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2038-LB: Improved Accuracy of a Fully Noninvasive CGM in a Diverse Population FREE

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Introduction and Objective: Conventional glucose assessments are typically performed via invasive BGM or CGM. We present here proof-of-concept of a fully non-invasive photoplethysmography (PPG)-based wristwatch CGM that estimates glucose levels largely within FDA iCGM Special Control (FiSC) norms across a clinically relevant dynamic range (80 - 250 mg/dL).

Methods: The LIFELEAF® wristwatch (LifePlus, Inc., San Jose, CA) estimates glucose levels by applying novel machine learning (ML) algorithms to PPG signal recorded by conventional optical sensors at the wrist. The algorithms utilize 17 distinct features including demographics (e.g., age, gender, BMI, skin tone), personal medical features (PMF) such as blood pressure and heart rate, and other proprietary PPG-derived measures to estimate glucose values. Wristwatch PPG with concurrently recorded BGM- or CGM-referenced glucose datapoints and PMF (N=5824) were collected during fasting as well as pre- and post-prandial states across multiple days from 248 diverse non- and pre-diabetic subjects from 12 countries (Figs. 1A & 1B). Datapoints were randomly split 70:30 for ML algorithm generation and validation testing, respectively.

Results: Findings were overall robust compared to FiSC norms (Figs. 1C & 1D).

Conclusion: We demonstrate feasibility of a non-invasive wristwatch CGM to estimate glucose levels largely within FiSC norms through ML-based algorithms incorporating initial device calibration, PMF, and proprietary features.

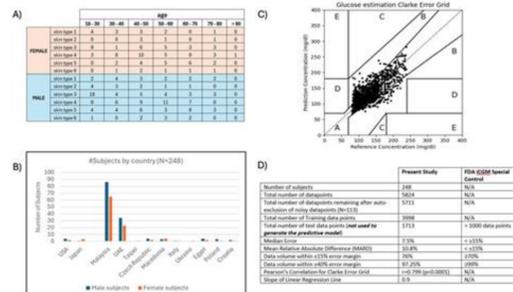


Figure 1. Patient Demographic Data and Results of Wristwatch Glucose Estimation. (A) Subject demographic distribution by sex, age, and Fitzpatrick skin type; (B) Subject demographic distribution by country; (C) Clarke Error Grid for wristwatch-predicted glucose (y-axis) vs. reference glucose level (x-axis); (D) Study statistics and comparison with FDA iCGM Special Control norms. The Clarke error grid also demonstrates significant linearity of fit (Pearson's $r=0.799$, $p<0.001$) with calculated linear regression line (not shown) having slope of 0.9.

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Disclosure

T.S. Bailey: Consultant; Ypsomed AG, i-Sense. Research Support; LifePlus, Abbott Diagnostics, Biolog, Concept Therapeutics, Dexcom, Inc., Eli Lilly and Company, Medtronic. Consultant; Medtronic. Research Support; Novo Nordisk. Consultant; Novo Nordisk, Sanofi. Research Support; Senseonics, vTv Therapeutics. Consultant; Abbott, Abbott Diagnostics, ACON, CeQur, HagarTech, MannKind Corporation, Perspiron, Sequel Med Tech. **J. Fischer:** Other Relationship; Bioconscious Technology. Consultant; Lifeplus Inc. Advisory Panel; Glooko, Inc. **I. Sen-Gupta:** Consultant; LifePlus, Inc., Neura Health. **B. Mboumbouo:** None. **A. Sanyal:** Board Member; LIFEPLUS, INC.

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