

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

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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). 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.

Sixteen patients with Type 1 Diabetes Mellitus wore the Multisensor under HUC. Each patient performed a maximum total of 24 study days over a period of 4 months with a total of 380 study days collected.

The study was split into two blocks, the measurements of the first 160 days were used for training a linear regression model. The trained hypoglycemia alert setting was then prospectively validated on the data obtained in the second block of 220 days.

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.

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.