Ventilator, resuscitator bag based

Country of origin | Norway
Primary function | Treatment
Category | Medical devices

Commercial information

List price (USD): 6000[1]

Price of consumables per use (USD): 50[1]

Development Stage: The product development is completed, the technical file has been assessed for conformity with MDD. A clinical investigation trial is in planning phase to create pivotal data necessary to support the product claims.[2]

Brand: Laerdal Medical[1]

Model: Laerdal Servi Ventilator[1]

Health problem addressed

In emergency situations where normal ventilators are unavailable, manual ventilation is the only alternative. Manual ventilation is not a good alternative because each patient occupies both hands of a health worker. Furthermore, ventilations are delivered inconsistently and inaccurately. Such emergency situations happen when there is a surge in patients needing ventilation or when existing ventilators are unavailable due to damaged infrastructure or lack of infrastructure, supplies or spare parts.[2]

Product description

The device is intended for ventilatory and respiratory assistance for monitored and intubated adult patients with normal healthy lungs, or with mild to moderate respiratory failure, requiring ventilation volumes of 200 – 800 ml when it can be used on patients under direct observation by healthcare professionals. It provides capacity in cases where more advanced critical care ventilators are unavailable. The technology functions with a processor-controlled stepper motor that compresses a self-inflatable silicone bag. The controlled and display parameters are tidal volume, rate, and I:E. Supplemental oxygen is possible through a bottle or an oxygen concentrator in order to achieve FiO2 0.21-1.0. The device has an adjustable PEEP on expiration diverter as well as a battery backup.[2]

Product details

Accessories: Laerdal Silicone Resuscitator adult bag with inlet valve, oxygen reservoir bag, oxygen tube, Laerdal Silicone Resuscitator patient valve, exhalation port, manometer connector, pressure sensor tube[3]

Consumables: HME filter, adjustable PEEP valve, patient tube, patient tube connector[1]

Lifetime: 5-10 years[1]

Energy Requirements: Continuous power supply (AC powered, 220V, 270W).[1] Device is also equipped with a backup battery. Maximum time to charge a fully depleted battery is 8h. Battery life in use is typically 5h for normal patient lungs and approximately 1h for very demanding patient lungs. Minimum battery life is 30 min.[2]

Facility requirements: Specific temperature and/or humidity range[1]

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1 Reported by manufacturer on 02 December 2020
2 Reported by manufacturer on 05 February 2021
3 Reported by manufacturer on 04 January 2021

WHO ASSESSMENT

WHO specification comparison

This Device cannot be considered in the criteria of ventilators used for Intensive Care as described in the WHO specifications the intended use of which is "to provide short-term (up to 48 hours) ventilatory and respiratory assistance to monitored patients who are under constant observation by healthcare professionals".

Compliant: Possibility for using external low-pressure oxygen (approx. 20 psi), as source. An oxygen concentrator can be connected in order to provide supplemental oxygen. The only ventilation mode available is volume control.5.5 hours of operational time of the ventilator.

Non-compliant: There are many non-applicable aspects because of the nature of the device, this ventilator is not intended to be connected to a Medical Oxygen and air high-pressure input port therefore some characteristics are not needed. The product has not been tested for compatibility with active humidifying systems and does not have pressure control ventilation, noninvasive ventilation or pressure support ventilation. FiO2 input is indirectly set by the user based on user setting of input O2 flow in relation to output minute volume of gas. The "Assisted Ventilation Mode" is not intended for patients in need of FiO2 > 0.21. Inspiratory pause cannot be set. Plateau pressure can be estimated manually – see pg 15 of User Guide. Only single limb proprietary circuit can be connected.

There are some aspects that couldn't be verified such as: Display parameters (Minute volume and status indicators for battery status, patient data, alarm settings,)

Regulatory assessment

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

Significant work is needed on developing robust pre-market regulatory, post-market regulatory, and quality system plans to ensure this prototype will be able to be successfully brought to market. Laerdal should develop their medical device support documentation and data.

Technology evidence assessment

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

The principle of this tool is very simple and easy to train. The equipment can also be used and maintained in LMIC if the cost per device will be lower. There are missing studies on clinical evidence regarding safety and nosocomial infections as this is stated as a benefit for this technology. The medical use is limited (volume-based ventilation).

Summary

Transferability	→	Technology readiness level	6
Evidence (according to GRADE)	!	Technology evidence assessment	Recommended with caution

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 for use in hospitals that is well supported by vendor sales and technical personnel. In addition, the vendor further supports the product with on-line video training. It is well constructed, easy to clean and operate with some limitation for its deployment in extreme environmental conditions. The product is suitable for use in intensive care units in low resource countries.