RhythmStar SL Operator Manual V.1.3

Wireless Remote

Cardiac Monitoring

Rx Only

Table of Contents

Indications for Use....3
Contraindications....3
Warnings....3
Precautions....4
Symbols Glossary....5
Device Description....6
Manual Event Recording Initiation....8
Charging Device Battery....9
Turning Device Power ON or OFF....10
Instructions for Patient Before Monitoring....11
Patient Hook-up....12
Troubleshooting....13
Clean Device Before and After Use....14
Store and Ship Devices....14
RhythMedix Customer Support....14
RhythmStar Limited Warranty....15
RhythmStar SL Specifications....16
Cybersecurity....18
Ordering Device and Charging Base....19
End-of-Service Life....19
Electromagnetic Compatibility (EMC)....20
Wireless Compliance....30

Figure 1. RhythmStar SL Device and Charging Base....7

Figure 2. Manual Event Recording Initiation....8

Figure 3. Device status lights....8

Figure 4 Device Placement....12

Indications for Use

The RhythmStar SL 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 SL is not intended for real-time monitoring.

The data received from the RhythmStar SL can be used for retrospective review, arrhythmia analysis, and further evaluation, reporting and signal measurements using RhythmStar system. The RhythmStar SL is not intended to sound any alarms.

The device does not deliver any therapy, administer any drugs, or provide for life support. The RhythmStar SL does not provide interpretive or diagnostic statements. Interpretation and diagnosis are the responsibility of a physician. RhythmStar SL 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. The RhythmStar monitor requires AT&T and/or Verizon 4G LTE coverage to perform properly.

Do not use the RhythmStar monitor for pacemaker spike detection.

Do not use the RhythmStar monitor on the airplane.

The performance of the RhythmStar SL device has been shown not to be negatively affected in the presence of electromagnetic interference (EMI) that is typically present in the use environment. In the presence of strong EMI, users may experience the following potential degradations in device performance:

1. Signal Quality Degradation: Strong EMI may introduce noise and artifacts into the ECG signal, leading to reduced signal quality. This may make it difficult to detect arrhythmias and other cardiac abnormalities.
2. Interference with Wireless Transmission: Strong EMI may disrupt the wireless communication between the device and the RhythmStar cloud server. The device may fail to transmit any data until the source of EMI is mitigated or removed.

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 and remove the entire device prior to defibrillation and clinical use. Clinical Use includes the MRI scans, CT scans, X-rays, surgical procedures, radiation therapy, high-intensity physical therapy sessions or those involving electrical stimulation, and other diagnostic procedures to avoid interference with the equipment or to provide unobstructed access to the areas being examined.

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.

Symbols Glossary

Symbols used on device and device labeling conform to standards.

Symbol	Description
	Indicates the medical device manufacturer. ISO 15223-1
	Indicates the manufacturer's catalogue number so that the medical device can be identified. ISO 15223-1
	Indicates the manufacturer's serial number so that a specific medical device can be identified. ISO 15223-1
	Indicates the need for the user to consult the instructions for use, that is, this Operator Manual. ISO 15223-1
	Device is only to be used if prescribed by a physician. For prescription use only. 21 CFR 801.109 (b) (1)
	Type BF Applied Part – An applied part that includes a patient connection that is intended to deliver electrical energy or an electrophysiological signal to or from the patient. IEC 60601-1 3rd Edition. IEC 60417-5333
	Non-ionizing electromagnetic radiation IEC 60417-5140, IEC 60601-1-2:2014, Clause 5.1.1
	Magnetic Resonance (MR) unsafe. Keep away from magnetic resonance imaging (MRI) equipment. ASTM F2503-13
IP26	IEC 60529 / Degrees of protection provided by enclosures (IP Code)

Device Description

The RhythmStar system is not intended for real-time monitoring.

The RhythmStar device is a portable, battery powered, wireless cardiac monitor which may be worn by a patient to record ECG data for up to 30 consecutive days. The device records continuous ECG data and captures patient activated and auto-triggered events. The device is capable of automatically delivering the data to the cloud server. The data can be delivered wirelessly by using a built-in 4G wireless data modem, or via USB connection.

The RhythmStar device is intended to be used with third-party ECG patch electrodes supplied to a patient by a physician or a monitoring center. The ECG electrodes are not a part of the device. RhythMedix recommends using ECG patch electrodes intended for event monitoring, such as Vermed A10091 available at https://hs.nisshamedical.com/.

The data received from the RhythmStar device can be used for retrospective review, arrhythmia analysis, reporting and signal measurements by RhythmStar system.

The device receives continuous analog ECG signal from the ECG patch electrodes attached to the patient's body, processes the signal by an analog frontend integrated circuit and stores the ECG data in the internal flash memory. The device delivers all recorded data to the remote server via mobile Internet connection using a built-in 4G modem.

To charge the monitor use a third-party USB power supply that complies with Class II IEC 60601-1 standard and can deliver DC 5V, 1A (5W) output. Power supply is not part of the device.

Patients are not intended to access the data recorded by the device.

The device is not affected by lint, dust, or light.

The device does not require periodic calibration or adjustment to maintain its Essential Performance.

The Essential Performance of the RhythmStar System is defined as ECG signal recording and accuracy of the ECG waveform representation, wireless functionality to upload recorded ECG data to the cloud server, and the ability to charge the battery of the RhythmStar SL device.

The RhythmStar device consists of a monitor and a USB charging base as shown on Figure 1 below.

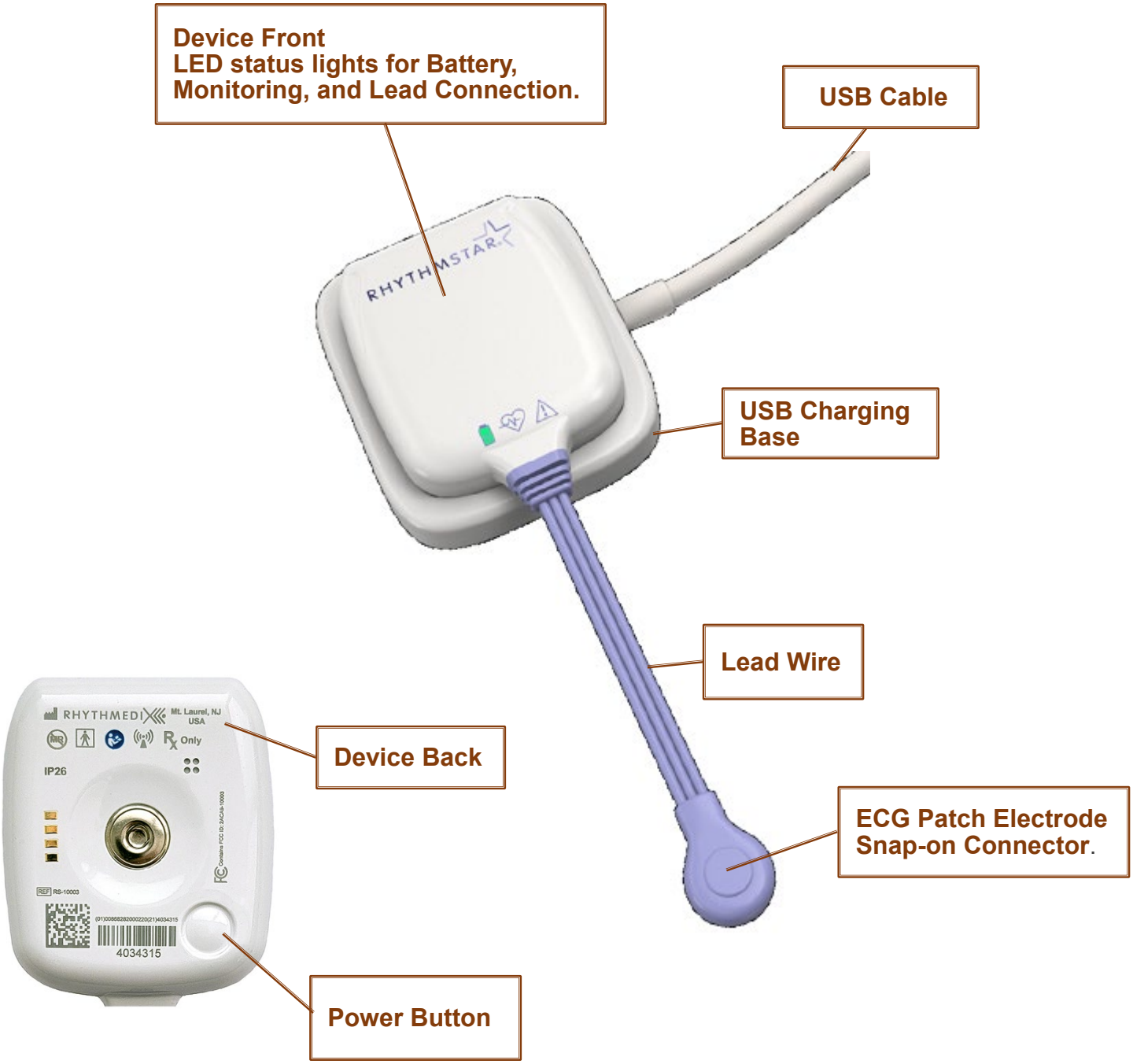


Figure 1. RhythmStar SL Device and Charging Base

Manual Event Recording Initiation

Firmly tap the device 2 times to manually initiate a symptomatic recording as shown on the following picture:

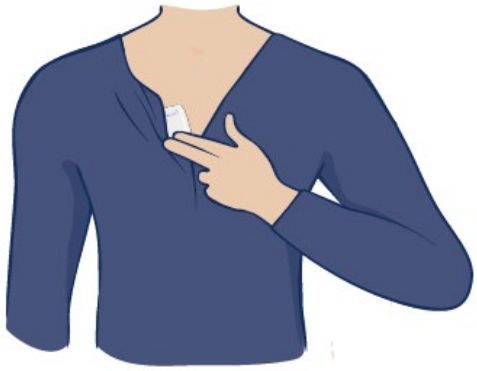


Figure 2. Manual Event Recording Initiation

Device Status Notifications

The device provides status notifications with LED lights and audible tones/beeps.

To NOT interrupt a patient's rest, the device will NOT beep between 9 p.m. and 9 a.m. in the time zone where device is used.

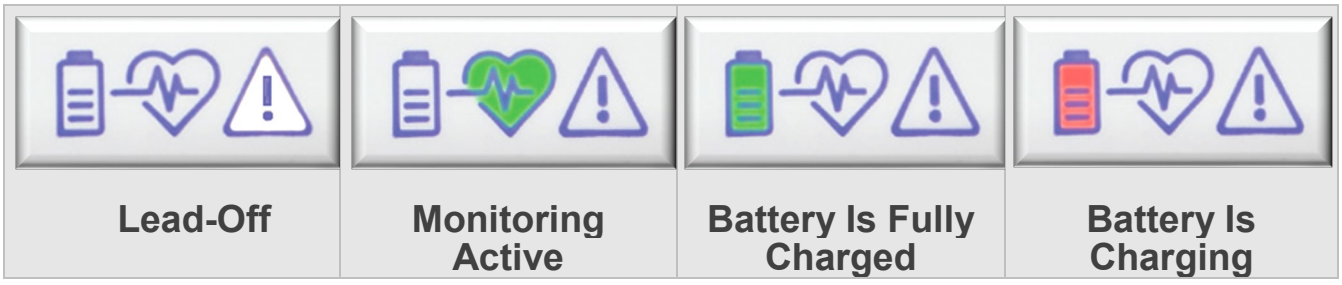


Figure 3. Device status lights

Lead-Off

When the device is initially turned ON, the Lead-Off WHITE LED lights up and it starts blinking until device is connected to the ECG electrodes attached to the patient.

The Lead-Off LED is not lit, and it is not blinking when the device is properly connected to the ECG electrodes and the electrodes are firmly attached to the patient's chest.

The Lead-Off WHITE LED will light up and blink every 5 seconds to indicate that the lead wire is disconnected from the ECG electrode. The device also beeps every minute until the lead wire is reconnected.

Monitoring Active

The Monitoring GREEN LED light ups and begins blinking every 10 seconds.

When the Monitoring GREEN LED is blinking, a patient can initiate a manual event recording by firmly tapping the device 2 times. The device beeps for 1 second to confirm recording has begun. The device will record for 30 seconds. During recording, the Monitoring GREEN LED will stop blinking and remain lit (Figure 3. Device status lights)

If the Monitoring GREEN LED is NOT blinking every 10 seconds while wearing the device, then it indicates that device is NOT recording ECG data. Refer to Troubleshooting steps in the “Troubleshooting” section and/or contact Customer Service.

Battery Charge

The device indicates the Battery Low condition when the remaining charge is below 20% capacity. The Battery RED LED starts blinking every 5 seconds and the device produces audible tone/beep 1 time every 60 seconds. Place the device on the USB charging base to recharge the battery.

When placed on the USB charging base, the Battery LED will be solid RED when device is charging, and it will turn solid GREEN when device is fully charged.

Charging Device Battery

Device owner should fully charge the device battery before storing device and again before shipping device to patients**.**

Advise patients to *fully* charge the monitor before beginning their monitoring study and whenever Battery Low is indicated. After *fully* charging the monitor, patients can expect to recharge the battery every 72 hours.

When a patient removes the device to replace electrodes, the patient may charge the battery until ready to reattach device and resume monitoring.

To charge the battery follow the following steps:

1. Connect the USB Charging Base to a third-party Class II IEC 60601-1 compliant USB power supply that can provide DC 5V, 1A output.
2. Place the device on the charging base. The Battery RED LED will light up if the battery is not fully charged.
3. Remove the device from the charging base when the GREEN LED lights up and remain lit until device is removed from charging base.

Turning Device Power ON or OFF

Patient should keep device always turned ON during patient monitoring study unless instructed by a monitoring center or physician practice to turn the device OFF.

To turn the device ON either:

a. Connect the USB charging base cable to USB power supply and briefly place device on the charging base, **OR**
b. Press and hold the Power button on the back of the device for 1 second until the Lead-Off WHITE LED lights up and starts blinking every 5 seconds.

To turn the device OFF:

Press and hold the Power button for 4 seconds. All LEDs will light up at the same time, the device will beep 2 times and then it will turn OFF.

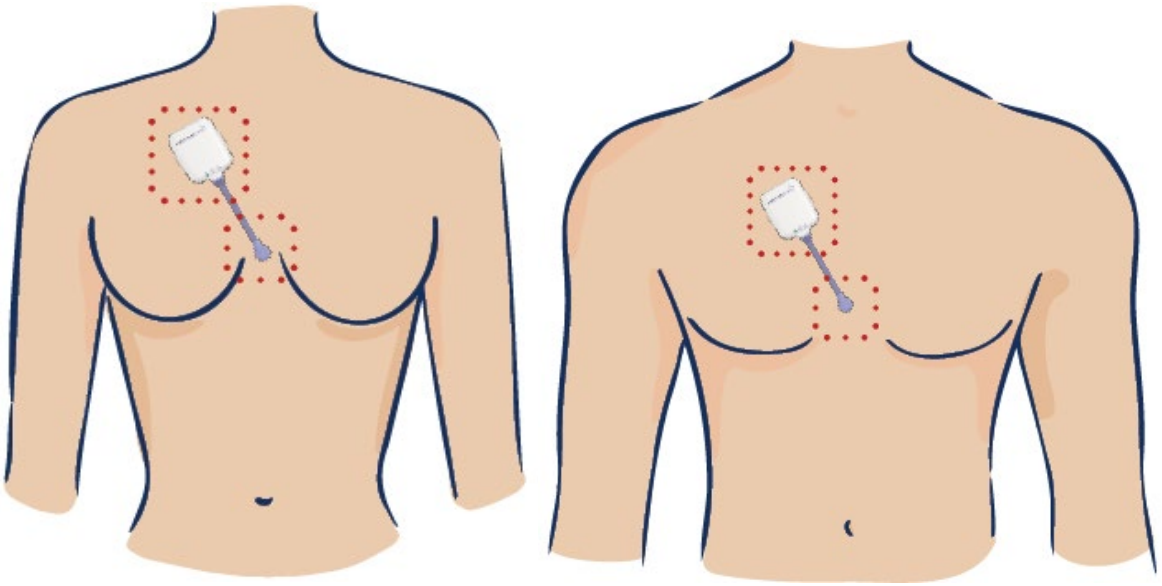
Instructions for Patient Before Monitoring

1. To provide physicians prompt access to your important heart information wear device at all possible times. Remove device to charge it or replace electrodes.
2. 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.
3. Fully charge device before beginning monitoring study and whenever battery low status is indicated. After fully charging the battery, expect to recharge the battery every 3 to 4 days. To extend battery life, charge the battery when you remove the device until you are ready to reattach the device and resume monitoring. Follow Battery Charge instructions on Page 9.
4. Device is water resistant. Do NOT submerge device into water. Remove device to swim.
5. For the best recording results, stay away from heavy electrical equipment or other sources of electromagnetic interference, such as electric blankets and heating pads.
6. If you feel a symptom, such as dizziness or rapid heartbeat, firmly tap the front of the device 2 times to begin a manual event recording.
7. Monitor device status lights and follow instructions to charge the battery and reconnect electrodes.
8. Follow electrode manufacturer's instructions to affix, replace, remove, and dispose electrode.
9. During monitoring period, keep electrode placement area clean, dry, and, if area is hairy, shave or clip hair. Do NOT use lotions or creams in electrode placement areas. **If electrodes irritate skin, reposition electrodes 1 to 2 inches in any direction away from prior position. See Figure 4 to affix electrodes**.
10. Contact Customer Service as soon as possible If the device is broken, not working, or if you experience any problems.

Patient Hook-up

1. Fully charge device following Instructions on page 9.
2. Turn the device On. Follow instructions on page 10.
3. Prepare Patient's Skin
    - If the area is hairy, shave or clip hair.
    - Clean skin with water or rubbing alcohol.
    - Let skin dry.

Refer to the following picture for device connection and electrode placement. Prepare patient's skin in 1-to-2-inch placement areas before affixing adhesive patch electrodes.



FEMALE MONITOR POSITIONING MALE MONITOR POSITIONING

Figure 4 Device Placement

4. Snap one adhesive electrode to the back of the device and another electrode to the lead wire connector.
5. Remove the protective backing from the adhesive electrodes and apply electrodes to chest as shown. The monitor should be placed approximately 3-4 finger widths (2-3 inches) beneath the right collar bone. The second electrode should be placed diagonally (at an angle of approximately 45 degrees) toward the center of the chest (sternum), as illustrated.
   Note: Minor variations in placement (up to 2 inches from the recommended position) are acceptable and will not affect the recording.
6. Replace electrodes as instructed by the electrode manufacturer. 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.
7. To reduce the possibility for skin irritation, vary electrode placement 1 – 2 inches in any direction away from prior position when electrodes are replaced.
8. Always wear the device as instructed and to avoid possible strangulation risk NEVER loop the lead wire around your neck.

Troubleshooting

Troubleshoot a malfunctioning device before requesting service.

Problem	Solution
Device does not turn On	Fully recharge device battery by placing the device on the charging base. If the Battery
Lead-Off LED light is blinking for longer than 30 seconds after device connected to the patient	Replace ECG electrodes. Ensure that the lead wire and the device are securely attached to the electrodes and that the electrodes are properly affixed to the patient.
Device is beeping/buzzing every 60 seconds but none of the status LED lights are lit and/or blinking	Place the device on the charging base for 30 seconds to reset and reboot the device. If the problem persists then contact Customer Service.
Battery light (Red) and Lead-Off (White) lights blink simultaneously up to 15 times then device produces audible tone (beep). The sequence repeats after 3 seconds	Device indicates an error condition that prevents the device from working as intended. Attempt to resolve the problem by placing the device on the charging base for 30 seconds to reset and reboot the device. If the problem persists then stop wearing the device and contact Customer Service.
Battery light is not illuminated when device is placed on the charging base, or the Battery light turns off during battery charging.	Unplug the USB power supply from electrical outlet and verify that electrical outlet is working. Remove the device from the charging base for 1 min, then plug in the USB power supply into working electrical outlet. Place device back on the charging base. If the problem persists then stop wearing the device and contact Customer Service.

Clean Device Before and After Use

1. Slightly dampen a soft cloth with a mild detergent and water, then apply cloth with light pressure to clean device.
2. If any adhesives are remaining on the device, remove adhesives with an adhesive remover solution or a cotton swab slightly dampened with a mild detergent, such as an alcohol-free hand soap or a mixture of 10% of sodium hypochlorite (bleach) solution and water. WARNING: 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.
3. Patient is not intended to perform any device maintenance while using the device.

Store and Ship Devices

Fully charge device batteries and then store devices according to the Environmental specification on page 16. If storing devices for an extended time, fully charge devices every 6 months. See Device and Battery Precautions on page 4.

Use protective packaging to ship devices and charging base to patients and provide protective packaging for patients to safely return equipment.

RhythMedix Customer Support

If after reading these instructions you need further help, send an email to RhythMedix Customer Support at: mailto:support@rhythmstar.com Enter device's serial number, charging base serial number, problem description, and your request in an email message. Device's expected service life is 5 years. If you need to return equipment for service, Customer Support will give you a Return Merchandise Authorization (RMA) number. Enter address below and the RMA number Customer Support provided on your shipping label:

RhythMedix, LLC
5000 Atrium Way, Suite 1
Mt. Laurel, New Jersey 08054
Attention: Repair, RMA Number: _____

Any repairs made to the product that are NOT covered by the warranty are billed to the customer.

Use protective packaging to return equipment for service. RhythMedix is NOT responsible for equipment received from customers that is damaged during shipment.

RhythmStar Limited Warranty

This RhythMedix device is guaranteed to be free from manufacturing and material defects for a warranty period of 2 years from the date it is shipped from RhythMedix to the original purchaser. If a hardware defect occurs and RhythMedix receives a valid customer complaint within the warranty period, RhythMedix will repair or replace (at RhythMedix's discretion) 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 RhythMedix or its representatives.

Except for the express warranties stated above, RhythMedix 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 RhythMedix for damages, including but NOT limited to, special indirect or consequential, arising out of or in connection with the use or performance of RhythMedix products.

RhythmStar SL Specifications

Characteristic	Specification
Physical	
Length	59 mm
Width	50 mm
Thickness	15 mm
Weight	38 g
Function	
ECG Channels	1
Memory	
Recording Time	30 days
Data Retention	10 years
Wireless	
Communication Technology	LTE CAT-M1 700/1700/1900 MHz
Power Class (B2, B4, B14, B13)	5
Output Power	20dBm
Electrical	
CMRR	100-115 dB
AC Range	±32.5 mVPP
DC Range	±650 mV
Input Impedance	>1500 MOhm
Input Leakage Current (TA = +25°C)	±0.1 nA
Frequency Response	0.05 – 40 Hz
Recovery Time	500 ms
ADC Resolution	18 Bits
ADC Sample Rate	256 Hz
Battery	
Battery Type	3.7 V, 700 mAh Rechargeable Li-Ion
Battery Life	72 hours
Environment	
Operating Temperature	0 – 35°C
Operating Relative Humidity	10 – 95 % RH (non-condensing)
Operating Atmospheric Pressure	70 – 106 kPa
Storage Temperature	-40 – 70 °C
Storage Relative Humidity	10 – 100 % RH (condensing)
Storage Atmospheric Pressure	50 -106 kPa
Ingress Protection	IP26

Asymptomatic Arrhythmia Detection

The RhythmStar SL incorporates a rule-based real-time arrhythmia detection algorithm based on beat-by-beat interval analysis. Refer to the following tables for QRS and AFIB detection performance summary.

Database	QRS Se	QRS +P	VEB Se	VEB +P
MIT-BIH	99.77%	99.81%	93.80%	96.19%
AHA	99.72%	99.82%	93.66%	96.71%
NST	96.59%	79.86%	82.63%	36.12%

Database	AF Se	AF +P
MIT-BIH AF	93.43%	96.88%

Heart Rate Calculation and Pause Determination

Heart rate is defined as an average rate of 8 consecutive R-R intervals. Pause is defined as an R-R interval greater than 3 seconds.

Cybersecurity

The RhythmStar SL device is a low cybersecurity risk device. The device user, including patients, monitoring center personnel, and physicians are not required to control, maintain, or handle any cybersecurity related activities to operate RhythmStar device. The security is built into the design of the device to protect the data and to make sure that the device cannot be exploited to gain access to healthcare facilities or home networks. Data sent from the device is encrypted to prevent data disclosure or tampering while in transit. The RhythmStar contains two electronic interfaces. Both receive and send data:

- USB Port
- Wireless data modem

The wireless data modem connects the RhythmStar device to the RhythmStar Cloud. The RhythmStar device connects with the cloud by using cryptographic key. The device and cloud operate on a secure communication protocol. Data transferred from the device to the cloud is encrypted and does not contain patient identifiable information to ensure the integrity and confidentiality of the data. The RhythmStar device can also receive configurations over the air from the cloud via an encoded command.

The device is compatible with the following browsers and operating systems:

- Windows desktop OS requirements for running RhythmStar USB Configurator application:
    - Windows 10 or later
- Supported mobile web browsers for patient diary logging (currently supported version or later):
    - Google Chrome version 126.0.6478.71
    - Safari 17.2.1
- The following web browsers are supported to access RhythmStar server web application (currently supported version or later):
    - Google Chrome version 114.0.1823.79
    - Safari version 17.2.1
    - Microsoft Edge version 114.0.1823.79
    - Mozilla Firefox version 115.0.2

The device stores ECG data for at least 30 days and can transfer data to the cloud using USB connectivity. Firmware updates are initiated by RhythMedix. There are no user actions needed to initiate a firmware update.

There is no ability to modify ECG data stored on the device, in the cloud, or in transit between the device and the cloud. ECG data is backed up in the cloud.

The RhythmStar system logs device and server communication activity that can be audited by RhythMedix. If an anomalous condition is causing the device to stop running, the device is designed to automatically restart. If a cybersecurity event is suspected or detected, please contact RhythMedix and discontinue use of the device.

Prior to decommissioning or disposing of the device, please contact RhythMedix for specific instructions on safely and securely disposing the device.

Ordering Device and Charging Base

Part Number	Description
SL	RhythmStar Model SL device
CBE-10003	RhythmStar Model SL USB charging base

End-of-Service Life

If you do NOT authorize repair of a malfunctioning device or if RhythMedix determines a device is nonrepairable, RhythMedix Customer Service will affix a NOT REPAIRED DO NOT USE label to device. It is the device owner's responsibility to recycle the device at end-of-service life. Before disposing device or charging base:

Clean device or charging base according to instructions on page 9.

Recycle device. To locate a Rechargeable Battery Recycling Corporation (RBRC) collection point within the United States near your location, enter your postal or zip code on the call2recycle website at: http://www.call2recycle.org/locator/.

Electromagnetic Compatibility (EMC)

The RhythmStar SL requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in these accompanying tables.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the RhythmStar SL, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING: A risk of increased emissions or decreased immunity may result if any additional cables are attached.

WARNING: This device has not been tested for compatibility with all other potential RF Emitters such as X-ray, Metal Detectors, Electrosurgical Equipment, Diathermy Equipment, 5G Cellular, NFC, WPT, or Electronic Article Surveil-lance (EAS) devices. Caution should be used if such emitters are present within the use environment.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

The following tables apply to the RhythmStar SL device while NOT charging:

Guidance and manufacturer's declaration – electromagnetic emissions		
The RhythmStar SL is intended for use in the electromagnetic environment specified below. The customer or the user of the RhythmStar SL should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	**Group 1**	**The RhythmStar SL uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.**
RF emissions CISPR 11	**Class B**	**The RhythmStar SL is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.**

Guidance and manufacturer's declaration – electromagnetic immunity			
The RhythmStar SL is intended for use in the electromagnetic environment specified below. The customer or the user of the RhythmStar SL should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	**±8kV contact ±15kV air**	**±8kV contact ±15kV air**	**Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.**
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	**30 A/m**	**30 A/m**	**Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.**
NOTE: U_T is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The RhythmStar SL is intended for use in the electromagnetic environment specified below. The customer or the user of the RhythmStar SL should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF **IEC 61000-4-6**	**3 Vrms** **0,15 MHz – 80 MHz** **6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz** **80 % AM at 1 kHz**	**3 Vrms** **0,15 MHz – 80 MHz** **6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz** **80 % AM at 1 kHz**	**Portable and mobile RF communications equipment should be used no closer to any part of the RhythmStar SL, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.** **Recommended separation distance:**
Radiated RF **IEC 61000-4-3**	**10 V/m** **80 MHz to 1 GHz** **3 V/m** **1 GHz to 2.7 GHz**	**10 V/m** **80 MHz to 1 GHz** **3 V/m** **1 GHz to 2.7 GHz**	**d = [3.5/10] √P 80 MHz to 800 MHz** **d = [7/10] √P 800 MHz to 2.7 GHz** **where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol:**
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. **NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.**			
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the RhythmStar SL is used exceeds the applicable RF compliance level above, the RhythmStar SL should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the RhythmStar SL.			

Guidance and manufacturer's declaration – electromagnetic immunity							
The RhythmStar SL is intended for use in the electromagnetic environment specified below. The customer or the user of the RhythmStar SL should assure that it is used in such an environment.							
Immunity test	**IEC 60601 test level**			**Compliance level**			**Electromagnetic environment - guidance**
IMMUNITY to proximity fields from RF wireless communications equipment	**MHz**	**Modulation**	**Field Strength**	**MHz**	**Modulation**	**Field Strength**	**Portable and mobile RF communications equipment should be used no closer to any part of the RhythmStar SL, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.** **Recommended separation distance:** **E = [6/d] √P** **d = [6/E] √P**
	385	18 Hz	27 V/m	385	18 Hz	27 V/m	
	450	18 Hz	28 V/m	450	18 Hz	28 V/m	
	710	217 Hz	9 V/m	710	217 Hz	9 V/m	
	745	217 Hz	9 V/m	745	217 Hz	9 V/m	
	780	217 Hz	9 V/m	780	217 Hz	9 V/m	
	810	18 Hz	28 V/m	810	18 Hz	28 V/m	
	870	18 Hz	28 V/m	870	18 Hz	28 V/m	
	930	18 Hz	28 V/m	930	18 Hz	28 V/m	
	1720	217 Hz	28 V/m	1720	217 Hz	28 V/m	
	1845	217 Hz	28 V/m	1845	217 Hz	28 V/m	
	1970	217 Hz	28 V/m	1970	217 Hz	28 V/m	
	2450	217 Hz	28 V/m	2450	217 Hz	28 V/m	
	5240	217 Hz	9 V/m	5240	217 Hz	9 V/m	
	5500	217 Hz	9 V/m	5500	217 Hz	9 V/m	
	5785	217 Hz	9 V/m	5785	217 Hz	9 V/m	
IMMUNITY to proximity magnetic fields IEC 61000-4-39	0.1342	2.1kHz	65 A/m	0.1342	2.1kHz	65 A/m	**where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (m), and E is the field strength in V/m. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:**
	13.56	50kHz	7.5 A/m	13.56	50kHz	7.5 A/m	
	0.030	CW	8 A/m	0.030	CW	8 A/m	
NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.							

Recommended separation distances between portable and mobile RF communications equipment as well as RF wireless communications equipment and the RhythmStar SL.

The RhythmStar SL is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the RhythmStar SL can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the RhythmStar SL as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)			
	80 to 800 MHz $d = [3.5/3]\sqrt{P}$	800 MHz to 2.7 GHz $d = [7/3]\sqrt{P}$	710, 745, 780, 5240, 5500, 5785 MHz $d = [6/9]\sqrt{P}$	385, 450,810, 870, 930, 1720, 1845, 1970, 2450 MHz $d = [6/28]\sqrt{P}$
0.01	0.117	0.233	0.067	0.021
0.1	0.369	0.738	0.211	0.070
1	1.170	2.333	0.667	0.214
10	3.689	7.379	2.108	0.700
100	11.667	23.333	6.670	2.143

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The following tables apply to the RhythmStar SL device while charging:

Guidance and manufacturer's declaration – electromagnetic emissions		
The RhythmStar SL is intended for use in the electromagnetic environment specified below. The customer or the user of the RhythmStar SL should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	**Group 1**	**The RhythmStar SL uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.**
RF emissions CISPR 11	**Class B**	**The RhythmStar SL is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.**
Harmonic emissions IEC 61000-3-2	**Class A**	
Voltage Fluctuations IEC 61000-3-3	**Complies**	

Guidance and manufacturer's declaration – electromagnetic immunity			
The RhythmStar SL is intended for use in the electromagnetic environment specified below. The customer or the user of the RhythmStar SL should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	**±8kV contact ±15kV air**	**±8kV contact ±15kV air**	**Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.**
Electrical fast transient/burst IEC 610004-4	**±2kV for power supply lines**	**±2kV for power supply lines**	**Mains power quality should be that of a typical commercial or hospital environment**
Surge IEC 61000-4-5	**±1kV live to neutral**	**±1kV live to neutral**	**Mains power quality should be that of a typical commercial or hospital environment.**
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	**0 % *U*T; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % *U*T; 1 cycle and 70 % *U*T; 25/30 cycles Single phase: at 0° 0 % *U*T; 250/300 cycle**	**0 % *U*T; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % *U*T; 1 cycle and 70 % *U*T; 25/30 cycles Single phase: at 0° 0 % *U*T; 250/300 cycle**	**Mains power quality should be that of a typical commercial or hospital environment. If the user of the RhythmStar SL requires continued operation during power mains interruptions, it is recommended that the RhythmStar SL be powered from an uninterruptible power supply or a battery.**
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	**30 A/m**	**30 A/m**	**Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.**
NOTE 1: U_T is the A.C. mains voltage prior to application of the test level. NOTE 2: In the event that the RhythmStar SL device experiences a dip in supply voltage or an interruption of electrical power, the RhythmStar SL device will stop charging until the supply voltage returns to normal. To ensure proper charging function ensure that RhythmStar SL is powered from an uninterruptible power supply or a battery.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The RhythmStar SL is intended for use in the electromagnetic environment specified below. The customer or the user of the RhythmStar SL should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF **IEC 61000-4-6**	**3 Vrms** **0,15 MHz – 80 MHz** **6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz** **80 % AM at 1 kHz**	**3 Vrms** **0,15 MHz – 80 MHz** **6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz** **80 % AM at 1 kHz**	**Portable and mobile RF communications equipment should be used no closer to any part of the RhythmStar SL, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.** **Recommended separation distance:**
Radiated RF **IEC 61000-4-3**	**10 V/m** **80 MHz to 1 GHz** **3 V/m** **1 GHz to 2.7 GHz**	**10 V/m** **80 MHz to 1 GHz** **3 V/m** **1 GHz to 2.7 GHz**	**d = [3.5/10] √P 80 MHz to 800 MHz** **d = [7/10] √P 800 MHz to 2.7 GHz** **where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol:**
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. **NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.**			
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the RhythmStar SL is used exceeds the applicable RF compliance level above, the RhythmStar SL should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the RhythmStar SL.			

Guidance and manufacturer's declaration – electromagnetic immunity							
The RhythmStar SL is intended for use in the electromagnetic environment specified below. The customer or the user of the RhythmStar SL should assure that it is used in such an environment.							
Immunity test	**IEC 60601 test level**			**Compliance level**			**Electromagnetic environment - guidance**
IMMUNITY to proximity fields from RF wireless communications equipment	**MHz**	**Modulation**	**Field Strength**	**MHz**	**Modulation**	**Field Strength**	**Portable and mobile RF communications equipment should be used no closer to any part of the RhythmStar SL, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.** **Recommended separation distance:** **E = [6/d] √P** **d = [6/E] √P** **where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (m), and E is the field strength in V/m. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:**
	385	18 Hz	27 V/m	385	18 Hz	27 V/m	
	450	18 Hz	28 V/m	450	18 Hz	28 V/m	
	710	217 Hz	9 V/m	710	217 Hz	9 V/m	
	745	217 Hz	9 V/m	745	217 Hz	9 V/m	
	780	217 Hz	9 V/m	780	217 Hz	9 V/m	
	810	18 Hz	28 V/m	810	18 Hz	28 V/m	
	870	18 Hz	28 V/m	870	18 Hz	28 V/m	
	930	18 Hz	28 V/m	930	18 Hz	28 V/m	
	1720	217 Hz	28 V/m	1720	217 Hz	28 V/m	
	1845	217 Hz	28 V/m	1845	217 Hz	28 V/m	
	1970	217 Hz	28 V/m	1970	217 Hz	28 V/m	
	2450	217 Hz	28 V/m	2450	217 Hz	28 V/m	
	5240	217 Hz	9 V/m	5240	217 Hz	9 V/m	
	5500	217 Hz	9 V/m	5500	217 Hz	9 V/m	
	5785	217 Hz	9 V/m	5785	217 Hz	9 V/m	
IMMUNITY to proximity magnetic fields IEC 61000-4-39	0.1342	2.1kHz	65 A/m	0.1342	2.1kHz	65 A/m	
	13.56	50kHz	7.5 A/m	13.56	50kHz	7.5 A/m	
	0.030	CW	8 A/m	0.030	CW	8 A/m	
NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.							

Recommended separation distances between portable and mobile RF communications equipment as well as RF wireless communications equipment and the RhythmStar SL.

The RhythmStar SL is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the RhythmStar SL can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the RhythmStar SL as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)			
	80 to 800 MHz $d = [3.5/10]\sqrt{P}$	800 MHz to 2.7 GHz $d = [7/10]\sqrt{P}$	710, 745, 780, 5240, 5500, 5785 MHz $d = [6/9]\sqrt{P}$	385, 450,810, 870, 930, 1720, 1845, 1970, 2450 MHz $d = [6/28]\sqrt{P}$
0.01	0.035	0.070	0.067	0.021
0.1	0.110	0.221	0.211	0.070
1	0.350	0.700	0.667	0.214
10	1.107	2.213	2.108	0.700
100	3.500	7.000	6.670	2.143

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Wireless Compliance

Contains FCC ID 2ACA9-10004

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. The equipment must not be co-located or operating in conjunction with any other antenna or transmitter. Proper operation of this radio device according to the instructions in this publication will result in user exposure substantially below the FCC recommended limits.

RhythmStar Model SL 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 on a body.

The highest reported SAR value for this body-worn device is: 0.874 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: 2ACA9-10004.

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 receiving antenna.
- Increase separation between equipment and receiver.
- Connect 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: “Harmful interference” is defined in 47 CFR §2.122 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

Third-party belt-clips, holsters, and similar accessories used with this monitor 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.

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.