# Ventilator, ICU with waveform display

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

## Commercial information

**List Price (USD):** $3000[1]

**Price of Consumables Per Use (USD):** $65[1]

**Development Stage:** The device is currently at demonstrator level. A collaboration is in place to develop a full software and hardware package to optimise the design for production in OECD-DAC countries.[2]

**Brand:** CERN[1]

**Model:** HEV/HPLV V2[2].

## Health problem addressed

The infectious nature of the COVID 19 disease and the number of patients who develop serious respiratory problems, requiring a long period of treatment, has highlighted the need for various items of key medical equipment such as ventilators. The device is designed as a high-quality, low-cost ventilator to provide artificial support for lung function of patients using technologies developed by the particle physics community for pressure and gas regulation. There is a collaboration in place that will optimise the design for low-resource settings, where aspects such as robustness, independence from hospital compressed air supply and remote training and post market surveillance are particularly important.[2]

## Product description

The device is a high-quality ventilator designed to support treatment and management of patients suffering from pulmonary lung disease and in particular in the context of the COVID-19 pandemic. It is controlled via a touchscreen with a sophisticated display of parameters and pressure/volume/flow curves. The supported ventilation modes are Pressure Control (including PRVC), Volume Control, Pressure Support and CPAP. The ventilator is designed to be low cost and easily assembled from readily available components. It is suitable for hospital use in or out of the ICU and is adaptable to a wide range of geographical settings.[2]

## Product details

**Accessories:** For invasive ventilation: Endotracheal tube, double limb respiratory circuit ended by Y piece, two filters, HME filter at the Y piece. For non-invasive ventilation: facemask in addition to the above.[1]

**Consumables:** All contaminated pieces are exchanged between patients; tube/facemask, filters and HME.[1]

**Other required products:** All mandatory ICU monitoring, in particular patient oximeter.[1]

**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 03 June 2020
2 Reported by manufacturer on 03 February 2020

# WHO ASSESSMENT

## WHO specification comparison

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

**Compliant:** Display easily readable, provide the information of 3 scalar waveforms, loop and parameters required in the technical specifications, alarms for FiO2, inspiratory pressure, apnea and others required. The oxygen is continuously measured via meter which takes a small continuous flow from the buffer.

**Non-compliant:** Medical air compressor or turbine in built not present; the manufacturers claim this is going to be considered for future prototypes, "the team has planned to include a separate multi-stage turbine to generate pressurized air independently of other infrastructure" ETHZ_HEV_Report Page 3. Volume control modes are not included but can be added if needed, only CPAP non-invasive mode is included. The RR allowed is 10-30 breaths/min, adjustable in increments of 2 , arxiv document page 4 vs the 10-60 breaths/min. System is currently designed to be used with disposable PEEP valves which can be manually interchanged to provide, typically 5 mbar adjustments of the PEEP. An upgrade to this system is under investigation (Compiled Info Request by the Manufacturer page 10)

**Some aspects that could not be verified:** Tidal Volume range, Adjustable peak pressure limitation/pressure-cycling mechanism above measured peak pressure, operating temperature and humidity, IP protection among others.

# 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. CERN 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 product shows how low cost ventilators can be developed. Beside this there are open issues regarding the intended group of users, the good manufacturing practice and potential safety topics. The actual model seems to be at an early stage without any kind of design to be useful in clinical settings. Especially issues such as PEEP adjustments are too complex for daily life usage.

## Summary

| | | | |
|---|---|---|---|
| Transferability | → | Technology readiness level | 5 |
| 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: Hospitals

This product is an innovative, high energy ventilator that was designed with a vision for local production in low resource countries by using standard available parts, open-source software controlling the operation and display. The ventilator provides typical ventilation support modes such as PRVC, SIMV-PC, and CPAP. The ventilator design deployed software-controlled solenoids, mechanical valves, and storage for buffering pressured air mixed with oxygen. The design dependence on pressurized vessels requires measurement and alarms relating to any possible system leaks. In addition, dependency on high-pressure gas input, may limit the applicability of the product to locations that have centralized piped-in gas. We could not find evidence for oxygen level measurements within the system as well as for supporting the product in the field.