Troubleshooting

Problem	Possible Solutions
Monitor battery power drains quickly	Ensure battery is being fully recharged every day. A full recharge takes approximately 4 hours and will last 16 hours. 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 screen is blank	It could be that the monitor is not turned on. 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.

PRECAUTIONS

DISPOSE OF BATTERIES PROPERLY

Observe all local laws for the disposal of alkaline batteries.

WHEN NOT IN USE, REMOVE SENSOR BATTERY

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

AVOID ELECTROMAGNETIC INTERFERENCE

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

POTENTIAL FOR ELECTROMAGNETIC INTERFERENCE

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

USE WITH IMPLANTED PACEMAKERS AND ICDs (DEFIBRILLATORS)

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

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

CAUTIONS

POWER DOWN Monitor AND SENSOR BEFORE SHOWERING

Power down the monitor and remove the sensor before showering. The CardioNet sensor and monitor are water resistant, not waterproof.

DO NOT GET THE Monitor AND SENSOR WET

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

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

WARNINGS

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.

6 SPECIFICATIONS, COMPLIANCE & SYMBOLS

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.

FUNCTIONAL	
Sample Rate	250 samples per second
Resolution	12 bits
Dynamic range	+/- 5 mV
Bandwidth	0.1 to 40 Hz
Channels	2
Battery Life: Monitor	Up to 16 hrs (with cleared memory & fully recharged battery)
Battery Life: Sensor	24 hrs (1 AA Alkaline)
Leakage Current	Less than .1 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	Type I

Note: This equipment has been tested and found to comply with the limits for medical devices to the IEC 601-1-2:1993, EN60601-1-2:1994, Medical Device Directive 93/42/EEC or the Electromagnetic Compatibility Directive 89/336/EEC (use applicable directive). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device
- Increase the separation between the equipment
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected
- Consult the manufacturer or field service technician for help

Equipment Symbols

BF Type Equipment

Consult Users Manual / Patient Education Guide

SN

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

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

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.