

BRIEF SUMMARY STATEMENT

BodyGuardian™ MINI and MINI PLUS

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.

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