KNOW LABS

Non-Invasive Blood Glucose Monitoring Using a Radiofrequency Sensor and a Machine Learning Model

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Background & Aims

Diabetes Mellitus (DM) affects over 530 million people globally and is a condition characterized by high blood glucose (BG) that can result in severe long-term health consequences if poorly managed. To mitigate the risks associated with DM, it is crucial to regulate BG levels through regular monitoring. Current methods of monitoring BG come with drawbacks in the form of pain and expense. **With the rapid increase in prevalence of DM, there is an increasing need for economical, accurate, and non-invasive continuous measures of BG.**

Here we present a validation for a novel sensor that rapidly scans through a wide range of radio frequencies (RF) and uses machine learning (ML) techniques for the purpose of non-invasive BG measurement.

Methods

- Across 110 tests, we collected 3,311 BG observations from 13 healthy participants over a series of tests lasting 2 – 3 hours.
- During each test, participants placed their forearm on the proprietary Know Labs RF dielectric sensor that measured their BG levels using sweeps across the 500 MHz – 1500 MHz range at 0.1 MHz intervals.
- Each sweep took approximately 22 seconds, including a one-second pause between sweeps.
- Concurrent measurements from a Continuous Glucose Monitor (CGM) were taken as reference.
- Participants ingested 37.5 grams of glucose solution to generate BG readings across normoglycemic and hyperglycemic ranges.
- Data were divided using a 60-20-20 (training-validation-test) split, preprocessed using novel techniques, and used to train a Light Gradient-Boosting Machine (lightGBM) model to estimate BG values.
- The model that yielded the best validation Mean Absolute Relative Difference (MARD) was then used to perform a final evaluation on the test dataset to provide a 'blind' evaluation of model performance.
- Additionally, we assessed the Mean Absolute Error (MAE), and the percent of predictions that fell within 15% and 20% of the reference value.

Results

We estimated BG values in the held-out test dataset with a MARD of 10.8% in the normoglycemic range and 15.9% in the hyperglycemic range (11.3% overall MARD); **see Table**. These results were significantly better than a chance model (two-sample *t*-test, $p<0.01$).

In a Surveillance Error Grid analysis of model accuracy, 89.0% of predictions fell in Risk Level 0, 10.1% in Risk Level 1, and 0.9% in Risk Level 2; **see Figure**.

	Observations	MARD (%)	MAE (mg/dL)	±15%	±20%
Hypoglycemic (<70 mg/dL)	2 (< .3%)	n/a	n/a	n/a	n/a
Normoglycemic (70-180 mg/dL)	608 (91.4%)	10.76 ± 0.79	12.0 ± 0.82	75.5 ± 3.4	83.6 ± 2.9
Hyperglycemic (>180 mg/dL)	53 (8.3%)	15.92 ± 2.98	33.43 ± 6.51	58.5 ± 13.3	67.9 ± 12.6

Table 1: MARD and MAE values and percentages falling within 15% and 20% of the reference value by glycemic status. Error values on the MARD give the 95% *t*-Confidence Interval. Error bars on the ±15% and ±20% give the 95% *z*-Confidence Interval for proportions.

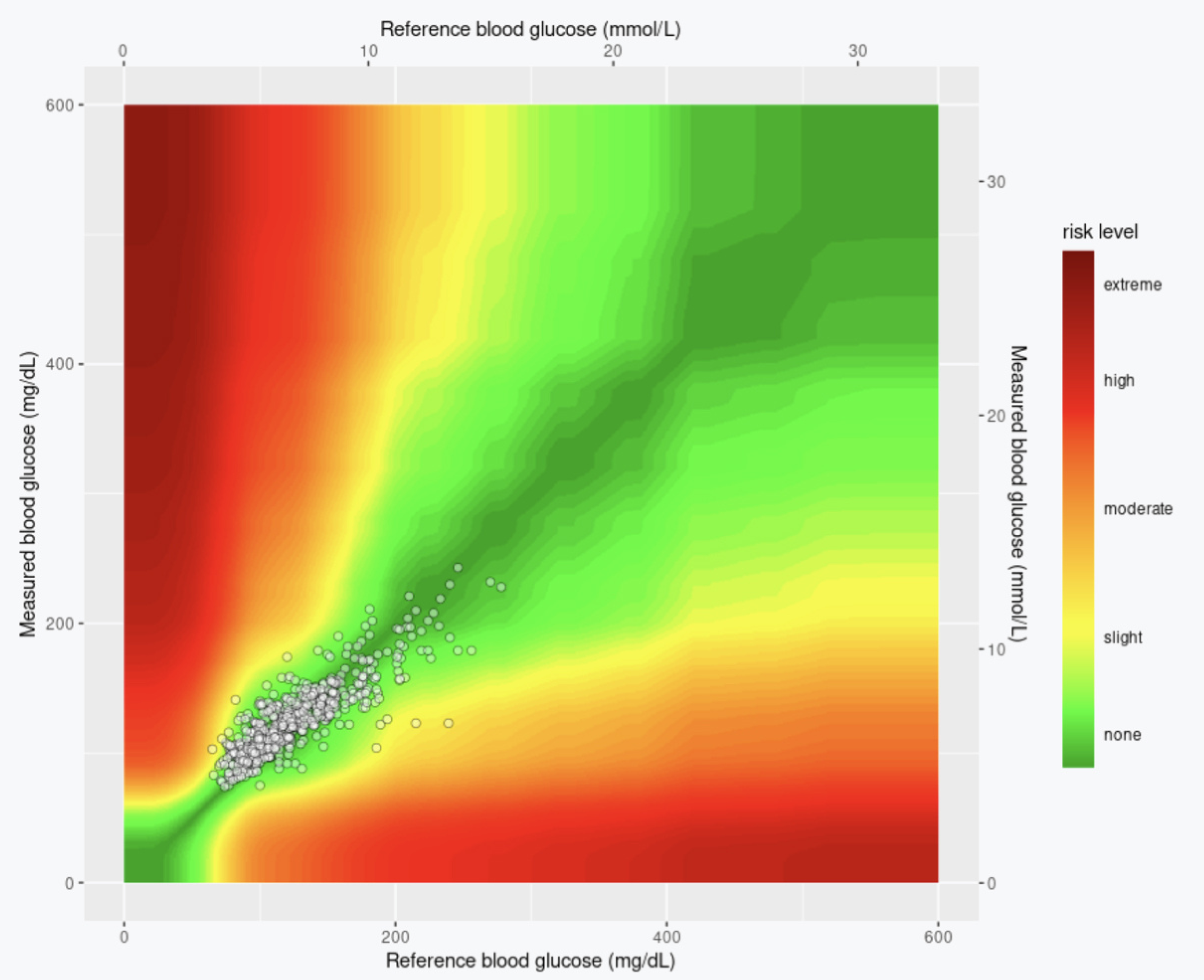

Figure 1: Surveillance Error Grid analysis comparing the 663 ML model estimations in the test dataset to the CGM reference.

Conclusion

These results demonstrate that the novel RF dielectric sensor and ML techniques described can estimate a reference BG value in the population under study. More research is underway to refine and expand these methods using a gold-standard blood glucose reference device and among a broader participant population with an expanded glucose range.

DK and VS are consultants for and own stock in Know Labs. JA and KC are employed by and have stock options in Know Labs. CW and KP are consultants for Know Labs.