Oxygen concentrator

Country of origin | Bangladesh
Primary function | Treatment
Category | Medical gas

Commercial information _

List price (USD): 400 Brand: OxyNLife Model: OxyNLife

Product description _____

The developed device selectively removes nitrogen from the air to produce a high purity oxygen stream by utilizing a state-of-the-art porous adsorbent. The device continuously draws in air and generates a steady stream of high-purity oxygen.

Product details.

Accessories: The device requires propriety software that comes with the device for It to function and achieve the target performance. Additionally, the device also needs filters (air, bacteria filters) as accessories.

Consumables: Face mask/nasal cannula for patients during use. The filter has to be changed every 6 months of use.

Warranty duration: Lifetime: 2-5 years

Energy requirements: Continuous power supply, AC, 110V, 220V, 340W

Facility requirements: Healthcare waste disposal facilities (disposal of oxygen face mask, nasal

canula and filters), disposal guidance provided by the manufacturer

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NOTE: Information reported by manufacturer before 17 December 2021

WHO ASSESSMENT

Clinical assessment

Hypoxemia is a condition in which the blood oxygen level is abnormally low. It can be caused due to various mechanisms and diseases and can lead to respiratory failure and the need for supplemental oxygen therapy. In many resource-limited settings, lower respiratory tract infections and tuberculosis, in addition to COVID-19, are a leading cause of hypoxemia and a significant source of morbidity and mortality, ranking among the top ten causes of death in low- and lower-middle-income countries.

Furthermore, it is estimated that only fewer than half of all health facilities have continuous oxygen supply in low-resource contexts. A lack of accessible oxygen, in particular, leads to preventable deaths, with an estimated 122,000 deaths from pediatric pneumonia each year that could be avoided if oxygen supplies and delivery systems were improved.

The COVID-19 pandemic has further increased the demand for oxygen worldwide, and the OxyNLife device intends to address this global health concern as a prototype oxygen concentrator. The device's inventive potential, however, is debatable based on the information supplied.

WHO specification comparison

OxyNLife device only partially complies with the related WHO requirements. Even if no non-compliance was found, the following device parameters and technical specifications could not be verified or were not included in the documents:

The type of oxygen outlet (required with 6 mm, or 1/4 inch, barbed fitting or equivalent) and how it is secured and shielded to avoid being broken or bent. The ability to continuously supply the specified oxygen concentration at elevations ranging from 0 to at least 2000 m (along with performance characteristics at altitudes higher than 2000 m) must be stated. The main power cable should be longer than 2.5 meters. It's unclear whether the DISS and barbed adaptors are included in the accessories list (for each outlet, if applicable). Storage and operating conditions related to temperature and humidity apply to the entire device, not just the sensor.



Mechanical shock resistance, mechanical vibration, electromagnetic compatibility, and electrical safety tests were all performed. The displayed parameters, display characteristics, and user-adjustable settings are all available. IP protection is provided.

Regulatory assessment



Pre-market assessment



acceptable





Not acceptable





Adequate documentation was not provided to perform a medical device Regulatory or Quality System review. Design verification and validation reports were not submitted for premarket assessment. No documentation available on quality management system, ISO 13485:2016 for quality system assessment. No documentation was provided on post-market activities.

As such, this product is in the prototype stage.

USA FDA Recognized Consensus Standards:

- ISO 80601-2-69:2014
- ISO 18562-1:2017
- ISO 18562-2:2017
- ISO 18562-3:2017
- ISO 18562: 2017
- ISO 80601-2-69:2020

WHO technical specifications for oxygen concentrators:

- ISO 80601-2-69:2014,
- IEC 60601-1:2012,
- IEC 60601-1-2:2014,
- IEC 60601-1-6:2013,
- IEC 60601-1-8:2012,
- IEC 60601-1-9:2013,
- IEC 60601-1-11:2010,
- ISO 13485:2003,
- ISO 14971:2007

Technology evidence assessment

Domains

Evidence assessment Risk/benefit Impact























The device is a prototype that was developed specifically for COVID-19. It has been tested in two hospitals with two patients, and it complies with the WHO oxygen concentrator guidelines. All used components are low-cost, according to the documents provided. As a result, the system's affordability in LMIC appears credible. It is simple to manufacture, use, and maintain the device. The information about the shelf life (0-2 years) raises questions. More information about medical, safety and cost-effectiveness is needed for further evaluation and recommendation.















Summary

Innovation



Ethical











Technology Not recommended. evidence still a prototype assessment

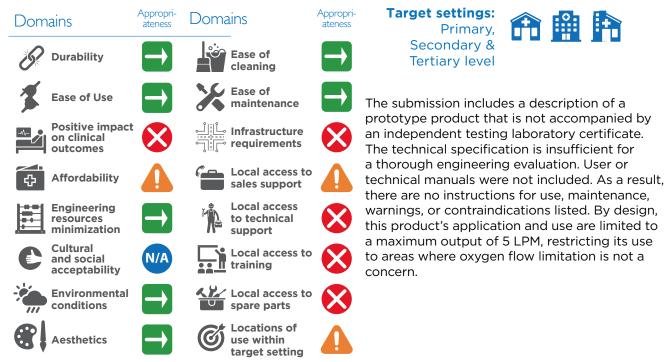


Green environment





Health technology and engineering management



Intellectual property and local production



Technology transferability



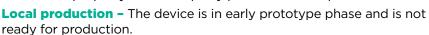




Local production



Intellectual property - Protected by trade secret. It uses proprietary software, which can be licensed to the manufacturer. The use of all intellectual property and third-party products will require clearance.





WHO related guidance material

- WHO Oxygen website https://www.who.int/health-topics/oxygen#tab=tab_2
- Oxygen therapy for children: a manual for health workers https://apps.who.int/iris/ handle/10665/204584
- Oxygen sources and distribution for COVID-19 treatment centres: interim guidance, 4 April 2020 https:// apps.who.int/iris/handle/10665/331746
- Coronavirus disease (COVID-19) technical guidance: Patient management https://www.who.int/ emergencies/diseases/novel-coronavirus-2019/technical-guidance/patient-management
- Living guidance for clinical management of COVID-19 https://www.who.int/publications/i/item/WHO-2019-nCoV-clinical-2021-2
- WHO recommendations on newborn health: guidelines approved by the WHO Guidelines Review Committee - https://www.who.int/publications/i/item/WHO-MCA-17.07
- WHO-ICRC Basic Emergency Care: approach to the acutely ill and injured https://www.who.int/ publications/i/item/basic-emergency-care-approach-to-the-acutely-ill-and-injured
- Emergency care https://www.who.int/emergencycare/systems/en/
- WHO Medical Emergency Checklist https://www.who.int/publications/i/item/who-medical-emergency-
- Guidelines for essential trauma care https://www.who.int/publications/i/item/guidelines-for-essentialtrauma-care
- WHO Global Health Estimates (the top 10 causes of death) https://www.who.int/news-room/factsheets/detail/the-top-10-causes-of-death
- WHO Coronavirus (COVID-19) Dashboard https://covid19.who.int/