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Increasing Visibility of Oxygen Concentrator Performance Using an Embedded Purity Display

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Abstract

Oxygen concentrators have and will continue to play an essential role in healthcare delivery in low- and middle-income countries (LMICs). Performance degrades over time resulting in reduced oxygen concentration, which has less therapeutic benefit for the patient. The World Health Organization recommends oxygen concentration of at least 82% for patient care. Oxygen concentrator manufacturers implement visible and audible alarms to indicate low oxygen concentration. However, the alarm thresholds vary widely, from 65% to 85%, and there is no consistency in the implementation of alarms across manufacturers. We propose the addition of a display that shows the actual oxygen concentration being generated. We believe this will allow clinicians, who are the primary users of oxygen concentrators in LMICs settings, to make more informed decisions. We tapped into the serial data communication for the diagnostic port of a DeVilbiss oxygen concentrator to intercept oxygen concentration levels, and displayed them on a clearly visible two-digit display. We developed a working oxygen concentration display, which we embedded into the front panel of a DeVilbiss oxygen concentrator. Serial data was decoded and formatted for display purposes using a microcontroller. The display digits were green and measured 0.8 inches (21 mm) in height. The display blinks once per second when oxygen concentration drops below 82%, making it more noticeable than the small, continuously lit visible indicators used by most manufacturers. The entire electronics cost less than USD 10, using parts we had available in-house. Our proof of concept allowed us to demonstrate the feasibility of the idea and think through the challenges and potential costs associated with this intervention. We recommend formal usability testing in the hope that it will reduce uncertainty around the potential risks and benefits of giving clinicians access to the actual concentration of oxygen being generated.

Keywords; *Oxygen concentrator, Low- and middle-income countries (LMICs), Biomedical engineering, Low-cost technology, Clinical decision making, Microcontroller.*

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1. Introduction

Oxygen concentrators play a pivotal role in modern healthcare by providing essential supplemental oxygen to individuals with respiratory conditions. These devices function by drawing in ambient air, filtering out nitrogen, and delivering up to 95.6% pure oxygen through patient interfaces such as nasal cannulas or masks. This therapeutic intervention is crucial for managing respiratory illnesses such as pneumonia, chronic obstructive pulmonary disease (COPD), and various other conditions where adequate oxygenation is essential for patient well-being.

The availability of oxygen can mean the difference between life and death. A study from Papua New Guinea showed a 35% reduction in pneumonia-related deaths following the introduction of oxygen therapy using oxygen concentrators.[1] While some hospitals have oxygen plants, these generally only provide oxygen access to a limited number of patient beds. Additionally, plants represent a single point of failure and require frequent and expensive maintenance.[2]

While the use of oxygen concentrators in low- and middle-income country (LMIC) settings has received some criticism, citing unreliability and lack of robustness, much of this is based on unfounded and ill-informed rumors.[3] One potential source of the rumors on effectiveness of oxygen concentrators stems from the fact that while oxygen concentrators are capable of producing oxygen with a concentration of up to 95.6%, performance decreases over time due to several factors. Performing routine maintenance on oxygen concentrators is paramount to ensuring their reliability and effectiveness in delivering oxygen therapy. Planned preventive maintenance by qualified technicians is critical for reducing the risk of unexpected failures. Workforce targets for biomedical engineers have been recently established.[4] However, anecdotally, current levels in many LMICs fall well below these targets. This makes the practice of planned preventative maintenance extremely challenging.

The World Health Organization (WHO) recommends oxygen purity levels above 82% for therapeutic use, except in the case of neonates, who may require lower concentrations to prevent oxygen toxicity.[5] Achieving and maintaining this standard is considered essential for ensuring that patients receive the appropriate oxygen levels needed to manage their medical conditions effectively. The only reliable means of accurately determining the concentration of oxygen being generated is to use an oxygen analyzer. However, while these devices are commercially available, they are still not widely accessible to biomedical engineers in LMICs. To alert users when oxygen concentrations fall below therapeutic levels, concentrators are equipped with both visible and audible alarms. These alarms are required under ISO 80601-2-69.[6] However, they are not always implemented in the same way. Table 1 shows a comparison of how visual indications for low oxygen concentration vary across five models of concentrators.

The threshold for low oxygen indication varies across different models of concentrator, ranging from 65% to 85% for the five models listed in Table 1. To compound the problem, indicator lamps can also be hard to see in direct sunlight. The inconsistency of audible alarms further adds to this confusion. Some concentrators make a continuous sound when the oxygen level is too low, while others only beep once and then remain silent, even if the problem continues.

Table 1. *Low oxygen visible indicator and threshold by concentrator make/model.*

Make/Model	Alarm Threshold	Normal concentration	Low Concentration
DeVilbiss 525	85%	Green	Amber
Longfian Jay-5	85%	Blue	Red
Shenyang Canta V8-WN-NS	82%	Green	Red
Philips Respironics EverFlo	82%	No indication	Yellow (Red Off)
Olive-5	65%	No indication	Red

This variability is evident in the five models in Table 1. A typical health facility in an LMIC setting will have more than 5 models making it difficult for clinicians to understand the alarms. The OpenO2 Team in Malawi, who maintain more than 2,500 oxygen concentrators, have identified 78 different makes and models currently in use across the country, and varieties range from 5 to 17 within the 26 district hospitals in the country.[7]

In spite of mandated alarms, concentrators are often "presumed" to be working when the compressor is rumbling and bubbles are visible in the humidifier bottle. In reality, this can be far from the truth. A 2019 study from Nigeria assessed 50 presumed working oxygen concentrators across eight health facilities and found that almost half were blowing nothing more than room air, and only two were producing oxygen concentrations greater than 85%.[8] Anecdotal evidence from ongoing assessments indicates that many oxygen concentrators remain non-functional or poorly maintained even after pandemic-related procurement efforts.

Whether due to inadequate training, limited understanding of model-specific alarm signals, or a lack of alternative oxygen sources, clinicians may continue using underperforming concentrators even when alarms sound and warnings are illuminated. While improvements in planned preventative maintenance and increased access to oxygen analyzers may improve detection of underperforming devices, this will not prevent them from being used if neither the workforce nor the replacement parts are available to conduct repairs. However, if improvements can be made to how visible and audible alerts are implemented, this can reduce risks associated with equipment use. We believe that a clearly visible oxygen purity display can empower users to make more informed decisions about whether and how to use concentrators. This idea has previously been presented as an example of grassroots innovation.[9] Here we describe our proof of concept and discuss the potential risks and benefits of this approach. We hope this will stimulate discussion within and between the clinical and biomedical engineering communities.

2. Approach

This work was conducted at the Global Health Informatics Institute (GHII), a Malawian non-governmental organization (NGO) dedicated to developing solutions at the intersection of science, engineering and global health to address problems of global health importance. Our team considered two approaches to measuring the concentration of oxygen being produced for display purposes.

Our first approach takes advantage of the presence of an onboard oxygen sensing device, which is commonly an ultrasonic sensor. Ultrasonic sensors measure the change in speed of sound waves passing through the stream of gas. Owing to the difference in densities between oxygen and nitrogen, the speed of sound in the gas mixture varies with composition, allowing the oxygen concentration to be determined

from the sound velocity. Manufacturers use this sensor to determine if the oxygen concentration falls below a predetermined threshold (typically 82%) and initiate visual and audible alarms. While it is impractical, and arguably reckless, to tap into this circuitry, some concentrators have a diagnostic port allowing for the connection of an external diagnostic device used to capture certain parameters of the oxygen concentrator such as oxygen concentration, flow rate, temperature, etc. Such ports can be seen on DeVilbiss 515 concentrators, some DeVilbiss 525 concentrators and on Philips/ Respironics Everflo concentrators. These ports commonly use standard serial communication protocols to transmit the information from the main control board inside the concentrator to the external diagnostic device. This data can be easily intercepted inside the concentrator and captured for display purposes.

Our second approach utilizes a dedicated oxygen sensor. Having previously developed hand-held oxygen analyzers for spot-checking concentrators during the COVID-19 pandemic, we had prior experience with commercially available ultrasonic sensors. [10] Unlike our first approach, integrating a dedicated oxygen sensor presents a more agnostic approach that can fit into any oxygen concentrator without having any specific knowledge of the internal working of the concentrator or the availability of a diagnostic port. The sensor is simply inserted into the tubing that connects the output of the flow meter to the oxygen output on the concentrator.

The implementation of both approaches is similar, in that we receive serial data either from an existing onboard diagnostic port or from a commercial sensor and display this data for the user.

We chose to focus on the first approach as it is less invasive and cheaper to implement. To verify the accuracy of the displayed concentration we used a commercial handheld ultrasonic oxygen analyzer model number RP-01 manufactured by Winpower Technologies.[11]

3. Results

Working with a DeVilbiss 515 oxygen concentrator, we parsed the serial data coming from the diagnostic port to extract the oxygen concentration derived from the onboard oxygen sensing device. We then developed a two digit display connected to a microcontroller and retrofitted it into the oxygen concentrator. The display, microcontroller and power supply are mounted on a circuit board shown in Figure 1. As feasibility was prioritised over optimization, we designed it around components that we already had available in house.

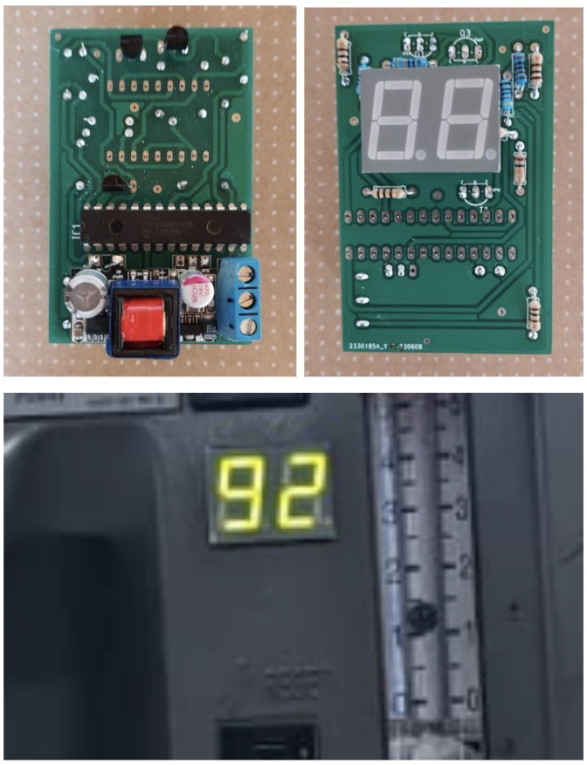

Figure 1. *Display board back (top left), front (top right) and installed (bottom).*

The display digits were green and measured 0.8 inches (21 mm) in height. The system we developed blinks the seven-segment display once per second when oxygen purity drops below 82%, making it more noticeable than the small, continuously lit indicators used by most manufacturers.

The displayed oxygen concentration differed from the reading of a commercial oxygen analyzer by no more than one percent. Based on this result, we retrofitted an additional DeVilbiss 515, as well as a DeVilbiss 525 concentrator. In these cases, we observed discrepancies of up to three percent. Notably, the second 515 displayed oxygen concentrations as high as 97%.

4. Discussion

We have demonstrated the feasibility of displaying the actual oxygen concentration being generated by leveraging existing features of the oxygen concentrator augmented with an easily-readable two-digit display, which we believe improves the usability of the device. Consider an oxygen concentrator that displays a “low oxygen” visual alert and sounds an audible alarm, signaling that the oxygen concentration has dropped to somewhere between 21% (room air) and 81%. In a London nursing home, the risk of harm from this issue alone is relatively low, particularly for a COPD patient whose caregiver understands the significance of the alarm and knows who to contact when it activates. However, the consequences can be far more serious in a crowded pediatric ward in Malawi, where more than 20 oxygen concentrators may be operating simultaneously alongside other medical devices. In such environments, the effectiveness of alarms mandated by ISO 80601-2-69 is significantly reduced for several reasons. LMICs face a critical shortage of healthcare personnel, leading to high patient-to-clinician ratios and limited attention for each patient.[12] During times of high patient volume, hospitals often consolidate patients into as few rooms as possible, placing beds so close together that there may be barely enough space to fit a concentrator between them. Nurses are typically limited to core tasks like taking vital signs and administering medications. As a result, patients frequently rely on family members acting as guardians to address other needs such as meals and bathroom assistance, further crowding the ward. In this context, a small blinking light or a beeping alarm can easily go unnoticed or be drowned out by the noise of surrounding equipment. Unlike the relatively calm environment of a London nursing home, in these busy, resource-limited settings, a clear and readable display of the oxygen concentration may be far more effective than traditional alarm systems.

The human resource shortage is not limited to clinical staff but also extends to the biomedical engineering workforce responsible for repairing and maintaining these medical devices.[4] Limited staffing combined with a lack of replacement parts with which to perform repairs and the high demand for oxygen often result in concentrators being operated even when alarms continue to sound long after service is required. This can result in alarm fatigue, where clinicians become desensitized to safety alarms due to their overwhelming frequency, leading them to ignoring alarms.[13]

The recognition that the classic concentrator design is not a good fit for LMIC settings is not new.[3] This issue received significant attention following the COVID-19 pandemic, and in 2021 UNICEF initiated the development of a target product profile (TPP) for a resilient oxygen concentrator primarily targeted at LMIC, intended to stimulate the

development of a durable, state-of-the-art oxygen concentrator designed to operate in challenging environments.[14] The TPP for this fit-for-purpose concentrator was developed through a consultative process involving multiple stakeholders. In addition to consultative meetings and interviews, a TPP survey was sent out to 178 participants, which included clinicians (21), biomedical technicians (10), manufacturers (13), product innovators (19), NGOs (22), Wholesalers (4), and government (1).[15] The device is intended for use in LMICs by a wide variety of clinicians, including nurses, midwives, clinical officers, doctors, and allied health partners, as distinct from North America or Europe where the primary user is the patient. Ineffective alarms were highlighted as a problem.[16] The TPP says the design should include alarms and indicators that are appropriate for acute care low-resource settings, saying that concentrators must include alarms to notify users of specific faults, such as low oxygen purity, further noting that "*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"*. This statement openly acknowledges the realities of the LMIC setting.

The inclusion of an oxygen concentration display in the user interface was first proposed in 2021 during the development of the Target Product Profile (TPP) and was incorporated into the accompanying survey. In a section focused on user interface improvements, participants were asked to rate the importance of an "oxygen purity display screen" using the following options: not needed, nice to have, important but not critical, or critical—must have. Since this feature was ultimately not adopted, it can be inferred that participants did not consider it sufficiently valuable. Although the TPP describes the types of participants involved, it does not provide a breakdown of responses by professional cadre. Notably, while this feature was not adopted, the TPP contains a recommendation that an "*Oxygen concentration display screen is included internally within the device for repair technicians to easily troubleshoot, but not visible for clinical users*".

Below we discuss three potential concerns that might have influenced the decision not to externally display the oxygen concentration, along with possible mitigation strategies.

Concern 1: *Users may confuse the displayed concentration with the patient's oxygen saturation (SpO_2) or their fraction of infused oxygen (FiO_2)*: This is a valid concern. However, this could be mitigated with labeling. This kind of proactive clarification is a proven strategy in human factors engineering to reduce errors and misinterpretations. Additionally, given the increased emphasis on pulse oximetry, text could be added to the label recommending that, when available, a pulse oximeter should be used to measure the patient's oxygen saturation (SpO_2).[4]

Concern 2: *Users may be concerned if they see the concentration fluctuate by a few percentage points, which can sometimes occur during normal operation*: Indeed fluctuation can occur, most commonly seen when the two sieve beds that alternately remove nitrogen from room air have deteriorated disproportionately. Since the beds cycle every few seconds, the average concentration received by the patient is represented by the average of the high and low reading. If a moving average of the concentration readings over a 1-minute

window is displayed then any fluctuation will likely not be apparent to the user.

Concern 3: *Users may be concerned if they see the oxygen concentration drop below a certain threshold (e.g. 90%), even though the user manual and ISO device specifications consider concentration above 82% to be within the proper operating range*: While the therapeutic effectiveness of oxygen does not primarily depend on achieving the highest possible purity, but rather on delivering oxygen concentrations that are sufficient to correct or prevent hypoxia, supported by oxygen saturation measurement using pulse oximetry, this is not widely understood by many healthcare workers.[17] Oxygen at concentrations above 30% is already therapeutic for many patients.[18] A solution predicated in hiding the concentration of oxygen being generated by the concentrator from these users will not advance oxygen therapy in the long term. Rather, finding ways to improve user understanding through pre- and in-service training and combined with well-designed and tested graphical reminders will allow the users to make more informed decisions, which should translate to improved patient outcomes. While there is no threshold below which we can scientifically argue that oxygen should not be provided, the simple statement "Send for maintenance when Oxygen Concentration stays below 82%" summarizes a best practice that can be easily understood.

The mental model of healthcare workers in LMIC settings is that concentrator performance is binary; it either works or it doesn't. Manufacturers essentially reinforce this binary mental model through the way they design most oxygen concentrator user interfaces. In short, if the concentrator turns on and the gas comes out, clinicians typically assume it to be working. If it does not turn on, or alarms, they assume it to be broken. As previously discussed, either out of necessity or because the meaning of alarm indicators may not be fully understood, concentrators operating below 82% are still used for patient care, with no visibility into their actual performance. The addition of an external display should allow users to make more informed decisions that would otherwise not be possible. Consider the following scenario:

Scenario: A 14 year-old boy with an oxygen saturation of 91% on room air and a 53 year-old man with an oxygen saturation of 86% on room air have both been prescribed oxygen therapy at 5 lpm. There are only two oxygen concentrators available, both are alarming and display a low oxygen indicator when turned on and the flow rate set to five liters per minute. How does the clinician decide how to allocate the concentrators?

With only visible and audible alarms for low oxygen concentration there is no strategy that can result in an optimal outcome. However, with an indication of the actual oxygen concentration, the clinician can give the better performing concentrator to the patient with the greater need. Should the concentration indicate nothing greater than the 21% found in room air, the clinician would likely not even waste time trying to use it, and would go to greater lengths to locate a replacement concentrator from elsewhere in the hospital.

Displaying oxygen purity during operation also serves as a valuable maintenance tool. It facilitates early detection of potential issues with oxygen delivery, such as clogged filters or mechanical malfunctions, prompting timely maintenance and preventing disruptions in therapy. For example, a technician could know if the machine has a faulty oxygen sensor based on the

comparison with a handheld analyzer. This proactive approach to monitoring and managing oxygen purity contributes to smoother healthcare operations and ensures that concentrators function optimally to meet patient needs.

This discussion would not be complete without some mention of the cost implications. Of the two approaches mentioned, utilizing the existing onboard oxygen sensing device would be the cheaper approach, incurring additional cost for the display alone. For our implementation the cost of parts was less than USD 10, and would be considerably cheaper if purchased in volume. One concern with this approach is that while the ultrasonic sensing approach most commonly used by concentrator manufacturers can be accurate, the degree of accuracy will vary based on the specific implementation. As the primary purpose of the oxygen sensing device in most concentrators is to determine if the concentration is above 82%, current implementations likely focus on accuracy at that specific point, and do not guarantee accuracy over the 21% - 95.6% range. This would explain concentrations greater than 95.6% mentioned in the results section, which exceeds the theoretical upper limit of oxygen concentration using the pressure swing adsorption process. Using the second approach of adding a commercial oxygen sensor will likely offer greater accuracy, but would more than double the cost. The additional cost of the display/sensor could potentially reduce the number of devices sold and therefore the number of beneficiaries. Whether the market will bear these additional costs is unknown. However, the introduction of a new fit for purpose oxygen concentrator designed against the UNICEF TPP will soon give us visibility into this.[19]

5. Conclusion

Oxygen therapy should not be a guessing game. The integration of a purity display into an oxygen concentrator enhances both device functionality and user confidence. By equipping concentrators with real-time oxygen concentration displays, we empower clinicians with greater clarity, confidence, and control. Moreover, a purity display also serves as a vital tool for technicians, facilitating early fault detection, faster troubleshooting, and more proactive maintenance, ultimately reducing device downtime. In settings where alarm fatigue, high patient loads, and limited technical support challenge the effectiveness of traditional alarms, a visible oxygen purity reading provides an additional layer of safety and operational efficiency.

Although concerns exist regarding user interpretation and device accuracy, these can be mitigated through better labelling and targeted training. At a modest additional cost, integrating a real-time purity display represents a simple yet transformative step toward building concentrators that are fit for purpose in LMIC healthcare environments, ultimately delivering safer and more effective oxygen therapy for all.

6. Recommendation

Formal usability testing will reduce uncertainty around the perceived risks and benefits of adding an external oxygen concentration display to oxygen concentrators designed specifically for use in LMIC settings, where clinicians are the primary users.

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Authors' Contributions

GPD conceived the idea of displaying the actual oxygen purity on the concentrator, and the idea of tapping into the "diagnostic port" on the device. KES led the technical development of the device, which included designing the PCB layout and assembling the display board. He established the serial communication interface between the display board and the oxygen concentrator's diagnostic port, enabling real-time data acquisition by decoding and interpreting the oxygen purity values in the data, and wrote the initial draft of the manuscript. ETN refined the PCB design, assembled and tested prototypes, and assisted in testing and troubleshooting. MDL provided close technical supervision, offered continuous guidance in system integration and data validation, and contributed to the refinement of the manuscript through detailed review and constructive feedback. All authors contributed to the writing of this manuscript and have read and approved the final version.

Declaration of Interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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