



# Mobile Cardiac Monitor



# Operator Manual

---

# Table of Contents

|            |                                                                                    |           |
|------------|------------------------------------------------------------------------------------|-----------|
| <b>1.</b>  | <b>Description.....</b>                                                            | <b>3</b>  |
| <b>2.</b>  | <b>Indications for Use.....</b>                                                    | <b>4</b>  |
| <b>3.</b>  | <b>Contraindications for Use.....</b>                                              | <b>4</b>  |
| <b>4.</b>  | <b>Precautions.....</b>                                                            | <b>5</b>  |
| <b>5.</b>  | <b>Parts.....</b>                                                                  | <b>6</b>  |
|            | 5.1 RhythmStar Monitor.....                                                        | 6         |
|            | 5.2 ECG Cable.....                                                                 | 8         |
|            | 5.3 Batteries.....                                                                 | 8         |
|            | 5.4 Battery Charger.....                                                           | 9         |
| <b>6.</b>  | <b>Electrode Application-Connecting the ECG.....</b>                               | <b>9</b>  |
|            | 6.1 Connecting the ECG cable to the patient.....                                   | 9         |
|            | 6.1.1 2-Channel (3-lead) Electrode Placement.....                                  | 10        |
|            | 6.1.2 3-Channel (5-lead) Electrode Placement.....                                  | 11        |
|            | 6.2 Connecting the patient ECG lead cable to the monitor.....                      | 12        |
| <b>7.</b>  | <b>Using the Monitor.....</b>                                                      | <b>12</b> |
|            | 7.1 Powering on the monitor.....                                                   | 12        |
|            | 7.2 Checking ECG signal quality.....                                               | 14        |
|            | 7.3 Recording a cardiac event.....                                                 | 15        |
|            | 7.4 Entering symptoms and activity level associated with<br>the cardiac event..... | 16        |
|            | 7.5 Recharging the battery.....                                                    | 17        |
| <b>8.</b>  | <b>Maintenance and Service.....</b>                                                | <b>18</b> |
|            | 8.1 Cleaning.....                                                                  | 18        |
|            | 8.2 Service.....                                                                   | 18        |
|            | 8.3 Troubleshooting.....                                                           | 19        |
|            | 8.4 Disposal of Battery.....                                                       | 20        |
| <b>9.</b>  | <b>Medical Device Symbols and Safety Signs.....</b>                                | <b>21</b> |
| <b>10.</b> | <b>Specifications.....</b>                                                         | <b>22</b> |
| <b>11.</b> | <b>RhythMedix Limited Warranty.....</b>                                            | <b>23</b> |
| <b>12.</b> | <b>Obtaining Warranty Service.....</b>                                             | <b>23</b> |
| <b>13.</b> | <b>Wireless Compliance.....</b>                                                    | <b>24</b> |
| <b>14.</b> | <b>Arrhythmia Detection Performance.....</b>                                       | <b>26</b> |
| <b>15.</b> | <b>Accessories.....</b>                                                            | <b>27</b> |
|            | <b>Appendix A - Handling Instructions for Lithium Ion Battery....</b>              | <b>28</b> |

---

## 1. Description

**Caution: US Federal law restricts this device to sale by or on the order of a physician.**

The RhythmStar device is a portable, battery powered, wireless cardiac monitor which may be worn by a patient to record ECG and activity level data for up to 30 consecutive days. The device can capture patient activated and auto-triggered cardiac events such as Bradycardia, Tachycardia, and Atrial Fibrillation as identified by an embedded arrhythmia detection algorithm. The device is capable to automatically deliver the data to the server. The data can be delivered to the server wirelessly by using a built-in wireless data modem or via USB connection. A medical professional, using the server, can adjust and program the device configuration and auto-triggering parameters.

The RhythmStar device consists of a monitor, a patient ECG lead cable, an externally rechargeable battery, and a wall battery charger. The RhythmStar device is intended to be used with 3rd party lead electrodes supplied to a patient by a physician or a monitoring center. High quality FDA approved lead electrodes should be used.

The RhythmStar system supports USB connectivity that can be used to send and receive data from/to RhythmStar and other devices. The server can deliver configuration parameters to the device, such as monitoring duration, pre/post activation recording duration, auto-trigger rate and duration limits, user interface preferences, and requests for additional data stored in the device memory.

The device receives continuous ECG signal from lead electrode sensors attached to the patient's body, analyzes the data and stores it in the on-board flash memory. Activity level data that represents the patient's activity related to the physical motion is measured by a built-in accelerometer and also stored in the device memory.

---

## 2. 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 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).

## 3. Contraindications for Use

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.).

---

## 4. Precautions

**PLEASE NOTE:** No Computerized information is completely reliable and physicians should review all ECG results.

- Use only patient ECG lead cables provided by Rhythmmedix with RhythmStar.
- Disconnect patient ECG lead cable before using a defibrillator.
- When viewing the ECG data, the presence of pacemaker signals in the ECG trace should not be considered true representations of the actual pacemaker stimulus amplitude.
- To avoid unintended battery discharge, do not leave the battery in RhythmStar when it is not in use.
- To receive the best recording results, instruct patients to stay away from heavy electrical equipment or other sources of electromagnetic interference. Equipment such as electric blankets and heating pads are included in this group.
- Avoid exposing RhythmStar or RhythmStar battery to water or excessive moisture.
- Do not expose RhythmStar or RhythmStar battery to extreme temperatures beyond the limits shown in the environmental specifications.

---

## 5. Parts

RhythmStar is shipped with the following components:

### 5.1 RhythmStar monitor

The RhythmStar monitor is a small, lightweight, portable, battery powered device which is typically worn on a patient's belt or waistband by placing the monitor in a "cell phone type pouch" (not supplied by RhythMedix).

#### Monitor Components

| Letter | Description            |
|--------|------------------------|
| A      | LCD display            |
| B      | Record Button          |
| C      | Menu Selection Buttons |

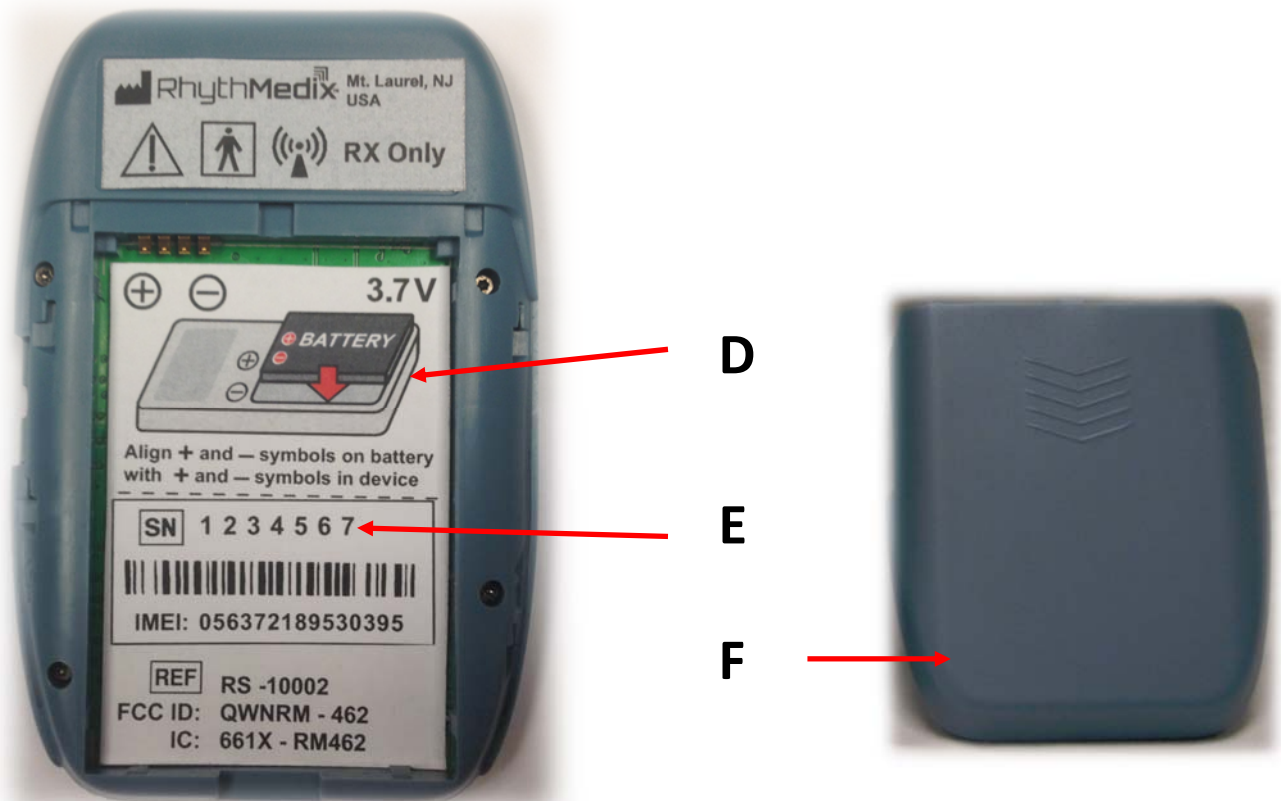
*Front view of the RhythmStar Monitor*



Monitor Components continued

| Letter | Description         |
|--------|---------------------|
| D      | Battery Compartment |
| E      | Serial Number       |
| F      | Battery Door        |

*Back view of the RhythmStar Monitor  
(battery door removed, no battery inserted)*



---

## 5.2 ECG Cable

The patient's ECG signal is conducted using the patient ECG lead cable. RhythmStar will not work with any other cables than those supplied by the manufacturer. With RhythmStar, you can choose between a 3- or a 5-lead ECG cable.

3-lead ECG Cable:



5-lead ECG Cable:



## 5.3 Batteries

RhythmStar uses an external rechargeable Lithium-Ion (Li-Ion) battery. This easily removable battery must be recharged with the supplied battery charger. Only IEC 62133 certified Li-Ion batteries supplied by RhythmMedix are to be used with RhythmStar.



---

## 5.3 Battery Charger

RhythmStar batteries must be charged with the included battery charger.



## 6. Electrode Application—Connecting the ECG

**NOTE:** RhythmStar device is intended to be used with 3rd party lead electrodes supplied to a patient by a physician or a monitoring center. High quality FDA approved lead electrodes should be used.

RhythmStar operates with the supplied patient ECG lead cables only! RhythmStar can operate with either a 3 or a 5-lead cable. Any attempt to connect another type of cable could damage the device or cause injury to the patient. Every effort should be made to handle and store the patient ECG lead cables with care to avoid damaging the lead wires and lead wires snaps.

### 6.1 Connecting the ECG cable to the patient

The quality of the ECG signal greatly depends on the contact between the electrode and the patient's skin. RhythmMedix recommends use of high-quality, Holter electrodes that have been approved by the FDA. Proper preparation of the patient's skin is required for obtaining a quality ECG recording. It is best to refer to your electrode manufacturer for instructions on proper skin preparation techniques. However, the following points can assist in obtaining quality ECG recordings:

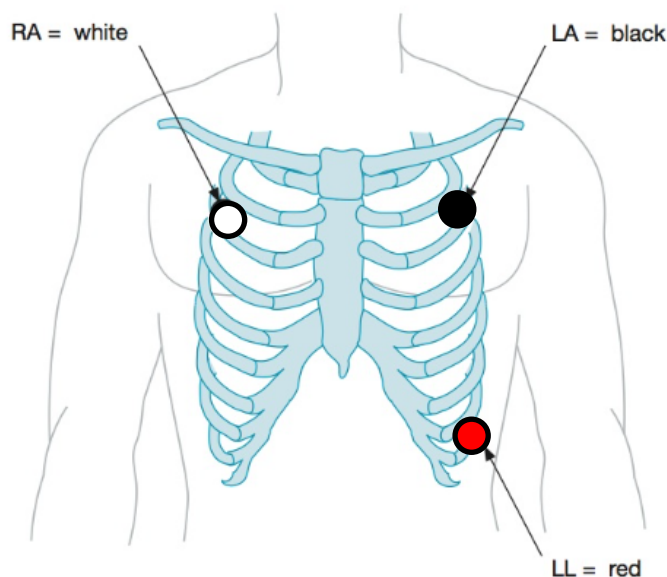
- If necessary, shave hair from the areas on the chest where the electrodes are to be placed.
- At each location where an electrode is to be placed, clean the skin with water or rubbing alcohol and let the skin dry.
- To avoid applying excessive pressure to the patient's body, attach the snaps of the ECG cable to the electrodes prior to placing them on the patient's skin.
- Generally, electrodes should be placed over bone structures. Artifact and noise result from placement of electrodes over large muscles or fatty tissue.

- 
- STEP 1:** Connect the patient ECG lead cable snap to the electrode.
- STEP 2:** Remove the protective backing from the electrode.
- STEP 3:** Apply the electrode to the patient's skin. Apply each electrode to match Figures 1 or 2 in this manual or as instructed by the physician.

### 6.1.1 3-lead configuration

Three color-coded lead wires are used to create two channels of ECG recording. This is a typical electrode placement:

**Figure 1—3-Lead Electrode Placement**

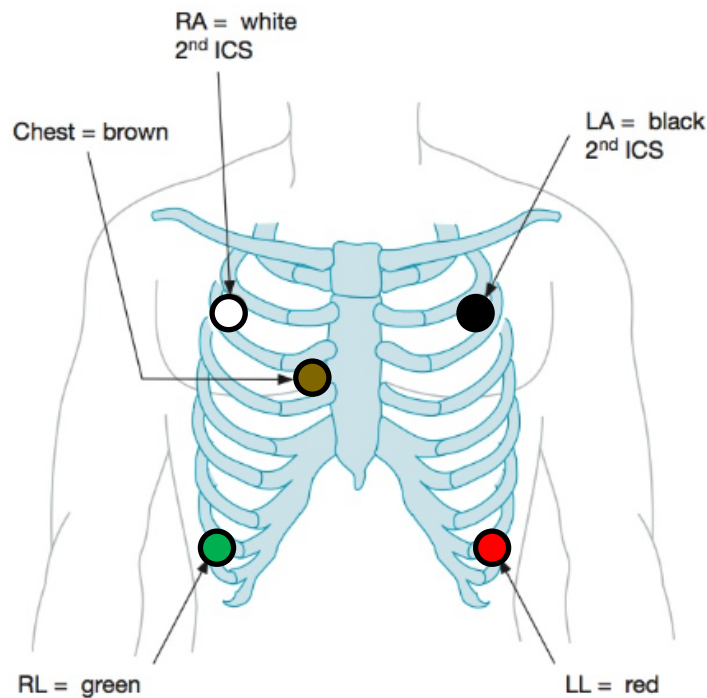


| #  | Color | Location                                                     |
|----|-------|--------------------------------------------------------------|
| RA | White | Upper-right portion of chest, 2 to 3 inches below collarbone |
| LL | Red   | Below left breast, over lower ribcage                        |
| LA | Black | Upper-left portion of chest, 2 to 3 inches below collarbone  |

## 6.1.2 5-lead configuration

Five color-coded lead wires are used to create three channels of ECG recording. This is a typical electrode placement:

**Figure 2—5-Lead Electrode Placement**

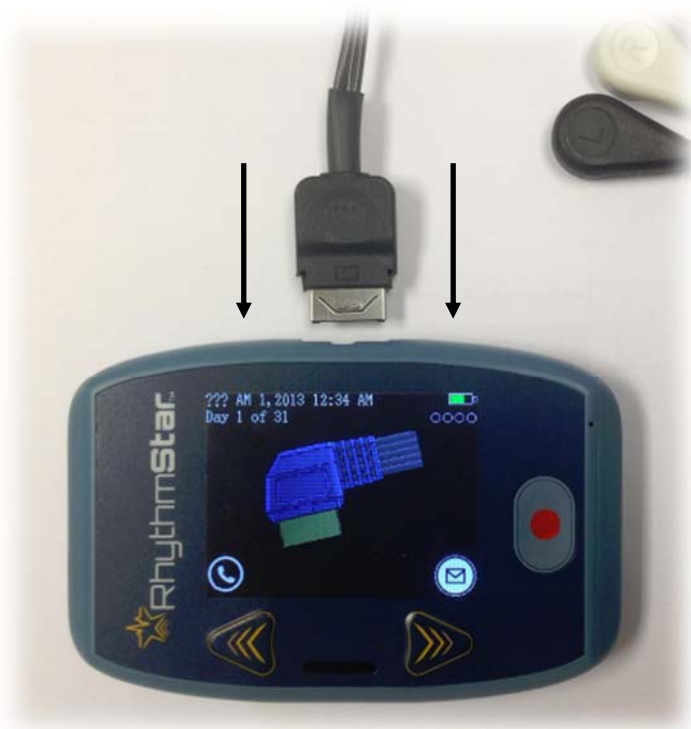


| #  | Color | Location                                                     |
|----|-------|--------------------------------------------------------------|
| RA | White | Upper-right portion of chest, 2 to 3 inches below collarbone |
| LL | Red   | Below left breast, over lower rib-cage                       |
| LA | Black | Upper-left portion of chest, 2 to 3 inches below collarbone  |
| RL | Green | Lower right rib margin over bone                             |
| V1 | Brown | Fourth intercostal space at the right boarder of the sternum |

---

## 6.2 Connecting the patient ECG lead cable to the monitor

The cable has a metal connector which can only be inserted one way into the cable receptacle opening on the top portion of the RhythmStar monitor. Once aligned, firmly insert the cable connector into the cable receptacle as pictured below:



## 7. Using the monitor

### 7.1 Powering on the monitor

RhythmStar does not contain a separate On/Off power button. When you are ready to begin using RhythmStar, insert a charged battery into the monitor as pictured on the following page.



**Step 1:** Locate the battery cover on the back of the monitor. Use your thumb to push down and toward the bottom of the monitor to slide the battery cover off.



**Step 2:** Insert a 3.7 volt battery, included with the RhythmStar, into the battery compartment following the polarity instructions (“+” on the battery to “+” on the wall of the battery compartment and “-” on the battery to “-” on the wall of the battery compartment).



**Step 3:** Replace battery cover on the back of monitor by gently aligning it as pictured and use your thumb to push up and toward the top of the monitor to slide the battery cover on.



**Step 4:** If the battery was successfully installed, after a few seconds, the screen should show the RhythmStar name and logo as pictured. RhythmStar is now powered and ready for use.

---

## 7.2 Checking ECG signal quality

To visualize the patient's ECG signal on the RhythmStar's LCD screen to inspect the quality of the ECG signal, follow the steps below:



**Step 1:** Make sure the patient ECG lead cable is connected to RhythmStar and insert the battery. Immediately after inserting the battery (and before the RhythmStar name and logo screen appears, you will briefly see the screen as pictured (a circle with counterclockwise movement).



**Step 2:** Press both Menu Selection buttons simultaneously.



**Step 3:** Provided the patient ECG lead wires are properly connected to the patient and the patient ECG lead wire connector is properly connected to RhythmStar, the patient's ECG signal will display as pictured. Use the Menu Selection buttons to select Ch1, Ch2 and Ch3. (Ch3 only available when using the 5-lead ECG cable)



**Step 5:** When you are satisfied with the ECG quality, press the Record Button to exit the ECG signal display and begin Monitoring the patient. RhythmStar will now display "MONITORING" as pictured.

---

## 7.3 Recording a cardiac event

The medical technician or physician should instruct the patient with an explanation of what should be marked as a cardiac event. The patient should be instructed to press the Record Button to start a recording when he or she experiences symptoms for which RhythmStar was prescribed. It is recommended that this feature be used by patients who can comprehend the instructions provided by the medical technician or physician and are capable of pressing the necessary buttons. RhythmStar will also be automatically recording and transmitting asymptomatic cardiac events as they occur without the patient needing to press the Record Button or interface with RhythmStar in any way.

**Follow the below instructions to record a cardiac event:**



**Step 1:** Instruct the patient to press the Record Button.



**STEP 2:** Upon pressing the Record Button, the screen will change to “RECORDING”. A red progress bar will begin and last until the recording is complete.

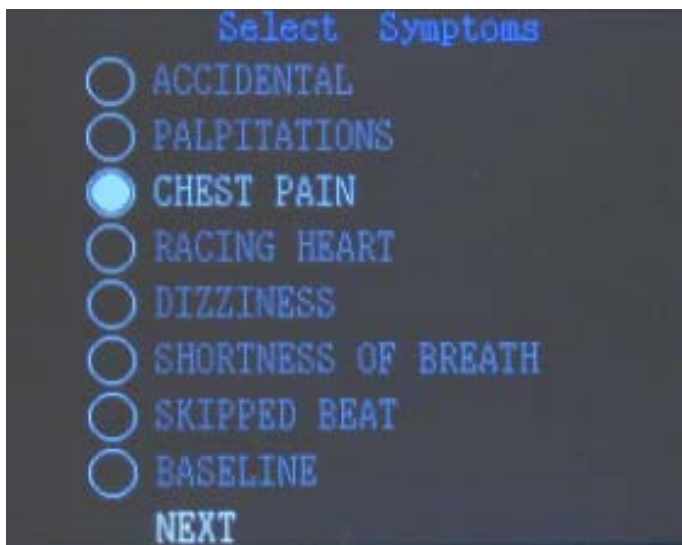
**NOTE:** Instruct patients to remain as still as possible for the duration of the recording.

---

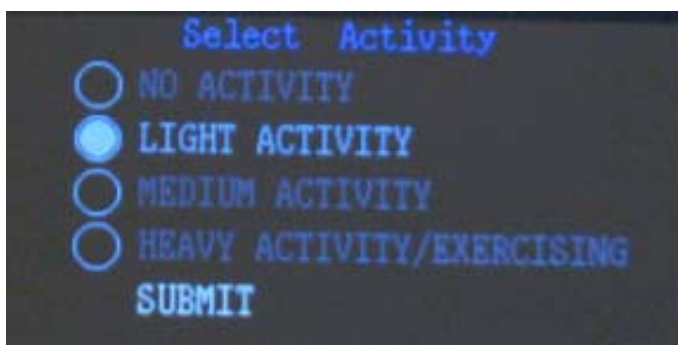
## 7.4 Entering symptoms and activity level associated with the cardiac event

After a recording is completed, RhythmStar will then prompt the patient to select the symptom or symptoms and the level of activity that he or she was feeling and doing at the time of pressing the Record Button.

**Follow the below instructions to enter symptom(s) and activity level associated with the cardiac event:**



**Step 1:** After each time a patient activated event recording is completed, RhythmStar will then display the “Select Symptoms” screen. The patient should be instructed to use the Menu Selection buttons to highlight the symptom selection (s) that best represent the reason for the event. By pressing the Record Button of a highlighted symptom, the empty circle next to the selection will fill. The patient can repeat this step to select more than one symptom if appropriate. Once symptom(s) are properly selected, the patient should highlight the “NEXT” selection and then press the Record Button to move on to the next screen.



**Step 2:** RhythmStar will next display the “Select Activity” screen. The patient should be instructed to use the Menu Selection buttons to highlight the activity level that best represents their activity level at the time that the Record Button was pressed. Only one activity level selection may be selected. Once the activity level is properly selected, the patient should highlight the “SUBMIT” selection and then press the Record Button. RhythmStar is now ready to record additional events.

---

## 7.5 Recharging the battery

**NOTE:** Only IEC 62133 certified Lithium-Ion batteries supplied by RhythmMedix are to be used with RhythmStar.

RhythmStar is powered by an externally rechargeable Lithium-Ion battery. Each RhythmStar device is supplied with (2) batteries and one battery charger. It is recommended that while one battery is being used in the RhythmStar monitor, the other battery is being charged. We recommend replacing the battery being used in the RhythmStar monitor with a fully charged battery every 24 hours to avoid any power outage on the monitor while RhythmStar is monitoring the patient.

To charge the battery, place the rechargeable Lithium-Ion battery into the charger. Next, plug the charger into the wall outlet (110 or 220V). Once properly placed, the charger will show either a solid red or blue indication light as shown below:

**Charging**—Indicated by solid Red light:

**Charged**—Indicated by solid Blue light:



---

## 8. Maintenance and Service

### 8.1 Cleaning

To clean RhythmStar:

1. Remove the battery from the monitor (DO NOT ATTEMPT TO CLEAN BATTERY):
2. Dampen a soft cloth with a mild detergent and water mixture. *An example of a mild detergent is an alcohol-free hand soap or sodium hypochlorite (bleach) solution 10% in water.*
3. Clean the monitor and patient ECG lead cables.
4. Remove any remaining adhesives from the patient ECG lead cables with an adhesive tape remover solution or swab of mild detergent.

NOTE: Do not use alcohol or acetone to clean the lead wires as this can cause the wires to stiffen and the insulating plastic to crack.

- Do not immerse the monitor in water or any other cleaning solution.
- Store the patient ECG lead cables suspended when possible.
- Avoid kinking the patient ECG lead cables.

### 8.2 Service

If there is a problem with the monitor, review the Troubleshooting section for a listing of problems and solutions. If additional assistance is required, contact RhythMedix customer support via phone at (856) 282-1080. Be prepared to provide the following information:

- Serial number of the monitor
- Description of the problem

Call customer support before returning a recorder to make shipping arrangements.

---

## 8.3 Troubleshooting

| Symptom                                            | Solution                                                                                              |
|----------------------------------------------------|-------------------------------------------------------------------------------------------------------|
| No Power                                           | Check battery power and recharge.                                                                     |
|                                                    | Install new or fully charged battery.                                                                 |
| Low battery                                        | Recharge battery.                                                                                     |
|                                                    | Install new or fully charged battery.                                                                 |
| Battery does not last the expected number of hours | Ensure a new battery is being used.                                                                   |
| Noise artifacts on ECG signal                      | Ensure all electrodes are securely attached to the patient and electrodes are of recommended quality. |
|                                                    | Ensure patient ECG lead cable is inserted completely                                                  |
| Any other errors                                   | Contact RhythmMedix Customer Service                                                                  |

---

## 8.4 Disposal of Battery

### **Storage and Disposing of Lithium-Ion (Li-Ion) batteries instructions:**

The RhythmStar monitor and battery should be stored at room temperature in a dry area. Make sure that the battery is removed from the monitor while in storage.

In the event that a battery becomes damaged or no longer holds its charge, the battery should no longer be used and should be recycled.

To locate a Rechargeable Battery Recycling Corporation (RBRC) collection point within the US, visit the website listed below and type in your postal or zip code. The closest drop off points in many stores such as Wal-Mar, Home Depot, Radio Shack, Best Buy will display.

<http://www.call2recycle.org/locator/>

Place the batteries that you wish to recycle into a box or bag and take them to the collection point. Hand the batteries over to the RBRC representatives at the collection point for recycling.

---

## 9. Medical Device Symbols and Safety Signs

| Symbol                                                                              | Description                         |
|-------------------------------------------------------------------------------------|-------------------------------------|
|    | Consult Instructions for use        |
|    | Type CF Applied Part                |
|    | Manufacturer Info                   |
|  | Emits Non-ionizing Radiation        |
| <b>RX Only</b>                                                                      | Prescription Only                   |
|  | Serial Number                       |
|  | Catalog Number                      |
| <b>IPX0</b>                                                                         | Non-protected against fluid ingress |

## 10. Specifications

| Characteristics          | Test Conditions                             | Min. | Typical           | Max. | Unit  |
|--------------------------|---------------------------------------------|------|-------------------|------|-------|
| Physical                 |                                             |      |                   |      |       |
| Length                   |                                             |      | 101               |      | mm    |
| Width                    |                                             |      | 66                |      | mm    |
| Thickness                |                                             |      | 13                |      | mm    |
| Weight                   | With battery                                |      | 90                |      | gm    |
| Functional               |                                             |      |                   |      |       |
| ECG Channels             | Cable selectable                            | 2    | 2                 | 3    | n/a   |
| Accelerometer            | ±2g/±4g/±8g                                 |      |                   |      |       |
| Sampling Rate            | Dynamically selectable                      | 1.56 | 30                | 800  | Hz    |
| Resolution               | Variable                                    | 8    | 12                | 14   | Bits  |
| Memory                   |                                             |      |                   |      |       |
| Recording Time           |                                             |      | 30                |      | days  |
| Data Retention           | microSDHC flash media                       |      | 10                |      | years |
| Wireless                 |                                             |      |                   |      |       |
| Communication Technology | UMTS/HSDPA                                  |      | 850/1900          |      | MHz   |
|                          | GSM/GPRS/EDGE                               |      | 850/900/1800/1900 |      |       |
| Time-Slot Class          |                                             |      | 12                |      | n/a   |
| Output Power             | WCDMA Band II & V                           |      | 0.302             |      | W     |
|                          | GSM850                                      |      | 2.13              |      |       |
|                          | PCS1900                                     |      | 1.74              |      |       |
| Electrical               |                                             |      |                   |      |       |
| CMRR                     |                                             | 90   | 105               |      | dB    |
| AC Range                 |                                             |      | ±6                |      | mV    |
| DC Range                 |                                             |      | ±300              |      | mV    |
| Input Impedance          |                                             |      | >10               |      | MOhm  |
| Frequency Response       |                                             |      | 0.05 to 40        |      | Hz    |
| Recovery Time            |                                             |      | 1.33              |      | sec   |
| ADC Resolution           |                                             | 12   | 12                | 16   | Bits  |
| ADC Sample Rate          |                                             | 125  | 250               | 1000 | Hz    |
| Battery                  |                                             |      |                   |      |       |
| Type                     | Replicable, externally re-chargeable Li-Ion |      | 3.7               |      | V     |
| Life                     | From full charge                            |      | 72                |      | hours |
| Storage Temperature      | < 30 days                                   | -20  |                   | 50   | C     |
| (shipped condition)      | > 30 days                                   | -20  |                   | 35   | C     |
| Relative Humidity        |                                             | 45   |                   | 85   | %     |
| Environmental            |                                             |      |                   |      |       |
| Operating Temperature    |                                             | 0    |                   | 40   | C     |
| Storage Temperature      |                                             | -25  |                   | 70   | C     |
| Relative Humidity        | Non-condensing 23 C                         | 10   |                   | 93   | %     |
| Atmospheric Pressure     |                                             | 700  |                   | 1060 | hPa   |

---

## 11. RhythmMedix Limited Warranty

This RhythmMedix product is warranted to be free from manufacturing and material defects, excluding batteries, charging adapters, and patient cables, for a period of one year from the date of shipment from RhythmMedix to the original purchaser (“Warranty Period”). If a hardware defect arises and a valid claim is received within the Warranty Period, RhythmMedix will repair or replace (at RhythmMedix’s option) the defective product free of charge for parts and labor.

This warranty does not apply to any product which has been damaged by accident or which has been misused, abused, altered, or repaired by anyone other than RhythmMedix or its Representatives.

Except for the express warranties stated above, RhythmMedix disclaims all warranties including implied warranties of merchantability and fitness. The stated express warranties are in lieu of all obligations of liabilities on the part of RhythmMedix for damages, including but not limited to, special indirect or consequential, arising out of or in connection with the use or performance of RhythmMedix products.

Any warranty claims must be initiated within the one (1) year warranty period. Any repairs made to the product that are not covered by the warranty are billed to the customer.

## 12. Obtaining Warranty Service

To obtain repairs, first obtain a Returned Merchandise Authorization (RMA) number from your RhythmMedix Representative. Include the RMA number on the shipment and ship postage prepaid to: RhythmMedix, 5000 Atrium Way, Ste 1, Mt. Laurel, NJ 08054  
Attention: Repair, RMA # \_\_\_\_\_

RhythmMedix will return in-warranty units postage prepaid.

---

## 13. Wireless Compliance

**FCC ID: 2ACA9-10002**

### **FCC Regulations Compliance Statement**

The Federal Communications Commission (FCC) has adopted a safety standard for human exposure to Radio Frequency (RF) electromagnetic energy emitted by FCC-certified equipment. This wireless electro- cardiovascular monitor has been evaluated under FCC Bulletin OET 65C (01-01) and found to be compliant to the requirements of uncontrolled environmental limits as set forth in CFR 47 Sections 2.1091, 2.1093 addressing RF Exposure from radio frequency devices when operated in accordance with the operation guidelines described in this manual. Proper operation of this radio device according to the instruction in this publication will result in user exposure substantially below the FCC recommended limits.

The RhythmStar contains a radio transmitter and receiver. It is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the U.S. Government. These limits are part of comprehensive guidelines and establish permitted levels of RF energy for the general population. The guidelines are based on standards that were developed by independent scientific organizations through periodic and thorough evaluation of scientific studies. The standards include a substantial safety margin designed to assure the safety of all persons, regardless of age and health.

The exposure standard for wireless mobile devices employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6W/kg. Tests for SAR are conducted using standard operating positions accepted by the FCC with the device transmitting at its highest certified power level in all tested frequency bands. Although the SAR is determined at the highest certified power level, the actual SAR level of the device while operating can be well below the maximum value. This is because the device is designed to operate at multiple power levels so as to use only the power required to reach the network. In general, the closer you are to a wireless base station antenna, the lower the power output.

Before a device model is available for sale to the public, it must be tested and certified to the FCC that it does not exceed the limit established by the government-adopted requirement for safe exposure. The tests are performed in positions and locations (for example, worn on the body) as required by the FCC for each model.

This device has been tested and meets FCC RF exposure guidelines when worn in a holster or belt clip over belt or waistband of an outer garment with 15mm minimum separation distance from the body.

The highest reported SAR value for this body-worn device is: 1.44 W/kg.

The FCC has granted an Equipment Authorization for this wireless electro-cardiovascular monitor with all reported SAR levels evaluated as in compliance with the FCC RF exposure guidelines. SAR information on this device is on file with the FCC and can be found under the “Display Grant” section of: <http://transition.fcc.gov/oet/ea/fccid/> after searching on FCC ID: 2ACA9-10002.

Third-party belt-clips, holsters, and similar accessories used by this device should not contain any metallic components. Body-worn accessories that do not meet these requirements may not comply with RF exposure requirements and should be avoided.

## FCC statement

- This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

Reorient or relocate the receiving antenna.

Increase the separation between the equipment and receiver.

Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

Consult the dealer or an experienced radio/TV technician for help.

**NOTE:** THE GRANTEE IS NOT RESPONSIBLE FOR ANY CHANGES OR MODIFICATIONS NOT EXPRESSLY APPROVED BY THE PARTY RESPONSIBLE FOR COMPLIANCE. SUCH MODIFICATIONS COULD VOID THE USER' S AUTHORITY TO OPERATE THE EQUIPMENT.

---

**IC ID: 11948A-10002**

## **Canadian Regulations Compliance Statement**

RhythmStar Complies with the Canadian RSS - 102 Issue 4: 2010 and IEC 62209-2: 2010 requirements. RhythmStar Conforme à la norme RSS - 102 Issue 4: 2010 et IEC 62209-2: 2010 requirements. This device complies with RSS 210 of Industry Canada. This Class B device meets all the requirements of the Canadian interference-causing equipment regulations. Cet appareil numérique de la Classe B respecte toutes les exigences du Règlement sur le matériel brouilleur du Canada.

This device complies with Industry Canada license exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Cet appareil est conforme aux normes CNR exemptes de licence d'Industrie Canada. Le fonctionnement est soumis aux deux conditions suivantes : (1) cet appareil ne doit pas provoquer d'interférences et (2) cet appareil doit accepter toute interférence, y compris celles susceptibles de provoquer un fonctionnement non souhaité de l'appareil.

---

## 14. Arrhythmia Detection Performance

The RhythmStar incorporates a real-time embedded arrhythmia detection algorithm. The processing steps include signal bandpass and morphological filtering, estimation of the motion artifact, analysis of the slope, width and amplitude of the signal, decision making logic to determine location and length of the QRS complexes, atrial activity analysis and template matching for AF detection.

Rhythmedix conducted algorithm performance testing according to the ANSI/AAMI EC57 standard. The MIT-BIH, AHA, and NST databases were used to verify performance of the algorithm. The algorithm performance testing summary is provided in the tables below:

### QRS Detection Performance

| Database | QRS Sensitivity | QRS Positive Predictivity |
|----------|-----------------|---------------------------|
| MIT-BIH  | 99.77%          | 99.81%                    |
| AHA      | 99.72%          | 99.82%                    |
| NST      | 96.59%          | 79.86%                    |

### AF Detection Performance

| Database   | AF Sensitivity | AF Specificity |
|------------|----------------|----------------|
| MIT-BIH AF | 93.43%         | 96.88%         |

---

## 15. Accessories

The following accessories are available for use with the RhythmStar:

| Part Number: | Description:                                    |
|--------------|-------------------------------------------------|
| PC-10003     | RhythmStar two-channel patient ECG lead cable   |
| PC-10005     | RhythmStar three-channel patient ECG lead cable |
| BP-10006     | RhythmStar Rechargeable Li-Ion battery          |
| BC-10007     | RhythmStar Li-Ion wall charger for battery      |
| PA-10008     | RhythmStar replaceable battery door             |

The following materials are provided with the RhythmStar:

| Part Number: | Description:                                  |
|--------------|-----------------------------------------------|
| PC-10003     | RhythmStar two-channel patient ECG lead cable |
| BP-10006     | RhythmStar Rechargeable Li-Ion battery        |
| BC-10007     | RhythmStar Li-Ion wall charger for battery    |
| PA-10008     | RhythmStar replaceable battery door           |

---

## Appendix A—Handling Instructions for Lithium Ion Battery

Please read and follow the handling instructions for the battery before use. Improper use of the battery may cause heat, fire, explosion, damage or capacity deterioration of the battery. However, the manufacturer will not guarantee against any accident caused by the usage which is not written here.

### (When using the battery)

| <b>DANGER</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                               |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"><li>• Do not dip or wet the battery in water, seawater, or other liquid. If the protecting device assembled in the battery is damaged, the battery may be charged with an abnormal current and voltage, which may result in the cause of heat generation, explosion, or fire of the battery.</li><li>• The battery has a predetermined polarity. If the battery will not connect well to the charger or equipment, do not try to connect the battery forcefully. Check the polarity first. In the case the battery is connected in reverse, it is charged reversely and may cause acid leakage, heat generation, explosion, or fire due to an abnormal chemical reaction.</li><li>• Do not put the battery into a fire or heat it. In such a case, the insulator in the battery may be melted, the gas release vent and protection mechanism may be damaged, all of which may cause heat generation, explosion, or fire.</li><li>• Do not connect the battery reversed in positive (+) and negative (-) terminals in the charger or equipment. In the case the battery is connected in reverse, it is charged reversely during charge, and causes an excessive current during discharge, and may cause heat generation, explosion, or fire due to an abnormal chemical reaction.</li><li>• Do not let the battery terminals ( + and - ) contact a wire or any metal ( like a metal necklace or a hairpin ) with which it carried or stored together. In such a case, the battery is shorted and causes an excessive current, which may result in heat generation, explosion, or fire.</li><li>• Do not apply heavy impact to the battery, or throw or drop it. Strong impact may damage the protecting device, which may result in heat generation, explosion, or fire of the battery.</li><li>• Do not drive a nail in, hit with a hammer, or stamp on the battery. In such a case, the battery may be deformed and shorted, and the protecting device may be damaged, which may cause heat generation, explosion, or fire of the battery.</li><li>• Do not solder the battery directly. Heat applied during soldering may damage the insulator or the gas release vent and protection mechanism, which may result in acid leakage, heat generation, explosion, or fire of the battery.</li><li>• Do not disassemble or alter the battery. The battery contains the protection mechanism and protection device in order to avoid any danger. If these are damaged, heat, explosion or fire may be caused.</li></ul> | <ul style="list-style-type: none"><li>• Charge the battery every 6 months to the amount specified by the manufacturer, even if the battery is not used. An excessive over-discharge may cause an abnormal chemical reaction, which may result in the cause of acid leakage, or fire of the battery.</li></ul> |

## WARNING

- Do not place or leave the battery and equipment in the reach of infants. Improper use of the battery may cause danger.
- Do not put the battery in a microwave oven or a pressure cooker. Sudden heat may damage the seal of the battery and may cause heat generation, explosion, or fire of the battery.
- Do not use the battery together with a dry battery or other primary battery or other battery of a different capacity, types and / or brand. In such a case, over-discharge during use, or over-charge during charge may occur and abnormal chemical reactions may cause heat generation, explosion, or fire of the battery.
- If you notice any bad odor, heating, discoloration, deformation, or any other change from what you are used to while using, charging, storing the battery, take it out of equipment or charger, and avoid using it. Using it in such state may result in heat generation, explosion, or fire.
- If the battery leaks or emits a bad odor, take it away from any fire immediately. The electrolyte may catch fire, which may cause heat generation, explosion, or fire.
- Do not let leaked electrolyte come into contact with eyes. In such a case, immediately wash the area of contact with clean water and seek help from a doctor. If not treated soon, prolonged contact may cause serious injury.

## CAUTION

- Do not use or leave the battery in a place exposed to strong direct sunlight, or in a car under the blazing sun, or high temperature sources. Such a high temperature may cause acid leakage.
- If you find the battery rusty, bad odor, heating, or any other defective before using the battery for the first time after purchase, do not use it. Take it back to the dealer instead.
- In case young children use the battery, instruct them on the contents of the instructions and ensure the battery is correctly used by them at all times.
- If the battery leaks and its electrolyte contact with skin or clothes, wash it well with tap water or other clean water right away. Leaving it, it may cause a rash on skin.
- If you have any question regarding the battery, contact RhythMedix.
- Read the instructions of your equipment regarding the battery installation and removal from the equipment so as not to mishandle and waste the battery.
- The battery was charged a little before shipment for temporary use by an end user. In case your equipment does not operate with the battery or in the case of a long use, charge the battery with a specified charger once.
- Carefully read the instructions of your equipment before use.
- When the battery is expected not to be used for a long time, take the battery out of the equipment and store it in a less humid area.
- In the case the battery terminals are dirty, clean the terminals with a dry cloth before use, otherwise, the contact with equipment might cause insufficiency, and power failure or charge failure.
- Despite being rechargeable, the battery has a limited life span. Replace it, when usage time becomes short.
- As for a used battery, please recycle, after covering the battery terminals ( + and - ) with a insulation tape or inserting it to individual poly-bag.

## (When charging the battery)

### DANGER

- Do not use any battery charger not specified by ( manufacturer's name ), also, follow the charge conditions specified by ( manufacturer's name ) If the battery is charged under other conditions ( a high temperature, a high voltage or current, or an altered charger ) not specified by ( manufacturer's name ), the battery may cause heat generation, explosion, or fire with abnormal chemical reactions.
- Do not connect the battery directly to an electric outlet or cigarette heater socket in a car. Applying a high voltage may generate an excessive current, and get an electric shock. In such a case, the battery may leak electrolyte, overheat, explode, or cause fire.
- Do not charge the battery near fire or in a car under the blazing sun. Such a high temperature may cause damage of the protecting device in the battery, which may result in heat generation, explosion, or fire.

### WARNING

- Discontinue charging after specified charging time even if the charge is not complete. Otherwise, the battery might cause heat generation, explosion, or fire.

### CAUTION

- Do not use the battery in other than the following conditions. Otherwise, the battery might cause heat generation, damage.  
Charge: 0° C ~ +45° C
- Carefully read the instructions for the specified charger to learn how to charge the battery.
- Do not charge the battery over the specified time described in the instructions.

## (When discharging the battery)

### DANGER

- Do not use or leave the battery in a place near fire, heaters, or high temperature sources. Such a high temperature may cause heat generation, explosion, or fire.
- Do not use the battery with any equipment other than specified. Any such practice may expose some types of equipment to an abnormal current, which may result in heat generation, explosion, or fire.

### CAUTION

- Do not use the battery in the place where the static electricity ( more than the limit of the manufacturer's guarantee ) occurs. Otherwise, the protecting device in the battery might be damaged and cause heat generation, explosion, or fire.

Do not use the battery in other than the following conditions

|                           |                                           |
|---------------------------|-------------------------------------------|
| Discharge                 | : -20° C ~ +60° C                         |
| Store (less than a month) | : -20° C ~ +50° C (on the charge of 50 %) |
| Store (more than a month) | : -20° C ~ +35° C (on the charge of 50 %) |



---

RhythMedix, LLC.  
Horizon Corporate Center  
5000 Atrium Way, Ste 1  
Mt. Laurel, NJ 08054



Tel 856.282.1080  
Fax 856.282.1333  
[www.rhythmmedix.com](http://www.rhythmmedix.com)

---