AEONMED VG70 Ventilator

Functionality Report

Dr Tom Clutton-Brock, Clinical Director MD-TEC

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The VG70 is a CE marked and FDA approved ventilator manufactured by Aeonmed in China. A number of units were purchased by the UK Department of Health and Social Care (DHSC) as part of its Ventilator Challenge programme launched in March 2020. The VG70 uses either 4bar oxygen from a wall outlet or can use up to 15lpm oxygen from a rotameter. Air is entrained by a small fan. The VG70 has the following modes available: VCV, PCV, PRVC, SIMV-V, SIMV-P, SIMV-PRVC, BIVENT, SPONT/PSV and non-invasive modes. Non-invasive modes were not tested.

Good points:

- Ventilates stiff lungs well using standard two hose breathing system
- PRVC works as expected
- Assisted modes trigger well
- UK Oxygen fittings supplied
- Stable trolley

Poor points:

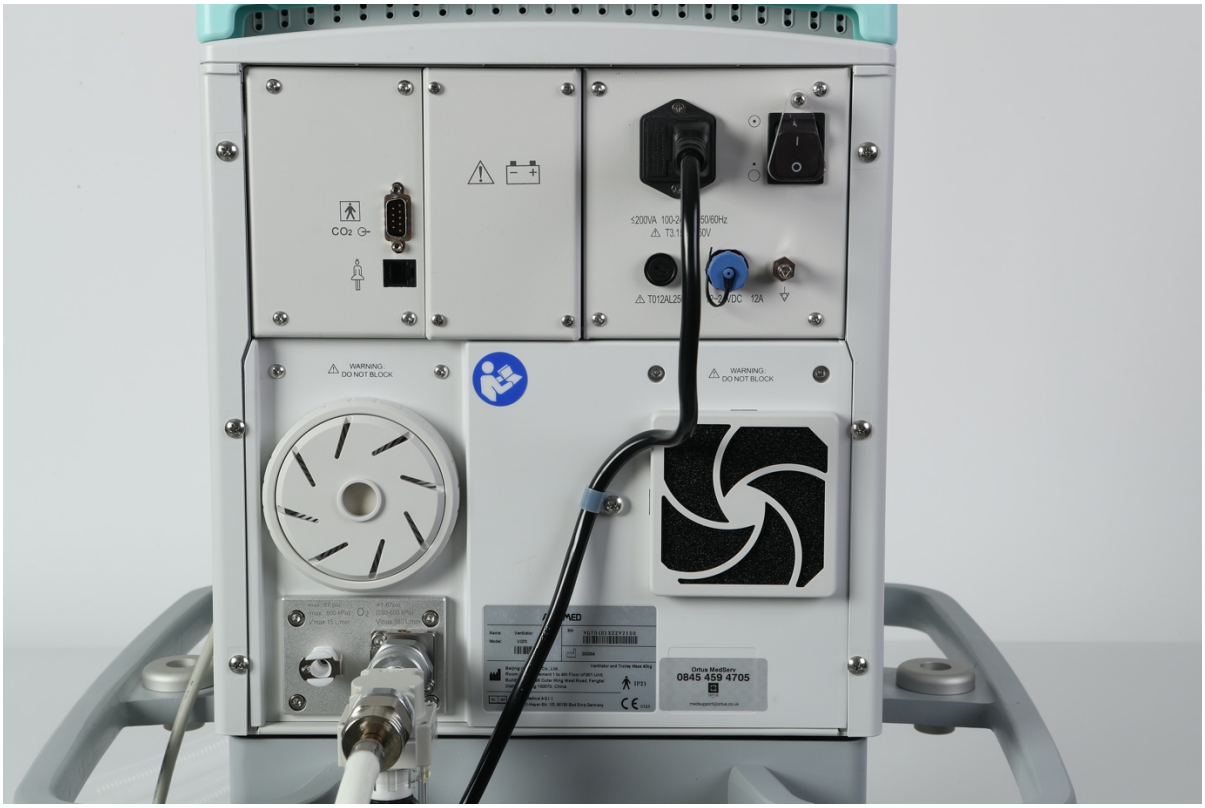
- Some on screen instructions missing
- Oxygen analyser under-reads even when calibrated
- Expiratory valve exhaust fitted with 22mm male connector
- Complete shutdown and prolonged restart if rear switch turned off
- Humidifier easily switched on by accident

Additional:

- Passed mains failure, switch off during inspiration, disconnect, occlusion and closed suction test without high flow adapter

Test Setup: The test set up included the VG70 with a single use twin hose breathing system, bacterial filters at the machine end and an HMEF at the patient end, attached to an IMT Medical Ventest 800 and an Ingmar Medical ASL 5000 lung simulator. Compliance was varied between 50 and 20 mls cmH_2O^{-1} with Resistance set at 13 cmH_2O l/s $^{-1}$. Results are in: VG70 Test Results 22.5.20.xlsx

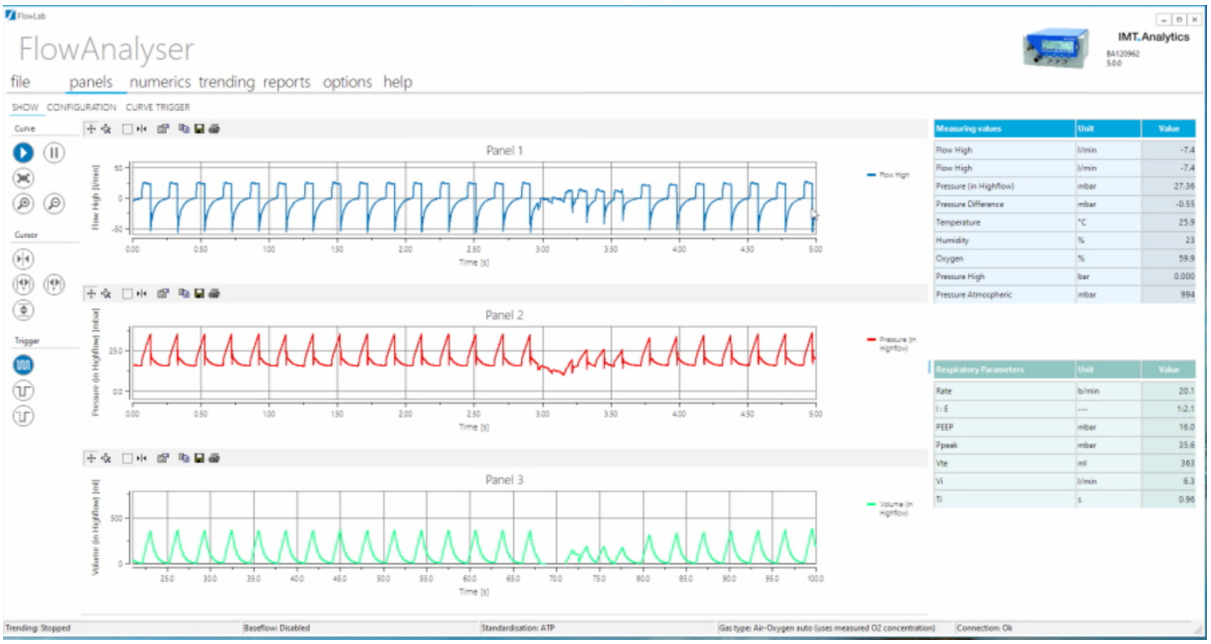
At RMVS default settings of 400mls, 20bpm, 15 PEEP in VCV mode the VG70 delivered 363 mls into a 20 mls/cmH_2O compliant test lung with a peak pressure of 35.4 cmH_2O. In PRVC mode the VG70 delivered 406 mls with a peak pressure of 35.0 cmH_2O.



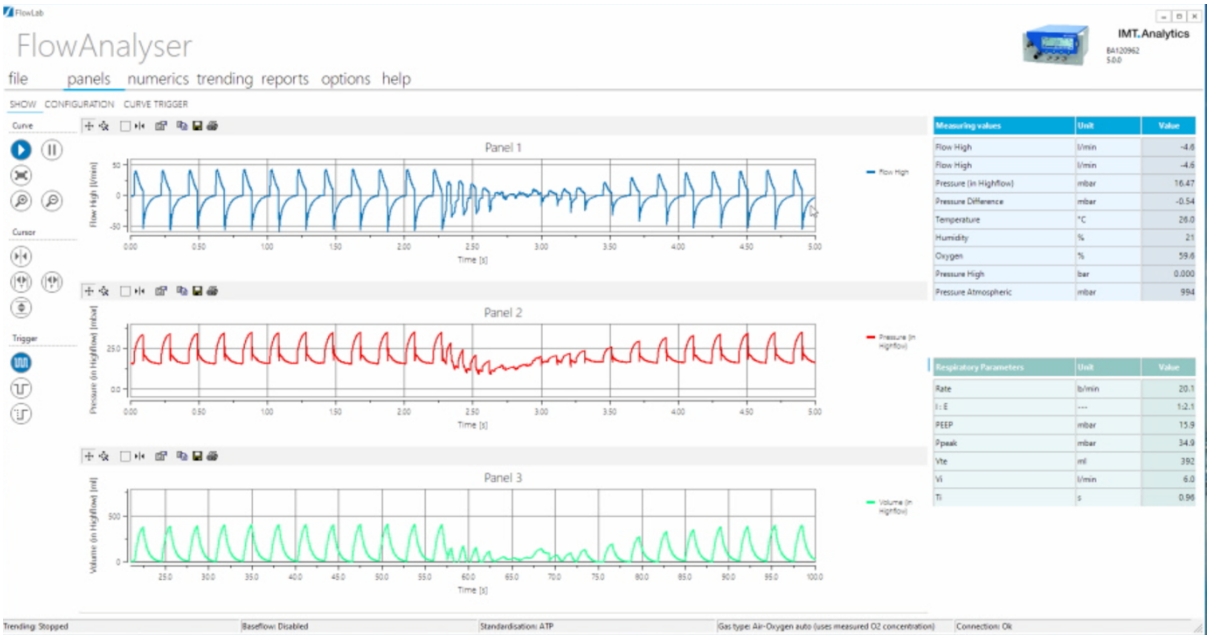
Rear view showing air and piped oxygen inlets

Oxygen hose connection with NIST (Oil and water trap not usually required in the UK)

Protected switch at rear shuts machine down without warning



PEEP maintained during closed suction during VCV



PEEP maintained during closed suction during PRVC

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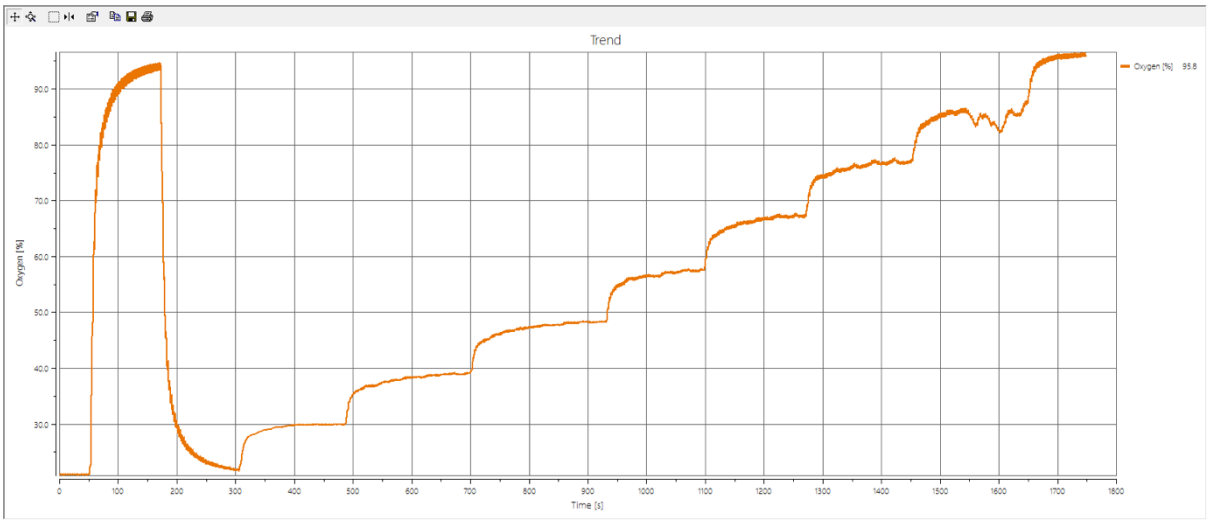
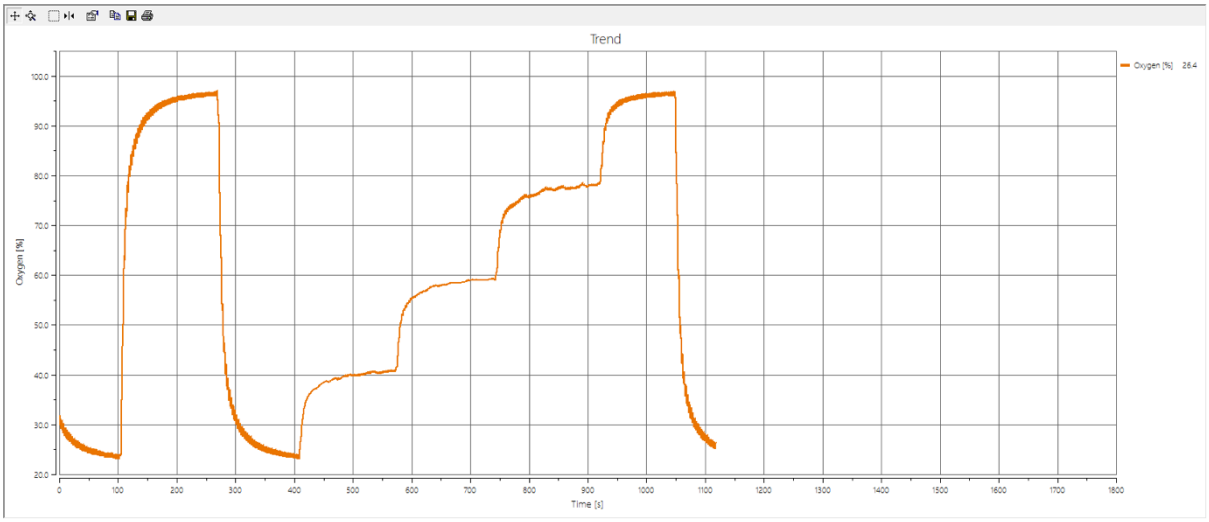


Oxygen delivered: 21-100, 30, 40, 50, 60, 70, 80, 90, 100% (before calibration)



Oxygen delivered: 21-100, 40, 60, 80, 100% (after recalibration)

Conclusions: The Aeonmed VG70 is a well specified ventilator that can be used in a critical care setting. PRVC and assisted modes work as expected. The slight under-delivery of oxygen is unlikely to be of clinical significance.

Care should be taken to ensure nothing is connected to the exhaust valve outlet connector and the humidifier should be left unplugged when not in use. On screen instructions need to be supplemented with additional guidance for pre-use checks.

Medical engineers and clinicians should undergo a brief period of training using a test lung before use on patients. A short training video would be helpful.

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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

Addendum A

Prior to completing the supply agreement with AEONMED, Medical Suppliers, **The Ortus Group**, completed their own internal review of the Ventilator and created documents and labels to apply to the VG70 to significantly reduce the risks below.

- **Instructions & Calibration - *Some on screen instructions missing***
  Although not all instructions are displayed on the VG70 screen, The Ortus Group have created detailed documents: 'VG70 Pre-Use Tests' and 'Calibration Guide' which will help you follow the set-up instructions for the device.

- **Oxygen Analyser - *Oxygen analyser under-reads even when calibrated***
  Although a small margin of difference in the oxygen analyser reading is not notable, improvements were made to the 'Calibration Guide' after initial use to ensure this information is accurate.

- **Expiratory Valves - *Expiratory valve exhaust fitted with 22mm male connector***
  Expiratory valve exhaust is fitted with 22mm male connector, however visual guides and instructional videos have been produced by The Ortus Group to reduce the risk of setting up this equipment incorrectly.

- **Complete Shutdown - *Complete shutdown and prolonged restart if rear switch turned off***
  If rear switch is turned off, a complete shutdown and prolonged restart is inevitable as a safety feature. The Ortus Group have highlighted this risk in the 'VG70 Pre-Use Tests' documentation.

- **Humidifier Warning- *Humidifier can be easily switched on***
  This risk has been highlighted in the 'Pre-Use Tests' documentation. A warning label has been supplied with each ventilator that can be fixed to the humidifier. * please note - The humidifier is a separate medical device, not every VG70 is supplied with the same humidifier that was used during this evaluation. The VG70 is compatible with a wide range of humidifiers

For more information from The Ortus Group please contact:

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Alternatively, please visit the **VG70 Support Page** on The Ortus Group website to view all supporting documents:

www.theortusgroup.com/vg70/