The Ventilator Challenge, two years on; the HEV and HPLV response

Part 1: The HEV Ventilator

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On behalf of the HEV Collaboration

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The HEV Ventilator Project

HEV is a novel ventilator designed in response to the COVID-19 crisis. It is a high quality, low cost ventilator suitable for use in ICUs, for invasive and non-invasive ventilatory support. Modes include Pressure control, Volume control, Pressure Support, Delivery of oxygen enriched air, CPAP.

Globally, pneumonia is the most common infectious cause of death. The pandemic has drawn attention to the lack of ventilation equipment in LMICs (Low to Middle Income countries), and HEV will remain relevant beyond COVID-19.


Medical support:
- Lise Piquilloud, Patrick Schoettker, CHUV, Lausanne
- Philipp Rostalski and Georg Mannel, Luebeck University
- Laurence Vignaux; Hôpital de La Tour, Genève
- Josef X. Brunner: Neosim, and ventilator design
- Gordon Flynn and David Reiner; Canberra Hospital, Canberra
- Hamish Woonton; Dandenong Hospital, Dandenong
- Bruce Dowd, Prince of Wales Hospital, NSW
- Carl Roosens, University Hospital Ghent
- M. de Carvalho, N. Dousse, M. Saucet, HUG Geneve

Loan of equipment from the HUG, via the special collaborative agreement between CERN and HUG, and the Pneumonology and Cardio-Respiratory Services and NIC centre of Hôpital de la Tour.
The Covid “Ventilator Crisis”

At the start of the pandemic, the ICU occupancy and the shortage of ventilators was palpable

“The United States needs a million Ventilators” - NYTimes, March 13 2020

These examples taken from the US, read more here: https://spectrum.ieee.org/geek-life/hands-on/the-great-ventilator-rush
Immediate reactions included:
- attempts to adapt existing equipment
- Design of **extreme emergency devices** (Xerox disposable, adapted breast pumps…),
- Design of devices to bolster non-ICU use e.g. transport, NIV..
- definition of emergency use authorisations with respect to ventilators

At the same time:
- new companies entered the game: Tesla, Ford, Virgin Orbit, GE, GM, AgVa, Dyson…
- Established companies ramped up production
- note that cheap emergency solutions already existed e.g. bubble CPAP machines in Malawi - not a ventilator but a very effective pediatric solution
Typically, one of two routes taken

How to design an affordable, available, ventilator?

Extremely rapid, simplified design, often based on “bag squeezing approach”, LED/simplified displays

High Quality Design aiming to perform at ICU level but use innovation to push down cost

Pros:
- cost, availability
- can meet basic standards

Challenges:
- Oxygen control and support for spontaneous breaths
- Fine pressure control challenging; unlikely to be selected for ICUs
- Full range of modes not available
- Lack of monitoring & control

Pros:
- ICU level performance
- Supported breathing solutions
- Sophisticated monitoring & control
- Simple to manufacture
- Adaptable to low income settings

Challenges:
- Industrialisation step

e.g. Virgin Orbit
While very helpful, the early government specifications were vague and conflicting. Neither the 18 March UK RMVS, nor the 7 April Australian TGA guide emphasised the requirement for **supporting spontaneous breathing**. It was not until 10 April that the UK revised the RMVS to stress the desirability of supporting spontaneous ventilation. **By then many teams had locked in a design architecture** and most would never change direction.
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DISFAVoured

e.g. Virgin Orbit

e.g. HEV
How to design an affordable ventilator?

Extremely rapid, simplified design, often based on “bag squeezing approach”, LED/simplified displays

Concerning high quality designs, the need in many high income countries dwindled, and remaining demand addressed by ramp up of production. New companies e.g. Dyson dropped out.

However the lack of medical equipment such as ventilators remains acute in many regions, extending beyond Covid

Emergency authorisation guidelines have been revised to become much more sophisticated: Now generally accepted that care standards should not be lowered to meet the standards of the ventilator
+ others, total 29 institutes
Two years ago we see the first email traces of the HEV project

Request by Professor Themis Bowcock (University of Liverpool) to cooperate on AMVENT

Support of CERN Management: HEV project starts March 26, buffer concept March 27

First proposal: Pressure support incorporated from the start to allow spontaneous breaths
Table top demonstrator

New idea proposed by Roberto Guida.

Separation of HEV into independent supply/patient sub-units

First demonstrator: 28th March 2020
Step-down pressure buffer between supply and patient introduces safety and robustness against variable gas supply.

Step-down pressure buffer makes precise pressure control more readily accessible.

Buffer allows a natural way to mix air and O2, so no need for an additional oxygen mixer.

Measuring O2 concentration on ‘static’ gas volume vs measurement on a gas stream does not require fast reaction time of meter (more precise method) and meter is not in flow of gas to patient.

From a pneumatic perspective, separating the fill and exhale cycle into two separate circuits makes the design, control and component selection easier and allows less expensive components to be selected.

Thermal control of the gas in the buffer is a possibility e.g. for extreme environments.

The delivered tidal volume can be calculated from the pressure drops in the buffer. (this is a precious monitoring cross check in addition to the standard tidal volume measurement (additional safety))
HEV Prototypes

- Touch screen
- Alarm indicator
- Air tubes to patient
- 10L buffer
- PCB with Embedded processors & I/O to valves and sensors
- 220V AC/DC & 24V battery UPS
- Cooling fan & input filter
HEV User Interface

Optimised with feedback from clinicians
Available on touchscreen, web, and mobile device
Option of data logging and post market surveillance
Quality of this interface a differentiator with RMVS ventilators
HEV User Interface

Expert settings

Buffers
- Calibration: 10000 ms
- Purge: 600 ms
- Flush: 600 ms
- Pre-fill: 100 ms
- Fill: 600 ms
- Pre-inhale: 10 ms

Valves
- Air in: 0
- O2 in: 0
- Exhale: 1
- Purge: 0
- Inhale: 0
- Inhale Opening: 0%

Breathing
- Inhalation: 1000 ms
- Pause: 10 ms
- Exhale fill: 0 ms
- Exhale: 4990 ms
- FSM State: EXHALE
- Respiratory Rate: 9.9834
- PEEP: 0.1772 mBar
- I:E Ratio: 0.2024
HEV User Interface

- Mode: PC-PSV
- Calibration: 10000 mBar
- Pre-fill: 100 mBar
- Air in: 0
- Exhale: 1
- Exhale Opening: 0%
- Inhale: 1000 mBar
- Exhale: 4990 mBar
- PEEP: 0.2417 mBar
- I:E Ratio: 0.2024
- Flush: 600 ms
- Inhale Opening: 0%
- Respiratory Rate: 9.9834
HEV Performance Examples (1/5)

Consistent, High Quality curves over all patient configurations
- Ventilator is able to support Covid patients throughout the disease progression

For full information on these quantitative results of pressure, flow and volume delivery, see https://arxiv.org/pdf/2007.12012
Consistent, High Quality curves over all patient configurations

- Ventilator is able to support Covid patients throughout the disease progression

Note that a fundamental aspect to be taken into account in the development of higher quality ventilators is the use of proper test devices for design verification (rather than simple bellows)

TestChest, Organis GmbH, Landquart, Switzerland

Accurate Pressure Delivery, Accurate Oxygen Delivery
- Clinicians can deliver precise therapies
HEV Performance Examples (3/5)

Pressure Delivery is precise, fast, and extremely reactive to patient inhalation
- Rise times of the order of 100 ms
- **Crucial for patient comfort**, and to optimise chances of weaning from ventilator
- Rise times are tunable for control by clinician (algorithm can provide suggestions to operator)

![Graph showing pressure delivery performance](image)

- @75% of P\_target in 50ms
- @75% of P\_target in 70ms
- @75% of P\_target in 90ms
- @75% of P\_target in 160ms
- @75% of P\_target in 280ms
Oxygen supply example: Raise Oxygen from 21% to 90%, hold, then bring back down to 50%

HEV supplies oxygen enriched air with the correct timescales and accuracies
Calculations are very accurate; sensor provides confirmation
Independent, precise, flow calculation from buffer pressure monitor for Inhale phase
Here compared to Hamilton differential pressure sensor measurement
HEV performance compared to commercial devices

Trigger reaction time (ideally should be below 150 ms)

Pressure integral at 500 ms compared to ideal (should be as high as possible)
HEV Regional Adaptability

- Two standalone alternatives designed to replace hospital compressed air supply in case of need
  - based on miniature turbines - designed by EPFL
  - based on air scroll pump - designed by NTUA
- Superior to commercial compressor (noise, power, adaptability)
- Potential for oxygen enrichment
Ergonomics can be adapted to regional requirements

Option A
- Possibility to mount turbine system
- Compressed air and oxygen bottles for short-term autonomy
- 48 cm

Option B
- Drawer with interchangeable exhaust block
- Buffer volume
- 38 cm
- 54 cm
- 40 cm

Universal, all-in-one solution
Compactified solution
HEV Test & Review

- **International Review** 23/04/20 [https://indico.cern.ch/event/910628/overview](https://indico.cern.ch/event/910628/overview)
- Conformity tests carried out under informal clinical supervision (Hôpital de la Tour) at CERN
- Remote test by the Director of the Medical Devices Testing and Evaluation Centre, UK [www.md-tec.com](http://www.md-tec.com)
- Test of unit at ETH Zürich, under Botner (BRCCH) Grant for the COVent project
- Tests of unit at Dräger (via collaboration with Lübeck University)
- Further tests planned at CHUV, Lausanne

**Feedback very positive**, with praise in particular for the user interface and the performance range. ETH Zurich have deemed HEV to be the best RMVS ventilator tested, and have selected it for ongoing use under their grant.

"It was very impressive to see that you were able to assemble such a system in this little period of time. And in all of our testing the HEV showed excellent performance in a large range of parameters. It was obvious that you literally hit the hammer on the nail despite the fact that all of you are actually experts in different domains. Congratulations ! For us it is amazing to see the energy and passion which people from CERN showed to achieve such outstanding results"

Testing at Drägerwerk, Lübeck
HEV Academic Engagement

- Teaching/research with a HEV prototype - University of Lübeck: “allowing unprecedented research and teaching opportunities”
- Letter of Intent to use HEV prototype for R&D received from ETH Zurich
- HEV development proceeding at BUAP, Puebla, Mexico
  - performance testing, development of calibration methods, and implementation of a code to calculate and display the volume flux circulating in every breathing cycle.
New algorithms developed at BUAP

PC-A/C-PRVC (Pressure Control - Assist Control - Pressure Regulated Volume Controlled) model with volume target.

Made possible via monitoring of pressure loss in buffer, plus sophisticated filtering and feedback algorithm
HEV Industrial Engagement

Potential Manufacture of prototypes / final units
(also individual institutes in HEV researching potential local entities)

Visit for testing and feedback

Ongoing collaboration for HPLV
JGA prototype

Four prototypes manufactured

HEV style design

To be used gain experience on manufacturability, for prototyping and development
After review by the respiratory expert panel, HEV and HPLV were selected to feature in the WHO compendium, as an “innovative technology that can have an immediate or future impact on the COVID-19 preparedness and response, have the potential to improve health outcomes and quality of life, and/or offer a solution to an unmet medical/health technology need”, and the academic description was published by Royal Society Open Science.
Thank You; Next stop HPLV!

More details at hev.web.cern.ch

Oscar Francisco, HEV innovation and development
Photograph by Julian Ordan, copyright CERN