

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, 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

<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, Lausann

Philipp Rostalski and Georg Mannel, Luebeck University

Laurence Vignaux; Hôpital de La Tour, Geneva

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 Geneva

Loan of equipment from the HUG, via the special collaborative agreement between CERN and HUG, and the Pneumology 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



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



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



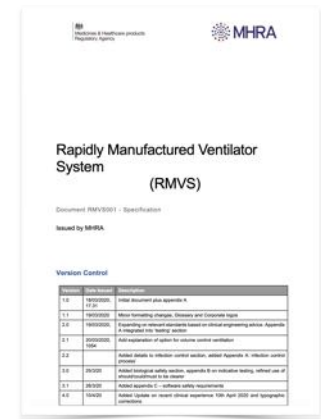
Helmet/scuba style ventilation



BiPAP/Anesthesia machines converted to ventilators



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



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

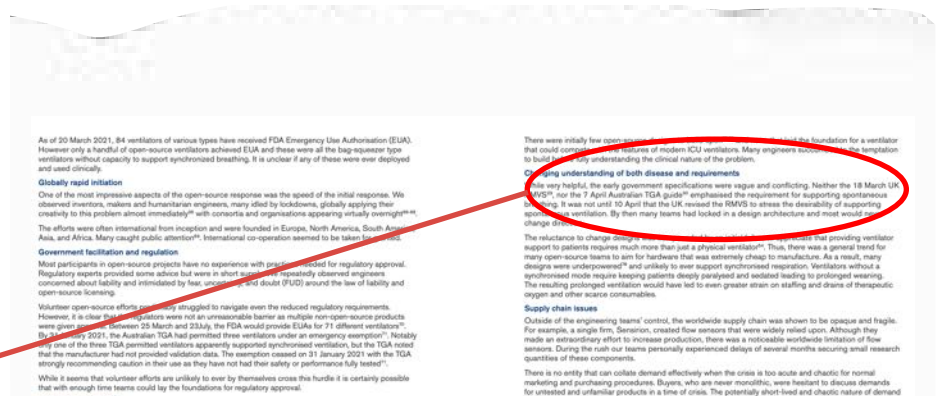
Public Invention, Austin, Texas, USA; founded the non-profit organisation Public Invention in 2018

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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DISFAVOURED

e.g. Virgin Orbit



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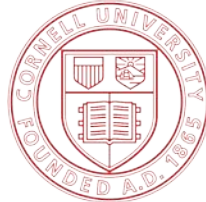
Concerning high quality designs, the need in many high income countries dwindled, and remaining demand addressed by ramp up of production. New companies e.g. Dyson dropped out.

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



IEV academic partners



Hôpitaux
Universitaires
Genève



UFRJ
UNIVERSIDADE FEDERAL
DO RIO DE JANEIRO



UNIVERSITY OF
LIVERPOOL



UNIVERSITÄT ZU LÜBECK
INSTITUTE FOR ELECTRICAL
ENGINEERING IN MEDICINE



UNIVERSITY OF
BIRMINGHAM

ETH zürich

+ others, total 29 institutes

Jan Buytaert¹, Paula Collins^{2,3}, Adam Abad Abad^{4,5}, Phil Allport⁶, Antonio Pizos Alvarez⁷, Kazuyoshi Akiba⁸, Oscar Augusto de Aguiar Francisco^{9,10}, Aurelio Bay¹¹, Florian Bernard¹², Sophie Baron¹³, Claudia Bertella¹⁴, Josef X. Brunner¹⁵, Themis Bowcock¹⁶, Martine Buytaert-De Jode¹⁷, Wiktor Byczynski¹⁸, Ricardo De Carvalho¹⁹, Victor Coco²⁰, Ruth Collins²¹, Nikola Dikic²², Nicolas Dousse²³, Bruce Dowd²⁴, Raphael Dumps²⁵, Paolo Durante²⁶, Walid Fadel²⁷, Stephen Farry²⁸, Antonio Fernández Prieto²⁹, Gordon Flynn³⁰, Vincius Franco Lima³¹, Raymond Frei³², Abraham Gallia Torreiro³³, Roberto Guida³⁴, Karol Hermessay³⁵, Andre Henriques³⁶, David Hutchcroft³⁷, Stefan Ilie³⁸, Aleksandar Jevtic³⁹, Christian Joram⁴⁰, Kasper Kapusniak⁴¹, Edgar Lemoci Cui⁴², Jana Lindner⁴³, Rolf Lindner⁴⁴, Marko Milovanovic⁴⁵, Sylvain Mico⁴⁶, Johan Morant⁴⁷, Georg Mörner⁴⁸, Donal Murray⁴⁹, Irina Nasteva⁵⁰, Niko Neufeld⁵¹, Igor Neuhold⁵², Francisco Pardo-Sobrinho Lopez⁵³, Eliseo Pérez Trigo⁵⁴, Gonzalo Pichel Jallas⁵⁵, Edyta Pilorz⁵⁶, Lisa Pigulloud⁵⁷, Carl Rössner⁵⁸, Philipp Rostanski⁵⁹, Freek Sanders⁶⁰, Eric Sauzet⁶¹, Burkhard Schmitt⁶², Patrick Schoetens⁶³, Rainer Schwenner⁶⁴, Heinrich Schindler⁶⁵, Arshana Sharma⁶⁶, Christophe Sigaud⁶⁷, Peter Sivhira⁶⁸, Jan van Leemput⁶⁹, Laurence Vignaux⁷⁰, Francois Vasey⁷¹, Hamish Wootton⁷², and Ken Wylie⁷³

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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.

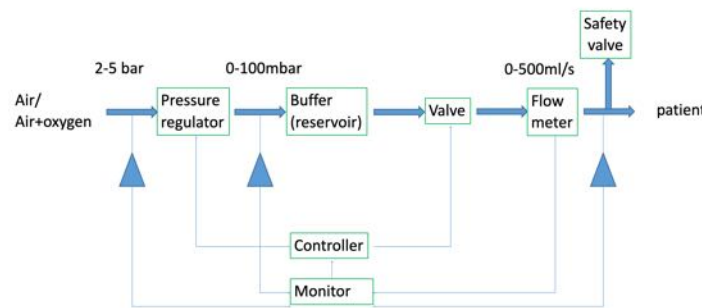
I don't know if there is an equivalent CERN exercise. If not then perhaps this could be suggested (Paula ??) In the meanwhile we would welcome ANY collaboration with Liverpool PP to contribute to this activity.

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,

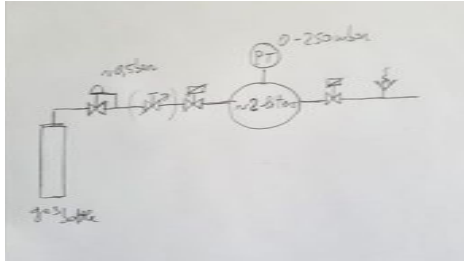
Themis

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



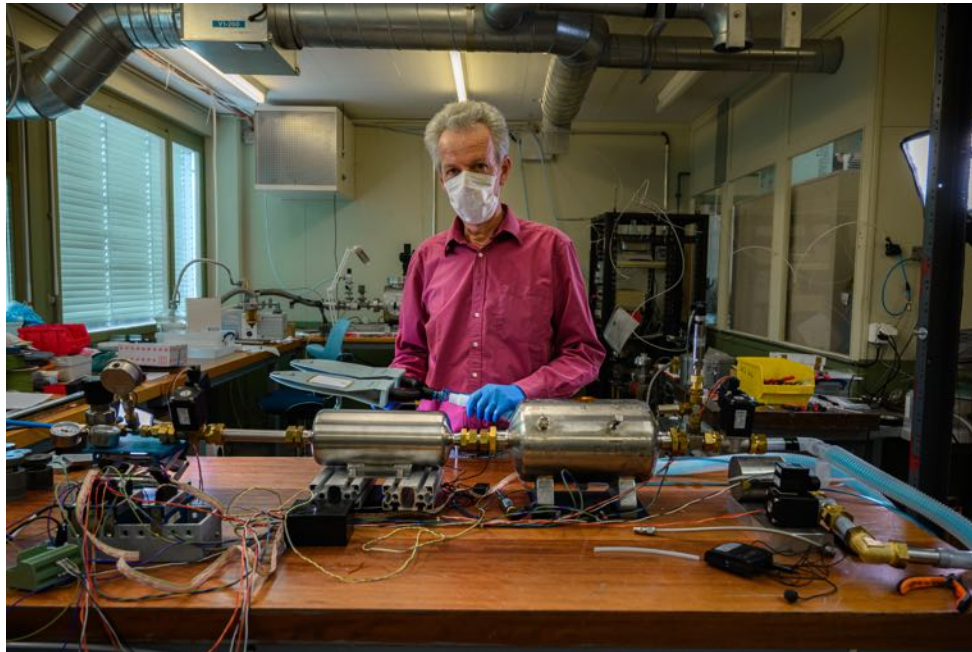
First proposal: Pressure support incorporated from the start to allow spontaneous breaths

Table top demonstrator



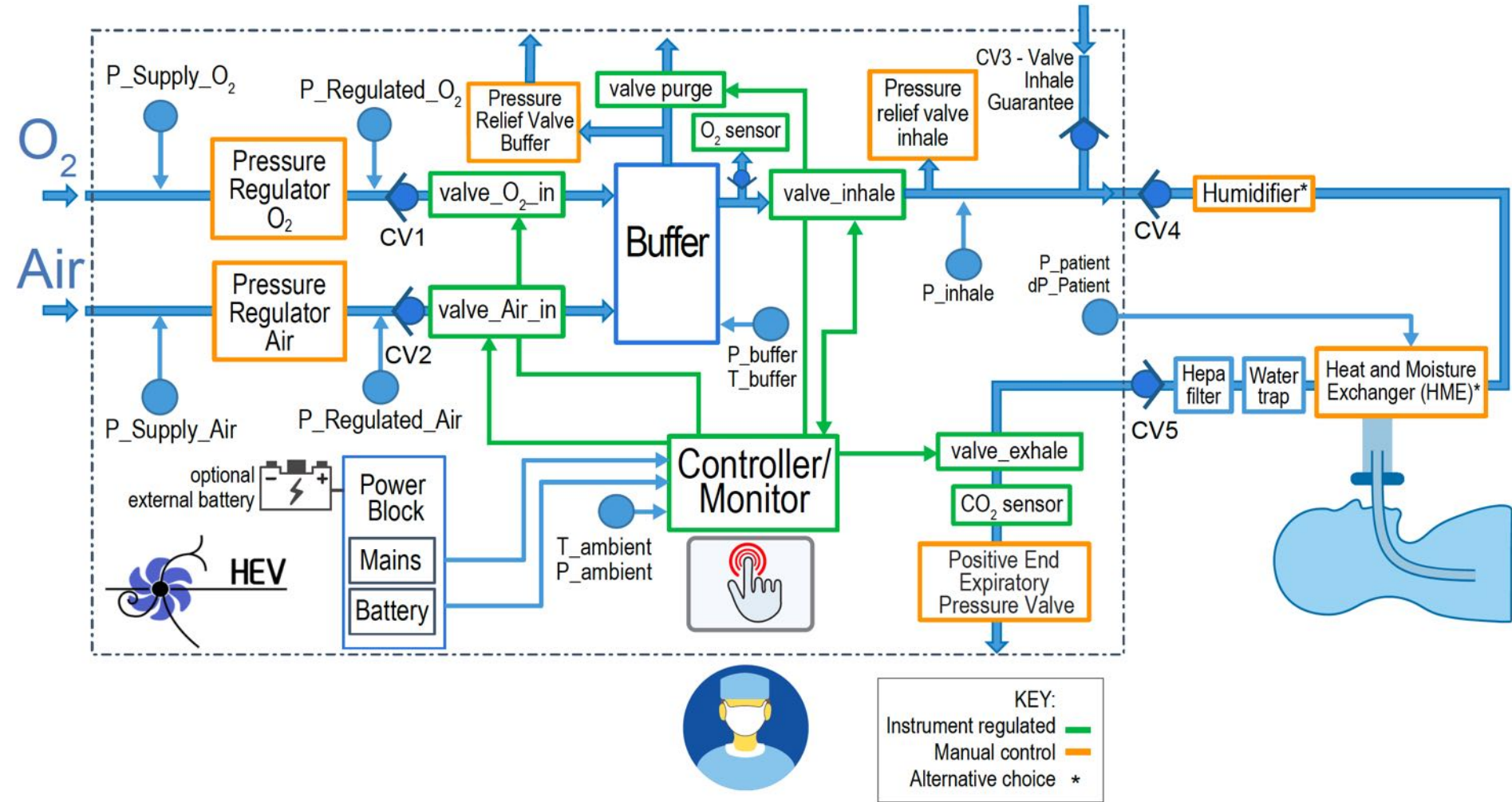
New idea proposed by Roberto Guida.

Separation of HEV into independent supply/patient sub-units

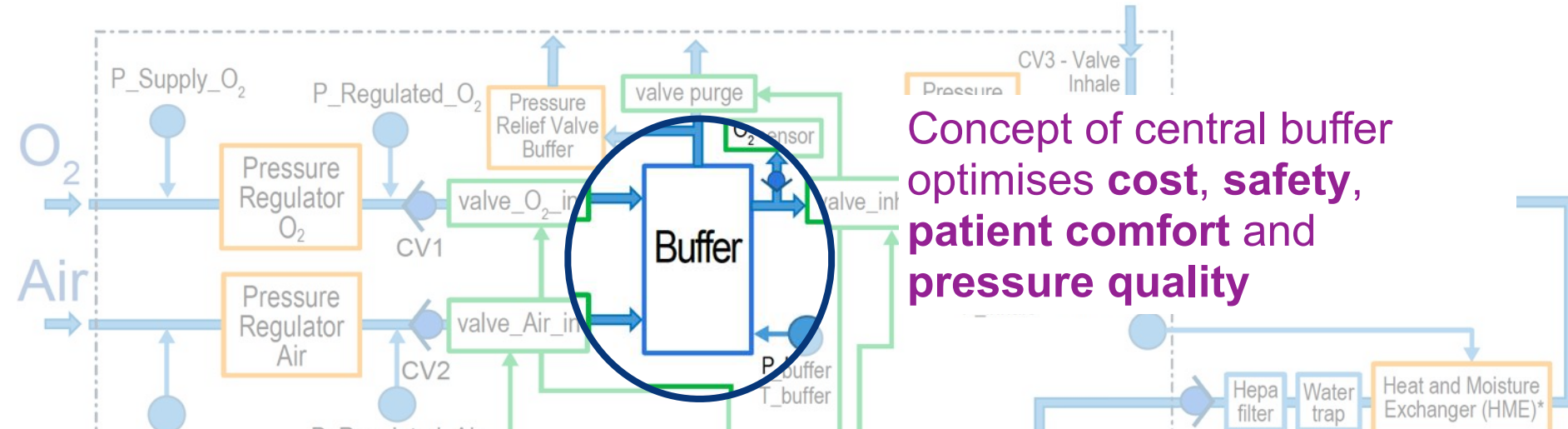


First demonstrator: 28th March 2020

HEV Design

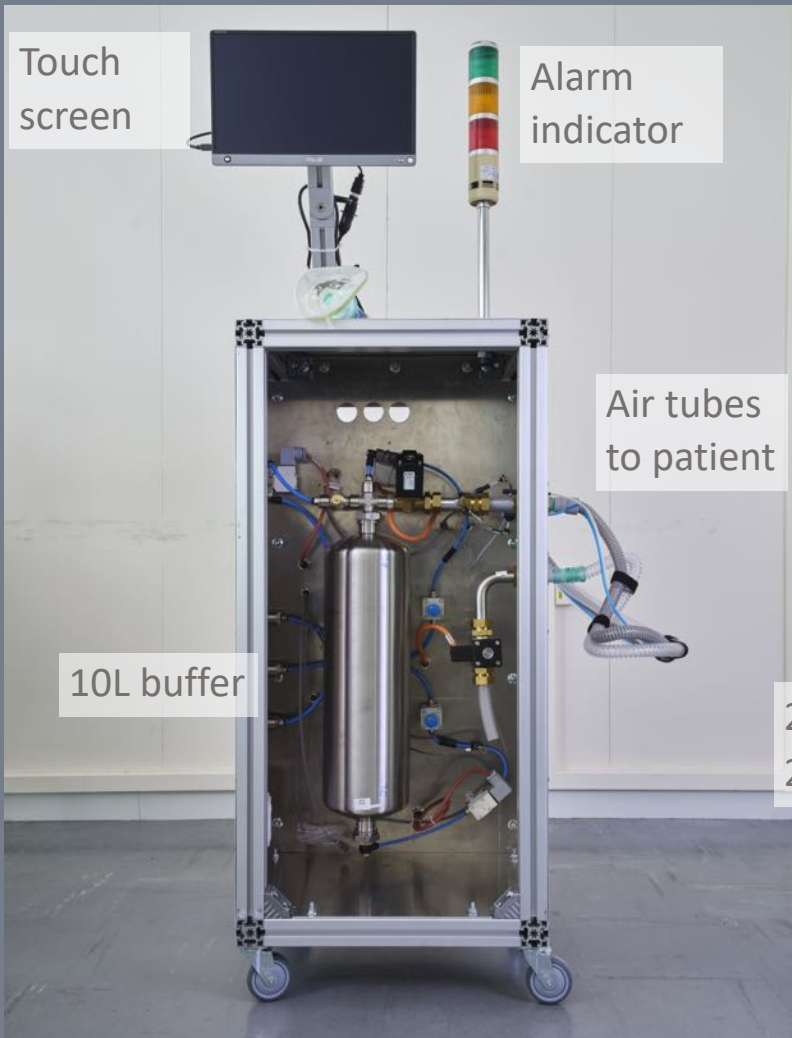


HEV Design

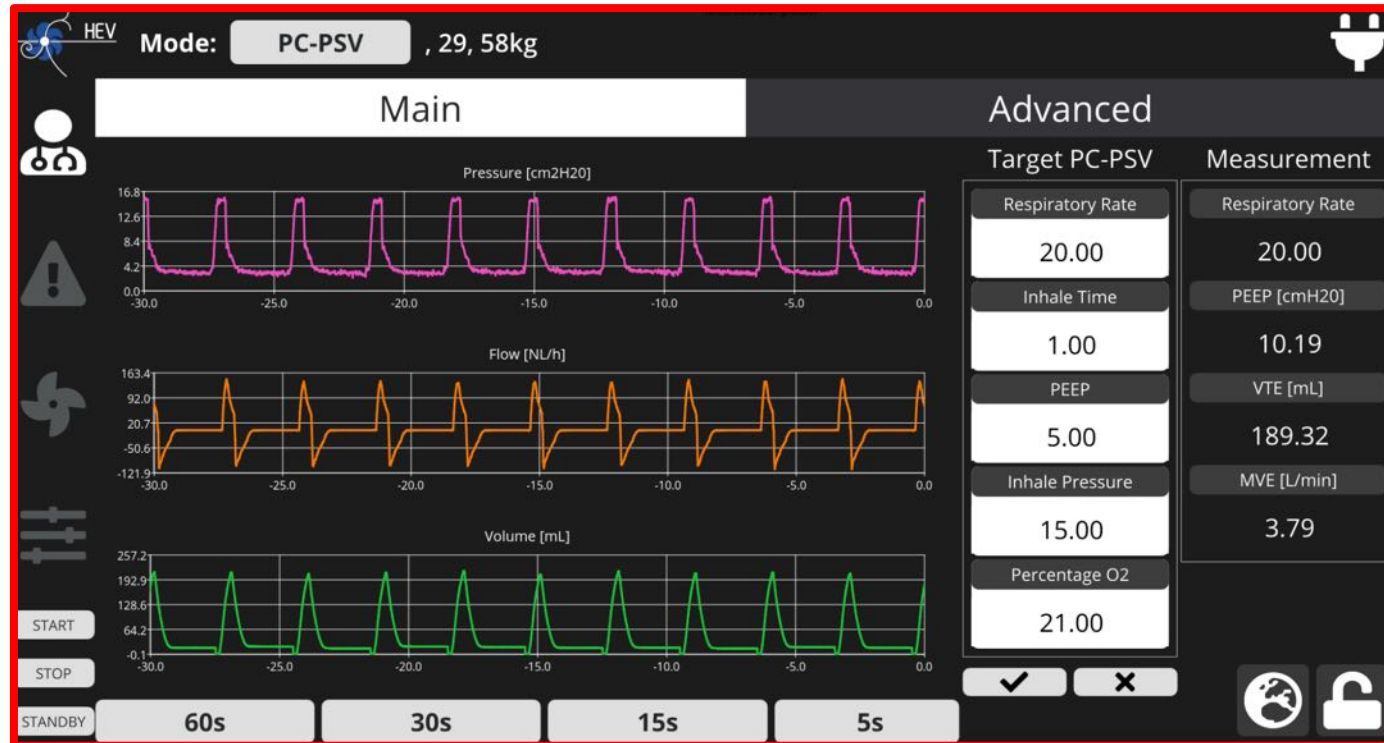


- Step-down pressure buffer between supply and patient **introduces safety** and **robustness against variable gas supply**
- Step-down pressure buffer makes **precise pressure control more readily accessible**
- Buffer allows a **natural way to mix air and O2**, so no need for an additional oxygen mixer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

The screenshot displays the HEV User Interface for a test mode. The interface is divided into several sections: a top status bar, a left sidebar with icons, a main settings area, and a bottom control bar.

Top Status Bar: HEV Mode: PC-PSV 29.58kg

Left Sidebar: HEV Mode: Test Person Person, 30, 80kg

Main Settings Area:

Expert settings

Buffers

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

Valves

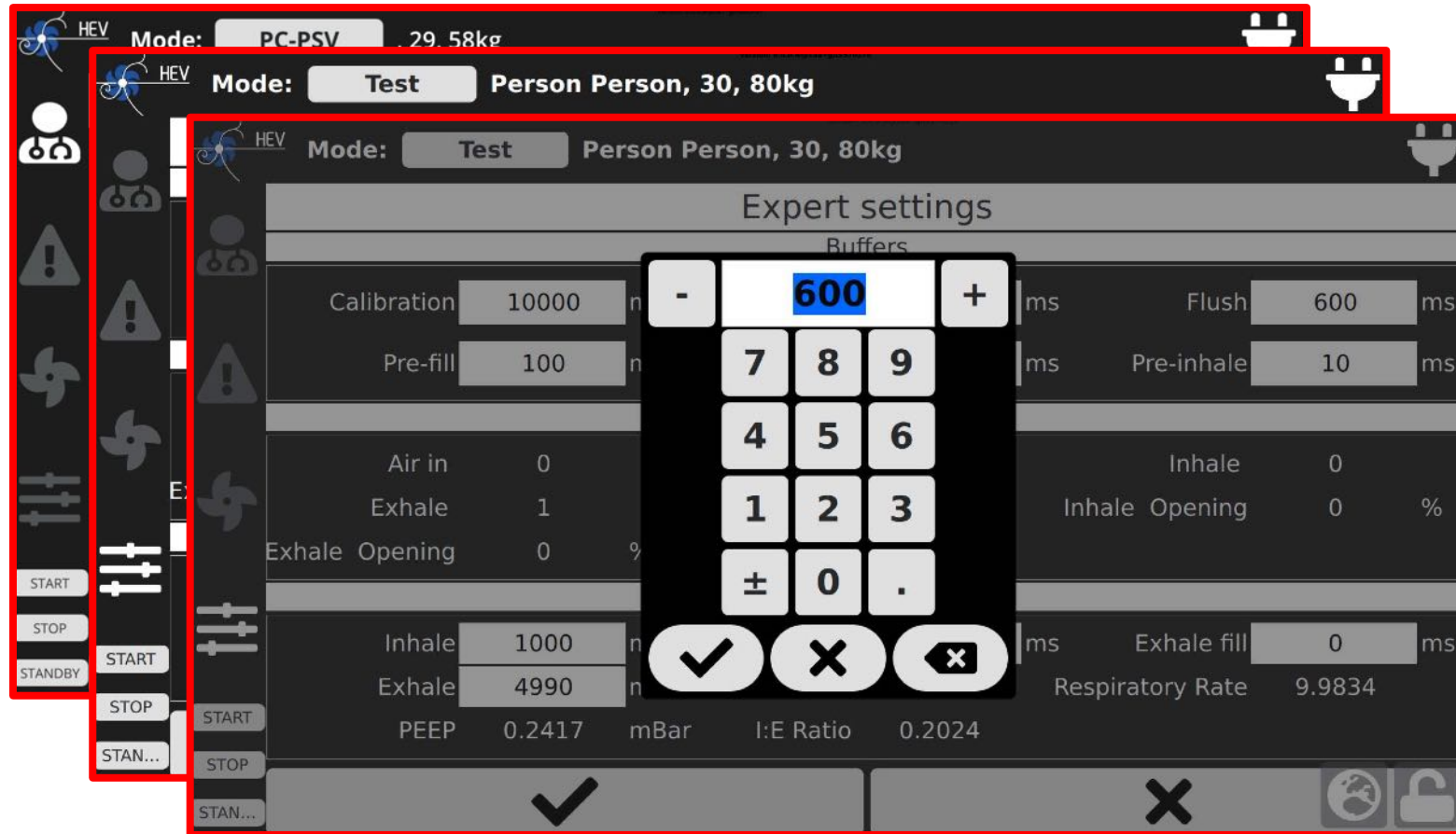
Air in	0	O2 in	0	Inhale	0
Exhale	1	Purge	0	Inhale Opening	0 %
Exhale Opening	0 %				

Breathing

Inhale	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				

Bottom Control Bar: START STOP STANDBY START STOP STAN... (checkmark icon) (X icon) (globe icon) (lock icon)

HEV User Interface



HEV User Interface

The image displays three overlapping screenshots of the HEV User Interface, each showing a different configuration screen. The topmost screen is the 'Expert settings' screen, which is currently in 'Test' mode for a 'Person Person, 30, 80kg'. It features a sidebar with various control icons (person, fan, warning, sliders, and buttons for START, STOP, and STANDBY). The main area is divided into sections: Buffers, Valves, and Breathing. A modal dialog box is open over the 'Valves' section, titled 'Set Duration, Buffer Purge: 700', with a checkmark button and a close button (X).

HEV Mode: PC-PSV 29.58kg

HEV Mode: Test Person Person, 30, 80kg

HEV Mode: Test Person Person, 30, 80kg

Expert settings

Buffers

Parameter	Value	Unit
Calibration	10000	ms
Purge	700	ms
Flush	600	ms
Pre-fill	100	ms
Fill	600	ms
Pre-inhale	10	ms

Valves

Parameter	Value	Unit
Air in	0	
Exhale	1	
Exhale Opening	0	%
Inhale	0	
Inhale Opening	0	%

Breathing

Parameter	Value	Unit
Inhale	1000	ms
Pause	10	ms
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Exhale	4990	ms
FSM State	EXHALE	
Respiratory Rate	9.9834	
PEEP	11.7251	mBar
I:E Ratio	0.2024	

Set Duration, Buffer Purge: 700

✓ X

START STOP STANDBY

START STOP STAN...

START STOP STAN...

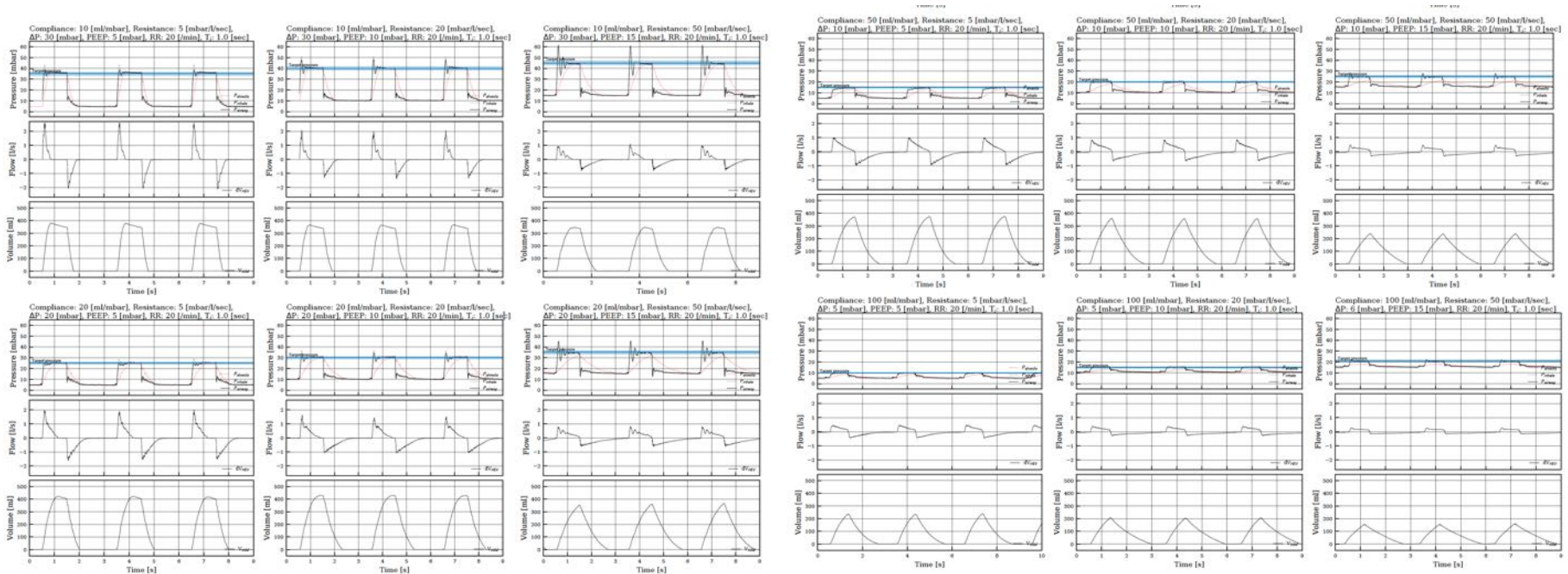
START STOP STAN...

✓ X

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)

Consistent
- Vent

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)



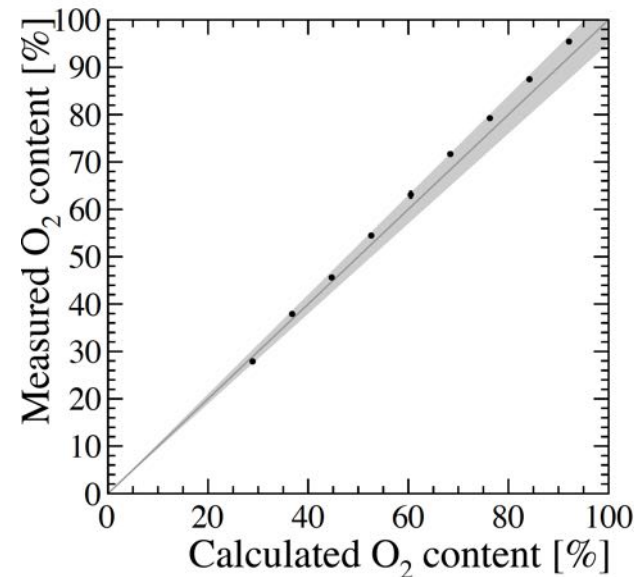
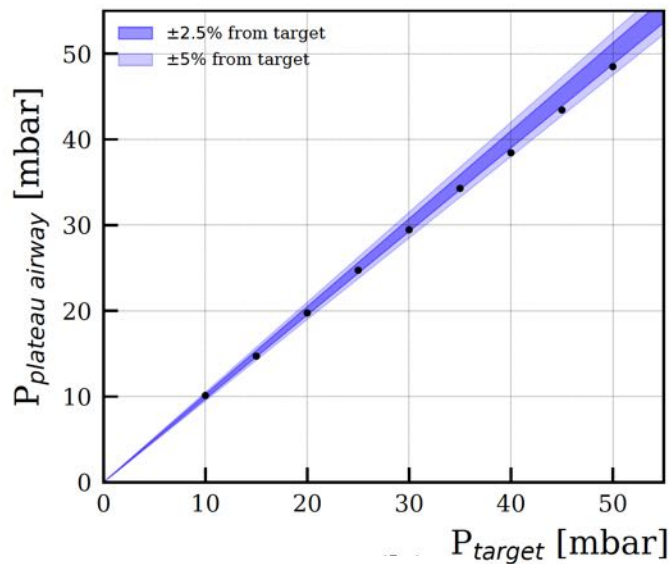
TestChest, Organix GmbH, Landquart, Switzerland

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

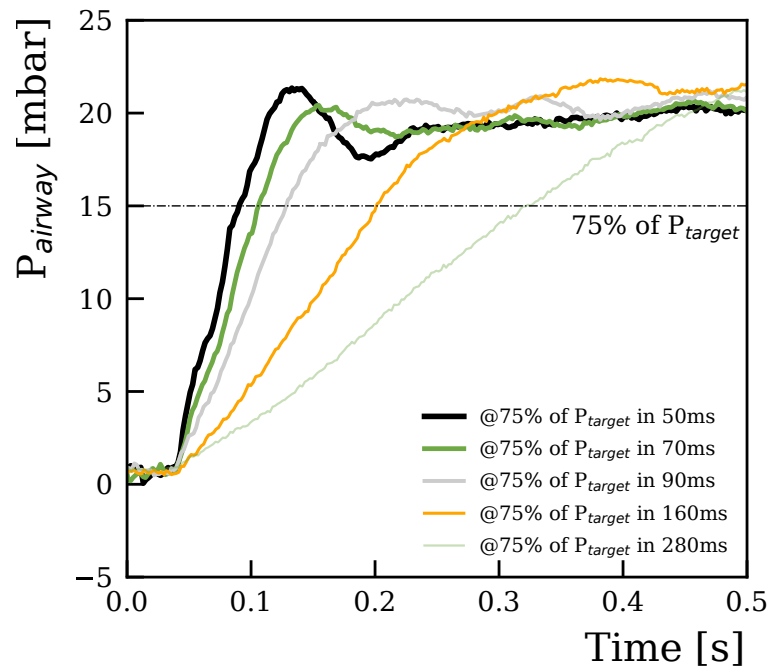
- Clinicians can deliver precise therapies



HEV Performance Examples (3/5)

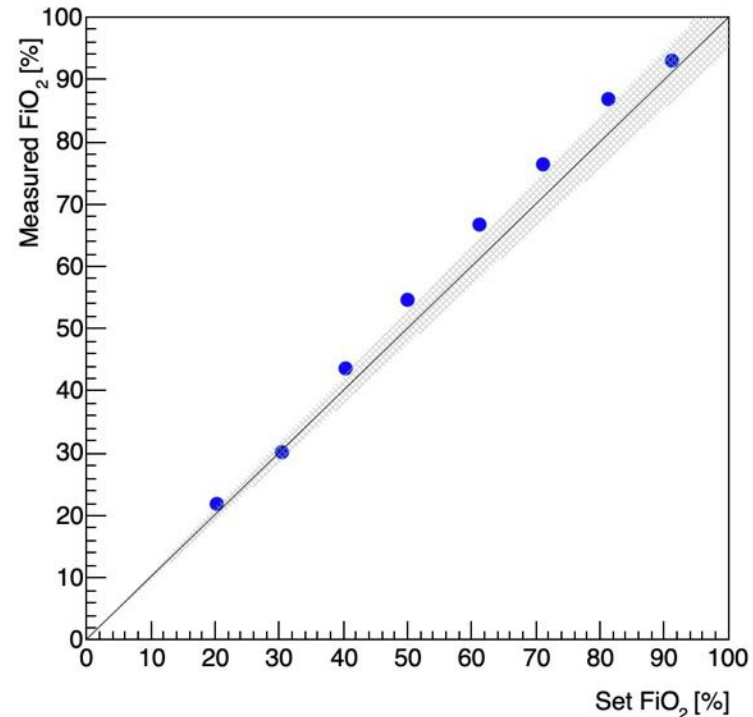
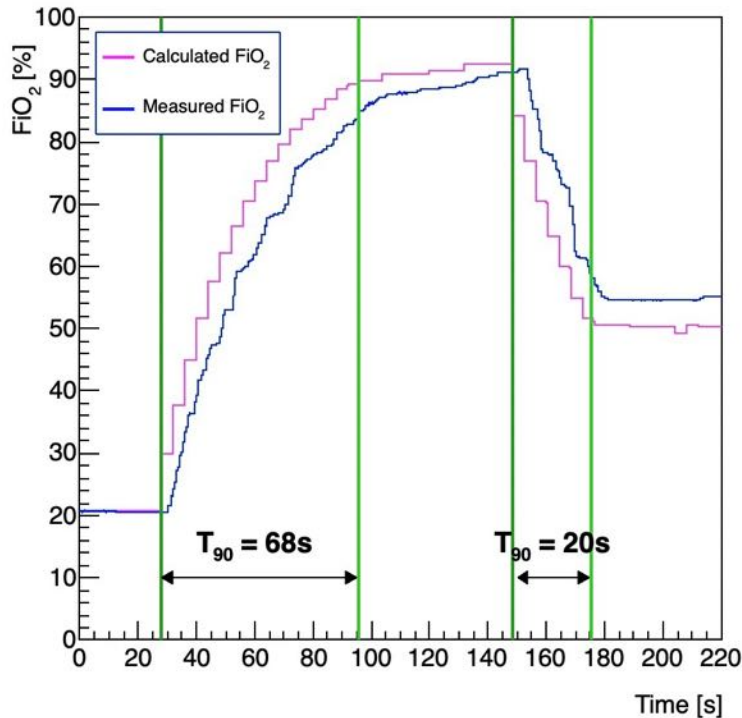
Pressure Delivery is precise, fast, and extremely reactive to patient inhalation

- 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%

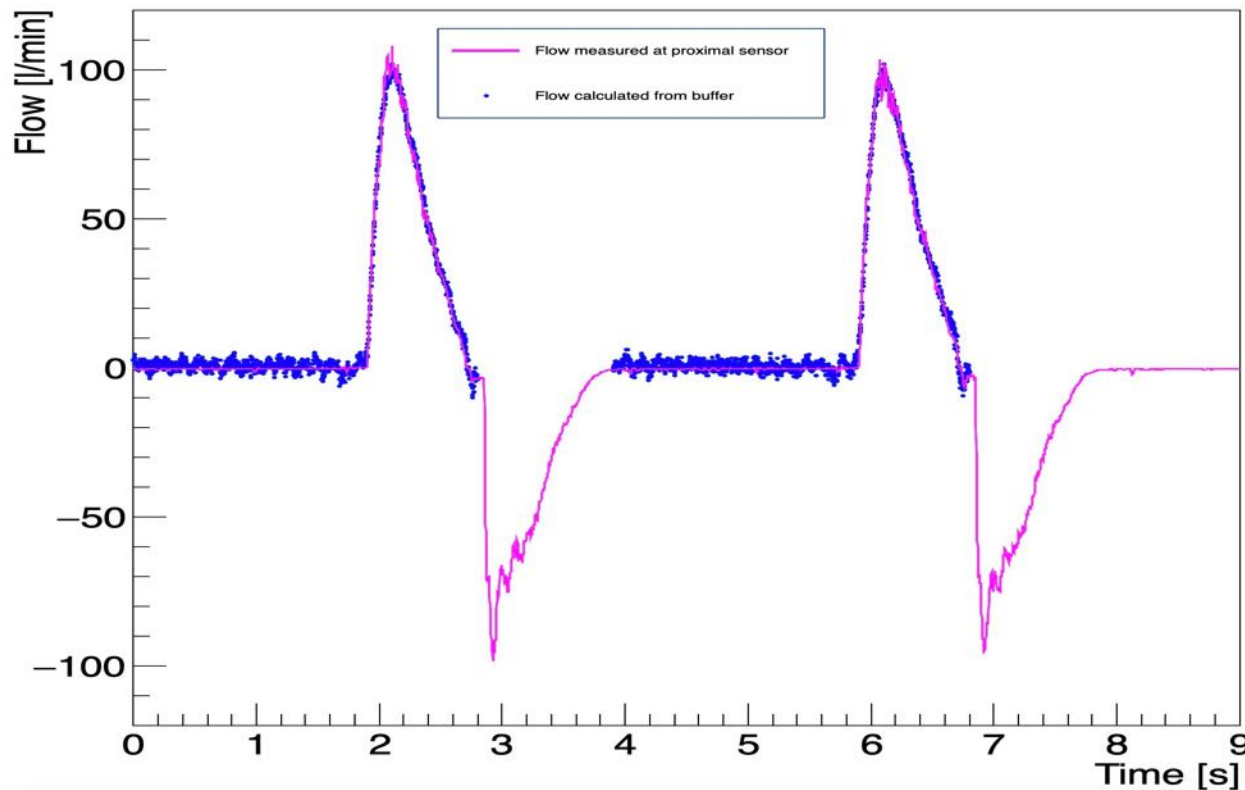


HEV supplies oxygen enriched air with the correct timescales and accuracies
Calculations are very accurate; sensor provides confirmation

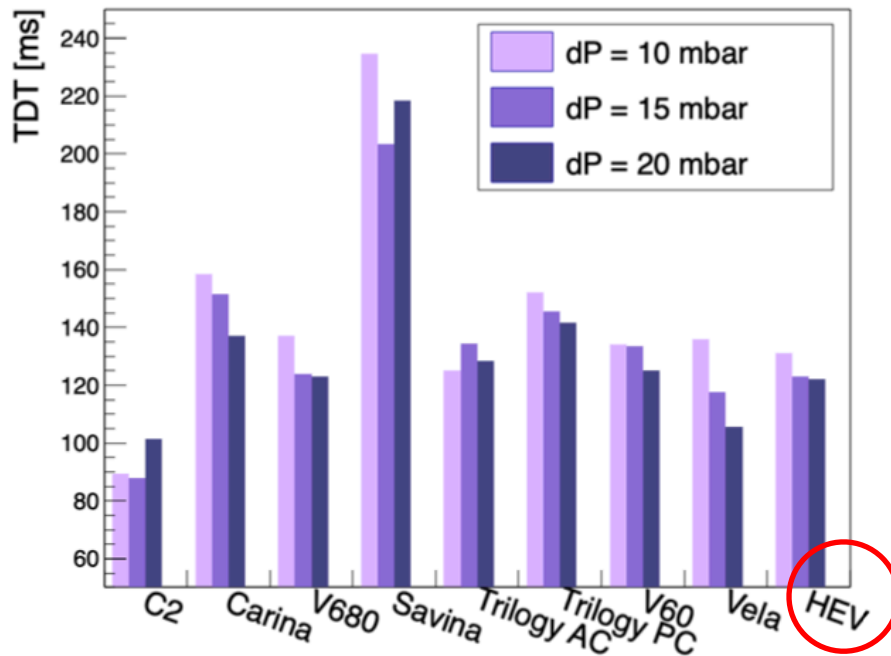


HEV Performance Examples (5/5)

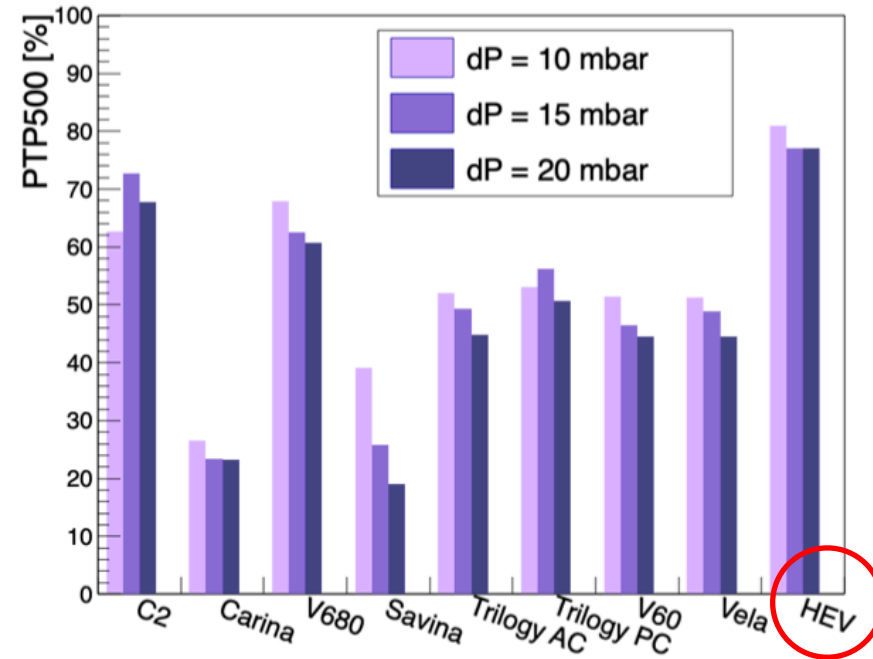
Independent, precise, flow calculation from buffer pressure monitor for Inhale phase
Here compared to Hamilton differential pressure sensor measurement



HEV performance compared to commercial devices



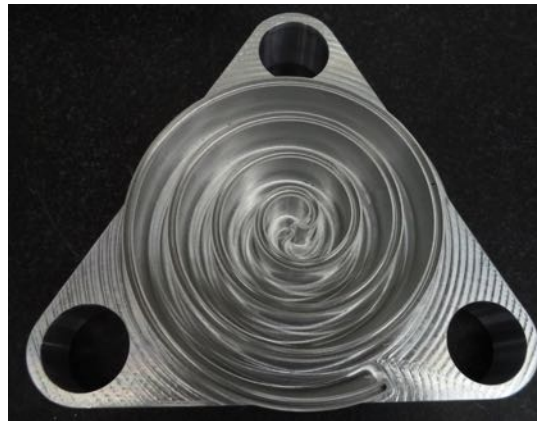
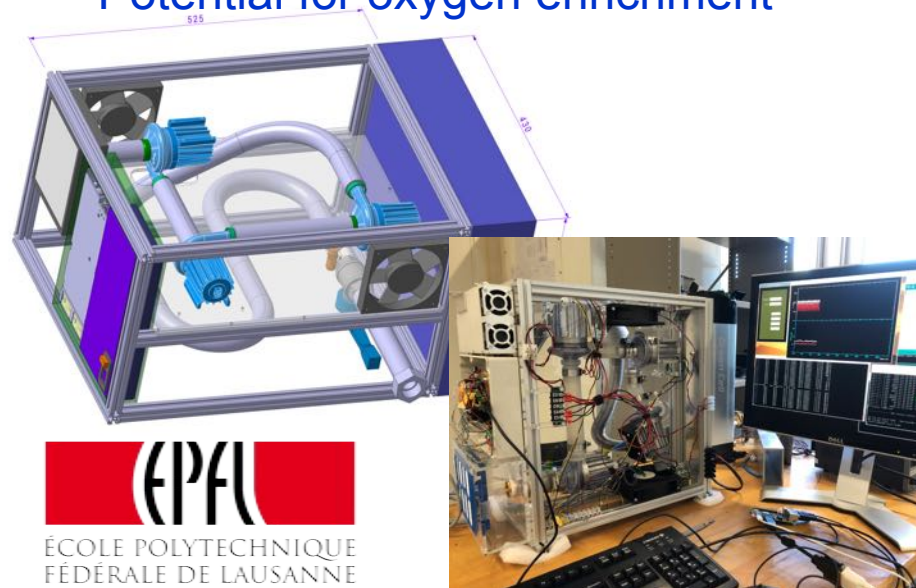
Trigger reaction time (ideally should be below 150 ms)



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

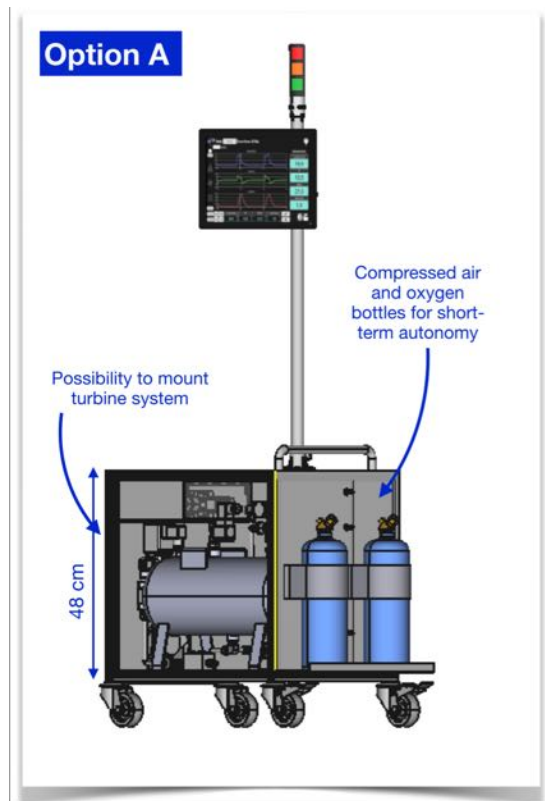


HEV Regional Adaptability

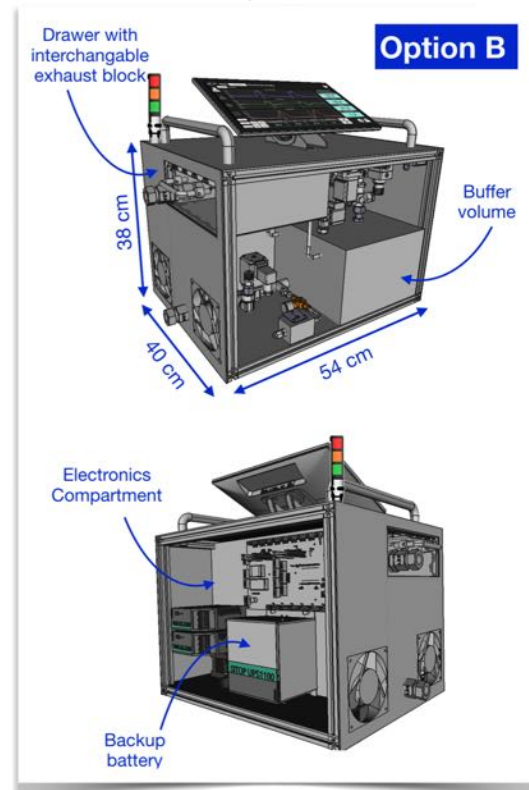
Ergonomics can be adapted to regional requirements



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 (BRCC) 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.



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



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

Dräger Visit for testing and feedback



**UK Research
and Innovation**

Ongoing collaboration
for HPLV

JGA prototype



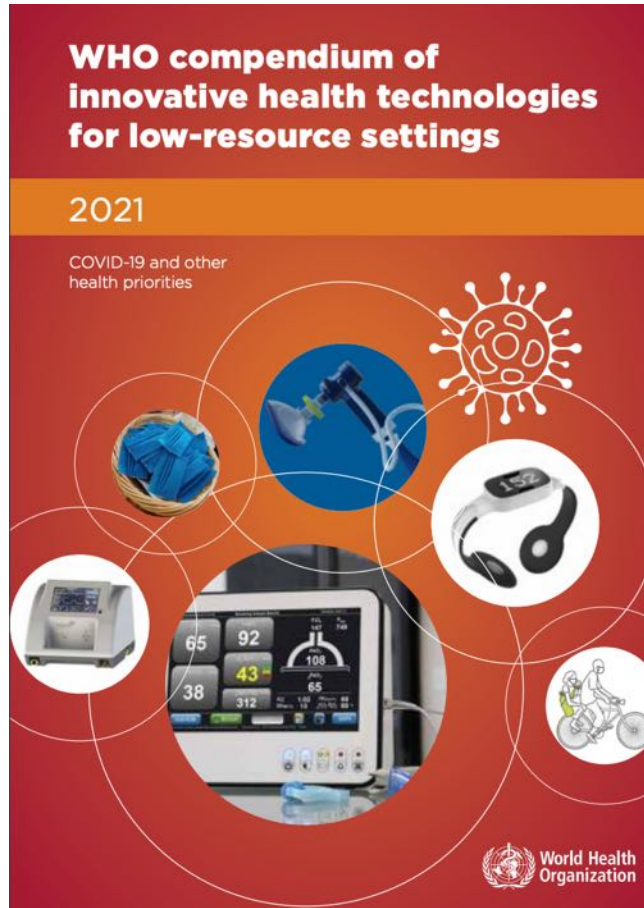
 **jean gallay sa**

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

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

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Thank You; Next stop HPLV!

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