RHYTHMSTAR®

Model RS-10003
Operator Manual

RHYTHMEDIX®

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Description

The newest member of the RhythmStar® System family of devices, Model RS-10003, is a small device that can be worn on a patient's chest.

Model RS-10003 is a battery powered, wireless cardiac monitor used to record a patient's ECG and motion activity level data for up to 30 consecutive days.

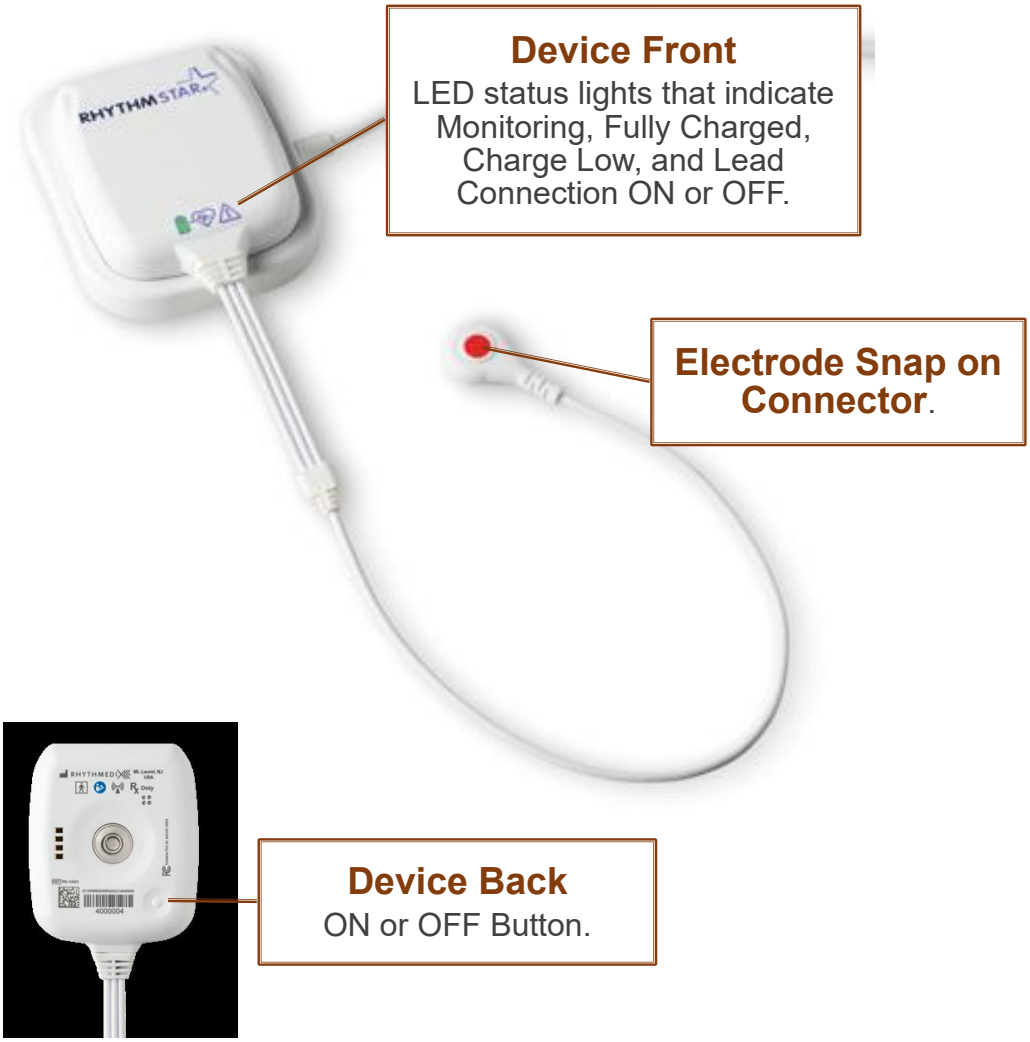
The Model RS-10003 device:

- 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.
- Measures motion activity level data with a built-in accelerometer and stores data in device's memory.

Data transmitted by the device can be stored, analyzed, and presented for review and analysis by a medical professional using compatible third-party software, such as the server software included in RhythMedix's RhythmStar System (K141813). The RhythmStar System server software can deliver configuration parameters to the device, such as monitoring duration, user interface preferences, and requests for additional data stored in the device's memory.

RhythMedix supplies a RhythmStar charging base that has a USB cable permanently attached to it. To charge device, patient must first connect the RhythmStar charging base to a Class II IEC 60601-1 compliant USB power supply and then place device on charging base.

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.).

Before Using Device

Read Precautions on page 16.

Fully charge device.

1. Connect the RhythmStar charging base to USB power supply.
2. Properly place device on the RhythmStar charging base and the device's Charge status light will illuminate RED if the device charge is low.
3. When device is fully charged, the device's Charge Status light will illuminate GREEN (as shown).

Adjust temperature of device:

If device has been stored at temperatures above or below the storage temperature limits -40 to 70 C (-40 to 158 F), place device in environment with room temperature, that is 20–22 C (68–72 F), for at least 30 minutes before use.

Power Device ON and OFF

ON

Connect charging base to power supply and briefly place device in charging base.

OR

Device Back
ON or OFF Button.

Locate ON/OFF button on the back of device. Press and hold the ON/OFF button for one (1) second until all LED status lights illuminate and flash once, device vibrates, and Lead Connection status LED illuminates **WHITE** and blinks for about 30 seconds as device starts up.

OFF

Press and hold the ON/OFF button for four (4) seconds and device will vibrate, all three (3) status LED lights will flash, and then device will turn OFF.

Note: The device automatically shuts OFF when device is not collecting ECG data for four (4) hours. The device should NOT be turned OFF during patient monitoring.

Device Status Lights

Device status lights are on the front of the device. When device is turned ON, all LED status lights illuminate and flash once, device vibrates, and Lead Connection status LED illuminates **WHITE** and blinks for about 30 seconds as device starts up.

When device is ON and NOT connected to patient, the Lead Connection status light on device front illuminates **WHITE** and blinks every five (5) seconds.

When device is first turned on, Lead Connection status light illuminates **WHITE** and blinks rapidly for 30 seconds until device start up is complete.

When device is ON and properly connected to patient, the Lead Connection **WHITE** status light will stop blinking and the Monitoring status light will illuminate **GREEN** and begin blinking every ten (10) seconds. When device is recording a patient activated event for thirty (30) seconds, the Monitoring status light will remain illuminated and will stop blinking.

If either of the two electrodes becomes disconnected after device is ON and properly connected to a patient, the Lead Connection status light will illuminate **WHITE** and blink every five (5) seconds, and the device will vibrate one (1) time every minute for five (5) minutes to indicate the electrode is disconnected.

When device, placed on the RhythmStar charging base that is connected to a power supply, becomes fully charged, Charge status light will illuminate **GREEN** until it is removed from the charging base.

When device charge is low, Charge status light will illuminate **RED** and begin blinking.

Prepare patient's skin before affixing electrodes.

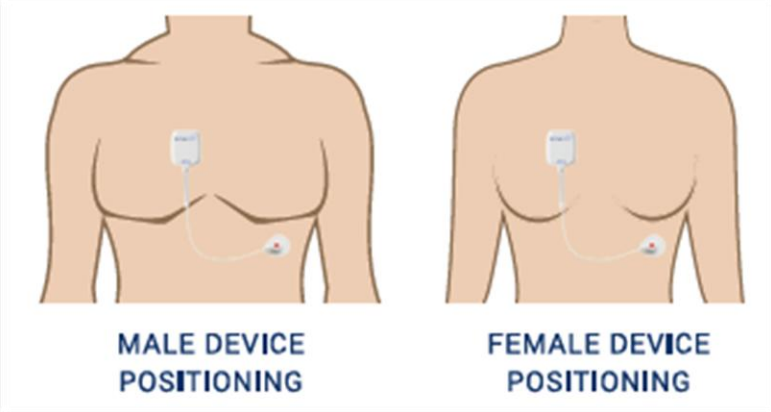
The quality of the ECG signal greatly depends on the contact between the ECG patch electrode and the patient's skin. Proper preparation of the patient's skin is required to obtain a quality ECG recording.

If there is hair on the patient's chest in the areas where the electrodes are to be placed, shave these areas. Use water or rubbing alcohol to clean the skin where the electrodes are to be placed and then let the skin dry.

Connect electrodes to device and affix electrodes to patient's chest.

1. Remove protective backing from electrode and affix electrode to back of device.
2. Remove protective backing from another electrode and attach electrode to device's snap on connector.
3. Affix electrode on back of device to patient's chest. See page 9.
4. Affix electrode on device's snap on connector to patient's chest. See page 9.

Device Connection and Electrode Placement on Patient's Chest



Patient Monitoring

If during device monitoring, patient experiences a symptom, patient should tap firmly two (2) times to manually trigger a device recording. Device will record event and patient's motion activity level for thirty (30) seconds the same way the device records a device autotriggered event.

During the monitoring study, patient should ONLY REMOVE the device to charge it for 20 to 30 minutes each day and to bathe, shower, or swim. The device is NOT waterproof.

After Using Device

Recharge Device

Patients are to remove device and charge it for 20 to 30 minutes each day. If patient does NOT charge device daily, it could take up to 3 hours to fully charge device.

1. Disconnect device from the ECG patch electrodes.
2. Connect the RhythmStar charging base to a USB power supply.
3. Place device on the charging base. If device is properly placed on the charging base, the Charge status light will illuminate **RED**.
4. After device is fully charged, the Charge status light will illuminate **GREEN** while the device is on the charging base.

Clean Device

1. Slightly dampen a soft cloth with a mild detergent and water. Apply light pressure to clean device.
2. If after cleaning any adhesives remain on device, remove adhesives with an adhesive remover solution or with a cotton swab slightly dampened with a mild detergent.

Note: An example of a mild detergent is an alcohol-free hand soap or a mixture of 10% of sodium hypochlorite (bleach) solution and 10% and water.

Troubleshooting

Troubleshoot a malfunctioning device before requesting service.

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

RhythMedix Service for Customers

If after reading these instructions you need further help, in an email message addressed to RhythMedix Customer Support at: mailto:support@rhythmstar.com enter device's serial number, charging base serial number, and request help. Expected service life of the device is 5 years.

If Customer Support asks you to return equipment for service, they will give you a Return Merchandise Authorization (RMA) number. Enter this address and the RMA number on the shipping label:

RhythMedix, LLC

5000 Atrium Way, Suite 1

Mt. Laurel, New Jersey 08054.

Attention: Repair, RMA Number: _____

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

Symbols Used

Symbols placed on device and in device labeling are used in conformance to standards. Symbol, description, and standard are provided below.

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
R_X Only	For prescription use only.
	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
IPX4	Protected against splashing water. IEC 60529

RhythmStar Limited Warranty

This RhythMedix device is warranted to be free from manufacturing and material defects for a warranty period of two (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.

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

Dispose of device and device charging base at end of service life.

At end of service life, do the following before disposing:

1. Clean the device or charging base according to instructions in Before Using Device section.
2. Recycle the 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/.

Order device and charging base.

Part Number	Description
RS-10003	RhythmStar Model RS-10003 device
CBE-10003	RhythmStar Model RS-10003 charging base
Not Required	RhythmStar Model RS-10003 Operator Manual is provided to customer at time of device purchase and upon customer request.

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

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.

This equipment does NOT include any parts or components that need to be serviced or maintained during use.

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

- 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.
- Drive a nail into, hammer, or stamp on the device. Otherwise 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.
- Put the device 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.
- Expose device to extreme temperatures (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.

Wireless Compliance Continued

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.