EUV-SK1

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Introduction

EUV-SK1 is an emergency-use ventilator that has been designed and built entirely within Saskatchewan to meet the *AAMI Emergency Use Ventilator (EUV) Design Guidelines* (*AAMI Guidelines*).[1] Health Canada responded to the urgent need for ventilators by issuing an *Interim order respecting the importation and sale of medical devices for use in relation to COVID-19.*[2] While this interim order relaxes some of the requirements for licensing and approval of the sale of ventilators, significant requirements to ensure the safety and reliability of approved EUVs remain. The *AAMI Guidelines* represent an international consensus on the essential clinical, engineering and testing requirements that will enable the rapid development EUV to safely treat patients with COVID-19 respiratory failure. It is OHM Tech's intention to receive full certification for the EUV-SK1 within a year. As a result, a number of additional standards, regulations, and guidance documents have informed the design, manufacture, and testing of EUV-SK1. A complete list of these standards, regulations, and guidance documents can be found in Appendix B.

Key features of the EUV-SK1

The EUV-SK1 VENTILATOR provides volume-controlled mechanical ventilation with assisted control to ventilator-dependent adult COVID-19 patients and is intended to be used in traditional healthcare facilities and spaces converted for the care of large numbers of COVID-19 patients.

Parameter ranges of the EUV-SK1 include:

- The Fractional Concentration of Inspirational Oxygen can be set in 5% increments from 21-100%.
- Tidal volume is adjustable in 25ml/breath increments between 200-800ml/breath
- Respiratory rate is adjustable in 1 breath/minute increments within a range of 10-30 breaths/minute.
- Inspiratory time can be set between 0.5 to 3.0s.
- The Positive End Expiratory Pressure (PEEP) is adjustable in 1 cmH20 increments between 0 to 40 cmH20.
- Trigger pressure drop can be set in 1cmH20 increments from 1 to 5 cmH20.
- The maximum measured airway pressure is 80 cmH20.

The EUV-SK1 Display Screen displays:

- Peak Pressure,

[1] https://www.aami.org/docs/default-source/standardslibrary/200410_cr501-2020_rev1-2.pdf?sfvrsn=699e62b7_2

[2] https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/interim-order-importation-sale-medical-devices-covid-19.html

- PEEP Pressure,
- Respiratory Rate,
- Plateau Pressure,
- Inspiration to Expiration Ratio,
- Actual Respiratory Rate (RR),
- Flow Rate,
- Tidal Volume,
- Maximum Measured Airway Pressure,
- Compliance.

EUV-SK1 notifies operators of an alarm condition by sound and an alarm symbol displayed on the monitor, as well as different colours for each alarm priority level (low, medium, high). Alarms will be triggered if:

- Gas supply failure: Alarm for inadequate oxygen and inadequate medical air supply,
- Electrical supply failure: The UPS will alarm if it loses connection to A/C power; it will automatically switch to its battery mode,
- Ventilator switched off when in mandatory ventilation mode,
- High Pressure: inspiratory airway pressure exceeded,
- Low Pressure: inspiratory pressure or PEEP not achieved,
- High Volume: increased tidal volume (Vt),
- Low Volume: decreased tidal volume (Vt).

When an alarm is triggered, operators can also easily refer to the alarm troubleshooting guide as it is located directly below the display monitor. EUV-SK1 uses *IEC 60417 Alarm Symbols*.

Each EUV-SK1 unit will be sold with hard copies of the operations and training manuals. A QR code is located below the monitor that links to an online version of the operations manual. Throughout the lifespan of the EUV-SK1, One Health Tech will maintain an online collection of the latest guidance on treating COVID-19 that is also accessible with the QR code.

Testing, Verification, and Certification

OHM Tech is subjecting EUV-SK1 to systematic and comprehensive testing of its functionality, reliability, and safety. These tests are being independently verified by Intertek Canada. In addition, Intertek Canada has reviewed the risk assessment OHM Tech completed for all electrical and mechanical components used in the EUV-SK1. Risk assessments are being completed on the EUV-SK1 for:

- Biocompatibility of all components that deliver breath and will come in contact with a patient's airway,
- Flow-through tests of air pathway to confirm low risk of presence of particulates and volatile organic compounds (VOCs),
- Safety and reliability of electrical components,
- Software performance,

- Consistency and accuracy of parameter ranges,
- Accuracy and reliability of mechanical components,
- Alarm sensitivity.

In addition, all vendors supplying components to the EUV-SK1 are pre-qualified to achieve OHM Tech's quality objectives.

OHM Tech, already *ISO 9001:2016* certified, will soon complete the process to receive *ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes* certification. *ISO 13485* certification provides additional assurance that the OHM Tech has the necessary policies and work procedures in place to ensure that the EUV-SK1 is safe and reliable.

About the One Health Medical Technologies Inc. Team

OHM Tech, a part of the RMD Group of Companies, employed a multi-disciplinary team of highly-skilled and experienced mechanical and electrical engineers, programmers, machinists, electricians, instrumentation and CAD/CAM technologists, fabricators, and project managers to create the EUV-SK1. As an ISO 9001:2015 certified company, OHM Tech was able to rely on its established and tested policies and work procedures to ensure that the EUV-SK1 meets the same quality objectives[3] as any other product produced by the RMD Group of Companies despite the accelerated timeframe from concept to completion. OHM Tech also has the capacity to build the EUV-SK1 entirely in-house thereby allowing it unparalleled quality control.

OHM Tech understands that the EUV-SK1 not only has to operate from an engineering and technical perspective, but that it also has to meet the needs of the people who would actually operate the machine. As a result, a respiratory therapist and an emergency room nurse have been involved in every stage of the design and development of the EUV-SK1 to ensure seamless adoption in clinical settings.

In furtherance of its commitment to excellence, RMD Group of Companies relied on its strong relationship with the University of Saskatchewan to engage with members of the Western College of Veterinary Medicine and the Colleges of Engineering, Medicine, and Law who provided on-going feedback on the design, functionality, and compliance of the EUV-SK1

[3] The RMD Group of Companies' Quality Statement is attached as Appendix A

Appendix A – Quality Statement

The RMD Group of Companies is committed to providing products and services that meet customers' requirements for quality and that satisfy both regulatory and important industry-specific quality management requirements. Our continuing focus on research- and development-supported design, manufacturing, repair, and maintenance solutions for provision of quality mechanical and electrical/electronic products and services is supported by considerable developed expertise. In these endeavours both management and staff are committed to supporting RMD's quality management system that drives continual improvement of product and service quality through decisions based on evidence and risk assessment.

Jim Boire, President and Founder

Appendix B – Certification, Standards, Regulations, and Guidance Documents Considered

AAMI

- AAMI Emergency Use Ventilator (EUV) Design Guidelines

IEC

- IEC 62366:2014 - Ed. 1.1 - Medical devices – Application of usability engineering to medical devices
- IEC 62304:2015 - Medical device software - Software life cycle processes
- IEC 60601 – Medical electrical equipment

ISO

- ISO 80601- Medical electrical equipment
- ISO 10993 - Biological evaluation of medical devices
- ISO 14971:2007 Medical devices – Application of risk management to medical devices
- ISO 14644 – Cleanrooms and associated controlled environments
- ISO 14698-1 – Cleanrooms and associated controlled environments – Biocontamination control
- ISO 14937 – Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
- ISO 17664 – Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices
- ISO 15001:2010 – Anaesthetic and respiratory equipment – Compatibility with oxygen
- ISO 9001:2015 – Quality management systems
- ISO 10993 – Biological evaluation of medical devices
- ISO 18562 – Biocompatibility evaluation of breathing gas pathways in healthcare applications

CAN/CSA

- CAN/CSA C22.2 NO 60601-1-14:2014 - Medical electrical equipment

Government of Canada

- *Medical Device Regulations*, SOR/98-282
- Interim order respecting the importation and sale of medical devices for use in relation to COVID-19
- Guidance Document for the Labelling of Medical Devices, not including *in vitro*
- diagnostic devices
- Guidance Document on supporting evidence to be provided for new and amended licence applications for Class III and Class IV medical devices, not including *IN Vitro* Diagnostic Devices (IVDDs)
- Updated Guidance Document: Guidance for the Labelling of Medical Devices, not including in vitro diagnostic devices - Appendices for the

Labelling of Soft Contact Lenses, Decorative Contact Lenses, and Menstrual Tampons

- Notice: Updated Guidance on the Recognition and Use Of Standards under the Medical Devices Regulations
- Guidance Document: Recognition and Use of Standards under the Medical Device Regulations
- Guidance Document: Quality Management System - Medical Devices - Guidance on the Control of Products and Services Obtained from Suppliers
- Notice: Importation or sale of ventilators - use of US FDA guidance and Canadian requirements for authorization under the Interim Order
- Notice: Use of FDA Guidance Materials to support Canadian Medical Devices Licence
- Guidance for the Interpretation of Significant Change of a Medical Device

GHTF

- Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices