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THE UNITED STATES FOOD AND DRUG ADMINISTRATION AUTHORIZES THE MILANO MECHANICAL VENTILATOR (MVM) IN THE EMERGENCY USE AUTHORIZATION SCOPE FOR COVID-19 VENTILATORS | INSTANT NEWS

MAY 12, 2020 | NEWSDESK

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

Opening

In more than one month, from March 19 to May 1, Milano Mechanical Ventilator (MVM) has changed from conception to reality, because it is now turning to production and to support patients who are greatly affected by COVID-19. In May 1 2020, United States Food and Drug Administration (US) stated that [MVM is included in the scope from Emergency Use Authorization \(EUA\)](#) for ventilators.

MVM is an innovative ventilator, designed and designed by the international collaboration of particle physicists and developed in collaboration with other related scientific communities. The mechanical design is simple, using a small number of parts to facilitate fast production. A powerful and complex control unit, programmed by a large number of researchers, produces strong and safe performance for the care and recovery of COVID-19 patients. Achieving this result in the shortest time is possible thanks to the collaboration of laboratories, institutes, universities and companies, especially throughout Italy, Canada and United States of America, maximizing the benefits that come from sharing skills and resources.

MVM Challenge

A small percentage of people infected with COVID-19 can become seriously ill, needing help to breathe. This has created demand for ventilators all over the world. To overcome this critical global problem, the MVM collaboration takes on the challenge of designing, developing, building, and authorizing safe and strong ventilators. A very important feature of MVM is the simplicity of its mechanical design, which allows for fast production. Another important feature is the advanced control system, which provides two ventilation modalities needed for the care of COVID-19 patients, while also ensuring ease of use for medical personnel.

The MVM initiative comes from the Global Matter Dark Matter Collaboration framework GADM Argument, an international scientific collaboration involved in the search for dark matter with experiments at the Gran Sasso Istituto Nazionale Laboratory in Fisica Nucleare at the Gran Sasso Laboratory in Italy and SNOLAB in Canada. This research involves gas handling systems and complex control systems, the same technology that is required in mechanical ventilators.

While in lockdown for the COVID-19 pandemic at Milan, Italy, Cristiano Galbiati (Gran Sasso Institute of Science, INFN and Princeton University), a spokeswoman for the GADM Collaboration, acknowledged the need for additional ventilators at the beginning of the pandemic. He launched the MVM project and began the development of the first prototype. With support from the INFN Italian National Institute for Nuclear Physics; groups from the University of Bergamo, Brescia, GSSI Gran Sasso Science Institute, Insubria, L'Aquila, Milano Bicocca, Milano "La Statale", Napoli "Federico II", Pisa, Pavia, Rome "La Sapienza", Siena; CNR National Research Council; Istituto Superiore di Sanità; Azienda Ospedaliera San Gerardo of Monza; and Elemaster, project leader and coordinator of other companies involved AZ Pneumatica, Saturn Magnetic, Bel Power Europe, Nuclear Instruments, CAEN and Camozzi, the MVM collaboration produced an initial prototype, which fully demonstrated the feasibility of conceptual design.

Laboratory facilities for the development of the first unit are provided by Elemaster S.p.A from Lomagna (LC), Italy. In addition to creating an MVM controller printed circuit board at home, Elemaster also led the assembly and prototype testing in collaboration with the partner companies involved. The Elemaster International Design Center, as the design authority of MVM, leads the shipment to the US FDA. laboratory facilities for the development of fi

This collaboration quickly developed to include three national laboratories in Indonesia Canada, including Canadian Nuclear Laboratories (CNL), TRIUMF and SNOLAB, through the leadership of the Nobel Prize winner, Dr. Arthur McDonald Queen's University.

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

European collaboration also includes researchers from: Politecnico di Milano and Museo della Fisica e Centro Study and Ricerche Enrico Fermi from Italy; APC, SUBATECH and Mines Paris Tech of France; CIEMAT and LSC, CAPA-UZ and ARAD from Spanish; AstroCeNT (CAMK PAN) from Poland; MPA Garching from German; University of Toronto from Canada; University of Rochester, University of California Los Angeles, The University of Houston, University of Massachusetts at Amherst, University of Nebraska-Lincoln United States of America; Liverpool University and Oxford University from great Britain.

Getting an MVM ventilator for patients requires collaboration outside nuclear and particle physicists. Government departments, regulators, producers and health service providers have made valuable contributions to the project.

The doctor sits on Italy, Canada, and enter United States of America provide guidance to ensure medical considerations are well integrated into the design. Anesthesiologists from the COVID-19 ward at Lombardy, one of the most severely affected pandemic districts, played a special role in providing detailed guidance for unit design. Detailed testing and performance qualifications were carried out at Ospedale San Gerardo in Monza, Italy.

The MVM collaboration is being enthusiastically supported by industry partners who assess spare parts availability, evaluate supply chains, and who will soon undertake mass manufacturing. Laboratory facilities for the development of the first unit are provided by Elemaster S.p. from Lomagna (LC), Italy, which also bears the primary responsibility for shipping to the U.S. US

Vexos Inc. will produce and distribute the MVM Ventilator under an exclusive license from Elemaster for America and other regions. To support MVM Ventilator requests, Vexos has formed a special task force team with key members of the engineering, quality, supply chain and manufacturing groups at ISO 13485: 2016 (Medical Devices Quality Management System) for their accredited facilities at LaGrange, Ohio, USA and Markham, Ontario, Canada. Since March, Vexos has been preparing additional production capacity and increasing supply chain pipelines for components and materials to meet the high demand for MVM ventilators.

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

MVM design

The MVM ventilator was inspired by Manley's ventilator, which was developed by Roger Manley in 1961, based on "the possibility of using gas pressure from an anesthetic machine as a motive force for a simple tool for ventilating the patient's lungs in the operating room". MVM is designed to meet ventilator requirements in the simplest possible way. MVM also incorporates advanced features that are directly recommended by participating anesthesiologists who provide care for COVID-19 patients at Lombardy, region in Italy the most severely affected by the COVID-19 epidemic. MVM features pneumatic valves that are electrically driven rather than mechanical switches and use a mechanical design that is stripped. This enables rapid progress from design to the production of fast, inexpensive, safe and reliable ventilators for hospitals and patients throughout the world. Modular designs can also be adapted to exchange components based on their availability in various regions of the world.

The final design of the MVM ventilator will be released soon [arXiv.org](https://arxiv.org). It will be licensed under CERN OHL v2.0 by Fondazione Aria.

Statement:

Cristiano Galbiati: "When, since the beginning of the pandemic diffusion in Indonesia Italy, it became clear that many patients would need respiratory assistance, we decided to provide our knowledge and ability to work together to build a new ventilator, strong but safe, accessible, and easily imitated. MVM is a new paradigm and shows the extraordinary impact that basic research can have on society, thanks to its unique capacity to produce new knowledge and technological innovation. It also highlights the importance of international and multidisciplinary collaboration to overcome the challenges of this new era: when borders between countries are closed and supply chains disrupted, our cross-border collaboration spreads much faster than viruses, moving light rapidly through the fiber of the internet. The inclusion of MVM within the EUA FDA scope for ventilators is a major milestone and a source of great satisfaction: Our Mechanical Ventilator Milan is now a reality, and we hope this will contribute to saving many lives. "

McDonald's Art: "We are at Canada very happy to participate in the development of this new ventilator design. For me personally, it's wonderful to work with an international team that covers a variety of skills, working very hard to save lives in these difficult times. Everyone is very happy that their talents can make a difference, true human spirit. "

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

"We respond enthusiastically to collaborative requests received from the international scientific community coordinated by Professor Cristiano Galbiati and professor Arthur McDonald, 2015 Nobel Physics Winner. Elemaster provides a full-time team of more than 40 specialists involved in project management, engineering design and process technology control, development and production of printed circuit boards, with the aim of developing, industrializing, and producing in time short. MVM Milano Ventilatore Meccanico's prototype batch, coordinating other companies involved as well. This product complies with all the international standard requirements of the project, which was made with the full contribution of the international scientific community, and it is revolutionary because it is easy to use and can be copied all the others in the world "

Direct Link:

Mechanical ventilator: mvm.care

Funding campaign: gofundme.com/f/emmeviemme

Paper Link:

Open source paper: arxiv.org/abs/2003.10405

Institutional Link:

Elemaster: elemaster.com

Vexos: www.vexos.com

INFN Istituto Nazionale at Fisica Nucleare: inf.it

Consiglio Nazionale delle Ricerche: cnr.it

Canadian Nuclear Laboratory: cnl.ca

TRIUMF: triumf.ca

SNOLAB: snolab.ca

Fermi National Acceleration Laboratory (Fermilab): fnal.gov

Carleton University: carleton.ca

McDonald Institute: mcdonaldinstitute.ca

Princeton University: princeton.edu

Queen's University: queensu.ca

Università degli Studi in Bergamo: unibg.it

Degli University of Studies in Brescia: unibs.it

Gran Sasso GSSI Science Institute: gssi.it

Università degli Studi dell'Insubria: uninsubria.eu

Degli University of Studies in Milano Bicocca: unimib.it

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

Laboratorio Subterráneo de Canfranc: isc-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 studie Ricerche Enrico Fermi: cref.it

Degli University Studies in Siena: unisi.it

University of Degli Studies dell'Aquila: univaq.it
University of Rochester: rochester.edu
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