

# Hypoglycemia detection capabilities of a Multisensor Device for Non-Invasive Continuous Glucose Monitoring under Home-Use Conditions

M.S. Talary, PhD; M. Mueller, MSc; L. Falco, PhD; O. De Feo, PhD; W. A. Stahel, PhD;  
A. Caduff, PhD

Solianis Monitoring  
Zurich, Switzerland  
andreas.caduff@solianis.com

## **Objective:**

We report on findings of the application of a novel Multisensor device under development for continuous non-invasive glucose monitoring under home-use conditions (HUC). The Multisensor yields signals from the skin-surface sensors for dielectric, optical, temperature, blood perfusion and hydration measurements. Despite the sparseness of reference blood glucose measurements, data from this Multisensor device was used to investigate the possibility of detecting hypoglycemic blood glucose levels and subsequently trigger an alarm based on the online compatible glucose level estimation model available at this stage of the development.

## **Method:**

Sixteen patients with Type 1 Diabetes Mellitus wore the Multisensor under HUC. Each patient performed a maximum total of 24 study days (15 patients 24, one patient 20 study days) over a period of 4 months with a total of 380 study days collected. The patients collected on average 11 capillary self monitoring of blood glucose (SMBG) measurements during each study day. The study was split into two blocks, the measurements of the first 160 days were used for training a linear regression model followed by a threshold based hypoglycemia alert system. The trained hypoglycemia alert setting was then prospectively validated on the data obtained in the second block of 220 days.

## **Results:**

When the Multisensor hypoglycemia alert threshold was set to 70 mg/dL, the prospective application of the hypoglycemia alert system on the second data block resulted in a true alert rate of 74% within a window of +/-15 min around a reference glucose measurement and a false alert rate of 69%. With a hypoglycemia alert threshold of 90 mg/dL, a true alert rate of 74% and a false alert rate of 48% was achieved.

## **Conclusion:**

With appropriate training, patients could easily attach the Multisensor, allowing stable measurements to collect continuous sensor data. Analyses of prospective models have given first indications of how hypoglycemia alarms can be given for such a Multisensor device under HUC. Based on these findings next development steps have been taken towards a more miniaturised Multisensor concept.