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From Particle Physics to Hospitals: The United States Food and Drug Administration Authorizes the Mechanical Ventilator Milano (MVM) within the scope of the Emergency Use Authorization for COVID Ventilators

NEW YORK, May 12, 2020 /PRNewswire/ -- FONDAZIONE ARIA and Vexos Inc.

Preamble

In a little more than one month, from March 19 to May 1, the Mechanical Ventilator Milano (MVM) has gone from conception to reality, as it is now shifting to production and to patients affected severely by COVID-19. On May 1, 2020, the United States Food and Administration (U.S. FDA) declared that the MVM falls within the scope of the Emergency Authorization (EUA) for ventilators.

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. The mechanical design is simple, using a small number of parts to facilitate rapid production of a powerful and complex control unit, programmed by a large number of researchers, ensuring a strong and safe performance for the care and recovery of COVID-19 patients. 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. This has created a world-wide demand for ventilators. To address this critical global challenge, the MVM collaboration took on the challenge to design, develop, build, and certify a safe and powerful, ventilator. A very important feature of the MVM is the simplicity of its mechanical design, which allows for quick production. Another important feature is the sophisticated control system, which makes available the two ventilation modalities required for the care of COVID-19 patients, while also ensuring ease of use for medical personnel.

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 particles at Istituto Nazionale di Fisica Nucleare's Gran Sasso Laboratory in Italy and in Canada. This research involves gas handling systems and complex control system technologies required in mechanical ventilators.

While in lockdown for the COVID-19 pandemic in Milan, Italy, Cristiano Galbiati (Gran Sasso Science Institute, INFN and Princeton University), the spokesperson for the GADM Collaboration, recognized the need for additional ventilators early in the pandemic. He launched the project and started the development of a first prototype. With support from INFN Istituto for Nuclear Physics; groups from the Universities of Bergamo, Brescia, GSSI Science Institute, Insubria, L'Aquila, Milano Bicocca, Milano "La Statale", Napoli "Federico II", Pavia, Roma "La Sapienza", Siena; CNR National Research Council; Istituto Superiore di Sanità; Azienda Ospedaliera San Gerardo of Monza; and Elemaster, project leader and coordinator.



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 other companies involved AZ Pneumatica, Saturn Magnetic, Bel Power Europe, Nuclear Instruments, CAEN and Camozzi, the MVM collaboration produced an initial prototype; fully demonstrated the viability of the conceptual design.

The laboratory facility for the development of the first units was made available by Elemaster S.p.A of Lomagna (LC), Italy. In addition to creating the MVM controller printed circuit board, Elemaster also led the assembly and prototype testing in collaboration with the other companies involved. The Elemaster International Design Center, as MVM design authority, submitted the design to the U.S. FDA. The laboratory facility for the development of the first units was made available by Elemaster S.p.A of Lomagna (LC), Italy.

The collaboration quickly expanded to include three national laboratories in Canada, Canadian Nuclear Laboratories (CNL), TRIUMF and SNOLAB, through the leadership of the MVM laureate, Dr. Arthur McDonald of Queen's University.

The US collaboration includes people from Fermi National Accelerator Laboratory (FNAL), the Princeton Plasma Physics Laboratory, two of the Department of Energy's national laboratories as well as staff from several US universities.

The European collaboration also includes researchers from: Politecnico di Milano and INFN della Fisica e Centro Studi e Ricerche Enrico Fermi of Italy; APC, SUBATECH and Mines Paris of France; CIEMAT and LSC, CAPA-UZ and ARAD of Spain; AstroCeNT (CAMK PAN) of Poland; Garching of Germany; University of Toronto of Canada; Rochester University, University of California Los Angeles, University of Houston, University of Massachusetts at Amherst, University of Nebraska-Lincoln of the United States; Liverpool University and University of Oxford of the United Kingdom.

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.

Clinicians sited in Italy, Canada, and in the United States provided guidance to ensure that clinical considerations were properly integrated into the design. Anesthesiologists from the wards in Lombardy, one of the districts most severely hit by the pandemic, played a key role in providing detailed guidance for the design of the unit. Detailed testing and qualification performance was carried out at Ospedale San Gerardo in Monza, Italy.

The MVM Collaboration is being enthusiastically supported by industry partners who are assessing parts availability, evaluating supply chains, and who will soon carry out the final manufacturing. The laboratory facility for the development of the first units was made available by Elemaster S.p.A. of Lomagna (LC), Italy, which also took primary responsibility for the submission to the U.S. FDA.

Vexos Inc. will manufacture and distribute the MVM Ventilator under an exclusive license with Elemaster for the Americas and other territories. In order to support the demand for MVM Ventilators, Vexos has formed a special task force team with key members of the engineering, quality, supply chain and manufacturing groups at their ISO 13485:2016 (Quality Management Systems for Medical Devices) accredited facilities in LaGrange, Ohio, USA and Markham, Ontario, Canada. Since March, Vexos has been preparing extra manufacturing capacity and a supply chain pipeline for components and materials to meet the expected high demand for MVM ventilators.

To facilitate rapid certification of the final design, additional direction is being provided by the Canadian government, Canada, the US Air Force, the US FDA, the Italian "Ministero della Salute" (Ministry of Health) and the Italian "Istituto Superiore di Sanità".

The MVM design

The MVM ventilator is inspired by the Manley ventilator, which was developed by Roy Manley in 1961, based on "the possibility of using the pressure of the gases from the anesthetic as the motive power for a simple apparatus to ventilate the lungs of the patients in the operating theatre". The MVM is designed to similarly meet the requirements of a ventilator as specified in the

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NEWS possible. The MVM also incorporates advanced features directly recommended by anesthesiologists participating who provided care for COVID-19 patients in Lombard in Italy most severely hit by the COVID-19 epidemics. The MVM features electrically d pneumatic valves rather than mechanical switches and uses a stripped-down mecha This enables fast progress from design to quick, inexpensive mass production of safe ventilators for hospitals and patients around the world. The modular design can also to swap out parts based on their availability in different regions of the world. The final design of the MVM ventilator will soon be released on arXiv.org. It will be lic under the CERN OHL v2.0 by the Fondazione Aria.

Statements:

Cristiano Galbiati: "When, from the inception of the diffusion of pandemics in Italy, it clear that many patients would have needed respiratory assistance, we decided to m available our knowledge and ability to cooperate to build a new, powerful yet safe, a and easy to replicate ventilator. MVM is a new paradigm and shows the incredible ir basic research can have on society, thanks to its unique capacity to generate new kn technological innovation. It also highlights the importance of international and multi collaboration to tackle the big challenges of this new era: at a time when borders bet countries were closed and supply chains were disrupted, our collaboration across bc spread much faster than the virus, moving at the speed of light through the internet inclusion of the MVM within the scope of the FDA EUA for ventilators is a major miles source of great satisfaction: our Mechanical Ventilator Milan is now a reality, and we contribute to saving many lives."

Art McDonald: "We in Canada have been very pleased to participate in the developm new ventilator design. For me personally it has been wonderful to work with an inter team covering such a broad range of expertise, working extremely hard to save lives difficult times. Everyone is very happy that their talents can make a difference, a true humanitarian spirit."

Gabriele Cogliati, President & CEO of Elemaster S.p.a. Electronic Technologies:

"We responded with enthusiasm to the request of collaboration received from the in scientific community coordinated by Professor Cristiano Galbiati and Professor Arthu Physics Nobel laureate 2015. Elemaster put at disposal a full time team of over 40 sp involved in project management, engineering design and process technologies conti circuits boards development and production, with the aim to develop, industrialize a manufacture in record time first prototypes batches of MVM Milano Ventilatore Mecca coordinating other involved companies, too. This product is compliant to all the inter standard requirements of the project, which was made with the full contribution of t international scientific community, and it's revolutionary as it is easy to use and repli other the world"

Direct Links:

Mechanical Ventilator: mvm.care

Funding campaign: gofundme.com/f/emmeviemme

Paper Link:

Open source paper: arxiv.org/abs/2003.10405

Institution Links:

Elemaster: elemaster.com

Vexos: www.vexos.com

INFN Istituto Nazionale di Fisica Nucleare: infn.it

Consiglio Nazionale delle Ricerche: cnr.it

Canadian Nuclear Laboratories: cnl.ca

TRIUMF: triumf.ca

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SNOLAB: snolab.ca

Fermi National Accelerator Laboratory (Fermilab): fnal.gov

Carleton University: carleton.ca

McDonald Institute: mcdonaldinstitute.ca

Princeton University: princeton.edu

Queen's University: queensu.ca

Università degli Studi di Bergamo: unibg.it

Università degli Studi di Brescia: unibs.it

GSSI Gran Sasso Science Institute: gssi.it

Università degli Studi dell'Insubria: uninsubria.eu

Università degli Studi di Milano Bicocca: unimib.it

Università degli Studi di Milano "La Statale": unimi.it

Università degli Studi di Napoli "Federico II": unina.it

Università degli Studi di Pavia: unipv.it

Università degli Studi di Pisa: unipi.it

Università degli Studi di Roma "La Sapienza": uniroma1.it

Politecnico di Milano: polimi.it

APC, CNRS/IN2P3, Université de Paris: www.apc.univ-paris7.fr

MINES ParisTech, Paris: mines-paristech.eu

SUBATECH, CNRS/IN2P3, IMT-Atlantique, Université de Nantes: www.subatech.in2p3

Centro de Investigaciones Energéticas, Medioambientales y Tecnológicas: ciemat.es

Laboratorio Subterráneo de Canfranc: lsc-canfranc.es

AstroCeNT (CAMK PAN): astrocent.camk.edu.pl

University of Toronto: utoronto.ca

Max-Planck-Institut für Physik : www.mpa-garching.mpg.de

Azienda Ospedaliera San Gerardo, Milano: asst-monza.it

Istituto Superiore di Sanità: iss.it

Museo della fisica e Centro studi e Ricerche Enrico Fermi: cref.it

Università degli Studi di Siena: unisi.it

Università degli Studi dell'Aquila: univaq.it

Rochester University: rochester.edu

University of California Los Angeles: ucla.edu

University of Houston: uh.edu

University of Massachusetts: umass.edu

University of Nebraska-Lincoln: unl.edu

Liverpool University: liverpool.ac.uk

University of Oxford: ox.ac.uk

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