Flow meter, PEEP valve development and performance testing for use in a volume-controlled emergency use ventilator (EUV-SK1)

J.R. Boire[1], B. Roberts[1], T. Calow[1], M. Johnston[1] and J.B. Montgomery[2]

[1] One Health Medical Technologies Inc., RMD Group of Companies, Saskatoon, Canada
[2]Western College of Veterinary Medicine and Division of Biomedical Engineering, University of Saskatchewan, Saskatoon, Canada

Abstract— **In March 2020 Health Canada (HC) released its "Interim order respecting the importation and sale of medical devices for use in relation to COVID-19"[1]. This led to the development, testing and HC approval of an emergency use ventilator (EUV-SK1) by a Saskatoon-based engineering and manufacturing company (RMD Engineering), with support from members of the Saskatchewan Health Authority (SHA) and subject matter experts from several colleges at the University of Saskatchewan (USask). The EUV-SK1 was designed as a volume-controlled ventilator, using medical air and oxygen. The main considerations for the design were minimizing the number of moving parts, keeping the majority of manufacturing inhouse and using readily available materials. These were important risk mitigation strategies amidst disruptions to the global supply chain and business closures during lockdown. At the start of the project, it became rapidly apparent that two of the critical components, the flow meter and the PEEP (positive end expiratory pressure) valve would have to be developed and built inhouse. The current industry standard for flow measurement in ventilators are mass flow meters, however, they were not available at the time, and all PEEP devices were of a proprietary nature, and again, unobtainable. Boyles law and the Venturi effect were leaned on, and differential pressure across an inhouse design of a variable rate mechanical orifice was used to overcome precision flow challenges. The PEEP, being the most critical component, required development of a proportionally controlled solenoid on top of a balanced check valve, both developed and produced inhouse during the pandemic. Performance testing was completed using a commercial test lung (active servo lung, ASL 5000™, Ingmar Medical). Testing was performed using the settings provided by Table 201.104 in ISO 80601-2-80 [2]. The EUV-SK 1 was further subjected to extensive inhouse and third-party testing for reliability and safety.**

Keywords— **COVID-19, emergency use ventilator, flow meter, PEEP valve, ventilator performance testing**

I. Introduction

RMD Engineering (RMD) has developed an emergency use ventilator (EUV-SK1) to help in the fight against the COVID-19 pandemic. Due to issues surrounding parts and materials availability and disruptions in supply chains, RMD designed and developed several key components inhouse. For each of these components a set of specifications and operational parameters needed to be developed. The design had to be validated to ensure that it satisfies all the specifications and operational requirements. Finally, each part needed to be verified and tested to ensure it meets the specifications.

II. Flow meter development

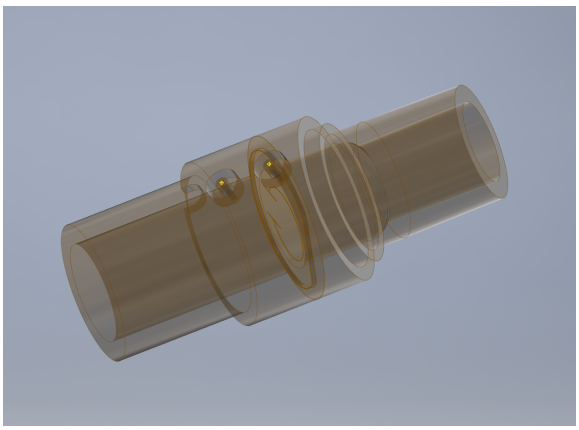

Fig. 1 Drawing of the flow meter developed by RMD

With shortages of all electronic components combined with the ability to manufacture all of the parts inhouse, it was decided that flow measurement could be attained, by using a variable orifice device that produces a variable differential pressure from one side of the flow meter to the other, but has high sensitivity on low flow, while not creating excessive pressure drop in the system at maximum flow. The relationship of flow to differential pressure has a nonlinear relationship that needs to be parameterized.

A. Design principles

Measuring flow with differential pressure drop across an orifice plate is standard practice in industry, however there are limitations placed on the allowable pressure drop across a ventilator, combined with the equivalent flowrates that the

ventilator must achieve accurately as a combination of inspired volume, inspiratory time, and inspiratory profile that exclude the use of a fixed orifice plate in the inspired air flow path. In this instance a variable flow orifice needed to be designed which met the pressure drop (approximately 12mm H_2O) required for accurate measurement at low flow to the maximum pressure drop across a ventilator air pathway (approximately 120mm H_2O) and delivered volume of 200 ml/inspiration to 800 ml/inspiration [3]. The proportion of inspiration time to expiration time, and respiratory rate also influenced the calculations to the point where experimental data needed to be gathered, and statistically analyzed to evaluate a relationship that could repeatedly give accurate measurements over millions of cycles.

B. Materials

The material requirements for medical devices present an interesting challenge in that all choices have to be supported by objective evidence every time a new device is manufactured. In this instance acrylic was sourced as it is the material used in incubators for premature infants. Therefore the theory was that it would have a high chance of being accepted as a material of construction for the body of the flowmeter which constituted a large portion of the air pathway. Even though the HC Interim Order did not require biocompatibility testing of materials, all materials used will eventually require biocompatibility testing from a third party certified test facility, if full certification of the EUV-SK1 is pursued.

The flexible orifice disc design was evaluated on many different types of material, and polyester was ultimately chosen for manufacturing, and longevity testing.

II. PEEP VALVE DEVELOPMENT

The PEEP (positive end expiratory pressure) valve controls the airway pressure at the end of the expiratory cycle. The position of the valve disc is controlled by the expiration proportional solenoid. During inhalation it is held closed, and during expiration it controls the flow of air out of the lungs and holds the programmed residual airway pressure that must be maintained after expiration, until the following inspiration cycle in order to prevent collapse of the alveoli. The spring mounted underneath the check disc counteracts the weight of the solenoid plunger, pushrod, and disc.

A. Design principles

Similar constraints to the flow meter, such as minimized pressure drop across the system, large variance in flow rates, large range of respiratory rates, and the ability to dynamically react to such extreme changes in pressures and flows due to physiological responses of the patient such as coughing influenced the design of the PEEP valve. The open area and pressure differential across the valve were balanced with the resulting closing forces required by the proportional control solenoid. In this project both the inspiration solenoid, and the PEEP solenoid were manufactured inhouse and design effort went in to balancing the requirement of both so that similar components could be used in the manufacturing to minimize the number of unique components required.

B. Materials

The PEEP valve and its components are located within the air pathway, and therefore in direct contact with the patient and subject to the same constraints as the flowmeter. Therefore, acrylic was again chosen as a material, but in this instance, due to the complex geometry, injection molding was utilized for manufacturing the components. Medical grade acrylic bead was sourced, and an injection mold was manufactured inhouse, and the parts molded for the upper and lower housing and the disc valve.

The counterbalance spring, proportional control solenoid piston, and the push rod that connects the control solenoid to the PEEP valve were manufactured form 316 stainless steel, a very common material in medical device manufacturing, with a good chance to be acceptable during third-party biocompatibility testing.

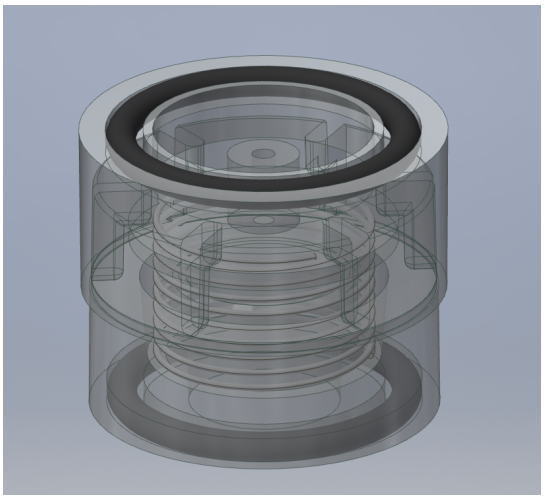

Fig. 2 Drawing of PEEP valve developed at RMD

IV. CONTROL PHILOSPHY

A. Design principles

The EUV-SK1 was designed to perform assist-control ventilation (AC) in volume control mode. The parameters for user adjustability were chosen in consultation with respiratory therapists and other clinical experts. Those parameters of interest to this paper are inspiratory tidal volume (V_{ti}), respiratory rate (RR), inspiratory time (T_i), and positive end-expiratory pressure (PEEP).

To achieve volume control, closed loop flow control was used. The target flow rate was calculated using tidal volume (V_t) and inspiratory time (T_i), and flow was calculated using the differential pressure reported by a transducer measuring across the inspiratory flow meter. The RMD designed proportional electric solenoid valve was used to directly control the flow rate of air delivered to the patient. Delivered volume was calculated throughout the inspiratory phase by integrating under the curve of measured flow, and target flow rate was updated based on how much volume and inspiratory time remains to be delivered.

Similarly during the expiratory phase, expiratory flow was calculated using a second identical differential pressure transducer and flow meter in the expiratory limb. Expiratory flow was controlled using the PEEP valve and proportional solenoid. Target expiratory flow was calculated using a function of delivered volume (V_t), remaining pressure to reach PEEP, and remaining time until the next breath (determined by respiratory rate and inspiratory time). The resulting curve is an inverse exponential to emulate a natural breath. Once desired PEEP is reached, the PEEP valve is closed to maintain pressure.

V. Performance Testing

A. Test lung

Performance testing of the EUV-SK1 was completed with the ASL 5000™ (active servo lung, Ingmar Medical) used as the test lung and following the ventilator setting prescribed by Table 201.104 in ISO 80601-2-80 [2].

B. Test parameters

Each performance test included a series of eight test settings. Prescribed test lung parameters included compliance and linear resistance. Prescribed settings on the EUV-SK1 included delivered volume, ventilatory frequency, inspiratory time (T_i), and PEEP [2].

Initially, each of the eight tests was performed in triplicate for each ventilator to determine if there was any significant variability in performance. When this was determined not to be the case, each test was completed once for each ventilator. In order to determine if there is a difference between the set and measured parameters, 10 consecutive breaths were analyzed, once steady state was reached.

C. Test results

The ventilator passed performance testing when the measured volume from each test was ±(4ml+15%) of the set volume, with a measure uncertainty of 8.3ml. The maximum error of PEEP in relation to the set value was +0.9 cmH_2O, with a measurement uncertainty of 0.13 cmH_2O. A sample of results of performance testing as it was submitted to Health Canada are summarized in Table 1.

Table 1 Measurement accuracy summary of EUV-SK1

Serial #	Delivered Vol. Max. Error (%)	Delivered Vol. Min Error (%)	Total Delivered Vol. Accuracy	PEEP Accuracy Max. Error (cmH_2O)
9	5.4	-9.0	±(4mL+9.0%)	0.8
11	5.4	-8.7	±(4mL+8.7%)	0.7
12	4.2	-14.3	±(4mL+14.3%)	0.6
16	2.4	-12.0	±(4mL+12.0%)	0.3
19	4.2	-10.0	±(4mL+10.0%)	0.8
20	4.6	-12.0	±(4mL+12.0%)	0.9
21	4.6	-10.7	±(4mL+10.7%)	0.9
23	4.4	-10.3	±(4mL+10.3%)	0.8
24	11.0	-9.3	±(4mL+9.3%)	0.8
25	6.4	-10.3	±(4mL+10.3%)	0.8

VI. Compliance with Ethical Requirements

A. Conflict of Interest

J. Boire and B. Roberts are co-owners of RMD. T. Calow and M. Johnston are employed by RMD. J. Montgomery contributed to this project during a sabbatical leave from USask and did not receive any renumeration from RMD. J. Boire and J. Montgomery have a personal, family relationship, which was disclosed to USask at the start of the project.

B. Statement of Informed Consent

The study reported here did not include any experiments involving animals or human subjects.

C. Statement of Human and Animal Rights

The study reported here did not include any experiments involving animals or human subjects.

VII. Conclusions

The implementation of agile project management and reliance on inhouse capability and production capacity, in conjunction with recruitment of local subject matter experts from the SHA and USask, led to HC approval of the EUV-SK1 within eight months from the start of the project. This is an excellent example of how the private and public sectors were able to combine their efforts and expertise and contribute to Canada's COVID-19 pandemic response.

Acknowledgment

We acknowledge the employees of the RMD Group of Companies, the SHA, as well as the students, faculty and senior administrators of USask who supported this project.

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Corresponding author:

Author: James R. Boire
Institute: RMD Engineering, Inc.
Street: 1 Cory Place, East Cory Industrial Park
City: Saskatoon, SK S7K 3J7
Country: Canada
Email: jboire@rmd-engineering.com