



Rhythm
EXPRESS™

by *VivaQuant*®

Rhythm Express® RX-1 mini
Remote Cardiac Monitoring System

PATIENT USE GUIDE

VivaQuant, Inc.
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Arden Hills, MN 55112
Tel. 1-866-ECG-TRUE (1-866-324-8783)

LP-015 Rev J



CAUTION: Carefully read all instructions prior to use. Observe all warnings and cautions in these directions. Failure to do so may result in patient complications.

INTENDED USE

The Rhythm Express remote cardiac monitoring system is intended for use by patients greater than 10 kg who either have or are at risk of having cardiac disease and those that demonstrate intermittent symptoms indicative of cardiac disease and require cardiac monitoring on a continuing basis. The device continuously records ECG data and upon detection by an ECG analysis algorithm or manually initiated by the patient, automatically delivers the recorded cardiac activity to the server where it is presented for review by a medical professional.

The data received from the Rhythm Express device can be used by another device for arrhythmia analysis, reporting and signal measurements. The Rhythm Express device is not intended to sound any alarms.

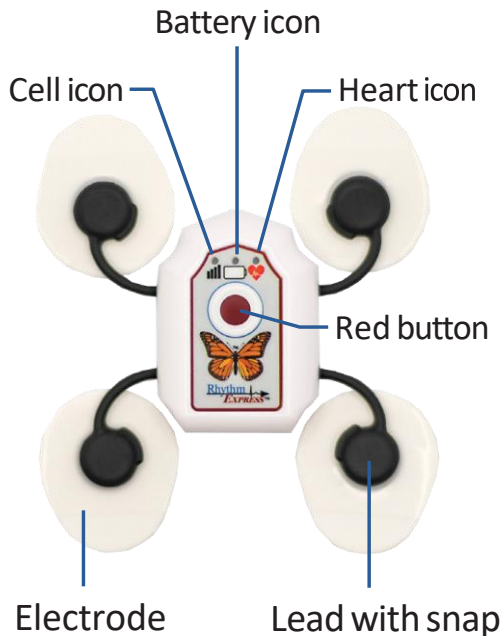
The device does not deliver any therapy, administer any drugs, provide interpretive or diagnostic statements or provide for any life support. The Rhythm Express system communicates events from the patient to the monitoring center within one to seven minutes (assuming cell service is available) and hence is not suitable for use as a real-time arrhythmia event monitor.

CONTRAINDICATIONS

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

About the RX-1 *mini* Device










RX-1 *mini* is a portable, battery-powered device that is used to monitor your heart rhythm continuously. When RX-1 *mini* detects an abnormal heart rhythm, it saves the electrocardiogram (ECG) in its memory. RX-1 *mini* is connected to a monitoring center using a secure, private cellular connection. Using the cellular network, RX-1 *mini* sends information about your heart rhythm to the monitoring center, where clinicians are alerted if an abnormal heart rhythm is detected. Additionally, RX-1 *mini* can record your symptoms by a 3-second press of the **Red** button on the device. The RX-1 *mini* lithium battery can be recharged using the charger provided with the device. The battery lasts for several days and the battery icon blinks amber when RX-1 *mini* has to be charged.



Environmental Specifications

Operating Temperature:	0 to 45 degrees C
Storage Temperature:	-25 to 45 degrees C
Relative Humidity:	10 to 95%
Atmospheric Pressure:	700 to 1060 hPa

RX-1 *mini* Important Features and Controls

	Direct current 5V dc 1.5 Amp
	RX-1 <i>mini</i> Type BF electrical isolation, device is not defibrillator proof. Electrodes are the applied parts.
	Not MRI safe
	Follow Instructions for use!
	This is the FCC logo indicating compliance with the FCC rules for wireless devices.
	Emits non-ionizing radiation
Rx only	Caution: Federal law restricts this device to sale by or on the order of a physician
IP64	Dust and water splash proof (RX-1 <i>mini</i>)
IP21	Protected from condensation and touch by objects greater than 12 mm (charger)
	Charger Class II equipment
	Indoor use only (AC/DC adapter charger)
	Red Button used to enter recording mode and mark symptomatic events

Note: the RX-1 mini has been tested for accidental submersion in water of 15 cm for up to 30 seconds.

Important Messages

Safety messages are indicated throughout this guide to draw attention to safety and other important information.

Warnings and Cautions

The following section contains a list of the warnings and cautions relevant to the RX-1 mini device.

WARNING: Disconnect device from patient before defibrillation. Exposure to defibrillation may damage the RX-1 mini device or may interfere with operation of the defibrillator.

WARNING: RX-1 mini is not intended for use as an emergency medical response system.

WARNING: 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.

CAUTION: 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.

CAUTION: 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.

CAUTION: This device is not intended for use during an MRI.

CAUTION: Use only specified parts and accessories to maintain operator and patient safety.

CAUTION: 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.

CAUTION: Do not allow electrodes or leads to contact an electrical power source or ground when in use on a patient. Contact in this manner could cause electrical shock of the patient.

- CAUTION:** 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.
- CAUTION:** Use only the specified charger for this device (AC/DC adapter), as listed in the system components of this manual. Using another charger may damage the device and may create a safety hazard.
- CAUTION:** Do not expose the device 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.
- CAUTION:** There are no user-serviceable parts inside. Opening the case will void all warranties and could result in permanent damage.
- CAUTION:** 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.
- CAUTION:** 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.
- CAUTION:** The user of this product is responsible for routine maintenance. Failure to do so may cause undue failure and possible health hazards.
- CAUTION:** VivaQuant equipment is identified by the UDI, Model, and serial number on the back of the device. Take care not to deface these numbers.
- CAUTION:** This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
- CAUTION:** 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.
- CAUTION:** This equipment should not be exposed to environmental conditions outside the listed specifications.

Using the RX-1 *mini*

Prepare Your Skin

The figure below shows the approximate location of the device on chest.

1. Prepare the skin at this location by trimming any hair.
2. Following the instructions for skin preparation provided by your physician.

NOTE: Do not use lotions or creams before applying the electrodes.

Apply the Electrodes to Your Chest

3. Connect the adhesive electrodes to the snaps on each of the four leads.
4. Remove the protective backing from electrodes and apply the electrodes to the skin at the location shown on the figure.



Changing Electrodes

Change electrodes as instructed by clinic staff.

To remove electrodes, gently grasp the edge/tab and peel back in a slow, continuous motion. A wet, warm washcloth may aid in removal of the electrodes. To avoid skin damage, do not rapidly remove the electrodes.

Note: To avoid excessive skin irritation, we suggest that when you change electrodes, place them next to the prior location. Place each electrode just to the side, above, or below where it was before. Never reuse electrodes. If an electrode is misplaced or not applied correctly, discard it and use a new electrode.

— Connecting Your Device for the First Time —

Starting a Recording (done only once)

Press **Red** button on the device for 5 seconds until you feel device buzz. The device will start recording within 10 seconds.

To confirm that the device is recording, briefly press the **Red** button (less than 1 second). The heart icon will blink green in groups of three.

Recording When you Travel

The RX-1 mini device will record data continuously and keep time according to your home location registered with your physician. Even if you travel across time zones, data will always be recorded and time stamped based on your home location provided that you keep your device charged. If you travel outside the U.S. data will still be recorded, but it will not be sent to the monitoring center until you return to the U.S.

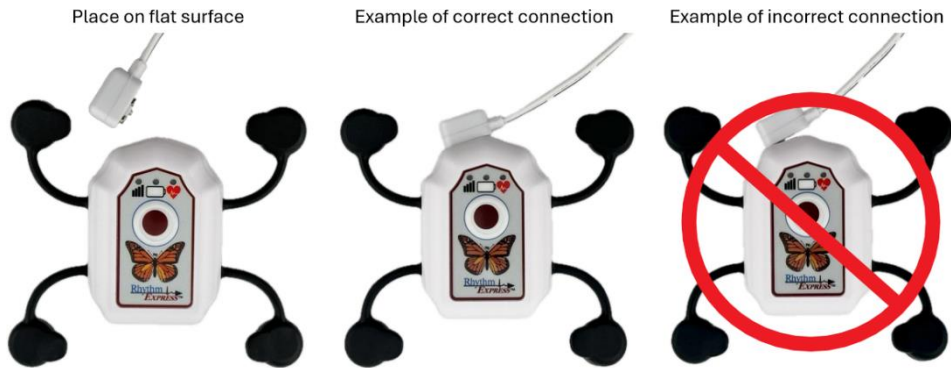
Recording Symptoms

When you feel symptoms that your physician asked you to record, press and hold the **Red** button on the device for 3 seconds until you feel the device buzz.

NOTE: For a period of 3 minutes following recording of a symptom, the RX-1 mini will not allow a new symptom to be recorded.

Charging Your Device

1. Disconnect the lead snaps from the skin electrodes. Do not wear device while charging.
2. Remove any debris or moisture from device connector using a cotton swab.
3. Plug the charger into a wall outlet.
4. Place the device and connector on a flat surface as shown below and bring the connector to the device until it snaps in place as shown in the middle figure below.



5. After plugging in the charger, confirm that the battery icon is either blinking or glowing green. If the device is not fully charged, the icon will blink green. Once fully charged, the battery icon will glow solid green.
 6. Once the battery is charged, disconnect the charger, and reattach the ECG leads to the electrodes. The RX-1 mini will automatically start monitoring your heart once connected.
Note The device may heat up while on charger, allow device to cool prior to placing on chest.
- Select a schedule for charging that works best for you, such as during your time showering or bathing. If the battery icon flashes amber following a brief press of the **Red** button the battery should be charged soon. If the icon flashes amber once every 10 seconds with no other lights, charge the device immediately.

Completing Your Study

Your physician has prescribed the duration of your recording of several days to a few weeks. When the recording has been completed, the heart icon will blink green on and off when Red button is briefly pressed. Disconnect the leads from the electrodes, remove the electrodes from your skin, and discontinue wearing the monitor. Return the device as directed by your monitoring center or physician.

Troubleshooting

Alert	Possible cause	Solution
Battery icon flashes amber	Battery is dead	Charge the device.
No icons light up after tapping the Red button for 1 sec	Battery is dead	Charge the device.
Heart icon flashes amber every 10 sec	An electrode is loose, or lead is unsnapped from an electrode	Check electrodes. Reconnect device to the electrodes.
All icons flash amber and device vibrates every second	Device is connected to charger while being worn	Disconnect device from electrodes
Other problems		Contact the monitoring center 1-866-ECG-TRUE (1-866-324-8783)

VivaQuant Rhythm Express RX-1 *mini* Limited Warranty

Products are warranted to be free from manufacturing material defects for a period of two (2) years from the date of shipment from VivaQuant to the original purchaser (the “Warranty Period”). This warranty does not apply to any product which VivaQuant determines has been modified or damaged by the customer. Excluded from this warranty are expendable supply items including, but not limited to, electrodes.

Except for the express warranties stated above, VivaQuant disclaims all warranties including implied warranties of merchantability and fitness. The stated express warranties are in lieu of all obligations of liabilities on the part of VivaQuant for damages, including but not limited to, special indirect or consequential, arising out of or in connection with the use or performance of VivaQuant Rhythm Express products.

Any action or breach of warranty shall be commenced within two (2) years of said breach or be forever barred. Any repairs made to the product, which are not covered by the warranty, shall be billed to the customer. Device is to be serviced by Factory Authorized Technicians only. Do not attempt to repair, modify, or service the VivaQuant Rhythm Express RX-1 mini device. Do not attempt to open or tamper with the device housing. Opening the housing will void this warranty.

This limited warranty does not cover any damage due to: (a) transportation; (b) storage; (c) improper use; (d) failure to follow the product instructions or to perform any preventive maintenance; (e) modifications; (f) unauthorized repair; (g) normal wear and tear; or (h) external causes such as accidents, abuse, or other actions or events beyond our reasonable control.

We extend this limited warranty only to the consumer who originally purchased the product. It does not extend to any subsequent owner or other transferee of the product. The Warranty Period is not extended if we repair or replace the product. We may change the availability of this limited warranty at our discretion, but any changes will not be retroactive.

THIS LIMITED WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS AND YOU MAY ALSO HAVE OTHER RIGHTS, WHICH VARY FROM STATE TO STATE. SOME STATES DO NOT ALLOW LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS, SO THE ABOVE LIMITATION MAY NOT APPLY TO YOU. SOME STATES DO NOT ALLOW THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATION OR EXCLUSION MAY NOT APPLY TO YOU.

THE REMEDIES DESCRIBED ABOVE ARE YOUR SOLE AND EXCLUSIVE REMEDIES AND OUR ENTIRE LIABILITY FOR ANY BREACH OF THIS LIMITED WARRANTY. OUR LIABILITY SHALL UNDER NO CIRCUMSTANCES EXCEED THE ACTUAL AMOUNT PAID BY YOU FOR THE DEFECTIVE PRODUCT, NOR SHALL WE UNDER ANY CIRCUMSTANCES BE LIABLE FOR ANY CONSEQUENTIAL, INCIDENTAL, SPECIAL OR PUNITIVE DAMAGES OR LOSSES, WHETHER DIRECT OR INDIRECT.

Publication Information

The information in this manual only applies to the VivaQuant Model RX-1 *mini* device. Due to ongoing product improvements, specifications in this manual are subject to change without notice.

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Contact Information

For General Information on the RX-1 mini

VivaQuant

1265 Grey Fox Rd. Suite 400

Arden Hills, MN 55112

www.rhythmexpressecg.com

1-866-ECG-TRUE (1-866-324-8783)

Email: support@rhythmexpressecg.com

For Customer Service

Contact the Monitoring Center

1-866-ECG-TRUE (1-866-324-8783)

VivaQuant shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance, or use of this material.

Thank you for using the Rhythm Express model RX-1 *mini*. We hope you had an enjoyable experience.

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Wireless Compliance

FCC IDs: 2AQ8D-RX-2 and 2AQ8D3

FCC Compliance Statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult VivaQuant for help.

Federal Communication Commission (FCC) Radiation Exposure Statement:

The RX-1 mini is in compliance with SAR for general population/uncontrolled exposure limits in ANSI/IEEE C95.1-1999 and has been tested in accordance with the measurement methods and procedures specified in OET Bulletin 65 Supplement C.

Phenomenon	EMC Standard or Test Method	Level of Performance
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact, ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated RF EM fields	IEC 61000-4-3	10 V/m from 80 MHz – 2.7 GHz 80% AM at 1 kHz
Proximity Fields from RF Wireless Communications Equipment	IEC 61000-4-3	IEC 60601-1-2 Table 9
Rated Power Frequency Magnetic Fields	IEC 61000-4-8	30 A/m at 60 Hz
Electrical Fast Transients/Bursts	IEC 61000-4-4	± 2 kV 100 kHz
Surges	IEC 61000-4-5	± 0.5 kV, ± 1 kV
Conducted Disturbances Induced by RF Fields	IEC 61000-4-6	3 V from 0.15 MHz to 80 MHz 80 % AM at 1 kHz 6 V from 0.15MHz and 80MHz in amateur radio bands
Voltage Dips, Short Interruptions, and Voltage Variations	IEC 61000-4-11	0 % 120 Vac; for 0.5 cycles 0 % 120 Vac; 1 cycle 70 % 120 Vac; 25/30 cycles interruption at 0 % 120 Vac; 250/300 cycles
Conducted Emissions	CISPR 11	Class B
Radiated Emissions	CISPR 11	Class B



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