RHYTHMSTAR®

SETUP GUIDE

Consult RhythmStar Operator Manual

Ref 1003-0424-ENG Rev4

TABLE OF CONTENTS

Getting Started.....4
What to Do While Monitoring.....8
Dos & Don'ts.....17
Returning Your Monitor.....18
Troubleshooting.....20
Technical References.....22

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:
This heart monitor is not a lifesaving device. Seek immediate medical attention if you feel you are having a medical emergency.

Prefer a Video?

- Open the camera app on your phone.
- Hold your camera so you can see the barcode on your screen.
- A message should appear. Tap on it to launch the video.

NOTE:

If you received this monitor by mail, please call 856.282.1080 and select option 2 to initiate monitoring.

If you have any questions or need further assistance during your monitoring period, please call the number above to speak with customer service.

THE RHYTHMSTAR KIT INCLUDES

- RhythmStar Monitor
- Adhesive Electrodes
- Charging Base
- USB Power Supply

NOTE:
To ensure that your doctor has all of your valuable health data and to avoid costly unreturned equipment charges, it is important to promptly return the monitor, charging base and USB power supply at the end of your prescribed monitoring period. Per USPS shipping regulations, the original provided USPS box with prepaid postage must be used.

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 before use to ensure it is fully charged.

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 in within 30 minutes to 3 hours.

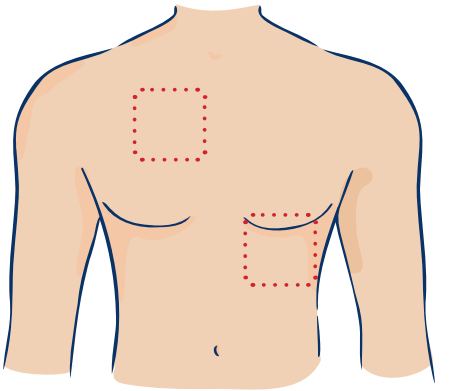
When the monitor is fully charged, the battery status light will remain a solid green.

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

SKIN PREP

If necessary, shave chest hair in the area where the electrodes can be applied (see image).

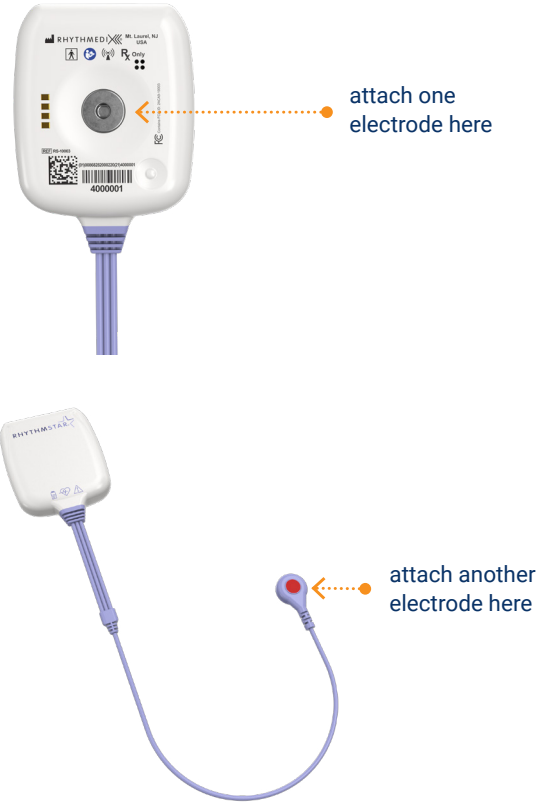
Using a washcloth and warm water clean the skin and allow it to dry thoroughly.



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

CONNECT ELECTRODES

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

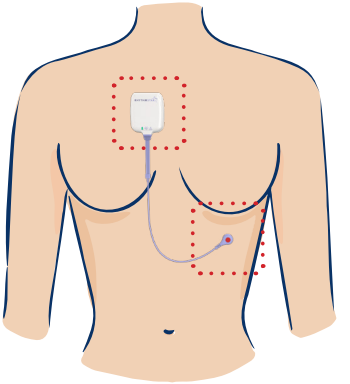


APPLY TO CHEST

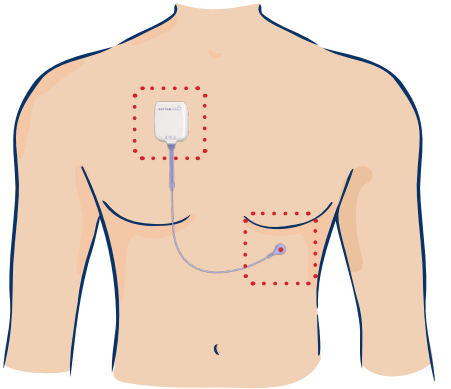
Peel the protective backing from the adhesive electrodes and apply to the chest in designated placement zones (see images), firmly pressing for a secure connection to the body.

NOTE:
To reduce the possibility for skin irritation, vary electrode placement 1-2 inches within the flexible placement areas shown when electrodes are replaced.
Minor variations in placement (up to 2 inches from the recommended position) are acceptable and will not affect the recording.

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.

It is important that the monitor be worn as much as possible during the prescribed study period.

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 experience a symptom such as dizziness or rapid heartbeat, firmly tap twice on the monitor. This will produce a slight vibration or beep and the green monitoring light will be solid for 30 seconds as the symptom is recorded.

If instructed by your physician, record your symptom in the RhythmStar app.

DEVICE CHARGING

RhythmStar has a built-in rechargeable battery that will need to be recharged every few days.

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 battery status light begins to flash red and the monitor periodically vibrates or beeps, the battery has reached 20% capacity and should be recharged as soon as possible.

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

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 can be worn while showering but should not be submerged in water, such as a pool or hot tub. Keep showers brief, and if possible, face away from the water as much as possible.

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.

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 or wear while swimming.
- **Do not** wear lotions in areas where the monitor and electrode will be applied.

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 box and seal the box for shipping.
4. Place the USPS prepaid mailing box 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: 856.282.1080

COMMON QUESTIONS

Do I always need to wear my monitor?

Yes, always wear your RhythmStar monitor 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 system, or a compatible arrhythmia analysis software that has been FDA cleared for Lead II analysis using non-traditional wet electrode placement. 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.

RHYTHMEDIX®