Physiological Monitoring for Emergency Responders

Market Survey Report

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FOREWORD

The U.S. Department of Homeland Security (DHS) established the System Assessment and Validation for Emergency Responders (SAVER) program to help emergency responders improve their procurement decisions.

Located within the Science and Technology Directorate (S&T), the Nation Urban Security Technology Laboratory (NUSTL) manages the SAVER program and conducts objective operational assessments of commercial equipment and systems relevant to the emergency responder community.

The SAVER program gathers and reports information about equipment that falls within the categories listed in the DHS Authorized Equipment List (AEL).

SAVER publications focus on answering two main questions: "What equipment is available?" and "How does it perform?"

SAVER knowledge products are created for the nation's first responders and made available to help them make operational and procurement decisions. NUSTL works with stakeholders to identify and prioritize project topics that address emergency responder needs, develops SAVER knowledge products, and coordinates with other organizations to leverage appropriate subject matter expertise. By ensuring federal, state, and local responders are prepared to make operational and procurement decisions, the program also serves as a cost-saving asset to DHS.

NUSTL also provides expertise and analysis on a wide range of key subject areas, including chemical, radiological, nuclear, and explosive weapons detection; emergency response and recovery; and related equipment, instrumentation, and technologies. Under the SAVER program, NUSTL in conjunction with DHS S&T's Operational Experimentation, conducted a market survey of commercially available physiological monitoring systems for emergency responders. This equipment falls under AEL reference number 01ZA-01-PPMS, titled "Personnel Physiological Monitoring System."

For more information on NUSTL's SAVER program and physiological monitoring systems or to view additional reports on other technologies, visit: www.dhs.gov/science-and-technology/SAVER.

U.S. Department of Homeland Security

SAVER

System Assessment and Validation for Emergency Responders

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EXECUTIVE SUMMARY

Physiological monitoring systems support emergency responder safety. First responders experience significant physiological stress during response operations, especially those of prolonged duration, or those requiring short bouts of exertion under high heat conditions, including exposure to a myriad of health hazards. Small sensors worn by responders, which can transmit physiological data to remote locations, can provide incident command with information about an individual responder's health status. Improved awareness of physiological factors helps incident command make decisions that increase responder safety. Currently, these systems for monitoring emergency responders do not appear to be in widespread use. In light of their benefits, however, they may become more prevalent in time. This report is intended to inform organizations that plan to purchase physiological monitoring systems about the features available on products in the current marketplace, so that they can select the system that best suits their needs.

The National Urban Security Technology Laboratory (NUSTL), through its Systems Assessment and Validation for Emergency Responders (SAVER) program and with the support of the DHS S&T Operational Experimentation Program, conducted a market survey of physiological monitoring systems for first responders. Information was gathered from a "technology scouting request" submitted to the DHS S&T Technology Scouting and Transition group in June 2020; a government-issued request for information posted on the System for Award Management website in August 2020; a SAVER focus group of first responders held in October 2020; and independent market research conducted from May 2020 through April 2021.

The market survey identified 15 commercially available physiological monitoring systems. All of the products in this report are capable of measuring and transmitting physiological parameters in near real-time; alerting, notifying, or providing status updates to remotely located staff of any conditions deemed an immediate health concern; functioning under extreme environmental conditions typically experienced by first responders; continually monitoring both heart rate and body temperature; and are available for purchase. NUSTL has not independently verified the information provided about, nor the performance of these products.

Nearly half the products listed in this report employ single-use patches that stick to the wearer's chest; the remainder have reusable wrist or arm bands, chest harness or upper body garments, a reusable chest patch design and an in-ear device sensors. There is a multitude of parameters that they measure in addition to heart rate and body temperature. More common measures for these devices include respiration rate, heart rate variability, electrocardiogram, and activity or movement. The battery life of the products varies but most of them could be used for the duration of a typical emergency responder work shift and could be used for long-term monitoring. Only two of the products had a battery life of less than 24 hours.

Costs associated with these products were obtainable from the vendor for only eight of the fifteen products; prices for additional products were identified by consulting third-party sources. For those products that operate with single-use sensors, the price ranges from $20 to $150 each. For those products that are reusable, the range is $450 to $6,000. Many, though not all, of these products also require recurring subscription and/or service fees.

Emergency response agencies that consider purchasing physiological monitoring systems should carefully research each system's overall capabilities and limitations and technical specifications in relation to their agency's operational needs. Users should seek information outside of, and in addition to, this report to help determine the current market as the report gets further from its published date.

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1.0 INTRODUCTION

The System Assessment and Validation for Emergency Responders (SAVER) program conducted a market survey on commercially available physiological monitoring products to provide first responders with information on these technologies. Physiological monitoring systems can measure and track vital signs of emergency responders such as heart rate, respiratory rate and body temperature. These systems can be used to infer a responder's health status and prevent injuries during incident response, routine duty shifts, training, and rehabilitation prior to reentry to an incident scene. Physiological monitoring sensors are wearable, non-invasive monitoring devices. Physiological sensors may be integrated into a shirt, a wristband, an adhesive patch or other form factors, and transmit data to a smartphone or a cloud server for viewing by other users, such as incident commanders. Use cases for physiological monitoring systems considered in this report are scenarios in which emergency responders have long response times, operate under strenuous work conditions, or both.

This market survey report (MSR) is based on information gathered from May 2020 to April 2021. Information sources included vendor websites, internet research, industry publications, a report from the DHS S&T Technology Scouting and Transition group, and a government-issued request for information that was posted on the System for Award Management website in August 2020. Additional information was obtained from the vendors through April 2021.

For inclusion in this report, each physiological monitoring technology had to meet the following criteria:

- Provides real-time monitoring of physiological conditions (e.g., temperature, heart function) with the ability to wirelessly transmit to and view the associated data on remote displays in real time
- Reports heart or pulse rate and body temperature (either skin or core body temperature)
- Alerts, notifies or provides updates to remote users (such as incident command) of potential health concerns for remote wearers based on physiological conditions measured
- Operates under environmental conditions experienced by first responders in the performance of their duties
- Available to emergency responder organizations as a commercial off-the-shelf (COTS) or government-off-the-shelf (GOTS) product

A comprehensive market analysis and market research was performed to develop a report that is representative of products in the marketplace. A large proportion of the products that meet the above criteria were developed for fitness and medical applications and not specifically for first responder use, but nonetheless could be considered for first responder applications and are included in this report.

2.0 PHYSIOLOGICAL MONITORING SYSTEMS OVERVIEW

Driven by advancements in battery power, wireless connectivity and physiological sensor technologies, physiological monitoring devices have become smaller, cheaper, and easily accessible to a variety of users. Physiological monitoring system manufacturers integrate sensors into multiple form factors, including smart fabrics, wristbands, chest straps and adhesive patches, that transmit data to be viewed by other users such as an incident commanders, health and safety officers, or rehabilitation officers.

2.1 Use Cases

Uses for physiological monitoring systems will vary by emergency responder agency. In general, they are intended to monitor the physical well-being of emergency responders during incidents. An incident commander may wish to have this information to help determine whether any individual responders should be checked on, given a rest period or pulled from the scene for further evaluation should the data suggest they are in physical distress. The most beneficial use cases will be for those responders in physically strenuous work conditions or when other high risks to a responder's health are present. Such responders include but are not limited to firefighters, hazmat technicians, search and rescue team members, and tactical law enforcement personnel. Ongoing monitoring may be considered for any responder over the course of their shift, not only for more active response scenarios that may raise health concerns.

2.2 Current Technologies

2.2.1 Sensors

Physiological monitoring sensors can be categorized as either single-use or reusable technologies. This MSR designates products as single-use or reusable technology based on the sensor.

Single-use technologies are designed to be disposed of after one use and are often used by only one user, for only one operational period or setting. Generally, they can be found at lower commercial price points. However, if single-use devices would need to be purchased regularly, their collective cost may exceed that of reusable devices. Single-use device battery life is typically longer than reusable ones. Reusable sensors are designed for multiple uses, with a battery that can be recharged or replaced. Generally, reusable technologies can be found at higher commercial price points. Fully charged reusable devices generally have a shorter battery life than single-use devices.

The sensors are also available in different form factors. Emergency responders may want to look for sensors that would easily and comfortably integrate with their standard uniform and would not hamper movement or motion nor interfere with their other equipment. Common form factors of physiological monitoring systems may include a vest, chest harness, wristband, armband or adhesive patch attached directly on the body. Depending on the model, single-use monitors generally require one to two physical contact points on the wearer's body in order to monitor physiological signs. These contact points are affixed with an adhesive substance. Reusable monitors, depending on the model, may require multiple physical contact points on the wearer's body to read physiological signs. As such, these products may come in the form of a chest strap, harness, wrist or arm band, or earpiece that may require more body coverage than a chest patch would provide.

2.2.2 Data Transmission and Viewing

Physiological monitoring systems transmit data in real-time or near real-time to enable effective triage. Most systems rely on wireless connections with portable third-party electronics, primarily cell phones, to capture and transmit the data to a cloud environment where it can then be accessed by remote users. In other instances, systems provide the electronic components that enable this capability. Agencies need to consider the type of external network connectivity used and coverage that exists in the intended use environments to ensure the systems would transmit data as needed. Systems may also archive data for future analyses so agencies can glean insights into responders' physiological reactions in a variety of situations. In most instances data is hosted in a virtual cloud or similar format that reduces the storage burden on responder agencies and is compliant with any relevant local, state and federal regulations related to data protection, encryption and storage. Some systems have local data storage capability on the sensors or integrated on-body electronics that can store the data when network connectivity is unavailable and perhaps transmit the data once a communication path is present. More information on applicable data standards is available in Section 2.3, Standards.

Physiological monitoring systems wirelessly transmit measured health data to a visualization dashboard platform that incident commanders can view in real-time. The data visualization platform is likely to be capable of displaying multiple users' data feeds at once. Many systems also support an intuitive "stoplight" visualization to signal responder health (e.g., red status for immediate danger, yellow for nearing danger thresholds, "green" for no danger) as well as providing additional alerts for concerns that the system's monitor may need to address immediately.

2.2.3 Cost Considerations

The cost of physiological monitoring systems can vary substantially depending on several factors including but not limited to the number of systems purchased, form factor, type of sensor (e.g., single-use versus reusable), battery type, system software and if any additional components or add-ons needed for operating the system. It is not unusual for the products to require subscription or service fees to enable the recurring use of software required for their system. Each department considering the purchase of a physiological monitoring system must keep in mind the cost of mass-deploying the product to its personnel.

2.2.4 Battery Features

The battery life of physiological monitoring sensors has improved in the last five years. Some products have battery life that can operate continuously for 24 hours, allowing for round the clock monitoring. Emergency responders may want to select sensors that can function continuously for a minimum of six hours or critical incident response. Many products in this report have internal batteries that are not replaceable. Some reusable physiological monitoring systems include or offer additional proprietary battery packs to extend battery life. Others use replaceable batteries that can be purchased from common retailers. Agencies may also want to consider if products that include visual battery life indicators offer additional benefit for their use cases.

2.2.5 Physiological Parameters

Physiological monitoring systems measure various types of cardiac activity, such as wearer heart rate (or pulse rate, which for the purpose of this report are assumed to be equivalent) and electrocardiographic (ECG) data. All products in this report include a measure of heart rate, while some also provide ECG monitoring, blood pressure measurements, or other cardiac indicators. Heart rate is the more common measure of cardiac activity but provides limited insight to a wearer's physical condition. While heart rate is a measure of blood flow through the body, ECG captures the heart's electrical activity, which can indicate additional cardiac health concerns. Products that provide ECG data range from using a single to a full 12 leads.

Physiological monitoring systems may also measure body temperature, either skin, core or both. Both types of measurements are important: skin temperature can indicate risk of exposure-related illness, while body core temperature may indicate infections or more severe heat-related effects. Skin temperature can reflect core body temperature, but measurements of skin temperature taken from the extremities (e.g., arms, legs, or fingers) may differ at the surface and offer slightly varied results depending on the location in which the measurement is taken. Skin temperature is not always a clear indicator of internal body temperature but may provide awareness of temperature changes that could impact a person's well-being before the core temperature changes. Systems in this report that indicate core body temperature are providing an estimate and derive it from other measures and do not provide a true measure as that would require invasive procedures.

Physiological monitoring systems can measure additional physiological characteristics (beyond heart rate and temperature) that may be of specific interest to emergency responders. While not deemed as critical, emergency responders have indicated that these additional measures are valuable to better ensure responder safety and maximize situational awareness. These measures include:

- Hydration level;
- Respiration rate;
- Blood oxygenation level;
- Blood pressure;
- Sleep metrics;
- Movement; and/or
- Level of strenuous activity.

2.2.6 Short-Term and Long-Term Monitoring

Physiological monitoring systems can be used for short-term operational period monitoring or longer-term 24/7 monitoring of emergency responders. Many physiological monitoring systems have been designed for out-patient, at-home monitoring and are now being adapted to fit the operational use and environmental needs of emergency response personnel. Systems providing short-term monitoring provide a clear indication of an individual's physiological measurements during an operational period or response activities where a responder may work at the scene less than an hour to a few hours with intermittent breaks for rehabilitation. Long-term monitoring can provide a more complete picture of a responder's health throughout a full 24-hour period or longer, exposing potential health trends and the impact of response activities on emergency response personnel over a more extended period.

Note that short and long-term physiological monitoring capabilities are not mutually exclusive, several products included in this report can perform and collect data under both use-cases.

2.3 Regulations, Compliance Requirements, and Standards

Several standards and regulations may be applicable. It is not the purpose of this section to determine whether they are necessary to be met for the use by emergency responders but to provide a list and aspects of types that may need to be considered. Since emergency responder use of physiological monitoring system technologies is relatively new, the adoption of standards for individual products may not be fully matured and new standards may be developed specifically to address this technology in the future.

2.3.1 Medical Device Regulations

The United States (U.S.) Food and Drug Administration (FDA) regulates medical devices (intended to provide diagnosis, cure, mitigation, prevention or treatment of a disease or condition) sold in the U.S. to assure their safety and effectiveness, and physiological monitoring devices used for medical purposes fall into this category. While physiological monitoring devices for responders are not regulated by the FDA, many of the devices used for responder applications are intended for medical purposes and have therefore been approved or cleared by the FDA.

In the European Union (EU), compliance with EU medical device regulations [1] [2] is required for medical devices being placed on the market. Compliant medical devices are designated as "Conformity European" and marked with "CE". The CE marking represents a manufacturer's declaration that products comply with the relevant EU requirements. The CE process is considered less challenging and less costly to obtain than FDA approval.

2.3.2 Health IT Requirements

For devices used in the U.S. that sync directly into hospitals' electronic medical records (EMR) systems, the United States Core Data for Interoperability Version 2 (USCDI v2) [39] applies. This is a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange.

2.3.3 Regulations for Protection of Personal Information

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) [3] was created to provide individuals with appropriate protection of their personal health information. Physiological monitoring systems collect and transmit health-related data that should be protected as such. Any instance in which an individual's physiological data is entered into an official medical records system must be HIPAA compliant [4]. Access to the data must be restricted to permitted individuals who require it in order to provide an effective response. Responder agencies using these systems should consider whether the systems provide the level of protection suitable with their legal understanding of HIPAA regulations and any additional privacy needs.

The Occupational Safety and Health Administration (OSHA) manages regulations, such as 29 CFR 1910.1020, "Access to employee exposure and medical records" [18] that pertains to the data exchange and confidentiality of personnel medical records, which could include outputs from a physiological monitoring system.

Agencies that intend to use physiological monitoring systems will need to become knowledgeable of state and local regulations on data privacy where they exist. Some US states are beginning to enact such laws.

Many products marketed outside of the US may also mention General Data Protection Regulation (GDPR) [10], self-identified as the "toughest privacy and security law in the world," which refers to the policies of the EU.

2.3.4 Radio Frequency (RF) Communication Regulations and Standards

RF devices must not cause interference to other RF devices and must function correctly in the presence of other RF devices.

In the US, physiological monitoring devices that transmit through wireless means must comply with applicable Federal Communications Commission (FCC) radio frequency (RF) regulations. FCC's Class B digital device 47 CFR Part 15 rules [14] apply to these products and help ensure that the products will not create RF interference with other electronic devices in use nearby.

Most of the products in this report use Bluetooth® to transmit data to an on-body device such as a smart phone which then retransmits the information. Some products use other RF communication technologies that are part of their inherent system architecture. These devices must also demonstrate that they will operate in the RF environment in which they are used.

The standards below may be applicable to these products:

(1) MIL-STD-461, Requirements for the Control of Electromagnetic Interference Characteristics of Subsystems and Equipment
(2) MIL-STD-464, Department of Defense Interface Standard: Electromagnetic Environmental Effects, Requirements for Systems
(3) IEC 61000-4-3, Radiated, radio-frequency, electromagnetic field immunity test
(4) IEC 60601-1-2, Electromagnetic Compatibility (EMC) Testing for Medical Devices

2.3.5 Safety Standards

It may be necessary to ensure the devices are safe for use in environments with explosive, flammable, or combustible atmospheres because it is likely that responders will operate in these environments. Devices demonstrated to be safe for use in such atmospheres are called "intrinsically safe."

There are several standards and certifications for demonstrating that equipment is intrinsically safe:

(1) UL 913, Standard for Intrinsically Safe Apparatus and Associated Apparatus for Use in Class I, II, III, Division 1, Hazardous (Classified) Locations, [22] is a safety standard used to certify
(2) SA-12.12.03, Standard for Portable Electronic Products Suitable for Use in Class I and II, Division 2, Class I Zone 2 and Class III, Division 1 and 2 Hazardous (Classified) Locations [40]
(3) European Union ATEX directive [19] [20]

The National Fire Protection Association (NFPA) recommends certification to UL 913 because its requirements are the most stringent of all relevant standards [41].

2.3.6 Data Security Standards

Many of the products in this report use the Advanced Encryption Standard (AES) [5] and Open Authentication (OAuth) [6] as approaches to protecting health data collected and used by physiological monitoring systems.

The International Organization for Standardization (ISO) Standard 27018:2019 [7] addresses protection of personal information for the public cloud computing environment. Another ISO standard, ISO 27001, addresses information security management [8].

The Cloud Security Alliance (CSA) oversees and has a mark available for products, its STAR (for Security, Trust, Assurance and Risk) Registry, a list of products that pass a third-party assessment of ISO 27001 in cloud computing environment context [9].

2.3.7 Data Format Standards

Physiological monitoring systems create, transmit, and may share data across multiple devices and platforms. The products should follow accepted data standards to ensure that the data is formatted to permit its desired use. Depending on the uses and the agencies involved, the applicable data format standards may vary. Some of these standards are the National Information Exchange Model (NIEM) [11], the Emergency Data Exchange Language Distribution Element [12], and the Common Alerting Protocol [13].

2.3.8 Durability Standards

Many standards specify requirements and test methods for equipment to operate in the environmental conditions that emergency responders often experience, including high and low temperatures, exposure to water and dust, vibration, and impact. There are several relevant standards that address durability and ruggedness:

(1) MIL-STD-810, Environmental Engineering Considerations and Laboratory Tests [16] – This standard includes tests for many environmental exposure conditions, including high and low temperature, thermal shock, impact shock, sand and dust, fluid immersion, and moisture, corrosion by salt fog, solar radiation, and vibration.
(2) International Electrotechnical Commission (IEC) 60529, Degrees of protection provided by enclosures (IP Code) [15] – The purpose of this standard is to rate the resistance of device enclosures to the ingress of dust and liquids.
(3) IEC 60068-2-31, Environmental Testing – Part 2:31: Tests – Test Ec: Rough Handling Shocks, Primarily for Equipment-type Specimens – This standard specifies test methods simulating rough handling shocks, impacts, and dropping.

2.3.9 Other Standards

Many other standards may be relevant for physiological monitoring systems. The National Fire Protection Association (NFPA) publishes various standards [17] that could be considered depending on the particular product selected. Other associations and professional bodies produce standards that could apply to physiological monitoring systems as used by emergency responders.

3.0 PHYSIOLOGICAL MONITORING SYSTEMS PRODUCT INFORMATION

This market survey report provides information on 15 wireless physiological monitoring devices for first responders. All products measure heartrate, at least one type of temperature (skin or estimated core) and at least one other physiological factor (e.g., blood oxygenation level). These products are sorted by sensor type with single-use devices listed in Table 3-1 and reusable products in Table 3-2, Within each table, they appear alphabetically by vendor followed by the product name. The individual product descriptions that follow the table follow this same order.

All products included in this report are commercially available. Most product information was obtained directly from the manufacturer or distributor, or their respective websites. When information could not be gathered in that manner, the source is specifically identified. The SAVER program has not independently validated the information obtained.

Product features listed by column order in Tables 3-1 and 3-2, are defined below:

Vendor indicates the company selling the product.

Product indicates the model name of the specific physiological monitoring system.

Cost indicates the price of the product rounded to the nearest U.S. dollar, as quoted by the vendor or posted on their website. Prices vary dramatically based on the framework used by the vendor: some require a subscription, while others calculate price based on the cost per unit.

Form Factor indicates how the device is intended to be worn by the user, including in-ear sensors, wrist- and armbands, patches, harnesses and vests.

Battery Life indicates the product's expected run time, given in hours, on one full charge or, if it is a single-use battery, the run time before the need for disposal (based on manufacturer specifications).

ECG indicates whether the product can measure the user's echocardiographic data, and if so, the number of leads provided are noted in parenthesis.

FDA/CE indicates if the product has been cleared by the FDA or certified by the CE.

Heart Rate (HR) indicates whether the product can measure the user's heart rate data.

Skin Temperature indicates whether the product can measure the user's skin temperature.

Core Body Temperature indicates whether the provides an estimate of the user's core temperature.

Other Physiological Measures indicates whether the product can measure additional user physiological data not already indicated by one of the categories above and, if so, what type.

Table 3-1 Physiological Monitoring Device Comparison Matrix, Single-Use Sensors

Vendor Product	Cost	Form Factor	Battery Life (hours)	FDA/ CE	Physiological Measures				
					HR	Temperature		ECG (# leads)	Other
						Skin	Core		
Biobeat **Biobeat Patch**	N/A	Patch	144	FDA, CE	✓	✓		Yes (1 lead)	Heart rate variability, blood pressure, mean arterial pressure, pulse pressure, systemic vascular resistance, stroke volume, cardiac output, cardiac index, respiratory rate, blood oxygen saturation, movement, and sweat
BioIntelliSense **BioButton**	N/A	Patch	2160	FDA	✓	✓		No	Respiration rate, body position, and sleep metrics
BioIntelliSense **BioSticker**	N/A	Patch	720	FDA	✓	✓		No	Heart rate variability, blood pressure, respiration rate, blood oxygen saturation, cough/sneeze/vomit frequency, movement, body posture, fall detection, and sleep metrics
Five Vital Signs **Triage-On-Demand (TOD) Biosensor**	$20 includes hardware, software, licensing, and distribution costs	Patch	168	FDA	✓		✓	Yes (1 lead)	Heart rate variability, respiration rate, movement, body position, fall detection, heat stress, hydration, orthostatic hypotension, and traumatic brain injury
VitalConnect **VitalPatch**	$150-250 per patch $100-200 monthly subscription	Patch	168	FDA	✓		✓	Yes (1 lead)	Heart rate variability, respiration rate, body posture, activity, and fall detection
VitIs **VitIs Monitoring System**	$150 per patch $95 base station	Patch	120	FDA	✓		✓	No	Respiration rate and blood oxygenation level

Table 3-2 Physiological Monitoring Device Comparison Matrix, Reusable Sensors

Vendor & Product	Cost	Form Factor	Battery Life (hours)	FDA/ CE	Physiological Measures				
					HR	Temperature		ECG (# leads)	Others
						Skin	Core		
Biobeat **Biobeat Wrist-Monitor**	N/A	Wrist Strap	72	FDA CE	✓	✓		No	Heart rate variability, blood pressure, mean arterial pressure, pulse pressure, systemic vascular resistance, stroke volume, cardiac output, cardiac index, respiratory rate, blood oxygen saturation, movement, and sweat
Biofourmis **Everion**	N/A	Arm Band	48	No	✓	✓		Yes (U)	Heart rate variability, blood oxygen saturation, skin blood perfusion, blood pulse wave, steps, stress, sleep, and sweat
Carre Technologies **Astroskin**	$6000 for Smart shirt, head gear, data recorder and has annual license fee	Garment with Headband	48	No	✓	✓		Yes (3 leads)	Heart rate variability, blood pressure, respiration rate, tidal volume, minute ventilation, blood oxygenation level, and activity
Cosinuss **Cosinuss° Two**	$450 includes data gateway	Earpiece	15	CE	✓		✓	No	Respiration rate, blood oxygen saturation, movement, and perfusion index
Empatica **E4 Wristband**	$1,690	Wrist Strap	24	CE	✓	✓		No	Heart rate variability, blood volume pulse, respiration rate, activity, galvanic skin response, and sleep metrics
Equivital **Blackghost + EQ02 LifeMonitor**	$1,800 (Hardware)with additional monthly software subscription	Body Harness	12	FDA CE	✓	✓	✓	Yes (2 leads)	Heart rate variability, blood pressure, respiration rate, blood oxygen saturation, movement, and heat stress
FireHUD **BioTrac Platform**	$1,900 with additional annual $180/device agreement	Wrist Strap/Arm Band	72	No	✓		✓	No	Heart rate variability, movement, exertion, and heat stress
Smartcardia **Smartcardia**	N/A	Patch	84	CE	✓	✓		Yes (1 lead)	Heart rate variability, perfusion index, respiration rate, blood oxygenation level, activity, and body posture
Zephyr Medtronic **Zephyr Performance Systems – BioModule**	N/A	Garment	24	FDA	✓		✓	Yes (U)	Heart rate variability, heart rate confidence, heart rate percent relative to max value and anaerobic threshold, respiration rate, motion, body posture, and caloric burn

3.1 Biobeat Patch, Biobeat

The Biobeat Patch Monitor is a single-use chest patch physiological monitoring system. The form factor of the product allows for adhesion to the skin on the chest. It is a disposable device. The sensor reports the wearer's:

- Heart rate
- Heart rate variability
- Skin temperature
- ECG (single lead)
- Blood pressure
- Mean arterial pressure
- Pulse pressure
- Systemic vascular resistance
- Stroke volume
- Cardiac output
- Cardiac index
- Respiratory rate
- Blood oxygen saturation
- Movement
- Sweat

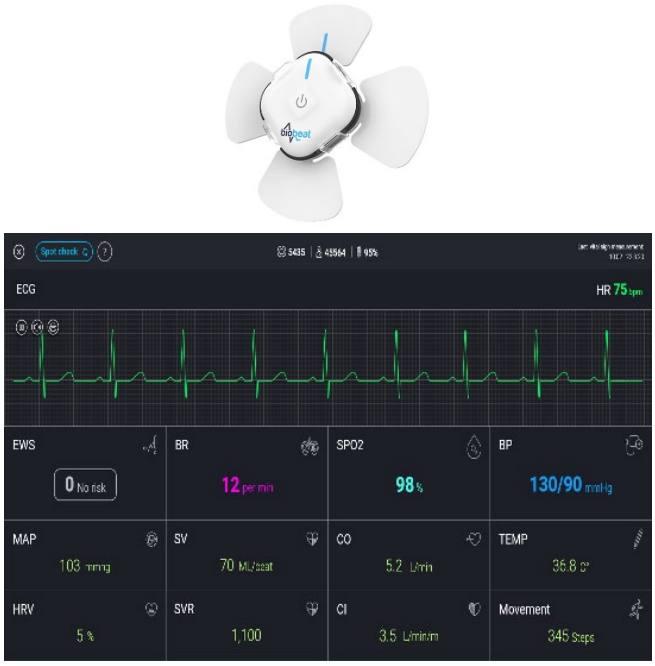

Figure 3-1 Biobeat Patch and Software Interface
Image Credit: Biobeat

The sensor contains a non-rechargeable lithium/manganese battery. The Biobeat is suitable as a long-term monitoring system since it typically has a battery life over 144 hours. Sensors have a shelf life of 3 years. Use of this product requires a prescription from a medical doctor.

The visual interface displays an unlimited number of users' data on one dashboard through the system's Biobeat application, which can also transmit information securely to the cloud for remote monitoring. The command center display creates a visualization of the user's historical and real time vital sign information via continuous parameter trend lines and raw data. The system includes smart alerts for thresholds that are customizable to each user and an "early warning score" system based on the UK's National Early Warning Score (NEWS) protocol for medical observation of patients.[1]

This monitoring system is compatible with any web platform, including iOS and Android, via the Biobeat application and syncs directly into hospitals' electronic medical records (EMR) systems. Data is transmitted from the app/gateway through Wi-Fi, Ethernet or sim card to the Biobeat web application, which can be accessed on a tablet, laptop or PC. The system is capable of transmitting its data to a gateway or a personal app on a smartphone, through Bluetooth Low Energy (BLE) 4.2. Through BLE, operating range between the Biobeat device and a gateway or smartphone is about 50 feet. In the event that communications are interrupted with the app or the cloud, the physiological monitoring system is equipped with internal memory for temporary data storage up to 4 hours.

[1] NEWS (National Early Warning Score) is a system used in the United Kingdom to determine the degree of illness of a patient and prompt critical care intervention.

The system can operate within a temperature range of 39.2 to 107.6 °F, a relative humidity range of 15 to 95% and an atmospheric pressure range of 703 to 1062 millibars (mbar). The sensor has an IP22 rating[2] so it must be protected from water sprays such as when the wearer is showering. The system is FDA-cleared, CE-certified and complies with HIPPA regulations. It has multiple additional certifications and compliances including AAMI, ANSI, IEC, EN, ISO and MDD. Consult the user manual or manufacturer for additional certifications and compliances information.

Vendor outreach is required for pricing information and further details on product features and specifications. The product can be obtained through a third-party business for about $360 each [23], but it's unclear whether each purchase includes all the same specifications. Use of the associated apps may have additional costs. Purchase price of a system includes training, 1-year warranty, technical support and gathered data.

3.2 BioButton, BioIntelliSense

The BioButton is a single-use, disposable patch physiological monitoring system that reports a wearer's:

- Heart rate
- Skin temperature
- Respiration rate
- Body position
- Sleep metrics

Figure 3-2 BioButton
Image Credit: BioIntelliSense

The form factor of the product allows for minimal obstruction and can stand up to heavy sweating and rigorous physical activity. The system has a self-contained 140 mAh lithium battery and is suitable for long-term monitoring system given its typically 90-day battery life. Seven adhesive pads are included with each unit purchased. The company recommends replacing the adhesive weekly at a minimum.

The visual dashboards for the system's BioMobile applications and enterprise triage display multiple users at once. The system can connect with medical-grade data services and remote patient monitoring (RPM) data services via its cloud-based platform application. The cloud interface displays encrypted user health information in a mobile-based badge notification and administrative dashboard. Using the BioButton with RPM or other partnering software makes it possible for an incident commander to monitor a full team of individuals.

The monitoring system for BioButton applies cloud-based analytic engines to each patient's previous data to establish a physiologic baseline for that individual. This allows the system to detect meaningful changes in one or more parameters during periods of significant deviation from the user's baseline. The BioButton can apply high and low thresholds for an individual's vitals. The system sends personal reports with raw data and information on vital signs to the wearer and can also send real time data to an onsite field incident commander.

[2] An IP22 rating means that the product provides ingress protection against solids greater than >12.5mm (e.g., fingers) and liquid ingress protection against dripping water tilted at an angle up to 15 from its normal position.

The system's mobile application is compatible with iOS and Android and is capable of transmitting data via encrypted BLE 4.2 wireless data transmission to BioButton's advanced cloud-based analytics platform. If communications are interrupted, the physiological monitoring system works in tandem with BioIntelliSense's Data-as-a-Service platform to continuously monitor users' health indicators and transmit them to the cloud for data analysis.

The system can operate within a temperature range of 32 to 122 °F, a relative humidity range of 0 to 95%, and an atmospheric pressure range from 703 to 1020 mbar. The patch has an IP47 rating: it will remain functional if submerged in less than 3 feet of water for less than 30 minutes. The system is FDA-cleared, HIPAA-compliant and equipped with AES-128 encryption [5] in rest and in transit. Consent-based terms of use and privacy are provided. The product complies with FCC's Class B digital device part 15 rules [14] .

Vendor outreach is required for pricing information and further details on product features and specifications. Two different news sources reported the cost of each patch as $1 or less a day by.[3]

The BioButton is sold by BioIntelliSense and also distributed by Philips as part of an integrated system that includes the sensor and the BATDOK monitoring software. The BATDOK monitoring software is a command interface software and application, as shown in Figure 3-3, developed by the US Air Force that consolidates and streamlines monitoring data in a secure platform that allows monitoring of multiple users. The software also allows incident commanders to use a tactical network/cellular connection/Wi-Fi mesh network to monitor wearers within a 30 feet coverage range.

Figure 3-3 BATDOK Dashboard
Image Credit: Air Force Research Laboratory (U.S.)

3.3 BioSticker, BioIntelliSense

The BioSticker is a single-use, disposable patch physiological monitoring system. The form factor of the product allows for minimal obstruction to movement and can stand up to heavy sweating and rigorous physical activity. The BioSticker offers a more robust suite of measures than the BioIntelliSense BioButton (reviewed in 3.2). The system reports the wearer's:

- Heart rate
- Heart rate variability
- Skin temperature
- Blood pressure
- Respiration rate
- Blood oxygen saturation
- Cough, sneeze, and vomit frequency
- Movement (i.e., steps, activity level, and gait analysis)
- Body posture

Figure 3-4 BioSticker
Image Credit: BioIntelliSense

[3] Earlier this year, The Washington Post cited BioButton's cost at $1 per day [37]. Similarly, Fox News' Detroit affiliate referred to the cost as $20 per month in its August 2021 new report [38].

- Fall detection
- Sleep metrics

The system has a self-contained 620 mAh lithium battery. BioSticker is suitable for long-term monitoring system since the sensor typically has a 30-day battery life. It's recommended that the adhesive be replaced weekly at a minimum. Seven adhesive pads are included with each unit.

Using the BioSticker and the HealthSuite Digital Platform (HSDP) or partnering software, an incident commander could monitor a full team of individuals. The dashboard interface displays as many devices as the agency would like to sync. The visual display can be customized to show user health information in different raw data formats. The system uses cloud-based analytic engines applied to each patient's trailing data to establish the physiological baseline for each individual. Statistically meaningful changes in one or more parameters can be detected during a significant deviation from the established user baseline. The BioSticker can apply high and low thresholds for an individual's vitals. The system sends personal reports with raw data and information on vital signs to the wearer; it can also send real time data to an onsite field incident commander. This BioSticker system's interactive mobile application is compatible with iOS, Microsoft and is capable of transmitting data to the cloud at periodic intervals when Bluetooth or wireless connections are available. BLE 4.2 data transmission links to the connected hub, which captures and transmits data to the designated care team. In the event that communications are interrupted, this physiological monitoring system is equipped with onboard memory that will retain data when disconnected from the network, then resume transferring data to HSDP once communications are restored.

The system can operate within a temperature range of 32 and 122 °F, a relative humidity range of 10 to 95% and atmospheric pressure range from 703 to 1020 mbar. The patch has an IP47 rating: it will remain functional if submerged in less than 3 feet of water for less than 30 minutes. The BioSticker has completed U.S. MIL-SPEC-810G [16] ruggedization testing and exceeds the parameters within the test.

The system is FDA-cleared and HIPAA-compliant. Certifications/attestations for this system include GDPR [10], CSA Star [9], ISO 27001 [8] and ISO 27018 [7]. The product complies with FCC's Class B digital device part 15 rules [14]. Vendor outreach is required for pricing information and further details on product specifications. Cost of each patch was listed as $145 by a third-party source.[4]

The BioSticker is distributed by Philips as part of an integrated system that includes the sensor and the BATDOK monitoring software. BATDOK is a command interface software and application, as shown in Figure 3-5, developed by the U.S. Air Force that consolidates and streamlines monitoring data in a secure platform, which allows monitoring of multiple users. The software also allows incident commanders to use a tactical network/cellular connection/Wi-Fi mesh network to monitor wearers within a 30 feet coverage range.

Figure 3-5 BATDOK Dashboard
Image Credit: Air Force Research Laboratory (U.S.)

[4] https://www.carekinesis.com/wp-content/uploads/COVID-FAQs-Final.pdf

3.4 Triage-On-Demand (TOD) Biosensor, Five Vital Signs

The Triage-On-Demand (TOD) Biosensor is a single-use patch physiological monitoring system. The system reports the following measures:

- Heart rate
- Heart rate variability
- Core body temperature
- ECG (single lead)
- Respiration rate
- Movement
- Body position
- Fall detection
- Heat stress
- Hydration
- Orthostatic hypotension
- Traumatic brain injury

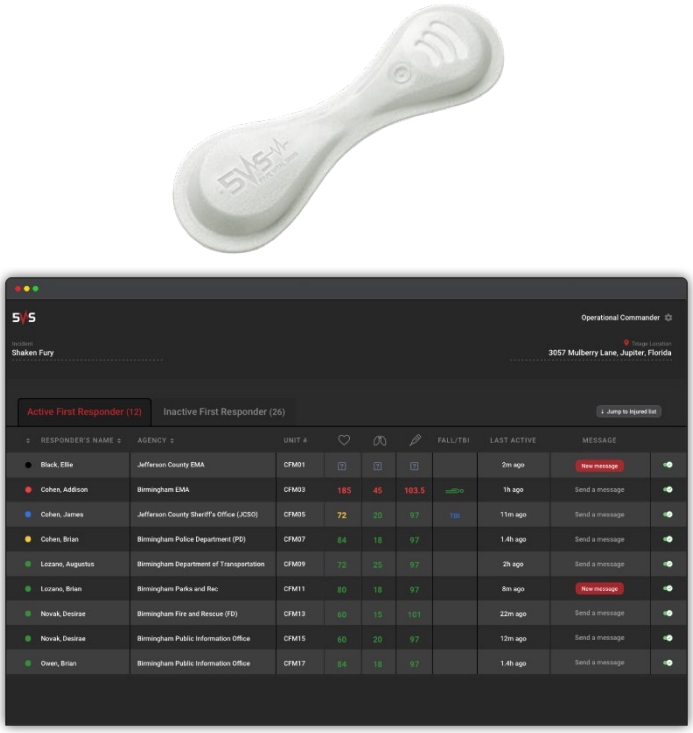

Figure 3-6 Triage-On-Demand Biosensor and Dashboard
Image Credit: Five Vital Signs

The 0.4 ounce band-aid sized biosensor product is equipped with an active grade hydrocolloid adhesive and is attached to the chest's left sternal border, located just above the heart. The patch contains a disposable zinc air battery. This product is suitable for long-term monitoring since it typically has a 168-hour battery life. The vendor has plans to transition to a reusable battery soon. Use of this product requires a prescription from a medical doctor

The monitoring interface can display an infinite number of users' data on one dashboard through the system's handheld relay and software. The visual display shows user information including the patient's name (or other identification) along with all of the physiological measures listed above. First responder health status is prioritized as "critical," "non-critical" or "healthy" (color coded as red, yellow and green, respectively). The system can send non-critical and critical alerts to the handheld relay as well as the dashboard.

This system is compatible with the Android operating system and is capable of transmitting data to a dashboard located anywhere within 90 feet of the device through reliable Bluetooth communication. In the event that communications are interrupted, the dashboard is capable of storing 15 minutes of a user's heart rate, respiratory rate, and body temperature data. The TOD Biosensor has an automatic reactivation of the relay for vital sign metrics with all data stored in a HIPAA-compliant cloud.

The system has been tested for operations in ambient temperatures of 50 to 105 °F. The system can operate in shallow water for up to 30 minutes. Accurate data capture is unaffected by heavy clothing and body movements. The system is FDA-cleared, meets HIPAA data transfer regulations, and is compliant with NIEM data standards [11].

The system currently costs less than $20/user/day, which includes the patch hardware, software, licensing and distribution. VitalConnect also distributes the sensor as a part of a different monitoring system. No warranty is offered, but Five Vital Signs will cover the cost of any defective product.

3.5 VitalPatch, VitalConnect

The VitalPatch is a single-use adhesive patch physiological monitoring system. The adhesive patch contains an integrated sensor module to measure the following vital signs:

- Heart rate
- Heart rate variability
- Core body temperature
- ECG (single lead)
- Respiration rate
- Body posture
- Activity
- Fall detection

Figure 3-7 VistaTablet, VistaPoint Desktop Interface, VistaPhone and VitalPatch
Image Credit: VitalConnect

The system contains an internal zinc air battery that can be disposed of with the patch. The product is suitable for long-term monitoring since it typically has a 168-hour battery life. Use of this product requires a prescription from a medical doctor

The form factor of VitalPatch allows it to be worn under other pieces of PPE that first responders may use in their line of duty. The patch is worn on the upper left of the chest. A second patch can be worn just above the stomach if posture is a desired measurement. The patch is also water-resistant and can be worn while bathing.

The software that monitors the patch sensors cannot be downloaded or installed on personal or agency devices. Instead, a mobile device with the software pre-installed is provided to users (included on purchase of the system). The patch transmits data to product-specific smartphones (VistaPhone) or tablets (VistaTablet) over a BLE connection. Wearers can view their data (or another single user's data) on VistaPoint software installed on these mobile devices. The devices then transmit data to a cloud server over a Wi-Fi connection. VistaPoint software is only compatible with the Android devices provided by the vendor with system purchase.

The VistaCenter software is a web-based platform that allows users to view the physiological data of any number of VitalPatch wearers and can be used on both Windows and Apple operating systems. The monitoring interface displays user health information in a customizable grid view. The dashboard provides users with instantaneous measurements of each wearer's physiological data. Upon query the software can provide additional details on each wearer, including data trends and estimated remaining battery life of the patch. VistaPoint software can also display blood pressure, weight and oxygen saturation as measured by third-party devices. The system can provide alerts on wearer health status based on the NEWS system [24], which is also indicated by a stoplight status for each wearer to indicate the level of risk of acute illness or overexertion.

As previously mentioned, the VitalPatch communicates with the VistaPhone or VistaTablet via a Bluetooth connection. The communications range is about 30 feet with a direct line of sight. In the event that communications between the patch and the phone or tablet are interrupted, the physiological monitoring system can store up to 10 hours of data on the patch, then transfer that to the software once communications are reestablished. The VistaPhone and VistaTablet transmit data to the VistaCenter software over a Wi-Fi or a cellular LTE connection. If this connection is lost, the mobile devices can store up to 10 days' worth of data.

The VitalPatch system can operate within a temperature range of 50 to 104 °F and a humidity range of 10 to 95%. The patch can also be used at altitudes of up to about 9800 feet and barometric pressure levels of 703 to 1062 mbar. The patch is water-resistant (equivalent of IPX7(particulate ingress protection not provided)). The system is a Class 2 device [14] cleared by the FDA and is HIPAA-compliant. Data transmissions use AES-CCM 128-bit encryption [5].

The system cost depends on the number of patches and mobile devices purchased. In general, the cost of one patch ranges from $150 to $250. A monthly subscription to the VistaCenter software ranges from $100 to $200. Each of these purchases include at least one mobile device (VistaPhone or VistaTablet), charging accessories, a skin preparation kit for application of the patch, and a patch removal kit.

3.6 Vitls Monitoring System, Vitls

The Vitls Monitoring System consists of a single-use adhesive patch called the Tego Vital Sign Sensor (VSS) and the Remote Patient Monitoring software platform. The sensor measures:

- Heart rate
- Core body temperature
- Respiration rate
- Blood oxygenation level

The VSS has a self-contained internal battery. The product is suitable for long-term monitoring since it typically has a 5-day battery life. The form factor of the product allows for easy disposal of the patch at the end of the 5-day monitoring period. The low profile and flexibility of the patch allows it to be worn under most PPE emergency responders might wear.

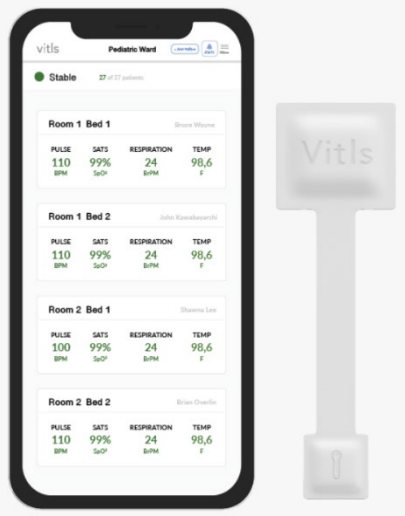

Figure 3-8 Vitls Patch and Mobile App
Image Credit: Vitls

The Remote Patient Monitoring software's interface displays up to 1,000 wearers on one dashboard through the system's Vitls Dashboard software. The software displays instantaneous measurements of each parameter for each wearer along with a patient identification number (referring to the wearer) and a device ID number (referring to the patch). Data trends for each wearer can be viewed upon query. Optional data fields requiring manual entry include patient location, age, height, weight, gender, and diagnosis. The system allows users to create thresholds for visual and audible "out-of-tolerance" alerts for any parameters. The software also allows remote viewers to make notes on the data feeds for each wearer.

This Vitls app is compatible with iOS and Android smartphones and tablets. The software is also compatible with any web browser and several EMR systems. Data is transmitted from the sensor over a BLE connection up to 80 feet to a base station (a sensor hub developed by Vitls) or a third-party smartphone or tablet. A single base station can host up to seven patches. The data is then transmitted to a HIPAA-compliant cloud database via a Wi-Fi or cellular LTE connection. The dashboard display retrieves data from this database. If communications between the sensor and the smart device are interrupted, the sensor stores data in onboard memory and retransmits it when a connection is re-established. Users are notified of any disruptions to the connection between the sensor and the smart device.

The system can operate within a temperature range of about 41 to 106 °F. The patch is waterproof and has a rating of IP27. The patch is recyclable for easy disposal.

The system is priced at $150 per Tego VSS patch. The Remote Patient Monitoring software (including access to the secure server library, a web-based or smart device dashboard, API connectivity and EMR connectivity) is included at no additional cost. The base station is priced at $95.

3.7 Biobeat Wrist Monitor, Biobeat

The Biobeat Wrist Monitor is a reusable wristband physiological monitoring system. The sensor reports wearers':

- Heart rate
- Heart rate variability
- Skin temperature
- Blood pressure
- Mean arterial pressure
- Pulse pressure
- Systemic vascular resistance
- Stroke volume
- Cardiac output
- Cardiac index
- Respiratory rate
- Blood oxygen saturation
- Movement
- Sweat

Figure 3-9 Biobeat Wrist Monitor
Image Credit: Biobeat

The form factor of the product allows for the wristband to be adjusted to fit most any user. The system contains a self-contained rechargeable lithium polymer battery. The product is suitable as a long-term monitoring system since it typically has a 72-hour battery life with continued use. It requires about four hours to completely recharge. Use of this product requires a prescription from a medical doctor.

The monitoring interface displays an unlimited number of users' data on one dashboard through the system's Biobeat application, which transmits information securely to the cloud for remote monitoring as well as displays a wearer's data. The visual display shows the user's historical and real-time vital signs health information via continuous parameter trend lines and raw data.

The system has customizable thresholds for each vital sign and for each user and can provide an early warning score (EWS) based on the NEWS (National Early Warning Score) protocol [24].

This system's software is compatible with any web platform; the cloud-based Biobeat application is compatible with iOS and Android devices. The system is capable of transmitting data to a gateway or a personal app on a smartphone, through BLE 4.2. Data is transmitted from the app/gateway through Wi-Fi, Ethernet or sim card to the Biobeat web application, which can be accessed on a tablet, laptop or PC. The range of operation between the Biobeat device and gateway/smartphone through BLE is not specified. In the event that communications are interrupted, the physiological monitoring sensor has an internal memory of up to 5 hours for temporary data storage while disconnected from the Biobeat application and cloud. The software allows the user to view graphs and historical data for each vital sign and each wearer and allows the user to export reports.

The system can operate within a temperature range of 39.2 to 107.6 °F. The sensor has an IP22 rating and must be protected from water sprays such as when showering. The system is FDA-cleared, CE-certified and HIPPA-compliant. It has multiple additional certifications and compliances including AAMI/ANSI/IEC/EN 60601-1+ED-3 for electrical medical equipment safety and performance [25] , IEC/EN 60601-1-2+ED-4 for electromagnetic compatibility of medical equipment [26], ISO 80601-2-61 titled "Accuracy Pulse Oximeter Equipment" [27] and MDD 93/42 EEC, the European Council Directive concerning Medical Devices [28]. The product can be cleaned with 70 to 85% ethanol.

Vendor outreach is required for pricing information and further details on product features and specifications. The product can be purchased through a third-party business for about $3000 each[5], but it's unclear whether that vendor includes all the same components as on offer via BioBeat. The use of apps may incur additional costs. Purchase of a system includes training, 1-year warranty, technical support, and data access.

3.8 Everion, Biofourmis

The Everion is a reusable armband physiological monitoring system. The system reports a wearer's:

- Heart rate
- Heart rate variability
- Skin temperature
- ECG
- Blood oxygen saturation
- Skin blood perfusion
- Blood Pulse Wave
- Steps
- Stress
- Sleep
- Sweat

Figure 3-10 Everion Armband, Desktop Interface, and Mobile App
Image Credit: Biofourmis

[5] https://www.mindtecstore.com/Products-by-BioBeat

The form factor of the product allows for the armband to be sized to fit any user. Since it is recommended to wear the product for periods under 12 hours to reduce skin irritation, the product is best suited for short-term monitoring. To extend the monitoring time the sensor should be repositioned or moved to the opposite arm.

The system uses a self-contained battery that typically runs for 48 hours on a full charge. The time needed to recharge the sensor is three hours. Four days of data at 1 Hz frequency can be stored on the device; older data is overwritten when the storage is full.

The visual interface is capable of displaying an unlimited number of users on one dashboard. The system's data analytics, machine learning and artificial intelligence (AI) feed data into the device's main dashboard so that alerts and analysis can be conducted on users' vital sign information. The interface displays user health information via a triage dashboard based on early warning scores and active alerts. Patients are listed in a bar display with current vitals. Users have the ability to review trends. The system is designed for use across the care continuum, from acute, to post-acute, to long-term management of chronic conditions. The system uses AI to produce clinically relevant alerts and provide context to any alerts. These can be set via dashboard, Short Message Service (SMS) or email, as needed by the customers.

The product is capable of transmitting data via BLE from the Everion sensor to a mobile device and from a mobile device to the Cloud using hypertext transfer protocol secure (HTTPS). The range of operation between the Everion device and a smartphone through a BLE connection is unspecified. If communications are interrupted, the physiological monitoring system automatically retries until it re-establishes communications. Measured data is buffered on the Everion device and phone application until communications are re-established. The data display is compatible with iOS and Android devices and the web-based dashboard runs on Google Chrome.

Biofourmis doesn't specify an operational temperature range for the product during use. It can be stored in temperatures from -4 to 140 °F. The relative humidity can vary from 15 to 95% and it can be used in atmospheric pressure from 862 to 1062 mbar environments. The Everion has an ingress protection rating of IP67, which means it is protected from dust and immersion in liquids up to 1-meter in depth for 30 minutes. The system complies with HIPAA, GDPR [10] and other applicable privacy standards.

Vendor outreach is required for pricing information and further details on product features and specifications. The Everion comes with a 1-year warranty. Purchase of a system includes patient monitoring, AI for clinical alerts, patient application, clinician dashboard and additional services such as logistics, patient monitoring/compliance as needed. The product is not distributed by any vendors in the United States other than Biofourmis.

3.9 Astroskin, Carre Technologies

The Astroskin is a reusable textile and headband physiological monitoring system. The system reports wearers':

- Heart rate
- Heart rate variability
- Skin temperature
- ECG (3-lead)
- Blood pressure
- Respiration rate
- Tidal volume
- Minute ventilation
- Blood oxygenation level
- Activity

Figure 3-11 Astroskin Shirt and Mobile App
Image Credit: Carre Technologies

The machine-washable smart shirt form factor allows users to purchase from among sizes 2XS to 4XL in male or female cuts for optimal fit. The antibacterial fabric also protects against ultraviolet radiation exposure. The Astroskin headband is worn on the head and can be further integrated with helmets, hats and other headgear. The sensor system connects to a removable and reusable data recorder. The Astroskin shirt contains two replaceable AA batteries. The product is suitable for long-term monitoring since its sensor will typically operate 48-hours continuously before needing replacement batteries.

The monitoring system includes continuous reporting and display of the wearer's physiological data. The visual interface displays one to three user's data on one dashboard. The Astroskin app is used on remote smartphone or iOS tablet to access the display. The visual display demonstrates user health information using raw data metrics and charts to show heart rate, ECG (3-Leads), respiration rate, and activity and temperature, among other metrics. The interface can be customized. The default display includes minimum and maximum recorded values for each metric and a longitudinal chart in both processed and raw data formats. Ranges and annotations are also displayed and can be managed. The system has many lights and haptic features that alert the wearer of potential issues with system functionality.

This system is compatible with Windows, OS X and iOS and is capable of transmitting data up to 164 feet via Bluetooth 2.1-2.4 GHz, depending on the environment. If communications are interrupted, the physiological monitoring sensor's data transmission will continue to play forward and remain on the recorder, which has a data storage capacity up to 600 hours of raw data, independent of the data transmission. The system has an open API.

The system can operate in temperatures up to 212 °F. The Astroskin shirts and head gear are tested to withstand over 50 wash cycles. The system is compliant with AES [5], HIPAA (not currently audited) [4], ISO 9001 Quality System [29] and OAuth2 [6]. It is not currently FDA-cleared. A complete system that includes the Astroskin smart shirt, head gear, recording device and annually renewed license for data storage costs about $6,000. Carre Technologies offers online training support and discounts on bulk purchases. The Astroskin recording device and headband have a one-year warranty, while the Astroskin garment is under warranty for 15 days after the shirt's assignment to a user.

3.10 Cosinuss° Two, Cosinuss

The Cosinuss° Two is a reusable earpiece physiological monitoring system. The system reports a wearer's:

- Heart rate
- Core body temperature
- Respiration rate
- Respiration rate intervals
- Blood oxygen saturation
- Movement
- Perfusion index

Figure 3-12 Cosinuss° Two Earpiece and Dashboard
Image Credit: Cosinuss

The earpiece form factor of the product does not require any potentially restrictive attachments to one's chest and is completely wireless. The Cosinuss° Two is made of soft, durable, skin-friendly material. The sensor can be cleaned with alcohol-based disinfectants. The sensor runs on a self-contained rechargeable lithium battery. The device typically has a 15-hour battery life of continuous use of full-monitoring capabilities and thus provides short-term monitoring within the defined scope. The onboard Bluetooth thermometer can operate continuously for five or more days while the sensor is monitoring a limited set of other physiological measures.

The monitoring interface displays an unlimited number of user's (by pseudonyms) and a range of factors including sensor battery life, measurement time, deviation score, and signal quality as well as the physiological data listed above on one dashboard. A stoplight display of data is available for physiological data. The system provides visual warning alerts using an overall deviation score calculated by adding up the individual scores of the four vital parameters (and adaptation from the EWS method). Each vital parameter value is scored according to its deviation from the medically accepted normal range. The overall deviation score is then provided to the monitoring personnel; the information is not accompanied by advice for intervention.

This system is compatible with Android via the Cosinuss° mobile application, LabApp and a web-based interface that works across all platforms. The standard or a custom BLE protocol can be used for AES-encrypted data transmission between the sensor and the gateway, with a maximum range of approximately 30 feet. A mobile network, Wi-Fi or a local area network can be used for communications between the gateway and the server. If communications are interrupted, the physiological monitoring system does not store any onboard data. If there is no stable BLE connection between the sensor and the receiving device, the measured data will be lost. If the BLE connection is stable between the sensor and the receiving device, the recorded data will be stored in the LabGateway offline and, whenever a stable internet connection is enabled, the data is then transmitted to the LabServer.

The system can operate within a temperature range of 59 to 113 °F. The system is 1.8 x 1.7 x 0.3 inches, weighs 0.2 ounces, operates within 703 to 1062 mbar atmospheric pressure and can be stored between -4 and 140°F. The system is certified with the consumer CE mark. All data storage and transmission use traffic encryption; AES, block cipher and HTTPS are used to protect transferred data. Cosinuss° Two is compliant with all EU GDPR requirements [10].

The system costs roughly $450, which includes the Cosinuss° Two physiological monitoring system and LabGateway data gateway. Vendor outreach is required for pricing information on the LabServer cloud server, other system components and further details on product features and specifications.

3.11 E4 Wristband, Empatica

The E4 Wristband is a reusable wristband physiological monitoring system. The system reports wearers':

- Heart rate
- Heart rate variability
- Skin temperature
- Blood volume pulse
- Respiration rate
- Activity
- Galvanic skin response
- Sleep metrics

Figure 3-13 E4 Wristband and Dashboard
Image Credit: Empatica

The form factor of the product allows for the E4 wristband to be adjusted to fit many sizes. The product is suitable for long-term monitoring system since its self-contained battery typically operates a minimum of 24 hours on a full charge, depending upon whether the device is in streaming or recording mode. The internal battery, from YJ Power, has a 300mAh capacity and requires a charging time of about two hours. The product has a lifetime of about 2 years or 500 charging cycles.

The monitoring interface displays an unspecified number of users at a time on a dashboard through the system's secure cloud platform and shows user health information in a raw data format. Empatica offers developer tools, allowing end-users to build their own applications and tools to access and monitor real-time E4 data. The system can send real-time data to a PC in a customizable format, tagging events and linking them to physiological signals. Additional alerting mechanisms may be possible through unique end-user configuration.

This system is compatible with Android and iOS and is capable of transmitting data via BLE Smart USB 2.0. The data range of transmission using BLE is about 33 feet. If communications are interrupted, the physiological monitoring data will automatically be uploaded from the internal data storage to E4 connect, their secure cloud platform after the session ends; 60 hours of data storage is available on the sensor.

The operational temperature range of this system is from 14 to 104 °F. The E4 wristband can operate in relative humidity from 20 to 95% and atmospheric pressure from 503 to 1200 mbar. The system is made of polyurethane (band), polycarbonate and glass fiber (case), and polycarbonate and silicon (lenses). The product has an IP22 rating.

The system is not FDA-cleared but is CE-Certified and HIPAA-compliant. Additionally, the E4 wristband is compliant with FCC CFR 47 Part 15b [14], IC (Industry Canada), RoHS (European Union) [30] and MIC (Japan) regulations [31] IEC standards for device safety and usability 60601-1-2:2014 [26], 60601-1-6:2010 [32] , 60601-1:2005 [25] and 60601-1-11:2010 [33] and ETSI EN 301 489-17 V2.2.1 [34] regarding electromagnetic compatibility.

Each E4 Wristband costs $1,690 with volume purchases reaching up to a 15% discount. Additional costs for service information, warranty, accessories and software could not be identified. Vendor outreach is required for additional pricing information and further details on product features and specifications.

3.12 EQ02+ LifeMonitor and Black Ghost, Hidalgo Equivital

The Equivital LifeMonitor Sensors (LifeMonitor) & BlackGhost Monitoring Software is a reusable body harness physiological monitoring system and supporting monitoring software. The system reports a wearer's:

- Heart rate
- Heart rate variability
- Body temperature (skin and core)
- ECG (2-lead)
- Blood pressure
- Respiration rate
- Blood oxygen saturation
- Movement
- Heat stress

Figure 3-14 EQ02+ LifeMonitor and BlackGhost, Harness, Monitor, and Desktop Display
Image Credit: Hidalgo Equivital

The form factor of the product, a chest harness with a small insertable sensor and built-in electrodes, is equipped with a strain gauge and can be laundered (hand washing recommended). The sensor contains a lithium polymer rechargeable cell battery that is self-contained. The product is intended for short-term monitoring and typically lasts at least 12 hours on a full battery charge. With an optional external battery pack, however, the system can run for over 96 hours, rendering it suitable for long-term monitoring.

The monitoring interface displays up to 1,000 users' data on one dashboard using BlackGhost encrypted web-based analytics software. The BlackGhost display shows user health information with raw data, live graphs and a color-coded stoplight system to help those monitoring data quickly process information. The system can monitor an individual's and team's physiology and physical location and can generate alerts sent via text message and/or email.

This system is compatible with Windows and Android and is capable of transmitting data over an unlimited range, as it is sent to a server (either locally hosted or cloud-based) via Bluetooth or tethered cable. If communications are interrupted, the physiological monitoring system data is stored onboard the sensor, the system buffers the encrypted data, then provides missing data once connectivity is restored. The stored data can be erased at any time. Once transmitted, the data is also stored on and can be accessed from the server (local or via the cloud).

The system can operate within a temperature range of 14 to 122 °F. The system is IPX7 (not rated against solids), as well as MIL-STD-810 [16] and MIL-STD-464 [35] tested. This product offers intrinsically safe (safe in explosive environments), ATEX-approved, versions of the sensor or of the sensor and battery. The system is FDA-cleared and CE-certified. All data is encrypted, consistent with NIEM [11] and AES [5] and HIPAA-compliant, as the product is already extensively used by the US Department of Defense.

The system cost depends on the number purchased. Basic pricing for hardware is $1800 per wearer; bulk discounts are offered, however, and total system costs can be lowered. The BlackGhost software requires an annual license. License cost is dependent on multiple variables, including the length of license term, number of sensors and number of logins. Purchase of a total system includes a 1-year warranty for all accessories and software, technical support and software and functional updates. An extended warranty is available at additional cost. The chest harness is not included in the 1-year warranty, rather, the manufacturer offers a separate 90-day warranty.

3.13 BioTrac Platform, FireHud

The BioTrac Platform is a reusable arm- or wristband physiological monitoring system. The system reports wearers':

- Heart rate
- Heart rate variability
- Core body temperature
- Movement
- Exertion
- Heat Stress

The system contains a self-contained battery. The product is suitable for long-term monitoring system since it typically has a 72-hour battery life.

The monitoring interface can display up to 300 users' data on one dashboard (though there is no limit on the software end) through the system's web-based application which is accessible from any internet-connected device. The display shows user health information, including standard metrics like heart rate, core body temperature and exertion, using combination of gauges, line charts, and color-coded metrics as visualizations.

Figure 3-15 BioTrac Platform's Wristband, Software Interface, and Gateway
Image Credit: FireHud

The form factor and size of the sensor (1.6 x 1.6 x 0.7 inch dimensions) allows the device to be worn underneath PPE. It secures on the upper arm directly above the elbow.

The BioTrac device is water and dust proof, making it easy to clean. The BioTrac band is adjustable, so it can be worn comfortably by most users.

The system allows an emergency response organization to set user-specific alerts, which can be sent via text message or online alerts, to emergency contacts should a user exceed their customized parameter thresholds.

This system is compatible with Windows, Linux, OS X, iOS and Android and is capable of transmitting data up to one mile from the device to a BioTrac Gateway by using its proprietary RF for deep building penetration from 902-928 MHz. The BioTrac Gateway can also be mounted for location tracking of vehicles. If communications are interrupted, the physiological monitoring system is equipped with automatic reactivation, but no data caching occurs, nor does it possess data storage capabilities.

The system can operate in temperatures up to 572 °F and has an IP rating of 68, which means it is protected from dust and immersion in liquids up to three meters deep for long lengthy periods. The system is compliant with AES 256 [5] and FCC regulations [14] but is not currently FDA-cleared.

System cost varies based on custom subscription terms, though the total hardware and software cost of the BioTrac Platform, including the physiological monitoring device, Gateway, Software Account and onboarding total is approximately $1,900. The BioTrac annual service contract agreement is an additional $180/device.

3.14 SmartCardia Inc., SmartCardia ScaAI Patch

The SmartCardia ScaAI Patch consists of a reusable sensor that mounts within a hypoallergenic disposable patch. The sensor measures:

- Heart rate
- Heart rate variability
- Skin temperature
- ECG (single lead)
- Perfusion index
- Respiration rate
- Blood oxygenation level
- Activity
- Body posture

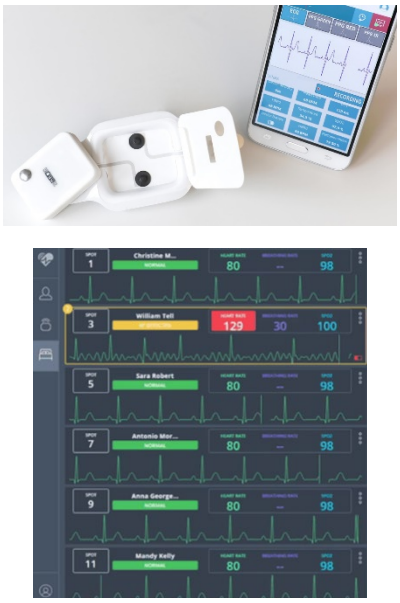

Figure 3-16 SmartCardia's ScaAI Patch and Dashboard
Image Credit: SmartCardia Inc.

The sensor has a rechargeable self-contained battery. The product is suitable for long-term monitoring system since it typically has an 84-hour battery life on a full charge. A single patch may be worn for 14 days before being replaced.

The software's interface displays at least 12 wearers on one dashboard. Numerical values and plots of data can be displayed for each wearer. The remote viewer can view each individual wearer's data as well. Real-time alerts are displayed in the system's user interface. Analysis of ECG data provides detection of arrythmias and other cardiac events.

The data is stored on the sensor (which has seven days' worth of capacity) and is simultaneously transmitted by BLE to a smartphone or similar device where it is sent to web servers to be accessed remotely through the internet. A mobile app is available for viewing the data as well.

All data is stored on an organization's local server, so that no data is provided to third parties companies. This helps ensure full data security, privacy and complete access to data. SmartCardia is an ISO 13485 [36] and ISO 9001 [29] certified medical device manufacturer and is also ISO 27001 [8] certified for data security and privacy. The ScaAI patch, cloud and software are CE-marked.

Vendor outreach is required for pricing information and further details on product features and specifications.

3.15 Zephyr Performance System, Medtronic

The Zephyr Performance System, developed by Medtronic, is a reusable garment-based physiological monitoring system. The system centers on the BioModule sensor that can be embedded into various garments including a chest strap, a loose-fitting shirt, a compression shirt or a sports bra. Using data from these sensors, Zephyr tracks the following physiological and biomechanical measures of the wearer:

Figure 3-17 Zephyr Performance System
Sports Bra, Compression Shirt, Chest Strap with BioModule, and ECHO gateway

Image Credit: Medtronic

- Heart rate
- Heart rate variability and confidence
- Heart rate percent relative to maximum values and anaerobic thresholds
- Core body temperature
- ECG
- Respiration rate
- Motion (including step count, velocity and jump height)
- Body posture
- Caloric expenditure and burn

The form factor of the product allows for wearers to choose the garment that is most suitable to their needs. The smart shirts and chest straps can be worn as a base layer under heavier PPE that emergency responders may use in their line of duty. The garments are flame-resistant, moisture wicking, and withstand up to 80 washings before needing replacement. The BioModule can also be used with an adhesive patch (the BioPatch), however, the patch is intended for clinical research rather than operational monitoring of wearers. The BioModule uses an internal rechargeable battery. A five-bay charger is available for the system. The product is suitable for long-term monitoring since it typically has a 24-hour battery life. The Zephyr system can also be used with a third-party QStarz 818XT GPS receiver unit to determine location. The system can also measure speed, distance traveled and elevation if the GPS unit is incorporated.

The accompanying OmniSense software suite uses combinations of these measurements to derive and report on additional physiological indicators that can be used to assess physical performance.

Indicators that OmniSense can derive from physiological measurements by the Zephyr sensors include:

- Fatigue
- Readiness
- Safety
- Overtraining and undertraining evaluation
- Fitness improvement
- Agility
- Wearer management
- Stress

The monitoring interface displays data on up to 100 users at a time on one dashboard using the system's OmniSense Live software. The display shows wearer health information in a customizable grid view, including the stoplight status of each wearer and up to 3 of the measurements listed above. Upon query the software can also display complete data, including data trends, for any wearer. Location data provided by the optional GPS unit can be viewed in third party software such as Google Maps or FalconView.

Figure 3-18 Zephyr System's OmniSense Software, Grid View
Image Credit: Medtronic

The system allows users to create out-of-tolerance alerts for any measured values. Baseline values can be set for each wearer in the OmniSense Analysis software, thereby allowing public safety agencies to set individual thresholds for the different stoplight status values and for thresholds that trigger alerts should they be crossed.

Physiological data is transmitted from the BioModule to a cloud-based server via the ECHO gateway. Transmission from the BioModule to the ECHO gateway has a range of up to 300 feet. An optional repeater is available which extends this range to up to 1000 feet.

The system can operate within a temperature range of 14 to 140 ˚F and a humidity range of 5 to 95%. The BioModule has an ingress protection rating of IP67, which means it is protected from dust and immersion in liquids up to one meter deep for 30 minutes. This product has FDA clearance.

The Zephyr Biomodule is also compatible with various products developed and sold by Honeywell Safety including the RAELink 3 mesh network node, ProRAE Guardian software, and Safety Suite Real Time software. The RAELink 3 is a mesh network node that supports short- and long-range communications. A single node can support up to eight Biomodule sensors wirelessly over a Bluetooth connection. Short-range communications between the Zephyr BioModule and the RAELink 3 have a coverage range of 30 feet. The RAELink 3 can also transmit data to a remote base station up to two miles away. The node is GPS-enabled and can provide location data on Zephyr wearers within range. Transmissions from the RAELink 3 are received by the ProRAE Guardian software and the Safety Suite Real Time software.

Both applications allow for data integration of physiological monitoring with environmental monitoring. Users can set thresholds for out-of-tolerance alerts for breath rate, heart rate, activity, posture and body temperature of Zephyr wearers. Nonetheless, Honeywell Safety does not sell the Zephyr system itself.

Vendor outreach to Medtronic is required for pricing information. The product is available through third-party businesses for $708 each[6], but it's unclear whether that purchase price includes all the same specifications/components as a purchase from Medtronic. Vendor outreach to Honeywell Safety is required for pricing information on the compatible RAELink products.

[6] https://www.amazon.com/BioHarness-Wireless-Professional-Physiological-Bluetooth/dp/B009ZUYNCW and https://wearabletech.io/zephyr-bioharness-3/

4.0 MANUFACTURER AND VENDOR CONTACT INFORMATION

Additional information on the products included in this market survey report can be obtained from the following companies.

Table 4-1 Manufacturer and Vendor Contact Information

Company	Address	Phone Number	Website/Email or Contact
Biobeat	Ef'al St 22 Petah Tikva, 4951122 Israel	+972 3-933-3022	www.bio-beat.com info@bio-beat.com
BioIntelliSense	17301 West Colfax Avenue Suite 152 Golden, CO 80401	+1 303-578-2648	biointellisense.com biointellisense.com/contact
Biofourmis	33 Arch Street 17th Floor Boston, MA 02110	+1 857-332-1073	www.biofourmis.com https://biofourmis.com/contact/
Carre Technologies	5800 rue Saint-Denis Suite 601, Montreal, QC H2S 3L5 Canada	+1 888-887-2044	www.hexoskin.com info@hexoskin.com
Cosinuss	Kistlerhofstraße 60 81379 Munich Germany	+49 (0)89 740 418 32	www.cosinuss.com/en info@cosinuss.com
Empatica	45 Bromfield Street Suite 901 Boston, MA 02108	+1 866-739-2049	www.empatica.com sales@empatica.com
Equivital	19 West 34th Street Suite 1018 New York, NY 10001	+1 646-207-4634	www.equivital.com sales@equivital.com
FireHUD	1701 Oakbrook Drive Norcross, GA 30093	+1 678-506-2998	www.firehud.co info@firehud.co
Five Vital Signs	1050 K Street NW Suite 900 Washington, DC 20001	+1 865-332-6743	www.fivevitalsigns.com jd@5vs.life
Smartcardia	EPFL Innovation Park Batiment C Route Cantonale 1015 Lausanne Switzerland	+41-788750864	smartcardia.com contact@smartcardia.com
VitalConnect	224 Airport Parkway Suite 300 San Jose, CA 95110	+1 408-963-4600	vitalconnect.com info@vitalconnect.com
Vitls	2450 Holcombe Boulevard Suite X+210 Houston, TX 77021	+1 415-949-9963	www.vitlsinc.com www.vitlsinc.com/contact
Medtronic	1 Annapolis Street Suite 200 Annapolis, MD 21401	+1 443-569-3603	www.zephyranywhere.com/ zephyranywhere.support@medtronic.com

5.0 SUMMARY

Emergency responders work in physically demanding, life-threatening situations. Physiological monitoring systems can be used to help ensure responders remain safe while performing their duties by monitoring key indicators of health. At the time of this report most commercial products are designed for medical applications rather than for the first responder marketplace. It's likely that increasing use of these systems among first responders could result in rapid technological changes and soon additional products may meet the requirements for consideration in this report.

To be included in this report, products had to be available for purchase and, at a minimum, include continual monitoring of both heart rate and body temperature. According to their manufacturers, all 15 products in this report are capable of: measuring and transmitting physiological parameters in near real-time, alerting remotely located staff of any conditions deemed an immediate health concern, and operating under the environmental conditions typically experienced by first responders. The products covered by this report vary substantially in form factor, battery life, measurement parameters, methods for displaying information, and several characteristics that may guide potential purchases. Six of the products listed in this report have single-use sensor patches that stick to the wearer's chest; the remainder have reusable sensors worn via wrist or arm bands, chest harnesses or upper body garments, in-ear device, or chest patch. Among the multitude of measures taken in addition to heart rate and body temperature, the most commonly included are respiration rate, heart rate interval, electrocardiogram, and activity or movement. The sensors for these included products also vary in how long they function on a single charge. Nevertheless, most devices herein could be used for the duration of typical emergency responder's shift and many could be used for long-term monitoring. Generally, single-use sensors can function longer than reusable sensors can last before needing replacement batteries or a recharge. Only two of the reviewed sensors have a battery life under 24 hours and one of those has an optional battery which can extend this time beyond 24 hours.

Product cost was available for only eight of the 15 products; contact individual companies for detailed pricing information and for quotes on the remaining seven. For single-use sensors, the prices range from $20 to $150 each, while the prices for reusable sensors range from $450 to $6,000. Many, though not all, of these products will also require subscription/service fees; subscription fees are listed for four of the eight products that made pricing information available. Emergency responder agencies that consider purchasing physiological monitoring systems should carefully research each product's overall capabilities and limitations in relation to their agency's operational needs. Users should seek information outside of, in addition to, this report with special consideration to market changes occurring after the report's published date.

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