RHYTHMEDIX

RHYTHMSTAR® W

Mobile Cardiac Monitor

Operator Manual

RHYTHMEDIX

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1. Description

RhythmStar-W is a wearable, battery powered, wireless cardiac monitor that may be worn by a patient to record ECG, bioimpedance, and motion activity level data for up to 30 consecutive days. RhythmStar-W can capture patient activated and auto-triggered events such as Bradycardia, Tachycardia, and Atrial Fibrillation as identified by the existing RhythmStar embedded arrhythmia detection algorithm (K141813).

RhythmStar-W is capable to automatically deliver the data to the Cloud server. The data can be delivered wirelessly by using a built-in wireless data modem or via USB connection.

RhythmStar-W consists of a monitor, an optional patient ECG lead cable, and a USB battery charger.

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

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

RhythmStar-W receives continuous ECG and bioimpedance signal from lead electrode sensors attached to the patient's body, measures the signal by an analog frontend integrated circuit and stores it in the embedded flash memory. Motion activity level data is measured by a built-in accelerometer and stored in the device's memory.

The data transmitted by RhythmStar-W can be stored, analyzed, and presented for review and analysis by a medical professional using compatible 3rd party software, such as the RhythmStar System (K141813), manufactured by Rhythmedix LLC.

2. Indications for Use

RhythmStar-W 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.

3. Contraindications for Use

RhythmStar-W is NOT intended for use under the following conditions:

- Patients with potentially life-threatening arrhythmias who require inpatient monitoring.
- Patients who the attending physician believes should be hospitalized.
- Infants weighing less than 10 kg. (22 lbs.).

4. Precautions

1. 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. CAUTION: No computerized information is completely reliable; physicians should review all ECG results.

2. 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.

5. RhythmStar-W Monitor and Charger

RhythMedix provides RhythmStar-W monitor and charger. See part numbers below:

Part Number	Description
RS-W-1500	RhythmStar-W monitor
RSW-BC-1010	RhythmStar-W charger

6. RhythmStar-W Monitor

RhythmStar-W monitor is a small, lightweight, battery powered, wearable cardiac monitor that is attached to third-party electrodes that are placed on the patient's chest.

LED monitor status indicators
Battery, Monitoring, Lead Connection (left to right)

Front View of RhythmStar-W Monitor

Back View of RhythmStar-W Monitor

7. RhythmStar-W Charger

Use only RhythMedix supplied charger to charge the RhythmStar-W monitor.

8. Electrodes

RhythmStar-W monitor is to be used with third-party electrodes supplied to a patient by a physician or a monitoring center. RhythMedix recommends use of high quality FDA approved lead electrodes, such as the model A10096SG rectangular foam electrodes by Vermed (see http://https://vermed.com/Electrodes/Default.aspx) or equivalent.

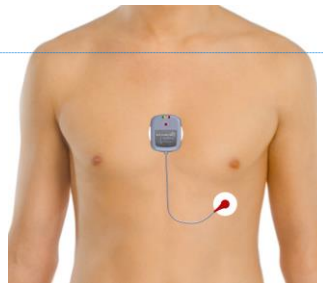
Commented [JD1]: One electrode or more than one (electrodes)?

9. Connecting RhythmStar-W to electrodes

The quality of the ECG signal greatly depends on the contact between the electrode and the patient's skin. RhythMedix recommends use of high-quality, Holter electrodes that have been approved by the FDA. Proper preparation of the patient's skin is required to obtain a quality ECG recording. Follow electrode manufacturer instructions for preparing patient's skin. The following suggestions may also be helpful:

Commented [JD2]: Different from recommendation made in paragraph above.

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



Commented [JD3]: Correct indent.

10. Powering on and Using RhythmStar-W Monitor

To turn on RhythmStar-W, then briefly press and hold the ON/OFF button on the back side of the monitor until monitor briefly vibrates and LED lights on front of device flash one at a time.

To turn off RhythmStar-W, press and hold the ON/OFF button for eight (8) seconds until monitor produces a longer vibration and LED lights illuminate for two (2) seconds.

11. Recharging RhythmStar-W Monitor

Step 1: First connect the RhythmStar-W Charger to a USB compliant power adaptor.

Step 2: Place RhythmStar-W into RhythmStar-W Charger. The monitor will only lay in the charger when properly positioned. After Rhythmstar-W is placed in the charger and charging begins, the battery status light will display steady **RED**. Depending on the battery charge level, it could take up to 2 hours to fully charge RhythmStar-W. After the monitor is fully charged, the battery status light will display steady **GREEN**.

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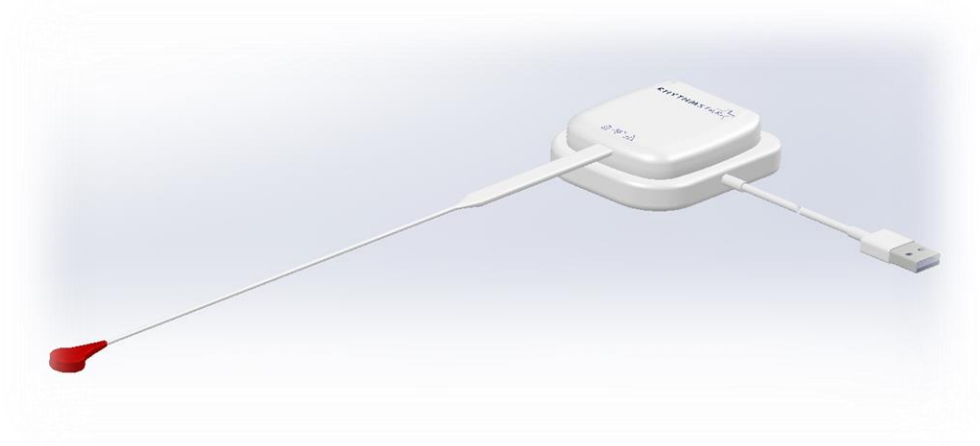

12. Operating RhythmStar-W Monitor

- When monitor is ON and not connected to patient, the Lead Connection status light will blink yellow every five (5) seconds.
- When monitor is ON and properly connected to patient, the Lead Connection status light will discontinue blinking, and then
- Monitoring status light will begin blinking green every (10) seconds.
- If during patient use, the electrode becomes disconnected from patient, the Lead Connection status light will blink every five (5) seconds and the monitor will vibrate once per minute for five (5) minutes.

13. Cleaning

To clean RhythmStar-W monitor:

1. Dampen a soft cloth with a mild detergent and water mixture. An example of a mild detergent is an alcohol-free hand soap or sodium hypochlorite (bleach) solution 10% in water.
2. Clean the monitor.
3. Remove any remaining adhesives from the monitor with an adhesive tape remover solution or swab of mild detergent.

14. Service

If there is a problem with RhythmStar-W monitor or charger, first review Section 15 Troubleshooting for a solution. If you need further help, include monitor's serial number and problem description in an email message to RhythMedix Customer Support at: support@rhythmstar.com

If RhythMedix Customer Support replies with a request to return monitor and/or charger for repair and provides a Return Merchandise Authorization (RMA) number, then use protective packaging to ship monitor and/or charger to: RhythMedix, RMA#_____, 5000 Atrium Way, Ste 1, Mt. Laurel, NJ 08054.

WARNING: RhythMedix is NOT responsible for monitors or chargers received from customers that are damaged during shipping.

15. Troubleshooting

Symptom	Solution
No Power	Check monitor power and recharge.
Low battery	Recharge monitor.
Noise artifacts on ECG signal	Ensure all electrodes are securely attached to patient and electrodes used are of quality recommended.

16. Meaning of RhythmStar-W Symbols

Symbol	Description
	Indicates the medical device manufacturer. Source: ISO 15223-1
	Indicates the manufacturer's catalogue number so that the medical device can be identified. Source: ISO 15223-1
	Indicates the manufacturer's serial number so that a specific medical device can be identified. Source: ISO 15223-1
	Indicates the need for the user to consult the instructions for use. (that is, this RhythmStar-W Operator Manual) Source: ISO 15223-1
	For prescription use only.
	Type CF Applied Part for cardiac application. Provides a higher degree of protection against electric shock than that provided by BF. It has much tighter leakage current limits to the patient.
	Ingress protection-protected against fluid ingress. Device is resistant to dust and can withstand exposure to water of up to a meter deep for half an hour.

Source: ISO 15223-1 Second edition Medical devices – Symbols to be used wit the medical device label, labeling, and information to be supplied. Part 1: General Requirements.

17. RhythmStar-W Monitor 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
Storage Temperature		-25		70	C
Relative Humidity	Non-condensing 23 C	10		93	%
Ingress Protection"			IP67		n/a

18. RhythmStar-W Limited Warranty

This RhythMedix product is warranted to be free from manufacturing and material defects for a period of two years from the date of shipment from RhythMedix to the original purchaser (“Warranty Period”). If a hardware defect arises and a valid claim is received 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 damaged by accident or that 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.

19. Obtaining Warranty Service

To return RhythmStar-W monitor or charger for service, send an email message requesting shipping instructions and a Returned Merchandise Authorization (RMA) number to RhythMedix Customer Support at: support@rhythmstar.com. Use protective packaging to ship monitor and/or charger, postage prepaid for in-warranty monitors, to: RhythMedix, 5000 Atrium Way, Suite 1, Mt. Laurel, NJ 08054 Attention: Repair, RMA # _____.

20. Wireless Compliance

21. Arrhythmia Detection Performance

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

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

QRS Detection Performance

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

AF Detection Performance

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