An Assessment of Insulin Pump Accuracy for Artificial Pancreas Efficiency

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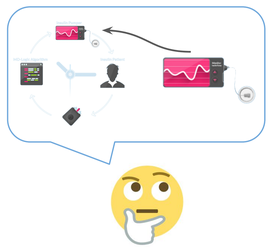
Insulin Pump is nowadays considered as one the main treatment for type 1 diabetes and is about to be one of the artificial pancreas (AP) main component. However, glycaemia in patients treated by pump is not optimal yet.
Insulin pump accuracy and performances are essentials and have not been so much studied so far, especially in a context of a closed-loop system.

INTRODUCTION

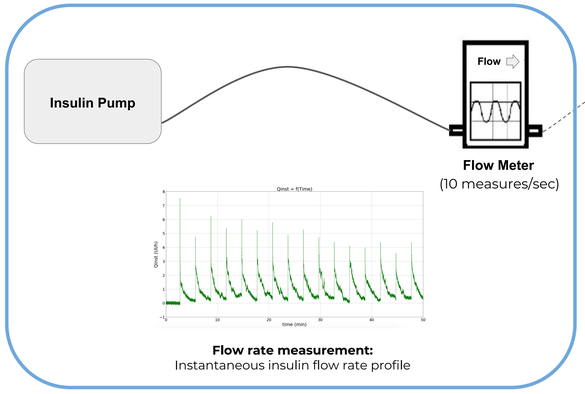
Gold standard method for insulin pump assessment are based on micro gravimetric measurement[1] and **does not account for sudden pump behavior changes[2].**
While closed-loop systems are likely to **readapt dose-to-inject** every 5 minutes[3].



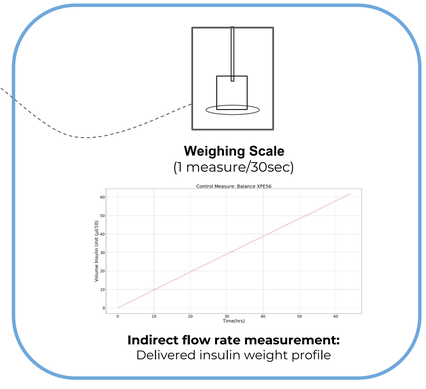
Insulin pump used on a **closed-loop system context** is brand new. However, infusion core technologies remain unchanged.
Our hypothesis is that set insulin doses delivered through pumps could present **inaccuracies.**
Considering the importance of injected doses for AP-algorithm[4], potential highlighted errors could feed AP-system to strengthen efficiency.

METHODS

NEW MEASUREMENT METHOD



CONTROL METHOD



Mass flow meter advantages:

- Plug & play setup
- Small environment perturbation
- Frequency Acquisition: 10Hz

Control measurement with weighing scale:

Introducing a new measurement method raised the question of precision. A second measurement with micro gravimetric standard method allowed to control or reveal measurement bias.

RESULTS

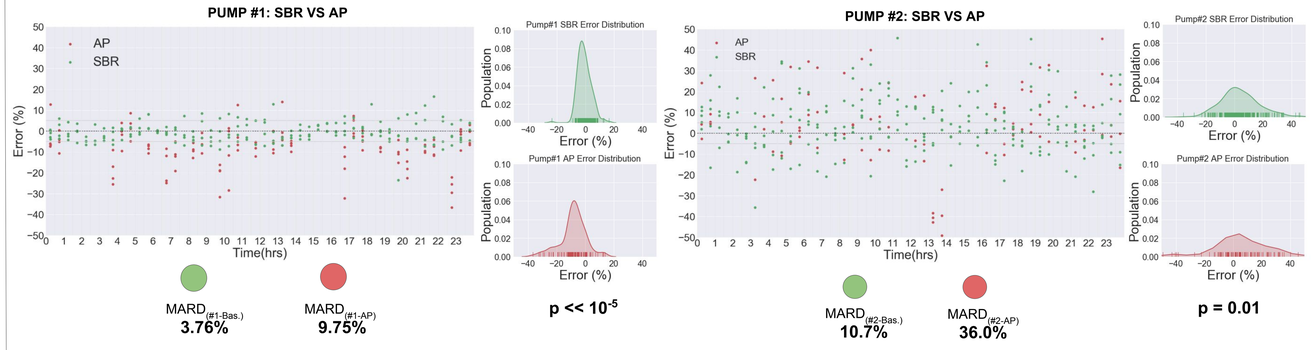
Here under is exposed two insulin pumps accuracy results. Precision were compared for pump delivering under **1UI/h standard basal rate (SBR)** mode and under **AP-like system (AP)** (based on a New England's article AP insulin profile[3]) mode for 24h delivering test.

Tested devices (pump#1: n=4 pump#2: n=6) are two differents pumps available on the market.

Precision was assessed with error pourcentage between expected dose and actual dose for each 30-minutes interval. MARD indicator (Mean Absolute Relative Difference) was used to express the absolute difference between actual and expected insulin dose.

SBR: PUMP #1 VS PUMP #2

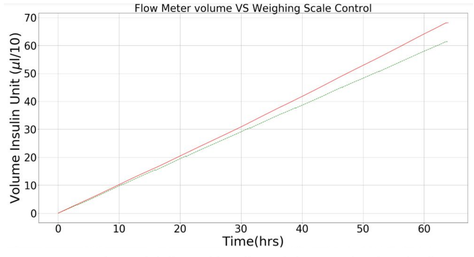
$MARD_{(\#1\text{-}Bas.)}$	$MARD_{(\#2\text{-}Bas.)}$	
3.76%	**10.7%**	**p < 0.01**



$MARD_{(\#1\text{-}Bas.)}$	$MARD_{(\#1\text{-}AP)}$	$p << 10^{-5}$
3.76%	**9.75%**	

$MARD_{(\#2\text{-}Bas.)}$	$MARD_{(\#2\text{-}AP)}$	p = 0.01
10.7%	**36.0%**	

Control Method Results:



Comparison of delivered insulin weight over the time (red) with flow rate cumulative sum of area under the curve

Back up balance control revealed a **mass flow meter measurement drift.** Tininess of flow rate during inter insulin-stroke phase make **mass flow meter uncertain** and induce a drift over the experiment.

$$\int_t Q(t)dt \qquad V_{total}$$

CONCLUSIONS

Insulin pump performances on AP-use:

- **Pumps performances** are **unequal** especially in a context of **AP** ✓
- **AP-like** delivering mode gives up to **39% error** ✓
- **Basal rate** delivering mode gives up to **10% error** ✓

Measurement method:

- ✓ New **direct flow meter-based measurement** method could be **promising**
- ✓ New method **precision for smallest flow rate** is still under consideration
- ✓ Kalman filter-based **mathematical method** to **improve precision** is currently under development

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References:

1. IEC Standard 60601-2-24
2. Jahn, L. G., Capurro, J. J. & Levy, B. L. Comparative dose accuracy of durable and patch insulin infusion pumps. J Diabetes Sci Technol 7, 1011–1020 (2013).
3. Bally, L. et al. Closed-Loop Insulin Delivery for Glycemic Control in Noncritical Care. New England Journal of Medicine 379, 547–556 (2018).
4. Doyle, F. J., Huyett, L. M., Lee, J. B., Zisser, H. C. & Dassau, E. Closed-Loop Artificial Pancreas Systems: Engineering the Algorithms. Diabetes Care