

Validation and clinical use of the Maquet (Getinge) original series Rotaflow extracorporeal membrane oxygenation device in hyperbaric conditions: a technical report

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Abstract

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Introduction: Extracorporeal membrane oxygenation (ECMO) has not been previously used clinically in the modern hyperbaric chamber. We describe the modifications, validation and clinical performance of the Maquet (Getinge) original series Rotaflow (Rotaflow 1), Quadrox-i adult microporous membrane oxygenator and permanent life support (PLS) circuit under hyperbaric conditions.

Methods: A Rotaflow 1 and Quadrox oxygenator underwent power supply modifications and rigorous safety testing in the hyperbaric environment using a PLS circuit primed with normal saline. Clinical validation was subsequently undertaken during a ‘last resort’ course of 13 hyperbaric oxygen treatment (HBOT) sessions for a patient suffering a life threatening vaso-invasive fungal infection requiring support with venovenous ECMO.

Results: Preliminary testing and subsequent clinical application in the hyperbaric chamber demonstrated steady flow through the circuit based on pump revolutions per minute, with up to 180 mL (10%) variability demonstrated between the console display compared to the independent flow meter. No significant changes to flow variability were noted during pressurisation and decompression phases. Device temperature remained within safe limits. No bubbles were visually or sonographically detected. There were no performance or integrity issues detected through compression, maintenance and decompression phases. During clinical use, the patient remained stable and hyperoxygenation targets were achieved. Membrane oxygenator oxygen inflow set at up to 8 L·min⁻¹ maintained CO₂ clearance.

Conclusions: After safety related modifications to the console’s power supply, the Rotaflow 1 console, Quadrox oxygenator and PLS circuit performed satisfactorily up to 243 kPa during repeated clinical use.

Introduction

Hyperbaric oxygen treatment (HBOT) is used in the treatment of arterial gas embolism, decompression sickness, necrotising soft tissue infections, late tissue radiation injury and complex wounds.¹ Treatment capability varies between hyperbaric centres, ranging from those which treat low-acuity ambulant patients only through to those that treat critically unwell intensive care patients requiring haemodynamic and ventilatory support. Our hyperbaric biomedical engineers have expertise in the validation of equipment for use under hyperbaric conditions, including validations of the HeartMate III left ventricular assist device,

a pleural vacuum relief device for use with an underwater seal and various syringe drivers.^{2–4}

Our hyperbaric centre regularly treats critically unwell patients.⁵ Over recent years, a number of patients receiving extracorporeal membrane oxygenation (ECMO) at our centre have had a clinical indication for HBOT but were unable to undergo HBOT as ECMO had not been validated for use within the hyperbaric environment. Validation of ECMO for the hyperbaric environment would allow patients to access potentially life-saving HBOT whilst continuing to receive cardiopulmonary support.^{1,6,7}

A patient in our intensive care unit (ICU) was critically ill following multi-trauma and was supported with venovenous (VV) ECMO for severe respiratory failure due to acute respiratory distress syndrome in his remaining lung following a pneumonectomy for refractory haemothorax. Complicating the patient’s burden of traumatic injury was a disseminated cutaneous filamentous fungal infection refractory to maximal medical and surgical therapies. In the absence of other treatment escalation options, HBOT was considered as a final line of therapy.⁸ The challenge in delivering HBOT was the ability to continue VV ECMO support within the hyperbaric environment. Fortuitously, biomedical adaptation of the power supply of the Maquet original series Rotaflow (Getinge AB, Göteborg, Sweden) console (Rotaflow 1) to ensure electrical safety had previously occurred, as well as testing of the console in the hyperbaric environment using a Permanent Life Support (PLS) Set circuit (Maquet, Rastatt, Germany) primed with normal saline (Figure 1). Ethics approval was pending to complete further testing under hyperbaric conditions while using blood in the circuit. No patient trials with this device had ever been conducted in hyperbaric conditions at our centre or reported in the literature.

Methods

HYPERBARIC SAFETY ASSESSMENT (IN-VITRO) AND MODIFICATIONS

Equipment validation for use in the hyperbaric environment is performed by experienced hyperbaric biomedical engineers at our centre. The testing matrix includes an assessment of general safety, oxygen safety and device performance, and is outlined in Table 1.

Biomedical engineering, technical, medical and nursing staff undertook a preliminary risk assessment for the ECMO console and circuit and identified several critical areas

requiring focused attention to ensure patient safety and system reliability: equipment malfunction such as pump failure, battery run-time, clotting of the Quadrox-i adult microporous membrane oxygenator (specifically HMO 70000, Maquet Cardiopulmonary AG, Hirrlingen, Germany) (Quadrox oxygenator) and the potential for components such as relays, motors or actuators to be ignition sources. Mitigation strategies identified for risks determined to be particularly important for ECMO devices in the hyperbaric environment included: physical inspection at component level, formal temperature testing of components identified on

Table 1

Key components of hyperbaric equipment safety assessment and validation

General
Checking for safety of use if modified within and outside the hyperbaric chamber
Checking for safety of use at the maximum chamber pressure
Check for any damage or concerns with maximum rates of pressurisation and depressurisation
Ability to clean parts safely and reprocessing of consumables
Evaluation of air spaces for venting or fluid replacement requirements
A multidisciplinary consultation process between technical staff, biomedical engineering, medical and nursing representation
Oxygen Safety
Identification of energy sources, battery types, electrical connection security
High temperature components
Motor/s configuration
Mechanical and electrical relays
Safety of use within different oxygen concentrations
Testing
Preliminary discussion and define scope
Device documentation and literature review
Internal inspection
Device modifications
Device performance testing
Preliminary tests 1–6
Operational tests 1–4
Additional tests 1–3
Calibration test
Device operational needs
Accept device
Approval and sign off

Figure 1

PLS System; Rotaflow console, drive and permanent life support (PLS) set. Image source: <https://www.getinge.com/int/products/pls-set/>



preliminary infra-red temperature screening, identification of battery chemistry types and run-time and routine preventive maintenance.

General safety

The Rotaflow 1 contains a nickel-cadmium battery which provides a run-time of approximately 45 minutes, which is insufficient for the duration of a standard HBOT session. The battery was therefore removed from within the console.

The ECMO console and circuit was initially subjected to pressures up to 304 kPa (3.0 atmospheres absolute [atm abs]) to test for structural integrity, using several pressurisation and depressurisation profiles as per our equipment testing matrix.

Oxygen safety

Assessment of power and electrical safety (including ignition risk), motor type and configuration, mechanical and electrical relays and temperature testing were performed. Modifications, where performed, are detailed below in the results section.

Circuit flow performance

Testing of the ECMO circuit flow was performed with an independent in-line flow sensor [SEN-HZ21WA (½") PVC] to validate the readings of the console at various chamber pressures. Other than insertion of the in-line flow sensor via two barbed fittings for in-vitro tests, the ECMO PLS set circuit was not modified.

Flow performance was assessed against the manufacturer's specifications with saline in the circuit, to a maximum pressure of 304 kPa and during hyperbaric chamber pressurisation and decompression rates of 180 kPa·min⁻¹.

Bubble assessments

An initial visual inspection was performed to assess for the generation or introduction of macroscopic bubbles in the oxygenator or the circuit during compression, maintenance and decompression phases using an ECMO circuit primed with normal saline and set to 2,290 revolutions·min⁻¹ (rpm). The chamber was pressurised and decompressed at 30 kPa·min⁻¹ and a plateau pressure of 243 kPa (2.4 atm abs) was used. The set O₂ flow rate to the membrane oxygenator was increased in intervals of 1 L·min⁻¹ until a final set flow rate of 7 L·min⁻¹ was achieved. ECMO circuit flow rate was also monitored throughout the course of this trial. After completion of O₂ flow rate tests at 243 kPa (2.4 atm abs) the circuit was clamped, revolutions reduced to zero, and the chamber decompressed at 30 kPa·min⁻¹. On return to normobaric conditions, the circuit was connected to a Getinge Rotaflow II (Rotaflow 2) console with an in-line ultrasonic bubble sensor (FBS 3/8" x 3/32" L1.7) to provide

an objective assessment of bubble status within the circuit. The pump was set to 1,885 rpm achieving a flow rate of 4.80 L·min⁻¹, to enable the bubble detector to complete its assessment.

CLINICAL TESTING

HBOT was considered for a critically ill patient who had failed to respond to all other treatment options and was on VV ECMO support. Following recommissioning of the legacy Rotaflow 1 device with its modified power supply, hospital biomedical engineering review and approval, ethics committee endorsement and informed consent from the patient's medical treatment decision maker, the device was utilised in an experimental capacity for this patient.⁹ A treatment pressure of 140 kPa (gauge) (2.4 atm abs) and compression and decompression rates of 30 kPa·min⁻¹ were utilised. Protocolised assessment of device stability, performance, bubble assessment and clinical status occurred during each of the 13 HBOT sessions that followed, and arterial blood gases were taken to ensure target oxygenation was achieved and ventilation maintained.

Results

HYPERBARIC SAFETY ASSESSMENT, MODIFICATIONS AND *IN VITRO* TESTING

General safety

The device was visually inspected and underwent all performance verification tests as per the Getinge service protocol. The device maintained structural integrity and performed according to the manufacturer's specifications up to the testing limit of 304 kPa (3 atm abs). There were no closed gas spaces that required venting, and no activation of console buttons occurred with pressure changes.

Oxygen safety

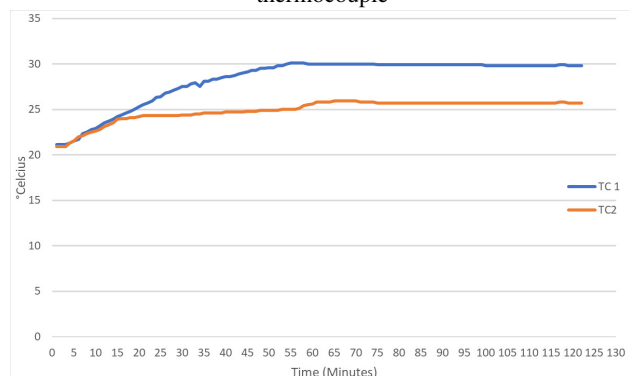
The console was reconfigured to run on a dedicated and highly redundant 24 V DC medical power supply installed into the hyperbaric chamber. Electrical component temperature testing of the power supply and control boards was performed under load and remained within recommended safe limits (Figures 2 and 3).¹⁰ The Rotaflow drive head has a brushless motor and was not modified. Nitrogen purging was introduced to reduce ignition risk from dust accumulation and/or static production and to improve cooling of the console's electronics.

Circuit flow assessment

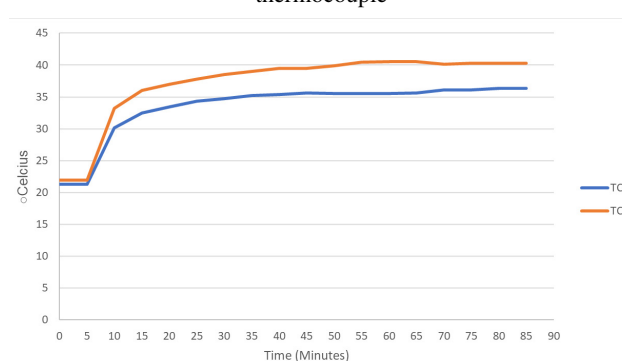
Flow performance of the Rotaflow 1 (set at 2,500 rpm, 4.63 L·min⁻¹ flow) was maintained to the manufacturer's specifications during saline PLS set circuit testing to 304 kPa (3 atm abs) with pressurisation and decompression rates of 180 kPa·min⁻¹. Preliminary flow tests demonstrated

Figure 2

Temperature data log of the Rotaflow power supply board; TC – thermocouple

**Figure 3**

Temperature data log of the Rotaflow control board; TC – thermocouple



sufficient agreement between the displayed rpm and flow on the console to suggest that it would be unlikely that flow variation during pressure changes would have clinically significant impacts on cardiopulmonary support.

The measured flow in the independent in-line flow sensor and displayed on the Rotaflow 1 console demonstrated consistency to within 180 mL·min⁻¹, that is, within 10% variance. There were otherwise no changes noted in displayed flow on the console or in-line flow sensor when compared at 101.3 and 284 kPa (1 and 2.8 atm abs) (Table 2). There were no significant changes in flow or rpm displayed on the Rotaflow 1 console when flow variability was assessed during 30 kPa·min⁻¹ pressurisation and decompression phases.

Bubble assessments

To assess for bubble formation, oxygen gas flow to the oxygenator was progressively increased from flowmeter indicated gas flow of 1 L·min⁻¹ up to 7 L·min⁻¹ at 243 kPa (2.4 atm abs) chamber pressure. Visual assessment throughout all phases did not indicate any bubble formation.

After completion of final O₂ flow rate tests, clamping of the circuit and decompression of the chamber, the circuit was assessed for bubbles by two ECMO physicians using an in-line bubble sensor (FBS 3/8" x 3/32" L1.7) on a Rotaflow 2 console, and no bubbles were detected.

CLINICAL TESTING

Thirteen daily HBOT sessions were completed over 15 days without interruption or dysfunction in the delivery of VV ECMO.⁸ Specifically, the structural integrity and performance of the device was maintained. No bubbles were visually or clinically suspected. Invasive mechanical ventilation parameters and ECMO blood and gas flows were titrated by experienced critical care and hyperbaric physicians.⁹ The patient remained clinically stable

Table 2

Independent in-line testing of flow rates at 101.3 and 284 kPa (1.0 and 2.8 atmospheres absolute); Rev·min⁻¹ – centrifugal pump revolutions per minute

Rev·min ⁻¹	Rotaflow display (L·min ⁻¹)	In-line flow sensor (L·min ⁻¹)
101.3 kPa (1 atmosphere absolute)		
2000	2.25	2.20
2200	2.42	2.40
2400	2.81	2.80
2600	3.13	3.01
2800	3.45	3.51
3000	3.61	3.70
3200	3.84	3.90
3400	4.51	4.41
3600	4.68	4.79
3800	4.71	4.72
4000	4.98	5.01
284 kPa (2.8 atmospheres absolute)		
2000	2.28	2.10
2200	2.55	2.45
2400	2.82	2.80
2600	3.09	3.01
2800	3.35	3.25
3000	3.62	3.70
3200	3.91	3.90
3400	4.19	4.01
3600	4.45	4.35
3800	4.71	4.72
4000	4.98	4.95

throughout the HBOT sessions without any significant changes to Rotaflow rpm, ventilation parameters or fresh gas flow as measured in actual litres per minute. Reductions in vasopressor support are typically expected during the course of HBOT due to hyperoxia-induced vasoconstriction and increased hydrostatic pressure, and this was demonstrated, as was the need for support to be increased again (although generally not back to pre-treatment levels) during the decompression phase.

Serial arterial blood gases were taken from a peripheral radial arterial line and pre- and post- oxygenator via 3-way connectors, demonstrating that target oxygenation was achieved and ventilation maintained. A standard blood gas machine has an upper reporting limit of ~700–800 mmHg pO₂, and as anticipated on un-diluted samples, the levels of hyperoxia generated were unreportable. The use of an experimental dilutional technique to assess the degree of hyperoxia suggested an oxygen partial pressure of ~1,500 mmHg. This correlated clinically with a loss of colour differentiation between return and access ECMO cannulae.

There were no HBOT related complications. Following his course of HBOT, the patient's clinical condition continued to improve and after a prolonged period of recovery and rehabilitation, he was discharged home with the ability to care for himself independently.⁸

Discussion

DEVICE MODIFICATION PRINCIPLES

In the hyperbaric environment, fire risk is not tolerated. Addressing fire risks related to ignition, fuel and ambient oxygen concentration are key to maintaining a safe hyperbaric environment. When validating equipment for use in the hyperbaric environment, other key principles include:

1. Ensuring structural integrity of the equipment
2. Identifying and venting any possible confined air spaces
3. Ensuring consistent and predictable equipment performance
4. Utilising nitrogen or air purge techniques to cool, deoxygenate and maintain cleanliness of internal equipment parts
5. Regular checking, maintenance and servicing by biomedical engineers and technicians.

The majority of the oxygen entering the gas port of the oxygenator is not transferred into the patient but is vented.¹¹ This has the potential to increase ambient oxygen levels and underscores the importance of ambient oxygen monitoring and adequate chamber ventilation. The National Fire Protection Agency (NFPA) 99 Standard for hyperbaric facilities in healthcare and Australian Standard 4774.2 are two of a number of useful guidance documents on safe practice.

BUBBLE CONSIDERATIONS

Intravascular gaseous microemboli (GME) occur routinely with ECMO, particularly at times of patient movement, IV fluid infusion and injection.¹² Transcranial Doppler commonly demonstrates cerebral microembolic signals in patients on veno-arterial (VA) ECMO, and to a lesser degree, VV ECMO support.^{13,14}

Under normobaric conditions, oxygenators reduce the volume of GME. For example, using similar equipment to the current report (Bioline heparin-coated tubing system, Rotaflow centrifugal pump and Quadrox-i Adult oxygenator without integrated arterial filter), one study found removal of larger bubbles (with effectiveness progressively increasing from GME diameters of 150 µm up) and reduced overall GME volume delivered, at the expense of an increase in the number of smaller bubbles post-oxygenator (perhaps due to fractionation of larger bubbles into smaller ones).¹⁵ Data are unavailable on oxygenator interactions with GME number and volume under hyperbaric conditions, although an *in-vitro* study showed GME removal was more effective under hypobaric conditions.¹⁶

Although existing GME would shrink upon pressurisation by Boyle's law, GME generated at pressure may expand in volume during decompression. The expected high fraction of oxygen in these bubbles is a mitigating factor in these concerns. Metabolic consumption of oxygen by the surrounding tissues will work to diminish and resolve bubbles. As a result, the risk of a clinically significant obstructive or inflammatory effect of oxygen bubbles should be minimal compared with the more concerning risks of air bubbles.

The Quadrox oxygenator is rated to a maximum blood flow of 7 L·min⁻¹ and gas flow of 14 L·min⁻¹ at sea level pressure. The practice in our ICU was to limit gas flow to 10 L·min⁻¹. Taking into account an increase in gas density at 140 kPa (gauge) (2.4 atm abs), the maximum indicated gas flow rate from the variable cross-sectional area 'ball in tube' flowmeter utilised was restricted to 8 L·min⁻¹ to reduce the risk of gas pressure damage to the oxygenator. Within this gas flow limitation during the HBOT sessions we provided, there were no observed issues with bubble entrainment or oxygenator malfunction and carbon dioxide clearance was adequate. In principle, the Quadrox oxygenator can receive gas flow with an oxygen concentration from 21% to 100% from a gas blender or can be supplied with 100% oxygen directly from a medical gas wall outlet through an oxygen flowmeter. Australian medical gas standards require gas supply delivery to flowmeters at 415 to 430 kPa above ambient pressure and flowmeters that can deliver up to 15 L·min⁻¹ of flow. This capacity is installed into our hyperbaric chambers.

Given some uncertainty around the potential for bubble formation, a 'safety stop' was introduced at 60 kPa (gauge) (1.6 atm abs) into the compression phase of our HBOT sessions to allow time for the ECMO attendant to check for equipment issues and to investigate for any visible bubble formation. To further reduce the risk of inert gas bubble formation, the modified HBOT treatment table contained no 'air breaks' and the patient ventilation gas was set to 100% oxygen from the time of arrival at the hyperbaric chamber until the time of return to the intensive care unit.

BLOOD FLOW CONSIDERATIONS

To adhere to manufacturer-recommended procedures and implement robust quality control measures, real-time flow monitoring was considered an essential safeguard to minimise risks associated with ECMO equipment in hyperbaric environments and promptly identify any potential complications resulting from the use of the device under hyperbaric conditions.

During HBOT our patient demonstrated preserved blood flow with a predictable non-clinically significant difference in console-displayed flow and the independent flow meter. This suggests that the blood flow in the ECMO circuit in hyperbaric conditions continues to behave similarly to normal saline flow, a Newtonian fluid, where shear rate does not affect viscosity of fluid.^{17,18}

LIMITATIONS

The Quadrox oxygenator is reported to reduce the delivered volume of GME by about 70%, and removes nearly all very large bubbles (350 µm and bigger) under normobaric conditions.¹⁵ This process has been demonstrated to be more efficient under *hypobaric* conditions (likely due to the increase in bubble volume that occurs with a reduction in ambient pressure due to Boyle's law), but it is not known if it is less effective under *hyperbaric* conditions, and if so, the clinical impact of this. However, within the limits of the technology available at the time of our testing and clinical use of the Rotaflow 1, no bubbles were visualised under hyperbaric conditions.

FUTURE DEVICE MODIFICATIONS

The Rotaflow 1 console required minimal modification for safe use in the hyperbaric environment and commissioning checks were performed by a Maquet/Getinge company representative after the change from battery to external power supply to facilitate our first HBOT with ECMO. The Rotaflow 1 has, however, been superseded by the Rotaflow 2. Given limited ongoing support for the older device it will be important to validate the new Rotaflow 2 console and components in the future.

As part of an equipment minimisation strategy, the ECMO heater was disconnected during HBOT. Hyperbaric validation of the ECMO heater or addition of an alternate heating mechanism would allow for improved thermal control of the patient in the chamber.

Additionally, assessment for suitability, and validation of other ECMO models would also be useful.

TREATMENT TABLE PRESCRIPTION

We adjusted our usual treatment table for this case and used an oxygen-only table with 85 minutes at 140 kPa (gauge) (2.4 atm abs), and pressurisation and decompression rates of 30 kPa·min⁻¹. We added a two-minute compression pause at 60 kPa (gauge) for ECMO equipment and staff safety checks. Considerations in the development of this table included maximising oxygen delivery time at pressure whilst ensuring a no-decompression obligation profile for inside staff so that decompression could be conducted at any time for any ECMO-related emergencies.

Conclusions

Our testing of the Rotaflow 1 with a PLS circuit primed with saline and subsequent clinical use with a veno-venous configuration has demonstrated safety and uncompromised performance of the device up to 304 kPa (3.0 atm abs) and 243 kPa (2.4 atm abs) respectively.

DIRECTIONS FOR FUTURE RESEARCH

Areas for future research include more detailed in-vitro testing of flow and pressure limits of the ECMO circuit using blood with differing levels of haematocrit and viscosity; this would add to our understanding of flow dynamics within the ECMO circuit and the relationship to ambient pressure and would highlight possible variations of device performance in the hyperbaric chamber. The bubble-handling characteristics of the Quadrox oxygenator under hyperbaric conditions should be further clarified, and an assessment made of the potential clinical impact of any potential differences in these characteristics to patients supported by VA compared to VV ECMO. Future trials of patients on a VA ECMO configuration will also help validate the safety of the equipment and configuration in line with the expected vasoconstriction and bradycardia related to HBOT. Finally, the newer model (Rotaflow 2) should be validated for use in the hyperbaric setting as this could significantly improve HBOT delivery protocols and workflows.

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