COROVENT

... Nový plicní ventilátor

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CoroVent – Motivation and background

- Insuffiecient number of lung ventilators in Italy
- Our long-time experience and success in design and research of ventilatory medical equipment
- Networking in respiratory care research
- => COROVENT

CoroVent – The Story

March 15, 2020 (Day 1)

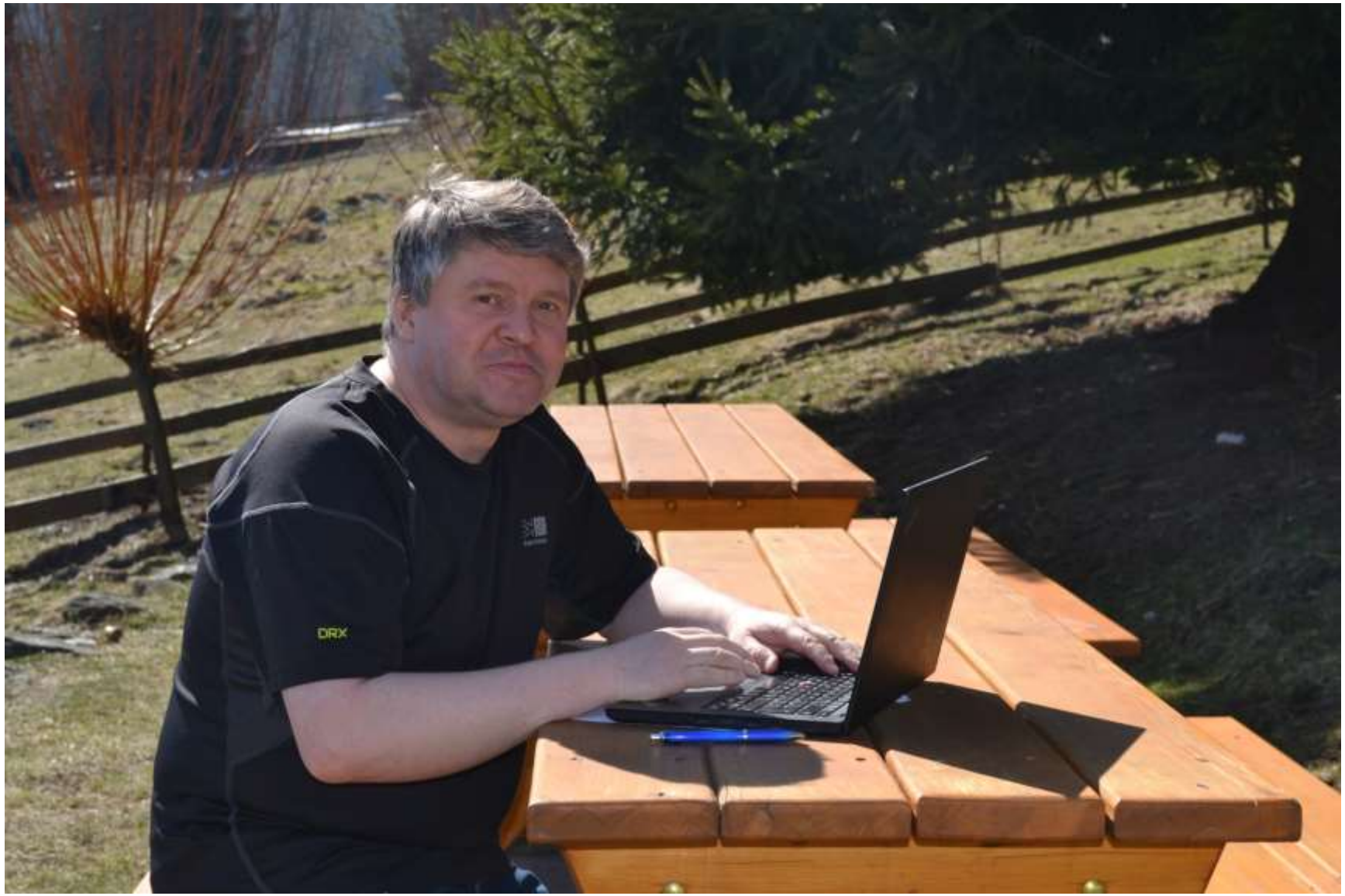
The idea of creating an emergency ventilator was adopted. The preliminary team of experts was created. The first version of the project description was written.

March 16, 2020 (Day 2)

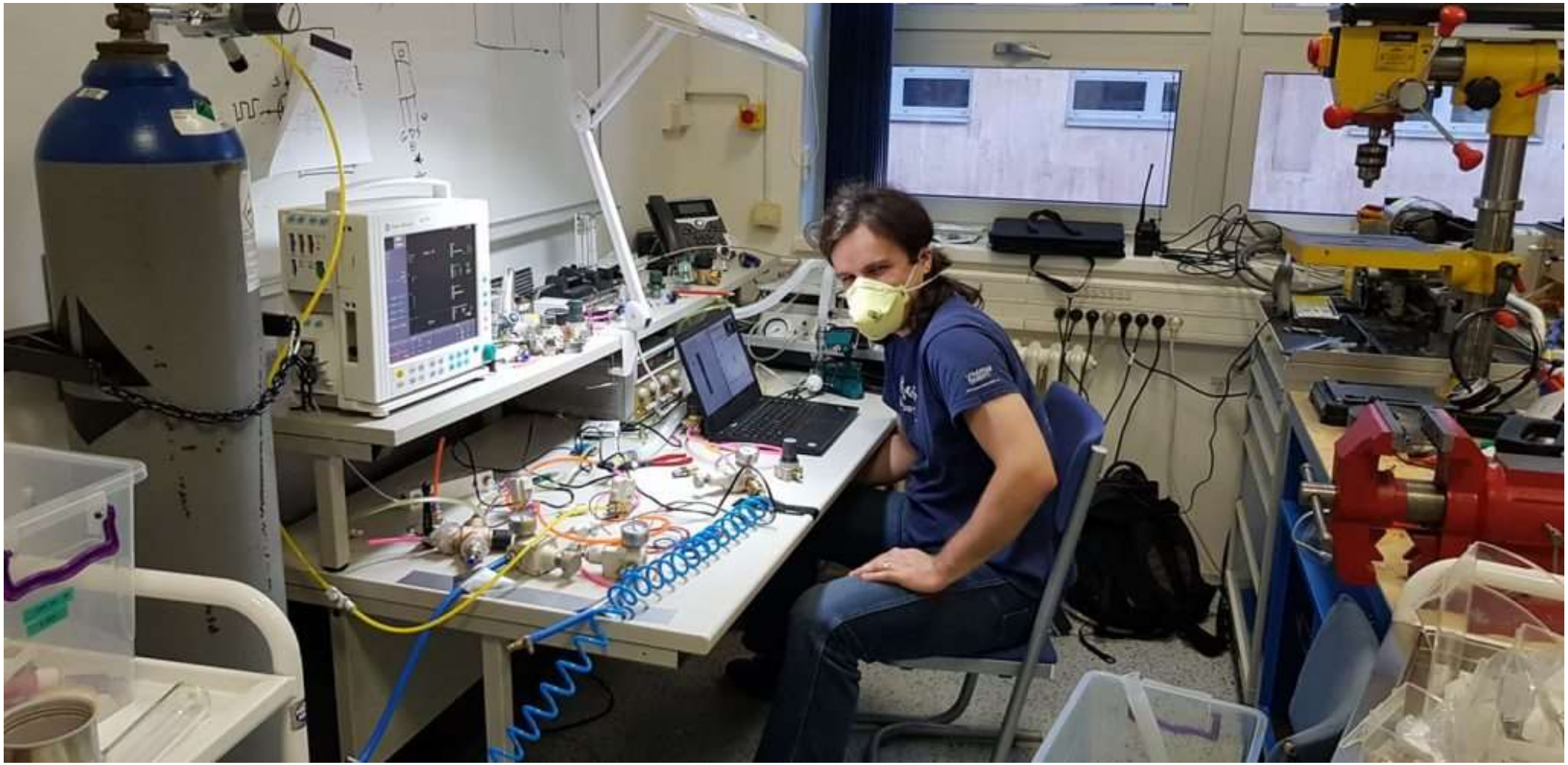
The project proposal was submitted to the Czech ministry of Health and the Czech Government. Medical requirements were summarized and discussed.

The CoroVent team core

The inventor 1:
Karel
1.5 months in the mountains
(Bumbálka, Špindlerův Mlýn)



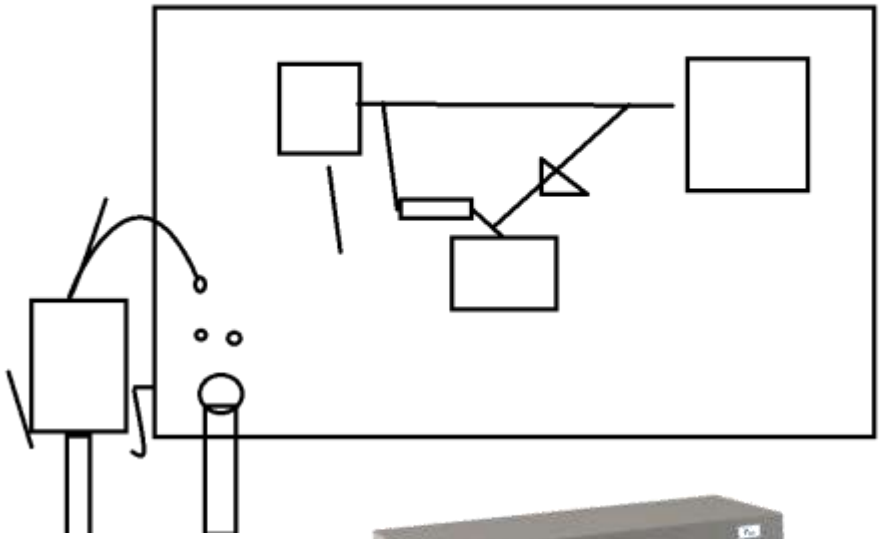
The CoroVent team core

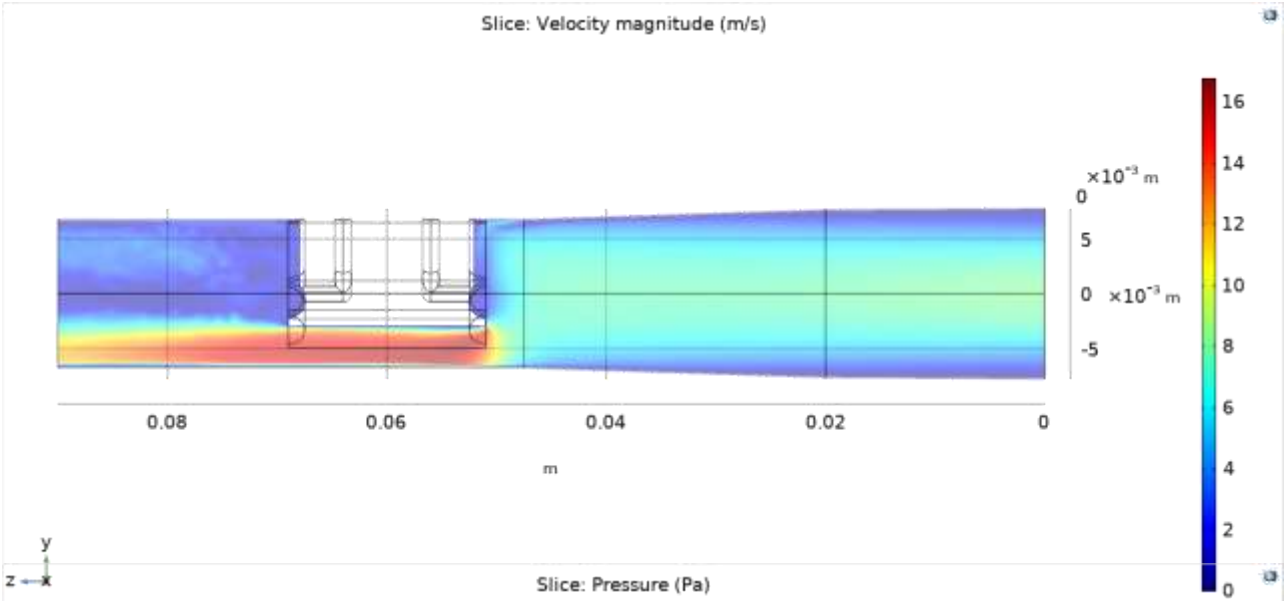


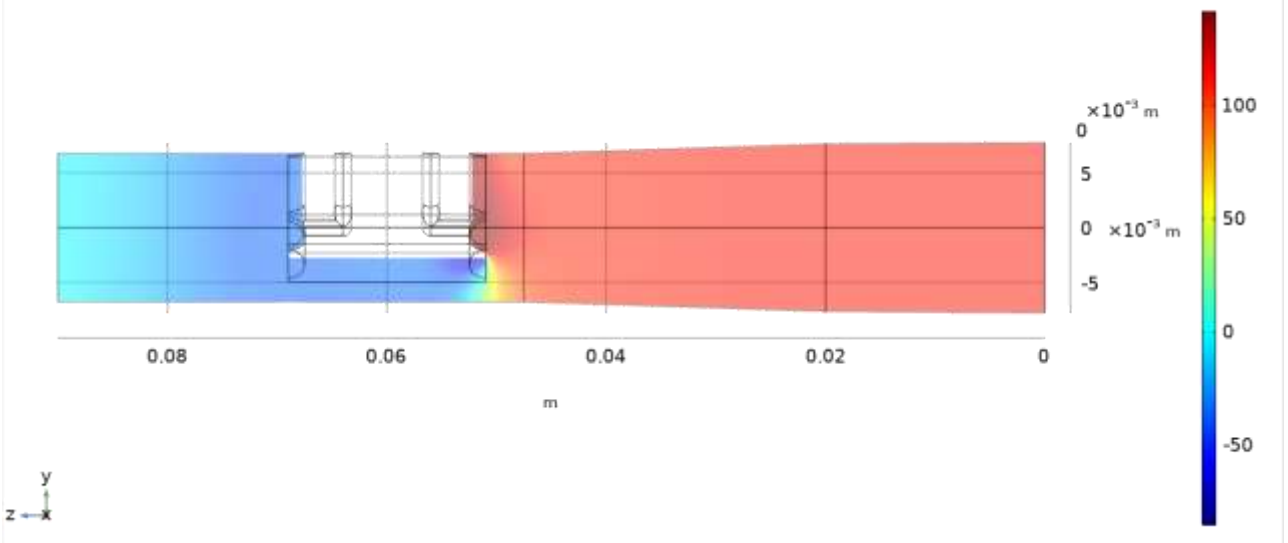
The inventor 2: Vašek, 1.5 months in the laboratory

(Faculty of Biomedical Engineering, Czech Tech Uni, Kladno)

Modern (digital) technology used during design



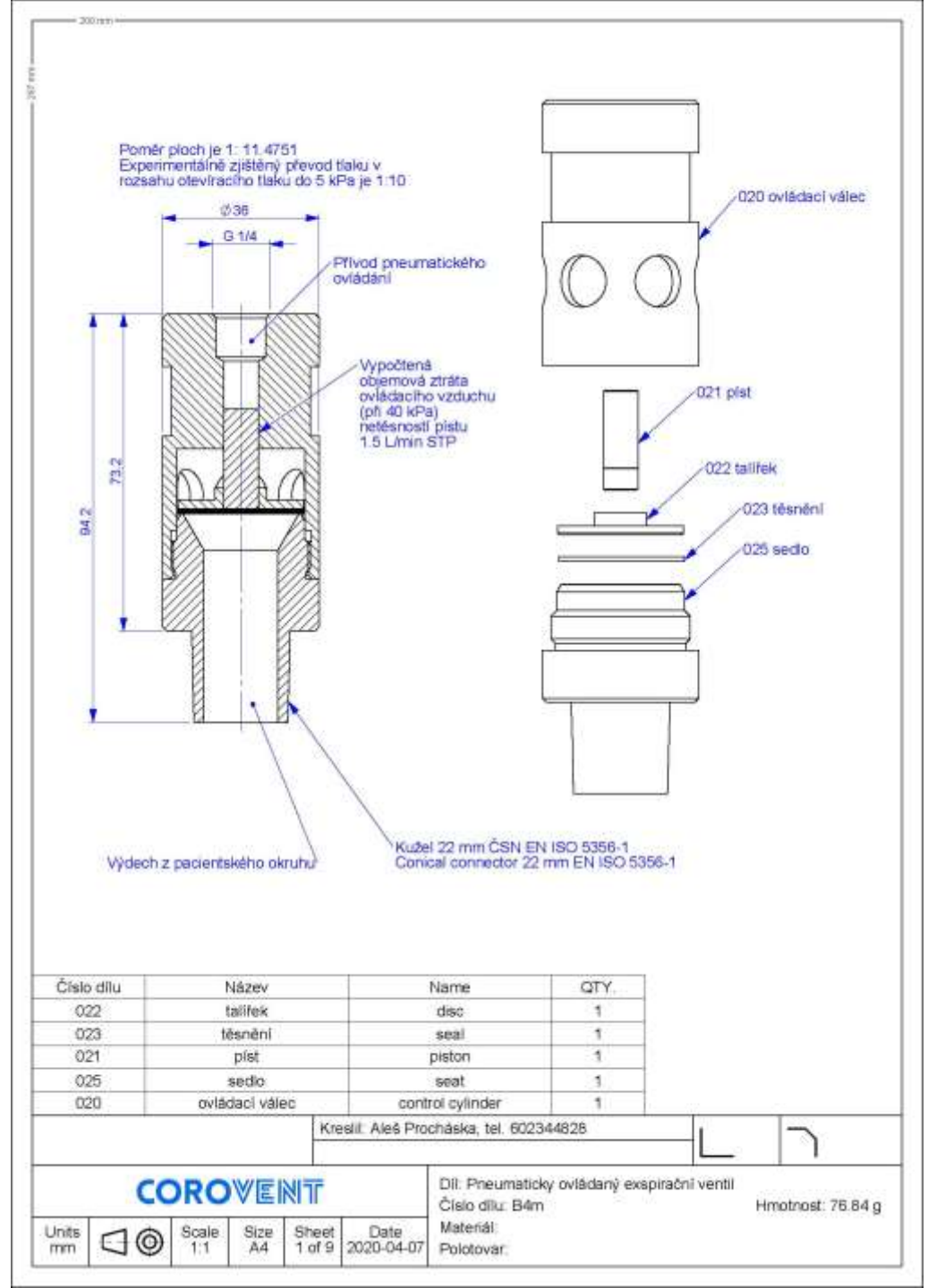




CoroVent – The Story

March 19 (Day 5) – ventilator designed
March 20 (Day 6) – 1st business meeting with partners
March 21 (Day 7) – transfering the design to the manufacturers, 2nd business meeting (21 members)

Professional design, experience of partners



Číslo dílu	Název	Name	QTY.
022	talířek	disc	1
023	těsnění	seal	1
021	píst	piston	1
025	sedlo	seat	1
020	ovládací válec	control cylinder	1

Kreslil: Aleš Procháska, tel. 602344828

COROVENT

Díl: Pneumaticky ovládaný exspirační ventil
Číslo dílu: B4m
Materiál:
Polotovar:
Hmotnost: 76.84 g

Units	Scale	Size	Sheet	Date
mm	1:1	A4	1 of 9	2020-04-07

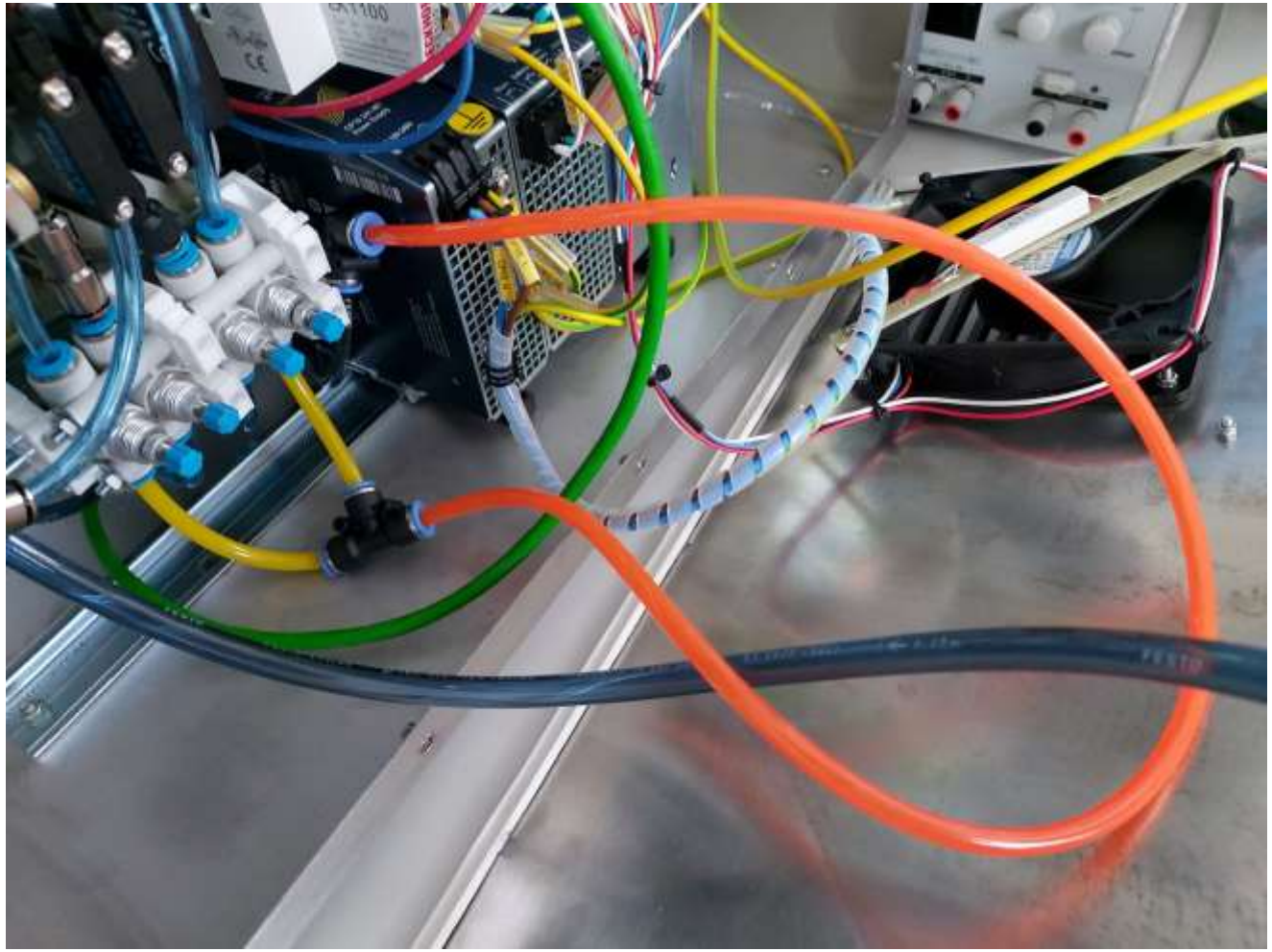
Extreme and fast support of Czech people

Air trafic between laboratory and the manufacturers

Financial support

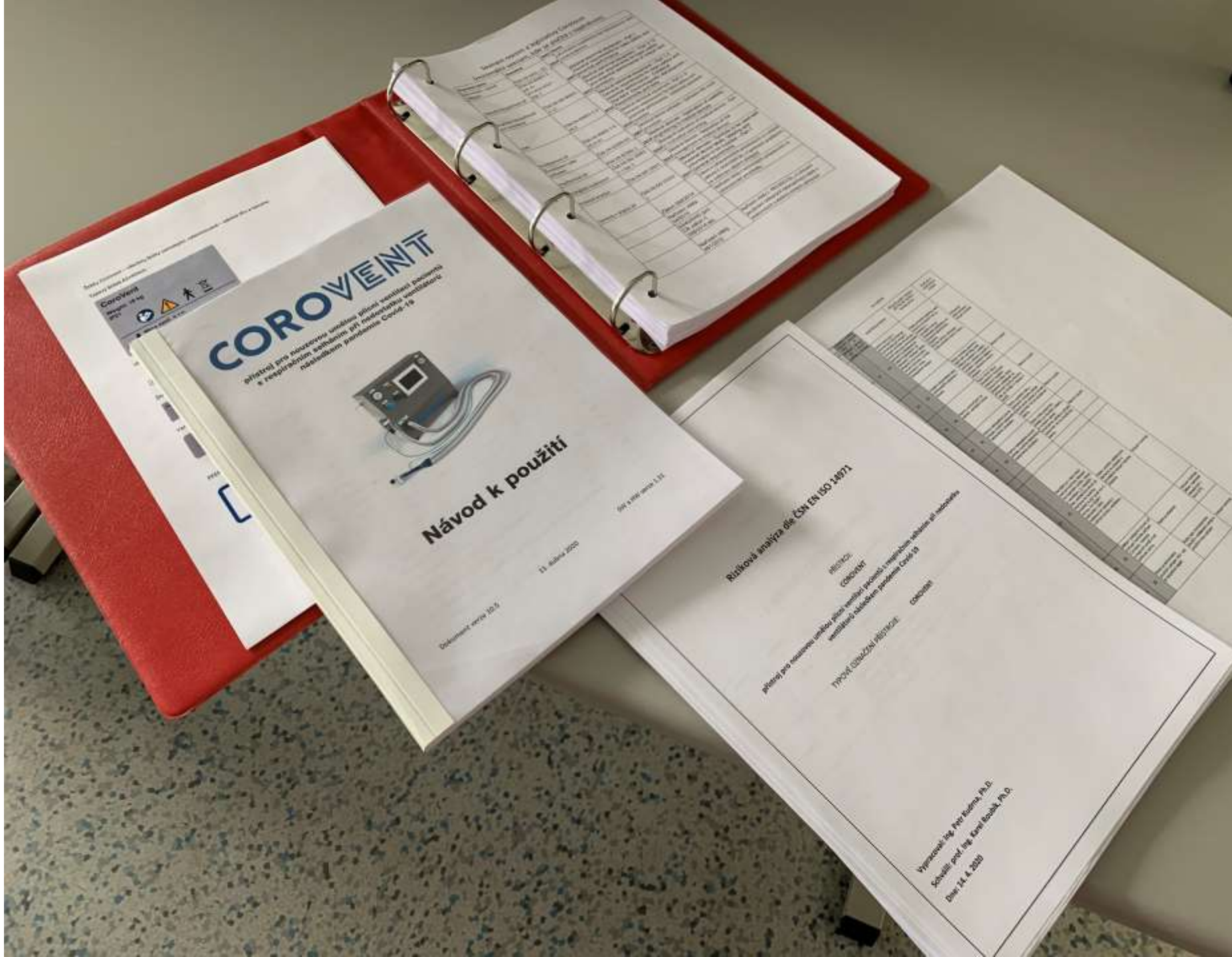
Organizational support (Covid-19CZ)

Creativity and „help“



Paperwork...

Documentation
Risk analysis
Biocompatibility
Certified components
Medical properties
Labeling
Packaging
etc.



Paperwork...

April 14 (Day 31)

Transfer to the Electrotechnical Testing Institute.

CoroVent – The Story

April 22 (Day 39)

We passed safety tests at the Electrotechnical Testing Institute (electromagnetic compatibility, immunity, general safety and IP21).

Elektrotechnický zkušební ústav, s. p.
Pod lisem 129/2
171 02 Praha 8 - Troja

TEST REPORT

Test Report No.: 020657-01/01 — Issued: 21. 4. 2020

Name of product:	**Ventilator / Plicní ventilátor**
Type of product:	**Corovent**
Ratings:	100 – 240V, 50-60Hz, max. 150VA
Serial number:	00003, 00004
Manufacturer:	**MICo, spol. s r.o.,** Sucheniova 270/6, 674 01 Třebíč, Czech Republic
Production site:	**DAWELL CZ s.r.o.,** Budischowského 1073, 674 01 Třebíč, Czech Republic
Ordering firm:	**MICo robotic s.r.o.** Sucheniova 270/6, 674 01 Třebíč - Stařečka, Czech Republic
Number of tested samples:	2
Samples submitted on:	14. 4. 2020
Location of testing:	Elektrotechnický zkušební ústav, s. p.
Tests performed	**from** 14. 4. 2020 **through** 21. 4. 2020
Other data:	Safety testing - partial - selection of the clauses according to the applicant´s order.
Tested according to:	ČSN EN 60601-1 ed.2:2007+A1:2014 cl. 4.11, 5.7, 5.9, 6, 7, 8.4.3, 8.5, 8.6, 8.7, 8.8, 8.9, 8.10, 8.11, 9.3, 9.4, 9.7, 11.1, 13, 15.3, 17

Compiled by: Ing. Josef Metter — Approved by: Ing. Petra Marie Tůmová, Testing laboratory manager

Test Report issued under the responsibility of:

ČSN EN 60601-1 ed.2
Medical electrical equipment
Part 1: General requirements for basic safety and essential performance

Report Reference No.	020657-01/01
Date of issue	21.4.2020
Total number of pages	98; 1 attachment (4 pages)
Testing Laboratory	Elektrotechnický zkušební ústav, s.p.
Address	Pod lisem 129/2, 171 02 Praha 8 - Troja, Czech Republic
Applicant's name	MICo robotic s.r.o.
Address	Sucheniova 270/6, 674 01 Třebíč, Czech Republic
Test specification:	
Standard	ČSN EN 60601-1 ed.2:2007 + A1:2012, cl. 4.11, 5.7, 5.9, 6, 7, 8.4.3, 8.5, 8.6, 8.7, 8.8, 8.9, 8.10, 8.11, 9.3, 9.4, 9.7, 11.1, 13, 15.3, 17
Test procedure	Safety testing - partial
Non-standard test method	N/A
Test Report Form No.	IEC60601_1P
Test Report Form Originator	UL(US), modified by EZU
Master TRF	2019-10-11

General disclaimer:

The test results presented in this report relate only to the object tested.
This report shall not be reproduced, except in full, without the written approval of the issuing CB testing laboratory. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.

CoroVent – The Story

U.S. FDA
Emergency Use Authorization

FDA U.S. FOOD & DRUG ADMINISTRATION

Authorized Ventilators

Authorized on August 21, 2020

Search:

Show 100 entries

Date of Authorization	Manufacturer	Product Name	Device Description
09/23/2020	Belkin International, Inc.	Belkin FlexVent Gas Operated Emergency Ventilator (Resuscitator)	Emergency Ventilator
09/18/2020	Medicreations LLC	MediVent ICU- MCV	Emergency Ventilator
08/21/2020	MICo Medical s.r.o.	MICo Medical CoroVent	Emergency Ventilator
08/18/2020	Breas Medical Inc	Z2 Bilevel	Ventilator, Continuous, Minimal Ventilatory Support

CoroVent – The Story

What is next...

Insufficiency of ventilators in foreign countries?

Full certification process (CE mark)

CoroVent 2.0

Completely new design of ventilators

TESLA

NASA

?

People do not know 1...

Oround 40% mortality of Acute Respiratory Distress Syndrome

Mechanical (artificial) ventilation does not heal the lungs!

Mechanical ventilation damages the lungs.

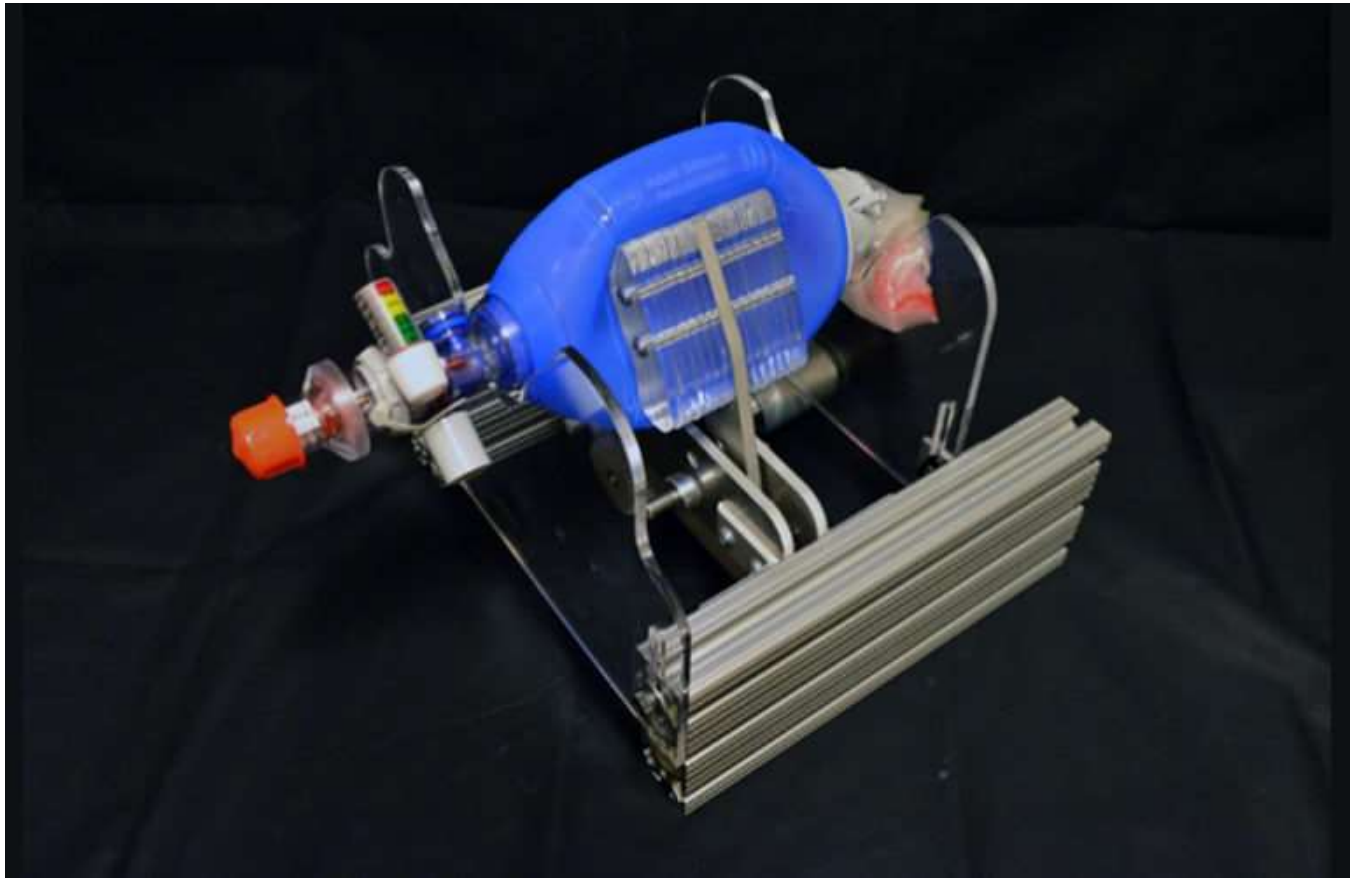
Mechanical ventilation gives the organism time to resolve the problem with lungs by itself.

People do not know 1...

„It is quite easy to put a patient on an artificial ventilation device and make things worse rather than better.“

From: More dangerous than the virus?
Converting manual resuscitators to ventilators
March 31, 2020 By Lee Teschler
https://www.medicaldesignandoutsourcing.com/more-dangerous-than-the-virus-converting-manual-resuscitators-to-ventilators/

The bag squeezer created at MIT uses mechanical paddles driven by a small motor to push air into the lungs. [Image courtesy of MIT, in the article]



People do not know 2:
Classification of medical devices (MEDDEV 2. 4/1 Rev. 9)

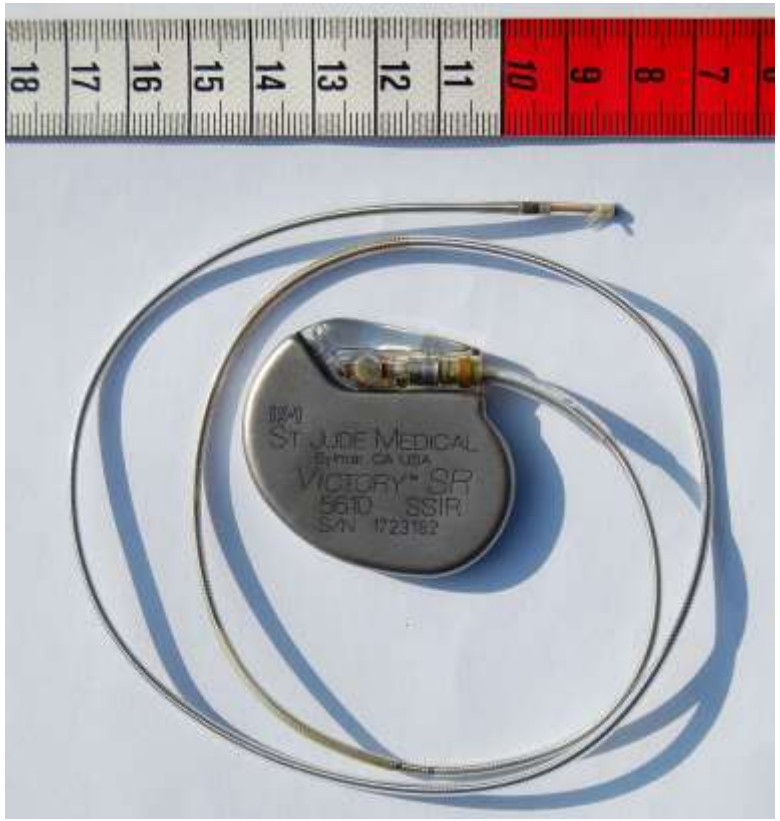
- Class I – nonsterile, nonmeasuring

bandage

.....

eye-test chart

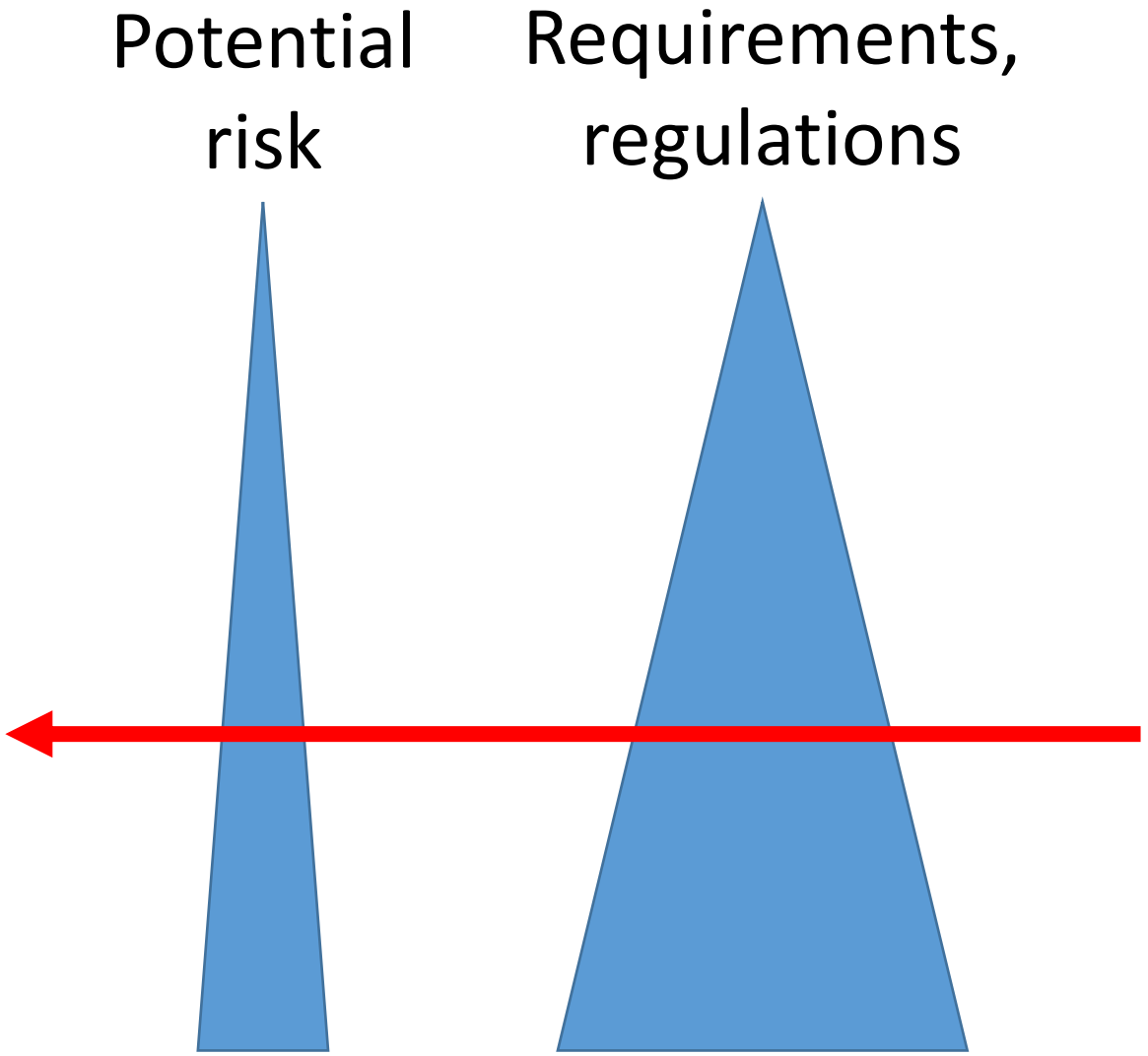
- Class III – implantable devices



pacemaker

People do not know 2:
Classification of medical devices (MEDDEV 2. 4/1 Rev. 9)

- **Class I**
- **Class IIa**
- **Class IIb**
- **Class III**



Ventilators: **Class IIb**

COROVENT

Summary

- Medical equipment – special regulations and requirements must be respected.
- Design should start respecting ISO (EN, ČSN...) standards from the very beginning.
- Interdisciplinary team required – experts in medical, technical and legislation problems and medical equipment certification.
- Necessary to respect „traditions“ in medicine if there is no time to defend your new solution.

Non-Conventional Ventilatory Team

Faculty of Biomedical Engineering,
Czech Technical University in Prague

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www.ventilation.cz

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