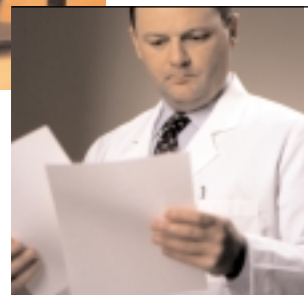
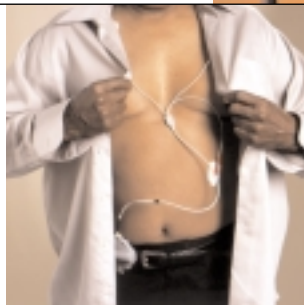




CARDIONET

HOME HEART MONITORING

Patient Education Guide



DRAFT

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DRAFT

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

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Model Number 1001
Lit Number - 100526 ■ Revision B ■ February 2004

1

I N T R O D U C T I O N

We Help Find Answers

The CardioNet Service monitors your heart rhythms continuously. This helps your doctor detect problems that occur infrequently, even while you sleep.

CardioNet works with you and your physician.

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 rhythm continuously, while people go about their normal daily activities. We can help physicians detect problems that may occur infrequently, whether you feel them or not, even while you are sleeping.

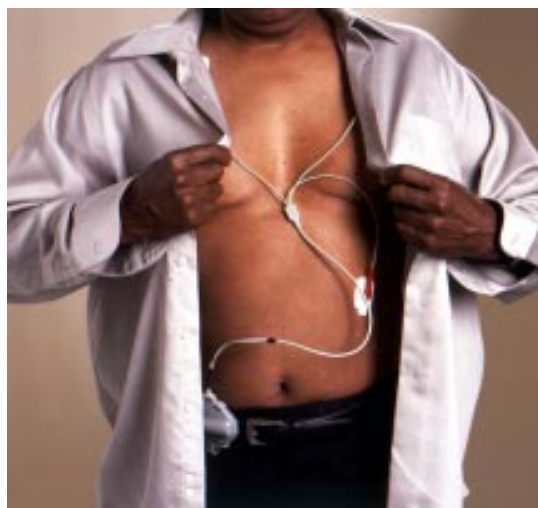
Our goal at CardioNet is to work as a team with patients and physicians to help people receive the best possible care. We are honored that we were chosen to serve you.

HOW THE CARDIONET SERVICE WORKS

When you're using the CardioNet Service, you'll wear a small, lightweight sensor. The sensor monitors each heartbeat and sends data to the portable CardioNet monitor.

The CardioNet monitor can be tucked away in a pocket or purse. It sends wireless communications to the CardioNet Center automatically when it detects an event, or when you report an event using the touch screen on the monitor.

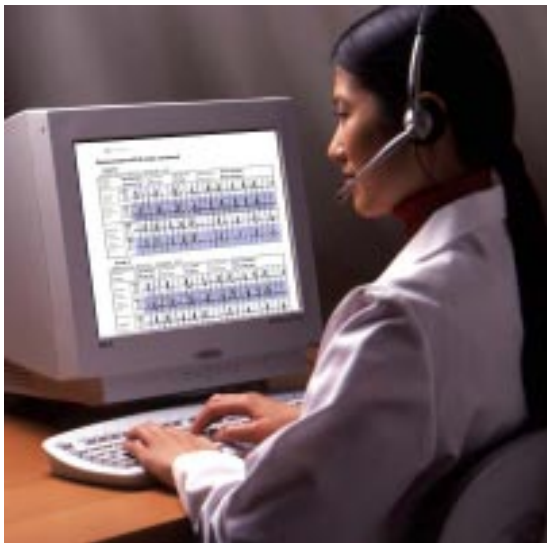
Lightweight sensor monitors each heartbeat.



Sensor with lead Wires

CardioNet monitor sends your information to the CardioNet Center

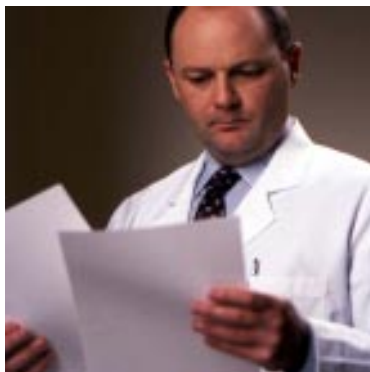




CardioNet Patient Service Center Monitors Heart Rhythms

The CardioNet Patient Service Center operates 24 hours a day, seven days a week. At the Center, specially trained cardiac technicians analyze your heart rhythms and report results to your physician.

Your physician reviews the results, discusses results with you and prescribes or adjusts treatment.



Physician Reviews Results

Avoid extra charges. Return all kit items except used batteries and used electrode pads to CardioNet when service is completed.

You might receive the latest version of the CardioNet Monitor, which has a color screen.



1. CardioNet Monitor

THE CARDIONET MONITORING KIT

The CardioNet Monitoring 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 the CardioNet Patient Service Center at 1-866-426-4401.

When service is ended, please return all the items to their labeled slots and send the kit back to the monitoring center, following the directions on the enclosed return address label.

It is important to return the patient supply kit no later than the very next day. Other patients may need to use the equipment.

YOUR SERVICE KIT CONTAINS

1. The CardioNet Monitor

This portable device constantly monitors your heartbeat and sends information to the CardioNet Patient Service Center. The CardioNet monitor uses wireless communication when you are away from home. It uses the regular phone system when the monitor is placed in the CardioNet base station. You will not be charged by the telephone company for calls made by your monitor.

Please handle the CardioNet monitor with care – don't drop it, lose it, or get it wet.



2. CardioNet Base Station

2. The CardioNet Base Station

The CardioNet base station is connected to your home telephone line and plugged into an electrical outlet in the bedroom or a central location in your house. The base station recharges the CardioNet monitor overnight and allows the CardioNet monitor to communicate with the monitoring center through the regular phone system. You will not be charged by the telephone company for calls made by your monitor.

Please put the CardioNet monitor in the base station whenever you are at home. In larger homes, two base stations may be required, so you can keep your sensor and monitor in contact as you walk around the house.



3. CardioNet Sensor

3. The CardioNet Sensor and Lead Wires

The CardioNet sensor, which can be worn around the neck or on a belt, senses each heartbeat and constantly sends the information to the CardioNet monitor. To communicate with the monitor, the sensor must remain within 30 feet of the monitor. Walls and other obstructions can reduce the range. If you go out of communication range, the sensor will beep to alert you – to either move back within range or to pick up the monitor and take it with you.

4. Electrode Pads

These sticky disposable pads snap onto the three electrode leads on the CardioNet sensor. You remove the backing and stick them onto your skin.

5. Batteries

These batteries are for the CardioNet sensor. The sensor battery must be replaced each day. Any new commercially available AA battery can be used with the CardioNet sensor.

6. Sensor Neck Strap

Use if you prefer to wear the sensor around your neck.

7. Sensor Belt Clip

Use if you prefer to wear the sensor on your belt.

8. Telephone Line In/Out

Use to plug your CardioNet base station into the telephone wall jack.

9. Base Power Plug

Use to plug your CardioNet base station into an electrical outlet.

10. Patient Education Guide & Pocket Reference Card

These guides contain helpful information about the CardioNet service and important contact numbers.

11. Patient Information Video

This ten-minute video contains helpful information about the CardioNet Monitoring Service.

12. Return Address Label and Shipping Form

Use the label and prepaid shipping form to return the kit after monitoring is finished.

PATIENT RIGHTS

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 we will stop providing service or provide poorer quality of service
6. You have the right to refuse service
7. By federal law (the HIPAA act) you have the right to privacy with regard to your medical information and to control the use of that information

The HIPAA act also provides that you have the right to request copies of your medical records and to have corrections made if there are errors in your records

Remember: Avoid additional charges. All kit items, except used batteries and used electrode pads must be immediately returned to CardioNet once service is completed, or you will be charged for them.

PATIENT RESPONSIBILITIES

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

WHO TO CALL FOR HELP

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.

MONITORING QUESTIONS: (866) 426-4401

BILLING QUESTIONS: (866) 426-4402

IMPORTANT INFORMATION

CardioNet home monitoring is a service used to help doctors diagnose and treat rhythm problems, not an emergency response service. If you require immediate medical assistance, you should contact Emergency Medical Services (9-1-1 in most communities).

It is possible that CardioNet could detect a problem that needs immediate attention while a patient is being monitored. If we do detect a problem that needs immediate attention, we will attempt to notify you so that you can obtain assistance from Emergency Medical Services. Our ability to contact and assist patients is limited by several factors such as cell phone coverage, our ability to determine patient location and differing Emergency Medical Services policies and systems in local communities.

2

SETTING UP

This section describes:

- Connecting the CardioNet Base
- Recharging the Battery
- Staying in Communications Range
- Wearing the Sensor

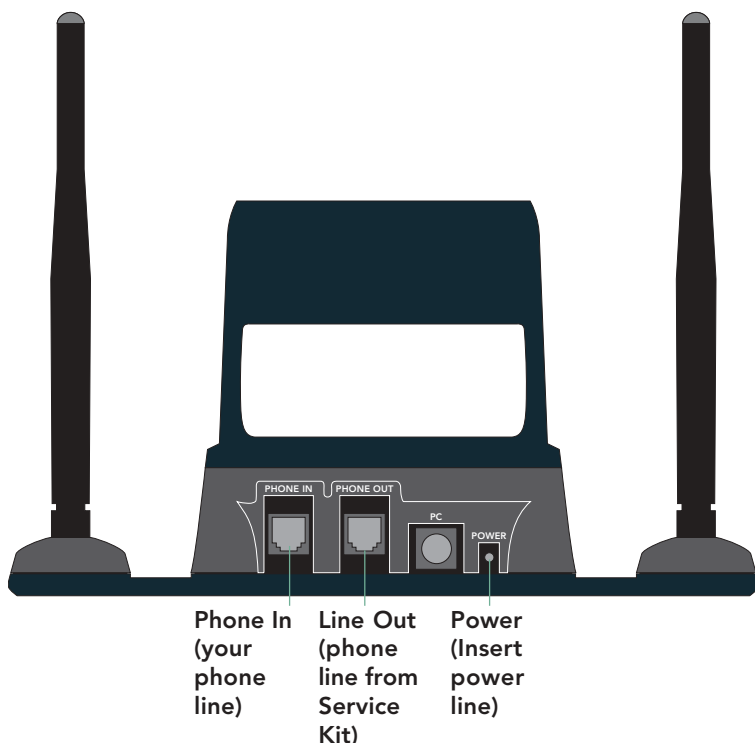
CONNECTING AT HOME

To connect the CardioNet base, find an electrical outlet and phone jack in a central location, preferably in your bedroom. As long as you are within range of the CardioNet monitor, your CardioNet sensor can continue sending heartbeats to the monitor. If you go out of range, the sensor beeps to alert you.

When you go to any area in your house where your sensor is out of communications range with your monitor, simply take the CardioNet monitor out of the recharging base and bring it with you.

In larger houses, a second base station is often used so that you can stay within range without carrying your monitor around.

At night, keep the CardioNet monitor in the recharging base near your bed. If you sleep on your stomach, your body may block communications between the monitor and the sensor and you may need to put the sensor next to your pillow. Whenever possible keep the monitor in the base. It takes around four hours in the base station to completely recharge the monitor battery.



SETTING UP THE BASE

1. Find an electrical outlet located close to a phone jack, preferably in your bedroom.
2. Unplug the telephone line from the back of your telephone.
3. Take the telephone line that you just unplugged and plug that line into the slot on the base labeled "Phone In".
4. Locate the second telephone line included in your CardioNet Service Kit. Plug one end of this line into the slot on the base labeled "Line Out". Plug the other end of this line into the back of your telephone.
5. Locate the power cord in your CardioNet Service Kit. Insert the small, round end of this line into the slot on the base labeled "Power". Plug the other end into an outlet.

CHECKING BATTERY POWER

See Page 20 for more details about checking battery power.

When your monitor is in the base, touch the battery symbol on the screen and the unit will tell you if the battery is fully charged. If the battery is not fully charged, leave the monitor in the base for a full recharge, which takes four hours.

STAYING IN RANGE

At home, leave the monitor in the base whenever possible.

The monitor's rechargeable battery provides between 12 and 16 hours of use for each four hours of recharging. If your battery indicator is low and it is still early in the day, we recommend you place the monitor in the base for recharging. When you are at home, leave the monitor in the base, unless you go to a part of the house where the sensor and monitor would be out of communications range. Whenever you begin to go out of communications range, the sensor will beep to alert you – reminding you either return within range or take your monitor with you.

LIMITATIONS OF CELL PHONE COVERAGE

When your CardioNet monitor is in the base station, it uses the regular telephone system for communications with the CardioNet 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 center and transmit ECG data.

As with consumer cell 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.

When the CardioNet monitor has data to transmit and is unable to communicate with the CardioNet center through cell phone communications, it will save the data and transmit it to the Center through the phone line when it is replaced in the base.



Place Monitor in Base to Recharge

WEARING THE CARDIONET SENSOR

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 the sensor by three lead wires: a white wire, a black wire and a red wire. The lead wires can be snapped on and off the electrodes. This allows you to take off the lead wires and attached sensor before showering – without removing the electrodes.

See Page 36 for more details about removing your sensor while showering.

If you notice an irritation or a rash developing where you place the electrode pads, please call us. You may need to use a different type of electrode pad.

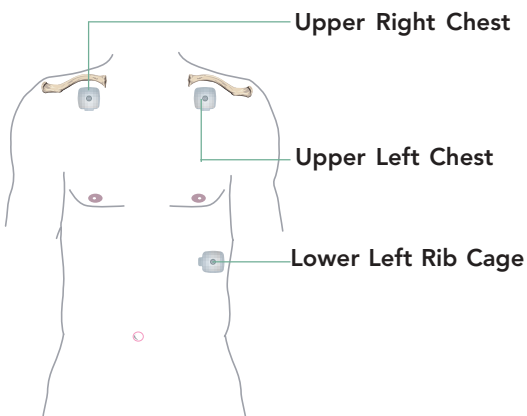
Sensor with Lead Wires



Placement of Lead Wires and Pads

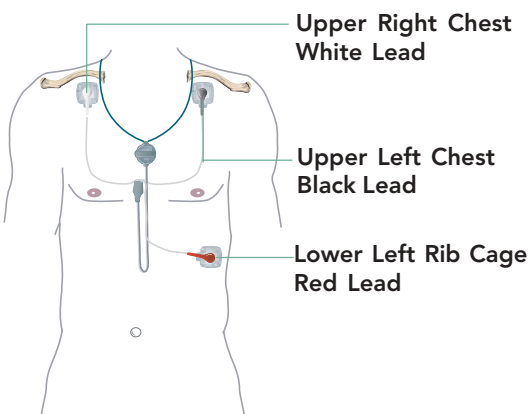
The electrode pads are placed as shown in the diagram below.

- White lead** – snaps on an electrode pad placed just below the center of your right collarbone.
- Black lead** – snaps on an electrode pad placed just below the center of your left collarbone.
- Red lead** – snaps on an electrode pad placed just on your left side, on the lower part of your rib cage.

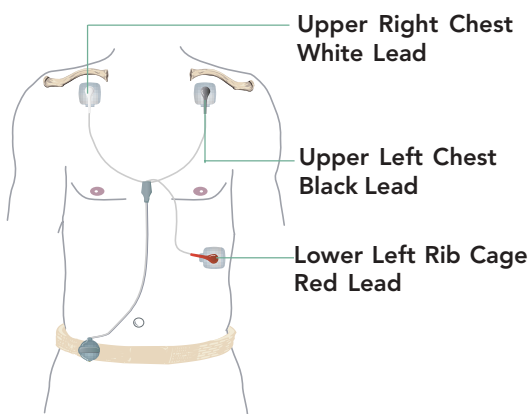


Placement of Pads

When you enroll in the CardioNet System, you will be shown the best locations for the electrode pads to detect changes in heart rhythms.



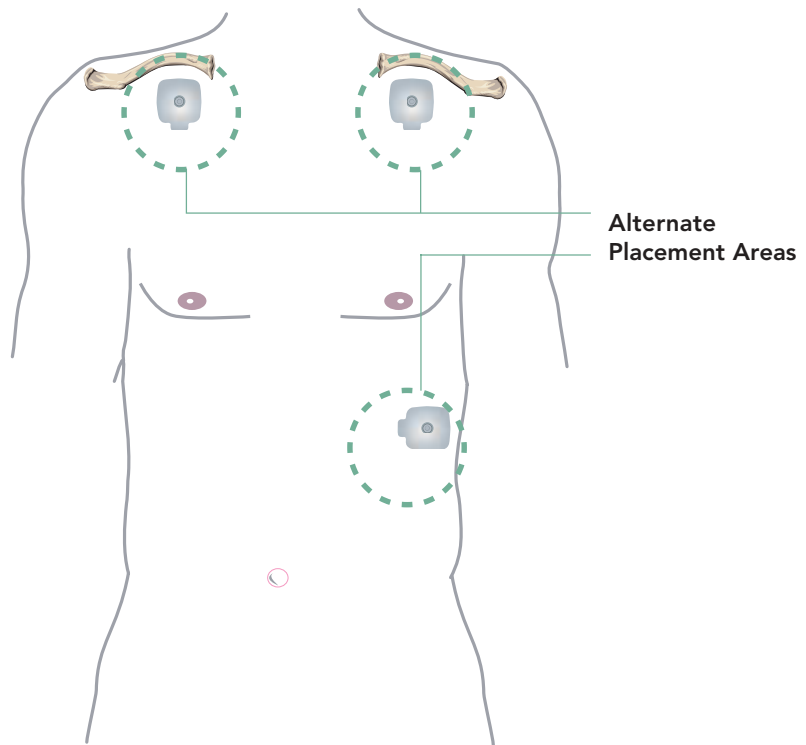
Placement of Leads Shown with Neck Strap



Placement of Leads Shown with Belt Buckle

SKIN PREP

This is a protective barrier for patients with known sensitivity or adhesion difficulties. Apply to clean, dry skin before electrode placement and allow to dry completely. Use one skin prep pad for all 3 electrodes.



Alternate Placement for Pads

If redness or irritation develops, you can place the electrode pad at another location near the original site. If redness or irritation develops at the alternate site, please call the CardioNet center immediately.

3

USING THE MONITOR

This section describes:

- Monitor On and OFF
- Using the Touch Screen
- Recording a Symptom
- Cell Phone Coverage
- Changing Monitor Options
- Checking Monitor Status
- Warnings and Alarms

The CardioNet monitor is your link with the CardioNet Patient Service Center. The CardioNet sensor sends each heartbeat to the monitor. When the monitor detects a targeted change in rhythm, or when you detect a symptom and enter your information, the monitor will establish a communications link with the CardioNet Patient Service Center. The monitor sends your ECG data, as well as any symptoms and activity information you have entered using the monitor's touch screen.

MONITOR ON AND OFF

Keep the monitor on at all times while you are on the CardioNet Service, unless you are changing the sensor batteries or not wearing the sensor – for example, when you take a shower.

See pages 38 - 41 for more information about how to remove the sensor while bathing or showering.

When the monitor is awake you see the main menu. When off or asleep, the screen is blank. Touch the button to wake it up.

The CardioNet monitor uses cellular communications to transmit data when you are away from home. If you have an implanted pacemaker or defibrillator, please follow the manufacturer's instructions regarding the use of cell phones. (See page 55 for more information.)

The green button at the bottom of the monitor turns it on or off and wakes it up. To turn the monitor off, you must also use the touch screen to confirm that you want to turn the monitor off.



MONITOR IS ON

The LED indicator light flashes green when you are being actively monitored. When the light flashes red, the monitor is trying to get your attention. An alert screen will appear with help or information.

MONITOR SCREEN IS ASLEEP

To save on battery power, the monitor screen becomes blank while you are not using the touch screen menus. You can tell that the monitor is still on because the LED indicator light will be flashing.

To wake the monitor up press the **On/Off** button. The screen information will appear.

MONITOR IS OFF

When you turn the monitor off, the screen is blank and the LED indicator light is not lit.



The LED light still flashes when the monitor is asleep. It goes off when the monitor is turned off.

The screen is blank when the monitor is asleep or turned off.

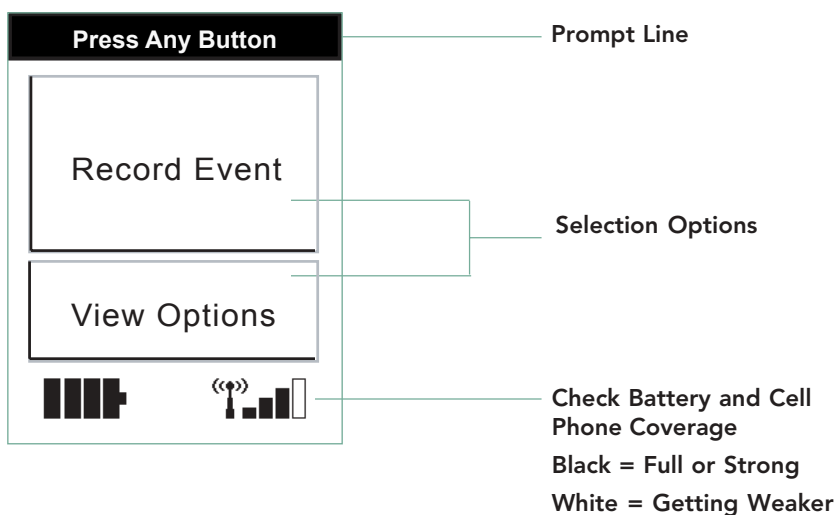
USING THE TOUCH SCREEN

The CardioNet monitor has a simple touch screen that is easy to view and use. To make selections, lightly touch the screen with your finger. Each screen that appears will guide you through the next step, using menus – choices you select.

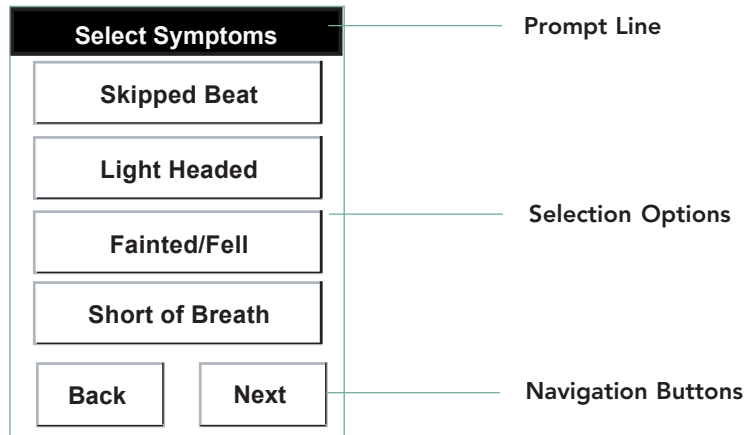
Most screen menus follow a simple pattern. At the top of each there is a prompt line that tells you the next step to take. The midsection lists options that you can choose. At the bottom of most menus are navigation buttons that allow you to move from screen to screen.

The two symbols at the bottom of the main menu let you check battery power and the strength of the cell signal.

MAIN MENU



SYMPTOMS MENU



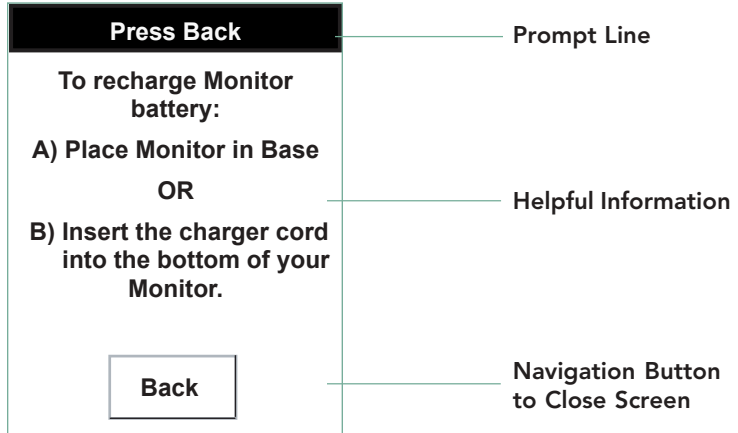
NAVIGATION BUTTONS

The navigation buttons at the bottom of each menu move you from screen to screen. Here's what the buttons do:

- | | |
|----------------|---|
| Confirm | Confirm accepts your selection and moves to the next menu. |
| OK | OK acknowledges you have read the information on the screen and closes the current menu. |
| Back | Back moves backward to the previous menu. |
| Next | Next moves forward to the next menu. |
| Silence | Silence turns off the audio alarm. |
| Help | Help moves to a helpful information screen. |

HELP MENU

The help and alert screens are slightly different in that the middle section provides additional information.

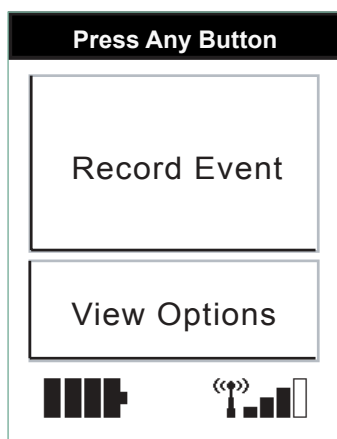


RECORDING AN EVENT

Your symptom and activity data is very important information that helps your physician treat or manage your condition. By entering your symptoms and activities each time you have an event, you will assist your physician in determining the best treatment.

To Record a Symptom

1. Make sure the monitor is on. If the screen is blank, press the **On/Off** button to turn on the monitor. The Main menu appears.



*To turn your monitor screen on, either touch the blank screen or press the **On/Off** button.*

2. On the Main menu touch **Record Event**.

A confirmation screen appears asking if you want to report an event.

Remember that there are two Symptoms menus.

A screenshot of a confirmation screen. At the top, a black header bar contains the text "Press Yes or No" in white. Below the header, the main area is white and contains the question "Do you want to report an event?" in bold black text. At the bottom of the screen, there are two rectangular buttons: "Yes" on the left and "No" on the right.

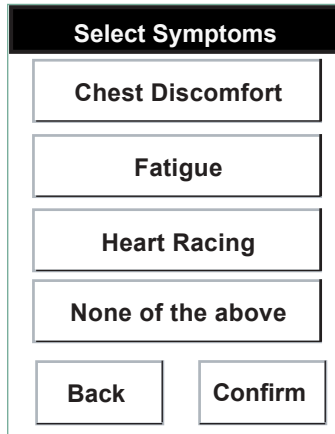
3. Touch **Yes**. If you have touched the Record Event screen by accident and do not wish to report an event, touch NO and you will return to the Main Menu.

The **first** of **two** Symptoms menus appears.

A screenshot of a "Select Symptoms" screen. At the top, a black header bar contains the text "Select Symptoms" in white. Below the header, there are four stacked rectangular buttons with the following text: "Skipped Beat", "Light Headed", "Fainted/Fell", and "Short of Breath". At the bottom of the screen, there are two rectangular buttons: "Back" on the left and "Next" on the right.

Select, one by one, each and every symptom that you feel. A check mark will appear next to symptoms you select. Touch **Next**.

- The **second** Symptoms menu appears.



Select Symptoms

Chest Discomfort

Fatigue

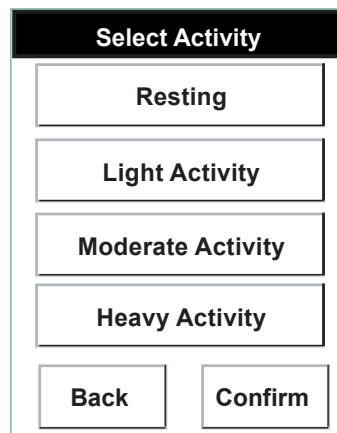
Heart Racing

None of the above

Back Confirm

Select any or all symptoms or touch **None of the above**. When done, touch **Confirm** to move to the Activities menu.

The Activities menu appears.



Select Activity

Resting

Light Activity

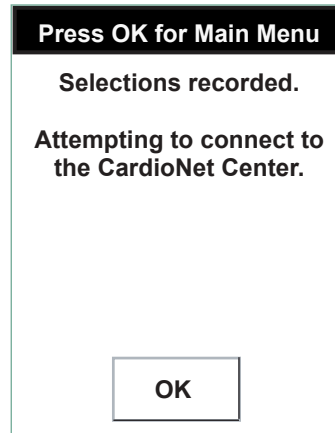
Moderate Activity

Heavy Activity

Back Confirm

4. Choose the activity that best reflects your level of exertion when you felt the symptom. When done, touch **Confirm**.

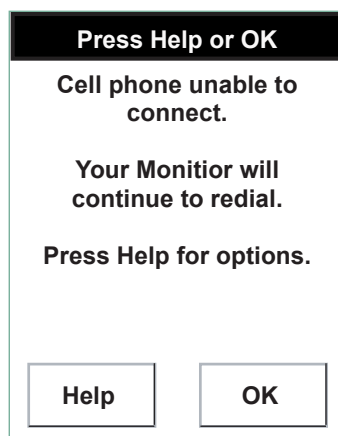
The following screen appears.



5. Touch **OK**. The monitor then attempts to send your activity information and your ECG data to the CardioNet Patient Service Center.

WHEN YOU ARE WITHOUT CELL PHONE COVERAGE

When the CardioNet monitor is not in its base station, it uses wireless telecommunications to communicate with the CardioNet Patient Service Center. If you are in an area without cell phone coverage and the monitor is unable to establish a connection with the Patient Service Center, the monitor stores the information it has collected and sends it later.



Monitor Cannot Establish Connection

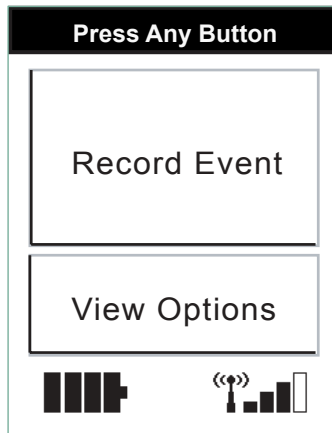
CHANGING MONITOR OPTIONS

Your CardioNet monitor lets you make adjustments to suit your needs. Adjustable features include:

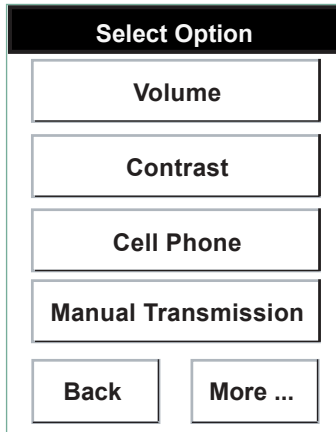
- Volume
- Contrast
- Cellular Power (on or off)
- Manual Transmission

Adjust Features

1. Make sure the monitor is on. The Main menu appears.



2. Touch **View Options**. The Options menu appears.



3. Choose any of the following options.

Volume adjusts the alarm tone to high, medium, low or vibrate. After making your selection, you'll hear the volume you have chosen. For Vibrate, you can feel the monitor vibrating.

Contrast adjusts the screen contrast to high, medium or low. After you make your selection the screen will adjust to the new brightness setting. You might find you need a different setting when you are outdoors rather than indoors.

Cell Phone turns the cell phone in the monitor OFF or ON. When the cell phone is off, the monitor is still recording heartbeats, but no data can be sent to the CardioNet Patient Service Center until the monitor is placed in the base.

Manual Transmission is currently not available.

Back returns to the Main menu.

More ... allows authorized technicians to check the monitor setup and modify landline dial parameters. See page 30 for more information.

4. After you make your selections, a screen will appear to ask you to confirm the selected option. Touch **Confirm**.

VERIFYING MONITOR SETUP

1. From the Options menu, touch **More ...** The Password menu appears.

Enter Password

1	2	3
4	5	6
7	8	9
*	0	#

Clear Enter

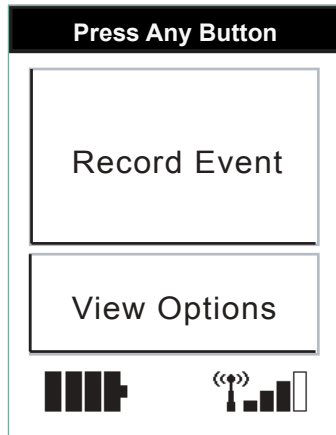
2. Enter the password. The options to verify the monitor setup appear. The following landline dial conditions can be modified.
 - Pulse dialing vs. Tone dialing
 - Dial prefix (For example, 9 to dial out, or *70 to disable call waiting.)

CHECKING MONITOR STATUS

By touching either the battery or the cell signal icon on the Main menu, you can easily view more information about both.

View the Battery Status

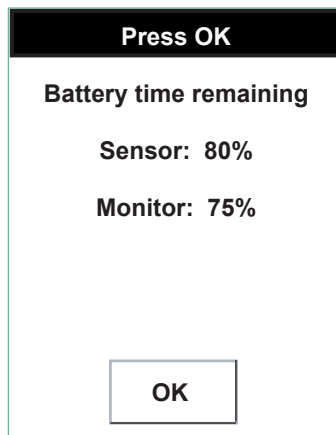
1. From the Main menu, touch the Battery icon.



Choose the Battery icon to check the power level of the monitor battery.

The monitor's rechargeable battery provides between 12 and 16 hours of use for every four hours of recharging. See [Setting Up](#) (Page 12) for more information.

2. The Battery Information menu appears.



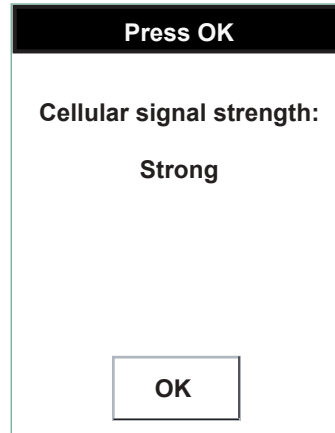
3. The screen tells you about sensor and monitor power levels. Touch **OK** to return to the Main menu.

VIEWING THE CELL SIGNAL STATUS

1. From the Main menu, touch the Cell Signal icon. The Signal Information menu appears.



Choose the Cell Signal icon to check the strength of the cellular signal in your current location.



2. This menu tells you how strong the cellular signal is in your current location.

When done, touch **OK** to return to the Main menu.

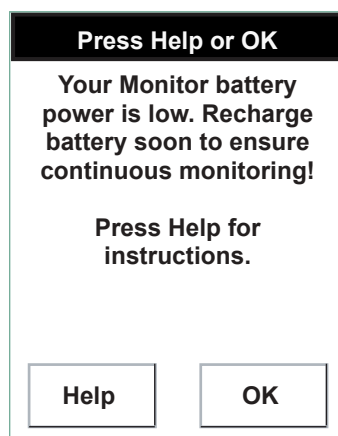
WARNINGS AND ALARMS

The monitor will beep to alert you when it is not able to function properly. The screen display will explain exactly how to respond.

Warnings are brief beeps. Alarms last longer and grow louder. Warnings can sometimes resolve themselves, but alarms always require action on your part. With alarms, you can immediately silence the audio tones by touching the **Silence** button on the touch screen. For both warnings and alarms you can also touch the **Help** button for more information on resolving the problem.

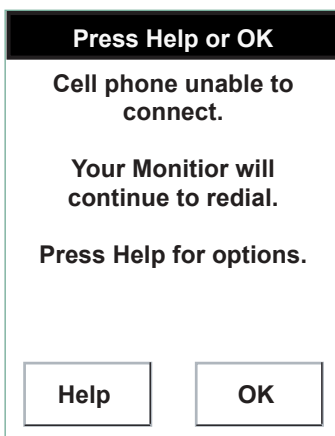
Below are examples of warnings and alarms.

See Trouble Shooting (Pages 44 - 58), for more information about warnings and alarms.

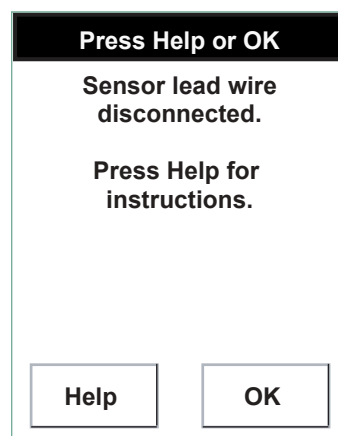


"Low Monitor Battery" Warning

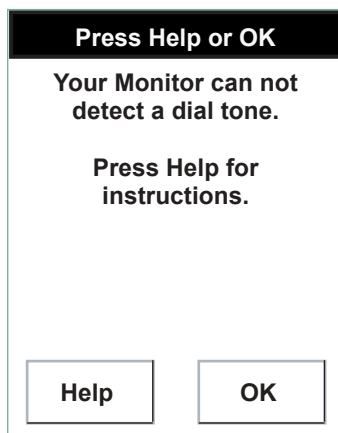
WARNINGS AND ALARMS CONTINUED



"Cannot Establish Phone Connection" Warning



"Sensor Lead Wire Disconnected" Warning



"No Dial Tone" Warning

4

S E N S O R C A R E

This section describes:

- Connecting the CardioNet Base
- Recharging the Battery
- Staying in Communications Range
- Wearing the Sensor

The CardioNet sensor is comfortable, easy to wear, and only requires a small amount of care. We recommend that you change the electrode pads every two days. When you shower or bathe you don't have to remove the electrode pads, but you must remove the sensor and electrode leads.

CHANGING ELECTRODE PADS

We recommend that you change your electrode pads every two days. Changing the electrode pads more frequently may cause irritation to the skin. Changing electrode pads less frequently may cause the electrode pads to wear down and weaken the heartbeat signal to the sensor.

Any time you change your electrode pads you should turn your monitor off first, using the **On/Off** button and the confirmation on the touch screen. This prevents the monitor from signaling an alarm because it cannot detect your heartbeats. Next, remove the sensor and old electrode pads. Then, apply new pads.

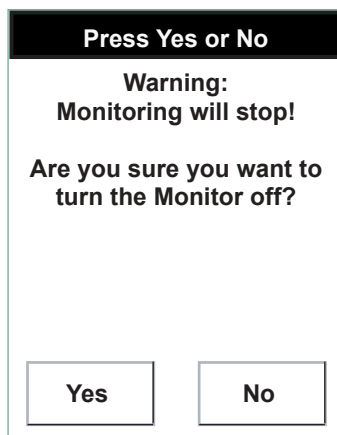
When you enrolled in the CardioNet System, you were shown the locations for the electrode pads that would provide the best possible measurements of changes in heart rhythms.

When you replace electrode pads, it is important to put the new electrode pads in the right spots. It is also very important to connect the right color lead to the right electrode – so the CardioNet monitoring center receives accurate heartbeat information.

Turn off the Monitor

1. If the screen is blank, touch it to wake up the monitor.
2. Press the **On/Off** button located on the front of the monitor.

A warning appears and asks if you really want to power down.



3. Touch **Yes** to confirm. A message briefly appears to let you know that the monitor is powering down. Wait for the monitor to completely power down. The touch screen will become blank.

Tip: If you need to change your electrode pads, it's best to do so after showering or bathing.

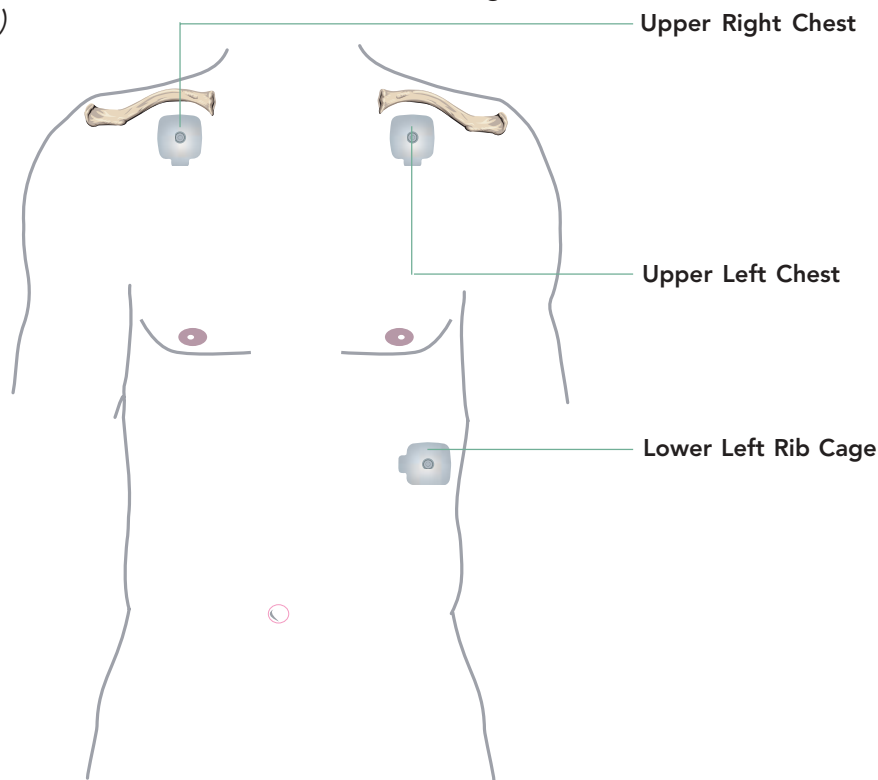
Remove Sensor and Pads

1. Unsnap the sensor leads from the electrodes.
2. Remove the electrode pads from your skin. Throw them away.

Apply the New Pad

1. Snap a new electrode pad onto the lead.
2. Peel off the paper in the back of the electrode pad.
3. Check the new electrode pad to make sure the gel on the back has not dried out. Electrodes with dried gel should be thrown away.
4. Apply pad to the same spot. If the skin is irritated, move the electrode to another location near the original site.

Place the new pads in the locations you were shown when you enrolled in the CardioNet System. If redness or irritation develops, you can choose another location near the original site. (See page 16.)



Placement for Pads

PLACING THE LEADS AND PADS

Remember that it is important to place the new electrode pads in the right spots, as close as possible to the original pad locations. It is also very important to connect the right color lead to each electrode – so the CardioNet Patient Service Center receives accurate heartbeat information.

White lead – snaps on an electrode pad placed just below the center of your right collarbone.

Black lead – snaps on an electrode pad placed just below the center of your left collarbone.

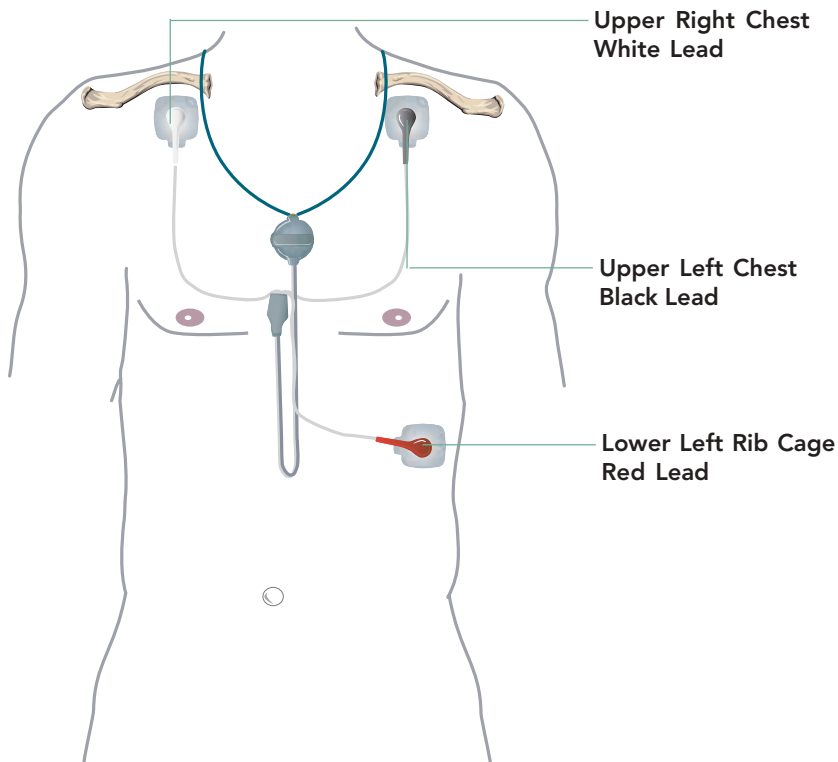
Red lead – snaps on an electrode pad placed just on your left side, on the lower part of your rib cage.



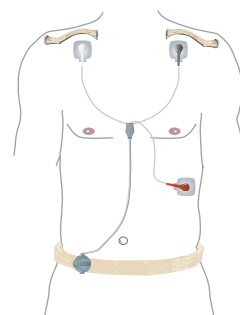
Electrode Pad



The sensor leads easily snap on and off the electrode pads.



Placement for Leads



When you're wearing the sensor on a belt clip, the sensor is upside down.

You can wear your electrode pads while showering or bathing. But be sure you remove the sensor and electrode leads. After showering, press the pads to the skin to assure tight surface contact.

SHOWERING OR BATHING

You'll need to remove your sensor and electrode leads before taking a bath or shower, but you can keep the electrode pads on.

Before removing the sensor, turn off the monitor. Remove the sensor and leads, but leave the pads in place.

To keep them from falling off, try to avoid getting the electrode pads soaked with water.

Gently wash the skin around the electrodes. After drying, press the pads to the skin.

Turn Off the Monitor

1. Press the **On/Off** button located on the front of the monitor. A warning appears and asks if you really want to power down.
2. Touch **Yes** to confirm. A message briefly appears to let you know that the monitor is powering down. Wait for the monitor to completely power down. The touch screen will become blank.

Remove the Sensor

1. Remove the sensor leads from the electrodes.
2. Leave the sensor electrode pads in place if you are not going to change them.
3. If you are going to change the pads, remove them and apply a new set after your shower or bath.

After showering

1. Press electrode pads worn during showering to the skin or apply new pads.
2. Reattach the sensor lead wires to the correct electrode pads.
3. Press the **On/Off** button to turn the monitor on and resume monitoring.

Call the CardioNet Patient Service Center's toll free number if you are getting low on replacement batteries. Call: (866) 426-4401

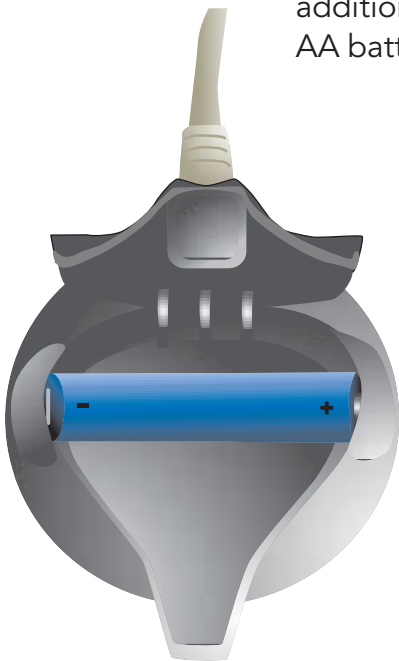
CHANGING THE BATTERY

The AA battery in the sensor must be replaced with a new, unused battery every 24 hours. We recommend you turn your monitor off before changing your sensor battery. This prevents the monitor from signaling an alarm because it cannot detect your heartbeats.

Replace the Battery

1. Pull open the battery door.
2. Remove the old battery and dispose of it in accordance with local regulations and EPA guidelines.
3. Put in a new AA battery, included in your CardioNet Service Kit. Insert the positive end as shown. The sensor chimes when the battery is correctly placed.
4. Close the cover.

If you are getting low on replacement batteries, contact the CardioNet Patient Service Center and ask for additional batteries. In an emergency, any available AA battery can be used with the CardioNet sensor.



Pull the top edge of the battery door to open it.

Insert the positive end as shown. The sensor chimes when the battery clicks in correctly. If there's no chime, you probably have the battery backwards.

5

T R O U B L E S H O O T I N G

This section describes:

- Responding to Warnings and Alarms
- Trouble Shooting
- Precautions and Cautions
- Cleaning
- Service

RESPONDING TO WARNINGS AND ALARMS

The monitor will beep to alert you when it is unable to function properly. The touch screen will explain what to do.

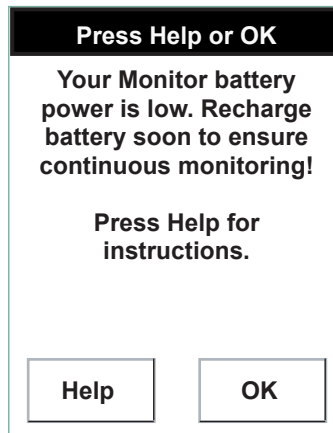
Warnings are brief beeps. Alarms last longer and grow louder. Warnings can sometimes fix themselves, but alarms always require action on your part. For alarms, you can immediately silence the audio tones by touching the **Silence** button on the touch screen. With both warnings and alarms you can also touch the **Help** button for more information.

The following examples of alarms and warnings show what appears on your screen and advise you on how to solve the problem.

LOW MONITOR BATTERY WARNING

Problem: Monitor battery is low.

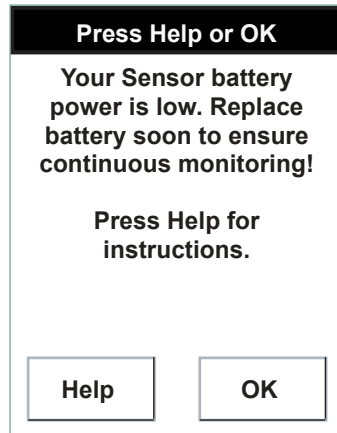
Solution: Return the monitor to the base for recharging.



LOW SENSOR BATTERY WARNING

Problem: Sensor battery is low.

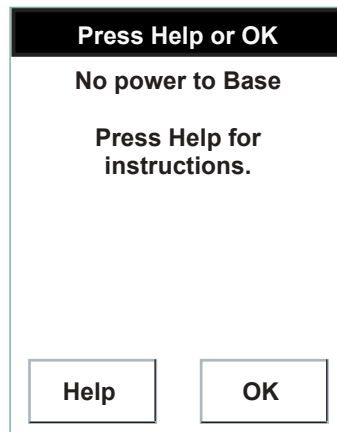
Solution: Install new battery. Or, if the battery is new, inspect battery compartment and clean contacts if necessary.



NO POWER IN BASE WARNING

Problem: Power cord is disconnected.

Solution: Reinsert the power cable into the base and into the wall outlet.

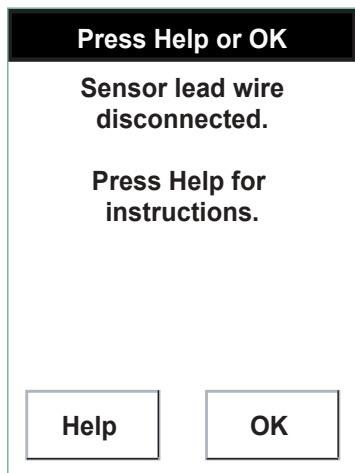


If the electrode pad loses contact or dries out you need to replace it immediately. The monitor detects when leads are disconnected and will alert you.

SENSOR LEAD WIRE DISCONNECTED WARNING

Problem: Either leads or pads are loose.

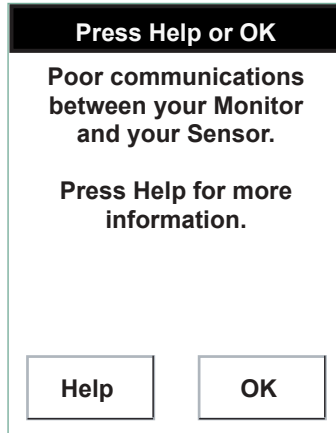
Solution: Make sure the electrode pads are pressed onto your skin. Check all the lead wire attachments.



POOR SENSOR COMMUNICATION WARNING

Problem: Sensor and monitor are having trouble communicating.

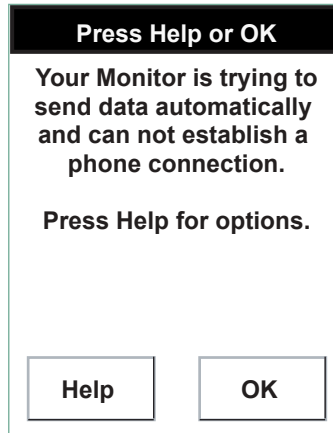
Solution: Move closer to your monitor or move the monitor closer to you. The monitor and sensor need to be in closer range to communicate.



SCHEDULED UPLOAD FAILED WARNING

Problem: Monitor needs to transmit data but can't establish a connection.

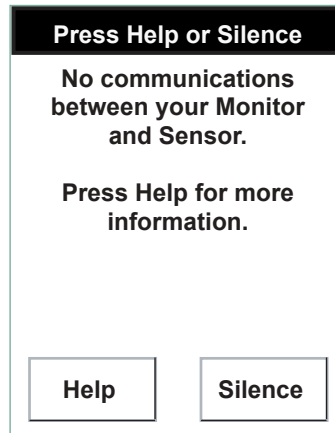
Solution: Put the monitor in the base.



POOR SENSOR COMMUNICATION ALARM

Problem: Sensor and monitor are not communicating.

Solution: Check for causes. Is there too much distance between them? Are there battery problems with either the sensor or monitor?

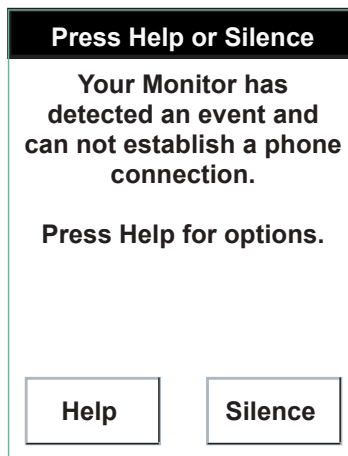


EVENT TRANSMISSION ALARM

Problem: Monitor has stored ECG data to transmit, but can't establish a connection.

Solution: Move to an area that has cellular coverage or put the monitor in the base. If you still are unable to establish a connection, call the CardioNet Patient Service Center for instructions.

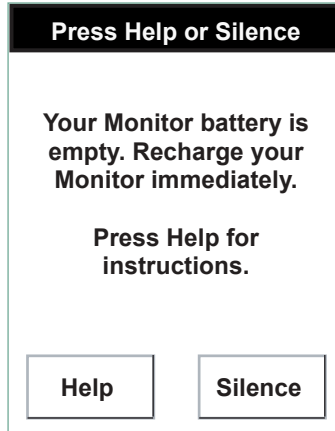
Telephone – (866) 426-4401.



EMPTY MONITOR BATTERY ALARM

Problem: Monitor is out of power.

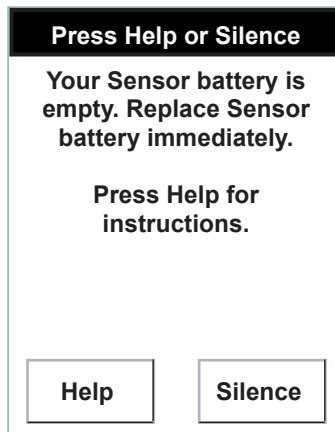
Solution: Place the monitor in the base.



EMPTY SENSOR BATTERY ALARM

Problem: Sensor battery is out of power.

Solution: Install a new AA battery.

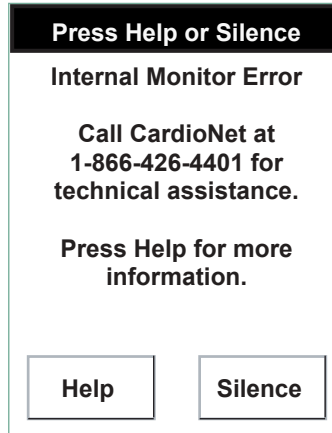


INTERNAL MONITOR ALARM

Problem: Monitor is not functioning.

Solution: Call the CardioNet Patient Service Center for help.

Telephone – (866) 426-4401.



TROUBLE SHOOTING

Trouble shooting sometimes involves a bit of detective work, but usually the monitor detects problems for you. The monitor beeps to let you know there is a problem and explains on the touch screen exactly how to respond on the touch screen.

A warning prompts you to resolve a problem by displaying an alert screen and beeping an audio tone. With some warnings the problem can fix itself and you won't need to take any action. With other warnings you will need to take some action, which will be described on the touch screen. An alarm lets you know that a problem has not been fixed and you must take action.

MONITOR BATTERY PROBLEMS

Ensure battery is being recharged for at least four hours per day. If you find the monitor is not holding its charge long enough, you may not have left it in the base long enough to fully recharge. The monitor must be left in its base for four hours to fully recharge.

NO DISPLAY ON MONITOR

First, ensure the monitor is turned on. If it is on, the LED will be flashing and the monitor may be low on power. Return monitor to base for recharging.

BEEPS IN BED

If you wear the sensor around your neck and sleep on your stomach, or if you wear it at your waist and sleep with your sensor side down, you may block communications between the sensor and the base station. This will cause warning beeps. To avoid beeps and maintain the vital communications link, try placing the sensor next to your pillow if you usually sleep on your stomach. If you normally sleep on your side and wear the sensor with a belt clip, make sure you place the sensor on your "up" side.

PHONE BUSY?

When the monitor is in the base station and has information to send to the CardioNet Patient Service Center, it will use your telephone line to transmit ECG data. You will not be charged by the telephone company for these calls. 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 ECG data being transmitted.

If you are expecting a critically important call, or need to place an urgent call while the monitor is transmitting data, you can temporarily remove the monitor from the base. It will either use wireless communications to transmit data to the CardioNet Center or use your telephone line to transmit the data once it is replaced in its base. Please remember to put the monitor back in the base station after you receive or place the telephone call. You should not interrupt an ECG transmission for routine calls. The data that your monitor is sending might need immediate review and response.

SKIN IRRITATION

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. Some people are especially sensitive to different gels and adhesives. You may need to use another type of electrode pad.

SENSOR BELT CLIP 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.

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. Damage from corrosion could result.

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.

THE CARDIONET SYSTEM 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:

- Keep a distance of at least six inches (15 cm) between the cellular phone and a pacemaker or defibrillator.
- 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.

CAUTIONS

CAUTION: POWER DOWN AND REMOVE SENSOR BEFORE SHOWERING

Power down the monitor and remove the sensor before showering. While the CardioNet sensor and monitor are water resistant, they are not waterproof. Refer to the section: Care for the Sensor (Page 35) for complete instruction on removal and reapplication before showering.

CAUTION: DO NOT GET THE MONITOR AND SENSOR WET

Make sure the monitor and sensor stay dry at all times.

WARNING: FOR ADULT USE ONLY

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

WARNING: 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.

WARNING: NOT AN APNEA MONITOR

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

WARNING: USE ONLY CARDIONET ELECTRODES

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

WARNING: DO NOT TAMPER

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

WARNING: 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.

WARNING: USE ONLY CARDIONET WALL ADAPTER

Do not use any wall adapter for the base other than the one provided in the CardioNet Service Kit.

WARNING: DO NOT CONNECT ANY DEVICE TO THE PC PORT ON THE BACK OF THE BASE

The PC port is to be used only by CardioNet personnel.

WARNING: DO NOT USE NEAR FLAMMABLE ANESTHETIC

The CardioNet System is not to be used in the presence of flammable anesthetic.

CLEANING

Clean the plastic case of the monitor and the sensor with a soft cloth dampened with soapy water. Wipe the external surfaces of the sensor, monitor and base.

Do NOT use soapy water on the touch screen. Clean the screen of the monitor with the screen cloth or cleaning tissues provided with the patient monitoring kit.

Do not spray or submerge any component with liquid or foam. Each component should be wiped with a soft damp cloth after cleaning to ensure no fluid has pooled on external surfaces.

SERVICE

If you experience additional problems with any components of the CardioNet Monitoring System, review the problems and solutions listed in the trouble shooting section. If additional assistance is required contact customer support.

Telephone: (866) 426-4401.

Before returning the CardioNet Monitoring System, call customer service to make shipping arrangements.

6

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

This section describes:

- Specifications
- Symbols
- Hardware Requirements
- FCC Compliance

SPECIFICATIONS

PHYSICAL

SENSOR

2.7 in. x 0.9 in height

Weight: 2.2 oz

SENSOR NECK STRAP

24 in.

MONITOR

5.8 in x 3.0 in x 1.1 in

Weight: 12.8 oz

LCD

3.0 x 2.3, touch screen, monochrome, backlight

BASE

7.8 in x 4.3 in x 6.1 in

Weight: 13.3 oz

FUNCTIONAL

Sample Rate 250 samples per second

Resolution 12 bits

Dynamic Range + / -5 mV

Bandwidth 0.5 to 40 Hz

Channels 2

Battery Life Monitor: (12-16 hours average with cleared memory and fully recharged battery), rechargeable

Sensor: (24 hr) AA Alkaline

Leakage current Less than .1 μ V Electrodes

TRANSMISSION

Sensor to Monitor	900 MHz ISM band RF transmission, digital error corrected. 30 foot range, retransmission if data is corrupted.
Monitor to Center	CDMA (PCS & cellular) wireless, digital error corrected. Telephone line modem, digital error corrected. Acoustic transmission, 1500 Hz center frequency, 8 bits resolution, 5 mV dynamic range. ECG recording intervals vary by type of event; the minimum is 15 seconds pre-event and 45 seconds post event. Wireless transmission subject to coverage of cellular network. Data received at Monitoring Center within minutes with good wireless coverage and/or modem communications. Urgent reports processed at time of data receipt. Daily reports processed once a day, by 3 PM.

OPERATING CONDITIONS

Operating temperature	20 - 45 °C
Operating humidity	10% - 95%, noncondensing
Storage temperature	-20 - 55 °C, noncondensing
Storage humidity	5% - 95%, noncondensing
Operation altitude	700-1060 millibars
Fluid Ingress Rating	IPX1

Note: Please protect the monitor and sensor from water and other fluids.

CONNECTORS

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

WALL ADAPTER

Manufacturer	Friwo, Inc. (15V, 1.0A)
Model number	FW7555M/15

Note: Both the Monitor and Sensor are internally powered continuous operation devices.




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	Class II

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

	Consult Manual
	Year of Manufacture
	Type BF Equipment
SN	Serial Number

HARDWARE REQUIREMENTS

IN HOME REQUIREMENTS

Touch tone or pulse telephone or good wireless coverage
AC powered electrical outlet with 120 VAC

FCC ID

Sensor	QBI-1007
Monitor	Monitor QBI-1006
Monitor	CDMA N7NSB555
Base	CARDT00B42061

FCC AND INDUSTRY CANADA (CS-03) 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 RULES PART 15

The Model 1001 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

FCC Part 68 Registration

The Model 1001 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 1001 is 0.01 B. 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.
510 Market St.
San Diego, CA 92101
619-243-7500

The telephone company can ask you to disconnect the equipment from the network until the problem is corrected or until you are sure that the equipment is not malfunctioning.

The Model 1001 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 1001 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 with the softcase supplied by CardioNet as an accessory to this device and was found to comply with the FCC exposure requirements.

When operating this device, a minimum separation distance of 1.5 cm must be maintained between the users body and the monitor, including its antenna, to comply with the FCC exposure limits.

To maintain compliance with FCC RF exposure requirement, use only carrying accessories that maintain a 1.5 cm separation distance between the user's body and the device, including the antenna. These carrying accessories should not contain metallic components in its assembly. The use of carrying accessories that do not satisfy these requirements may not comply with FCC RF exposure requirements, and should be avoided.

This particular device has not been designed for held-to-ear use and should never be used against the ear.

For more information about RF exposure, please visit the FCC website at www.fcc.gov.

**CardioNet Ambulatory ECG System
and Arrhythmia Detector**

**Manufactured by CardioNet Inc.
510 Market Street
San Diego, CA 92101**

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