

## COMMON QUESTIONS

### **Do I need to wear my device at all times?**

Yes, always wear your RhythmStar Wearable device to help ensure the Monitoring Center and your physician can access important heart information as promptly as possible. RhythmStar Wearable is water resistant, allowing you the freedom to go about your daily activities while wearing the monitor. However, it is recommended to remove and charge the RhythmStar Wearable device for 20-30 minutes each day.

### **Can I travel wearing my device?**

If you plan on being away for several days, take the charging base and USB power supply with you so you can recharge the device. Do not forget to bring some extra adhesive electrodes. If you are traveling by air, the monitor may trigger airport detectors, but it will not be damaged. You may leave the device on and monitoring during air travel.

### **Do I need wireless internet access or a cellular data plan?**

No, RhythmStar Wearable has built in 4G cellular technology and sends your heart information to the Monitoring Center via cellular network. There is no cost to you for data transmission and you do not need to use / pair your phone to the device as data is sent directly without the need for an external communication device.

### **How often do I need to recharge my device?**

RhythmStar Wearable has a built-in rechargeable battery. It is recommended to charge the device for 20-30 minutes each day using the RhythmStar Charging Base and USB power supply. The battery indicator will be a steady red color while charging and then turn to green when the device is fully charged.

### **How long does it take to charge my device?**

If you do not charge your RhythmStar Wearable device for 20-30 minutes each day, it may take up to 3 hours to completely recharge the monitor.

### **What happens if the device feels warm to the touch?**

RhythmStar Wearable operates on extremely low power. The device should not increase in temperature. However, if the unit does feel warm, please remove and contact a RhythmStar Care Coordinator.

## INTENDED USE

The RhythmStar 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.

The data received from RhythmStar device can be used by another device for arrhythmia analysis, reporting and signal measurements. The RhythmStar 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 any life support. RhythmStar is for prescription use only (Part 21 CFR 801 Subpart D).

## CONTRAINDICATIONS

The RhythmStar system is not intended for use under the following conditions:

- Patients with potentially life-threatening arrhythmias who require inpatient monitoring.
- Patients who the attending physician believes should be hospitalized.
- Infants weighing less than 10 kg (22 lbs.).

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

RhythmStar meets current FCC Radio Frequency Emissions Exposure Guidelines.

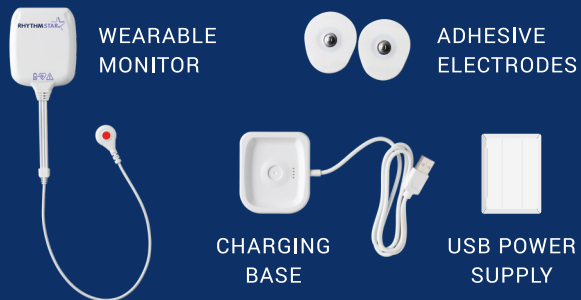


WEARABLE REMOTE  
CARDIAC MONITORING SYSTEM

## Quick Start Guide

*Simply Connected*

## WHAT'S INCLUDED



## QUICK START GUIDE

- 1 Turn RhythmStar Wearable on by briefly pressing the ON button on the back side of the monitor until the monitor vibrates and LED lights on the front flash once. If battery status light flashes red, RhythmStar should be charged prior to use. (See LED icon images in Step 5 for reference.)



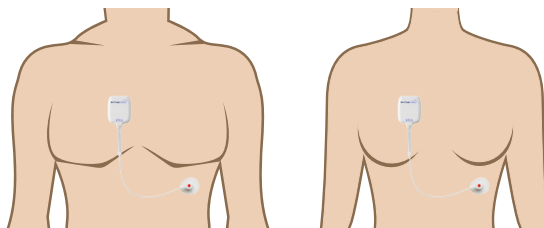
To charge, connect charging base to power supply and place RhythmStar Wearable onto charging base until the battery status light turns from solid red to solid green indicating the device is fully charged and ready for use. (See LED icon images in Step 5 for reference.)

The RhythmStar Wearable device should be charged for 20-30 minutes each day otherwise, it may take up to 3 hours to completely recharge the monitor.



- 2 Prepare your skin by:
  - Trimming chest hair as needed.
  - Clean skin with warm water and let the skin dry.
  - Do not use lotions or creams prior to applying the adhesive electrodes.


- 3 Snap one adhesive electrode to the back of the RhythmStar Wearable monitor and another to the red connector.
- 4 Remove the protective backing from the adhesive electrodes and apply electrodes to chest as illustrated:





MALE DEVICE POSITIONING


FEMALE DEVICE POSITIONING

- 5 Confirm the monitor is working properly using the colored LED icons on the front of the device:

 **Monitoring** – Monitoring status light will blink green every 10 seconds. This indicates that the monitor is functioning as intended. The Green monitoring light will become solid when recording a patient activated event for 30 seconds. (See Step 6 for reference.)

 **Battery Charged** – When the monitor is in the charging base and the base is connected to a power supply, the battery status light will become a solid green indicating the monitor is fully charged.

 **Battery Low** – When the battery is running low, the battery status light will begin to flash red. Once the monitor is placed in the charging base and the base is connected to a power supply, the battery status light will remain a solid red indicating that the monitor is in the process of being recharged.

 **Lead Connection** – When the monitor is ON and not connected, the lead connection status light will flash yellow every 5 seconds. The yellow light will also be rapidly blinking/flickering during boot up for about 30 seconds after turning the monitor on. When the monitor is on and properly connected, the lead connection status will discontinue flashing. If at any time during use the lead connection status light begins to flash yellow, it is necessary to check the connection to ensure the adhesive electrodes are firmly snapped to both the monitor and the red snap connector and that

the electrodes are securely adhered to the skin. For additional assistance, contact a RhythmStar Care Coordinator.

- 6 If you experience a symptom while wearing the monitor, firmly tap twice on the device. The device will produce a slight vibration in response to the “double-tap”. The Green monitoring light will be solid (not blinking) for 30 seconds to indicate that the device is recording the event. This will provide a special indicator within the recorded data to indicate that you experienced a symptom, which may assist your physician as they review your monitoring data.



## DURING MONITORING

- Adhesive electrodes should be changed as needed and should never be reused.
- The RhythmStar Wearable device is water resistant to water splashes but should not be worn when you bathe, shower, or swim.
- At any point, contact a RhythmStar Care Coordinator with any concerns or questions.

## WHEN YOUR STUDY IS COMPLETE

Unless your physician instructs you to return the monitor to their office, the monitor and related accessories (the charging base, the USB power supply and any unopened packages of adhesive electrodes) must be promptly returned to RhythmMedix to avoid any unnecessary charges. Place the monitor and accessories into the packaging box and place the box into the provided prepaid mailing bag for return.