

One Company. One Device. Robust Data.

For all the rhythms of life.

BODYGUARDIANTM MINI Family of Monitors

s^{Boston}fic CDX

Comprehensive cardiac care. Only from Boston Scientific Cardiac Diagnostics.

BodyGuardian[™] MINI family of monitors combines the expertise and credibility of Boston Scientific Cardiac Diagnostics (BSC CDx) with leading remote cardiac monitoring technology for a device unlike any other.

BodyGuardian MINI offers patients the flexibility to live their lives uninterrupted. It is fully waterproof, submersible and offers a variety of adhesives for adults and pediatrics* alike. **Because not all lifestyles or skin types are the same.**

BodyGuardian MINI family of monitors offers multiple business models and data that integrates seamlessly with your electronic medical records. You get a single workflow solution from ordering to reading, with timely actionable data and high diagnostic yields.







BodyGuardian[™] MINI - easy to use for physicians and patients.

BodyGuardian[™] MINI family of monitors are arrhythmia monitors that are approved for adults and children and offers sensitive skin options. The device is designed for patient comfort and to deliver data with high diagnostic yields. With enhanced data download capabilities, BodyGuardian MINI allows for immediate and actionable diagnoses for your patients.





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SIMPLE PATIENT EXPERIENCE	BODYGUARDIAN" MINI	BODYGUARDIAN [™] MINI PLUS
Monitoring Services	Holter	MCT / Event / Holter
Different Adhesive Options for Adults & Pediatrics	\checkmark	
Multiple Channels	\checkmark	
Multiple Patch & Lead Set Options	\checkmark	
Fast Hook-up / No Skin Abrasion / No Alcohol Use	\checkmark	
Submersible / Waterproof	\checkmark	
Ability to Move & Reposition	\checkmark	\checkmark
Various Placement Options / Audible Notifications	\checkmark	\checkmark
Application in Office / Shipment to Patient's Home	\checkmark	\checkmark

SWIFT & SEAMLESS WORKFLOW	BODYGUARDIAN [®] MINI	BODYGUARDIAN" MINI PLUS
1 Device for Staff Training / 1 Device for Inventory	\checkmark	\checkmark
Fast Report Delivery / Office Upload Capability / ER Data Access	~	~
Remote Service Transition without Patient Returning to Office	\checkmark	~
High quality P-wave Tracings / Ventricular Arrhythmias Detection	\checkmark	\checkmark
Afib / PAC & PVC Burden	\checkmark	\checkmark
Morphological Templates	\checkmark	
Stream Every Beat to the Cloud		\checkmark
Transmit Events Upon Triggered Recording		\checkmark
Customer Access All Rhythms & Beats via ECG Insight™	\checkmark	MCT / Holter only
Wi-Fi		\checkmark
Instructional Videos	\checkmark	\checkmark
Language Translation Capability		\checkmark
Study Duration	Up to 15 Days	Up to 30 Days

Go beyond standard EMR integration with BodyGuardian[™] MINI Family of Monitors.

Flexible Integration Support

We work with your clinical and IT teams to ensure the most streamlined and efficient integration based on your workflow. You will also have a dedicated EMR integration expert to help manage your workflow integration project.

Compliant

EDIC

BSC CDx activities with any project follow HIPAA, HITECH, SOC2 Security (Encryption, Visibility, Scalability) and HL7 Interchange guidelines. BSC CDx meets the three levels of health information technology interoperability defined by HIMSS. We have the right fit to integrate into your all-digital EMR system. We provide high diagnostic data to assist with clinical decision-making including:



Discrete Data Elements (DDE) Integration Capabilities



Application Program Interface (API) for Raw Data



Orders and Results Interface

EMR Service Offerings:



Physician's specific criteria



Electronic enrollment



transfer

We have integrated with over 800 sites including:



MEDITECH Vathenahealth

eClinicalWorks

Epiphany



and many more

Meeting today's needs for unique reporting.

- Clinical accuracy leveraging BeatLogic[™] and AI deep neural networks along with human oversight
- MCT report provides embedded hyperlinks into full disclosure allowing you to navigate through every beat of the study – ECG Insight[™]

ECG Insight[™]: The complete beat-to-beat story at your fingertips

ECG Insight[™] provides the physicians full disclosure to make timely, data-driven clinical decisions.





Arrhythmia detection and identification comes standard with BeatLogic[™]

BeatLogic is the suite of FDA cleared artificial intelligence algorithms that make up the BSC CDx cloud-based ECG analysis platform. It uses AI to automate ECG interpretation enabling technicians to quickly deliver accurate reports and critical notifications. We are the only major ambulatory ECG monitoring company that publicly publishes the sensitivity and specificity of our algorithms for a wide variety of rhythms against a largely broad database of patients.¹



Bring it all together with PatientCare Portal.

PatientCare is a self-managed, cloud-based, HIPAA-compliant portal that allows you to gather, interpret and manage near real-time patient data. PatientCare can be integrated with EMR systems allowing you to have access to patient information and care plans.

Simple

One device and one software licensed for all modalities

Targeted Actionable reports based on your protocol needs

Transparent

Complete beat-to-beat data access

Flexible Configurable workflow

Compliant

Licensed and certified IDTF partner

Accurate

Driven by deep learning, you can build and edit highly accurate reports

PatientCare is scaled to fit your needs.

Our complete service offering includes:



*Pediatric patients above 10kg (22lbs).

1. Teplitzky, B., McRoberts, M., Ghanbari, H. Deep learning for comprehensive ECG annotation. Heart Rhythm, Vol 17, No 5PB, May 2020

BODYGUARDIAN[™] MINI Family of Monitors

INTENDED USE: The BodyGuardian MINI is intended for use in clinical long-term ambulatory ECG monitoring, data transfer and analysis. BodyGuardian MINI is indicated for adult and pediatric patients who require ECG monitoring inside or outside hospital or healthcare facility environments. The sensor does not provide interpretive statements. Final interpretation and diagnosis is the responsibility of a physician.

CONTRAINDICATIONS: The sensor is contraindicated for those patients requiring attended, in-hospital monitoring for life threatening arrhythmias and for use on pediatric patients weighing 22 lbs. (10kgs) or less. Safety Precautions: The sensor does not directly provide diagnosis as a supervising physician is responsible for ECG data interpretation. Do not disassemble, try to repair, or modify sensor. Sensor does not have any electrical stimulation capabilities.

Warnings: Do not attempt self-diagnosis or self-treatment based on acquired data. Not suitable for use in MRI environment. Patients with known skin allergies or hypersensitivities to adhesives or hydrogel may experience reactions. Patients should consult with their health care professional to select a BodyGuardian MINI Strip or alternate electrode option that is most appropriate for their needs. Apply the BodyGuardian MINI Strip or alternate electrode only to intact, clean skin. Do not apply over open wounds, lesions, infected or inflamed areas. The BodyGuardian MINI Strips are for single patient use only. The device is not intended to be used at the same time with high frequency (HF) surgical equipment or with a defibrillator. Patients who have active implantable medical device (for example a heart pacemaker), should consult supervising physician or doctor before use. When using the MINI ECG monitor connected in Bluetooth mode (in the MINI Plus configuration) the monitor should be kept within 10 feet (approximately 3 meters) to the companion device (smartphone) to facilitate wireless communication. To avoid danger of electrical shock and electromagnetic disturbances, the computer and associated equipment used with the ECG Sensor should comply with IEC/EN 60950 (IT and office equipment safety) or EN60601-1 (Medical electrical equipment safety) standard. If a computer that does not comply with the IEC/EN 60601-1 requirements is used in the patient environment, the computer and peripherals must be plugged in using an isolation transformer that fulfills the requirement. CRM-1424006-AA

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

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Cardiac Diagnostics, Inc.

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