

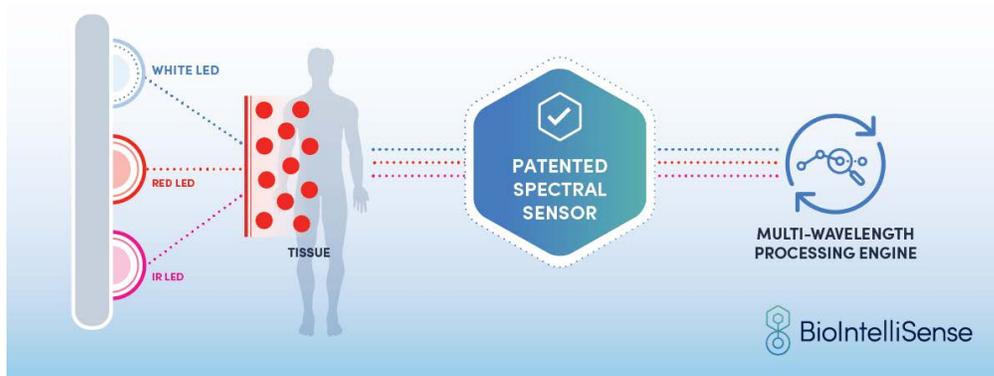
## BioIntelliSense Launches Patented, FDA-cleared Pulse Oximetry (SpO<sub>2</sub>) Sensor Technology that Addresses Skin Pigmentation and Motion Monitoring Challenges

- Breakthrough pulse oximetry (SpO<sub>2</sub>) optical sensor solution offers medical-grade accuracy of oxygen level measurement across skin tones and while in motion
- Patented SpO<sub>2</sub> sensor chipset, integrated processing and reference design capability to power the next generation of medical and consumer wearable devices

DENVER, November 1, 2022 – [BioIntelliSense](#), a continuous health monitoring and clinical intelligence company, today announced the launch of its patented, FDA-cleared, pulse oximetry (SpO<sub>2</sub>) sensor chipset and integrated processing technology that accurately measures blood oxygen levels across the full range of light to very dark skin pigmentation, as well as during movement and activity. These capabilities represent a significant advancement in the field of oximetry which has historically been challenged by reduced accuracy during activity and in people with darker skin.<sup>1,2,3,4</sup> BioIntelliSense’s pulse oximetry (SpO<sub>2</sub>) technology enables SpO<sub>2</sub> monitoring anywhere, anytime, whether in clinical settings, at home, or beyond.

“Addressing these foundational skin pigmentation and motion challenges in the measurement of blood oxygen levels is transformative for the pulse oximetry category and allows for the democratization of this advanced technology across consumer and medical grade devices,” said James Mault, MD, founder and CEO of BioIntelliSense. “This is a significant milestone in providing clinically accurate SpO<sub>2</sub> measurements across diverse patient populations which may contribute to improving healthcare equity.”

### Breakthrough-enabling technology



The BioIntelliSense sensor and processing solution is a patented technology, which received FDA 510(k) clearance as the SpO<sub>2</sub> technology component in a finger-based monitor in 2021.<sup>5</sup> Unlike traditional red and infrared LED architectures, this technology additionally employs a white light emitter, combined with a novel spectral sensor.

The sensor’s oximetry signal processing is designed with an extended dynamic range, maximizing the optical front-end performance, even with very small modulations due to darker skin pigmentation. BioIntelliSense’s solution also continuously adjusts each emitter intensity of the perfused tissue in real time, compensating for higher absorption levels in darker skin tones by increasing tissue illumination. In multiple clinical hypoxia studies, with and without motion protocols, the BioIntelliSense SpO<sub>2</sub> solution has demonstrated consistent accuracy, exceeding ISO standard 80601-2-61:20171 for darkest skin tones – on par with light skin tones – including at low oxygen saturation ranges.



This patented SpO<sub>2</sub> chipset technology, integrated processing and reference design capability uniquely positions BioIntelliSense to enable the next generation of medical and consumer wearable devices that overcome historical challenges in accurate pulse oximetry measurement.

### Wearable and channel partnerships

BioIntelliSense is actively collaborating with the Medtronic Patient Monitoring business, one of the global pulse oximetry market leaders. Today, Medtronic Patient Monitoring solutions touch more than 100 million patients annually in hospitals. As recently announced, BioIntelliSense entered into an exclusive strategic partnership with Medtronic for the U.S. hospital distribution rights of the BioButton® multi-parameter wearable for continuous, connected monitoring.

“By leveraging our extensive reach and commercial channels, the Medtronic Patient Monitoring business is excited to work together with our partners at BioIntelliSense to expand access to meaningful technologies to patients anytime, anywhere,” said Frank Chan, Ph.D., president of the Patient Monitoring business, which is part of the Medical Surgical Portfolio at Medtronic.

In addition, licensing agreements have been executed with [LifeSignals](#) and [Biostrap](#) to integrate the BioIntelliSense SpO<sub>2</sub> sensor chipset and integrated processing solution into their medical grade wearable device solutions.

BioIntelliSense will be participating in today's [“FDA Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee regarding Pulse Oximetry.”](#)

### REFERENCE

1. US Food & Drug Administration. Pulse oximeter accuracy and limitations: FDA safety communication. Accessed October 28, 2022. <https://www.fda.gov/medical-devices/safety-communications/pulse-oximeter-accuracy-and-limitations-fda-safety-communication>
2. Sjoding MW, Dickson RP, Iwashyna TJ, Gay SE, Valley TS. Racial bias in pulse oximetry measurement. *N Engl J Med.* 2020;383(25):2477-2478.
3. Keller MD, Harrison-Smith B. Skin colour affects the accuracy of medical oxygen sensors. *Nature.* 2022; 610: 449-451.
4. Torp KD, Modi P, Simon LV. Pulse oximetry. In: *StatPearls.* Treasure Island, Florida: StatPearls Publishing; 2022. Accessed October 28, 2022. <https://www.ncbi.nlm.nih.gov/books/NBK470348/>
5. FDA clearance K200160, cleared on 02/15/2021.

### About BioIntelliSense

BioIntelliSense is ushering in a new era of continuous health monitoring and clinical intelligence for remote patient monitoring (RPM). Its medical-grade Data-as-a-Service (DaaS) platform seamlessly captures multi-parameter vital signs, physiological biometrics and symptomatic events through an effortless patient experience. The medical-grade BioButton® wearable device makes remote monitoring and early detection simple. Through the platform's advanced analytics, clinicians have access to high-resolution patient trending and reporting to enable medical grade remote care from in-hospital to home.

For the latest news and information on how BioIntelliSense is making early detection simple™ through medical-grade wearable technology and cost-effective data services, visit our website at [biointellisense](#). Follow BioIntelliSense on [Twitter](#) and [LinkedIn](#) for the latest news and information.

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