Rhythm EXPRESS™

by VivaQuant®

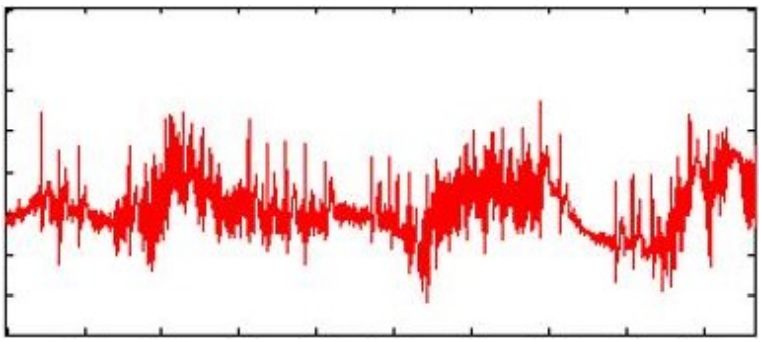
Model RX-1 *mini*

Remote Cardiac Monitoring System

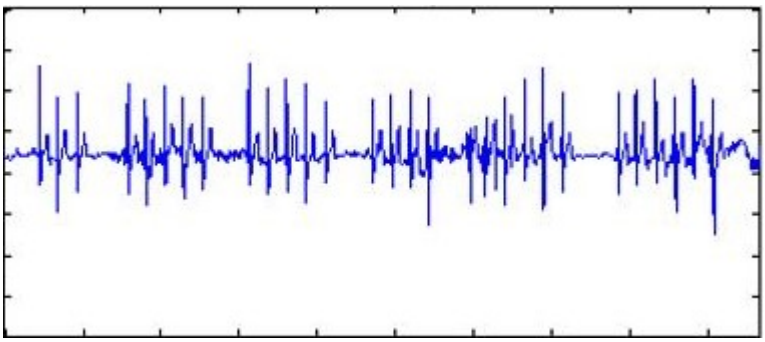
The right reading. The first time.

Actual size

- **THE SMALLEST One-Piece MCT**
  One Button and Water-Tight
- **Unprecedented Noise Suppression**[1]
  Clean, accurate MCT, Holter, Extended Holter, and Event Recorder reports
- **Long Rechargeable Battery Life**
  5 to 7 days on a single charge*
- **Purchasing Models**
  - Subscription month-to-month
  - Pay per study (Fee For Service)
  - Split Bill (IDTF)



Before Processing

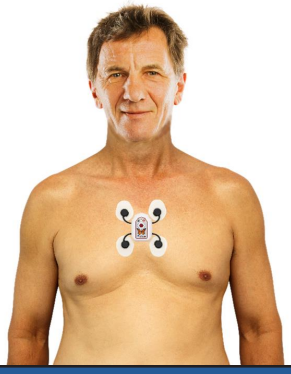


After Processing

*battery life depends on operating mode and cellular signal quality

[1]Brockway_et_al-2017-Clinical_Pharmacology_&_Therapeutics

Ordering Information: 866-324-8783



MCT and Event Recorder Monitoring CPT Codes			
MCT Global	**93228 and 93229**	**Event Global**	**93268**
Holter (up to 48 hours) Global	**93224**		

INDICATIONS FOR USE

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

Patients greater than 10 kg 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 diagnosed sleep disordered breathing including sleep apnea (obstructive, central) to evaluate possible nocturnal arrhythmias.

Patients requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation/atrial flutter.

CONTRAINDICATIONS

Patients with potentially life-threatening arrhythmias who require inpatient monitoring.
Patients who the attending physician thinks should be hospitalized.

WARNINGS

Disconnect device from patient before defibrillation. Exposure to defibrillation may damage the RX-1 mini device or may interfere with the operation of the defibrillation. RX-1 mini is not intended for use an e ergenc medical response system. Keep out of reach of children. This device includes use of small parts and wires cords which could pose a choking or strangulation hazard to unattended children.

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 mini device is designed for use with standard electrodes. Some people are sensitive to materials used in skin electrodes. If a reaction occurs, remove the device and electrodes from the body. This device is not intended for use during an MRI. Use only specified parts and accessories to maintain operator and patient safety. The RX-1 mini is designed to meet or exceed requirements for electromagnetic compatibility, 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 electrodes or lea s to co tact an electrical power source or ground when in use on a patient. Contact in this manner could cause electrical shock of the patient. Disconnect the leads 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 charger for this device (AC/DC adapter), 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 mini device has been designed to tolerate normal drops and shocks. However, excessive impact and shocks should be avoided to prevent damage to the device. The RX-1 mini device uses a Lithium battery. This battery may present a fire or chemical burn hazard if mistreated. Do not disassemble, heat above 45° C (113° F), or incinerate. Return the device to the monitoring center or follow applicable local regulations for disposal. The user of this product is responsible for routine maintenance. Failure to do so may cause undue failure and possible health hazards. VivaQuant equipment is identified by the UDI, 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 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 or maintenance procedures. Submerging the device in water could result in damage. This equipment should not be exposed to environmental conditions outside the listed specifications.

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This product is not made with natural rubber latex.

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