A Made-in-Saskatchewan ventilator designed and built to support Canada's COVID 19 pandemic response

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I. Introduction

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 the University of Saskatchewan.

II. From concept to approval in eight months

Design objectives: 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.

Challenges in design and material acquisition: 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 is 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 was leaned on, and differential pressure across an inhouse design of a variable rate mechanical orifice were 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: 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 third-party testing.

Usability testing: The purpose of usability testing is to prevent use error and improve patient safety. Usability testing included two parts, a completion of tasks by experienced users (respiratory therapists and intensive care nurses) and a user experience questionnaire completed by the same users. Both were modified from previous published studies [3, 4].

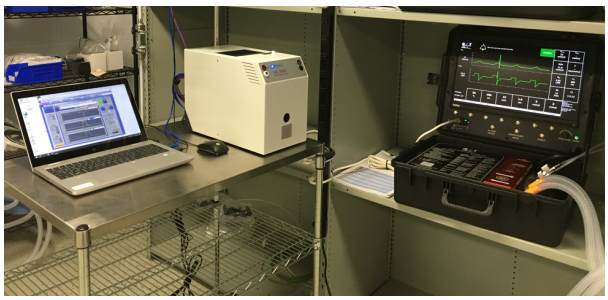

Fig. 1 EUV-SK1 (right) and ASL 5000 with attached laptop (left) for data analysis used for performance testing of the EUV

Next steps: Further work is in progress to turn the EUV-SK1 into a fully certified ventilator.

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References

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