Rhythm EXPRESS™

by VivaQuant®

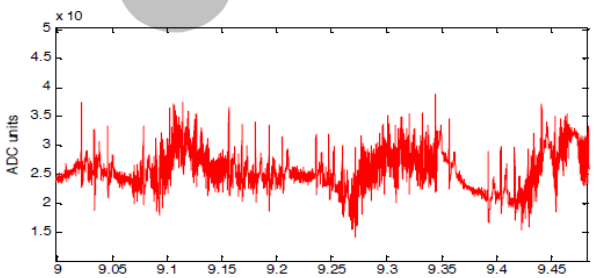
Model: RX-1 *mini*

Remote Cardiac Monitoring System

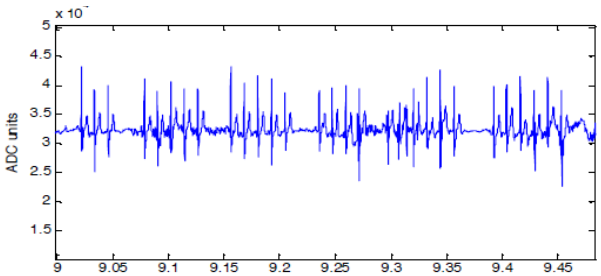
The right reading. The first time.

Actual Size

- **One-Piece Patch with Cell Modem**
  no extra hardware, water-tight and only **ONE** button
- **Unprecedented Noise Suppression**[1]
  clean accurate MCT and Event Recorder reports
- **Long Rechargeable Battery Life**
  up to 5 days on a single charge
- **Monthly Subscription Option**
  - You own device and have on-line access
  - We provide analysis, support and prepare reports
  - Fee is the same regardless of volume
- **Fee for Service Option: a per-test fee**
  - Purchase or lease devices
  - If you don't use, you don't pay fee



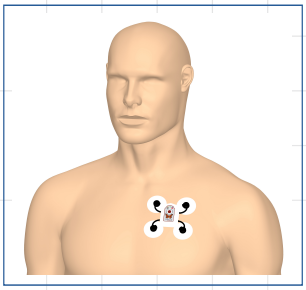
Before Processing



After Processing

[1]Brockway_et_al-2017-Clinical_Pharmacology_&_Therapeutics

Ordering Information: 1-866-ECG-TRUE(1-866-324-8783)	
RX-1mini ECG Monitor, Charger	Catalog Number (CFN): **51-0026**



MCT and Event Monitoring CPT Codes			
MCT		**Event Monitor**	
MCT Read	**93228**	**Event Hookup**	**93270**
MCT Technical	**93229**	**Event Read**	**93272**
MCT Global	**93228 and 93229**	**Event Technical**	**93271**
		Event Global	**93268**

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

Patient leads must be removed from electrodes before defibrillation. Exposure to defibrillation may damage the RX-1 *mini* device or may interfere with operation of the defibrillator. RX-1 *mini* 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-*mini* 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. This 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-*mini* device has been designed to tolerate significant shock and abuse. However, excessive shock and impact should be avoided in order to prevent damage to your device and voiding the warranty. The RX-1-*mini* 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 product is responsible for routine maintenance. Failure to do so may cause undue failure and possible health hazards. VivaQuant, Inc. 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 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.

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This product does not contain latex.

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