Model RX-1
Remote Cardiac Monitoring System

The right reading. The first time.

- **Four-Lead, Two Channel Device:** Mobile Cardiac Telemetry (MCT) and Event Recorder with ECG data reviewed by a US-based monitoring center

- **Onboard Algorithm** proven on over 75,000 hours of real-world ECGs. Wavelet analytics removes 95% of noise\(^1\) and artificial intelligence provides superb detection of AFib/AFI, PVCs, brady, tachy and pauses. More efficient processing results in up to 14 days of battery life on a single charge!

- **Collaboration:** VivaQuant and the FDA are using Rhythm Express technology to find ways to improve accuracy of drug cardiac safety assessment

- **Freedom** from daily charging, additional hardware and logbooks. Water resistant to stand up to spills and drops. Owning the equipment puts you in control of reimbursement.

\(^1\)Brockway et al. 2017-Clinical Pharmacology & Therapeutics
**INDICATIONS FOR USE**

The RX-1 ECG monitor with arrhythmia detection is intended for use in the following indications:

- Adult patients who have a demonstrated need for cardiac monitoring. These may include but are not limited to patients who require monitoring for: a) non-life-threatening arrhythmias such as supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, PACs, PSVT) and ventricular ectopy; b) evaluation of Brady arrhythmias and intermittent bundle branch block, including after cardiovascular surgery and myocardial infarction; and c) arrhythmias associated with co-morbid conditions such as hypothyroidism or chronic lung disease.

- Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath).

- Patients with palpitations with or without unknown arrhythmias to obtain correlation of rhythm with symptoms.

- Patients who require outpatient monitoring of antiarrhythmic therapy: a) monitoring of therapeutic and potential proarrhythmic effects (e.g. QT prolongation) of membrane active drugs; and b) monitoring of effective drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation or atrial flutter).

- Patients recovering from cardiac surgery who are indicated for outpatient arrhythmia monitoring.

- Patients with symptoms that may be due to arrhythmia. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath).

- Patients with symptoms that may be due to arrhythmia. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath).

**CONTRAINDICATIONS**

Patients who are in the vicinity of machinery and are using a lanyard to support the device, the device and lanyard should be placed under a shirt or other garment to avoid being inadvertently entangled in the machinery. Patient leads must be removed from electrodes before defibrillation. Exposure to defibrillation may damage the RX-1 device or may interfere with operation of the defibrillator. RX-1 is not intended for use as an emergency medical response system.

**WARNINGS**

If you are in the vicinity of machinery and are using a lanyard to support the device, the device and lanyard should be placed under a shirt or other garment to avoid being inadvertently entangled in the machinery. Patient leads must be removed from electrodes before defibrillation. Exposure to defibrillation may damage the RX-1 device or may interfere with operation of the defibrillator. RX-1 is not intended for use as an emergency medical response system.

**CAUTIONS**

This device captures and presents data reflecting a patient's physiological condition that, when reviewed by a trained medical professional, can be useful in determining a diagnosis. However, the data should not be used as the sole means for determining a patient's diagnosis. The RX-1 device is designed for use with standard electrodes. Some people are allergic to the materials used in skin electrodes. If an allergic reaction occurs, remove the device and electrodes from the body. The device is not intended for use during an MRI. To maintain designed operator and patient safety, any peripheral equipment and accessories that can come in direct patient contact must be in compliance with IEC 60601-1. Hardware is designed to meet or exceed IEC 60601-1-2; however, some environmental electrical interference may cause an artifact in the ECG. The quality of ECG signals may be adversely affected by electromagnetic interference from heavy machinery, electric blankets, and similar apparatus, resulting in non-physiological waveforms with the potential for misinterpretation. Do not allow ECG leads to come in contact with an electrical power source. Contact could cause unacceptable levels of electrical current to flow to the patient. Disconnect the lead wires from the electrodes prior to charging. Although the charger has been tested to assure that it meets safety standards, failure could result in electrical shock. Use only the specified, certified charger for this device (AC/DC adapter), as listed in the system components of this manual. Using another AC adapter may damage the device and may create a safety hazard. Do not expose the device or lead wires to autoclaving or steam cleaning, as damage could result. Recommended cleaning procedure is to wipe the exterior surfaces with a cloth dampened with warm water and mild detergent solution and then dry with a clean, soft cloth. There are no user-serviceable parts inside. Opening the case will void all warranties and could result in permanent damage. The RX-1 device uses a Lithium Ion battery. This battery may present a fire or chemical burn hazard if mistreated. Do not disassemble, heat above 45°C (113°F), or incinerate. Dispose of the device in accordance with applicable local regulations. The user of this device is responsible for routine maintenance. Failure to do so may cause undue failure and possible health hazards. VivaQuant, LLC equipment is identified by the UID, Model, and serial number on the back of the device. Take care not to deface these numbers. This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. This equipment is resistant to water but should not be submerged in water. Remove device prior to entering a pool or bath and do not submerge device during cleaning and maintenance procedures. Submerging the device in water could result in damage. This equipment should not be exposed to environmental conditions outside the listed specifications.

**Ordering Information:** 1-888-ECG-TRUE (1-888-324-8783)

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<tr>
<th>RX-1 ECG Monitor, Lead Wires, Charger, Manuals</th>
<th>51-0021</th>
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<tbody>
<tr>
<td>Charger</td>
<td>50-0229</td>
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<tr>
<td>RX-1 Lead Wire 30cm</td>
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<td>RX-1 Lead Wire 45cm</td>
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<td>RX-1 Lead Wire 60cm</td>
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<tr>
<td>RX-1 Lead Wire 100cm</td>
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**This product does not contain latex.**

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