

# KNOW LABS

## TRANSFORMING NON-INVASIVE MEDICAL DIAGNOSTICS

### PRELIMINARY FINDINGS

Know Labs' Sensor Technology Application  
to Monitor Blood Oxygen Saturation Levels

December 22, 2023

NYSE American: KNW



# DISCLOSURE

## CAUTION ABOUT FORWARD-LOOKING STATEMENTS

This document contains forward-looking statements that are based on the Company management's beliefs and assumptions and on information currently available to the Company. All statements other than statements of historical facts are forward-looking statements. These statements relate to future events or to the Company's future financial performance and involve known and unknown risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements include, but are not limited to, statements about: goals and strategies; future business development, financial condition and results of operations expected product development outcomes, including obtaining regulatory clearance, expected changes in revenue, costs or expenditures; growth of and competition trends in industry; and expectations regarding demand for, and market acceptance of, our products. You can identify forward looking statements by terms such as "may," "could," "will," "should," "would," "expect," "plan," "intend," "anticipate," "believe," "estimate," "predict," "potential," "project" or "continue" or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond the Company's control and which could materially affect results. In evaluating these forward-looking statements, you should consider various factors, including: Company management's ability to change the direction of the company; ability to keep pace with new technology and changing market needs; and the competitive environment of the business. These and other factors may cause the Company's actual results to differ materially from any forward-looking statement. Forward-looking statements are only predictions. The forward-looking events discussed in this document and other statements made from time to time by the Company or its representatives, may not occur, and actual events and results may differ materially and are subject to risks, uncertainties and assumptions about the Company. The Company is obligated to publicly update or revise any forward-looking statement, whether as a result of uncertainties and assumptions, the forward-looking events discussed in this document and other statements made from time to time by the Company or its representatives might not occur. See offering documents for further risks and disclosures. Past performance is not indicative of future results. There is now guarantee that any specific outcome will be achieved. Investments may be speculative, illiquid and there is a total risk of loss.

### **General securities market uncertainties resulting in economic considerations.**

Recent unease regarding the aforementioned geo-political considerations and increasing inflation has caused the United States and worldwide national securities markets to have undergone unprecedented stress due to the uncertainties of regarding the economy and the resulting reactions and outcomes of governments, businesses, and the general population. These uncertainties have resulted in declines in all market sectors, increases in volumes due to flight to safety and governmental actions to support the markets. As a result, until economic outlook has stabilized, the markets may not be available to the Company for purposes of raising required capital. Should we not be able to obtain financing when required, in the amounts necessary to execute on our plans in full, or on terms which are economically feasible, we may be unable to sustain the necessary capital to pursue our strategic plan and may have to reduce the planned future growth and/or scope of our operations.

### **We need additional financing to support our technology development and ongoing operations, pay our debts and maintain ownership of our intellectual properties.**

We are currently operating at a loss and using substantial cash to fund our operation. We believe that our cash on hand will be sufficient to fund our operations through September 30, 2024. We will need additional financing to implement our business plan and to service our ongoing operations, pay our current debts (described below) and maintain ownership of our intellectual property. There can be no assurance that we will be able to secure any needed funding, or that if such funding is available, the terms or conditions would be acceptable to us. If we are unable to obtain additional financing when it is needed, we will need to restructure our operations and/or divest all or a portion of our business. We may seek additional capital through a combination of private and public equity offerings, debt financings and strategic collaborations. Debt financing, if obtained, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, and could increase our expenses and require that our assets secure such debt. Equity financing, if obtained, could result in dilution to our then-existing stockholders and/or require such stockholders to waive certain rights and preferences. Strategic collaborations may include features which could limit the Company's ultimate potential. If such financings is not available on satisfactory terms, or is not available at all, we may be required to delay, scale back, eliminate the development of business opportunities and our operations and financial condition may be materially adversely affected.

### **We have a history of operating losses and there can be no assurance that we can achieve or maintain profitability.**

We have experienced net losses since inception. As of June 30, 2023, we had an accumulated deficit of \$118,715,000 and net losses in the amount of \$12,353,000, \$20,071,000 and \$25,360,000 during the nine months ended June 30, 2023 and the years ended September 30, 2022 and 2021, respectively. There can be no assurance that we will achieve or maintain profitability. If we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable would impair our ability to sustain operations and adversely affect the price of our common stock and our ability to raise capital. Our operating expenses may increase as we spend resources on growing our business, and if our revenue does not correspondingly increase, our operating results and financial condition will suffer. Our businesses have produced minimal revenues and may not produce significant revenues in the near term, or at all, which would harm our ability to continue our operations or obtain additional financing and require us to reduce or discontinue our operations. You must consider our business and prospects in light of the risks and difficulties we will encounter as business with an early-stage technology in a new and rapidly evolving industry. We may not be able to successfully address these risks and difficulties, which could significantly harm our business, operating results and financial condition.

### **If we are unable to secure a sales and marketing partner or establish satisfactory sales and marketing capabilities at our company, we may not be able to successfully commercialize our technology.**

If we are not successful entering into appropriate collaboration arrangements or recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty successfully commercializing our technology, which would adversely affect our business, operating results and financial condition.

We may not be able to enter into collaboration agreements on terms acceptable to us or at all. In addition, even if we enter into such relationships, we may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend heavily on the success of the efforts of these third parties. If we elect to establish a sales and marketing infrastructure, we may not realize a positive return on this investment. In addition, we must compete with established and well-funded pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize technology without strategic partners or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

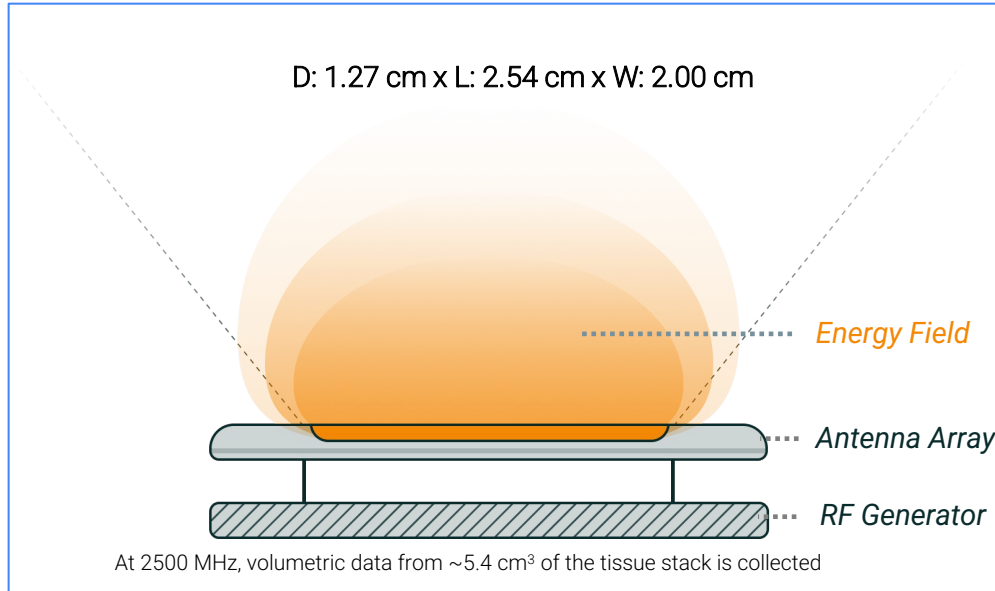
### **Government regulatory approval may be necessary before some of our products can be sold and there is no assurance such approval will be granted.**

Our technology will have a number of potential applications in fields of use which will require prior governmental regulatory approval before the technology can be introduced to the marketplace. For example, we are exploring the use of our technology for certain medical diagnostic applications, with an initial focus on the monitoring of blood glucose. There is no assurance that we will be successful in developing glucose monitoring medical applications for our technology. If we were to be successful in developing glucose monitoring medical applications of our technology, prior clearance by the FDA and other governmental regulatory bodies will be required before the technology could be introduced into the marketplace. Our devices leverage Machine Learning (ML) and Artificial Intelligence (AI) to process the massive data collected through the Bio-RFID sensor. ML/AI also controls the sensor operation, enabling the device to emit and capture data, and, ultimately, to identify and measure blood glucose levels. Machine learning-enabled device software functions (ML-DSF) continue to be evaluated by the FDA, which recently released new guidance proposing a science-based approach for AI/ML-enabled medical devices to be modified and improved more quickly. There is no assurance that such regulatory approval would be obtained for a glucose monitoring medical diagnostic device or other applications requiring such approval. The FDA can refuse to grant, delay, and limit or deny approval of an application for clearance of marketing a glucose monitoring device for many reasons. We may not obtain the necessary regulatory approvals or clearances to market these glucose monitoring systems in the United States or outside of the United States. Any delay in, or failure to receive or maintain, approval or clearance for our products could prevent us from generating revenue from these products or achieving profitability.

# Know Labs Non-invasive Technology Platform

RF Spectroscopy	Uses radio and microwave frequencies to accurately identify and measure a wide range of organic and inorganic materials and molecules
Form Factor Agnostic	Integrated into a variety of wearable, mobile or bench-top form factors
Pain-free	No needles nor invasive transmitters poking the skin
No Consumables	Low bill of materials translates into a high potential to be less expensive than current options available in the market
ML/AI-Powered Algorithms	Cutting-edge ML/AI powering accurate real-time measurements with high correlation to gold standards
Predictive Health	100+ potential applications with multiple concurrent biomarkers to enable predictive health & monitoring of metabolism – <u>blood glucose monitoring is our current priority.</u>

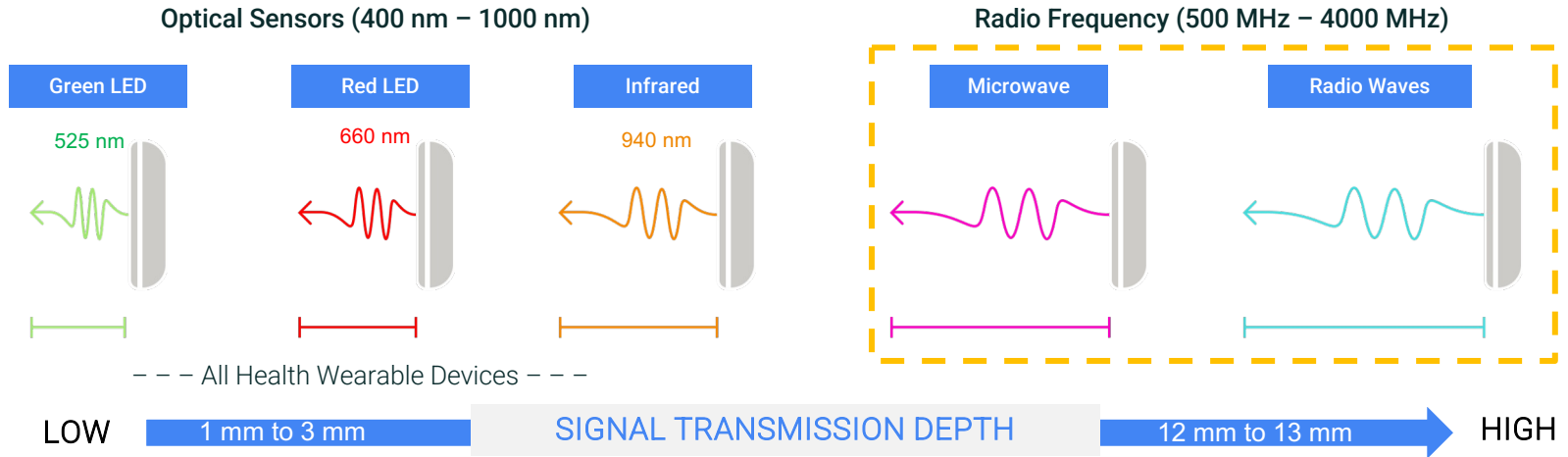
# Know Labs Sensor: Volumetric 3D Data Collected Real Time



- IP-protected Antenna Array, Microwave spectrum that emits and captures radio wave signals, generates the “Energy Field” into 3D “Tissue Stack”
- IP-protected RF Generator enables frequency sweeps in the microwave spectrum, from 300 MHz to 4,400 MHz, at various intervals, 1.5M data points collected per hour = >400 per second
- 6 Key Parameters Customizable with Each Sweep: power, frequency range, frequency step, dwell time, antenna permutations = >30,000 combinations.

# Overcoming the Limitations of Physics

RF Dielectric Spectroscopy sweps entire tissue stack to collect high resolution data at high speed that fixed wavelength optical sensors are incapable of achieving



# Delivering accuracy from *in vitro* to *in vivo* testing – Glucose Studies

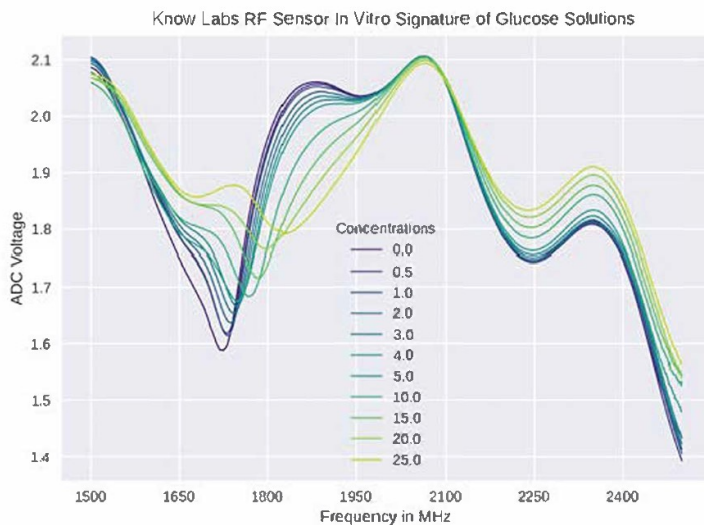
## IN VITRO

RF spectroscopy sensor based on dielectric permittivity can measure different concentrations of glucose in solution

## IN VIVO

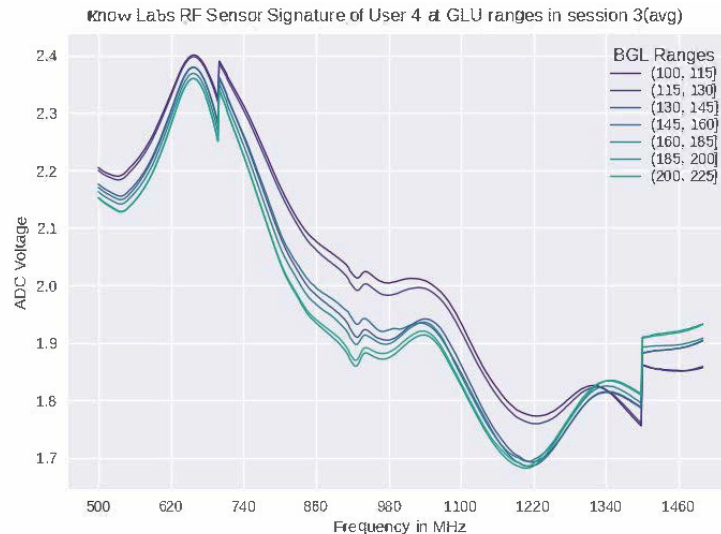
RF sensors apply the same principle to measure variance in blood glucose in BGL ranges.

## In Vitro Glucose Solutions Readings



**IN VITRO:** ADC Voltage (y-axis) measuring voltage variance based on glucose concentration and frequency sweeps

## In Vivo Glucose Readings Over 3 Hour Test



**IN VIVO:** ADC Voltage (y-axis) measuring voltage variance based on dielectric permittivities of blood glucose and frequency sweeps

# Know Labs Generation 1 Prototype Device



Using Gen 1 Prototype on Forearm

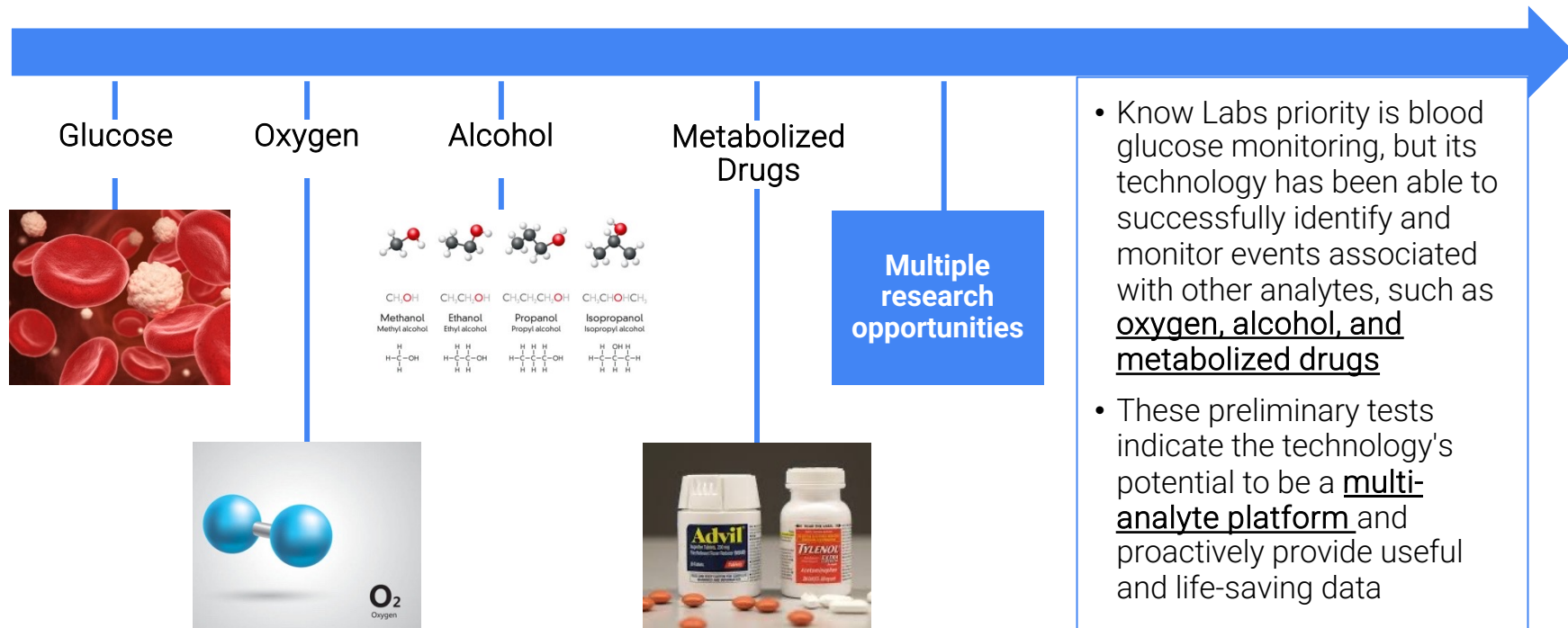


Using Gen 1 Prototype on Hand

## Gen 1

- “Computer mouse” form factor
- Place your palm or arm on the portable device for on-demand, non-invasive data collection

# Opportunities Beyond Glucose





# Blood Oxygen Saturation Monitoring: Key Challenges

- Pulse oximeters are the most used device to monitor blood oxygen saturation levels
  - Most pulse oximeters are accurate to within 2% to 4% of the blood oxygen saturation level
  - Pulse oximeters use a light source that shines through the fingertip. Analyzing the light that passes through the finger can determine the percentage of oxygen saturation level in the red blood cells.
- However, they may be less accurate in people with dark skin pigmentation, as pointed out by the FDA, media, and research by the medical community
- Skin temperature and thickness can also reduce the accuracy of pulse oximeters



- Know Labs' technology can be an affordable alternative to the current "monopoly" of pulse oximeters
- Skin pigmentation should not interfere with radio-frequency signals, Know Labs' technology foundation

# Blood Oxygen Saturation Monitoring: FDA & Media References



## Pulse Oximeter Accuracy and Limitations: FDA Safety Communication

The Coronavirus Disease 2019 (COVID-19) pandemic has caused an increase in the use of pulse oximeters, and a recent report ([Sjoding et al. External Link Disclaimer](#)) suggests that the **devices may be less accurate in people with dark skin pigmentation**. The U.S. Food and Drug Administration (FDA) is informing patients and health care providers that although **pulse oximetry is useful for estimating blood oxygen levels, pulse oximeters have limitations and a risk of inaccuracy under certain circumstances that should be considered.**

Updated Nov. 16, 2023 - [Link](#)



Published May. 21, 2022 - [Link](#)



Updated Nov. 16, 2023 - [Link](#)

# “Breath Holding” Testing Protocol

## Primary Objective

Assess whether the Know Labs’ sensor can accurately monitor blood oxygen saturation levels

## Rationale

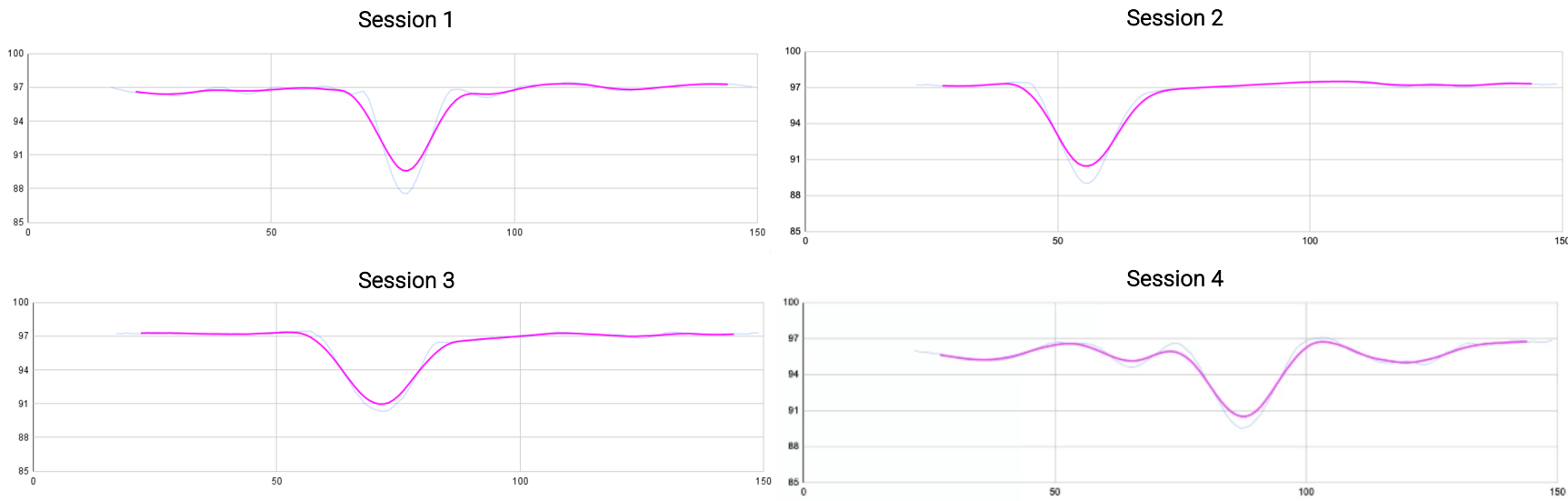
- The first thing that happens when you hold your breath is oxygen levels decrease. This is followed by an increase in carbon dioxide levels. After a minute or two, your cells start to behave differently. (WebMD: [What happens when you hold your breath?](#))
- By running a short breath-hold test with a protocol that eliminates other variables, the main hypothesis to be tested is if the sensor can capture one of the events listed above

## Protocol

- Participant’s oxygen saturation level is captured in real-time through a medical SpO2 device
- Participant rests forearm on Know Labs’ sensor
- Participant breathes normally for 90 seconds so the sensor can capture the signal baseline
- Participant holds their breath for 20 to 30 seconds
- Participant resumes normal breathing
- Participant remains still throughout the entire test (roughly 150 seconds)

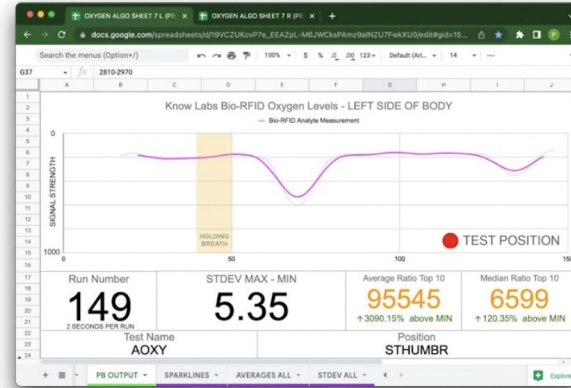
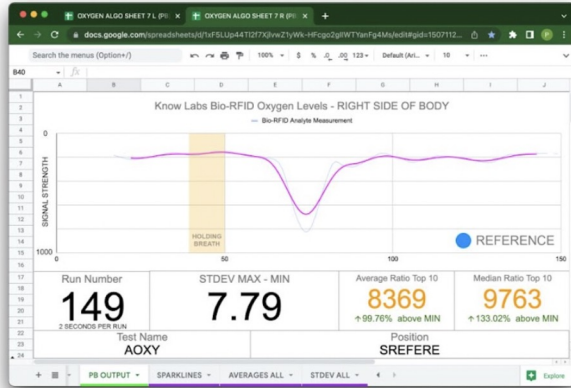
# Preliminary Results: Breath Holding Event Capture

— Sensor Processed Signal  
— SpO2 Value [%]



The product team has conducted roughly 1,000 “Oxygen” tests on users with different racial and gender identities. These tests have been repeatable, reliable, and successful across this diverse set of participants, with no latency and good correlation to SpO2 readings.

# Preliminary Results: Different Locations in the Body



DATA FILE: 20220707\_172512\_AOXY\_U0000000001\_SREFERE\_ST0010.00\_RAW01\_000\_DR0000.csv  
DATA FILE: 20220707\_172514\_AOXY\_U0000000001\_STHUMBR\_ST0010.00\_RAW01\_000\_DL0000.csv  
(PROPRIETARY INFORMATION - DATA NOT SUPPLIED)

The Know Labs' sensor is designed to work on multiple locations on the body and in any form factor. The sensor has performed with accurate and reliable results in

11 different testing locations on the body

# Conclusions & Next Steps

- It is premature to affirm that Know Labs' technology can accurately identify and monitor blood oxygen saturation levels, primarily because breath holding may initiate several events in the human body, such as oxygen level decrease, carbon monoxide levels increase, blood pressure increase, nitrogen narcosis, and low heart rate
- However, considering the format and length of the test (20s to 30s of breath holding) and the good correlation of the signal with a medical SpO2 device, it is reasonable to affirm that
  - Know Labs' sensor can monitor an event associated with breath-holding
  - Initial evidence implies the event monitored is the blood oxygen saturation level fluctuation
- Additional testing is required to confirm these preliminary findings and hypotheses. Still, the results are promising, as Know Labs' technology could address many of the issues currently experienced with photonics-based devices or pulse oximeters and provide an affordable alternative to the current "monopoly" held by them
- Know Labs remains focused on the development of its blood glucose monitoring devices. An oxygen monitoring application will be pursued when additional resources are available. In the meantime, Know Labs has built relevant IP covering this application.

# THANK YOU

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