Ventilator, for low oxygen inlet pressure

Country of origin | Viet Nam
Primary function | Supporting or sustaining life
Category | Medical device

Commercial information

List price (USD): $4,500[1]
Price of consumables per use (USD): $10[1]
Number of units distributed: 0-100[2]
Currently marketed in: All countries that recognize and accept CE Mark and do not have their own regulatory requirements.[2]
Brand: Impala[1]
Model: V1[1]

Health problem addressed

The principal indications for technology are airway protection and respiratory failure. A compromised airway, or an airway at risk of compromise, may be identified by physical examination and ancillary testing. The technology is indicated for use with a wide range of patients such as acute lung injury, apnea, acute respiratory acidosis, hypoxemia, COPD, hypotension including sepsis, shock, congestive heart failure, and neurological diseases, requiring respiratory support for a wide range of clinical conditions in hospital, hospital type facilities.[2]

Product description

The technology is an intensive-care ventilator that provides continuous or intermittent positive pressure ventilation for the care of individuals who require mechanical ventilation. The device contains a built-in pump to generate positive end-expiratory pressure (PEEP) and Peak Inspiratory Pressure (PIP) without necessity of any external air sources. An integrated blender and oxygen monitoring function also allows oxygen-rich (>21% O^2) air with accurate fraction of inspired oxygen (FiO^2) to be safely delivered to the patient. It may be used for both invasive and non-invasive ventilation.[2]

Product details

Accessories: Control unit with 12V adaptor, reusable breathing circuit, single use HME-HEPA filter, silicon masks, oxygen hose, oxygen hose connector, stand, AC cord, and user manual[3]
Consumables: Nasal masks[1]
Warranty duration: 1 year[2]
Lifetime: 5-10 years[1]
Energy requirements: Rechargeable battery, continuous power supply, solar power (AC powered, 110V/220V, 60W, 3-hour battery life, 1-hour battery recharge cycle, 3-hour solar recharge cycle)[1]

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1 Reported by manufacturer on 5 June 2020
2 Reported by manufacturer on 10 January 2021
3 Reported by manufacturer on 23 December 2020

WHO ASSESSMENT

WHO specification comparison

This device partially complies with the WHO technical specifications for intensive care ventilators.
Compliant: The device allows for use of an external low-pressure oxygen (approx. 20 psi) source. The user manual states that "the gas sources must provide pressure within the range of 10 to 60 psi (0.7 to 4.1 bar)". If the gas sources are outside of this range, the device may not be able to produce the desired $\%FiO^2$. However, the oxygen inlet for all pressure ranges is CGA 1240.
Non-compliant: The device does not comply with the WHO specifications for operating temperature and humidity. While the WHO specifications state that the required operating temperature is 5–40 °C and the required humidity range is 0–95% relative humidity (RH), the manufacturer states that this device can only operate between 19°C to 37°C and 30%RH to 90%RH. There is no apnea alarm explicitly specified and the gas supply failure and power failure alarms are indirect. Overall, the alarms should be revised. The inspiratory pressure setting starts at 5 cmH2O instead of 0cmH20 as required. The continuous battery-operating mode is 3 hours instead of the requested 4 hours.
Some aspects of the device could not be verified such as the means for limiting reverse gas flowrate (leakage), the filter and water trap filter for input post, and the mechanical safety valve. The inspiratory pause maneuver capability to measure plateau pressure could also not be verified. It is unclear if there is an adjustable peak pressure limitation/pressure-cycling mechanism above measured peak pressure. Additional unverifiable features include the I: E inverse ratio, loop (axis) displays, display of minute volume (expired), occlusion pressure detection, and spontaneous ventilation.

Regulatory assessment

Pre-market assessment	Proceed with caution
Post-market assessment	Proceed with caution
Quality system assessment	Proceed with caution

Some requested information and documentation for all three Regulatory and Quality Assessment categories is absent. Therefore, a thorough review of this product was not possible at this time. At the time of this report creation, Medical Technologies has obtained an EU MDD CE Mark for the Impala Ventilator. The regulatory status for the various accessories is currently unclear. Medical Technologies has obtained an ISO 13485:2016 certificate. Medical Technologies must also ensure they comply with local country import and pre-market regulations.

Technology evidence assessment

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

The system may be used for a limited time during transport for controlled breathing scenarios (up to 3h). The cost is comparable to similar devices. Maintenance must be performed by trained personnel such as a technician or nurse. Use of the device on COVID patients may be restricted due to potential additional risk.

Summary

Transferability	→	Technology readiness level	8
Evidence (according to GRADE)	!	Technology evidence assessment	Recommended with caution

Health technology and engineering management

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

Target setting: ICUs and patient transport

This product is indicated for continuous or intermittent mechanical ventilation support of patients weighing at least 5 Kg as prescribed by the attending physician. The device can operate on AC power or by a 6x rechargeable battery source when a continuous power supply is not available, such as during a power outage. A fully charged battery can support up to 3 hours of operation and the battery can be recharged within 1 hour. A software provides several operation modes as well as troubleshooting for the user. Parameter tolerances of +/- 10% may be questionable for small patients. The manufacturer states that a trained technician is required to perform maintenance and repairs. The recommended servicing frequency is between 6-12 months. The air filter needs to be cleaned or replaced every 6 months and the oxygen sensor needs to be replaced every 12-18 months. The listed price of $4,500 USD plus $10 USD per use is reasonable. There are concerns regarding the availability of local access to sales and technical support, but it is possible this type of support may improve as the company grows.