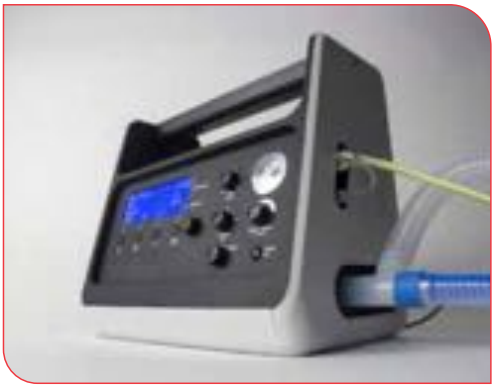
Intensive care ventilator

Country of origin | United States of America
Primary function | Supporting or sustaining life
Category | Medical device



Commercial information

List price (USD): 2500
Brand: World Ventilator Foundation
Model: WorldVent

Product description

This emergency use ventilator utilizes the following proven approaches. Solenoid operated inspiratory and expiratory valve control typical of modern ICU vent designs; few moving parts

Entrainment of room air via venturi action with all O_2 delivered to the patient without waste

Standard silicon piezoresistive pressure sensors with a fixed orifice, airway flow sensor

Commercial component controller using compiled SW without operating systems

Commercial AC/DC power supply with standard Li-Ion battery

Product details

Accessories: Flow Sensor: Single piece molded component that creates a differential pressure signal as a function of airway flow.

Consumables: Generic versions of: Patient Breathing Circuit, Airway Pressure Sense Line, Inspiratory Filter

Lifetime: 5-10 years

Energy requirements: Rechargeable battery, continuous power supply, DC, 12V, 24W, 1-hour battery recharge cycle, 0.5-hour battery life

Facility requirements: Gas supply (Oxygen)

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NOTE: Information reported by manufacturer before 17 December 2021

WHO ASSESSMENT

Clinical assessment

Lower respiratory tract infections and respiratory diseases are a major source of morbidity and mortality in many resource-limited settings, ranking among the top ten 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.

In intensive care and critical care settings, the WorldVent ventilator could provide an easy-to-use alternative to traditional ventilators. Single-level controls and a simple interface may aid the user's familiarization with the ventilator, assuming that appropriate training is provided and reliable power supply is ensured (even though the ventilator has a backup battery).

WHO specification comparison

The WORLDVENT ventilator does NOT comply with the "ICU VENTILATOR" WHO technical specifications.

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

Non-compliances: External low-pressure source compatible (< 35 psi). Pressure Control Ventilation (PCV) mode not available. NIV modes not provided (CPAP or BiPAP). FiO_2 range 21-100% not provided (60-100 discrete values). Tidal Volume range required at least 20 – 1500 ml (300 – 900 ml is available). Minimum RR requested is 10–60 breaths/min (10-34 bpm range provided). PEEP range: 0–20 cmH2O required (5-20 cmH2O provided). Real-time scalar waveforms, at least two simultaneously, not available. Loop (axis) displays for pressure-volume and flow-volume not available. Expiration time, Minute volume and End-Tidal CO_2 parameters not displayed. "High/Low FiO_2", "High/Low RR", "Low Minute Volume" and "Low PEEP" alarms not available. Power supply requirements (100–240 V AC 3 10% required).

Not possible to be verified: If paediatric patient could be treated. Oxygen-air mixture accuracy. Internal function testing/leak testing. "IP" protection level certification. If "PLATEAU and MEAN airway pressure" parameters can be displayed and if "adjustable peak pressure limitation/pressure-cycling mechanism above measured peak pressure" is available. Availability of single-limb and double-Limb breathing circuits for adult/paediatric are available.

Regulatory assessment

Pre-market assessment	Proceed with caution
Post-market assessment	Not acceptable
Quality system assessment	Not acceptable

This is an FDA EUA authorized ventilator under product code QOT. Adequate documentation was not provided to perform a medical device Regulatory or Quality System review on this product. A summary document of the design verification and validation reports was submitted but did not provide the actual test reports for pre-market assessment. Documentation on the quality management system ISO 13485:2016 for quality system assessment is not available. Documentation was not provided on post-market activities.

This product was assessed as prototype.

This product is classified as an EU MDR class IIb and USA FDA class II (product code CBT or MNT, depending on the specific claims).

The following are the FDA's Recognized Consensus Standards for this product type:

ISO 5356-1 ;2004 ISO 80601-2-12 ;2011, ISO 5359 ;2014, ISO 18082 ;2014 [Including AMENDMENT 1 (2017)], ISO 18562-1 ; 2017, ISO 18562-2;2017, ISO 18562-3 ;2017, ISO 18562-4;2017, ISO 80601;2017, ISO 80601;2020

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 prototype ventilation system developed to meet the needs of low-resource settings to address COVID-19 related needs. Also suitable for patients requiring short-term supportive care. It requires minimal training, is easy to use and manufacture, and has a low operating cost. The maintenance requirement is also minimal. Due to the device's durability, implementation and running costs seem affordable in LMICs. It is also portable and works in case of disruption of power supply with backup battery (0.5 hours). As a result of its simplistic design, this product meets basic safety and performance standards for critical care ventilation. Local production may be possible but not planned currently. The device is patent-protected. In summary, this device shows high potential to be beneficial in saving lives in LMICs and therefore could be recommended.

Summary

Innovation		**Technology evidence assessment**	**Recommended**
Technology readiness level	**7**		

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: Secondary & Tertiary level

The mechanical ventilator prototype is a well-designed product with attention to low-resource settings condition, but we could not find enough evidence to evaluate the financial aspects (i.e. initial cost, maintenance, battery replacement, and spare parts cost). Manufacturer claims that internal battery will support the ventilator operation for over 30 minutes facilitating protection for patient care during power disruption or transport. However, while the product's features support clinical needs, the maintenance requirement, guidance for testing gear needed and for performing functionality tests, as well as access to technical training for critical life support product are lacking.

Intellectual property and local production

Technology transferability	!
Openly access intellectual property	✗
Local production	!

Intellectual property – The software is proprietary. The device is under trade secret and patent protection. The design of the device is also protected. The status of the patent applications is pending. The status of the trademark application for WORLDVENT is also pending. The use of all intellectual property, including any third-party-owned rights, will require clearance. Caution advised due to pending patent application.

Local production – It is not ready for production since it is in the prototype phase. The production knowledge is with the contract manufacturer. Local production will suit only regions with considerable product demand. Good QMS, an established electronics assembly industry and testing capability are also required.

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