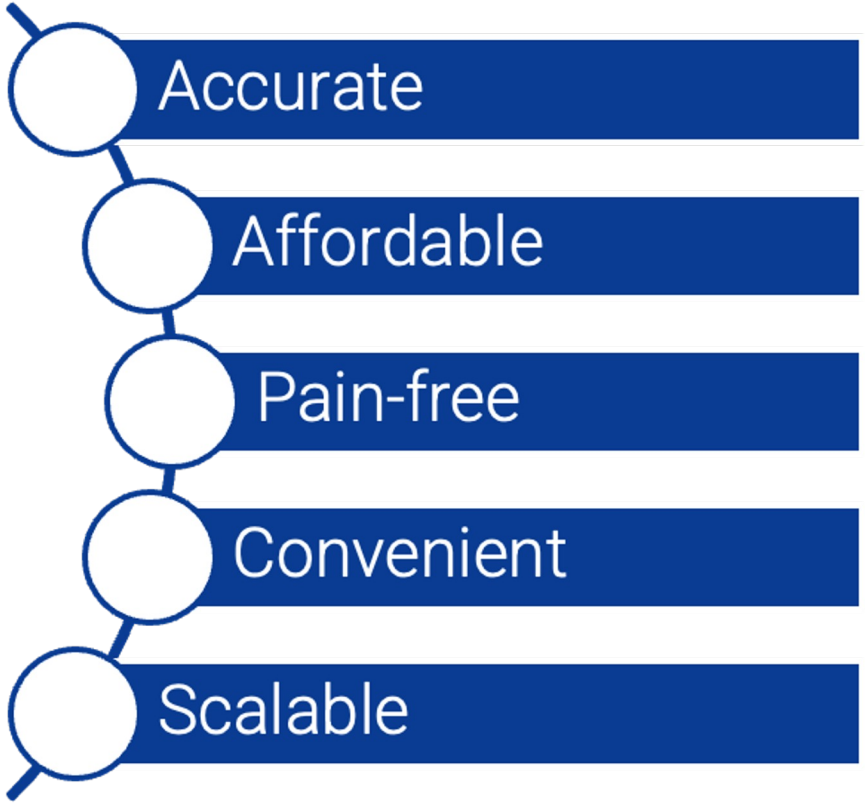
Efficacy of a Non-Invasive Blood Glucose Monitor for Diabetes Management Using a Radiofrequency Sensor and Machine Learning

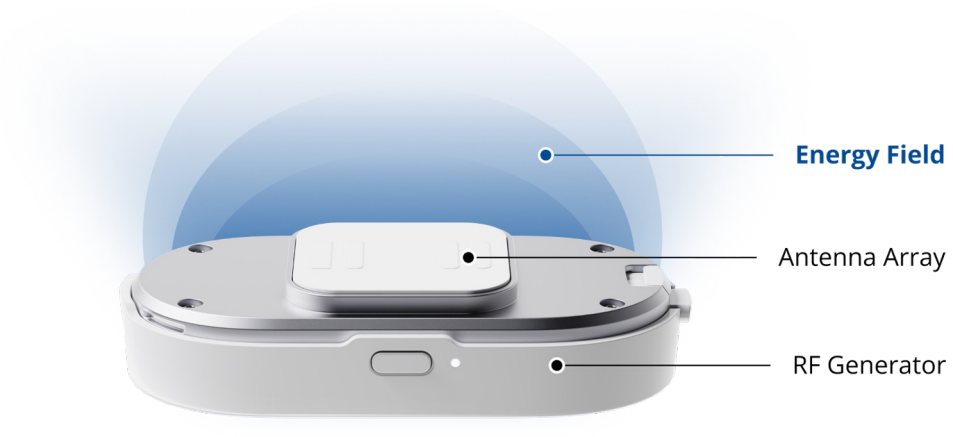
Dominic Klyve[1], James Anderson[2], Kaptain Currie[2], Carl Ward[3], Kinara Pandya[3], and Virend Somers[4]

[1]Central Washington University, [2]Know Labs Inc., [3]Edge Impulse, Inc., [4]Mayo Clinic

Building a non-invasive continuous glucose monitoring device



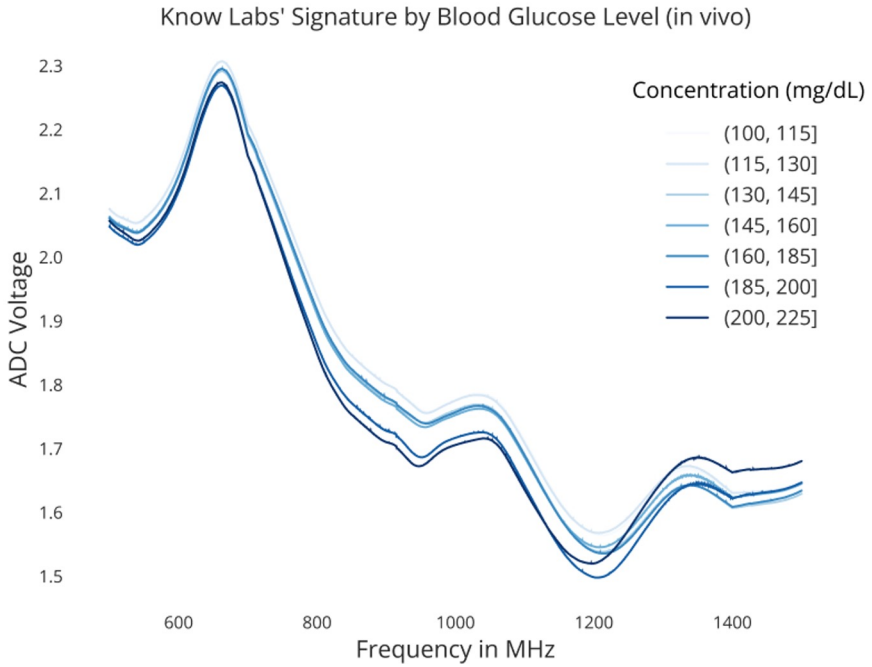
Know Labs' RF Dielectric Sensor: Volumetric Data



Antenna Array that emits and captures radio wave signals in the microwave spectrum and generates an **"Energy Field"**, collecting "volumetric data"

RF Generator enables frequency sweeps from 300 to 4,400 MHz at a rate of ~**500 frequencies per second**

Know Labs' RF Dielectric Sensor



The signal received is modified due to the **dielectric properties of blood glucose**

ADC Voltage (y-axis) measuring voltage based on dielectric permittivities of blood glucose and frequency sweeps

Clinical Protocol

Know Labs' Lab in Seattle, WA

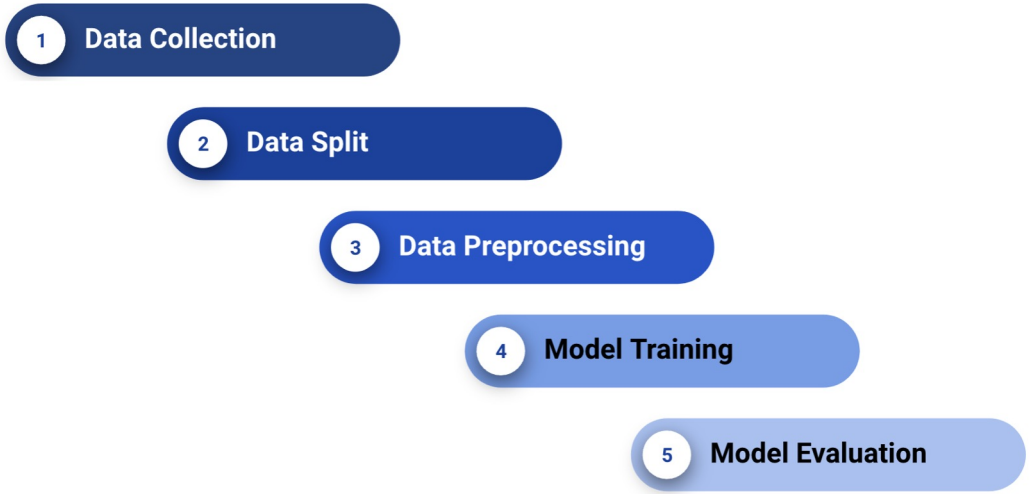
People with prediabetes and **T2 diabetes**

Ten study participants' forearms continuously scanned during a **75g Oral Glucose Tolerance Test**

Venous blood collected every five minutes using a peripheral intravenous catheter and analyzed using an FDA-cleared blood glucose hospital meter as a reference device

Venous blood glucose readings paired with RF sensor scans for data analysis

Data Analysis



80% of data collected (520 paired values) used to **train** an **ML model** to estimate the reference venous blood glucose values from the RF sensor data

Model tested on remaining **20%** for 'blind' evaluation

Accuracy of model estimates assessed using Mean Absolute Relative Difference (**MARD**)

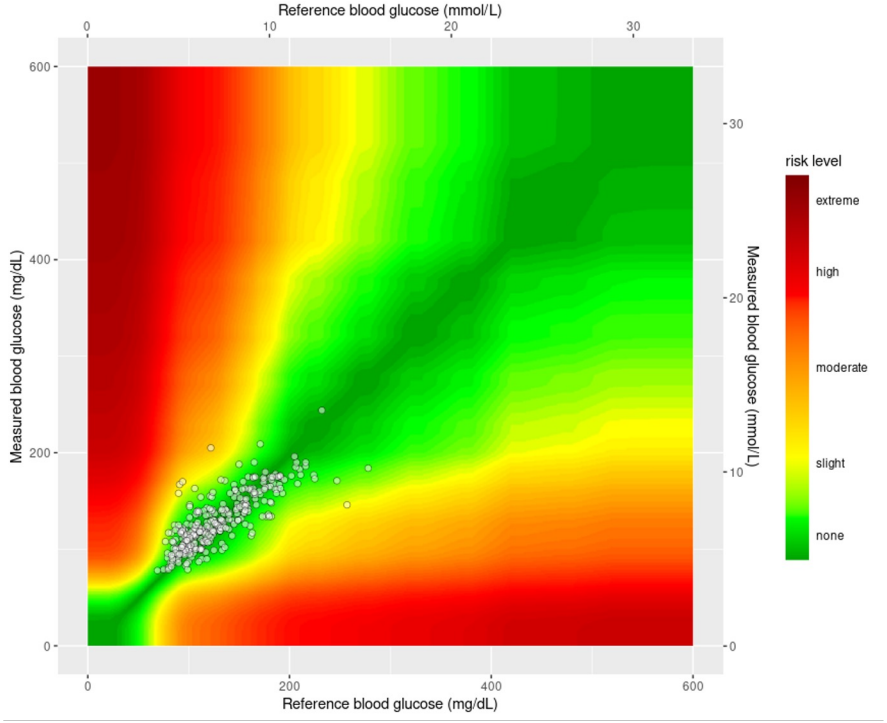
Results: RF Sensor Compared to Venous Blood

Glucose Range (mg/dL)	*n*	MARD(%)	±15%	±20%
Hypoglycemic (<70)	4	9.5 ± 8.3	75.0 ± 4.2	100.0 ± 0.0
Normoglycemic (70-180)	99	11.0 ± 2.7	75.8 ± 0.8	83.8 ± 0.7
Hyperglycemic (>180)	27	11.5 ± 3.1	66.7 ± 1.8	85.2 ± 1.3
Total	130	11.1 ± 2.1	73.8 ± 0.8	84.6 ± 0.6

Blood glucose was estimated on the test dataset with a **MARD of 11.1 ± 2.1%** relative to venous blood

No significant difference in accuracy between **normoglycemic (11.0 ± 2.7%)** and **hyperglycemic ranges (11.5 ± 3.1%)**

Results: Surveillance Error Grid Analysis of Model Accuracy



100% of estimations in Risk Grades A and B.

82.3% in **A**
17.7% in **B**

Conclusion

Novel RF sensor, paired with ML techniques, **holds considerable promise for the non-invasive measurement of blood glucose.**

If made widely available, the sensor could afford several population-level advantages:

- Real-time blood glucose readings pain and needle-free
- No costly, single-use disposables

More readings available to more patients brings significant, potential concomitant health benefits.

Further Clinical Research Aims

The KnowU™, Non-Invasive Wearable CGM

Deploy the KnowU™ in large-scale, external clinical studies while making refinements to the device and its algorithms.

Determine the technology's performance throughout:

- continuous wear
- more real-world environments
- within more expansive glycemic ranges, including the hypoglycemic range (<70 mg/dL)

To stay updated on the latest results, visit
www.knowlabs.co/research-and-development