Basal rate CSII accuracy assessment using a new developed evaluation method

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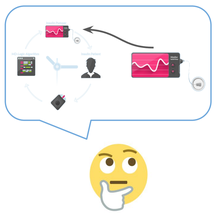
INTRODUCTION

Insulin pump (IP) is a widely-adopted contemporary **treatment for type 1 diabetes** and is a major component of an **artificial pancreas (AP)[1].**

IP accuracy is **essential for glycaemic control** and to-date such metric has not been given sufficient study, especially at the **range of the lowest basal rate.**
Plus, the gold-standard assessment **method IEC 60601-2-24 has some limitations[2].**

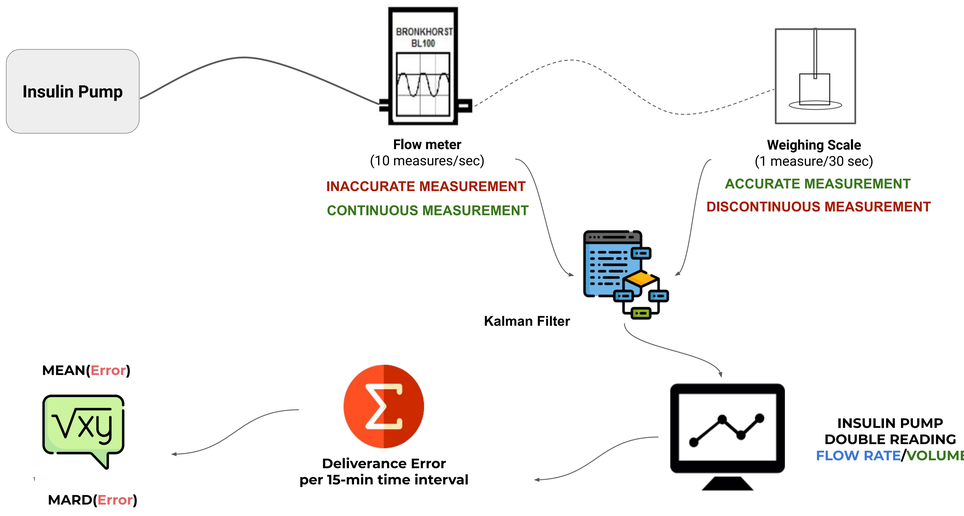


Our study presents a **new accurate and reactive method for CSII system evaluation** based on **direct flow measurement.**

Our hypothesis is that set insulin doses delivered through pumps could present **inaccuracies.**
In the future, considering the importance of injected doses for AP-algorithm[3], potential highlighted errors might feed AP-system to strengthen efficiency.

METHODS

A **double measurement test bench** (continuous **flow rate** and weighed insulin **volume) enriched with a Kalman filter-based (KF) optimization** has been developed to assess insulin pump more consistently.
KF compensates for each measurement weaknesses based on the other's strengths.



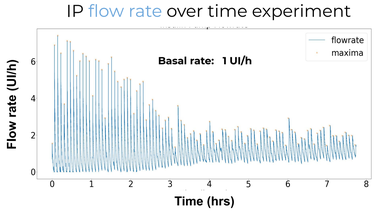
Two off-the-shelves insulin pumps are assessed at **0.1 UI/h** and **1 UI/h** basal rate to illustrate the new method. Tests last 8 hours and **4 tests replicas were performed for reproducibility purpose (i.e. n=4).**

RESULTS

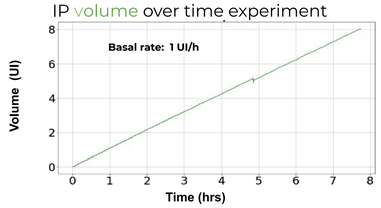
Precision of pump is analyzed with error pourcentage between expected dose and actual dose for each 15-minutes interval. Overall test error indicators include all the replicas (n=4). Dose error is displayed for one replica (n=1).
We also display **continuous flow rate** and **volume** of insulin delivered over the experiment for one replica (n=1)

PUMP A : 1 UI/h and 0.1 UI/h

IP flow rate over time experiment



IP volume over time experiment



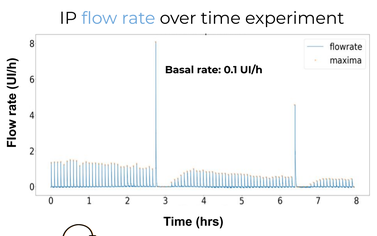
IP dose %error over experiment

Overall test error indicators

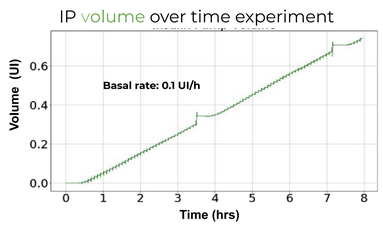
Numerical indicators: Pump A at 1UI/h	
Mean% mean(SD)*	**Mean ARD%** mean(SD)**
-0.9 (3.2)	**12.7 (6.7)**

*mean and SD of errors mean for 4 replicas
**mean and SD of errors MARD for 4 replicas

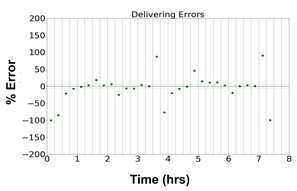
IP flow rate over time experiment



IP volume over time experiment



IP dose %error over experiment



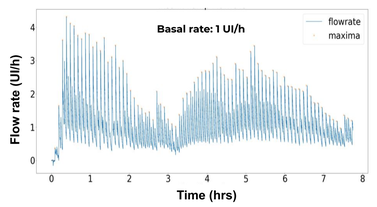
Overall test error indicators

Numerical indicators Pump A at 0.1UI/h	
Mean% mean(SD)*	**Mean ARD%** mean(SD)**
1.55(5.5)	**22.7 (2.8)**

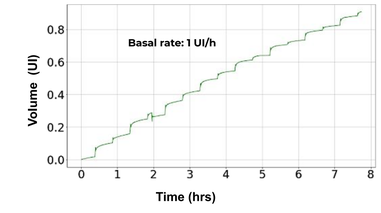
*mean and SD of errors mean for 4 replicas
**mean and SD of errors MARD for 4 replicas

PUMP B: 1 UI/h and 0.1 UI/h

IP flow rate over time experiment



IP volume over time experiment



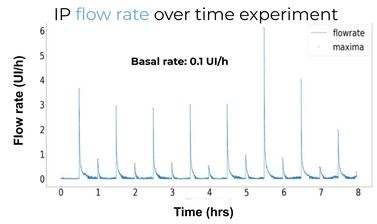
IP dose %error over experiment

Overall test error indicators

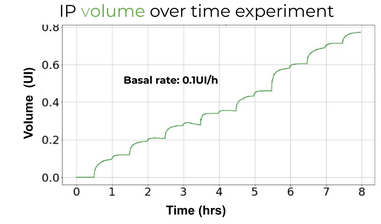
Numerical indicators Pump B at 1 UI/h	
Mean% mean(SD)*	**Mean ARD%** mean(SD)**
-0.6 (3.4)	**21.6 (1.4)**

*mean and SD of errors mean for 4 replicas
**mean and SD of errors MARD for 4 replicas

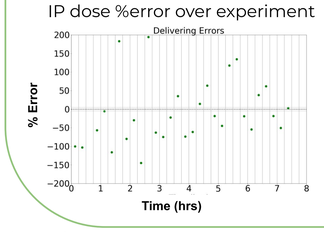
IP flow rate over time experiment



IP volume over time experiment



IP dose %error over experiment



Overall test error indicators

Numerical indicators Pump B at 0.1 UI/h	
Mean% mean(SD)*	**Mean ARD%** mean(SD)**
-8.2 (25.9)	**61.3 (13.8)**

*mean and SD of errors mean for 4 replicas
**mean and SD of errors MARD for 4 replicas

Overall precision indicators are **mean %error and mean absolute relative difference** (mean ARD). Mean ARD is used to avoid sub and over-delivering error compensation through the overall test. Due to reproducibility purpose, four-tests for each conditions are considered to calculate these indicators. Mean and standard deviation (SD) of errors for the whole replicas are displayed.

CONCLUSIONS

- Continuous **insulin flow rate** displayed for the **first time** ✓
- **Delivering error can reach 61%** (especially for lowest basal rate) ✓
- ✓ **Mean ARD indicator** is complementary to mean %error
- ✓ Insulin pump **micro-bolus stroke** are **unequal**

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2. IEC 60601-2-24 Infusion pumps - what's the story? MEDTEQ Available at https://www.medteq.net/article/2018/9/21/iec-60601-2-24-infusion-pumps-whats-the-story.
3. Bally, L. et al. Closed-Loop Insulin Delivery for Glycemic Control in Noncritical Care. New England Journal of Medicine 379, 547–556 (2018).