



PHYSICIAN'S
INSERVICE
MANUAL
Model CN1006
(C5)

CONTACT INFORMATION

CardioNet Monitoring Center

Tel. 866-727-3397

- For all clinical issues
- To extend or discontinue monitoring service
- For “fetch requests” for additional ECG data

Main Business Number

Tel. 866-426-4404

- For non-clinical issues

Physician Relations Hotline

Tel. 800-242-3980

- Assistance with physician reimbursement for interpretation of MCOT

To Fax in a Prescription

- Use the number printed at the top of the Patient Prescription/Order Forms provided to your practice. Additional forms are also available from your CardioNet Account Executive.

Caution: Federal law restricts this device to sale or use by or on the order of a physician or other authorized health practitioner.

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– 220-0083-01 - Revision A

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CARDIONET: MOBILE CARDIAC OUTPATIENT TELEMETRY

CardioNet developed and introduced a new, integrated technology and service – Mobile Cardiac Outpatient Telemetry – which allows heartbeat-by-heartbeat ECG monitoring, analysis and response, at home or away, 24/7/365.



Heartbeat By
Heartbeat
Surveillance



At Home or Away
Event Detection and
Transmission



24/7/365
CardioNet Analysis
Response, Reporting



MD Telemetry Reports
by Internet, Fax

CardioNet's Mobile Cardiac Outpatient Telemetry (MCOT) assists physicians in the diagnosis and management of difficult-to-diagnose arrhythmias. Given the infrequent and asymptomatic nature of some arrhythmias, it is often challenging to capture an event with conventional monitoring technology, such as Holter and cardiac event monitoring.

The CardioNet System detects and transmits both symptomatic and asymptomatic arrhythmias, based on monitoring parameters defined by the prescribing physician. Patients are not required to sense or transmit events. However, if patients feel symptoms they can use the touch screen on the CardioNet monitor to enter their symptoms and activity level, which are transmitted to the CardioNet Monitoring Center along with their ECG. The physician receives a daily telemetry report containing a representative ECG strip of the events detected; a time and date stamp of the event, including any reported symptoms and activity.

The CardioNet device retains up to 720 hours of ECG data on each patient, allowing physicians to request additional data through "fetch" requests to the CardioNet Monitoring Center.

CardioNet MCOT offers physicians a powerful new diagnostic and patient management tool for a wide range of monitoring indications.

TECHNOLOGY OVERVIEW

CardioNet integrates patient monitoring, wireless communications technology, and the Internet to allow cardiac rhythm related problems to be quickly identified, quantified, and treated.

The CardioNet System is comprised of a sensor with three leadwires, a monitor, and base. The lightweight sensor (invisible under clothing) is worn by the patient. It continuously records and analyses two channels of ECG and transmits the ECG by a radio frequency (RF) link to the monitor.

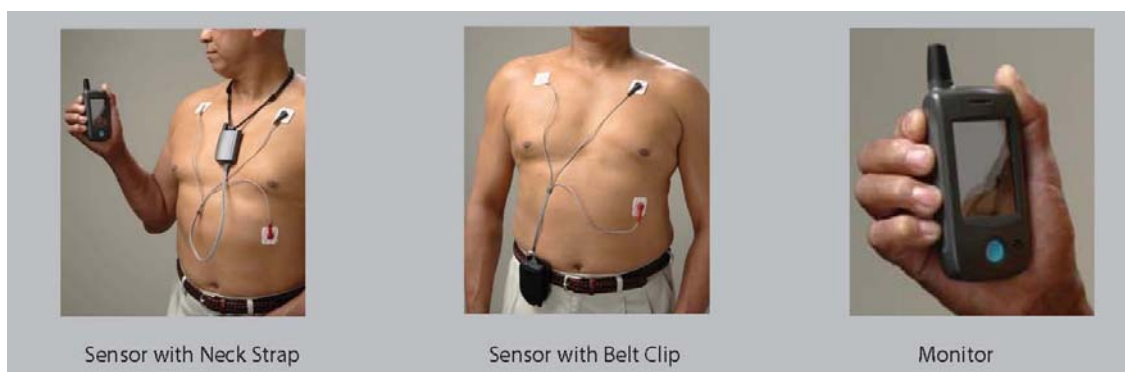
The monitor is approximately the size of a PDA device. It has a powerful microprocessor, extensive memory, embedded algorithm, LCD display, and wireless modem. The monitor is powered by a rechargeable lithium battery, which powers the monitor for at least 10 hours.

The C5 monitor's microprocessor is programmed with an algorithm that identifies arrhythmias according to parameters selected by the prescribing physician. The standard algorithm detection parameters and physician notification criteria established by CardioNet's Medical Advisory Board can be individualized for each patient, practice and physician.

The sensor continuously acquires the patient's ECG in real time, and regularly transmits this information to the monitor. When an abnormal rhythm has been identified or when the patient enters a symptom, the data is transmitted to the CardioNet Monitoring Center for review, interpretation and response by a certified monitoring specialist.

When the patient is at home and base is in use, the patient's telephone line may be used to transmit the data. Cellular communication is the primary means used to transmit events. If an event occurs when the patient is in an area where cellular coverage is inadequate, the monitor stores the data and transmits the event when the patient has moved into an area with cellular coverage – or uses regular telephone lines to transmit the event once the monitor can communicate with the base.

The CardioNet C5 Monitor stores a minimum of 30 days of the patient's ECG data. Physicians can request that CardioNet “fetch” additional data, beyond that contained in the Telemetry Reports, by contacting the CardioNet Monitoring Center.



Sensor with Neck Strap

Sensor with Belt Clip

Monitor

SERVICE OVERVIEW

First, the prescribing physician is registered in the CardioNet service. All applicable contact and demographic data is collected and entered into the CardioNet Patient Enrollment and Management System (PEMS) by a CardioNet representative. When a physician identifies a patient who is appropriate for CardioNet services, the practice faxes a Patient Prescription/Order form to CardioNet along with the patient insurance information.

Important Information: Urgent Events

CardioNet is not an emergency response service. If patients experience symptoms that concern them, they should seek medical help.

In the course of monitoring a patient's heart, CardioNet may detect cardiac events which are potentially life-threatening and which were not anticipated by the patient's physician. As directed in the Physician Notification Criteria, CardioNet will attempt to contact the physician and patient if ordered.

CardioNet's ability to obtain information regarding a cardiac event and to contact a patient or his/her 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 the patient or his/her physician
- If a patient or physician is not accessible by telephone, CardioNet will not succeed in making contact with them

When CardioNet does detect a potentially serious cardiac event as defined by the patient's physician, we will attempt to contact the patient's physician for direction. CardioNet will also attempt to contact the patient and inform him/her of a cardiac event that has been received that requires evaluation in the emergency room, per the physician's notification criteria. The patient may decide to seek medical help by calling EMS directly or the patient may ask that CardioNet assist them in contacting EMS.

In all cases, due to the limitations of the CardioNet service as described above, patients should not delay seeking medical help if they experience symptoms that concern them and are so instructed in the Patient Education Guide. Also, patients are instructed in the Patient Education Guide not to rely on CardioNet as an emergency response service.

PHYSICIAN REPORTS

Three types of reports may be issued to physicians during monitoring:

- Daily Telemetry Reports: sent every 24 hours for all patients, which contains sample strips of arrhythmias detected and patient-reported symptoms, heart rate and AF frequency and duration data.
- Urgent Reports: issued when an event occurs that the physician has defined as urgent.
- Summary Reports: Provides a summary of all billable days of service.

Physician reports are available by fax or through PEMS, CardioNet's Internet-based patient management system. For information or in-service on PEMS, please contact your CardioNet Account Representative.

The CardioNet Monitoring Center is staffed with highly qualified and experienced cardiac monitoring specialists. At a minimum, all monitoring specialists are CCT certified. They have experience in cardiovascular monitoring, hospital based C.C.U. and I.C.U. telemetry, and/ or emergency medical services.

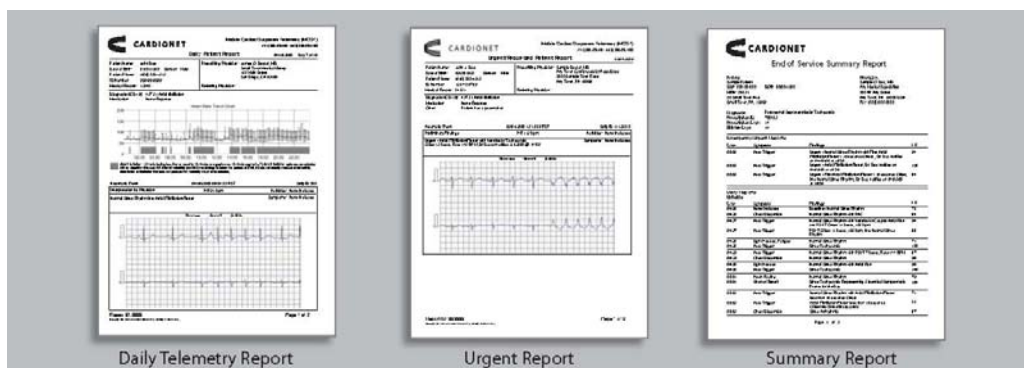
As a Medicare provider, CardioNet is licensed as an Independent Diagnostic Testing Facility (IDTF).

The CardioNet monitoring specialists serve a vital role in continuously analyzing and responding to arrhythmic events. The monitoring specialists provide a thorough preliminary analysis of the patient's ECG to insure that the initial interpretation is accurate and presented in the appropriate time and manner as requested by the physician.

Calls may be monitored and recorded for quality assurance. CardioNet requires that all monitoring specialists participate in additional training and educational programs. A continuous QA process with independent oversight has been established for all facets of the service center operation.

The monitoring specialists, based on defined physician guidelines, prepare Daily Telemetry Reports for final physician review and interpretation.

The CardioNet Monitoring Center continuously analyzes events, responds appropriately, and issues telemetry reports 24/7/365.



PRESCRIBING CARDIONET

Prescribing CardioNet monitoring for a patient is easy, once your practice has been enrolled in our service. Simply fill out a CardioNet Patient Prescription/Order Form, (provided to your practice when it was enrolled) sign it and fax it to the number listed on the top of the form. Also fax one of the following:

- A copy of the front and back of the patient's insurance cards or
- The CardioNet Patient Enrollment form or
- The patient's fact sheet

The practice will receive a faxed confirmation that the referral has been received.

CARDIONET AMBULATORY ECG MONITOR WITH ARRHYTHMIA DETECTOR

Indications for Use:

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

1. Patients who have a demonstrated need for cardiac monitoring. These may include but are not limited to patients who require Monitoring for: a) non-life threatening arrhythmias such as supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, PACs, PSVT) and ventricular ectopy; b) evaluation of bradyarrhythmias and intermittent bundle branch block, including after cardiovascular surgery and myocardial infarction; and c) arrhythmias associated with co-morbid conditions such as hyperthyroidism or chronic lung disease.
2. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; c) dyspnea (shortness of breath).
3. Patients with palpitations with or without known arrhythmias to obtain correlation of rhythm with symptoms.
4. Patients who require outpatient monitoring of antiarrhythmic therapy: a) Monitoring of therapeutic and potential proarrhythmic effects of membrane active drugs, b) Monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation).
5. Patients recovering from cardiac surgery who are indicated for outpatient arrhythmia Monitoring
6. Patients with diagnosed sleep disordered breathing including sleep apnea (obstructive, central) to evaluate possible nocturnal arrhythmias
7. Patients requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation or atrial flutter.
8. Patients requiring measurement, analysis and reporting of QT interval, excluding patients with a documented history of sustained atrial fibrillation or atrial flutter.
9. Patients who require monitoring for potential arrhythmias based on risk factors (e.g. atrial fibrillation).

10. Patients requiring measurement of ST segment changes. The device is not intended to sound any alarms for ST segment changes.
11. The device is intended to identify Cyclic Variation of Heart Rate (CVHR) pattern to evaluate need of further testing for sleep disorders

FOR USE ON ALL PATIENTS

The CardioNet MCOT system is intended for use on adults, children and infants weighing less than 22 pounds.

Contraindications for use:

1. Patients with potentially life-threatening arrhythmias who require inpatient Monitoring.
2. Patients who the attending physician recommends should be hospitalized for ECG monitoring.
3. This device should not be used for monitoring of QT interval during the initiation of antiarrhythmic therapy, where in-hospital monitoring is required by the labeling of that drug.
4. The device does not replace the QT interval measurement by a trained observer using diagnostic 12 lead ECG in a clinical environment. This device is not intended to sound any alarms for QT interval changes.
5. The device does not annotate QT interval for QRS durations >160 ms or for T wave amplitudes $\leq 5\%$ of the peak QRS amplitude.

TECHNICAL SPECIFICATIONS

The technical specifications are subject to change.

PHYSICAL	
Sensor	3 inches x 1.9 inches x 0.7 inch; Weight: 3.0 oz. with battery
Monitor	4.7 inches x 2.6 inches x 0.9 inch; Weight: 6 oz.
LCD	2.27 inches x 1.7 inches; Touch screen: color
Base	4.3 inches x 3.7 inches x 1.0 inches; Weight: 6.0 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	Minimum 10 hrs (with cleared memory & fully recharged battery)
Battery Life: Sensor	24 hrs (1 AAA Alkaline)
Leakage Current	Less than .1 μ A Electrodes

TRANSMISSION	
Sensor to Monitor	900 MHz ISM band RF transmission, digital error corrected. 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. CDMA (PCS & cellular) wireless, digital error corrected. Telephone line modem, digital error corrected. 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 is received at Monitoring Center within minutes with good wireless coverage and/or modem communications.

OPERATING CONDITIONS	
Operating Temperature	Sensor: 20 - 45°C; Monitor ; 0 - 45°C
Operating Humidity	10% - 95% non-condensing
Storage Temperature	-20 - 65°C non-condensing
Storage Humidity	5% - 95% non-condensing
Operation Altitude	700 - 1060 millibars

TECHNICAL SPECIFICATIONS

CONNECTIONS	
Base	Power in (15V, 1.2A max); Phone in (RJ-11); Phone out (RJ-11)
Monitor	Power in (15V, 1.2A max)
Wall Adaptor	Power in (100-240 VAC); Power out (15V, 1A or 15V, 1.67A)

STANDARDS COMPLIANCE	
Monitor	EN60601-1; AAMI EC-38; FCC Part 15
Sensor	EN60601-1; AAMI EC-38; FCC Part 15
Base	EN60950; FCC Part 15, 68
AECG Equipment	Type I
<p>Note: This equipment has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:2001, Medical Device Directive 93/42/EEC or the Electromagnetic Compatibility Directive 89/336/EEC (use applicable directive). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: • Reorient or relocate the receiving device • Increase the separation between the equipment • Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected • Consult the manufacturer or field service technician for help</p>	

EQUIPMENT SYMBOLS



BF Type Equipment



Consult Users Manual/
Patient Education Guide

SN

Serial Number



Non-Ionizing
Radiation Transmitter

IN-HOME REQUIREMENTS

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

FCC COMPLIANCE

FCC ID	
Sensor ISM	QBI-1011
Monitor ISM	QBI-1012
Monitor Cell Modem	RI7CC864-DVAL
Base	QBI-1013

ARRHYTHMIA DETECTION ALGORITHM PERFORMANCE ANALYSIS

The CardioNet C5 System incorporates an arrhythmia analysis algorithm whose performance is presented below:

The algorithm results were obtained from the respective databases in strict accordance with EC-57 and with 0% downtime on both databases.

Performance Measure	MIT Arrhythmia Database	AHA Database
Average QRS Detection Sensitivity %	99.96	99.74
Average QRS Detection Positive Predictivity %	99.83	99.83

The CardioNet C5 system does perform analysis of ST Segment changes. The ST Segment analysis is done on all leads without any signal scaling or gain adjustment. There are no operator selectable detection criteria for ST segment shifts.

The ST algorithm has been tested for accuracy of the ST segment data. The significance of the ST segment changes need to be determined by a physician.

HEART RATE MEASUREMENT REPORT

The performance of the analysis algorithm for heart rate detection on standard databases is shown below. The average RMS errors for the AHA, MIT-arrhythmia, and NST databases are 1.23%, 1.08%, and 15.84% respectively for the C5 product (model CN1006).

Sustained heart rate (SHR) is inversely proportional to the RR interval averaged over 10 seconds or 12 consecutive beats, whichever is shorter. The Heart Rate Trend Graph shows SHR and its minimum and maximum values during that interval.

FCC RULES PART 68

FCC Part 68 Registration

The Model CN1006 complies with FCC Rules, Part 68. On this equipment is a label that

contains, among other information, the FCC Part 68 registration number.

REN

The ringer equivalence number (REN) is used to determine the quality of devices that may be connected to the telephone line. Excessive RENs on the telephone line may result in the devices not ringing in response to an incoming call. In most, but not all areas, the sum of RENs should not exceed five (5.0). To be certain of the number of devices that may be connected to a line, as determined by the total RENs, contact the local telephone company.

Note: RENs are associated with loop-start and ground-start ports. It is not used for E&M and digital ports. The REN assigned to the Model CN1006 is 0.0B. If requested, this information must be given to the telephone company.

SERVICE

In the event of equipment malfunction, all repairs should be performed by CardioNet Inc. or an authorized agent. It is the responsibility of users requiring service to report the need for service to CardioNet Inc. or to one of our authorized agents. Service can be facilitated through our office at:

CardioNet Inc.
1010 Second Avenue, Suite 700
San Diego, CA 92101
619-243-7500

The Model CN1006 interface connects to the Public Switched Telephone Network through a FCC registered NCTE which specifies the type of network jack to be used.

DISRUPTION OF THE NETWORK

If the Model CN1006 disrupts the telephone network, the telephone company can discontinue the service temporarily.

Telephone Company Facility Changes

The telephone company can make changes in its facilities, equipment, operations, or procedures that can affect the operation of equipment.

FCC RADIO FREQUENCY EXPOSURE INFORMATION

In August 1996, the Federal Communication 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 passed SAR (Specific Absorption Rate) testing.

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

PACEMAKER DETECTION RESULTS

Pacemaker detection: Meets AAMI EC38

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 RULES PART 15

The Model CN1006 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.

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, 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 of CardioNet system with implanted pacemakers and ICDs (defibrillators)

If the patient has an implanted pacemaker or defibrillator (ICD), the manufacturer may have recommended certain precautions when using a cellular phone. Since the CardioNet monitor contains a cellular phone, the patient 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.
- Refer to the manufacturer's information for guidance regarding your pacemaker or ICD and possible interference issues.

CAUTIONS AND WARNINGS

Caution: Power Down Monitor 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 Patient Education Guide 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.

Caution:

CardioNet's ability to obtain information regarding a cardiac event and to contact a patient or his/her 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 the patient or his/her physician.
- If a patient or physician is not accessible by telephone, CardioNet will not succeed in making contact with them.

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. Refer to the Patient Education Guide for complete instruction on skin preparation, electrode placement, and removal.

Warning: Do Not Tamper

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

Warning: Not an Emergency Response Service

CardioNet is not an emergency response service. If a patient experiences symptoms that concern the patient, they should seek medical help.

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 80°C (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.