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Federal Institute of Metrology METAS

Traceability of pulsed flow rates consisting of constant delivered volumes at given time interval

H. Bissig, M. Tschannen, M. de Huu

Agenda

1. Pulsed flow rates from Insulin Pumps
2. METAS gravimetric method
3. Tethered pump – measurement setup and results
   - Discrete volume analysis per unit time
4. Patch pump – measurement setup and results
   - Discrete volume analysis per unit time
5. Conclusion

Pulsed flow rates

- pulsed flow rates consisting of constant delivered volumes at given time interval

Tethered pump

https://www.medtronic-diabetes.ch/

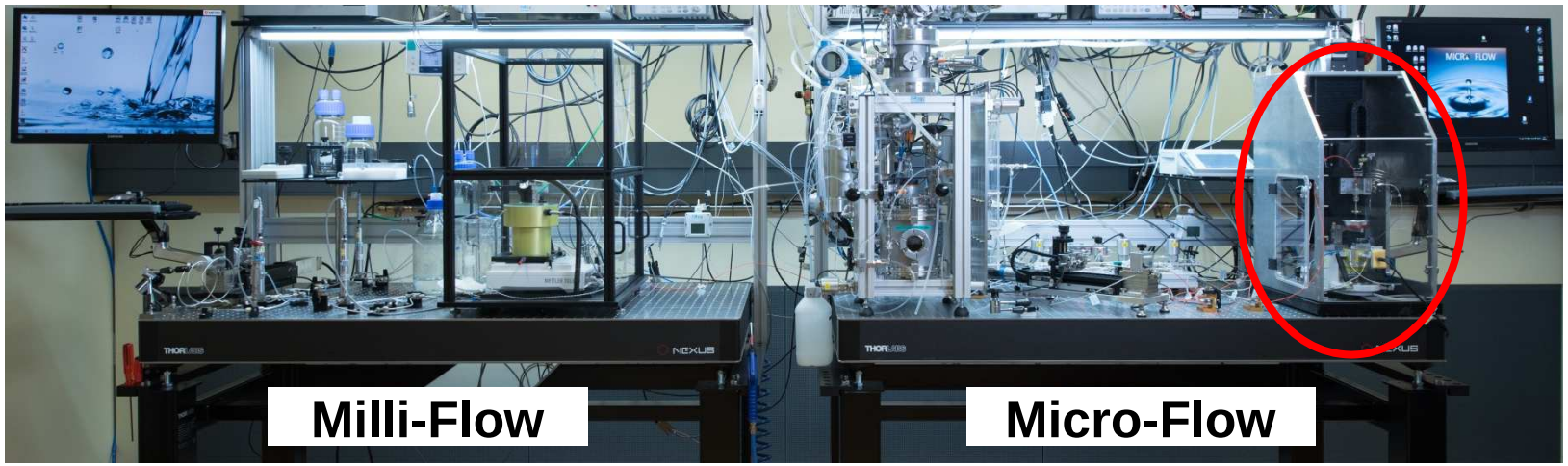
Patch pump

https://www.myomnipod.com/

Flow rate = 500 nL / time interval

How to perform the measurements?

METAS facilities for very low flow rates

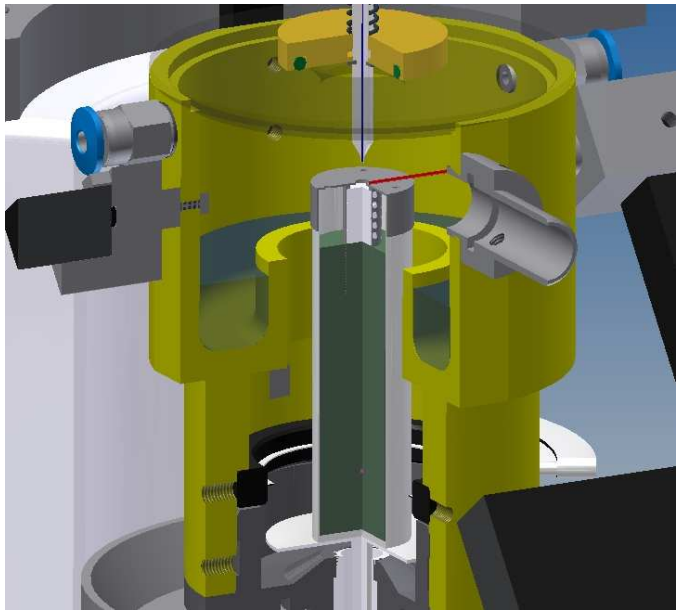


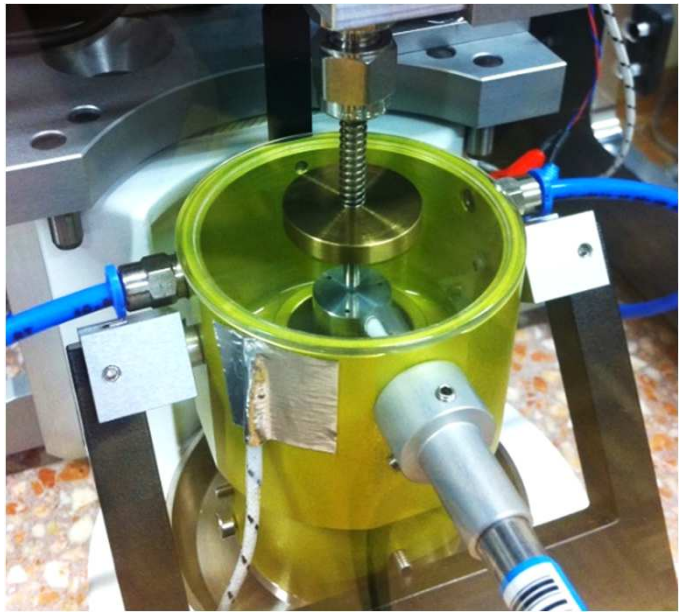
- **Flow rates: 50 nl/min – 400 ml/min (3 µL/h – 24 L/h)**
- **Pressure range: 0 – 8 bar**
- **Temperature: room temperature (22°C)**
- **Uncertainty: 1.0 % – 0.07 % (steady flow rate)**

METAS Gravimetric Method

- Continuous water collection
- Control of evaporation

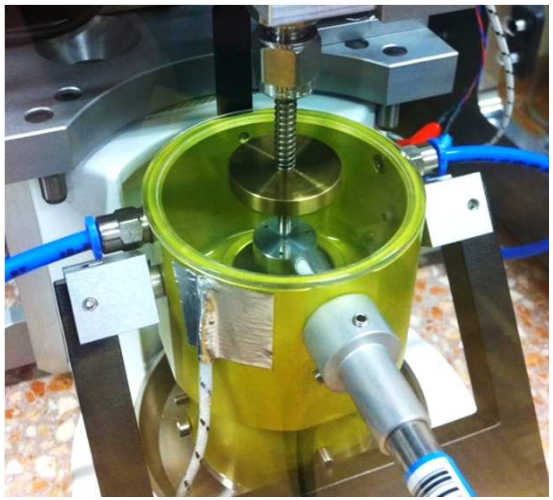
Micro-Flow

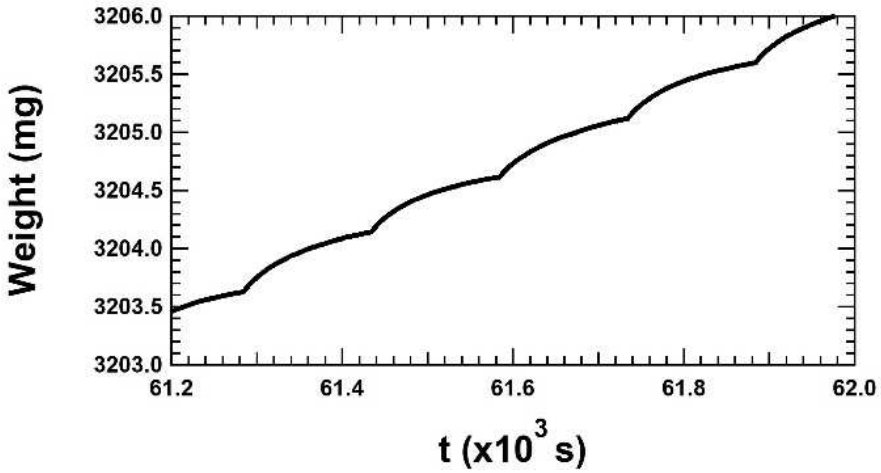




Tethered pump – measurement setup

- Flow generator connected to the piping of the facility



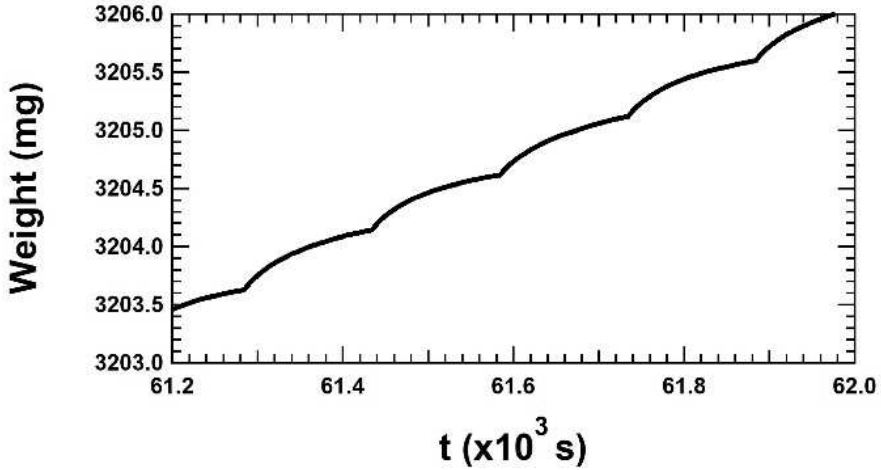


Flow rate 200 nL/min
= 500 nL every 2.5 min

Teflon line (elastic) dampens the step function

Tethered pump – results

- Flow rate determined with Linear Fit – not the best method



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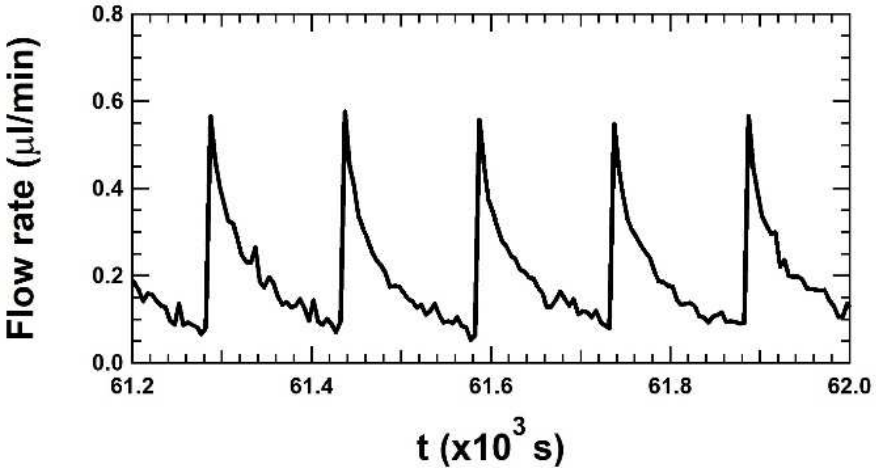


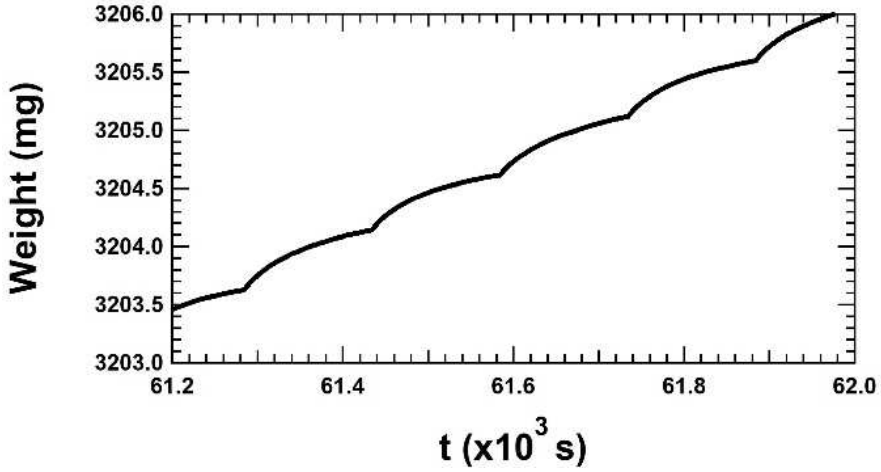
Linear Fit

Fit window 5 s

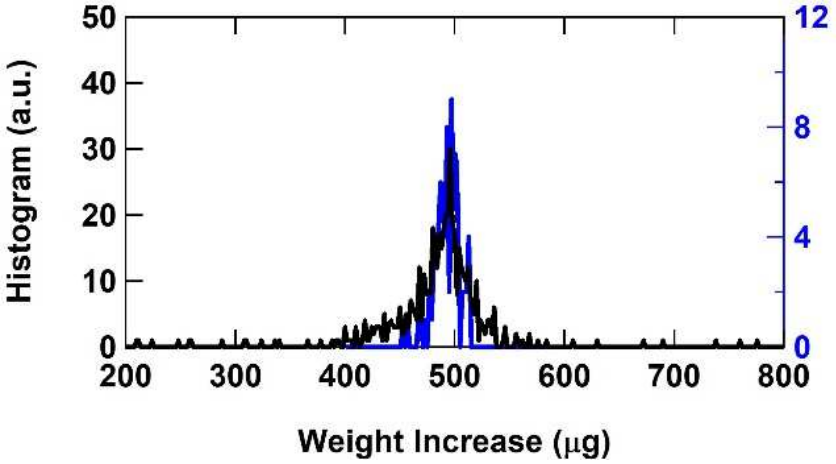
With much larger fit windows
It is possible to determine
a constant flow rate

Tethered pump – results

- Discrete volume analysis per unit time – appropriate method



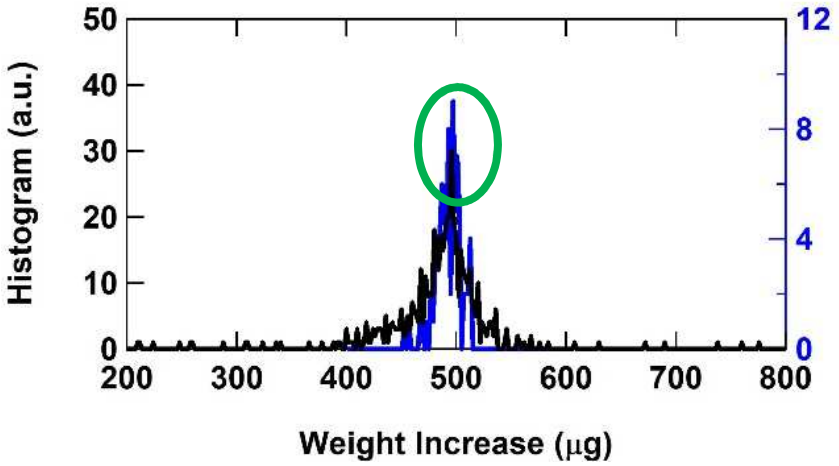
Analyse like a step function



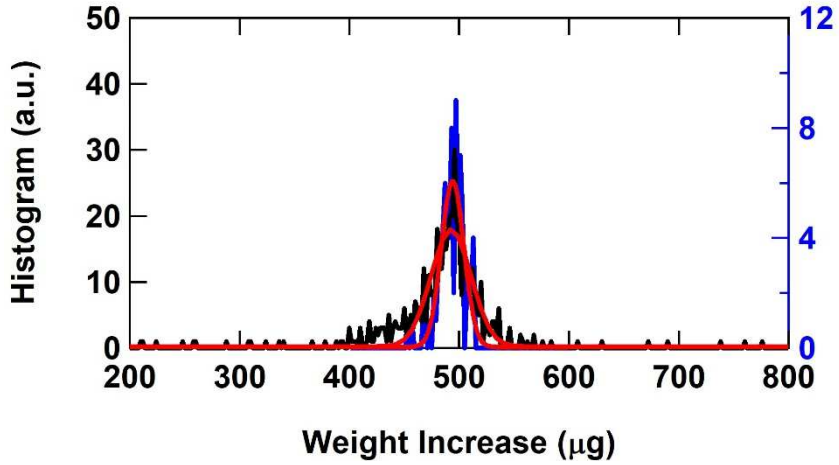
Raw data

Tethered pump – results

- Discrete volume analysis per unit time – appropriate method



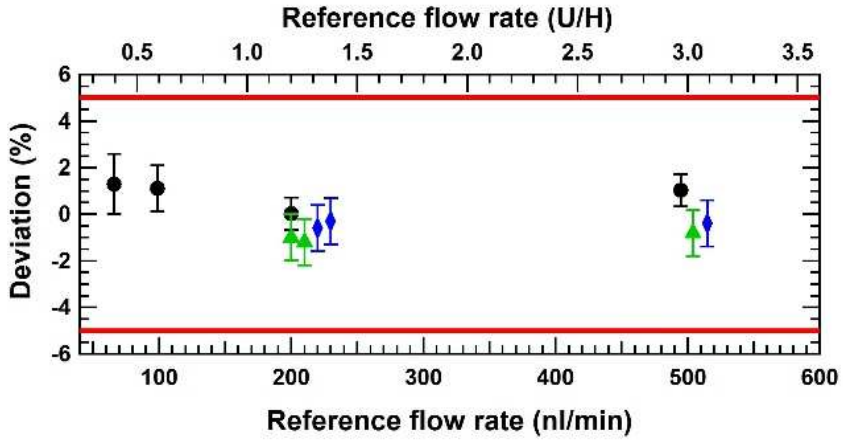
Peak of the histogram



Maximum of Gaussian Fit

Tethered pump – results

- Discrete volume analysis per unit time – appropriate method



Peak of the histogram

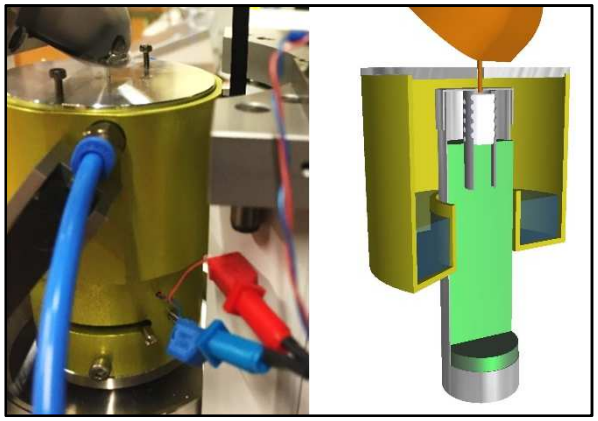
Maximum of Gaussian Fit

Linear Fit

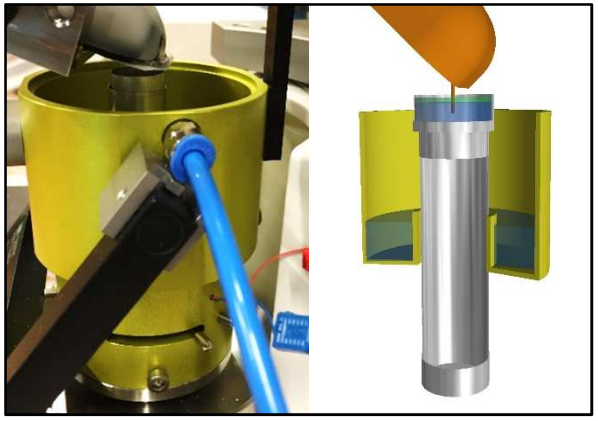
First approach – there's room for improvement

Patch pump – measurement setup

- Flow generator positioned directly above measurement beaker. Plastic tubing (part of the Insulin pump)



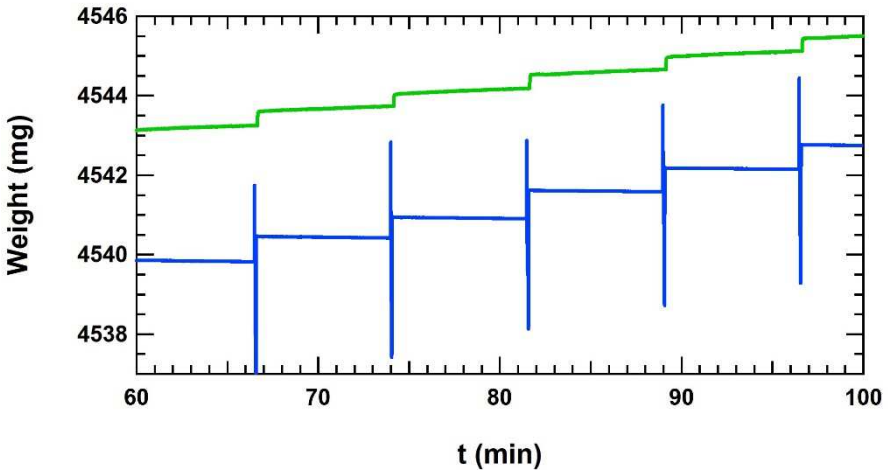
Water bridge to glass filter (beaker)



Plastic tubing immersed in water (oil cover)

Patch pump – results

- Discrete volume analysis per unit time – appropriate method



Flow rate 66.6 nL/min
= 500 nL every 7.5 min

Water bridge to glass filter (beaker)

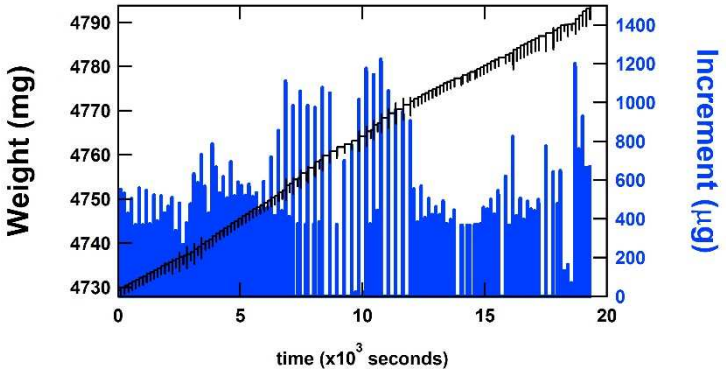
Capillary force changes visible at steps

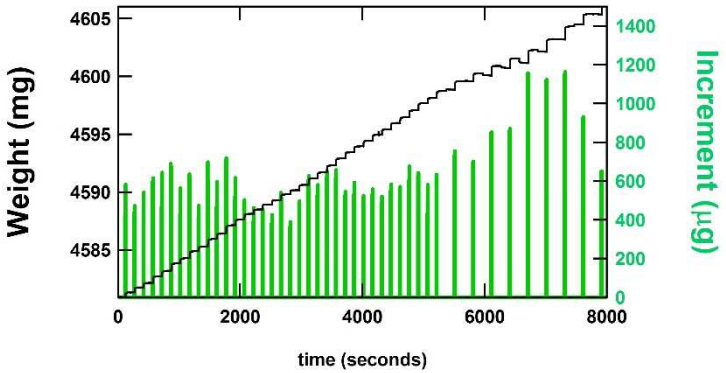
Plastic tubing immersed in water (oil cover)

Slight increase after steps ?

Patch pump – results

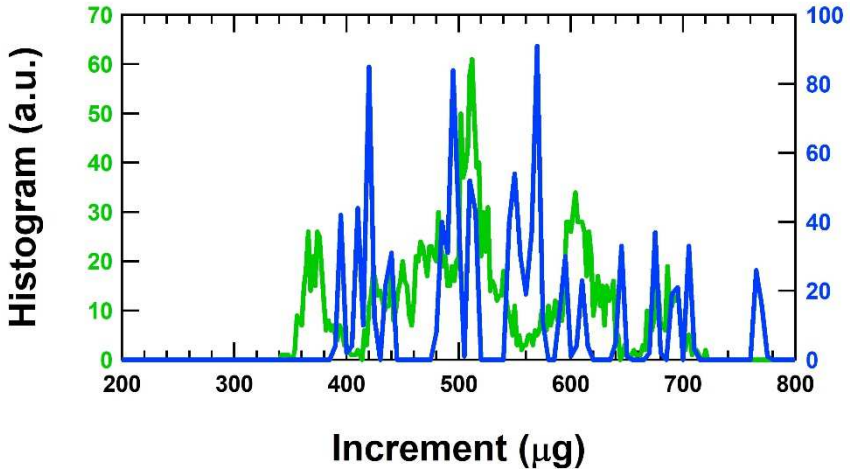
- Discrete volume analysis per unit time – appropriate method





Water bridge to glass filter (beaker)

Plastic tubing immersed in water (oil cover)

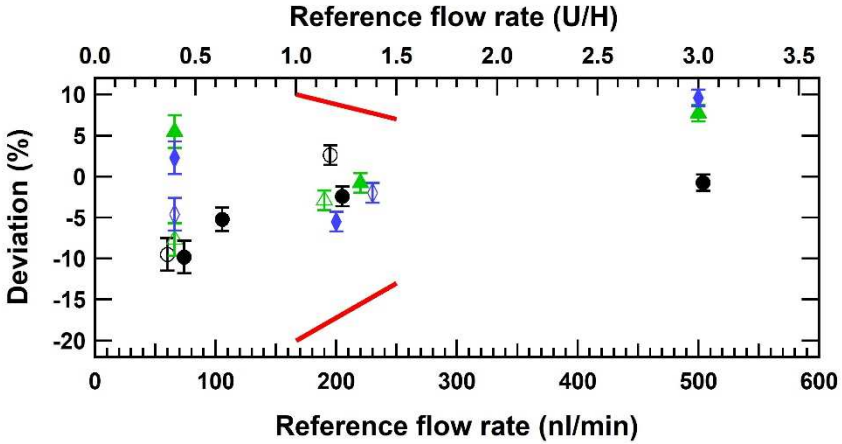


Peak of the histogram ?

Maximum of Gaussian Fit ?

Patch pump – results

- Difficulty to distinguish effects of gravimetric method and flow generator



Need for improvement

MEDD II
Drugmetrology.com

Water bridge to glass filter (beaker)

Plastic tubing immersed in water (oil cover)

Peak of the histogram

Maximum of Gaussian Fit

Linear Fit

Conclusion

- Measurements of insulin pumps delivering a volume of 500 nL at a given time interval
- Tethered pump and patch pump have been characterized for flow rates from 70 nL/min to 500 nL/min.
- The standard flow rate determination due to the continuous collection of water on the balance is not taken into account the delivery type
- Determination of the delivered volume per unit time is the appropriate method
- Room for improvements in the case of the tethered pump
- Need for improvements in the case of the patch pump
- Difficulty to distinguish effects of gravimetric method and flow generator

Thank you very much for your attention