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Certification Exhibit

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ACS Project: 16-2030

Manufacturer: Cardionet
Model(s): 100-0025-01, 900-0604-00

User Manual

CARDIONET®

MOBILE CARDIAC OUTPATIENT TELEMETRY™

CARDIONET MCOT™
MANUAL

We'd know about it

Mobile Cardiac Outpatient Telemetry™

Better Detection. Better Reporting. Validated by Clinical Data.

CARDIONET® MCOT™

Better Information. Better Care.

CARDIONET LIMITED WARRANTY

CardioNet products are warranted to be free from manufacturing and material defects for a period of one (1) year from the date of shipment from CardioNet to the original purchaser. This warranty does not apply to any product which CardioNet determines has been modified or damaged by the customer. Excluded from this warranty are expendable supply items including, but not limited to, electrodes, lead wires, and batteries. Except for the express warranties stated above, CardioNet 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 CardioNet for damages, including but not limited to, special indirect or consequential, arising out of or in connection with the use or performance of CardioNet products. Any action for breach of warranty shall be commenced within one (1) year of said breach or be forever barred. Any repairs made to the product, which are not covered by the warranty, shall be billed to the customer. Device is to be serviced by Factory Authorized Technicians only. Do not attempt to repair, modify, or service the CardioNet CN1006 MCOT system. Do not attempt to open or tamper with MCOT System. Opening the case will void product warranty.

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01.
OVERVIEW

The CardioNet Mobile Cardiac Outpatient Telemetry ™ (MCOT ™) system is an ambulatory ECG Monitor with the capability to detect cardiac arrhythmias and transmit ECG data to a staffed Monitoring center.

The subject device is comprised of two (2) main components: 1) a patient-worn Sensor, and 2) a Monitor

A Sensor acquires the ECG signal from the patient's body and transmits the signal to a PDA sized Monitor where the data is stored and analyzed by an automated arrhythmia detection algorithm residing in the Monitor. When events are detected by the analysis algorithm or when indicated by the patient pressing the Record Symptom button on the Monitor, the Monitor will transmit the data to the Monitoring Center. Data is uploaded to the Monitoring Center via Cellular RF modem transmission. The data is received and reviewed by trained technicians at the Monitoring Center.

Caution: U.S. federal law restricts this device to sale by or on the order of a physician.

02.
INDICATIONS FOR USE

1. Patients who have a demonstrated need for cardiac monitoring. These may include but are not limited to patients who require monitoring for: a) non-life threatening arrhythmias such as supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, PACs, PSVT) and ventricular ectopy; b) evaluation of bradyarrhythmias and intermittent bundle branch block, including after cardiovascular surgery and myocardial infarction; and c) arrhythmias associated with co-morbid conditions such as hyperthyroidism or chronic lung disease
2. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath).
3. Patients with palpitations with or without known arrhythmias to obtain correlation of rhythm with symptoms.
4. Patients who require monitoring of antiarrhythmic therapy: a) Monitoring of therapeutic and potential proarrhythmic effects of membrane active drugs, b) Monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation).
5. Patients recovering from cardiac surgery who are indicated for outpatient arrhythmia monitoring.
6. Patients with diagnosed sleep disordered breathing including sleep apnea (obstructive, central) to evaluate possible nocturnal arrhythmias.
7. Patients requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation or atrial flutter.
8. Patients requiring measurement, analysis and reporting of QT interval, excluding patients with a documented history of sustained atrial fibrillation or atrial flutter.
9. Patient who require monitoring for potential arrhythmias based on risk factors (e.g. atrial fibrillation).
10. Patients requiring measurement of ST segment changes. The device is not intended to sound any alarms for ST segment changes.

CONTRAINDICATIONS:

1. Patients with potentially life-threatening arrhythmias who require inpatient monitoring.
2. Patients who the attending physician thinks should be hospitalized.
3. This device should not be used for monitoring of QT interval during the initiation of antiarrhythmic therapy, where in-hospital monitoring is required by the labeling of that drug.
4. The device does not replace the QT interval measurement by a trained observer using diagnostic 12-lead ECG in a clinical environment. This device is not intended to sound any alarms for QT interval changes.
5. The device does not annotate QT interval for QRS durations >160 ms or for T wave amplitudes ≤5% of the peak QRS amplitude.

FOR USE ON ADULT AND PEDIATRIC PATIENTS ONLY

The CardioNet MCOT System is intended for use on adults and children. It is not intended to be used on infants weighing less than 10kg (22 lbs).

03.
PRECAUTIONS

A. DISPOSE OF BATTERIES PROPERLY

Observe all local laws for the disposal of alkaline batteries.

B. WHEN NOT IN USE, REMOVE SENSOR BATTERY

Do not leave the battery in the Sensor when it is not in use.

C. AVOID ELECTROMAGNETIC INTERFERENCE

For the best recording results, you should avoid close proximity to heavy equipment or other sources of electromagnetic interference such as electric blankets, heating pads, water beds, etc.

D. POTENTIAL FOR ELECTROMAGNETIC INTERFERENCE

There is a potential for electromagnetic interference to other devices while using the CardioNet Service.

E. USE WITH IMPLANTED PACEMAKERS AND ICDs (DEFIBRILLATORS)

If you have an implanted pacemaker or defibrillator (ICD), the manufacturer may have recommended you take certain precautions when using a cellular phone. Since the CardioNet Monitor contains a cellular phone, you should take the same precautions when carrying and using the Monitor. In general, most manufacturers recommend the following:

- You should keep a distance of at least six inches (15 cm) between the cellular phone and a pacemaker or defibrillator.
- You should hold the cellular phone on the opposite side of the body from the pacemaker or defibrillator.
- Do not carry a cellular phone in a breast pocket or on a belt if that would place the phone within six inches of the pacemaker or defibrillator.
- You should refer to the manufacturer's information for guidance regarding your pacemaker or ICD and interference issues.

04.
CAUTIONS

A. POWER DOWN MONITOR AND SENSOR BEFORE SHOWERING

Power down the Monitor, remove the Sensor, and remove battery from Sensor before showering. The CardioNet Sensor is water resistant, not waterproof.

B. DO NOT GET THE MONITOR AND SENSOR WET

Make sure the Monitor and Sensor stay dry at all times.

C. CLEANING

Use a soft cloth to clean the equipment.

D. LIMITATIONS OF COVERAGE

CardioNet's ability to obtain information regarding a cardiac event and to contact you or your physician in a timely manner is limited by a number of factors including:

- Transmission of information about a cardiac event to CardioNet's Monitoring Center is potentially limited by the availability of cellular phone coverage.
- There is an inherent time delay from the time that an event is detected to when the events are analyzed and confirmed by a Certified Cardiac Technician (CCT).
- There is an inherent time delay from when the event is analyzed and confirmed by the CCT to when CardioNet is able to make contact with you or your physician.
- If you or your physician are not accessible by telephone, CardioNet will not succeed in making contact with you or your physician.

05.
WARNINGS

A. NOT AN APNEA MONITOR
The CardioNet Monitor is not to be used as an apnea monitor.

B. NOT AN EMERGENCY RESPONSE SERVICE
CardioNet is not an emergency response service. If you experience any symptoms that concern you, seek medical help.

C. DO NOT TAMPER WITH DEVICE
There are no serviceable parts in the CardioNet MCOT TM System components. Removing the cover of any component may alter device performance.

D. DO NOT TAMPER WITH MONITOR BATTERY
The Monitor battery can present a fire or chemical burn hazard if mistreated. Do not disassemble, heat, incinerate, or recharge using any device other than the CardioNet supplied power cord.

E. USE ONLY CARDIONET POWER CORD IN SINGULAR OUTLET
Do not use any power cord other than the one provided in the CardioNet service kit. A multiple portable socket outlet or extension cord should not be used with the equipment.

F. DO NOT USE NEAR FLAMMABLE ANESTHETIC
Units are not to be used in the presence of flammable anesthetic.

06.
MEDICAL PRACTICE INSTRUCTIONS

DEPLOYING THE DEVICE

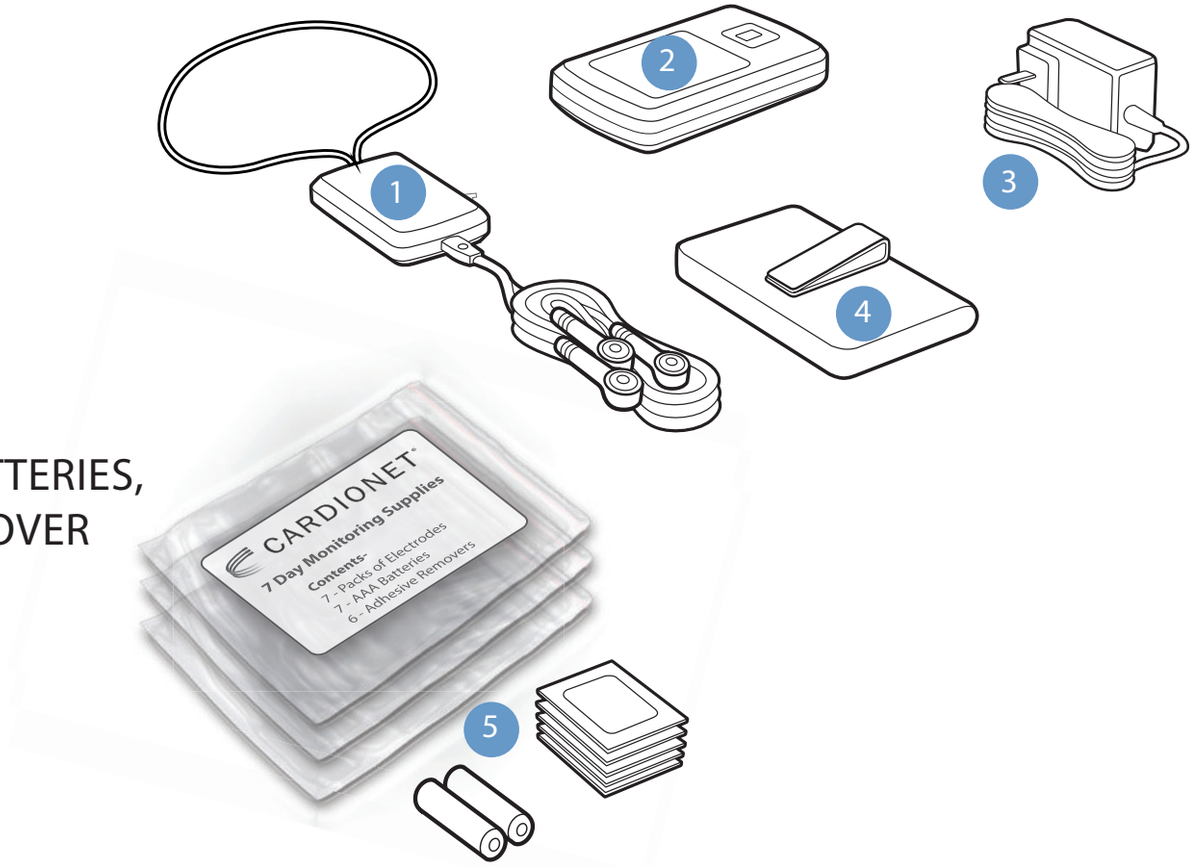
1. Receive and store Monitor and Sensor sets in a secure area at practice.
2. To provide devices for a new prescription, retrieve a Monitor and Sensor from available inventory.
3. Turn ON Monitor and insert the battery in Sensor.
   Note: If there is already a battery in the Sensor, remove it and reinsert it.
4. Go to https://access.cardionet.com and go to Enrollment screen. Click on 'MCOT FFS Enrollment' and it will display Prescription/Order information to be filled out.
5. Enter Patient information and prescription information. From the on-screen list, select the serial numbers of the Monitor and Sensor chosen in step (2).
6. Click 'Activate Prescription'.
7. The Monitor screen will display message 'PAIRING'. Once pairing is completed, click on Continue.
8. Choose the language and click on Continue.
9. Once Activation is completed, the Monitor will display message showing paired Sensor number for verification.
10. Once the Monitor-Sensor verification is confirmed, the device state is updated as Activated/Unavailable.
11. Once the pair is Activated, the set is ready to be sent to the patient.
12. Turn OFF Monitor and remove battery from Sensor; put the Monitor and Sensor in the kit.

RECEIPT OF DEVICE

1. Receive the device set sent by patient. Unpack it and disinfect it.
2. Turn ON Monitor and insert the battery in Sensor.
3. Go to https://access.cardionet.com webpage and go to prescriptions under Device Maintenance tab.
4. Click on 'Deactivate'. This will reset the device including purging of old data and un-pairing of Monitor and Sensor.
5. If the device is returned back for replacement, click on 'Replace' and follow the process of deployment per above.
6. Once the device set is Deactivated, the screen will show status of Monitor and Sensor as 'Available'.
7. Turn OFF the Monitor and remove the Sensor battery.
8. Shelve the device in secure area.

07.
KIT CONTENTS

1. SENSOR
2. MONITOR
3. POWER CORD
4. MONITOR CASE
5. ELECTRODES, BATTERIES, & ADHESIVE REMOVER



08.
MONITOR AND SENSOR

TOUCH SCREEN
To operate monitor, touch the screen where indicated. Monitor is still functioning when dark (Screen will go dark after 1 minute).

CHARGING LIGHT (when charging)
Orange = Charging
Green = Fully Charged

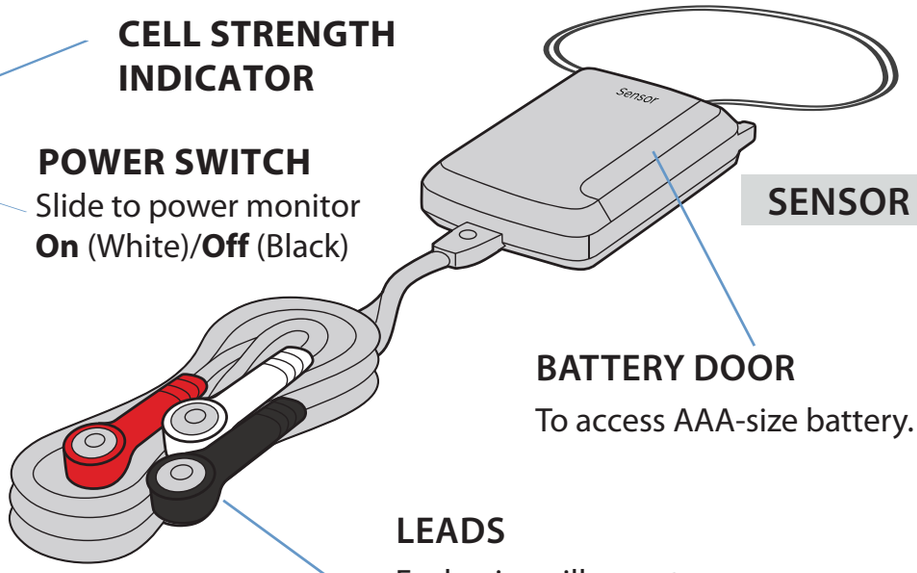
STATUS LIGHT
Intermittent Green = Communication with sensor
Red = Read the screen for instructions

WAKE BUTTON
If you want to view the screen, press the Wake button.

MONITOR

CELL STRENGTH INDICATOR

POWER SWITCH
Slide to power monitor **On** (White)/**Off** (Black)



SENSOR

BATTERY DOOR
To access AAA-size battery.

CHARGING PORT
Plug power cord end here to charge the monitor.

LEADS
Each wire will snap to an electrode that will be attached to your body.

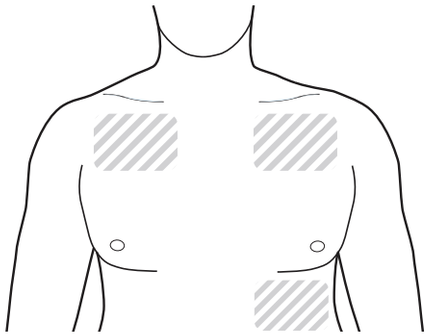
Your monitor should remain with you at all times. Although your monitor detects and transmits arrhythmias automatically, it is important to use the monitor's Record Symptom button to notify CardioNet and your doctor when you are feeling a symptom.

09.
ATTACHING THE ELECTRODES TO YOUR SKIN

Note: Please do not use the adhesive remover wipes prior to placing electrodes on your skin. These should only be used to remove adhesive from your skin after removing electrodes if needed.

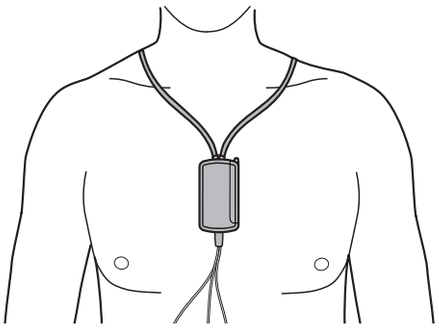
1

Electrodes are placed in the shaded areas; wash and dry these areas. Do not use powder or lotion. If you have chest hair, shave these areas.



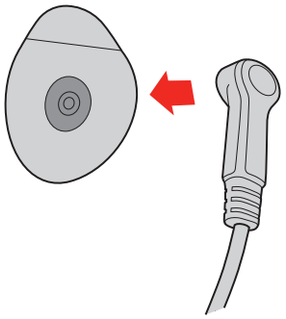
2

Remove sensor and neck strap from box. Place the cloth strap over your head around your neck.



3

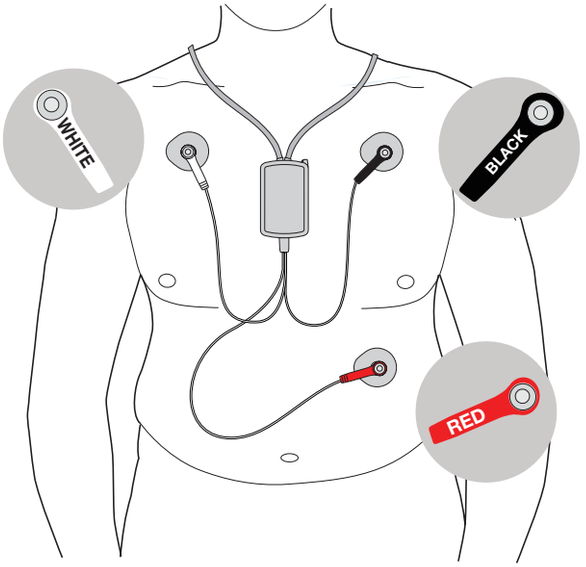
Tear open electrode pack and remove 3 electrodes. Snap the lead (wires) end onto the electrodes.



4

White (Right)

Peel the adhesive backing off the White electrode. Place the electrode about 3 fingers width below your right collar bone.



Black (Left)

Peel the adhesive backing off the Black electrode. Place the electrode about 3 fingers width below your left collar bone.

Red (Left Side)

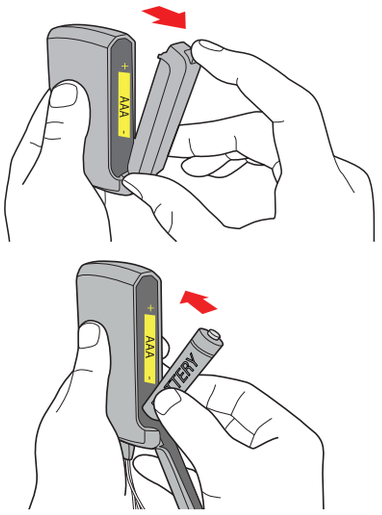
Peel the adhesive backing off the Red electrode. Place the electrode on the lower left side of your rib cage, in line with the electrode under your left collar bone.

You should now have all three wires attached to the electrodes in the positions shown. Wait 15 minutes before proceeding to step 5.

5

Open the door of your sensor. Place a AAA battery from the CardioNet MCOT Kit into the sensor as shown below. Use the AAA battery image on the inside of the sensor to ensure that the plus (+) and minus (-) ends of the battery are properly oriented. If you have inserted the battery correctly, you will hear a chime. Close the sensor door.

Note: You will need to change your sensor battery every day.

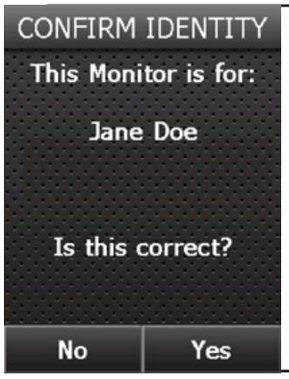


10.
GETTING STARTED WITH MONITORING

1. The monitor should be powered on (green light above the screen). If it isn't, please turn it on using the power switch on the right side of the monitor.

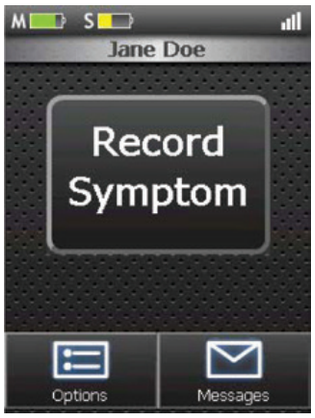
2. If the monitor is on, and the screen is dark, touch the Wake button (black button, with white square on it) to light up the screen.

3. Confirm identity.

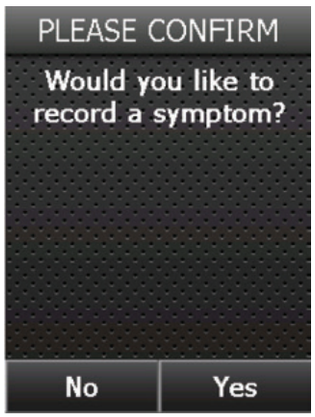


Please verify that your name is correct. If correct, press Yes, and read the monitor screens that follow. If incorrect, including spelling, press No. Turn off the monitor, take off the sensor and remove the battery, and call your physician.

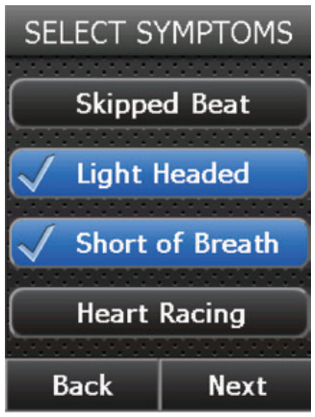
11. RECORDING SYMPTOMS



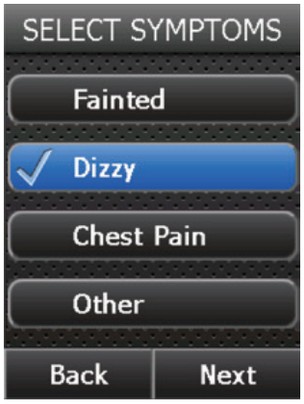
1
Touch Record Symptom to proceed.



2
Yes to proceed. No to return to the Main Menu

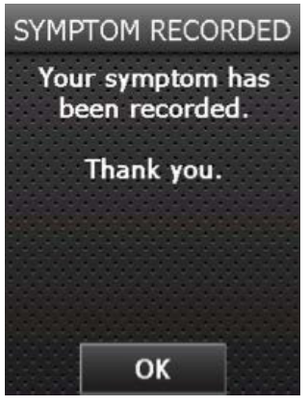


3
Touch any symptoms you are feeling. Touch Next for additional symptom options.



4
Touch any additional symptoms you are feeling. Touch Next to proceed.

5
Touch your current activity level. Touch Done to proceed.



6
Confirmation message received that your symptom was recorded.

Please remember to keep your monitor with you at all times so that you may record any symptoms you feel.

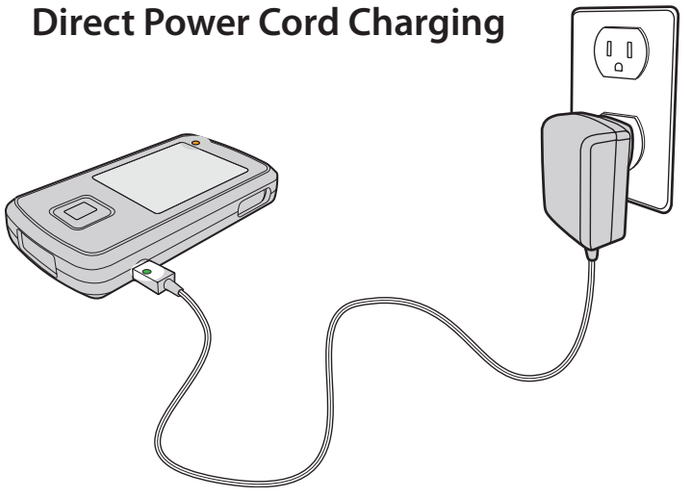
It is important to use the monitor to record any symptoms you may feel. When you feel a symptom, press Record Symptom and follow the instructions.

Data will be transmitted to CardioNet automatically. There is no need to call to confirm receipt.

CardioNet MCOT™ is not an emergency response service. If at any time you experience a symptom that you feel is a medical emergency, you should immediately dial 911 for medical assistance.

12.
CHARGING THE CARDIONET MCOT™ MONITOR

Direct Power Cord Charging



It is important to charge the monitor every night. It may take up to 4 hours to fully charge the monitor.

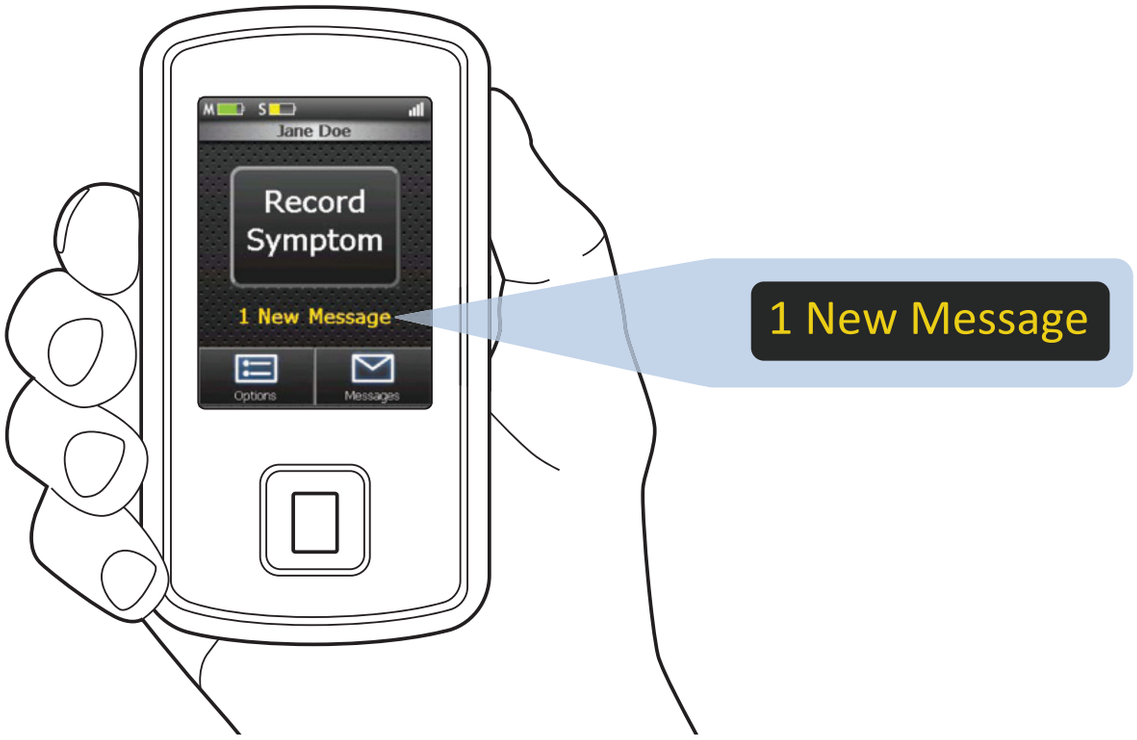
DIRECT POWER CORD CHARGING

Take the power cord with you if you plan to be away from home all day. To charge the monitor, plug the power cord into the hole on the side of the monitor. Look for the orange light on the top left of the monitor. The "Charge Monitor" alarm will sound when the battery is critically low.

CHECKING BATTERY POWER

Locate the battery power gauges in the top left of the monitor screen. The picture on the left represents the monitor battery level (M) and the picture on the right represents the sensor battery level (S). Touch this picture to display current battery levels.

13.
RECEIVING TEXT MESSAGES

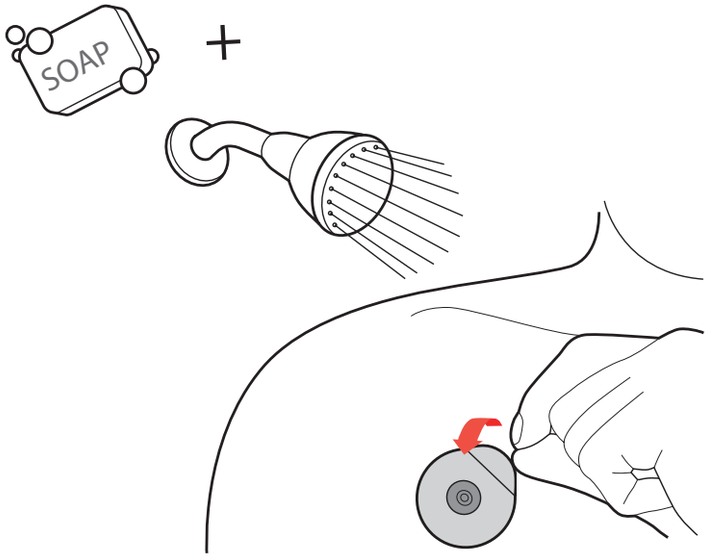


ABOUT TEXT MESSAGES

CardioNet may send you text messages during your monitoring. If you hear an alert and see the New Message statement on the screen, you have a new text message.

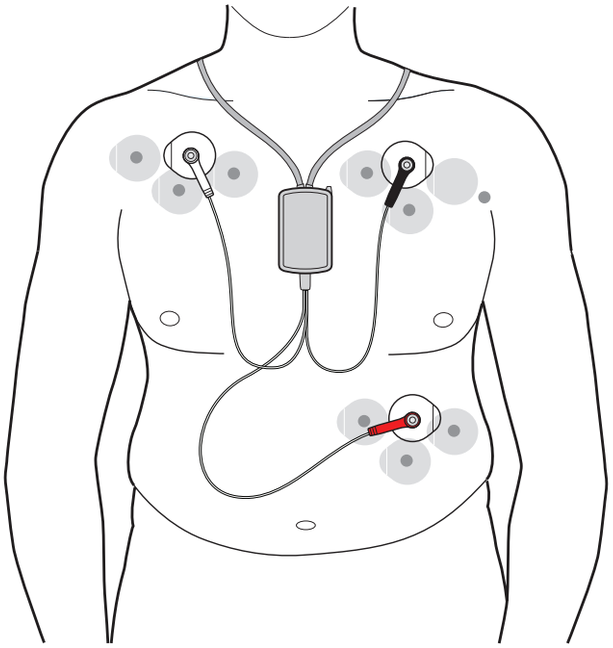
Touch the Messages button to read the message.
Follow the instructions on the screen. Press OK when you are finished.

14.
SKIN CARE & REPLACING ELECTRODES



Change your electrodes every other day. When removing the electrodes, never pull them off quickly. Use soap and water and gently lift the old electrodes from your skin.

If necessary, use the adhesive remover wipes to take the excess adhesive off your skin. Wash and dry the areas thoroughly before putting on new electrodes.



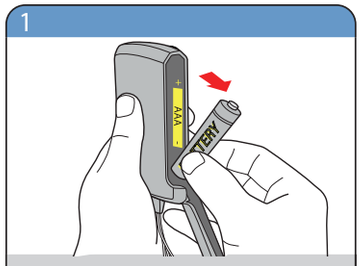
When you replace your electrodes, do not put new electrodes in the same locations each time. It is very important that you move them from the original locations to protect your skin. Please refer to the suggested alternate locations in the illustration.

15.
SHOWERING, BATHING AND SWIMMING

Note: The electrodes are water resistant. You may wear them for showering and bathing.

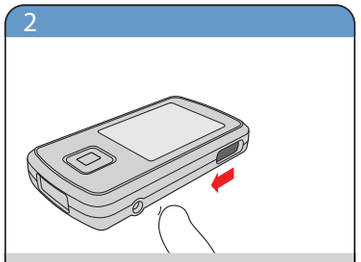
BEFORE showering, bathing or other water activities:

1



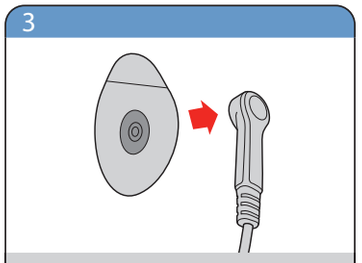
Remove the sensor battery.

2



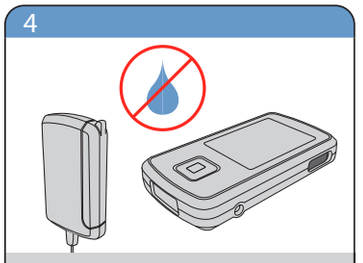
Turn off the monitor.

3



Unsnap the lead wires from the electrodes.

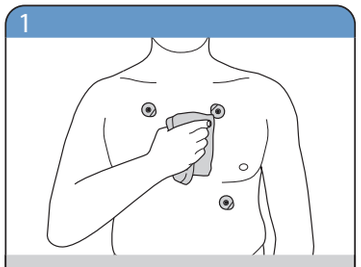
4



Keep the monitor and sensor out of the bathroom and away from water and steam.

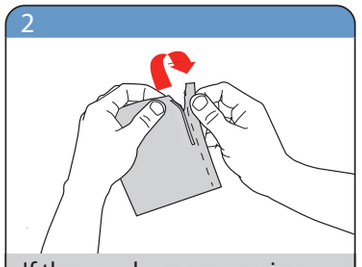
AFTER showering, bathing or other water activities:

1



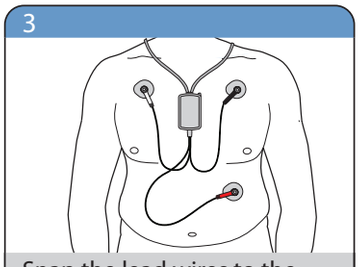
Dry the electrodes.

2



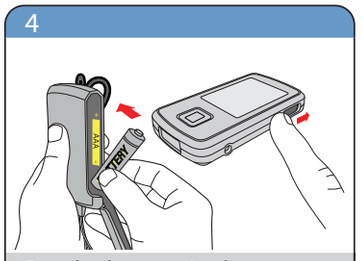
If they are loose or moving around, put on new electrodes and wait 10-15 minutes before following the next steps.

3



Snap the lead wires to the electrodes. White on RIGHT, Black on LEFT, Red on RIB.

4

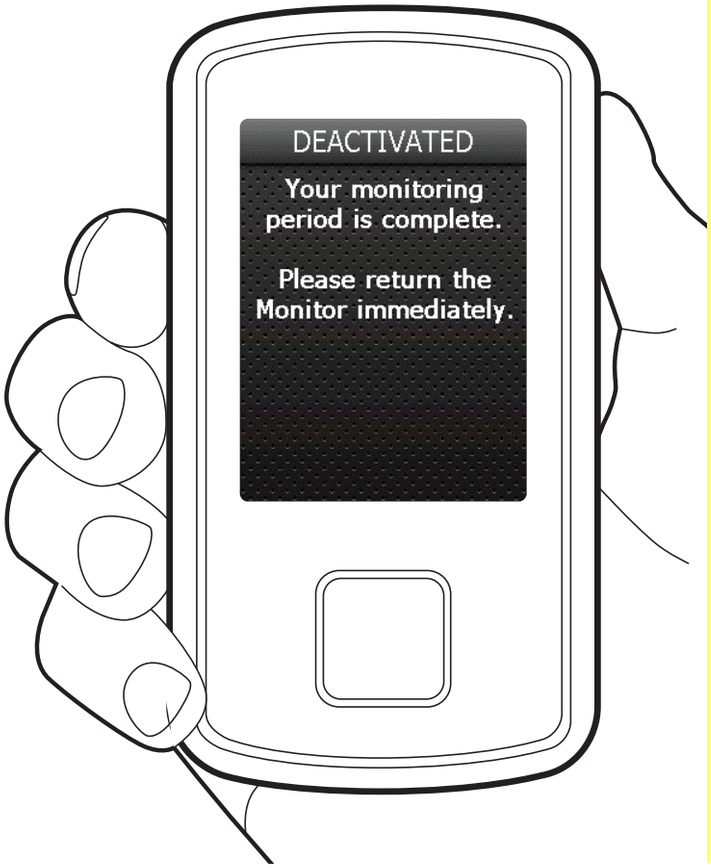


Put the battery in the sensor. Turn on the monitor.

16. TROUBLESHOOTING

Problem	Possible Solution
Monitor Battery Low	Ensure that you recharge the battery every day by correctly by plugging the power cord directly into the side of the monitor. A full recharge takes approximately 4 hours. The orange light shown on page 18 will be lit if the Monitor is charging. The monitor battery life can vary day-to-day depending upon several factors, including cell communication and cell coverage. This may require you to charge the battery sooner on some days than on other days. Refer to page 18 for more information.
Blank Monitor Screen	Ensure that the monitor is on by confirming that the light on the top of the Monitor is green. If you press the wake button, the monitor screen should light up. If it does not, the monitor may be low on power. You should recharge the monitor.
Lead Off	Check that the lead is snapped firmly onto the electrode. Press on the electrode to ensure it is firmly adhered to the skin. If you have just changed your electrodes, press Silence on your Monitor screen. Your electrodes may take up to 15 minutes to properly adhere.
Irritated or Reddened Skin	An allergic reaction to the adhesive or gel on the electrodes is possible and can cause irritated skin. If you experience irritation, worse than minor itching, call your physician.
No Communication	1. Your Monitor and Sensor may not be close enough to communicate. Move the Monitor closer to the sensor. 2. Check to make sure the sensor battery has been inserted correctly with the proper (+) (-) orientation. 3. Replace the Sensor battery if alarm continues after correcting battery orientation.

17. RETURNING THE UNIT



ABOUT DEACTIVATION MESSAGE

When your monitoring is complete, a message will appear on your Monitor. It is your responsibility to return the kit back as soon as possible so that other patients can benefit using this valuable service and to avoid being charged for the equipment.

Please follow these steps when you receive the message that your monitoring is completed

- Take off the Sensor. Remove Sensor battery.
- Turn off the Monitor using the Power switch on the side of the Monitor.
- Place everything back in the kit properly so that the device is not damaged.

RETURN THE PACKED KIT BACK TO YOUR PHYSICIAN'S OFFICE AS INSTRUCTED BY YOUR PHYSICIAN.

18.
EQUIPMENT SYMBOLS

SYMBOL	DESCRIPTION
	Type BF Applied Part
	Attention: Consult accompanying documents.
	Non-Ionizing Radiation Transmitter

MANUFACTURER NAME AND ADDRESS

Manufacturer: Braemar Mfg, LLC

1285 Corporate Center Drive
Suite 150
Eagan, MN, 55121
USA

Phone: 1-800-327-2719
Fax: 1-651-286-8629
E-mail: sales-braemar@gobio.com
Web: http://www.GoBio.com

Contact Braemar Mfg for further technical information.

19. SPECIFICATIONS

PHYSICAL
Sensor 3 inches x 1.9 inches x 0.7 inches; Weight: 3.0 oz. with battery
Monitor 4.7 inches x 2.6 inches x 0.9 inches; Weight: 6.0 oz.
Display 2.27 inches x 1.7 inches; Touch screen: color

FUNCTIONAL
Sample Rate 250 samples per second
ECG Resolution 12 bits
Dynamic range of ECG +/- 5 mV
Bandwidth 0.1 to 40 HZ Channels 2
Battery Life: Monitor 10 hrs (with cleared memory & fully recharged battery)
Battery Life: Sensor 24 hrs (1 AAA Alkaline)
Leakage Current Less than .1 µ A Electrodes

TRANSMISSION
Sensor to Monitor 900 MHz ISM band RF transmission, digital error corrected.
Minimum 150 foot range. Retransmission if data is corrupted.
Monitor to Center CDMA (PCS and cellular) wireless, digital error corrected.

OPERATING CONDITIONS
Operating Temperature- 0 - 45°C
Operating Humidity 10% - 95% noncondensing
Storage Temperature -20 - 65°C noncondensing

CONNECTIONS
Monitor Power in (15V, 1.2A max)

WALL ADAPTOR
Power In: 100 – 240 VAC; Power Out: 15V, 1.0A; or 15V, 1.67A

STANDARDS COMPLIANCE
Monitor EN60601-1; AAMI EC-38; FCC Part 15
Sensor EN60601-1; AAMI EC-38; FCC Part 15
AECG Equipment Type I

IN HOME REQUIREMENTS
1. Cellular / PCS wireless coverage suitable for data transmission
2. AC powered outlet

FCC COMPLIANCE
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 interference received including interference that may cause undesired operation.

FCC ID
Sensor ISM QBI-1011
Monitor ISM QBI-1014
Monitor Contains:
FCC ID: Q2331308
FCC ID: RI7CE910-DUAL

FCC RULES PART 15
The Model CN1006 has been tested and complies with the limits for Part 15 of the FCC Rules for a class B digital device. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a residential environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, can cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is
- connected.
- Consult the dealer or an experienced radio/TV technician for help.

CHANGES OR MODIFICATIONS NOT EXPRESSLY APPROVED BY CARDIONET COULD VOID THE USER'S AUTHORITY TO OPERATE THE EQUIPMENT

Model CN1006 Monitor can be linked to any Bluetooth compatible receiver.

SERVICE

In the event of equipment malfunction, all repairs should be performed by CardioNet or an authorized agent. It is the responsibility of users requiring service to report the need for service to CardioNet or to one of our authorized agents. Service can be facilitated through our office at:
CardioNet 1000 Cedar Hollow Road, Suite 102, Malvern, PA 19355. Tel #1 888-312-2328.

FCC RADIO FREQUENCY EXPOSURE INFORMATION

In August 1996, the Federal Communications Commission (FCC) of the United States, with its action in Report and Order FCC 96-326, adopted an updated safety standard for human exposure to radio frequency (RF) electromagnetic energy emitted by FCC regulated transmitters. Those guidelines are consistent with the safety standard previously set by both U.S. and international standards bodies. The design of this device complies with the FCC guidelines and these international standards. Use only the supplied antenna. Unauthorized antennas, damaged antennas, modifications, or attachments could impair call quality, damage the device, or result in violation of FCC regulations. Please contact CardioNet if damage to the unit is apparent.

BODY-WORN OPERATION

This device was tested and was found to comply with the FCC exposure requirements. The device was also tested and found to comply with SAR (Specific Absorption Rate) testing. For more information about RF exposure, please visit the FCC website at www.fcc.gov.

ELECTRODES

Conductive parts of Electrodes and associated connectors, including NEUTRAL ELECTRODE, should not contact other conductive parts including earth.
For questions on electrodes, contact:
S&W Healthcare – www.swhealthcare.com or 1-800-843-1201
Kendall – www.tycohealthcare.com or 1-800-962-9888
Kendall 233 and S&W electrodes have been tested for up to 72 hr. wear
Vermed – http://www.vermed.com/ or 1-800-245-4025

BioTelemetry™ inc

HEALTHCARE

CardioNet/Mednet

1000 Cedar Hollow Road
Suite 102
Malvern, PA 19355

Manufactured by
Braemar Inc.
1285 Corporate Center Drive
Suite 150
Eagan, MN 55121

220-0126-01 Rev E