PROTOTYPE PRODUCT

Mechanical ventilator

Country of origin | United States of America
Primary function | Treatment
Category | Medical device

Commercial information

List price (USD): 4000
Year of commercialization: N/A
Number of units distributed: N/A
Currently marketed in: N/A
Brand: OneBreath, Inc.

Product description

OneBreath's ventilator addresses the need for continuous ventilation in the absence of compressed gas or electricity and provides a range of settings utilizing a portable O2 concentrator. Preventative maintenance is minimal and a simple and intuitive user interface controls state-of-the-art clinical features including Volume Targeted Pressure Control (VTPC), spontaneous breath support modes, programmable PEEP, neonatal ventilation, and accurate blending and sensing capabilities.

Product details

Accessories: Includes AC power cord and oxygen sensor
Consumables: The disposable breathing circuits, endotracheal tubes, bacterial filters (optional)
Lifetime: 2-5 years
Energy requirements: Rechargeable battery, Continuous power supply, AC, 110V, 220V, 4-hour battery recharge cycle, 24-hour battery life

Contact: Matthew Callaghan | Email: info@onebreathventilators.com | Phone: +1 650 646 4984 | Web: www.onebreathventilators.com

NOTE: Information reported by manufacturer before 17 December 2021

WHO ASSESSMENT

Clinical assessment

In many resource-limited settings, lower respiratory tract infections, along with COVID-19 and respiratory diseases, are a major source of morbidity and mortality, ranking among the top 10 causes of death in low- and lower-middle-income countries. The COVID-19 pandemic has heightened the global demand for high-quality, safe, and affordable medical equipment to treat patients with respiratory failure, particularly those who require mechanical ventilation. Pending regulatory and technical evaluation, OneBreath may provide a suitable solution for mechanical ventilation for patients with respiratory failure, provided that the healthcare workforce receives appropriate, relevant training in its clinical use and maintenance.

WHO specification comparison

OneBreath ventilator partially complies with "Transport ventialtor", "Sub-acute ventilator" and "ICU ventilator" WHO technical specifications.

The following main non-compliances and non-verifiable (or not specified) requirements are listed:

Non-compliance: Volume Control Ventilation (VCV) mode is required. Real-time scalar waveform for volume not available. Tidal Volume expired not displayed. ONLY FOR "ICU VENTILATORS": Tidal Volume range required at least 20–1500 ml, while only 20–1000 ml is available. Three scalar waveforms are required to be displayed at the same time while only two are simultaneously available. Loop (axis) displays for pressure-volume and flow-volume not available. Expiration time and End-Tidal CO_2 parameters not displayed

Not possible to be verified: Oxygen-air mixture accuracy. Internal function testing/leak testing. "IP" protection level certification. Display brightness and contrast control capabilities. Not clear if "Inspiratory pause manoeuvre capability to measure plateau pressure" is available. Not clear if "PEAK, PLATEAU and MEAN airway pressure" and "RR (spontaneous and mechanical)" parameters can be displayed and if "adjustable peak pressure limitation/pressure-cycling mechanism above measured peak pressure" is available. "High/Low FiO_2", "High/Low RR", "High/Low Tidal Volume" and "Low PEEP" alarms availability. Availability of single-limb breathing circuits for adult/paediatric.

Regulatory assessment

Pre-market assessment	Not acceptable
Post-market assessment	Not acceptable
Quality system assessment	Not acceptable

Adequate documentation was not provided to perform a medical device Regulatory or Quality System review on this product. Design verification and validation reports were not submitted for pre-market 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.

Technology evidence assessment

Domains	Evidence assessment: Risk/benefit ratio	Evidence assessment: Impact
Medical	!	!
Safety	!	!
Economy	!	!
Organizational	→	→
Legal	!	!
Social	!	!
Ethical	!	!
Green environment	!	!

The device is a patent-pending prototype made in the United States and Singapore. There is no provision for local manufacture. According to manufacturer tests, the device is simple to use and maintain in rural locations. It is portable and can be used in multiple settings, including ICUs, Emergency rooms, and transportation. Despite this, the device has yet to receive regulatory approval, and the manufacturer has not provided any clinical study data. The unit costs appear to be reasonable, yet they are not inexpensive. In this aspect, affordability is unlikely to be guaranteed in LMI settings. The device is a prototype. In conclusion, a recommendation could not be made based on the current level of evidence.

Summary

Innovation		Technology evidence assessment	Not recommended, still a prototype
Technology readiness level	5		

Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness
Durability	→	Ease of cleaning	!
Ease of Use	→	Ease of maintenance	!
Positive impact on clinical outcomes	!	Infrastructure requirements	→
Affordability	!	Local access to sales support	✗
Engineering resources minimization	→	Local access to technical support	✗
Cultural and social acceptability	N/A	Local access to training	✗
Environmental conditions	→	Local access to spare parts	✗
Aesthetics	→	Locations of use within target setting	!

Target settings: Rual, Urban, Indoors, Ambulance, Secondary & Tertiary level

The core design is based on proven innovation (turbine). The user interface is intuitive. Internal disinfection of the ventilator between patients' use is not addressed. The manufacturer mentions periodic maintenance, however, there is no information on training or parts availability in the submission. Disposables that are not proprietary are indicated. A field evaluation is pending.

Intellectual property and local production

Technology transferability

Openly access intellectual property

Local production

Intellectual property – It is patent-protected. Some patents are owned by third parties. All applicable patents will require clearance before they can be used. The breath delivery and ventilator management code is proprietary. For the user interface, third-party authorisation is also necessary. Proceed with due diligence.

Local production – It is not yet ready for production; it is still in the prototype stage.

WHO related guidance material

- WHO Global Health Estimates (the top 10 causes of death) - https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death
- WHO Coronavirus (COVID-19) Dashboard - https://covid19.who.int/
- 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
- Therapeutics and COVID-19: living guideline - https://apps.who.int/iris/handle/10665/345356
- 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/
- Guidelines for essential trauma care - https://www.who.int/publications/i/item/guidelines-for-essential-trauma-care
- Severe Acute Respiratory Infections Treatment Centre - https://www.who.int/publications/i/item/10665-331603