TEST-RIG FOR AUTOMATED TESTING OF CONTINUOUS GLUCOSE SENSOR PROTOTYPES

Patrick Christian Boesch[1,2], Anders Lyngvi Fougner[1,2], Reinold Ellingsen[1,3], Dag Roar Hjelme[1,3], Øyvind Stavdahl[1,2]

patrick.c.bosch@ntnu.no anders.fougner@ntnu.no reinold.ellingsen@ntnu.no dag.hjelme@ntnu.no oyvind.stavdahl@ntnu.no

[1]Artificial Pancreas Trondheim – The APT research group (www.apt-norway.com), Norwegian University of Science and Technology, Trondheim, Norway

[2]Department of Engineering Cybernetics, Norwegian University of Science and Technology, Trondheim, Norway

[3]Department of Electronic Systems, Norwegian University of Science and Technology, Trondheim, Norway

Introduction

Background:

- Continuous Glucose Monitoring (CGM) is the current state-of-the-art for blood glucose monitoring in type 1 diabetics [1].
- A glucose sensor is a key component of every CGM-system.
- Developing new, faster and more accurate glucose sensors requires thorough testing of the prototypes.
- Manual testing procedures are time consuming and tedious, and challenging to reproduce precisely

Aim:

- Build an automated test-rig for glucose sensors in order to improve reproducibility of test sequences and enable in vitro testing of CGM-sensors with complex test protocols, to investigate parameters like nonlinear responses, drift, saturation, calibration errors and others that can not be obtained with traditional impulse or step responses, while reducing the time spent supervising a test set-up.

Method

An automated test rig was developed according to the architectures illustrated in Fig. A and B.

It incorporates the following main features:

- Peristaltic pumps for adding glucose or Phosphate Buffered Saline (PBS) in order to obtain the desired glucose concentrations in the system.
- Modular and low cost design to allow for modifications of the set-up and easy transport and assembly.
- Temperature and pressure sensors to characterize and document the test conditions.
- Modular, exchangeable test chamber to accommodate a variety of sensor types.
- Circuit volume is kept stable by removing and adding the same volume.
- Remote access for supervision and control of experiments.
- Closed loop test circuit in temperature controlled water bath.
- Automated sampling mechanism to obtain samples of the fluid in circulation at discrete time points of the test sequence for verifying the glucose concentrations.
- Simple and user-friendly Graphic User Interface (GUI).
- Pre-mixed glucose solutions (e.g. 50mg/ml) can be used.
- Volume balance is ensured by monitoring the circuit pressure.
- Intuitive file structure for inputs and outputs.

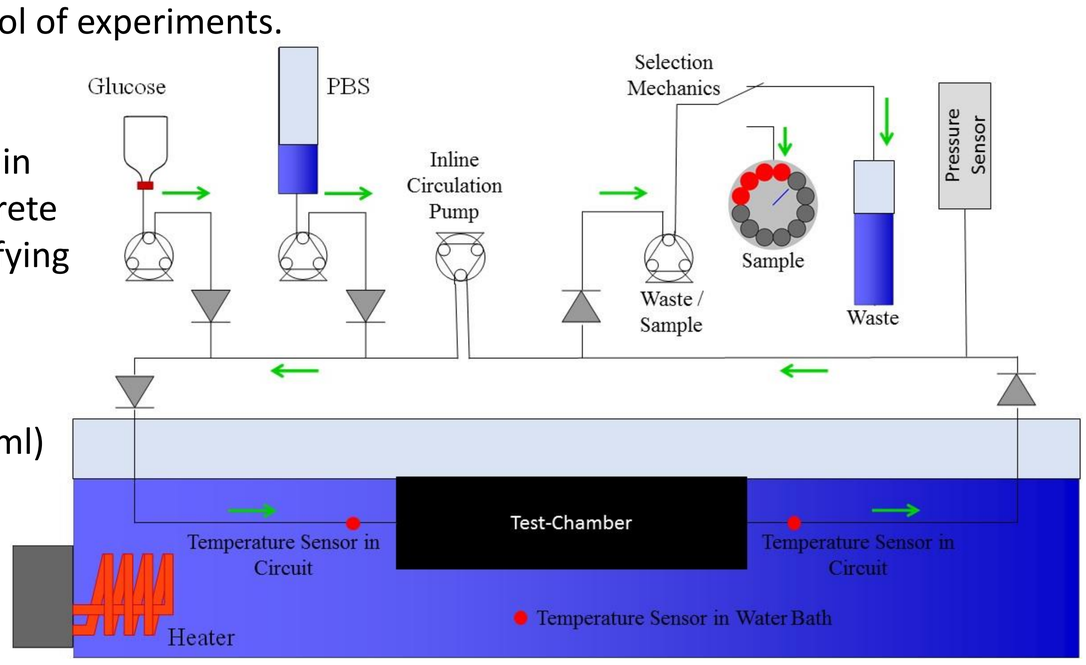

Fig. A: Schematics of the fluid circuit of the test-rig

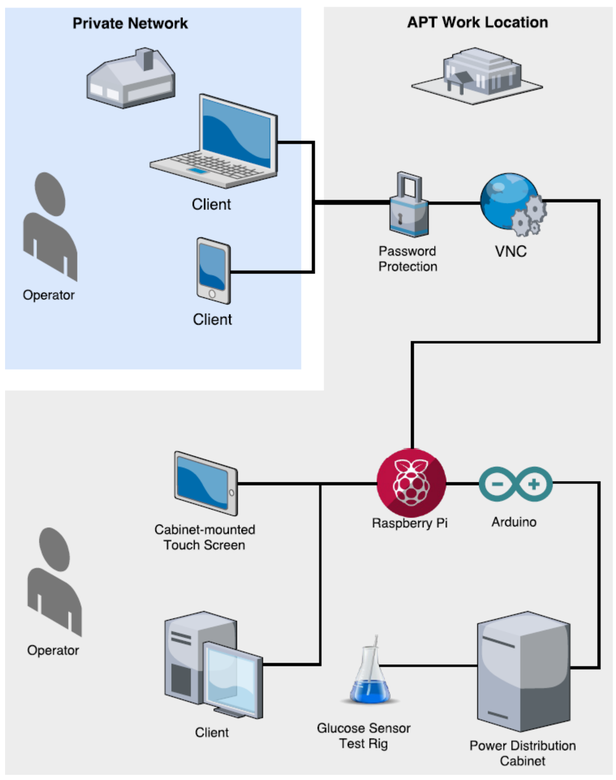

Fig. B: Network architecture with Virtual Network Computing (VNC) - Integration

First Prototype

Summary of the first test-rig prototype:

- Closed loop volume of <20ml in the fluid circuit allows fast changes of the glucose concentration.
- Water bath for different temperature profiles (e.g. simulation of fever or hypothermia).
- Various glucose profiles and their combinations can be tested (e.g. ramp, sinus,..).
- Able to increase glucose concentrations at >20mM/min and decrease at ≥-0.1 mM/min.
- Mixing error for the glucose concentrations of <10% (theoretically ≤1% possible, but more testing/refining is required).
- Intended for a glucose range of 0-30mM, but higher concentrations theoretically possible.
- Fully automated test sequences of ≥10h.
- Cleanable with 99% ethanol (can be used to flush the entire system).
- Intuitive GUI (Fig. C) with control over all active parts of the system and a software that leads you through the set-up of the system step-by-step.

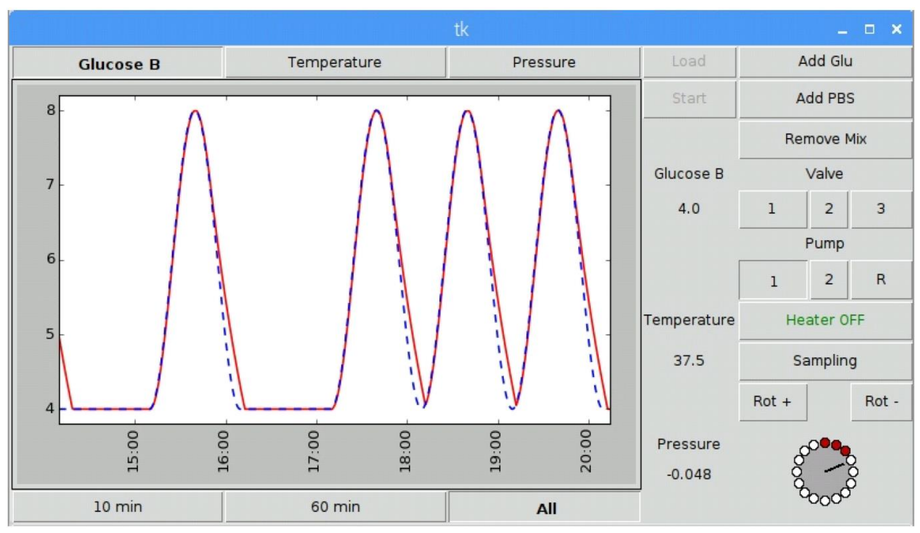

Fig. C: Screenshot of the test-rig GUI

Conclusions

A first prototype of a test-rig for glucose sensors was built and successfully tested. It has potential to significantly simplify the testing of glucose sensor prototypes. However, there are several points that require refining or improvement. The most important are:

- Further reduce circuit volume.
- Improve and simplify the calibration procedure for the peristaltic pumps.
- Run more test sequences to determine a more exact mixing error for the glucose concentration.
- Refine implementation of pressure sensor and possibly use it for pump calibration.

References

[1] T. Danne et al. “International Consensus on Use of Continuous Glucose Monitoring,” *Diabetes Care,* vol. 40, no. 12, p.1631-1640, December, 2017. Available: https://doi.org/10.2337/dc17-1600

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NTNU – Trondheim
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