Target Product Profile:

Resilient Oxygen Concentrator

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Disclaimer

This TPP is intended to supersede UNICEF's previously published TPP for oxygen concentrators. This TPP does not constitute tender specifications, nor is UNICEF bound to tender or procure products that arise as a result of this TPP.

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This report was prepared by Florin Gheorghe from the Product Innovation Center of UNICEF Supply Division, in collaboration with Rebecca Kirby and Kara Palamountain from NEST360.

This document summarizes the contributions and general consensus achieved through a Delphi-like process to develop a Target Product Profile for oxygen concentrators suited for low-resource settings. Over 150 participants were engaged in this process and have contributed significantly to the results presented here. The authors of this report are grateful for the support and input from a wide range of stakeholders from around the world and from across specialties, including clinicians, biomedical engineers, technical experts, product innovators, manufacturers, NGOs and implementers, government stakeholders, donors, and many more. Some of these contributors are listed in Appendix A and B.

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Abbreviations

°C	Degrees Celsius
AC	Alternating current
ARDS	Acute respiratory distress syndrome
bCPAP	Bubble continuous positive airway pressure
CE Mark	Conformité Européenne – certification mark
COPD	Chronic obstructive pulmonary disease
COVID-19	Disease caused by the SARS-CoV-2 virus
CPAP	Continuous positive airway pressure
DC	Direct current
FDA	Food and Drug Administration
Hz	Hertz
IMDRF	International Medical Device Regulators Forum
ISO	International Standards Organization
kg	Kilogram
LMIC	Low-income and middle-income countries
LPM	Liters per minute
LRS	Low-resource settings
NCD	Non-communicable diseases
NICU	Neonatal intensive care unit
PICU	Pediatric intensive care unit
PQS	WHO performance, quality, and safety catalogue and prequalification
PSA	Pressure swing adsorption
RDS	Respiratory distress syndrome
SMPS	Switched-mode power supply
TPP	Target product profile
UNICEF	United Nations Children's Fund
V	Volts
VSA	Vacuum swing adsorption
VPSA	Vacuum-pressure swing adsorption
W	Watts
WHO	World Health Organization

1. Introduction

The objective of a Target Product Profile (TPP) is to achieve consensus among users, buyers, and implementers on the ideal product requirements and communicate these to product developers to support innovation. This TPP outlines the desired performance characteristics of an oxygen concentrator that is fit-for-purpose for low-resource settings (LRS).

Each requirement in this TPP lists a minimal and an optimal target:

Minimal target: This represents the “must meet” requirements necessary for suitability of oxygen concentrators within LRS. If these criteria are not met, the oxygen concentrator is likely to be considered unsuitable for use in a global health context.

Optimal target: This represents the “should aim for” recommendations. The criteria represent a significant improvement over the current oxygen concentrator, resulting in a quantifiable reduction in total systems cost, performance, safety, fit-for-purpose, and increased reach.

How this TPP was developed

This TPP was developed in collaboration with NEST360 using a Delphi-like process. Prior to the start of the Delphi-like process, an initial learning phase took place as described below.

Background learning

An initial desk review was conducted examining the existing literature and previous TPPs published by PATH (PATH, 2015) and NEST360/UNICEF (Appendix D), providing context on oxygen concentrator use and challenges in LRS.

To gain further clarity on the context and need, clinical and technical experts were engaged in three ways: First, UNICEF stakeholders at the global and country level were interviewed to understand and learn from recent experiences with concentrator deployments during the COVID-19 pandemic. Next, a ‘User Innovation Panel’ was formed with clinical users and biomedical engineers from across 7 countries, consisting of semi-structured interviews and cultural probes. Finally, the Oxygen CoLab, under the COVIDaction program funded by UK Aid, engaged over 100 experts from across domains through a series of workshops and interviews. These experts were continually and iteratively engaged throughout the TPP process to better understand the challenges and drivers of success for concentrators in LRS.

This extensive engagement led to a deep understanding of the problem and solution space, including:

- A landscape review of next-generation oxygen technologies[1]. Although promising, most of these are not at the scale, readiness level, or cost required for concentrators. For this reason, this TPP is written with a PSA-based[2] technology platform in mind.
- A deep understanding of the users, context, and challenges in LRS allowed for prioritization of key requirements, informing product developers on where to focus their efforts. These are noted as high priority within the TPP requirements table.
- Understanding of gaps in the ISO standards that drive the design and testing of concentrators, as well as the physics and failure modes of current devices. This TPP takes a balanced view of today's limitations as well as the latest research to push the boundaries of what is thought possible, while remaining in the realm of reality and available science.
- Additional background context as well as innovative ideas to address the TPP requirements will be included in an accompanying TPP Context report. Additional learning will also be published by the Oxygen CoLab separately.
- Finally, extensive engagement with manufacturers and innovators led to understanding the barriers, motivations, likelihood, and routes to developing an LRS concentrator.

Delphi-like process

The above background learning informed the Delphi-like TPP process that followed. This collaboration with NEST360 engaged over 100 clinical users, biomedical engineers, implementers, decision makers, innovators, scientists, funders, and manufacturers. The resulting TPP is based on a consensus among these stakeholders.

An initial kick-off meeting launched the process with 87 participants in attendance. A survey was sent to 178 participants, receiving 54 detailed responses. This survey asked participants to rank their agreement with a given set of product requirements and to comment where there was disagreement. Results from the survey were analyzed and a Consensus Meeting was held to discuss areas of disagreement (less than 75% agreement), revise collectively, move towards consensus, and to agree on the priority requirements. All requirements achieved consensus above 75%, though most were close to 100%. The final list of requirements was circulated iteratively among experts and product developers for final feedback before being frozen.

Participants and organizations involved in this process are described in Appendix A and B. The demographics of the Delphi-like process are described in Appendix C.

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[1] Ceramic oxygen generation, magnetic oxygen separation, structured and folded zeolite beds, metal organic frameworks, water and oxygen separation membranes, electrolysis, algae photosynthesis, sterling engines, and others were considered.

[2] References to pressure swing adsorption (PSA) technology in this TPP are meant to be inclusive of vacuum swing adsorption (VSA), vacuum-pressure swing adsorption (VPSA), or other similar systems.

Because of the richness of a priori research, expert input through the Oxygen CoLab, and extensive iterative contributions throughout the Delphi-like TPP process, this report and the accompanying TPP Context report convey the themes that have emerged throughout. This document does not provide a chronological summary of the Consensus Meeting dialogue.

2. TPP Requirements

Extensive consultations have informed the key characteristics of an oxygen concentrator that is fit-for-purpose for LRS:

1) Resilient in challenging environments and low-quality power conditions, while producing high purity and preventing against early degradation of the system and components. The device must be designed for:
    a. Continual operation for long periods in hot environments.
    b. Storage and operation in simultaneously hot and humid environments. The device must have a suitable shelf-life before first use, tolerate highly variable on-off duty cycles once in use, and be able to operate for long periods continuously in these conditions.
    c. Continual use and longevity in dusty environments, without relying on frequent cleaning and replacement of filters.
    d. Resilience to poor-quality power conditions through internal voltage stabilization and spike protection, enabling continual use in variable power conditions while preventing damage to the device.
2) Energy efficient, enabling use with solar power while being cost efficient when run on generator and grid power.
3) Meets the human factors/usability needs of LRS users that increase confidence in the product and reduce use-related patient safety risks. These include overdraw protection, increased information for users, and alarms and indicators that are appropriate for acute care LRS settings.
4) Designed with longevity and minimal maintenance requirements in mind. The device and components are reliable, robust, have a long life, and require minimal repairs to work effectively in settings with inadequate access to spare parts and trained technicians.

The general characteristics listed above, which are detailed in the priority requirements in the table below, represent the most significant updates to the TPP from its previous version, as well as the product improvements that are likely to have the highest impact in LRS. The table below outlines the full list of requirements, including the priority requirements labelled as such.

Additional background on the challenges faced by concentrators in LRS, details on each of the priority requirements, and possible solutions or innovative approaches for meeting the TPP can be found in the accompanying TPP Context report.

TPP requirements

Priority	Characteristic	Optimal	Minimal
USE CASE			
	Intended Use	To provide medical oxygen for use in a healthcare setting.	
	Target Operator	For use in low- and middle-income countries by a wide variety of clinicians, including nurses, midwives, clinical officers, doctors, and allied health partners.	
	Target Population	Neonate (<28 days) through to adult patients.	
	Target Setting	Target use in primary health facilities (health post, health centre, clinics) and secondary health facilities (general, regional, or district hospital). Also often used as backup or mixed source at tertiary health facilities (national, teaching, or specialty hospital).	
SAFETY AND STANDARDS			
	Quality Management	ISO 13485 Quality management system.	
	International Standards	Standards applicable to the manufacturer and the manufacturing process (compliance to the latest available version): ISO 13485; ISO 14971. Standards applicable to the product (compliance to the latest available version, or equivalent): ISO 80601-2-69; IEC 60601-1; IEC 60601-1-2; IEC 60601-1-6; IEC 60601-1-8; IEC 60601-1-9; IEC 60601-1-11; IEC 62366.	
	Regulatory Approval	At least one of: CE marking, approved by US FDA or another stringent regulatory body of a founding member of IMDRF (e.g. Japan, Australia, or Canada)	
TECHNICAL CHARACTERISTICS			

	Flow Rate	10 LPM.[3]	
	Pressure	20 PSI.[4]	
	Flow Meter	At least 2 flowmeters, with each reading 0 to 10 LPM, in increments of 0.5 LPM (ideally 0.25 LPM if possible). Each outlet must have a flow meter.	At least 1 flowmeter (ideally two) reading 0 to 10 LPM, increments of 1 LPM (ideally 0.5 LPM). Each outlet must have a flow meter.
	Time to Reach 95% of Specified Performance	< 5 minutes.	
	Oxygen Concentration	93% +/- 3%.[5]	
	Mobility	Whole unit moveable with wheels on at least two feet.	
	Oxygen Outlet	Recessed, replaceable metal barbs.	
	Noise Level	<50 decibels; low as possible.	
	Weight	<27 kg.	
USER INTERFACE			

[3] 10 LPM was agreed to in the consensus meeting, however it is recognized that some health facilities would benefit from a 5 LPM device, and that these may have a cost advantage, leveraging greater economies of scale for 5 LPM products. Manufacturers are encouraged to integrate the priority requirements across their portfolio products, including 5 LPM. Further discussion on flowrate is included in the TPP Context Report.

[4] The objective is to enable use with complementary products that may require higher pressures (e.g. certain bCPAP and other products) and to enable distribution of oxygen from one concentrator to multiple patients at farther distances across a ward.

[5] The rated oxygen concentration must be met at all flowrates and while operating long term in all environmental conditions and altitudes described in this TPP.

High	Indicators and Alarms	Audible and visual alarms clearly labeled or marked with pictures for low oxygen purity (<82%), high temperature, low/high/no-flow rate, low battery, power supply failure, and low/high pressure, as per ISO 80601-2-69. User interface easy to operate; numbers and displays to be clearly visible. Alarms must continue to notify users (via continuous or intermittent visual and audible alarms) until manual override.[6] The device should alarm again daily to remind users of the need for service	
High	Overdraw Protection	The device must physically restrict maximum flow such that users cannot inadvertently cause a flow greater than the designed maximum flow of the system.[7]	
High	Display Parameters	Oxygen flow rate (on flowmeter). Non-resettable digital or analog meter displaying cumulative hours of operation. Oxygen concentration display screen is included internally within the device for repair technicians to easily troubleshoot, but not visible for clinical users. Component status indicator (e.g. for showing sieve bed health/performance or compressor performance) visible to repair technicians. Component status indicator for filter cleaning visible to clinical users.	
	Oxygen Sensor and Indicator	Device must be equipped with an oxygen concentration sensor, preferably ultrasonic, that lasts for the lifetime of the device.[8] Visual and audible indicator, preferably with color coding	Device must be equipped with an oxygen concentration sensor, preferably ultrasonic, that lasts for the lifetime of the device. Visual and audible indicator that continues to notify users

[6] It is important for alarms to draw the attention of users in a busy ward, both visually and audibly, however the device must allow users to manually override this alarm. Once acknowledged, the device must be able to be used at purity levels below 82% as this might be the only oxygen source a health facility has and continual alarming would render it unusable. It is recognized that this may not align with ISO 80601-2-69, however manufacturers are encouraged to find a creative solution to meet this TPP requirement while fitting with regulatory requirements.

[7] Overdraw of the system may be caused by incorrect use a dual flow device, an external flow splitter, or even a single flow device since fully opened flowmeters may allow a flowrate reaching 500% of the maximum rating (Arora, 2021).

[8] Consider including a way for users or technicians to test whether the sensor itself is still working, or a status indicator internally showing this.

		for normal (green), early warning (amber), and low purity <82% (red). Low purity continues to notify users until manual override.	until manual override.
High	Minimum Operable Flow Rate	Flow meter must be accurately and precisely operable from a minimum flowrate of 0.5 LPM (preferably 0.25 LPM).	Flow meter must be accurately and precisely operable from a minimum flowrate of 1 LPM.
High	Flow Meter Labeling	Device labelling must make it clear to users what the total rated flow of the device is and how to safely use multiple flow meters at once. This should be clearly visible at time of use on the interface or on a quick-reference job aid attached to the device.	
	User Adjustable Settings	Flowrate.	
ENVIRONMENT AND STORAGE			
High	Intermittent Use	The device must be able to operate and be intermittently stored (e.g. on/off duty cycle ranging from hours to months at a time) in environments that experience nighttime temperature swings of up to 20 degrees C and humidity up to 95% RH. The device must remain fully functional throughout its lifetime while experiencing such a duty cycle.	
High	Warehouse Storage[9]	The device must be capable of being stored in conditions from -10 to 65 C and 15-95% relative humidity for minimum 3 years.	The device must be capable of being stored in conditions from -10 to 65 C and 15-95% relative humidity for minimum 1 year.
High	Heat (Operating)	The device must be able to operate and meet the rated purity in temperatures from 10 to 40	

[9] Although bringing a new product to market may take several years, manufacturers are encouraged to consider “low hanging fruit” product modifications that could be made in the short term. One example of this could be improved packaging that is moisture resistant and enables a long shelf life. Such a modification may be relatively low cost and quick to implement, resulting in a product with a significant edge above existing devices, and would be of interest for upcoming procurement cycles.

		degrees C. The device must be designed to ensure the delivery of the rated purity with daily continuous operation at high temperature. Components and heat management of the device are designed for operation in hot environments, to ensure a long product lifetime.	
High	Humidity (Operating)	The device must be designed to meet the rated purity with daily continuous operation in humid environments ranging from 15-95% relative humidity while simultaneously experiencing temperature up to 40 C.	
High	Dust	The device must be able to operate in dusty environments. Intake filters must have an average arrestance of 90%. Compressor filters must have an efficiency of 95% of dust <10 um.[10]	The device must be able to operate in dusty environments. Intake filters must have an average arrestance of 70%. Compressor filters must have an efficiency of 90% of dust <10 um.
High	Filters	All filters on the device are interchangeable with commonly available filters in LRS (e.g. automotive, HVAC, vacuum filters). Filters should be durable, easy to remove, easy to clean, and reusable.[11]	All filters should be durable, easy to remove, easy to clean, and reusable.
	Altitude	Capable of supplying the rated oxygen concentration continuously at elevation ranging from 0 to at least 2000 m.	

[10] NEST360 has tested designs for a high arrestance and high efficiency external filter (equivalent to HEPA) that could be used to keep dust out of the cabinet without causing increased pressure or impacting airflow and heat management. However, this would require more frequent cleaning and replacement, which is already a challenge in LRS. Manufacturers are encouraged to find creative solutions for keeping dust out of the device without increasing the need for user maintenance of filters. This could include air pre-treatment, passive dust separation or dust settling before reaching the cabinet filter, etc. NEST360 will soon publish data on particle size and volume found in an LRS hospital environment.

[11] It is understood that validation of all possible commonly available filters may be challenging with quality management requirements, however manufacturers are encouraged to consider creative solutions for both meeting the TP requirements and regulatory requirements.

	POWER REQUIREMENTS		
High	Power Efficiency	The device achieves a variable power usage of <40 W / LPM that scales with flowrate (e.g. 160 W at 4 LPM, 240 W at 6 LPM).	The device achieves a non-variable power usage of <60 W / LPM.
High	Power Protection	Built-in power protection aligned with WHO PQS V1.6 standard for voltage stabilizers for cold chain equipment, i.e.: - Stabilization from input 110-264V SMPS / 110-278V for AC to an output of -15% / +10% nominal 230V. - Automatic shut-off and withstand 415V. - Transient overvoltage per PQS. Additionally: - Randomized start-up delay (AC systems). - Protection against electric shock.	Standard surge protection.
High	Power Source	Mains power.[12]	
	Voltage	Model must match the voltage and frequency of the purchasing country's local power grid (e.g., 110-120 VAC at 60 Hz or 220-240 VAC at 50 Hz)	
	Electrical Plug and Cable	Compatible with local power outlet, rated above amperage and voltage requirements. Plug is moulded directly to cable.	Compatible with local power outlet, rated above amperage and voltage requirements.

[12] Although a battery of 30-60 minutes and up to several hours would be highly desirable, it is believed this would be cost prohibitive for integration into the concentrator. However, manufacturers are encouraged to identify creative and cost-effective ways to include battery backup of at least 30 minutes.

	DURABILITY AND LIFETIME REQUIREMENTS		
High	Durability and Robustness	User interface components (e.g. knob, flowmeter, humidifier bottle, oxygen outlet, etc.) must be robust and durable for the lifetime of the product. All should be replaceable with off-the-shelf components. All should be recessed and protected to avoid accidental damage.	
High	Product Lifetime	Lifetime of 7 years for the device, not including wear components.	Lifetime of 5 years for the device, not including wear components.
High	Compressor Lifetime	Operational lifetime of 40,000 hours when integrated into the concentrator system, assuming preventative maintenance. Compressor rebuild not required before 15,000 hours. Heat management and dust management of the system must support this objective.	Operational lifetime of 30,000 hours when integrated into the concentrator system, assuming preventative maintenance. Compressor rebuild not required before 10,000 hours. Heat management and dust management of the system must support this objective.
High	Sieve Bed Lifetime	Operational lifetime of 4 years. Component storage shelf-life of 3 years.	Operational lifetime of 3 years. Component storage shelf-life of 3 years.
	TRAINING AND MAINTENANCE		
High	User Instructions	User manual and additional training materials (checklists, videos, guides) in English, French, and Spanish. Attached to device with labels and markings where possible. User manuals must be tested with a range of healthcare workers in LMICs. Job aids are to be included with the product (e.g. on preventative maintenance, safe use, maximum flow, alarms, etc.).	
High	Repair Instructions	Repair manuals must be user tested with biomedical engineers and technicians in LMICs. Manuals must be available in English, French, Spanish. Manuals to be visual and include pictograms. Video repair guides should be made available.	
	User Skill Level	Minimal to none.	

	Technical Skill Maintenance	Minimally trained technician.	Trained technician with training in basic operation and maintenance.
	Decontamination	Easy to clean flat surfaces, compatible with common disinfecting agents including chlorine.	
	Cleaning Interval	Minimal or no user cleaning and maintenance required.	
	Preventive Maintenance	Should not need preventive maintenance more than once a year.	
	Corrective Maintenance	Should not need corrective maintenance more than once in two years	
	Spare Parts	Basic low-cost spare parts (e.g. filters, compressor seals, check valves, etc.) should be included with the device, if possible stored within the cabinet.	
	Tools Required	No specialized tools required.	

Repairability

Participants in the TPP process have outlined a number of opportunities for improving repairability of the concentrator. These are all strongly recommended for an LRS concentrator:

Easy access and repair

- No specialized tools should be required for repairs; minimal tools required that are easily available in any country.
- Frequently changed components should be the easiest to access and quick to remove and replace (compressor, valves, sieve beds, PCB boards, starting capacitors); components should not be stacked inside machine (e.g. sieve beds could be top loading and not buried behind other items that must be removed).
- Sieve beds should be easily field serviceable (i.e. replaceable). Some technicians prefer field refillable sieve beds as well.
- The system and its components should be designed to be repaired; the tools or jigs required to do so are made available.
- Components should be intuitive and foolproof to install (e.g. asymmetrical and impossible to install wrong, or made to fit in any configuration).

Troubleshooting

- Error codes or component fault indicators are available on a diagnostic screen; device gives you details of any fault using on-board diagnostics.
- Clear troubleshooting instructions (e.g. during low purity some manuals show a lot of possible causes instead of being specific).

Access to information and support

- Technical and user manuals should be made easily accessible online.
- Well-illustrated manuals, including pictographs that are accessible to anyone regardless of language barriers, detailed wiring diagrams, and detailed explanation of how devices work.
- Remote sensing and testing (i.e. telemetry) is seen as valuable for fleet management and predictive maintenance; however this is only useful if a service infrastructure exists within the facility, government, or private sector in-country, or if manufacturer representatives are easily accessible for remote troubleshooting.
- Access to on-site or online training.
- On-line support via email, chat, WhatsApp, or other asynchronous communication; easy to contact the manufacturer for guidance.
- A forum with case examples of other users who have had typical problems and their resolutions.

Spare parts

- As much as possible, spare parts should be universal and interchangeable across brands, models, or even from other commonly available products (e.g. automotive or HVAC filters).
- Basic spare parts should be supplied with a new unit (e.g. enough filters for lifetime of product).
- Local access to spares, training, and repair should be ensured through local service partnerships and distributors.

3. Uses, users, and use environments

Further details on the topics below are presented in the accompanying TPP Context report.

Uses

Primary use case: Primary healthcare and lower-level hospitals

Although the oxygen concentrator can play a role across the healthcare system, it is especially suited for the primary healthcare (PHC) level (e.g. health post, health centre, clinic) and secondary level hospital settings (e.g. district, regional, or general hospital).

The lower end of these facilities may not have sufficient demand to justify liquid medical oxygen or a PSA plant. Furthermore, in many cases concentrators can be more cost-effective (Dobson, 1991) (Duke T, 2010) (Peake, 2021) and reliable than oxygen cylinder supply due to these facilities being remote and inaccessible at certain times of the year. Country oxygen planning exercises (UNICEF, 2021) and national oxygen roadmaps commonly recommend the use of concentrators in facilities that have access to reliable power and are located beyond a certain distance to the nearest PSA plant. This threshold can range from 5km to 150km depending on country preferences and national oxygen strategy.

Power availability and the need for ongoing maintenance are two key considerations for oxygen concentrators. The maintenance issue is partly addressed by the characteristics of the target LRS oxygen concentrator (e.g. resilience to challenging environments and poor-quality power, robustness of components, etc.). The power issue can also be overcome through the use of complementary technologies such as low- and medium-pressure oxygen storage systems (Peake, 2021) (Otiangala, 2021) (Calderon, 2019) and solar power (Eriksson, 2017) (Duke, 2021) (Huang, 2021).

Secondary use cases

Backup and mixed source at secondary and tertiary facilities

Secondary (e.g. district, regional, or general hospital) and tertiary (e.g. national, teaching, or specialist hospital) facilities may have on-site oxygen generation, ready access to oxygen cylinder supply, and piped oxygen infrastructure. However, it is not uncommon that this oxygen is limited to ICUs, HDUs, surgery, and emergency departments, and may not reach all patients and wards across the hospital. This may be due to the limited supply of these oxygen sources, high cost of cylinders, or due to the geographic spread of LMIC hospitals where it is impractical to pipe an entire hospital campus.

Thus, oxygen concentrators may be used in some larger hospitals that have other oxygen sources. In other facilities, oxygen concentrators are used as backup oxygen sources in the event of a disruption in cylinder supply or breakdown of an oxygen plant.

Concentrators and COVID-19

The WHO Living Guidance for Clinical Management of COVID-19 (WHO, 2021) recommends supplemental oxygen therapy for patients with severe COVID-19 pneumonia in the range of 5-15 LPM. However, patients with critical acute respiratory distress syndrome (ARDS) can require supplemental oxygen flow upwards of 100 LPM. For this reason, COVID-19 wards are preferably equipped with high flow and high-pressure oxygen sources rather than oxygen concentrators.

In some instances, health facilities may use concentrators for patients in the early stages of severe COVID-19 where 10 LPM flow is sufficient. Where hospital capacity is more limited, patients may be sent home with oxygen concentrators. Furthermore, concentrators may play a role in the recovery phase or for patients with long-term needs (i.e. “long COVID”).

Homecare

Although the homecare market in LRS and LMICs is not as developed as that in North America and Europe, the need is large and growing. According to the WHO (WHO, 2021), noncommunicable diseases (NCDs), or chronic diseases, account for 59% of all deaths globally, with over three quarters taking place in LMICs. The disease burden from NCDs is considerable and will be matched by demand as LMIC economies grow and the ability to pay for oxygen in the home increases. Anecdotal evidence in LRS has shown that when oxygen supply is increased at the healthcare centre and hospital level and community awareness is created, the demand from the homecare segment follows with requests for home supply of concentrators.

Common uses

Medical oxygen is a critical life sustaining medicine for patients across LRS, including 4.2 million children with pneumonia requiring oxygen every year (UNICEF, 2020). Pneumonia alone claims the lives of over 800,000 children under the age of five per year and is an important area of focus, however oxygen is critical across the entire healthcare system for all ages and a wide range of conditions.

Oxygen concentrators in LMICs are used for patients ranging from neonates, infants, and older pediatric populations all the way through adults. Depending on age and delivery method, neonate and pediatric patients require typical flows between 1-4 LPM, and sometimes much lower. The flow from a 10 LPM concentrator can therefore be split across several patients using a dual-flow concentrator or an external flow splitter. For adult patients, a 10LPM concentrators typically serves 1-2 patients.

Low flow oxygen therapy using concentrators is used for a wide range of health conditions including asthma, pneumonia, diarrhea, malaria, birth asphyxia, obstetrics and maternal health, in addition to chronic diseases such as COPD.

Oxygen may be delivered through nasal prongs or cannulas, nasal or nasopharyngeal catheters, and face masks. Patient interfaces such as reservoir masks, headboxes, tents, hoods, and incubators are not commonly used with concentrators, both due to their higher flow requirements and their limited availability in many LRS.

The oxygen concentrator may also be used in conjunction with other products. One essential product for neonates is CPAP, some of which can accept low pressure oxygen input and can thus be served by a concentrator. In some facilities, concentrators are used with an oxygen storage system or as part of a piped oxygen distribution system to deliver oxygen to fixed locations across a ward. Higher flow medical devices such as ventilators and anesthesia machines are not suitable for use with a concentrator due to the high pressure and flow requirements.

In these settings, it’s not uncommon that an oxygen concentrator is run continuously for days or even weeks at a time. They may also experience shut-off periods ranging from minutes and hours during power outages, or when put in storage overnight or for days, weeks, or months at a time.

Users

Unlike in North America or Europe where patients are the primary user, concentrators in LRS are mainly used by nurses, midwives, doctors, and other cadres of healthcare workers. These users will vary widely in age, education, language, and product training. Patients have essentially no interaction with oxygen concentrators in an acute LRS health facility.

Product training is a noteworthy challenge, especially at the lower-level health facilities where access to training opportunities is more limited. However, even in higher health facilities there may be users rotating between hospital wards whose familiarity with, and frequent use of, oxygen concentrators is more limited. Product developers should make concentrators easy to understand and use and leave no opportunity for error or misuse.

Clinical users are often working in environments with very high patient to clinician ratios. Alarm and indicator fatigue is likely as the mental and physical load on users can be quite high. Common tasks like filter cleaning are rarely or never performed and the device must be designed with this in mind.

Trained biomedical engineers are not common in many LRS facilities, especially in lower-level sites, instead relying on more generally skilled technicians and repair people. These individuals may not have any formal training nor any specialized tools beyond a basic tool set.

The Oxygen CoLab and Spark Health Design have conducted usability testing of several models of concentrator in Kenya in Nigeria, with results expected in mid-2022. This report will include guidance for manufacturers on the challenges experienced by users, as well as a recommended methodology for manufacturers conducting human factors work in LRS.

Use environments

PHC and secondary facilities can range in size from just 5-10 beds and up to several hundred, with varying levels of equipment, infrastructure, and training.

Within these facilities, concentrators are commonly used across general adult, pediatric, neonatal, and maternity wards, as well as NICUs and PICUs. In some facilities, oxygen concentrators are used for adult ICU, operating theatre, or emergency wards, however this is not as common or recommended since the patients and equipment (e.g. ventilators, anesthesia machines) in these wards often require higher flow or higher pressure than a concentrator can provide. These facilities are often crowded with beds, equipment, and patients.

It is also important to consider where the devices are kept during storage and transit. Warehouse conditions across the supply chain are unlikely to be climate controlled. At the hospital level, products may be stored for up to several months before initial deployment and in between uses, with variable duty cycles.

Power considerations

The WHO estimates that tens of thousands of health facilities are not connected to the grid, while tens of thousands of hospitals face unreliable power conditions. In some countries where UNICEF works, half of health facilities are not connected to the national grid.

Power efficiency of concentrators is another factor that is key due to the high cost of grid power, expensive fuel for generators, and limited capacity of solar photovoltaic systems.

Lastly, the quality of power available in LRS is typically poor, with frequent sags, surges, spikes, and outages (PATH, 2020) (Hinman, Power quality challenges in low-resource settings, 2019) (Hinman, Overvoltage challenges in low-resource settings, 2021). This low-quality power is a key cause of early breakdowns and must be protected against.

Environmental conditions

Heat, humidity, dust, and high altitude are a common challenge for concentrators that were originally designed for climate-controlled settings in the US and Europe. Further information on these challenges, and opportunities for innovation, are listed in the TPP Context report.

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Appendix A – Participants

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Bernard Olayo
Betsy Asma
Beverly Bradley
Brian Palmer
Bob Fary
Bob Murdoch
Callum Kenny
Caroline Soyars
Chris LaPorte
Cindy McWhorter
Deborah Lester
Derek Watt
Dirk Rittmueller
Elana Robertson
Elizabeth Johansen
Elizabeth Molyneux
Evan Spark-DePass
Gabriel Ofovwe
Gabriela Jiminez Moyao
Gary Abusamra
Gene Saxon
George Banda
George Yikwanga
Gerard Roe
Gerry Douglas
Habtamu Tolla
Hamish Graham
Helen Petach
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Irokazi Nwakor
Ivan Muhumuza
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Jennifer Werdenberg
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Laurie Marks
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Lynne Ruddick
Madeline Cowie
Maria Oden
Mark Adkins
Mark Ansermino
Martha Gartley
Marwa Saleh
Michael Ruffo
Mohammad Ameel
Mulugeta Mideksa Amene
Mustafa Aledou
Nancy Smoot
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Niaz Karim
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Nikki Tyler
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Roberto Ayala
Robert Neighbour
Roger Rassool
Salvador Aquino
Sushil Kumar Kabra
Stephen Pickering
Tayo Olaleye
Tedbabe Degefie Hailegebriel

Appendix B – Organizations

Alex Ekwueme Federal University Teaching Hospital

All India Institute of Medical Sciences, New Delhi, India

BC Children's Hospital

Build Health International

CAIRE Inc.

Canadian Red Cross

CCBRT, Dar es Salaam, Tanzania

CENETEC-Salud, Mexico

Centre for International Child Health, MCRI, University of Melbourne

Center for Public Health and Development, Kenya

Chaban Medical

Clinton Health Access Initiative (CHAI)

College of Medicine, Malawi

College of Medicine, University of Ibadan

Colibri – Vital Visions

Council of International Neonatal Nurses

COVIDaction / Oxygen CoLab

Diamedica

Drive DeVilbiss Healthcare

EPFL EssentialTech

Fishtail Consulting Ltd.

FREO2

GCE

Ghana Health Service

Global Health Informatics Institute

Global Health Labs

Hewa Tele

Inogen

Invacare

Jiang Su Yuyue Equipment & Supply Co., Ltd

Kamuzu University of Health Sciences

LeanMed

London School of Hygiene and Tropical Medicine

Longfian Scitech Co., Ltd.

MedGlobal

Medical Research Council Unit, The Gambia

Ministry of Health and Sanitation, Sierra Leone

NASA

NEST360

Nidek Medical Products, Inc.

Ola During Children's Hospital

Open O2

Oxus America, Inc.

Oxygen for Life Initiative

PATH

Philips

Prime Biomedical

Rice 360 Institute of Global Health Technologies

Sanrai International

Shenyang CANTA Medical Tech Co., Ltd

Spark Health Design

Texas Children's Hospital

Thornhill Medical

UNICEF

United Mission Hospital Tansen, Nepal

University of British Columbia

University College Hospital, Ibadan, Oyo State, Nigeria

University of Global Health Equity

USAID

World Health Organization

Appendix C – Demographics

The charts below represent the demographics of the TPP Survey. The chart on the left shows the type of participant, while the chart on the right shows the area of expertise of the participants.