MVM Milano Ventilatore Meccanico





Fernando Ferroni Gran Sasso <mark>Science</mark> Institute & INFN



An amazing story

- March 21, 2020: An international collaboration initiates a project to develop an innovative, robust, low cost, as open as possible, easy to make Mechanical Ventilator in view of the possible needs caused by COVID-19 crisis
- March 31, 2020: A solid version of the design on arXiV (<u>https://arxiv.org/abs/2003.10405v2</u>) [last revised on Aril 10]

continued....

- April 3, 2020: First test on lung simulator at Ospedale San Gerardo (Monza)
- May 5, 2020: FDA authorises the MVM within the scope of emergency use
- September 30, 2020: Vexos receives Health Canada authorisation for the manufacture of the MVM ventilator

a real speed record

- 6 months from conceptual design to certification
- for such a complex medical device a real achievement

Outline

- why ?
- how ?
- Technicalities
- INFN role
- achievement
- lesson learned
- what next ?

Why ?

- in March there was the sense of tragedy looming over North Italy (Lombardy in particular) and the bad feeling that COVID-19 would not stop soon to jeopardise the life of many communities and nations
- Physicists always claim to be able to bring real benefit to society. If not in this occasion, when ?
- Let's say ...a social duty

at the time

Setting the stage

9% of patients hospitalised for COVID-19 in Lombardy needed intensive care

Setting the stage (ii)

Out of which 88% needed invasive mechanical ventilation

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the idea

- Cristian Galbiati was in Milano observing the developing tragedy.
- He shared his willing to do something with Art McDonald and they came out with the fact that DarkSide collaboration would have had a lot of expertise with 'gases' and 'tools to operate them'
- Cristian knows very well the industrial substrate of Brianza and had vey good relations with local companies

How

- Convince DarkSide collaboration to coalesce on this project
- involve other good willing institutions (Fermilab....) and people
- anchor the project on a local company (Elemaster S.p.A in Lomagna)
- get medical doctors (pneumologists) of Milano Bicocca
- create a working structure that looks like a particle physics experiment
- embark a Technical coordinator with the proper experience (prof. Carlo Mapelli from PoliMi)

The key

Synergy between research institutions, medical doctors and industry from the beginning of the project

no one had an idea on how a ventilator looks like, so...

961

A new mechanical ventilator

ROGER W. MANLEY, DA

Senior House Officer, Department of Clinical Measurement Westminster Hospital





FIG. 1 The ventilator



FIG. 2 Diagram of the ventilator showing mechanism

structure and workflow

- Electronics group
- Mechanical group
- Integration group
- Software group
- Medical interface group
- Communication group

Spokesperson

Steering board

how do you work in pandemics time and red zones

- Zoom, zoom, zoompeople having access to labs (CNL, SNOLAB, TRIUMF, Fermilab, INFN unitsandElemaster S.p.A)
- A general meeting every day at 5p.m. CET
- Working group meetings almost daily following GM
- Steering board meeting daily at 9 p.m.
- Working in two so different time zones a big advantage

Principles

- Make it simple
- Use components off the shelves and as cheap as possible
- Make the design free (and this part deserves a complex discussion)

Pro's

- it was an unbelievable experience, a lifetime one for many. A reassurance that our job is indeed beneficial to entire society
- the experimental proof that if you forget the need to go through tenders disciplined 'codice degli appalti', official searches for industrial partners, MoU signed by many institutions
- the demonstration that companies are indeed able to fully understand our way of doing and make full use of it

Con's

- impossibility to quantify our contribution in terms of financial rewarding
- Vexos (Canada-US manufacturing company) has signed a contract of ~ 100 MCan\$'s
- still debating how much could come back to Fondazione Aria (the brand owner). Say 2.5 % ?
- the hurdles of making the design of the product 'really' free. The complication brought by being a medical device

Technicalities

Definitions

Principles of mechanical ventilation

Analogue to electrical circuit

Resistance (R) describes the opposition to a gas flow entering the respiratory system during inspiration, which is caused by frictional forces. Resistance is calculated as the ratio between the pressure driving a given flow and the resulting flow rate (\dot{V}). R = $\Delta P / \dot{V}$ (the analogue of ΔV = I R in electricity) The dimension of resistance is usually cmH₂O/(L/s).

Compliance

Resistance



Compliance (C) describes the elastic property of the respiratory system including the lung and the chest wall. $C_{STAT} = V_T/\Delta P$ (change in lung volume/change in trans pulmonary pressure) The dimension of compliance is usually mL/cmH₂O

Modes of operation

Possibile ventilation strategies

Used by MVM: PCV and PSV



Neil R MacIntyre, Respiratory Care January 2011, 56 (1) 73-84; DOI: https://doi.org/10.4187/respcare.00953

Schematics



Flow diagrams



Looking inside





More pic's



and finally

The nightmare

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as you cannot read, I'll magnify few of the sixty-three lines

Issue	Activity	System Component	Lead	Workforce	Document Name	First Draft	Review Draft	MVM Reviewer	MVM Review	DA Reviewer Editor
4.2	Software Implementation (Code)	sv	Dario Pennisi	Fabrizio Guglielmo	No Document Required			No Review Required		No DA Check Required
4.3.	Software Implementation (Code)	GUI	Marco Del Tutto	Carmelo Pellegrino	No Document Required			No Review Required		No DA Check Required
4.4.	Software Implementation (Code)	DRs	Alessandro Razeto	-	No Document Required			No Review Required		No DA Check Required
4.5.	Unit Test Procedure and Stubs	FW	Angelo Gargantini	Andrea Bombarda Michele Benzi Francesco Prelz Vicente Pesudo	<u>MVM-UTP-001-Firmware</u>			Patrizio Pelliccione		No DA Check Required
4.6.	Unit Test Procedure and Stubs	sv	Dario Pennisi	Massimiliano Agneni Fabrizio Guglielmo	MVM-UTP-002-Supervisor			Patrizio Pelliccione		Stefano Manni
4.7.	Unit Test Procedure and Stubs	GUI	Angelo Gargantini	Andrea Bombarda Mariusz Suchenek	MVM-UTP-003-GUI			Patrizio Pelliccione		No DA Check Required
4.8.	Unit Test Procedure and Stubs	DRs	Bryerton Shaw	-	MVM-UTP-004-Drivers			Patrizio Pelliccione		No DA Check Required
4.9.	Unit Test Report	FW	Angelo Gargantini	Andrea Bombarda Silvia Bonfanti	MVM-UTR-001-Firmware			Patrizio Pelliccione		Report to Be Checked for Full Success

No software certification demonstrated by proper documentation, no MVM authorisation !

Testing

Testing at Elemaster

O. Putignano,

C. Galbiati, N. Papini

in many places

Testing at the hospital J.Raaf, E. Gramellini and E.Dahl

In Cook Chicago County Hospital

Testing at TRIUMF

R.Krucken et al.

Testing at the hospital 0.Putignano, G. Foti, G. Bellani In Ospedale San Gerardo, Monza, Italy

if you want to know more

- <u>https://indico.cern.ch/e/MVM</u> on July 30, 2020 (from which I have stolen most of the material, thanks Walter !)
 [C. Galbiati, W. Bonivento, O. Putignano]
- a paper has been submitted to Physics of Fluids (not yet published)

The novel Mechanical Ventilator Milano for the COVID-19 pandemic

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An unavoidable comment

- ~ 240 authors (~ 30 from INFN area)
- representing 73 affiliations (~10 units from INFN)
- put together in pandemics time, with almost null physical contacts and a lot of individuals
- weren't we travelling too much ?

INFN contributions to MVM (staff only)

Bologna

- E. Scapparone
- Electronics coordination.

Cagliari

- W. Bonivento, M. Caravati
- Documentation, paper writing, outreach activities.

CNAF

S. Antonelli, C. Pellegrino, F. Giacomini, S. Longo

- Software coordination;
- User Interface and real time control system software development;
- MVM web site.

LNGS

I. Kochanek, A. Razeto, D. Sablone

- •Motherboard PCB design;
- •MVM Unit functional test;
- •Control system design and firmware development;
- •Control system performance optimization.

Milano

F. Prelz

•Graphic User Interface software development.

What is MVM now

- a commercial product distributed by VEXOS in Canada
- available for 'less developed countries' as a charity action by Canadian gov't (ongoing actions)
- ~6000 machines in stock in Canada, 1000 more finished, 3000 almost finished
- Italian production at Elemaster S.p.A not going as CE not given yet

SERVICES & SOLUTIONS VEXOS ADVANTAGES MARKETS CERTIFICATIONS

MVM Ventilator

Request Information

Support and Training

Introducing the MVM Mechanical Ventilator

Manufactured by VEXOS in North America

KEY FEATURES

- LARGE SCALE PRODUCTION
- LOW COST
- SIMPLICITY OF CONSTRUCTION
- CONVENIENCE OF DEPLOYMENT
- CUSTOMIZABILITY
- COMPACT UNIT
- USER FRIENDLY
- EASY SET UP

This ventilator is a low cost solution for providing ventilatory support for patients suffering from COVID-19.

Have we got were we hoped?

- The machine has been a success, it works
- It is a low cost, easy to make using components readily available, object
- Most of the cost to the customer comes from maintenance that as for all medica devices is a long term engagement
- If you would do for charity it would come at 2k\$ likely
- VEXOS charge 10kCAN\$ all included

anything wrong ?

 The difficulty with european CE that stalled Elemaster from becoming a global producer. Entirely due to slow approach of the 'Organismo notificato' [IMQ] that is dealing with the issue. Certification of medical devices in Europe is a bit of a mess (info crosschecked with ISS experts). Certification expected by mid-March.

not completely irrelevant

PANDEMIA

I 300 ventilatori fuori uso «Così è impossibile fare nuove terapie intensive»

di Lorenza Castagneri

Prodotti dalla Siare engineering di Bologna e inviati in Piemonte dal commissario Domenico Arcuri, ora sono abbandonati

the most serious issue

- Except for the schematics shown in the arXiV paper nothing else has been given to potential companies that could have produced the machine
- on one side that was probably enough for a smart company, certainly insufficient for many
- why so....two issues were considered

open access problem

- Availability of components. The ability of producing low cost and speedy relies on a supply chain that guarantee a timely distribution. If many tries to acquire the same components one could run in trouble. One of the unit comes from a company that is unable to ramp up production in case of world wide request.
- Risk to end up in court if something goes wrong with a machine built by somebody on your detailed design that includes a list of components. Long discussions with CERN TT lawyers convinced us that the case was beyond our ability to deal properly with it in a very short time. Actually this consideration was part of the decision of CERN to stop their effort on the same scope.
- Still many were unhappy of this ending. Let me be clear there is no patent behind MVM, except for the brand.

An interesting reflection on private-public connections

When nothing is certain, anything is possible: open innovation and lean approach at MVM

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An interesting manual on how-to

Phase	Challenges faced	How these challenges were overcome				
Concept/seed	Respond promptly to the dramatic need for mechanical ventilators during the COVID-19 pandemic	Vision to recognize an opportunity Resilience and willingness to help				
	Translate the vision into MVM: the	High level of related knowledge				
	first conceptualization	Excellence in research				
		Self-confidence				
	First collaborators' involvement	Project lead reputation and international network				
	Freedom-to-operate analysis	Standard device parts selected				
	Funding	Crowdsourcing				
	Lockdown	Use of new technologies to ease communication				
MVP and prototyping	Multidisciplinary and specific knowl-	University as a platform				
	edge required	New partners joining				
		One-shot collaborations				
	User testing	Users' involvement (physicians of Monza Hospital)				
		Lead users				
	Coordination	Strong leadership				
		Strong commitment of all participants				
	Time constraints	Speed up response time and learning process				
	Movement limitations due to the lockdown	Involvement of private and public part- ners located in the Lombardy region (for instance, Elemaster S.p.a and Monza Hospital)				
IP management and production	Decision of the IP protection level	CERN Open Hardware license				
	Product liability	Manufacturing firms are responsible for manufacturing and maintenance				

a bit of self celebration

The success of the MVM case is unique as it adopts open innovation practices to generate technology innovation, in addition to a lean perspective. Through the MVM project description, this study offers a framework that explains the interplay between open innovation and lean approach, highlighting the different internal and external forces and types of collaborations, and offering fine-grained insights into the role of universities as platforms of multidisciplinary knowledge. This framework might serve as a basis for future theoretical and empirical research, providing practitioners with new best practices that are essential when facing a severe crisis like COVID-19.

what next/ conclusion

- I believe that, although under very special circumstances, we have shown that an interaction public-private can be an extraordinary success
- In the market of medical devices there is a lot of space to fill with this logic, of course, complemented by formal agreements that guarantees respect of IP and a fair share of the revenues