



RHYTHMSTAR<sup>®</sup> 

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# SETUP GUIDE



Consult RhythmStar Operator Manual

Ref 1003-0424-ENG Rev1

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## WELCOME

Setting up RhythmStar® is quick and easy!

By following the steps in this guide, your physician will be able to monitor your heart to determine if you are experiencing any irregular heart rhythms.

**Let's get started.**

**NOTE:**

If you received this monitor by mail, please call 844.749.8461 and select option 2 to initiate monitoring.

## THE RHYTHMSTAR KIT INCLUDES

- RhythmStar monitor
- Adhesive electrodes
- Charging base
- USB power supply

## WHAT'S INCLUDED



RHYTHMSTAR  
MONITOR



ADHESIVE  
ELECTRODES



CHARGING  
BASE



USB POWER  
SUPPLY

## TURN ON THE MONITOR

Connect the charging base to the USB power supply and plug into a wall outlet.

Place the monitor in the charging base to turn on and ensure it is fully charged. When fully charged, the battery indicator light will turn green.

**NOTE:**

If the battery light status continually flashes red, the monitor should be charged prior to use. (see page 15 for charging).





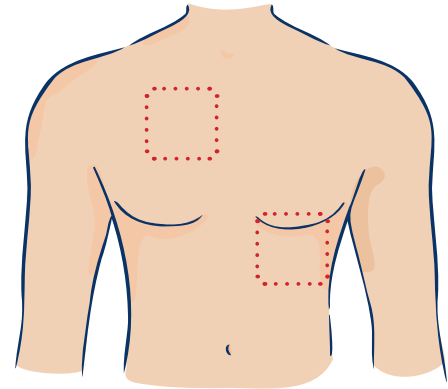
## SKIN PREP

Shave any chest hair in the flexible placement areas where the electrodes can be applied (see image).

Using a washcloth and warm water clean the skin and allow it to dry thoroughly.

### NOTE:

Do not use any lotions or creams within the electrode placement areas prior to applying the adhesive electrodes.



## CONNECT ELECTRODE

While leaving the protective backing on each electrode, snap one to the back of the monitor and another to the end of the lead.



attach one  
electrode here



attach another  
electrode here

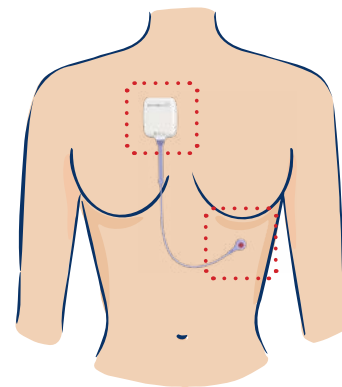
## APPLY TO CHEST

Remove the protective backing from the adhesive electrodes and apply to the chest. Firmly press to ensure a secure connection to the body, as illustrated:

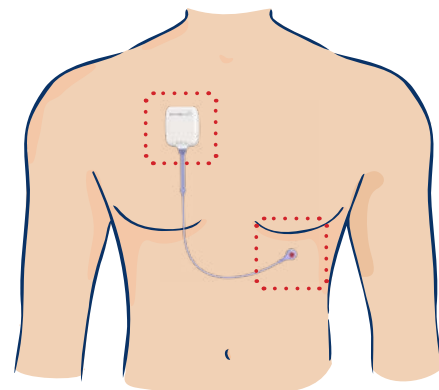
**NOTE:**

Varying placement within the flexible placement areas can help reduce skin irritation.

FEMALE  
MONITOR  
POSITIONING



MALE  
MONITOR  
POSITIONING



## CONFIRM CONNECTION & MONITORING



### **Lead Off:**

If either lead is not connected, the lead-off light will flash every 5 seconds and the monitor will either vibrate or beep.

If at any time while wearing the monitor the lead-off light begins to flash, check the connection to ensure the adhesive electrodes are firmly snapped to both the monitor and the connector and both are firmly secured to the skin.

(see page 11 for more information on how to apply electrodes)

**Monitoring:**

A blinking green light indicates the monitor is functioning as intended. This monitoring light will become solid for 30 seconds when recording a patient activated event.

(see page 14).

## RECORDING SYMPTOMS

If you received a welcome text message or email, your provider would like for you to record symptoms experienced during your monitoring period.

Follow the instructions provided in that message to access the RhythmStar app.



## DEVICE CHARGING

RhythmStar has a built-in rechargeable battery that will need to be recharged from time to time.



Once the monitor is placed in the charging base, the battery status light will remain a solid red until fully charged.

Depending on the battery level, the monitor should reach a full charge within 30 minutes to 3 hours.



When the monitor is fully charged, the battery status light will remain a solid green.

When the battery status light begins to flash red and the monitor periodically begins to vibrate or beep, the battery has reached 20% capacity. You should attempt to charge as soon as possible.

## DURING YOUR MONITORING PERIOD

Adhesive electrodes should be changed as needed. To remove, gently lift the electrode and wipe the skin underneath with a washcloth and warm soapy water as you continue to peel the electrode off.

The RhythmStar monitor is water resistant to water splashes but should not be worn when you bathe, shower, or swim.

**NOTE:**

Electrodes are single-use only and cannot be reused. Depending on several factors (environment, activity level, etc.), you can expect to replace electrodes every 2-3 days OR every time the monitor is disconnected for charging or bathing/showering.



## DOS & DON'TS

- Do wear your monitor as much as possible during your prescribed study period.
- Do charge your monitor when the battery light starts to flash red.
- Do return your monitor promptly after use to ensure complete study results.
- Do **not** submerge in water.
- Do **not** wear lotions in areas where the monitor and electrode will be applied.
- Do **not** shower or bathe with the device on.

## RETURNING YOUR DEVICE

1. Place your monitor in the charger until fully charged (when solid green battery light appears) to ensure all data is fully transmitted.
2. 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 RhythMedix to avoid any unnecessary charges.
3. Place the monitor and related accessories in the provided USPS prepaid mailing bag and seal the bag for shipping.
4. Place the mailing bag in your mailbox, a local mailbox or take it to the nearest US Post Office.



At any point, contact a  
RhythmStar Care Coordinator  
with any concerns or questions.

**Customer Care: 844.749.8461**

## COMMON QUESTIONS

### **Do I always need to wear my monitor?**

Yes, always wear your RhythmStar monitor (except during showering or bathing) to help ensure the Monitoring Center and your physician can quickly access important information about your heart.

### **Will the monitor disrupt my sleep?**

To NOT interrupt your sleep, the monitor will NOT vibrate or beep between 9 p.m. and 9 a.m. in the time zone where the monitor is used.

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

Several factors will determine how often recharging is required but expect to recharge the monitor every 2-4 days.

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

Your monitor should reach full charge within 30 minutes to 3 hours, depending on its initial battery level.

### **Is it normal to experience skin irritation or itchiness?**

Do not use the RhythmStar monitor if you have known allergic reactions to adhesives or hydrogels or a family history of adhesive skin allergies. If allergic symptoms, severe skin irritation, or signs of skin infection develop, remove the monitor and adhesive from your chest and discontinue wear. Reaction to adhesives may include severe redness and itching, hives, and blisters. Contact your healthcare provider and monitoring center to report the reaction.

## TECHNICAL REFERENCES

### INDICATIONS FOR 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 and upon detection by an ECG analysis algorithm or manually initiated by the patient, automatically delivers all recorded cardiac activity to the cloud server where it is presented and can be retrospectively reviewed by a medical professional at a monitoring center. The RhythmStar system is not intended for real-time monitoring.

The data received from the RhythmStar device can be used for retrospective review, arrhythmia analysis, and further evaluation, reporting and signal measurements using RhythmStar server, or a compatible third-party software. The RhythmStar system is not intended to sound any alarms.

The device does not deliver any therapy, administer any drugs, or provide for life support. The RhythmStar system does not provide interpretive or diagnostic statements. Interpretation and diagnosis are the responsibility of a physician. RhythmStar is for prescription use only.

## CONTRAINDICATIONS

Do not use the RhythmStar monitor on patients with potentially life-threatening arrhythmias who require real-time or in-patient monitoring.

Do not use the RhythmStar monitor in combination with external cardiac defibrillators or high frequency surgical equipment, near strong magnetic fields or devices such as MRI.

Do not use RhythmStar to monitor patients with a neurostimulator, as it may disrupt the quality of ECG data.

Do not use RhythmStar to monitor patients who do not have the competency to wear the device for the prescribed monitoring period. The RhythmStar monitor is not intended for infants weighing less than 10 Kg (22 lbs).

## WARNINGS

Do not use the RhythmStar monitor on patients residing in areas with limited to no cellular coverage.

Do not use the RhythmStar monitor on the airplane.

Do not use the RhythmStar monitor on patients with known allergic reactions to adhesives or hydrogels or with family history of adhesive skin allergies. If allergic symptoms, severe skin irritation, or signs of skin infection develop, remove the monitor and adhesive from the patient's chest and discontinue wear. Reaction to adhesives may include severe redness and itching, hives, and blisters. Contact your healthcare provider and monitoring center to report the reaction.

The RhythmStar monitor is Magnetic Resonance (MR) environment unsafe. Do not expose the RhythmStar monitor to a MR environment. The MR magnet core can attract the ferromagnetic materials in the RhythmStar monitor, creating a risk of projectile injury to the patient and others in proximity to the RhythmStar monitor and MR device. Metal components in the RhythmStar monitor can heat during MR scanning, resulting in the potential for thermal injury and burns.



Do not use the RhythmStar monitor on patients with broken skin. Only apply to intact skin.

Do not modify the RhythmStar equipment without the authorization of the manufacturer.

Do not use device if it has been damaged.

## **PRECAUTIONS**

During storage and prior to prescription for a patient, do not exceed the temperature and humidity limitations for the RhythmStar monitor. Devices exposed to environmental conditions outside the specified range may have degraded battery performance. Observe the temperature and humidity specifications for transportation and storage listed in the instructions for use.

Proper placement of the RhythmStar monitor on the patient's chest is important for recording ECG data. Carefully follow all steps in the application instructions to ensure the device is properly positioned and securely attached to the patient's chest.

Avoid delays in recording ECG data. Apply the monitor immediately after charging the device battery. If the Monitoring light on the RhythmStar monitor does not flash green after 30 seconds from applying the RhythmStar monitor to the patient's chest, contact the monitoring center.

Monitoring center or physician practice are responsible for monitoring device communication activity and contacting the patient for troubleshooting.

To avoid damaging the device's plastic enclosure, do NOT use cleaning solvents or adhesive removers, such as GOO GONE® or UNI-SOLVE, that include either Glycol Ether or Dipropylene Glycol Methyl Ether ingredients.

Disconnect patient leads before defibrillation.

Conductive parts of the electrode connectors should not contact other conductive parts including earth.

Keep device and packaging away from young children and pets. Contents may be harmful if swallowed.

## DANGER

- Always follow the charge conditions specified by the manufacturer. If the battery is charged under other conditions such as, a high temperature, a high voltage/current, or an altered charger NOT specified by the manufacturer, the battery may cause heat generation, explosion, or fire due to abnormal chemical reactions.
- If you notice any unusual odor, heat, discoloration, deformation, or any other characteristic apart from what you are used to while using, charging, or storing the device, then take it out of the charging base, and avoid using it. Using it in such a state may result in heat generation, explosion, or fire.

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