Original Article

Journal of Diabetes Science and Technology
1–8

DOI: 10.1177/19322968261447289
journals.sagepub.com/home/dst
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Workshop on Noninvasive Glucose Monitoring 2025

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Abstract

This second workshop on noninvasive glucose monitoring was held at the Massachusetts Institute of Technology (MIT) on November 5, 2025 (https://sites.mit.edu/nigm-workshop). Eleven invited speakers, representing industry, academia, clinical practice, and regulatory affairs, gave presentations that covered (1) an overview of the noninvasive glucose monitoring technologies; (2) the state of the art in noninvasive glucose monitoring technologies, such as Near-Infrared (NIR), photoacoustic, photothermal, and Raman spectroscopies; (3) a clinician's perspective on the impact of the current continuous glucose monitoring devices for patient care; and (4) regulatory considerations. Four posters were also presented by junior researchers in the field.

Keywords

accuracy, blood glucose, blood glucose meter, continuous glucose monitoring, noninvasive glucose monitoring, self-monitoring of blood glucose

Introduction

On November 5, 2025, the MIT Laser Biomedical Research Center hosted its second workshop on noninvasive glucose monitoring (Figure 1) that attracted about 80 attendees from diverse backgrounds including:

- Companies currently developing the next-generation glucose monitoring sensors;
- Companies currently producing continuous glucose monitoring sensors;
- Academic researchers;
- Clinicians who are using the current continuous glucose monitoring sensors for patient care;
- Regulatory experts;
- Related biotech and consumer electronics companies;
- Students and junior researchers who have an interest in this field;
- Potential investors and venture capital organizations.

Below is the agenda for the workshop. This report summarizes the key points of each presentation.

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Figure 1. Group photo.

8:00 to 8:20 Reception

8:20 to 8:30 Opening Remarks (Prof. Peter So and Dr. Jeon Woong Kang, MIT)

8:30 to 9:10 James Causey (Simimed): Sweet Dreams: Noninvasive (Electromagnetic) Glucose Measurement and Monitoring

9:10 to 9:50 Prof. Devin Steenkamp (Boston Medical Center): Challenges with Current CGM Technology

9:50 to 10:30 Sung Park (Reed Smith LLP): FDA's Evolving Digital Health Framework and Practical Implications

10:30to 10:45 Coffee break

10:45 to 11:25 Prof. H. Michael Heise (South Westphalia University of Applied Sciences): Near-infrared Spectroscopy Methods for a Non-invasive Blood Glucose Assay Based on Skin Reflection Measurements—Contributions to the State of Current Diabetes Technology Research

11:25 to 12:05 Dr. Anders Weber (RSP Systems): Meeting the Performance Requirements for Spectroscopy-Based Noninvasive Glucose Sensors

12:05 to 12:45 Prof. Vasilis Ntziachristos (Technical University of Munich & Helmholtz Zentrum München): Advancements in Noninvasive Blood Glucose Monitoring Using Depth-Gated Mid-Infrared Optoacoustic Sensing

12:45 to 1:20 Lunch

1:20 to 2:00 Jean-Guillaume Coutard (Independent Consultant, Former CTO of Eclypia): Lessons Learned from the Development of NI-CGM Using QCL-Based Mid-Infrared Photoacoustic Spectroscopy

2:00 to 2:40 Apurv Kamath (Dexcom): From BGM to CGM. The Techno-Clinical-Economic Drivers of Change. A Personal View

2:40 to 3:20 Prof. Ishan Barman (Johns Hopkins University): Vascularized Skin-Mimetic Phantoms for Advancing Noninvasive Glucose Monitoring

3:20 to 3:35 Coffee break

3:35 to 4:00 Prof. Werner Mäntele (DiaMonTech): Clinical Validation of Noninvasive Blood Glucose Measurements by Mid-infrared Spectroscopy

4:00 to 4:25 Dr. Miyeon Jue (Apollon): Development and Validation of a Noninvasive Continuous Glucose Monitoring System Using Raman Spectroscopy

4:25 to 4:35 Closing remarks

Poster presentations:

Lorenza Pia Foglia (DTU): Glucose Detection in Liquids with THz-ATR Spectroscopy: A Comparative Study of the Matrix Effect

Elyse Moores (MIT): Automated System for Production of Liquid Tissue Phantoms to Test Optical, Noninvasive Glucose Monitors

Kasey Shashaty (MIT): Toward Real-time Noninvasive Transdermal Glucose Sensing via Stimulated Raman Scattering (SRS)

Murat Yessenov (Harvard): Miniature Spectrometers for Raman Spectroscopy Using Rotated Chirped Bragg Grating

Sweet Dreams: Noninvasive (Electromagnetic) Glucose Measurement and Monitoring Noninvasive Glucose Sensing: The Challenges, Opportunities, and Progress

James Causey (Simimed)

Noninvasive glucose monitoring using electromagnetic methods holds strong conceptual appeal but faces significant scientific and regulatory barriers that challenge near-term replacement of existing technologies. Current standards—self-monitoring of blood glucose (SMBG) and continuous glucose monitors (CGMs)—are highly accurate, widely adopted, and supported by rigorous regulatory frameworks. In contrast, no noninvasive device has achieved Food and Drug Administration (FDA) clearance for direct glucose measurement, and the agency has explicitly warned against consumer devices that claim to do so. The core technical limitation lies in the inability to achieve both sensitivity and specificity: while signals correlated with glucose can be detected, isolating glucose from other biological variables remains a fundamental physics challenge, particularly in wearable, real-world conditions.

Regulatory expectations further compound these challenges. Clinical-grade glucose monitoring, in the United States, requires strict adherence to standards such as ISO 15197:2013 and FDA pathways like 21 CFR 862.1355, which demand high accuracy and reliability for therapeutic decision-making. Metrics such as Mean Absolute Relative Difference (MARD), often used in early-stage development with SMBG as reference devices, can be misleading when compared to validated clinical systems. Historical efforts, including partially-successful systems, demonstrate that even technically promising approaches can fail due to regulatory classification, usability constraints, and investor withdrawal. As a result, pursuing a direct, noninvasive replacement for SMBG or CGMs for intensive glucose management is currently impractical from both a technical and commercial standpoint.

A more viable strategy is to reposition noninvasive sensing technologies toward adjunctive or general wellness applications. Rather than attempting to deliver precise glucose measurements for clinical use, these systems can provide trend-based insights into metabolic activity, supporting lifestyle decisions related to diet, exercise, and overall health. The general wellness category offers a lower regulatory barrier in the United States, provided that no explicit medical claims are made. Emerging regulatory pathways, such as recent De Novo classifications, may eventually expand opportunities, but near-term success depends on aligning product design with achievable performance and appropriate market positioning.

Challenges With Current CGM Technology

Devin Steenkamp, MD (Boston University)

Continuous glucose monitoring (CGM) is regarded as the standard of care for individuals living with type 1 diabetes (T1D) and type 2 diabetes (T2D) who are using insulin therapy. CGM has revolutionized the approach to intensive diabetes management through three major advancements: (1) supporting intensive insulin use with improved hypoglycemia mitigation; (2) providing real-time and retrospective opportunities for patients and their clinicians to review personalized glycemic data to refine treatment, address behavioral challenges, and relate glycemic metrics to the lived experience of the user; (3) underpinning increased adoption of automated insulin delivery systems that modulate insulin delivery based on CGM-derived glucose inputs.

However, despite all the advancements in the field over recent decades, current CGM technology remains limited by important dermatological, environmental, device accuracy, and financial challenges. Major limitations include (1) short wear-time, which ranges from 7 to 15 days for the most commonly worn on-body sensors; (2) the need for durable on-body adhesion, which can result in skin conditions, including allergic or irritant contact dermatitis and risk of sensor dislodgement[1]; (3) interstitial glucose trajectory "lags" behind capillary glucose and tends to be less representative of true glycemic status in the first 12 to 24 hours of sensor wear. Furthermore, subcutaneously inserted sensors are susceptible to compression artifact, resulting in spurious hypoglycemia, most commonly occurring in the nocturnal period.[2] (4) Long-term sensor applications have a significant financial and environmental cost given that applicators and sensors are all disposable.[3] Future-generation CGM technology needs to improve upon these shortcomings while improving on usability and accuracy.

FDA's Evolving Digital Health Framework and Practical Implications

Sung Park (Reed Smith LLP)

The presentation outlines the evolving regulatory and legal landscape surrounding digital health and noninvasive medical technologies, with a focus on glucose monitoring innovation. It emphasizes that the definition of a medical device, broadly interpreted by the US Food and Drug Administration (FDA), encompasses not only hardware but also software functions intended for diagnosis, treatment, or prevention of disease. While the digital health market continues to expand rapidly, attracting significant investment and innovation, the medical device regulatory framework, which was originally established in 1976, has struggled to keep pace with emerging technologies. This has led to inconsistencies in interpretation, reliance on guidance documents, and increasing uncertainty for developers navigating approval pathways such as De Novo classification and 510(k) clearance.

A central theme is the tension between innovation and regulatory enforcement, particularly in borderline areas such as general wellness products and clinical decision support software. Case studies, including enforcement actions against certain new entrants to the market, illustrate how FDA may classify seemingly wellness-oriented features as medical devices if they imply diagnostic use. The agency has demonstrated a willingness to aggressively enforce its interpretations, even against well-known companies, reinforcing the importance of carefully defining product intent and claims. These actions highlight the risk that "bad facts make bad precedents," potentially shaping stricter oversight across the industry and creating additional barriers to innovation.

To succeed in this complex environment, companies must strategically align product development and commercialization with regulatory expectations. This includes understanding which features may trigger FDA jurisdiction, evaluating the necessity and timing of regulatory approval, and addressing the concerns of investors and partners who prioritize speed to market and risk mitigation. While opportunities remain strong (particularly in areas like workflow tools and digital health platforms), developers must balance innovation with compliance, avoid high-risk claims, and continuously monitor regulatory developments. Ultimately, success depends on a proactive, informed approach to navigating regulatory risks while advancing technologies that meet both market demand and legal requirements.

Near-Infrared Spectroscopy Methods for a Noninvasive Blood Glucose Assay Based on Skin Reflection Measurements—Contributions to the State of Current Diabetes Technology Research

H. Michael Heise (South Westphalia University of Applied Sciences)

Sensor research in the field of diabetes technologies has recently made enormous progress. In particular, invasive electrochemical sensors are available for people with diabetes which allow continuous measurement of glucose concentration in subcutaneous adipose tissue, but with limited duration of use and associated costs. For many years, optical vibration spectroscopy-based measurement systems have been proposed for noninvasive, reagent-free ("green") blood glucose analysis via skin measurements, but their applicability for people with diabetes so far has not yet been established due to insufficient measurement accuracy. An overview of the state of the art, especially based on near-infrared spectroscopy including the short-wave near-infrared region, will be provided with a focus on the results of our own working group, also from recent studies based on skin phantoms, with details in particular on the measurement technology used, limitations, and performance.

Meeting the Performance Requirements for Spectroscopy-Based Noninvasive Glucose Sensors

Anders Weber (RSP Systems)

Spectroscopy-based sensors for diabetes management must be designed to withstand the rigors of practical use, while maintaining adequate analytical quality. Particularly challenging is the building of prediction models that are impervious to interferences from a changing environment in general, and in particular from endogenous and exogenous substances present in varying amounts in the spectroscopic measurement volume in the skin.

The below sequence of developments performed at RSP Systems will be presented:

A. Basic development
   a. Device optimization through numerous hardware and prediction model iterations
   b. Separation (in time) of calibration and prediction
   c. Building and demonstrating robustness for real-world applications, for example, home use
B. Adaptation for manufacture
   a. Serial manufacture of 100+ devices, adapting prediction models to handle inter-device variability
   b. Enabling prediction model transfer from a data repository to naive devices
   c. Quantitating interference from substances in the skin

On this basis, RSP Systems has realized Raman devices for practically useful noninvasive glucose monitoring. Hardware specifications and prediction models have been based on an extensive framework of clinical data, with a particular focus on the development of spectral processing algorithms and multivariate model architectures.

Advancements in Noninvasive Blood Glucose Monitoring Using Depth-Gated Mid-Infrared Optoacoustic Sensing

Vasilis Ntziachristos (Technical University of Munich & Helmholtz Zentrum München)

Accurate and frequent blood glucose assessment is critical for effective diabetes management, but conventional finger-pricking methods remain uncomfortable and carry a risk of infection. While noninvasive glucose monitoring (NIGM) techniques offer promise as alternatives, most current approaches measure glucose indirectly in the interstitial fluid, where glucose dilution and differing glucose dynamics from blood limit their precision compared to direct blood analysis. In this talk, we present the depth-gated mid-infrared optoacoustic sensor (DIROS), designed to overcome these limitations by enabling noninvasive, depth-selective detection of glucose in blood-rich layers of the skin. DIROS employs time-gating strategies to localize optoacoustic signals at specific depths for improving measurement accuracy. Initial studies in mice demonstrated the principle of DIROS. Building on these promising results, we conducted the first pilot investigation of DIROS in healthy volunteers, and we demonstrate the first results using a multivariate modeling approach.

Lessons Learned From the Development of NI-CGM Using QCL-Based Mid-Infrared Photoacoustic Spectroscopy

Jean-Guillaume Coutard (Independent Consultant, Former CTO of Eclypia)

Continuous and noninvasive glucose monitoring remains a primary goal in the field of medical technology. This presentation aims to share the key learnings from an ambitious development project to create a wearable, noninvasive glucose monitoring device, from its initial design to clinical trials.

The technological approach was based on mid-infrared photoacoustic (PA) spectroscopy,[4] a technique renowned for its high sensitivity in detecting biomolecules.[5] For the first time, this method was integrated into a portable device designed for continuous monitoring on the human body. The light source utilized quantum cascade lasers (QCLs), chosen for their high power and room-temperature operation.

The development of this device, conducted under the ISO 13485 regulation for medical devices, was built on several key innovations:

- An optimized sensor: The core of the PA-QCL sensor was designed using a proprietary physical model to manage thermal and viscous losses and to optimize the optical path.[6]
- An "AI-First" approach: To guide the product development and to overcome the challenge of data collection, a "digital twin" was created. This tool[7] simulated the entire detection chain—from device properties to skin physiology—to generate a vast database of synthetic data. This data was crucial for training our artificial intelligence algorithms for glucose prediction.
- An industrial vision: A consistent focus was placed on cost reduction and mass production, notably through the fabrication of QCLs on a standard CMOS pilot line.[8]

Preliminary results from volunteers with and without diabetes demonstrated the relevance of the glycemic predictions, leading to the launch of a clinical trial with patients with type 1 diabetes.[9]

This presentation aims to discuss the challenges encountered and the successes achieved, offering insights into the potential and technological hurdles of PA spectroscopy for the future of noninvasive glucose monitoring.

From BGM to CGM. The Techno-Clinical-Economic Drivers of Change. A Personal View

Apurv Kamath (Dexcom)

How and why has continuous glucose monitoring (CGM) replaced episodic blood glucose monitoring (BGM) in the management of diabetes across much of the world?

What overlooked or underserved physiological or psychosocial needs have successive generations of CGM sought to meet?

What enabling technologies and innovations have catalyzed CGM adoption, and what patterns can be drawn from their integration and utilization?

Vascularized Skin-Mimetic Phantoms for Advancing Noninvasive Glucose Monitoring

Ishan Barman (Johns Hopkins University)

Noninvasive glucose monitoring remains one of the most persistent challenges in biomedical optics. Although Raman and near-infrared spectroscopy have shown promise in capturing glucose signatures transcutaneously, their clinical translation has been slowed by the absence of reliable, physiologically faithful testbeds that can emulate the intricate optical, mechanical, and biochemical milieu of human skin. Existing tissue phantoms typically reproduce bulk optical scattering but fail to capture metabolite diffusion, dynamic blood flow, and vascular heterogeneity—factors that critically shape photon propagation and analyte specificity.

In this talk, I will present our recent advances in developing vascularized, skin-mimetic optical phantoms that bridge this translational gap. Our agarose-based layered phantom replicates the hierarchical structure and viscoelasticity of skin while supporting physiologically relevant metabolite diffusion. By tuning agarose concentration, we matched the elastic moduli and stress-relaxation times of the dermis and epidermis. Fluorescence imaging using glucose analogs confirmed diffusion coefficients closely aligned with human dermal values (≈260-310 $\mu m^2/s$). The low Raman background of agarose enables accurate, label-free quantification of glucose and urea within physiological ranges ($R^2 > 0.9$), providing the first reproducible solid-state platform for Raman-based metabolite sensing.

Building upon this foundation, we developed VITRO-P (Vascular Integrated Tissue Replica Optical-Phantom), a generative-design framework that revolutionizes the creation of programmable, vascularized optical phantoms. Using a node-based computational pipeline implemented on the Grasshopper platform, VITRO-P constructs intricate vascular networks through a sequence of algorithmic steps: (1) placement of user-defined branching nodes; (2) attraction-based spatial organization to mimic physiological vessel density gradients; (3) Voronoi tessellation to introduce natural heterogeneity; and (4) iterative elimination of blind ends and dynamic assignment of inlet/outlet boundaries to preserve flow continuity. The algorithm further adapts vessel tapering along flow paths and performs real-time path re-planning to avoid intersections with embedded inclusions (eg, bone or sensor modules). This computational generative design allows on-demand tailoring of vascular geometry, density, and connectivity—transcending the static nature of

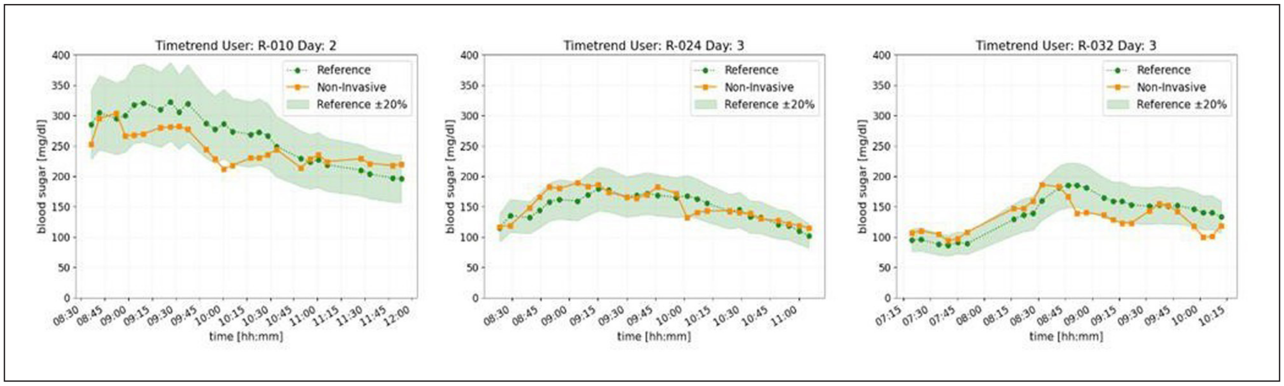

Figure 2. Exemplary time course of blood/tissue glucose for three individuals (R-010: type 2 diabetes patient, R-024: type 1 diabetes patient; R-032: healthy volunteer).

patient-derived vascular models and enabling reproducible exploration of interindividual variability.

The computationally generated architectures are fabricated using 3D-printed, water-soluble sacrificial molds, allowing rapid, leak-free embedding of vascular networks within agarose, Polydimethylsiloxane (PDMS), or silicone matrices. The resulting phantoms sustain pulsatile flow up to 58 mL min^{-1} for over three weeks, maintaining physiological flow velocities (40-250 mm s^{-1}) comparable to human fingertip arteries. By coupling mechanical and optical realism with generative vascular complexity, VITRO-P enables the first platform capable of simulating tissue heterogeneity and hemodynamics critical for evaluating transcutaneous glucose sensors.

Beyond its direct application to noninvasive glucose monitoring, VITRO-P represents a paradigm shift in how synthetic tissues are designed—transforming phantom fabrication from a laborious, static process into a computationally programmable and data-driven endeavor. Its generative approach not only provides standardized yet tunable benchmarks for optical device validation but also generates large design datasets for training physics-informed machine learning models that predict light-tissue interactions.

Together, these works establish a unified ecosystem for rigorous, reproducible evaluation of optical sensing technologies. They create a translational bridge between algorithmic design, physical fabrication, and in vivo relevance—paving the way toward clinically robust, calibration-free, noninvasive glucose monitoring and beyond.

Clinical Validation of Noninvasive Blood Glucose Measurements by Mid-Infrared Spectroscopy

Werner Mäntele (DiaMonTech)

Background: Noninvasive glucose monitoring (NIGM) is considered the holy grail of diabetes technology. Currently, diabetes is predominantly managed based on finger pricking and analysis of a drop of blood with test strips fitting into a glucometer. This invasive, painful, and uncomfortable procedure is one of the reasons for insufficient diabetes management. Sensors for continuous glucose monitoring (CGM) in interstitial fluid (ISF) using a subcutaneous microscopic filament present a minimally-invasive alternative. A true NIGM for the diabetes patient is not available yet despite intense research and development.

Methods: DiaMonTech has demonstrated an NIGM technology that targets glucose in ISF. An infrared beam from a quantum cascade laser excites glucose molecules at wavelengths between 8 and 12 µm, where glucose has specific fingerprint absorbance. Absorption results in a small amount of heat in the skin, which is detected on the surface using a proprietary photothermal deflection technique. This procedure is painless, harmless, and does not require consumables.

Results: For clinical validation at the Institut für Diabetes Technologie (IfDT) at Ulm (Germany), a table-top prototype of the noninvasive glucometer (D-Base) was used. In a single-center clinical test with 36 individuals, the accuracy of the NIGM device was evaluated in two subsequent sessions per individual, with different amounts of calibration data (Figure 2).

The NIGM measurements closely follow the general shape (absolute values and trend) of the invasive reference curve and are well within the acceptable band. Four different algorithms were tested for data analysis. The accuracy for the best algorithm, expressed as Mean Absolute Relative Difference (MARD), was 20.7% and 19.6% for the two sessions. The data indicate that a reliable NIGM is possible with a minimal amount of three invasive calibrations on day 1 valid for a period of one week or more (Figure 3).

Conclusions: This is equivalent to the performance of early CGM systems cleared by the Food and Drug Administration (FDA) for adjunctive use by people with diabetes. It demonstrates that glucose can be reliably measured with this noninvasive technology and opens new perspectives for a better management of diabetes. DiaMonTech has already miniaturized optics and electronics toward a

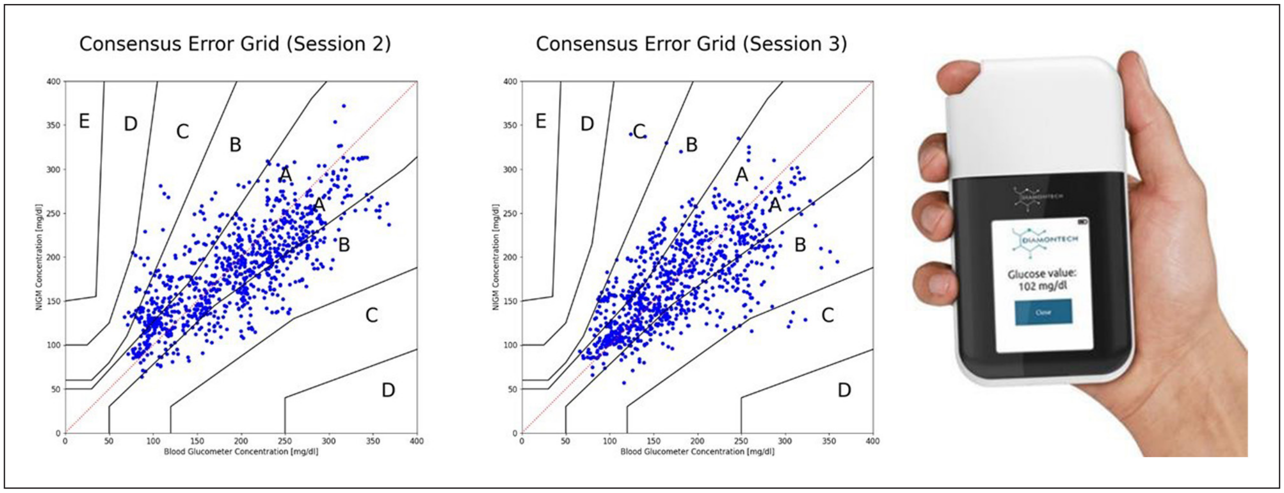

Figure 3. Consensus Error Grid (CEG) analysis and D-pocket.

handheld version "D-Pocket." The detection method in the D-Pocket is essentially the same as that in D-Base. The D-Pocket has the footprint of a common smartphone. It is currently a prototype under development. The D-Pocket is planned as an individual companion for the people with diabetes, with the capacity for 30 to 50 measurements with one battery charge. Go-to-market is planned for mid-2026.

Development and Validation of a Noninvasive Continuous Glucose Monitoring System Using Raman Spectroscopy

Miyeon Jue (Apollon)

Apollon Inc. (Seoul, Korea) is developing a noninvasive continuous glucose monitoring (CGM) system based on band-pass Raman spectroscopy.[10,11] This approach enables selective detection of glucose signals from interstitial fluid beneath the skin without the need for blood sampling or sensor insertion.

Building on our previous research, Apollon has fabricated a first-generation prototype device for clinical studies and is currently conducting validation experiments, while also pursuing miniaturization for practical use.

Phantom studies have demonstrated a strong correlation between glucose concentration and Raman signals, confirming the accuracy and reproducibility of the method. Preliminary human studies further showed promising signal-to-noise characteristics, supporting the feasibility of clinical application.

Further small-scale clinical trials with healthy participants under standardized fasting and glucose challenge protocols are planned to evaluate device performance.

These results highlight the potential of Raman-based technology for noninvasive glucose monitoring. Apollon aims to advance this approach toward a reliable and user-friendly CGM system that can improve convenience and accessibility in diabetes management.

Conclusion

This report summarizes the efforts of several research groups from academia and industry on noninvasive glucose monitoring. They represent only a small fraction of the many groups working in this field. Several technologies were presented, and challenges, opportunities, risks, and regulatory considerations were discussed. The workshop's presentations covered (1) an overview of the noninvasive glucose monitoring technologies; (2) the state of the art in noninvasive glucose monitoring technologies, such as NIR, photoacoustic, photothermal, and Raman spectroscopies; (3) a clinician's perspective on the impact of the current CGM devices for patient care; and (4) regulatory considerations.

It is the successful second workshop where potential competitors "on the search for the holy grail" have gathered and freely exchanged information on methodologies, results, and clinical/regulatory considerations. As one outcome, a regular continuation of this workshop and the need for benchmarking metric have been agreed.

Abbreviations

CGM, continuous glucose monitoring; DIROS, depth-gated mid-infrared optoacoustic sensor; DM, diabetes mellitus; FDA, Food and Drug Administration; ISF, interstitial fluid; ISO, International Organization for Standardization; NIGM, noninvasive glucose monitoring; SMBG, self-monitoring of blood glucose; VITRO-P, Vascular Integrated Tissue Replica Optical-Phantom; YSI, Yellow Springs Instruments.

Acknowledgments

We would like to thank Elyse Moores for organizing the event and setting up the website.

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Funding

The authors disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This work was supported by National Institutes of Health (P41EB015871), Korea Technology and Information Promotion Agency for SMEs (TIPA) (No. RS-2025-25458481), MIT Laser Biomedical Research Center, Apollon, BaySpec, and Teledyne.

Declaration of Conflicting Interests

The authors declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: A.W. is a CEO of RSP Systems. V.N. is a founder and equity owner of Maurus OY, sThesis GmbH, Spear UG, Biosense Innovations P.C., and I3 Inc. J.W.K. and P.T.C.S. have received research support from Apollon. J.-G.C. is a former CTO of Eclypia. A.K. is a VP of Dexcom Inc. W.M. is a CSO of DiaMonTech AG. M.J. is a CTO of Apollon Inc. D.S. is a consultant for Abbott Diabetes Care and receives research funding, through his institution from diabetes technology companies including Abbott Diabetes Care, Insulet, Tandem Diabetes Care, and Sequel Med-Tech.

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