RHYTHMEDIX®

RhythmStar System of Devices Model RS-10003 Device Operator Manual V. 4.1 R1

Wearable Remote

Cardiac Monitoring

RhythmStar System of Devices Model RS-10003 Device Operator Manual is intended for the RhythMedix device customer. To help you instruct patients on RS-10003 device use, see **Instructions for Patient Before Monitoring** on page 8.

To improve the user experience, device hardware and software changes are made that may change the appearance of the device or accessories and affect the user experience. When controlled changes are completed, devices already on the market may differ in appearance and in user experience from newly marketed devices. See Examples below.

1. When 4.1 software is installed, devices continue to issue status notifications with LED lights and will either *vibrate* or *beep*. To NOT interrupt a patient's rest, the device will NOT *vibrate* or *beep* between 9 p.m. and 9 a.m.in the time zone where device is used.
2. Devices produced and serviced before 03/15/2023 have white lead wires, which based on customer feedback, were found to discolor over time and could not be reused. RhythMedix introduced purple lead wires on 03/15/2023. White lead wires will not be used on any devices marketed and serviced after 04/01/2023.

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Description

Model RS-10003, latest and smallest member of the RhythmStar® System family of devices (K141813), is a battery-powered, wireless cardiac monitor that records a patient's ECG data for up to 30 consecutive days. Model RS-10003 can conveniently be worn on the patient's chest.

Model RS-10003:

- Receives continuous ECG signal from adhesive patch electrodes affixed to the patient's body, measures the ECG signal by an integrated analog front-end circuit and stores it in the device's flash memory.
- Records patient activated and autotriggered events such as Bradycardia, Tachycardia, and Atrial Fibrillation that are identified by the RhythmStar® System (K141813) arrhythmia detection algorithm.
- Automatically delivers patient's recorded data to the Microsoft® Cloud server using a built-in wireless data modem or USB connection.

Data transmitted by the device can be stored and analyzed. Using compatible third-party software, such as RhythMedix's RhythmStar System (K141813) server software, data can be presented to a medical professional for review and analysis. Medical professionals can specify device configuration parameters for monitoring duration, user interface preferences, and amount of data storage.

RhythMedix supplies a RhythmStar charging base with a permanently attached USB cable that when connected to a Class II IEC 60601-1 compliant USB power supply can be used to charge the device's internal, non-removable battery.

The device is to be used with third-party ECG patch electrodes supplied to a patient by a physician or a monitoring center. RhythMedix recommends using high-quality FDA premarket approved ECG patch foam electrodes available at: https://hs.nisshamedical.com/ProductSearch.aspx?str=A10091 (NISSHA Medical Technologies acquired Vermed in 2015)

Indications for Use

The device is intended for use by patients who:

- Have or are at risk of having cardiac disease.
- Demonstrate intermittent symptoms indicative of cardiac disease.
- Require cardiac monitoring on a continuing basis.

Contraindications for Use

The device is NOT intended for use by:

- 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.).

Autotriggered and Manually Initiated Device Recording

- Device records when the RhythmStar® System (K141813) arrhythmia detects events such as Bradycardia, Tachycardia, and Atrial Fibrillation and auto-triggers recording.
- If patient during device monitoring experiences a symptom patient can firmly taps front of device 2 times to manually initiate a recording.

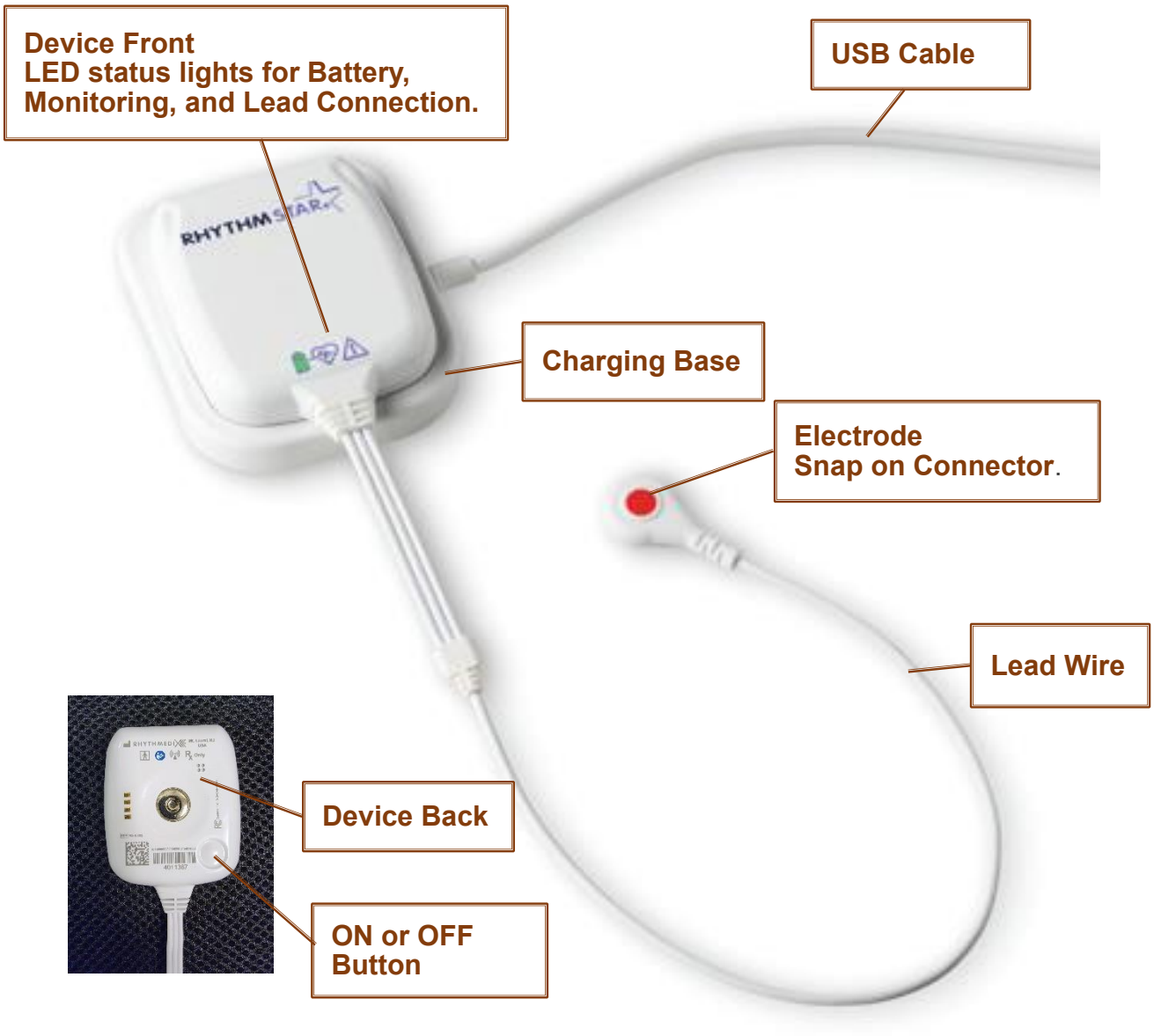


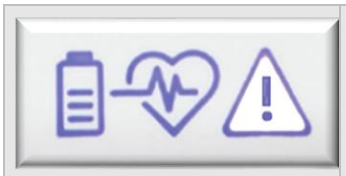
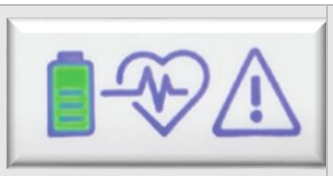
Figure 1 RhythmStar RS-10003 Device and Charging Base

Caution: Device and charging base are water resistant, NOT waterproof. Do NOT submerge in water.

Device Status Notifications

Device issues status notifications with LED lights and either vibrates or beeps.

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

			
Lead Connection	**Monitoring Active**	**Battery Fully Charged**	**Battery Low Charge**

Lead Connection

When device is turned ON, device vibrates or beeps and then Lead Connection WHITE LED light ups and blinks for about 30 seconds until device start up is complete.

When device is ON and either electrode affixed to device or electrode affixed to patient's chest is disconnected, the Lead Connection WHITE LED will light up and blink every 5 seconds and device vibrates or beeps 1 time every minute until electrode is reconnected.

Monitoring Active

When device is ON and properly connected to patient, the Lead Connection WHITE LED stops blinking and the Monitoring GREEN LED light ups and begins blinking every 10 seconds.

If during device monitoring, a patient experiences a symptom, patient can use 2 fingers to firmly taps front of device 2 times to start a device recording, device vibrates or beeps for 1 second to confirm recording has begun. Device will record for 30 seconds. During recording, the Monitoring GREEN LED will stop blinking and remain lit. See page 3

Battery Charge

When battery of device placed on charging base is fully charged, the Charge GREEN LED will light up and remain lit until device is removed from charging base.

When device battery charge is low, Charge RED LED will light up and begin blinking and device vibrates or beeps until placed on the charging base.

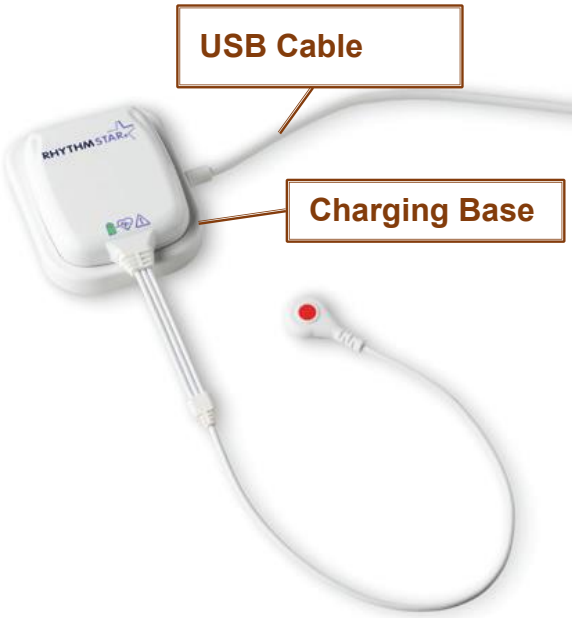
Charge Device Battery

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

Advise patients to *fully* charge battery before beginning their monitoring study and whenever battery low is indicated. After *fully* charging battery, patients can expect to recharge battery ever 2 to 4 days.

When patient removes device to bathe, shower, or replace electrodes, patient may charge battery until ready to reattach device and resume monitoring.

1. Connect the USB cable that is permanently attached to the RhythmStar charging base, to a Class II IEC 60601-1 compliant USB power supply.
2. Place device on the charging base to charge device battery.
   If battery charge is low, the device Charge RED LED will light up and device will vibrate or beep until it is placed on the charging base.
   To avoid interrupting a patient's rest, device will NOT vibrate or beep when battery charge is low between 9 p.m. and 9 a.m.
3. When device is fully charged, the device's Charge GREEN LED will light up and remain lit until device is removed from charging base.

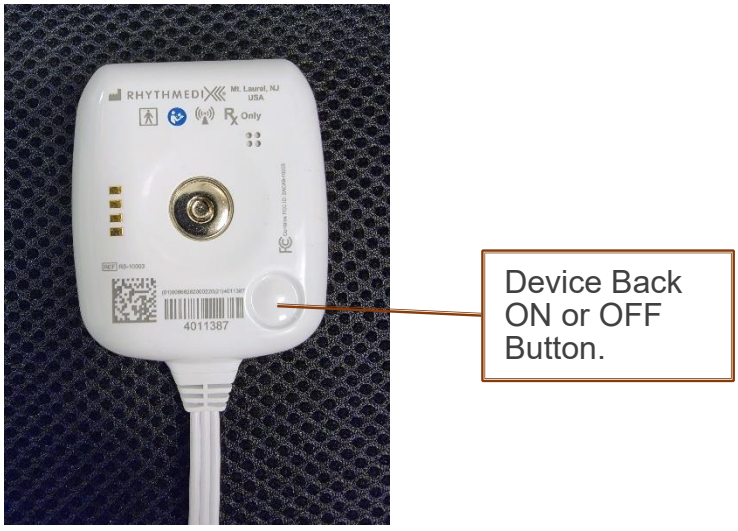


Turn Device ON or OFF

Patient should keep device turned ON at all times during patient monitoring study unless instructed by a monitoring facility technician to turn device OFF then back ON to restart device.

Turn ON

1. Either:
    a. Connect charging base USB cable to power supply and briefly place device on charging base. **OR**
    b. Press and hold the ON or OFF button on the back of device for 1 second until device either vibrates or beeps. *Lead Connection WHITE LED lights up and blinks for about 30 seconds as device turns ON and completes start up.*



Turn OFF

2. Press and hold the ON or OFF button for 4 seconds. *Device will vibrate or beep and 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 battery, replace electrodes, and bathe, shower, or swim.
2. Fully charge device before beginning monitoring study and whenever battery low status is indicated. After fully charging battery, expect to recharge battery ever 2 to 4 days. To extend battery charge, charge battery when you remove device until you are ready to reattach device and resume monitoring. Battery Charge instructions on page 6.
3. Device is water resistant, NOT waterproof. Do NOT submerge device into water. Remove device to bathe, swim, or shower.
4. For the best recording results, stay away from heavy electrical equipment or other sources of electromagnetic interference, such as, electric blankets and heating pads.
5. If you feel an arrhythmia symptom, such as dizziness or rapid heartbeat, use 2 fingers to firmly tap front of device 2 times to begin a manual recording of your heart rhythm.
6. Monitor device notifications and follow instructions to charge low battery and reconnect electrode.
7. Follow electrode manufacturer's instructions to affix, replace, remove, and dispose electrode.
8. 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. Refer to
9. Figure 2 Electrode Placement to affix electrodes.

Patient Hook-up

1. Fully charge device following Instructions on page 6.
   Note: When device that is OFF is placed on charging base, device automatically turns ON within 30 seconds . Keep device ON at all times.
2. Prepare Patient's Skin

Refer to device connection and electrode placement picture and decide where to place electrodes on patient's chest. Prepare patient's skin in 1-to-2-inch placement areas before affixing adhesive patch electrodes.

- If area is hairy, shave or clip hair.
- Clean skin with water or rubbing alcohol.
- Let skin dry.

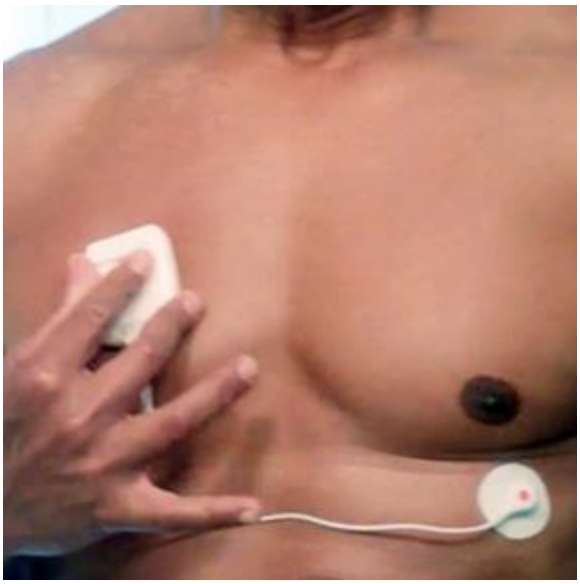
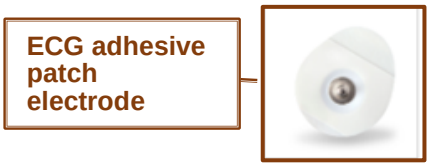


Figure 2 Electrode Placement

3. For best quality ECG recording, follow electrode manufacturer's instructions. Remove protective backing from one electrode and then affix electrode to back of device.



4. Remove protective backing from second electrode and then affix electrode to device's snap-on connector.
5. Remove protective backing from electrode affixed to device back in step 3, and then affix electrode to patient's chest.
6. Remove protective backing from electrode affixed to device's snap-on connector and then affix electrode to patient's chest.

Troubleshoot Malfunction

Troubleshoot a malfunctioning device before requesting service.

Problem	Solution
No Power	Check device battery power. If low, recharge device.
Low battery	Fully recharge device battery.
Noise artifacts on ECG signal	Ensure ECG adhesive patch electrodes are the quality recommended. Ensure all electrodes are securely attached to device and affixed to patient.

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 on 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.

Store and Ship Devices

Fully charge device batteries and then store devices and charging bases in a dry place at temperatures around 68 F. If storing devices for an extended time, fully charge devices every 3 to 4 months. See Device and Battery Precautions on page 12 and Environmental conditions on page 11.

Use protective packaging to ship device and charging base to patients and provide protective packaging for patients to safely return equipment to you. RhythMedix Customer Service finds the greatest device misuse is crushed and broken devices.

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 warranted 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 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 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 Device Model RS-10003 Specifications

Characteristics	Test Conditions	Min.	Typical	Max.	Unit
Physical					
Length			59		mm
Width			50		mm
Thickness			15		mm
Weight	With battery		40		gm
Functional					
ECG Channels	Cable selectable	1	1	2	n/a
Accelerometer Resolution	3-Axis	8	14	16	Bits
Memory					
Recording Time			30		days
Data Retention	embedded flash media		10		years
Wireless					
Communication Technology	LTE CAT-M1		700/1700/1900		MHz
Power Class	B2, B4, B12, B13		3		n/a
Output Power			0.25		W
Electrical					
CMRR		100	115		dB
AC Range			±32.5		mVPP
DC Range			±650		mV
Input Impedance			>1500		MOhm
Input Leakage Current	TA = +25°C	-1	±0.1	+1	nA
Frequency Response			0.05 to 125		Hz
Recovery Time			500		ms
ADC Resolution			18		Bits
ADC Sample Rate		125	256	512	Hz
Battery					
Type	Rechargeable Li-Ion		3.7		V
Life	From full charge		72		hours
Environmental					
Operating Temperature		0		50	C
Operating Relative Humidity	non-condensing	10		95	%
Operating Atmospheric Pressure		70		106	kPa
Storage Temperature		-40		70	C
Storage Relative Humidity	Including condensation	10		100	%
Storage Atmospheric Pressure		50		106	kPa
Ingress Protection			IPX4		n/a

Order Device and Charging Base

Part Number	Description
RS-10003	RhythmStar Model RS-10003 device
CBE-10003	RhythmStar Model RS-10003 charging base with permanently connected USB cable
RS-10003 V. 4.1	Access to PDF of RhythmStar Model RS-10003 V. 4.1 Device Owner's Operator Manual R0 is provided to customer at time of device purchase and upon request.

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 device owner's responsibility to recycle device at end-of-service life. Do the following before disposing device or charging base:

1. Clean device or charging base according to instructions on page 6.
2. 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/.

Device and Battery Precautions

RhythmStar device does NOT provide interpretive or diagnostic statements. Interpretation and diagnosis are the responsibilities of a trained healthcare professional or physician. No computerized information is completely reliable, and physicians should review all ECG results.

When viewing ECG data, the presence of pacemaker signals in the ECG trace should NOT be considered true representations of the actual pacemaker stimulus amplitude.

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.

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 state may result in heat generation, explosion, or fire.
- Disconnect patient leads before defibrillation.

Danger: Do NOT

- Submerge device or charging base in water. Remove device before showering bathing, or swimming.
- Attempt to disassemble equipment or replace the battery. Otherwise, the battery may be shorted and result in heat generation or fire.
- Use or leave the device near fire, heaters, inside an automobile in hot weather or under strong sunshine. Such conditions of high temperature may damage the internal battery, and the battery may be shorted and result in heat generation, explosion, or fire.
- Apply any heavy impact to the device, throw, or drop it. Otherwise, the battery may be shorted and result in heat generation, explosion, or fire.
- Expose device to extreme temperatures, that is, beyond the limits shown in the environmental specifications.
- Modify this equipment.

Wireless Compliance

Contains FCC ID 2ACA9-10003

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 instruction in this publication will result in user expo-sure substantially below the FCC recommended limits.

RhythmStar Model RS-10003 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: 2ACA9-10003.

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.

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.

Symbols Used

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
℞ Only	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