Development of gas Flow measurement capabilities for medical applications, test bench for mechanical ventilators

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outline

- Context
- Objectives
- Test bench for ventilators
- Flow traceability up to 200 L/min with LFE as working standards
- Primary gravimetric flow standard up to 10 L/min
- Lessons learned
- Future challenges

Context

- The mechanical ventilators are medical devices that provide support to patients by keeping them ventilated while their mayor illness is treated.
- The SARS-CoV-2 weakens the patients and limits their breathing capacity.
- There is a worldwide crisis on health care access, insufficient materials, equipment and devices.
- There has been several proposals, designs and prototypes, of low cost ventilators to alleviate the pandemic impact.

Covid-19: Ventilación mecánica para no intensivistas; edX-Javeriana (2020)

¿what do we do?

Design and build a prototype?

Or

Provide traceability and metrological advice to those who are currently developing and building prototypes?

Literature review: ISO 80601-2-12

- ISO standard to stablish the requirements for critical care ventilators

1 Ventilator under test
2 Pressure sensor
3 Flow sensor
4 Oxygen sensor
5 Computer
6 Temperature sensor
7 Resistance
8 Pressure sensor
9 Test lung

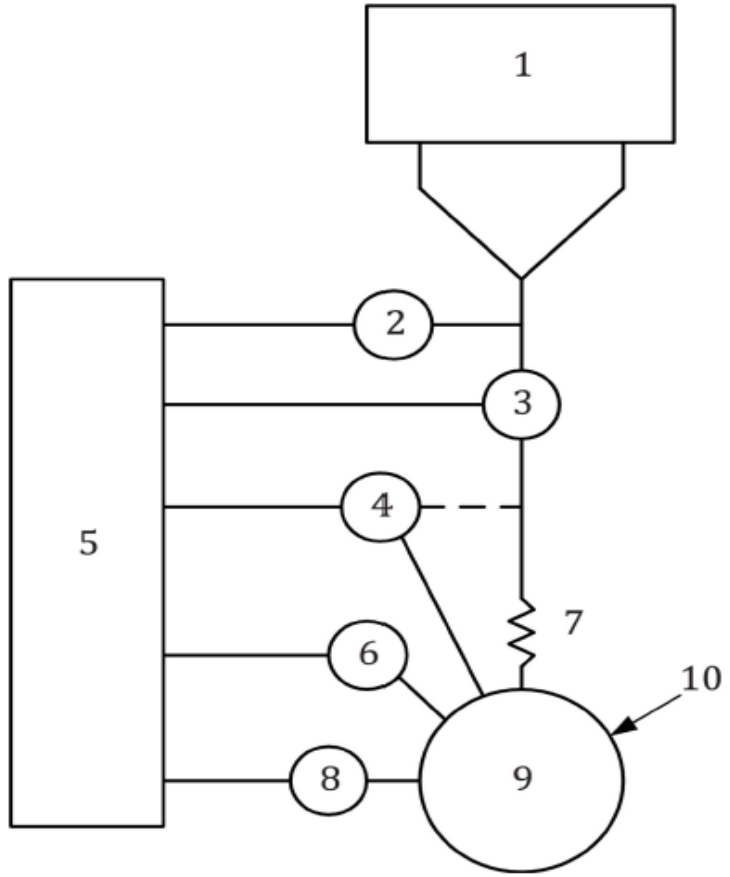


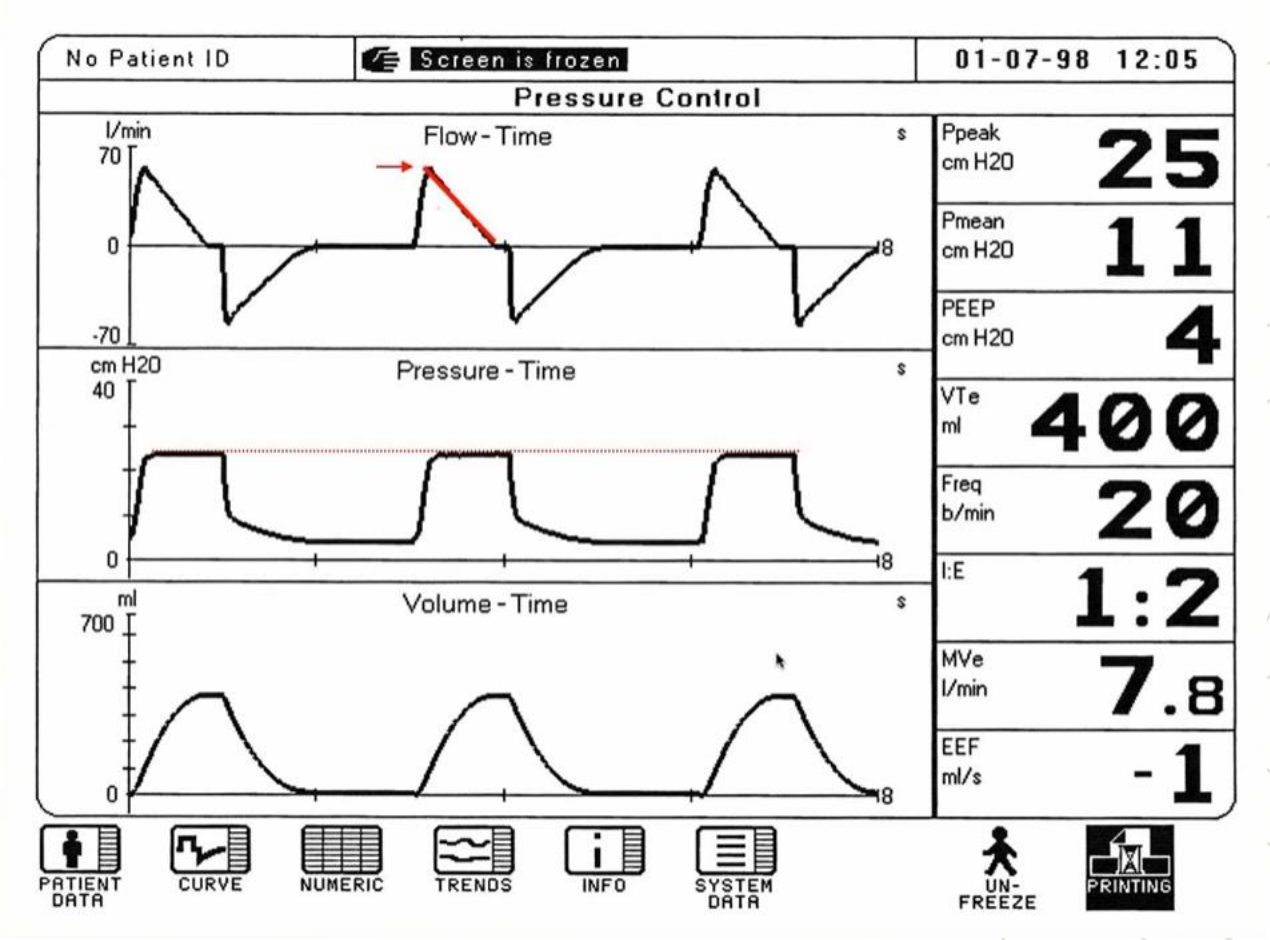
Diagram of the test bench described on the ISO standard.

ISO 80601-2-12:2020

Scope of the project

- Verification of ventilators according to point *200.12.1 Accuracy of controls and instruments.*

- Establish the maximum errors for the operation of ventilators in pressure control and volume control modes.



Example of a mechanical ventilator display.

ISO 80601-2-12:2020

Covid-19: Ventilación mecánica para no intensivistas; edX-Javeriana (2020)

Solution 1

- Gas flow analyzer
  - Easy to use
  - Compact
  - ¿Traceability?
  - ¿What's its use after the pandemic?

Citrex H5

Fluke VT305

TSI Certifier

Solution 2

- Build a test bench from different parts and sensors
  - We already have traceability for pressure instruments. (CMCs)
  - Get a test lung.
  - Get some flow sensors/standards.

We need a new lab, gas flow!?

Objectives

- To provide traceability for new low cost ventilators and commercially available critical care ventilators.
  - Ventilator test bench

- Develop flow measurement capabilities.
  - Transfer/working standards
  - Primary gravimetric standard (maybe)

Ventilator test bench

Ventilator test bench

Ventilator test bench setup

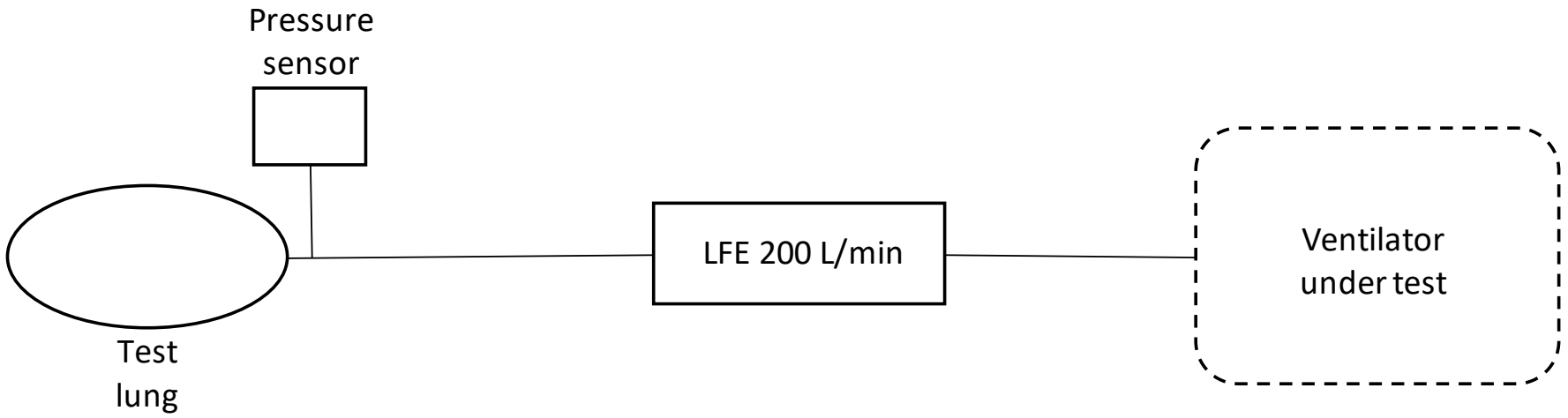


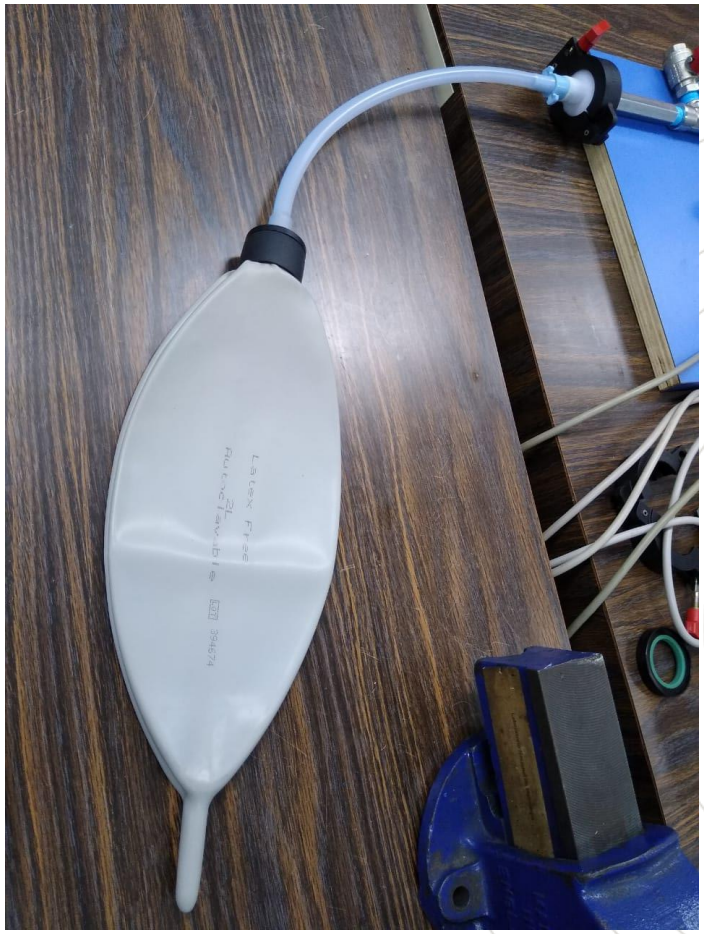
Diagram of the ventilator test bench

- The setup is made to measure peak pressure, tidal volume, PEEP among other parameters.

- Hooked to a computer and programed with LabVIEW.

About the test lung

- There are different types of test lungs, generally of fixed volume (container) or variable volume (elastic bag).
- The important parameter to know from a test lung is its compliance.
- Compliance is the relationship between volume and pressure inside the lung (mL/hPa).



Test lung at LCM; compliance 18 mL/hPa

D. W. Hill, V. Moore; Brit. J. Anaesth. (1965)

Flow traceability

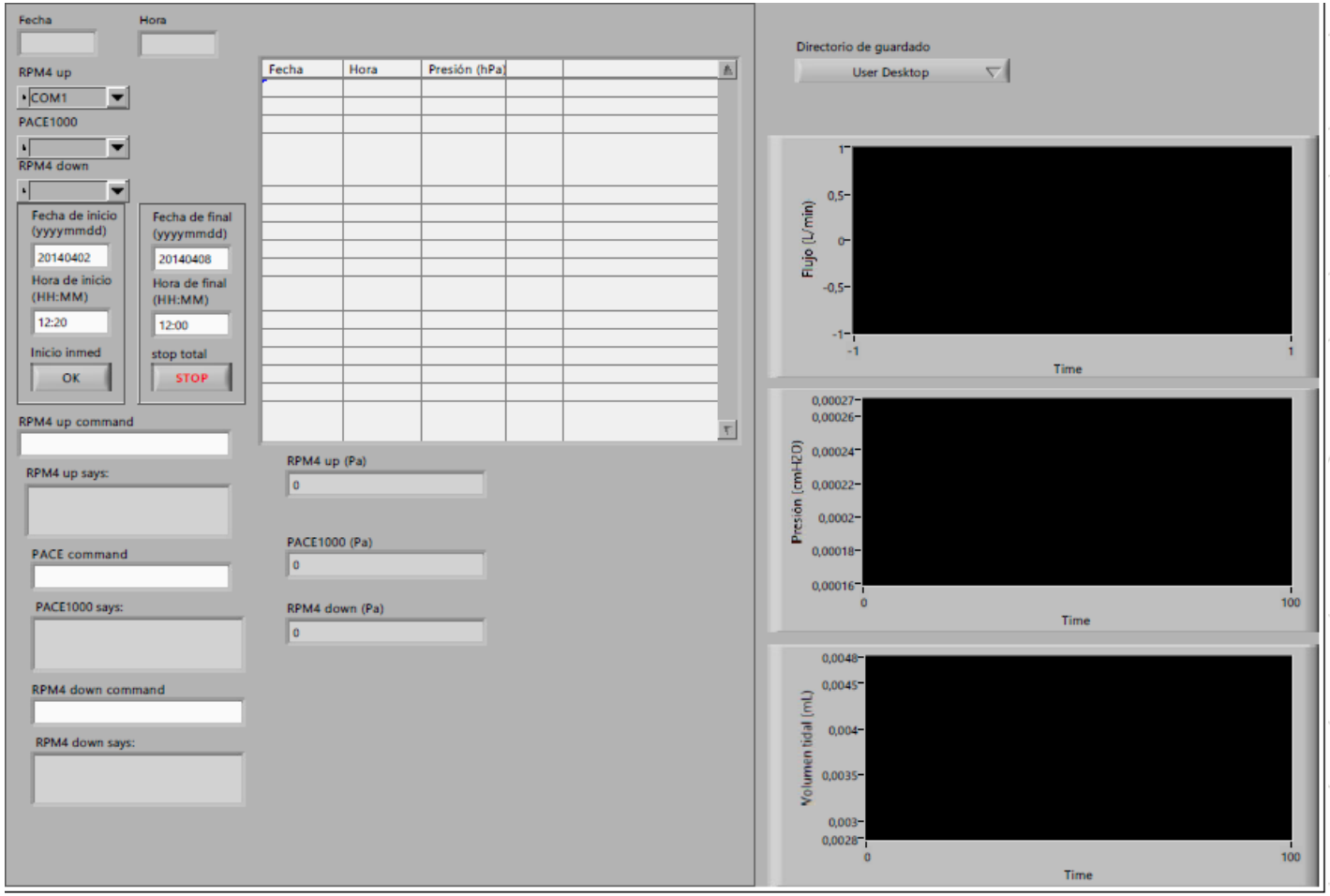
- Laminar flow elements. Flow is a function of the differential pressure across the element.
- Traceability comes from pressure and the determination of the discharge coefficient.
- "No drift".
- Usually working/transfer standards.
- Three ranges (air):
  - 1 L/min (0,02 g/s)
  - 10 L/min (0,2 g/s)
  - 200L/min (4,0 g/s)

LCM laminar flow elements

J. Wright; NCSL Workshop & Symposium (1998)

Ventilator test bench setup

- I:E ratio is too fast compared with the communication of the sensors to the computer.
- The project catch the attention of health authorities:
  - 977 ventilators in use, possibility to establish metrological control.



LabVIEW front panel for ventilator testing

Collaboration with the RESPIRA UCR project

- Project by the University of Costa Rica to develop a low cost critical care ventilator based on an "ambu" bag.
- Calibration of several differential pressure sensors for the different stages of the prototype.

Final prototype delivered to the health authorities Oct-Nov 2020

First meeting at the lab, late April 2020

Collaboration with the FLUXUS MASK project

- Project by the University of Costa Rica, development of a CPAP ventilator based on a scuba diving mask.

- Verification of the relief pressure of the PEEP valves used for the prototype.

First meeting at the lab, mid June 2020

LFE calibration system

LFE calibration system

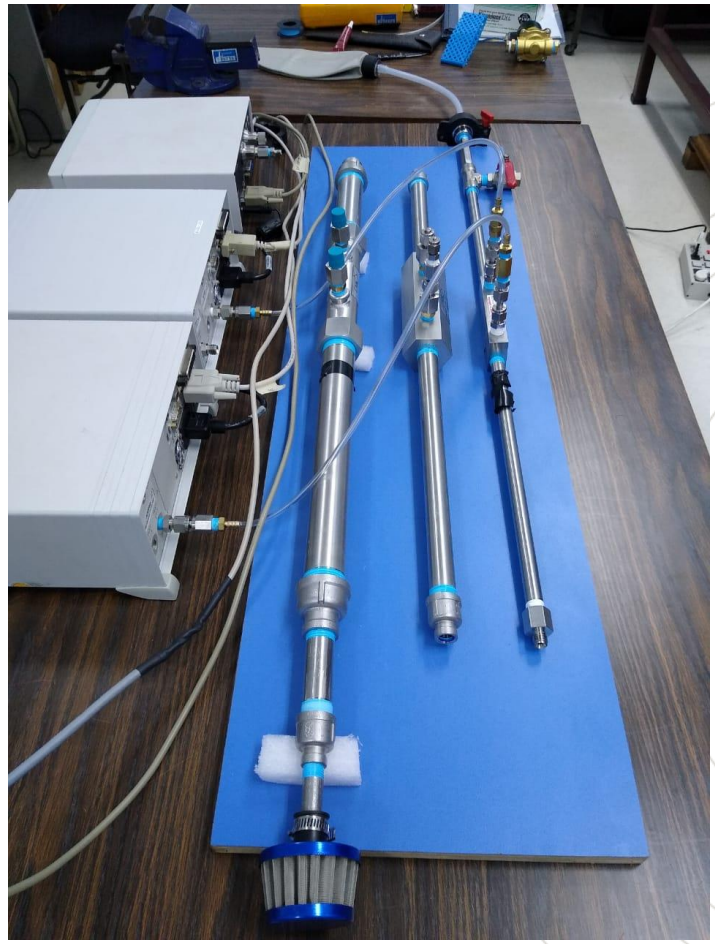
Ventilator test bench

LFE calibration setup

Actual messy workspace (reality)

LFE calibration Setup

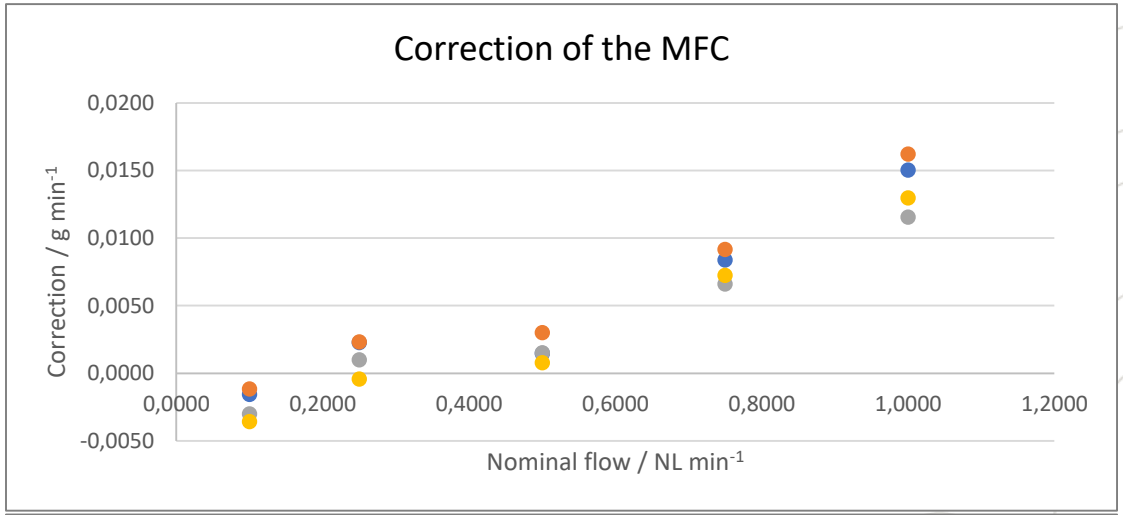
- LFEs measure volumetric flow.
- Differential pressure through the LFEs is measured with two absolute pressure transducers (mass flow measurement).
- Temperature is measured at the pipe Surface (viscosity correction to actual conditions).

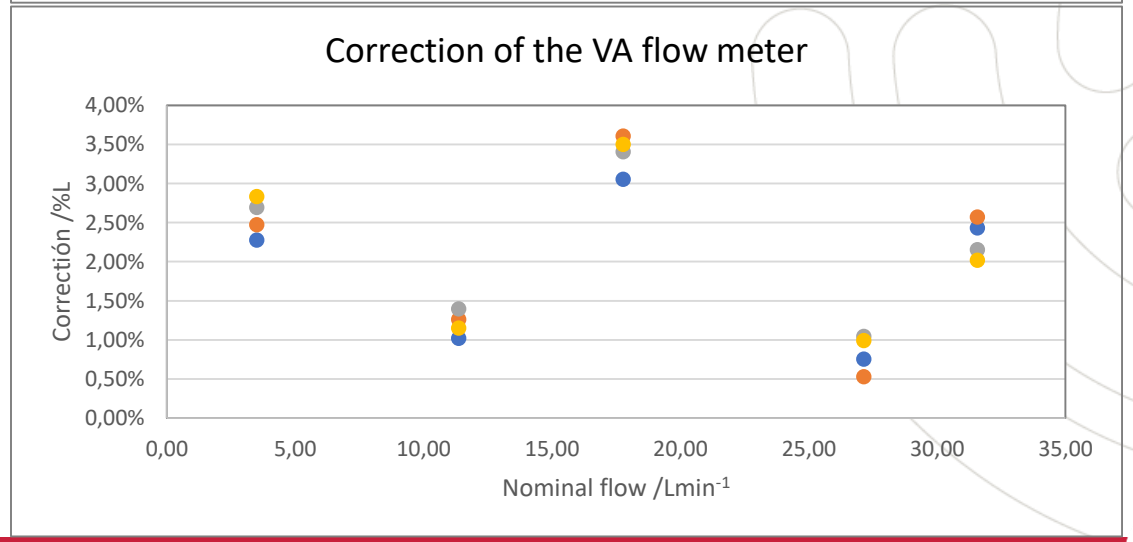


Partially assembled LFE system

Some "calibration" **Tries**

- Attempts to calibrate one MFC and one variable area flow meter (rotameter).
- As attempts, both seem to be repeatable. Fyll uncertainty analysis hasn t been done.
- Further validation to be performed early 2021. (Calibration of a flow meter with calibration certificate from an accredited lab or with declared CMCs)





Primary gravimetric standard

Primary gravimetric standard

LFE calibration system

Ventilator test bench

Primary gravimetric gas flow standard setup

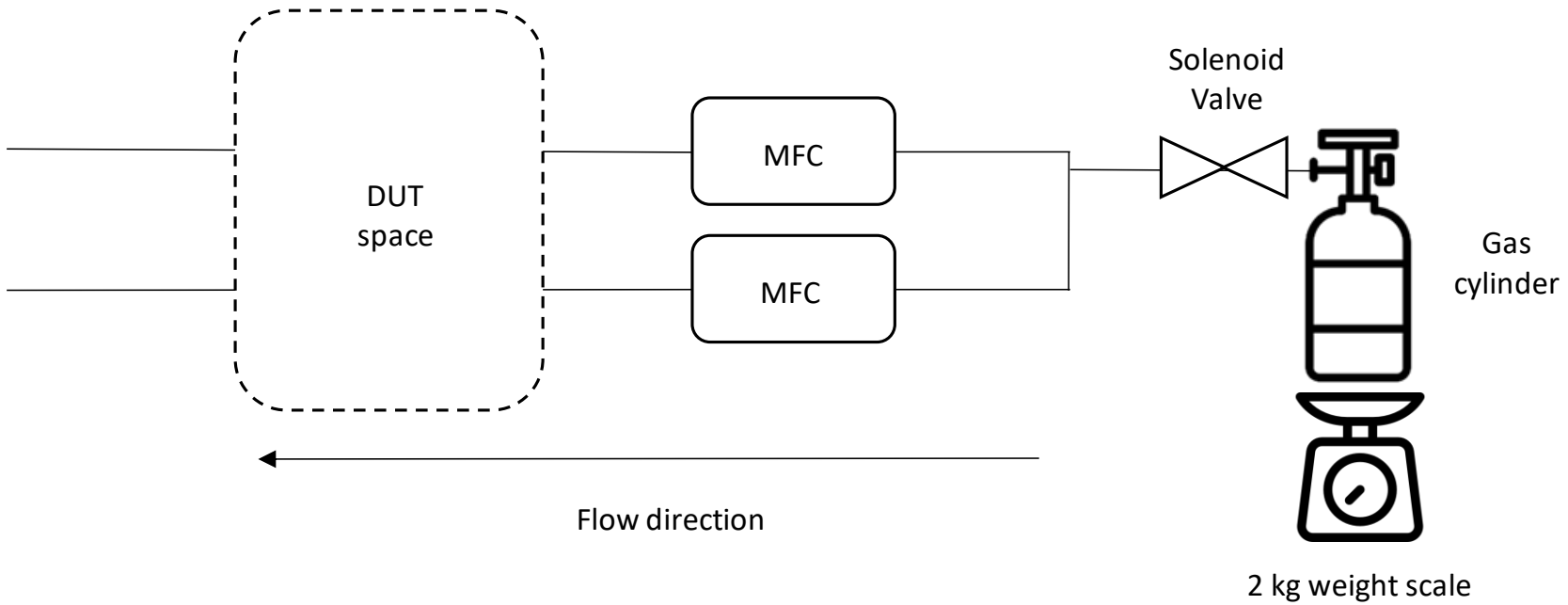


Diagram of the primary calibration setup

- The standard measures the weight loss (mass difference) of the cylinder for a determined amount of time

$$Q_m = \frac{\Delta m}{\Delta t}$$

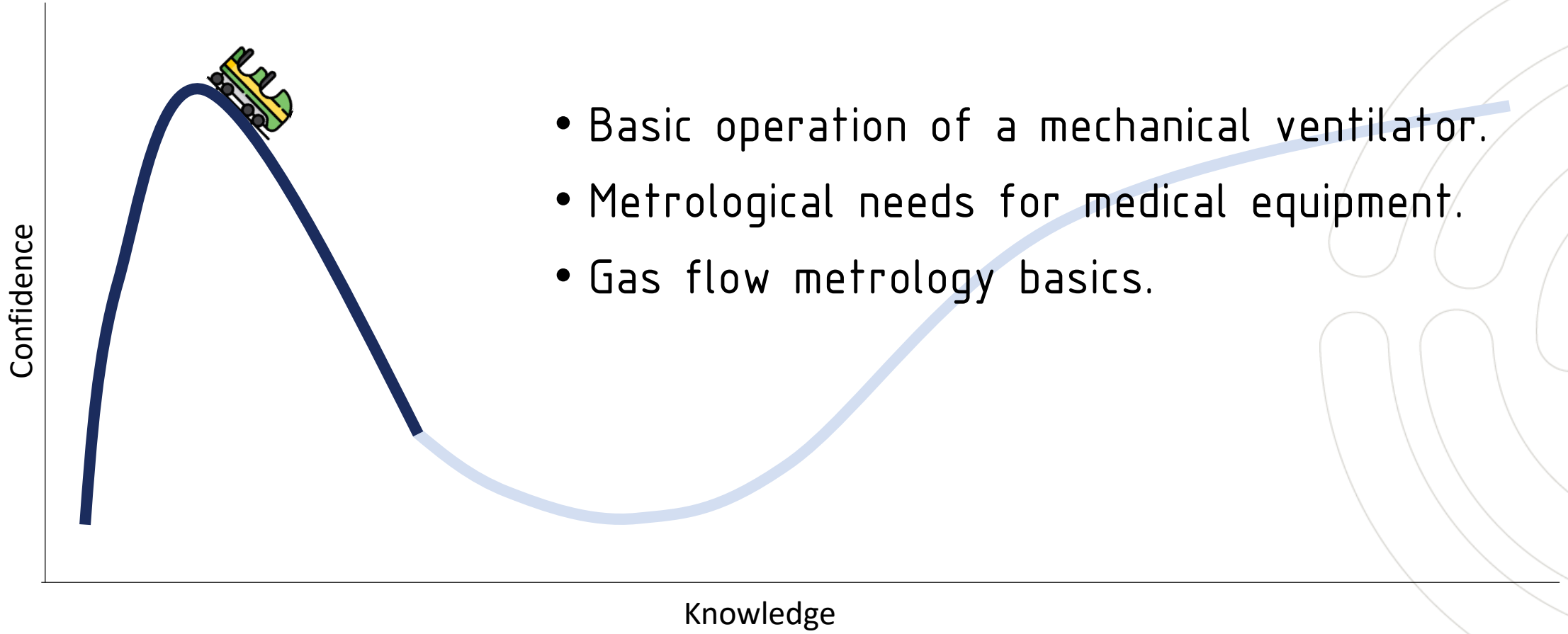
C. Rombouts; NCSL Int. Workshop & Symposium (2014)

Primary gravimetric gas flow standard

- Early stage of a standard.
- Going one step at the time.
  - To do list:
    - Gather all the parts ✓
    - Calibrate the weight scale ✓
    - Hydrostatic test of the cylinder ?
    - Fill the cylinder safely (up to 100 psi so far) ✓
    - Determination of cylinder external volume (buoyancy correction)
    - Time measurement
    - Put everything together
    - Automatization
    - Make it work

Weighting the gas cylinder

Lessons learned



- Basic operation of a mechanical ventilator.
- Metrological needs for medical equipment.
- Gas flow metrology basics.

Future challenges

- Perform well on the upcoming international comparison ($|E| < 1$).
- Complete the stages/setups mentioned before.
- Provide traceability to the industry.
- Declare CMCs.