, the prices reflect Chinese companies solely and may not reflect broader pricing trends globally.

Concentrator supplier landscape

Considerations for product deployment

Oxygen concentrators are indicated as priority medical devices in the case management of COVID-19 patients.¹ Oxygen concentrators are electrically powered medical devices designed to concentrate oxygen from ambient air and deliver oxygen to the bedside, typically through a nasal cannula. They are intended to deliver continuous oxygen, typically between 3 liters per minute (LPM) and 15 LPM at low pressures. While various configurations of these devices are available in the market, this landscape covers concentrators with output flow rates of 5 LPM, 8 LPM, and 10 LPM, as outlined in the World Health Organization (WHO) technical specifications.²



Considerations for product selection

To inform decisions on which products should be considered for procurement, the following selection criteria can be considered:

- Quality: Availability of ISO [International Organization for Standardization] 13485, ISO 80601-2-69, and IEC [International Electrotechnical Commission] 60601-1-11 certifications; registration in stringent regulatory authority (SRA) markets such as CE [Conformité Européenne, or European Conformity] and US Food and Drug Administration [FDA]); and export authorization from the supplier's country.
- Ability to service the market: Production capacity and capability to either scale or allocate required volumes for
 procurement, as well as availability of bundled spares, accessories, and warranty.
- Functional requirements: Prioritization of critical elements for the context of use, including but not limited to:
 - o Oxygen purity.
 - Output pressure.
 - Power efficiency.
 - o Filter system.
 - Necessary features for usability (e.g., monitor, outlets, wheels, and alarms).
- Operational requirements: Capability to be used within a specific temperature range and range of relative humidity, as well as with basic power requirements. These should be based on specific geography and context of use.
- **Price**: Pricing that is competitive within the global market and provision of critical product features, requirements for prepayment, and potential procurement volumes per supplier.

Based on information collected, the following product requirements may impact the number of models available for procurement:

Flow rate (measured in LPM): Models capable of increased flow rates are typically available in lower volumes due to
lower consumer-level demand and require longer lead times due to the additional size and complexity in
manufacturing. Many suppliers offer several models of varying flow rates.

- Ability to operate at greater than 65 percent relative humidity: All models identified were able to operate at
 between 20 and 65 percent humidity, with some able to operate at up to 95 percent humidity. Buyers should
 carefully consider the operating environment to determine the required operating range for temperature and
 humidity, as higher requirements will limit the availability to suitable models.
- Audio/visual alarms: Models offer various combinations of audible and/or visual alarms for specifications such as low oxygen concentration (less than 82 percent), low battery, power supply failure, high temperature, low-/high-/no-flow rate, and/or low/high pressure. However, few models offered all of these alarms on the base model. Additional alarms may be requested or added for an additional fee.
- Ability to operate in ambient temperatures in excess of 35°C: All models identified were able to operate at between 10°C and 35°C, with many able to operate at up to 40°C.
- *Warranty*: Most suppliers identified were able to offer a one-year warranty, and many were able to offer up to three years for an additional fee.
- **Spare parts and accessories**: Most suppliers have a detailed list of spare parts and accessories which can be bundled with the oxygen concentrator. These can include filters, humidifier bottle, nebulizer, spares, and flow splitters.

Identified suppliers

The ten companies identified below possess substantial available production capacity and the requisite quality certifications to verify their ability to meet international quality standards. Of these, all ten companies offer qualifying 5 LPM models, two offer qualifying 8 LPM models, and three offer qualifying 10 LPM models. Available production capacities based on most recent communications are summarized in Table 1.

Table 1. Summary of priority suppliers with available production capacity for SRA-approved oxygen concentrators.

Supplier		ISO 13485	Key International Markets	Estimated Production Capacity (Monthly)
10 LPM Concentrators				30,000
Jiangsu YuYue Medical Equipment & Supply Co., Ltd.	Yes	Yes	87 countries, including US, Columbia, India, Mexico, Sri Lanka	12,000
Longfian Scitech Co., Ltd.	Yes	Yes	160+ countries, with 10 years of export history, including in Africa, South Asia, Central America	8,000
Shenyang Canta Medical Tech	No	Yes	50+ countries, including North America, Europe, SE Asia, Middle East, Africa	10,000
Foshan Keyhub Electronic Industries	Yes	Yes	Foreign markets, including India, South America, SE Asia	10,000*
8 LPM Concentrators				6,200
Jiangsu YuYue Medical Equipment & Supply Co., Ltd.	Yes	Yes	87 countries, including US, Columbia, India, Mexico, Sri Lanka	3,200
Shenyang Canta Medical Tech	Yes	Yes	50+ countries, including North America, Europe, SE Asia, Middle East, Africa	15,000
Jiangsu Konsung Medical Equipment	Yes	Yes	Foreign markets, including US, Sri Lanka, Columbia, India	3,000
5 LPM Concentrators				55,740
Beijing Shenlu Medical Device Co.	Yes	Yes	20+ countries, including India, Iran, Chile, Thailand, Yemen, Georgia, Argentina, Slovenia, Oman, Malaysia, Jordan, Bangladesh, Algeria, Kenya	3,600
Jiangsu YuYue Medical Equipment & Supply Co., Ltd.	Yes	Yes	87 countries, including US, Columbia, India, Mexico, Sri Lanka	12,000
Jiangsu Folee Medical Equipment	Yes	Yes	SE Asia, Europe, the Americas	4,000

Supplier		ISO 13485	Key International Markets	Estimated Production Capacity (Monthly)
Longfian Scitech Co., Ltd.	Yes	Yes	160+ countries, with 10 years of export history, including in Africa, South Asia, Central America	8,000
Shenyang Aerti tech Co., Ltd	Yes	Yes	Top 3 foreign markets: South Asia, Eastern Asia, Africa	1,740
Shenyang Canta Medical Tech	Yes	Yes	50+ countries, including North America, Europe, SE Asia, Middle East, Africa	15,000
Shenyang Sysmed Co., Ltd	Yes	Yes	Foreign markets, including US, India, Sri Lanka	8,400
Foshan Keyhub Electronic Industries	Yes	Yes	Foreign markets, including India, South America, SE Asia	10,000*
Jiangsu Konsung Medical Equipment	Yes	Yes	Foreign markets, Including US, Sri Lanka, Columbia, India	2,800
Zhengzhou Olive Electronic Technology Co., Ltd.	Yes	Yes	120 countries worldwide, including South America, Africa, South Asia	1,200
Total # of devices				91,940

^{*}Combined capacity between all concentrators

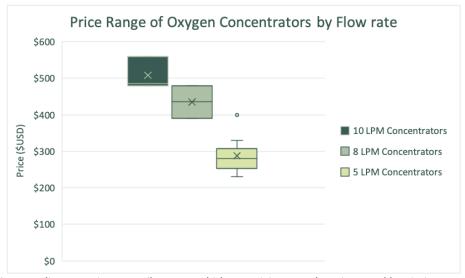
Abbreviations: CE, Conformité Européenne [European Conformity]; LPM, liters per minute; SRA, stringent regulatory authority.

Based on the information collected, all suppliers identified have significant experience in international markets, including lowand middle-income countries (LMIC), and sufficient production capacities. Procurement agreements may be prioritized by available volumes and lead times, as well as individual product considerations described in the section above.

Aggregated price range

Prices should be taken as indicative only and will be highly variable depending on urgency, volumes required, and other contextual factors. Initial quotes received ranged from US\$230 to \$400 for 5 LPM models, \$390 to \$480 for 8 LPM models, and \$480 to 560 for 10 LPM models. Figure 1 shows the anonymized pricing data collected from prioritized suppliers for the 5, 8, and 10 LPM models. Models identified offered all critical features, with some variation in spares and accessories offered at the base price.

Figure 1. Aggregated price range from identified suppliers for 5, 8 and 10 LPM models.



X= mean, Line = median, Box = interquartile range, Whiskers = minimum and maximum. Abbreviation: LPM, liters per minute.

Cylinder supplier landscape

Considerations for product deployment

Oxygen cylinders are priority medical devices in the case management of COVID-19 patients.¹ Oxygen cylinders are dedicated refillable containers for holding oxygen/medical gases in a high-pressure, nonliquid state. They are designed to store and transport medical oxygen within and between health facilities and can be connected to a manifold for pipeline distribution or used bedside to provide oxygen directly to a patient.

Considerations for product selection

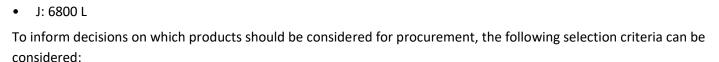
In this document, the following <u>sizes commonly used in health</u> <u>facilities</u> were considered, expressed as volume of gaseous oxygen at standard temperature and pressure (in liters [L]):



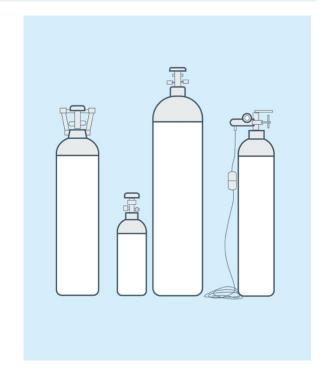
• E: 680 L

• F: 1360 L

G: 3400 L



- Quality: Availability of <u>ISO 13485</u> certifications if procuring from a medical device supplier; otherwise, availability of certifications pertaining to storage and transport of medical oxygen (such as <u>ISO 9809-1</u>, <u>7866</u>, <u>9001</u>, <u>BS [British Standards] EN [European standards] 1975</u>, <u>CEN [European Committee for Standardization] EN 12245</u>, <u>DOT [Department of Transportation]-3AA</u>), registration in SRA markets (i.e., CE and/or FDA), and export authorization from the supplier's country.
- Ability to service the market: Production capacity and capability to either scale or allocate required volumes for procurement, as well as availability of bundled accessories and warranty.
- Functional requirements: Prioritization of critical elements for the context of use, including but not limited to:
 - Valve type.
 - o Material.
 - Nominal pressure.
 - Compatibility with connected devices.



- Operational requirements: Capability to be used within a specific temperature range, within a range of relative humidity and elevation, and with color coding to meet local gas-storage standards. These should be based on specific geography and context of use.
- **Price:** Pricing that is competitive within global markets and provision of critical product features, requirements for prepayment, and potential procurement volumes per supplier.

Based on information collected, the following product requirements may impact the number of models available for procurement or procurement price:

- *CE/FDA marking*: Oxygen cylinders are not regulated as medical devices and therefore do not have independent regulatory approval. Instead, the FDA and European Medicines Agency regulate cylinders as container/closure systems for drugs, in this case medical gas. In addition, they may need to meet current Good Manufacturing Practices for the United States or Europe, depending on the geography.
- *Material*: Cylinders are typically constructed from steel, aluminum, carbon fiber, or other composite materials. Trade-offs exist between various materials—for example, cylinders made of steel/aluminum will be available at substantial cost savings over carbon fiber, but at an increased weight.
- Valve type: Integral vs. standard valves vary in cost. Integral valves are typically not available from Chinese manufacturers and are offered instead by oxygen generator suppliers inside a chain of custody agreement, due to cost and other considerations. If choosing a standard valve, buyers may wish to ensure compliance to international ISO and US standards (i.e., pin index ISO 407 / BS EN 850 / CGA [Compressed Gas Association] 870 valves, CGA 540 valve, 5/8" [British Standard Pipe] BSP [F] Bullnose BS 341 valve), as well as choose according to the size/pressure of the cylinder and to any applicable regulation. Most Chinese manufacturers carried pin index and bullnose valve products which met WHO specifications.
- Inclusion of accessories (i.e., pressure regulators, flowmeters, manometers, humidifiers, pressure gauges, and
 multiple fittings according to international standards): Accessory functions may be achieved by attaching individual
 devices, configured in a single composite device, or integrated into the cylinder construction, where available.
 Accessories will need to be individually reviewed to ensure they meet functional and quality requirements.
 Manufacturers who carry cylinders often provide these accessories, as well, and may offer premade bundles
 designed for specific contexts of use.
- Compatibility with filling and distribution: Cylinders must be fit for use with the prevailing configuration for filling or distribution, such as filling stations and distribution manifolds. These requirements in the place of intended use should be carefully checked to confirm compatible connections, including DISS [Diameter-Index Safety System] connections and 6 mm barbed outlets. Buyers should require documentation that prove cylinders offered conform to these local requirements during the Expression of Interest or bid process.
- **Safety features**: Specific ISO, ANSI [American National Standards Institute], and other international color coding for oxygen should be available, as well as inclusion of a safety overpressure release valve.

Buyers should carefully select required specifications and options based on the intended use of the cylinders and the requirements of existing filling and delivery systems and require suppliers to provide documentation of conformity.

Identified suppliers

Nine companies identified below possess the requisite quality certifications to verify their ability to meet international quality standards. Of these, six offered qualifying models with CE certification. Available production capacities based on most recent communications are summarized in Table 2.

Table 2. Summary of identified suppliers for cylinders.

Supplier	Quality Certifications	Estimated Production Capacity (Monthly)
Medease Life Co., Ltd.	ISO 13485	1,200–2,000*
Shanghai Bene High Pressure Container Co., Ltd.	ISO 9001	8,000
Shenyang Gas Cylinder Safety Technology	EN 1975 EN 12245, CE	2,000
Shandong Bee Gas Energy Tech Co., Ltd.	ISO 9809, ISO 9809-1,ISO 9809-3 DOT-3AA	12,000
Jiangsu Minnuo Special Equipment Co., Ltd.	ISO 9001	352–900*
Liaoning Alsafe Technology Co., Ltd.	ISO7866	20,000
Nanjing Ocean Industry Co., Ltd.	CFS, ISO 13485	1,000
Zhuolu High Pressure Vessel Co. LTD	ISO 9809-3	2,000
Shenyang Zhongfu Kejin Pressure Vessels Co., Ltd.	ISO 7866, TPED	30,000
Total # of devices		33,888

^{*}Depending on size

Abbreviations: CE, Conformité Européenne [European Conformity]; CFS, Commodity Flow Survey; DOT, Department of Transportation; EN, European standards; ISO, International Organization for Standardization; TPED, Transportable Pressure Equipment Directive.

Based on the information collected, procurement agreements may be prioritized by available volumes and lead times, as well as individual product considerations described in the section above.

Aggregated price range

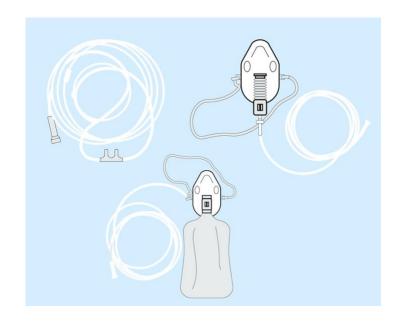
Prices should be taken as indicative only and may be highly variable depending on the urgency of the order, volumes required, requirements for various international regulatory specifications or certifications, and other contextual factors. Initial quotes received from identified suppliers ranged from \$54 to \$229 for J or equivalent size (~6800 L nominal content / oxygen capacity), with a median of \$71.

Last updated August 26, 2020

Delivery interface supplier landscape

Considerations for product deployment

Three oxygen delivery interfaces have been indicated as priority medical devices in the treatment of severe COVID-19 patients: nasal oxygen cannula (nasal prongs), venturi masks, and masks with reservoir bag. 1,2 They serve to deliver oxygen to patients in a variety of ways: nasal cannulas are single-use, nonsterile devices that deliver oxygen through the nasal cavity when connected to an oxygen source; venturi masks provide total inspiratory flow at a prespecified fraction of inspired oxygen; and masks with reservoir bags deliver higher concentrations of oxygen directly to the upper airway of the patient. This landscape provides a market overview of all three products as outlined in the WHO technical specifications.



Considerations for product selection

As the products examined here tend to lack standard specifications, suppliers of oxygen delivery interfaces can typically manufacture their products using a broad range of specifications as requested by the purchaser. In addition, most suppliers originate from countries where there is little regulation. Therefore, buyers should prepare detailed specifications prior to approaching suppliers to optimize time spent landscaping and procuring the products required.

To inform decisions on which products should be considered for procurement, the following selection criteria can be used:

- *Quality*: Availability of <u>ISO 13485</u> certifications, registration in SRA markets (i.e., CE and/or FDA), and export authorization from the supplier's country, as applicable.
- Ability to service the market: Production capacity and capability to either scale or allocate required volumes for procurement, as well as availability of bundled products, accessories, and warranty.
- Functional requirements: Prioritization of critical elements for the context of use—specifically, for delivery interfaces—include but are not limited to:
 - o Compatibility with standard connections.
 - o Low-resistance design.
 - Flow capacity.
 - Malleability.

- Operational requirements: Capability to be used within a specific temperature range and range of relative humidity and elevation; with appropriate sizing, materials, and components (including valves, connectors, etc.); and with oxygen concentration / oxygen-to-air mixture compatibility. These should be based on specific geography and context of use.
- *Price*: Pricing that is competitive within the global market and provision of critical product features, requirements for prepayment, and potential procurement volumes per supplier.

Based on information collected, a *CE/FDA marking* requirement may impact the number of models available for procurement. In some countries, including China, delivery interfaces fall under a class of products where CE and FDA compliance is self-certified and/or optional.

Supplier catalogues do not explicitly list all possible combinations and configurations—especially as they relate to sizing. However, most suppliers claim to carry products in all sizes common to domestic and international markets.

Identified suppliers

The eight companies identified below possess substantial available production capacity. All products included have ISO 13485 certification, as well as CE and FDA registration. Based on the information collected, all suppliers identified have significant experience in international markets, including LMIC. Many suppliers contacted reported that export and international sales, including regulatory approvals, were outsourced to international distributors. In these cases, manufacturers that do not have export permits and certifications may have export agents and distributors that will be able to make volumes available quickly on their behalf. Estimated total production capacities based on most recent communications are summarized in Table 3.

Table 3. Summary of priority suppliers with available production capacity for SRA-approved oxygen delivery interfaces.

Supplier	CE	FDA	Key International Markets	Product	Estimated Total Production Capacity (Monthly)
	Yes	Yes		Cannula - adults	1,600,000
	Yes	Yes	20+ years of experience, 100+ countries	Cannula - pediatric	1,600,000
	Yes Yes	Yes	SE Asia: Singapore, Philippines, Malaysia, etc.	Oxygen mask with reservoir bag - adults	1,600,000
MFlab Yes	Yes	Africa: South Africa, Libya, Egypt, Kenya, Namibia, Gabon.	Oxygen mask with reservoir bag - pediatric	1,600,000	
	Yes Yes	Middle East	Venturi mask - adults	1,600,000	
	Yes	Yes	ivildule East	Venturi mask - pediatric	1,600,000
	Yes	Yes		Oxygen tubing	4,000,000
	Yes	Yes		Cannula - adults	600,000
	Yes	Yes		Cannula - pediatric	600,000
	Yes	Yes		Oxygen mask with reservoir bag - adults	200,000
Weracon	Yes	Yes	Exports to 68 countries, including US, UK, Germany	Oxygen mask with reservoir bag - pediatric	200,000
	Yes	Yes		Venturi mask - adults	80,000
	Yes	Yes	Venturi mask - pediatric		80,000
	Yes	Yes		Oxygen tubing	600,000
	Yes	Yes		Cannula - adults	30,000

Supplier	CE	FDA	Key International Markets	Product	Estimated Total Production Capacity (Monthly)
Kyoling	Yes	Yes	Mainly US, Europe	Oxygen mask with reservoir bag - adults	30,000
Ryomig	Yes	Yes	Mainly 03, Europe	Venturi mask - adults	30,000
	Yes	Yes		Oxygen tubing	30,000
	Yes	Yes		Cannula - adults	80,000
	Yes	Yes		Cannula - pediatric	80,000
	Yes	Yes	Exports to Pakistan and United Arab Emirates, among	Oxygen mask with reservoir bag - adults	40,000
Excellentcare	Yes	Yes	others	Oxygen mask with reservoir bag - pediatric	40,000
	Yes	Yes		Venturi mask - adults	80,000
	Yes	Yes		Venturi mask - pediatric	80,000
	Yes	Yes	Oxygen tubing		200,000
	Yes	Yes		Cannula - adults	240,000
	Yes	Yes		Cannula - pediatric	240,000
	Yes	Yes	30+ countries, including US, Europe, Middle East, Asia, South America	Oxygen mask with reservoir bag - adults	50,000
Jodismed	Yes	Yes	- 500017781101102	Oxygen mask with reservoir bag - pediatric	50,000
	Yes	Yes		Venturi mask - adults	50,000
	Yes	Yes		Venturi mask - pediatric	50,000
	Yes	Yes		Oxygen tubing	240,000
	Yes	Yes		Cannula - adults	200,000
Shaoxing Jenston	Yes	Yes	EU markets, SE Asia, Mideast, Africa, the Americas	Oxygen mask with reservoir bag - adults	200,000
	Yes	Yes		Venturi mask - adults	40,000
	Yes	Yes		Oxygen tubing	320,000
Shenzhen	Yes	Yes	N/A	Oxygen mask with reservoir bag - adults	40,000
Yuantai	Yes	Yes		Venturi mask - adults	40,000
	Yes	Yes		Oxygen tubing	132,000
Huankang Medical	Yes	Yes	Exports to Europe, SE Asia, Middle East, South America, Africa	Cannula - adults	400,000

Abbreviation: SRA, stringent regulatory authority.

Aggregated price range

Prices should be taken as indicative only and will be highly variable depending on urgency, volumes required, and other contextual factors. Initial price ranges were quoted as follows:

Cannula: \$0.14 to \$0.39 a unit.

Oxygen mask with reservoir bag: \$0.38 to \$1.43 a unit.

Venturi mask: \$0.43 to \$1.57 a unit.

Oxygen tubing: \$0.12 to 0.43 a unit."

 $^{^{\}mbox{\tiny II}}$ Typically, between 1.5 and 2.0 meters (m).

Figure 2 shows the anonymized pricing data collected from prioritized suppliers for each product.

Price Range for Various Oxygen Delivery Interfaces \$1.80 \$1.60 \$1.40 \$1.20 ■ Cannula (adult+peds) Price (\$USD) \$1.00 ■ Mask with reservoir bag (adult+peds) Venturi mask (adult+peds) \$0.80 Tubing \$0.60 \$0.40 \$0.20 \$-

Figure 2. Aggregated price range from identified suppliers for 5 LPM models.

X= mean, Line = median, Box = interquartile range, Whiskers = minimum and maximum. Abbreviation: LPM, liters per minute.

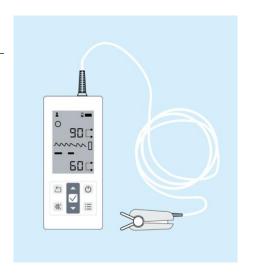
Last updated April 29, 2020

Handheld pulse oximeter supplier landscape

Considerations for product deployment

Pulse oximeters have been indicated as priority medical devices for patient monitoring in COVID-19 case management.¹ They are designed to monitor blood oxygen saturation (SpO₂) levels through transcutaneous measurements using plethysmography. Pulse oximeters are used to screen patients to determine whether oxygen therapy is needed, as well as to monitor patients who are on oxygen therapy. This landscape covers handheld pulse oximeters only.⁵

Given the overlap between pulse oximeter and patient monitor suppliers, it may be advantageous to issue purchase orders for both products simultaneously for the benefit of increased negotiating leverage, improved volume-based pricing discounts, and more efficient procurement and delivery processes.



Considerations for product selection

A high-quality supplier is identified as having the capacity to deliver models which have critical features for their target use. This can be determined by gathering detailed technical and quality certification documents and reviewing these against WHO specifications and/or a set of internal technical specifications. To inform decisions on which products should be considered for procurement, the following selection criteria can be considered:

- Quality: Availability of ISO 13485, ISO 80601-2-69, and IEC 60601-1-11 certifications; registration in SRA markets (i.e., CE and/or FDA); and export authorization from the supplier's country.
- Ability to service the market: Production capacity and capability to either scale or allocate required volumes for procurement, as well as availability of bundled spares, accessories, and warranty.
- Functional requirements: Prioritization of critical elements, including but not limited to:
 - Features relating to SpO₂ and pulse rate measurement range and accuracy.
 - Suitable alarms for patient monitoring.
 - Ability to be used with different-sized probes for adult and pediatric patients.
 - A display containing plethysmograph.
- Operational requirements: Capability to be used within a specific temperature range and a range of relative humidity, with replaceable or rechargeable battery power. Operational requirements should be based on specific geography and context of use.
- Price: Pricing that is competitive within the global market and provision of critical product features.

Based on information collected, the following product requirements may impact the number of models available for procurement:

• *Ingress Protection (IP) rating* (protection of electrical enclosures from foreign bodies): All models provided moisture protection with a rating of IPX1 or better.

- Device weight: All models identified weighed between 400 and 500 g.
- Ability to operate at greater than 75 percent relative humidity: All models identified were able to operate at less than 75 percent humidity, with some able to operate at up to 90 percent humidity.
- Warranty: All suppliers identified were able to offer a one-year warranty. Many were able to offer a two-year standard warranty for an additional fee.
- **Spare probes**: In particular, probes have a limited lifetime and can be a considerable portion of the cost of the product over time. This should be factored into the total cost of ownership.

Identified suppliers

Eight companies identified below possess substantial available production capacity and the requisite quality certifications to verify their ability to meet international quality standards. Available production capacities based on most recent communications are summarized in Table 4.

Table 4. Summary of priority suppliers with available production capacity for SRA-approved handheld pulse oximeters.

Supplier	Product Model	CE	ISO 13485	Key International Markets	Estimated Production Capacity (Monthly)
Utech	UT100	Yes	Yes	Europe, South America, Africa, Australia	5,000
Edan	Н100В	Yes	Yes	163 countries globally, including US and Europe; 6% of sales in Africa	3,000
Mindray	PM60	Yes	Yes	190+ countries; subsidiaries in 32 countries, including the Americas, Asia, N/S/E/W Africa; dedicated staff across Africa	2,800
Biolight	M800	Yes	Yes	160+ countries, with 10 years of export history, including in Africa, South Asia, Central America	9,000
Contec	CMS60C	Yes	Yes	Europe, North America, Asia, Africa, India	2,000
ChoiceMMed	MD300M	Yes	Yes	US, Europe, India, Africa, China; 250K sq. ft. warehouse in US to serve online and retail purchasing of fingertip pulse oximeter	1,500
TOTAL					17,100

Abbreviations: CE, Conformité Européenne [European Conformity]; SRA, stringent regulatory authority.

Based on the information collected, all suppliers identified have significant experience in international markets, including LMIC, and sufficient production capacities. Procurement agreements may be prioritized by available volumes and lead times, as well as individual product considerations described in the section above.

Aggregated price range

Prices should be taken as indicative only and will be highly variable depending on urgency, volumes required, and other contextual factors. Initial quotes received ranged from \$80 to \$217 per unit, with a median of \$100. Figure 3 shows what the anonymized pricing data collected from prioritized suppliers are and how the price range is influenced with the inclusion of specific technical requirements.



Figure 3. Aggregated price range from identified suppliers.

X= mean, Line = median, Box = interquartile range, Whiskers = minimum and maximum. Abbreviation: IP, Ingress Protection.

Models at the low end of the price range offered all critical features except one, and the specific missing feature varied in each case:

- Two of seven products investigated claimed IPX2 protection or better.
- Four of seven products investigated claimed to be able to function in a range of 10 to 90 percent humidity.
- Key price differentials were found in products with at least a two-year warranty offered at baseline, which increased the average price point by \$17 per unit.

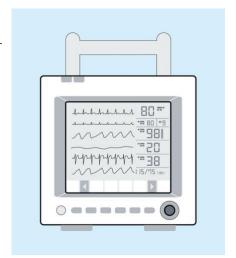
Last updated April 29, 2020

Patient monitor supplier landscape

Considerations for product deployment

Patient monitors, of varying configurations, have been indicated as priority medical devices for monitoring COVID-19 patients.¹ Patient monitors measure, calculate, and display physiological parameters (including vitals) for the continuous monitoring of hospitalized patients in severe condition and critical patients in intensive care units. While varying configurations of these devices are available in the market, this landscape covers products described as "basic" and "advanced" in terms of parameter configurations as outlined in the WHO technical specifications.²

Given the overlap between pulse oximeter and patient monitor suppliers, it may be advantageous to issue purchase orders for both products simultaneously for the benefit of increased negotiating leverage, improved volume-based pricing discounts, and more efficient procurement and delivery processes.



Considerations for product selection

A high-quality supplier is identified as having the capacity to deliver models which have critical features for their target use. This can be determined by gathering detailed technical and quality certification documents and reviewing these against WHO specifications and/or a set of internal technical specifications. Based on WHO guidelines, available in WHO COVID-19 Oxygen Devices Technical Specifications, Section 3.5,⁶ two main product categories were prioritized in this document:

- Multiparametric advanced patient monitors with seven desired measurement parameters: electrocardiogram, carbon dioxide, invasive blood pressure, SpO₂, pulse rate, respiratory rate, and temperature.
- *Multiparametric basic patient monitors* with five desired measurement parameters: noninvasive blood pressure, SpO₂, pulse rate, respiratory rate, and temperature.

To inform decisions on which products should be considered for procurement, the following selection criteria can be considered:

- Quality: Availability of ISO 13485, ISO 80601-2-69, and IEC 60601-1-11 certifications; registration in SRA markets (i.e., CE and/or FDA); and export authorization from the supplier's country.
- Ability to service the market: Production capacity and capability to either scale or allocate required volumes for
 procurement, as well as availability of bundled spares, accessories, and warranty.
- Functional requirements: Prioritization of critical elements for the context of use, including but not limited to:
 - Features relating to the ability to measure the desired parameters to the requisite performance.
 - o Suitable adjustable alarms for patient monitoring.
 - Appropriate display features.

- Operational requirements: Capability to be used within a specific temperature range and range of relative humidity, with replaceable or rechargeable battery power, appropriate input power, and protections against defibrillator discharges and electrosurgical units. Operational requirements should be based on specific geography and context of use.
- Price: Pricing that is competitive within the global market and provision of critical product features.

Based on information collected, the following product requirements may impact the number of models available for procurement:

- Screen size: Based on information collected, patient monitors with a screen size of 12" captured the range of products that tend to contain the most critical functional parameters for a broad range of applications (ruling out smaller vital-sign monitors that only contain basic parameters) and also tend to ensure large enough screen size for clinicians to monitor patients from a short distance if needed. However, it should be noted that many of the suppliers are able to provide other screen sizes (i.e., 10" and 14") if desired—with concurrent impact on pricing.
- Compatibility with pacemakers: Buyers should consider compatibility for use with pacemakers, such as models
 which use separate modes for pacemaker patients and/or have the ability to automatically detect that pacemakers
 will be required in target use cases. Despite generally being preferable due to enhanced safety measures, models
 offering automatic pacemaker detection appear rare in the Chinese market, and none of the models listed in Table 5
 below offers this feature.
- Ability to operate at greater than 85 percent relative humidity: All models identified were able to operate at less than 85 percent humidity, with some able to operate at up to 90 percent humidity.
- *Warranty*: All suppliers identified were able to offer a two-year warranty. Many were able to offer a warranty for up to five years for an additional fee.
- Spare parts and accessories: Most suppliers have a detailed list of spare parts and accessories which can be bundled with the patient monitor. Required spare parts and accessories should be outlined individually in the procurement order and may incur additional costs on top of the base product. In particular, probes have a limited lifetime and can be a considerable portion of the cost of the product over time. This should be factored into the total cost of ownership.

For basic patient monitors, there are *noninvasive blood pressure measurements*, with a range of measurements possible. Most suppliers offer a range from 30 to 300 millimeters of mercury; however, some ranges from models identified varied slightly from this standard (e.g., from 10 to 270).

Identified suppliers

Five companies identified below possess substantial available production capacity and the requisite quality certifications to verify their ability to meet international quality standards. Available production capacities based on most recent communications are summarized in Table 5.

Table 5. Summary of priority suppliers with available production capacity for SRA-approved advanced and basic patient monitors.

Supplier	Product Type	Product Model	Screen Size	CE	ISO 13485	Key International Markets	Estimated Production Capacity (Monthly)
Utech	Advanced	PM5000 with 8 parameters	12.0"	Yes	Yes	Europe, South America, Africa,	1,000
	Basic	PM5000 with 6 parameters	12.0"	Yes	Yes	Australia	1,000
Edan	Advanced	X12 with optional invasive blood pressure, EtCO2 & 12 lead electrocardiogra m	12.1"	Yes	Yes	163 countries globally, including US and Europe; 6% of sales in Africa	5,000
	Basic	X12	12.1"	Yes	Yes		5,000
Contec	Advanced	CMS9000	12.1"	Yes	Yes	Europe, North America, Asia,	500
	Basic	CMS8000	12.1"	Yes	Yes	Africa, India.	1,000
	Advanced	Q5	12.1"	Yes	Yes	160+ countries, with 10 years of	31,000
Biolight	Basic	\$12	12.1"	Yes	Yes	export history, including in Africa, South Asia, Central America	20,000
	Advanced	EPM12M	12.0"	Yes	Yes	190+ countries;	3,000
Mindray	Basic	UMEC15	15.0"	Yes	Yes	subsidiaries in 32 countries, including the Americas, Asia, N/S/E/W Africa; dedicated staff across Africa	400
Subtotal – Advanced Patient Monitors							
Subtotal – Basic Po	atient Monitors						12,400
TOTAL							19,400

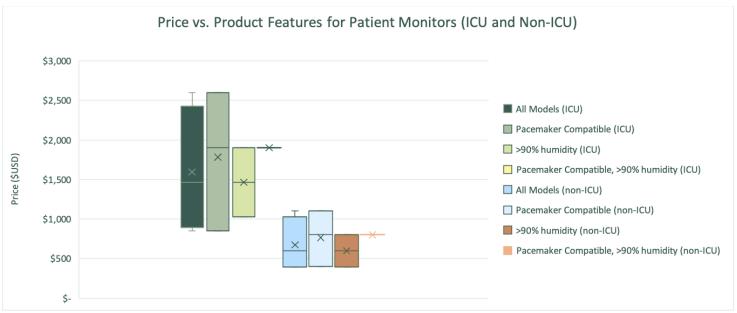
Abbreviations: CE, Conformité Européenne [European Conformity]; ISO, International Organization for Standardization; SRA, stringent regulatory authority.

Based on the information collected, all suppliers identified have significant experience in international markets, including LMIC, and sufficient production capacities. Procurement agreements may be prioritized by available volumes and lead times, as well as individual product considerations described in the section above.

Aggregated price range

Prices should be taken as indicative only and will be highly variable depending on urgency, volumes required, and other contextual factors. Initial quotes received for advanced patient monitors ranged from \$849 to \$2,600, and basic patient monitors ranged from \$395 to \$1,100. All prices include spares and accessories; however, the exact quantity and type may vary between suppliers. Figure 4 shows what the anonymized pricing data collected from prioritized suppliers are and how the price range is influenced with the inclusion of specific technical requirements.

Figure 4. Aggregated price range from identified suppliers for basic and advanced patient monitors.



X= mean, Line = median, Box = interquartile range, Whiskers = minimum and maximum. Abbreviation: ICU, intensive care unit.

Models identified offered all critical features, with some variation in spares and accessories offered at the base price. Key price drivers were as follows:

- Pacemaker compatibility, which increased the average price point by \$93 per unit for basic models and \$188 per unit for advanced models.
- Both the ability to operate at greater than 90 percent humidity and pacemaker compatibility, which increased the average price point by \$126 per unit for basic models and \$305 per unit for advanced models.

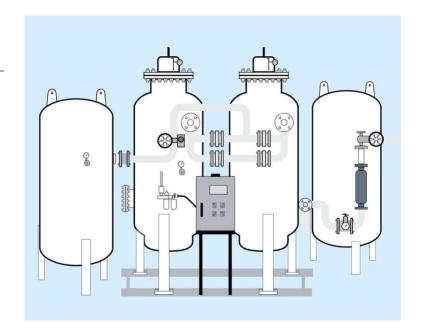
Last updated April 29, 2020

Vacuum / pressure swing adsorption plant supplier landscape

Considerations for product deployment

Oxygen has been identified by the WHO as an essential medicine, required at all levels of the health care system. Pressure swing adsorption (PSA) oxygen generation plants are designed to produce medical grade oxygen at scale and can deliver oxygen at varying flow rates directly to health facilities via piping or compressed and stored in cylinders for storage and distribution. This landscape provides a global market overview of suppliers for PSA plants as outlined by the WHO technical specifications.⁷

When deploying a solution involving a PSA plant, in addition to selecting a supplier, buyers should consider the ecosystem where the product is deployed. This is including but not limited to:



- Clarity on service offerings: While many manufacturers may be able to install and maintain PSAs, either directly or through third-party service providers, there is a significant amount of uncertainty about levels and quality of service provided by each supplier. Given the maintenance and management needs of PSA plants, a more detailed understanding of who is providing these services, where they are based, and what level of service they can provide is critical to differentiating between product offerings.
- Ownership and operating models: Articulating a more refined set of ownership models offered by manufacturers can assist with evaluating suppliers. For instance, the option of a leasing model as opposed to outright purchases of PSAs could be of interest to some buyers. Beyond ownership alternatives, suppliers may also offer services and support for downstream activities, such as operating plants, in certain geographies. PSA plants have considerable operating costs but can last up to 20 years or more if maintained and managed appropriately. Therefore, this aspect should be carefully considered over the expected lifetime of the plant.
- Compatibility with delivery system: Buyers should consider the method with which the oxygen will be delivered to patients. A piped system offers various trade-offs when compared to a cylinder-based transport and storage solution. Compatibility of the PSA plant with either system should be carefully considered and would necessitate a detailed review of additional products, such as oxygen compressors and oxygen cylinders. A brief review of cylinders is included above.

• Supporting infrastructure: This may include appropriate housing if the plant is not containerized, continuous power (3-phase)ⁱⁱⁱ for when the plant is in operation, or cylinder filling equipment^{iv} (if applicable), including an oxygen compressor.

In addition to the above, buyers should consider how demand will vary in the current pandemic setting and in a normalized situation, post-pandemic. For example, plans can be made for transporting excess oxygen outside of peak demand periods to nearby health care facilities to serve a broader subset of health care facilities.

Considerations for product selection

A high-quality supplier is identified as having the capacity to deliver models which have critical features for their target use. This can be determined by gathering detailed technical and quality certification documents and reviewing these against WHO specifications and/or a set of internal technical specifications. Since suppliers of PSA plants can generally manufacture a wide range of capacities, it can be challenging to make direct comparisons across various product offerings. For comparison, three use cases were considered for medium to high oxygen needs, based on cubic meters per hour (m³/hr):

- 30 m³/hr
- 45 m³/hr
- 90 m³/hr

These specific use cases were defined to compare PSA model offerings; they enable a more nuanced evaluation of cost, volume, and lead-time curves across manufacturers. Manufacturers will have varying predefined models, and some may be constrained to deliver only those with capacities below 45 m³/hr. However, any buyer is advised to conduct a custom-sizing exercise based on the number of patients the plant is expected to serve and the oxygen needs of each patient. Such input may vary depending on a number of factors, including the facility level and wards requiring oxygen supply.

To inform decisions on which products should be considered for procurement, the following selection criteria can be considered:

- Quality: Availability of pertinent ISO certifications (e.g., <u>13485</u>; <u>9001</u>; <u>7396-1</u>; <u>8573-1</u>, <u>-2</u>, and <u>-4</u>; <u>5011</u>; and <u>21969</u>) and IEC certifications, registration in SRA markets (i.e., CE, TUV [Technischer Überwachungsverein, or Technical Inspection Association], and/or FDA), and export authorization from the supplier's country.
- Functional requirements: Prioritization of critical elements for the context of use, including but not limited to:
 - Ability to produce 93 percent pure oxygen or higher.
 - o Audible and visual alarms for temperature, pressure, oxygen levels, and power and system failures.
 - Active reserve source and dew points.
 - Continuous output pressure of 44 to 87 psi for hospital piping or the ability to feed an oxygen compressor for cylinder filling.
 - o Ability to be skid-mounted or containerized to facilitate fast setup and installation.

iii Medical equipment with motors, such as a PSA, can require 3-phase continuous power, enabling constant power, unlike single-phase power.

iv For PSA technologies, oxygen piping and oxygen cylinders and/or tanks are required to deliver oxygen directly to patients.

- Operational requirements: Capability to be used within a specific temperature range and range of relative humidity and elevation, as well as with basic power requirements, which are particularly critical to define for PSA plants. For example, an elevation of 300 m above sea level can directly impact the air intake compressor. These should be based on specific geography and context of use.
- Ability to service the market: Production capacity and capability to either scale or allocate required volumes for
 procurement, offer alternatives for ownership and operating models, and provide after-sales installation and
 maintenance services in LMIC, as well as lead times.
- Durability: Prioritization of a long life span, backed up by at least a two-year warranty.
- **Price**: Pricing that is competitive within the global market and provision of critical product features, requirements for prepayment, and potential procurement volumes per supplier.

Based on information collected, the following product requirements may impact the number of models available for procurement, lead times, or price:

- Skid mount / containerization: In general, buyers must consider the choice between skid mount and containerization and associated trade-offs between cost and mobility. Manufacturers reported that it would be impossible to skid-mount or containerize PSAs above a certain size threshold (for example, above 90m³/hr), even if the plant was built in a twinned configuration.
- Inclusion of oxygen compressors, cylinders, and other accessories: Specific suppliers may include oxygen compressors in the cost, require a separate purchase, or bundle oxygen compressors from another supplier for an additional fee.
- Lead times and shipping times: American and European suppliers tended to report longer production lead times than their Chinese counterparts. In multiple instances, suppliers attributed longer lead times to a shortage of oxygen compressors due to a reliance on a single company, Rix, who maintains a dominant position in the American and European markets. Chinese suppliers appear to have domestic sources for oxygen compressors and are not dependent upon Rix. As a result, some companies in the United States and Europe require 12 weeks or longer for production and anywhere from 30 days to eight weeks for shipping. Chinese firms reported much faster lead times on average and indicated an expectation of four to six weeks for shipping. However, all lead times and shipping times should be taken as indicative only, as they will be highly dependent on the final details of any procurement order.
- **Price and type of installation/maintenance**: All manufacturers reported that they offer installation and maintenance, though some suppliers include this in the price of the product, while others require a separate fee. In addition, several manufacturers offer remote support for installation and maintenance.
- Conditions of target site: While all manufacturers reported that they were able to meet temperature, humidity, and elevation requirements, most mentioned that they would need information on specific site conditions to ensure that PSAs were built according to these requirements. Suppliers commonly reported that elevation would influence both price and air compression needs.

Identified suppliers

Sixteen companies identified below possess substantial available production capacity and the requisite quality certifications to verify their ability to meet international quality standards. Technical and operational features to consider based on recent communications are captured in Table 6.

Table 6. Overview of quality and technical specifications compliance for PSA suppliers globally.

		Skid- mounted	Installation	Dura	bility	Environment:	Alarms	
Supplier	Country	and/or container options	and maintenance (either provided?)	10 -year life span	48-month warranty	temperature, humidity, and elevation specifications ^v	(audible and visual alarms ^{vi})	Quality
AirSep	United States	✓	Plant installation, start-up, and commissioning and training of staff built into price. Factory- trained / authorized AirSep dealers in country or region to provide technical support.	✓	1 year from date of start- up or 18 months from shipment. Extended warranty available.	√	✓	CE, ISO 13485
Can Gas Systems Company Limited	China	✓	Available by free remote guidance or on-site service in Africa, Asia, Europe.	✓	✓	✓	✓	CE, other certification for export of medical products (China)
G. Samaras	Greece	✓	No, distributor responsible for installation and maintenance.	Response pending	24 months, with option to extend.	✓	✓	CE, ISO based on EU pharmacopeia
Hunan Eter Electronic Medical	China	Skid available up to 45 m3	Remote or on- site services available.	✓	Option for up to 48 months.	✓	Yes, text to phone alarms also available.	ISO 14001 /13485/9001
Hydrogaz	Poland	✓	Yes	√	Yes, with service agreement.	√	Yes, text to phone alarms also available.	CE, EN ISO 7396-1:2016 and EU pharmacopeia
Jiangyin Dongpeng Purifying Equip.	China	√	Yes, free except for airfare, hotel, and meals.	✓	✓	√	✓	CE certification ISO 9001/14001
Novair	France	✓	Yes, directly or through local providers.	√	12 months, with option to extend.	√	√	CE, ISO 7396-1 and US/EU pharmacopeia compliance
OGSI	United States	Yes, but not at focus sizes	Yes, built into the cost of the system except for airfare, hotel, and meals.	√	12 months, with option to extend.	√	√	ISO quality certificate
Oxymat	Slovakia	✓	Yes, with technician rate depending on	✓	12 months, with option to extend.	✓	✓	CE, approval ISO 7396-1 -

-

 $^{^{\}rm v}$ Temperature from 10°C–40°C; relative humidity from 15%-95%; elevation from 0 to at least 2,000 m.

vi Including high temperature; low/ high pressure; low oxygen (<90%); power failure; system failure; second/reserve source active; air dryer pressure dew point (>3°C).

		Skid- mounted	Installation	Dura	bility	Environment:	Alarms	
Supplier	Country	and/or container options	and maintenance (either provided?)	10 -year life span	48-month warranty	temperature, humidity, and elevation specifications	(audible and visual alarms ^{vi})	Quality
			the country of installation.					EU pharmacopeia
Oxywise	Slovakia	√	Technicians for commissioning and training worldwide available.	√	Yes, with a service contract.	√	√	TUV, CE, EN ISO 9001:2015 and EN ISO 13485:2012
Pneumatech Medical Gas Solution	Germany	Skid: no; Container: yes	Yes, with offer of engineers to send or online service training for countries with no presence.	√	12 months, with 24-month extension if procuring only original service parts.	√	√	CE, ISO
ShanDong MedTech	China	Container available up to 30 m3	Remote or on- site installation.	√	√	√	√	CE, TUV ISO 13485/8359/ 10083
Suzhou Hengda Purification Equip.	China	√	Yes, on-site for US\$100/day.	√	√	√	√	CE, other certification for export of medical products
Sysadvance	Portugal	✓	Yes, partners (agents, distributors, and suppliers) in Latin America, Africa, and Asia.	√	Yes, subject to service contract.	✓	√	CE

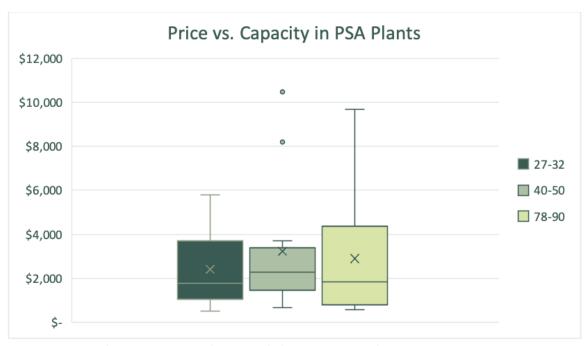
Abbreviations: CE, Conformitè Europëenne [European Conformity]; EN, European standards; EU, European Union; ISO, International Organization for Standardization; TUV, Technischer Überwachungsverein [Technical Inspection Association].

Based on the information collected, all suppliers identified have significant experience in international markets, including LMIC, and sufficient production capacities. Procurement agreements may be prioritized by available volumes and lead times, as well as individual product considerations described in the section above.

Aggregated price range

Prices should be taken as indicative only and will be highly variable depending on urgency, units required, and other contextual factors. When possible, the team has made direct comparisons between products by evaluating costs per unit of PSA capacity, though some companies reported that price would depend on order size. Figure 5 below shows the prices represented as cost per unit of capacity, arranged by small, medium, and large production capacities. Note that operations, repair and maintenance, and human resources contribute a significant portion of the cost for a PSA plant over its lifetime. Each variable scales differently and should be carefully considered in the overall cost. One-time costs, including shipping, installation, or remote technical support for installation, may also be useful to consider.

Figure 5. Aggregated price range from identified suppliers for various production capacities (USD per m³/hr)



X= mean, Line = median, Box = interquartile range, Whiskers = minimum and maximum. Abbreviation: m³/hr, cubic meters per hour; PSA, pressure swing adsorption.

Variation in price increases significantly in larger capacities, although the average price per unit is similar. Other key price drivers include, but are not limited to, the following:

- Supplier country of origin, where models from suppliers based in China were \$1,498 per m³/hr below average.
- Inclusion of container, which **increased** the average price point by \$2,794 per m³/hr.

Last updated April 29, 2020

References

- World Health Organization (WHO) website. List of priority medical devices for COVID-19 case management page. April 9, 2020. <u>https://www.who.int/publications/m/item/list-of-priority-medical-devices-for-covid-19-case-management</u>. COVID-19: Essential Resource Planning publications.
- 2. WHO. *COVID-19 Technical Specifications for Procurement of Oxygen Therapy and Monitoring Devices*. Geneva: WHO; 2020. https://www.who.int/medical_devices/priority/Tech_Specs_O2_Therapy_monitoring_final_draft.pdf?ua=1.
- 3. WHO. *COVID-19 Technical Specifications for Procurement of Oxygen Therapy and Monitoring Devices*. Geneva: WHO; 2020:6. https://www.who.int/medical_devices/priority/Tech_Specs_O2_Therapy_monitoring_final_draft.pdf?ua=1#page=6.
- 4. WHO. *COVID-19 Technical Specifications for Procurement of Oxygen Therapy and Monitoring Devices*. Geneva: WHO; 2020: 20–23. https://www.who.int/medical_devices/priority/Tech_Specs_O2_Therapy_monitoring_final_draft.pdf?ua=1#page=20.
- 5. WHO. COVID-19 Technical Specifications for Procurement of Oxygen Therapy and Monitoring Devices. Geneva: WHO; 2020: 31–33. https://www.who.int/medical_devices/priority/Tech_Specs_O2_Therapy_monitoring_final_draft.pdf?ua=1#page=31.
- 6. WHO. COVID-19 Technical Specifications for Procurement of Oxygen Therapy and Monitoring Devices. Geneva: WHO; 2020: 38–47. https://www.who.int/medical_devices/priority/Tech_Specs_O2_Therapy_monitoring_final_draft.pdf?ua=1#page=38.
- 7. WHO. *Technical Specifications for Pressure Swing Adsorption (PSA) Oxygen Plants*. Geneva: WHO; 2020. https://www.who.int/publications/i/item/technical-specifications-for-pressure-swing-adsorption(psa)-oxygen-plants

For more information path.org/programs/market-dynamics/covid-19-and-oxygen-resource-library Contact us at oxygen@path.org