



## NUVANT™ Mobile Cardiac Telemetry (MCT) System Indications for Use, Contraindications and Precautions

### Rx only

#### Indications for Use

The NUVANT™ Mobile Cardiac Telemetry (MCT) System is intended to continuously measure, record and periodically transmit physiological data. The System is indicated for those patients who require monitoring for the detection of non-lethal cardiac arrhythmias. The NUVANT System model monitors, derives and displays:

- ECG
- Heart Rate

#### Contraindications

1. Patients with known allergies or hypersensitivities to adhesives or hydrogel.
2. Patients with potentially life-threatening arrhythmias, or who require inpatient / hospital monitoring.

#### Precautions

1. PiiX should not be used on patients with implantable devices with active minute ventilation sensors.
2. Patient trigger magnet should not be used in patients who have implanted devices with active magnet features in the vicinity of the PiiX.
3. PiiX should be removed prior to external defibrillation or an MRI scan.
4. PiiX may cause mild discomfort, skin irritation, redness, itching, rash or contact dermatitis in some individuals. The device should be removed if any pain or discomfort occurs. If skin irritation or redness persists after the device has been removed, a topical anti-inflammatory cream may be applied to the area (in consultation with your health care provider).
5. PiiX is intended for single patient use.
6. PiiX should not be applied to broken, damaged or irritated skin.
7. PiiX is water resistant but not waterproof. It should not be submerged in water (showering is acceptable, but swimming and submersion bathing are prohibited).
8. PiiX should not be disassembled.
9. Replace the PiiX if it peels off; do not reapply the PiiX (it is meant for one-time use).
10. Replace the PiiX if it appears damaged or if it is not activated within 15 minutes of application
11. No creams or lotions should be applied immediately prior to use of PiiX.
12. Store PiiX in a cool, dry location. The device is designed to withstand environmental temperature fluctuations between 0° to 40°C.

The NUVANT System is not intended to replace direct communication with your healthcare provider. The system data should not be used alone, but should be used along with all other clinical data and exams to come to a diagnosis. The system is not intended to alarm or alert physicians, and will not summon emergency response in the event you need help. Talk to your healthcare provider immediately if you have any concerns, or if your condition changes.

#### **Customer Service**

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