Successful Miniaturization of an Osmotic-Pressure Based Glucose Sensor for Continuous i.p. and s.c. Glucose Monitoring by Means of Nanotechnology

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Lifecare Laboratory, Mainz, Germany
Lifecare AS, Bergen Norway
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Conflicts of Interest

During the last three years, Andreas Pfützner has recieved research support, consulting fees, speaker fees and travel support from the following companies and organizations:

Astra Zeneca, Hamburg, Germany; CASSPharma, Franklin TN, USA; CDP Swiss, Zurich, Switzerland; CESRA, Regensburg, Germany; deFaire Medical, Stockholm, Sweden; dentognostics, Solingen, Germany; Diabetologen Hessen, Marburg, Germany; Diakard Inc., Franklin TN, USA; Digital Diagnostics, Mainz, Germany; Humana, Hamburg, Germany; Kontor3, Kassel, Germany; Lifecare AS, Bergen, Norway, Lifescan, Inverness, UK; MedTrust, Marz, Austria; Nal vonMinden, Münster, Germany; Norgine, London, UK; NovoNordisk, Copenhagen, Denmark; Osmotex, Zurich, Switzerland; Perosphere Technologies, Danbury CT, USA; PharmACT, Berlin, Germany; Requalité, Munich, Germany; Sanofi, Berlin, Germany; Sciema, Mainz, Germany; Trilinear Bioventures, Huntsville AL, USA

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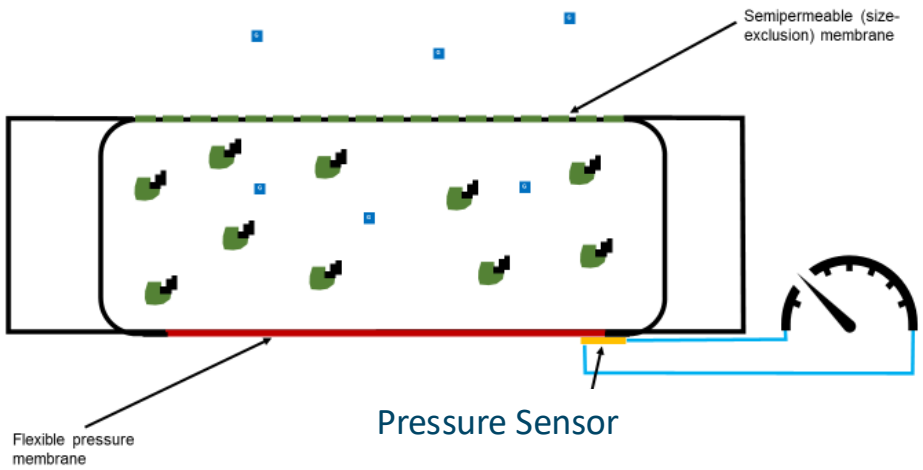
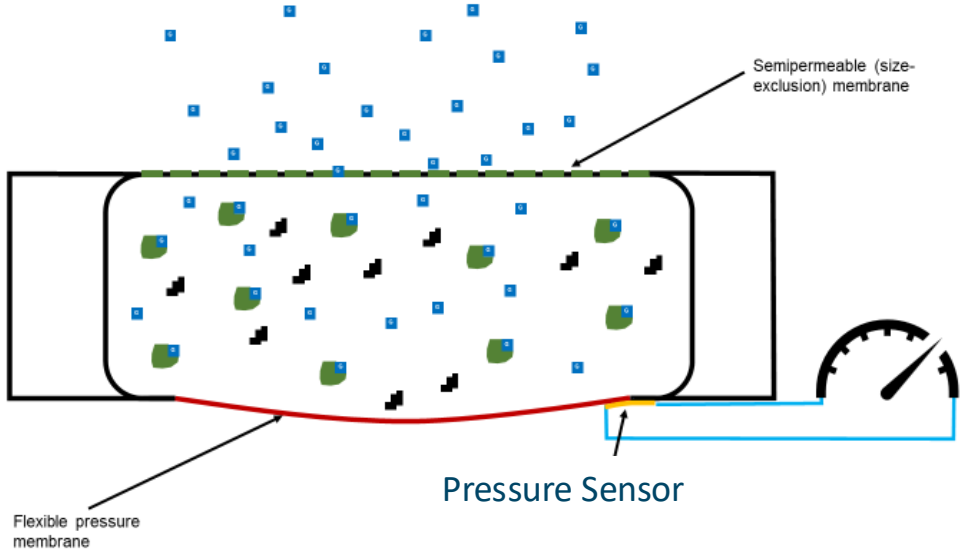
and
received support by the European Union's Horizon 2020 research and innovation program under grant agreement No 951933 (ForgetDiabetes)

Sencell measurement principle

Low glucose concentration in the interstitial fluid



High glucose concentration in the interstitial fluid



GBM: Glucose-Binding Molecule, e.g. Concanvalin A

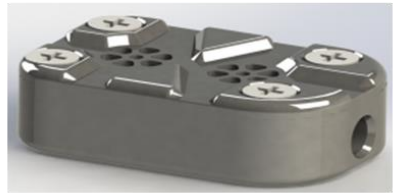
GL: Glucose ligand – a molecule that can bind to the GBM, e.g. dextrane

G: isolated glucose molecule

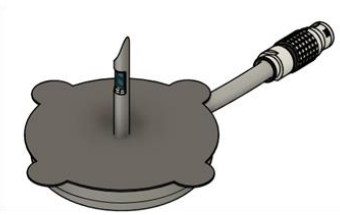
The Sencell development challenge

Laboratory prototype
chamber volume ~300 µL

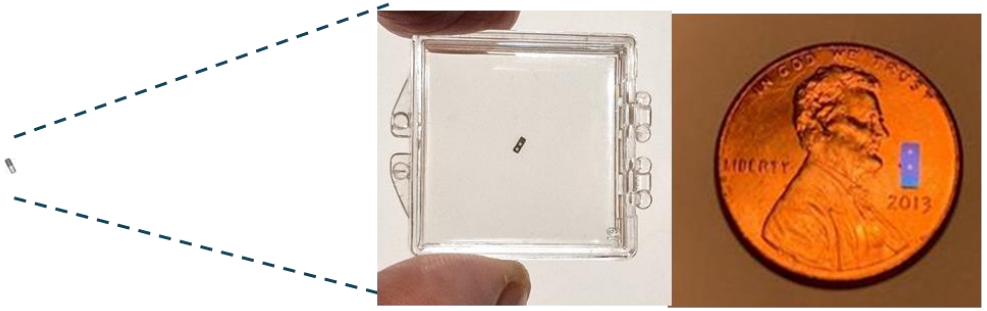
Preclinical I prototype
chamber volume ~250 µL



Preclinical II prototype
chamber volume ~70 µL



needle sensor for human studies
chamber volume ~700 nL



core sensor unit for human studies and CE mark
chamber volume ~700 nL

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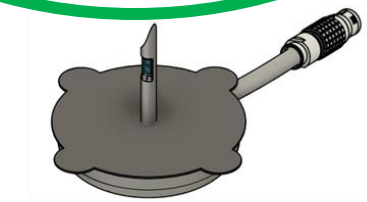

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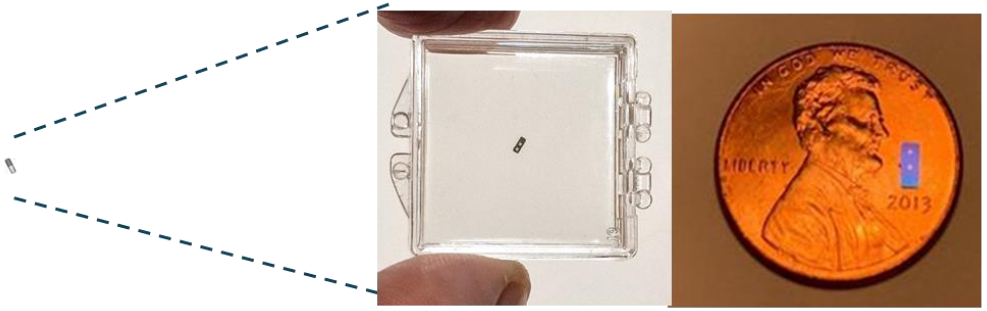

core sensor unit for human studies and CE mark
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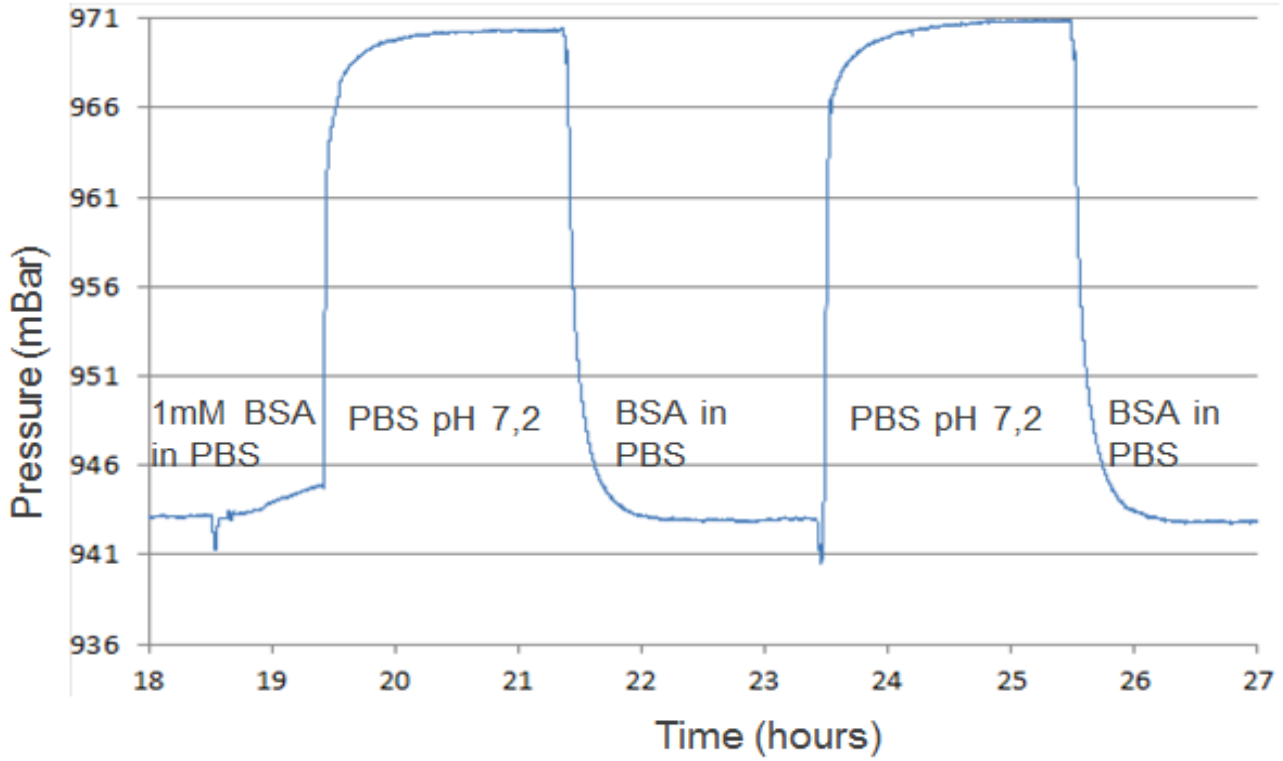
BSA Bench Test

Tests with BSA solutions show excellent stability.
Osmotic pressure values for BSA (~27mbar) are in accordance with literature values (~31mbar)



The Sencell development challenge

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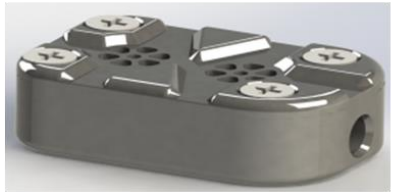
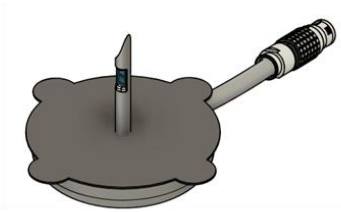


Preclinical II prototype
chamber volume ~70 µL



needle sensor for human studies
chamber volume ~700 nL

core sensor unit for human studies and CE mark
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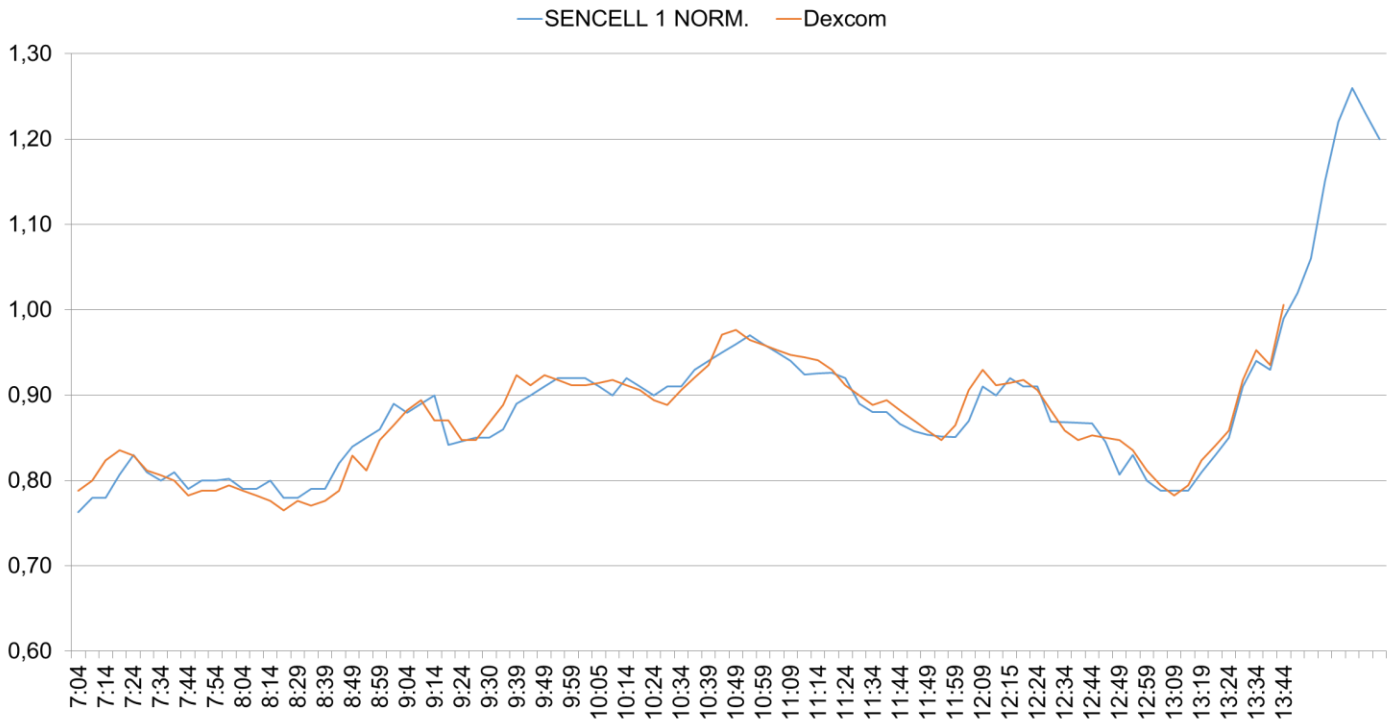
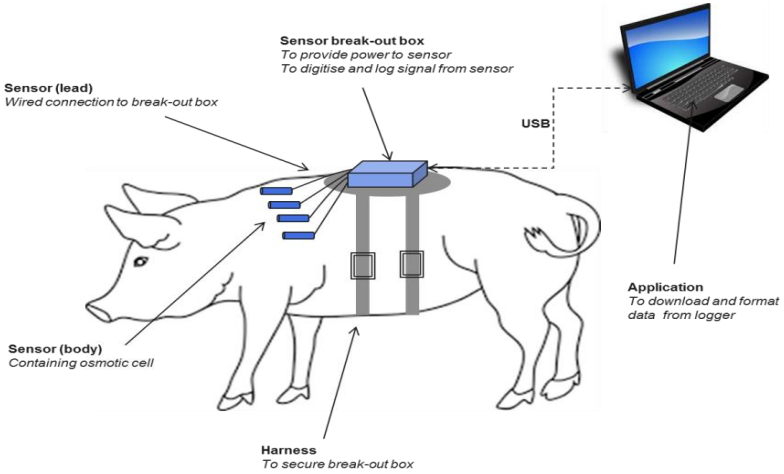
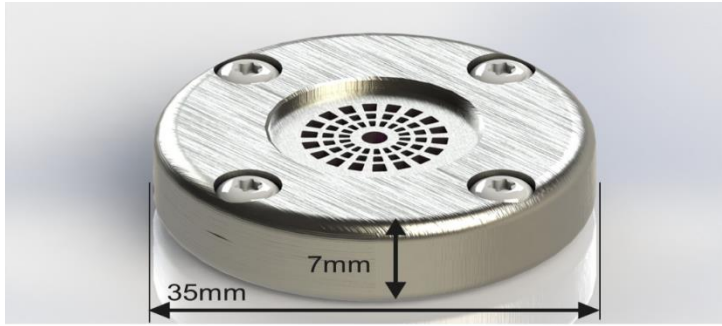
Preclinical I Results







Results are presented after single-point calibration, noise reduction, and and removal of movement artefacts

The Sencell development challenge

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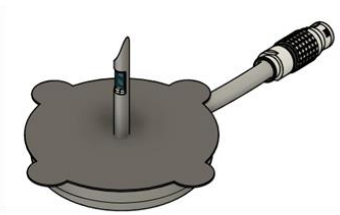
Preclinical I prototype
chamber volume ~250 µL

Preclinical II prototype
chamber volume ~70 µL



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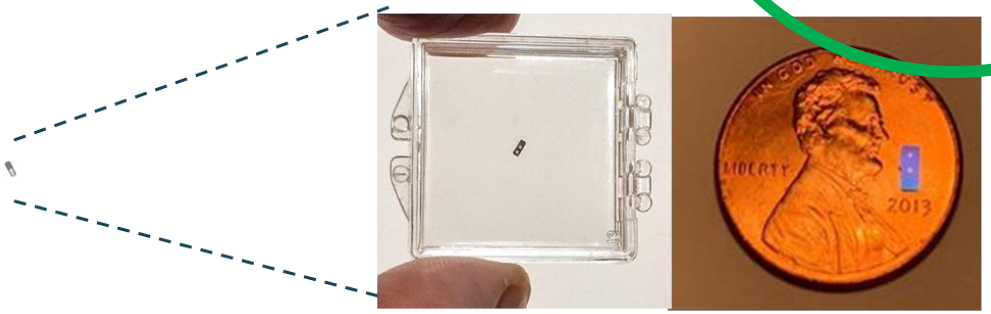

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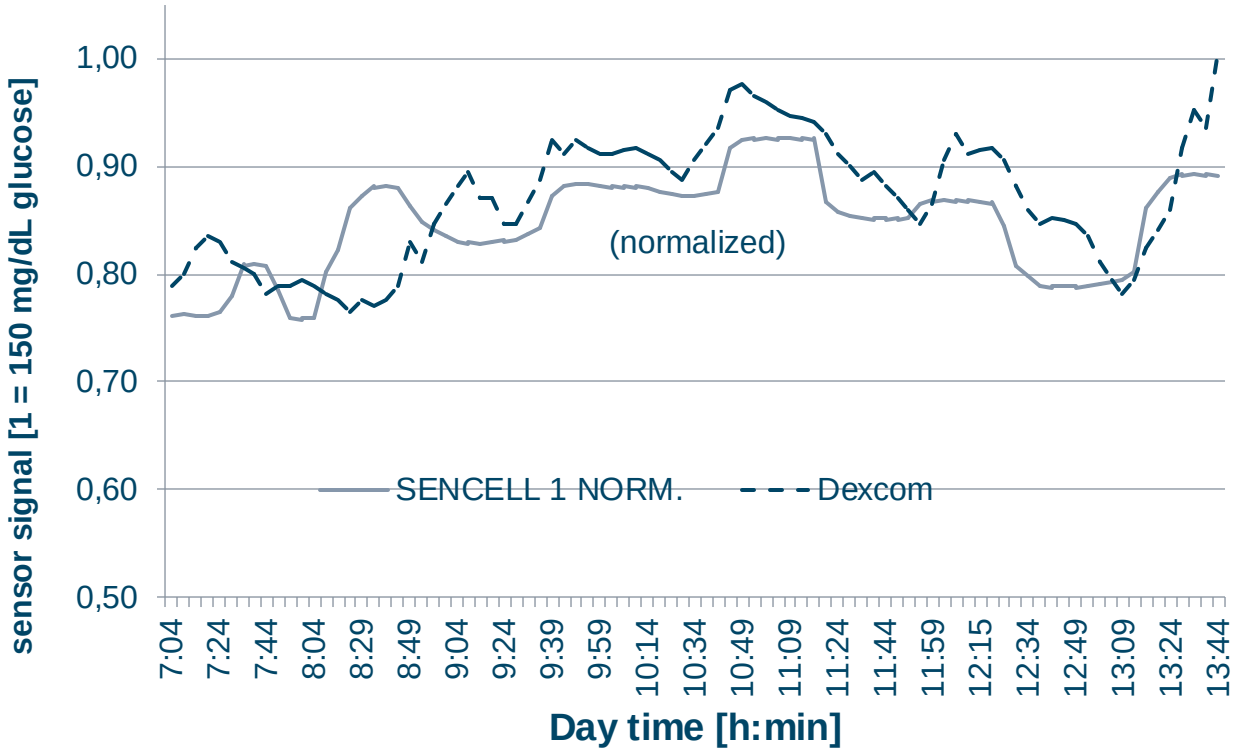
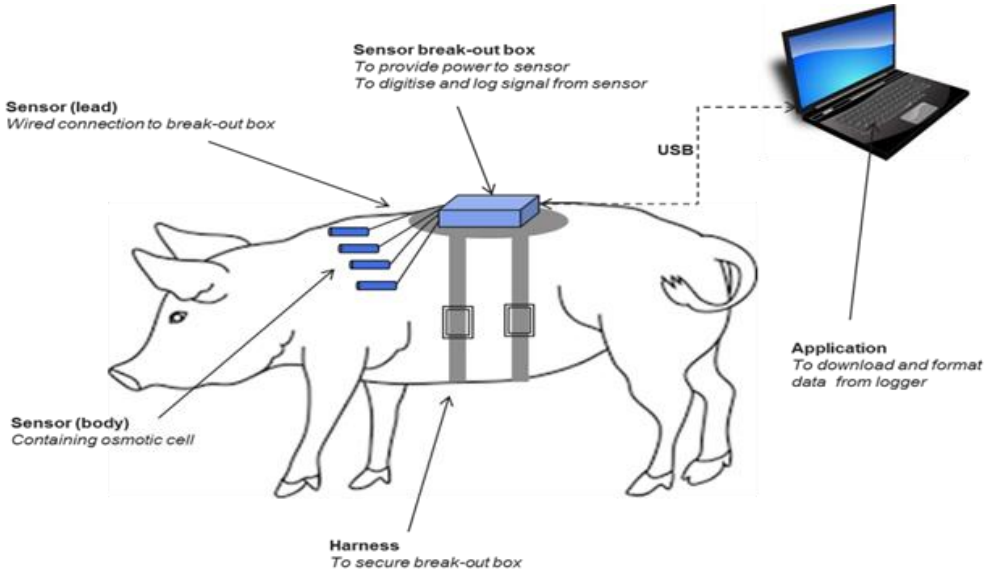
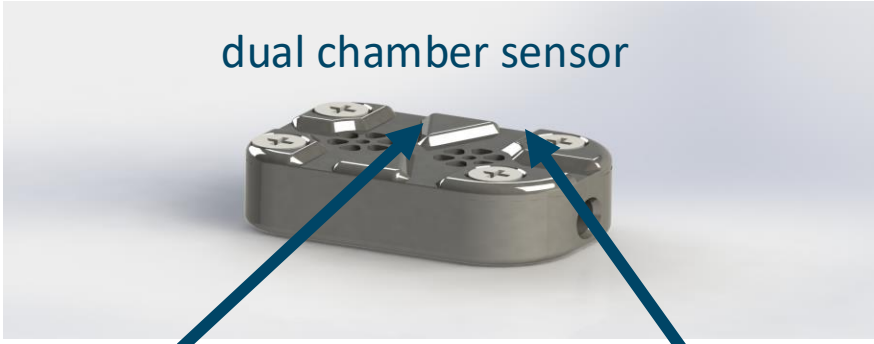
Preclinical I Results







Results are presented as raw data after single-point calibration

The Sencell development challenge

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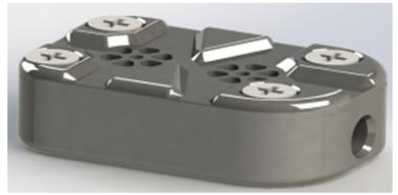

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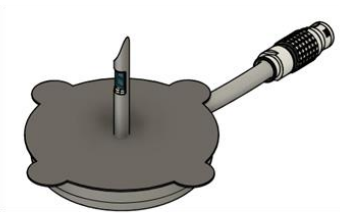

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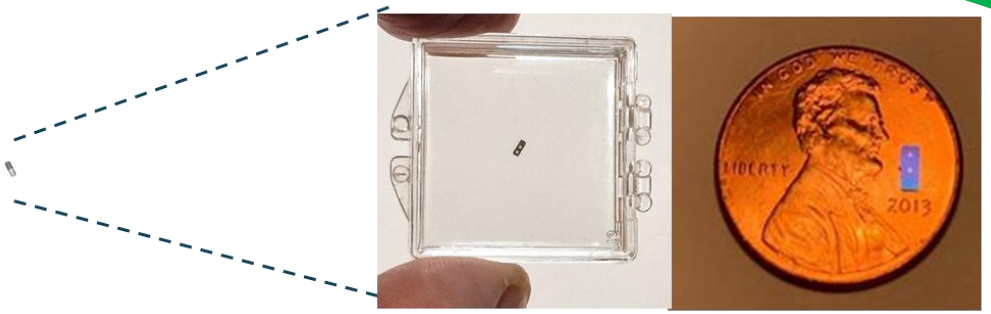

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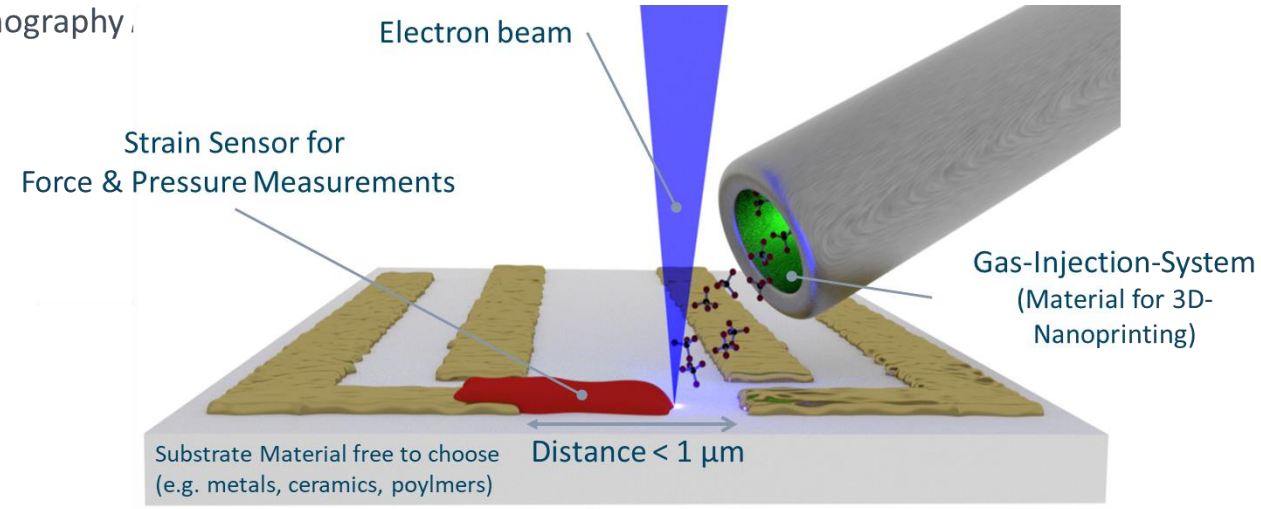
NTR Sensor Characteristics

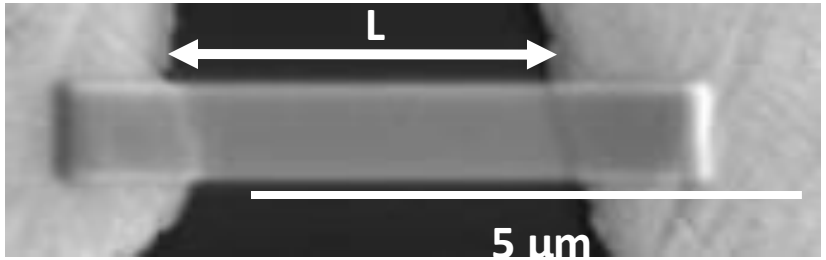
Manufacturing by FEBID

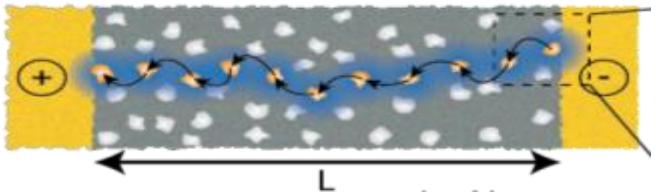
3D Nanoprinting:
Maskless Lithography



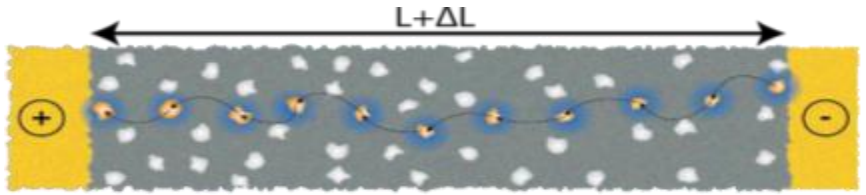
Miniaturization	Materials	Rapid Prototyping
Resolution 10 nm	**Print on Any Substrate-Material**	**Within Minutes**

Tunneling-process: “Hopping”



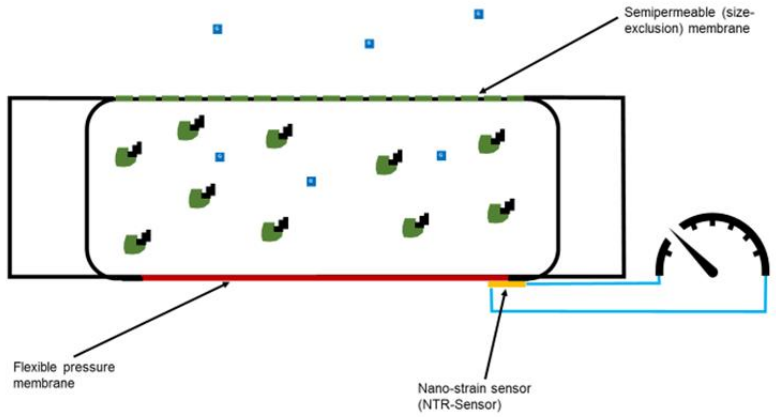


Change in resistivity



Location of the NTR Pressure Sensor

low glucose concentration in the interstitial fluid



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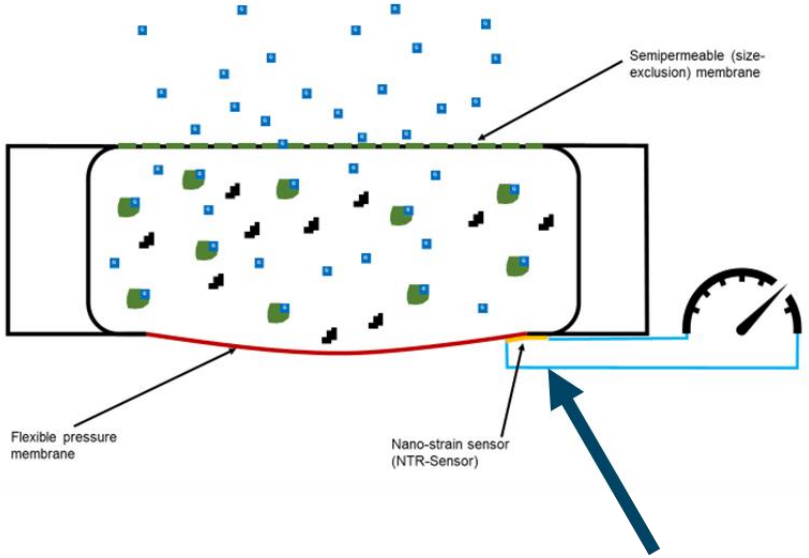

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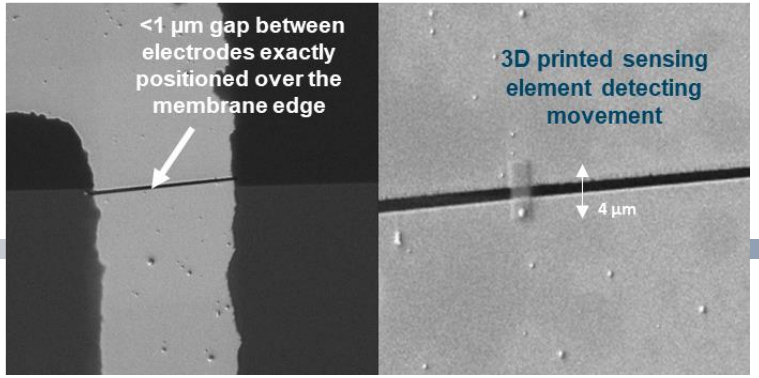

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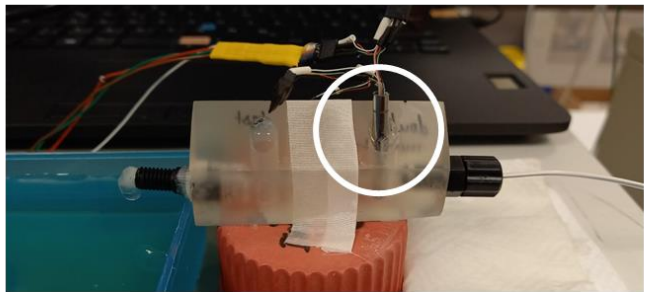
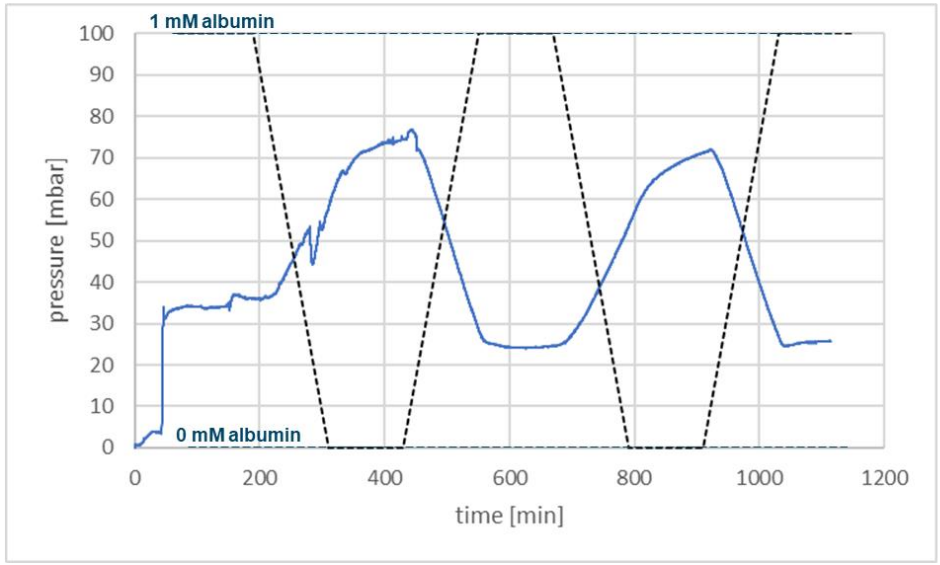
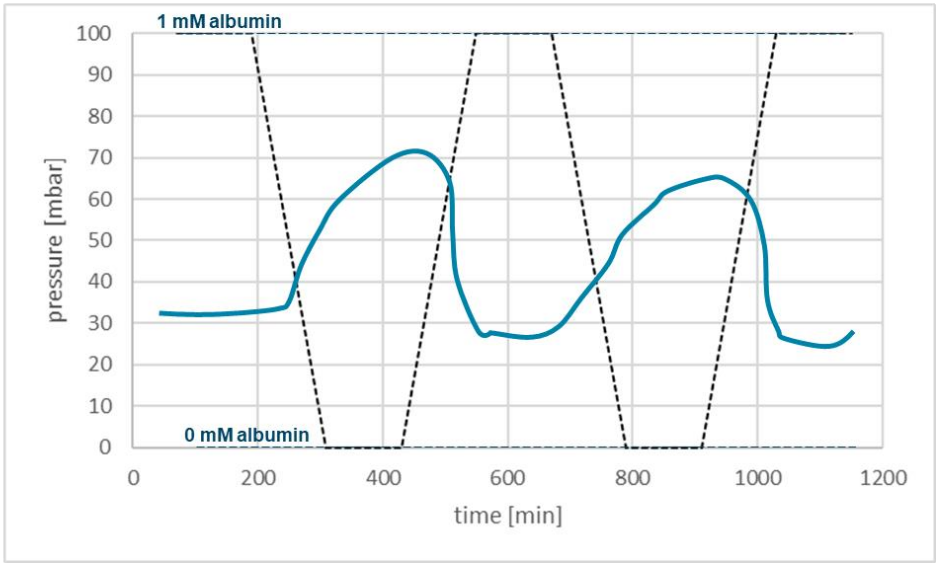
BSA Bench Test (performed with a test bench developed for dynamic CGM testing)

A laboratory prototypes

B miniaturized (needle sensor) prototypes







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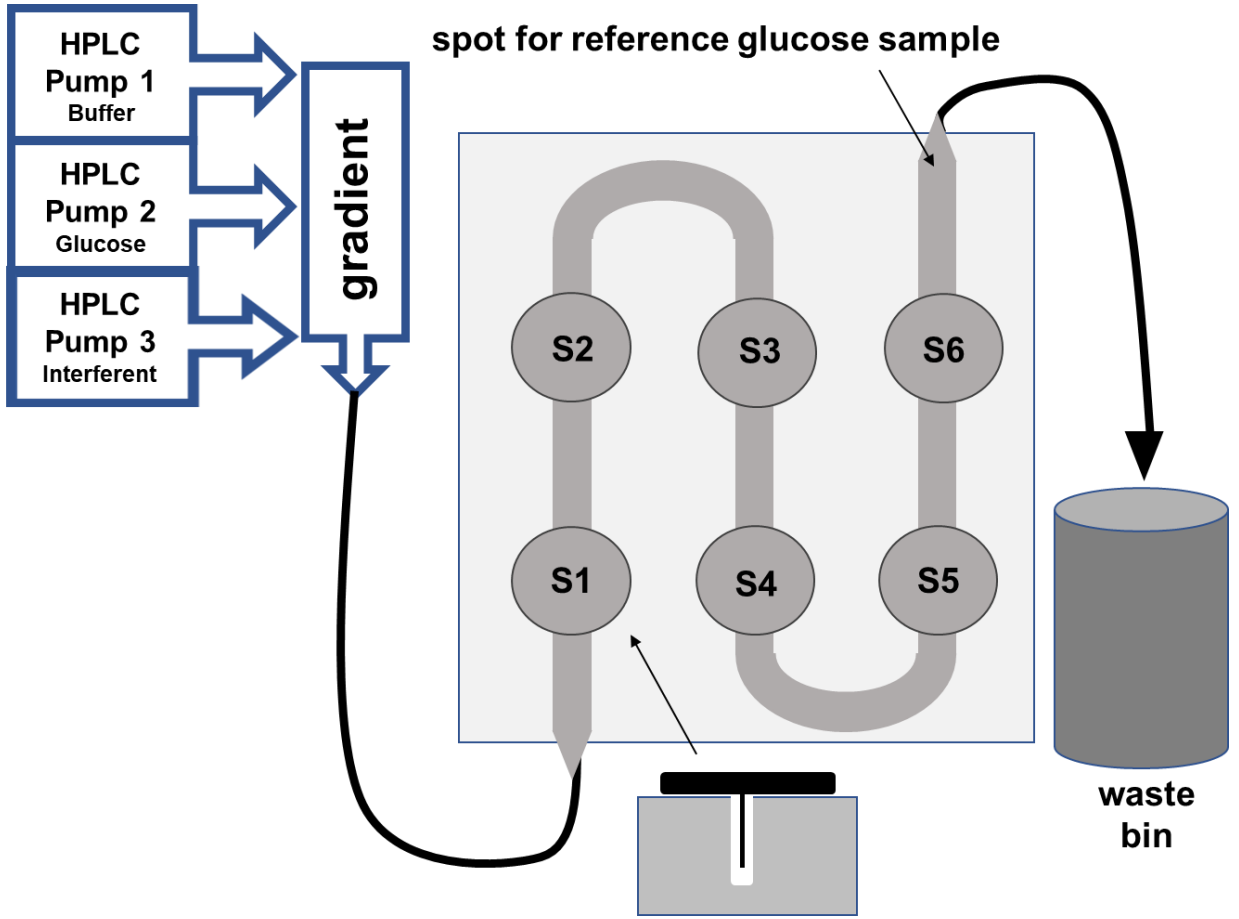
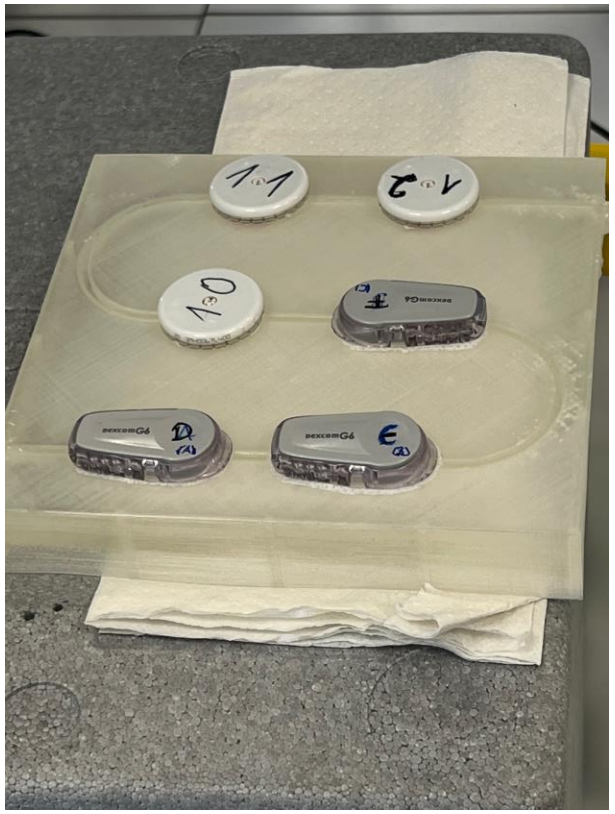
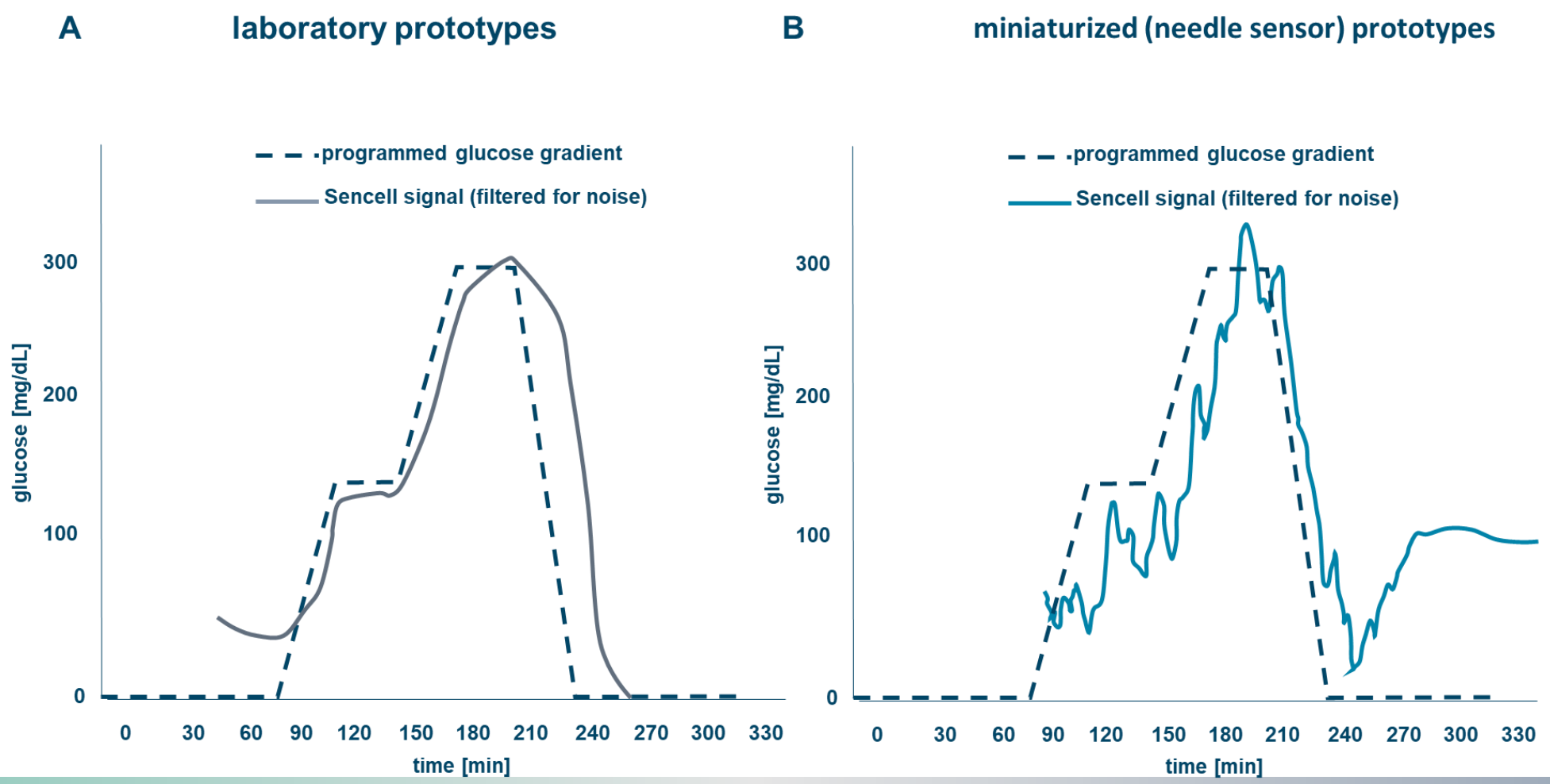
DynaCGM -Test Bench for Dynamic CGM Performance and Interference Testing





Pfützner et al., J. Diabetes Sci. Technol. (epub ahead of print) doi: 10.1177/19322968221095573, 2022

DynaCGM – Dynamic Glucose Performance Test



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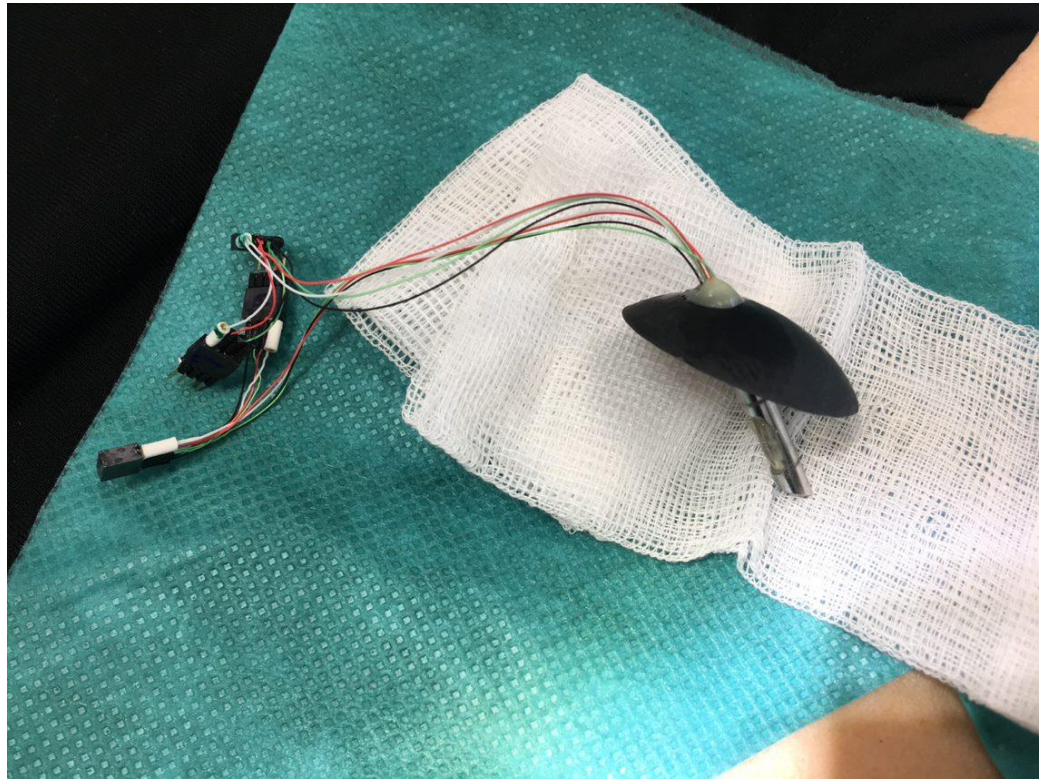
Sencell First Insertion (wired needle sensor)



Clinical Pilot Study

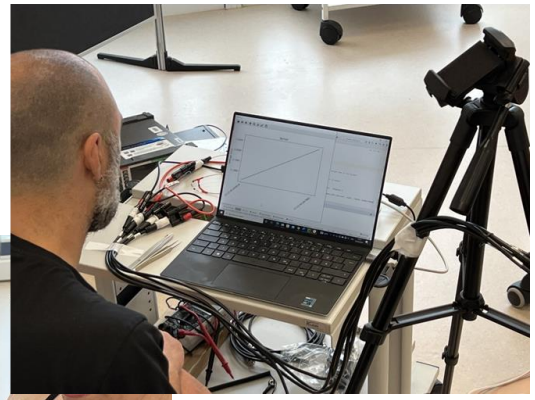
LIFC-SEN-001

First in human-Study

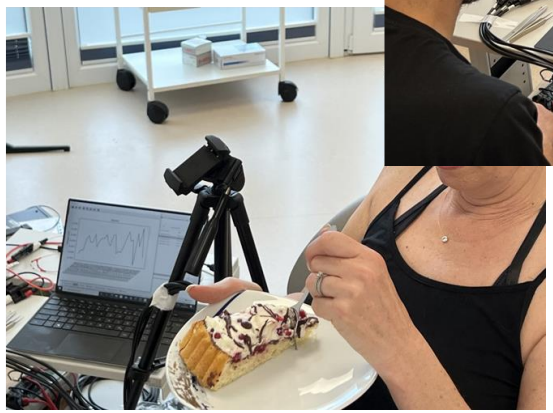
10 Healthy volunteers & 5 subjects with diabetes
Maximal duration: 3 days

Goal:
Collect comparator data for predictive algorithm development
Improve device functionality

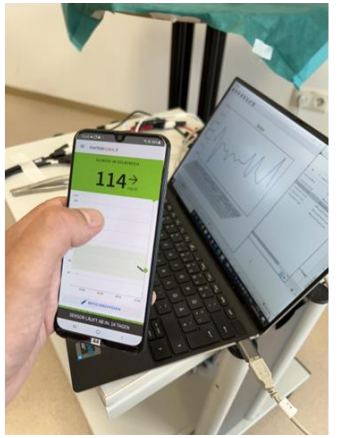
System Set-up



Glucose Challenge



Measurement

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