Ventilator, with extended battery time

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

Commercial information

List price (USD): $15,000[1]
Year of commercialization: 2018[1]
Number of units distributed: 101-1,000[1]
Currently marketed in: Sub-Saharan Africa and Southeast Asia[2]
Brand: Gradian Health Systems[1]
Model: Gradian CCV[1]

Health problem addressed

Mechanical ventilators, when operated by a trained medical professional, provide respiratory support to patients who cannot breathe or require assistance to breathe due to illnesses, such as pneumonia, COPD, and COVID-19, trauma, or other complications. They are essential to sustaining life while patients undergo treatment or until treatment can be accessed. A major factor inhibiting access is inadequate infrastructure to support delivery of critical care in facilities and during transport.[1]

Product description

A comprehensive care ventilator can assist or replace the breathing of a patient requiring respiratory support, in any care setting. Gas is drawn from compressed sources of oxygen and medical air, or entrained from room air by an in-built compressor, and mixed by an integrated gas blender to an oxygen concentration prescribed by the care provider. A closed-loop control system regulates the delivery of breath through a breathing circuit, according to the prescribed mode and settings.[1]

Product details

Accessories: Rolling stand, bag of 3 extra filters, kit – handle, swivel hooks, stand mount, external battery, extra exhalation valve, reusable adult and pediatric breathing circuits, SpO^2 monitor, HMEs, test lung, air and oxygen hoses, power cords, reservoir cylinder, humidifier and accessories.[3]

Consumables: It is recommended that the device be used with bacterial/viral filters in order to avoid cross-contamination. When using the device without an active humidifier, a Heat and Moisture Exchanging Filter (HMEF) is recommended.[1]

Other required products: Patient interfaces such as endotracheal tubes and non-invasive ventilation masks are required to use the device. The device should only be used in the presence of and in conjunction with other monitoring and life-supporting equipment required for administration of adequate critical care.[1]

Warranty duration: 3 years[1]

Lifetime: 10-15 years[1]

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1 Reported by manufacturer on 14 August 2020
2 Reported by manufacturer on 8 January 2020
3 Reported by manufacturer on 15 December 2020

WHO ASSESSMENT

WHO specification comparison

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

Compliant relevant characteristics: There is the option for using external low-pressure oxygen (approx. 20 psi) as a source. However, the instructions of use indicate that "Proper tidal volumes may not be provided with a gas source not providing a minimum of 80 LPM at 280 kPa (40 psi)". The device includes non-invasive ventilation, an oxygen conservation feature, and IP22 degree of protection. The device can be used continuously in battery operating mode with standard ventilation for up to 21 hours total (7 hours on internal battery and 14 hours on external battery).

Non-compliant: The oxygen-air mixture accuracy is 12% as opposed to the WHO specification of 4%. The inspiratory pressure is 15 - 55 cmH2O instead of the WHO specified range of 0–40 cmH2O. The device does not have minute volume alarms and single limb circuits cannot be connected. Additionally, the device does not measure leak percentage or display/monitor minute volume and spontaneous minute volume. The display shows numerical indicators but no waveforms for all ventilation parameters.

Aspects that could not be verified: Minute volume alarms

Regulatory assessment

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

All WHO requested information and documentation for all three Regulatory and Quality Assessment categories was provided. At the time of this report creation, the product was both EU CE Marked under the MDD and US FDA 510(k) cleared. The regulatory status for the various accessories was provided. The product's manufacturer (Allied Health) has obtained an MDSAP ISO 13485:2016 certificate. Gradian provided all top-level SOPs for their regulatory and quality system responsibilities for the WHO countries. Gradian 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 ventilator provides basic configuration for volume control assistance. It is a me-too ventilator without innovative approaches. The price includes additional tools. Local production options seem to be available in some low- and middle-income countries, but there must be compliance with local country regulations. Maintenance is also offered locally.

Summary

Transferability	!	Technology readiness level	9
Evidence (according to GRADE)	!	Technology evidence assessment	Recommended

Health technology and engineering management

Target setting: Hospitals and transport

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 intended for a variety of settings, including austere environments with unreliable access to oxygen and or electricity. It incorporates a pulse oximeter and provides for 3 years of parts and service warranty. It can function on internal battery power for up to 7 hours and on an external battery source for up to 14 hours. It is also a portable device that can be used for patient transport. Video-based user and support training is provided. Although judged to be easy to use, technical support is dependent on adequate availability of vendor training and spare parts.