CardioNet® MCOT®

Patient Education Guide



 $B \tilde{i}o Telemetry$

HEALTHCARE

Formerly CardioNet

Contact Us:

Toll Free: 1 (866) 426-4401



Online Video Tutorials

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

Share your Thoughts

Please share your experience with us by filling out our survey at www.cardionet.com

Table of Contents

1	Before You Begin	04
---	------------------	----

- 2 Getting Started 16
- Things To Know 26
- 4 Frequently Asked Questions 34





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

CardioNet®MCOT®



Before You Begin

In this Section:

- About Our Service
- Kit Contents
- Getting to Know your Monitor
- Getting to Know your Sensor
- Skin Preparation
- Sensor 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.

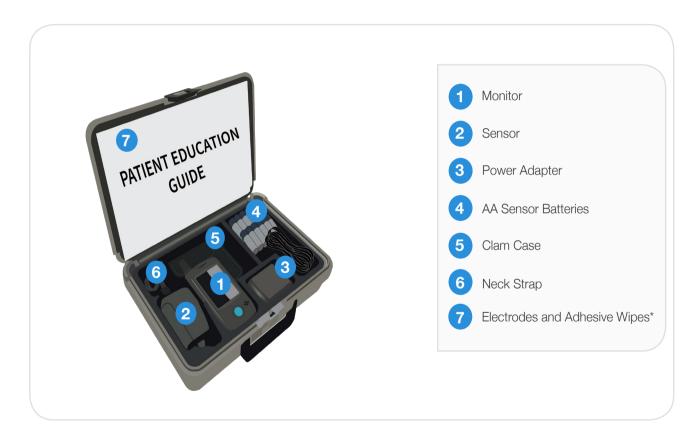
CardioNet MCOT - Before You Begin

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

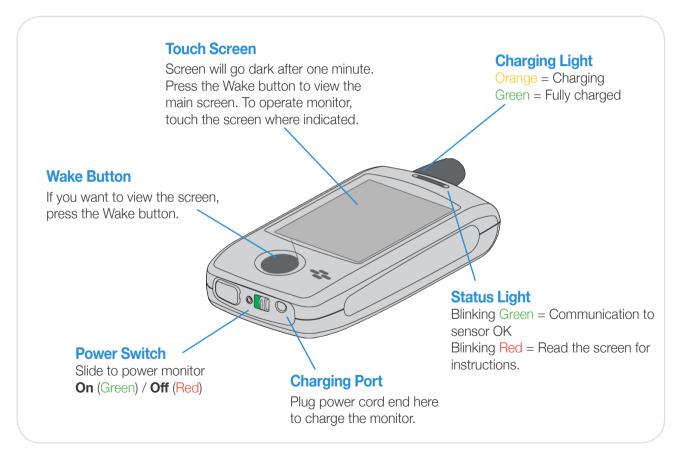
1 Kit Contents



^{*}Please note: Electrodes and adhesive wipes are located behind the Patient Education Guide.

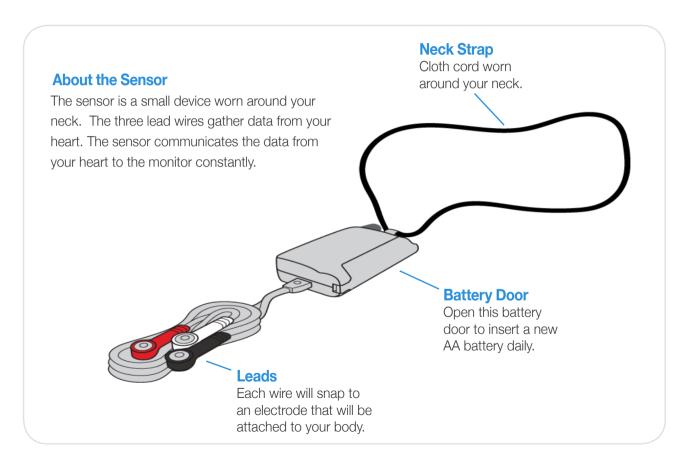
1 Getting to Know your Monitor

CardioNet MCOT - Before You Begin



1

Getting to Know your Sensor



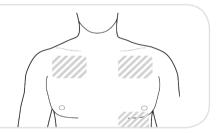
1 Skin Preparation

CardioNet MCOT - Before You Begin

In order to begin service, you will need to send an initial reading of your heart, known as a baseline. Prior to recording and transmitting the reading, proper skin preparation is vital.

Wash/Shave:

- Electrodes will be placed in the shaded areas pictured.
- Wash with soap and water, then dry these areas. Do not use powder or lotion.
- If you have chest hairs, shave these areas.



Please Note:

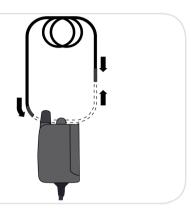
Do not use the adhesive remover wipes prior to placing electrodes on your skin. Adhesive remover wipes should only be used, as needed, to remove excess adhesive from skin after removing electrodes. Wash and dry these areas of skin with soap and water after use of adhesive remover wipes.



1 Sensor Preparation

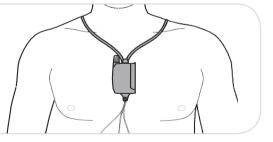
Sensor & Neck Strap:

- Remove the sensor and neck strap from the box.
- Feed the end of the strap through the loop on the top of the sensor.



Attaching Neck Strap:

• Place the cloth strap over your head and around your neck.

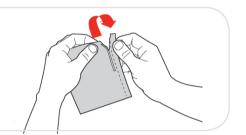


1 Attaching the Electrodes

CardioNet MCOT - Before You Begin

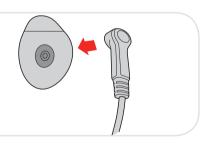
Electrodes:

- Remove the electrodes from the box.
- Tear open the electrode pack and remove three electrodes.



Lead Wires:

Snap each of the three lead wires onto the electrodes.

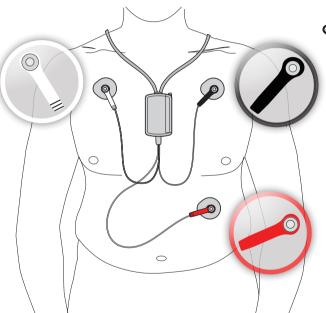


Attaching the Electrodes



White (Right)

Peel the adhesive off the white electrode. Place the white electrode approximately three (3) fingerswidth below your collarbone on your right side.





Black (Left)

Peel the adhesive off the black electrode. Place the black electrode approximately three (3) fingers-width below your collarbone on your left side.



Red (Left Side)

Peel the adhesive off the red electrode. Place the red electrode on the lowest rib on your left side.

You should now have all three lead wires attached to the electrodes in the positions shown.

1 Inserting the Sensor Battery

CardioNet MCOT - Before You Begin



Take a Break

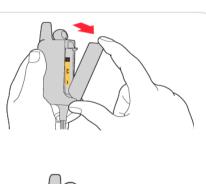
Before proceeding to the next step, wait 15 - 20 minutes while your electrodes fully adhere to your skin. This increases the likelihood of a successful initial reading.

Sensor Battery

- Open the door of your sensor.
- Insert a AA battery provided in your kit into the sensor.
- Ensure that the battery orientation is correct; use the plus
 (+) and minus () as a guide. Make sure that the (+) end is facing up.
- Close the sensor door.
- The sensor will make a chime sound when the battery is installed.

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®

2

Getting Started

An ECG recording is categorized as an "event." The first "event" recorded is considered a baseline- the initial reading of your heart. Sending an initial reading allows CardioNet to compare any symptomatic ECG recordings to your baseline.

In this Section:

- Activating the Monitor
- Recording a Baseline
- Recording an Event

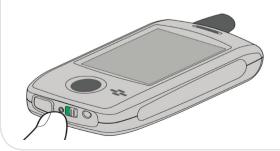
Activating the Monitor

Recording a Baseline Event:

It is vital to activate the monitor and transmit a baseline to the CardioNet monitoring center. Once your initial reading has been transmitted, you will be able to record multiple events on the monitor.

Step 1:

Power the monitor ON by sliding the power switch on the bottom of the monitor over to show the green square. Wait for the screen to display the words "Welcome to CardioNet."



Step 2:

Touch **Continue** on the screen to begin setup of your monitor.

Welcome to CardioNet! The next 5 screens will require you to agree or disagree before you begin monitoring. Continue

Activating the Monitor

CardioNet MCOT - Getting Started



2

Activating the Monitor

Step 6: Step 7: Step 8: Touch **Yes** on the screen to agree Touch **Yes** on the screen to allow Disregard this screen and that you will return the CardioNet press Continue to proceed CardioNet to use your data for monitoring equipment immediately with activation. Do not turn the research purposes (without your upon completion of monitoring. monitor off. identity). You may also select No. 4. Agree or Disagree 5. Agree or Disagree Thank You I will return the Please refer to the I will allow CardioNet **CardioNet** to use my data activation section of **Monitoring Equipment** the Patient Education (without my personal immediately upon information) for Guide after completing completion of research purposes. the consent screens. monitoring. Continue

2 Recording a Baseline

CardioNet MCOT - Getting Started

Step 9:

If you see "Leads OK", touch **Next** on the screen. If you see "Leads Fail," your skin may not be clean or your electrodes may not have

adhered to your skin.
Check pages 11-14 for details.

Step 10:

Locate your patient number/ password on the shipping label of the UPS shipping bag.

Step 11:

Enter your patient number/ password from the shipping label by touching the numbered keypad. Touch **Enter** on the screen. *Example: 510932*

Monitor Battery: 55% Sensor Battery: 75% Cell Strength: 80% Leads: Leads OK Back Next





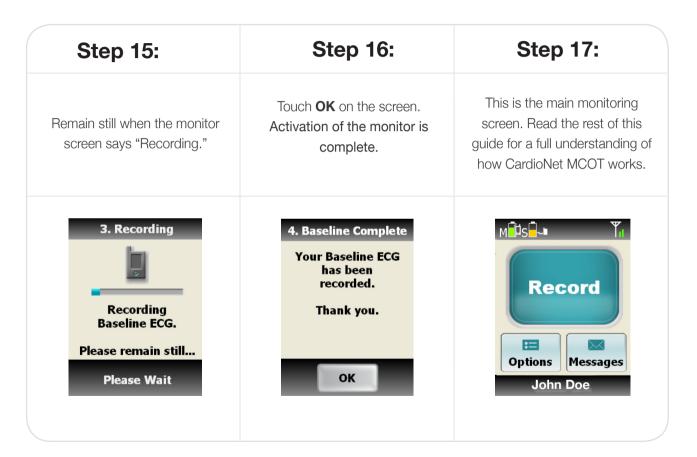
2

Recording a Baseline

Step 12: Step 13: Step 14: Touch **Next** on the screen to begin Touch Record Baseline Find a comfortable position with recording your baseline. If the monitor **ECG** on the screen, then your feet flat on the floor. Touch reads "Activation Failed," please call remain still for 90 seconds. **Next** on the screen. CardioNet at 1-866-426-4401 **Activated** 1. Prepare 2. Record **Activation** was Find a comfortable Please press successful! **Record Baseline ECG** position. and remain still We will now record a You will need for 90 seconds. baseline ECG. to remain still for several minutes. **Record Baseline ECG** Next Next

2 Recording a Baseline

CardioNet MCOT - Getting Started



Recording an Event

Recording an Event:

Please remember to take the monitor with you at all times so that you may record any symptoms that you feel. When you feel a symptom, press Record and follow the instructions. Data will be transmitted to CardioNet automatically. There is no need to call to confirm receipt.

Step 1:



Touch Record to proceed.

Step 2:



Touch **Yes** to proceed. Or touch No to return to the Main Menu.

Recording an Event

CardioNet MCOT - Getting Started



Skipped Beat Light Headed Short of Breath Racing Back More...

Touch any symptoms that you are feeling. The buttons will turn dark blue to indicate your selections. Touch **More** to proceed.

Step 4:



Touch any additional symptoms you are feeling.

Touch **Next** to proceed.

Step 5:



Touch your current activity level.

Touch **Done** to complete this process.

You're doing great!

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



CardioNet®MCOT®

3

Things To Know

In this Section:

- Daily Use & Maintenance
- Charging the Monitor
- Skin Care Electrode Use
- Skin Care Bathing and Swimming
- Concluding Service

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



Record symptoms as they occur



Change the battery in your sensor daily



Keep the monitor and sensor in close proximity



Change your electrodes every other day



Follow instructions on the monitor for any messages/alerts received

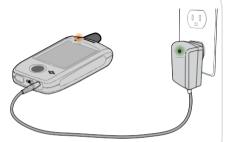
3 Charging the Monitor

CardioNet MCOT - Things To Know

It is important to charge the monitor as instructed. Charging may take up to four hours if the monitor battery is depleted. Charge the monitor throughout the day as needed to ensure that information is efficiently transmitted.

Charging Using the Power Cord

To charge the monitor, plug the power cord into the charging port. Look for the orange light on the top of the monitor. The "Monitor Charging" screen will also appear and display the battery levels. Take the power cord with you if you plan to be away from home all day.



Checking Battery Power

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



YELLOW: Battery is 25-74% charged

RED: Battery is 5-24% charged

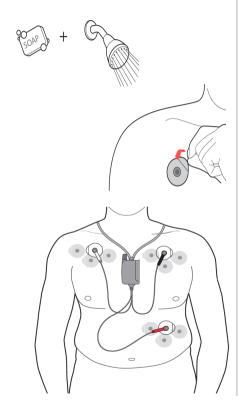
No Color: Indicates the battery is empty and needs to be charged immediately.

*There are several variables that can affect how quickly the monitor's charge is depleted. These include: data transmission, cell signal and data-gathering.



3

Skin Care - Electrode Use



Change your electrodes every 2 - 3 days. When removing the electrodes, never pull them off quickly. Use soap and water to 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.

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

When applying new electrodes, do not place new electrodes in the same location each time. This may cause skin irritation. Please refer to the suggested alternate locations in the illustration.

An allergic reaction to the glue or gel on the electrodes is possible and can cause irritated skin. If you experience irritation worse than minor itching, call CardioNet toll-free at 1-866-426-4401.



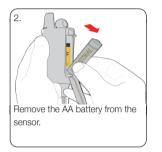
Skin Care - Bathing and Swimming

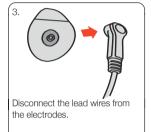
CardioNet MCOT - Things To Know

Please follow these instructions for disconnecting the monitor before showering, bathing, or other water activities. The electrodes are water-resistant and can be worn in the shower.

BEFORE showering, bathing, or other water activities:



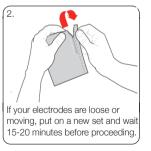


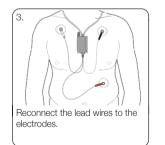




AFTER showering, bathing, or other water activities:









3 Concluding Service



Deactivation Message

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

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

- Turn off the monitor using the power switch on the bottom on the monitor.
- Take off the sensor and remove the battery.
- Place all the items into the kit. Complete the Patient Satisfaction Survey online at www.CardioNet.com

Please Note

Your device cannot be returned to your physician. It must be sent back to CardioNet directly.

- Your physician will receive a summary-report of your service and readings.
- For further information regarding diagnosis and findings, please speak to your doctor.

3 Concluding Service

CardioNet MCOT - Things To Know

Returning the Device

Upon completion, return the CardioNet monitor to CardioNet's distribution center immediately.

- Place the device and unused supplies back into the CardioNet kit.
- Place the kit into the shipping bag, located in the kit.
- 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®



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 my heart is in an irregular rhythm?
- 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 20 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.



CardioNet MCOT - Frequently Asked Questions

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** > **Change Volume** and then choosing the setting you would prefer.

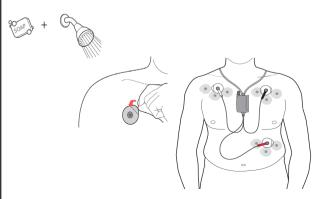
How often should I change the electrodes?

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.



PAGE 37



CardioNet Service FAQ

CardioNet MCOT - Frequently Asked Questions

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 20 minutes before inserting a battery into my sensor and turning it on?

Yes. A new set of electrodes may take up to 20 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

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 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.) Data from the device may be used by another device to analyze, measure or report QT interval. The device is not intended to sound any alarms for QT interval changes

Contraindications:

- 1.) Patients with potentially life-threatening arrhythmias who require inpatient monitoring.
- 2.) Patients who the attending physician thinks should be hospitalized.

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 and monitor are 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 20cm from the base.

INTENTIONALLY APPLIED CURRENTS

Lead failures are detected by a 3V dc signal which is applied to each patient electrode connection through 33 megaohm resistor with respect to the reference electrode.

Warnings:

FOR ADULT USE ONLY

The CardioNet System is intended for Adult Use only. It shall not be used on infants weighing less than 22 pounds.

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 above 80C (176 F), 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 CONNECT ANY DEVICE TO THE PC PORT ON THE MONITOR

The PC port is to be used only by CardioNet personnel. Do not connect items which are not specified as part of the system.

DO NOT USE NEAR FLAMMABLE ANESTHETIC

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

Specifications

PHYSICAL

Sensor 3 inches x 4 inches x 1 inch; Weight: 4.0 oz. with battery

Sensor Neck Strap Adjustable 20 to 32 inches

Monitor 6 inches x 3 inches x 1.0 inches; Weight: 8 oz. LCD 2.27 inches x 1.7 inches: Touch screen: color, backlit

Base 7 inches x 4 inches x 2.5 inches; Weight: 12 oz.

FUNCTIONAL

Sample Rate 250 samples per second

Resolution 12 bits

Dynamic range +/- 5 mV

Bandwidth 0.1 to 40 HZ Channels 2

Battery Life: Monitor Up to 16 hrs (with cleared memory & fully recharged battery)

Battery Life: Sensor 24 hrs (1 AA Alkaline)
Leakage Current Less than .1 u A Electrodes

TRANSMISSION

Sensor to Monitor 900 MHz ISM band RF transmission, digital error corrected.

150 foot range. Retransmission if data is corrupted.

Monitor to Center CDMA (PCS and cellular) wireless, digital error corrected. Telephone line modern, digital error corrected.

OPERATING CONDITIONS

Operating Tempera- Sensor: 20 - 45 o C; Monitor ; 0 - 45 o C

Operating Humidity 10% - 95% noncondensing Storage Temperature -20 - 65 o C noncondensing

Storage Humidity 5% - 95% noncondensing

Operation Altitude 700 - 1060 millibars

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

Manufacturer Friwo, Inc (15V, 1.0A)

Model Number FW755M/15

Note: Both the monitor and sensor are internally powered

STANDARDS COMPLIANCE

Monitor EN60601-1; AAMI EC-38; FCC Parts 2,15,22,24

Sensor EN60601-1; AAMI EC-38; FCC Part 15

Base EN60950; AAMI EC-38; 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 601-1-2:1993, EN60601-1-2:1994, 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



Serial Number

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 Bules. 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-1008 Monitor ISM OBI-1009

Monitor Cell Modem Q9EQ2438F-M

Base OBI-1010

FCC RULES PART 15

The Model 1004 has been tested and complies with the limits for a class B digital Device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference 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 1004 complies with FCC Rules, Part 68. On this equipment is a label that contains, among other information, the FCC Part 68 registration number.

RFN

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 1004 is 0.16. 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. 1010 Second Avenue, Suite 700 San Diego, CA 92101 619-243-7500.

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 1004 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 1004 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 antennas, 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.

Flectrodes

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 origination 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

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

QUESTIONS AND COMPLAINTS

notice in written form.

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, trademarks, trade secrets, copyrights or other intellectual
- 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 unenforceable, it shall be deemed adjusted to the minimum extent to

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.



Formerly CardioNet

CardioNet®MCOT®

1000 Cedar Hollow Road, Suite 102, Malvern, PA 19355
Toll Free: 1 (866) 426-4401 • customerservice@cardionet.com • www.cardionet.com

Copyright © 2015. All rights reserved. Doc 101166 Rev H