

COMMON QUESTIONS

DO I NEED TO WEAR RHYTHMSTAR AT ALL TIMES?

Yes, unless showering or exposed to water, always wear your RhythmStar to help ensure the Monitoring Center and your physician can get your important heart information as promptly as possible.

CAN I TRAVEL WEARING RHYTHMSTAR?

If you plan to be away for longer than 24 hours, take the charger and the additional battery with you as well. If you are traveling by air, the monitor may trigger airport detectors, but it will not be damaged. Prior to your trip, the monitoring center can instruct you how to turn off the cellular radio on the device by placing in "Flight Mode".

DO I NEED WIRELESS INTERNET ACCESS OR A CELLULAR DATA PLAN?

No, the RhythmStar has built in cellular technology and sends your ECG to the Monitoring Center via cellular network. There is no cost to you for the transmissions.

HOW OFTEN DO I NEED TO CHANGE THE RECHARGEABLE BATTERY IN THE RHYTHMSTAR?

Several factors, including the cellular network coverage quality and the amount of data being transmitted can impact battery life. It is recommended that you place a fully charged battery into RhythmStar once daily.

HOW LONG DOES IT TAKE TO CHARGE A BATTERY?

3 hours.

WHAT HAPPENS IF THE RHYTHMSTAR GETS WARM IN TEMPERATURE?

Much like a cell phone or other personal electronic device, RhythmStar can become warm from time to time.

RhythmStar complies with applicable surface temperature standards and limits. Placing RhythmStar in a pocket or unventilated area will increase the temperature and should be avoided.

Ref 10002-052-00-ENG Rev5

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 for 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 and IC Radio Frequency Emission Exposure Guidelines.

RHYTHMSTAR[®]

MOBILE CARDIAC MONITORING SYSTEM



QUICK START GUIDE

RHYTHMEDI[®]

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1 LOCATE COMPONENTS OF YOUR RHYTHMSTAR MOBILE CARDIAC MONITORING SYSTEM



ADHESIVE ELECTRODES



CHARGER & BATTERIES



2 INSERT A CHARGED BATTERY INTO THE MONITOR



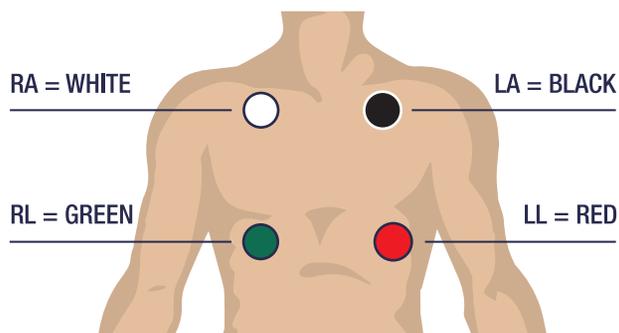
3 INSERT THE METAL CONNECTOR OF ECG CABLE INTO THE MONITOR

4 PREPARE YOUR SKIN

- Trim hair on chest as needed.
- Clean skin with warm water and let the skin dry.
- Do not use lotions or creams before applying adhesive electrodes.

5 APPLY THE ECG CABLE TO YOUR CHEST

- Connect the adhesive electrodes to the ECG cable snaps.
- Remove the protective backing from the adhesive electrode.
- Apply the adhesive electrodes to your chest in the configuration shown below.



6 CONFIRM THAT THE MONITOR IS WORKING

Insert battery, wait approximately a minute or so. When the solid green MONITORING message appears, you are now monitoring and ready to go about your normal daily activities.

If the green MONITORING message does not display and you see the message ACTIVATION PENDING in yellow or any other message, contact the Monitoring Center.



7 WHENEVER YOU FEEL SYMPTOMS, PRESS AND HOLD THE RED RECORD BUTTON ON THE MONITOR

The monitor will then prompt you to select the symptom(s) and the level of activity you were feeling and doing at the time of pressing the button.



DURING MONITORING

- Once applied, you should change the adhesive electrodes as needed (electrodes should never be re-used).
- Keep the RhythmStar monitor away from all liquids, extreme heat, or places that are damp or dusty. When you shower, you can keep the adhesive electrodes on, but you must remove the monitor and ECG Cable before entering water.
- Contact the 24/7 Monitoring Center at any time if you need assistance using the RhythmStar.

WHEN YOUR STUDY IS COMPLETE

When you see the solid yellow MONITORING COMPLETE message, you may remove the adhesive electrodes and discontinue wearing the monitor.

Return the RhythmStar Mobile Cardiac Monitoring System along with any unused adhesive electrodes, RhythmStar components and packaging as directed by your physician or Monitoring Center.