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Background and Unmet Need

Diabetes Mellitus is increasing at an unprecedented pace; more than half a billion people are living with diabetes worldwide. The disease affects men, women, and children of all ages in every country, and that number is projected to more than double to 1.3 billion people in the next 30 years, with every country seeing an increase¹. The latest, most comprehensive calculations show the current global prevalence rate is 6.1%, making diabetes one of the top 10 leading causes of death and disability.

Vigilance, typically provided by monitoring devices, is important for diabetes management. In addition to traditional glucose monitors, state-of-the-art continuous glucose monitoring devices include minimally invasive microneedle patches. However, these patches have been found to be uncomfortable and can irritate the skin. Some patients have also been found to be sensitive to the adhesive coating of the patch and some brands limit recommended use period to only 14 days.² Skin irritation, common among persons with diabetes, may also be exacerbated. In addition, these devices measure glucose variations in interstitial fluids. It is well known that glucose variation in interstitial fluids is delayed from glucose variation in blood. A delay that impacts the timely management of diabetes and can be dangerous in extreme scenarios³.

As result, there is a need for a product that offers the capabilities of commercially available continuous glucose monitor devices but may be more easily incorporated into the patient's everyday life and further reduce risk of skin irritation, while providing instantaneous readings that directly correspond to the variation of glucose in blood and without any delay.

Further, because of the prevalence of diabetes, the blood glucose monitoring device market is significant, having been valued at \$15.80 Bn in 2022 and expected to reach \$32.99 Bn by 2030, at a CAGR of 9.9%.⁴

Opportunity

Dr. Costantine and his team have developed non-invasive biomarker monitor sensors that utilize certain electromagnetic circuits comprising of flexible and wearable antennas and microwave components to provide a completely continuous and non-invasive solution to biomarker monitoring.

The Costantine technology enables continuous measurement of biological and chemical markers, including blood glucose. This technology may be integrated into multiple, diverse garments and accessories, including jewelry. With an accompanying mobile app, this technology will enable an easy-to-use and highly accurate biomarker monitoring system effortlessly integrated into the user's everyday life. The computing system developed in conjunction with this technology enables very accurate, selective, and highly sensitive readings to glucose variations.

While commercially available continuous glucose monitoring devices utilize microneedle patches, this technology is a completely non-invasive method and may be tailored to be worn on multiple regions of the body. The technology's highly scalable nature and compatibility with various areas of the body, enable its use in varied garments and accessories to offer a stylish, convenient, and concealed solution to glucose monitoring in persons with diabetes. Further, the device is perfect for monitoring young children and infants, as it may be incorporated into everyday garments, such as socks. Other examples include, but are not limited to, gloves, arm sleeves, necklaces, and earrings.

¹ The Lancet, *Global, regional, and national burden of diabetes from 1990 to 2021, with projections of prevalence to 2050: a systematic analysis for the Global Burden of Disease Study 2021.* Volume 402, Issue 10397, P203 -234, July 15, 2023.

² https://www.freestyle.abbott/us-en/safety-information.html

³https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3837059/#:~:text=We%20conclude%20that%20in%20the,space%20is%205–6%20min. ⁴ Blood Glucose Monitoring System Market Size., Fortune Business Insights, May 2023.

Because the device utilizes radio waves rather than micro needles, it eliminates the risk of skin irritation.

Finally, as this technology may be integrated into everyday garments or jewelry, it can enhance the privacy of the patient's health status.

Unique Attributes

- Highly scalable technology to be manufactured into multiple garments or worn accessories and / or jewelry.
- Completely non-invasive platform with continuous biomarker monitoring.
- Discrete monitoring device solution to enhance user privacy.

Clinical Applications

An over the counter, portable, non-invasive, and continuous glucose monitor device.

Stage of Development

Proof of concept and functional prototype, with individually protected components

Intellectual Property

- 1. "Wireless Contactless Continuous Biomarker Sensor and Its Methods of Use," USPTO Provisional Patent Application, April 2023.
- 2. "An Antenna Array or A Group of Antenna Elements for Biomarker Monitoring, Nerve Stimulations and Methods of Use," US 2022/0054087A1, published February 24, 2022. Also published in Canada, China, EP.
- 3. "Biomarker Monitoring Sensor and Methods of Use," US2022/0039682A1 Published February 10, 2022, Also published in Canada, China, EP. Inventors: **J. Costantine**, R. Kanj, A. A. Eid, M. Bteich, Y. Tawk, A. H. Ramadan
- "Antenna Design for Biomarker Monitoring and Methods of Use," US Patent US 11,134,860 B2, Issued October 5 2021, also issued in China and published in Canada. Inventors: J. Costantine, R. Kanj, A. A. Eid, J. Hanna, A. Ramadan, Y. Tawk
- "Novel Non-Invasive Biological, Chemical Markers and Tracers Monitoring Device in Blood Including Glucose Monitoring Using Adaptive RF Circuits and Antenna Design," US Patent US 11,197,612 B2, Issued December 14, 2021, also published in China. Inventors: J. Costantine, R. Kanj, and A. A. Eid

Collaboration Opportunity

Seeking licensee for commercialization or collaboration to advance preclinical development.

References and Publications

- J. Hanna, Y. Tawk, S. Azar, A. H. Ramadan, B. Dia, E. Shamieh, S. Zoghbi, R. Kanj, J. Costantine, and A. A. Eid, "Wearable Flexible Body Matched Electromagnetic Sensors for Personalized Non-Invasive Glucose Monitoring," Scientific Reports, Vol 12, no. 1, pp. 14885, Sep. 2022.
- M. Bteich, J. Hanna, J. Costantine, R. Kanj, Y. Tawk, A. H. Ramadan, and A. A. Eid "A Non-Invasive Flexible Glucose Monitoring Sensor Using a Broadband Reject Filter," in *IEEE Journal of Electromagnetics, RF and Microwaves in Medicine and Biology*, vol. 5, no. 2, pp. 139-147, 2021.
- *J. Hanna, M. Bteich*, Y. Tawk, A. H. Ramadan, *B. Dia*, *F. A. Asadallah, A. Eid*, R. Kanj, **J. Costantine**, and A. A. Eid, "Non-Invasive, wearable, and tunable electromagnetic multi-sensing system for continuous glucose monitoring mimicking vasculature anatomy," *Science Advances*, Vol 6, No 24, eaba5320, June 2020.
- Forbes: https://www.forbes.com/sites/helenalbert/2020/06/13/gloves-arent-just-for-covid-19-this-one-can-be-used-to-help-diabetes-patients/#f81b1451380b
- Nature Middle East: <u>https://www.natureasia.com/en/nmiddleeast/article/10.1038/nmiddleeast.2020.63</u>
- Science Breaker: <u>https://www.thesciencebreaker.org/breaks/health-physiology/ediamond-a-life-changing-glucose-monitoring-solution-for-diabetics</u>

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