MVM
Milano Ventilatore Meccanico

Fernando Ferroni
Gran Sasso Science 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 (https://arxiv.org/abs/2003.10405v2) [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

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…

A new mechanical ventilator

1961

ROGER W. MANLEY, DA

Senior House Officer, Department of Clinical Measurement
Westminster Hospital

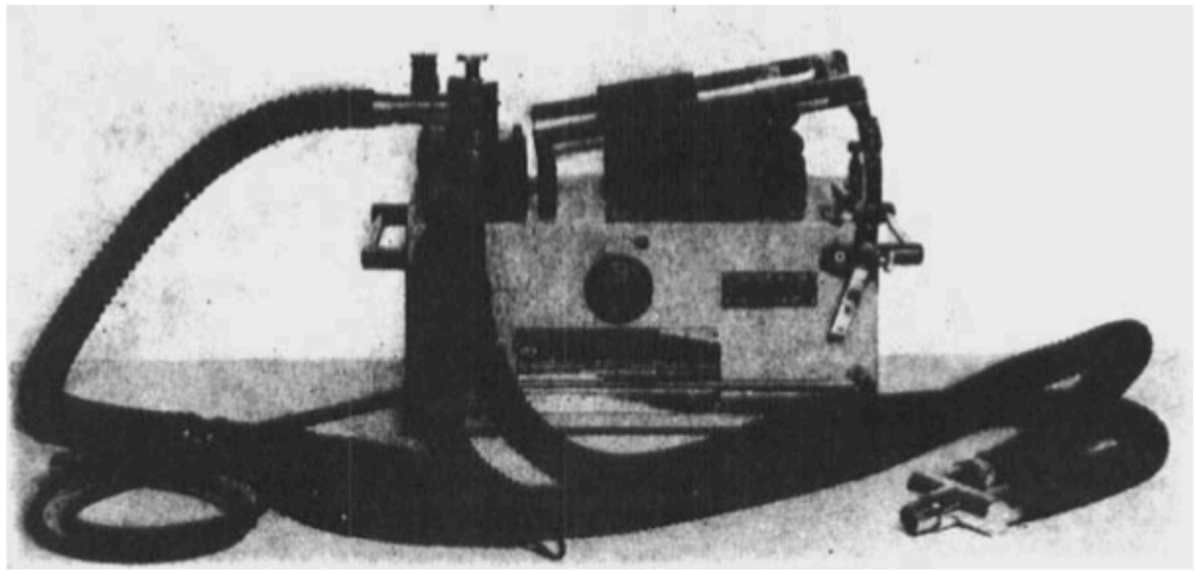
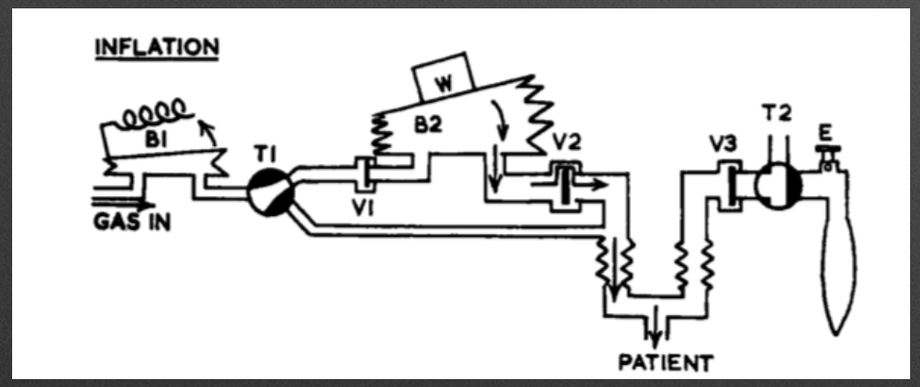
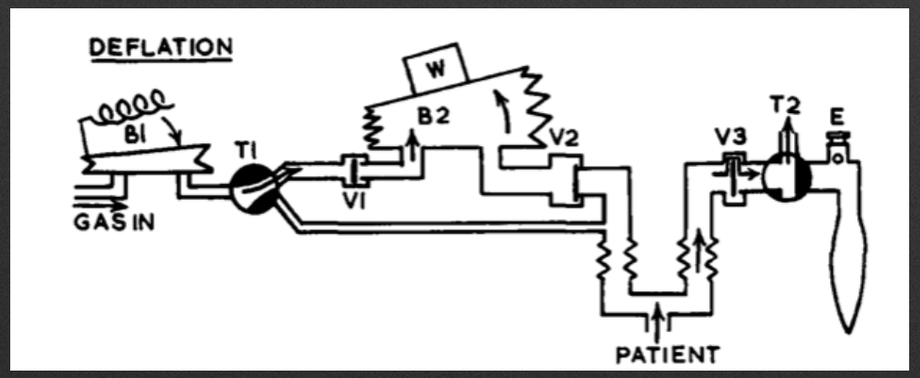


FIG. 1 The ventilator





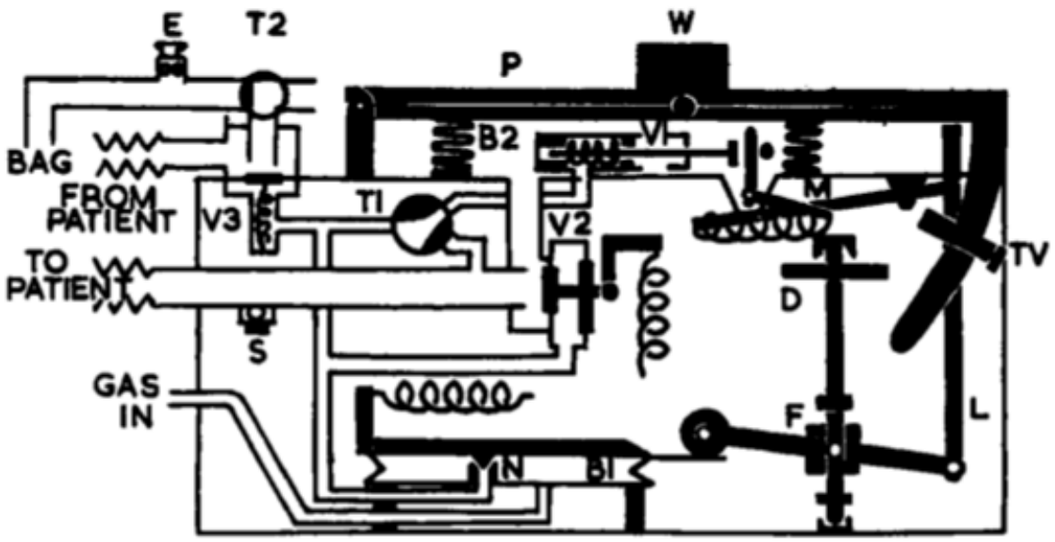


FIG. 2 Diagram of the ventilator showing mechanism

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, zoom ….people having access to labs (CNL, SNOLAB, TRIUMF, Fermilab, INFN units ….and ….Elemaster 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

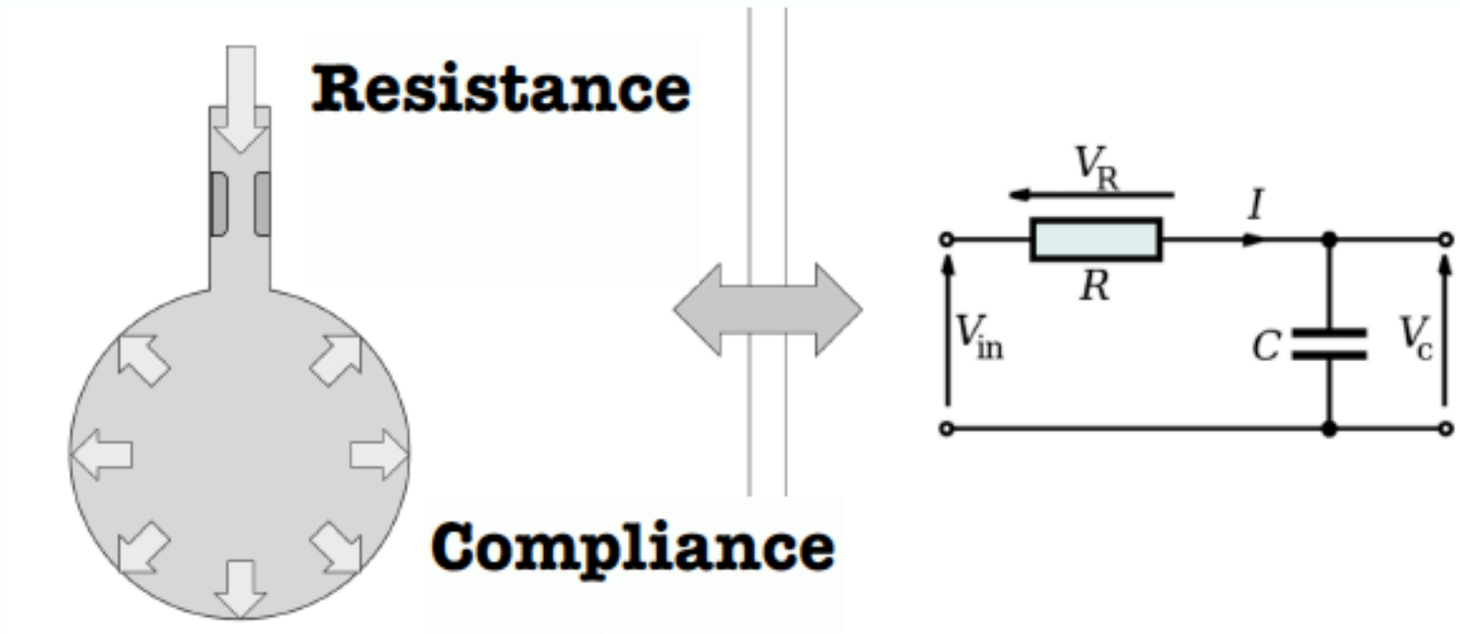
- impossibility to quantify our contribution in terms of financial rewarding
- Vexos (Canada-US manufacturing company) has signed a contract of ~ 100 MCan$’s
- still debating how much could come back to Fondazione Aria (the brand owner) . Say 2.5 % ?
- the hurdles of making the design of the product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

Technicalities

Definitions

Principles of mechanical ventilation

Analogue to electrical circuit



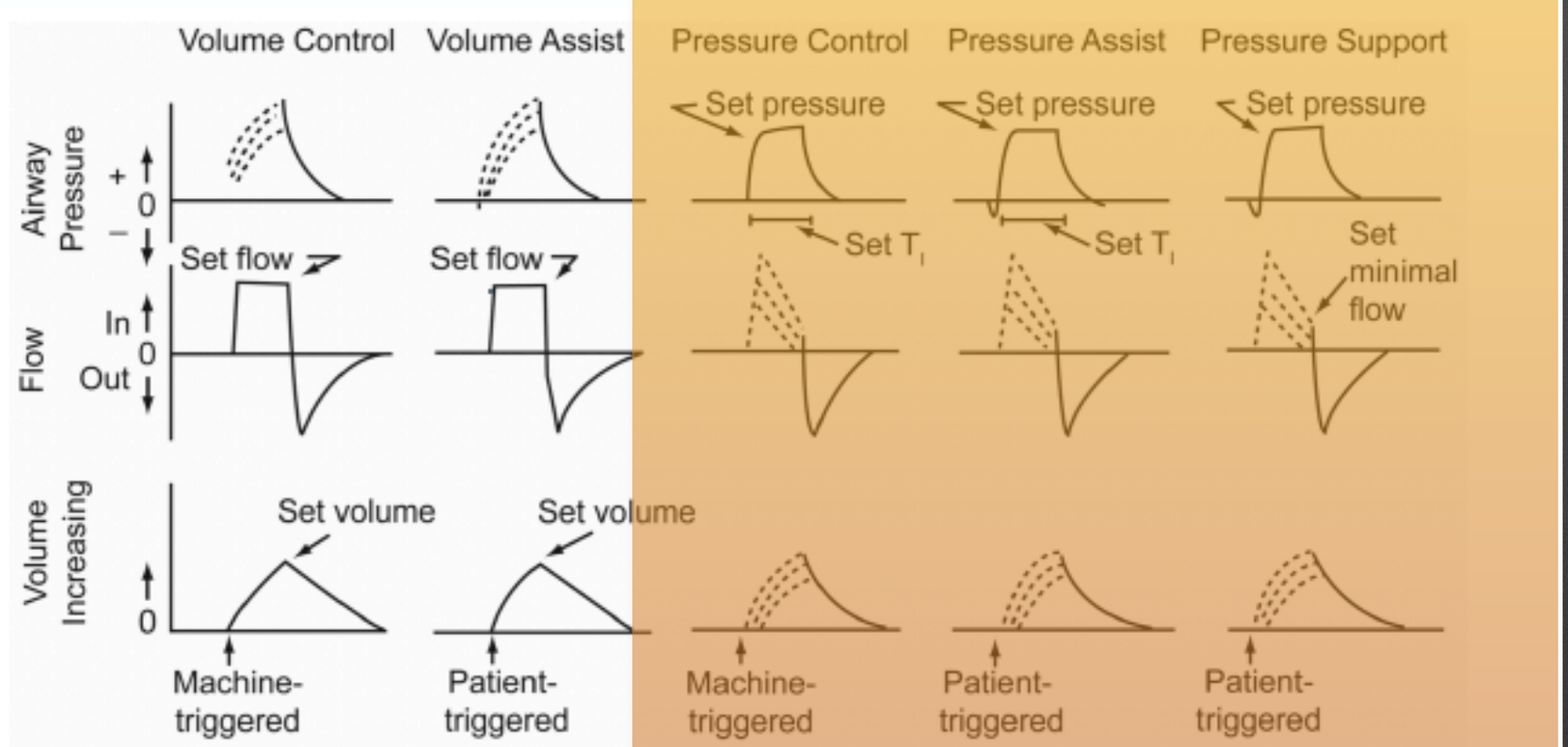
Resistance (R) describes the opposition to a gas flow entering the respiratory system during inspiration, which is caused by frictional forces. Resistance is calculated as the ratio between the pressure driving a given flow and the resulting flow rate ($\dot{V}$).
$R = \Delta P / \dot{V}$ (the analogue of $\Delta V = I R$ in electricity)
The dimension of resistance is usually $cmH_2O/(L/s)$.

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/cmH_2O

Modes of operation

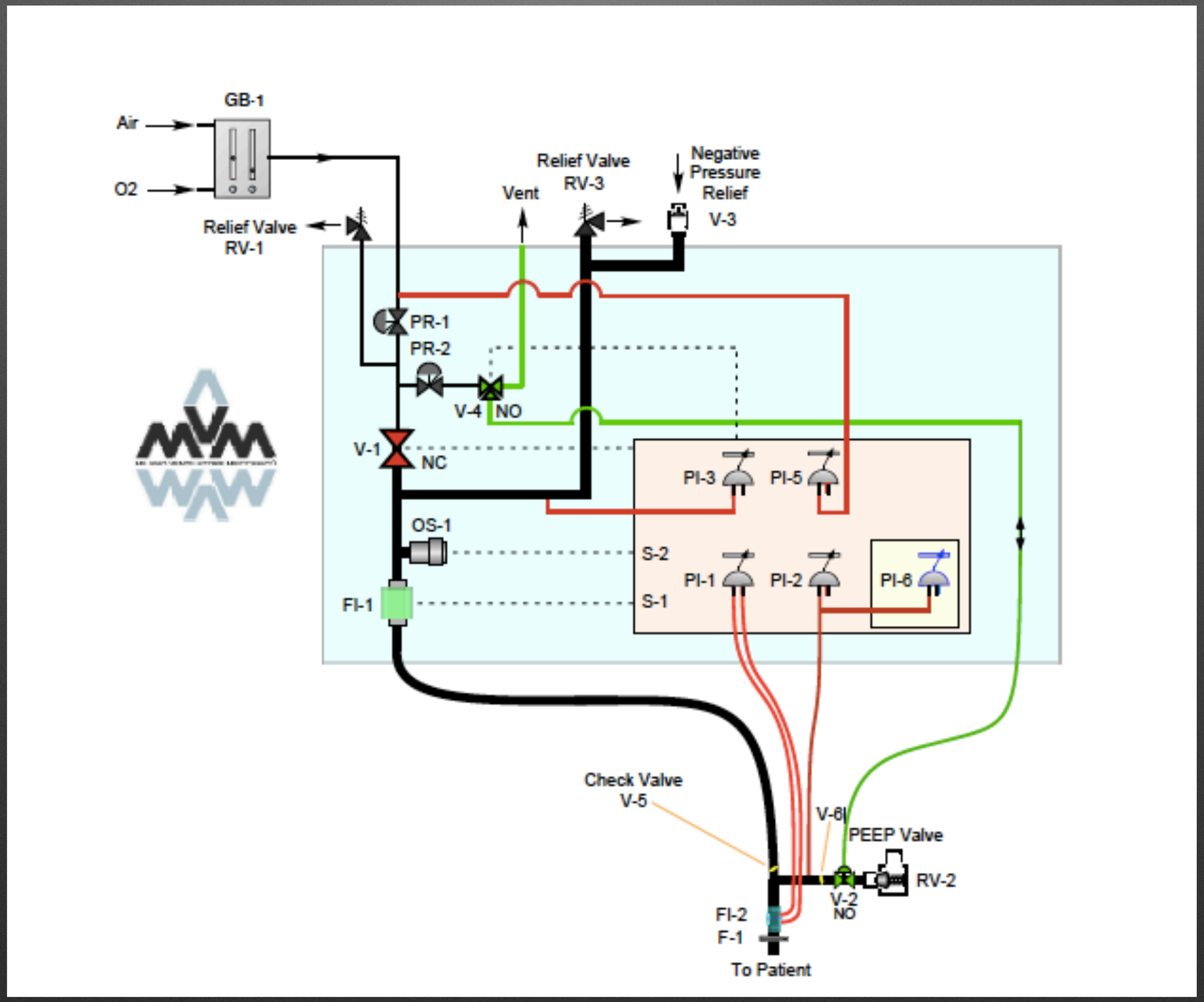
Possibile ventilation strategies

Used by MVM: PCV and PSV

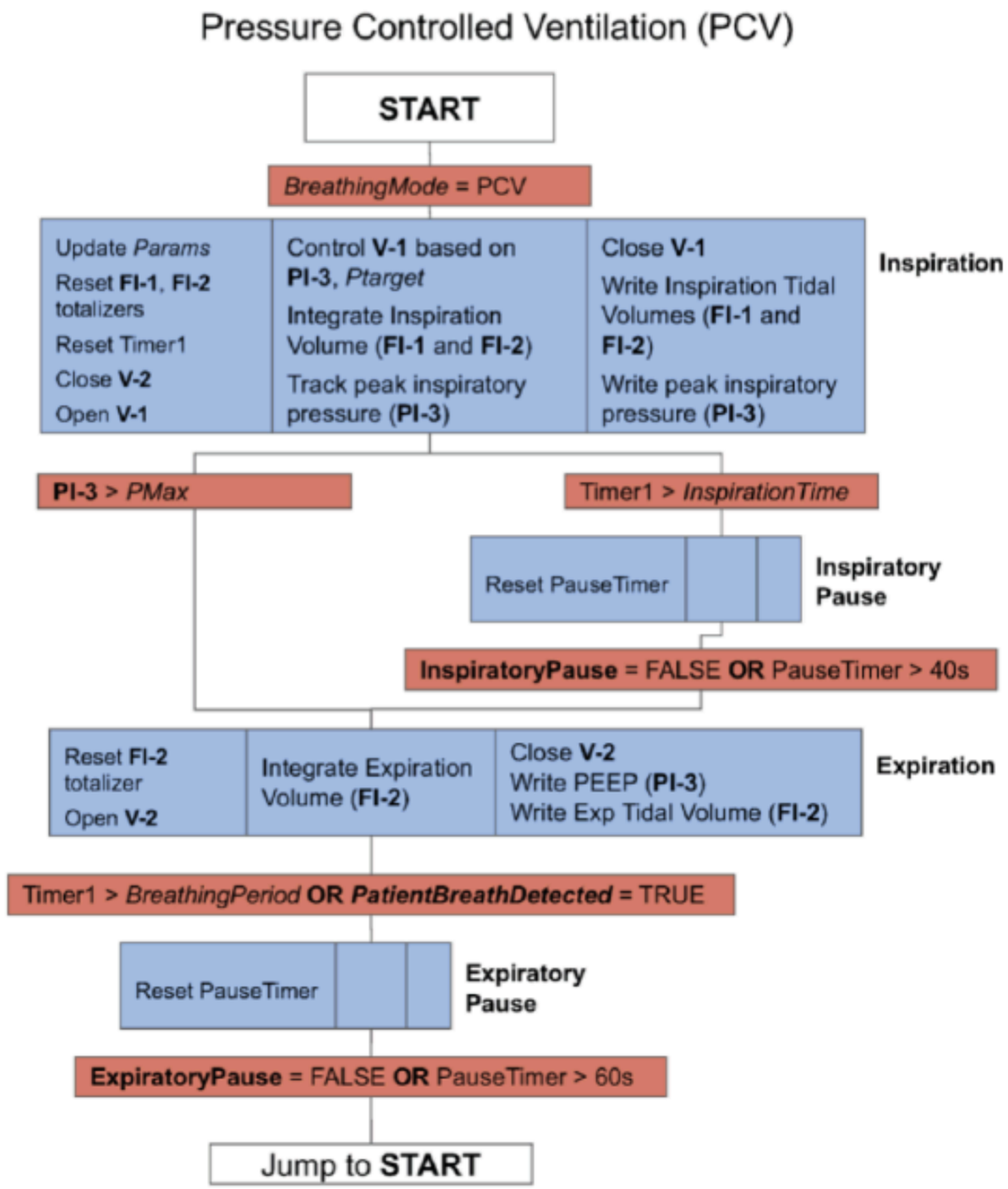


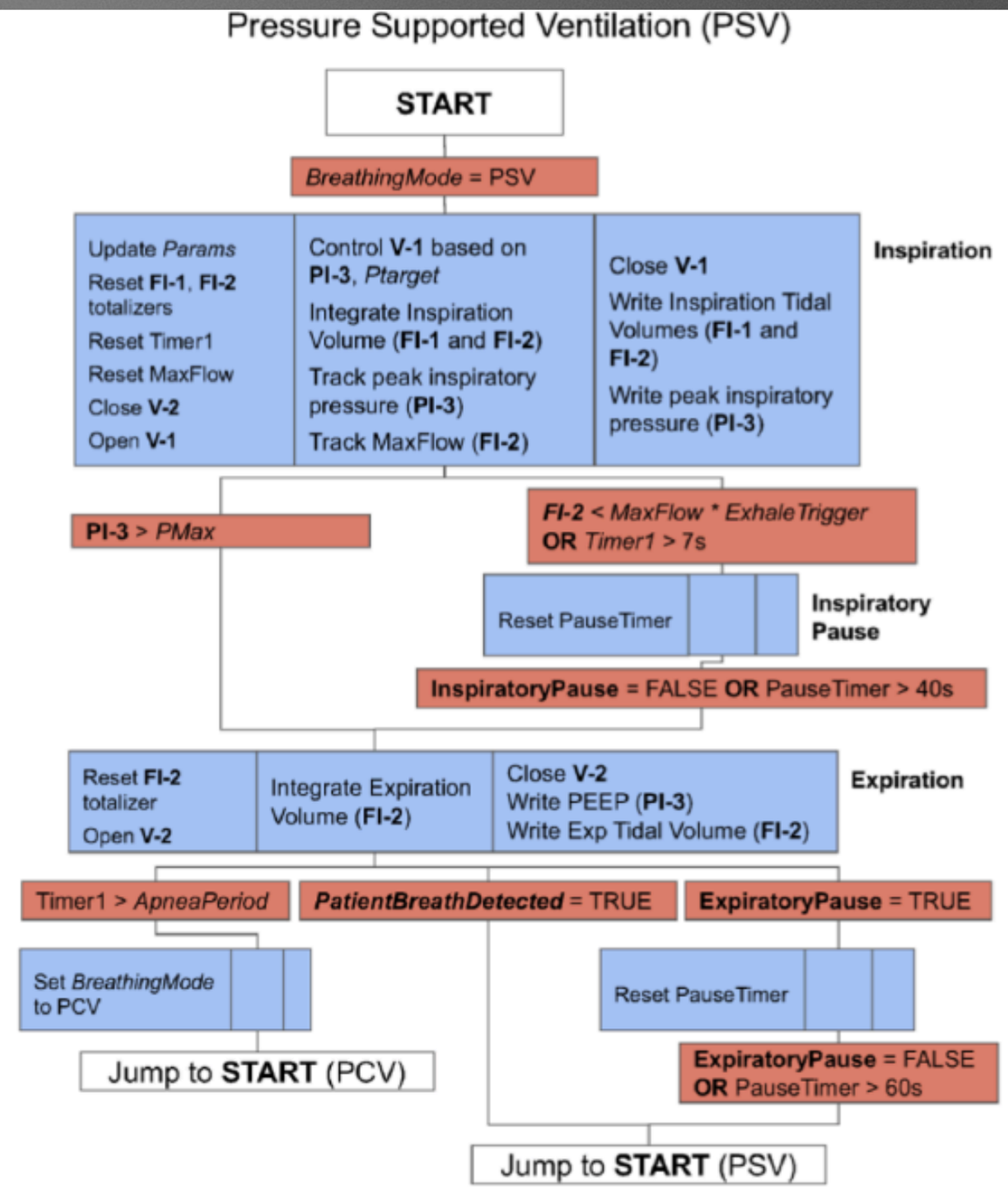
Neil R MacIntyre, Respiratory Care January 2011, 56 (1) 73-84; DOI: https://doi.org/10.4187/respcare.00953

Schematics

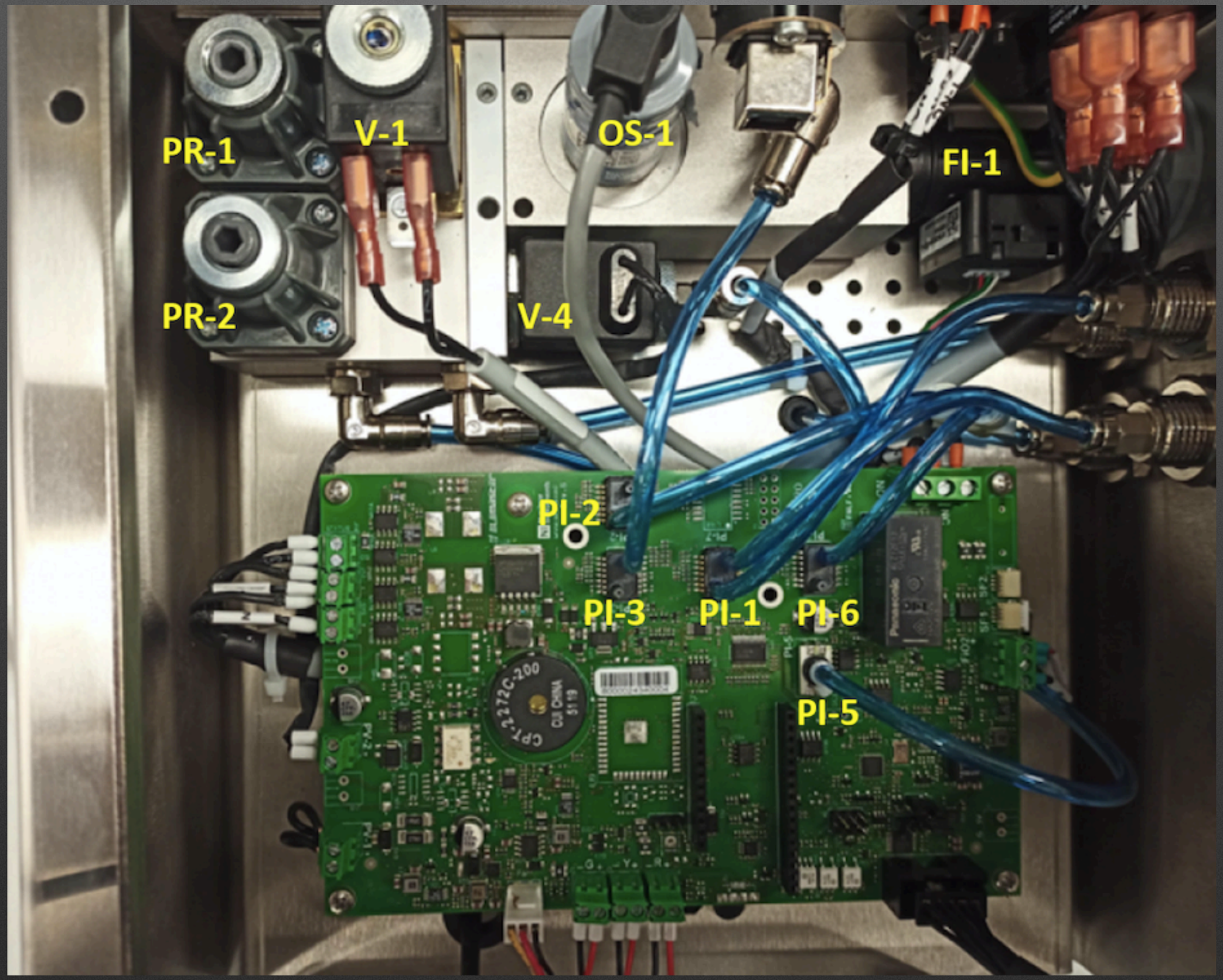

GB-1
Air
O2
Relief Valve
RV-1
Vent
Relief Valve
RV-3
Negative
Pressure
Relief
V-3
PR-1
PR-2
V-4
NO
V-1
NC
PI-3
PI-5
OS-1
S-2
PI-1
PI-2
PI-6
FI-1
S-1
Check Valve
V-5
V-6
PEEP Valve
RV-2
V-2
NO
FI-2
F-1
To Patient

Flow diagrams





Looking inside



Pictures

More pic's


S1
USB
12 V
NEVER
DISCONNECT
Connect only to
BPEU4035
EMERGENCY
INTAKE VALVE
DO NOT
OBSTRUCT
PATIENT
HIGH-PRESSURE
RELIEF VALVE
DO NOT REMOVE
OR OBSTRUCT
DEVICE
HIGH-PRESSURE
RELIEF
VALVE
MEDICAL
AIR+O2
3.7 - 5.2 bar
100 l/min


MVM Mechanical Ventilator
Model: MVM Basic
REF 000-95991
VEXOS
IP22
SN
FLOW SENSOR
PATIENT
SIDE
MVM
SIDE
PATIENT
PORT
PRESSURE
PORT
EXPIRATORY
VALVE


O2
INLET
AIR
INLET


CENTER

and finally

The nightmare

You can't imagine !

Certified software

Huge effort of many people and labs!

Issue	Activity	System Component	Lead	Workforce	Document Name	First Draft	Review Draft	MVM Reviewer	MVM Review	DA Reviewer Editor	DA Review
1. Software Development Planning			Dave Trask								
1.1.	System Development Plan	N.A.	Dave Trask	Matt Daley Marienna MacDonald	MVM-SDP-001-System Development Plan			Angelo Gargantini		Stefano Manni	
1.2.	MVM Document Template	N.A.	Dave Trask	Matt Daley Marienna MacDonald	MVM-Template-002-Document Template			Walter Bonivento		Stefano Manni	
1.3.	System Requirements Template	N.A.	Dave Trask	Matt Daley Marienna MacDonald	MVM-Template-003-System Requirements			Masayuki Wada		Stefano Manni	
1.4.	Software Architectural Design Template	N.A.	Dave Trask	Matt Daley Marienna MacDonald	MVM-Template-003-Software Architectural Design Template			Masayuki Wada		Stefano Manni	
1.5.	Review & Comment Form	N.A.	Dave Trask	Marienna MacDonald	MVM-Template-003-Review & Comment Form			Walter Bonivento		Stefano Manni	
1.6.	Software Requirements Specification SWP	N.A.	Dave Trask	Marienna MacDonald	MVM-SWP-001-Software Requirements Specification			Angelo Gargantini		Stefano Manni	
1.7.	Software Design Description SWP	N.A.	Dave Trask	Marienna MacDonald	No Document [Google Template is referenced in SDP]			Masayuki Wada		Stefano Manni	
1.8.	Software Coding Guidelines SWP	N.A.	Dave Trask	Marc Paterno Ben Smith	MVM-SWP-003-Software Coding Guidelines			Angelo Gargantini		Stefano Manni	
1.9.	Software Testing SWP	N.A.	Matt Daley	Richard Brown Marienna MacDonald	MVM-SWP-004-Software Testing			Angelo Gargantini		Stefano Manni	
1.10.	Change Control SWP	N.A.	Dave Trask	Matt Daley Francesco Guescini Eugene Kim	MVM-SWP-005-Change Control			Angelo Gargantini		Stefano Manni	
1.11.	Configuration Management SWP	N.A.	Dave Trask	Matt Daley Francesco Guescini Eugene Kim	MVM-SWP-006-Configuration Management			Masayuki Wada		Stefano Manni	
1.12.	Software Development Environment SWP	N.A.	Dave Trask	Konstantin Olchanski	MVM-SWP-008-Software Development Environment			Andrew Renshaw		Stefano Manni	
1.13.	Software Development Environment MVM	N.A.	Konstantin Olchanski	Frank Malacino Alejandro Ramirez Sebastian Torres-Lara	MVM-SDE-001-Software Development Environment			Andrew Renshaw		Stefano Manni	
1.14.	SOUP Software Work Practice	N.A.	Dave Trask	Martin Laclaustra Vicente Pesudo Eugene Kim	MVM-SWP-011-SOUP SWP 01			Shawn Westerdale		Stefano Manni	
1.15.	SOUP Identification and Evidence of Acceptance	MVM	Shawn Westerdale	Nosuke Morikawa Tom Thorpe Valentina Zambrano	MVM-SA-001-SOUP Evidence of Acceptance			Bryerton Shaw		Stefano Manni	
1.19.	Non-Conformance & Corrective Action Program	N.A.	Sergio Sala	Nicola Papini Massimiliano Redaelli	MVM-NC-CAP-001-Program			Kaspars Fricbergs		No DA Check Required	
1.20.	Identification, Processing and Notification of Non-Conformances, Defects, and Failures to comply	N.A.	Sergio Sala	Nicola Papini Massimiliano Redaelli	MVM-NC-CAP-002-Flow			Kaspars Fricbergs		No DA Check Required	
1.21.	System Requirements	MVM	Reiner Krücken	Matt Daley Mitch King	MVM-SR-001-System Requirements			Pierre-A. Amaudruz		Stefano Manni	
1.22.	Software Architectural Design MVM	MVM	Masayuki Wada	Patrizio Pelliccione Javier Romualdez	MVM-SAD-001-Software Architectural Design			Paolo Agnes		Stefano Manni	
1.23.	HAZOP & FMEDA	MVM	Dave Trask	Richard Brown Masayuki Wada Thomas Lindner Mitch King	MVM-Assessment-002-HAZOP FMEDA			Marco Breviario		Stefano Manni	

Issue	Activity	System Component	Lead	Workforce	Document Name	First Draft	Review Draft	MVM Reviewer	MVM Review	DA Reviewer Editor	DA Review
1.24.	Safety Concept and Software Classification	MVM	Marco Breviario	Andrea Bisioggia	MVM-SC-001-Safety Concept			Dave Trask		Stefano Manni	
1.25.	Cyber Security	MVM	Dave Trask	Matt Daley Abdul Basith Sonu Abi	MVM-CSRT-001 - Health Canada Cyber Security Assessment			Pierre-A. Amaudruz		Stefano Manni	
1.26.	Release Management SWP	N.A.	Dave Trask	Matt Daley Francesco Guescini Eugene Kim	MVM-SWP-007-Release Management			Andrew Renshaw		Stefano Manni	
2. Software Requirements Analysis			Angelo Gargantini								
2.1.	Software Requirements Specification	OCS	Angelo Gargantini	Silvia Ricciardone Silvia Bonfanti	MVM-SRS-001-OCS			Pierre-A. Amaudruz		Stefano Manni	
2.2.	Software Requirements Specification	Controller	Angelo Gargantini	Silvia Ricciardone Silvia Bonfanti	MVM-SRS-002-Controller			Pierre-A. Amaudruz		Stefano Manni	
2.3.	Software Requirements Specification	Alarms	Angelo Gargantini	Silvia Ricciardone Silvia Bonfanti	MVM-SRS-003-Alarms			Patrizio Pelliccione		Stefano Manni	
2.4.	Software Requirements Specification	Drives Pressure Sensors	Shawn Westerdale	Nosuke Morikawa Tom Thorpe Valentina ZAMBRANO	MVM-SRS-004-Pressure Sensor Drives			Pierre-A. Amaudruz		Stefano Manni	
2.5.	Software Requirements Specification	Drives Flow Meter	Shawn Westerdale	Nosuke Morikawa Tom Thorpe Valentina Zambrano	MVM-SRS-005-Flow Meter DCI942			Pierre-A. Amaudruz		Stefano Manni	
2.6.	Software Requirements Specification	Drives Gas Sensor	Shawn Westerdale	Pierre Amaudruz Nosuke Morikawa Tom Thorpe Valentina ZAMBRANO	MVM-SRS-006-Gas Sensor Drives			Pierre-A. Amaudruz		Stefano Manni	
2.7.	Software Requirements Specification	Drives Vacuum Meter	Shawn Westerdale	Nosuke Morikawa Tom Thorpe Valentina Zambrano	MVM-SRS-007-Vacuum Meter DCI942			Pierre-A. Amaudruz		Stefano Manni	
2.8.	Software Requirements Specification	Pressure Control Loop	Shawn Westerdale	Nosuke Morikawa Tom Thorpe Valentina ZAMBRANO	MVM-SRS-008-Pressure Control Loop			Pierre-A. Amaudruz		Stefano Manni	
2.9.	Software Requirements Specification	Supervisor	Eric Sahi	Angelo Gargantini	MVM-SRS-009-Supervisor			Pierre-A. Amaudruz		Stefano Manni	
2.10.	Communication Protocol Specification	PCS/OCS	Pierre-A Amaudruz	Thomas Lindner Masayuki Wada	MVM-SRS-010-Communication Protocol			Pierre-A. Amaudruz		Stefano Manni	
3. Software Components/Architecture Design Specification			Masayuki Wada								
3.1.	Software Design Description	PC	Masayuki Wada	Francesco Guescini Maria Ravellese Patrizio Pelliccione	MVM-SDD-001-Controller			Angelo Gargantini		Stefano Manni	
3.2.	Software Design Description	OCS	Masayuki Wada	Marco Del Tutto Michael Wang	MVM-SDD-002-OCS			Paolo Agnes		Stefano Manni	
3.3.	Software Design Description	Interface	Masayuki Wada	Konstantin Olchanski Patrizio Pelliccione	MVM-SDD-003-Interface			Andrew Renshaw		Stefano Manni	
3.4.	Software Design Description	DAs	Andrew Renshaw	Francesco Guescini	MVM-SDD-004-Drivers			Shawn Westerdale		Stefano Manni	
3.5.	Software Design Description	PV	Francesco Guescini	Patrizio Pelliccione Andrew Renshaw	MVM-SDD-005-Supervisor			Pierre-A. Amaudruz		Stefano Manni	
4. Software Unit Testing			Angelo Gargantini								
4.1.	Software Implementation (Code)	PV	Daniele Pellegrino	Alessandro Ranzio	No Document Required			No Review Required		No DA Check Required	

Issue	Activity	System Component	Lead	Workforce	Document Name	First Draft	Review Draft	MVM Reviewer	MVM Review	DA Reviewer Editor	DA Review
4.2	Software Implementation (Code)	SV	Dario Pennisi	Patrizio Pugliese	No Document Required			No Review Required		No DA Check Required	
4.3.	Software Implementation (Code)	HUI	Marco Del Tutto	Daniele Pellegrino	No Document Required			No Review Required		No DA Check Required	
4.4.	Software Implementation (Code)	DAQ	Alessandro Ranzio	-	No Document Required			No Review Required		No DA Check Required	
4.5.	Unit Test Procedure and Rules	PV	Angelo Gargantini	Andrea Bombardo Michele Bozzi Francesco Ferla Vincente Pesudo	MVM-STP-001-Firmware			Patrizio Pelliccione		No DA Check Required	
4.6.	PLC TWC Procedure and Rules	SV	Dario Pennisi	Massimiliano Ragazzi Patrizio Pugliese	MVM-STP-002-Supervisor			Patrizio Pelliccione		Stefano Manni	
4.7.	PLC TWC Procedure and Rules	HUI	Angelo Gargantini	Andrea Bombardo Mariano Nuchemab	MVM-STP-003-HUI			Patrizio Pelliccione		No DA Check Required	
4.8.	PLC TWC Procedure and Rules	DAQ	Bryerton Shaw	-	MVM-STP-004-Drivers			Patrizio Pelliccione		No DA Check Required	
4.9.	PLC TWC Report	PV	Angelo Gargantini	Andrea Bombardo Silvia Bonfanti	MVM-STR-001-Firmware			Patrizio Pelliccione		Report to Be Checked For Full Success	
4.10.	Unit Test Report	SV	Dario Pennisi	Massimiliano Ragazzi Patrizio Pugliese	MVM-STR-002-Supervisor			Patrizio Pelliccione		Stefano Manni	
4.11.	Unit Test Report	HUI	Angelo Gargantini	Andrea Bombardo Vincente Pesudo Patrizio Zambrano	MVM-STR-003-HUI			Patrizio Pelliccione		Report to Be Checked For Full Success	
4.12.	PLC TWC Report	DAQ	Bryerton Shaw	Angelo Gargantini	MVM-STR-004-Drivers			No Review Required		Report to Be Checked For Full Success	
4.13.	Static Code Analysis	PV	Bryerton Shaw	-	Automatically Generated by CI			No Review Required		No DA Check Required	
4.14.	Static Code Analysis	DAs	Bryerton Shaw	-	Automatically Generated by CI			No Review Required		No DA Check Required	
4.15.	Static Code Analysis	SV	Bryerton Shaw	-	Automatically Generated by CI			Patrizio Pelliccione		No DA Check Required	
4.16.	Code Review	PV	Angelo Gargantini	-	No Document Required (CR/Issues)			No Review Required		No DA Check Required	
4.17	Code Review	DAQ	Bryerton Shaw	-	No Document Required (CR/Issues)			No Review Required		No DA Check Required	
4.18.	Code Review	SV	Alessandro Ranzio	-	No Document Required (CR/Issues)			No Review Required		No DA Check Required	
4.19.	Code Review	HUI	Dai Shih	Roberto Gastaldi Patrizio Zambrano	No Document Required (CR/Issues)			Angelo Gargantini		No DA Check Required	
4.20.	Static Code Analysis	HUI	Dai Shih	Roberto Gastaldi Patrizio Zambrano	No Document Required (CR/Issues)			Angelo Gargantini		No DA Check Required	
4.21.	Build Unit TWC Firmware (Archive)	PV	Francesco Ferla	Michele Bozzi	No Document Required (Included in the Development Environment Document)			Konstantin Olchanski		No DA Check Required	
5. Integration and System Testing			Valerio Ippolito								
5.1.	Integration Test Procedure	SV	Valerio Ippolito	Fabio Bucile Nicolas Ravanavat Patrizio Pelliccione Roberto Gastaldi Tormaso Borrelli	MVM-STP-001-Integration Test Procedure					Stefano Manni	

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

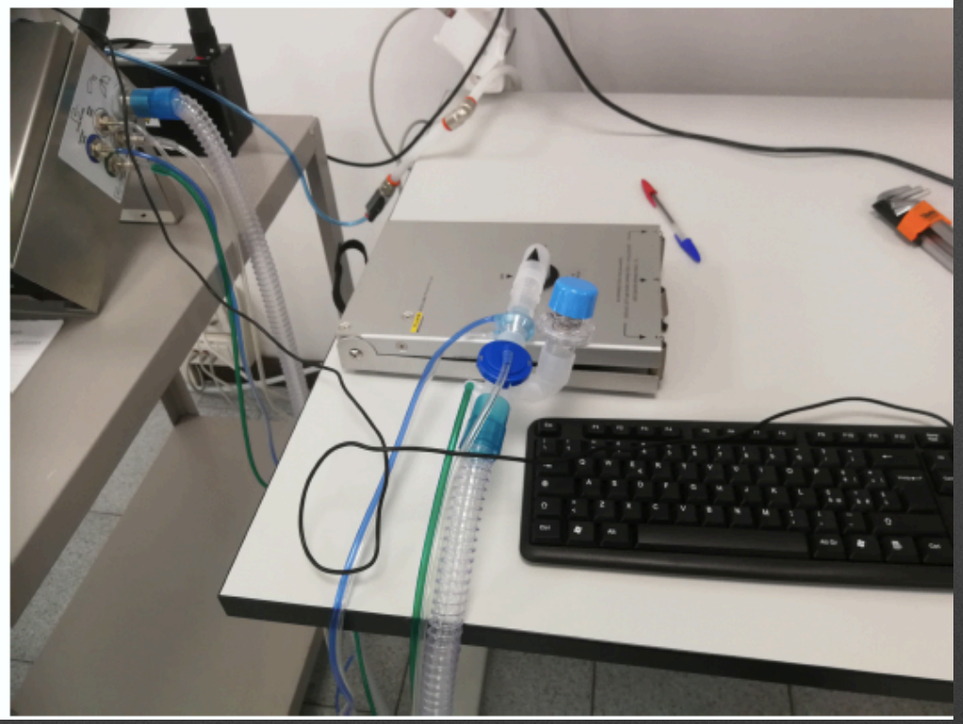
Issue	Activity	System Component	Lead	Workforce	Document Name	First Draft	Review Draft	MVM Reviewer	MVM Review	DA Reviewer Editor
4.2	Software Implementation (Code)	SV	Dario Pennisi	Fabrizio Guglielmo	No Document Required			No Review Required		No DA Check Required
4.3.	Software Implementation (Code)	GUI	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	MVM-UTP-001-Firmware			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 TRIUMF

R.Krucken et al.

Testing at the hospital

J.Raaf, E. Gramellini and E.Dahl

In Cook Chicago County Hospital

Testing at the hospital

O.Putignano, G. Foti, G. Bellani

In Ospedale San Gerardo, Monza, Italy

if you want to know more

- https://indico.cern.ch/e/MVM 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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[7]APC, Université de Paris, CNRS, Astroparticule et Cosmologie, F-75013 Paris, Fra

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[11]Dipartimento di Fisica, Università di Pisa, Pisa 56124, Italy

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[18]INFN Sezione di Cagliari, Cagliari 09042, Italy

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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

VEXOS
Local Service. Global Capabilities.

MVM
MILANO VENTILATORE MECCANICO

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

R&D MANAGEMENT

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

Maria Chiara Di Guardo[1,*], Elona Marku[1], Walter Marcello Bonivento[2], Manuel Castriotta[1], Fernando Ferroni[3], Cristiano Galbiati[4,5], Giuseppe Gorini[6] and Michela Loi[1]

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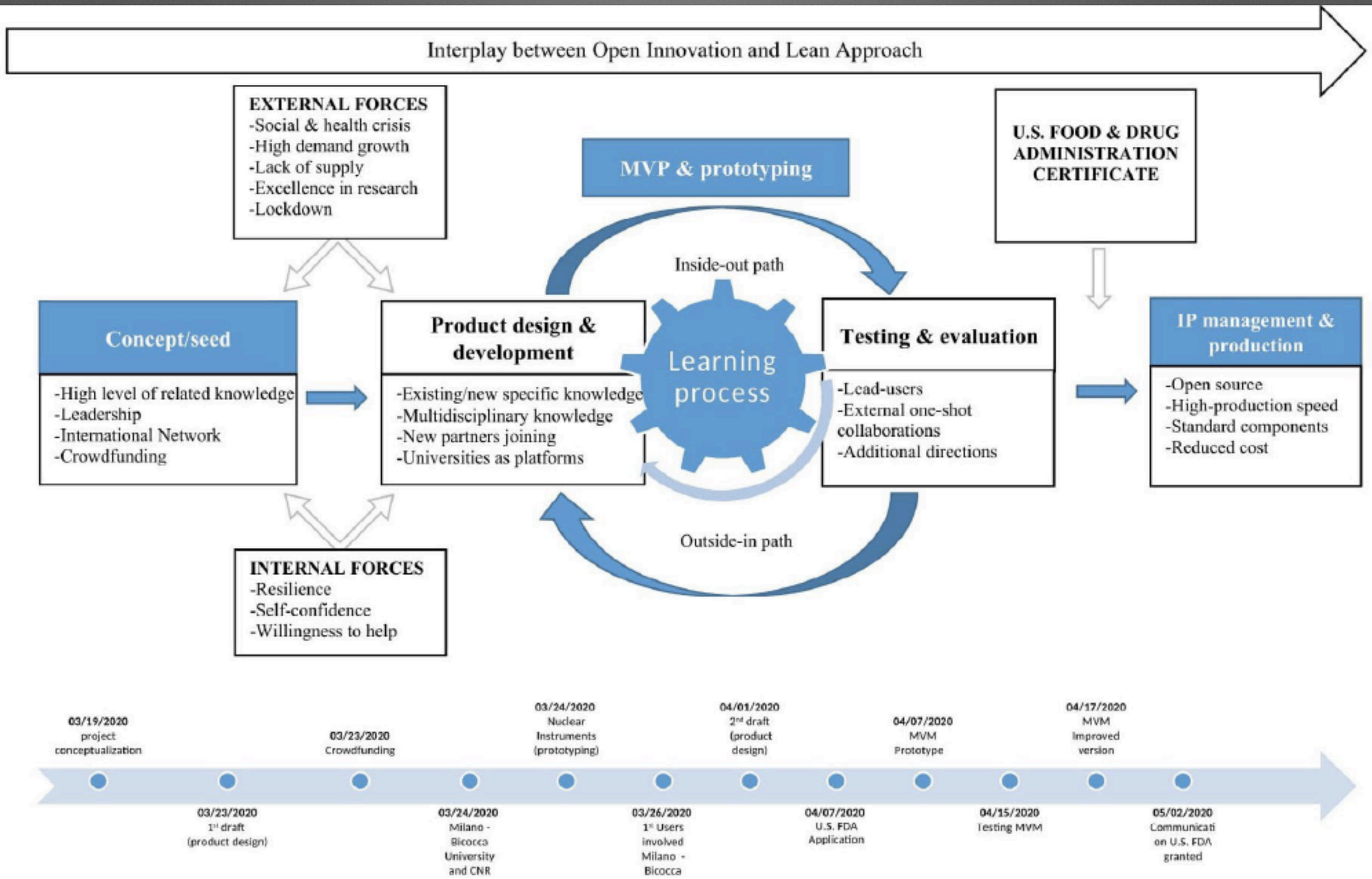
Interplay between Open Innovation and Lean Approach
EXTERNAL FORCES
-Social & health crisis
-High demand growth
-Lack of supply
-Excellence in research
-Lockdown
MVP & prototyping
U.S. FOOD & DRUG ADMINISTRATION CERTIFICATE
Inside-out path
Concept/seed
-High level of related knowledge
-Leadership
-International Network
-Crowdfunding
Product design & development
-Existing/new specific knowledge
-Multidisciplinary knowledge
-New partners joining
-Universities as platforms
Learning process
Testing & evaluation
-Lead-users
-External one-shot collaborations
-Additional directions
IP management & production
-Open source
-High-production speed
-Standard components
-Reduced cost
Outside-in path
INTERNAL FORCES
-Resilience
-Self-confidence
-Willingness to help
03/19/2020 project conceptualization
03/23/2020 1st draft (product design)
03/23/2020 Crowdfunding
03/24/2020 Milano - Bicocca University and CNR
03/24/2020 Nuclear Instruments (prototyping)
03/26/2020 1st Users involved Milano - Bicocca
04/01/2020 2nd draft (product design)
04/07/2020 U.S. FDA Application
04/07/2020 MVM Prototype
04/15/2020 Testing MVM
04/17/2020 MVM Improved version
05/02/2020 Communicati on U.S. FDA granted

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 first conceptualization	High level of related knowledge 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 knowledge required	University as a platform 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 partners 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