

OSMOTIC-PRESSURE BASED CONTINUOUS GLUCOSE MONITORING: RESULTS FROM A FIRST HUMAN PILOT STUDY OF A NEEDLE-BASED SENSOR PROTOTYPE

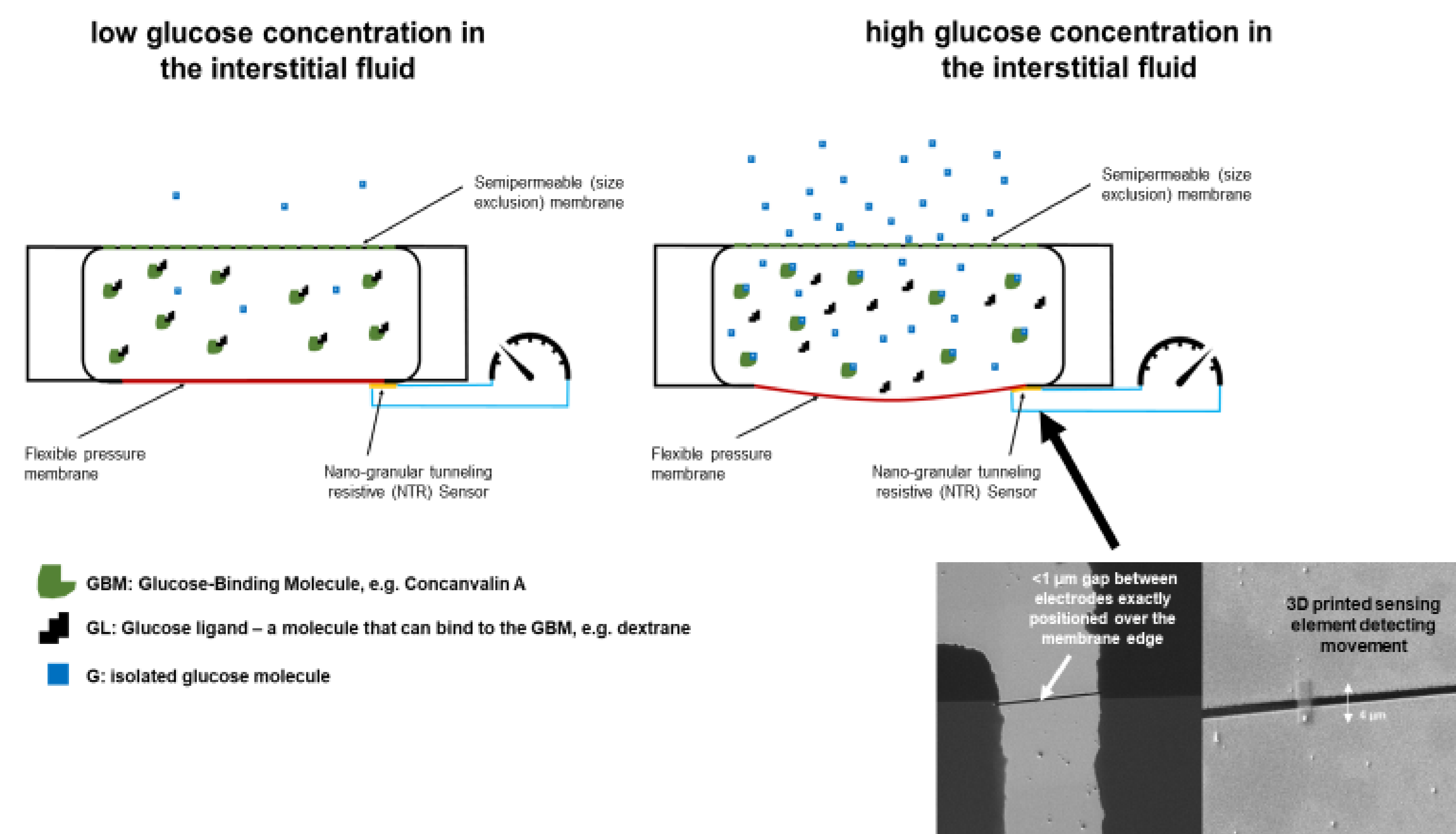


Pfützner A., Hanna M., Kalasauske D., Thomé N., Stamm B., Mehta M., Holter J., Mainz, Germany; Reutlingen, Germany; Wiltz, Luxembourg; Bergen, Norway

Background

The Sencell sensor (Lifecare AS, Bergen, Norway) uses glucose induced changes in an osmotic pressure chamber for continuous measurement of glucose concentrations in the subcutaneous tissue (see Fig. 1). A close to linear correlation between the raw sensor signal and the glucose concentration and a very long duration of use (of up to 6-12 months or longer) are theoretically to be expected. The final device is planned to have the size of a grain of rice and to be implanted employing wireless energy and data transfer.

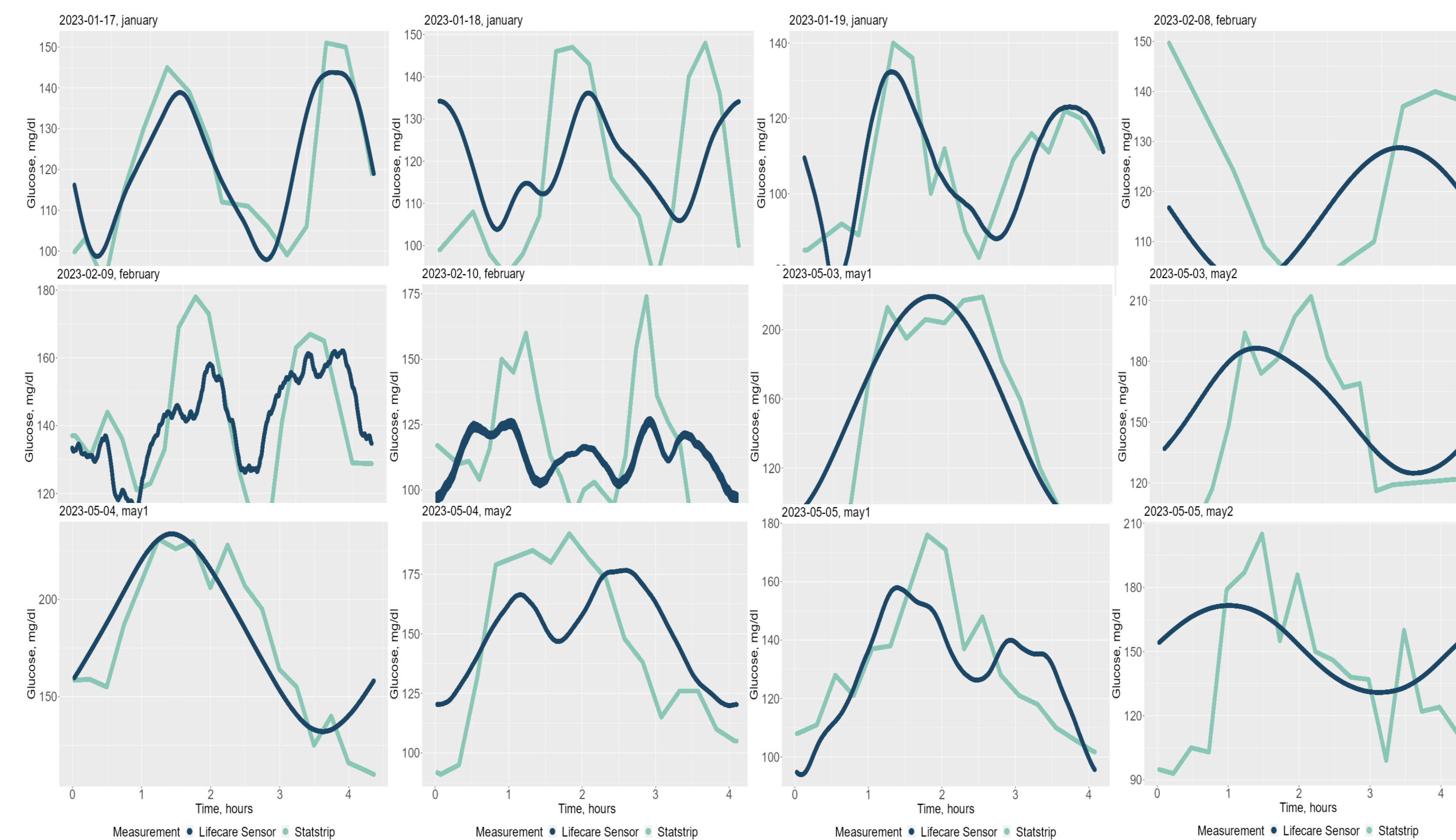
Fig.1: Mode of action principle of the Sencell device



Methods

For a first clinical proof of concept study in humans, a wired version of the core sensing technology was embedded into a 4 mm diameter needle and inserted into the abdominal subcutaneous tissue of 8 healthy volunteers and a type 1 patient. The study was conducted to collect first human proof-of-concept performance data for algorithm development during meal experiments and for further device optimization. The raw data was analyzed after one-point calibration and minor trend correction in comparison to the Statstrip blood glucose meter and the Freestyle Libre 2 or Dexcom G7 glucose sensor.

Fig.2: Individual patient results



Conclusion:

The osmotic-pressure based continuous glucose sensor was shown to track s.c. glucose concentrations in a comparable manner as commercially available needle sensors. These results support the further development of Sencell towards a clinically usable medical device.

Reference:

Pfützner A, Tencer B, Stamm B, Mehta M, Sharma P, Gilyazev R, Jensch H, Thomé N, Huth M. Miniaturization of an Osmotic Pressure-Based Glucose Sensor for Continuous Intraperitoneal and Subcutaneous Glucose Monitoring by Means of Nanotechnology. *Sensors (Basel)*. 2023 May 7;23(9):4541.

Results

Nine participants (6 female, 3 male, age: 49±11 years) delivered a total of 261 direct comparator data-points (vs. Statstrip blood glucose meter) during repeated meal experiments with observation periods between 2 h and up to 72 days. The osmotic-pressure sensor followed glucose changes similar to the FreeStyle Libre 2 or Dexcom G7 device (Fig. 2) and reached an overall MARD of 9.6% in comparison to StatStrip. In the retrospective analysis with the newly developed algorithm, 90.8 % and 9.2 % of the datapoints were lying in zones A and B of the consensus error grid, respectively, (Fig 3.).

Fig.3: Retrospective consensus error-grid analysis

