

Non Invasive Glucose Monitoring with a Dielectric Spectroscopy based Multi-Sensor Platform

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Solianis Monitoring AG is developing a multi-sensor device for non invasive continuous glucose monitoring (NI-CGM) in which one key element is the application of Dielectric Spectroscopy (DS). Changes in the dielectric properties of skin at various penetration depths have been investigated, and these changes will be shown to be correlated to the change in glucose concentration in patients during intravenously and orally induced glucose excursions within experimental clinical studies. A multi sensor approach is required since a number of extrinsic and intrinsic factors can affect the DS measurements. The multi-sensor concept includes fringing field capacitive sensors for broad band DS, optical, sweat/moisture, acceleration and temperature sensors to compensate for such factors. This work describes the current results of the ongoing technological development. It is shown that the concept is applicable, not only within strictly controlled clinical conditions using an intravenous glucose clamp technique, but also in more challenging environmental conditions where the patients experience conditions that are closer to “daily life” including the administration of glucose orally and controlled movements.

Eight patients with diabetes mellitus (4 T1DM, age 43 ± 9 y; BMI 26.1 ± 2.9 kg/m², duration of diabetes 22 ± 14 y; HbA1c $7.4\pm 0.9\%$ and 4 T2DM patients, 66 ± 2 y; 30.6 ± 1.8 kg/m²; 10 ± 8 y; $6.9\pm 0.3\%$) performed up to four study days. Glucose was administered orally to induce a hyperglycaemic excursion to a target level of 15 mmol/L. Euglycemia was re-established by s.c. insulin administration. In two of the four study days defined movements were introduced including sequences of cycling, walking around and regular deskwork. In the other two study days in addition to the movement blocks and the oral glucose administration, patients drank 3 litres of water. A multiple regression analysis was performed to establish a global model including all subjects and all study days. In a next step a personal model was established including the same parameters as the global one, but the coefficients were parameterised to each study subject to optimise the model performance. The models generated were tested for potential overfitting and demonstrated that an essential modeling parameter was the DS sensor that measured the change in dielectric properties deeper in the skin tissue. With the personal model glucose excursions could be tracked with an R² of 0.71 and an MARD of 17.9%, the global model yielded an R² of 0.6 and an MARD of 21.5% respectively.

These results demonstrate that glucose variations in patients can be monitored continuously by measuring changes in the dielectric properties of skin and underlying tissue. The multi-sensor approach is required to enable the dielectric properties of the skin at different penetration depths to be measured, and to compensate for perturbing effects that influence these measurements in closer to “daily life” conditions. Future steps will develop the data evaluation routines and algorithms to allow real time signal processing of the multi-sensor data and transformation into clinically relevant information for patients with diabetes in an outpatient setting.