INDUSTRIALIZING AN OPEN SOURCE VENTILATOR DESIGN TO FIGHT COVID-19

Sponsored by London Life Members Affinity Group and London Engineering in Medicine & Biology Chapter

Oct 20, 2020

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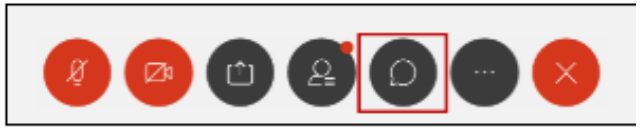
Event Guidance

- Thanks for joining us today
- All attendees are muted without video camera
- Questions or other input will be via the Chat feature

  -hover in bottom middle of screen



- We will monitor Chat and read questions and comments at the end (or interrupt if appropriate)
- Event will be recorded and a link provided later
- A copy of the presentation will be posted on vTools after.
- My email: murraymacdonald@ieee.org

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Wayne Hawkins

- SVP & GM, Vexos in Markham ON

- 25+ years of Operations experience including 19+ years in the EMS industry
- in progressively senior roles spanning Global Program Management, Operations Management and Site General Management.
- New Product Introduction, Manufacturing Engineer and Quality Assurance roles at Ford Electronics (Visteon) and Nortel.
- Bachelors' in Mechanical Engineering,University of Ottawa.

VEXOS Local Service. Global Capabilities. MVM MILANO VENTILATORE MECCANICO JMP Solutions Industrial Technology Partner to the Fortune 1000

Cyril Fernandes

- SVP – Global Business Development, Vexos

- part of the EPM Global Services team since 2006 focused on marketing and business development activities
- over 25 years' experience in Senior Operations roles across varied organizations
- a wealth of experience in business development, operations, manufacturing and global manufacturing strategies.

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Brent Bell, P.Eng.

- Engineering Manager, Automation & Robotics Div.,
  JMP Solutions, London

- 12 years of experience in custom industrial automation machine integration
  - for a variety of industries and customers across North America.
- B.E.Sc. (ME) from Western University
- registered member (P.Eng.) in Ontario

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IEEE
Advancing Technology for Humanity

Industrialization of an Open Sourced Ventilator Design

Presented by Vexos

Cyril Fernandes
SVP Global Business Development

Wayne Hawkins
SVP & GM, Markham
Manufacturing Facility

Presented by JMP Solutions

Brent Bell, P.Eng,
Engineering Manager, Automation & Robotics Division

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IEEE - Webinar – October 20th

Vexos Electronic Manufacturing - Overview

Helping our customers achieve their goals for more than 25 years

2019 Awards

Recognized as the leading EMS provider in our category

Our Commitment to Customers is the highest reliability standards in quality, delivery and cost in our industry:

- Over 25 years of service and expertise to our OEM customers
- World class manufacturing facilities and global network of strategic partners
- Engineering support and expertise through our Technical Centers
- 180,000 + square feet of manufacturing capability
- 700+ customer focused employees
- Strong sourcing connections and economies of scale
- Ability to scale and grow with customers demand and requirements
- Specializing in Low-to-Mid Volumes
- High-to-Low Complexity Mix
- Vexos received top honors by their customers for best in class for two categories: **Manufacturing Quality and Technology**

JMP Solutions - Overview

VEXOS Local Service. Global Capabilities. | MVM Milano Ventilatore Meccanico | JMP Solutions Industrial Technology Partner to the Fortune 1000

JMP Solutions

1. Process Automation
2. Control System Integration
3. Information Systems
4. Automation & Robotics
5. Automated Guided Vehicles
6. Material Handling
7. Networking & Security

250+
engaged, dedicated employees!

THE JMP PROMISE
We guarantee an extraordinary customer experience with every project we execute.

JMP hires the best. We are proud of our company, our people and the team we've created. Certified as a "Great Place to Work" 2013 through 2019!

OUR VALUES
Integrity *Leadership*
Excellence *Relationships*
Respect *Collaboration*

OUR LOCATIONS

OUR BHAG

1 By 2035, we will be one of the world's top 3 independent system integrators in the provision of automation, control and information solutions to industry.

OUR PURPOSE

We help people and businesses realize their full potential by continually redefining what is possible.

MVM Project Structure

MVM International / ARIA
Cristiano Galbiati
professor of physics at Princeton University professor of physics at Princeton University and Global Argon Dark Matter Collaboration (GADM)

ELEMASTER Technologies
Gabriele Cogliati, President & CEO
European Manufacturing & Design partner

MVM Canada - Collaboration national laboratories in Canada The McDonald Institute - leadership of Nobel laureate, Dr. Arthur McDonald of Queen's University, Canadian Nuclear Laboratories (CNL), TRIUMF and SNOLAB

VEXOS
Wayne Hawkins - SVP & GM, Markham
Cyril Fernandes - SVP Global BD
North American Manufacturing partner

JMP Solutions
Scott Shawyer - President and CEO
Brent Bell - Engineering Manager
Laurens VanPagee – VP Engineering

Vexos & JMP MVM Team

WAYNE HAWKINS
SVP & GM, MARKHAM
- 25+ years experience
- Previously served operations management roles at Celestica, Ford Electronics and Nortel

CYRIL FERNANDES
SVP, BUSINESS DEVELOPMENT
- 25+ years experience
- Has served as part of the EPM Global Services business development team since 2006

BRIAN MORRISON
VP, GLOBAL ENGINEERING
- 16+ years experience

MFG ENG (4)
TEST ENG (5)
PROCESS ENG (7)
ENG SUPPORT (4)

KASPARS FRICBERGS
VP, GLOBAL QUALITY
- *25+ years experience*

QUALITY ASSURANCE (4)

STEPHANIE MARTIN
SVP, GLOBAL SUPPLY CHAIN
- 25+ years experience

SUPPLY CHAIN TEAM (4)

SCOTT SHAWYER
President and CEO

BRENT BELL, P.ENG
ENGINEERING MANAGER

PROJECT MGMT (1)
MECHANICAL ENG (4)
ELECTRICAL ENG (2)
MFG ENG SUPPORT (6)
PROCUREMENT (3)

LAURENS VANPAGEE
VP ENGINEERING

FACILITY MGMT (1)
QUALITY ASSURANCE (4)
PRODUCTION TEAM (40)

Preamble

- The MVM is an innovative ventilator, conceived and designed by an international collaboration of particle physicists and developed in cooperation with other relevant scientific communities.
- Simple Mechanical design is simple, using a small number of parts to facilitate rapid production. Focused on strong and safe performance for the care and recovery of COVID-19 patients.
- In a little more than one month, from March 19 to May 1, the Mechanical Ventilator Milano (MVM) went from concept to reality
- May 1, 2020, the United States Food and Drug Administration (U.S. FDA) declared that the MVM falls within the scope of the Emergency Use Authorization (EUA) for ventilators.
- September 30, 2020 - Vexos receives Health Canada approval under Interim Order (IO)
- Achieving this result in a such a short time was made possible thanks to the cooperation of laboratories, institutes, universities and companies mainly across Italy, Canada and the United States, maximizing the benefits that come from the sharing of skills and resources.

The MVM Challenge

- A fraction of the people infected with COVID-19 can become severely ill, needing help to breathe. This has created a world-wide demand for ventilators. To address this critical global issue, the MVM collaboration took on the challenge to design, develop, build, and certify a safe and powerful, ventilator.

- The MVM initiative originated in the framework of the GADM Global Argon Dark Matter Collaboration, an international scientific collaboration engaged in the search of dark matter with experiments labs and with worldwide partners. This research involves gas handling systems and complex control systems, the same technologies required in mechanical ventilators.

- While in lockdown for the COVID-19 pandemic in Milan, Italy, Cristiano Galbiati (Princeton University), the spokesperson for the GADM Collaboration, recognized the need for additional ventilators early in the pandemic. He launched the MVM project and started the development of a first prototype in partnership with Elemaster S.p.A of Lomagna (LC), Italy.

- The collaboration quickly expanded to include international partners including national laboratories in Canada: Art McDonald Institute for Astroparticle Physics Research Institute, Canadian Nuclear Laboratories (CNL), TRIUMF and SNOLAB, through the leadership of 2015 Nobel laureate, Dr. Arthur McDonald of Queen's University.

The MVM Challenge

- The laboratory and hospital facilities for the development and testing of the first units was performed by a team headed by Elemaster in conjunction with local hospitals in Northern Italy.

- Clinicians and anesthesiologists located in Italy, Canada, and in the United States provided guidance to ensure medical considerations were properly integrated into the design.

- Getting the MVM ventilator to patients requires collaboration beyond nuclear and particle physicists. Government departments, regulators, manufacturers and health care providers have made valuable contributions to the project.

- Vexos Inc. will manufacture and distribute the MVM Ventilator under an exclusive license from Elemaster for the Americas and other territories partnered with JMP Solutions in London, ON.

The MVM Design

- The MVM ventilator is inspired by the Manley ventilator, which was developed by Roger Manley in 1961, based on “the possibility of using the pressure of the gases from the anesthetic machine as the motive power for a simple apparatus to ventilate the lungs of the patients in the operating theatre”.

- The MVM is designed to meet the requirements of a ventilator as simply as possible. The MVM also incorporates advanced features directly recommended by anesthesiologists participating who provided care for COVID-19 patients.

- The MVM features electrically driven pneumatic valves rather than mechanical switches and uses a stripped-down mechanical design.

- This enables fast progress from design to quick, inexpensive mass production of safe, reliable ventilators for hospitals and patients around the world. The modular design can also be adapted to swap out parts based on their availability in different regions of the world.

Challenges

- Design Challenges
  - At times, multiple critical mechanical, electrical, and software design revisions per day
  - International design groups working in parallel
  - Regulatory compliance requirements
    - Different health care jurisdictions have unique requirements
  - North American vs. European equivalency
    - Italian design authority on project
  - Cost optimization for maximizing reach to patients in need
  - Constant evolving firmware and software

- How Vexos and JMP overcame
  - Communication, communication, communication!
    - Many daily web meetings, BOM's, filesharing services, action registers, etc.
  - Collaborating to find creative solutions via alternate components during industrialization
    - i.e. Fluidics circuit components, oxygen sensor, patient circuit components

Challenges

- Supply Challenges
  - In the height of the COVID-19 lockdown, suppliers had reduced capacity to respond and support
    - Key supplier staff working remotely or not at all
  - International import/export considerations of many components
    - Trade constraints imposed for traditional ventilator components
  - Production of custom components during lockdown
  - Sourcing of directly equivalent alternates where applicable

- How Vexos and JMP overcame
  - Leveraging existing networks together
  - Securing supply chain for equivalent alternates to align with production schedule
  - Highly coordinated effort to provide supply chain feedback to the design process in order to iterate rapidly

Challenges

- Health Canada (HC) Approval for MVM Ventilator
  - Multiple Regulatory body coordination
    - FDA (under EUA)
    - CE Approvals
    - Specific HC

- How Vexos and JMP overcame
  - Internal teams Worked with local (North American) regulatory bodies in lockstep with the HC Approval process with product testing. Highly iterative process
  - Engaged with Medical Device Approval experts in preparation of submission to HC
  - Worked with larger Canadian MVM team in the pre-test process and internal approvals prior to formal submissions

Challenges

- Production Challenges
  - Delivery of 10,000 units in a short timeframe

- How Vexos and JMP overcame
  - Rapid creation of manufacturing (Assembly, Test, Pack) on factory floor
    - Created dedicated Lab and production space, invested in test infrastructure and labor buildup geared towards rapid completion of volume.
  - Stable, Repeatable build and test process
    - Utilized Vexos' award winning manufacturing, quality and training systems to ensure an efficient and effective production plan, process and implementation
  - Significant materials logistics
    - Partnered with local logistics partners for inbound and outbound freight

Vexos - Chronology Key Milestones

MVM TEAM ▶ **ESTABLISH VEXOS MVM – TEAM & PARTNERS** ▶ **ONBOAR**

Executive Engagement	Team Selection	Kick-off Meeting	Daily Project Meeting	Weekly Customer Meeting	Weekly Executive Meeting	Execution to Production
Mar-2020	Apr - 2020	Apr - 2020	Apr - 2020	Jun - 2020	Jun - 2020	Oct - 2020

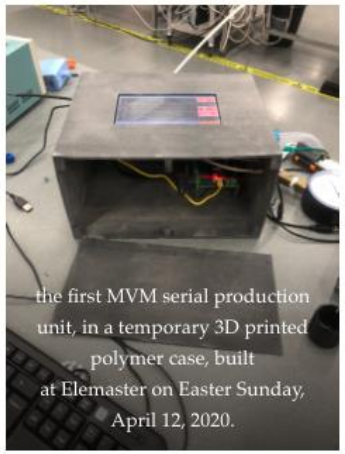
MVM VENTILATOR – KEY MILESTONES

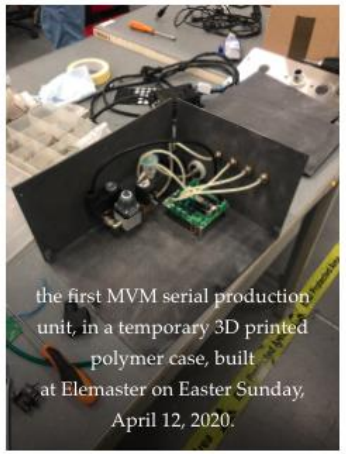
MVM CANADA	GoC Order Confirmation	Pre-Production	HC Submission	Forecasted completion
• Mar. 2020 formation • Key participants include Vexos, JMP Solutions, Triumf, Snolab and Fermilab • Daily structured meetings to track project's progress	• May 2020 • 10000 Ventilators	• June 2020 • Prototype to gather data for certification and validation	• Aug. 2020 • Formal approval received in Sep. 2020	• Dec. 2020 to Jan. 2021 • Initial ramp Oct. 2020 • Full ramp Nov. 2020

LAUNCH

MVM Ventilator Launched

Early Development


the first MVM serial production unit, in a temporary 3D printed polymer case, built at Elemaster on Easter Sunday, April 12, 2020.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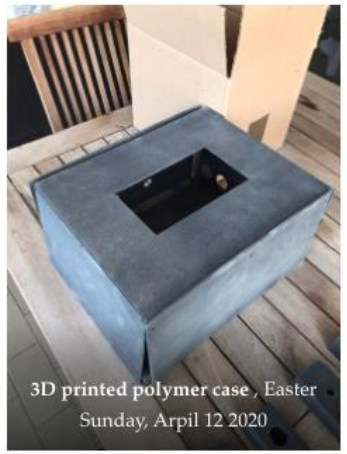
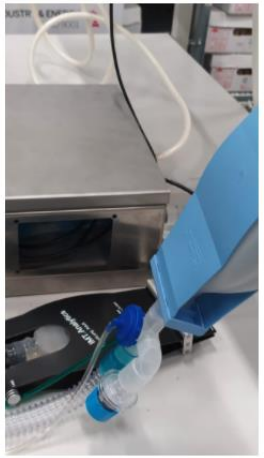
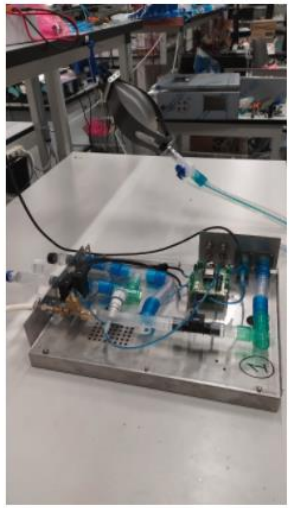
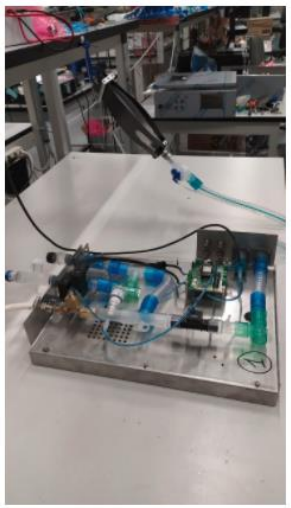
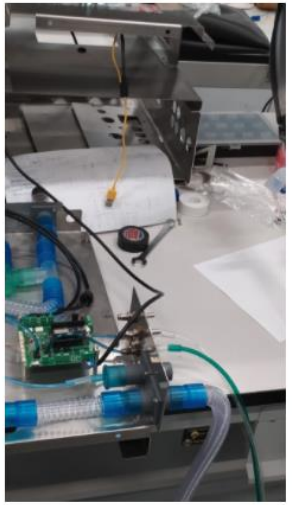

3D printed polymer case , Easter Sunday, Arpil 12 2020

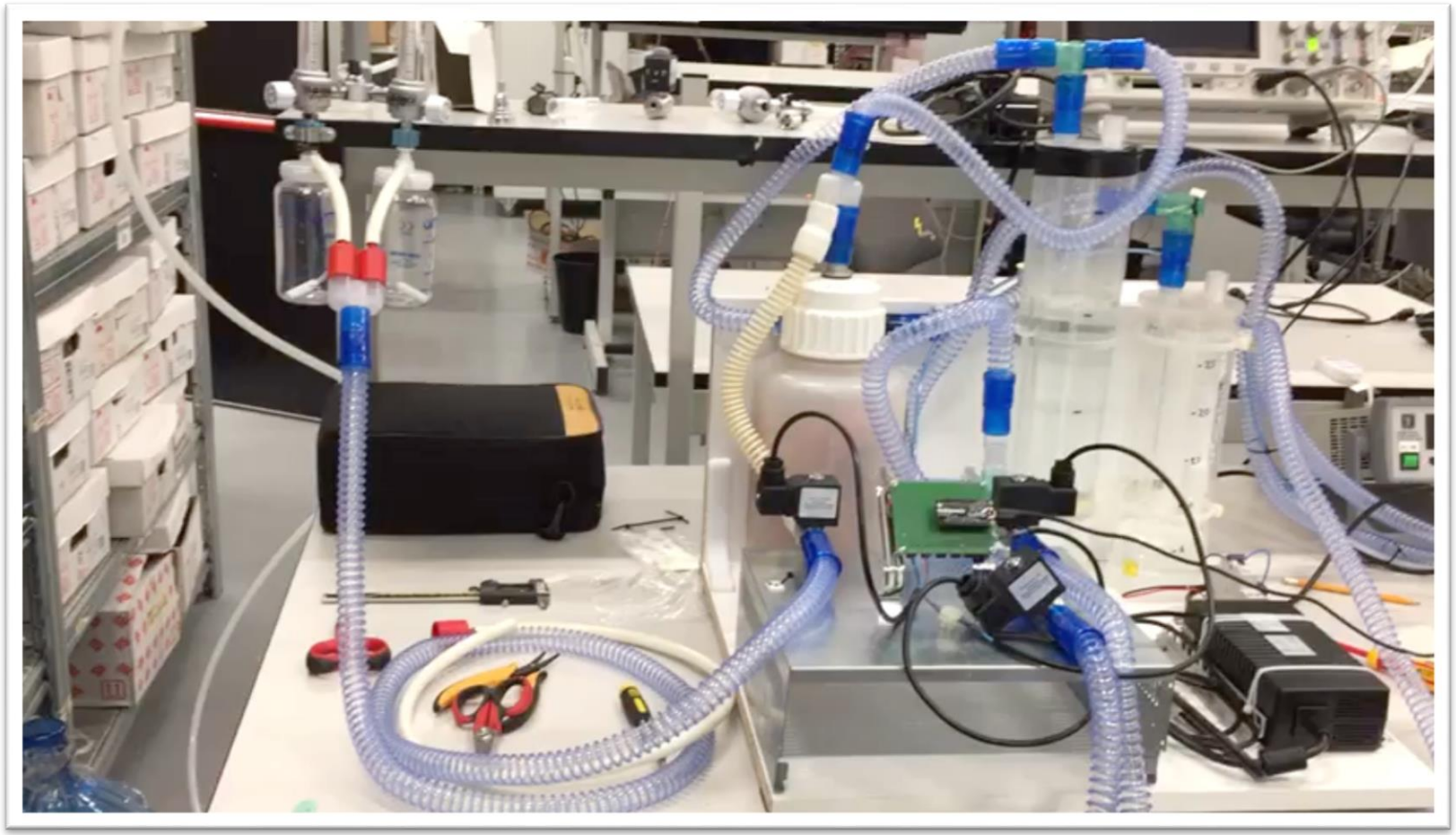




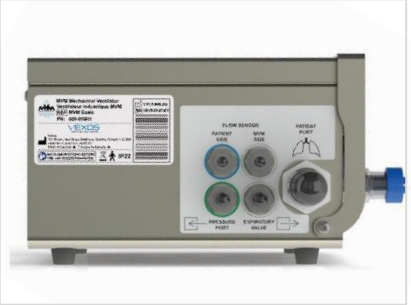


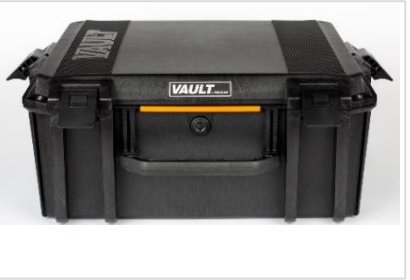


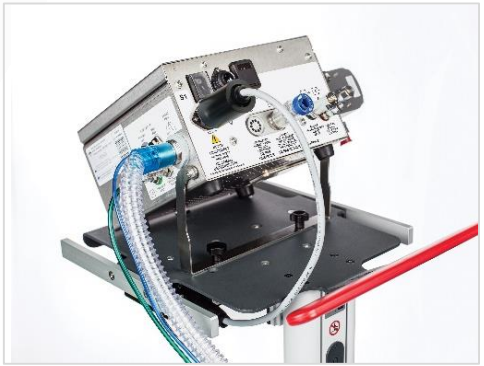
Early Development

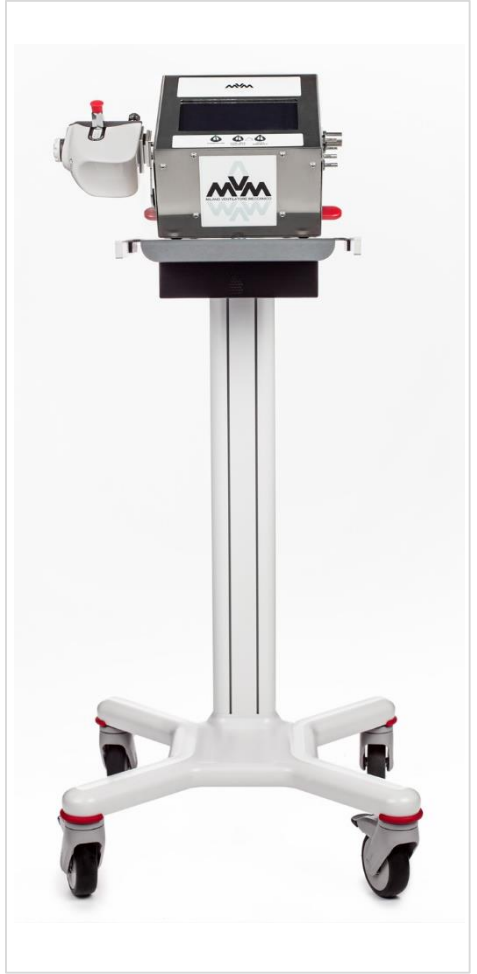


Final Product









MVM Ventilator - Video

Final Words

- The MVM Ventilator program could not have been done without the cooperation of a broad swath of organizations spanning governmental, institutional and commercial bodies
  - International MVM Consortium
  - MVM Canada
  - Government of Canada Support
    - Health Canada
    - Public Health Agency of Canada
- Canada is now self sufficient in its ventilator manufacturing (0 to full capability) with the contracts awarded to the various organizations including Vexos/JMP.

Useful Links

For more technical information about the MVM Ventilator

- https://www.vexos.com/mvm-ventilator

International MVM Group

- https://mvm.care/who-we-are-en/

Canadian MVM

The McDonald Institute

- https://mcdonaldinstitute.ca/

Canadian Nuclear Laboratories

- https://www.cnl.ca/en/home/default.aspx

SNOLAB

- https://www.snolab.ca/

TRIUMF

- https://www.triumf.ca/

THANK YOU

For more information contact.

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QUESTIONS?

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Thank you to our presenters

Wayne Hawkins

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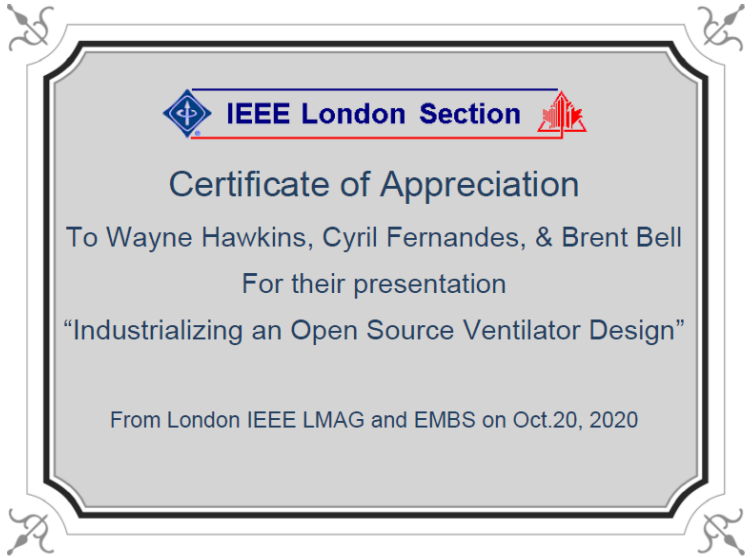

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Announcements

- IEEE Canada major awards nominations are due Nov. 30
  https://www.ieee.ca/en/awards/member-awards/

- Engineering Institute of Canada (EIC) awards and fellowship nominations are due November 15
  http://eic-ici.ca/honours_awards/

- If you haven't already, remember to renew your membership
  https://www.ieee.org/membership/renew.html

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Thank You!

Merci Beaucoup!