Vortran-Type Pneumatic Ventilator

- *#project-pneumatic-ventilator*٣فؤءosal to build a pandemic Diaphragm-based ventilator which is powered by O2 or air pressure. It is a replica of the design of the GO2VENT, a successful commercial pneumatic ventilator: https://www.vortran.com/go2vent

6
Video showing commercial device is here:
https://www.youtube.com/watch?v=JRKIyEJAEhA&feature=emb_rel_pause

Z.ZZZ

Contacting Vortran:

We attempted contact via email, phone, and attempting to track down manufacturers but were not able to establish communication in the short time (March 16th day) we worked on this. Obviously just contacting them and assisting in their established production is Plan A here.

There are similar designs from other companies which might also work:

- ZS ZZ….,.....,.,,,,,...,.,Lagaay International: https://www.lagaay.com/shop/product/12064

V Technical description / function

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S_. figure below:

Gas inlet connector - connection to pressurised gas supply
Pressure relief valve - safety device to prevent over-pressure / injury to patient.
One Way Valve - simple diaphragm allows patient to inhale if loss of supply pressure

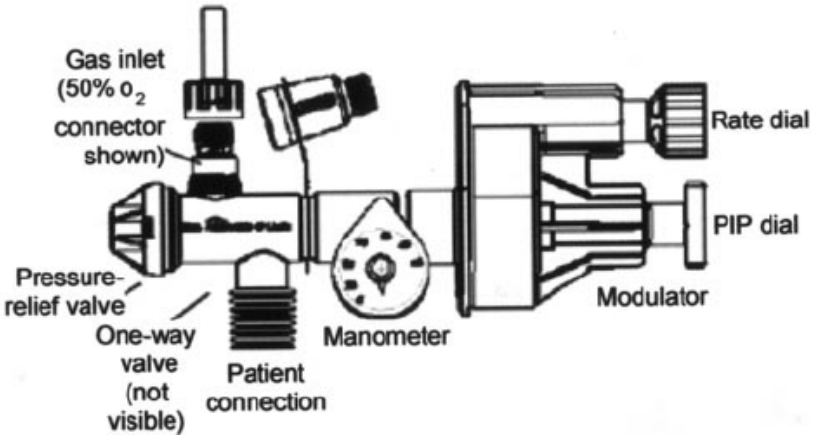
Patient connection - allows connection of flexible breathing tube
Modulator - comprises:

Rate dial - controls the rate of exhalation, thereby controlling the breathing rate

- Exhalation goes out this port, unfiltered

PIP dial - adjusts the peak inspiratory pressure and tidal volume by changing the spring force on the modulator silicon diaphragm valve

Manometer - optional pressure read-out for expiratory pressure



PIP = Peak Inspiratory Pressure

This design was chosen as it is simple, requires no electronics or machining, and has a successful clinical history. Rather than reinventing the wheel, we are focused on adapting existing emergency ventilators to be compatible with home manufacturing.

Airway pressure monitor not included but available for purchase:
https://www.vortran.com/airway-pressure-monitoring
This could also be manufactured more easily because it only needs to monitor without feedback except alarm.

Shortcomings:

We have been told (late in our development) that it's possible/likely that open loop ventilators can't keep a stable tidal volume or rate in a clinical setting. If that is a fundamental failing of this class of ventilators then we accept defeat in their inability to treat ARDS Corona symptoms. We assume the medical expertise of review staff will be able to determine this, and apologize for wasting your time if so.

If you're wondering how PEEP is adjusted on this device, it is not - it's baked-in to the device upon manufacturing at 25% of the PIP value. We believe this might be made adjustable via the Rate dial by adding resistance to the exhale, but we could be mistaken.

Similarly the exhaled gas is not filtered, and so we would suggest adding an N95-quality (or similar) filtration to the output. We realize this adds a similar resistance that would both enable PEEP and possibly interfere with the Rate - this would be a question for either: better designers than us, the original manufacturers, medical professionals, or some hands-on experimentation.

Manufacturing:

All components are made with K-Resin or Polycarbonate, aside from two valves made out of silicone (and one partially nylon), and a spring to apply pressure to the PIP gauge. Our 3D modeller believes this is fairly doable with an adequate print setup, and it has the benefit of being very modular. We don't forsee a need for the manometer (providing hospitals are not short their own), but otherwise we believe this is about as minimal as a reasonable ventilator is going to get.

(That said, we are also submitting another project called the "Army Pneumatic Ventilator" which

is a single piece of plastic, and has many of the same features as this device. So if you're optimizing for the minimum, we recommend that. If you'd prefer a bit more usability and aren't daunted by the parts of this device, then we recommend this one.)

Again, we hope/pray that we will be able to access the original design files before attempting a mass production, but if we have to reverse-engineer them - then we will.

✅ "I've read this" section

Add in the table below the people you definitely want their eyes on this proposal. Sometimes there are no comments to be made but it's good to know people have read the proposal

Name	**Status**
	Read
Aron Cohen	Read
Glen Oomen	
Alex Haussmann	Read
Dan Vasiliu	Read
Jorge Arthur Schneider Aranda	Read

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4 PAGE PROPOSAL CUTOFF - SUPPLEMENTAL INFORMATION FOLLOWS

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(Apologies, reviewers. This was also our collaboration document)

https://rtsleepworld.com/2020/04/07/vortran-medical-and-xerox-partnering-to-mass-produce-go2vent-disposable-ventilators/

April 7, 2020 - Xerox Holdings Corporation and Vortran Medical Technology **are teaming up to speed and scale production of Vortran's GO2Vent ventilator and related Airway Pressure Monitor (APM-Plus) for hospitals and emergency response units fighting the battle against COVID-19.**

Please see this work:

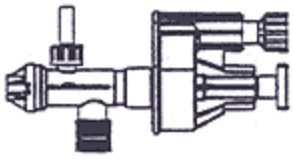
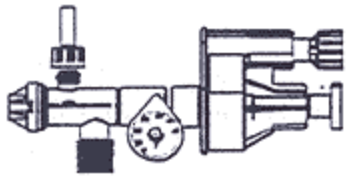
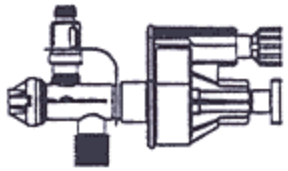
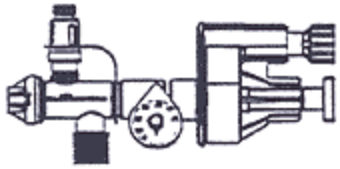
https://rapidvent.grainger.illinois.edu

Importants Data:
Specially for calculations and simulations
Please correct if something is missing or wrong

Name	**Unit**	**Expected Measurement Range**	**Required Accuracy**		**Comments**
Temperature (T)	[C]	30-45			
Volume (V)	ml/kg	8-15ml/kg	Tidal volume (lung volume difference between inspiration and expiration, without effort) ==>>up to 1000 mL/breath, also it should measure levels of <8 mL/kg		
Oxygen (PO2)	l/min	<20l/min	>25 L/min required		

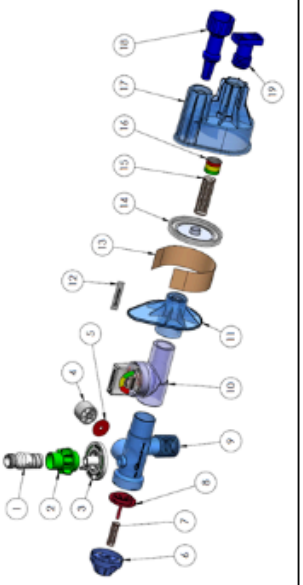
Carbon Dioxide (PCO2)			etCO2 (end-tidal CO2 level, which means the success of ventilation) == 35-45 mmHg		
Pressure (P)	[Pa]	<2500			
Humidity		20-80%	Humidity should be up to 100% because of human breath's humidity		
Flow Rate	[l/s]	0,04 - 0,25l/s			
Rate	[Breath/min]	10-18	10-30 (at least 25)		
Plateau (Hold)	s	0,5s			
I:E-Ratio		1:2			

Design variants / configurations:

☐ Model RT 	☐ RT w/Manometer 
 ☐ Model RC	 ☐ RC w/Manometer

- **Biocompatibility Testing**

Device Nature of Body Contact Category: **External Communicating**			Duration of Contact for the Device: **Up to 30 days**	
	Part No.	**Part Description**	**Patient Contact Status** **Substantial Equivalence Device (510K #)**	**Material/Color**
1.	6007	100% - 50% VAR Nozzle	**Indirect patient contact K153733**	Polycarbonate/White
2.	6008	FiO2 Controller Knob	**Indirect patient contact K041473**	HDPE/Green
3.	6009	Entrainment Barrel	**Indirect patient contact K153733**	Polycarbonate/White
4.	2015	One-Way Valve Body	**Indirect patient contact K041473**	HDPE/Natural
5.	2016	One-Way Valve Flapper	**Indirect patient contact K153733**	Silicone/Red
6.	6005	Pop-Off Valve Cap	No patient contact	Polycarbonate/Blue
7.	6010	Pop-Off Valve Spring	No patient contact	Beryllium Copper
8.	2012	Pop-Off Valve Piston	**Indirect patient contact K041473**	HDPE/Red
9.	6006	Patient Tee	**Indirect patient contact K041473**	K-Resin®/Clear/Blue
10.	2291	Manometer Assembly	**Indirect patient contact K153733**	N/A
11.	6003	Modulator Bottom, Single Port	**Indirect patient contact K153733**	Polycarbonate/Clear/ Blue
14.	2182B	Diaphragm	No patient contact	Silicone/Natural
	2181B	Hard Center	**Indirect patient contact K041473**	Nylon/Natural

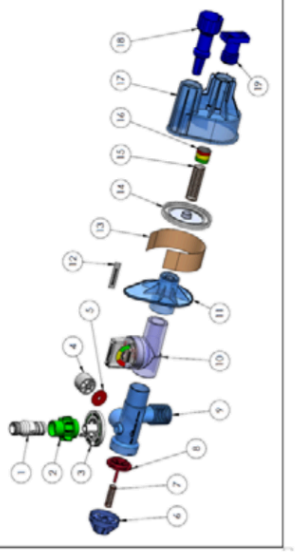


- **Biocompatibility Testing (Continued)**

Device Nature of Body Contact Category: **External Communicating**			Duration of Contact for the Device: **Up to 30 days**	
	Part No.	**Part Description**	**Patient Contact Status** **Substantial Equivalence Device (510K #)**	**Material/Color**
15.	6004	Pressure Dial Spring	No patient contact	Beryllium Copper
17.	6002	Modulator Top	No patient contact	Polycarbonate/Clear/ Blue
18.	6017	Rate Dial	No patient contact	HDPE/Blue
19.	6016	Pressure Dial	No patient contact	HDPE/Blue

Discussion:

1) **Rationale for Not Needing Biocompatibility Testing**: Considering the material used in the components of the new device (VORTRAN® GO$_2$VENT™) and the fact that the same material used as those in the predicated devices manufactured by VORTRAN Medical and produced with the same manufacturing process, the material of the new device is compatible and requires no additional biocompatibility testing.



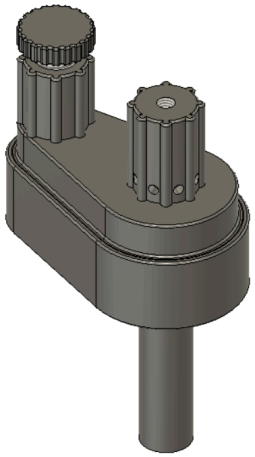
https://www.accessdata.fda.gov/cdrh_docs/pdf16/K162968.pdf

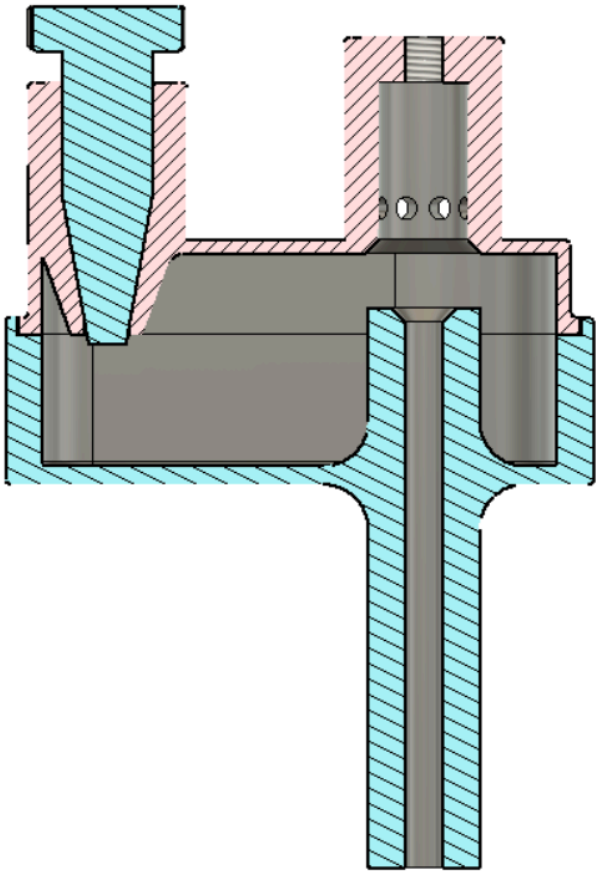
Designs:

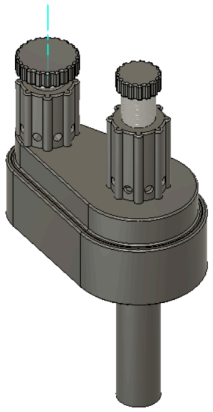
Purpose: We will attempt to collect up-to-date designs in this section so Designers, Printers and Testers can collaborate quickly. Please post your design files along with a picture/render (if possible) and your Slack handle for communication.

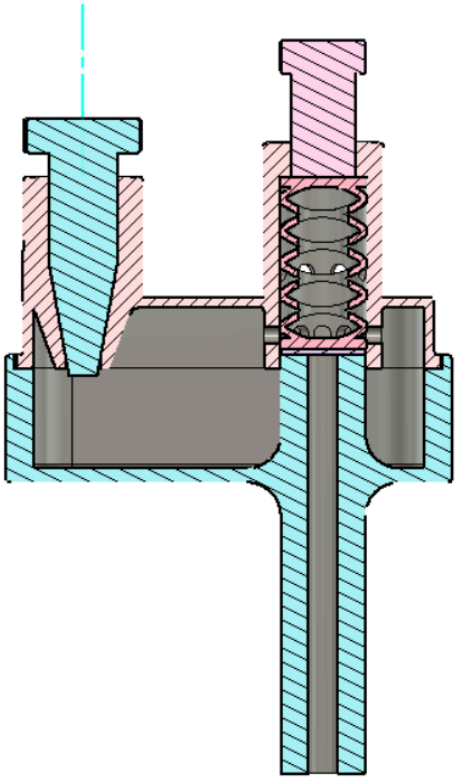
Note that it's possible/likely we'll be getting more information or direct design files from the creators of this device, so be prepared to have to replace your designs with theirs. Otherwise, best to treat each segment of the device separately: highest priority is the Modulator (@erdem karaman's render below), followed by the T intake section connecting patient lungs to oxygen tube. Middle manometer section is optional and possibly won't be needed. FiO2 Controller knob - probably will want though. Try to develop each piece separately as per the "Biocompatibility Testing" diagram above (sorry, best we got for cross-section breakdown of parts). Note that there are silicon and spring parts involved in this design too!
Dimensions/specifications we are reverse-engineering, and what you see is what you get! Post your findings in this doc as you find them.

@Erdem Kahraman (just render, msg for design files)(design files posted in slack channel, will be updated as I go along(erdem kahraman))









(Other Designers: List Slack handle, render, files, and description/comments here! Post just your name even if you're mid-design, so others can collaborate with you)

Parker H

Status

If you can help with any of these, please create a section in the document devoted to them. **Don't wait to be asked, do!**

Currently

- Attempting to contact the manufacturer
- Finding resources and patents
- Looking for medical professionals with experience with this device
- Evaluating if it provides for the humidification necessary **Parker H**
- Evaluating if it can operate for long enough without maintenance or monitoring, particularly diaphragm stick **Parker H**
- Examining if it can be 3D printed **please help!**
- Evaluating if it can provide the support COVID patients require **please help!**
- Creating or finding 3D model of the diaphragm assembly **Nathan H**

Evaluation of efficacy/safety/use characteristics (Parker H)

Questions to answer:

1. General/heuristic med. Pro. experience of Vortran device.
2. Does product provide necessary humidification for need.
3. Maintenance, monitoring schedules, both recommended and field-relevant.
4. Are there better, passive/non-actuated devices already deployed we should look at for reproduction.
   Response from anesthesiologist: Critical parameters, PEEP a must, they are fitting anti-viral filters on all vent. Equip., 100% O2 acceptable but they try not to use, FO2 important, tidal volume and cycle rate most important, Stanford hospital uses Draeger vents exclusively, no emergency vent. Info. Was not able to ask about maintenance, monitoring, or ster. Scheduling. Will find out as I can.

Future

- Contact distributors in the US, if we can't reach manufacturer

Done

- Find patents describing device:

- https://patents.justia.com/assignee/vortran-medical-technology
- https://patents.justia.com/patent/20190247599

  - According to aspects of the present disclosure, in one embodiment a valve assembly is attached to a capacitor such that upon pressurizing to a first positive pressure threshold induces the valve assembly to open, the pressurized air is released to the patient, and then as the pressure in the capacitor drops to a second pressure threshold the valve closes and the capacitor begins to build pressure until the first positive pressure threshold is achieved and the process repeats. In one embodiment, the valve assembly includes a diaphragm functional surface affixed to a moveable valve face and a fluidic communication port, wherein the fluidic communication port is in close proximity (and optimally in direct contact) with the functional surface of the moveable valve face, the contact region there between the valve assembly and fluidic communication port describing an actionable surface area. Relative to the valve assembly and integrated therein, is an incremental index knob. By introduction of an incremental index knob the rate of a biasing force performing work against the actionable valve face of the diaphragm functional surface allows for defined, reproducible, and predictable performance of the valve assembly, thereby increasing the potential for correct operation across a range of oscillating rates supporting a broad spectrum of patient therapies and types.

Resources

- Commercial device: GO2VENT
- https://www.lagaay.com/shop/product/12064 - **Please don't buy if you're not a medical professional. We do not want to reduce the available supply.**
- User's Guide: https://3ae9a7bb-a7ff-44f5-89b9-6a830b38c121.filesusr.com/ugd/a51c58_9dbe6b70c8ef47ac94f647bf1fe52f37.pdf

Diaphragm Assembly Design

Please help map this patent into a design: https://patents.justia.com/patent/20190247599

- Figures are not included in the online filing

.https://patentimages.storage.googleapis.com/ac/2a/4b/b3f6b3483c5291/US6067984.pdf (found on google patents, someone please crosscheck that this is the right thing)
https://3ae9a7bb-a7ff-44f5-89b9-6a830b38c121.filesusr.com/ugd/a51c58_9dbe6b70c8ef47ac94f647bf1fe52f37.pdf (this is the user guide might come in handy)

Diaphragm operation

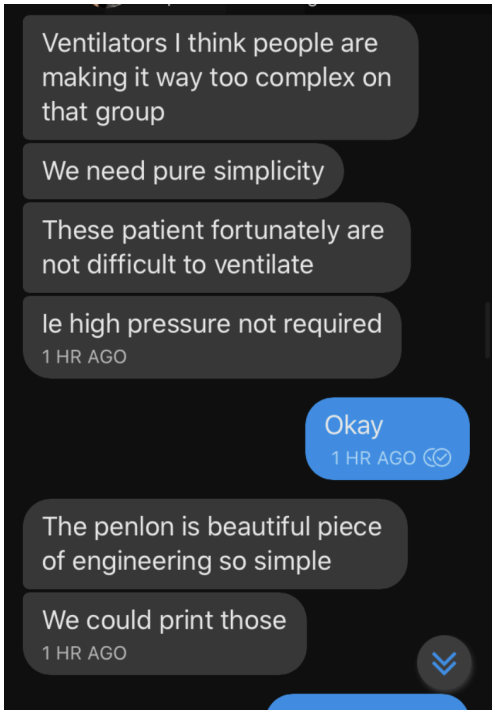
The VAR works via a simple diaphragm valve. The Peak Inspiratory Pressure (PIP) knob adjusts the pressure at which the diaphragm opens (and therefore also adjusts the tidal volume). When this pressure is reached, the valve opens and air from the patient's lungs exits the valve body via the rate adjustment knob, which changes the size of the exit orifice, thereby changing the rate of exhale. Once the pressure is reduced sufficiently, the diaphragm closes and the supply air fills the patient's lungs.

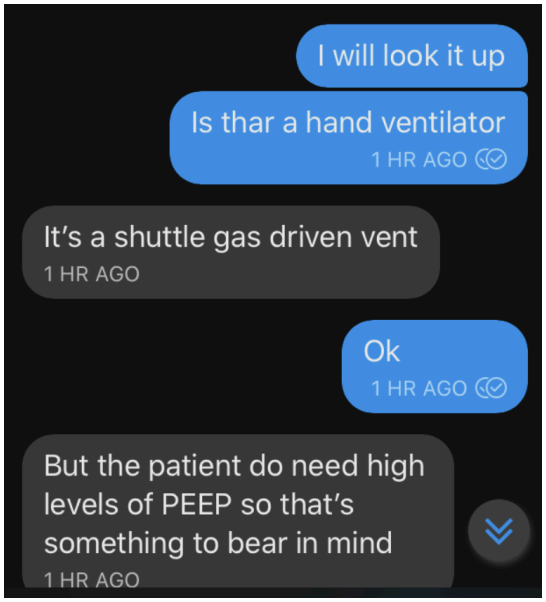
Other Pneumatic Ventilators

Penlon

https://www.penlon.com/getmedia/f8bbb004-9824-4c92-87d2-b77aa8524e5a/Nuffield-200-Ventilator-Sales-EN-0117.pdf

From an Anesthesiologist in the UK





Sure Vent

https://www.quadmed.com/files/1ebc022c-5204-4463-8ed9-31f56b2703bf.pdf

Requirements

• Be reliable. It must work continuously without failure (100% duty cycle) for blocks of 3 days - 24 hours a day. If necessary, the machine may be replaced after each block of 3 days x 24 hours a day use.
• Provide at least two settings for volume of air/air O2 mix delivered per cycle/breath. These settings to be 450ml +/- 10ml per breath and 350ml +/- 10ml per breath.
• Provide this air/air O2 mix at a peak pressure of 350 mm H2O.
• Have the capability for patient supply pipework to remain pressurised at all times to 150mm H20.
• Have an adjustable rate of between 12 and 20 cycles/breaths per minute.
• Deliver at least 400ml of air/air 02 mix in no more than 1.5 seconds. The ability to change the rate at which air is pushed into the patient is desirable but not essential.

• Be built from O2 safe components to avoid the risk of fire and demonstrate avoidance of hot spots.
• Be capable of breathing for an unconscious patient who is unable to breathe for his or herself. Ability to sense when a patient is breathing, and support that breathing is desirable but not essential.
• Be able to supply pure air and air O2 mix at a range of concentrations including at least 50% and 100% Oxygen. Oxygen shortages are not expected, but the ability to attach a Commercial Off The Shelf (COTS) portable O2 concentrator machine may be a useful feature.
• Support connections for hospital Oxygen supplies – whether driven by piped or cylinder infrastructure
• Be compatible with standard COTS catheter mount fittings (15mm Male 22mm Female)
• Fail SAFE, ideally generating a clear alarm on failure.

SUPPORTING REQUIREMENTS
The RMVS must:
• be intuitive to use for qualified medical personnel familiar with ventilator use. Must not require extensive training to use effectively. Relevant usage instructions must be attached / intrinsic to the device
• be capable of being easily cleaned / decontaminated using readily available materials
• have successfully been subjected to a testing and assurance process that is appropriate for the exceptional circumstances
• have transparent design, supply chain, manufacture and testing processes that are of sufficient quality to enable MHRA officials to deem appropriate for usage in exceptional circumstances
• not be excessively cumbersome so that it would impede hospital operations or prevent easy movement within hospital premises
• be made from materials and parts readily available

Section for Discussion (if needed)

Is the problem of the virus being aerosolized by this device already addressed?

Dan V: What about running the exhaust air flow through a tank filled with an antiseptic solution? Think air bubbled inside an aquarium. If the air is atomized finely enough (think of it as coming from an airstone at the bottom of the tank), the released airflow should be safe(r).

As I gather hospitals solve this issue with antiviral filters on all valves. Is that sufficient?