Ventilator, mechanical, pressure control

Country of origin | Italy
Primary function | Monitoring
Category | Medical device

Commercial information

List price (USD): $6,000[1]
Price of Accessories Per Unit: $600[1]
Price of Consumables Per Use (USD): $60[1]
Year of Commercialization: 2020[2]
Number of Units Distributed: 101-1,000[1]
Currently Marketed In: Canada, United States[1]
Brand: Mechanical Ventilator Milano (MVM)[1]
Model: Basic-0010[1]

Health problem addressed

The large number of people affected by SARS-CoV-2 created an urgent demand for ventilators on a global scale. The demand exceeds the capacity of existing supply chains, especially in some regions where cross-border supply has been disrupted. This need motivated the development of a reliable, fail-safe, and easy to operate mechanical ventilator that can be quickly produced at a large scale with readily available parts.[2]

Product description

The electronically-controlled mechanical ventilator can be operated in two modes: pressure controlled ventilation (PCV) and pressure support ventilation (PSV). The system connects directly to a line of pressurized medical oxygen or medical air, and relies on regulation of the flow to deliver gas to the patient at a pressure in the range suitable for treatment. Pressure regulation of the end-expiratory cycle is achieved by discharging the expiratory flow through a valve to set the desired PEEP.[1]

Product details

Accessories: Gas blender, gas blender hoses, catheter mount, power supply, reducing adapter, device stand[2]
Consumables: Patient respiratory circuit, respiratory circuit flow meter, breathing system filter, tracheal tube, PEEP valve[2]
Warranty Duration: 1 year[2]
Lifetime: 5-10 years[1]
Energy Requirements: Rechargeable battery, continuous power supply (AC powered, 110V/220V, 60W, 24-hour battery recharge cycle, 2-hour battery life)[1]
Facility Requirements: Specific temperature and/or humidity range, gas supply[1]

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1 Reported by manufacturer on 18 May 2020
2 Reported by manufacturer on 27 January 2021

WHO ASSESSMENT

WHO specification comparison

This device partially complies with the WHO technical specifications for intensive care ventilators.

Compliant: The device only provides pressure support modes. All requested alarms and most of the requested display parameters are present. The device has IP22 degree of protection and an internal testing/leak function. The operating temperature range is 10-40°C although the battery charging is only guaranteed in an ambient temperature range of 10-35°C.

Non-compliant: The device does not have volume control and non-invasive ventilation modes. The continuous operating mode is 2 hours rather than the specified 4 hours. Using an external low-pressure oxygen source is not possible. The tidal volume range is 50 mL to 1500 mL rather than 20-1500 mL as stated in the WHO specifications.

Some aspects could not be verified such as a mechanical safety valve, loop axis, and spontaneous ventilation. The air and oxygen pressure and leak display could also not be verified. The time required to fully recharge the battery is unknown.

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, MVM has obtained an US FDA Emergency Use Authorization and Health Canada Medical Device COVID-19 Authorization (IO319627). The regulatory status for the various accessories is currently unclear. MVM has an ISO 13485:2016 certificate. MVM 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	✕	→	⚡

This pressure-controlled ventilator has a basic design and is mainly built with generally available products. The software is open source. GMP practice must be ensured in order to guarantee safety. Even though local production is available in some low- and middle-income countries, they must also ensure compliance with local country regulations.

Summary

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

Health technology and engineering management

Target setting: Hospitals

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	→		

This product is a mechanical ventilator that can operate in 2 modes: pressure controlled and pressure support ventilation. It is connected directly to pressurized oxygen or medical air and relies on the regulation of the flow to deliver gas to the patient. It has a user operation control allowing for setting parameters and alarm levels. The vendor suggests that the routine maintenance requirement is limited to cleaning and disinfection between uses. The product relies on external sources of gas rather than an internal turbine. Although the vendor states that many of the parts used in the construction of the product are off the shelf, perceived lack of technical support and spare parts limit the locations of use.