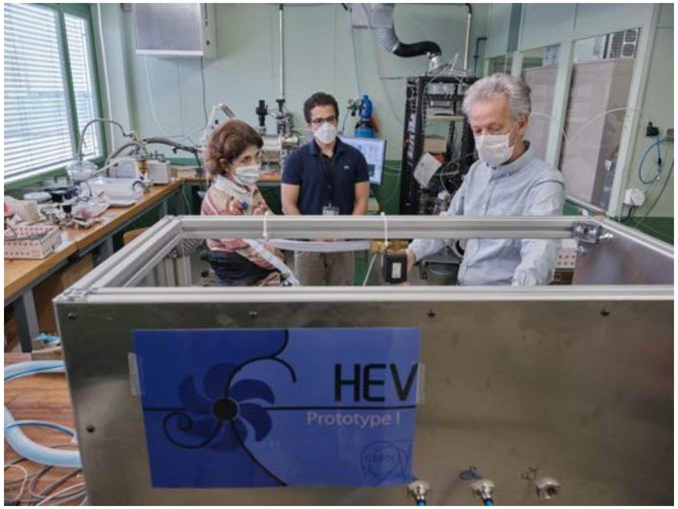
hev.web.cern.ch

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

Part 1: The HEV Ventilator

June 2nd 2022 - CERN Knowledge Transfer Seminar
Paula Collins & Jan Buytaert
On behalf of the HEV Collaboration



Photograph by Maximilien Brice, copyright CERN

The HEV Ventilator Project

HEV is novel ventilator designed in response to the COVID-19 crisis

It is a high quality, low cost and 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, pneunomia 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


HEV collaboration

https://arxiv.org/pdf/2007.12012 - 29 collaborating institutes, led by physicists and engineers from the LHCb collaboration, and managed by a CERN steering committee

CERN groups

EP-DT (Detector Technologies) group (mechanical design, pneumatic components)
EP-ESE (Electronics Systems) group, (electronics design and integration)
EP-LBD,LBC,LBO (LHCb experiment groups)
HSE (Safety at CERN) unit (medical contacts, working practices at CERN during Covid-19 era, working relationship with HUG, conformity with applicable legislation and health and safety requirements)
BE-CO, BE-ICS, webpage, open source consultation, functional safety analysis of control systems
DG-LS, IPT-KT, ongoing consultation on deployment, knowledge transfer and legal aspects.

Medical support

Lise Piquilloud, Patrick Schoettker, CHUV, Lausanne
Philipp Rostalski and Georg Mannel, Luebeck University
Laurence Vignaux; Hôpital de La Tour, Geneve
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

CERN AGAINST COVID-19

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

ENGLISH ESPAÑOL 中文

The New York Times

And, the calculations based on the C.D.C.'s scenarios suggested, 2.4 million to 21 million people in the United States could require hospitalization, potentially crushing the nation's medical system, which has only about 925,000 staffed hospital beds. Fewer than a tenth of those are for people who are critically ill.

NEWS

Who gets a ventilator? Hospitals facing coronavirus surge are preparing for life-or-death decisions

The Washington Post

Democracy Dies in Darkness

Spiking U.S. coronavirus cases could force rationing decisions similar to those made in Italy, China

Elderly, end-stage cancer patients might get lower priority for ventilators under some state pandemic plans

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

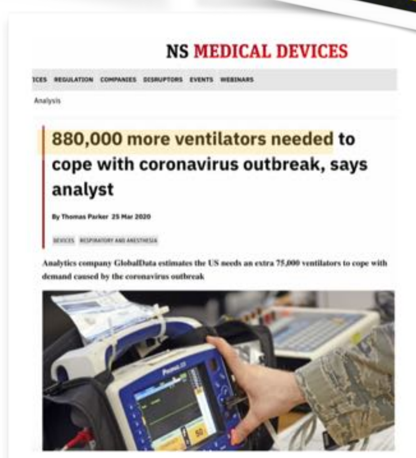
Critical Supply Shortages — The Need for Ventilators and Personal Protective Equipment during the Covid-19 Pandemic

NEW YORK POST

BETSY MCCAUGHEY

OPINION

We didn't have to have ventilator shortage — leaders chose not to prep for pandemic



NS MEDICAL DEVICES

880,000 more ventilators needed to cope with coronavirus outbreak, says analyst

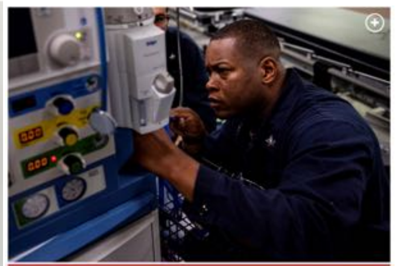
These examples taken from the US, read more here: https://spectrum.ieee.org/geek-life/hands-on/the-great-ventilator-rush

The Covid "Ventilator Crisis"

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

Helmet/scuba style ventilation


A NAVY hospital employee converting an anesthesia machine into a ventilator on the USNS Mercy off the coast of Southern California.

BiPAP/Anesthesia machines converted to ventilators


UMMC doctor designs ventilator for COVID-19 patients

Homemade solutions (here a garden hose, timer, valve…)


MHRA

Rapidly Manufactured Ventilator System

(RMVS)

Version Control

Emergency guidelines

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

e.g. Virgin Orbit

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:

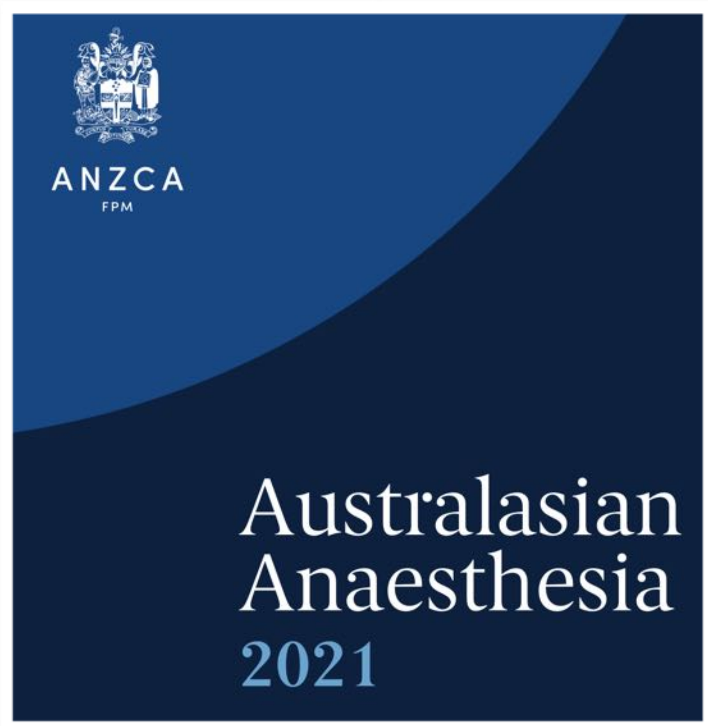
- ICU level performance
- Supported breathing solutions
- Sophisticated monitoring & control
- Simple to manufacture
- Adaptable to low income settings

Challenges:

- Industrialisation step

e.g. HEV

Medical Journal Viewpoints



Open-source hardware and the great ventilator rush of 2020

Erich B Schulz, MBBS, MBA, FANZCA
Senior Staff Specialist, Department of Anaesthesia, Mater Health, Brisbane, Queensland, Australia
Dr Schulz has previously practiced medical informatics and was once an accidental medical administrator.

Robert L Read, PhD
Public Invention, Austin, Texas, USA; founded the non-profit organisation Public Invention in 2018
Dr Read is a professional computer programmer and manager, and amateur mathematician and electrical engineer.

Ben Coombs, ME(Hons)
Public Invention, Auckland, New Zealand
Mr Coombs holds a Master of Engineering (Honours) in mechanical engineering from The University of Auckland, New Zealand where he researched sustainable aerospace composite materials and manufacturing methods. He is a professional software engineer and has been involved in open-source respiration engineering since the start of the pandemic.

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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How to design an affordable, available, ventilator?

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DISFAVOURED

e.g. Virgin Orbit

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e.g. HEV

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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

HEV academic partners

1862 RĪGAS TEHNISKĀ UNIVERSITĀTE

neosim

EPFL ÉCOLE POLYTECHNIQUE FÉDÉRALE DE LAUSANNE

IGFAE

USC UNIVERSIDADE DE SANTIAGO DE COMPOSTELA

CORNELL UNIVERSITY FOUNDED A.D. 1865

HUG Hôpitaux Universitaires Genève

Nikhef

CHUV Centre hospitalier universitaire vaudois

MANCHESTER 1824 The University of Manchester

UFRJ UNIVERSIDADE FEDERAL DO RIO DE JANEIRO

CERN

UNIVERSITY OF LIVERPOOL

UNIVERSITÄT ZU LÜBECK INSTITUTE FOR ELECTRICAL ENGINEERING IN MEDICINE

BUAP

UNIVERSITY OF BIRMINGHAM

ETH zürich

+ others, total 29 institutes

Jan Buytaert, Paula Collins, Adam Abed Abud, Phil Allport, Antonio Pazos Álvarez, Kazuyoshi Akiba, Oscar Augusto de Aguiar Francisco, Aurelio Bay, Florian Bernard, Sophie Baron, Claudia Bertella, Josef X. Brunner, Themis Bowcock, Martine Buytaert-De Jode, Wiktor Byczynski, Ricardo De Carvalho, Victor Coco, Ruth Collins, Nikola Dikic, Nicolas Dousse, Bruce Dowd, Raphael Dumps, Paolo Durante, Walid Fadel, Stephen Farry, Antonio Fernández Prieto, Gordon Flynn, Vinicius Franco Lima, Raymond Frei, Abraham Gallas Torreira, Roberto Guida, Karol Hennessy, Andre Henriques, David Hutchcroft, Stefan Ilic, Aleksandar Jevtic, Christian Joram, Kacper Kapusniak, Edgar Lemos Cid, Jana Lindner, Rolf Lindner, Marko Milovanovic, Sylvain Mico, Johan Morant, Michel Morel, Georg Männel, Donal Murray, Irina Nasteva, Niko Neufeld, Igor Neuhold, Francisco Pardo-Sobrino López, Eliseo Pérez Trigo, Gonzalo Pichel Jallas, Edyta Pilorz, Lise Piquilloud, Xavier Pons, David Reiner, Carl Roosens, Philipp Rostalski, Freek Sanders, Eric Saucet, Burkhard Schmidt, Patrick Schoettker, Rainer Schwemmer, Heinrich Schindler, Archana Sharma, Christophe Sigaud, Peter Svihra, Jan van Leemput, Laurence Vignaux, Francois Vasey, Hamish Woonton, and Ken Wyllie

HEV start point

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

From: "Bowcock, Themis" <Themis.Bowcock@liverpool.ac.uk>
Subject: VELO+LHCb+Ventilators
Date: 20 March 2020 at 16:13:44 CET
To: "Paula Collins (Paula.Collins@cern.ch)" <Paula.Collins@cern.ch>, "Giovanni Passaleva" <giovanni.passaleva@cern.ch>
Cc: "Chris Parkes (chris.parkes@cern.ch)" <chris.parkes@cern.ch>, "Vossebeld, Joost" <Joost.Vossebeld@liverpool.ac.uk>

Our lab has just been asked (and OKd by STFC) to see if it can contribute to the design of an emergency ventilator system for the CoVid19 crisis.

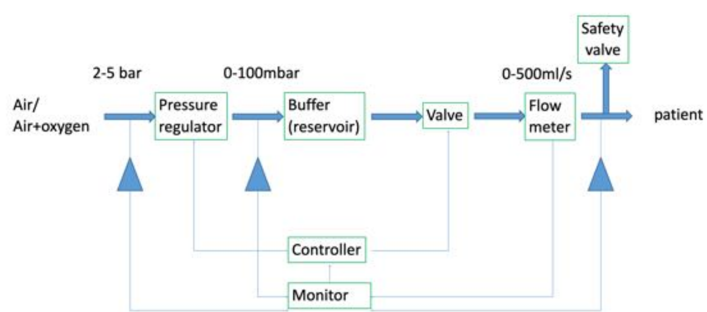
I don't know if there is an equivalent CERN exercise. If not then perhaps this could be suggested (Paula???) In the meanwhile we would welcome ANY collaboration with Liverpool PP to contribute to this activity.

Please answer directly back to Joost Vossebeld (our head of Group) if you feel you know any group or anyone who can contribute. The Liverpool LHCb VELO group will answer this call which I believe is of the utmost priority.

Personally I believe the expertise, or resources, of CERN and our groups could not be better invested at this moment in time,

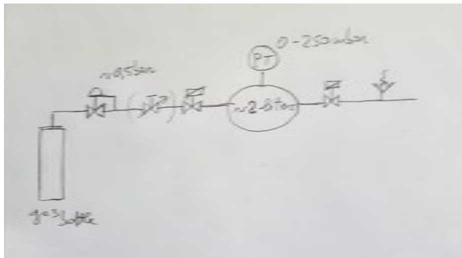
Themis

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



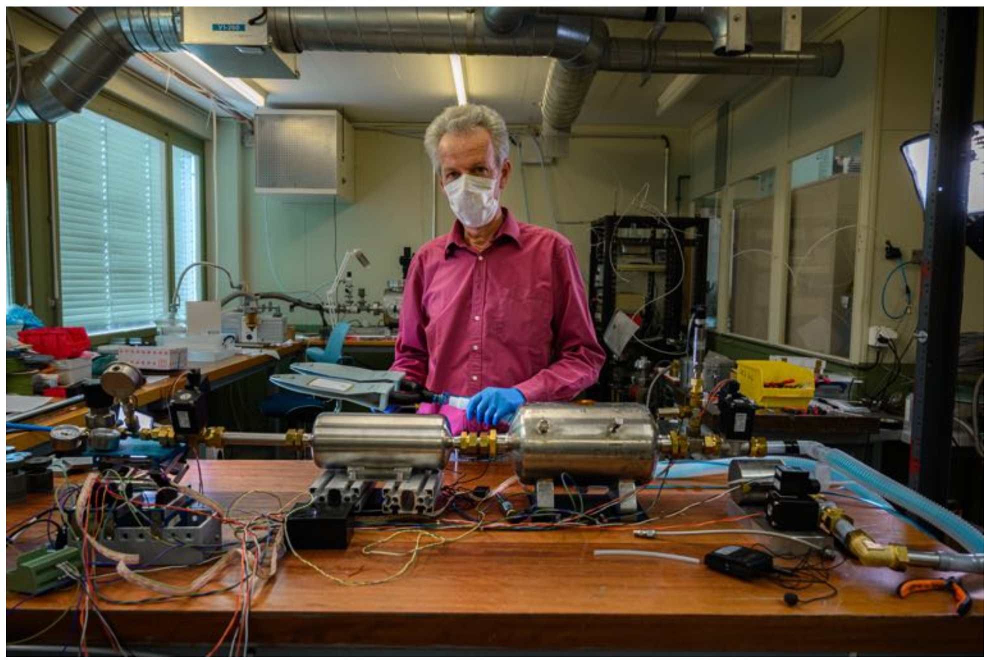
First proposal: Pressure support incorporated from the start to allow spontaneous breaths

Table top demonstrator



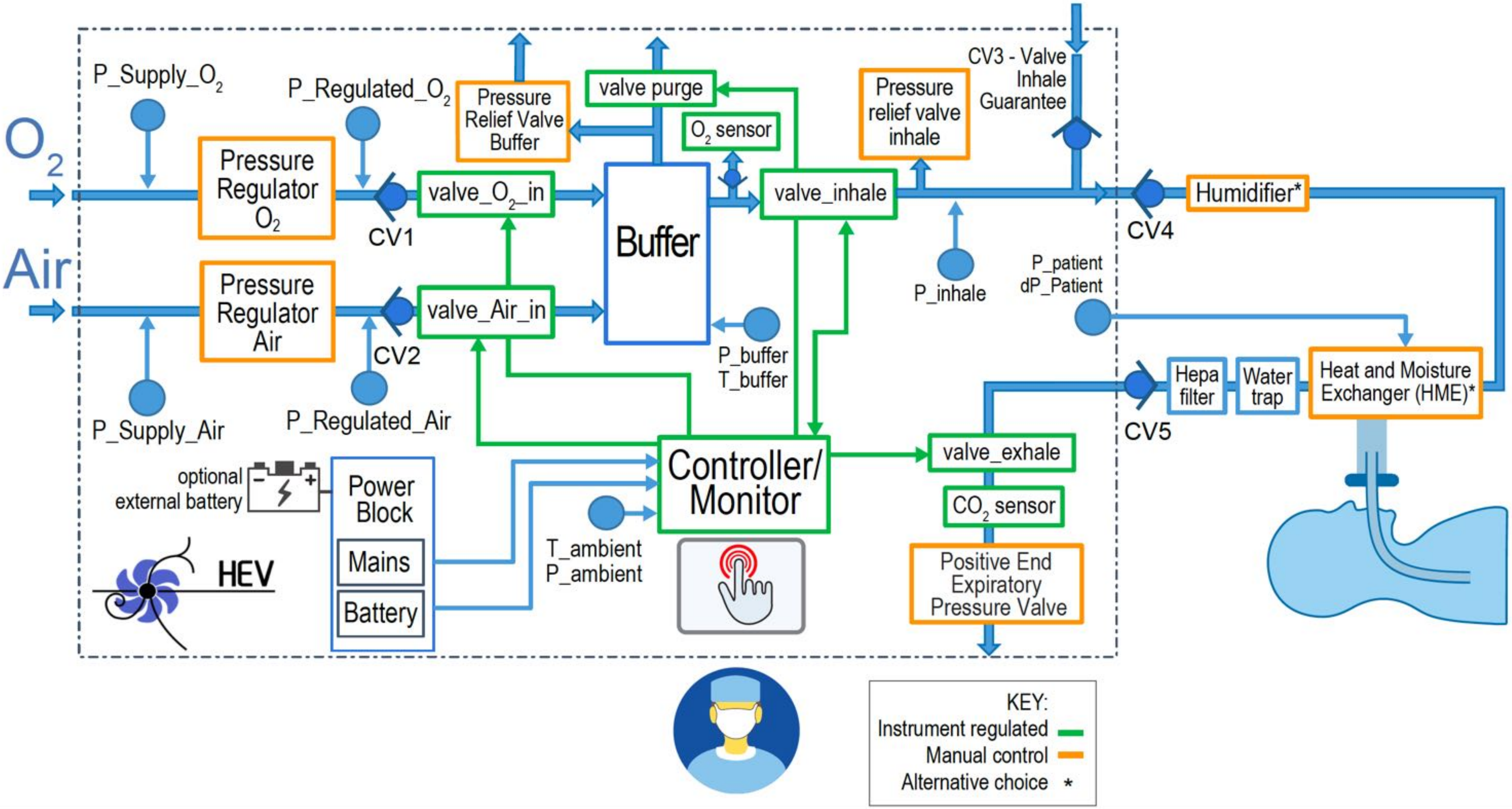
New idea proposed by Roberto Guida.

Separation of HEV into independent supply/patient sub-units



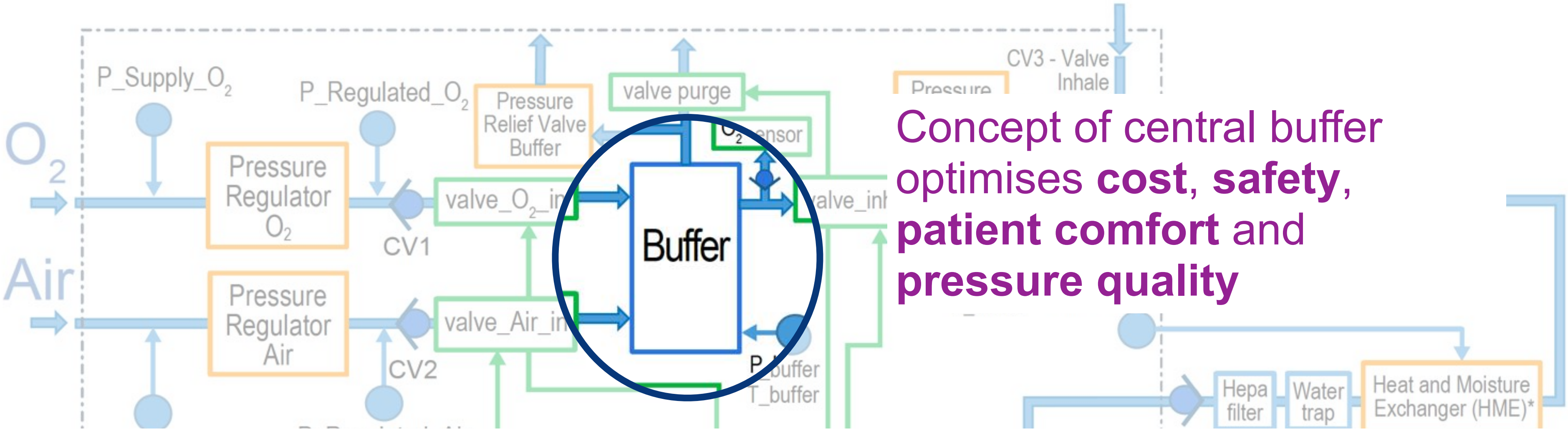
First demonstrator: 28th March 2020

HEV Design



O2
Air
P_Supply_O2
P_Regulated_O2
Pressure Regulator O2
Pressure Relief Valve Buffer
valve purge
O2 sensor
Pressure relief valve inhale
CV3 - Valve Inhale Guarantee
CV1
valve_O2_in
Buffer
valve_inhale
CV4
Humidifier*
Pressure Regulator Air
valve_Air_in
CV2
P_inhale
P_patient
dP_Patient
P_buffer
T_buffer
P_Supply_Air
P_Regulated_Air
Hepa filter
Water trap
Heat and Moisture Exchanger (HME)*
CV5
optional external battery
Power Block
Mains
Battery
Controller/ Monitor
valve_exhale
CO2 sensor
T_ambient
P_ambient
Positive End Expiratory Pressure Valve
HEV
KEY:
Instrument regulated
Manual control
Alternative choice *

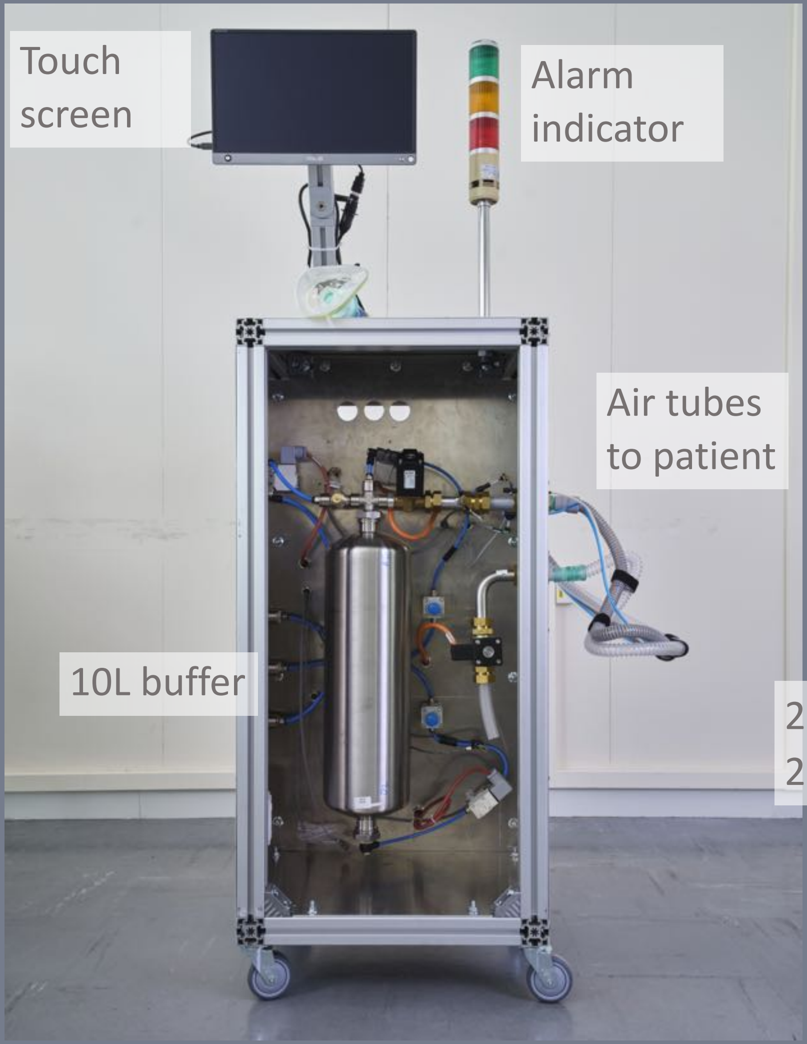
HEV Design

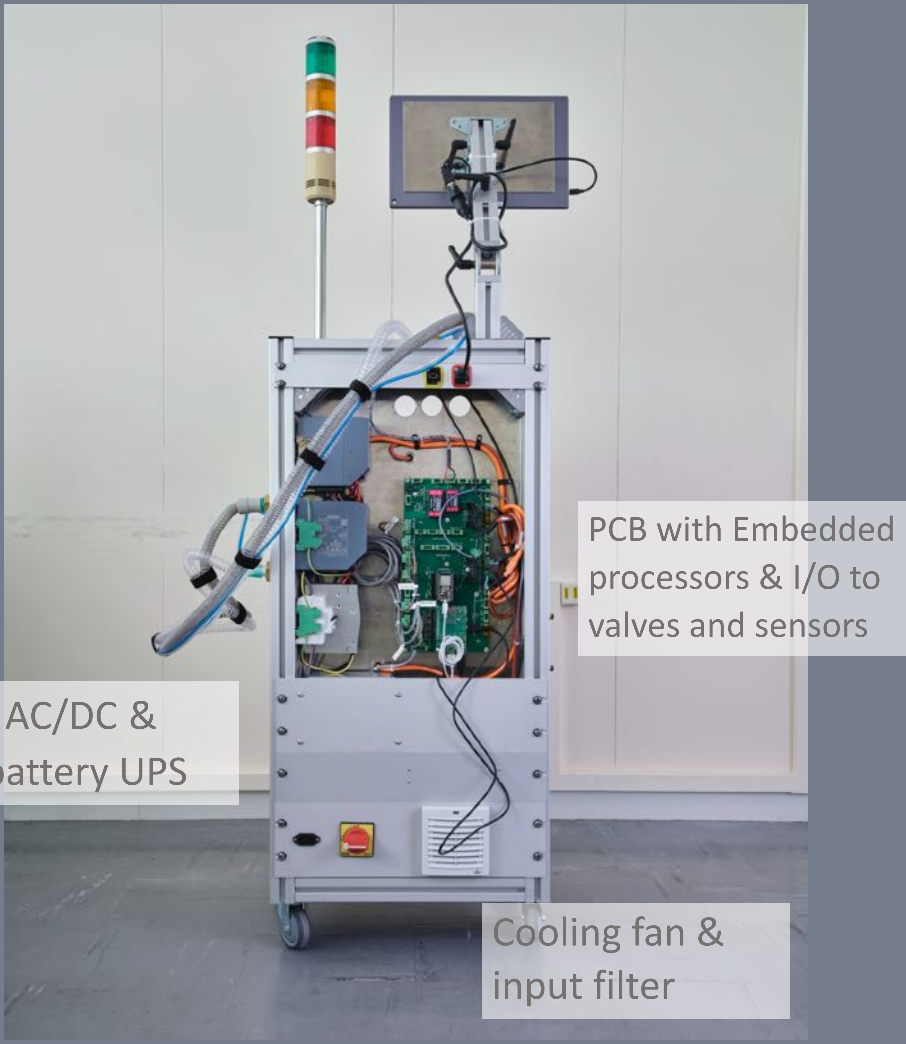


Concept of central buffer optimises **cost**, **safety**, **patient comfort** and **pressure quality**

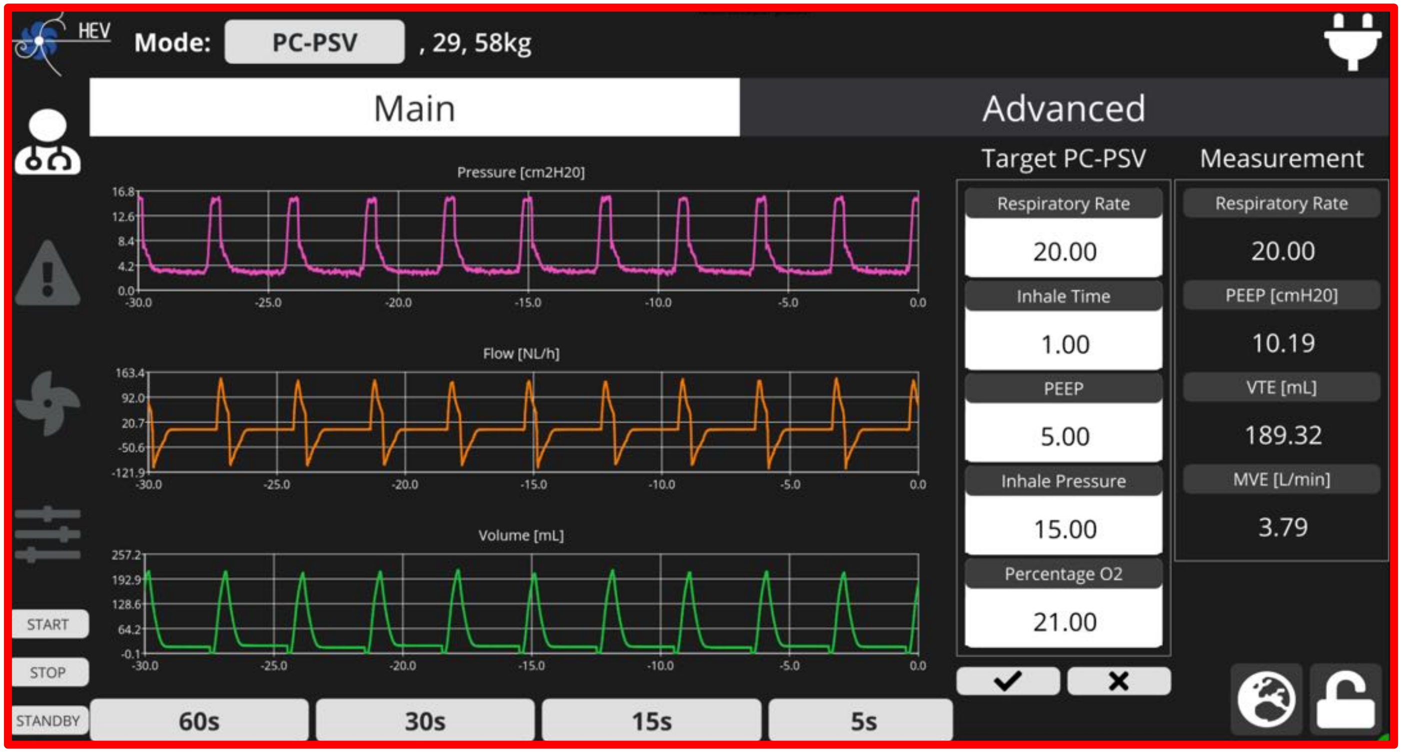
- Step-down pressure buffer between supply and patient **introduces safety** and **robustness against variable gas supply**
- Step-down pressure buffer makes **precise pressure control more readily accessible**
- Buffer allows a **natural way to mix air and O2**, so no need for an additional oxygen mixer
- **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



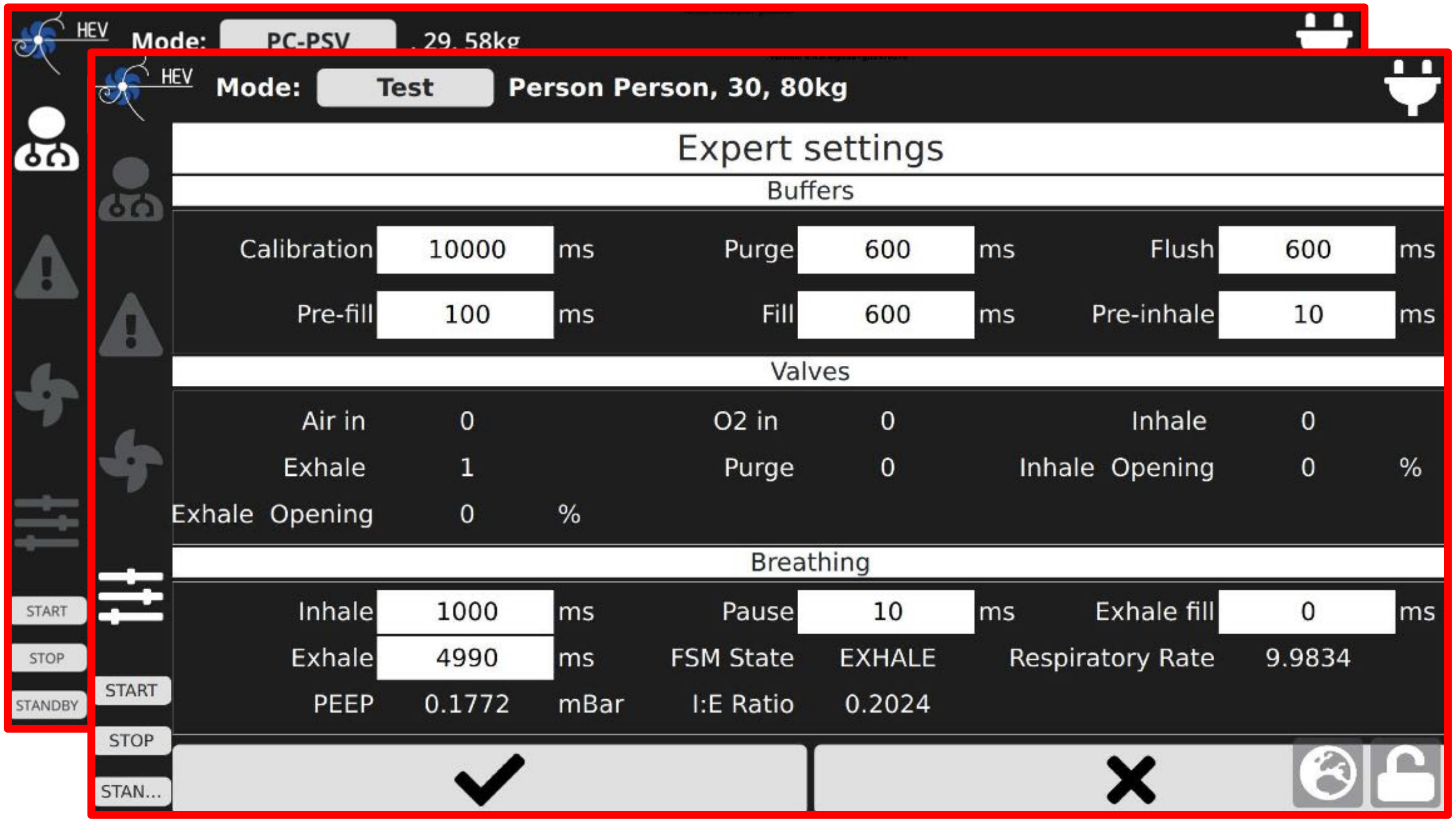


HEV User Interface

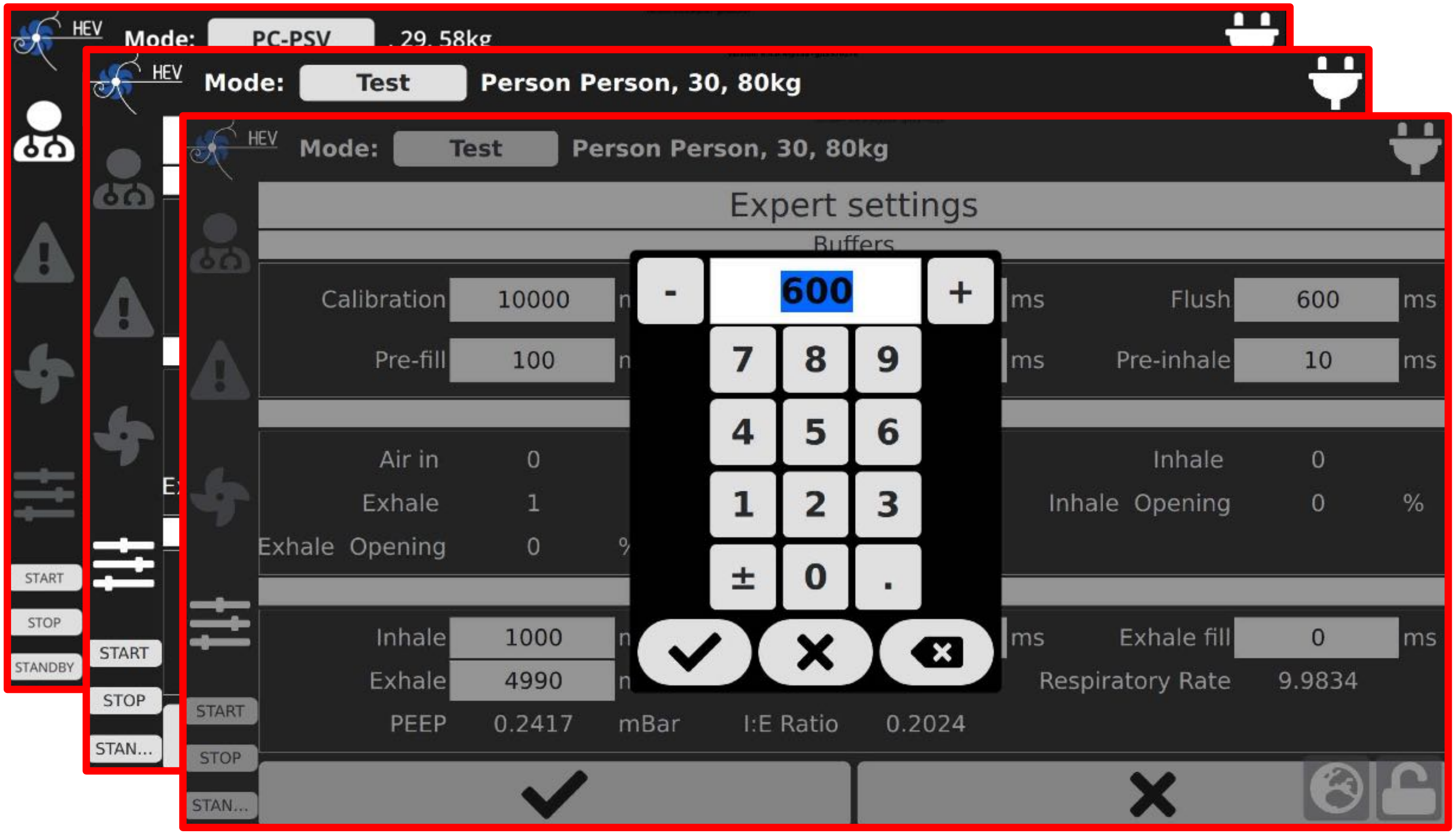


- Optimised with feedback from clinicians
- Available on touchscreen, web, and mobile device
- Option of data logging and post market surveillance
- Quality of this interface a differentiator with RMVS ventilators

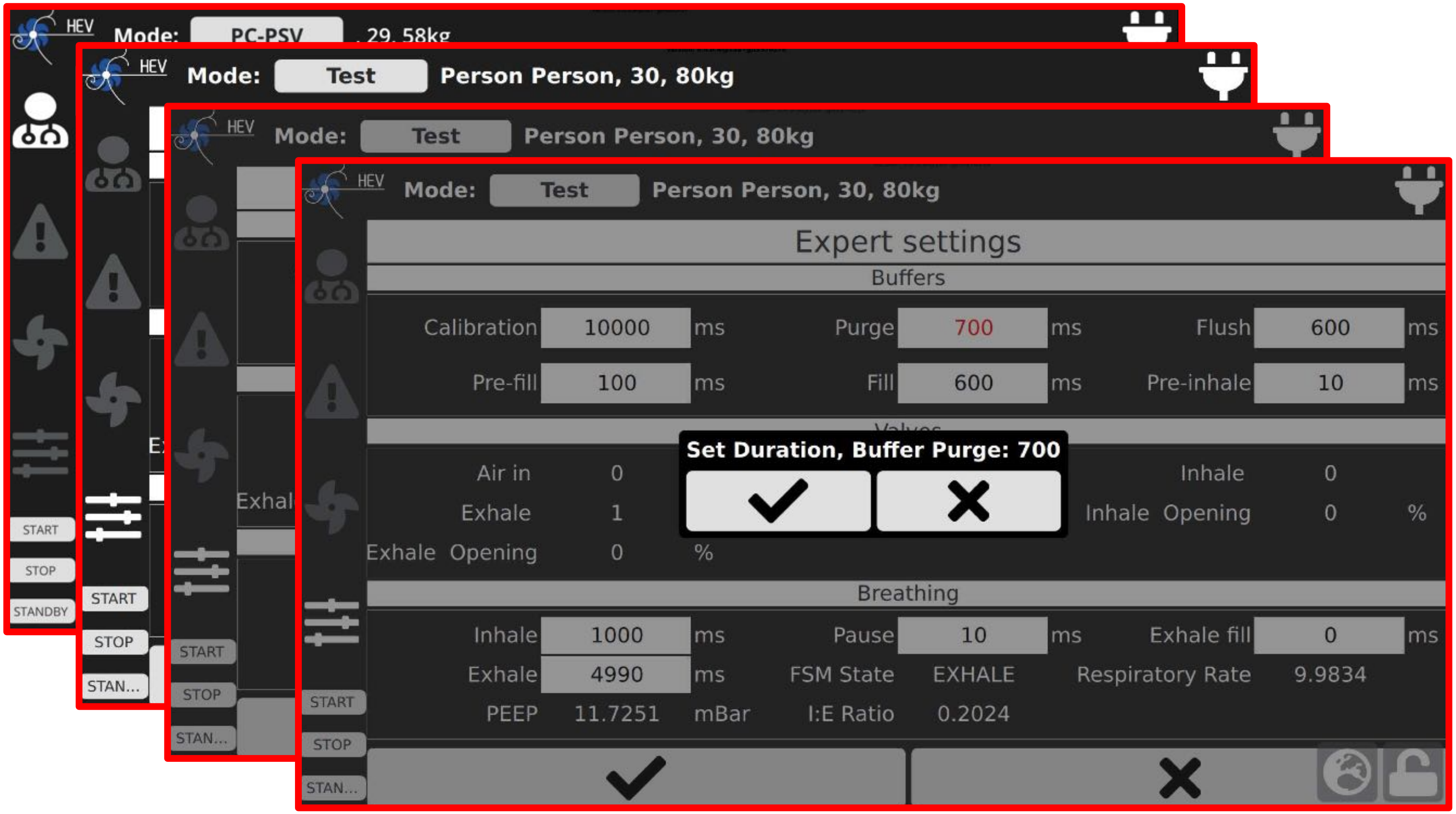
HEV User Interface



HEV User Interface



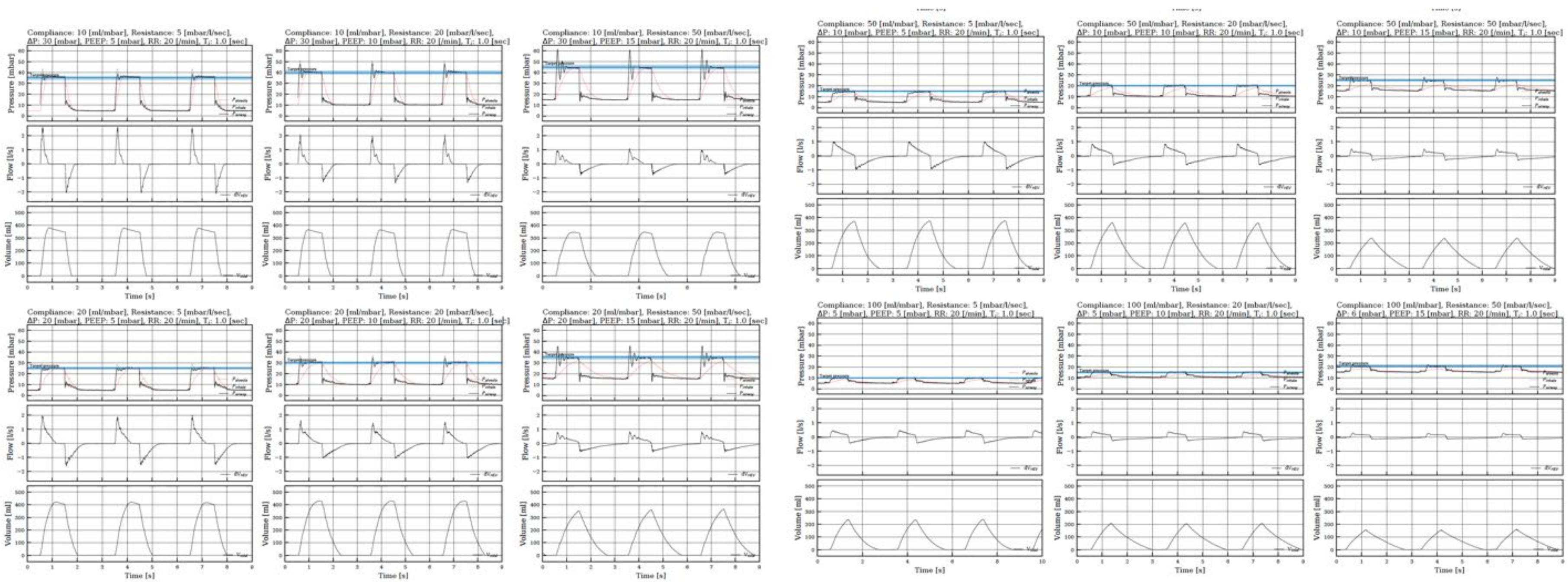
HEV User Interface



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

HEV Performance Examples (1/5)

Consis

- Vent

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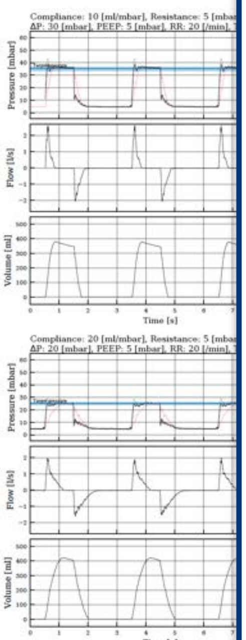
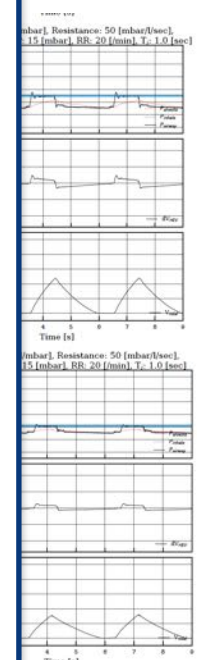


Note that a fundamental aspect to be taken into account in the development of higher quality ventilators is the use of proper test devices for design verification (rather than simple bellows)

TestChest, Organis GmbH, Landquart, Switzerland

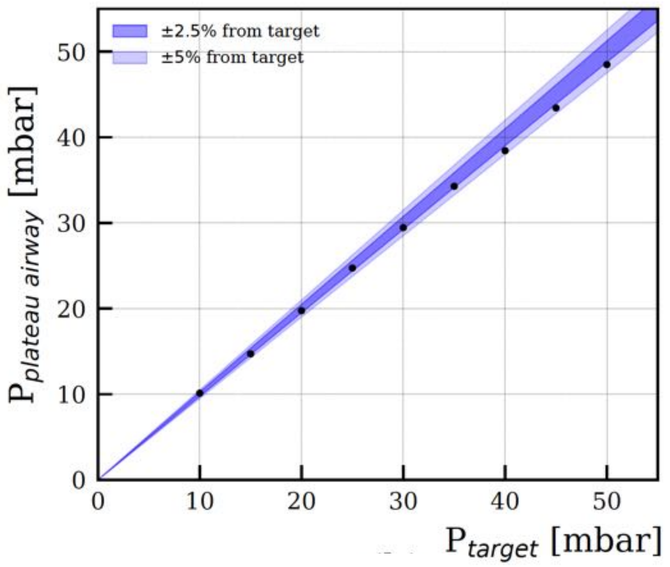


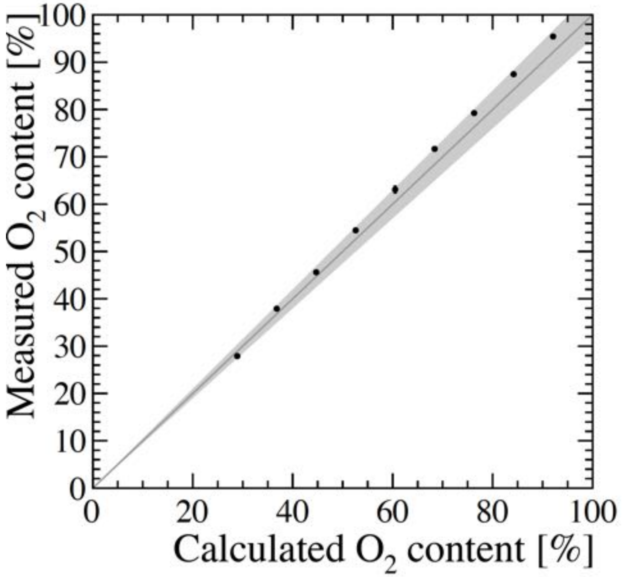
For full information on these quantitative results of pressure, flow and volume delivery, see https://arxiv.org/pdf/2007.12012

HEV Performance Examples (2/5)

Accurate Pressure Delivery, Accurate Oxygen Delivery

- Clinicians can deliver precise therapies

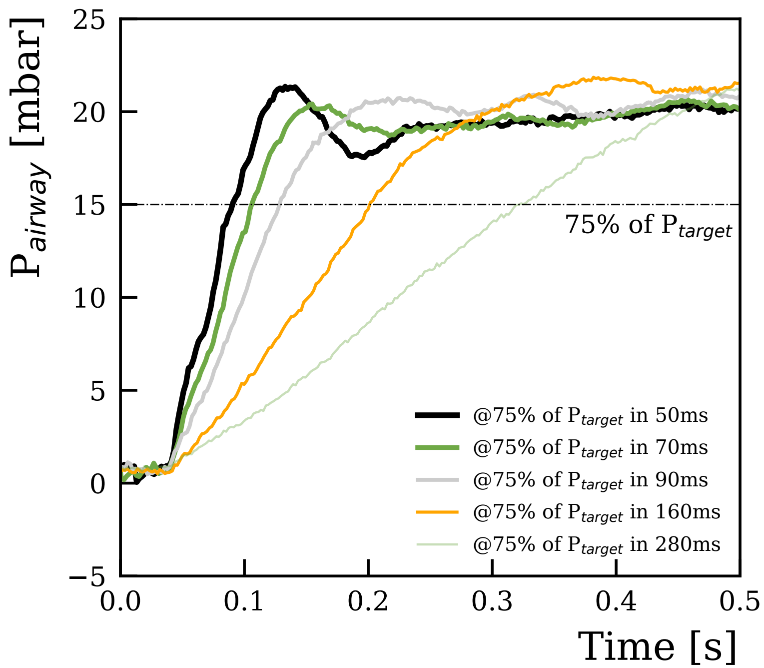




HEV Performance Examples (3/5)

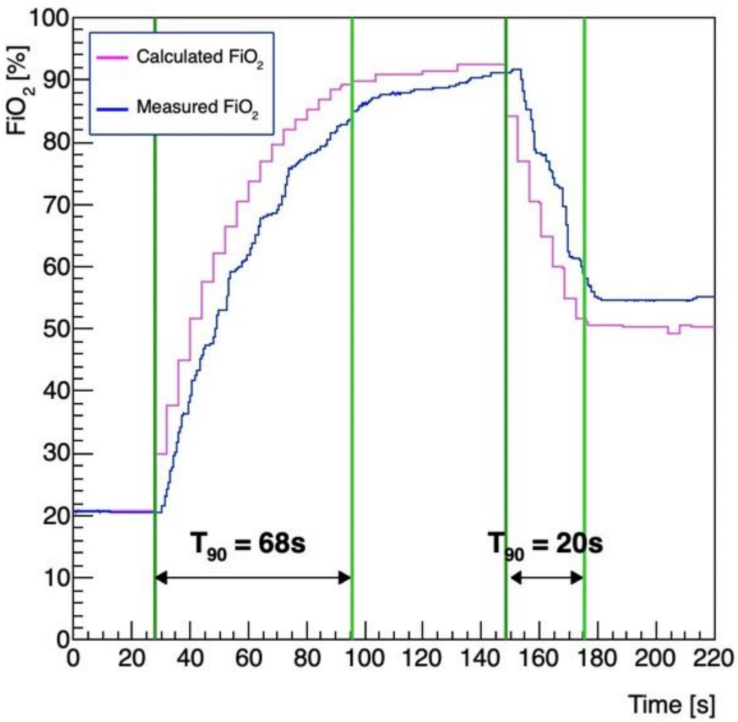
Pressure Delivery is precise, fast, and extremely reactive to patient inhalation

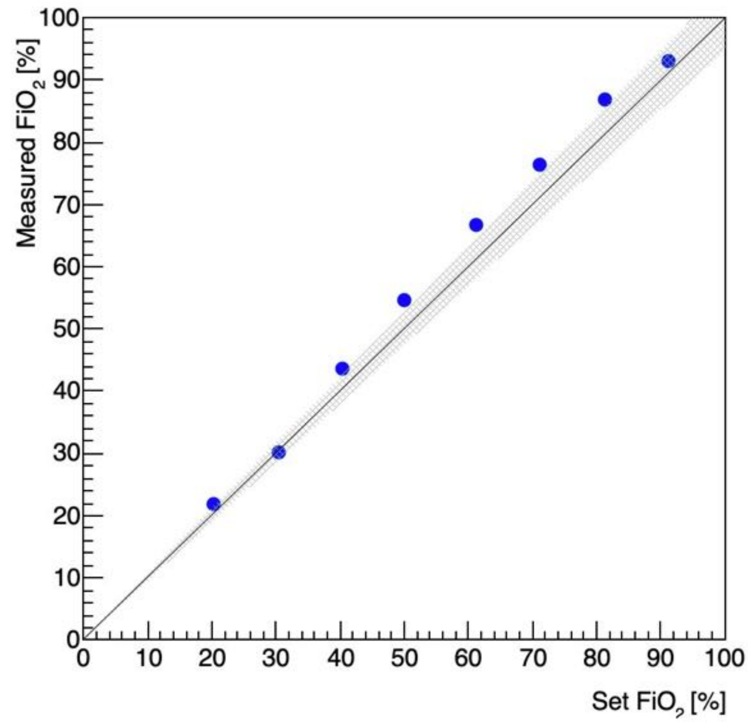
- Rise times of the order of 100 ms
- **Crucial for patient comfort**, and to optimise chances of weaning from ventilator
- Rise times are tunable for control by clinician (algorithm can provide suggestions to operator)



HEV Performance Examples (4/5)

Oxygen supply example: Raise Oxygen from 21% to 90%, hold, then bring back down to 50%



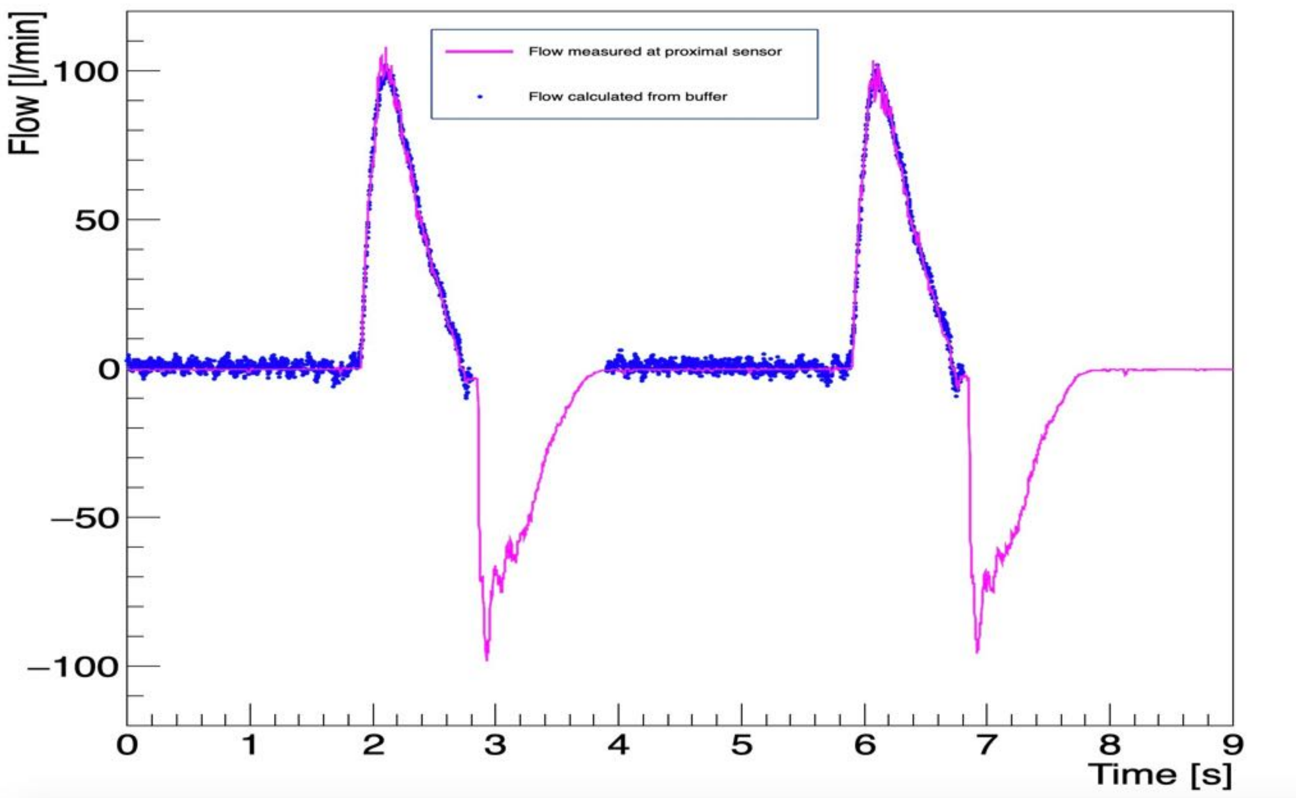


HEV supplies oxygen enriched air with the correct timescales and accuracies
Calculations are very accurate; sensor provides confirmation

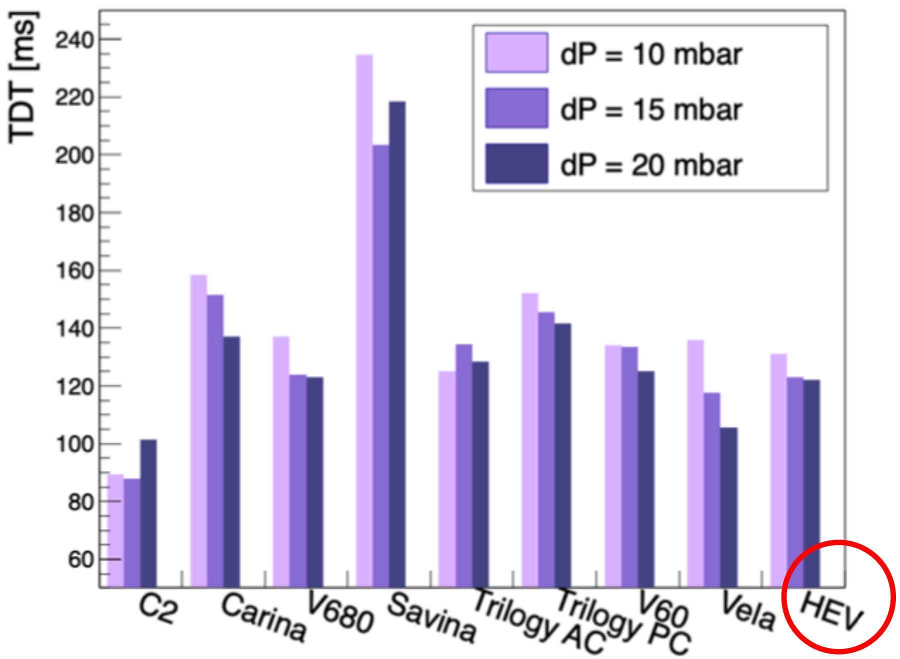
Major Advantage of HEV over other RMVS

HEV Performance Examples (5/5)

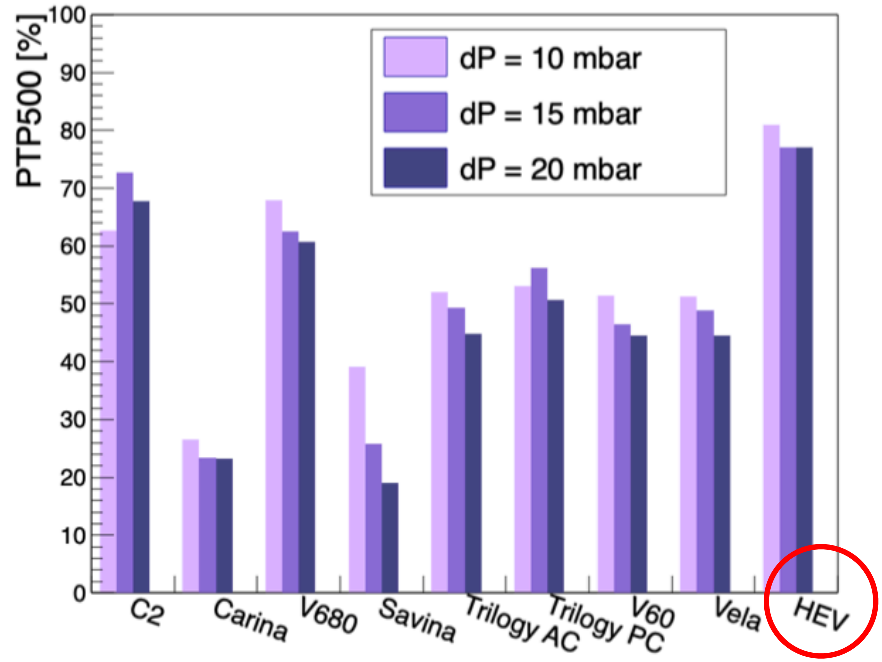
Independent, precise, flow calculation from buffer pressure monitor for Inhale phase
Here compared to Hamilton differential pressure sensor measurement



HEV performance compared to commercial devices



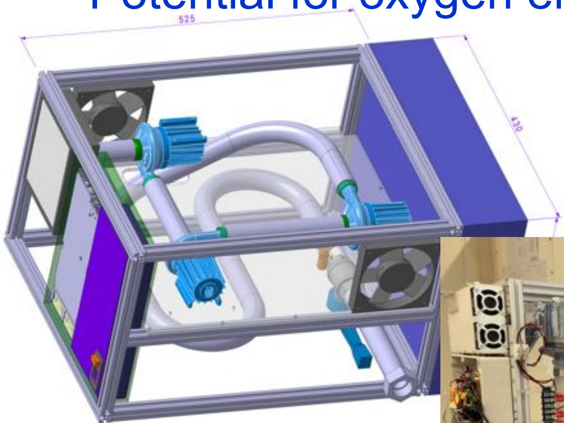
Trigger reaction time (ideally should be below 150 ms)



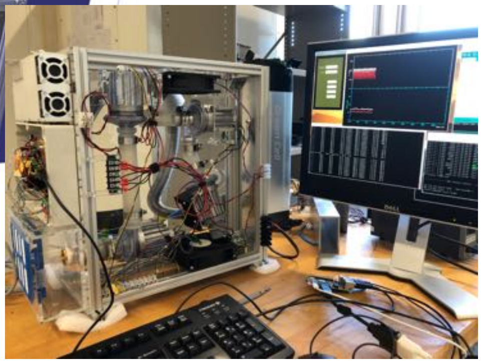
Pressure integral at 500 ms compared to ideal (should be as high as possible)

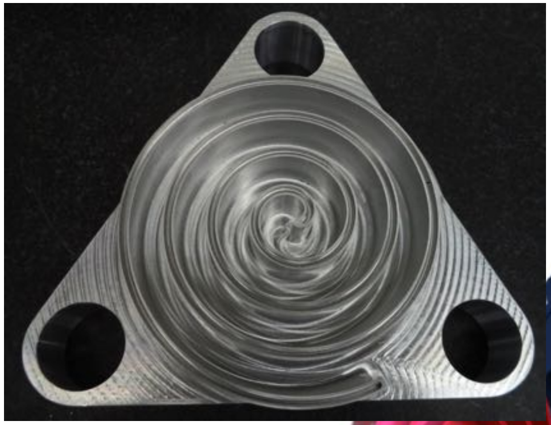
HEV Regional Adaptability

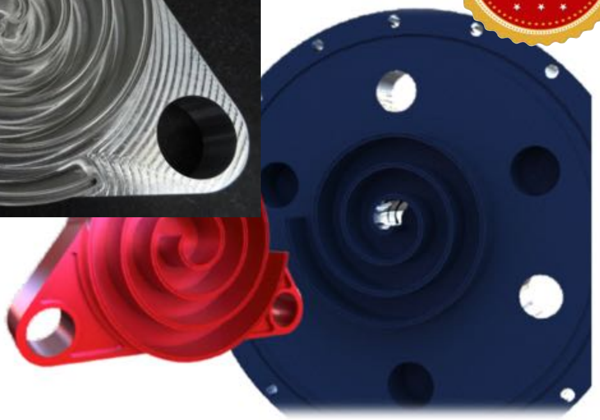
- Two standalone alternatives designed to replace hospital compressed air supply in case of need
  - based on miniature turbines - designed by EPFL
  - based on air scroll pump - designed by NTUA
- Superior to commercial compressor (noise, power, adaptability)
- Potential for oxygen enrichment



ÉCOLE POLYTECHNIQUE
FÉDÉRALE DE LAUSANNE



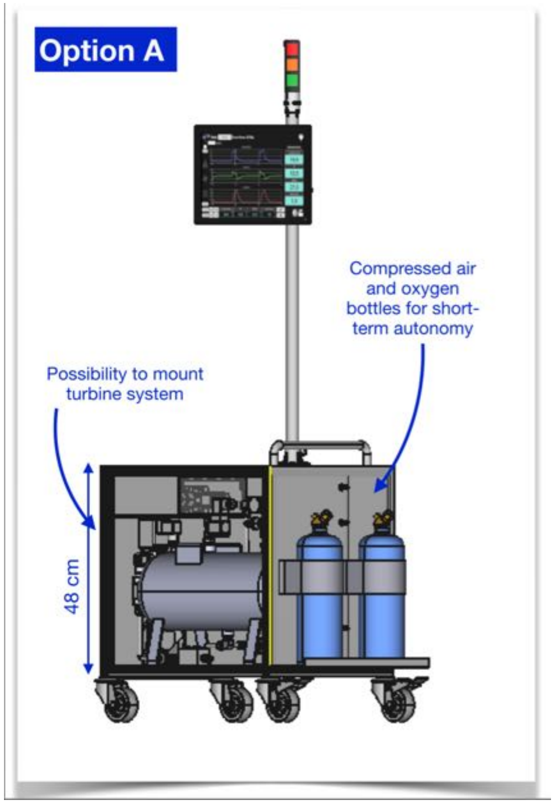


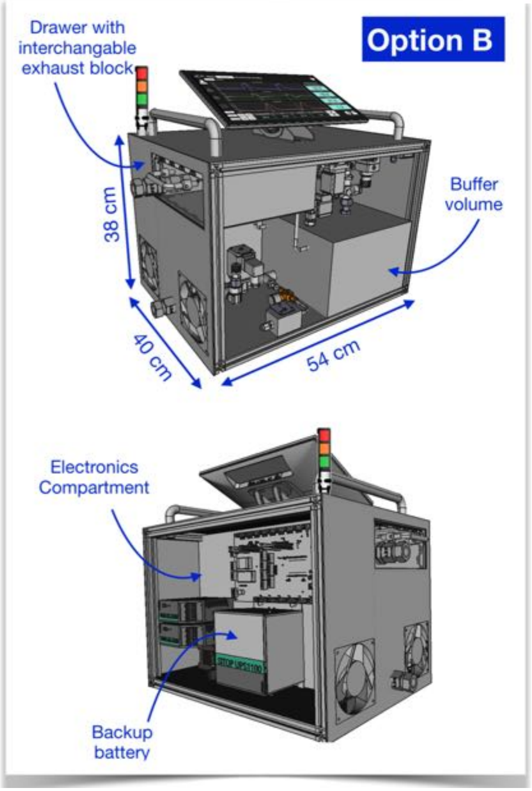


HEV Regional Adaptability

Ergonomics can be adapted to regional requirements

Universal, all-in-one solution





Compactified solution

HEV Test & Review

- **International Review** 23/04/20 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
- **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.

BUAP

Tests with manikin in Puebla

Presentation of HEV to the German Minister of Research and Education

Foto © Tim Jelonnek / Universität zu Lübeck

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

jean gallay sa

AXIS ENTERPRISES PVT. LTD.

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

Dräger

Visit for testing and feedback

UKRI

UK Research and Innovation

Ongoing collaboration for HPLV

JGA prototype

CERN

IGFAE

USC
UNIVERSIDADE DE SANTIAGO DE COMPOSTELA

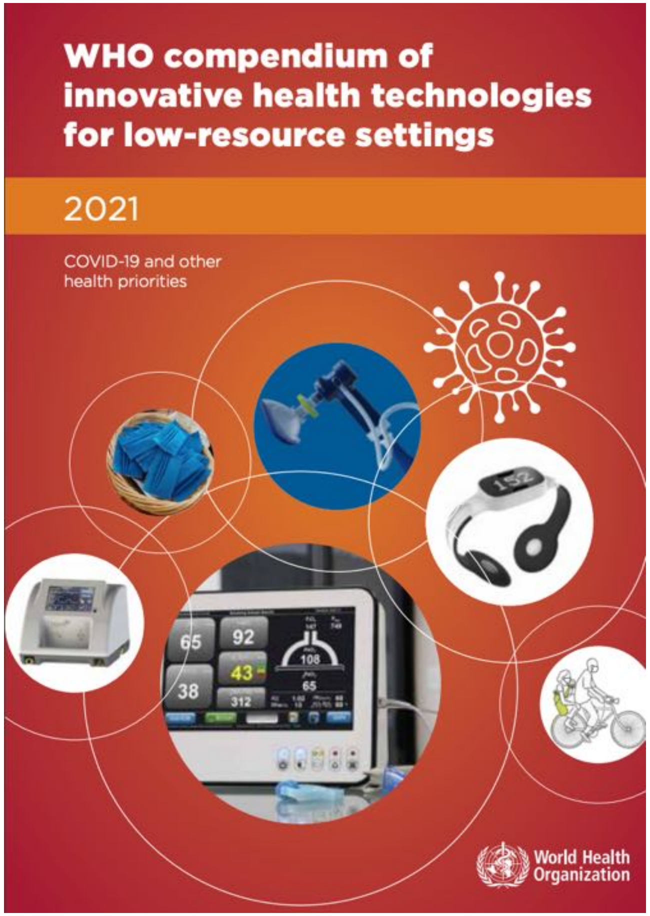
jean gallay sa

Four prototypes manufactured

HEV style design

To be used gain experience on manufacturability, for prototyping and development

HEV current status



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Research

Article submitted to journal

Subject Areas:
Mechanical Ventilator, Biomechanical Engineering

Keywords:
Covid-19, ventilation modes, Triggering, Oxygen enrichment

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The HEV Ventilator - at the Interface between Particle Physics and Biomedical Engineering

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A high quality, low-cost ventilator, dubbed HEV, has been developed by the particle physics community working together with biomedical engineers and physicians around the world. The HEV design is suitable for use both in and out of hospital intensive care units, provides a variety of modes and is capable of supporting spontaneous breathing and supplying oxygen enriched air. An external air supply can be combined with the unit for use in situations where compressed air is not readily available. HEV supports remote training and post market surveillance via a web interface and data logging to complement standard touch screen operation, making it suitable for a wide range of geographical deployment. The HEV design places emphasis on the ventilation performance, especially the quality and accuracy of the pressure curves, reactivity of the trigger, measurement of delivered volume and control of oxygen mixing, delivering a global performance which will be applicable to ventilator needs beyond the COVID-19 pandemic. This article describes the conceptual design and presents the prototype units together with a performance evaluation.

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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 t https://royalsocietypublishing.org/doi/10.1098/rsos.211519o 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