



DRAFT Clinician's User Manual Rhythm Express™ Model RX-1

For Research Only.

This device is not cleared for sale by FDA.

VivaQuant
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St. Paul, MN 55126
Tel. 1-866-ECG-TRUE (1-866-324-8783)

Rx only CAUTION: U.S. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE ON OR BY THE ORDER OF A PHYSICIAN.



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

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One or more of the following patents may be applicable: US 8,632,465, US 8,478,389, US 8,433,395, US 9,050,007, U.S. 8,632,465, U.S. 8,543,195, U.S. 9,294,074, U.S. 9,314,181, and U.S. 9,339,202. Other US and foreign patents are pending.

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Manual Overview





The User Manual describes how to safely operate the Rhythm Express™ RX-1 device in accordance with its function and intended use. This manual is intended solely as a reference for the operation of the RX-1 device.

This manual is intended for use by clinical professionals. It is assumed that the reader has a working knowledge of medical terminology and procedures as required for monitoring cardiac patients.

Explanation of Symbols Used in this Manual

Symbol	Meaning
	Follow instructions for use
	Caution!
IP64	Resistant to water and dust ingress (RX-1)
IP21	Protected from condensation and touch by objects greater than 12 mm (charger)
	Type BF Applied Part. Avoid contact between conductive parts of electrodes and other conductive parts, including earth. device is not defibrillator proof
	Charger Class II equipment,
	For indoor use only (AC/DC adapter charger)
Rx only	Caution: Federal law restricts this device to sale by or on the order of a physician
	Manufacturer: VivaQuant, 4339 Nancy Place, Suite 100, St. Paul, MN 55126 Tel. 1-866-ECG-TRUE (1-866-324-8783), Web: www.vivaquant.com
	This is the FCC logo indicating compliance with the FCC rules for wireless devices.

Chapter 1: Manual Overview

	Emits non-ionizing radiation
5V  1.5A	Direct current
	Up/down arrows used to scroll through menu
	Red PTE Button used to enter recording mode and Patient Triggered Events

Glossary

Auto trigger: The ability to automatically detect an arrhythmia.

ECG (Electrocardiogram): The heart's electrical activity recorded from electrodes on the surface of the body.

Event Recorder: A system for continuous monitoring of the ECG. Arrhythmias are detected, and the patient can report the occurrence of symptoms.

Mobile Cardiac Telemetry: A system for continuous monitoring of the ECG. Arrhythmias are detected, the patient can report the occurrence of symptoms, and heart rate is measured continuously for reporting to a physician.

Heart rate: The number of times the heart beats in a minute, measured in beats per minute.

Holter monitor: A device worn by a patient for recording continuous ECG, typically for diagnosing brief temporary arrhythmias

Monitoring center: The monitoring center is responsible for reviewing clinical data transmissions and reporting them to the physician.

Patient Triggered Event (PTE): Occurs when a patient reports the occurrence of symptoms by pressing the large button on the keyboard of the RX-1.

Routine Event: An autodetected event that matches the event notification criteria established by the physician for a routine clinical event. ECG strips corresponding to these events are transmitted to the monitoring center during scheduled and ad hoc connections.

WARNING: Indicates a potential hazard or unsafe practice which, if not avoided, could result in death or serious injury.

CAUTION: Indicates a potential hazard or unsafe practice which, if not avoided, could result in minor personal injury or damage to the product or property.

NOTE: Indicates additional information or tips to help you get the most out of your equipment.

Urgent Event: An autodetected event that matches the event notification criteria established by the physician for an urgent clinical event. These events are of high clinical significance. ECG strips corresponding to these events are transmitted within a few minutes of onset of the event.

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Overview

This chapter provides an overview of the Rhythm Express RX-1 ECG Monitor and Arrhythmia Detector. The following information can be found in this chapter:

- Device description
- Intended use
- Indications for use

Device Description

RX-1 is a portable battery-powered wearable recorder for use by trained clinical staff to collect ECG from patients in a home, clinical, or outpatient setting for up to 30 consecutive days. The device can capture patient activated and auto-triggered cardiac events such as bradycardia, tachycardia, pause, and atrial fibrillation via an on-board ECG waveform analysis algorithm. The device can automatically deliver the data wirelessly to a server using a built-in wireless cellular data modem where it can be reviewed by a physician or other qualified professional. A medical professional can adjust the device notification criteria and auto triggering parameters using the server and securely communicate the updated device notification criteria to the device using the cellular network. Device notification parameters include arrhythmia detection thresholds, monitoring duration, and operating mode.

The RX-1 consists of a monitor, DIN 40 standard lead wires, and a wall battery charger. The RX-1 device is intended to be used only with lead wires supplied by VivaQuant. High quality FDA-cleared lead electrodes designed for long-term ambulatory monitoring should be used, such as 3M 2259 or equivalent.

RX-1 can record ECG as either an Event Recorder (ER), Mobile Cardiac Telemetry (MCT) or Wireless Holter (WH) device. As an Event Recorder, the device continuously detects arrhythmias and transmits them at a predetermined interval. Upon feeling symptoms, as directed by a physician, the patient can press the Red Patient Triggered Event (PTE) button on the device to mark the time symptoms occurred. The device then prompts the patient to assign a symptom type and will immediately connect with the cellular network. Once a secure connection is established on the cellular network, the device will transmit an ECG strip overlapping the time at which the red PTE button was pressed. Once received at a monitoring center or clinic, the ECG can be evaluation by a physician or other trained professional to aid in diagnosis.

When operating as an MCT device, RX-1 functions the same as ER mode with the addition that the RX-1 detects the location of each heart beat and transmits to the monitoring center for reporting to the physician as an aid in diagnosis. In addition, while in MCT mode, the server provides for retrieval of any ECG strip during the recording session. When operating as a WH device, RX-1 functions the same as MCT mode except that the server automatically retrieves all ECG strips recorded by the device.

When not actively monitoring a patient, the RX-1 can be placed in Standby Mode to save battery charge. Standby Mode essentially puts the device to sleep to preserve the battery and uses only about 1% of remaining battery capacity for each week the device is in Standby Mode. The device can be charged when in Standby Mode.

Intended Use

The Rhythm Express remote cardiac monitoring system is intended for use by patients 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 and can be reviewed by a medical professional.

Comment [bp1]: Changes here must be made everywhere. The indications are publicly approved during the 510(k). They must be consistent in all labelling and requirements.

The data received from the Rhythm Express device can be used by another device for arrhythmia analysis, reporting and signal measurements. The Rhythm Express remote cardiac monitoring system 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.

Contraindications

1. Patients under the age of 18
2. Patients with potentially life-threatening arrhythmias who require inpatient monitoring.
3. Patients who the attending physician thinks should be hospitalized.

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).
- 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.

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Safety Information

This chapter provides warnings and cautions relating to use of the RX-1 device. All personnel that use this device should read and be familiar with the content of this section prior to use.

VivaQuant asserts that the product covered by this manual is safe, reliable, and effective provided that the product is used in accordance with the instructions for use, as provided in this manual. Observance of all safety messages will help protect the user and the patient against those hazards.

Cautions and Warnings

WARNING: Wear the device and lanyard under a shirt or other garment to avoid becoming entangled in your surroundings.

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

WARNING: RX-1 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 long 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 device is designed for use with standard electrodes. Some people are sensitive to the 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 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 ECG leads to contact an electrical power source. Contact could cause electrocution of the patient.

CAUTION: 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.

Chapter 3: Safety Information

CAUTION: Use only the specified, 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.

CAUTION: 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.

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 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 device uses a Lithium Ion battery. This battery may present a fire or chemical burn hazard if mistreated. Do not disassemble, heat above 70° C (160° F), or incinerate. Dispose of the device in accordance with applicable local regulations.

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 and 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. If the RX-1 is result in a change in performance contact customer support at 1-866-ECG-TRUE (1-866-324-8783).

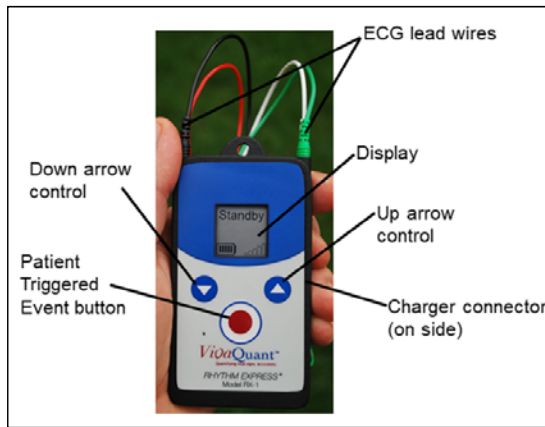
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Using the RX-1 to Monitor a Patient

This chapter guides you through the steps necessary to prepare the RX-1 for a new recording session, complete hookup of the device, initiate a monitoring session, and terminate a monitoring session.

Rhythm Express RX-1

The RX-1 is a small, battery-powered device that is typically worn on a waistband, a lanyard, or on a patient’s belt in a cell-phone-type pouch (not provided by VivaQuant).



RX-1 Device

Device Components

Feature	Description
ECG lead wires	These 4 leads conduct the signal from the electrodes on the patient’s skin to the device. Use only the electrodes provided by VivaQuant. RX-1 may not meet the required performance if other leads are used.
Display	The LCD display provides the user with feedback on device operation.
Menu selection buttons up down Arrow control	Used to move cursor on the display to select symptoms after pressing PTE button. These buttons can also be used in combination with the PTE button to control operation in some cases.
Patient Triggered Event (Red PTE) button	Used to mark the location of a patient triggered event while recording. It is also used to control operation of the device when operating in certain modes.
USB connector	Used to connect a battery charger.

Overview of RX-1 Device Operation

The device acquires a two-channel ECG, continuously evaluates the incoming signals to remove noise, and detects bradycardia (brady), tachycardia (tachy), pause, and atrial fibrillation (AF) using an on-board embedded algorithm. RX-1 can also mark patient triggered events and offers the patient the ability to select from a menu of common symptoms to aid in assessment of symptom-rhythm correlation. RX-1 uses standard DIN40 ECG lead wires to connect to standard commercially available skin electrodes to sense the patient's ECG. A cellular modem embedded within the RX-1 is used to establish a secure communications link to a server that is accessible from a monitoring center or clinic. Auto- and patient-triggered ECG arrhythmia strips are communicated to the server for viewing and incorporation into a report by a medical professional.

Connecting to the Cellular Network and Signal Strength

To maximize cybersecurity, all communications with the server are originated by the device. The device attempts to communicate with the server upon the following conditions: (Note that for a connection to be established, cellular service must be available. If no cell service is available, the device will retry until a connection is established.)

- Expiration of the server connection interval timer. This timer, built into the device, causes the device to attempt a connection at regular intervals (i.e. every 30 minutes). Whenever the device connects, all rhythm information is transferred to the server.
- Upon a patient triggered event. When the device is actively recording, and the patient presses the Red PTE button (for 5 seconds) on the device, the device marks the time of button press and initiates communication with the server via the cellular modem.
- When the device detects an arrhythmia meeting urgent criteria, it attempts to establish a communication link with the server to avoid the potential delay of waiting for expiration of the server connection interval timer. Auto detection of an arrhythmia that meets urgent criteria. Urgent criteria are determined by a physician and are selected for clinical import. For example, a physician may have selected a routine tachycardia threshold to be 140 bpm but selected urgent tachycardia threshold to be 180 bpm.
- A connection can be manually initiated by pressing the red PTE button for more than 5 seconds if the device is in Standby, Charging, or Recording. If the device just connected, or tried and failed to connect, the device will wait about 1 minute before attempting to connect.

When the device is connected or attempting to connect to the server, the cloud icon appears on the display. The cellular signal icon is updated when the modem first connects to the tower and continues to display signal strength until disconnected. When the device is not connected, the cell signal strength icon is not updated and the cloud icon disappears.



Device Notification Criteria

To set up the device prior to the start of a recording session, monitoring center or clinic staff are required to select criteria for arrhythmia detection and other useful information on the portal. This information is then communicated to the device via the wireless cellular link on the next connection. Table 1 below shows selectable criteria.




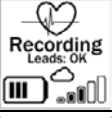

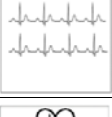



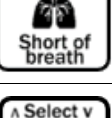







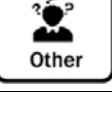
Table 1. Device notification criteria.

Parameter	Description
Mode	Selects either WH, MCT, or ER as the operating mode for recording
Time zone	Selects the time zone where the patient resides
Tachycardia rate threshold – urgent event	Specifies heart rate threshold necessary to trigger an urgent event
Tachycardia rate threshold – routine event	Specifies heart rate threshold necessary to trigger a routine event
Tachycardia Number of beats	The number of beats in a consecutive run above the tachycardia rate threshold required to trigger detection of a tachycardia event
Bradycardia rate threshold – urgent event	Specifies heart rate threshold necessary to trigger an urgent event
Bradycardia rate threshold – routine event	Specifies heart rate threshold necessary to trigger a routine event
Bradycardia Number of beats	The number of consecutive beats that must fall below the bradycardia rate threshold to trigger an event.
Pause threshold – urgent event	Specifies minimum pause duration necessary to trigger an urgent event
Pause event threshold – routine event	Specifies minimum pause duration necessary to trigger a routine event
Atrial fibrillation event – urgent	When checked, an AF event of 4 minutes or more in duration will trigger urgent notification
Audible notification	When checked audible notifications will be enabled
Recording duration	Specifies the recording duration in hours
Hookup mode enable	If hookup mode is enabled, the device scrolls the patient’s ECG on the display prior to entering recording mode. If not enabled, the device directly enters recording mode. If the device is sent to the patient for hookup, this mode should be disabled.



NOTE: We suggest that Hookup be disabled unless a clinician is present during hookup.

The RX-1 includes three buttons; a Red PTE button, and two smaller up down arrow buttons, as shown in **Error! Reference source not found.** above. The function of these three buttons depends upon the current operating state of the device, as indicated in the table below. Note that in the screen images in the table, the word “Connected” will only appear when the device is connected to the server via the Internet.

Table 2. Actions provided by PTE button vs. Operating State.

Shown on Display	Action Taken	Result	
	Press PTE for more than 5 seconds	Device transitions to Ready, provided that the device solid state drive has been erased and the device has been configured for the next patient to be monitored.	
	Press PTE for more than 5 seconds	Device transitions directly to recording mode, provided that the remaining battery capacity is at least 3 bars and Hookup mode is disabled.	
	Press PTE for more than 5 seconds	Device transitions to Hookup mode (if enabled) and displays an ECG trace for each channel. If PTE is not pressed for 60 seconds, the device starts recording ECG.	
	Press PTE for more than 5 seconds	Device transitions to Recording mode and starts recording ECG.	
	Press PTE for 1--2seconds	Displays symptom icon for Short of Breath. If PTE is pressed again while this icon is displayed, Heart Pounding is selected at the classification of the patient symptom.	
	Press PTE to tag this patient triggered event with Short of Breath as the patient symptom	Press Up Arrow to select Other as symptom. Press Down Arrow to select heart pounding (palpitations) as symptom.	
	Press PTE to tag this patient triggered event with heart pounding as the patient symptom	Press Up Arrow to select Short of Breath as symptom. Press Down Arrow to select Dizzy as symptom.	
	Press PTE to tag this patient triggered event with Dizzy as patient symptom	Press Up Arrow to select Heart Pounding as symptom. Press Down Arrow to select Chest Pain as symptom.	
	Press PTE to tag this patient triggered event with Chest Pain as the patient symptom	Press Up Arrow to select Dizzy as symptom. Press Down Arrow to select Other as symptom. Other indicates that the patient is experiencing something other than is described in other icons.	

Chapter 4: Using the RX-1 to Monitor a Patient

	Press PTE to tag this patient triggered event with Other as the symptom	Press Up Arrow to select Chest Pain as symptom. Press Down Arrow to select Short of Breath as symptom.	
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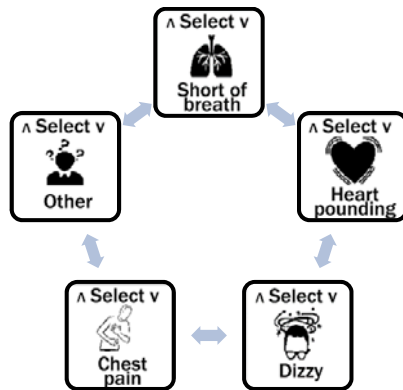
NOTE: We suggest that Hookup be disabled unless a clinician is present during hookup.

Recording Symptoms

1. When a physician requested symptom is experienced, press and hold the Red PTE button on the device for 1-2 seconds.
2. One of the symptom icons shown below will appear on the display.
3. The Up or Down Arrow buttons can now be pressed to step through the possible selections.
4. Once the symptom that best describes what the patient is feeling is displayed, press the Red PTE button again. This will capture the symptom for later viewing by a medical professional.

Note: Another symptom may not be recorded for 3 minutes.

If none of the symptoms match what you are experiencing, select “Other.” If no symptom is selected within 30 seconds, the screen will return to show that it is recording, and no symptom will be recorded.



After pressing the Red PTE button to record a symptom, the Short of breath icon appears. The Up and Down arrow keys will skip between icons to allow selection of the symptom icon that matches the patients symptom.

Battery Charging and Status

Battery status is provided on the display in most operating modes.

Battery displays (number of bars)	Battery Charge
5	Fully charged
4	75-95%
3	50-75%
2	20-50%
1	5-20%
0	Less than 5% remaining

Once the battery icon displays 0 bars, the device allows for one communication attempt with the server to indicate that the battery is near the end of its life then the device will stop acquiring data. It is recommended that the device be connected to a charger once the device displays 1 bar on the battery icon. Full charge will be reached in approximately 2 hours. Battery life for MCT mode is about 14 days.



Remove leads from electrodes then plug RX-1 into charger.

Caution: Disconnect the lead wires from the patient electrodes before charging. Use only the charger provided with the device to charge the battery.

Notifications

The Rhythm Express™ RX-1 device provides status information to the server on each connection. The server can provide alerts and notification information to the monitoring center staff as to battery status, quality of the ECG signal, and whether a lead is disconnected. The RX-1 can also provide an audible notification directly to the patient, when configured by the server. The audible notification will beep when any of the following conditions are met:

- Both ECG leads are disconnected for more than 30 minutes.
- The device has detected an Urgent Arrhythmia Event and has been unable to connect with the server within 15 minutes of onset of the event.
- The device has been unable to connect with the server for more than 4 hours.
- The battery is nearly depleted and needs to be charged immediately.

Preparing the RX-1 Device for a Recording

Preparing a device for a new patient involves the following tasks:

- Press the red PTE button for at least 5 seconds until the display shows either **Standby** or **Ready**. If the device was prepared for the next patient, the display will show **Ready**. If not, it will show **Standby**.
- Confirm that the battery is charged to at least 1 bar on the battery icon. If the battery is not charged to at least 3 bars, a new recording session cannot be initiated.
- If the display shows **Standby**, use the server to select device notification settings. Once the settings are entered on the server, press the red PTE button for 5 seconds to initiate a connection with the server. Once the settings have been downloaded to the device, **Ready** will appear on the display.

Comment [HS2]: This has been changed to one bar correct?

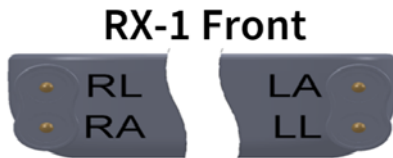
NOTE: We strongly suggest that all lead wires be connected to the device by a clinician. Leads are designed to be difficult to remove and may require the use of a tool (e.g. pliers or forceps).

Connecting the ECG Leads to the Patient

The quality of the ECG signal depends on the contact between the electrode and the patient's skin. We recommend the use of electrodes 3M 2259 or Ambu BlueSensor VLC, designed for long-term ambulatory monitoring.

- Use only the ECG leads provided by VivaQuant, plug the ECG leads into the device according to the label next to the connectors as shown below.
- The color of each lead wire plugged into the four connectors on the RX-1 should be as follows:

RL ---- Green	LA ---- Black
RA ---- White	LL ---- Red

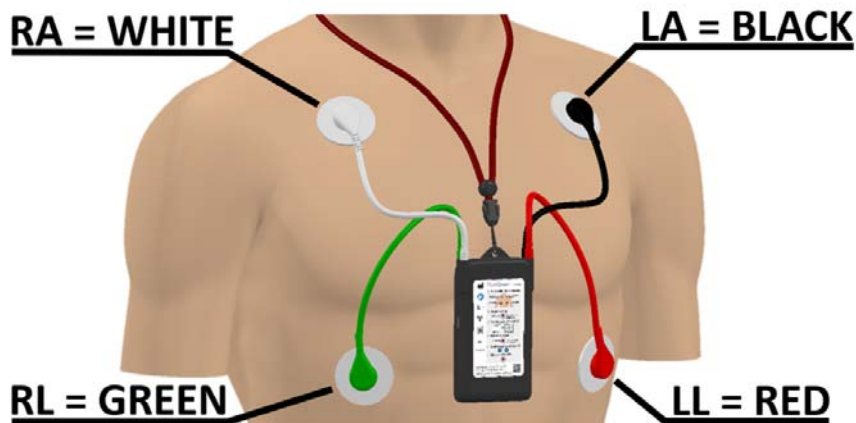


RX-1 ECG lead wire connection locations.

Chapter 4: Using the RX-1 to Monitor a Patient

Preparation of the patient's skin is important to obtain a good quality ECG recording. It is best to refer to your electrode manufacturer for instructions on proper skin preparation techniques. However, the following points can assist in obtaining good quality ECG recordings:

- Identify the locations of the electrodes. For a two-lead recording, use the location shown in the figure below. Placing electrodes over bone structures will reduce artifact and noise.
- Select a lead wire length to comfortably reach from the electrode location to the device. Use a white lead for the right arm (RA) electrode, a black lead for the left arm (LA) electrode, red lead for the left leg (LL) electrode, and green for the driven right leg (DRL) electrode.
- At each electrode location, shave hair if necessary.
- Using the 3M 2259 electrode, use the abrasive patch on the back of the ECG electrode to mildly abrade the skin at the location of each electrode by gently rubbing the abrasive patch over the area three or four times. If you are using a different electrode, follow the manufacturer's recommendations for skin preparation.
- Attach the ECG lead snap to each electrode and attach the electrode to the skin. If the electrode is mistakenly attached to the wrong location, use a new electrode to correct the mistake. Reusing an electrode can result in poor quality signals.
- **Note:** Make a short loop in the lead wire near each electrode and tape the loop to the skin. This will prevent the lead wire from tugging on the electrode during movement and can improve the recording quality.



ECG lead placement.

Initiating a Recording

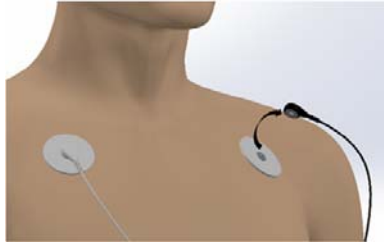
- If Hookup Mode is enabled: When the display shows **Ready**, press the red PTE button for 5 seconds. If the ECG electrodes and lead wires are connected, the patient's ECG will scroll across the display. Once confirmed that the electrodes are connected correctly, press the red PTE button again for 5 seconds to start recording. If the red PTE button is not pressed within 120 seconds, the device will automatically start recording.
- If Hookup Mode is disabled: When the display shows **Ready**, press the red PTE button for 5 seconds to start recording.

Charging the Battery During a Recording Session

We recommend charging the battery when the charge indicator shows only 1 bar of charge. In normal operation, charging the battery should only be required about once per week.

To charge the battery,

1. Disconnect the ECG lead wire snaps from the skin electrodes, leaving the lead wires plugged into the device



Disconnect the ECG lead wire snaps from the skin electrodes

2. Plug the USB cable from the charger into the RX-1 connector.

Note: Use only the charger provided with the device for charging. When the device is charging, a lightning bolt will appear inside the battery icon every few seconds.



Battery charging

- When the battery is fully charged, 5 bars will appear in the battery icon. The device will reach full charge in approximately 2 hours. To maximize the diagnostic utility of RX-1, reconnect the device as soon as charging is complete.
- We recommend replacing the electrodes at this time by following the instructions in **Connecting the ECG Leads to the Patient**.
- For comfort, reposition the location of each electrode slightly to avoid placing it at the same location.
- Use only the ECG leads provided by VivaQuant and follow the instructions in the above section, **NOTE: We strongly suggest that all lead wires be connected to the device by a clinician. Leads are designed to be difficult to remove and may require the use of a tool (e.g. pliers or forceps).**
- **Connecting the ECG Leads to the Patient** **NOTE: We strongly suggest that all lead wires be connected to the device by a clinician. Leads are designed to be difficult to remove and may require the use of a tool (e.g. pliers or forceps).**
- **Connecting the ECG Leads to the Patient**, and the color-coding in the figure above.

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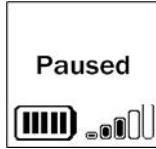
Caution: Disconnect the ECG lead wires from the electrodes prior to charging. Although the charger has been tested to assure that it meets safety standards, failure could result in electrical shock.

Chapter 4: Using the RX-1 to Monitor a Patient

Caution: Use only the specified, 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.



Time to recharge the battery.



Battery fully charged.

Terminating a Recording

The recording is automatically terminated upon expiration of the recording duration timer set when configured by the server. Alternately, the recording can be terminated via a command from the monitoring center provided upon physician orders. Upon termination, the device will automatically transmit remaining patient data on the next connection with the server.



When the recording is complete, the RX-1 will transition from Recording Mode (left above) to Standby. Remove the electrodes and device and return it to the monitoring center or clinic, as directed.

5

Maintenance, Service, and Troubleshooting

Storing the RX-1

The RX-1 may be stored for about 2 months without significantly depleting the battery charge level. Store the device in a clean, dry environment at a temperature between 10° and 25° C. Under no circumstances should the device be stored above 70° C. Damage to the device could result.

The device will connect with the server, and automatically confirm that all data have been transferred to the monitoring center, before it erases the RX-1 solid state drive. Once this is complete, the device will show **Standby** on the display. The device can be charged while in **Standby** Mode. If you wish to configure the device for the next patient prior to storing, configure the device on the server prior to placing the device in **Standby** Mode.

Cleaning the RX-1

The device must be cleaned after each patient. To clean the RX-1 and lead wires, use a soft cloth dampened with a mixture of warm water and mild detergent solution or 10% bleach, and then dry with a clean, soft cloth.

Caution: Do not use alcohol or acetone to clean the device or lead wires as this can damage the material. Do not expose the device or lead wires to 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.

Service








If you experience a problem with the RX-1, review the troubleshooting section for a listing of problems and solutions. If additional assistance is required with setting up, using or maintaining the equipment or if you notice changes in the performance of the RX-1 device contact customer support at 1-866-ECG-TRUE (1-866-324-8783)

Please, have the serial number of the device and description of the problem available when you call.

Disposal

This device contains electronic components and a lithium battery. Dispose of this device in compliance with local, state, and national regulations.

Troubleshooting

Problem	Possible cause	Solution
Screen is blank	Battery is dead	Charge the device
Device is in recording mode, but data are not being collected. 	Battery is near full depletion. Recording has been paused to prevent battery from going completely dead.	Charge the device.
Device is in recording mode, but data are not being collected. 	Both leads have been disconnected for more than 30 minutes	Check electrodes and lead wires. Reconnect device to electrodes.
High level of noise and/or artifact on the recording	Electrodes have come loose or poor skin preparation	Remove electrodes, prep skin at new location near old electrodes, and replace.
Device does not connect to the cellular network and the cloud icon does not display	Cell signal may be too weak	Move to a new location (e.g. near a window). If you are inside a building, go outside if possible. To initiate a new connection without having to wait for the a scheduled connection, press the red PTE button and the up arrow for 5 seconds until the cloud icon appears on the display. 
Battery does not last the expected number of hours	The number of recharges may have exceeded the rated life of the battery.	Call for a return materials authorization to have the device serviced
Screen reads "Call for Service" 	Device is not ready to record	Contact the monitoring center. 1-866-ECG-TRUE (1-866-324-8783)
Screen no longer reads Leads: OK instead reads Off: -RA, -LA, -RL, -LL 	Lead indicated has become disconnected	Check/reconnect lead to electrode and lead to RX-1 connections, if connections are okay replace the electrode indicated
Screen reads "Disconnect leads!" 	Leads are connected to electrodes while connected to charger	Disconnect leads from electrodes 
Other problems		Contact the monitoring center. 1-866-ECG-TRUE (1-866-324-8783)

Chapter 5: Maintenance, Service, and Troubleshooting

If you observe unexpected operation or events, we encourage you to report them via email, letter, or telephone to:

VivaQuant customer service

4339 Nancy Place, Suite 100

St. Paul, MN 55126

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

Email support@vivaquant.com

Please provide a detailed description of the circumstances, the serial number of the device, and the date the issue was observed.

6

Features and Specifications

Rhythm Express™ Model RX-1 Features

- Combination device—operates as a Wireless Event Recorder, Wireless Holter or Mobile Cardiac Telemetry Device.
- Operating mode and settings can be changed wirelessly
- Long-life rechargeable Lithium Ion battery.
- Designed for maximum patient compliance. Reliable and simple operation in a one-piece device.
- Protected against water spray and brief water immersion.
- Significantly less expensive to operate than other devices.
- Employs VivaQuant MDSP™ technology to reduce cellular data volume by > 95%, improve connectivity, and improve arrhythmia detection accuracy under typical ambulatory conditions.
- High-reliability design and simple operation reduce customer support calls.
- Automatic detection of brady, tachy, pause, and AF in Event Recorder and MCT Mode.

Arrhythmia Detection

The RX-1 incorporates a real-time embedded arrhythmia detection algorithm. The processing steps employ VivaQuant's proprietary MDSP technology to remove noise, described in US Patent 8,632,465 (other patents issued and pending). MDSP noise reduction technology has been shown to reduce noise by up to 26 dB (about 95%). Following noise reduction, QRS complexes are detected using a proprietary technique described in US Patent 9,408,549 and beat-to-beat (btt) RR intervals and btt heart rate (HR) are subsequently computed. Pause events are identified by the absence of a detected QRS for longer than the pause threshold defined by the Device Notification Criteria settings. Tachycardia (tachy) is detected based upon N consecutive beats exceeding the rate threshold setting. Bradycardia (brady) is detected if X consecutive beats are below the brady threshold. Tachy and brady rate thresholds as well as N and X are defined in the Device Notification Criteria settings.

Atrial fibrillation (AF) is detected using a proprietary technique described in US Patent 9,314,181. The technique involves fitting a function to a sequence of btt HR values. The variability and entropy are conditionally evaluated to assess the degree to which the RR values are irregularly irregular. Segments that are identified as potentially containing AF are then evaluated for the presence of P-waves to mitigate false positive events.

VivaQuant conducted performance testing according to the 60601-2-47 standard. A summary of performance is shown in the tables below:

Database	QRS Sens.	QRS PPV
MIT-BIH	99.9	99.8
AHA	99.7	99.8
NST	96.7	89.5

Chapter 6: Features and Specifications

Database	AF Sens.	AF PPV
MIT-BIH AF	100	96

Specifications

Characteristic	Condition	Min.	Typ.	Max.	Unit
Physical					
Length			112		mm
Width			63		mm
Thickness			12.9		mm
Weight	Without lead wires		110		g
Dust & water ingress (RX-1)			IP64		
Dust & water ingress (charger)			IP21		
Functional					
Operating modes	Event recorder, wireless Holter and mobile cardiac telemetry				
Arrhythmia events detected	Brady, tachy, pause, AF				
Event storage capacity				No limit	
ECG channels			2		
User feedback	LCD display and beeps				
Memory					
Recording time	Continuous, 2 channels		30		Days
Memory type	Non-volatile				
Wireless					
Cellular data technology			Verizon LTE		700 & 1700 MHz bands
Output power			225		mW
Electrical					
CMRR			>90		dB
AC range			±6.25		mV
DC range			±400		mV
Input impedance			≥10		MOhm
Frequency response			0.05-40		Hz
Recovery time			≤1.33		sec
Resolution (ADC)			24		Bits
Resolution (stored data)			12/3		Bits/μV
ADC sample rate			200		Hz
Battery					
Type	Lithium Ion, internal, rechargeable		3.7		V
Expected service life			5		Years
Life (MCT mode)	From full charge		14		Days
Life (ER mode)	From full charge		14		Days
Number of recharge cycles			>400		
Environmental					
Operating temperature		0		40	Deg. C

Chapter 6: Features and Specifications

Storage & transport temperature		-25		70	Deg. C
Relative humidity	Non-condensing	10		93	%
Atmospheric pressure		700		1060	hPa

Accessories

The following accessories are provided with the RX-1 device and are available for purchase:

Part Number		Description
Length (cm)	Part Number	ECG lead wires available in sets of 4 of 30, 45, 60, and 100 cm lengths
30	50-0235	
45	50-0232	
60	50-0234	
100	50-0233	
50-0229		Battery charger.

Comment [BB3]: Device is not an accessory

Comment [BB4]: We do not provide electrodes.

ECG Electrodes

We recommend a good quality ECG electrode suitable for long-term use. We have experienced good success with 3M 2259 and Ambu BlueSensor VLC.

7

VivaQuant Limited Warranty

Products are warranted to be free from manufacturing material defects for a period of one (1) year from the date of shipment from VivaQuant to the original purchaser. 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, and lead wires.

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 products.

Any action or breach of warranty shall be commenced within one (1) year 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 RX-1 device. Do not attempt to open or tamper with the device housing. Opening the housing will void this warranty.

Obtaining Warranty Repairs

To obtain repairs, first obtain a Returned Merchandise Authorization (RMA) number from your VivaQuant representative. Include the RMA number on the shipment and ship postage prepaid to:

VivaQuant
4339 Nancy Place, Suite 100
St. Paul, MN 55126
Attention: Repair, RMA # _____

VivaQuant will return warranty units postage prepaid.

8

Wireless Compliance

Contains FCC ID: [2AQ8D-RX-1-SQVZ](#)

FCC Regulations 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 the factory for help.

Federal Communication Commission (FCC) Radiation Exposure Statement:

The RX-1 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.

FCC RF Radiation Exposure Statement:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

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RF STATEMENT

Medical Electrical Equipment needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the following section.

- Interference may occur in the vicinity of equipment marked with the following symbol, .
- Portable and mobile RF communication equipment (e.g. cell phones) can affect Medical Electrical Equipment. The use of accessories and cables other than those specified may result in increased emissions or decreased immunity.
- The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
- Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
- The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Any other accessories, transducers and cables may result in increased emissions or decreased immunity and EMC performance.
- The device should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, it should be observed in order to verify normal operation in the configuration in which it will be used.
- Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

NOTE: VivaQuant is not responsible for any changes or modifications made to the device or charger. Such modifications could void the user's warranty and authority to operate the equipment and may create a safety hazard.

Chapter 8: Wireless Compliance

Publication Information

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

VivaQuant™ and Rhythm Express™ are trademarks of VivaQuant. All other marks referenced in this guide are owned by their respective owners.

Contact Information

For General Information and Customer Service

VivaQuant 4339 Nancy Pl. St. Paul, MN 55126 www.vivaquant.com 1-866-ECG-TRUE (1-866-324-8783)
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Email: support@vivaquant.com

Part number (this manual) - LP-002 Revision [B1](#)

Part number (RX-1) – 51-0019

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.

VivaQuant makes no warranty of any kind regarding this material, included, but not limited to, the implied warranties or merchantability and fitness for particular purpose.

This device complies with the FDA Unique Device Identification (UDI) system. Information identifying this device is provided in the label adhered to the back of the device and on the device packaging. Device ID/SN is set by the manufacturer and is secured from accidental modification.

Global Medical Device Nomenclature (GMDN)

GMDN	41651
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