

#### **Patient Education Guide**

CardioNet Ambulatory ECG System and Arrhythmia Detector Manufactured by CardioNet Inc. 1010 Second Ave., Suite 700 San Diego, CA 92101

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# TABLE OF CONTENTS

INT	RODUCTION	1
	How the CardioNet Service Works.	2
	Your CardioNet Monitoring Supplies	4
	Your Rights as a Patient.	6
	Your Responsibilities as a Patient	6
	Who to Call with Questions	6
	In the Case of an Emergency	7
	What to Do When your Monitoring is Over	8
GET	TING STARTED	9
	Connecting from Home 10	n
	How to Install the CardioNet Base	) 1
	About the CardioNet Base	4
	How to Activate the CardioNet Sensor	5
	Tips for Wearing the CardioNet Sensor	8
	How to Activate the CardioNet Monitor	9
USI	NG THE Monitor	5
	How to Turn your Monitor On and Off	6
	How to Record an Event	8
	How to Change Monitor Options	С
	How to Check Battery Power	4
	How to Check Cell Phone Coverage	5
	Receiving Messages from CardioNet	6
	How to Read a Text Message	7

SEN	NSOR CARE
4	Tips for Changing Electrode Pads40How to Change Electrodes and Attach Sensor41Remove Before Showering or Bathing44How to Change the Sensor AA Battery45
TRO	OUBLESHOOTING
)	Responding to Monitor Alerts and Alarms48Troubleshooting Device Problems51Precautions53Cautions54Warnings55
SPE	ECIFICATIONS, COMPLIANCE & SYMBOLS 57
0	Specifications58Equipment Symbols60In Home Requirements60FCC Compliance62

### INTRODUCTION

### In this Chapter:

- How the CardioNet Service Works
- Your CardioNet Monitoring Supplies
- Your Rights as a Patient
- Your Responsibilities as a Patient
- Who to Call with Questions
- In the Case of an Emergency
- What to Do When your Monitoring is Over

### How the CardioNet Service Works



When you're using the CardioNet service, you'll wear a small, lightweight sensor on your chest. The sensor detects and analyses each heartbeat and sends data to the portable CardioNet monitor. The CardioNet monitor can be tucked away in a pocket or purse. When the sensor detects an event, or when you report an event using the touch screen on the monitor, it transmits the data to the CardioNet Monitoring Center.

### How the CardioNet Service Works



The CardioNet Monitoring Center operates 24 hours a day, 7 days a week. At the Center, specially trained cardiac technicians analyze your heart rhythms and report results to your physician. Your physician reviews the report, discusses results with you and prescribes or adjusts treatment as needed.

#### The CardioNet Kit

The CardioNet Kit contains the supplies you will need while you are on the CardioNet Monitoring Service. If any items are missing or broken, or if you have any questions about how to use them, please call CardioNet at 1-866-426-4401.

When service is ended, follow the detailed instructions in *What to Do When Your Monitoring is Over* located in this chapter and please return the equipment promptly to the CardioNet Monitoring Center.

Picture	Item and Description
Kit Photo Here	<b>CARDIONET SHIPPING KIT</b> The CardioNet shipping kit contains all the items you will need during your monitoring service. You can also reference the inside lid of the kit for information on where each item is located in the kit.
Ų	<b>CARDIONET SENSOR</b> The sensor can be worn around the neck or on a belt. It detects each heartbeat and sends data to the CardioNet monitor. To communicate with the monitor, the sensor must remain close to the monitor. Walls and other obstructions can interfere with the communications between the sensor and the monitor. If you go out of communications range, the sensor and monitor will beep to alert you.
	<b>CARDIONET Monitor</b> The monitor constantly analyzes data from the sensor and sends events to the CardioNet Monitoring Center. The monitor uses wireless communication when not in the base and uses the regular phone system when the monitor is placed in the base. You will not be charged by the telephone company for calls made by your monitor.
	<b>CARDIONET BASE</b> The base recharges the CardioNet monitor and allows the monitor to communicate with the Monitoring Center using your home phone system. The bases are connected to your phone line and plugged into electrical outlets in your bedroom and another room in your home.

# Your CardioNet Monitoring Supplies

Picture	Item and Description
A set of the set of th	<b>ELECTRODES</b> Electrodes are disposable sticky pads that snap onto the three colored lead wires on the CardioNet sensor. You remove the backing and stick them to clean, dry, hairless skin. If you need more electrodes call CardioNet at 1-866-426-4401.
Energizer Energizer Bauer einer Bauer einer Bauer einer Bauer einer Bauer einer Bauer einer	AA BATTERIES The AA batteries provide power to the CardioNet sensor. The battery must be replaced each day. Please use only CardioNet-supplied AA batteries. If you need more batteries call CardioNet at 1-866-426-4401.
	SENSOR NECK STRAP & BELT CLIP Use the neck strap if you prefer to wear the sensor around your neck. Use the belt clip if you prefer to wear the sensor on your belt.
	<b>POWER PLUG &amp; TELEPHONE CORD</b> Use the black power plug to connect the CardioNet base station to an electrical outlet. Use the telephone cord to connect your CardioNet base station into the telephone wall jack. Detailed information on how to install your base is provided in Chapter 2: <i>How to Install the CardioNet</i> <i>Base</i> .
	<b>PATIENT EDUCATION GUIDE &amp; VIDEO</b> The Patient Education Guide and Patient Information Video contain helpful information about the CardioNet service and important contact numbers.
UPS	<b>UPS SHIPPING LABEL</b> Put the kit in the white plastic bag, seal it and stick the UPS pre-paid shipping label to the white plastic bag to return the kit after monitoring is finished.

### Your Rights as a Patient

- 1. You have the right to be treated with dignity, courtesy and respect.
- 2. You have the right to high quality service.
- 3. You have the right to excellent training on how to use the CardioNet technology and service.
- 4. You have the right to receive high-quality service regardless of race, religion, political belief, sex, sexual preference or source of payment.
- 5. You have the right to complain or suggest improvements in service without worrying that CardioNet will stop providing service or provide a poorer quality of service.
- 6. You have the right to refuse service.

### Your Responsibilities as a Patient

- 1. Use the CardioNet equipment with care.
- 2. Return equipment to CardioNet immediately, when monitoring is completed.
- 3. Provide CardioNet with the information CardioNet needs to provide you with quality care.
- 4. Treat CardioNet employees with respect.

### Who to Call with Questions

If you have any questions about your monitoring service or billing, please call one of our toll free numbers. Customer service is available 24 hours a day, 7 days a week.

*Customer Service:* 1-866-426-4401 *Monitoring Questions:* 1-866-426-4401 *Billing Questions:* 1-866-426-4402

# In the Case of an Emergency

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

In the course of monitoring your heart, CardioNet may detect cardiac events which are potentially life-threatening and were not anticipated by your physician. As directed in the physician notification criteria, if CardioNet detects such an event, CardioNet will attempt to contact you and your physician as soon as possible.

However, 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.

When CardioNet does detect a potentially serious cardiac event as defined by your physician, CardioNet will attempt to contact your physician for direction. CardioNet will also attempt to contact you and inform you of any cardiac event that has been received that may require evaluation in the emergency room, per your physician's notification criteria. You may decide to seek medical help by calling your Emergency Medical Services (EMS) directly or you may ask that CardioNet assist you in contacting EMS.

The CardioNet system was designed to help physicians diagnose and treat heart rhythm problems. There are other serious heart conditions that may not be detected by the system. Because of this, and because of the limitations of the CardioNet system described above, you should not delay seeking medical help if you experience symptoms that concern you. Also, you should not rely on CardioNet as an emergency response service.

### What to Do When your Monitoring is Over

When your prescription is over and CardioNet has received data for the number of days your physician has requested, the monitor will be deactivated in the middle of the night. You may hear the monitor beep. If in the morning the screen on your monitor states that your prescription has ended, turn the monitor off and remove the battery in the sensor. Remove the electrodes from your body.

Pack items in the kit by following the instructions on the inside of the kit lid. Before you close the kit, complete the Patient Satisfaction Survey and place it with the Patient Education Guide, laminated reminder card and Pocket Guide on the top of the contents of the kit. If you have not returned the Patient Enrollment Form, include a signed copy with these items as well. After everything is in the kit, close the lid and put the kit in the white plastic bag that was included in the kit contents. Seal the white bag. Stick the UPS pre-paid mailing label on the outside of the white plastic bag.

The kit is now ready to return and you can choose one of 3 ways to return it to CardioNet:

- 1. You can call UPS 1-800-742-5877 and UPS will pick it up. If you call UPS you will need to explain that it's a pre-paid 2nd Day Air package. You will not be charged anything.
- 2. You can drop off the kit at Staples, the UPS Store, or another location with UPS drop-off.
- 3. You, or a family member, can bring it to your work if they have daily UPS pick-up.

If you do not return the kit CardioNet will bill you for the contents.

Please return the kit as soon as you can so other patients can use the equipment.

# GETTING STARTED

### In this Chapter:

- Connecting from Home
- How to Install the CardioNet Base
- About the CardioNet Base
- How to Activate the CardioNet Sensor
- Tips for Wearing the CardioNet Sensor
- How to Activate the CardioNet Monitor

### **Connecting from Home**

This chapter describes the steps you will need to take in order to set up the CardioNet monitoring system and begin monitoring. You may want to ask for assistance from a family member if you are not comfortable doing these steps on your own.

The first step you (or a family member) needs to do is to install the base. The instructions on the next few pages will assist you in completing the installation. The base needs to be installed in the room where you sleep. When setting up a base, you will need a phone jack and an electrical outlet. When your monitor is on the base, your sensor will still be able to communicate with the monitor as long as they are within range of each other. If you go out of communications range, the monitor and sensor will beep to alert you. To ensure good communication, stay close to the monitor while it is in the base or simply take the monitor out of the base and bring it with you when you leave the room. You can go about your normal daily activities - just wear your sensor and bring your monitor with you wherever you go.

At night keep the monitor in the base near your bed. The monitor will recharge and it will also transmit your heart data to CardioNet's Monitoring Center. As you sleep, you can remove the sensor from the neck strap or belt clip and lay it on the bed next to you on the same side of the bed as your monitor. The sensor will move with you as you move. Try not to lie on top of the sensor. The monitor and sensor can not communicate with one another through bodies (your own body, your partner's, your child's, your pet's, etc.) If the monitor beeps at night, sometimes just repositioning the sensor near the monitor will stop the beeping. If the beeping continues, it might be for another reason, like "lead disconnected." You can read the message on the screen for information on how to resolve the problem.

After the base is installed, connect yourself to the sensor using the instructions in this chapter. After you are wearing the sensor, you will need to activate your monitor. Activating the monitor will require a password which you can obtain by calling CardioNet at 1-866-426-4401.

### How to Install the CardioNet Base

The table below will help you gather all the items you will need to install each CardioNet base. All items are located in your CardioNet kit.



#### How to Install the CardioNet Base



Find an electrical outlet located close to a telephone jack, preferably in your bedroom.

Pick up the receiver of your home phone and listen to ensure there is a dial tone. Locate the telephone cord plugged into the back of your home phone. Unplug the telephone cord from the back of your telephone. On the CardioNet base, locate the slot labeled "Phone In" on the back of the base. Take the telephone cord you just unplugged from the back of your phone and plug it into the slot on the base labeled "Phone In".

### How to Install the CardioNet Base



In the CardioNet kit, find the telephone cord. Locate the slot labeled "Phone Out" on the back of the base. Plug one end of this telephone cord into the slot on the base labeled "Phone Out". Plug the other end of this cord into the back of your telephone. In the kit, locate the power cord. On the back of the base, locate the round hole labeled "Power". Plug the small, round end of the power cord into the slot on the base labeled "Power". Plug the other end into an electrical outlet.

Check your home phone for a dial tone.

### About the CardioNet Base

#### The Base Recharges your Monitor

The base functions as a recharging station for your CardioNet monitor. When you insert the monitor into the base correctly, "Monitor is Charging" will appear on the screen. The monitor's rechargeable battery provides between 12 to 16 hours of use. If you plan to be away from home for more than 12 hours, you should bring one of the black power cords with you. At some point during the day, plug the power cord into an electrical outlet and charge your monitor by inserting the other end of the power cord into the hole on the side of the monitor.

#### The Base Transmits Events Using your Home Telephone

When your CardioNet monitor is in the base, it uses your home telephone system for communications with the CardioNet Monitoring Center. When you are away from home – or whenever your CardioNet monitor is out of the base station – the monitor uses cell phone technology to contact the CardioNet Monitoring Center and transmit data. You do not need a cell phone. The monitor uses its own cell phone.

As with consumer cellular phones, calls can sometimes be delayed or blocked by coverage problems, heavy traffic on cell phone networks, or physical obstructions such as buildings or mountains.

If the CardioNet monitor has data to transmit and is unable to communicate with the CardioNet Monitoring Center through cellular communications, the monitor will store the data and transmit it when cell coverage becomes available or through your home telephone system when the monitor is placed in the base.

If you pick up your telephone while the monitor is in the base and transmitting data, you will hear static, like the sound a fax machine makes. Hang up the phone and wait a few minutes while the data is sent and then you will get a dial tone. If you must use your phone and the monitor is transmitting data, take the monitor out of the base and make your call. When you are done with the call, however, you should return your monitor to the base right away to complete the transmission. If you are on the phone and the monitor wants to transmit data, you might hear clicking sounds. If you are using a dial-up connection to access the Internet on the same phone line as the base, and the monitor is in the base transmitting data, it may disconnect you from the Internet. Hang up and the monitor will transmit the data. When the monitor is in the base and transmitting data, your telephone line will have a busy signal for incoming calls. You will not be charged for any calls your monitor makes to CardioNet.

The table below will help you gather all the items you will need to begin using your CardioNet sensor. All items are located in your CardioNet kit.





Lift the lid of your sensor and place one AA battery inside. Use the diagram on the inside of the sensor to make sure you insert the battery with the proper positive and negative orientation. If you have inserted the battery correctly, you will hear a chime. Neck strap: unsnap the neck strap and thread it through the loop on the sensor. Snap the ends together and place it over your head. The 2 tabs allow you to adjust the length of the strap. Belt clip: attach the clip to your pants, skirt or belt. Snap the flat side of the sensor into the clip with the wires pointing upward. First make sure you do not have any lotion, powder or hair in the three locations (steps 4-6). If you have lotion or powder on, you should wash off the areas with soap and water and dry the skin completely. If you have any hair in these locations, you must shave it all off before putting the electrodes in place.



Open one pack of electrodes. Snap the 3 leads (from the end of your sensor wires) onto the 3 electrodes. Peel off the electrode from the backing with the WHITE lead attached. Place this electrode just below the center of your right collarbone. Press so that the electrode is adhered to your skin. Peel off the electrode from the backing with the BLACK lead attached. Place this electrode just below the center of your left collarbone. Press so that the electrode is adhered to your skin. Peel off the electrode from the backing with the RED lead attached. Place this electrode on your left side, on the lower part of your rib cage. RED on ribs. Press so that the electrode is adhered to your skin.

### Tips for Wearing the CardioNet Sensor

#### How the Electrodes Work

The CardioNet sensor uses three electrode pads, carefully placed on your body to detect heartbeats by sensing electrical changes on the surface of your skin. The electrode pads are attached to three leads - a white lead, a black lead and a red lead. The leads can be snapped on and off the electrodes. This allows you to take off the leads and sensor before showering – without removing the electrode pads.

It is very important that you follow the instructions in Chapter 4: *Changing Your Electrodes*. By following these instructions carefully you are providing CardioNet with a clear reading of your heartbeats while maintaining the health of your skin.

#### If You Experience Skin Irritation

If you experience skin irritation or a rash or at any time you experience discomfort wearing the electrodes, please contact CardioNet at 1-866-426-4401.



Before proceeding, please contact a CardioNet Customer Service Representative at 1-866-426-4401. The table below will help you gather all the items you will need to activate your CardioNet monitor. All items are located in your CardioNet kit.





Switch the power switch on the green/on position. Wait for the monitor to power up. Activation screen 1 will appear. Your name should appear on the screen.

Look at the back of your sensor. The 5 digit SNV number should match the number on this screen.

Touch Yes to proceed.

Activation screen 2 is shown.

In the blue folder in your kit, locate "CardioNet's Notice of Confidentiality and Privacy Practices".

Touch **Yes** to indicate that you have received this document.

Activation screen 3 is shown.

Touch **Yes** to indicate that you agree to return your CardioNet kit and all its contents immediately after your monitoring is complete.



Activation screen 4 is shown.

In your kit, locate the "Patient Enrollment Form."

Touch **Yes** to indicate that you agree with the Terms and Conditions on the form.

Activation screen 5 is shown.

Touch **Yes** to indicate your consent to allow CardioNet to use your data for research purposes. Your identity will not be used and will be kept private. Activation screen 6 is shown.

If you are not already speaking with a Customer Service Representative, please call CardioNet at 1-866-426-4401.

Touch **Continue** on your screen to proceed.



Activation screen 7 is shown.

While you are talking with our Customer Service Representative, they will give you a password to enter.

Enter the password and touch **Enter** to continue.

Place the monitor in the base. You may need to hang up the phone now.

The Activating Monitor screen appears.

During this time, your monitor is attempting to connect with the center and activate your prescription. This could take several minutes.

If activation fails, a screen containing instructions will appear (see page 25).

When the monitor has connected and activation is complete, the Activation Successful screen is shown.

Touch **Continue** to proceed and begin the process of recording a baseline ECG.



Before you begin recording your baseline ECG, find a comfortable place to sit or lay down. When you are comfortable press **Continue** on the screen. When you are comfortable and are certain you can remain still for up to 2 minutes, press **Record Baseline** on the screen. While your baseline ECG is recording the screen will show you a blue bar to indicate your progress. Please wait and remain still unitl this screen changes.



Once your baseline ECG has been recorded, the Baseline Recorded confirmation screen wil appear. **Press Continue** to go to the Main Menu. The Main Menu screen is displayed. You are now ready to begin your monitoring session with CardioNet.



If the monitor is unable to connect to the CardioNet \* center, the activation will fail.

If the "Activation failed" screen appears, do not proceed until you have called CardioNet's Customer Service at 1-866-426-4401.

If you disagree with any of If you have guestions or the Activation screens you : need assistance at any may choose **No**. However, if you do not consent free at 1-866-426-4401. to all of the Activation screens, CardioNet may not be able to provide monitoring to you. Please call CardioNet at 1-866-426-4401 to discuss your options. Please do not call your physician.

time, call CardioNet toll

#### USING THE Monitor

#### In this Chapter:

- How to Turn your Monitor On and Off
- How to Record an Event
- How to Change Monitor Options
- How to Check Battery Power
- How to Check Cell Phone Coverage
- Receiving Messages from CardioNet
- How to Read a Text Message

#### How to Turn Your Monitor On and Off



. USING THE Monitor

With your monitor off, loocate the black toggle switch on the bottom of the device. It show red. Move it to the right. It will show green.

You will hear a start up sound and the CardioNet "C" logo will appear. When the touch screen displays the Main Menu, the monitor is on and awake. With your monitor on, loocate the black toggle switch on the bottom of the device. It show green. Move it to the left. It will show red.

The "Good bye..." screen will appear.

The "Good bye" screen indicates that your device is shutting down. Do not move to toggle switch until the screen is blank and the device is completely off.

The only times you will need to turn the monitor off are when you change the sensor battery, change your electrodes, or take a shower or bath.

### How to Turn Your Monitor On and Off



When the monitor is awake, the touch screen is lit and the LED light at the top right side of the monitor blinks red or green.

A green blinking LED light means you are being monitored.

A red blinking LED light means you are not being monitored.

When the monitor is asleep, the touch screen is blank and not lit.

The LED light at the top right side of the monitor is on and blinking red or green.

Sleeping helps the monitor save battery power while you are not using the touch screen. When the monitor is charging, the LED light at the top left side of the monitor will illuminate in orange. The monitor battery icon, located on the Main Menu in the uper left corner will blink and will change colors as it recharges.

Always leave your monitor on, even when charging.

#### How to Record an Event



Follow these steps if you are experiencing any symptoms.

Ensure that your monitor is on and awake.

On the Main Menu touch the **Record** button.

On the monitor's touch screen, a confirmation screen will appear.

Touch the **Yes** buton to continue to step 3.

If you have touched the Record button by accident and do not wish to record an event, touch **No** and you will return to the Main Menu. The first of two symptom screens appears.

Select each symptom that you feel. The button will depress and change to a dark blue color.

Touch **Next** and repeat for the second symptom screen.

When you are finished, touch **Next**.

### How to Record an Event



Choose the activity level that best reflects your level of exertion when you felt your symptom.

When you are finished, touch **Next**.

Your event information has been recorded and stored. The monitor will then attempt to contact and transmit the data to the CardioNet Monitoring Center.

Touch **OK** to return to the Main Menu.

When you wish to record another event, press the **Record** button.



Ensure the monitor is on and awake.

Touch the button labeled **Volume**.

From the Main Menu, touch the **Options** button.

labeled Choose a desired volume.

Touching **High**, **Medium** or **Low** places a check mark next to your selection. You will hear a tone for the volume you have chosen. Vibrate disables the audio sounds and you will feel the monitor vibrating.

Touch **Confirm** to save.



Ensure the monitor is on and awake.

From the Main Menu, touch

the **Options** button.

Touch the button labeled **Display**.

Choose a desired brightness for the screen.

Touching the **Bright**, **Medium** or **Dim** button adjusts the LCD screen brightness and you will see the new setting you have chosen.

Touch OK to save.

Display



Ensure the monitor is on and awake.

Touch the button labeled **Cell Power**.

From the Main Menu, touch the **Options** button.

Never turn off your cell phone. The cell phone off feature is ONLY for use when flying.

Cell Phone

# Choose either **Yes** or **No**.

When the cell phone is off, monitoring continues, but no data can be sent unless the monitor is in the base or the cell phone is turned back on.

The cell icon on the Main Menu now displays "OFF".



Pressing the **Record Baseline** button will display the first screenin this process. You should only proceed when speaking with an authorized CardioNet Customer Service Representative.

If you enter this screen by accident, exit by touching **Back** you will return to the Options Menu.



Pressing the **Service** button will display a password screen. This screen allows Cardionet personel to troubleshoot your monitor. These screen can only be accessed while you are speaking with an authorized CardioNet Customer Service Representative.

If you enter this screen by accident, exit by touching **Enter**, then **OK** and you will return to the Options Menu.

# Service or Send...

#### How to Check Battery Power



A battery icon that is filled with a green color indicates your monitor and / or sensor have full power.

A battery icon that is partially filled with a yellow color indicates a low battery in either your monitor or sensor.

A battery icon that is minimally filled with a red color indicates either your monitor or sensor battery is empty.

The monitor's rechargeable battery provides 16 hours of use for every 4 hours of recharging.

The sensor AA battery should be replaced at the same time every day.

If your monitor or sensor battery icon are red in color you, should recharge or replace the battery immediately.

### How to Check Cell Phone Coverage

Four green bars located to the right of the cell icon indicate a very strong cell signal.

No bars to the right of the cell icon indicates no cellular signal.

The word OFF to the right of the cell signal indicates your cell phone has been turned off. To turn back on, touch the **Options** button on the Main Menu, select **Cell Power**, then select **Yes**. Please remember, the cell phone off feature is only for use when flying.

You can't change your cell strength unless you change your current location.

If the icon indicates no cellular coverage and the monitor is not in the base, your data will be stored until the monitor has a cellular connection or is placed in the base.



#### **Receiving Messages From CardioNet**

#### About Text Messages

There are times when CardioNet may want to send you a message regarding your monitoring. If you see the blue envelope on the Messages button with the word "NEW" blinking on it, you have received a text message. In order to read the message, touch the Messages button and your message will appear on the screen. When you are done reading and responding to the message, touch OK to return to the Main Menu. The blue envelope will remain on the button and you can read your message again at any time by pressing the button. If you receive another message, the word "NEW" will appear and blink on your envelope. You will need to touch the button again to read your new message.



### How to Read a Text Message



Ensure the monitor is on and awake.

If you have received a new text message, an envelope will blink "**NEW**".

From the Main Menu, touch the **"Messages"** button located at the bottom right corner of the screen. The date and time the text message was sent to you is displayed.

Read the text message and follow any instructions provided.

When you have finished, touch **OK** to return to the Main Menu.

The envelope icon no longer reads **"NEW"**. You can regain access to the text message by touching the **"Messages"** button.

If you receive another text message, the envelope icon will change and blink "**NEW**" again.

### SENSOR CARE

### In this Chapter:

- Tips for Changing Electrode Pads
- How to Change Electrodes and Attach Sensor
- Remove Before Showering or Bathing
- How to Change the Sensor AA Battery

# **Tips for Changing Electrode Pads**

#### Changing your Electrode Pads and Keeping Your Skin Healthy

Change your electrodes every other day. If they come loose before that time, replace them immediately. If you are showering or bathing on the day you need to change them, remove them in the shower or bath. Lather them up with soap and water and pull them off gently. When you are done with your shower, dry your skin and follow the instructions in *How to Change your Electrodes*. If you do not remove the electrodes in the shower or bath, you will still need to use soap and water to loosen them. The goal is to be gentle with your skin. Never pull the electrodes off quickly like a band-aid.

If the electrodes come loose or are moving around before the two days are over, replace them immediately. It is very important that the electrodes adhere to your skin at all times. You may want to press lightly on your electrodes in the morning when you wake up and throughout the day to make sure they are adhered to your skin.

Do not put the electrodes in the exact same location each time you change them. It is very important that you rotate the locations near the original sites. This will help preserve your skin. If, at any time, redness or irritation occurs, call CardioNet at 1-866-426-4401. Do not wait until the irritation is severe before you call.

The "Skin Prep" in your kit can be used if you experience mild skin irritation. Wipe the 3 areas with one skin prep. Let it dry and then apply the electrodes. The skin prep provides a barrier between the electrodes and your skin. It is usually not necessary to use the skin prep and should only be used if you have sensitive skin or are experiencing mild skin irritation.

Adhesive remover is also included in your kit and can be used if you have any adhesive residue left on your skin. The adhesive remover can irritate your skin so make sure you wash it off after using. It is not necessary to use the adhesive remover and should only be used if you can see visible adhesive still on your skin after washing with soap and water.

Do not use lotion or powder on your chest while you are being monitored and remove all hair on your chest in the locations of the electrodes. Follow the instructions in the next few pages on *How to Change Electrodes*.

### How to Change Electrodes and Attach Sensor



With your monitor on, locate the black toggle switch on the bottom of you monitor. Move the switch from green to red.

The blue "Good bye..." screen will appear. Once this screen disappears, the monitor has completely powerd down. Open the battery door by pushing the door snap up.

Remove the battery by grabbing both sides and lifting it out.

Unsnap the three leads from the electrode pads.

Using soap and water, gently lift the old electrode pads off your skin. Never pull them off quickly.

Throw the old electrode pads away.

### How to Change Electrodes and Attach Sensor



It is very important that you place each electrode in another location near the original site to protect your skin. Open one pack of electrodes. Snap the 3 leads to the electrodes. Peel off one electrode at a time from the backing and apply them in the proper location (see step 5) to clean, dry, hairless skin.

WHITE ON RIGHT. Place the electrode with the WHITE lead on the right, under your collar bone.

**BLACK ON LEFT.** Place the electrode with the BLACK lead on the left, under your collar bone.

**RED ON RIB.** Place the electrode with the RED lead on your lower left rib cage.

Turn the sensor on by inserting one AA battery into the sensor battery compartment. You will hear a chime if the battery is inserted correctly.

Turn your monitor on by locating the black toggle switch on the bottom of your monitor. Move the switch from red to green.

### How to Change Electrodes and Attach Sensor





# Skin Irritated?





If you choose to wear the sensor on your chest, you will need the neck strap.

Unsnap the strap and thread it through the loop on the sensor. Snap the ends together and place it over your head. The 2 tabs allow you to adjust the length of the neck strap. If you choose to wear the sensor on your belt, you will need the belt clip.

Attach the clip to your pants, skirt or belt. Insert the end of the sensor with the loop pointing downward into the narrow opening on the clip. Snap the other end into the wide opening with the wires pointing upward. If your skin is red or irritated, you can use the "Skin Prep" located in your kit. This provides a protective barrier between your skin and the electrode. Wipe all 3 locations with one skin prep. Allow to dry and place electrodes on top. If the skin irritation continues, call CardioNet at 1-866-426-4401.

### **Remove Before Showering or Bathing**



With your monitor on, press the blue power button located on the lower right part of the monitor. On the monitor's touch screen, a confirmation screen will appear.

Press Yes to turn the monitor off. The sensor is not water proof, but the electrodes are. Therefore, you'll need to remove your sensor before taking a bath or shower, but you can keep the electrode pads on.

To prevent the electrodes from falling off while you are in the shower, avoid soaking the electrode pads. Gently wash the skin around the electrodes.

While you are drying off, use your towel and press the electrodes onto your skin. This will help dry the electrodes and to ensure a tight surface contact with your skin.

If your electrodes are 2 days old, remove the old electrodes and apply new electrodes. Removing the old electrodes during your shower - while they are wet - may be gentler on your skin.

# How to Change the Sensor AA Battery



Press the blue power button located on the lower right part of the monitor.

On the monitor's touch screen, a confirmation screen will appear.

Pressing **Yes** will turn the monitor off.

Open the battery door by pushing the door tab up.

Remove the old battery by placing your finger in the recessed area, wedging your finger underneath the battery and lifting upward. Put in a new AA battery, included in your CardioNet kit. Note the battery direction on the label on the inside of the sensor cover. If properly installed, the sensor will chime. If the sensor doesn't chime, recheck the battery direction.

Close the sensor cover and turn your monitor on.

### TROUBLESHOOTING

#### In this Chapter:

- Responding to Monitor Alerts and Alarms
- Troubleshooting Device Problems
- Precautions, Cautions and Warnings

### **Responding to Monitor Alerts and Alarms**

#### When the monitor or sensor beeps

When the monitor beeps it has nothing to do with the condition of your heart, so don't become concerned. The monitor will beep to alert you when it is unable to function properly. The touch screen will explain what to do. With both alerts and alarms you can always touch the Help button for further instructions.

Alerts display an information screen that will disappear after 15 seconds and have an audio tone of two brief beeps. Alarms display an information screen that persists and alarm tones that grow louder over time.

Alerts can sometimes fix themselves, but alarms always require action on your part. For alarms, you can immediately silence the audio tones by touching the Silence button on the touch screen.

The table below will help you identify the possible problem and the actions you can take to find a solution for each monitor alert or alarm.

Screen	Problem	Possible Solutions
No Communications Your Monitor needs to communicate with your Sensor.	<b>NO COMMUNICATIONS</b> The sensor you are wearing on your body and the monitor are not communicating.	Move closer to your monitor or move the monitor closer to you. OR Check if the sensor battery is empty or oriented incorrectly
		Check that all leads are
Lead Disconnected	One or more leads are unsnapped	snapped to the electrodes.
Check all contacts. Press Help for	OR	Check all electrodes to
instructions.	One or more electrodes are not stuck well to your skin.	ensure they are stuck to your skin. Apply new electrodes if needed.

# **Responding to Monitor Alerts and Alarms**

Screen	Problem	Possible Solutions
Low Gateway Battery Your Monitor battery is low. Charge battery soon to ensure continuous monitoring! OK	<b>LOW MONITOR BATTERY</b> The rechargeable battery in the monitor is low.	Return the monitor to the base for recharging. <b>OR</b> Directly recharge the monitor by plugging the base power cable into the monitor.
Low Sensor Battery Your Sensor battery is low. Replace battery soon to ensure continuous monitoring! OK	<b>LOW SENSOR BATTERY</b> The sensor AA battery is low.	Install new battery. OR If the battery is new, inspect battery compartment and clean contacts if necessary.
Internal Monitor Error Internal Monitor Error 1234 Call CardioNet at 1-800-555-0000 for technical assistance. Help Silence	INTERNAL MONITOR ERROR The monitor is not functioning.	Call the CardioNet Patient Service Center for help. Call Toll free: 1-866-426-4401.
Internal Sensor Error Internal Sensor Error 1234 Call CardioNet at 1-800-555-0000 for technical assistance. Help Silence	INTERNAL SENSOR ERROR The sensor is not functioning.	Call the CardioNet Patient Service Center for help. Call Toll free: 1-866-426-4401.

### **Responding to Monitor Alerts and Alarms**

Screen	Problem	Possible Solutions
Transmit Data	INFORMATION TO SEND	Put the monitor in the base.
Your Monitor is trying to send data and cannot reach the network.	The monitor needs to transmit data but can not establish a connection to CardioNet.	<b>OR</b> Move to an area with cell phone coverage.
Press Help for options. Help OK		

### **Troubleshooting Device Problems**

#### About Troubleshooting

Troubleshooting sometimes involves a bit of detective work, but usually the monitor detects problems for you and can assist you with resolving the problem. The monitor beeps to let you know there is a problem with the equipment. The touch screen shows you a message on how to respond to the alert or alarm. For every alert and alarm the touch screen has a help menu. Any time an alert or alarm appears and you do not know what to do, you can press the Help button to access detailed instructions on how to troubleshoot the problem.

An alert prompts you to resolve a problem by displaying an information screen and beeping an audio tone. With alerts the problem can fix itself and you won't need to take any action. With alarms you will need to take some action and information on how to resolve the problem will be provided on the touch screen. An alarm persists to let you know that a problem has not been resolved and you must take action.

#### If your Problem Can't be Resolved

If you experience additional problems with any components of the CardioNet Monitoring System, review the problems and solutions listed in the troubleshooting section. If additional assistance is required contact customer support toll free at 1-866-426-4401.

Most alerts or alarms have a help screen. If you need more information, press the **Help** button to access detailed instructions on how to troubleshoot the problem.



# Troubleshooting

Problem	Possible Solutions
Monitor battery	Ensure battery is being fully recharged every day. A full recharge takes approximately 4 hours and will last 16 hours.
power drains quickly	Ensure the monitor is being placed in the base correctly. If the monitor does not make contact with the plug in the base, it may not recharge.
Monitor	It could be that the monitor is not turned on.
screen is blank	Ensure the monitor is turned on by confirming that the LED light is flashing red or green. If the monitor is asleep, press the blue button. The screen should light up. If it doesn't, the monitor may be low on power. Return the monitor to the base for recharging.
Monitor beeps while you are in bed	It is possible for your body to block communications between the sensor and monitor. This will cause warning beeps. To avoid beeps and maintain the communications link, place the sensor near the monitor on the bed next to you. Try not to lie on top of it or to get between the sensor and monitor while you are sleeping.
Your phone line is busy	When the monitor is in the base station and sending information it will use your telephone line. If someone calls you while the monitor is using the line, they will get a busy signal. If you try to place a call while the monitor is transmitting data, you will hear a high-pitched sound. This is the sound of monitor data being transmitted.
Skin is irritated or reddened	If you notice that the skin under or around your electrode pads is becoming sensitive, irritated or painful, or if you develop a rash, please call the CardioNet Patient Service Center immediately at 1- 866-426-4401. Some people are sensitive or allergic to adhesives. CardioNet will send you another type of electrode pad.
Sensor belt clip is difficult to put on	If you're wearing a thicker belt and finding that it is difficult to slide on the Sensor Belt Clip, first remove the CardioNet Sensor from the clip. Slide just the clip onto your belt and then reposition the sensor on the clip.



#### **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.



#### 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.

#### 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.



#### FOR ADULT USE ONLY

The CardioNet System is intended for Adult Use only. It shall not be use 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

Do not use any power cord for the base other than the one provided in the CardioNet service kit.

#### 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 USE NEAR FLAMMABLE ANESTHETIC

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

# S P E C I F I C A T I O N S , C O M P L I A N C E & S Y M B O L S

#### In this Chapter:

- Specifications
- Equipment Symbols
- In Home Requirements
- FCC Compliance

# 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 0.8 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.

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 µ 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 modem, digital error corrected.

#### OPERATING CONDITIONS

Operating Tempera-	Sensor: 20 - 45 °C; Monitor ; 0 - 45 °C
Operating Humidity	10% - 95% noncondensing
Storage Temperature	-20 - 65 °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	Туре І

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  $\mbox{device}(s)$  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 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-1008
Monitor ISM	QBI-1009
Monitor Cell Modem	Q9EQ2438F-M
Base	QBI-1010

#### FCC COMPLIANCE

#### 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.

#### 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 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.

#### FCC COMPLIANCE

#### **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 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.