Webinar Ventilators: Part 2

Presentation 4

Activity #1

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Researcher

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Fluid flow and pressure laboratories

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Pressure Laboratory (Mechanical Metrology Division)
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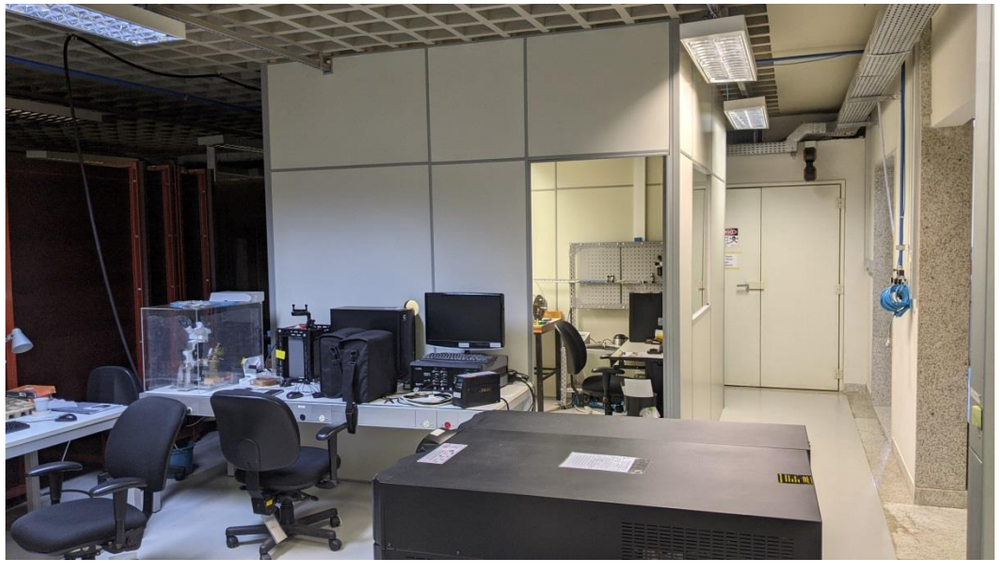
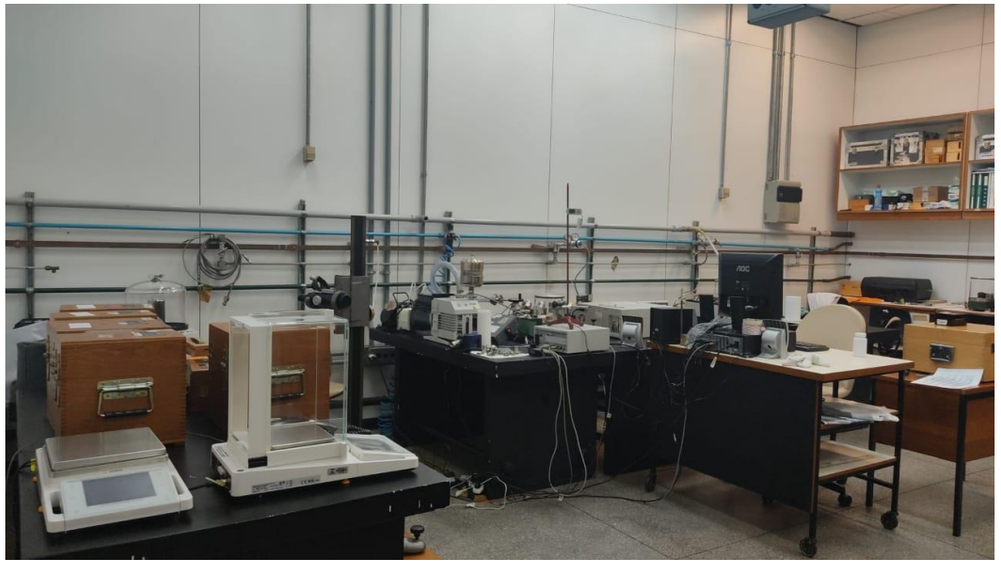




Approved proposal

- **Design of a testing/calibration device to be coupled to mechanical ventilators and other medical equipment**
  - Design a portable device and fixed bench
  - Traceability to national standards.
  - Low cost
- **Possible operation modes**
  - Static and dynamic calibration (Volume and flowrate)
  - Differential and absolute Pressure calibration
  - Inspiratory time, respiratory rate, Peak and PEEP pressure, I:E ratio, etc
- **Results:**
  - Improvement in quality of the involved products
  - To expand the scope of laboratory calibration services;
  - Technology transfer

ISO 80601-2-12

ISO 80601 Part 2-12 Particular requirements for basic safety and essential performance of critical care ventilators

201.12 Accuracy of controls and instruments and protection against hazardous outputs

201.12.1 Accuracy of controls and instruments

201.12.1.101 Volume-control inflation type

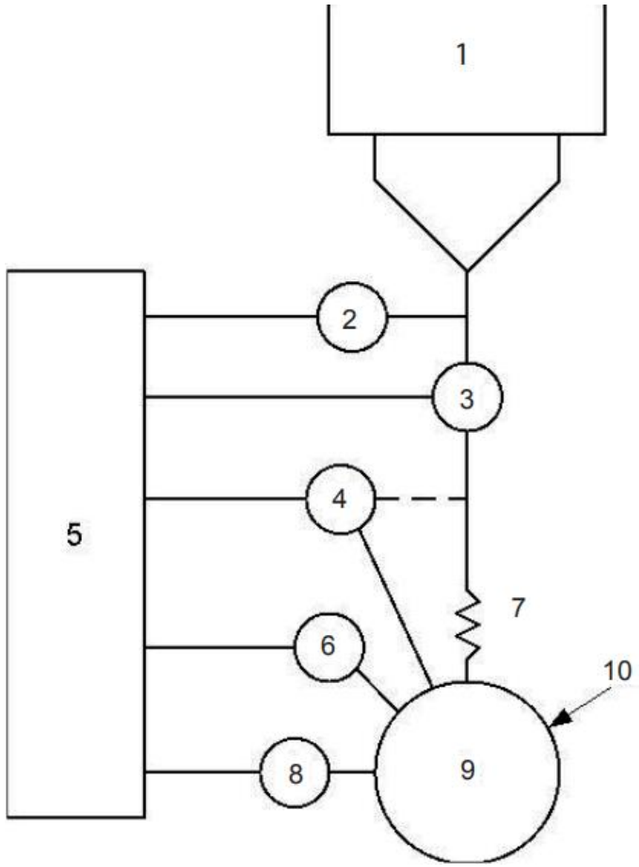
201.12.1.102 Pressure-control inflation type

201.12.1.103 Other inflation types

201.12.1.104 Inspiratory volume monitoring

201.12.1.105 Response of the ventilator to an increase in set O2 concentration

ISO 80601-2-12



Key

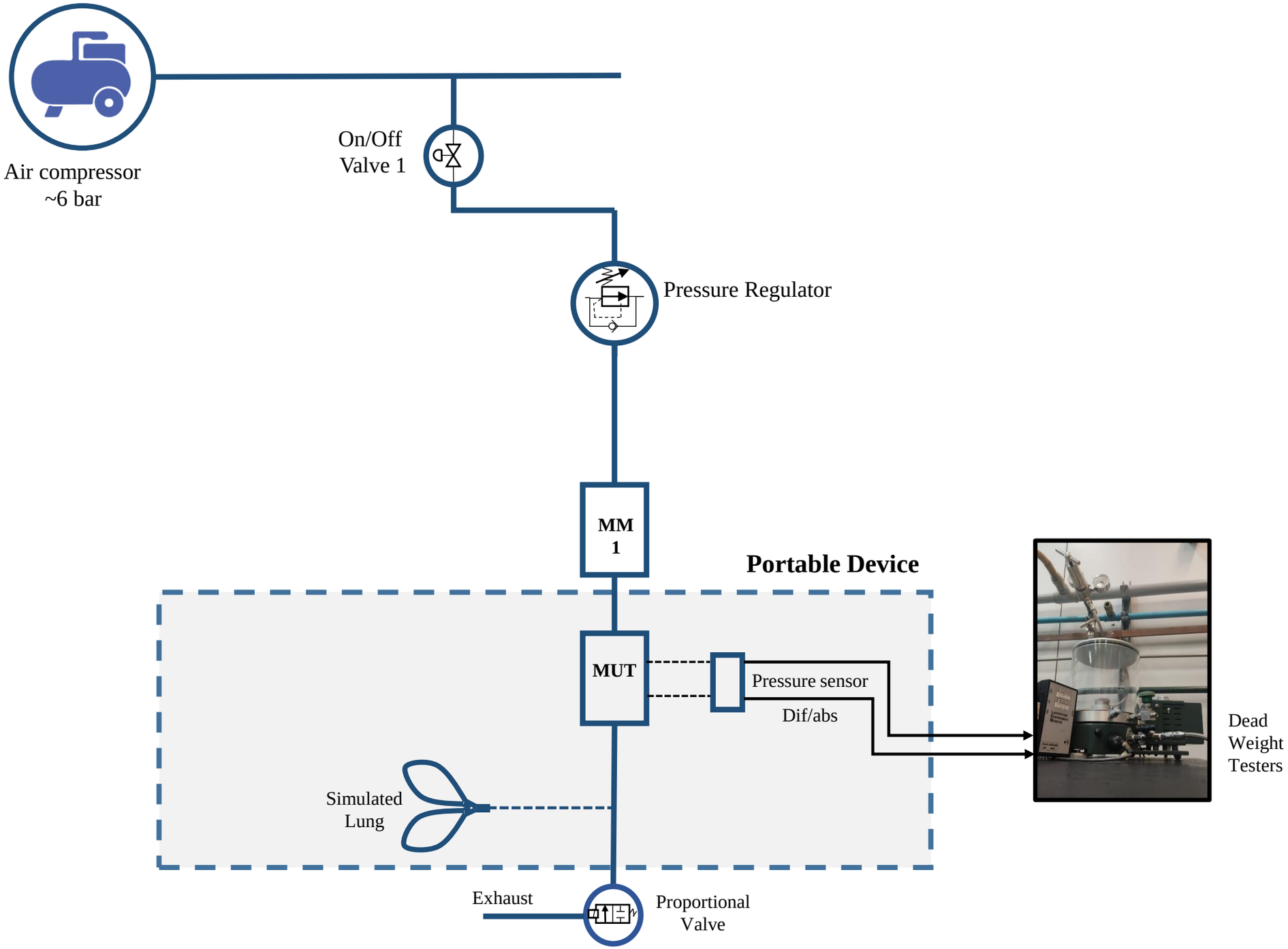
1	ventilatory support equipment under test (single or dual limb)
2	pressure sensor
3	flow sensor, with a 10 % to 90 % rise time of no greater than 10 ms (applies for volume-controlled breath type only)
4	artificial leakage/Oxygen sensor
5	data acquisition system, with minimum sample rate of 200 samples/s
6	temperature sensor
7	resistance in series with the test lung (Rlung)
8	pressure sensor, with a 10 % to 90 % rise time of no greater than 10 ms
9	compliance of the test lung (Clung)
10	test lung

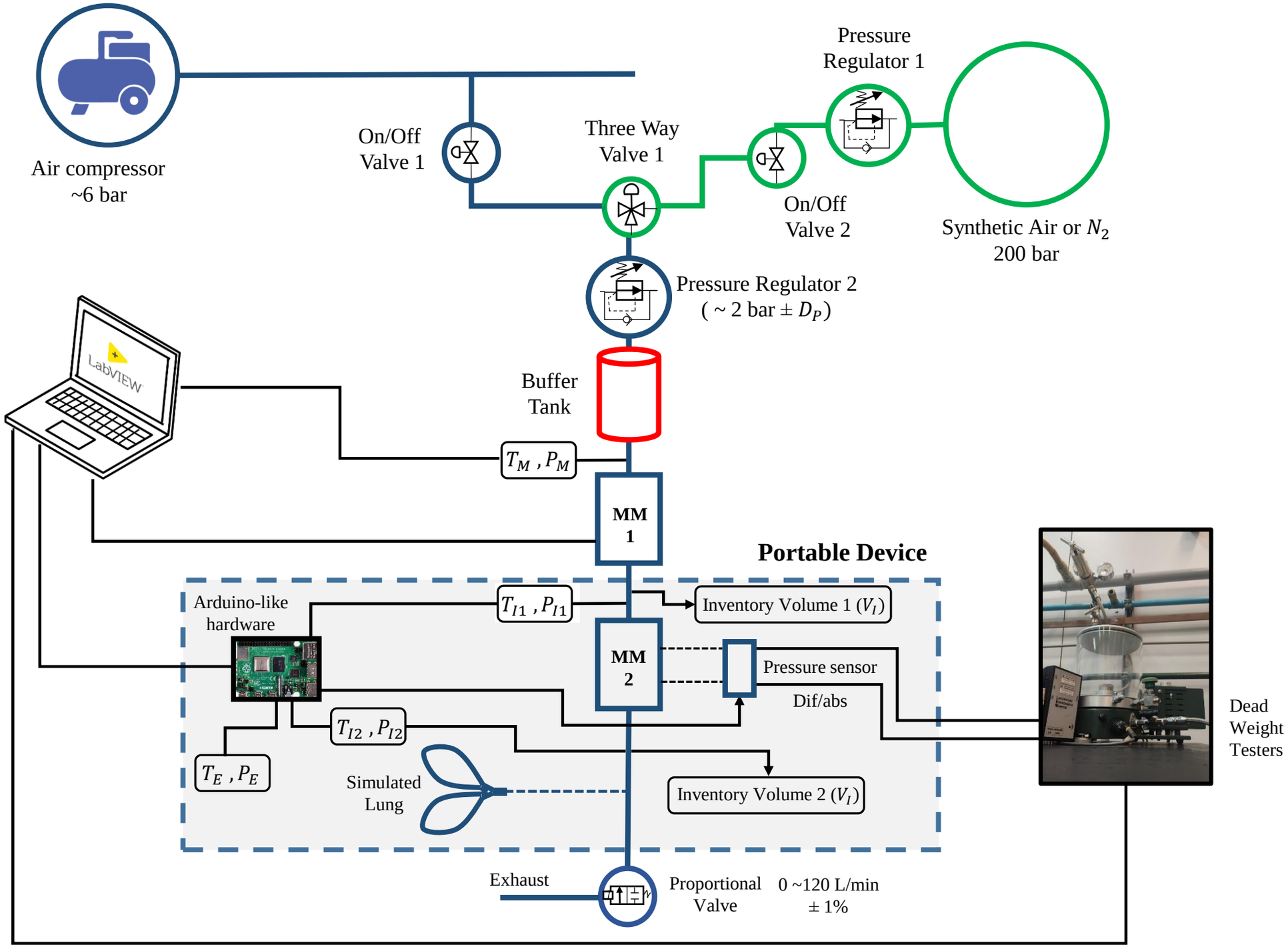
ISO 80601-2-12

Número do ensaio	Parâmetros do pulmão de ensaio		Configurações do VENTILADOR				
	Complacência (mL/hPa) ± 10 %	Resistência linear [22][31][33] (hPa/L/s) ± 10 %	Volume (mL)	Frequência respiratória (ciclos/min)	Tempo inspiratório (s)	FiO_2 (%)	PEEP (hPa)
1	50	5	500	20	1	30	5
2	50	20	500	20	1	90	10
3	20	5	500	20	1	90	5
4	20	20	500	20	1	30	10
5	20	20	300	20	1	30	5
6	20	50	300	20	1	90	10
7	10	50	300	20	1	30	10
8	10	20	200	20	1	90	5
9	3	20	50	30	0,6	30	5
10	3	50	50	30	0,6	30	10
11	3	200	50	30	0,6	60	5
12	3	50	30	30	0,6	30	5
13	3	200	30	30	0,6	90	10
14	1	50	30	30	0,6	90	5
15	1	200	30	30	0,6	30	10
16	1	200	20	60	0,4	30	5
17	1	200	15	60	0,4	60	10
18	1	50	10	60	0,4	60	5
19	0,5	50	5	60	0,4	60	10
20	0,5	200	5	30	0,4	30	5
21	0,5	200	5	60	0,4	30	10

Número do ensaio	VOLUME LIBERADO pretendido[a] (mL)	Parâmetros do pulmão de ensaio		Ajustes do VENTILADOR				
		Conformidade (mL/hPa) ± 10 %	Resistência linear [22][31][33] (hPa/L/s) ± 10 %	Frequência ventilatória (ciclos/min)	Tempo inspiratório[b] (s)	Pressão[c] (hPa)	FiO_2 (%)	PEEP (hPa)
1	500	50	5	20	1	10	30	5
2	500	50	20	20	1	15	90	10
3	500	20	5	20	1	25	90	5
4	500	20	20	20	1	25	30	10
5	300	20	20	20	1	15	30	5
6	300	20	50	20	1	25	90	10
7	300	10	50	20	1	30	90	5
8	200	10	20	20	1	25	30	10
9	50	3	20	30	0,6	15	30	5
10	50	3	50	30	0,6	15	30	10
11	50	3	200	30	0,6	25	60	5
12	30	3	50	30	0,6	10	30	5
13	30	3	200	30	0,6	15	90	10
14	30	1	50	30	0,6	30	90	5
15	30	1	200	30	0,6	30	30	10
16	20	1	200	60	0,4	20	30	5
17	15	1	200	60	0,4	15	60	10
18	10	1	50	60	0,4	10	60	5
19	5	0,5	50	60	0,4	15	60	10
20	5	0,5	50	30	0,4	10	30	5
21	5	0,5	200	60	0,4	15	30	10

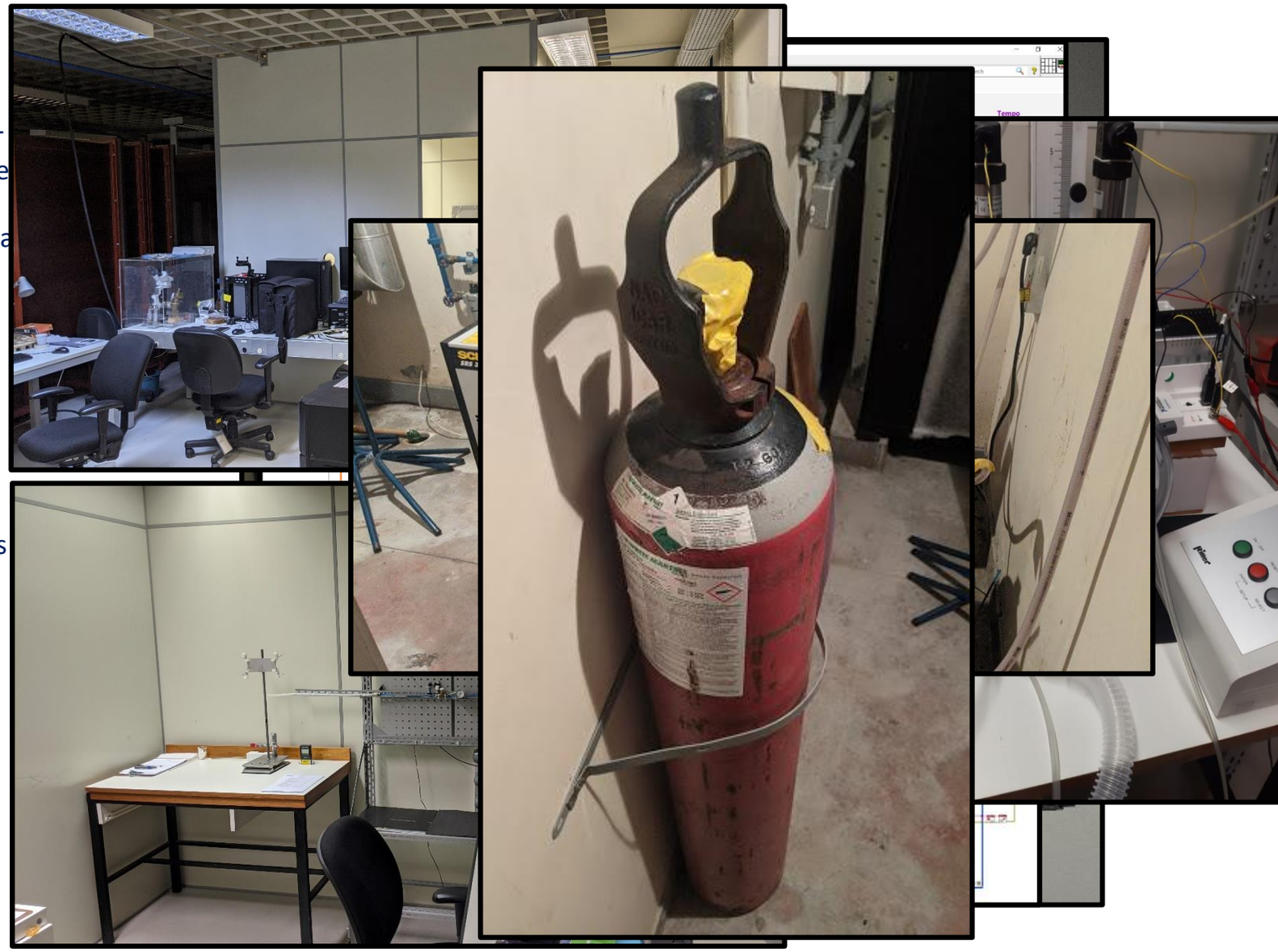
Tests for volume controlled and pressure controlled operation – Source:ISO 80601-2-12 Equipamento eletromédico Parte 2-12: Requisitos particulares para a segurança básica e o desempenho essencial de ventiladores para cuidados críticos


Air compressor
~6 bar
On/Off
Valve 1
Pressure Regulator
MM
1
Portable Device
MUT
Pressure sensor
Dif/abs
Simulated
Lung
Exhaust
Proportional
Valve
Dead
Weight
Testers


Air compressor
~6 bar
On/Off
Valve 1
Three Way
Valve 1
Pressure
Regulator 1
On/Off
Valve 2
Synthetic Air or N_2
200 bar
Pressure Regulator 2
(~ 2 bar ± D_P)
Buffer
Tank
LabVIEW
T_M , P_M
MM
1
Portable Device
Arduino-like
hardware
T_{I1} , P_{I1}
Inventory Volume 1 (V_I)
MM
2
Pressure sensor
Dif/abs
T_{I2} , P_{I2}
T_E , P_E
Simulated
Lung
Inventory Volume 2 (V_I)
Exhaust
Proportional
Valve
0 ~120 L/min
± 1%
Dead
Weight
Testers

Calibration bench - Flow

- **Flow source:**
  - **Air compressor**
    - Steady state
    - Unstable (pressure regulator
    - Not Clean (Dental air compre
  - **Compressed gas cylinder**
    - Synthetic air/Any other availa
    - Stable and clean
- **Master Meter**
  - Drum type;
  - Large inertia;
  - Slow response to flow variations;
  - U ~ 0.27%
- **Data Acquisition/ User interface**
  - NI Labview
  - NI cDaq w/ 9205 and 9203 modules
- **Calibration**
  - Static
  - MM x MUT
  - Flow and volume
  - U ~ 0.8 %, k=2 (flow)

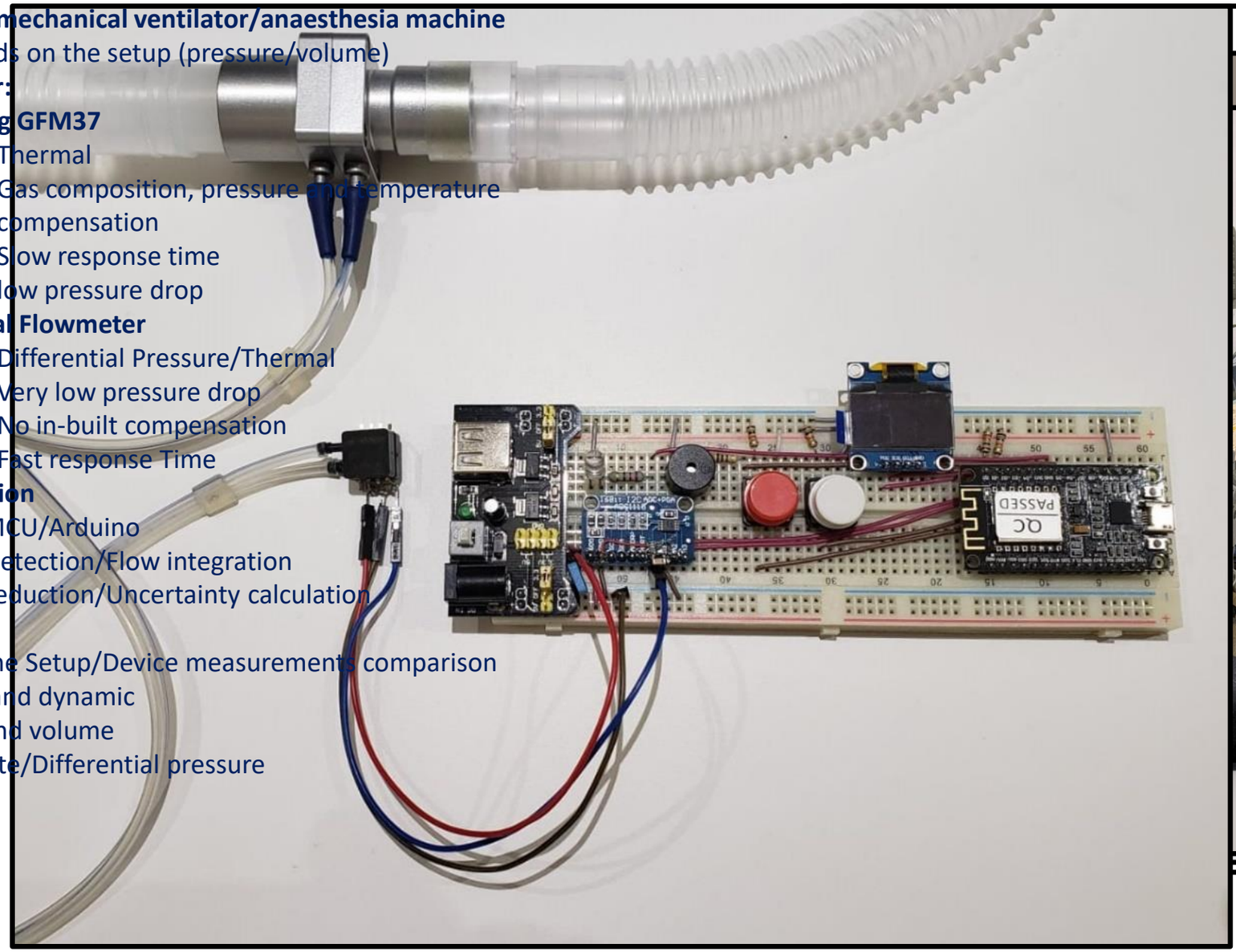


Calibration bench - Pressure

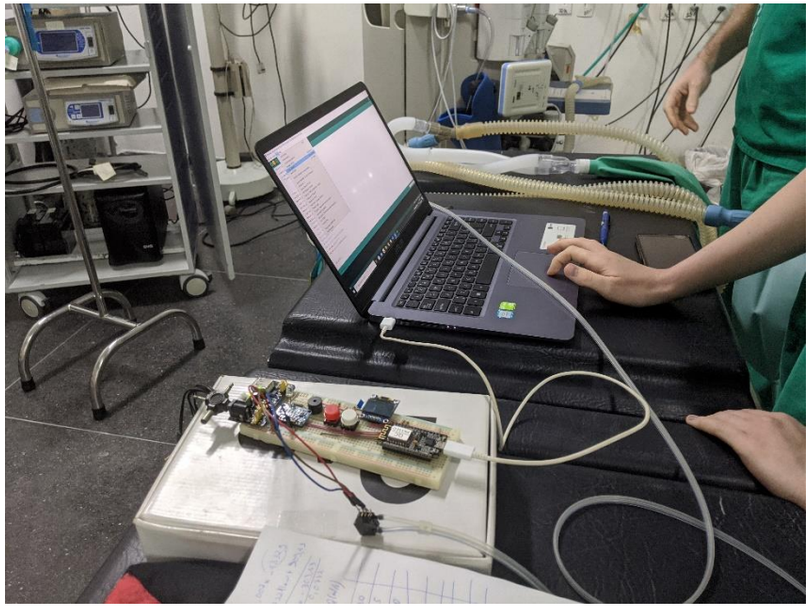
- **Standard**
  - Dead weight - Ruska
  - U ~ 60 ppm (absolute/differential)
- **Calibration modes**
  - Differential
  - Absolute

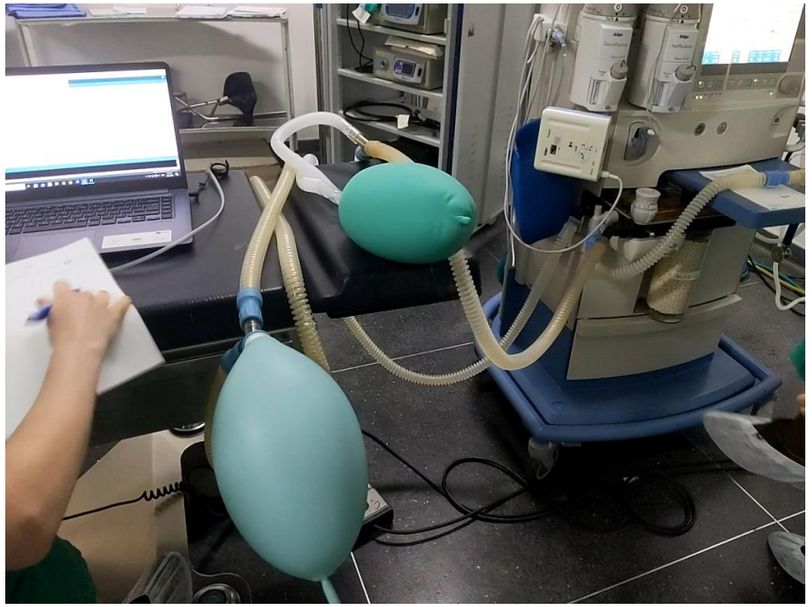
Portable device

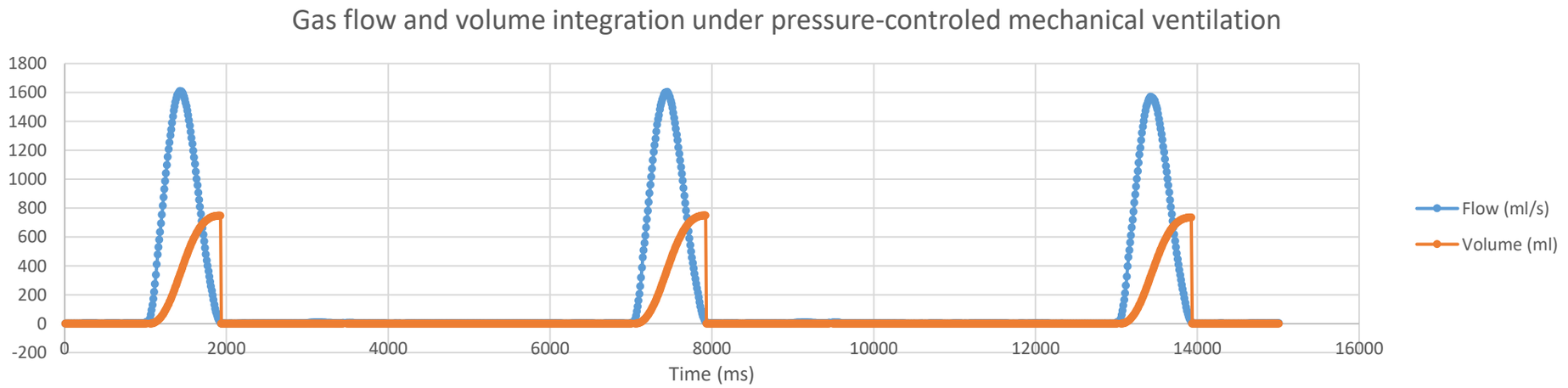
- **Flow source: mechanical ventilator/anaesthesia machine**
  - Depends on the setup (pressure/volume)
- **Master Meter:**
  - **Aalborg GFM37**
    - Thermal
    - Gas composition, pressure and temperature compensation
    - Slow response time
    - low pressure drop
  - **Medical Flowmeter**
    - Differential Pressure/Thermal
    - Very low pressure drop
    - No in-built compensation
    - Fast response Time
- **Data Acquisition**
  - NodeMCU/Arduino
  - Cycle detection/Flow integration
  - Data Reduction/Uncertainty calculation
- **Calibration**
  - Machine Setup/Device measurements comparison
  - Static and dynamic
  - Flow and volume
  - Absolute/Differential pressure



Results






Gas flow and volume integration under pressure-controled mechanical ventilation
1800
1600
1400
1200
1000
800
600
400
200
0
-200
0
2000
4000
6000
8000
10000
12000
14000
16000
Time (ms)
Flow (ml/s)
Volume (ml)

Work to do

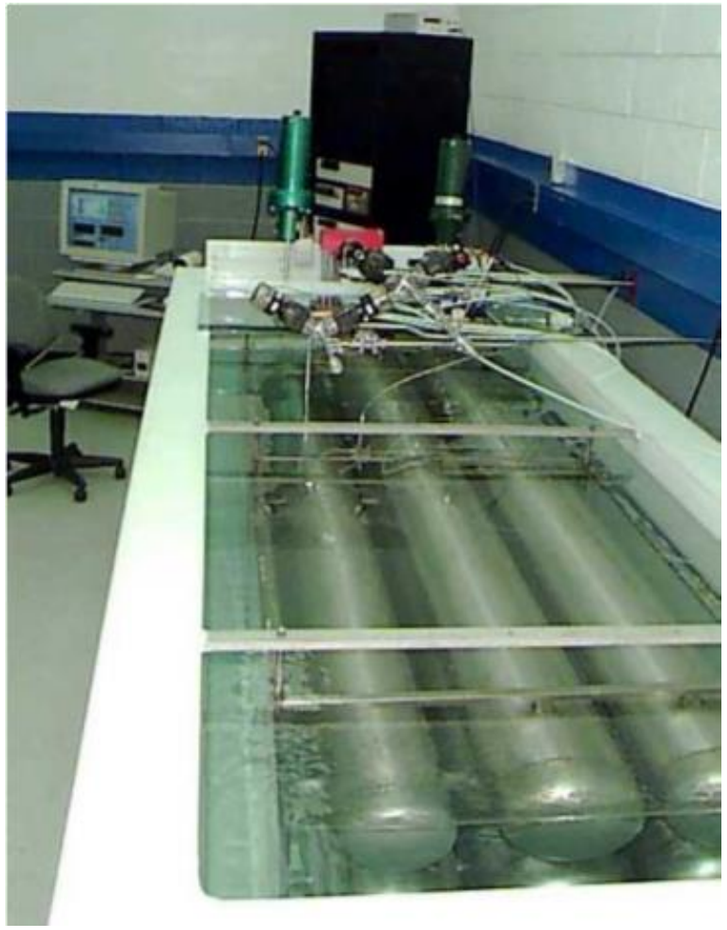
- **Flow calibration bench**
  - Flow stabilization
  - Build calibration line and finish automation/User interface system
  - Finish mathematical model and uncertainty calculation
  - Work on ISO 17025 requirements
- **Portable device**
  - Finish data acquisition/reduction system
  - Develop user interface
  - To assess ISO 80601 compliance
  - Build prototype
  - In-situ tests
- **Cooperation with other NMIS**
  - Share progress
  - Comparison

Future Challanges and Lessons learned

- **There is little interaction between medical and metrological communities**
  - Better understanding of uncertainty
  - Improvements in medical devices

- **Encourage the testing of medical devices**
- **Make the portable device low cost and readily available**

- **Primary Standard**
  - Bell Prover
  - PVTT



Questions?

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