RHYTHMSTAR®

MOBILE CARDIAC
MONITORING SYSTEM

Quick Start Guide

Simply Connected

WHAT'S INCLUDED

MONITOR

CHARGER AND BATTERIES

ECG CABLE

ADHESIVE ELECTRODES

QUICK START GUIDE

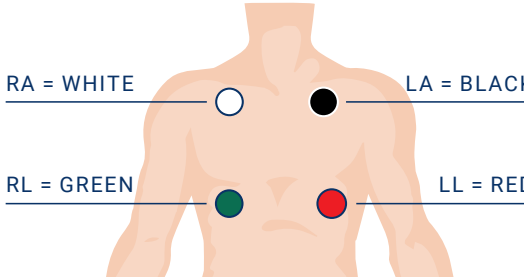
1. Locate components of your RhythmStar Mobile Cardiac Monitoring System.
2. Insert a charged battery into monitor.
3. Insert metal connector of ECG cable into monitor.

4 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.

5 Apply 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 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 RhythmStar. RhythmStar will then prompt you to select the symptom(s) you were feeling and the level of activity you were doing when you pressed the RECORD button.

DURING MONITORING

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

WHEN YOUR STUDY IS COMPLETE

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

Return the RhythmStar monitor, charger, batteries, ECG cables, any unused adhesive electrodes, and packaging as directed by your physician or Monitoring Center.

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 device 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 Monitoring Center 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 selecting “Flight Mode”.

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

No, 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 RhythmStar?

Several factors, including the cellular network coverage quality and the amount of data being transmitted can impact battery life. To ensure battery performance, place a fully charged battery into RhythmStar each day.

How long does it take to charge a battery?

3 hours.

What happens if my RhythmStar feels warm?

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.

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.

For all billing or financial responsibility matters, please call 844.753.1390.

RHYTHMEDIX®

5000 Atrium Way, Suite #1
Mt. Laurel, NJ 08054
P: 856.282.1080 | F: 856.282.1333
rhythmedix.com

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