

# High Performance Low-Cost Ventilator

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April 28, 2021



UNIVERSITY OF  
LIVERPOOL



UK Research  
and Innovation



# HEV - A ventilator from the HEP Community

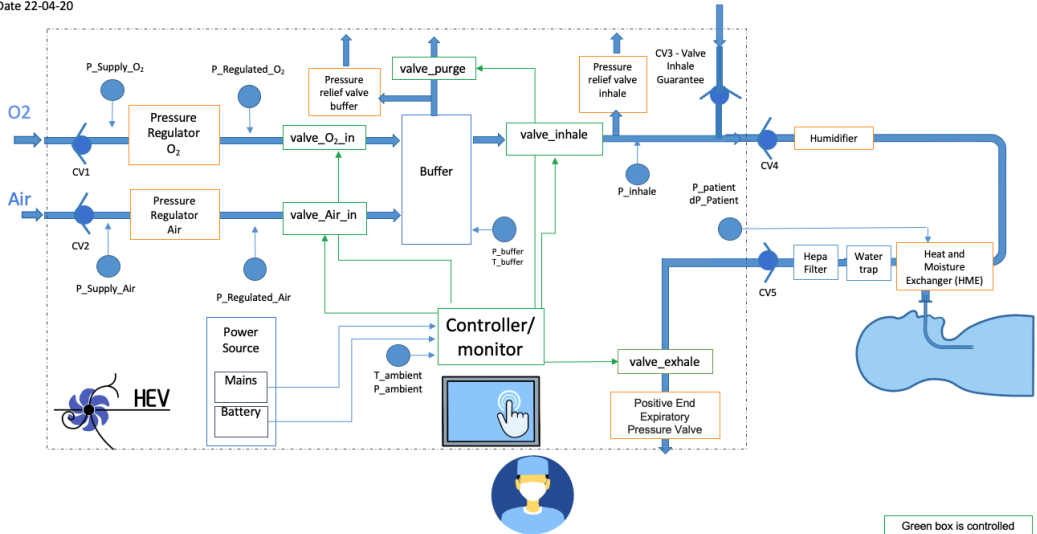
- Developed in response to COVID-19 one year ago
- Initial concept at Liverpool
- Continued/Extended at CERN in collaboration with colleagues from CERN detector and electronics teams, CERN LHCb, Manchester, Riga, Santiago, Lausanne, Rio de Janeiro
- “We can do this - some valves, tubing, and control software...”



# Design

Version number: 12

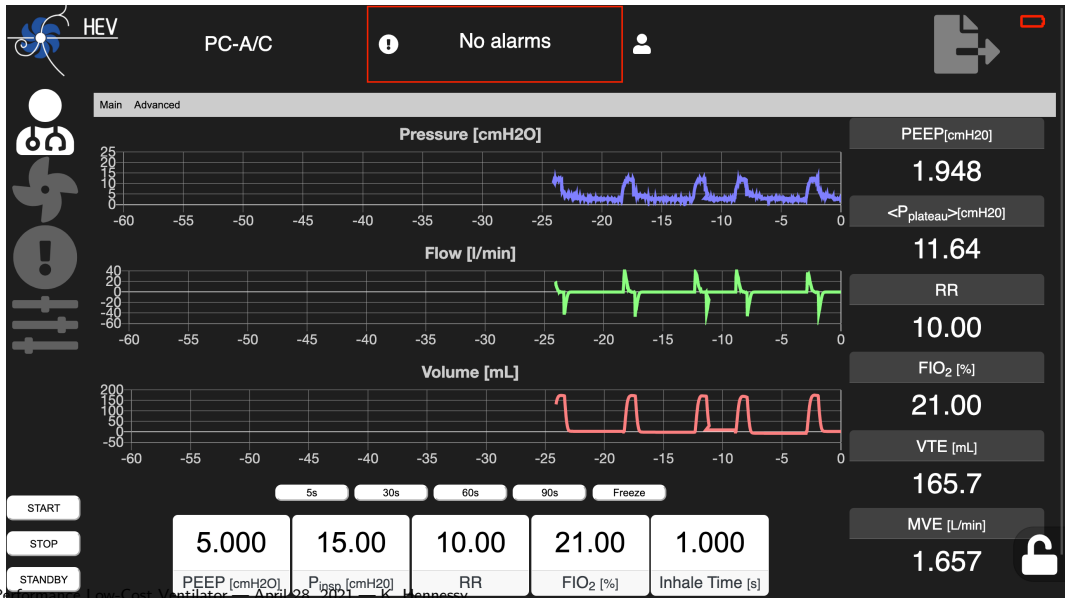
Date 22-04-20



# Prototype



# Web GUI



# HPLV - Towards a medially approvable device

- Successful grant proposal to UKRI and Govt ODA (overseas aid) to take HEV from prototype to a medically certifiable device
- In conjunction with Brazil as overseas partner
- Working with ventilator experts at MD-TEC (Medical Devices Testing and Evaluation Centre) - Prof. Tom Clutton-Brock
- Conform to required standards and requirements for medical devices
- Liverpool leading the software WP

BRITISH STANDARD

## Medical device software — Software life-cycle processes

BS EN  
62304:2006  
+A1:2015  
*Incorporating  
corrigendum  
November 2008*

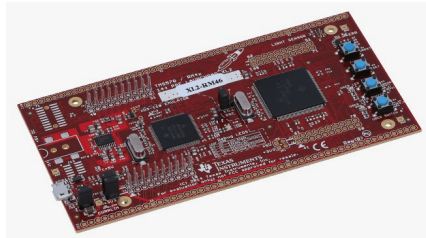
Provided by BSI UK. Limited access during COVID-19 emergency. Personal use only.

# What certifiable means...

- Building with medically approved parts
- O<sub>2</sub> safe, electrically safe, redundancy...
- Requirements documents
- Formal risk analysis
- Unit testing, system testing, documentation of testing
- Experts
- Certifiable in Brazil
- *engage with companies to produce final device for certification*

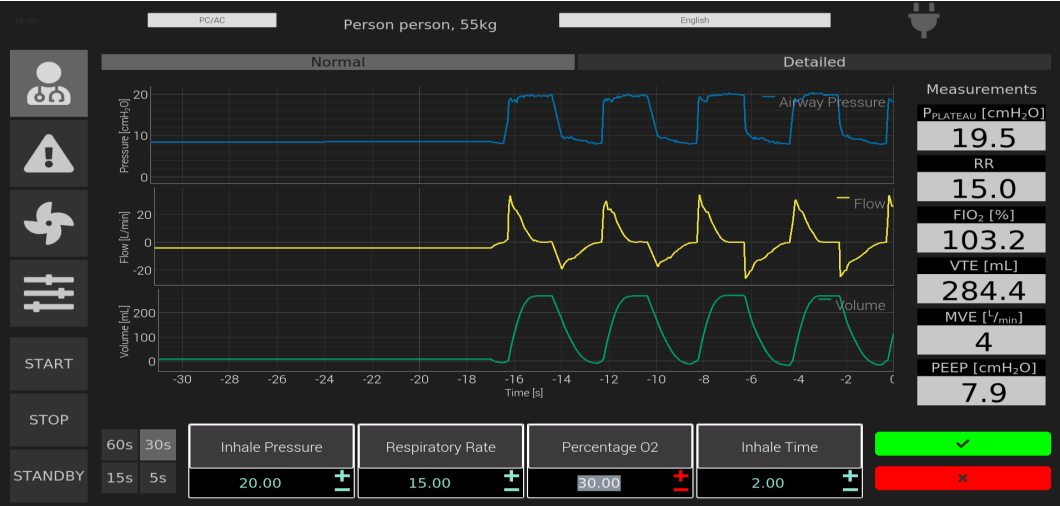
IDENTIFICATION OF				RISK ANALYSIS				RISK EVALUATION			
Req ID	User Requirement	Requirement	Requirement (Description)	Item	Pre-existing/Control Measures	Existing Risks	Severity (S)	Severity (S)	Severity (S)	Severity (S)	Severity (S)
REQ1	Accidental operation of an off switch must be prevented	Unintended shutdown of ventilator	Patent design requiring monitoring support	Regulator 1	2 second press of button + confirmation message required before off action initiated	None	Minor	Catastrophic/Fatal	High	Prevented by this Control	N/A
REQ2	The ventilator shall include a means for the healthcare professional operator to control the ventilation mode or settings during start-up and auto-changing events.	Incorrect parameters/incorrect auto changing to a confirmed	Unintended / Incorrect auto changing to a confirmed	Regulator 1	Confirmation required to apply any change to settings. After use the ventilator the change shall only auto change to a confirmed	Yes	Impossible	Catastrophic/Fatal	High	Prevented by this Control	N/A
REQ3	System subcomponents must allow operator input to change values for settings.	Incorrect parameters/incorrect auto changing to a confirmed	Unintended / Incorrect auto changing to a confirmed	Regulator 1	Patent software mechanism to lock and prevent changing settings.	Yes	Minor	Catastrophic/Fatal	High	Prevented by this Control	N/A
REQ4	The ventilator shall have means to indicate possible the immediate loss of operation of the ventilator, either manually or by operator action.	Unintended shutdown of ventilator	Patent design requiring monitoring support	Regulator 1	High priority warning control measures	Yes	Impossible	Catastrophic/Fatal	High	Prevented by this Control	N/A
REQ5	The ventilator should also have means to indicate visually the low level for low pressure maintenance or the time until the next recommended parameter maintenance.	Unintended shutdown of ventilator	Patent design requiring monitoring support	Regulator 1	High priority warning control measures	Yes	Impossible	Catastrophic/Fatal	High	Prevented by this Control	N/A
REQ6	Setting of alarm volume by healthcare professional operator is a part of	Incorrect parameters/incorrect auto changing to a confirmed	Unintended / Incorrect auto changing to a confirmed	Regulator 1	High priority warning control measures	N/A	Impossible	Catastrophic/Fatal	High	Prevented by this Control	N/A

Risk Traceability Matrix



TI Hercules RM46 safety-compliant MCU

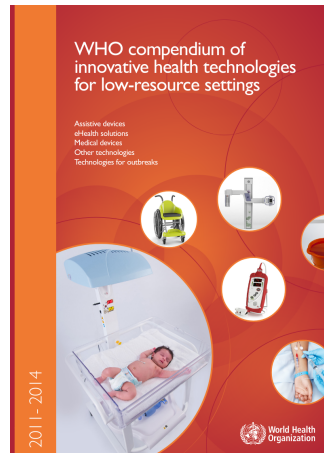
# HPLV UI





# Concluding remarks

- Remarkable response from Liverpool to the COVID crisis
- Liverpool team:
  - Stephen Farry
  - David Hutchcroft
  - Themis Bowcock
  - Adam Abed Abud
  - me
  - including support from J. Taylor, J. Bland, J. Vosseveld.
- HEV to be included in the *WHO compendium* of innovative health technologies for low-resource settings



Beyond COVID-19, Respiratory diseases such as pneumonia cost many lives every year, and ventilators are a luxury of higher income countries. Maybe we can change that...

**backup**

# Design

