CardioNet® MCOT™ OS

Patient Education Guide

Contact Us:
Toll Free: 1 (866) 426-4401

BioTelemetry inc
HEALTHCARE
Formerly CardioNet

Online Video Tutorials

For helpful video instruction, select the patient tab at our website www.cardionet.com

Share your Thoughts

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Table of Contents

Hi.

Welcome to CardioNet.® Look for me throughout this guide for helpful tips.

CardioNet MCOT™ OS

1 Before You Begin

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- Kit Contents
- Getting to Know your Monitor
- Getting to Know your Sensor
- Skin Preparation
- Attaching the Electrodes
- Inserting the Sensor Battery

1 About Our Service

The CardioNet® service was developed to help doctors detect and treat heart problems that may not happen often enough to be found during a routine ECG in the physician's office. CardioNet® monitors heart rhythms continuously, while people go about their normal daily activities. We can help physicians detect problems that may infrequently occur, whether you feel them or not, even while you are sleeping.

Our goal at CardioNet® is to work as a team with patients and physicians to help people receive the best possible care.

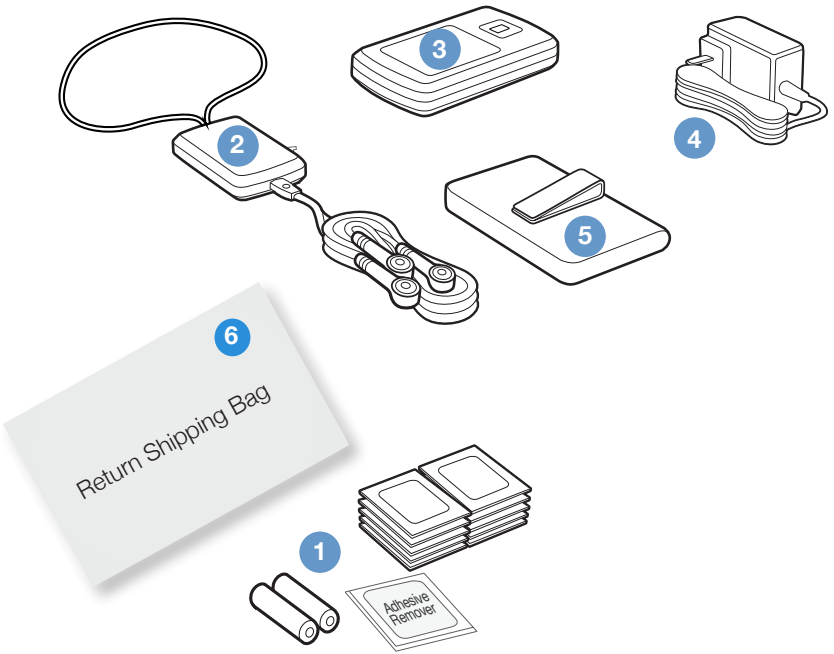
We are honored that we were chosen to serve you.

1 Contacting Us

If you have any questions about your monitoring service or billing, please call one of our toll-free numbers.

Customer Service: 1-866-426-4401
Billing Department: 1-855-572-3999

1 Kit Contents

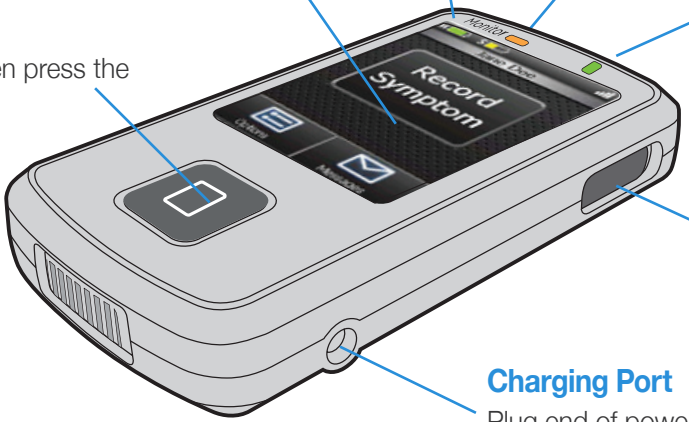


1. Supply Bag: Electrodes, Batteries, & Adhesive Remover
2. Sensor
3. Monitor
4. Power cord
5. Monitor case
6. Return Shipping Bag

1 Getting to Know your Monitor

The CardioNet monitor is a small portable device that gathers data from the sensor and sends the information to CardioNet's 24 hour Monitoring Center. The monitor automatically transmits data using a built-in cell phone. Although the monitor will transmit ECG's from your heart automatically, it is important to record symptoms as you feel them. This will provide additional information on the reports received by your physician.

1 Getting to Know your Monitor



Touch Screen
Screen will go dark after 1 minute. Press the Wake button to view the main screen. To operate monitor, touch the screen where indicated.

Battery Strength Indicator

Charging Light
Orange = Charging
Green = Fully charged

Status Light
Solid Green = Communication to sensor OK.
Solid Red = Read the screen for instructions.

Wake Button
To view the screen press the Wake button.

Power Switch
Slide to power monitor **On** (White) / **Off** (Black)

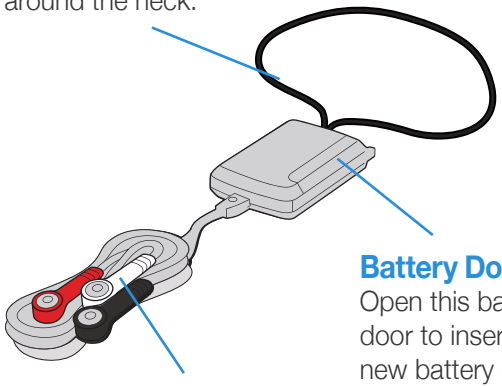
Charging Port
Plug end of power cord here to charge the monitor.

1 Getting to Know your Sensor

About the Sensor

- The sensor is a small device worn around your neck.
- Three lead wires gather data from your heart.
- The sensor communicates the data, from your heart, constantly to the monitor.
- CardioNet recommends that you keep the sensor and monitor in the same room to eliminate loss of communication between the devices.

Neck Strap
Cloth cord worn around the neck.



Battery Door
Open this battery door to insert a new battery daily.

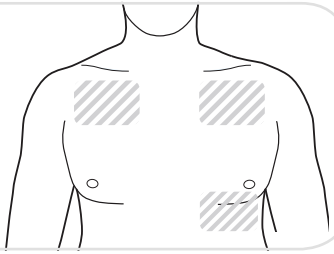
Leads
Each wire will snap to an electrode that will be attached to your body.

1 Skin Preparation

Prior to attaching electrodes, proper skin preparation is vital. Ensure that skin is clean, dry and free from any lotion, powder, or oil. This may help the electrodes adhere to your skin more tightly, and allow your heart readings to appear more clearly to CardioNet's Monitoring Center.

Wash/Shave:

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



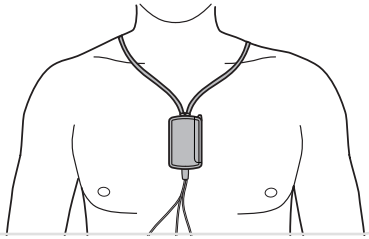
Please Note:

Do not use the adhesive remover wipes prior to placing electrodes on your skin. Adhesive remover wipes should only be used, as needed, to remove excess adhesive from skin after removing electrodes. Wash and dry these areas of skin with soap and water after use of adhesive remover wipes.

1 Attaching the Electrodes

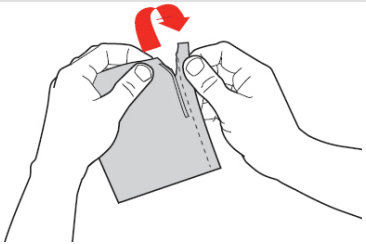
Sensor & Neck Strap:

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



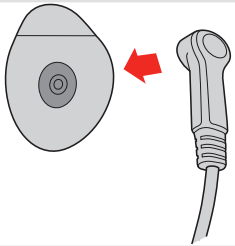
Electrodes:

- Remove electrode pack from the supply bag.
- Tear open electrode pack and remove 3 electrodes.



Lead (Wires):

- Snap the lead (wires) end onto the 3 electrodes prior to placing on body.

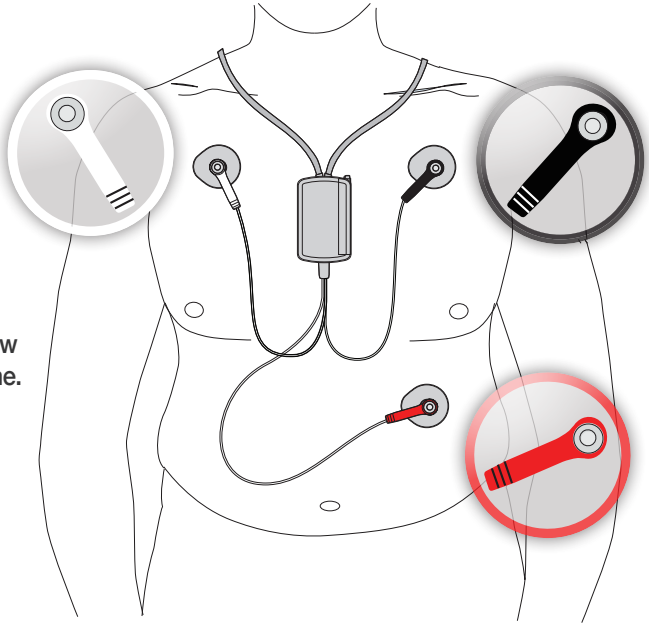


1 Attaching the Electrodes

White (Right)

Peel the adhesive backing off the White electrode.

Place the white electrode about 3 fingers width below your right collar bone.



Black (Left)

Peel the adhesive backing off the Black electrode.

Place the black electrode about 3 fingers width below your left collar bone.

Red (Left Side)

Peel the adhesive backing off the Red electrode.

Place the red 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 lead wires attached to the electrodes in the positions shown.

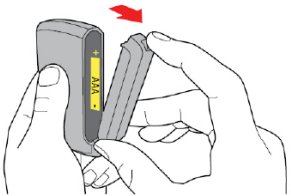
1 Inserting the Sensor Battery

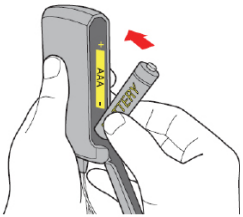
Take A Break

Before proceeding to the next step, wait **10-15 minutes** while your electrodes fully adhere to your skin. This increases the likelihood of a successful initial reading.

Sensor Battery

- Open the door of your sensor. Place a AAA battery from the CardioNet MCOT Kit into the sensor as shown.
- 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.





Please Note:

You will need to change your sensor battery every day.

In this section, we'll complete the activation process to begin monitoring.

CardioNet MCOT™ OS

2 Getting Started

In this Section:

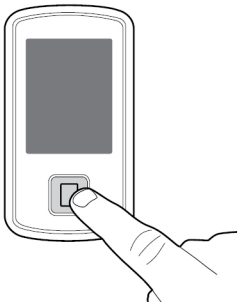
- Activating the Monitor
- Recording a Baseline
- Recording Symptoms
- All About Power - Battery Life
- Daily Use & Maintenance

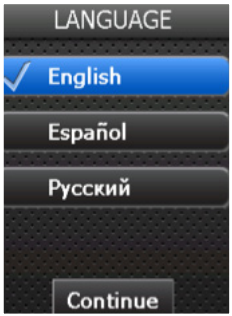
Power on Monitor

- Power the monitor ON using the switch located on the side of the monitor.
- The monitor may take a few minutes to start up.

Wake Button

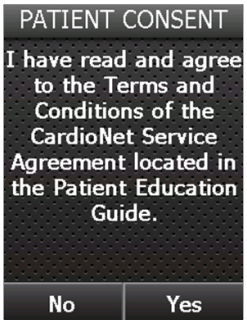
- The monitor screen will go dark after one minute to conserve power, use the WAKE button (black button with white square) to light the monitor screen.





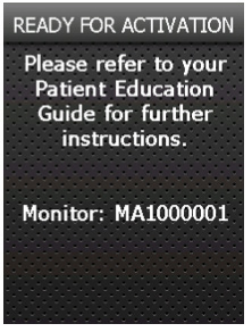
Select Language

- You will be asked to select a language, select corresponding language.



Consent Screens

- Read and touch **YES** to the screens that follow.
- You will be prompted to consent to allow CardioNet to use your data (without your personal information) for research purposes.



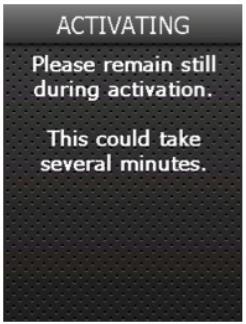
Prescription Processing

- This screen may appear while your prescription is being processed.
- If displayed for greater than one hour, remove the battery from the sensor and power monitor off for two minutes, and then turn back on.
- If the monitor continues to display this screen contact CardioNet at 1-866-426-4401.

Confirm Identity

- Confirm the information displayed on the screen.
- If any of the information is incorrect. Turn off the monitor, remove the battery from your sensor and contact CardioNet at 1-866-426-4401.

2 Activating the Monitor



Activation Signal

- Once you have confirmed your identity the CardioNet monitor will activate and retrieve an initial reading of your heart, remain still.
- Once your initial reading is received the main monitoring screen will appear.

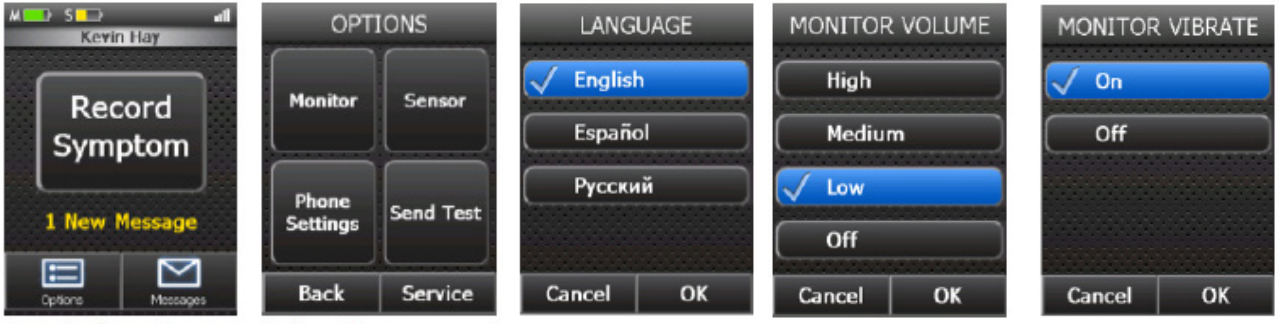
Setup Complete

- This will be the primary screen shown during the duration of your monitoring. You will receive a text message from CardioNet's Monitoring Center confirming that you are monitoring.
- Continue with the following pages for information on daily use, maintenance, things to know, and Frequently Asked Questions.

To Record a Symptom:

1. Select **Record Symptom** on your monitor screen. Tap **Yes** to record symptom.
2. Select corresponding symptom, choosing **Next** will provide additional symptoms for selection.
3. Select **OK**, and then select your level of activity.
4. Press **Done** when complete, then **OK**.
5. You will receive a confirmation message indicating your symptom was recorded.

Please Note:
If you select **Fainted,** you will need to confirm that you lost consciousness.



2 Daily Use & Maintenance

CardioNet's MCOT monitor is extremely convenient and easy to use. While on service you will be required to do the following in order to provide your physician with the most valuable data.

CardioNet Daily Usage Checklist

- Charge your monitor daily
- Change the battery in your sensor daily
- Change your electrodes every other day
- Record symptoms as they occur
- Keep the monitor and sensor in close proximity
- Follow instructions on the monitor for any messages/alerts received

You're doing great!

This next section goes into detail about the daily usage of your monitor.

CardioNet MCOT™ OS

3 Things To Know

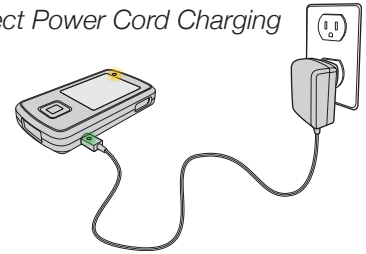
In this Section:

- All About Power - Charging
- All About Power - Battery Life
- Skin Care - Replacing Electrodes
- Skin Care - Bathing and Swimming
- Skin Care - Issues
- Ending Service - Indicators
- Ending Service - Returning the Kit

Charging the Monitor Using the Power Cord

- The CardioNet monitor battery lasts up to 12 hours on a full charge.
- There are several variables that can affect how quickly the monitor's charge is depleted. These include but are not limited to, data transmission, cell signal, and data gathering.

Direct Power Cord Charging



Checking Battery Power

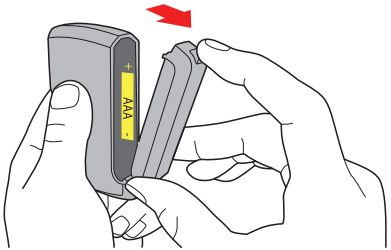
- To check the battery levels in both your sensor and monitor, tap on the battery icons on the top left of your monitor screen.
- These will give you an estimate of how much battery life is left for each device.

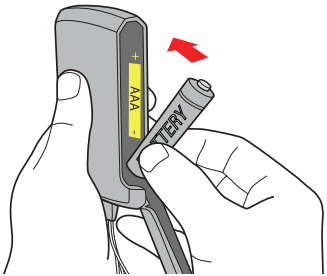
M = Monitor S = Sensor

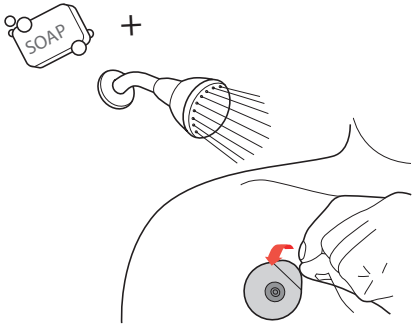
Battery Strength Indicator

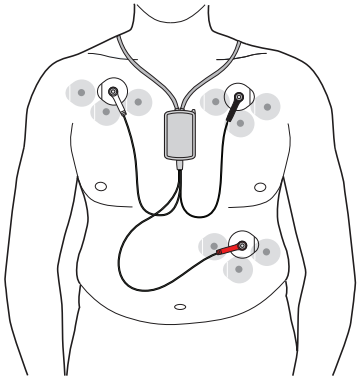
Sensor Battery

- The sensor battery will last 24 hours or longer.
- The battery in your sensor must be replaced each day.
- You will hear a chime indicating that the battery was inserted correctly in the sensor.









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.

When removing or replacing electrodes, it is important that you have the battery removed from the sensor and the monitor turned off (using the power switch).

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.

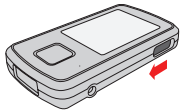
When you replace your electrodes, do not put new electrodes in the same locations each time. It is very important that you move them from the original locations to protect your skin. Please refer to the suggested alternate locations in the illustration.

3 Showering, Bathing, Swimming

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

BEFORE showering, bathing or other water activities:

1

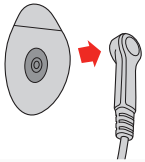


Turn off the monitor.

2

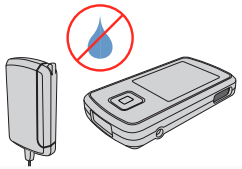
Remove the sensor battery.

3



Unsnap the lead wires from the electrodes.

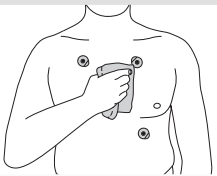
4



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

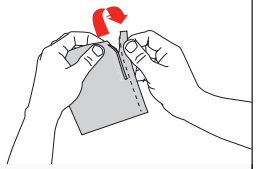
AFTER showering, bathing or other water activities:

1



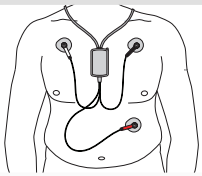
Dry the electrodes.

2



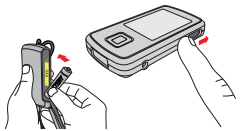
If they are loose or moving around, put on new electrodes and wait 10-15 minutes before following the next steps.

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.

Electrodes Not Sticking

Occasionally, some patients experience issues with electrodes not adhering to their skin firmly. To reduce this risk, please make a note of the following:

- "Hydrating" and "Moisturizing" soaps and body washes may make it more difficult for electrodes to adhere to the skin.
- Using medical tape to keep the electrodes adhered may help.
- You may need to change the electrodes more often.

Please Note:

- You can request additional supplies by emailing CardioNet at customerservice@cardionet.com, include your first and last name, the number of electrode packs remaining, and where you would like your supplies delivered or call Customer Service at 1-866-426-4401.
- If you continue to have issues, please contact Customer Service at 1-866-426-4401.

Irritated Skin

Minor skin irritation can occur when wearing any electrode for several days, weeks, etc. CardioNet provides each patient with hypo-allergenic and latex free electrodes.

To reduce the risk of skin irritation, ensure that you are doing the following:

- Changing the electrodes every other day
- Slightly changing the location of the electrode
- Ensuring skin is clean and dry prior to placing electrodes

Please Note:

- CardioNet cannot authorize you to end service or remove the monitor, only you and/or your physician can make that decision.
- If your skin irritation is worse than minor itching call CardioNet at 1-866-426-4401.

About the Deactivation Message

When your monitoring is complete, a message will appear on your monitor.

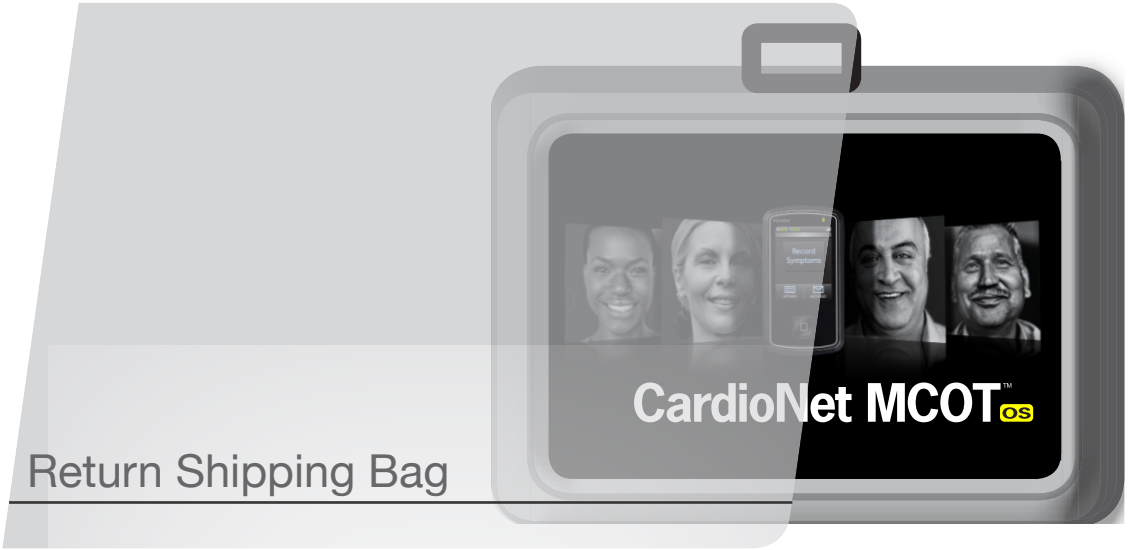
You do not need to call CardioNet. You are responsible to return the kit as soon as possible so that other patients can benefit from using this valuable service, and to avoid being charged for the equipment.

Please follow these steps the morning you receive the message that your prescription is complete:

- Take off the sensor. Remove the sensor battery.
- Turn off the monitor using the power switch on the side of the monitor.

Packing Up the Kit

- Place everything neatly in the kit.
- Place the kit in the self-addressed shipping bag provided in your supplies.
- Follow the return instructions provided in the kit or online at www.cardionet.com/patients.



You've got questions,
I've got answers!

CardioNet MCOT™ OS

4 Frequently Asked Questions

CardioNet Service FAQ:

- What happens if a lead wire becomes disconnected?
- Why is the monitor making noise?
- When do I record events?
- How do I shower while wearing the monitor?
- How often should I charge the monitor?
- Can I travel with the monitor?
- Is it okay to wear the monitor while exercising?
- I don't want the monitor to beep. Can I change the volume settings?
- How often should I change the electrodes?
- Should I wear the CardioNet monitor at all times?
- Will the monitor alert me if something is wrong?
- Is the information that is recorded by the monitor transmitted immediately to my doctor or only to CardioNet?
- Do I have to let my electrodes sit on my skin for 15 minutes before inserting a battery into the sensor and turning the monitor on?
- How far away from the sensor can I keep the monitor?

What happens if a lead wire becomes disconnected?

You will hear a tone. Check to see that the leads are firmly attached. The leads may be attached to the electrode, but the electrode may not be fully adhered to your skin. Rub the electrodes in a circular motion. If the problem continues, change your electrodes.

Why is the monitor making noise?

There are several reasons why the monitor will make noise. Aside from recording events, here are the most common reasons:

- A lead wire is disconnected
- Monitor recordings need to be transmitted
- A battery change is needed

When do I record events?

Record events when you are feeling symptoms.

How do I shower while wearing the monitor?

The monitor and sensor must be removed and stored in a moisture-free area before showering.

Before showering, bathing, or participating in any aquatic activity:

- Turn off the monitor and remove battery from sensor.

When you are ready to reconnect:

- Attach the lead wires to the electrodes (change the electrodes if they are loose or falling off).
- Insert AA battery into the sensor.

How often should I charge the monitor?

Charge the monitor throughout the day when possible (it will not overcharge). The monitor should also be charged overnight while you are asleep.

Can I travel with the monitor?

Yes, you can. If traveling by air, do the following:

- Turn off the monitor.
- Remove battery from the sensor.
- Pack devices into your carry-on luggage.

Once you have landed and are ready to reconnect:

- Attach electrodes and insert battery into sensor.
- Turn on monitor.

You will hear a chiming sound if you have inserted the battery correctly.

Is it okay to wear the monitor while exercising?

Yes. Please wear your monitor while doing all the activities that you normally do, including exercise, unless otherwise instructed by your physician.

I don't want the monitor to beep. Can I change the volume settings?

Yes. The volume on the monitor can be changed simply by touching **Options > Monitor Options > Volume** and then choosing the setting you would prefer.

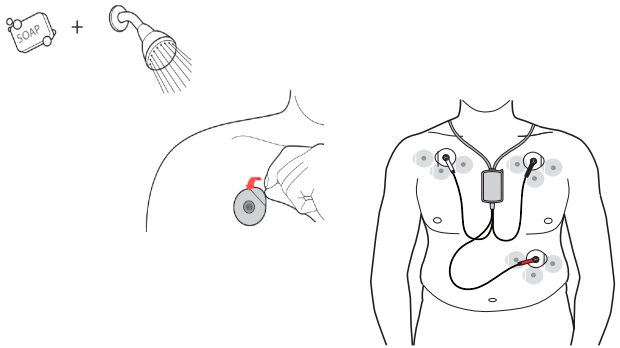
How often should I change the electrodes?

Change the electrodes every 2-3 days or more frequently if they no longer stick to your skin.

- Use soap and water to gently lift the old electrodes from your skin.
- When placing new electrodes on your skin, be sure to rotate the areas as illustrated in the Skin Care and Electrode Use section.

Please Note:

It is very important that you move the electrodes from the original locations to protect your skin.



Should I wear the CardioNet monitor at all times?

Yes. It is very important for you to wear the sensor and keep the monitor on at all times (except while bathing or swimming) to ensure that we are continuously receiving your monitor's data.

Will the monitor alert me if something is wrong?

No. Your monitor will in no way alert you about what your heart is doing. The monitor will only alert you if the monitor and/or sensor are having technical issues, such as a lead being off or the battery being low. If you feel that you need emergency assistance, please dial 911 immediately.

Is the information that is recorded by the monitor transmitted immediately to my doctor or only to CardioNet?

The information recorded by your monitor is transmitted to CardioNet and then sent to your ordering doctor daily.

Do I have to let my electrodes sit on my skin for 15 minutes before inserting a battery into my sensor and turning it on?

Yes. A new set of electrodes may take up to 15 minutes to fully adhere to your skin. If the monitor is restarted before this time, it may trigger a false alert of a disconnected lead.

How far away from the sensor can I keep the monitor?

It is important for you to keep the monitor nearby in case you need to record a symptom. There is no specific distance that the monitor and sensor can be kept apart. We encourage you to keep both devices in the same room at all times. The devices will beep if too far apart; they will be unable to communicate effectively.

CardioNet Mobile Cardiac Outpatient Telemetry
Addendum to the Patient Education Guide – Model CN1006 (C5)

Indications for Use:

The CardioNet Ambulatory ECG Monitor with Arrhythmia Detection intended use is for:

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 outpatient 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 arrhythmia (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.) Patients who require Monitoring for potential arrhythmias Based on risk ractors (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 recommends should be hospitalized for ECG Monitoring.
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, PEDIATRIC AND INFANTS PATIENTS
The CardioNet MCOT System is intended for use on adults and children as well as on infants weighing less than 10 kg (22 lbs).

Precautions
DISPOSE OF BATTERIES PROPERLY
Observe all local laws for the disposal of alkaline batteries.
WHEN NOT IN USE, REMOVE Sensor BATTERY
Do not leave the battery in the Sensor when it is not in use.
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.
POTENTIAL FOR ELECTROMAGNETIC INTERFERENCE
There is a potential for electromagnetic interference to other devices while using the CardioNet Service.
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.
• Don't 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.

Cautions

POWER DOWN Monitor AND Sensor BEFORE SHOWERING

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

DO NOT GET THE Monitor AND Sensor WET

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

CLEANING

Use a soft cloth to clean the equipment. In case of a spill on equipment, please disconnect the equipment and return it to CardioNet using the return shipping instructions provided in your kit.

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 standard telephone lines and/or 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

MAINTAIN MINIMUM DISTANCE FROM Base

Due to RF exposure, maintain a minimum distance of 7.87 inch (20cm) from the Base.

Warnings

FOR USE WITH TELEPHONE SYSTEM

Any patient whose life may be put at significant risk by the unavailability of the telephone system should not be Monitored by the CardioNet System.

NOT AN APNEA Monitor

The CardioNet Monitor is not to be used as an apnea Monitor.

USE ONLY WITH CARDIONET ELECTRODES

While wearing the CardioNet Sensor, use only electrodes provided by CardioNet.

NOT AN EMERGENCY RESPONSE SERVICE

CardioNet is not an emergency response service. If you experience any symptoms that concern you, seek medical help.

DO NOT TAMPER WITH DEVICE

There are no serviceable parts in the CardioNet System components. Removing the cover of any component may alter device performance.

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 Base or the CardioNet supplied power cord.

USE ONLY CARDIONET POWER CORD IN SINGULAR OUTLET

Do not use any power cord for the Base 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.

DO NOT USE NEAR FLAMMABLE ANESTHETIC

Units are not to be used in the presence of flammable anesthetic.

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

Base 4.3 inches x 3.7 inches x 1.0 inch; Weight: 6.0 oz.

FUNCTIONAL

Sample Rate 250 samples per second

ECG Resolution 12 bits

Dynamic range of ECG +/- 5 mV

Bandwidth 0.05 to 40 HZ Channels 2

Battery Life: Monitor Up to 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. Telephone line modem, digital error corrected.

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

CONNECTIONS
Base Power in (15V, 1.2A max); Phone in (RJ-11); Phone out (RJ-11)
Monitor Power in (15V, 1.2A max)

WALL ADAPTOR
Power In: 100 – 240 VAC; Power Out: 15V, 1.0A; or 15V, 1.67A
Note: Both the Monitor and Sensor are internally powered

STANDARDS COMPLIANCE
Monitor EN60601-1; AAMI EC-38; FCC Part 15
Sensor EN60601-1; AAMI EC-38; FCC Part 15
Base IEC60950; FCC Part 15, 68
AECG Equipment Type I
Note: This equipment has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:2001, Medical Device Directive 93/42/EEC or the Electromagnetic Compatibility Directive 89/336/EEC (use applicable directive). These limits are designed to provide reasonable protection against harmful interference in a typical medical 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 other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, 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 device
- Increase the separation between the equipment
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected
- Consult the manufacturer or field service technician for help

Equipment Symbols

 BF Type Equipment  Consult Users Manual /Patient Education Guide SN Serial Number  Non-Ionizing Radiation Transmitter

In Home Requirements
1. Touch tone, pulse telephone or cellular / PCS wireless coverage suitable for data transmission
2. AC powered outlet

FCC Compliance
This device complies with part 15 and 68 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-1012
Monitor Cell Modem RI7CC864-DUAL
Base QBI-1013

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.

CHANGES OR MODIFICATIONS NOT EXPRESSLY APPROVED BY CARDIONET INC. COULD VOID THE USER'S AUTHORITY TO OPERATE THE EQUIPMENT
FCC RULES PART 68 REGISTRATION

Model CN1006 complies with FCC Rules, Part 68. On this equipment is a label that contains, among other information, the FCC Part 68 registration number.
REN
The Ringer Equivalence Number (REN) is used to determine the quality of devices that may be connected to the telephone line. Excessive RENs on the telephone line may result in the devices not ringing in response to an incoming call. In most, but not all areas, the sum of RENs should not exceed five (5.0). To be certain of the number of devices that may be connected to a line, as determined by the total RENs, contact the local telephone company. NOTE: RENs are associated with loop-start and ground-start ports. It is not used for E&M and digital ports. The REN assigned to the Model CN1006 is 0.0B. If requested, this information must be given to the telephone company.

SERVICE
In the event of equipment malfunction, all repairs should be performed by CardioNet, Inc. or an authorized agent. It is the responsibility of users requiring service to report the need for service to CardioNet, Inc. or to one of our authorized agents. Service can be facilitated through our office at: CardioNet Inc 1000 Cedar Hollow Road, Suite 102, Malvern, PA 19355 Tel #1 610-729-7000.
The telephone company can ask you to disconnect the equipment until the problem is corrected or until you are sure that the equipment is not malfunctioning.
The Model CN1006 interface connects to the Public Switched Telephone Network through a FCC registered NCTE which specifies the type of network jack to be used.

DISRUPTION OF THE NETWORK
If the Model CN1006 disrupts the telephone network, the telephone company can discontinue your service temporarily. If possible, the telephone company will notify you in advance. If advance notice is not practical, they will notify you as soon as possible. You are also informed of your right to file a complaint with the FCC.

TELEPHONE COMPANY FACILITY CHANGES
The telephone company can make changes in its facilities, equipment, operations, or procedures that can affect the operation of your equipment. If they do, you should be notified in advance so you have an opportunity to maintain uninterrupted telephone service.

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
Vermed - www.vermed.com or 1-800-245-4025

CardioNet Monitor, Sensor and Base is property of CardioNet Inc. and should be returned to CardioNet Inc. 1000 Cedar Hollow Road, Suite 102, Malvern, PA 19355

TERMS AND CONDITIONS OF THE CARDIONET SERVICE AGREEMENT

PLEASE READ THIS DOCUMENT CAREFULLY BEFORE ACTIVATING THE MONITOR.
To activate your monitor and begin service you will be asked to accept the terms of this Agreement. Answering "Yes" to the questions on the monitor's touch screen prior to activation is your acceptance of the terms listed in this document. If you do not agree with the terms of this document please notify CardioNet immediately.

ASSIGNMENT OF BENEFITS

I request that payment of authorized health insurance benefits, including Medicare benefits, if I am a Medicare beneficiary, to be made on my behalf to CardioNet for any medical services provided to me by CardioNet. I authorize any holder of medical and/or insurance information about me to release to CardioNet, my health insurance carrier, or the Centers for Medicare and Medicaid Services (CMS) any information needed to determine these benefits or the benefits payable for related services provided under this agreement.

This assignment includes all dates of services rendered by CardioNet for all insurance plans. A copy of this authorization will be sent to CMS or my health insurance carrier if requested. The original will be kept on file by CardioNet.

I understand that I am fully responsible to CardioNet for any co-payments, co-insurance, deductibles, payments made directly to me by my health insurance carrier for CardioNet services, and, when allowed by law, services not-covered or payable under my health insurance plan. I also understand that by signing this form and/or accepting these terms electronically, I am accepting financial responsibility as explained above for all payment for services received from CardioNet.

By signing this document and/or accepting these terms electronically, I acknowledge that I have received a copy of CardioNet's Notice of Privacy Practices. This acknowledgement is required by the Health Insurance Portability and Accountability Act (HIPAA) to ensure that I have been made aware of my privacy rights.

SERVICE AGREEMENT

Financial Terms
I understand that I am fully responsible and agree to pay for any co-payments, co-insurance, deductibles, all payments made directly to me by my insurer for CardioNet services, and when allowed by law, services not-covered (not payable) under my health insurance plan.

I acknowledge that I am financially responsible for the loaned CardioNet Monitoring System (sensor, monitor, bases, and accessories), which I am obligated to return to CardioNet upon completion of the service. If I do not immediately return the Monitoring System, I hereby authorize CardioNet to invoice me for, and agree to pay CardioNet, the value of the Monitoring System and any associated collection costs should collection or legal costs be incurred by CardioNet.

OPERATIONAL NOTICES

I hereby acknowledge that, given the variance in cellular phone coverage and signal strength, the CardioNet Monitoring System may not always provide continuous transmission of my ECG rhythm to the CardioNet Service Center. In the event that there is no cellular phone coverage or adequate signal strength to transmit recorded events, I will move to an area to optimize transmission capability or connect the monitor and base to a direct telephone line as requested.

I hereby acknowledge that the CardioNet Monitoring System is intended to aid in diagnosis only, and is not designed for prevention or treatment of any event or condition. I agree to immediately discontinue use of the CardioNet Monitoring System upon any sign of discomfort or other problems directly related to the CardioNet Monitoring System, and to promptly report such discomfort or other problems to CardioNet.

I give CardioNet my consent and permission to communicate with other members of my household, if necessary, with regard to my CardioNet service. I also authorize CardioNet to provide my monitoring data to my physician and his /her staff and to Emergency Medical Services by phone, e-mail, fax or through secure Internet access.

I will also be asked to give CardioNet permission to use my monitoring data, **without my identity**, in clinical research and case studies. This is an option and not required to continue to receive CardioNet monitoring services.

Notice of Confidentiality and Privacy Practices

This notice describes how medical information about you may be used and disclosed and how you can get access to this information. Please review it carefully.
Protecting Your Health Information
CardioNet, LLC understands the importance of keeping your health information private. We are required by law to maintain the privacy of health information that identifies you or can be used to identify you. We are also required to provide you with this notice of our privacy practices, our legal duties and your rights concerning your health information. We are required to abide by the terms of this notice currently in effect. We may modify or change our privacy practices described in this notice from time to time, particularly as new laws and regulations become effective. Any changes will be effective for all the health information that we maintain, even information in existence before the change. If we materially modify our privacy practices, you may obtain a revised copy of this notice by contacting us using the information listed at the end of this notice, or by accessing our website at www.cardionet.com.

CARDIONET'S USES AND DISCLOSURES OF YOUR HEALTH INFORMATION
Uses and Disclosures That May Be Made Without Your Authorization or Opportunity to Object
CardioNet may use and disclose your health information, without your authorization, in the following ways:
Treatment: We may use and disclose your health information to provide, coordinate or manage your treatment. For example, we may disclose your health information to a provider who requests this information to treat you.
Payment: We may use and disclose your health information to bill and get payment for health services we provide to you. For example, we may disclose your health information to your health insurance plan to obtain payment for services provided to you.
Health Care Operations: We may use and disclose your health information in order to support our business activities. For example, we may use your health information to conduct quality improvement activities, to engage in care coordination and case management, to conduct business management and general administrative activities, and other similar activities.
Health & Wellness Information: We may use your health information to contact you with information about health related services or appointment reminders. If you do not wish to receive this type of information, you may request to opt-out of receiving this information by sending an email to privacy@cardionet.com or calling the phone number below.
Research; Death; Organ Donation: We may use or disclose your health information for research purposes in limited circumstances. We may disclose your health information to a coroner, medical examiner, funeral director or organ procurement organization for certain purposes.
Public Health and Safety: We may use and disclose your health information to the extent necessary to avert a serious and imminent threat to your health or safety or the health or safety of others. We may disclose your health information to appropriate authorities if we reasonably believe that you are a possible victim of abuse, neglect, domestic violence or other crimes.
Required by Law: We will use or disclose your health information when we are required to do so by law.
Process and Proceedings: We may disclose your health information in response to a court or administrative order, subpoena, discovery request or other lawful process.
Law Enforcement: We may disclose your health information, so long as applicable legal requirements are met, to a law enforcement official, such as for providing information to the police about the victim of a crime.
Inmates: We may disclose your health information if you are an inmate of a correctional institution and we created or received your health information in the course of providing care to you.
Military and National Security: We may disclose your health information to military authorities if you are a member of the Armed Forces. We may disclose your health information to authorized federal officials for lawful intelligence, counterintelligence and other national security activities.
Workers' Compensation: We may disclose your health information as authorized by and to the extent necessary to comply with laws relating to workers' compensation or other similar programs, established by law, that provide benefits for work-related injuries or illness without regard to fault.
Business Associates: We may disclose your health information to persons who perform functions, activities or services to us or on our behalf that require the use or disclosure of your health information. To protect your health information, we require the business associate to appropriately safeguard your information.
To You: We will disclose your health information to you, as described in the Individual Rights section of this notice.

USES AND DISCLOSURES THAT MAY BE MADE EITHER WITH YOUR AGREEMENT OR THE OPPORTUNITY TO OBJECT
Unless you object, we may disclose to a member of your family, a relative, a close friend or any other person you identify, orally or in writing, your health information that directly relates to that person's involvement in your health care. If you are unable to agree or object to such disclosure, we may disclose such information as necessary if we determine that it is in your best interest based on our professional judgment. We may use or disclose your health information to notify or assist in notifying a family member, personal representative or any other person that is responsible for your care of your location or general condition.

USES AND DISCLOSURE BASED ON YOUR WRITTEN AUTHORIZATION

Marketing: We must obtain your written authorization to use and disclose your health information for most marketing purposes.

Sale of Health Information: We must obtain your written authorization for any disclosure of your health information which constitutes a sale of health information.

Other Uses: Other uses and disclosures of your health information will be made only with your written authorization, except as described in this notice or as otherwise required or allowed by applicable law.

In the event that we ask for your authorization to use or disclose your health information, we will provide you with an appropriate authorization form. Once you've given us a written authorization, you can revoke that authorization at any time, except to the extent that we have taken action in reliance on your authorization.

INDIVIDUAL RIGHTS

Access: You have the right to see or get an electronic or paper copy of your health information by submitting a request to us in writing using the information listed at the end of this notice. There are certain exceptions to your right to obtain a copy of your health information. For example, we may deny your request if we believe the disclosure will endanger your life or that of another person. Depending on the circumstances of the denial, you may have a right to have this decision reviewed. We will charge you a fee to cover the costs incurred by us in complying with your request.

Disclosure Accounting: You have the right to an accounting of disclosures of your health information made by CardioNet by submitting a request to us in writing using the information listed at the end of this notice. This right only applies to instances when CardioNet or our business associates disclosed your health information for purposes other than treatment, payment, health care operations, upon your written authorization, and certain other activities. The right to receive this information is subject to certain exceptions, restrictions and limitations. You must specify a time period, which may not be longer than 6 years. You may request a shorter timeframe. You have the right to one free request within any 12-month period, but we may charge you for any additional requests in the same 12-month period. We will notify you about any such charges, and you are free to withdraw or modify your request in writing before any charges are incurred.

Restriction Requests: You have the right to request restrictions on the use and disclosure of your health information by submitting a request to us in writing using the information listed at the end of this notice. Your request must state the specific restriction requested and to whom you want the restriction to apply. We are not required to agree to these additional restrictions, except we must agree not to disclose your health information to your health plan if the disclosure (1) is for payment or health care operations and is not otherwise required by law, and (2) relates to a health care item or service which you paid for in full out of pocket. If we agree to a restriction, we will abide by our agreement (except in an emergency).

Confidential Communication: You have the right to receive certain communications confidentially. That means you can request that we communicate with you by alternative means or to an alternative location by submitting a request to us in writing using the information listed at the end of this notice. We will accommodate your request if it is reasonable and specifies the alternative means or location. We may also condition this accommodation by asking you for information as to how payment will be handled.

Amendment: You have the right to amend your health information in our records for as long as we maintain the information. You must make a request in writing, using the information listed at the end of this notice, to obtain an amendment. Your written request must explain why the information should be amended. If we agree to amend your, we will make reasonable efforts to inform others of the amendment and to include the changes in any future disclosures of that information. We may deny your request if, for example, we determine that your health information is accurate and complete. If we deny your request, we will send you a written explanation and allow you to submit a written statement of disagreement to be appended to the information you want amended.

Paper Notice: If you receive this notice electronically you are entitled to receive this notice in written form. Please contact us using the information listed at the end of this notice to obtain this notice in written form.

Breach: You have the right to be notified if you are affected by a breach of unsecured health information.

QUESTIONS AND COMPLAINTS

If you want more information about our privacy practices or have questions or concerns, please contact us using the information listed at the end of this notice.

If you are concerned that we may have violated your privacy rights, or you disagree with a decision we made about your rights to your health information you may complain to us using the information listed at the end of this notice. You may also complain to the U.S. Department of Health and Human Services. We support your right to protect the privacy of your health information. We will not retaliate against you in any way if you choose to file a complaint with us or with the U.S. Department of Health and Human Services.

Contact Information:	CardioNet, LLC Privacy Officer
Telephone:	610-729-7000
E-mail:	privacy@cardionet.com
Address:	1000 Cedar Hollow Road, Suite 102 Malvern, PA 19355
Update Effective Date:	November 22, 2013

I CERTIFY THAT I UNDERSTAND AND AGREE TO THE FOREGOING TERMS AND TO THE FOLLOWING CARDIONET STANDARD TERMS AND CONDITIONS.

CARDIONET STANDARD TERMS AND CONDITIONS

1. Use of Cardiac Monitoring System ("System") and Access to and Use of CardioNet Monitoring Service ("Service"). Subject to Patient's compliance with the terms and conditions on both sides of this enrollment form (the "Agreement"), CardioNet hereby grants Patient a personal, nonexclusive, nontransferable license to use the System and to access and use the features and functions of the Service solely for purposes of monitoring Patient's heart rate as prescribed by Patient's physician. Patient expressly acknowledges and agrees that the Service, which is available only by physician prescription, is used solely to assist physicians in diagnosis and treatment, and is not intended for use as an emergency response system for patients who may experience serious or life-threatening medical problems. Patient is aware that cell phone coverage limitations and delays in land-line telephone communications could significantly delay transmission and analysis of patient monitoring data. Patient agrees to contact CardioNet immediately if problems are experienced using the system or if signs of physical discomfort occur, and to discontinue use of the system if the physician or CardioNet believe service discontinuation is advisable. Patient shall not, in whole or in part, sublicense, provide access to, tamper with, modify, distribute, use in a service bureau or time-sharing capacity, export in violation of applicable laws and regulations, rent, loan, transfer, disassemble, or reverse engineer or create a derivative work of the System or Service. Patient shall not, in whole or in part, transfer or assign this Agreement or any right granted hereunder, except upon the prior written consent of CardioNet. Any prohibited transfer or assignment shall be null and void. Subject to the licenses granted herein, as between CardioNet and Patient, CardioNet holds all right, title and interest in and to the System and the Service including, without limitation, any patents, trademarks, trade secrets, copyrights or other intellectual property rights therein. CardioNet reserves all rights not expressly granted to Patient under this Agreement.

2. Term and Termination. This Agreement shall commence on the date that CardioNet accepts Patient's enrollment hereunder, and shall continue until terminated by either party as set forth herein. Either party may terminate this Agreement, for any or no reason, upon thirty (30) days' written notice to the other party, except that this Agreement shall immediately terminate if Patient breaches Paragraph 1 above. Upon any termination of this Agreement, Patient shall immediately discontinue all use of the Service, and shall promptly return the System to CardioNet. The limitations in Paragraph 1, and Paragraphs 3-6 shall survive any termination of this Agreement.

3. NO WARRANTY. THE SYSTEM AND THE SERVICE ARE PROVIDED BY CARDIONET HEREUNDER SOLELY ON AN "AS-IS" AND "AS AVAILABLE" BASIS WITHOUT WARRANTY OF ANY KIND. TO THE MAXIMUM EXTENT PERMITTED UNDER APPLICABLE LAW, CARDIONET HEREBY DISCLAIMS ANY AND ALL WARRANTIES, EXPRESS, IMPLIED OR STATUTORY, INCLUDING, BUT NOT LIMITED TO, ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE, NON-INFRINGEMENT AND/OR QUIET ENJOYMENT, AS WELL AS ANY IMPLIED WARRANTIES OTHERWISE ARISING OUT OF COURSE OF DEALING, COURSE OF PERFORMANCE OR TRADE USAGE. PATIENT FURTHER ACKNOWLEDGES AND AGREES THAT CARDIONET SHALL NEITHER BE RESPONSIBLE NOR LIABLE FOR PATIENT'S INABILITY TO ACCESS OR USE THE SERVICE AS A RESULT OF ANY DEFICIENCY IN THE INTERNET, THE TELEPHONE SERVICE, OR OTHER CONNECTION BETWEEN CARDIONET AND PATIENT. PATIENT EXPRESSLY ACKNOWLEDGES AND AGREES THAT NEITHER THE SYSTEM, NOR THE SERVICE (AS WELL AS ANY SUPPORT GIVEN BY ANY CARDIONET SUPPORT STAFF), NOR ANY MATERIAL AVAILABLE THROUGH PATIENT'S USE OF THE SYSTEM OR SERVICE IS INTENDED TO PROVIDE PATIENT WITH MEDICAL ADVICE, A DIAGNOSIS OR TREATMENT. PATIENT MUST ALWAYS SEEK THE ADVICE OF PATIENT'S PHYSICIAN OR OF ANOTHER QUALIFIED MEDICAL PRACTITIONER WITH ANY QUESTIONS PATIENT MAY HAVE REGARDING A SPECIFIC MEDICAL CONDITION OR PERCEIVED CONDITION.

4. LIMITATION OF LIABILITY. TO THE MAXIMUM EXTENT PERMITTED UNDER APPLICABLE LAW: (I) IN NO EVENT SHALL CARDIONET OR ITS LICENSORS OR SUPPLIERS BE LIABLE TO PATIENT FOR ANY INDIRECT, INCIDENTAL, SPECIAL, CONSEQUENTIAL OR PUNITIVE DAMAGES ARISING OUT OF OR RELATED TO THIS AGREEMENT INCLUDING, WITHOUT LIMITATION, LOST PROFITS, COSTS OF DELAY, ANY FAILURE OF DELIVERY, BUSINESS INTERRUPTION, COSTS OF LOST OR DAMAGED DATA, UNAUTHORIZED DISCLOSURE TO OR ACCESS OF PATIENT DATA, OR LIABILITIES TO THIRD PARTIES ARISING FROM ANY PERSONAL INJURY OR PROPERTY DAMAGE CLAIM OR ANY OTHER TYPE OF CLAIM, EVEN IF CARDIONET HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES; AND, (II) IN NO EVENT SHALL CARDIONET'S AGGREGATE LIABILITY UNDER THIS AGREEMENT EXCEED THE AMOUNT PAID BY PATIENT TO CARDIONET UNDER THIS AGREEMENT. THE PARTIES AGREE THAT THE ALLOCATION OF LIABILITY SET FORTH IN THIS SECTION 5 FORMS AN ESSENTIAL BASIS OF CARDIONET'S WILLINGNESS TO GRANT PATIENT THE USE OF THE SYSTEM AND ACCESS TO AND USE OF THE SERVICE AND IS INDEPENDENT OF EACH AND EVERY LIMITED REMEDY THAT PATIENT MAY HAVE.

5. Indemnity. Patient agrees to indemnify and hold harmless CardioNet, and its officers, directors, employees, agents and suppliers from and against all claims of third parties arising out of or related to Patient's use or misuse of the System and/or the Service, or attributable to Patient's breach of this Agreement. CardioNet shall control the defense and any settlement of such claim, and Patient shall cooperate with CardioNet in defending against such claims.

6. General Provisions. This Agreement may be modified or amended only by a written instrument signed by Patient and CardioNet. Any terms and conditions issued by Patient shall not be binding on CardioNet and shall not modify these Terms and Conditions. No term or provision contained herein shall be deemed waived and no breach excused unless such waiver or consent shall be in writing and signed by the party against whom enforcement thereof is sought. Neither party hereto shall be liable to the other for any failure to perform its obligations under this Agreement due to causes beyond the reasonable control of that party, including, but not limited to, strikes, boycotts, labor disputes, embargoes, unavailability of or failures due to telecommunication networks (including, without limitation, the Internet), acts of God, unavailability of or insufficient utilities, acts of public enemy, acts of governmental authority, floods, riots, or rebellion. This Agreement shall be governed by and construed solely in accordance with the laws of the State of Pennsylvania, without reference to its choice of law rules. Any and all proceedings arising under or in any way relating to this Agreement shall be maintained in the state or federal courts located in Montgomery County, Pennsylvania, which courts shall have exclusive jurisdiction for such purpose, and Patient hereby consents to the personal jurisdiction of such courts. Patient acknowledges that in the event of an actual or threatened violation of the terms and conditions of this Agreement, CardioNet may not have an adequate monetary remedy and shall be entitled to seek injunctive relief without any requirement to post bond, in addition to any other available remedies. If any term or provision of this Agreement is illegal or unenforceable, it shall be deemed adjusted to the minimum extent to cure such invalidity or unenforceability and all other terms and provisions of this Agreement shall remain in full force and effect.

Important Reminder:
CardioNet 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.

BioTelemetry inc

HEALTHCARE

Formerly CardioNet

CardioNet® MCOT™ OS

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