MILANO VENTILATORE MECCANICO

PRESS RELEASE

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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-19 VENTILATORS

In a little more than six weeks, 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 support of patients affected severely by COVID-19. As of 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.

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. Its mechanical design is simple, using a small number of parts to facilitate rapid production. The powerful and sophisticated control unit, programmed by a large number of researchers, results in strong and safe performance for the care and recovery of COVID-19 patients. Achieving this result in 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 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. 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 modes 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 with experiments at Istituto Nazionale di Fisica Nucleare's Gran Sasso Laboratory in Italy and SNOLAB in Canada. 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 (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 MVM project, and started the development towards a first prototype. With support from INFN Italy's National Institute for Nuclear Physics; groups from the Universities of Bergamo, Brescia, GSSI Gran Sasso Science Institute, Insubria, L'Aquila, Milano-Bicocca, Milano La Statale, Napoli Federico II, Pisa, Pavia, Roma Sapienza, Siena, CNR National Research Council, Istituto Superiore di Sanità, Azienda Ospedaliera San Gerardo of Monza. The MVM project engaged industry and Elemaster, the project leader has coordinated with several companies including AZ Pneumatica, Saturn Magnetic, Bel Power Europe, Nuclear Instruments, CAEN and Camozzi. The MVM collaboration produced an initial prototype, which 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 in-house, Elemaster also led the assembly and prototype testing in collaboration with the partner companies involved. The Elemaster International Design Center, as MVM design authority, led the submission to the U.S. FDA.

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

The US collaboration includes people from Fermi National Accelerator Laboratory (Fermilab) and 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 Museo della Fisica e Centro Studi e Ricerche Enrico Fermi of Italy; APC, SUBATECH and Mines Paris Tech of France; CIEMAT, LSC, CAPA-UZ and ARAID of Spain; AstroCeNT (CAMK PAN) of Poland; MPA 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 medical considerations were properly integrated into the design. Anesthesiologists from the COVID-19 wards in Lombardy, one of the districts most severely hit by the pandemics, played a special 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 mass 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. The Vexos Corporation is engaged to establish production sites in Canada and in the U.S.A.

To facilitate rapid certification of the final design, additional direction is being provided by Health 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 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 similarly meet the requirements of a ventilator as simply as possible. The MVM also incorporates advanced features directly recommended by participating anesthesiologists who provided care for COVID-19 patients in Lombardy, the region in Italy most severely hit by the COVID-19 epidemics. 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.

The final design of the MVM ventilator will soon be released on arXiv.org. It will be licensed under the CERN OHL v2.0 by the Fondazione Aria.

STATEMENTS:

Cristiano Galbiati: "When, from the inception of the diffusion of pandemic in Italy, it became clear that many patients were going to need respiratory assistance, we decided to make available our knowledge and ability to cooperate to build a new, powerful yet safe, accessible, and easy to replicate ventilator. MVM is a new paradigm, and shows the incredible impact that basic research can have on society, thanks to its unique capacity to generate new knowledge and technological innovation. It also highlights the importance of international and multidisciplinary collaboration to tackle the big challenges of this new era: at a time when borders between countries were closed and supply chains were disrupted, our collaboration across borders spread

much faster than the virus, moving at the speed of light through the internet fibers. The inclusion of the MVM within the scope of the FDA EUA for ventilators is a major milestone and a source of great satisfaction: our Mechanical Ventilator Milan is now a reality, and we hope it will contribute to saving many lives."

Art McDonald: "We in Canada have been very pleased to participate in the development of this new ventilator design. For me personally it has been wonderful to work with an international team covering such a broad range of expertise, working extremely hard to save lives in these 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 international scientific community coordinated by Professor Cristiano Galbiati and Professor Arthur McDonald, Physics Nobel laureate 2015. Elemaster put at disposal a full time team of over 40 specialists involved in project management, engineering design and process technologies control, printed circuits boards development and production, with the aim to develop, industrialize and manufacture in record time first protypes batches of MVM Milano Ventilatore Meccanico, coordinating other involved companies, too. This product is compliant to all the international standard requirements of the project, which was made with the full contribution of the international scientific community, and it's revolutionary as it is easy to use and replicable all over 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
INFN Istituto Nazionale di Fisica Nucleare: infn.it
Consiglio Nazionale delle Ricerche: cnr.it
Canadian Nuclear Laboratories: cnl.ca
TRIUMF: triumf.ca
SNOLAB: snolab.ca

McDonald Institute: mcdonaldinstitute.ca
Carleton University: carleton.ca
Fermi National Accelerator Laboratory (Fermilab): fnal.gov
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.fr
SUBATECH, CNRS/IN2P3, IMT-Atlantique, Université de Nantes: www-subatech.in2p3.fr
Centro de Investigaciones Energéticas, Medioambientales y Tecnológicas: ciemat.es
Centro de Astropartículas y Física del Altas Energías, Universidad de Zaragoza: capa.unizar.es
Fundacíon Agencia Aragonesa para la Investigacíon y el Desarrollo: www.araid.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 : mpp.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
University of Rochester: rochester.edu
University of California Los Angeles: ucla.edu
University of Houston: uh.edu
University of Massachusets: umass.edu
University of Nebraska-Lincoln: unl.edu
Liverpool University: liverpool.ac.uk
University of Oxford: ox.ac.uk

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