VivaQuant™

Quantifying vital signs. Accurately.

Clinician's User Manual

Rhythm Express® Model RX-1 *mini*

Remote Cardiac Monitoring System

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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.

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.

Contents

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Manual Overview

The User Manual describes how to safely operate the Rhythm Express™ RX-1 mini device in accordance with its function and intended use. This manual is intended solely as a reference for the operation of the RX-1 mini 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!
	Not MRI safe
IP64	Dust and water splash proof (RX-1 mini)
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. Electrodes are the applied parts.
	Charger Class II equipment
	For indoor use only (charger)
Rx only	Caution: Federal law restricts this device to sale by or on the order of a physician
	Manufacturer: VivaQuant, Inc. 1265 Grey Fox Road, Suite 400, St. Paul, MN 55112 Tel. 1-866-ECG-TRUE (1-866-324-8783), Web: www.vivaquant.com, www.rhythmexpressecg.com
	This is the FCC logo indicating compliance with the FCC rules for wireless devices.
	Emits non-ionizing radiation
5V ⎓ 1.5A	Direct current

	Red Button used to enter recording mode, mark symptomatic events, and activate lighted icons to check device operation

Glossary

Accelerated Communication: A communication session that occurs without waiting for the Server Connection Interval (SCI) timer to expire. Accelerated delivery occurs under two conditions: a) The patient triggers a symptomatic event, or b) an arrhythmia event matching criteria set in the DNC for accelerated delivery is detected. If cell service is present, the delay between when such an event occurs and when the corresponding ECG strip is received at the monitoring center is between 1 and 7 minutes.

Autotriggered Event: An arrhythmia event that is automatically detected by the arrhythmia detection algorithm onboard the RX-1 mini. There are two types of autotriggered events: a) accelerated delivery, and b) standard delivery. Each type of event has different detection thresholds specified in the DNC and accelerated delivery can be enabled/disabled for each type of arrhythmia. If accelerated delivery is enabled for tachyarrhythmia, the rate threshold must be > than the rate threshold for standard delivery. If accelerated delivery is enabled for brady arrhythmia, the rate threshold must be < than the rate threshold for standard delivery. If accelerated delivery is enabled for pause, the pause threshold for accelerated delivery must be > than the pause threshold for standard delivery. If accelerated delivery for AFib/AFl is enabled, then an accelerated communication occurs if the duration of AFib/AFl is > 5 minutes.

Brady event: A brady event is detected when the HR of N consecutive beats is less than the specified HR threshold. Brady threshold and N are specified in the Device Notification Criteria file.

Device Notification Criteria (DNC): Settings that define the thresholds for detection of arrhythmias by the device and other parameters such as Server Connection Interval (time between scheduled communications with the server). When the specified criteria for arrhythmia detection are met, the device sends notification that an event has occurred, along with the corresponding ECG strip, to the server via the cellular network. The DNC contents are specified by a physician and are contained in a file that is communicated to the device from the server prior to the start of a recording. Arrhythmia thresholds and certain other settings can also be modified while a recording is in progress.

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

Event Recorder (ER): A system for continuous monitoring of the ECG. Arrhythmias are automatically detected, and the patient can report the occurrence of symptoms. ECGs associated with automatically detected events and patient reported symptoms are communicated to a monitoring center for review by trained personnel.

Heart rate (HR): The number of times the heart beats in a minute, measured in beats per minute. Beat-to-beat and averaged HR are provided. Beat-to-beat HR is computed as 1/RR (min). Mean heart rate is

calculated by averaging RR intervals and then computing the HR from the mean RR value for the specified interval.

Mobile Cardiac Telemetry (MCT): A system for continuous monitoring of the ECG. Arrhythmias are automatically detected, the patient can report the occurrence of symptoms, and heart rate is measured continuously for reporting to a physician. MCT also allows a physician to request that certain ECG tracing(s) can be retrieved for viewing. ECGs associated with automatically detected events and patient reported symptoms are communicated to a monitoring center for review by trained personnel.

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

Patient Triggered Event (Red): Occurs when a patient reports the occurrence of symptoms by pressing the large button on the keyboard of the RX-1 mini. If cell service is present, the delay between when a Red is triggered and when the corresponding ECG strip is received at the monitoring center is typically between 1 and 7 minutes.

Pause event: Absence of a heart action potential for the time specified in the Device Notification Criteria.

Standard Communication: A communication session that occurs upon expiration of the Server Connection Interval (SCI) timer. An event that matches the standard delivery criteria established by the physician for an autodetected arrhythmia event. ECG strips corresponding to these events are transmitted to the monitoring center during scheduled and accelerated connections (e.g. if a connection is initiated to send a Red). SCI can be set to between 15 minutes and 2 hours.

Tachy event: A tachy event is detected when the HR of N consecutive beats exceeds the HR threshold specified in the Device Notification Settings. N is specified in the Device Notification Settings.

Wireless Holter (WH): A system for recording continuous ECG and reporting the occurrence of patient symptoms. When RX-1 mini operates in WH mode, all recorded ECGs and patient symptom information are communicated to the monitoring center for analysis by other software. Analysis of ECG recorded in WH mode is not performed on the server or portal.

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.

2

Overview

This chapter provides an overview of the Rhythm Express RX-1 mini 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 mini 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, pre-mature ventricular contractions (VE beats/PVCs), and atrial fibrillation/flutter 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. In addition to cellular communications, the device can also communicate with the server via an embedded Wi-Fi link when not recording patient data. Cellular and Wi-Fi will never communicate at the same time. 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 mini consists of a monitor with leads, and a wall battery charger. Electrodes designed for long-term ambulatory monitoring should be used, such as Ambu BlueSensor VLC, 3M 2259, Vermed A10091, or similar.

RX-1 mini 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 button on the device to mark the time symptoms occurred. The device then promptly connects 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 button was pressed. Once received at a monitoring center or clinic, the ECG can be evaluated by a physician or other trained professional to aid in diagnosis.

When operating as an MCT device, RX-1 mini functions the same as ER mode with the addition that the RX-1 mini detects the location of each heartbeat 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 mini 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 mini can be placed in Standby Mode to save battery charge. Standby Mode essentially puts the device to sleep to preserve the battery and uses less than about 5% of fully charged battery capacity for each week the device is in Standby Mode. The device can be charged when in Standby Mode.

The RX-1 mini comes in two configurations: standard and long lead. In the long lead version the RA leg is about 15 mm longer to provide a higher amplitude ECG. In some cases, this can improve p-wave visibility.

Long lead

Standard lead

Indications for 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.

Additional Indications

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.

3

Safety Information

Below are warnings and cautions relating to use of the RX-1 mini 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.

Warnings and Cautions

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 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 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 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 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 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.

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 70° C (158° 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 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.

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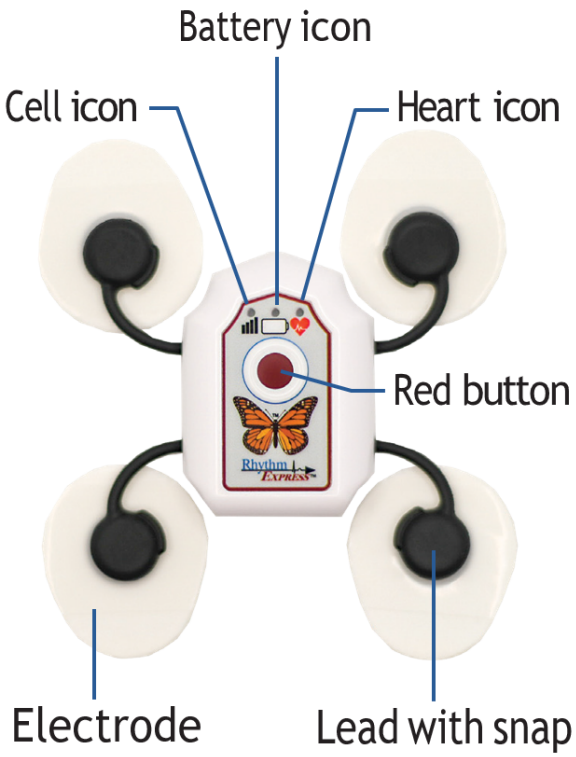
Using the RX-1 mini to Monitor a Patient

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

Rhythm Express RX-1 mini

The RX-1 mini is a small, wireless, battery-powered device that is attached to patient chest via disposable standard or custom patch electrodes.



RX-1 mini Device

Device Components

Feature	Description
ECG leads	These 4 leads conduct the signal from the skin electrodes to the device. We suggest that you use electrodes recommended by VivaQuant as they have been tested to meet minimum performance requirements. However, other electrodes suitable for long-term monitoring should function well.
Lighted icons	These lights provide the user with feedback on device operation.
Red button	Used to mark the location of a patient symptomatic event. It is also used to initiate transition to Recording state and activate Icons to communicate the operating state of the device.
Charger connector	Located on the end near the Battery icon. Used to connect a battery charger.

Overview of RX-1 mini Device Operation

The device acquires a two-channel ECG, continuously evaluates the incoming signals to remove noise, and detects bradycardia (brady), tachycardia (tachy), pause, pre-mature ventricular contractions (VE beats/PVCs), and atrial fibrillation/flutter (AFib/AFl) using an on-board embedded algorithm. RX-1 mini 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 mini uses built-in leads to connect to standard commercially available skin electrodes to sense the patient's ECG. A cellular modem and Wi-Fi module embedded within the RX-1 mini are 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 Network and Server

To maximize cybersecurity, all communications with the server are originated by the device. The device attempts to communicate with the server when any of the following conditions are met. Note that for a connection to be established, cellular service must be available. If no cell service is available or if the signal strength is too low to establish a reliable connection, the device will retry. If retry doesn't work, it will try to connect after meeting one of the following conditions.

- 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 and device status (e.g. battery level) is transferred to the server.
- Upon a patient triggered event. When the device is actively recording, and the patient presses the Red button on the device (for longer than 5 seconds), the device marks the time of button press and, assuming cell service is available, initiates communication with the server via the cellular modem within 5 minutes with an average delay of about 2.5 minutes.
- Upon detecting an arrhythmia meeting the criteria for accelerated delivery, if cell service is available it attempts to initiate communication with the server via the cellular modem within 5 minutes with an average delay of about 2.5 minutes.

The device will also connect via Wi-Fi if secure Wi-Fi service is available, the device is not recording patient data, the server connection interval expires, or the user initiates a manual communication. When the device is connected to the cell network, the cell icon will blink green. When the device is connected to the Wi-Fi network, the cell icon will blink magenta.

Cybersecurity Recommendations for Customers

There are a number of actions that clinic staff can take to mitigate the risk of a cybersecurity breach. These include:

1. Use the multifactor authentication feature provided by the portal.
2. Maintain your network with qualified staff. We recommend that background check be performed on all IT personnel before providing them with access to your network.

3. Employ a firewall in your facility. Use it to whitelist IP addresses accessible by the Portal. IP addresses to be whitelisted are confidential, but can be obtained from VivaQuant by authorized clinic staff.
4. Keep PC Windows security updates current.
5. Install anti-malware on each computer in your facility.
6. Maintain physical security of computers where the portal is used.
7. Employ an inactivity timer to log a user off that has left their computer for more than a specified time. Require entry of credentials to access the portal after returning.
8. Use computer screen privacy filters to reduce the risk of eavesdropping on screen content while the portal is open.

Device Notification Criteria (DNC)

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 information on the portal. This information is then saved in the DNC and communicated to the device via the wireless cellular link on the next connection. Table 1 below shows selectable criteria.

Table 1. Device Notification Criteria (DNC).

Parameter	Description
Mode	Selects either WH, MCT, or ER as the operating mode for recording. Mode can only be changed when the device is in Standby. Once a recording is started, this cannot be changed.
Time zone	The server populates the time zone based upon on the patient's zip code. All data collected are time stamped in UTC. The server adjusts the time applied to the data based upon the time zone. If a patient travels and changes time zones during a recording, all time stamps remain consistent with the time zone selected at registration.
Tachycardia rate threshold – accelerated delivery	Specifies heart rate threshold necessary to trigger a tachycardia event meeting criteria for accelerated delivery
Tachycardia rate threshold – standard delivery	Specifies heart rate threshold necessary to trigger a tachycardia event meeting criteria for standard delivery
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 – accelerated delivery	Specifies heart rate threshold necessary to trigger a bradycardia event meeting criteria for accelerated delivery

Bradycardia rate threshold – standard delivery	Specifies heart rate threshold necessary to trigger a bradycardia event meeting criteria for standard delivery
Bradycardia Number of beats	The number of consecutive beats that must fall below the bradycardia rate threshold to trigger an event.
Pause threshold – accelerated delivery	Specifies minimum pause duration necessary to trigger a pause event meeting criteria for accelerated delivery
Pause event threshold – standard delivery	Specifies minimum pause duration necessary to trigger a pause event meeting criteria for standard delivery
Atrial fibrillation/flutter event – accelerated delivery	When checked, an AFib/AFl event of ≥ 300 sec in duration will trigger accelerated communication of an AFib/AFl event.
Audible notification	When enabled, the device will provide haptic feedback when leads have been disconnected for > 30 minutes and when the device enters the lower power state due to low battery.
Recording duration	Specifies the recording duration in hours

The RX-1 mini includes a Red button and three icons (Cell icon, Battery icon, and Heart icon) that indicate the cell connection status, operating state, and battery condition of the device, as shown above. The Red button can be used to light up the icons, to start a recording, and mark a symptomatic event. During normal operation, a short momentary press of the Red button will result in the icons illuminating for about 10 seconds to indicate the operating status.

Table 2. Device status via Icons

Operating Status	Heart Icon	Battery Icon	Cell Icon	What it means
Response to lead disconnected while in recording				
One or more leads are off during recording	Amber flash about every 10 sec	Off		No response to momentary Red button press while lead is off

Battery very low				
Device is in low-power mode due to very low battery	Off	Flashes amber about every 10 secs.	Off	If battery is nearly dead, device enters low power state. If entered when device was recording, recording is paused. It is essential that the device be charged immediately to avoid a pause in ECG recording.

Operating Status	Heart Icon	Battery Icon	Cell Icon	What it means
Expanded notification on – Response to momentary Red button press				
Standby, but	Flashes	Flashes	Flash green if >1 of last	Device has completed a patient

not in inventory	green for about 10 sec	amber if battery is low	3 communications was successful Flash amber if none were successful	recording. Patient data are still available to upload to monitoring center. Device is not yet ready to configure for a new patient.
Standby and in inventory	Glows constant green for 10 sec	Flashes amber if battery is low	Flash green if >1 of last 3 communications was successful. Flash amber if none were successful	Device is available to be configured for a new patient.
Ready	Glows constant blue for 10 sec	Flashes amber if battery is low	Flash green if >1 of last 3 communications was successful Flash amber if none were successful	Device is configured for a new patient. Upon pressing Red button for 5 secs, recording will start.
Recording	Flashes green in groups of 3	Flashes amber if battery is low	Flash green if >1 of last 3 communications was successful Flash amber if none of last 3 communications was successful	Device is actively recording data on both channels.

Table 3. Actions provided by Red button vs. Operating State.

Icon	Action Taken	Result: icons	
Device is in Standby	Press Red button for 5 secs	Goes to Ready if in inventory and configuration is available on server: • Heart icon = Flash blue • Cell icon = Flash green while connected to server • Haptic upon Red button press	Device in Ready: Heart icon = Glow constant blue for about 10 secs. If transition fails: Heart icon = Flash amber and device buzzes
Device is in Ready	Press Red for 5 secs	Device transitions to Recording	Device is in Recording: Heart icon = Flash green in groups of 3
Device is in Recording	Press Red 3 secs	Event is marked to indicate that patient felt symptoms	Mark Patient event • Heart icon = flashes green in groups of 3 • Device buzzes upon button press

Pre- and Post-Trigger ECG Trace

Upon marking a symptomatic event, the time of button press and the corresponding ECG trace are communicated to the server to allow viewing of at least 180 seconds prior to and 15 seconds after Red button press. For autotriggered events, the time and duration of the event, the type of event, and the ECG trace are communicated to the server. The ECG trace communicated to the server allows viewing of the event plus at least 15 seconds prior to onset and 15 seconds after offset of an arrhythmia event < 4

minutes in duration. For events > 4 minutes in duration, onset and offset are communicated separately. ECG trace is communicated to allow viewing of at least 15 secs prior to and 60 seconds after onset and 60 seconds prior to and 15 seconds after offset.

Heart Icon Indicates Device Status

Device state is indicated by the pattern of Heart icon following a momentary Red button press.

Table 4. Determining operating state by momentary Red button press

Device State	State icon response	What it means
Standby but not in inventory	Flashes green for about 10 sec	Device has completed a patient recording. Patient data are still available to upload to monitoring center, if needed. Device is not yet ready to configure for a new patient.
Standby and in inventory	Constant green for about 10 sec	Device is available to be configured for a new patient.
Ready	Constant blue for about 10 sec	Device is configured for a new patient. Upon pressing Red button for 5 secs, recording will start.
Recording	Flash green in groups of 3 for about 10 secs	Device is actively recording data on both channels.

Battery Charge Level

Battery status is indicated by Battery icon. The battery icon can be activated by a momentary Red button press. However, if the battery is nearly dead, it will flash amber about every 10 seconds regardless of the Red button press.

Table 5. Battery Icon following momentary Red button press

Battery icon	What does it mean?
Solid green.	Fully charged (>95%)
Flash green once per 3 sec. Charging.	0-95%

Table 6. Battery Icon.

Battery icon	Charger Connected	Battery Icon Activated by Momentary Red Button Press
Solid green	Fully charged (>95%)	Fully charged (>95%)
Blinks Green about every 3 sec	34% to 95% charged	34% to 95% charged
Flash Amber once per 3 sec	5-34%	Short press of Red button
Always flash Amber about once per 10 sec	N/A	Regardless of any action
Never flashes	N/A	Battery completely dead

It is recommended that the device be connected to a charger once the Battery LED starts flashing amber. Full charge will be reached in less than 1.5 hours. Battery life for MCT and ER mode is about 5 days.

Remove each lead from the electrode snap, then plug RX-1 mini into charger.

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.

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.

To prevent damage to the battery due to excessive discharge, the RX-1 mini provides multi-level protection to preserve the battery and any data that was acquired. Once the battery reaches < 5% remaining capacity, the device will enter a low-power state (referred to as Shutdown) and the Battery icon will flash amber continuously about every 10 seconds. Upon entering this state, the device allows for one communication attempt with the server to indicate that the battery requires charging. If the device was recording data, recording and communications with the server will be suspended. The RX-1 mini will continue in this low-power state for up to 60 days. If the battery is charged during the 60 days and prior to recording termination, the device will return to its prior operating state. If it was recording data prior to entering this state, recording will continue. If the device is not charged before the end of this 60-day period, a protection circuit located in the battery will shut off battery output and the device will completely shut down. If the device was recording when this happened, the recorded data will be preserved but the recording will not continue after charging the battery. When a charger is connected,

the device will return to Standby and will send any uncommunicated data to the server. If the battery is discharged to the point where it enters shut-down, the battery must be charged within 1 year to avoid permanent damage. If the battery is permanently damaged, please arrange to return the device to the factory for replacement.

Connection Status

Connection status is indicated by Cell icon. This light blinks green when connected to the cell tower and blinks magenta when connected to a secure Wi-Fi network. If enhanced notifications are enabled, the Cell icon is activated by momentary press of the Red button to show status of the connection as shown below.

Cell icon	Connection status	Enhanced notification enabled
Flashes Green	connected to server via cellular	Doesn't matter
Flashes Amber	None of the last 3 communications was successful	Enabled
Flashes Green	At least one of the last 3 communications was successful	Enabled
Flashes Magenta	Connected to server via Wi-Fi	Doesn't matter

Notifications

The Rhythm Express™ RX-1 mini 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 mini can also provide a haptic notification directly to the patient. The haptic notification will cause device to buzz when any of the following conditions are met:

- Both ECG leads are disconnected for more than 30 minutes when device is in Recording state and enhanced notification is enabled in Device settings. The device will buzz once per 10 sec for 15 min
- When ECG leads and charger are both connected, the device will buzz and icons will flash amber every few sec until corrected.
- A failure is detected during self-test. Self-test is performance automatically when preparing the device for a new patient.
- An attempt is made to prepare the device to start a new recording by pressing the Red button to transition from Standby to Ready, but Device has not been configured for a new recording. The device will buzz 5 times.

Preparing the RX-1 mini Device for a Recording

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

NOTE: A device cannot be prepared for a new recording unless the prior recording has been finalized. This means that the prior recording must be completed, all data must be uploaded to the server, and the device must be released from prior recording.

- Confirm that the patient is registered and the configuration was sent to device. In the Portal, this device will show in Ready state.
- Press the Red button for at least 5 seconds until a buzz is noted. During this time, the device performs a self-test and attempts to connect to the server via cell or Wi-Fi to download the DNC. During this time, Heart icon will flash blue until Ready State has been entered. The Cell icon will flash green or magenta while connected to the server.
- If a server connection is available via cellular or Wi-Fi and device has been configured, the device becomes **Ready** which is indicated by Heart icon glowing constant green for about 10 sec, when Red button is pressed momentarily.
- If something went wrong and the device was not able to transition to **Ready**, Heart icon will flash amber and the device will buzz. After 10-15 seconds the device will return to **Standby**. Confirm that a DNC is available on the server, confirm cell service or Wi-Fi is available, and press the Red button again. If still unsuccessful, check the troubleshooting guide at the end of this manual.

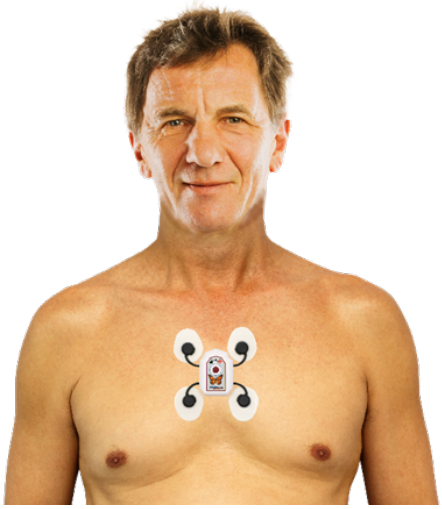
  Confirm that the battery is charged to at least 35% as indicated by the Battery icon flashing green in response to a momentary press of the Red button. If the battery is not sufficiently charged, a new recording session cannot be initiated.

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 Ambu BlueSensor VLC, Vermed A10091, or a similar electrode designed for long-term ambulatory monitoring.

Preparation of the patient's skin is important for good quality ECG recordings. The following can be helpful to obtain good quality ECG recordings:

- Identify the area where electrodes will be attached to the skin. Placing electrodes over bone structures will reduce artifact and noise. We recommend a location similar to that shown in the figure below.
- At each electrode location, shave hair if necessary and follow manufacturer's recommendations for skin preparation. A close shave can sometimes lead to excessive itching. Hence, it may be beneficial in some patients with chest hair to leave some stubble as this can sometimes lead to more comfortable wear.
- Attach the ECG lead snap to each electrode, remove covering on sticky surface, and attach the electrodes to the skin all at once. If the electrode is mistakenly attached to the wrong location, use a new electrode. Reusing an electrode can result in poor quality signals.



Recommended Device and ECG lead placement

Initiating a Recording

Device **Ready state** is indicated by Heart icon glowing constant blue for about 10 sec following a momentary Red button press. When the device is in **Ready,** press the Red button for 5 seconds to start recording. You will feel a confirmatory buzz from the device as it begins to record.

You can confirm that a recording is in progress by observing that the Heart icon flashes green in groups of three following a momentary press of the Red button. Once in recording, symptomatic events can be captured by pressing the Red button for 3 seconds until a buzz is felt. If one or more connections to electrodes is loose, the Heart icon will flash amber once about each 10 seconds to indicate a lead is disconnected from an electrode. When a lead is off, the Heart icon will only flash amber and will not respond to a momentary Red button press.

Charging the Battery During a Recording Session

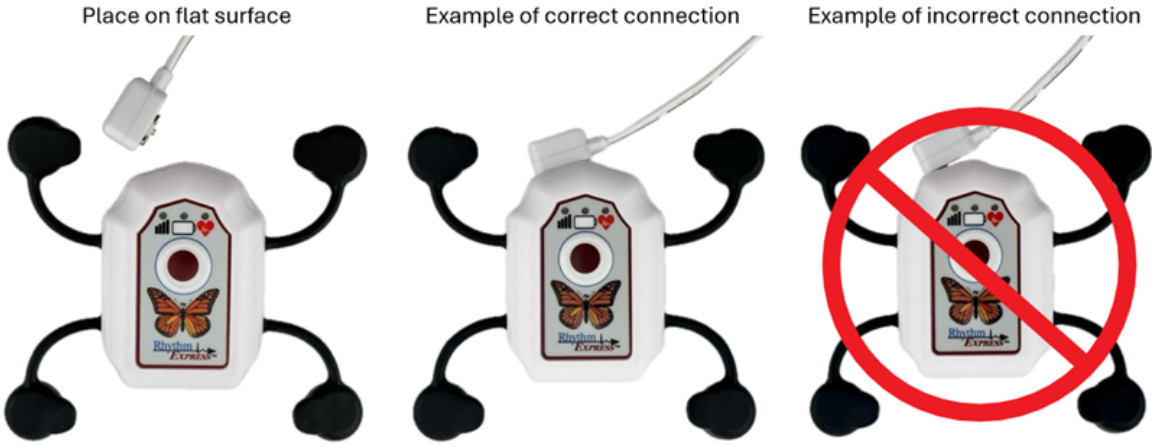
We recommend charging the battery when the Battery icon flashes amber in response to a momentary press of the Red button or whenever it's convenient. For example, some people find it convenient to charge the device once a day while they shower. However, if the battery icon continually flashes amber about once every 10 seconds, charge the device immediately to assure continuation of the recording.

To charge the battery:

1. Disconnect the RX-1 mini from the skin electrodes
2. Be sure that the RX-1 mini and the charge receptable are dry before connecting to avoid damage to the device.
3. Plug the charger into a wall outlet.
4. Plug the charge cable into the connector located on the pointed end of the device.

RX-1 mini device connected to a charger

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 sense that the leads are reconnected to the skin and automatically start monitoring the patient's heart.

   Note: The device may heat up while on charger, allow device to cool prior to placing on chest.

Note: Use only the charger provided with the device for charging. When the device is charging, the Battery icon will Flash green once per 3 sec until full charge (95%). Once the full charge is reached, the Battery icon will glow constant green once full charge is reached. The device will reach full charge in less than 1.5 hours when the device is fully discharged, less if the device is partially discharged. To maximize the diagnostic utility of RX-1 mini, 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 exactly the same location.

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.

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.

Terminating a Recording

The recording is automatically terminated upon expiration of the recording duration timer set when the device was prepared for the recording. Alternately, the recording can be terminated via a command from the monitoring center provided on physician orders. Upon termination, the device will automatically transmit remaining patient data on the next connection with the server. The device will connect with the server, and automatically confirm that all data have been transferred to the monitoring center. Once this is complete, the device will enter Standby as indicated by Heart icon flashing green in response to a momentary Red button press. Remove the electrodes and device and return it to the monitoring center or clinic, as directed.

Release a Device to Inventory

Following the transfer of data to the server at recording completion, the device remains in Standby with continuous data from the recording remaining on the RX-1 mini solid state drive. This allows time for the clinician to review the arrhythmia report and retrieve additional data, if necessary. Once the report is finalized, the device can be released back to clinic inventory and all data from the prior recording are erased from the RX-1 mini solid state drive via the server. The device is now available to assign to a new patient.

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Maintenance, Service, and Troubleshooting

Storing the RX-1 mini

The RX-1 mini may be stored for about 1 month without significantly depleting the battery charge level. Store the device in a clean, dry environment at a temperature between 10° and 45° C. Under no circumstances should the device be stored above 45° C. Damage to the device could result.

Cleaning the RX-1 mini

The device must be cleaned after each patient. To clean the RX-1 mini and leads, 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. Alternately, use a disinfecting towelette such as CaviWipes™ containing a blend of isopropanol and diisobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride in concentration not to exceed 17.5% and .28%, respectively.

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.

Service

If you experience a problem with the RX-1 mini, 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 mini device contact customer support at the number shown on the label on the back of the device.

Please, have the serial number found on the back 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
All icons flash amber and haptic buzzes repeatedly	Both Charger and Leads are connected	Disconnect leads from electrodes or unplug the charger
No icons light up in response to a momentary Red button press	Battery is dead	Plug in the charger. If Battery icon does not light within 30 minutes of charging, contact the monitoring center at the number on the back of the device.

Device is in recording, but data are not being collected. Battery icon flashes amber every 10 sec. all other icons are off.	Device has entered a low power state because the battery is nearly dead. Recording has been paused and communications have been disabled to prevent battery from going completely dead.	Plug in the charger immediately.
Device is in recording, but data are not being collected on one or both channels. Heart icon is flashing amber.	The RX-1 mini leads have been disconnected	One or more electrodes is disconnected. Check electrodes and leads. 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 is in Standby, Ready or Pause state and enhanced notification is enabled. Cell icon flashes amber following momentary press of Red button.	None of the last 3 communication attempts was successful. Cell signal may be too weak or non-existent	Move to a new location (e.g. near a window) or go outside where the cell signal is usually stronger than inside a building. If device establishes a cell connection, the Cell icon will flash green once per 3 sec when device is communicating with the server.
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
Upon pressing Red button to transition from Standby to Ready, the Heart icon flashes amber and the device buzzes.	Device is not ready to record	Contact Technical Services at the number on the device case.
Other problems		Contact Technical Services at the number on the device case.

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

VivaQuant customer service
1265 Grey Fox Road, Suite 400
St. Paul, MN 55112
Support: Tel. 1-866-ECG-TRUE (1-866-324-8783)
Email support@rhythmexpressecg.com

Please provide a detailed description of the circumstances, the serial number of the device (found on the back), and the date the issue was observed.

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Features and Specifications

Rhythm Express™ Model RX-1 *mini* 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 battery.
- Designed for maximum patient compliance. Reliable and simple operation in a one-piece device.
- Protected against water spray and brief water immersion.
- 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, VE/PVCs, and AFib/AFl in Event Recorder and MCT Mode.

Arrhythmia Detection

The RX-1 mini 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 (btb) RR intervals and btb 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/flutter (AFib/AFl) is detected using a proprietary technique described in US Patent 9,314,181. The technique involves fitting a function to a sequence of btb 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 AFib/AFl are then evaluated by operators at the monitoring center for the presence of P-waves to mitigate false positive events.

VivaQuant conducted performance testing according to the 60601-2-47 standard. QRS detection and AFib/AFl event detection performance is shown in the tables below.

Database	**QRS Sens.**	**QRS PPV**
MIT-BIH	99.8	99.9
AHA	99.6	99.8
NST	99.9	88.8
Database	**AFib/AFl Sens.**	**AFib/AFl PPV**
MIT-BIH	99	99

Specifications

Characteristic	Condition	Min.	Typ.	Max.	Unit
Physical					
Length			58		mm
Width			42		mm
Thickness			17		mm
Weight			45		g
Dust & water ingress (RX-1 mini)			IP64		
Dust & water ingress (charger)			IP21		
Functional					
Operating modes	Event recorder, wireless Holter and mobile cardiac telemetry				
Arrhythmia events detected	Brady, tachy, pause, AFib/AFl, premature ventricular contractions (PVCs)				
Event storage capacity				No limit	
ECG channels			2		
User feedback	LED icons, keypad tactile feedback, and haptic				
Memory					
Recording time	Continuous, 2 channels		30		Days
Memory type	Non-volatile				
Wireless					
Cellular data technology	Verizon LTE		786.9		MHz
Cellular output power			225		mW
Wi-Fi	802.11 b/g/n		2.4		GHz
Wi-Fi output power			14		dB
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, internal, rechargeable		3.7		V
Expected service life			2		Years
Life (MCT mode)	From full charge, non-full disc.		5		Days

Life (ER mode)	From full charge		5		Days
Number of recharge cycles			>250		
Environmental					
Operating temperature		0		45	Deg. C
Storage & transport temp.		-25		45	Deg. C
Relative humidity	Non-condensing	10		95	%
Atmospheric pressure		700		1060	hPa

Accessories

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

Part Number	**Description**
50-0565	Battery charger
50-0597	Case with printed labels
A10091	Vermed Electrodes

ECG Electrodes

We recommend a good quality ECG electrode suitable for long-term use. We have experienced good success with Ambu BlueSensor VLC and Vermed A10091.

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VivaQuant Rhythm Express 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 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 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.

Obtaining Warranty Repairs

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

VivaQuant, Inc.
1265 Grey Fox Road, Suite 400
St. Paul, MN 55112
Attention: Repair, RMA # _____
VivaQuant will return warranty units postage prepaid.

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Electromagnetic Compliance

The RX-1 mini device has been tested and found to comply with the limits for medical devices to IEC 60601-1-2:2014. These limits are designed to provide reasonable protection against harmful interference in a typical installation.

1. This device radiates radio frequency energy in normal use and, if not installed and used in accordance with instructions in this manual, may cause harmful interference to other devices in the vicinity. If this device does cause harmful interference to other devices, the user is encouraged to try to correct the interference by one or more of the following measures:
    - reorient or relocate the other device(s)
    - increases separation distances between the RX-1 mini and other device(s)
    - consult the manufacture of other device(s) or call service for help
2. The Interference may occur in the vicinity of equipment marked with the following symbol, .
3. 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.
4. 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.
5. 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.
6. 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.
7. 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.
8. 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.

If performance of the system is lost or degraded due to electromagnetic interference, the recording will restart once the interference is removed.

The RX-1 mini uses a Wi-Fi modem for communication over 802.11 b/g/n on the 2.4 GHz band with a power of 14 dB and a Cat M1 modem to communicate on band B13 of the Verizon LTE cellular network at 225mW. Duty cycle is limited to 13%.

The RX-1 mini is delivered ready to use with no configuration or adjustment necessary for connection to the cellular network.

Guidance and Manufacturer's Declaration Electromagnetic Emissions		
The RX-1 mini device is intended for use in the electromagnetic environment specified below. The customer or the user of the RX-1 mini device should assure that is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 2	The RX-1 mini emits RF energy to perform its function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The RX-1 mini devices suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings for domestic purposes.

Guidance and Manufacturer's Declaration Electromagnetic Immunity			
The RX-1 mini device is intended for use in the electromagnetic environment specified below. The customer or the user of the RX one device should assure that is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±15 kV air	±8 kV contact ±15 kV air	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst	±2 kV for power supply lines	±2 kV for power supply line,	
Surge IEC 61000-4-5	±2 kV for power supply lines	±2 kV for power supply line	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles	Pass	

	<5% UT (>95% dip in UT) for 5 sec		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80MHz ISM Bands 6 Vrms 10 V/m 80MHz to 2.7 GHz Proximity Fields of Table 9 4th Ed.	3 Vrms 6 Vrms 10V/m Pass	Portable and mobile RF communications equipment should be used no closer to any part of the unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strength from fixed RF transmitter's, as determined by electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with this symbol. 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidance lines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
a Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength and the location in which the unit is used exceeds the applicable RF compliance level above, then the unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating a unit. b Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3V/M.			

Recommended separation distances between portable and mobile RF communications equipment and the RX-1 mini device

The RX-1 mini device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the RX-1 mini device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications

equipment (transmitters) and the RX-1 mini device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmit		
	150 kHz to 80MHz d=1.2√P	80MHz to 800 MHz d=0.35√P	800MHz to 2.5 GHz d=0.7√P
0.01	0.12	0.035	0.07
0.1	0.38	0.11	0.22
1	1.2	0.35	0.7
10	3.8	1.1	2.2
100	12	3.5	7

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 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.

The FCC IDs for this device are 2AQ8D-RX-2 and 2AQ8D3.

Federal Communication Commission (FCC) Radiation Exposure Statement:

The RX-1 mini is in compliance with SAR for the 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.

Wireless Quality of Service

The RX-1 mini device utilizes an embedded cellular modem to communicate with the server at the clinical monitoring center. These communications are not critical to the health of the patient as this device is not intended to be used for lifesaving patient monitoring or those likely to undergo serious health consequences during their monitoring session. The RX-1 mini device has sufficient memory to

store all data in onboard non-volatile memory for the 30-day duration of the study. Thus, if a period where the modem is unable to communicate with the server occurs, the device will store this data and communicate it to the server as soon as a connection can be established. Operating settings for each device will be determined by the physician and communicated to the device via the cellular connection. The device verifies the validity of the settings before the recording is started. Thus, the required quality of service is achieved through design features that mitigate the impact of loss of connectivity. With respect to the loss of data due to limited quality of cellular service, the system provides for confirmation through multiple means that all data have been communicated from the RX-1 mini device to the server prior to preparing the SD card (solid-state drive) for the next recording session.

Wireless Coexistence

The RX-1 mini monitor uses an established cellular modem. As the device is an ambulatory device it is used in the home healthcare environment and is equivalent to the use of cellular telephones and similar technology. These devices have a strong track record of limited interference from competing technologies, in part due to the use of dedicated spectrum. Cellular signals are rarely interrupted by other technologies in the home but if it is, there are mitigations for limited quality of service as described above. The device while in normal operation will change channels to maintain connectivity when interference occurs.

Security of signals and Data

To enhance security, all server communications are initiated by the device and the cellular modem embedded in the RX-1 mini device will only communicate with the specified server and IP address controlled by VivaQuant under contract to Amazon Web Services (AWS). No data are transferred between the server and device until a secure encrypted connection has been established and all encrypted communications meet the requirements of NSA Suite B Cryptographic algorithms. This modem is certified via the Verizon Network security protocols for safe operation on their network. The device uses a FIPS compliant certificate serial number to render a certificate unique each RX-1 mini device. The RX-1 mini device and server must authenticate each other before a connection can be established. The data sent via the cellular modem uses mbedTLS for secure data transmission. This secure file transfer protocol uses data encryption to protect from intercept, and TCP/IP to guarantee delivery.

> **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.

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.

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

For General Information and Customer Service
VivaQuant 1265 Grey Fox Road, Suite 400 St. Paul, MN 55112 www.rhythmexpressecg.com Support - 1-866-ECG-TRUE (1-866-324-8783) Email: support@rhythmexpressecg.com

Part number (this manual) - LP-014 Revision K (Deviation)
Part number (RX-1 mini) – 51-0023 & 51-0043

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