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## CONTACT INFORMATION

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(866) 426-4404

Patient Service Center (866) 727-3397 Physician Notification  
(866) 426-4401 Patient Inquiries

Enrollment (866) 426-4403 Fax

Billing (866) 426-4402

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

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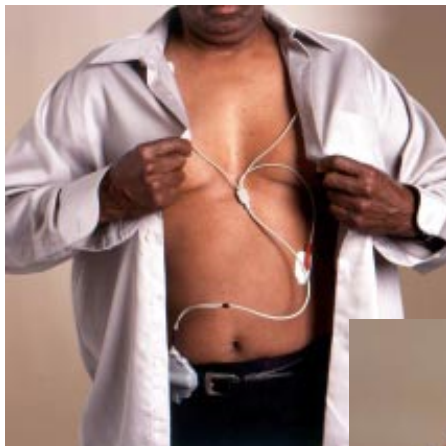
## INTRODUCTION

### CardioNet: Mobile Cardiac Outpatient Telemetry

CardioNet has developed 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.

CardioNet's Mobile Cardiac Outpatient Telemetry 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 actual arrhythmia with conventional monitoring technology, such as Holter and cardiac event monitoring.

With the CardioNet System, we are able to automatically detect and capture asymptomatic and symptomatic arrhythmias, based on monitoring parameters defined by the prescribing physician. In addition, the patient can utilize the touch screen on the CardioNet

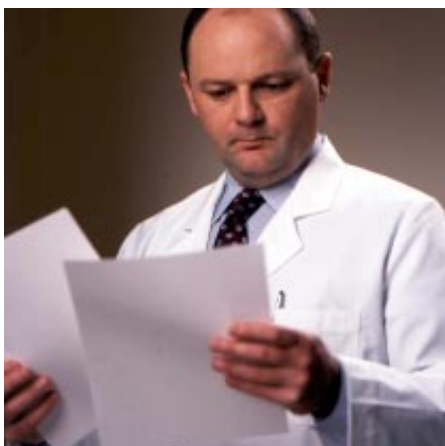


**Patient Monitored  
24/7/365**

monitor to enter their symptoms and activity level at the time of a documented event. The physician then receives a representative ECG strip of the event; a time and date stamp of the actual event, including symptoms and activity, and is therefore able to make a more informed and accurate diagnosis.



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



**Physician Receives  
CardioNet Report**

**Patient Enters Symptoms  
and Activities**

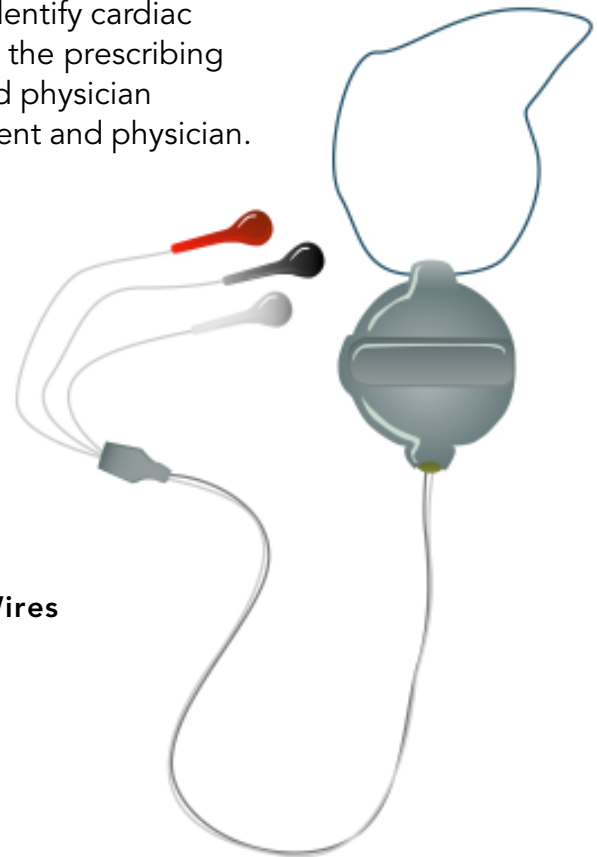
## PRODUCT DESCRIPTION

CardioNet merges patient monitoring, wireless communications, and the Internet to allow targeted cardiac rhythm related problems to be identified, quantified, and communicated to the prescribing physician in a timely and efficient manner.

The CardioNet System is comprised of a sensor, monitor, and base. The lightweight sensor is worn by the patient on a lanyard or belt clip, it continuously records two channels of ECG, and transmits the ECG by a radio frequency (RF) link to the monitor. The sensor is powered by a disposable alkaline battery, which typically lasts 24-36 hours. While using the sensor, the patient is required to wear (3) disposable electrodes to record their ECG.

The monitor is approximately the size of a PDA device. It has a powerful microprocessor, extensive memory, imbedded algorithm, LCD display, wireless modem, and a global positioning system (GPS). The monitor is powered by a rechargeable lithium battery, which typically lasts 18 hours.

The monitor's microprocessor is programmed to identify cardiac rhythm problems within guidelines established by the prescribing physician. The algorithm detection parameters and physician notification criteria are individualized for each patient and physician.



**Sensor with Lead Wires**



### CardioNet Monitor in Base

The monitor continuously analyzes the ECG in real time as it is transmitted from the sensor. When an abnormal rhythm has been identified based on the monitoring parameters, the data is automatically sent via a wireless modem to the CardioNet Patient Service Center for additional review and interpretation by a certified monitoring specialist.

In the case of a patient-initiated event, the monitor automatically prompts the patient to enter their symptoms and activities from a predetermined list on the touch screen display.

When the patient is at home and an event occurs while the monitor is in the base, the patient's normal telephone line is used to transmit the data. If an event occurs when the patient is in an area where cellular coverage is inadequate, the patient may elect to transmit their ECG directly, using a regular telephone.

The base utilizes an AC power supply and is connected to the patient's telephone line. The base also consists of two antennas, which allows the patient to have an expanded RF range within their home. When the patient is mobile, the RF range or leash length between the monitor and sensor is estimated to be 25-50 feet. The sensor and monitor are designed to alert the patient if and when they are out of RF range or cellular coverage.

The CardioNet monitor has sufficient memory to store a minimum of twenty-four hours of the patient's ECG. A daily protocol exists to upload the patient's 24-hour ECG data, including related events and trends from the monitor to the Patient Service Center.

## SERVICE OVERVIEW

First, the prescribing physician is registered in the CardioNet service. All applicable contact and demographic data is collected and inputted 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, a patient enrollment is initiated by his/her office, included is patient demographics, insurance information, indications for usage, duration, thresholds, and medical necessity where applicable. Upon completion, the enrollment form is submitted to the Patient Service Center – either by fax or Internet.

For non Medicare patients, the physician practice may utilize the CPT code 93799-26 when billing for the professional interpretation, including the narrative description “ECG arrhythmia detection and alarm system.” An individual payor may establish or recommend alternative codes to be used to reflect the professional interpretation for CardioNet related services. The physician practice may wish to contact their provider representative to establish the appropriate billing requirements for CardioNet.

Additionally, if you are currently required by the payor to provide a referral through the payor system you should continue to follow that procedure. Also if you are required to contact the payor for pre-authorization/authorization to provide professional interpretation for diagnostic services continue to do so, this will also apply to CardioNet. When speaking to a payor or claims representative, it is important to note that CardioNet is not a Holter or event monitor. CardioNet mobile telemetry is a unique, proprietary technology and service offering, and is not the equivalent of any other monitoring technology or service.

CardioNet will provide an in-home patient educator to train the patient on the use of the CardioNet System. CardioNet has a wealth of resources including in-home educators and print and video training tools to insure the highest level of patient confidence and compliance.



*CardioNet provides a wealth of educational tools, including the Patient Education Guide, the Patient Pocket Guide, and a video.*

### Important

CardioNet outpatient telemetry is a diagnostic service, not an emergency response service. It is possible, however, that a patient may develop a life-threatening arrhythmia while on our service. If we detect such an event, CardioNet will attempt to assist the patient in accessing EMS services. Physicians should be aware that our ability to assist ambulatory patients is limited by many factors including cell phone coverage, the inherent limitations of GPS locating technology and local EMS policies.



### **Monitoring Specialists Review and Interpret Data to Ensure Accuracy**

The CardioNet Patient Service Center is staffed with highly qualified and experienced cardiac monitoring specialists. At a minimum, all monitoring specialists are CCT certified. They have extensive experience in cardiovascular monitoring; including the hospital based C.C.U. and I.C.U. telemetry, emergency medical services, and other cardiac call center environments.

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

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

All calls are monitored and recorded for quality assurance. CardioNet requires that all monitoring specialists participate in additional training and educational programs. A continuous QA process has been established for all facets of the service center operation.

The monitoring specialists, based on defined physician guidelines, prepare daily patient summary reports for final physician review and interpretation. In the case of a patient notification threshold event, the prescribing physician is contacted immediately and an urgent report is submitted for review and interpretation. Reports are tailored to the needs and requirements of the physician and are sent via the Internet, facsimile, or standard mail.

The CardioNet Patient Service Center is fully staffed and available 7x24, 365 days of the year.

## PATIENT ENROLLMENT

The Patient Enrollment Form is located in the CardioNet Patient Enrollment and Management System (PEMS). The client can access the CardioNet Patient Enrollment and Management System application at [www.cardionet.com](http://www.cardionet.com). This is a secure and restricted website and the user is required to be enrolled as a CardioNet client. Forms are also available from the CardioNet Patient Service Center. If you are not a CardioNet registered user, please contact the Patient Service Center.

Please enter your username and password to log in.

Username	<input type="text"/>
Password	<input type="password"/>
<input type="button" value="Login"/>	

*Log in to access the CardioNet Patient Enrollment and Management System.*

After you have entered your user name and password, click the log in button on your screen. You now have access to the CardioNet Patient Enrollment and Management System. The name of the client, physician or practice should appear on the upper left of the PEMS application. You may also refer to the CardioNet *Quick Start Guide* for instructions on enrolling a patient.

Using the CardioNet navigational tree on the left side, click on Documents and Forms. A document tab will open with a list of applicable forms. Click on *Patient Enrollment Form* (MON300) and print a copy. Follow the same process and procedure for *Patient Prescription Form* (MON302). Each form must be completed to enroll a patient on CardioNet's service.

The Patient Enrollment Form includes patient demographics, emergency information, primary and secondary insurance, patient waiver and assignment of benefits. Using this form please input all the appropriate information in the fields listed. In addition to any insurance information that is listed on the form, please provide CardioNet with a copy (front and back) of the patient's insurance card.

The patient's signature is required on all enrollment forms prior to submitting to CardioNet.



The *Patient Prescription Form* includes the patient name, prescribing physician, physician group name, and duration of monitoring requested, diagnosis and ICD-9 code. Using this form input all the appropriate information in the fields listed. The prescribing physician is required to sign the *CardioNet Patient Prescription Form* prior to enrolling the patient.

Please fax both completed forms, including a copy of the patient's insurance card to the CardioNet Patient Service Center.

The enrollment information will be entered into the CardioNet patient database; the patient's insurance carrier will be contacted for preauthorization as required, upon approval, the delivery of the CardioNet System will be scheduled as soon as possible.

Please see "Sample Forms and Reports" section of this manual for examples of reports and forms.

## ELECTRONIC PATIENT ENROLLMENT

CardioNet provides an additional method for enrolling patients in our service, electronic enrollment. If the user prefers to use CardioNet's electronic enrollment process, you can access the CardioNet Patient Enrollment and Management System (PEMS) application at [www.cardionet.com](http://www.cardionet.com). Use the Physician Log In and enter the username and password, and then click on Enroll Patient. The application will open to Patient Demographics. Please be advised that all fields and applicable tabs (Emergency and Insurance Information) must be completed prior to submitting an electronic enrollment.

Note: Electronic Patient Enrollment is not currently an active application in PEMS.

The screenshot displays the 'Carlsbad Medical Group' PEMS application interface. On the left is a green sidebar menu with options: 'Active Patients', 'Enroll Patient', 'Modify Patient', 'Pending Prescriptions', 'Enroll Physician', 'Modify Physician', 'Create User', 'Modify User', 'Locations', 'Documents and Forms', 'Change Password', 'Log out', and 'Home'. The main content area shows the 'Demographics' tab selected, with a form for patient enrollment. The form includes fields for Last Name, First Name, Home Phone, Work Phone, Address 1, Address 2, City, State (a dropdown menu), Postal Code, Country (a dropdown menu), and Social Security Number. A red asterisk indicates required information. A 'Welcome, Jeff Hopper' message is visible at the top of the sidebar.

### Enroll Patient Online

## **CARDIONET AMBULATORY ECG MONITOR WITH ARRHYTHMIA DETECTOR**

### **Indications for Use**

1. Patients who have demonstrated a need for cardiac monitoring and are at low risk of developing primary ventricular fibrillation or sustained ventricular tachycardia
2. Patients with dizziness or light-headedness
3. Patients with palpitations
4. Patients with syncope of unknown etiology
5. Patients who require monitoring for non life-threatening arrhythmias, such as atrial fibrillation, other supraventricular arrhythmias, evaluation of various bradyarrhythmias and intermittent bundle branch block. This includes postoperative monitoring for these rhythms
6. Patients recovering from coronary artery bypass graft (CABG) surgery who require monitoring for arrhythmias
7. Patients requiring monitoring for arrhythmias inducing co-morbid conditions such as hyperthyroidism or chronic lung disease
8. Patients with obstructive sleep apnea to evaluate possible nocturnal arrhythmias
9. Patients requiring arrhythmia evaluation for etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation
10. Data from the device may be used by another device to analyze measure or report QT interval. The device is not intended to sound any alarms for QT interval changes.

### **Contraindications**

1. Patients who have a history of sustained ventricular tachycardia or a documented occurrence of ventricular fibrillation
2. Patients who the attending physician thinks will be at risk for ventricular tachycardia or ventricular fibrillation as indicated by the following:
  - A measured ejection fraction of less than 35% with complex ventricular ectopic activity ( $\geq 10$  PVCs per hour or repetitive PVCs)
  - Unstable angina defined as chest pain at rest, a new onset of angina, or a change in existing patterns of angina
  - Patients with a recent ( $\leq 3$  months) myocardial infarction (MI)
  - Patients who are candidates for or have had recent heart valve surgery
3. Patients who the attending physician thinks should be hospitalized.

## REPORTS

When a physician group and/or physician is enrolled in CardioNet's service, preferred reporting methods for different events (Internet, fax, mail or telephone) are established for each physician user. Physicians may elect to modify or change their preferred report delivery methods by selecting "Modify Physician" in the CardioNet Patient Enrollment and Management System, or contacting the CardioNet Patient Service Center directly.

Fax or mail reports are forwarded to the physician by the CardioNet Patient Service Center. To access Patient Reports using PEMS, the user must log in to [www.cardionet.com](http://www.cardionet.com). Use the Physician Log In, and enter the user name and password. The name of the physician practice or physician will appear in the top left of your screen. Using the navigational tool bar on the left side, please click on Active Patients.

A list of all active patients will appear under the Patient Reports tab. Included with a list of active patients will be the type of report, date of report, report delivery method, time and date the report was sent from the Patient Service Center, and a confirmation to indicate that the user has either read or needs to review the report listed. To select a patient report you wish to review, click on the patient's name.

Note: The user must have Adobe Acrobat Reader in order to view and print a CardioNet patient report.

CardioNet provides reports for physician review, such as the: *Urgent Notification Mobile Telemetry* and *Daily Mobile Telemetry*. An *Urgent Report* is provided to the physician when a patient has an event, symptomatic or asymptomatic, that meets the physician defined notification threshold. The *Daily Report* is provided to the prescribing physician for each day the patient is on service with CardioNet. The *Daily Report* includes a heart rate trend graph and selected patient events for the previous 24-hour period.



### **A Representative ECG for the Urgent Report**

The *Urgent Report* provides a six second sample of the patient's ECG, Channel 1 and 2. The report includes a time and date stamp of the actual event, preliminary findings of the CardioNet monitoring specialist, symptoms and activities reported by the patient, and how the event was initiated, automatic or patient initiated.

Note: The Patient Service Center has an established procedure for contacting the prescribing physician in advance of receiving an *Urgent Notification Mobile Telemetry Report*. Escalation and notification protocols have been approved by the Patient Center Medical Director to deal with Emergency, Urgent, and Daily patient events. Refer to *Physician Notification Order Form (MON305)*. Each client or physician as part of the CardioNet enrollment process is responsible for providing appropriate contact numbers for normal business hours, after hours, weekends and holidays.

The client or physician user can request additional ECG data from the Patient Service Center to support a particular event or report.

Please see "Sample Forms and Reports" section of this manual for examples of reports and forms.

## **PHYSICIAN NOTIFICATION**

As part of the CardioNet client enrollment process, the Physician Notification criteria will be established for the client (physician practice) or individual prescribing physician. The *Physician Notification Order Form* (MON305) is to be completed and signed prior to enrolling a patient on CardioNet's service. CardioNet's Medical Advisory Board provides a set of default values based on established clinical practice monitoring guidelines.

An Emergency notification threshold cannot be downgraded for physician notification purposes. The physician may elect to change or modify an Urgent or Daily patient event threshold to a higher priority notification.

Please see "Sample Forms and Reports" section of this manual for examples of reports and forms.

### **Modifying Physician Notification**

A physician may request that the notification criteria be changed or modified for a particular patient at the time a patient is enrolled or during the course of monitoring. If the patient is being actively monitored, the client must complete and sign a *Physician Notification Change Order* (MON306). Upon receipt of the form by the Patient Service Center, it will be reviewed and approved by a clinical manager. The change will be noted in the patient's medical record and the monitor will be reconfigured to reflect the change where applicable.

The *Patient Prescription Form* (MON302) should be used when enrolling a new patient on the CardioNet service. Refer to Patient Enrollment.

## **BILLING**

The patient is responsible for providing the CardioNet Patient Service Center with all applicable insurance information at the time of enrollment. CardioNet will bill the patient's primary insurance company. In addition, CardioNet will also bill the secondary insurance company, if provided by the patient. A copy of the patient's insurance card is to be provided with the enrollment. The patient/responsible party/legal guardian is required to sign the Patient Enrollment Form.

CardioNet will bill the insurance company for only those services provided directly by CardioNet to the patient. In most cases, this is defined as the technical component, which includes monitoring and all equipment required to monitor the patient. The physician is responsible for billing the patient's insurance carrier for the professional component, which is defined as the physician interpretation.

### **Insurance Verification and Benefit**

CardioNet requires that a patient's insurance coverage is confirmed and benefits are verified. If the insurance verification determines that services requires a pre-authorization CardioNet takes the appropriate step to comply with the insurance company. It is imperative that the Physician always complies with the requirements of the Insurance Company regarding the referral process and subsequent pre-authorization/authorization as determined by the patient/members benefit plan. If additional information (certificate of medical necessity, etc.) by the insurance company is required to obtain authorization, CardioNet will immediately contact the prescribing physician. If CardioNet is not able to obtain authorization from the insurance company to provide services for the patient, the prescribing physician and patient will be notified immediately. The patient may then elect to continue on service with CardioNet, and therefore would assume 100% financial responsibility for all related charges.

CardioNet has established an appropriate set-up and technical fee for Mobile Cardiac Outpatient Telemetry. Medicare in the state of Pennsylvania established a new policy (M-60) on February 11, 2002, to address "Real-Time Cardiac Surveillance System." Please review the LMRP M-60 policy description, indications and limitations, and/or medical necessity.

## **Physician Reimbursement Coding Guidelines**

The LMRP determined that no existing CPT code fully and accurately describes this new technology; therefore services should be reported by using CPT Code 93799 and include the narrative "ECG arrhythmia detection and alarm system." Providers are instructed to bill one (1) unit of procedure code 93799, per day of cardiac surveillance.

The TC (Technical) and 26 (Professional) modifiers should be used with CPT Code 93799 to identify what component of the monitoring was performed.

The Professional Component includes review and interpretation of each 24-hour cardiac surveillance as well as 24-hour availability and response to surveillance events.

CardioNet, based on relevant policies and procedures from all non-Medicare insurance providers, will bill for its services in a similar manner, unless otherwise instructed.

## **Patient Responsibility**

CardioNet has established an initial set-up and technical fee for Mobile Cardiac Outpatient Telemetry. CardioNet will bill the patient's insurance company for the intended service duration as defined by the prescribing physician. In certain instances, the patient's insurance company may regard CardioNet as an out of network provider. It is not our intent to penalize the patient if their insurance company regards CardioNet as an out of network provider. CardioNet will continue to bill and collect from the patient all applicable co-payments and deductibles. CardioNet will make every reasonable effort to insure that the patient's financial responsibility will not exceed their normal *in plan* benefits. With the exception of Medicare, CardioNet will obtain insurance pre-authorization for all services to be provided by CardioNet. All services will be billed to the applicable parties upon completion of the prescribed service period, or upon discontinuation of service as requested by the physician, patient, or insurance company.



## **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 AND WARNINGS**

### **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 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.

### **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 of 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.

## TECHNICAL 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  $\mu$  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:

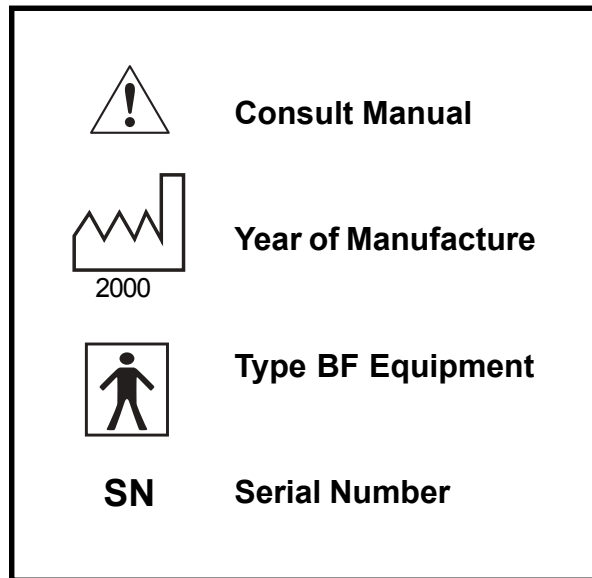
- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help

## UL Listed

The CardioNet monitor and base have been tested to UL 2601, No. EN60601-1.

The CardioNet base is compliant with EN60950.

## EQUIPMENT SYMBOLS



## HARDWARE REQUIREMENTS

### In Home Requirements

Touch tone telephone  
AC powered outlet

### FCC ID

Sensor	QBI-1007
Monitor	QBI-1006
Monitor cell	NBZNRM-6832
Base	CARDT00B42061

## **ARRYTHMIA DETECTION ALGORITHM PERFORMANCE ANALYSIS**

The CardioNet 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.

<b>Performance Measure</b>	<b>MIT Arrhythmia Database</b>	<b>AHA Database</b>
QRS Detection Sensitivity %	99.93	99.88
QRS Detection Positive Predictivity %	99.85	99.89
PVC Detection Sensitivity %	95.44	94.07
PVC Detection Positive Predictivity %	96.94	97.72
PVC Detection False Positive Rate %	0.229	0.222

## 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 2.08%, 1.07%, and 30.9% respectively.

### Heart Rate Calculation

The average heart rate is calculated by computing the mean of the actual RR-intervals, in the last 6 seconds or 8 RR-intervals (whatever is shorter).

The actual RR intervals are calculated based on the QRS detected events:

Actual RR = the time between the last detected QRS complex and the previously detected QRS complex, in milliseconds

In the CardioNet reports, the heart rate displayed on the ECG strips themselves is the average of the rate for the beats displayed in that strip.

#### AHA ECG Database (Summary of results from 78 records)

	<b>ErrSum</b>	<b>RefSu</b>	<b>Nmeas</b>	<b>MeanRefHR</b>	<b>RMSerror(%)</b>
Sum	130111.6913	2167402.8283	26706		
Gross				81.15792.7197	2.7197
Average				81.4511	2.0762

#### MIT-BIH Arrhythmia Database (Summary of results from 44 records)

	<b>ErrSum</b>	<b>RefSu</b>	<b>Nmeas</b>	<b>MeanRefHR</b>	<b>RMSerror(%)</b>
Sum	25694.4788	1016331.6122	13030		
Gross				77.9994	1.8003
Average				78.0769	1.0691

#### NST Database (Summary of results from 12 records)

	<b>ErrSum</b>	<b>RefSu</b>	<b>Nmeas</b>	<b>MeanRefHR</b>	<b>RMSerror(%)</b>
Sum	3098725.4772	266364.2826	3576		
Gross				74.4867	39.5198
Average				74.4867	30.8921



## RUN-BY-RUN REPORT

### AHA ECG Database

Record	CTs	CFN	CTp	CFP	STs	SFN	STp	SFP	LTs	LFN	LTp	LFP	CSe	C+P	SSe	S+P	LSe	L+P
Sum	904	95	1048	35	379	85	487	12	26	53	75	4						
Gross													90	97	82	98	33	95
Average													72	78	55	97	76	91

Total couplets: 999

Total short runs: 464

Total long runs: 79

### MIT-BIH Arrhythmia Database

Record	CTs	CFN	CTp	CFP	STs	SFN	STp	SFP	LTs	LFN	LTp	LFP	CSe	C+P	SSe	S+P	LSe	L+P
Sum	564	84	575	35	32	20	42	5	10	3	15	0						
Gross													87	94	62	89	77	100
Average													78	74	60	87	78	100

Total couplets: 648

Total short runs: 52

Total long runs: 13

## VENTRICULAR FIBRILLATION EPISODE REPORT

### AHA VF Detection

Record	TPs	FN	TPp	FP	ESe	E+P	DSe	D+P	Ref duration	Test duration
Sum	9	0	26	0					1:28:50.140	1:10:59.646
Gross					100	100	79	99		
Average					100	100	77	96		

Summary of results from 78 records

### MIT-BIH Detection

Record	TPs	FN	TPp	FP	ESe	E+P	DSe	D+P	Ref duration	Test duration
Sum	1	0	1	0					1:37.900	1:44.032
Gross					100	100	91	86		
Average					100	100	92	86		

Summary of results from 44 records

### CU Detection

Record	TPs	FN	TPp	FP	ESe	E+P	DSe	D+P	Ref duration	Test duration
Sum	26	5	28	2					40:38.772	24:55.332
Gross					84	93	53	86		
Average					87	96	52	76		

Summary of results from 30 records

## PACEMAKER DETECTION RESULTS

Pacemaker detection: Meets AAMI EC38

## **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 A 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 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 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](http://www.fcc.gov) .

## **SAMPLE FORMS AND REPORTS**

Examples of the forms listed below follow.

- Patient Enrollment Form
- Physician Enrollment Form
- Client Enrollment Form
- Patient Prescription Form
- Physician Notification Orders Form
- Physician Notification Change Orders Form
- Daily Mobile Report
- Urgent Mobile Telemetry Report
- End of Service Report

To access electronic versions of forms and reports, log on to [www.cardionet.com](http://www.cardionet.com).