

If you have any questions,
please contact us.



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LP-055 B

Cautions and Warnings

From Patient Use Guide

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

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

WARNING: Keep out of reach of children. This device includes use of small parts and wires/cords which could pose a choking or strangulation hazard to unattended children.

CAUTION: This device captures and presents data reflecting a patient's physiological condition that, when reviewed by a trained medical professional, can be useful in determining a diagnosis. However, the data should not be used as the sole means for determining a patient's diagnosis.

CAUTION: The RX-1 *mini* device is designed for use with standard electrodes. Some people are sensitive to materials used in skin electrodes. If a reaction occurs, remove the device and electrodes from the body.

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

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

CAUTION: The RX-1 *mini* is designed to meet or exceed requirements for electromagnetic compatibility, however, some environmental electrical interference may cause an artifact in the ECG. The quality of ECG signals may be adversely affected by electromagnetic interference from heavy machinery, electric blankets, and similar apparatus, resulting in non-physiological waveforms with the potential for misinterpretation.

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

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

CAUTION: Use only the specified charger for this device (AC/DC adapter), as listed in the system components of this manual. Using another charger may damage the device and may create a safety hazard.

CAUTION: Do not expose the device to autoclaving or steam cleaning, as damage could result. Recommended cleaning procedure is to wipe the exterior surfaces with a cloth dampened with warm water and mild detergent solution and then dry with a clean, soft cloth.

CAUTION: There are no user-serviceable parts inside. Opening the case will void all warranties and could result in permanent damage.

CAUTION: The RX-1 *mini* device has been designed to tolerate normal drops and shocks. However, excessive impact and shocks should be avoided to prevent damage to the device.

CAUTION: The RX-1 *mini* device uses a Lithium battery. This battery may present a fire or chemical burn hazard if mistreated. Do not disassemble, heat above 45° C (113° F), or incinerate. Return the device to the monitoring center or follow applicable local regulations for disposal.

CAUTION: The user of this product is responsible for routine maintenance. Failure to do so may cause undue failure and possible health hazards.

CAUTION: VivaQuant equipment is identified by the UDI, Model, and serial number on the back of the device. Take care not to deface these numbers.

CAUTION: This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

CAUTION: This equipment is resistant to water but should not be submerged in water. Remove device prior to entering a pool or bath and do not submerge device during cleaning or maintenance procedures. Submerging the device in water could result in damage.

CAUTION: This equipment should not be exposed to environmental conditions outside the listed specifications.

Troubleshooting

Alert	Possible cause	Solution
Battery icon flashes amber	Battery is dead	Charge the device
No lights after tapping Red button	Battery is dead	Charge the device
Heart icon flashes amber every 10 seconds	An electrode is loose, or lead is unsnapped from an electrode	Check/replace electrodes Reconnect device to the electrodes
Icons flash amber & device vibrates every second	Device is connected to charger while being worn	Disconnect device from electrodes
Steady blue light above heart icon	Monitor waiting for activation	Press & hold red button until device vibrates
Intermittent flashing amber light over cell icon	Monitor unable to connect to cell tower	Go to area with better reception if possible
Other problems		Contact monitoring center 866-324-8783

FAQs

Can I travel with the monitor?

Yes. The device will record data continuously and keep time according to your home location registered with your physician, even when traveling. When traveling through a TSA checkpoint, tell the agent that you are wearing a cardiac monitor. They may want to examine it. You can wear the device when traveling on an airplane.

Can I wear the monitor during my MRI?

No. Remove the device prior to an MRI.

Can I shower, bath, or swim with the monitor?

You can shower with the device. This equipment is resistant to water but should not be submerged. Remove device prior to soaking in a pool or bath.

How does the data get to the doctor?

When RX-1 *mini* detects an abnormal heart rhythm, it saves the information in its memory. RX-1 *mini* sends this data to the monitoring center using a secure, private cellular connection. In some cases, your doctor will configure the device so data is reviewed 24/7 and abnormal heart rhythms are reported to your doctor.

What should I do if I have skin irritation?

If a reaction occurs, remove the device and electrodes from the body. The RX-1 *mini* device is designed for use with standard electrodes. However, some people are sensitive to materials used in skin electrodes.

How can I tell if the device is working?

If the device is working, the Heart icon light will blink green in groups of 3 when the Red button is briefly pressed.

Can I wear the monitor while it charges?

No. Disconnect the leads from the electrodes prior to charging.

Can I wear the monitor while using supplemental oxygen?

Yes. Wearing the monitor while using supplemental oxygen is allowed. However, the device has not been evaluated for use in the presence of flammable anesthetic mixtures, such as in an operating room.

QUICK START GUIDE

Rhythm Express® RX-1 *mini*

Remote Cardiac Monitoring System



LP-055 Rev B

Congratulations!

Your doctor has chosen the best to monitor your heart rhythm, The Rhythm Express RX-1 *mini*.

Why has your doctor asked you to wear this monitor?

Your doctor wants to better understand your heart rhythm to better guide your care. The RX-1 *mini* you will wear continuously records the electrical activity of your heart. The heart activity your doctor is looking for is often short-lived, sometimes lasting only a few seconds. It's therefore important that you wear the monitor as much as possible, so your doctor receives the best information.

How does the Device work?

The RX-1 *mini* checks for any abnormal heart rhythms. Data is securely transmitted to our monitoring center using a cellular modem inside the device. Depending on how your doctor configured the RX-1 *mini*, our team of expert certified cardiac technicians in Memphis, TN and Dallas, TX reviews the information. All you need to do is wear the monitor!

Cardiac Monitoring is *not* an emergency service.

If your clinic has instructed you how to use the device and placed it on your chest, skip to **Getting Started**

If you received your device in the mail, by UPS or by FedEx, call (866) 324-8783 for assistance with hookup. Once your recording is done, return promptly using the shipping label provided.

Go to the "Patients" section of our website via the link or QR code below to access helpful video instructions or the Patient Use Guide for a complete list of device use instructions and other important information:

<https://rhythmexpressecg.com/patients/>



The RX-1 *mini* is manufactured in the U.S.A.



Components



RX-1 *mini* device

Gathers data on your heart rhythm and forwards it to the monitoring center



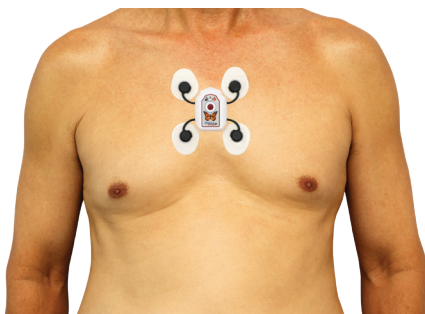
Charger

Charges the battery in the RX-1 *mini* device.



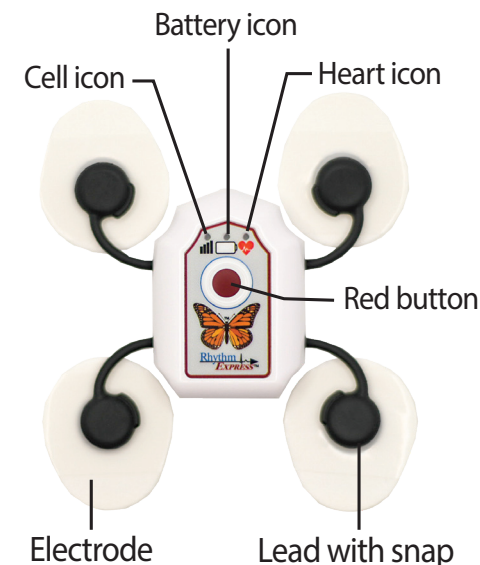
ECG electrodes

Senses the electrical signals of the heart on the skin. The snap connects to the RX-1 *mini* leads.



Suggested device placement

Getting Started



- Prepare the skin by shaving any hair. We recommend vigorously rubbing the skin with a Smith & Nephew Skin-Prep pad (or similar).
- Do not apply any lotions, creams, or powders before applying the electrodes.
- Connect the adhesive electrodes to the snaps on each of the four leads.
- Remove protective backing from the electrodes and apply to the skin at the suggested location shown on the figure at the left.

Connecting

- Press and hold the Red button on the device for 5 seconds until you feel device vibrate.
- To confirm the device is recording, briefly press the Red button (less than 1 second).
- The Heart icon will blink green in groups of three.

Recording Symptoms

- To record symptoms as directed by your physician, hold the Red button on the device for 3 seconds until you feel the device vibrate.
- For the next 3 minutes, the RX-1 *mini* will not allow a new symptom to be recorded.

Changing Electrodes

- Change electrodes as instructed by your physician or if they come loose from your skin.
- When changing electrodes, remove the device and charge it before applying new electrodes.
- Disconnect the leads from the electrodes one at a time using the small tab on each lead.
- To remove electrodes, gently grasp the edge/tab and peel back in a slow, continuous motion.
- A warm, wet washcloth may aid in removal of the electrodes. To avoid skin damage, do not rapidly remove the electrodes.
- To avoid excessive skin irritation place them next to the prior location. Place each electrode just to the side, above, or below where it was before.
- Never reuse electrodes. If an electrode is misplaced or not applied correctly, discard it and use a new electrode.



Charging

- Keeping your device charged is important. Charge when convenient or when battery icon blinks amber (indicates low battery). Charging usually takes less than 1 hour.
- Always remove device from chest when charging. The electrodes can remain on the skin during charging if not being replaced.
- Remove any debris or moisture from device connector using a cotton swab.
- Plug the charger into a wall outlet. Place the device and connector on a flat surface and bring the connector to the device until the magnet snaps in place. The battery icon will blink green when charging and turn solid green once fully charged.
- The device may heat up while on charger, allow device to cool prior to placing on chest.

Completing

- Disconnect the leads from the electrodes one at a time, remove the electrodes from your skin, and discontinue wearing the monitor.
- Heart Icon flashes green when red button briefly pressed.
- Return the RX-1 *mini* as instructed.