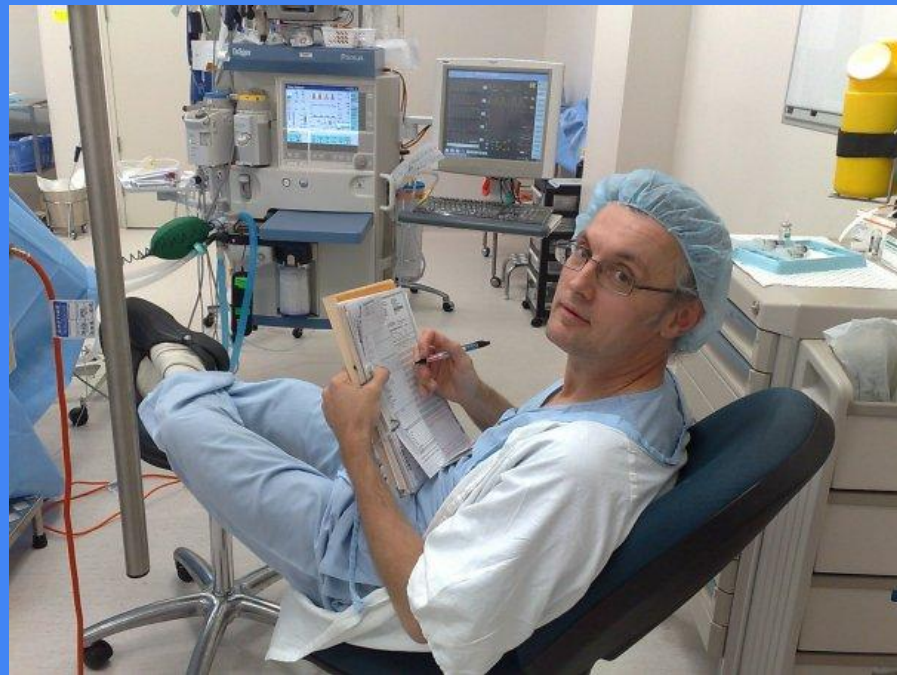# OpenVentCon2020: Clinical Issues

Dr Erich Schulz, Senior Staff Anaesthetist, Mater Health Services Brisbane, Australia @ErichSchulz

Thank you to Dr Read and Public Invention

and I'd like to acknowledge that here in Brisbane Australia, I sit in stolen land

How did I get involved?

- I'm an expert in putting people to sleep and waking people up again, this happens to require learning advanced respiratory physiology and included 1000's of hours using ventilators
- Thanks to excellent local public health I've had a [fair bit of time on my hands](#)
- When the call went out for ventilators I realised that:
  - many of the attempts to make ventilators, while galant, were missing an adequate briefing
  - the problem was solvable but it was going to require inter-team teamwork

Too much to talk about

So I wrote [a document on what engineers need to know about ventilators](#).

Then I wrote another [smaller set of scrappy notes on why and how ventilation and ventilatators in the Covid19 outbreak have beens so confusing](#) (this contains references for some of the figures I've stolen)

Then I realised many makers didn't realise [how expensive ICU care care is](#), that [we need to restructure the existing hardware projects](#), and then more recently that maybe [we should get people to work together on the software](#), at least.

How do doctors think?

- best possible outcome in the situation
- "informed consent"
    - risks
    - benefits
    - alternatives
- in a crisis, do the best you can.

Tips from a doctor

- best honest
- publish early
- break up the job into small bits
- do the best you can
- not every innovation will succeed
- "proof" is hard

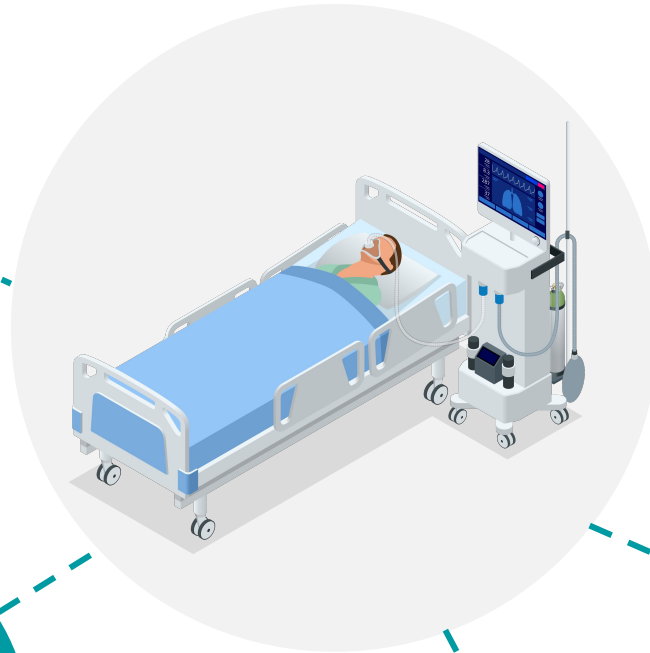# FDA Emergency Use: Ventilators Q&A

Michelle Lott, RAC
Principal & Founder, leanRAQA

Regulatory pathway

Software / App & Cloud

Accessory *vs.* Component *vs.* Finished device

Is it a medical device?

Supply chain

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Terminology: Important distinctions

Authorization ≠ Clearance ≠ Approval

Emergency Use Authorization (EUA)

510(k) Premarket Notification clearance

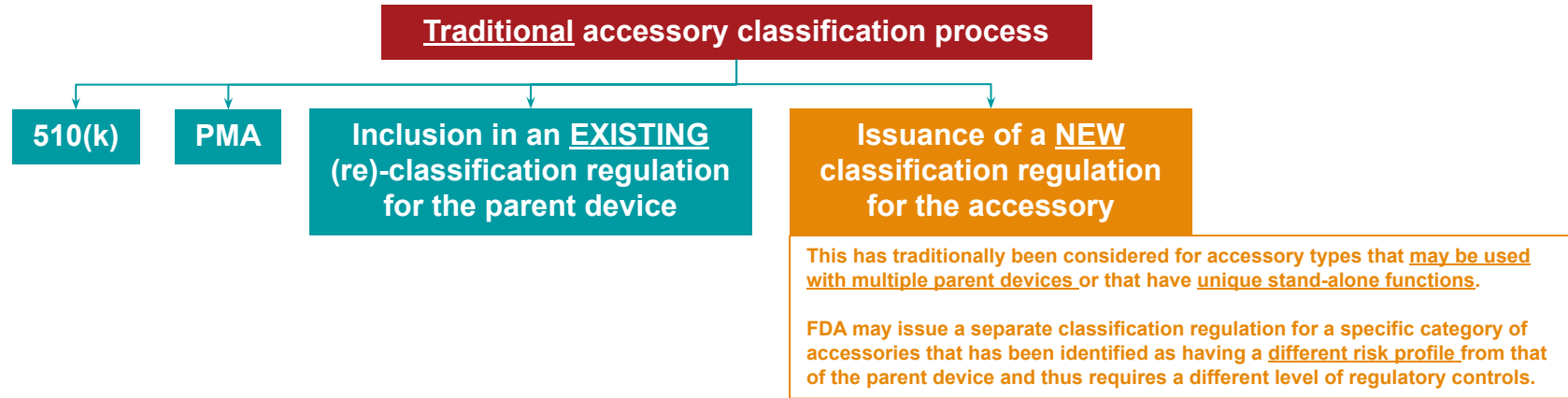**Premarket Application (PMA) approval**

lean**RAQA**
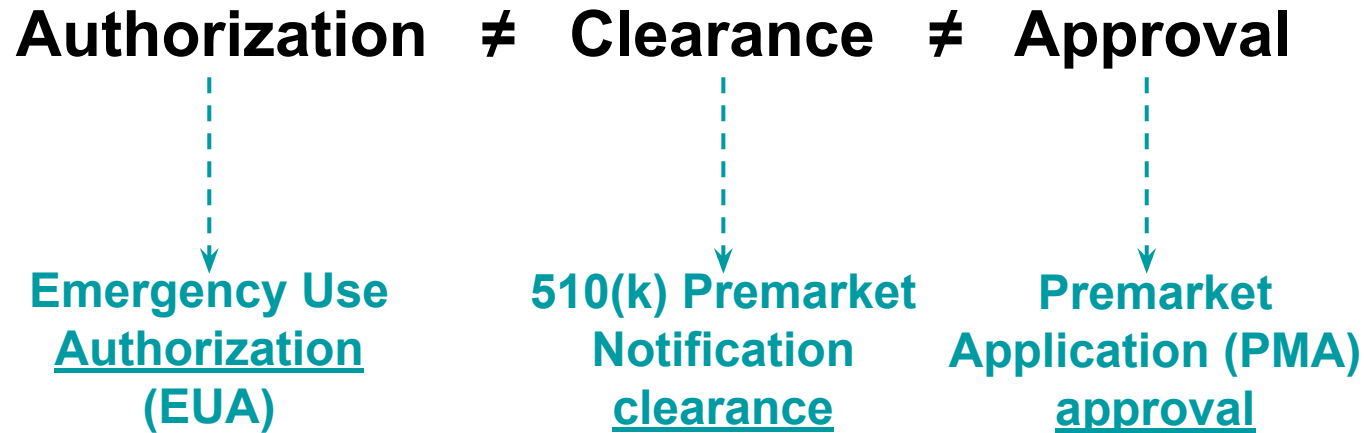
ACCESSORY *vs.* COMPONENT *vs.* FINISHED DEVICE

Relevant definitions

► **<u>Accessory</u>** → `Can be optional`
  – A finished device that is intended to **support**, **supplement**, and/or **augment** the performance of one or more parent devices.

► **<u>Component</u> (21 CFR 820.3(c))** → `Not optional`
  – Any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be **included as part of** the finished, packaged, and labeled device.

► **<u>Finished Device</u> (21 CFR 820.3(l))**
  – Any device or accessory to any device that is **suitable for use or capable of functioning**, whether or not it is packaged, labeled, or sterilized.

  → `Stand-alone`

► **<u>Parent Device</u>**
  – A finished device whose performance is **supported**, **supplemented**, and/or **augmented** by one or more accessories.

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Classification of accessories

Traditional accessory classification process

| 510(k) | PMA | Inclusion in an **EXISTING** (re)-classification regulation for the parent device | Issuance of a **NEW** classification regulation for the accessory |

This has traditionally been considered for accessory types that <u>may be used with multiple parent devices</u> or that have <u>unique stand-alone functions</u>.

FDA may issue a separate classification regulation for a specific category of accessories that has been identified as having a <u>different risk profile</u> from that of the parent device and thus requires a different level of regulatory controls.

► **FDA guidance document "<u>Medical Device Accessories - Describing Accessories and Classification</u> Pathways," Classification of the accessory is no longer inherited from the parent device**

– Classification of an accessory is based on the benefit/ risk profile of the accessory

• An accessory can potentially be lower risk than the parent device

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Accessory *vs.* Component *vs.* Finished Device

Q1 **I want to build an alarm that bolts onto other ventilators. What would this be classified as?**

▶ **If sold to other ventilator companies, ventilator companies take responsibility (including clearance/approval)**

▶ **The classification process begins with the analysis of whether the article under consideration is an <u>accessory</u> as described in this <u>FDA guidance</u> document or a <u>component</u>.**

   – If labelling, promotional materials, or other evidence of intended use demonstrates that the alarm is intended for use with a parent device (either a particular brand or device type), and it supports, supplements, and/or augments that device, FDA generally considers the alarm to be an accessory, and thus a device as defined in section 201(h) of the FD&C Act. This includes those alarms labelled as being "optional".

▶ **More importantly, you would have to validate the performance of the alarms to multiple ventilators on the market – this can be an enormous undertaking.**

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Accessory *vs.* Component *vs.* Finished Device

Q2 **Can a single component for a ventilator get FDA clearance/approval, for example a valve, sensor or controller?**

▶ **If the component does not have a stand-alone intended use, generally, no.**

▶ **Some accessories – Yes, depending on the intended use.**
  – i.e. software, mobile app, etc.
  – MOD (*Accessory to Continuous Ventilator (Respirator)*)
  – Know your available product codes

▶ **It all depends on how you package and intend to market your product.**
  – i.e. Kit Configuration vs. individual components.

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Accessory *vs.* Component *vs.* Finished Device

Q3 **I'm making a valve for a ventilator that could be used on many other ventilators - do I need FDA clearance/approval for just this part? Would it be easier for other teams if I did get clearance/approval ?**

► **If sold to other ventilator companies, ventilator companies take responsibility (including clearance/approval)**

► **However, you could validate the performance or technical specifications in a way to facilitate adoption.**

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Accessory *vs.* Component *vs.* Finished Device

Q4 **Our ventilator is very complex and some parts we have built ourselves. Does this count as one FDA application? Or do we need to get each custom part approved?**

▶ **The EUA is primarily intended for finished medical devices or accessory to finished devices.**

▶ **It would depend on your product claims and intended use.**

▶ **However, under normal circumstances a single FDA submission will suffice.**

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IS IT A MEDICAL DEVICE?

Is it a medical device?

► **Calibration tool is <u>NOT</u> a medical device**

► **Considerations:**
  – Design Inputs/Outputs
    • What specifications do you need so the tool is versatile with multiple ventilators?
  – Performance testing standards
    • What standard must the ventilator meet after calibration?
    • Calibrating the calibrator
  – QMS requirements
    • How will the calibration be documented or record?

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Is it a medical device?

▶ **Does it have a medical purpose?**

- For use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease?

▶ **21 CFR 868.5440 definition:**

- *"A portable oxygen generator is a device that is intended to release oxygen for **<u>respiratory therapy</u>** by means of either a chemical reaction or physical means (e.g., a molecular sieve)"*

Device	Generator, Oxygen, Portable
Regulation Description	Portable oxygen generator.
Regulation Medical Specialty	Anesthesiology
Review Panel	Anesthesiology
Product Code	CAW
Premarket Review	Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1)
	ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices (DHT1C)
Submission Type	510(k)
Regulation Number	868.5440
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No

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REGULATORY PATHWAY

Regulatory pathway

Q7 — **What is the process if we update our design? Do we need to reapply from the start?**

► **Specified in the EUA Letter if granted. Example of terms:**
  – *"electroCore, Inc. may request changes to any materials, components, parts, or accessories. Such requests will be made in consultation with and require concurrence of OHT1/OPEQ/CDRH"*

► **The process depends on standard operating procedures based on your Engineering/Design Change SOP(s).**

► **From a regulatory standpoint, as long as the design change does not change the intended use, indications for use or question the safety and effectiveness of the product, you would complete an Engineering Change Notice and conduct a regulatory assessment.**
  – "Deciding When to Submit a 510(k) for a Change to an Existing Device"

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Regulatory pathway

Q8 **If our project receives an EUA letter, can we later get FDA clearance/approval? Would this be a separate application?**

▶ **EUA is only in effect during the time of the Emergency Declaration. Upon termination, any products authorized must be removed from use.**

▶ **To continue marketing after termination of the EUA, you should submit a separate application (510k or De Novo).**
   – Consider Pre-Sub
   – Begin right away after you receive an EUA letter

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Regulatory pathway

Q9 **We are not sure what Class our device is and how this affects the FDA timeline and costs. Are there any specific rules for ventilators or is it case-by-case?**

► **Both, there are specific rules and it is dependent on each product, intended use and product specifications and/or claims.**

► **How does the technology for your product compare and contrast in light of other cleared ventilators? (Substantial Equivalence)**

► **Good place to start is regulatory pathway assessment (RPA)**

   – Go to website to download RPA example:
      leanraqa.com/about/regulatory-pathways-assessment

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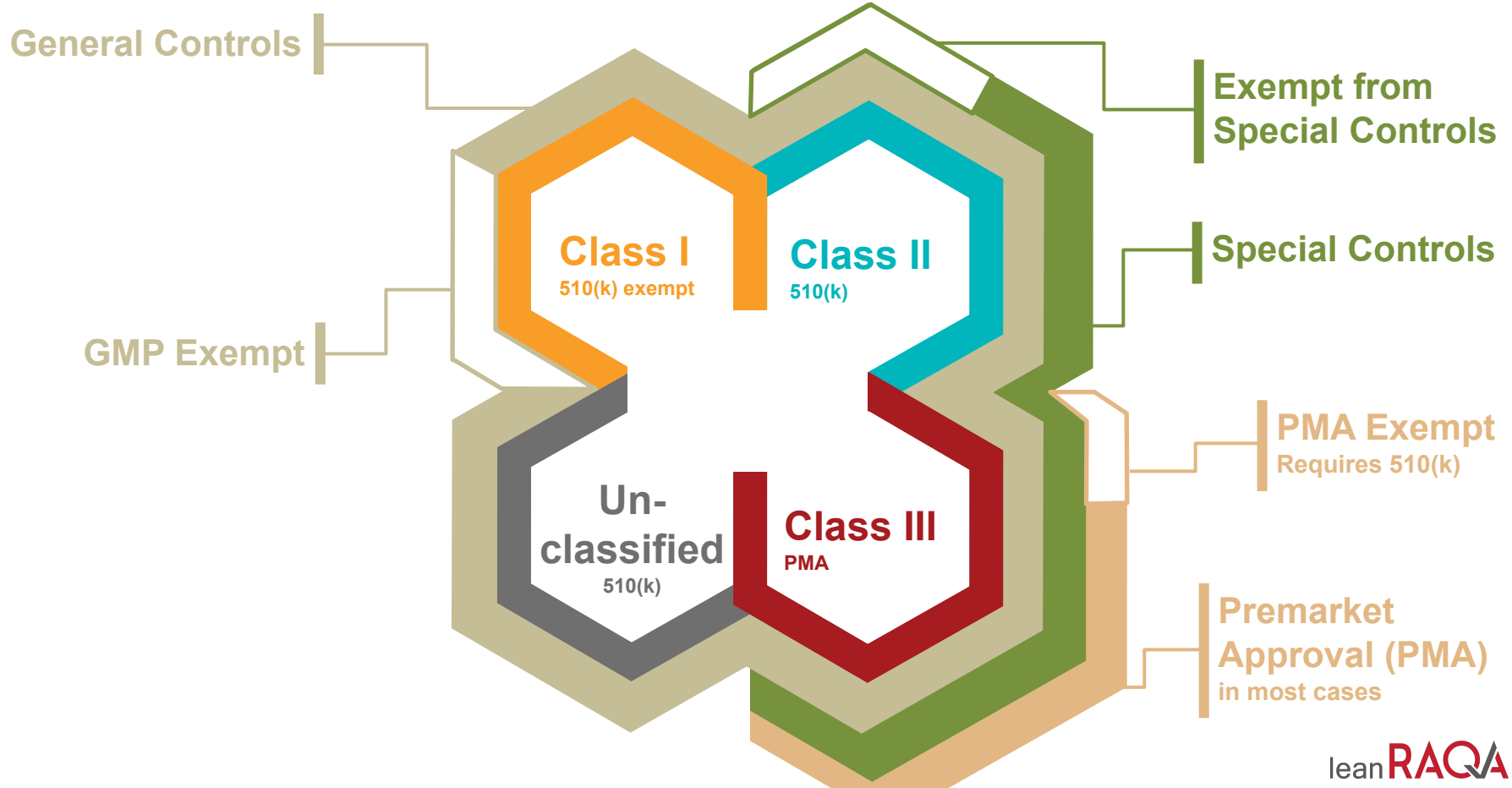
Regulatory pathway

Table 1. Ventilators

21 CFR Reg. #	Device Type				Product Code	Class
868.5895	Ventilator	Continuous	–	Facility Use	CBK	II
				Home Use	NOU	
			Minimal Ventilatory Support	Facility Use	MNT	
				Home Use	NQY	
			Non Life-Supporting		MSN	
	Mechanical Ventilator				ONZ	
868.5925	Ventilator, Emergency, Powered (Resuscitator)				BTL	
868.5160	Gas-machine, Anesthesia				BSZ	
868.5905	Ventilator, Non-Continuous (Respirator) Including masks and interfaces under the same product code (limited to masks used with a ventilator, does not refer to PPE such as surgical masks. 21 CFR 878.4040)				BZD	
	Conserver, Oxygen				NFB	
	Device, Positive Pressure Breathing Intermittent				NHJ	
	Resuscitator, Manual, Non Self-Inflating				NHK	
868.5454	High flow/high velocity humidified oxygen delivery device				QAV	

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Regulatory pathway

Table 2. Ventilator Tubing Connectors & Ventilator Accessories

21 CFR Reg. #	Device Type	Product Code	Class
868.5240	Anesthesia breathing circuit	OFP	I
		CAI	
868.5260	Filter, Bacterial, Breathing Circuit	CAH	II
868.5270	Heated Breathing Circuit	BZE	
868.5340	Cannula, Nasal, Oxygen	CAT	I
868.5450	Generator, Oxygen, Portable	CAW	II
868.5450	Humidifier, Respiratory Gas, (Direct Patient Interface)	BTT	
868.5580	Mask, Oxygen	BYG	I
868.5730	Tube, Tracheal (W/Wo Connector)	BTR	II
	Airway Monitoring System	OQU	
868.5895	Accessory to Continuous Ventilator (Respirator)	MOD	
868.5965	Attachment, Breathing, Positive End Expiratory Pressure	BYE	
868.5975	Set, Tubing and Support, Ventilator	BZO	I

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SUPPLY CHAIN

Supply chain

If we can't get a specific component because of supply chain interruptions, can we swap it out for an identical or very similar one?

► **It would depend on the component and its intended purpose/performance on the finished product.**

► **Hypothetically, you can, as long as you have identified and tested the replacement component to the performance of the OEM component and there are no new concerns of safety of effectiveness. However, this would have to be pre-evaluated with the appropriate testing.**

► **Testing may include performance, biocompatibility, sterility, shelf-life, etc.**

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SOFTWARE / APP & CLOUD

Software / App & Cloud

Q11 **How do we update our software? Are we allowed to do this over the internet?**

► **Yes – if performed using secure internet connection with cybersecurity protocols**

► **Federal Communications Commission (FCC) oversees the use of the public Radio Frequency (RF) spectrum within which RF wireless technologies operate.**

► **FDA's policies on wireless medical devices are coordinated with the FCC and provide more predictability and a better understanding of regulatory requirements.**

► **Follow <u>FDA guidance</u> to ensure cybersecurity is considered within the design and development of the medical device.**

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Everybody Plays a Role

▶ **Medical device manufacturers (MDMs) and healthcare delivery organizations (HDOs) must ensure appropriate cybersecurity safeguards are in place.**

– **MDMs** are responsible for remaining vigilant about identifying risks and hazards associated with their medical devices, including risks related to cybersecurity.

– **HDOs** should evaluate their network security and protect their hospital systems.

– Both **MDMs and HDOs** are responsible for putting appropriate mitigations in place to address patient safety risks and ensure proper device performance.

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Software / App & Cloud

Are our ventilators allowed to connect to the cloud to send telemetry?

▶ **You can if you establish and conform to FDA Cybersecurity requirements and HIPAA Privacy Rule.**

▶ **The HIPAA Privacy Rule**
- Establishes standards to protect individuals' medical records and personal health information (PHI) for entities that conduct health care transactions electronically.
- Requires appropriate safeguards to protect the privacy of PHI without patient authorization.
- Gives patients rights over their health information, including rights to examine and obtain a copy of their health records, and to request corrections.
- Is located at 45 CFR Part 160 and Subparts A and E of Part 164.

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Software / App & Cloud

Q13 **Can we have an app for a mobile phone controlling a ventilator? Would the app be a separate product from the ventilator?**

▶ **The app would be considered a Mobile Medical Application (MMA) and is regulated by the FDA.**

– A "mobile medical app" is a mobile app that incorporates device software functionality that meets the definition of device in section 201(h) of the FD&C Act; and either is intended:

  • to be used as an accessory to a regulated medical device; or

  • to transform a mobile platform into a regulated medical device.

▶ **Yes, the app can be separate from ventilator or be considered an accessory to the ventilator.**

– In both instances a regulatory assessment and/or clearance is required.

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Software / App & Cloud

Q14 **I am making a ventilator controller that I want other teams to be able to use on their ventilators. I will be aiming for ISO standards compliance and keeping proper documentation, but I'm unsure if I need to get FDA clearance/approval for the software, or can I leave the application to the teams using the software?**

▶ **Clearance/approval with hardware**
  – Referring to FDA's guidance on <u>Software contained in Medical Devices</u>,
    • The guidance applies to software devices regardless of the means by which the software is delivered to the end user, whether factory-installed, installed by a third-party vendor, or field- installed or -upgraded.
  – Consider ISO 62304 and TIR 45 for best practices in software development documentation

▶ **Manufacturer's responsibility to validate that it can be used appropriately with their system**

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Software

```
              ┌──────────────┐
              │   Software   │
              └──────┬───────┘
     ┌───────────┬───┴────────┬────────────┐
     ▼           ▼            ▼            ▼
```

| Part of a medical device | Stand-Alone (Software as a medical device, SaMD) | Accessory to a medical device | Not a medical device |

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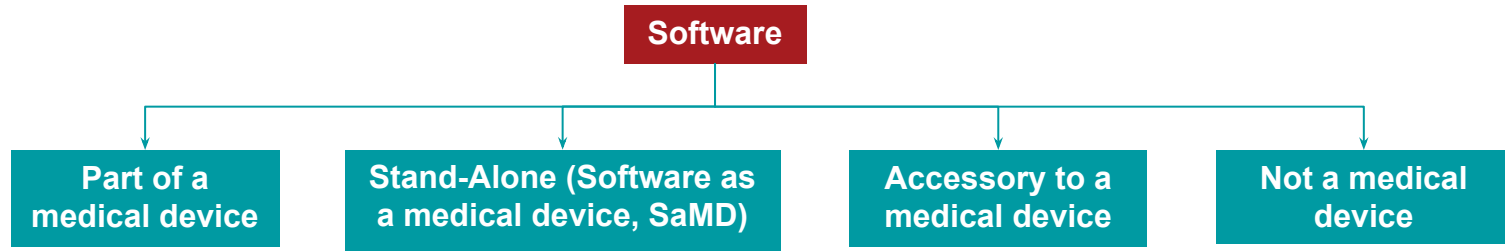
IMDRF Framework [1 of 2]

► **Two major factors for the risk categorization of a SaMD**
 – The significance of information provided by a SaMD to the health care decision
 – The state of the health care situation or condition

State of health care situation or condition	Significance of information provided by SaMD to health care decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I

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► **Two major factors for the risk categorization of a SaMD**

– The significance of information provided by a SaMD to the health care decision

– The state of the health care situation or condition

Criticality of health care situation or condition	
INCREASING→	**Critical:** Where accurate and/or timely diagnosis or treatment action is vital to avoid death, long-term disability or other serious deterioration of health of an individual patient or to mitigation impact to public health.
	Serious: Where accurate diagnosis or treatment is of vital importance to avoid unnecessary interventions
	Non-serious: Where an accurate diagnosis and treatment is **important but not critical** for interventions.

Significance of information	
INCREASING→	**Treat or diagnose:** • To provide therapy to a human body • To diagnose/screen/detect a disease or condition
	Drive clinical management: • To aid in treatment by providing enhanced support to safe and effective use of medicinal products or a medical device. • **To aid in** diagnosis to help predict risk of disease/condition **or in making a definitive diagnosis** • To **triage/identify early signs** or disease or **condition**
	Inform clinical management: • To inform options • To provide clinical information by aggregating relevant information

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Your regulatory strategy

Your regulatory submissions

Your quality systems
and compliance

Your **EMERGENCY USE**

Your due diligence

Your technical support

Your grief counseling

lean**RAQA**

Your Michelle Lott, RAC

michelle@leanRAQA.com

520.275.9838

companies	industries
large	medical device
mid-sized	emergency use
small	biologics
startup	pharma
	cosmetics
	dietary supplements

Risk Management
&
Open source medical device development

E.g. ventilators

Pierre Lonchampt, PhD
(Industry / Helpful Engineering)

1

WHY?

Assumption / context

"Giving the design away"

Design and development

?

Manufacturing and distribution "(and regulatory release)"

"Community/ies"

FOSS

Non-profit

"Manufacturer of record"

IP, Licensing etc...

Regulations / responsability

Investment/ profitability

org/cern_ohl_p_v2.txt

Website Homepage Forum
You ... ...ovided that You ensure
that the ... ...ess to any Notices applicable
to the Product.
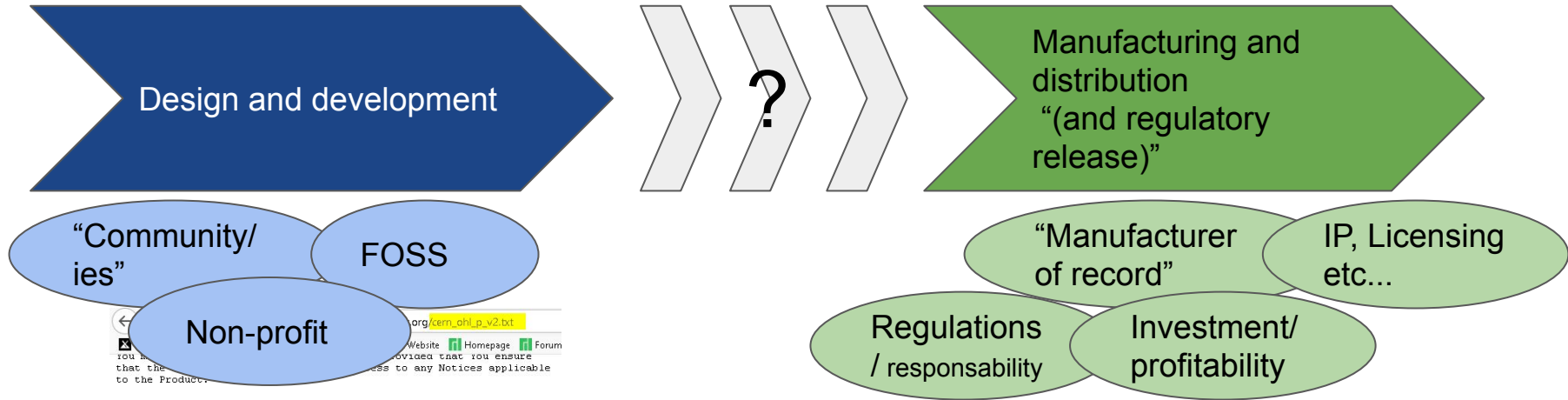
5 DISCLAIMER AND LIABILITY

5.1 DISCLAIMER OF WARRANTY -- The Covered Source and any Products
    are provided 'as is' and any express or implied warranties,
    including, but not limited to, implied warranties of
    merchantability, of satisfactory quality, non-infringement of
    third party rights, and fitness for a particular purpose or use
    are disclaimed in respect of any Source or Product to the
    maximum extent permitted by law. The Licensor makes no
    representation that any Source or Product does not or will not
    infringe any patent, copyright, trade secret or other
    proprietary right. The entire risk as to the use, quality, and
    performance of any Source or Product shall be with You and not
    the Licensor. This disclaimer of warranty is an essential part
    of this Licence and a condition for the grant of any rights
    granted under this Licence.

HELPFUL QA

3

Risk Management - Why?

- Why not leave this lot (QA, RA, Risk Management) completely to the "manufacturer of record" ?
- Ethics
  - Being Helpful and Safe
  - Would you use it on your grandma?
  - Even if you do NOT HAVE TO [Accessory / mod]
- Confidence AND efficient communication/documentation [Michelle : "Make it easier"]
  - Internal
    - Community -> lack of experience, potentially high volatility   -> formal record of design rationale
    - Ability to engage experts
  - External
    - Convince / engage "Manufacturer(s) of record"
  - User / doctors
    - [Worst case scenario / Leaving aside any "regulatory clearance"] :
      - -> Doctors will "do no harm"

Risk Management - Why ? (2)

- I read the FDA EUA, there is nothing about "Risk Management" .What does the regulations say exactly about that ?

- Covid / Emergency

FDA EUA

Appendix A. Criteria for Safety, Performance and Labeling

To be added to Appendix B, ventilators, ventilator tubing connectors, and ventilator accessories must be determined to meet the applicable criteria for safety, performance and labeling set forth below. FDA will add a ventilator, ventilator tubing connector, or ventilator accessory to the list of authorized products in 0 upon submission of a request from the sponsor as described in Section II and after confirmation that the applicable safety, performance and labeling criteria have been met, and pursuant to the Conditions of Authorization in this EUA.

Declarations of Conformity

Sponsors should provide declarations of conformance with the following standards as applicable:

- IEC 60601-1: 2012: *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance*
- IEC 60601-1-2: 2014: *Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests*
- IEC 60601-1-11: 2015: *Medical Electrical Equipment Part 1-11: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment*
- Any other applicable collateral/particular standards in the IEC 60601-1: 2012 family
- IEC 62304: 2015: *Medical Device Software – Software Life Cycle Processes*
- AAMI TIR69: 2017: *Technical Information Report Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems*
- ANSI/IEEE C63.27: 2017: *American National Standard for Evaluation of Wireless Coexistence*
- AAMI TIR69: 2017: *Technical Information Report Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems*
- ISO 10993: First Edition 2018-08: *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process*
- ISO 18562-1 First Edition 2017-03: *Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 1: Evaluation and Testing Within a Risk Management Process*
- ISO 18562-2 First Edition 2017-03: *Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 2: Tests for Emissions of Particulate Matter*
- ISO 18562-3 First Edition 2017: *Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 3: Tests for Emissions of Volatile Organic Compounds*
- ISO 18562-4 First Edition 2017-03: *Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 4: Tests for Leachables in Condensate*

In addition, sponsors should provide declarations of conformance with the following particular standards as applicable to the device:

- ISO 10651-5 First Edition 2006-02-01: *Lung Ventilators for Medical Use - Particular Requirements for Basic Safety and Essential Performance - Part 5: Gas Powered Emergency Resuscitators*
- ISO 17510 First Edition 2015-08-01: *Medical devices -- Sleep apnoea breathing therapy Masks and application accessories*
- ISO 80601-2-12 First Edition 2011-04-15: *Medical Electrical Equipment - Part 2-12: Particular Requirements for the Safety of Lung Ventilators - Critical Care Ventilators [Including: Technical Corrigendum 1 (2011)]*
- ISO 80601-2-13 First Edition 2011-08-11: *Medical Electrical Equipment -- Part 2-13: Particular Requirements for Basic Safety and Essential Performance of an Anaesthetic Workstation [Including: Amendment 1 (2015) and Amendment 2 (2018)]*
- ISO 80601-2-69 First Edition 2014-07-15: *Medical Electrical Equipment - Part 2-69: Particular Requirements for Basic Safety and Essential Performance of Oxygen Concentrator Equipment*
- ISO 80601-2-70 First Edition 2015-01-15: *Medical Electrical Equipment - Part 2-70: Particular Requirements for Basic Safety and Essential Performance of Sleep Apnoea Breathing Therapy Equipment*
- ISO 80601-2-74 First Edition 2017-05: *Medical Electrical Equipment - Part 2-74: Particular Requirements for Basic Safety and Essential Performance of Respiratory Humidifying Equipment*
- ISO 80601-2-79 First Edition 2018-07: *Medical electrical equipment - Part 2-79: Particular Requirements for Basic Safety and Essential Performance of Ventilatory Support Equipment for Ventilatory Impairment*
- ISO 80601-2-80 First Edition 2018-07: *Medical Electrical Equipment - Part 2-80: Particular Requirements for Basic Safety and Essential Performance of Ventilatory Support Equipment for Ventilatory Insufficiency*

Device Specifications and Instructions for Ventilators and Accessories

Sponsors of ventilators, ventilator tubing connectors, and ventilator accessories should provide the following specification information.

For devices for delivering ventilatory support, sponsors should provide specific information and instructions regarding the device's:

- Available ventilation modes, patient interfaces, ventilatory parameter ranges (e.g., maximum inspiratory pressure, positive end-expiratory pressure, respiration rate, flow, delivered tidal volume, triggering, etc.)
- Battery specifications (if applicable), including runtime, how users are notified of device battery status (e.g., alarms), and expected use life that is supported by testing. For devices with external or replaceable internal batteries, the sponsor should provide information regarding chemistry, including information regarding design, capacity, and software and/or hardware risk mitigations for overcharging,

You can NOT comply with IEC60601, IEC62304, ISO10993 or ISO18562, without RISK MANAGEMENT

4 General requirements

4.1 * Conditions for application to ME EQUIPMENT or ME SYSTEMS

Unless otherwise specified, the requirements of this standard shall apply in NORMAL USE and reasonably foreseeable misuse.

When applying this standard to ME EQUIPMENT or ME SYSTEMS intended for the compensation or alleviation of disease, injury or disability, the definitions and requirements that use the term PATIENT shall be considered as applying to the person for whom the ME EQUIPMENT or ME SYSTEM is intended.

4.2 * RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS

A RISK MANAGEMENT PROCESS complying with ISO 14971 shall be performed.

In applying ISO 14971:

– The term "medical device" shall assume the same meaning as ME EQUIPMENT or ME SYSTEM.

60601-1 © IEC:2005   – 81 –

– The term "fault conditions" referred to in ISO 14971 shall include, but shall not be limited to, SINGLE FAULT CONDITIONS identified in this standard.

– The policy for determining acceptable RISK and the acceptability of the RESIDUAL RISK(S) shall be established by the MANUFACTURER.

– Where this standard or any of its collateral or particular standards specify verifiable requirements addressing particular RISKS, and these requirements are complied with, the RESIDUAL RISKS addressed by these requirements shall be presumed to be acceptable unless there is OBJECTIVE EVIDENCE to the contrary.

62304 © IEC:2006   – 11 –

INTRODUCTION

Software is often an integral part of MEDICAL DEVICE technology. Establishing the SAFETY and effectiveness of a MEDICAL DEVICE containing software requires knowledge of what the software is intended to do and demonstration that the use of the software fulfils those intentions without causing any unacceptable RISKS.

This standard provides a framework of life cycle PROCESSES with ACTIVITIES and TASKS necessary for the safe design and maintenance of MEDICAL DEVICE SOFTWARE. This standard provides requirements for each life cycle PROCESS. Each life cycle PROCESS is further divided into a set of ACTIVITIES, with most ACTIVITIES further divided into a set of TASKS.

As a basic foundation it is assumed that MEDICAL DEVICE SOFTWARE is developed and maintained within a quality management system (see 4.1) and a RISK MANAGEMENT system (see 4.2). The RISK MANAGEMENT PROCESS is already very well addressed by the International Standard ISO 14971. Therefore IEC 62304 makes use of this advantage simply by a normative reference to ISO 14971. Some minor additional RISK MANAGEMENT requirements are needed for software, especially in the area of identification of contributing software factors related to HAZARDS. These requirements are summarized and captured in Clause 7 as the software RISK MANAGEMENT PROCESS.

7

UK MHRA

Medicines & Healthcare products Regulatory Agency

b. Must be PAT tested to the adapted IEC 60601, IEC 62353 standards

4. All elements in the gas pathway must meet biological safety and low-pressure oxygen safety standards, especially to minimise risk of fire or contamination of the patient's airway.

Monitoring and Alarms

IEC60601-1-8:2006 is the one re limits and priorities are complex

Biological Safety

The authoritative standard covering this area is ISO 18562-1:2017 "Biocompatibility evaluation of breathing gas pathways in healthcare applications. Evaluation and testing within a risk management process"

Medicines & Healthcare products Regulatory Agency

Appendix C

Software development requirements for a Rapidly Manufactured Ventilator System.

The authoritative standards for the development of software for medical devices are BS EN 62304:2006+A1:2015 Medical device software — Software life-cycle processes and BS EN ISO 14971:2012 Medical Devices – Application of risk management to medical devices. Where possible software for a Rapidly Manufactured Ventilator System should be developed in a facility that has experience of developing software using these standards.

A Rapidly Manufactured Ventilator System incorporating software is likely to be a high-risk device that will almost certainly, before the implementation of software risk control measures (RCMs), have the capability to cause serious injury or death. Because it is likely that the software will be developed to an accelerated life cycle it is essential that the following principles are adhered to:

1. The software is developed under strict process control using a quality management system, ideally BS EN ISO 13485 or BS EN ISO 9001.
2. A process is followed to determine the risks arising from the operation of the software and to mitigate those risks. This is most easily done by the application of BS EN ISO 14971.
3. A software development process is followed to achieve a low probability of failure of the software in use. This is most easily done by the appropriate application of BS EN 62304 based on the risk management process in 2 above.
4. Less emphasis need be placed on the requirements of BS EN ISO 62304 software post-production monitoring and maintenance processes.

c. Instructions for use should be built into the labelling of the ventilator, e.g. with 'connect this to wall' etc.

d. Must include clear labelling of all critical functions and controls using standard terms, pictograms and colours that will be readily recognised by UK healthcare staff.

7. Must have transparent design, supply chain, manufacture, quality assurance and testing processes that are of sufficient quality to enable MHRA officials to deem appropriate for usage in exceptional circumstances.

8. Must not be excessively cumbersome so that it would impede hospital operations or prevent easy movement within hospital premises.

9. Must be made from materials and parts readily available in the UK supply chain (anticipating increasing global restrictions on freight movement).

10. Standards – there are many standards that exist in this area. Below is a list of the most relevant ones. They are not formal regulatory requirements, but many are harmonised against regulatory requirements. Consider them as helpful advisory standards for now. MHRA will lead an exercise to define which can be 'safely' relaxed for this emergency situation.

a. BS EN 794-3:1998 +A2:2009 Particular requirements for emergency and transport ventilators
b. ISO 10651-3:1997 Lung Ventilators for Medical Use - Emergency and Transport
c. BS ISO 80601-2-84:2018 Medical electrical equipment. Part 2-84. Particular requirements for basic safety and essential performance of emergency and transport ventilators – especially the parts on 'patient gas pathway' safety (very similar to IEC 60601)
d. ISO 80601-2-12:2020 Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
e. BS ISO 19223:2019 Lung ventilators and related equipment. Vocabulary and semantics

Testing

1. It is accepted that full demonstration of compliance to ISO 80601-2-12:2020 is unrealistic in the time frame required for development. Nevertheless, compliance with the essential safety standards must be demonstrated for patient safety.

2. It is not anticipated that devices will be CE marked and approval by the MHRA will be through the "Exceptional use of non-CE marked medical devices" route (https://www.gov.uk/guidance/exceptional-use-of-non-ce-marked-medical-devices)

8

FDA EUA / UK MHRA / EU

- Note the "as applicable", 'Likely' , 'Should'...
- Why are there so many standards ?
- How to know what is 'applicable'?

10. Standards – there are many standards that exist in this area. Below is a list of the most relevant ones. They are not formal regulatory requirements, but many are harmonised against regulatory requirements. Consider them as helpful advisory standards for now. MHRA will lead an exercise to define which can be 'safely' relaxed for this emergency situation.

- Making a guess of what sort of "exercise" the MHRA will lead ? What sort of "assessment" the member states competent authorities will carry out ?

peter0/09 MDCG 2020-9 Regulatory Requirements for Ventilators and Reated

− + Automatic Zoom

4.2. Derogation procedure – placing on the market authorised by the relevant authorities of one Member State in the interest of public health

The relevant authority of one Member State may decide to authorise the placing on the market of devices in the interest of protection of health, even if the applicable conformity assessment procedures have not been finalised or initiated ('national derogation').

In view of the epidemiological context as well as the exponential growth in demand for medical devices, the Commission has published a Guidance on medical devices, active implantable medical devices and in vitro diagnostic medical devices in the Covid-19 context.

Question 5 of this guidance provides information on the derogation procedures for medical devices which is established in Article 11(13) of the MDD. In particular, the guidance specifies that the Covid-19 context warrants the application of such derogations.

By amendment of 23 April 2020[13], Article 59(1) of Medical Devices Regulation (EU) 2017/745 (MDR) empowers Member States to adopt national derogations under both the MDD and the MDR from the date of entry into force of that amendment.

The relevant competent authority of the Member State in this case authorises the placing on the market within its territory and can also organise the purchase.

In practice, this implies that each competent authority would need to assess whether the products produced by the manufacture provides an adequate level of safety in respect to the applicable legal requirements. The assessment procedures can vary among Member States and in some cases will involve the support of third parties (e.g. testing laboratories).

In the exceptional COVID-19 context, the assessment procedures will ensure a short-term supply while guaranteeing patient safety[14]. The Member State will evaluate the available technical documentation to find evidence that essential performance and safety requirements are guaranteed in the context of use. In particular, the role of healthcare teams and health facilities is essential to allow a rational use and a continuous assessment
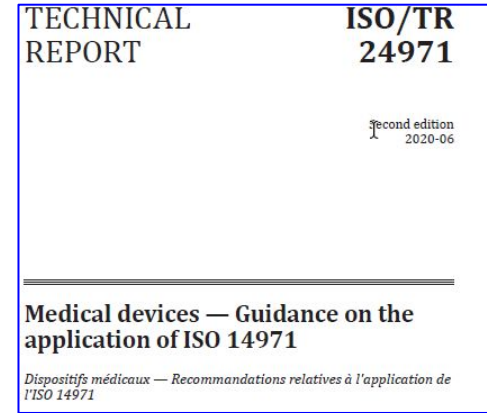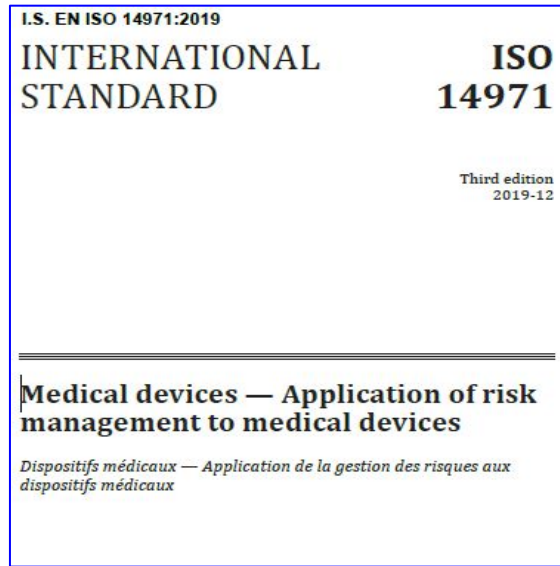
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Conclusion 1 (the 'why')

RISK MANAGEMENT should be the FIRST standard you aim at :

- It is required to be able to aim at the other standards anyway
- It is what justify / put in context most (if not all) the other ones!
  - "How" -> Risk Controls
  - - > Prioritize the work
- (My guess:) It is what regulators rely on to set the bar in regards to the level of emergency ("should", "safely relaxed"...)
  - FDA/MHRA/EU Member states ...what about all the other countries (the EUA does not apply anywhere else than in the USA!)
  - Using the same language

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How ?

ISO 14971

I.S. EN ISO 14971:2019

INTERNATIONAL STANDARD — **ISO 14971**

Third edition
2019-12

Medical devices — Application of risk management to medical devices

Dispositifs médicaux — Application de la gestion des risques aux dispositifs médicaux

TECHNICAL REPORT — **ISO/TR 24971**

Second edition
2020-06

Medical devices — Guidance on the application of ISO 14971

Dispositifs médicaux — Recommandations relatives à l'application de l'ISO 14971

- BS / IS EN … :2012 vs :2019… does not [really] matter
- This is a PROCESS standard
- Note also ISO/TR 24971 guidance
- Copyright material...but during Covid they are available for free

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Definitions

risk management
systematic application of management policies, *procedures* (3.13) and practices to the tasks of analysing, evaluating, controlling and monitoring *risk* (3.18)

risk
combination of the probability of occurrence of *harm* (3.3) and the *severity* (3.27) of that *harm* (3.3)

harm
injury or damage to the health of people, or damage to property or the environment

risk analysis
systematic use of available information to identify *hazards* (3.4) and to estimate the *risk* (3.18)

hazard
potential source of *harm* (3.3)

risk estimation
process (3.14) used to assign values to the probability of occurrence of *harm* (3.3) and the *severity* (3.27) of that harm

risk evaluation
process (3.14) of comparing the estimated *risk* (3.18) against given *risk* (3.18) criteria to determine the acceptability of the *risk* (3.18)

risk control
process (3.14) in which decisions are made and measures implemented by which *risks* (3.18) are reduced to, or maintained within, specified levels

Definitions (2)

hazardous situation
circumstance in which people, property or the environment is/are exposed to one or more *hazards* ([3.4](#))

reasonably foreseeable misuse
use of a product or system in a way not intended by the *manufacturer* ([3.9](#)), but which can result from readily predictable human behaviour

Note 1 to entry: Readily predictable human behaviour includes the behaviour of all types of users, e.g. lay and professional users.

Note 2 to entry: *Reasonably foreseeable misuse* can be intentional or unintentional.

residual risk
risk remaining after *risk control* ([3.21](#)) measures have been implemented

risk assessment
overall *process* ([3.14](#)) comprising a *risk analysis* ([3.19](#)) and a *risk evaluation* ([3.20](#))

Process summary

Obviously - the "manufacturer or record" will have to finish the job
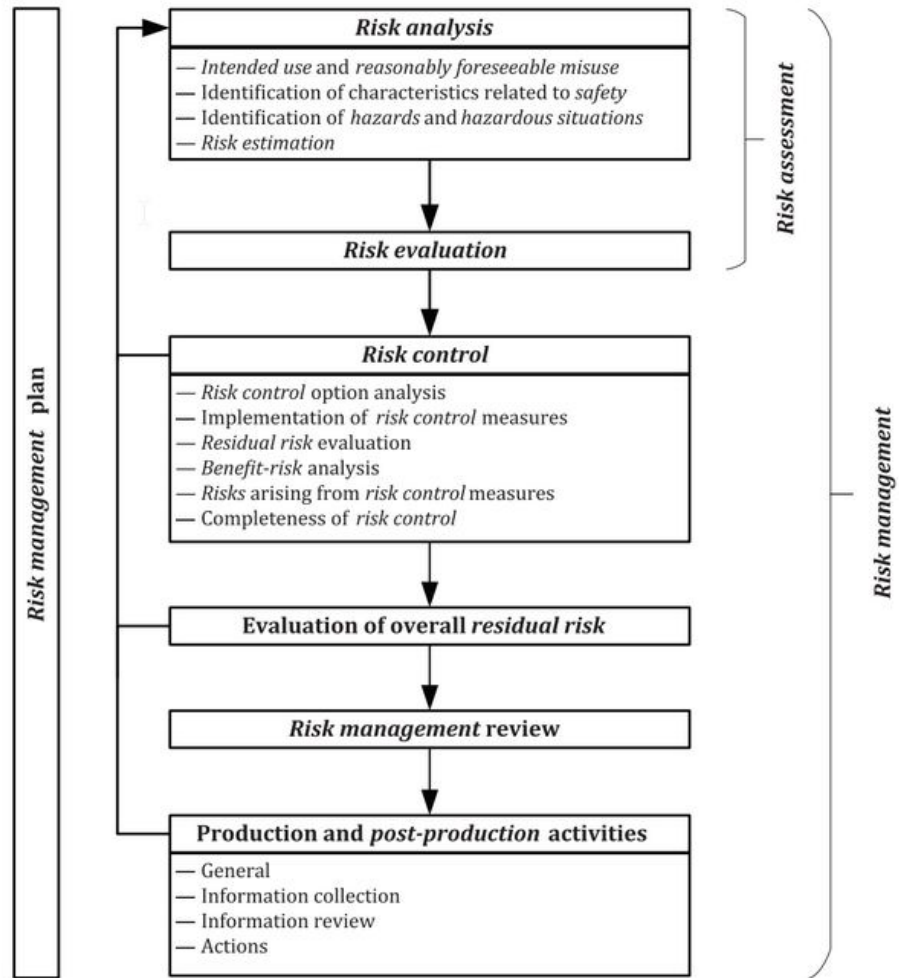
Figure 1 — A schematic representation of the *risk management process*

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Plan

- SCOPE. Define the device and the goal of the project in terms of "giving the design away" [Michelle : accessory / component etc].
- RESPONSIBILITIES
- Establish risk acceptability [??? -> we'll see later]
- Identify resources for REVIEWS
- Helfpul may help with documenting/ signatures/ templates https://tinyurl.com/HelpfulQMS
- DO IT and update when needed.
- [Michelle] -> Regulatory Pathway

4.4   Risk management plan

Risk management activities shall be planned. For the particular *medical device* being considered, the *manufacturer* shall establish and document a *risk management* plan in accordance with the *risk management process*. The *risk management* plan shall be part of the *risk management file*.

This plan shall include at least the following:

a)   the scope of the planned *risk management* activities, identifying and describing the *medical device* and the *life cycle* phases for which each element of the plan is applicable;

b)   assignment of responsibilities and authorities;

c)   requirements for review of *risk management* activities;

d)   criteria for *risk* acceptability, based on the *manufacturer's* policy for determining acceptable *risk*, including criteria for accepting *risks* when the probability of occurrence of *harm* cannot be estimated;

NOTE 1   The criteria for *risk* acceptability are essential for the ultimate effectiveness of the *risk management process*. For each *risk management* plan the *manufacturer* needs to establish *risk* acceptability criteria that are appropriate for the particular *medical device*.

e)   a method to evaluate the overall *residual risk*, and criteria for acceptability of the overall *residual risk* based on the *manufacturer's* policy for determining acceptable *risk*;

NOTE 2   The method to evaluate the overall *residual risk* can include gathering and reviewing data and literature for the *medical device* being considered and similar *medical devices* on the market and can involve judgment by a cross-functional team of experts with application knowledge and clinical expertise.

f)   activities for *verification* of the implementation and effectiveness of *risk control* measures; and

g)   activities related to collection and review of relevant production and *post-production* information.

NOTE 3   See ISO/TR 24971[9] for guidance on developing a *risk management* plan and on establishing criteria for *risk* acceptability.

NOTE 4   Not all parts of the plan need to be created at the same time. The plan or parts of it can be developed over time.

If the plan changes during the *life cycle* of the *medical device*, a *record* of the changes shall be maintained in the *risk management file*.

Compliance is checked by inspection of the *risk management file*.

Analysis

Intended use: Home ? Emergency ? Ward ? ICU ? Age? Short term? Country ? What specialty Doctor? Nurse? Supervised? Only Covid? What [exact] clinical indication?...

Accessories, kit etc...

Product classification/code / predicates

Then you can start thinking about the foreseeable misuse. (Use Usability Engineering - IEC62366)

Characteristics - > Helpful can help

https://tinyurl.com/HelpfulQMS

(Safety Characteristics table courtesy https://decusbiomedical.com/

Risk analysis

- Intended use and reasonably foreseeable misuse
- Identification of characteristics related to safety
- Identification of hazards and hazardous situations
- Risk estimation

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Category: HE-QS
Title: HE-QS-TPLT007-RiskCharacteristics

Version	State	Effective Date	Document ID
01	Effective	30-JUN-2020	357612
	HE number or QMS number TPLT007		

	routine cleaning and disinfection. In addition, consideration should be given to the effect of cleaning and disinfecting agents on the safety or performance of the device. >			
10	Is the medical device intended to modify the patient environment? < Factors that should be considered include: - temperature; - humidity; - atmospheric gas composition; - pressure; - light. >			
11	Are measurements taken? < Factors that should be considered include the variables measured and accuracy and the precision of the measurement results. >			
12	Is the medical device interpretative? < Factors that should be considered include whether conclusions are presented by the medical device from input or acquired data, the algorithms use, and confidence limits. Special attention should be given to unintended applications of the data or algorithm. >			
13	Is the medical device intended for use in conjunction with other medical devices? < Factors that should be considered include identifying any other medical devices, medicines or other medical technologies that can be involved and the potential problems associated with such interactions, as well as patient compliance with the therapy. >			

Analysis (2)

Identify hazards and hazardous situations:

- MHRA Medical Device Alerts (UK) www.gov.uk/drug-device-alerts
- SwissMedic Recalls & FSCA (Switzerland) https://fsca.swissmedic.ch/mep/#/
- US FDA MAUDE Database (USA) www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
- US FDA Medical Device Recalls (USA) www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/textsearch.cfm
- US FDA TPLC Total Product Life Cycle (USA)https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm.
- Google, Scientific Lit., PROFESSIONAL BODIES
- Look around Helpful, Git, etc
- INVOLVE experts [MICHELLE, ERICH]
- STANDARDS again !!
- Great opportunity for collaboration between teams

White box / bottom up - vs Black box / top down ("in" the product, vs "with" the product). For complex / life saving / critical care products, both (or more!) are required. They are complementary.

Risk analysis

- *Intended use* and *reasonably foreseeable misuse*
- Identification of characteristics related to *safety*
- Identification of *hazards* and *hazardous situations*
- *Risk estimation*

ISO 14971:2019(E)
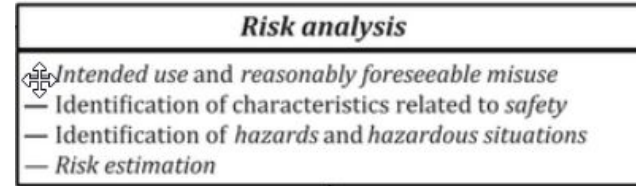
Table C.1 — Examples of *hazards*

Energy *hazards*	Biological and chemical *hazards*	Performance-related *hazards*
Acoustic energy	**Biological agents**	**Data**
— infrasound	Bacteria	— access
— sound pressure	Fungi	— availability
— ultrasonic	Parasites	— confidentiality
Electric energy	Prions	— transfer
Electric fields	Toxins	— integrity
Leakage current	Viruses	**Delivery**
— earth leakage	**Chemical agents**	— quantity
— enclosure leakage	Carcinogenic, mutagenic, reproductive	— rate
Magnetic fields	Caustic, corrosive	**Diagnostic information**
Static discharge	— acidic	— examination result
Voltage	— alkaline	— image artefacts
Mechanical energy	— oxidants	— image orientation
Kinetic energy	Flammable, combustible, explosive	— image resolution
— falling objects	Fumes, vapors	— patient identity / information
— high pressure fluid injection	Osmotic	**Functionality**
— moving parts	Particles (including micro- and nano-particles)	— alarm
— vibrating parts	Pyrogenic	— critical performance
Potential (stored) energy	Solvents	— measurement
— bending	Toxic	
— compression	— asbestos	
— cutting, shearing	— heavy metals	
— gravitational pull	— inorganic toxicants	
— suspended mass	— organic toxicants	
— tension	— silica	
— torsion	**Immunological agents**	
Radiation energy	Allergenic	
Ionizing radiation	— antiseptic substances	
— accelerated particles (alpha particles, electrons, protons, neutrons)	— latex	
— gamma	Immunosuppressive	
— x-ray	Irritants	
Non-ionizing radiation	— cleaning residues	
— infrared	Sensitizing	
— laser		
— microwave		
— ultraviolet		
Thermal energy		
Cryogenic effects		
Hyperthermic effects		

Jeff 12:16 PM

Hey. I wanted to share with this group a serious concern of mine. From personal testing and other groups we learned Ambu bags tend to tear creating a hole after a few days of use. They simply were not designed to handle the friction/cycles. It worries me to see so many ventilator designs that use Ambu bags. They really are not safe

5:16 PM

Thanks for sharing your concern @Dr. Jeff. Would concur with you. Some caveats though. There are obviously many manufacturers for such bags (ambu/bvm). Some/most are reusable whereas some are single-handful use. Laerdal is probably the widely used brand which has both versions.

To briefly add, the lifespan of the reusable ones would depend on:

- the material
- the nature of its usage (these pressurised usage are clearly not what it was initially designed for, hence the quick wear and tear),
- how it "performed" during actual use
- how it is cleaned/sterilised (if reusable)
- manufacturer recommendation (re: usage and etc)

Also, this was an issue clearly defined and delineated by most working groups from the very beginning. I hope this helped to verify and reassure your concerns.

Cheers

Analysis (3)

Risk Estimation = Severity + Probability

Qualitative is better than "poor quantitative"

Comprehensive/broad is more important than "apparently accurate"

Whitebox / Blackbox likely to use different scales

Risk analysis

- Intended use and reasonably foreseeable misuse
- Identification of characteristics related to safety
- Identification of hazards and hazardous situations
- Risk estimation

ISO 14971:2019 requires the manufacturer to perform risk estimation. Various methods can be used to estimate risk. Those methods should examine, for example:

— the circumstances in which a hazard is present;

— the sequence of events leading to a hazardous situation;

— the probability of a hazardous situation occurring;

— the probability of a hazardous situation leading to harm;

— the nature of the harm that could result.

Table 2 — Example of three qualitative severity levels

Common terms	Possible description
Significant	Death or loss of function or structure
Moderate	Reversible or minor injury
Negligible	No injury or slight injury

Table 3 — Example of three qualitative probability levels

Common terms	Possible description
High	Likely to happen, often, frequently, always
	Likely to happen several times during the lifetime of the medical device
Medium	Can happen, but not frequently
	Likely to occur a few times during the lifetime of the medical device
Low	Unlikely to happen, rare, remote
	Not likely to occur during the lifetime of the medical device

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QA

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Evaluation

- For each identified hazardous situation, the manufacturer shall evaluate the estimated risks and determine if the risk is acceptable or not, using the criteria for risk acceptability <u>defined in the risk management plan</u>.
- If the risk is acceptable and the estimated risk shall be treated as residual risk.
- If the risk is not acceptable (or in the "middle")
  - -> risk control

		Qualitative *severity* levels				
		Negligible	**Minor**	**Serious / Major**	**Critical**	**Catastrophic / Fatal**
Semi-quantitative probability levels	**Frequent**					
	Probable	R_1	R_2			
	Occasional		R_4		R_3	
	Remote	R_6				
	Improbable			R_5		

Key

� gray	unacceptable *risk*
light gray	investigate further *risk control*
white	insignificant or negligible *risk*

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Control

Identify means of reducing the risk associated with the unacceptable (or "in the middle") hazard/hazardous situation identified previously.

PRIORITY: Inherent safe design -> Protection -> Information / training

Table 6 — Examples of *risk control* measures

Medical device	Hazard	Hazardous situation	Inherently safe design	Protective measure	Information for safety
Syringe (for single use)	Biological con-tamination	Reuse after previous use on another patient	Self-destruction after use	Clear indication of first use	Warning against reuse
Implantable pacemaker	Loss of func-tionality	Pacemaker stops functioning due to early battery depletion	Reliable long-life batteries	Alarm before battery depletion	Information on typical battery lifetime
Mechanical patient ventilator	Air pressure	Software failure causes excessive pressure in pa-tient airway	Blower incapable of delivering high pressure	Over-pressure valve in ventilator or in breathing hose	Instruction to use only breathing hose delivered by *manufacturer*
IVD blood analyser	Systematic error or bias	Incorrect result reported to clini-cian	Self-calibration	Metrologically traceable calibrators provided	Instruction to verify calibration with trueness controls
X-ray equipment	Ionising radi-ation	Staff exposed to stray radiation	Not feasible (stray radiation always occurs)	Lead shields and lead aprons	Information on radiation level in occupancy zones

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Control (2)

Risk control

— *Risk control* option analysis
— Implementation of *risk control* measures
— *Residual risk* evaluation
— *Benefit-risk* analysis
— *Risks* arising from *risk control* measures
— Completeness of *risk control*

"Closing the loop" with the technical standards (IEC60601 etc)

- These standards are "state of the art" to demonstrate safety.
    - E.g. "Electrification through enclosure leakage". Standard provides:
        - Construction requirements
        - Testing requirements
    - Ability to CONFIDENTLY N/A a lot of the standard's clauses
    - Ability to CONFIDENTLY design something that will pass the test (...later - paid by the manufacturer)

Control (3)

Risk control
— *Risk control* option analysis
— Implementation of *risk control* measures
— *Residual risk* evaluation
— *Benefit-risk* analysis
— *Risks* arising from *risk control* measures
— Completeness of *risk control*

- Implement -> Design features, documentation.
- VERIFY implementation [Design Controls]
- VERIFY effectiveness of implementation
  - Can be hard / too early
  - ! Experts judgment / testing
- TRACEABILITY
- Evaluate Residual Risk
- Risk benefits
- Risk arising from risk controls

Completeness:

"Final steps..."

- ...Of an iterative process
- Evaluation of overall residual risk
  - Comprehensive review/summary of all previous stages
  - Global risk/benefit analysis
  - MANDATORY application expert involved
- Risk Management review
  - Process "QA" review
- Prod / post production activities
  - Out of scope here - but note 1 scenario: One design, with permissive open source license given to 2 different manufacturers who manufacture independently in 2 different countries. Post-production, manufA discovers inherent design fault leading to unacceptable risk. Even if not LEGALLY (not the manufacturer), it is the community ETHICAL responsibility to monitor and raise the issue to manufB.

24
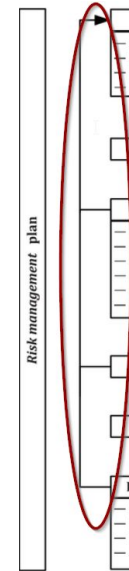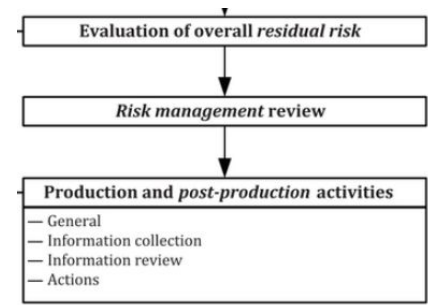
Practically?

- System/Subsystems, FMEA, Fault Tree etc….
  - No single best option. Use your judgement. Use what you know/are comfortable with.
  - Plenty of guidance in 14971/24971
- Traceability challenge
  - No ultimate solution. Commercial solution $$. Open source solutions (Redmine)
- Document. Author. Review. Version control
  - https://tinyurl.com/HelpfulQMS

What About SW

- IEC62304 -> refer 14971 with some specific points:
- No probability in Risk Evaluation. (Assume the bug will happen)
- Safety class A/B/C ->
  - Ventilator applications of SW most likely class C - >whole SW system
    - Unless maybe subsystem can be convincingly demonstrated to be non critical. (E.g. just a "fancy" display with no required clinical info?)
  - Leads to highest level of requirements for design controls
    - Simplified version: document Units Requirements and Unit Testing
- Design/Test etc -> Subsystems and SYSTEM INTEGRATION
  - You cannot assess just the SW risk independently from the interaction with the HW and the whole System intended use.

Other points about this process:

- Reviews, multidisciplinary, Subject matter experts, Clinical Experts, Fresh Pair of Eyes => This is an opportunity to work differently
- Disclaimers, warnings, information about residual risks. Latest updates have affected these aspects. Simplified version: you cannot "warn your way out of an unacceptable risk". Be honest and transparent.
- Misuse, Icons, UI/UX design - fundamental aspects. Particularly in this context -> stress, emergency use, lack of training, deployment in different countries etc. Usability Engineering standard IEC62366.
- ALARMS -> worth its own conference!
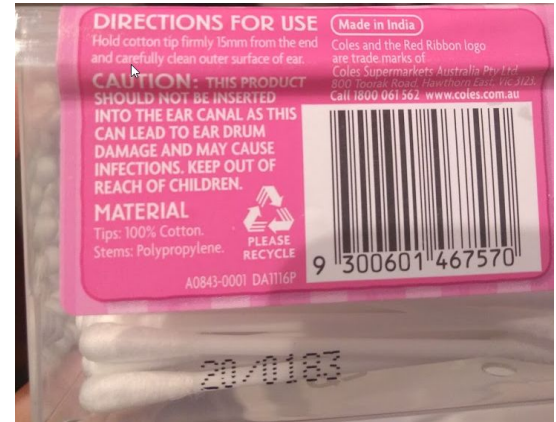
Erich Schulz ✳️ 12:08 PM
here's a great paper on evaluating ventilator UI's - I love the fact they basically hooked up ICU specialists to lie detectors to see how stressed the interface made them! https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5474229/

> **PubMed Central (PMC)**
> A new global and comprehensive model for ICU ventilator performances evaluation
> This study aimed to provide a new global and comprehensive evaluation of recent ICU ventilators taking into account both technical performances and ergonomics. Six recent ICU ventilators were evaluated. Technical performances were assessed under two FIO[2] ...

Conclusion

- Doing something is better than nothing

- Documenting is better than just doing

- Writing a plan before is better than just documenting after

- Update / review often (Agile)

  Feed into your DESIGN INPUTS, requires DESIGN VERIFICATION

- Check out 14971 itself (and 24971).

- Be honest and transparent. Document. ReviewS - bring fresh experts.

- Reddit from the "Why" conclusion:
  - Risk Management to Identify / Prioritize / Justify standards to aim for
  - Pitching tool for Manufacturers and Likely Regulators
  - Opportunity for collaboration in the open source movement - new format for transparency

Conclusion 2

Risk management the ultimate tool:

Identify / prioritize the most critical tech standards

"Pitch" your design to

- Team members
- Manufacturers
- Users
- Regulators
  - MHRA/FDA…
  - LMICs
- Opportunity to progress
  - Open source / transparency
  - Standards harmonization

Join us on Helpfulengineering Slack   #qa-ra

Email me at qa.ra@helpfulengineering.org

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VENT-CON 2020:
Quality Assurance and Regulatory Compliance

Design Controls

Adam Gosik-Wolfe
Santosh Rohit Yerrabolu, PhD

Intro - Who we are

Adam Gosik-Wolfe
Medical Device Engineer
Masters in Mechanical Engineering

Santosh-Rohit Yerrabolu, PhD
Medical Devices Engineer
Regulatory Affairs

Classification - a measure of risk

Higher Risk = Higher Class = Stricter Design Controls

FDA : 21 CFR 820- Some devices in Class 1 and all devices in Class 2 and Class 3

EU - MDR: Class I, Class I - reusable, Class I - measuring, Class I - sterile, Class IIa, Class IIb and Class III

- FDA Classification: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm
- 21 CFR 820: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820&showFR=1&subpartNode=21:8.0.1.1.12.3
- EU MDR device classification rules:: https://emergobyul.com/sites/default/files/europe-medical-devices-regulation.pdf#page=58

Regulatory Process - US

Device classification in the USA →	Class I*	Class II	Class III**
How long you should expect to wait after submission until approval is granted.[1]	1 month	6-9 months	18-30 months
Validity period for device approval.[2]	Does not expire	Does not expire	Does not expire
Complexity of the registration process for this classification.[3]	Simple — Complex ②	Simple — Complex ④	Simple — Complex ⑤
Overall cost of gaining regulatory approval.[4]	Low — High ①	Low — High ③	Low — High ⑤

https://www.emergobyul.com/resources?field_resource_type_tid_selective%5B%5D=10

Regulatory Process - EU

Device classification in Europe →	Class I Self-certified	Class I Sterile, measuring or reusable surgical instrument	Class IIa	Class IIb	Class III
How long you should expect to wait after submission until approval is granted.[1]	See note 1*	See note 1	See note 1	See note 1	See note 1
Validity period for CE Marking certificate.[2]	Not applicable	5 years	5 years	5 years	5 years
Registration renewal should be started this far in advance.[3]	Not applicable	6 months	6 months	6 months	6 months
Complexity of the registration process for this classification.[4]	Simple — Complex ①	Simple — Complex ②	Simple — Complex ③	Simple — Complex ④	Simple — Complex ⑤
Estimated cost (USD) of gaining regulatory approval.[5]	Low — High ②	Low — High ③	Low — High ④	Low — High ⑤	Low — High ⑤

https://www.emergobyul.com/resources?field_resource_type_tid_selective%5B%5D=10

Design Control Traceability Matrix (DCTM)

- User needs
- Design Inputs
- Design Outputs
- Acceptance criteria - V & V
- Design Transfer
- Design Change Control
- Design History File
- Design Reviews as a tool

Design Process Flow
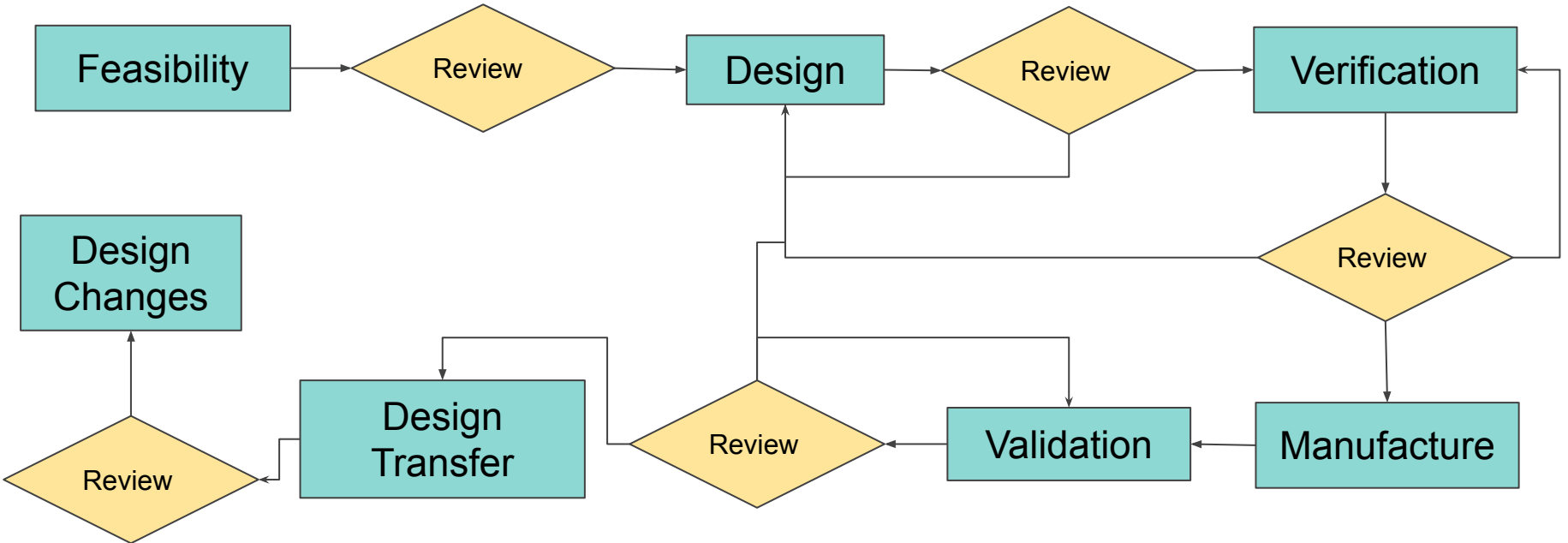
User Needs

- What does the surgeon/ healthcare provider/ patient/ end user need?
- These are not necessarily specific or technical.

"Doctor needs a patient contact-free tool temperature measuring tool at a office facility"
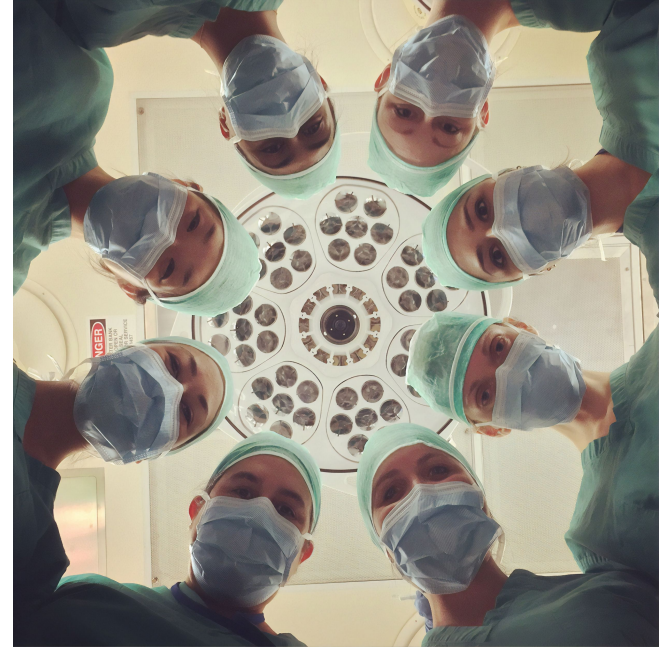
Design Inputs

- Engineering specifications or requirements to satisfy the user need.
- Should be "complete, unambiguous and non-conflicting"

"01: Thermometer must measure temperature between 90F to 105F with an accuracy of +/- 1F"
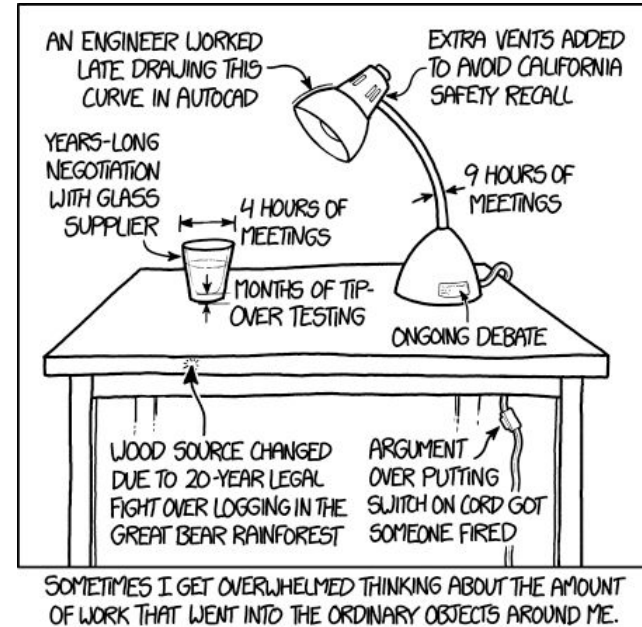
Design Outputs

- Result of a design effort
- Describe "adequate evaluation of conformance to design input requirements"

"Infrared thermometer with an LED display"

Verification and Validation Testing - V&V

- Verification - "confirms that the design output meets the design input requirements."
- Validation - "conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions"

Manufacturing Validation

- For validation testing, manufacture components using the same intended production methods as the final product.
- Validation testing can include mechanical testing or clinical trials.

Design Transfer

- Transfer from 'Design' to 'Production'
    - Can the design be produced?
    - Ensures that "device design is correctly translated into production specifications"
    - Methods of Manufacturing

Design Change Control

Design History File

- DHF contains "all of the documentation created during the product development phase of your medical device(s)"

Traceability Example

U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

Example - Infusion Pump

User Need

Pump must function in an operating room environment.

Design Input

Pump must function uninterrupted when used with other products that generate an electromagnetic field.

Design Output

•PCB with filtering circuit

•Pump EMI shield

•Software signal filtering code and error handling code

Design Review

Design Verification

•Simulated EMI testing on hardware and software

•Dimensional verification of shield

•Verification of system error handling due to EMI

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Questions?

- User needs
- Design Inputs
- Design Outputs
- Acceptance criteria - V & V
- Design Transfer
- Design Change Control
- Design History File
- Design Reviews as a tool

Open Ventilator Composability and Collaboration

-- Robert L. Read, Public Invention
@pubinvention
read.robert@gmail.com
With Lauria Clarke and Geoff Mulligan

Things we didn't known on March 15th (5 months ago)

- Non-invasive Ventilation is essential
- Therapeutic Oxygen is essential
- Social distancing works (but only if you do it)
- Co-morbidity is a problem
- Mortality of invasive ventilation for COVID-19 is very high
- Coronavirus affects more than the lungs
- People who don't die still get terribly sick
- Young people die less often but may have long-term debilitation
- Previously unknown drug therapies help a lot

...some of these have implications for what we are doing.
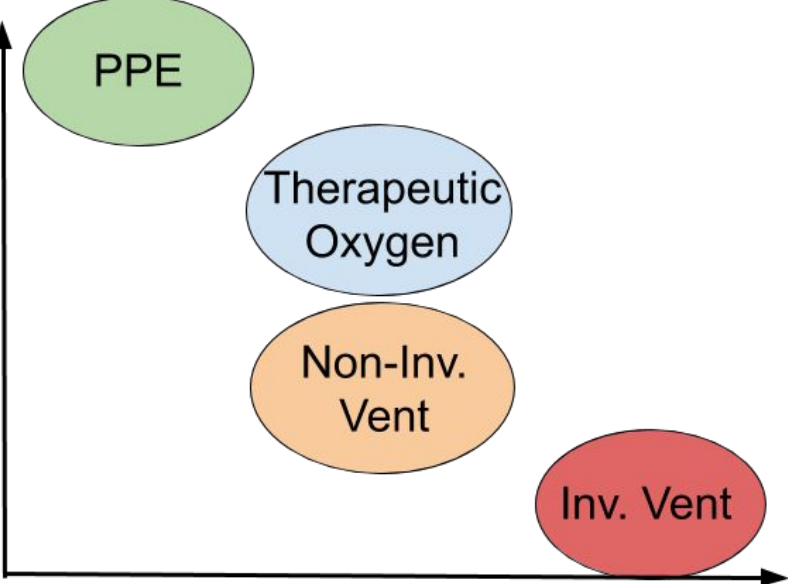
Question: In 2021, will the story be:

"In response to a world-wide shortage of ventilators, 1000 technology volunteers…"

GOOD:
"In response to a world-wide shortage of ventilators, 1000 technology volunteers…"

"...created 100 independent emergency ventialtor projects, 4 or 5 of which successfully saved some lives and then were shelved or abandoned."

GREAT:
"In response to a world-wide shortage of ventilators, 1000 technology volunteers…"

"...created an open source, composable ventilator ecosystem that saved many lives by adapting to the rapidly evolving crisis and forever changed the way medical devices are made."

Analysis of Open Source COVID-19 Pandemic Ventilator Projects

Look Down! We've added tabs for modules to encourage modularity!

| April 15, 2020 | Public Invention | https://www.pubinv.org | | Home Repo: | https://github.com/PubInv/covid19-vent-list |

Rank by Average

Link to definition of evaluation criteria: https://docs.google.com/document/d/e/2PACX-1vRl9yZ27KvslftcNvweHgH1A81pO8gHL62TWpY_VY-UELWdK9x-4-3hNw3DbkemClzExPsg8RfnxilP/pub

Project Name	Project Link	Openness	Buildability (1 unit)	Community Support	Functional Testing	Reliability Testing	COVID-19 Suitability	Clinician Friendly	Average	Manufacturability (1000s)	Date Last Evaluated	Point of Contact	Team Needs	Drive
Ambovent	https://1nn0v8ter.rocks/AmboV	5	5	5	4	3	4	4	4.29	3	2020-05-15	dreliram@gmail.		AmbuB
Medtronic Puritan Bennett (PB) 5(	http://newsroom.medtronic.con	4	2.5	4	5	5	4	5	4.21	4	2020-04-19			Pump
MUR (Minimal Universal Respirat	https://www.mur-project.org/	4	4	4	3.5	4	3.5	3.5	3.79	2.5	2020-04-19	https://www.mur-project.org/		Pressu
Open Source Ventilator Project	https://simulation.health.ufl.edu	4	3.5	5	3.5	2.5	4	3.5	3.71	4	2020-04-19	https://simulation		Bellows
Rice OEDK Design: ApolloBVM	http://oedk.rice.edu/apollobvm/	5	4	4	2.5	2.5	3	2.5	3.36	2.5	2020-04-19	amy.k@rice.edu		AmbuB
A.R.M.E.E. Ventilator	www.armeevent.com	5	5	4	2	3	2	2.5	3.36	5	2020-04-19	warrenkoch@gm		Pnuem
COVID-19 Rapid Manufacture Ve	https://www.instructables.com/	5	4	4	3	0	3.5	3.5	3.29	2.5	2020-04-19	https://www.instr		AmbuB
OpenVentilator (PopSolutions)	https://www.popsolutions.co/en	5	3.5	4	3.5	3	2	2	3.29	3	2020-04-08	contact@openve		Bellows
Low-Cost Open Source	https://github.com/jcl5m1/venti	5	4	4	3	1	3	3	3.29	3	2020-04-19	https://github.con		Pump
DIY-Beatmungsgerät [Respirator]	https://devpost.com/software/d	5	4	3	2.5	2	3	3	3.21	0	2020-04-19	https://docs.goog		AmbuB
MakAir	https://github.com/makers-for-li	4.5	2.5	5	3	2	2	3	3.14			quentin.adam@c		
OperationAIR	https://www.operationair.org/	4	4	4	3	2	3	2	3.14		2020-05-05	info@operationai		Mass F
PREVAIL NY	https://jmawireless.com/prevail	4.5	4	3	2.5	0	4	3.5	3.07	3.5	2020-04-19	customerservice(		AmbuB
VentilAid	https://www.ventilaid.org/	5	4	4	3	0	2.5	2.5	3.00	2.5	2020-04-08	media@urbicum.		Bellows
CoroVent	https://www.corovent.cz/	3.5	2.5	4	4	0	3.5	3.5	3.00		2020-04-10	simon.rakosnik@		Bellows
Flow-i Bridge Project	https://grabcad.com/library/flow	4	2.5	3	2	2	3.5	4	3.00		2020-04-25		clinical validation	Servo (
Protofy Team OxyGEN	https://oxygen.protofy.xyz/	5	4	4	3	1	2	1	2.86	3	2020-04-19	https://www.oxyg		AmbuB

Over 100 somewhat open-source ventilator projects right now... a better way to use thousands of skilled engineers is to modularize the problem.

Be humble:

- There will not be just one ventilator solution
- Flexibility of Treatment
- Transparency of Quality
- Third Party Testing
- Conformity to Standards

To Achieve GREAT:

- Cancel the "not invented here" instinct.
- Invest in reuse of other teams' work wherever possible.
- Invest in communication---A LOT.
- Be open source from day one.
- Plan to save lives this summer, but don't lose sight of the long game.

Most basic possible composition of ventilator components

Air Drive → Air → Sense Module → Air → Non-invasively or invasively ventilated patient

Commands

PIRCS - Respiratory Control Standard Commands

Measurements

PIRDS - Respiratory Data Standard Measurements

Controller

User Interface

Clinician

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Most basic possible composition of ventilator components

Air Drive → Air → Sense Module → Air → Non-invasively or invasively ventilated patient

Commands

PIRCS - Respiratory Control Standard Commands

Measurements

PIRDS - Respiratory Data Standard Measurements

Controller

User Interface

Clinician

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VentOSFramework

Phase 1: C-Language Simulation
in Virtual Environment

Phase 2: Fakes are replaced with
hardware and controller moved to MCU

Test Suite Runner and Virtual Environment

Faking System

Fake Patient Inflating Valve (PIV)

Fake Air Drive

Fake Patient:
$P\_v = V' * R + V / C + k$, where R, C, k are known. V evolves in each step as the addition of V'.

PIV Interface

Air Drive Interface

Sensor System (Similar to VentMon)

On/Off   Pneumatic control

Closed Loop DF@P

Controller

PCV Mode Algorithm

VCV Mode Algorithm

Other modes...

Algorithms are Class Instances

PIRDS Measurements

Data Logger

Alarm Events

Fake Alarm System

PIRCS Commands

Clinical Control Interface and Display

Settings and configuration

Need to both include configuration (eg alarm thresholds and states) in test cases, and also use it (and "state") to mock UI elements to update settings

VentOS is (hopefully) a new project at Helpful Engineering. Supports testing *in silico* using a dependency injection system

Most basic possible composition of ventilator components

Air Drive → Air → Sense Module → Air → Non-invasively or invasively ventilated patient

Commands — PIRCS - Respiratory Control Standard Commands

Measurements — PIRDS - Respiratory Data Standard Measurements

Controller

User Interface

Clinician

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VentMon In Action

Respiration Data Standard has JSON and byte bindings....(https://github.com/PubInv/PIRDS-respiration-data-standard)

```
[
{ "event": "M", "type": "P", "loc": "A", "num": 0, "ms": 302520, "val": 10188 },
{ "event": "M", "type": "D", "loc": "A", "num": 0, "ms": 302520, "val": 81 },
{ "event": "M", "type": "F", "loc": "A", "num": 0, "ms": 302520, "val": 17255 },
{ "event": "M", "type": "P", "loc": "A", "num": 0, "ms": 302583, "val": 10178 },
{ "event": "M", "type": "D", "loc": "A", "num": 0, "ms": 302583, "val": 71 },
{ "event": "M", "type": "F", "loc": "A", "num": 0, "ms": 302583, "val": 14025 },
{ "event": "M", "type": "P", "loc": "A", "num": 0, "ms": 302646, "val": 10166 },
{ "event": "M", "type": "D", "loc": "A", "num": 0, "ms": 302646, "val": 59 },
{ "event": "M", "type": "F", "loc": "A", "num": 0, "ms": 302646, "val": 6360 },
{ "event": "M", "type": "P", "loc": "A", "num": 0, "ms": 302709, "val": 10152 },
{ "event": "M", "type": "D", "loc": "A", "num": 0, "ms": 302709, "val": 45 },
{ "event": "M", "type": "F", "loc": "A", "num": 0, "ms": 302709, "val": -1205 },
{ "event": "M", "type": "P", "loc": "A", "num": 0, "ms": 302773, "val": 10141 },
{ "event": "M", "type": "D", "loc": "A", "num": 0, "ms": 302773, "val": 34 },
{ "event": "M", "type": "F", "loc": "A", "num": 0, "ms": 302773, "val": -2570 },
{ "event": "M", "type": "P", "loc": "A", "num": 0, "ms": 302837, "val": 10133 },
{ "event": "M", "type": "D", "loc": "A", "num": 0, "ms": 302837, "val": 26 },
{ "event": "M", "type": "F", "loc": "A", "num": 0, "ms": 302837, "val": -1545 },
{ "event": "M", "type": "P", "loc": "A", "num": 0, "ms": 302901, "val": 10128 },
```

```
1594857533:M:P:A:0:17380842:10120
1594857533:M:D:A:0:17380842:4
1594857533:M:F:A:0:17380842:-5
1594857533:M:P:A:0:17380906:10120
1594857533:M:D:A:0:17380906:4
1594857533:M:F:A:0:17380906:0
1594857533:M:P:A:0:17380970:10120
1594857533:M:D:A:0:17380970:4
1594857533:M:F:A:0:17380970:0
1594857534:M:P:A:0:17381034:10120
1594857534:M:D:A:0:17381034:4
1594857534:M:F:A:0:17381034:0
1594857534:M:P:A:0:17381098:10120
1594857534:M:D:A:0:17381098:4
1594857534:M:F:A:0:17381098:0
1594857534:M:P:A:0:17381162:10120
1594857534:M:D:A:0:17381162:4
1594857534:M:F:A:0:17381162:-10
1594857534:M:P:A:0:17381226:10120
```

Standards are Paramount

- Public Invention Respiration Data Standard (PIRDS) is a common way to represent and communicate sensor data
  (https://github.com/PubInv/PIRDS-respiration-data-standard)
- Pressure, flow, temperature, humidity, FiO2
- Supports redundants sensors through numbering
- Defines abstract locations of sensors (e.g., airway, ambient, expiratory limb)
- Defines units so as to avoid floating point
- Labels all samples with milliseconds
- Has byte-level and JSON bindings
- Makes VentMon and BreathPlot independent; each can be used separately

EVERY ventilator team represents data somehow or another; why not use a standard?

BreathPlot uses this standard…(https://github.com/PubInv/vent-display)

Example of Sensor Module: The VentMon T0.2

Ten have now been shipped free of charge. Sign up today for yours!

(https://www.pubinv.org/project/ventmon/)

Video:

https://www.youtube.com/watch?time_continue=3&v=OV9MrMjVOCI&feature=emb_logo

Currently a "Tester", not a "Monitor", but no reason it could not be included whole-cloth in a design, saving time and reducing duplication.

JPL built a pretty good (not open) emergency ventilator...

But it has no means of displaying a pressure/volume curve...

Don't change it; bolt-on a VentMon!
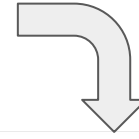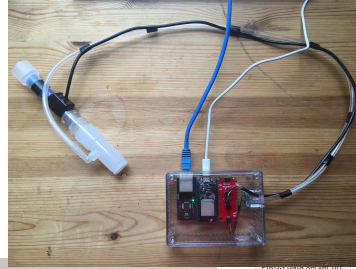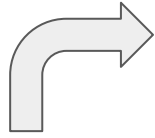
Note: Michelle's talk on "Parent Devices" and "component" devices and accessories!
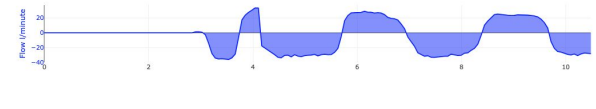
Is the VentMon good?

Maybe not. But it is a module with a well-defined interface---you can build a better to the same interface.

PIRDS >> VentMon

Upcoming Breath Plot Needs which demand Cooperation...

- Compare traces in time
- Look through a multi-week data log
- Draw and perhaps analyze Pressure-Volume loops for patient dyssynchrony

Keys to Composability

- Standards
- Openness
- Testing
- Investment in Regulatory Approval

But we need other standards...

- Most of all, standard alarm definitions!
- We have just barely started a "Control Standard" which defines ventilator modes (PIRCS) (https://github.com/PubInv/pubinv-respiration-control-standard)
- Need a standard for closed-loop specification of an air-drive, which we have defined as "power-on-the-airway" or "dynamic float at pressure (DF@P)" (https://github.com/PubInv/work-on-the-airway)

Maybe you can identify or define new standards?

Standards >> Components!

But Components matter! We need:

- Plotting (BreathPlot) (https://github.com/PubInv/vent-display)
- Data Logging (https://github.com/PubInv/PIRDS-logger)
- Verified Algorithms (e.g., work-of-breathing and dyssynchrony detection)
- Alarm condition detection algorithms
- Alarm announcing (audio and visual) hardware
- A 22mm airway Patient Inflating Valve
- Clinician friendly display/controls and standards
- AIR DRIVES!
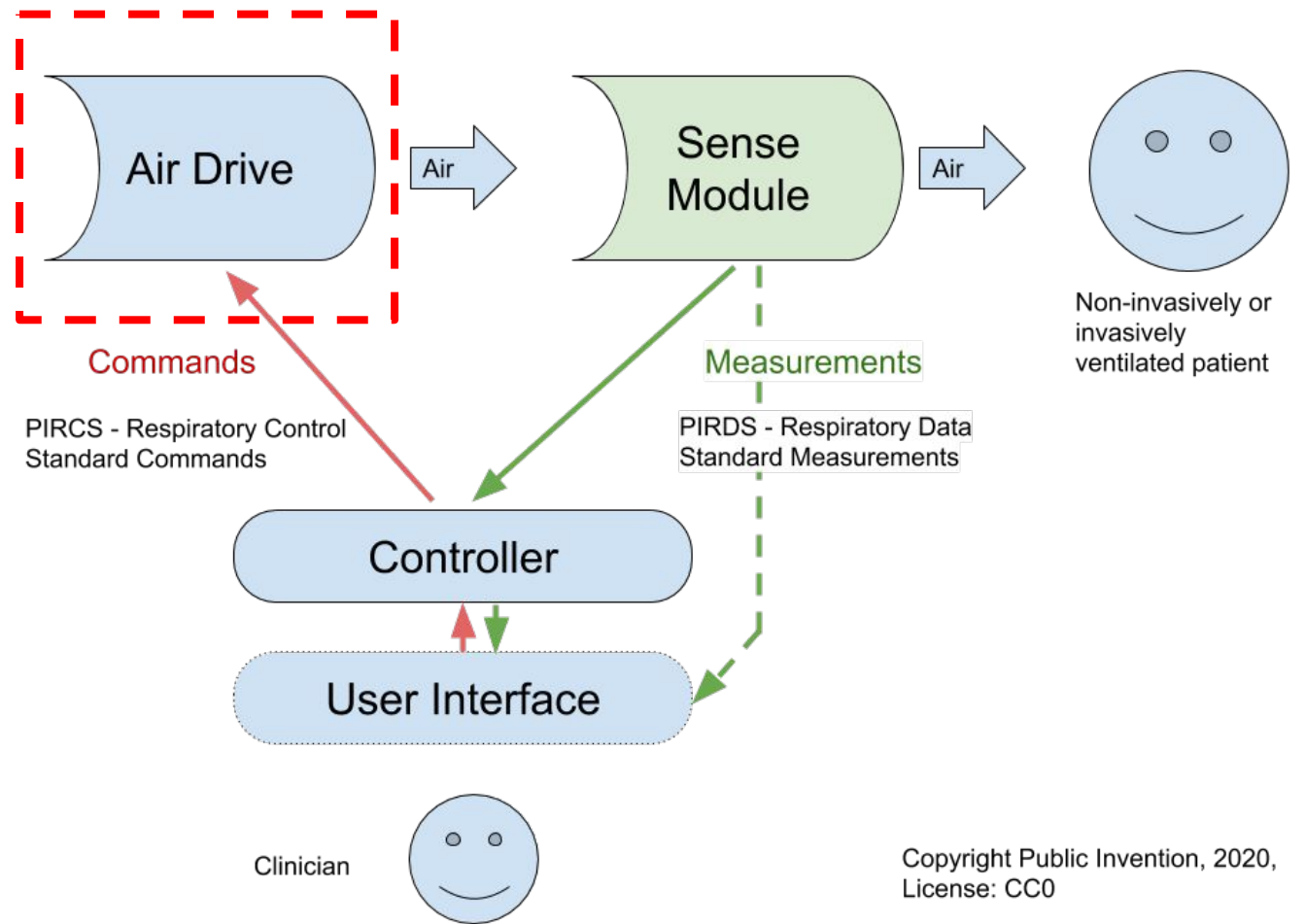
A composable Air Drive is the biggest possible win. Define a standard for controlling it based on demanded flow at a specified pressure.

(https://github.com/PubInv/work-on-the-airway)

Seven Hypotheses

1. Good Faith
2. Testing >> Design
3. Composability Clearance
4. Good Standards/Interfaces
5. Third-Party Testing
6. Paperwork Paradox
7. Community Capability

Thank you.

Seven Hypotheses

1. Good Faith: Assume regulatory agencies will mostly do the right thing.
2. Testing >> Design: A majority of effort and creativity needs to go in to the design of testing rather than the design of the machines.
3. Composability Clearance: It will be easier for us to obtain regulatory clearance with highly composable solutions, possibly with components that were never cleared independently before.
4. Good Standards Interfaces: Module interaction can be trusted only with excellent, well-defined, testable interfaces.
5. Third-Party Testing: The open-source community can easily implement and benefit from extensive third-party testing.
6. Paperwork Paradox: We can be MORE Agile with more paperwork.
7. Community Capability: Improving communal capability beats product delivery.

Good Faith

Assume regulatory agencies will mostly do the right thing.

Testing >> Design

A majority of our effort must go into testing.

We can take inspiration from NASA and Space-X and implement Agile testing. We can use standardized methodologies:

- Unit testing
- Test-driven development
- Integration testing
- Stress testing
- Dependency injection

By making all tests fully open and reproducible, we increase confidence.

Simplicity of physical domain makes extensive simulation possible via e.g. MatLab/Simulink. We can be far better than medical device manufacturing firms.

Testing >> Design

VentOS, a brand new project at Helpful Engineering, is building a dependency injection framework for testing control algorithms written in C in a way that can be directly transferred to hardware.

Public Invention volunteers have taken the MIT MatLab/SimuLink lung model and modified to support pressure ventilation, and are simulation ventilation modes with it.

Composability Clearance

It will be easier for us to obtain regulatory clearance with highly modular solutions, possibly with modules that were never cleared independently before.

Modularity allows leveraging and reusing extensive testing and documentation burdens.

Good Standards and Interfaces

Module interaction can be trusted only with excellent, well-defined, testable interfaces.

Good Module interfaces make regression testing far easier.

Third-Party Testing

The open-source community can easily implement and benefit from extensive third-party testing. This fits in well with our normal cultural practices.

Paperwork Paradox

We can be faster and MORE Agile as a community with more paperwork done by individual teams.

A team that makes one component that obtains clearance makes the work of every team easier.

Communal Capability

Improving communal capability beats individual product delivery.

This may be a starter pandemic.

-- my buddy John.

Call to Actions and Offers...

To order a VentMon free-of-charge, visit:

https://www.pubinv.org/project/ventmon/

Public Invention needs volunteers, especially a good JavaScript programmer to work on BreathPlot.

A 510k submission often requires a demonstration of substantial equivalence to a legally marketed device, commonly known as a

"predicate device" or "predicate." For a new device to be considered substantially equivalent to a predicate device, the new device must

have the same intended use as the predicate device and the same technological characteristics—or different technological characteristics

that do not raise different questions of safety and effectiveness than the predicate device.

-- https://app.slack.com/client/TCWFL7SNM/DE09MUWAW/details/pins

Substantial equivalence...the key to Air Drive separation

In the context of a predicate device, the term "substantially equivalent" or "substantial equivalence" has typically been understood to mean

that the new, proposed device has the same intended use as the predicate device and has found to have the same technological

characteristics, such as a comparison of the specifications, materials, and technology to the predicate device.

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A demonstration of

substantial equivalence may be achieved by using appropriate clinical or scientific data. Such data should demonstrate that the device is

as safe and effective as a legally marketed device, and does not raise different questions of safety and effectiveness than the predicate

device does.

Introducers, not designers, need FDA clearance...

Q: Who is responsible for submitting a premarket notification (510(k)) or obtaining an emergency use authorization (EUA) for a device?

A: Among others, the entity that intends to introduce a device into the US market is responsible for submitting a premarket notification to FDA (unless the device is exempt from such requirements), or during a public health emergency, ensuring an EUA is in place for the device prior to market introduction.

Modularity Scenarios

Swap out a module protected by an equivalent API

Use an improved module (e.g., better ventilator control)

Improved software

Failure of clearance for a module in use

Modules that Never Existed Before...

- Air Drive
- Alarming Device
- Decision Support System
- Dys-synchrony Analysis System
- Long-term (hours and days) analysis tool

Suggested best practice:

- Give designs a codename that DOES NOT suggest they are ready for medical use, and use trademark law to retain strict use of that mark.
- Give manufacturable products a marketing name that DOES suggest they for medical use

A Legal Perspective on Risk Management

Marc Jones, esq., CISSP, CIPP, CIPT

CivicActions

- I am a lawyer, but I am not your lawyer (IAALBIANYL)
- General Counsel at CivicActions
- None of this is legal advice
- This is the last cat photo

Skilz

- Not a maker
- Typos
- Free Software Licensing

- GovCon
- Board of PubInv
- Pro Bono for FOSS NGOs

CivicActions

TOC

➜ **Types of Liability**

➜ **Risk Management**

➜ **How it is managed in Free Software**

➜ **Questions**

CivicActions

Types of Liability

Optional subtitle

CivicActions

1. **Criminal Liability**
2. **Civil Liability**
   a. **Torts**
   b. **Regulatory**
   c. **Contractual**

CivicActions

1. **Torts**
   a. **Torts**

   b. **Negligence**

   c. **Product Liability**

2. **Contracts**
   a. **breach of contract**

   b. **breach of warrant**

3. **Regulatory - compliance with regulations**

CivicActions

Negligence

- Duty ("*exercise the care a reasonably prudent person would in similar circumstances*"),

- Breach of that duty,

- Injury or damage, and

- Causation.

CivicActions

Strict Liability

- **That the defendant:**
    - engaged in conduct or an activity that is considered inherently dangerous and unreasonable, or
    - produced a product that contained an unreasonably dangerous defect.
- **Show that you were harmed by the conduct, activity or product and that it was the actual and proximate cause of your injury.**
- **You suffered actual damages.**

CivicActions

Breach of Warranty

- **Implied Warranty of Merchantability - A product must be fit for the ordinary purpose for which it was sold**

- **Basically about if the product was designed well for the intended purpose**

- **It is implied in sale of goods and has specific requirements for disclaiming it**

CivicActions

Managing Risk

Optional subtitle

CivicActions

Managing Risk

- **Limiting the harm you are likely to cause**

- **Limiting your likelihood of being held liable**

- **Limiting the extent of your liability**

CivicActions

Limiting the harm you are likely to cause

- **Use best practices in developing products**
- **Follow safety procedures**
- **Training**
- **Have an effective QA process in place**
- **Don't engage in ultrahazardous activities**
- **Don't do anything!**

CivicActions

Limiting your likelihood of being held liable

- **Behave reasonably**
    - **Use best practices in developing products**
    - **Follow safety procedures**
    - **Have an effective QA process in place**
    - **Comply with regulations**
    - **Licensure**
- **Don't engage in ultrahazardous activities**
- **Don't create or distribute consumer products**
- **Disclaim Warranties**

CivicActions

Limiting the extent of your liability

- **Incorporation**
- **Insurance**
- **Transfer liability to a partner/Intermediaries**
- **Disclaim warranties**
- **Volunteer Protection Act and similar acts**

CivicActions

Example

Optional subtitle

CivicActions

1. **Incorporate as a nonprofit**
2. **Use free software licenses containing a warranty disclaimer**
3. **Don't sell consumer products**
4. **Compliance with laws**
5. **Liability Insurance & D&O**

CivicActions

Open Discussion

CivicActions
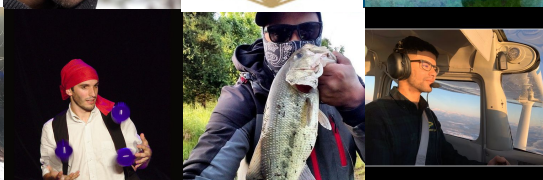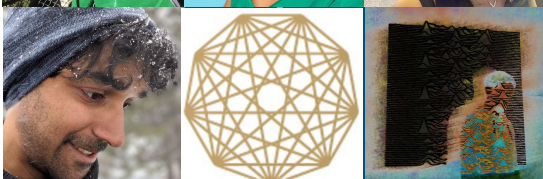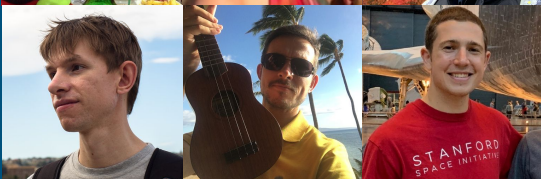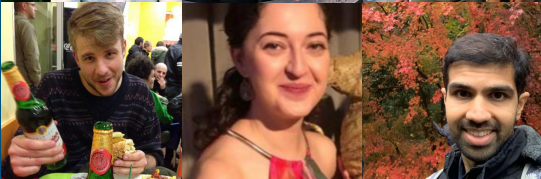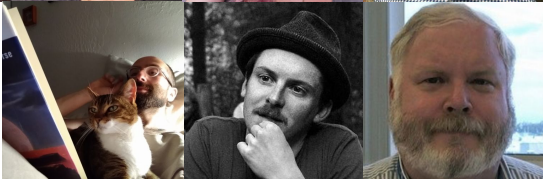
A Fully-Featured Open-Source Ventilator

- Blower-driven design can run on electricity alone using ambient air
- Patient Synchrony with Pressure Assist and Pressure Support modes
- Inhale and exhale filtering
- Full Graphical UI with large 7" display
- Patient data live-plotting and logging
- Full suite of settable visual and audio alarms
- External battery backup with internal option

PIP: up to 55cmH2O | PEEP: 5-20cmH2O | RR: up to 30bpm | FiO$_2$: 21-100%

Testing
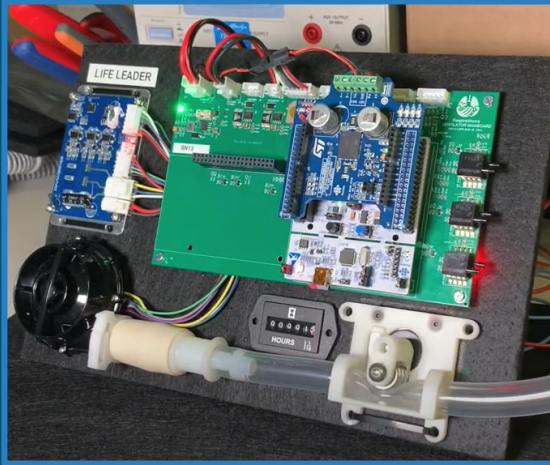
Reliability

Equivalent to 100+ days continuous operation, and counting
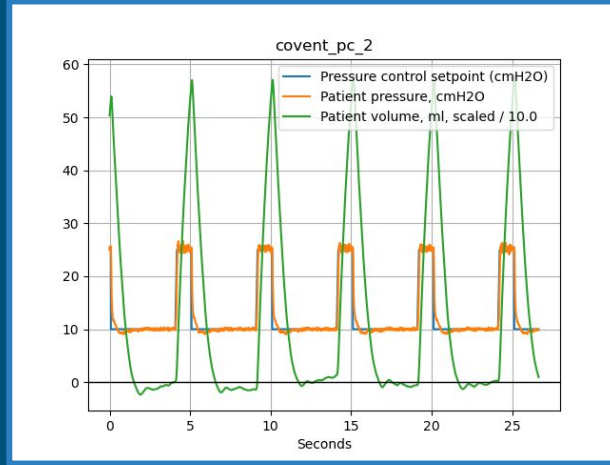
Performance

Consistent automated testing based on ISO 80601 test cases
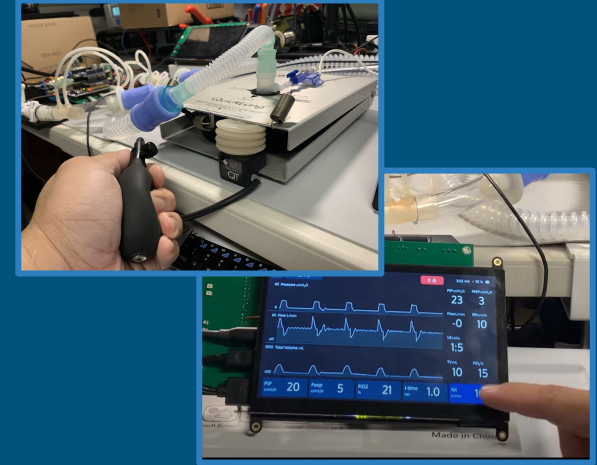
Functionality

Testing both patient and user interaction. Code-coverage-based software testing
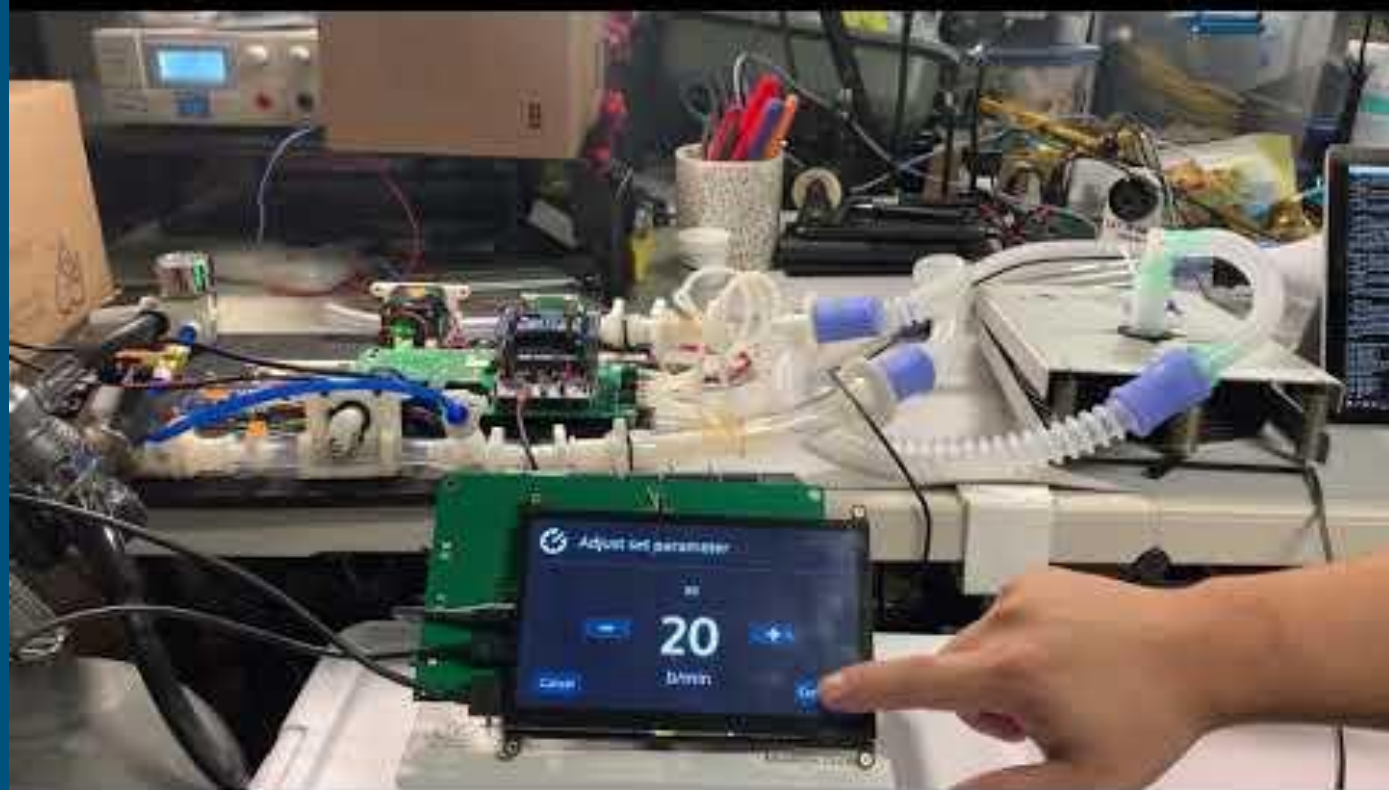
Manufacturability
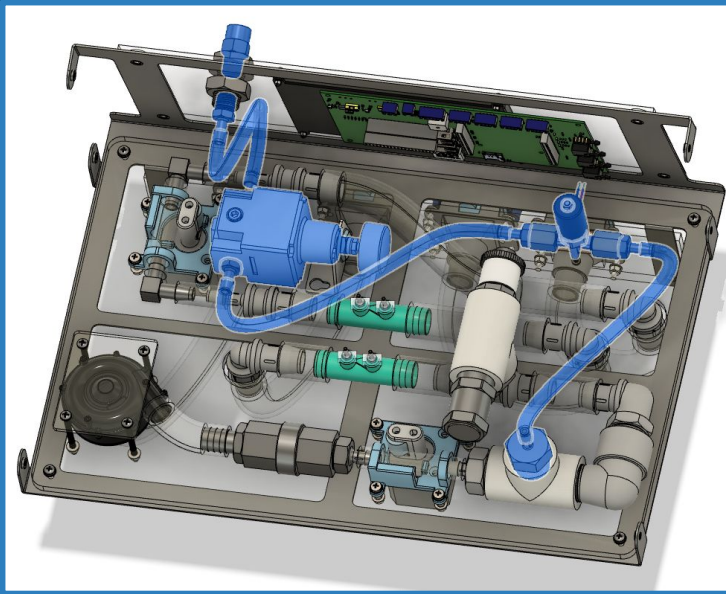
- Design is free of medical supply-chain components
- Selection focused on industrial and automotive components
- Common folded sheet metal and flat panel construction
- Common electrical PCB process with no special techniques

RespiraWorks Commitment to Open-Source

An open-source, IP-free design empowers organizations to leverage local resources to help their people.

Money should not be the only resource by which people can obtain life-saving medical equipment.

Revenue motivation should go largely to those manufacturing and delivering equipment to those who need it.

Our mission is to **radically democratize the ventilator**.

THE TEAM

DARREN **LEWIS**
Project Lead & Mechatronics

A Design Manager working in Dyson's New Product Concepts team in R&D, with 10 years industry experience developing complex electro-mechanical systems into products.

ROSS **GOODWIN**
Mechanical

Ross is an Associate Principle Engineer working in Dyson's motor development team, with over10 years of experience developing high speed turbomachinery

KIAN MING **YAK**
Mechanical

Yak is a mechanical engineer with 5 years of experience developing and launching products in multiple industries, including audio, AR and IOT..

DONALD **ROBSON**
Embedded Firmware

Donald is an Embedded Development Engineer at Graphcore, with a varied career encompassing mechanical design, mechatronics and firmware development.

CRISTIAN **TARAN**
Project Management

Cristian is a software engineer with more than 15 years of experience in developing software and managing software engineering teams in diverse industries.

JONAS **FEHR**
Mechatronics & Software

Jonas is a creative coder working mainly in the field of light- and media art. He has a broad skill set, ranging from electronics over software to mechanical engineering.

ANGUS **THOMSON**
Electronics

Angus is the founder of CircuitBuilder - a web-based platform designed to simplify the process of creating custom electronics. He has nearly 20 years experience in wide range of industries.

RICK **COLLINS**
Electronics

Rick studied electronics since the age of 15 resulting in an MSEE. Working for a number of companies his niche developed into board level design and programming FPGA devices.

SAM **PARTRIDGE**
Embedded Firmware

Sam is an Embedded Test Engineer at Graphcore with a PhD in High Frequency Engineering. They have experience in developing automated hardware test systems as well as embedded firmware.

SAM **RILEY**
Verification

Sam is a Safety Critical Programmable Elements Certification Engineer. He works as part of MoD Software and cyber security Certification team.
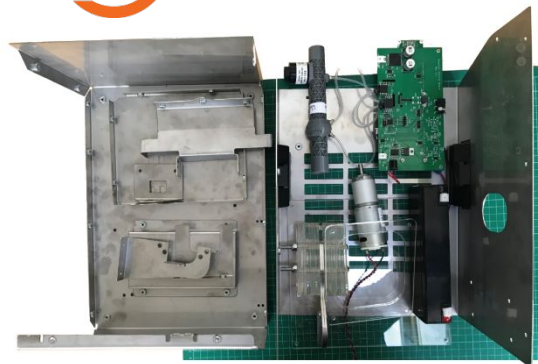
BASED ON AN AMBU-BAG

RAPID MANUFACTURE

VISUAL MONITORING

UNIVERSAL

- Based on MHRA requirements
- Not dependent on airline
- Aiming for FDA EUA

OpenVent-Bristol
Version 3.0

AMBU BAG / BVM

Based on an Ambu bag which has existing medical device approval for manual ventilation and availability worldwide

VISUAL MONITORING

For visual feedback of bag compression

CONSTRUCTION

Laser cut sheet stainless steel for good strength, water drip resistance, bio compatibility and quickly scalable

LCD USER INTERFACE

To display measured values and set values for example; airway pressure, tidal volume, I:E ratio & ventilation mode

SIMPLE MECHANISM

1 moving part, simply an arm mounted to a motor

VISUAL AIRWAY PRESSURE MONITOR

Airway pressure displayed with horizontal bar graph

PEEP VALVE

Adjustable PEEP valve, to maintain positive pressure at all times

MEMBRANE BUTTON PANEL

To minimise crevices for germs to hide

AIR OUTLET

Standard 22mm tapered push-fit air outlet, compatible with existing tubing

OpenVent-Bristol
Flow Sensor Unit

Manufactured in house to control supply chain

Simple design

CNC machined:
- **No tooling cost & lead time**
- **High accuracy & repeatability**

Medically approved materials and finished

FLOW SENSING

PRESSURE SENSING

SGX-VOX
OXYGEN SENSOR
S/N: 000430

SGX-VOX
OXYGEN SENSOR
S/N: 000430

OXYGEN SENSING
Supplier confirmed

3D print sensor design shown above

Existing ventilator sensor

OpenVent-Bristol sensor

OPENVENTBRISTOL.CO.UK
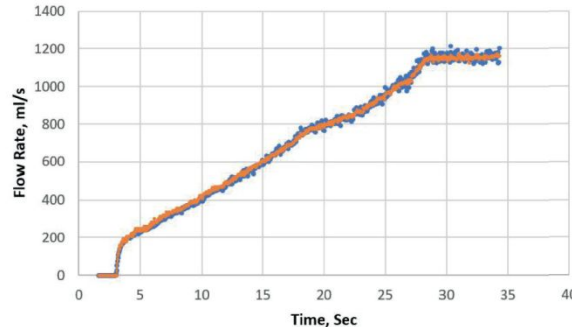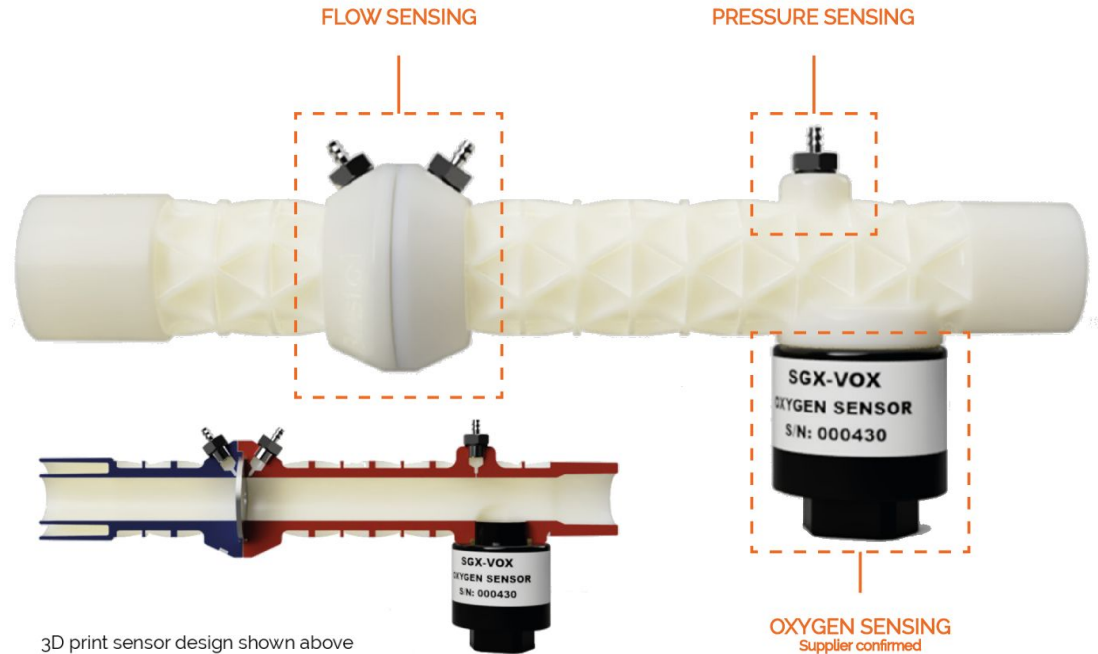
OpenVent-Bristol

Pressure Controlled Ventilation

NPL National Physical Laboratory

Ingmar Medical ASL 5000 test lung
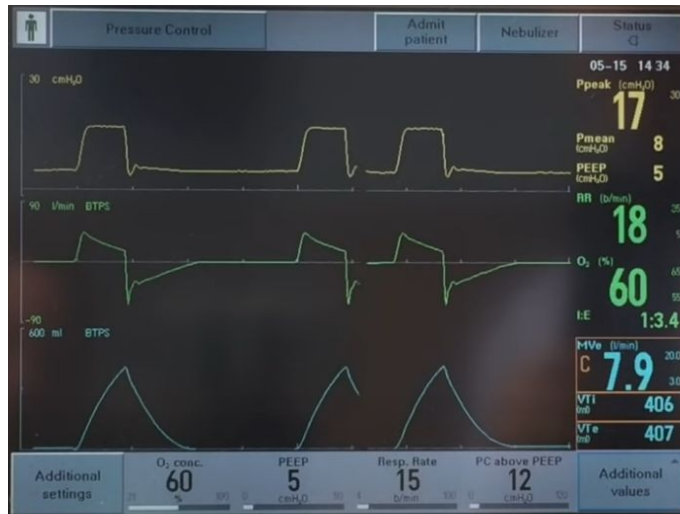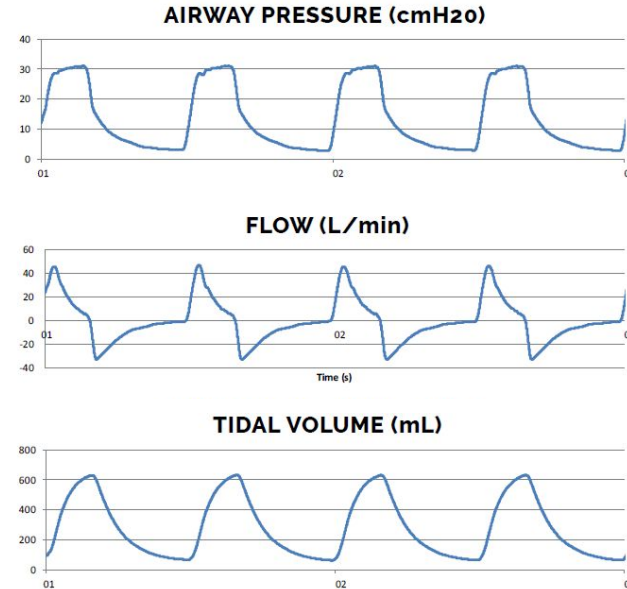
Data above recorded from IngMar Medical ASL 5000 test lung in Pressure Controlled Ventilation mode, with set pressure of 30 cmH2O and PEEP of 5cmH2O.
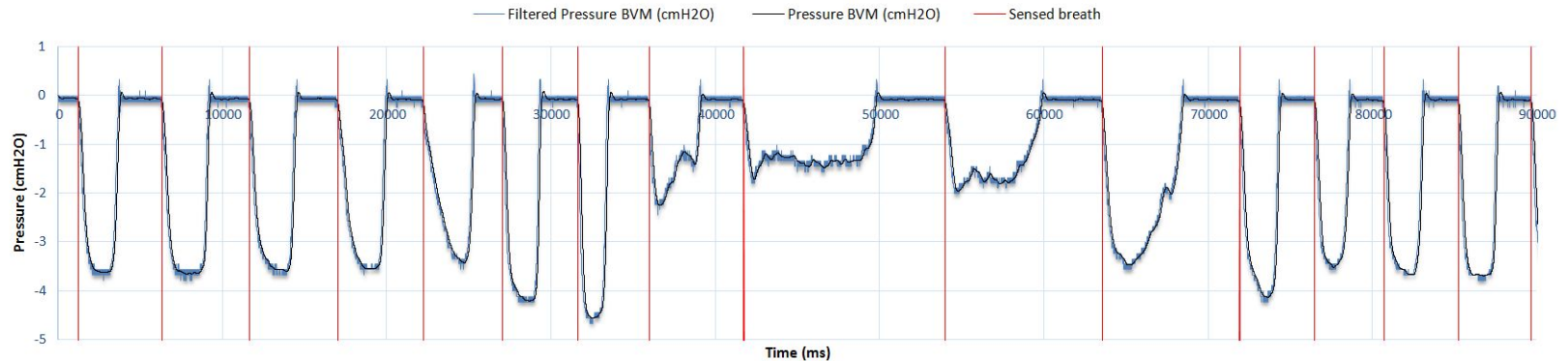
OpenVent-Bristol

Spontaneous PCV mode (patient triggered)

- More people treated with this mode
- Important for patient recovery

Breath sensing with ventilation off

Legend: Filtered Pressure BVM (cmH2O) — Pressure BVM (cmH2O) — Sensed breath

OpenVent-Bristol

Status

Looking for collaborations:

- **FUNDING**

- **MANUFACTURERS**

- **USERS**

Contact: OpenVentBristol.co.uk

Component sponsors:

CircuitBuilder

L.W. Jenkins Ltd

S Electronics LTD

Podd's Print & Signage

BlueThink

www.ARMEEVentilator.com
HE: #project-oscillating-ventilator

Exhale Out ->

<- To Patient

Comes in any combo of:

PIP: 20-40 cmH2O
PEEP: 0-20 cmH2O
I:E: 1:1 - 1:3
RR: 8-30 bpm
TV: 200-1000 ml

(Subject to changing patient lung capacity, resistance and compliance)

<- (Middle V) Airfoil Where The Magic Happens

<- From Air Flow Source

ArmyVent@gmail.com
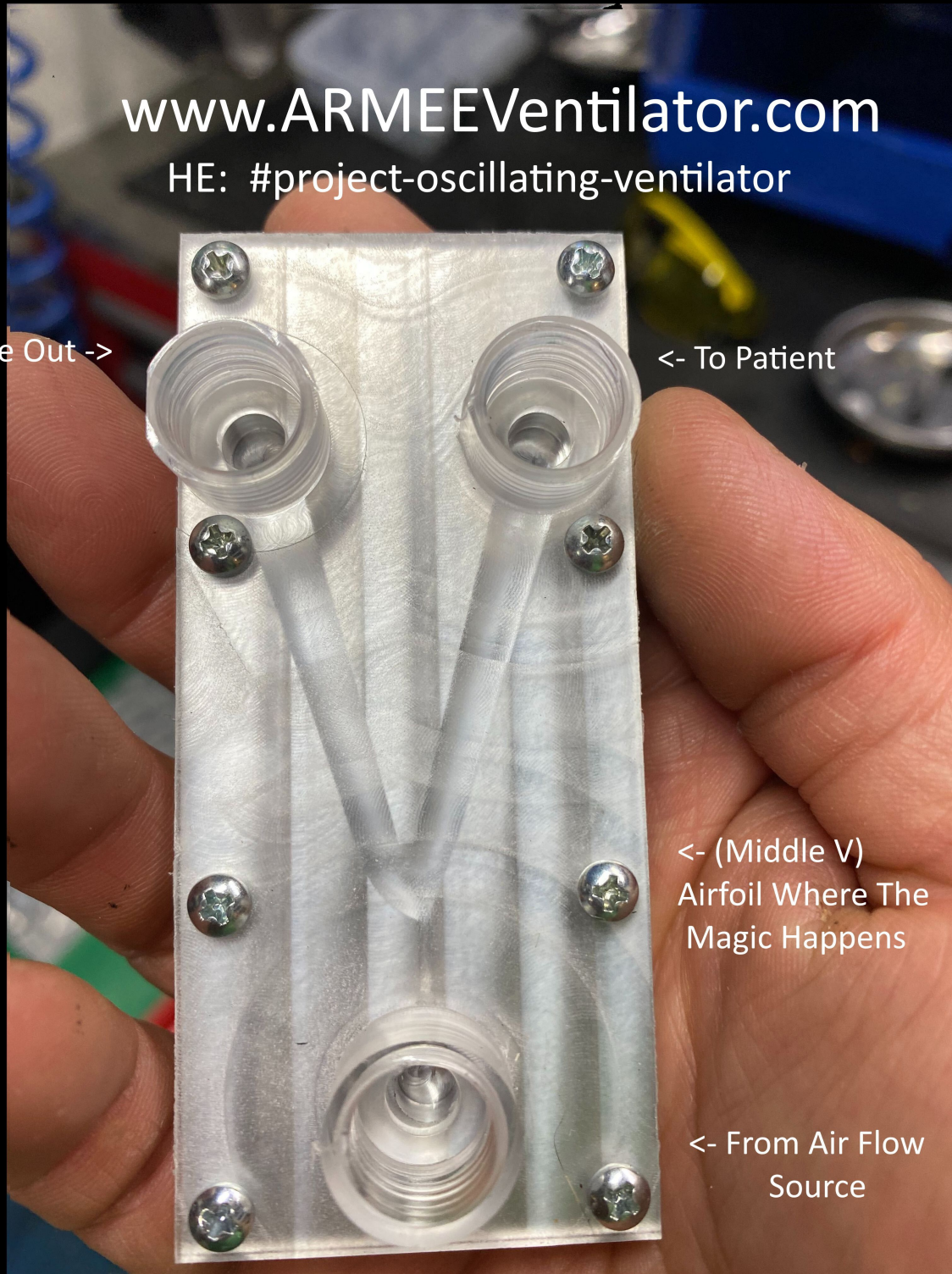
Project Tetra:
4-way Ventilator Splitting

Mark M Roden, PhD

#project-tetra, Helpful Engineering Slack

Project Goals

- Be able to attach multiple patients to a single ventilator in the event of a ventilator shortage

- Be as safe as possible, but still only for emergency use. Individual ventilators are still preferable

- Be as locally producible as possible

- Be open source

- Be able to pass an FDA EUA process when centrally manufactured

- Could have non-COVID-19 use cases, but not the main focus

# Risk Assessment
(Provided by the ASA)

1. Volumes going to the most compliant lung segments
2. PEEP not manageable
3. Alarm monitoring not feasible
4. Individual management impossible
5. Cardiac arrest requires stopping care for all patients
6. Added circuit volume defeats self test
7. External monitoring required
8. Patients deteriorate at different rates
9. Sudden patient deterioration really affects other patients
10. Ethics of risking more patients

A design to address all the risks

1. Volumes going to the most compliant lung segments– Allow per-patient volume adjustment

2. PEEP not manageable– managed by the ventilator when the circuit is properly closed

3. Alarm monitoring not feasible– Patients require constant monitoring anyway, and pressure loss alarms definitely function

4. Individual management impossible– Allow per-patient volume adjustment

5. Cardiac arrest requires stopping care for all patients– Allow for straightforward patient attachment/detachment that does not compromise other patients

6. Added circuit volume defeats self test– Addition of a bias circuit avoids this problem

7. External monitoring required– Provide external monitoring

8. Patients deteriorate at different rates– Allow per-patient volume adjustment

9. Sudden patient deterioration really affects other patients– Allow for straightforward patient attachment/detachment that does not compromise other patients

10. Ethics of risking more patients– If all previous concerns are addressed and the device is used only in emergencies, we believe that this concern is mitigated

Additional Risks Not Raised by the ASA

1. Can't get knocked over, must be portable until it isn't.
2. Power for monitoring systems must handle 20 minutes of power outage
3. Must be buildable in the field OR must pass FDA EUA approval
4. Knobs cannot move due to pressure
5. Cannot leak aerosolized virus to the room (important in PEEP management)
6. Cannot cross-contaminate patients (viral load, different strains, etc.)
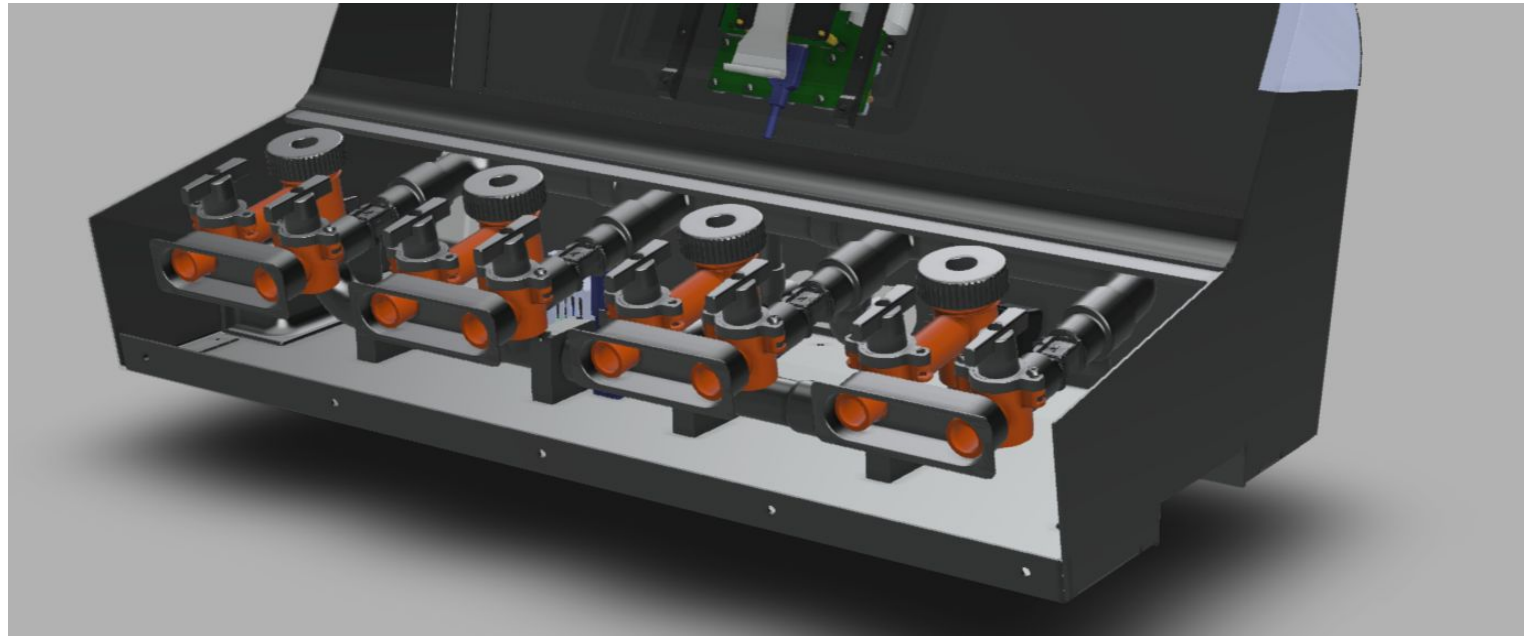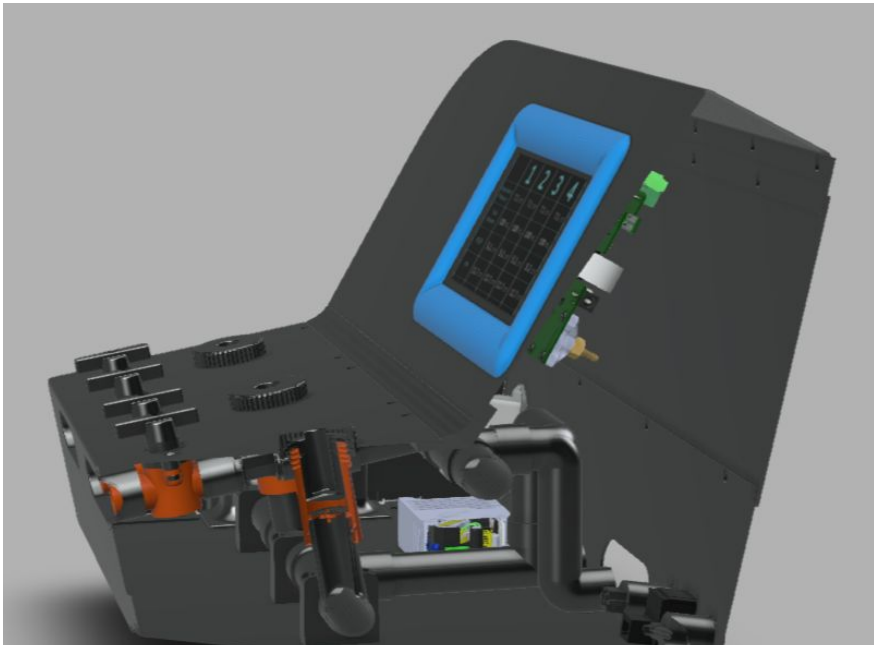
3D Models

Construction in progress!
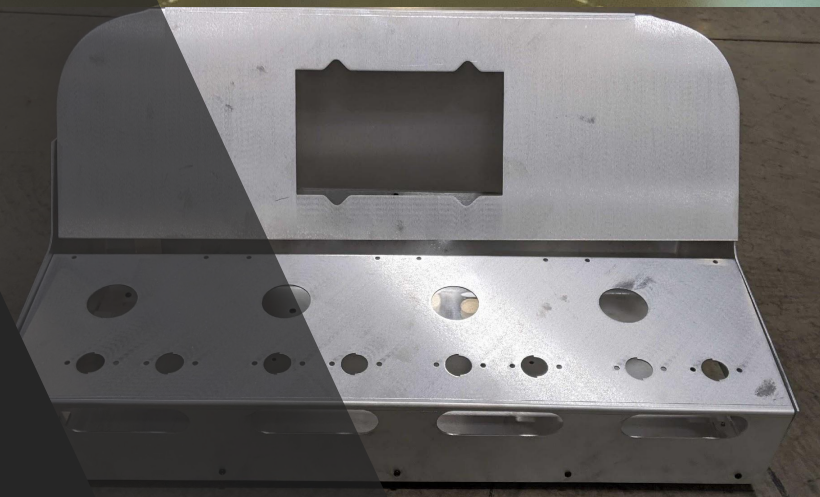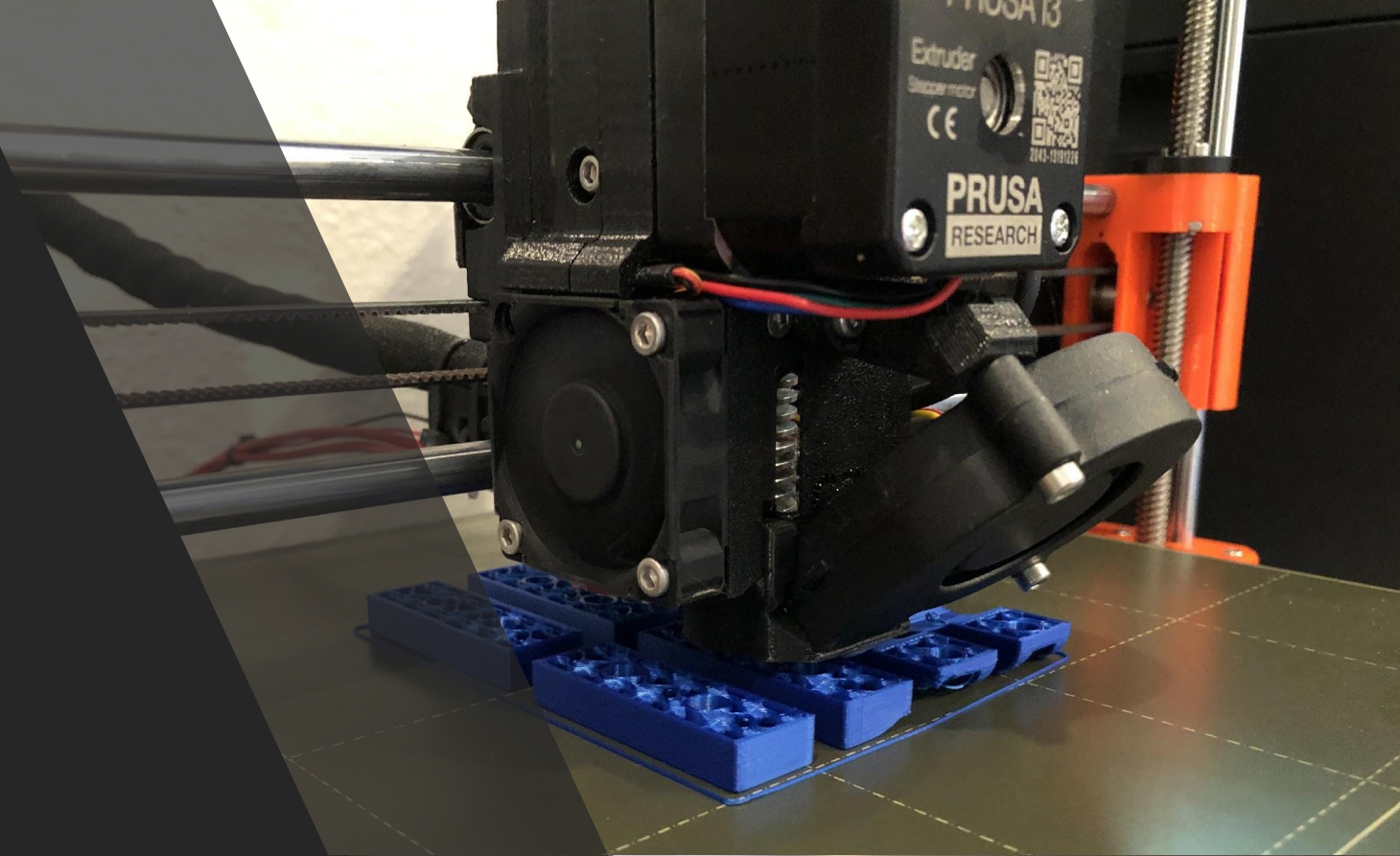
Project Apollo

Why
- Ventilators need oxygen! (typical FiO 0.4 … 0.9)
- Oxygen generation is a big problem in developing countries.
    - No established infrastructure.
    - Oxygen bottles are expensive
- People are already looking at alternative (local) ways for producing oxygen

What
- Goal of the Apollo prototype = enabling people around the world to build the prototype as fast as possible
- Focus = Simplicity and speed of build
- Final goal = Enable people to iterate and publish their own designs in the community

How
- Follow the published build documentation
- Buy/source the materials (check out the BOM)
- Build the prototype
- Validate O2 concentration and flow. Use a **good** O2 and flow sensor.
- Think about risk analysis and assessment: template for Apollo-derived design
- Document and iterate your own design. Publish your findings to the community!

Collaborations
- Peru, Afghanistan, Guatemala

Documentation
- http://project-apollo.org

https://www.youtube.com/watch?v=29PIJpMIkpY&feature=youtu.be