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# NON-INVASIVE BLOOD GLUCOSE MONITORING IN PEOPLE WITH DIABETES USING AN RF SENSOR AND VENOUS BLOOD COMPARATOR

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**Background & Aims:**

The high expense and discomfort of current blood glucose (BG) monitoring techniques necessitate the development of a continuous, economical, non-invasive monitor. Our ongoing clinical study assesses the accuracy of the novel Know Labs radiofrequency (RF) sensor for non-invasive BG measurement in participants with prediabetes and T2 diabetes using venous blood as comparative reference.

**Methods:**

Participants' forearms were continuously scanned for up to three hours using the sensor, which rapidly sweeps through a wide band of radio frequencies to measure BG. Venous blood was collected using a peripheral intravenous catheter every five minutes during a 75g Oral Glucose Tolerance Test and analyzed using a blood glucose monitoring test system (StatStrip, Nova Biomedical). A light Gradient Boosting Model (lightGBM) was trained on interim data consisting of 520 paired RF and reference BG values from 10 participants over 21 sessions, then tested on 130 held-out paired values.

**Results:**

On the held-out test dataset, BG was estimated with a Mean Absolute Relative Difference (MARD) of 11.1 ± 2.1% relative to venous blood (Table 1). We observed similar accuracy in normoglycemic (11.0 ± 2.7%) and hyperglycemic ranges (11.5 ± 3.1%). A Surveillance Error Grid analysis of model accuracy showed 82.3% of estimations in Risk Grade A and 17.7% in Risk Grade B (Figure 1). Importantly, no estimations fell in the higher Risk Grades.

| 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 |

**Table 1:** MARD values and percentages falling within 15% or 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.

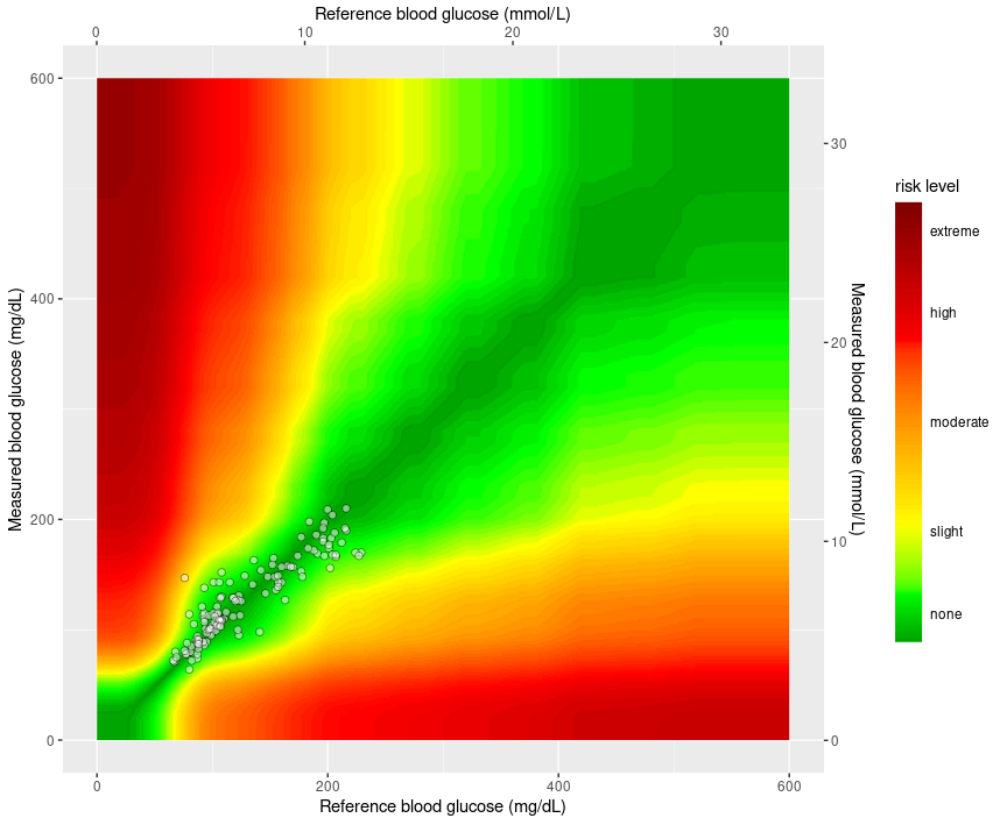


**Figure 1:** Surveillance Error Grid analysis comparing the 130 Know Labs' estimations in the test dataset to the venous blood reference.

## Conclusions:

These interim results suggest that the ML model applied on RF sensor data can measure BG non-invasively, and further data collection and model refinement will continue.

## Disclosure of Conflicts of Interest:

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.

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