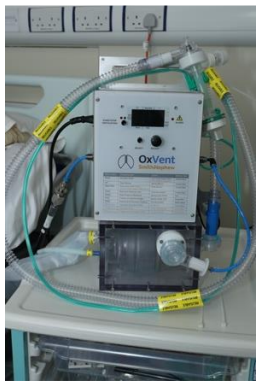
OxVent Ventilator
Ventilator Challenge Reports



Dr Tom Clutton-Brock FRCP, FRCA, FFICM , Clinical Director MD-TEC

Date: 24 / 04 / 2020

On March 16th 2020 the Prime Minister asked British industry to design and develop ventilators that could be used to support critically ill patients suffering from COVID-19. At that time the worst-case scenario predicted this would include very large numbers of patients. This would exceed the number of currently available devices, even considering the increased manufacture of existing CE marked ventilators and overseas purchases.

The response was nothing short of extraordinary and within ten days or so prototype machines had been produced and submitted for testing and consortia of British industry had started manufacturing existing devices in large numbers.

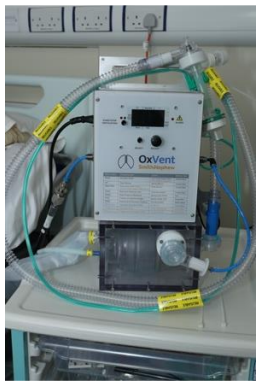
Over the five weeks since the challenge was announced the clinical picture has become clearer and it seems likely that fewer ventilators will actually be required immediately. This is very good news for thousands of UK patients and their relatives. Additionally, as a result of the very high-quality treatment NHS patients have received in intensive care, many patients have survived the initial period of ventilatory support. They now require ventilators which incorporate an assisted mode of ventilation usually only found in higher specification intensive care machines.

Not all of the proposed solutions are now required but there is no reason why manufacturers should not explore a route to market through CE marking or via derogation in a different country.

The OxVent uses a single-use, self-inflating, resuscitation bag-in-a-box driven by compressed medical air. It uses a small microprocessor unit with a display and controls for selecting required variables and an oxygen sensor and external spirometer. The breathing system is a single hose with attached patient one-way valve, pressure relief valve and PEEP valve. The latest version tested was able to ventilate stiff lungs although some volume is lost through the relief valve. The latest version also has an assisted breathing mode. The reliability of the longer-term use of single-use valves needs determining as does the reliability of the software control.

Medical Devices Testing and Evaluation Centre

OxVent Ventilator



The following reports are structured against aspects of the current draft of the Rapidly Manufactured Ventilator System (RMVS) requirements document, currently at version 4.0.

	Unacceptable		Possible		Acceptable

These reports are not exhaustive as only a single unit has been rapidly tested and the unit's compliance with the essential requirements of the medical device regulations is assessed as part of its technical file review by the MHRA. This includes materials, construction, quality management, hazard mitigation and reliability.

RMVS v4.0 Context: "*The requirements set out the clinical requirements based on the consensus of what is 'minimally acceptable' performance in the opinion of the anaesthesia and intensive care medicine professionals and medical device regulators given the emergency situation.*

Clinical experience in the UK of COVID-19 has developed rapidly in a way that impacts on the requirements of the ventilators needed. Firstly, more weight is being put on the closed suctioning tests because clinical advice is that respiratory secretions are much more copious than in 'normal' critical care pneumonia, necessitating suction of secretions up to hourly and that de-recruitment of lung during suctioning is particularly severe. Second, the duration of intubation is longer than 'normal' and so the relative number of ventilators needed in different categories is changing.

While a mix of transport, simple mandatory ventilation and complex full featured ventilators is still needed, a greater proportion of these need to be capable of supported spontaneous breathing modes to provide resource for the latter portion of intubation episodes".

References:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/879382/RMVS001_v4.pdf

Medical Devices Testing and Evaluation Centre

OxVent Ventilator (Evaluated 10/04/2020 & 23/04/2020)

Description: "Bag-in-a-Box" device with air and oxygen entrainment. Driven by compressed air with oxygen monitoring and spirometry. Single hose with external PEEP valve.
Advantages: Compact, easy to operate, can be very oxygen efficient
Disadvantages: Low PEEP at low breath rates. Switched off during test. Controls prototype. Life of bag unknown.

Feature	Present	Comment	Rating
Mandatory ventilation	VCV		
Setting breath rate	Yes		
Set maximum pressure	Yes		
Pressure display	Yes		
Maximum pressure alarm	Yes		
Disconnect alarm	Yes		
Set volume	Yes		
Volume display	Yes	Needs calibration at start	
Set PEEP	Yes	On disposable valve, poor	
PEEP display	Yes		
Set oxygen fraction	Yes	Rotameter flow	
Oxygen display	Yes		
Oxygen usage	Yes	Good	
Set Inspiration:Expiration ratio	Yes		
Gas failure alarm	Yes	Oxygen Alarm sounds	
AC power failure alarm	Yes		
Battery back-up	Yes		
Closed suction capability	Yes	With high flow adapter	
Supported breathing capability	Yes	Assisted mode	
Apnoea alarm / failsafe	Yes	Reverts to set rate min.10	
Labelling	Yes	Fair	
Gas and electrical connections	Yes	Wall air, rotameter oxygen, 240v	
Ease of Use	Yes	Fair	
Unit life (14 day or longer)	Yes	Unsure, single use bag	
Consumables	Yes	Filters, PEEP valve, Hose?	

OxVent Ventilator

RMV Test Report

Dr Tom Clutton-Brock, Clinical Director MD-TEC

11th April 2020

Supplied as a version that looked very like the prototype tested before with the addition of a small bracket to support the oxygen fuel cell and yellow adhesive labels on the components intended to be reused between patients.

Summary:

- Compact and lightweight. Reasonably easy to clean
- Could be run off industrial compressed air
- Uses readily available single hose breathing systems with the addition of the spirometer
- Repeated use of single use breathing system components a concern
- Time to taken to calibrate too long
- Low O_2 consumption, potentially just above MV O_2
- Controls fiddly and display poor, still looks like a prototype

Introduction: The device uses a Marshall single-use, self-inflating-bag (SIB) resuscitator with its one-way valve and oxygen-air entrainment valve sealed into a clear plastic box. Compressed Medical Air (could be industrial compressed air) is fed into the box through a re-purposed one-way patient valve. Compressing the air in the box causes the bag to collapse and forces the air-oxygen mix into the breathing system hose. Inspiratory gas passes through a one-way patient valve with an attached adjustable PEEP valve through an Intersurgical spirometer into the FHME attached to the catheter mount and endotracheal tube.

The ventilator works in a volume-controlled mode with feedback from the spirometer and monitoring of tidal volumes, pressures and oxygen concentration.

Physical properties: The OxVent weighs 7.25 Kg and is easily mounted on a suitable trolley. Although light enough to be used as a transport ventilator the requirement for oxygen and compressed air would preclude this.

Gas supply and gas usage: The device uses MA 4bar to drive it connected by small bore push-fit pneumatic connectors. Oxygen is fed from a rotameter into the entrainment port of the SIB to allow for inspired oxygen concentrations from 21 to nearly 100%. It is efficient in oxygen usage potentially only requiring just above minute volume.

Electrical Supply: The OxVent uses 240v AC with a securely fitted IEC plug and has a battery back-up providing 1 hour of back-up power.

Set up: Attachment of the breathing system and spirometer connections is straightforward although the oxygen sensor is still vulnerable to damage and disconnection despite the small steel bracket installed.

Start up: The spirometer needs to be placed undisturbed and the oxygen fuel cell in room air for sensor calibration after switch on. Prompts appear on the LCD display when powered on saying "*Close O2 supply, disconnect ventilator from patient. Press Rotary button when ready*". These are incorrect as oxygen supply must not have been "on" for sensor to be in room air and ventilator will not have been attached to patient at this stage before spirometer zero. If the ventilator has recently been in use then it is unclear how to ensure oxygen above 21% is not in the fuel cell housing.

Pressing the rotary encoder starts the calibration sequence which only takes 5 seconds to complete. Settings are as the default settings in the RMVS and can be adjusted by pressing the SELECT button to highlight, pressing again to produce small arrows at the sides of the variable and using the rotary knob to adjust. Pressing set again confirms. This is fiddly at the start but improves rapidly with practice. The alarm tone sounds throughout this sequence. Ventilation is started with the START / STOP button.

Performance: The test set up was with the OxVent attached by the supplied breathing system with a bacterial filter at the machine end, the patient one-way valve, PEEP valve,

spirometer and an HMEF at the patient end to an IMT Medical Ventest 800 via a catheter mount to a Drager silicone test lung. Compliance = 28 mls cmH_2O^{-1} and Resistance approximately 5 cmH_2O l/s^{-1}.

At the suggested RMVS default settings of 400mls, 20 bpm, 15 PEEP and PIP set at 35 cmH_2O (maximum in this device) the ventilator delivered tidal volumes of 258 mls. At lower levels of PEEP tidal volumes very close to set were achieved. This is either as a result of gas leaking from the pressure relief valve at the patient one-way valve end or from the compliance of the whole system with the SIB in circuit.

Spirometers of the type used in this device are sensitive to the exact configuration of the connections and filters and the set up used to create the calibration curves should be clearly identified.

Oxygen concentrations on the ventilator agreed well with those displayed on the Ventest 800. It is perfectly possible to operate the OxVent without any additional oxygen although the low alarm limit at 35% should prevent this. A default lower alarm limit of 60% at start up would be safer.

Measured PEEP levels were within an acceptable range of those set on the adjustable valve.

Mains failure test: Passed, alarm sounds, battery back-up

Stop vent during inspiration: Passed, gas vents through PEEP valve

Occlusion test: Passed, alarm sounds and pressure relief valve opens (takes a long while to recover to normal settings)

Closed suction test (unassisted): Failed, PEEP to zero

Closed suction with high flow adapter: Passed PEEP maintained to acceptable levels

Displays, controls and alarms: The alarm sound is the same for all alarm types which is acceptable as alarm state is displayed on LCD screen. There is no alarm tone pause button. Push button controls are flimsy and there are “hand cut” openings for the 3 coloured LED alarm and function indicators.

Settings are not easily adjusted by accident on the ventilator itself as they require multiple button pushes as described above. The PEEP valve is subject to accidental manipulation but no more so than other valves of this type.

Readings of set and measured variables are displayed although the difference between them could be clearer.

High pressure, low pressure, disconnect and mains failure alarms all functioned satisfactorily.

Almost every setting change produced an alarm without it always being evident why.

Breathing system and hoses: The OxVent supplied uses a single-use one-way patient valve to deliver compressed air to the box. A single-use Marshall SIB with entrainment and one-way valves to a single-use breathing system hose, patient valve with PEEP valve and a single-use Intersurgical spirometer. From the labelling applied it appears that the plan is to reuse all of these components. The oxygen fuel cell is not single use.

Cleaning and contamination: Cleaning the OxVent should be relatively straightforward although the design of the controls on the front will trap dirt behind them with time. If patient and machine end filters are accidentally not fitted, then the inside breathing system will be contaminated. This is not easily removed for decontamination and the whole device should be disposed of.

Usability: The OxVent is of a design that will be wholly unfamiliar with intensivists, anaesthetists, intensive care nurses and ODPs. With the exception of the calibration routine and incorrect visual prompts the set-up is fairly straightforward and can be described in a suitably produced "Quick Set Up Guide". The compact size of the device does not allow for detailed instructions on the casing.

With a 30-minute period of intense training a non-clinical student, with knowledge of the basics of mechanical ventilation, could set it to start up settings and start ventilation.

Residual risk:

Residual Risk	Mitigation	Level	Likelihood
Lifetime of single use components unknown	Limit maximum use	High	High
Failure to ensure oxygen fuel cell is in room air at start up	Correct LCD prompts. IFU. QSG	High	High
Failure to use same connector and filter configurations as used for spirometer calibration	Labelling, Quick Guide and Video	Medium (effects on calibration not large)	Medium
Failure to turn on adequate oxygen flow	Low level alarm at 35%. Quick Guide and Video	High	High
Failure to appreciate Pmax is fixed at 35 cmH_2O	Labelling, Quick Guide and Video	High	High
Device unable to deliver set Vt with reduced compliance lungs and PEEP	Patient selection, Quick Guide and video	High	High

Change in final version from the one tested	Re-test final version	High	High
Assume breathing system is single use and dispose after use	Labelling, Quick Guide and Video	High (cost & availability of oxygen fuel cells)	High
Air inlet obstructed	Quick Guide and Video	High	Low
Correct set up of breathing system and filters required	Quick Guide and Video	High	High

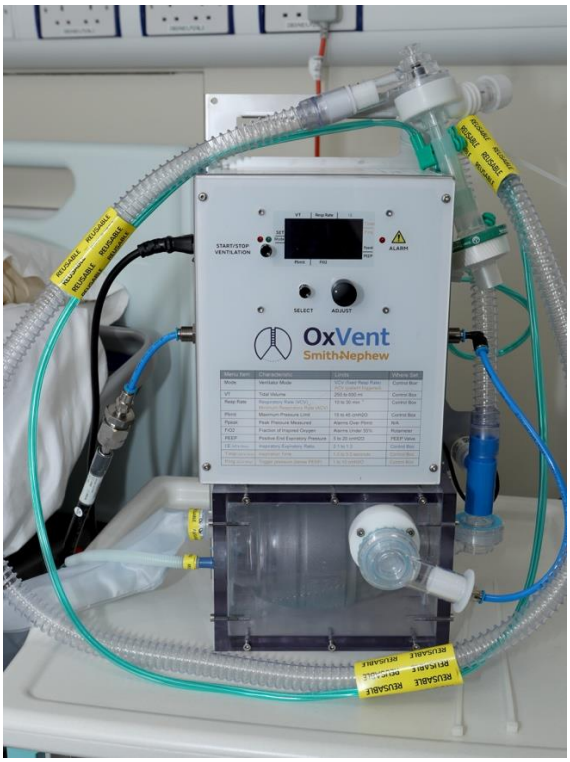
OxVent Ventilator Version 2

RMV Test Report

Dr Tom Clutton-Brock, Clinical Director MD-TEC

23rd April 2020

Supplied as a version similar to the ones tested before but with updated volume delivery software and an assisted mode of ventilation.



Summary:

- Compact and lightweight. Reasonably easy to clean
- Could be run off industrial compressed air
- Uses readily available single hose breathing systems with the addition of the spirometer, Repeated use of single use breathing system components a concern
- Spirometer calibration faster, oxygen calibration no longer needed
- Delivers much better tidal volumes to stiff lungs
- Low O_2 consumption, potentially just above MV O_2
- Controls fiddly and display poor, still looks like a prototype
- Triggered mode works well referenced to PEEP

Introduction: The device uses a Marshall single-use, self-inflating-bag (SIB) resuscitator with its one-way valve and oxygen-air entrainment valve sealed into a clear plastic box. Compressed Medical Air (could be industrial compressed air) is fed into the box through a re-purposed one-way patient valve. Compressing the air in the box causes the bag to collapse and forces the air-oxygen mix into the breathing system hose. Inspiratory gas passes through a one-way patient valve with an attached adjustable PEEP valve through an Intersurgical spirometer into the FHME attached to the catheter mount and endotracheal tube.

The ventilator works in a volume-controlled mode with feedback from the spirometer and monitoring of tidal volumes, pressures and oxygen concentration.

Physical properties: The OxVent weighs 7.25 Kg and is easily mounted on a suitable trolley. Although light enough to be used as a transport ventilator the requirement for oxygen and compressed air would preclude this.

Gas supply and gas usage: The device uses MA 4bar to drive it connected by small bore push-fit pneumatic connectors. Oxygen is fed from a rotameter into the entrainment port of the SIB to allow for inspired oxygen concentrations from 21 to nearly 100%. It is efficient in oxygen usage potentially only requiring just above minute volume.

Electrical Supply: The OxVent uses 240v AC with a securely fitted IEC plug and has a battery back-up providing 1 hour of back-up power.

Set up: Attachment of the breathing system and spirometer connections is straightforward although the oxygen sensor is still vulnerable to damage and disconnection despite the small steel bracket installed.

Start up: The spirometer needs to be placed undistrurbed for calibration after switch on. Prompts appear on the LCD display when powered on saying "*Disconnect ventilator from patient. Press Rotary button when ready*". This now works well

Pressing the rotary encoder starts the calibration sequence which only takes 5 seconds to complete. Settings are as the default settings in the RMVS and can be adjusted by pressing the SELECT button to highlight, pressing again to produce small arrows at the sides of the variable and using the rotary knob to adjust. Pressing set again confirms. This is fiddly at the start but improves rapidly with practice. The alarm tone sounds throughout this sequence. Ventilation is started with the START / STOP button.

Performance: The test set up was with the OxVent attached by the supplied breathing system with a bacterial filter at the machine end, the patient one-way valve, PEEP valve, spirometer and an HMEF at the patient end to an IMT Medical Ventest 800 to an Ingmar Medical ASL5000 simulator running under a software plugin to Laerdal LLEAP. Compliance = 15-30 mls cmH_2O^{-1} and Resistance 8 cmH_2O l/s^{-1}.

Results of the performance test are in the attached spreadsheet (OxVent Final Test Results V2 23.4.20.xlsx). At the suggested RMVS default settings of 400mls, 20 bpm, 15 PEEP and PIP set at 40 cmH_2O (maximum in this device) the ventilator delivered tidal volumes of 445 mls into a lung compliance of 20 mls cmH_2O^{-1}. At lower levels of PEEP and lower tidal volumes PEEP was not maintained at the set level, probably due to the performance of the valve chosen. At pressures of 40 cmH2O the pressure relief valve opens at the beginning of inspiration and small amounts of tidal volume are lost.

Assisted Breathing: Labelled "Assist CV" at start up this mode uses an adjustable pressure trigger referenced to PEEP. Using the ASL 5000 breathing function this mode worked well.

Spirometers of the type used in this device are sensitive to the exact configuration of the connections and filters and the set up used to create the calibration curves should be clearly identified.

Oxygen concentrations on the ventilator agreed well with those displayed on the Ventest 800. It is perfectly possible to operate the OxVent without any additional oxygen although the low alarm limit at 35% should prevent this. A default lower alarm limit of 60% at start up would be safer.

- Mains failure test: Passed, alarm sounds, battery back-up
- Stop vent during inspiration: Passed, gas vents through PEEP valve
- Occlusion test: Passed, alarm sounds and pressure relief valve opens (takes a long while to recover to normal settings)
- Closed suction test (unassisted): Failed, PEEP to zero
- Closed suction with high flow adapter: Passed PEEP maintained to acceptable levels

Displays, controls and alarms: The alarm sound is the same for all alarm types which is acceptable as alarm state is displayed on LCD screen. There is no alarm tone pause button. Push button controls are flimsy and there are "hand cut" openings for the 3 coloured LED alarm and function indicators.

Settings are not easily adjusted by accident on the ventilator itself as they require multiple button pushes as described above. The PEEP valve is subject to accidental manipulation but no more so than other valves of this type.

Readings of set and measured variables are displayed although the difference between them could be clearer.

High pressure, low pressure, disconnect and mains failure alarms all functioned satisfactorily.

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Breathing system and hoses: The OxVent supplied uses a single-use one-way patient valve to deliver compressed air to the box. A single-use Marshall SIB with entrainment and one-way valves to a single-use breathing system hose, patient valve with PEEP valve and a single-use Intersurgical spirometer. From the labelling applied it appears that the plan is to reuse all of these components. The oxygen fuel cell is not single use.

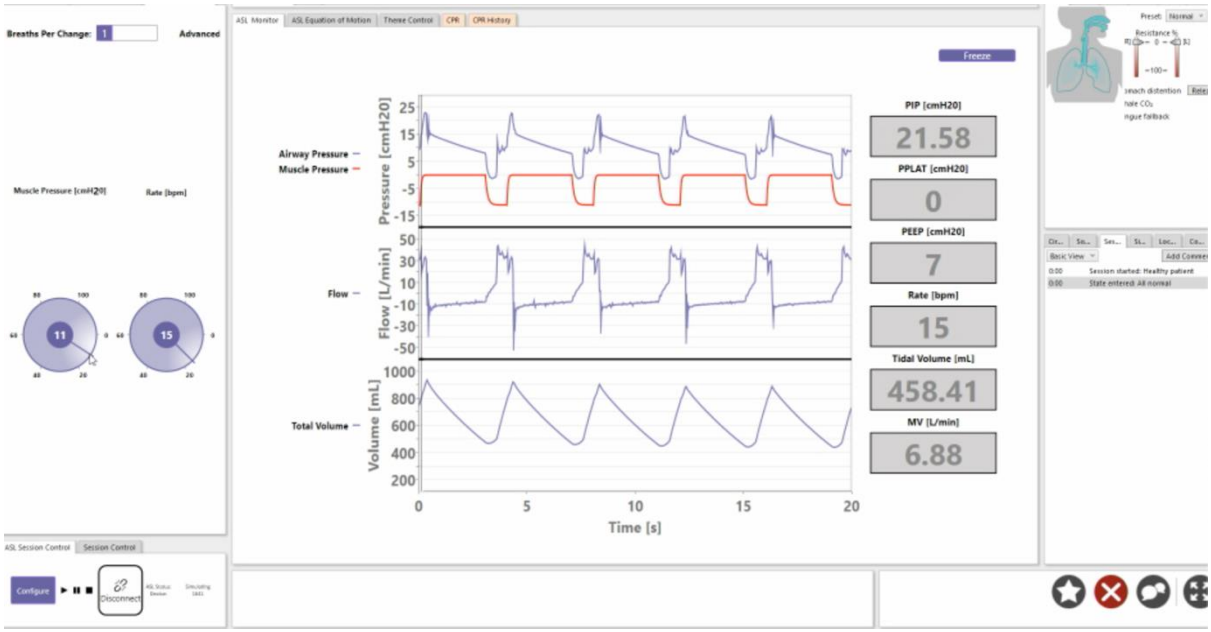
Cleaning and contamination: Cleaning the OxVent should be relatively straightforward although the design of the controls on the front will trap dirt behind them with time. If patient and machine end filters are accidentally not fitted, then the inside breathing system will be contaminated. This is not easily removed for decontamination and the whole device should be disposed of.

Usability: The OxVent is of a design that will be wholly unfamiliar with intensivists, anaesthetists, intensive care nurses and ODPs. The set-up is fairly straightforward and can be described in a suitably produced "Quick Set Up Guide". The compact size of the device does not allow for detailed instructions on the casing.

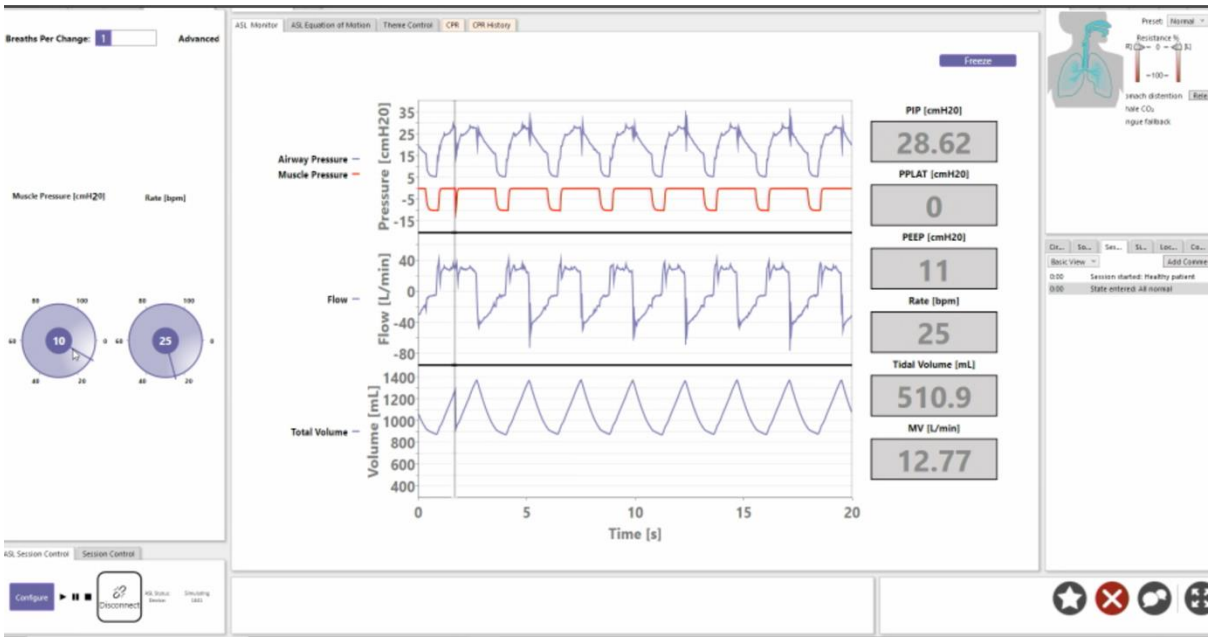
With a 30-minute period of intense training a non-clinical student, with knowledge of the basics of mechanical ventilation, could set it to start up settings and start ventilation.

Residual risk:

Residual Risk	Mitigation	Level	Likelihood
Lifetime of single use components unknown	Limit maximum use	High	High
Failure to use same connector and filter configurations as used for spirometer calibration	Labelling, Quick Guide and Video	Medium (effects on calibration not large)	Medium
Failure to turn on adequate oxygen flow	Low level alarm at 35%. Quick Guide and Video	High	High
Failure to appreciate Pmax is fixed at 40 cmH_2O	Labelling, Quick Guide and Video	High	High
Change in final version from the one tested	Re-test final version	High	High
Assume breathing system is single use and dispose after use	Labelling, Quick Guide and Video	High (cost & availability of oxygen fuel cells)	High
Air inlet obstructed	Quick Guide and Video	High	Low
Correct set up of breathing system and filters required	Quick Guide and Video	High	High



Assisted CV mode. Rate 15, Peep 7.5. Trigger at 3 cmH_2O below PEEP. Triggering well



Assisted CV mode. Rate 25 Peep 10. Trigger at 3 cmH_2O below PEEP. Triggering well

The Medical Devices Testing and Evaluation Centre (MD-TEC)

MD-TEC was initially funded by a European Regional Development Fund grant from European Strategic Investment Funds. Funding was matched by The University of Birmingham, University Hospitals NHS Foundation Trust and The University of Aston.

Initially funded to support Small to Medium Enterprises in Birmingham and Solihull Local Enterprise Partnership, from January 2020 MD-TEC has moved to a commercial model working with healthcare technology industry across the world.

The Centre is in the Institute of Translational Medicine managed by Birmingham Health Partners. It has a fully equipped simulation suite with an operating theatre, intensive care unit, ward and outpatient areas. Core business is undertaking formative and summative usability testing to ISO 62366 to support the regulation of medical devices and *in vitro* diagnostics.

We work very closely with the NIHR funded Trauma Management MedTech Cooperative and have "state-of-the-art" simulation mannequins, audio-visual equipment and live-steaming capabilities.

MD-TEC receives no income or inducements for any COVID-19 related work and is independent from the UK Government and the MHRA. It does use test equipment provided through the Cabinet Office and some from generous loans from other sources.

Its Clinical Director, Dr Tom Clutton-Brock, has been a Consultant in Intensive Care and Anaesthesia for 30 years and has a career long experience in the design, development and regulatory approval of medical devices.

The reports produced for the Ventilator Challenge are intended to be an unbiased expert opinion supported by limited testing of clinical functions and usability.

Glossary (Not all may be used in this report):

APL	Adjustable Pressure Relief Valve
BPM	Breaths per minute
cmH_2O	Centimetres of Water pressure
FGF	Fresh Gas Flow
FiO_2	Fractional concentration of inspired concentration (1.0 = 100%)
ICU	Intensive Care Unit
LPM	Litres per Minute
MA	Medical Air
MV	Minute Volume
PCV	Pressure Controlled Ventilation
PEEP	Positive End Expiratory Pressure
PIP	Peak Inspiratory Pressure (Plateau)
PRVC	Pressure Regulated Volume Control
PSV	Pressure Supported Ventilation
RMV(S)	Rapidly Manufactured Ventilator (Specification)
SpO_2	Pulse oximetery saturation
Test lung	Typically a 1 or 2 litre single use reservoir bag
Vt	Tidal Volume