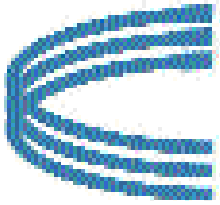


CARDIONET

MONITORING AT THE SPEED OF LIFE™

CardioNet Ambulatory ECG System
and Arrhythmia Detector

Document Number - 100008
Revision E

Model Number 1001

Physician's Operation Manual

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

CARDIONET
MONITORING AT THE SPEED OF LIFE™

Table of Contents

Section I

Clinician Instructions

Section I is for clinicians such as nurses and / or technicians who will be the providing the education and instruction for patients starting on the CardioNet Service.

Included in this section are instructions for preparing and educating the patient for successful CardioNet Monitoring. Also included in this section are instructions, tools, and helpful hints to guide clinicians through maintenance and configuration of the CardioNet Monitor.

Overview

Description

The CardioNet Monitoring System 1001 is a battery operated, ambulatory arrhythmia detector designed for continuous 24 hour, 7 day per week ECG monitoring. The CardioNet Monitoring System consists of three components; a Sensor, a Monitor and a Base. The CardioNet System provides a practical and convenient method for collecting diagnostic ECGs over an extended period of time.

The CardioNet Monitoring System has the capability to record, store and transmit ECG and event data. The ECG and event data is continuously recorded in digital flash memory within the device. The System contains an on board algorithm, which performs of real time ECG analysis and arrhythmia detection. When an event occurs, whether it is symptomatic or asymptomatic, the Monitor automatically sends the ECG data to the CardioNet Monitoring Center either via the built in cellular phone or the land line telephone connection of the base.

The multi-lead design provides enhanced ECG waveform definition and enables a more effective identification of artifact. With a sampling rate of 250 measurements per second and 12 bit A to D, the device produces the necessary amplitude and resolution to detect very fast QRS complexes seen in some atrial arrhythmias.

The LCD display with touch panel enables all users to easily control a variety of functions, so that operation of the device is tailored to the needs of the physician, the patient and the clinician.

The CardioNet System: Monitor, Sensor and Base

Indications for Use

The CardioNet system is for use on low risk arrhythmia patients and specific indications for use are as follows:

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 lightheadedness
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
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, possibility secondary to atrial fibrillation
10) Data from the device may be used by another device to analyze, measure or report QT interval. This device does not sound any alarms for QT interval changes

Contraindications for Use

The CardioNet system is for use on low risk arrhythmia patients and is contraindicated for use on the following patients:

1) Patients who have a history of sustained ventricular tachycardia or a documented occurrence of ventricular fibrillation

2) Patients the attending physician thinks will be at risk for ventricular tachycardia or ventricular fibrillation as indicated by the following:

- A measured ejection fraction (EF) less than 35% with complex ventricular ectopic activity (≥ 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 (≤ 3 months) myocardial infarction (MI)
- Patients who are candidates for or have had a recent heart valve surgery

3) Patients who the attending physician thinks should be hospitalized

Precautions

Patient leads must be removed before external defibrillation.

Observe all local laws for the disposal of alkaline batteries.

Do not leave the battery in the Sensor when it is not in use. Damage from corrosion could result.

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

Warnings and Cautions

Caution: Power Down and Remove Before Showering
While the CardioNet Sensor and Monitor are water resistant, they are not water proof. Patients must be instructed to turn the Monitor off and remove both the Sensor and Monitor before showering or swimming. Refer to page 11 for instruction on removal and reapplication.

Warning: For Adult Use Only
The CardioNet Monitoring System is intended for Adult use only. It shall not be used on infants weighing less then 22 lbs.

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

Warning: Do not use any telephone other than the phone that is connected to the CardioNet Base while the patient is being monitored. If dialing tones are heard in a remote telephone, hang up immediately to allow the CardioNet Monitor to dial the Monitoring Center.

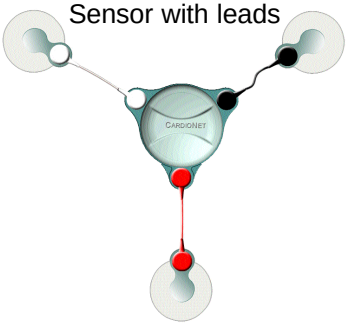
Warning: There are no serviceable parts in the CardioNet System. Removing the cover of any of component (other than the battery compartment) may alter performance.

Features

Operation Features

CardioNet Sensor without leads

CardioNet
Sensor with leads

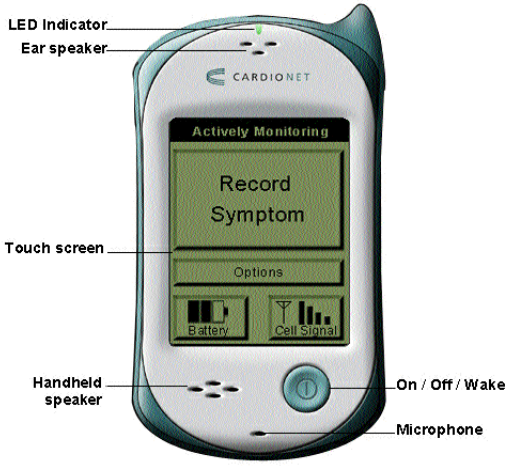


The CardioNet Monitor has two separate components: the Sensor and the Monitor. The Sensor is worn by the patient and acquires ECG data from the electrodes. The Monitor can be worn by the patient or can be located up to 30 feet away. The Monitor receives the ECG data from the Sensor and performs real time arrhythmia analysis. When an event occurs, (either symptomatic or asymptomatic) the Monitor attempts to call the CardioNet Monitoring Center via either the cell phone or telephone land line and to transmit the event for review by trained CardioNet personnel.

CardioNet Monitor

Physical Features

During monitoring, the CardioNet System has several features to ensure ease of use and patient compliance.



LED Indicator: Blinks green to indicate Monitor is actively analyzing ECG data. Blinks red to indicate Monitor is not collecting and analyzing ECG data.

Ear Speaker: Voice communications will be heard through the ear speaker when the Monitor is not in the Base.

Touch Screen: Interactive touch screen menus allow patients to enter symptoms, record activities, adjust Monitor settings and view Monitor status.

Speaker phone: Voice communications will be heard through the speaker phone when the Monitor is in the Base.

On / Off / Wake: Turns the Monitor on or off and wakes from standby mode.

Preparing the CardioNet System

Configure Monitor - Patient Profile

The Monitor-Patient profile consists of information specific to the patient. Each profile is determined by the physician prior to monitor placement as part of the monitoring prescription. A Monitor-Patient profile will contain information regarding Monitor screen preferences, automatic download time preferences and automatic threshold levels. Physicians can customize a Monitor Patient profile for a patient or can chose the default settings. Please refer to the physician's prescription prior to choosing your patient's Profile settings.

Download Monitor - Patient Profile to Monitor

Choose any Cardionet System for placement on a patient. Place the Monitor into a Base connected to the computer that has been designated as a the CardioNet Utility PC. Open the software application on the computer's desktop listed as "CardioNet". Once the Monitor is placed in the Base, the CardioNet software will supply a list of your physician's patients waiting to receive a CardioNet Monitoring System. The Software will prompt the clinician to select the patient who will be receiving the System.

After the patient selection has been made, the default Monitor - Patient Profile will be displayed. Any changes to the Profile as indicated by the physician on the prescription can be made at this time (physicians refer Physician Instructions, pg III). Once all choices have been indicated, the software will display a confirmation notification indicating the Monitor is ready for placement on the selected patient.

Preparing the Patient

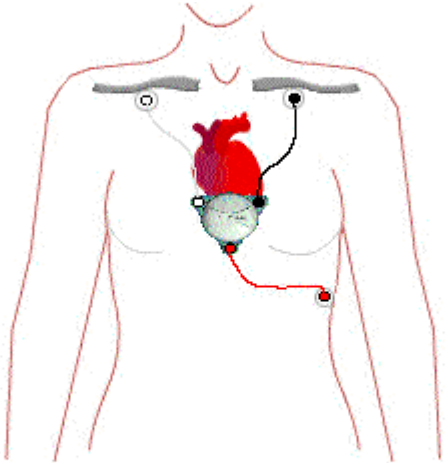
Electrode Application

With CardioNet's on board analysis of ECG, proper electrode and lead placement is imperative to achieve good results. The diagram on the following page demonstrates CardioNet's recommended placement for the electrodes, the leads and the Sensor. However, optimum electrode placement may vary slightly according to patient body shape and size. Verify good quality baseline ECG signals after placing electrodes.

Use only electrodes supplied by CardioNet or ones designed for longer term monitoring. Proper preparation of the patient's skin is absolutely essential for obtaining a quality ECG recording. Refer to your electrode provider for instructions on proper skin preparation.

Correct application of the electrodes, demonstrated on the following pages, is imperative for proper ECG analysis. Please refer to the diagram for accurate placement.

CardioNet Electrode and Lead Placement



CH 1 -
CH 1 +

CH 2 -
CH 2 +

CH 3 -
CH 3 +

White lead: Center of the right clavicle

Black lead: Center of the left clavicle

Red lead: Left anterior axillary line, in the 7th to 8th intercostal space.

***** Optimum electrode placement may vary slightly according to patient body shape and size. Verify good quality baseline ECG signals after placing electrodes.

* Tape may be used to secure the lead wires in the event of excess signal noise on the ECG.

Educate the patient

Explain the preparation and the position for proper electrode placement.

Explain that if any electrode loses contact or dries out during the monitoring process it must be replaced immediately. Additionally, the CardioNet Monitor will recognize when leads are disconnected or worn out and will alert the patient.

Explain that new electrodes should be examined prior to application. Electrodes with dried gel should not be used.

Show the patient how to install a fresh AA battery into the Sensor.

Explain reattachment of the Sensor lead set to the electrodes. Show the patient how to connect the lead set and secure the lead wires.

Explain that the Sensor and the Monitor MAY NOT be worn during showering or swimming. The adhesive electrodes ONLY may be worn in the shower, but they should not get soaked. The skin around the electrodes should be gently washed and the electrodes repressed to the skin after drying.

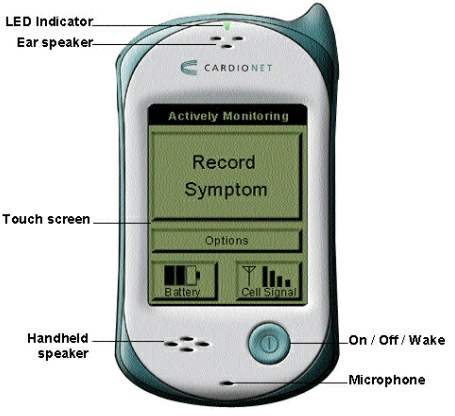
Power down and remove before showering:
1) Press the On / Off / Wake button located on the front of the Monitor.
2) Touch the Options button on the LCD screen.
3) Touch the Monitor Power button on the LCD screen.
4) Touch the Off button on the LCD screen.
5) At the prompt for confirmation of you choice, press OK on the LCD screen to turn power off.
6) Wait for the Monitor to completely power down. The LCD screen will indicate the Monitor is turning off and then become blank.
7) Remove the battery from the Sensor
8) Remove the Sensor leads from the electrodes. The patient may choose to wear the electrodes during a shower or remove the electrodes and apply a new set before reattaching the Sensor.

After Showering:
1) Re-press electrodes worn during showering or apply new electrodes.
2) Reattach the Sensor to the electrodes and replace Sensor battery.
3) Turn the Monitor on to resume monitoring by pushing the On/ Off/ Wake button located on the front of the Monitor.

Instruct the Patient

Instructing the patient on the operations and functions of the CardioNet Monitoring System is a key component of successful monitoring. The following includes instructions for interaction with the CardioNet Monitor, including entering symptoms and activities, changing Monitor options, and viewing Monitor status.

Review of features



LED Indicator: Blinks green to indicate Monitor is actively analyzing ECG data. Blinks red to indicate Monitor is not collecting and analyzing ECG data.

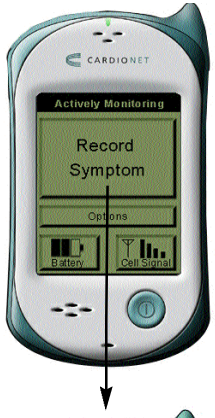
Ear Speaker: Voice communications will be heard through the ear speaker when the Monitor is not in the Base.

Touch Screen: Interactive touch screen menus allow patients to enter symptoms, record activities, adjust Monitor settings and view Monitor status.

Speaker phone: Voice communications will be heard through the speaker phone when the Monitor is in the Base.

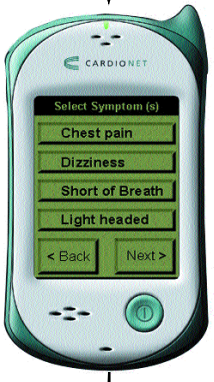
On / Off / Wake: Turns the Monitor on or off and wakes from standby mode.

Entering Symptoms and Activities



Main Menu

When the patient touches the Record Symptoms area on the screen with their fingertip, the Symptoms Menu will appear and the patient will be prompted to make a selection.



Symptoms Menu

Patients have four choices to select for symptoms on the Symptoms Menu. One or more symptoms can be selected.

The < Back selection will return the patient to the Main Menu

The Next > selection will advance the patient to the Activity Menu

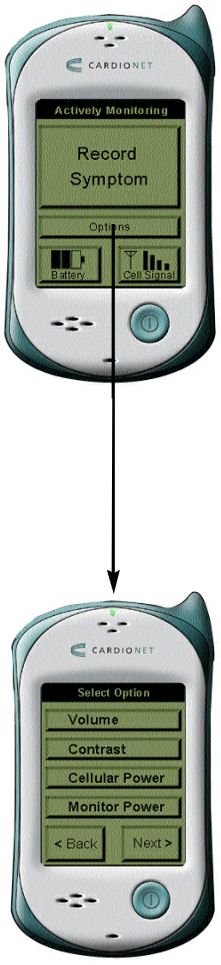
Activity Menu

Patients have four choices to select for symptoms on the Symptoms Menu. Only one activity can be selected from the Activity Menu.

The < Back selection will return the patient to the Symptoms Menu

The Done > selection will return the patient to the Main Menu

Changing Monitor Options



Main Menu

When the patient touches the options area on the screen with their fingertip, the Options Menu will appear and the patient will be prompted to make a selection.

Volume

The Volume option allows the patient three audible tones: high, medium, and low and a vibrate option.

Contrast

The Contrast option allows the patient to adjust the contrast of the screen to high, medium or low when better viewing is necessary.

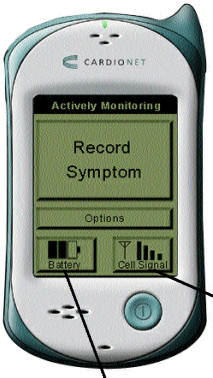
Cellular Power

The Cellular Power option allows the patient to turn the cell phone in the Monitor off or on. When the cell phone is off, the Monitor is still recording, but no automatic transmissions can be made to the CardioNet Monitoring Center unless the Monitor is placed in the base.

Monitor Power

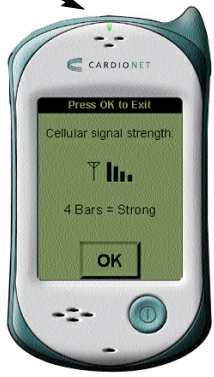
The Monitor Power option allows the patient to turn the monitor off. This is recommended any time the patient wants to shower, swim or change electrodes.The Monitor will not record ECG data when the power is off.

Viewing Monitor Status



Main Menu

When the patient touches the icons area on the screen with their fingertip, the screen will provide more in-depth information on battery power or cell signal strength.



Battery Power

The battery power screen provides more in-depth information on the time remaining for the Sensor and the Monitor batteries.

Cell Signal Strength

The cell signal strength screen provides more in-depth information on how strong the cellular signal at the Monitor's location.

Installing the Base

Patients will need to be instructed how to install the Base when they return home. Installing the Base properly ensures that the Monitor battery will properly recharge and that the ECG data can be sent while the Monitor is in the Base. Patients will need to unplug their existing telephone line from the wall. The telephone cable (already attached to the patients telephone) then inserts into the "Phone In" port of the Base. The additional provided telephone cable then inserts to the Base "Line In" port, then into the telephone jack in the wall.

CardioNet Base

Recharging the Monitor

The CardioNet Monitor contains a rechargeable battery which can be replenished in the Base. This battery requires a charge of 4 hours for each 18 hours of use. When in the Base, the LCD on the Monitor will indicate the battery charge status. To fully charge, leave the Monitor in the Base for four hours. Touching the battery icon on the screen will indicate how much battery life is remaining on the Monitor.

Downloading ECG

The CardioNet Monitor is configured to download ECG data automatically at specified times as designated by a physician. Automatic transmission times will be configured during the initial patient set up, the default is once per 24 hours. Data can also be downloaded manually by patient activation of the call button. Detailed instructions should be provided by the physician to determine when patients should use the call button.

Service and Maintenance

Cleaning

Dampen a soft cloth with disinfecting solution. Wipe the external surfaces of the Sensor, Monitor and Base. 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 via telephone or fax listed below.

Telephone:	619.243.7500
Fax:	619.243.7700

Call customer support before returning a CardioNet Monitoring System to make shipping arrangements.

Troubleshooting

Problem	Recommended Solution
Low Battery on Sensor	Install new battery.
	Inspect battery compartment, clean contacts if necessary.
Low Battery on Monitor	Return Monitor to Base for recharging.
Battery does not last 18 hours	Ensure battery is being recharged for at least 4 hours per day.
No splash screen when Monitor is turned on.	Return Monitor to Base for recharging.
No Display on Monitor	Ensure Monitor is turned ON.
	Return Monitor to Base for recharging.
Monitor displays electrode placement warning.	Check electrode placement and connections.
No connection when call button is pressed	Ensure Monitor is in cellular range.
	Place Monitor in base.
	Ensure Monitor is turned ON.

Specifications

Dimensions

Sensor Dimensions
4.1 x 0.7
Weight: 2.1 oz

Sensor neck strap
12 x 24 x 0.2

Monitor
5.9 x 3.3 x 1.0
Weight: 11.0 oz

Base
4.0 x 4.0 x 3.6
Weight: 6.1 oz

LCD
3.0 x 2.3, touch screen, monochrome, EL backlight

Functional

Channels	2
Resolution	12 Bit
Recording	Full Disclosure
Sample Rate	250 Samples / sec
Frequency Response	0.5 hZ - 40 Hz
Battery Life	Monitor: (18 hr) rechargable Sensor: (24 hr) AAA Alkaline

Base Connectors
Power in (12V 1.2A)
Phone in (RJ11)
Phone out (RJ11)
Serial RS232

Operating conditions

Sensor
- Immersion resistant (IPx-0)
- Operating temperature 20 - 45 C
- Storage temperature -20 - 65 C
- Relative humidity 10% - 95%, noncondensing

Monitor and Base
- Splash resistant (IPx-0)
- Operating temperature 0 - 45 C
- Storage temperature -20 - 65 C
- Relative humidity 10% - 95%, noncondensing

Equipment symbols

Symbol	Description
	Consult Manual
	Year of Manufacture
	Type B Equipment
SN	Serial Number

Hardware Requirements

In Home Requirements

Touch tone telephone
AC powered outlet

PC Requirements

Serial port installed

Section II

Physician Instructions

Section II is for physicians who will be prescribing patients for the CardioNet Monitoring Service.

Detailed instructions covered in this section:

- Monitor Screen Preferences
- Automatic Download Preferences
- Arrhythmia Detection Preferences
- Disclosure of Technical Specifications

Automatic Download Preferences

When manual measurements of the ECG by CardioNet's trained personnel are required, the physician can indicate preferences for automatic transmission of ECG data in the physician's prescription. This is recommended for patients requiring measurements of the PR interval, the QRS complex, or the QT interval.

Options will be listed on the prescription as follows:

QD (Once per 24 hours)
BID (Two times per 24 hours / every 12 hours)
TID (Three times per 24 hours / every 8 hours)
QID (Four times per 24 hours / every 6 hours)
Q4 (Six times per 24 hours / every 4 hours)

The default for automatic download of ECG without a cardiac event is one time per 24 hours. The physician will receive a strip of ECG data reviewed by CardioNet personnel that will include all measurements indicated by the physician on the prescription.

The following options can be listed on the prescription as follows:

PR interval
QRS complex
QT interval

One or multiple selections can be made.

Arrhythmia Detection Preferences

The CardioNet System is for use on low risk patients with the following contraindications:

1) Patients who have a history of sustained ventricular tachycardia or a documented occurrence of ventricular fibrillation.

2) Patients the attending physician thinks will be at risk for ventricular tachycardia or ventricular fibrillation as indicated by the following:

- A measured ejection fraction (EF) less than 35% with complex ventricular ectopic activity (≥ 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 (≤ 3 months) myocardial infarction (MI)
- Patients who are candidates for or have had a recent heart valve surgery.

3) Patients who the attending physician thinks should be hospitalized.

CardioNet's on board algorithm continually analyzes ECG for potential arrhythmias on the following list. Any arrhythmia may be omitted from the list on the prescription by the prescribing physician. The optional item - Pacer spike detection - will not be routinely detected unless indicated by the physician.

Arrhythmias will be listed on the prescription as follows:

CardioNet Event Threshold Table

Arrhythmia	Value
Bradycardia	≤ 40 BPM & sustained > 60 sec
Tachycardia	≥ 150 BPM & sustained > 60 sec
Irregular Rhythm to Detect Atrial Fibrillation / Flutter	Irregular HR (IRR ≥ 25) > 60 sec
PVC's	≥ 8 occurrences in one minute
Ventricular Bigeminy	≥ 6 occurrences in one minute
Ventricular Trigeminy	≥ 6 occurrences in one minute
Ventricular Tachycardia	≥ 100 BPM & sustained ≥ 4 beats
Ventricular Fibrillation	Onset
Pause	≥ 2 seconds
Long Pause	≥ 3 seconds

*Irregular R to R is defined as: $\frac{\text{Standard deviation}}{\text{RR mean}} \times 100$ [0.01 sec]

Disclosure of Technical Performance Specification

1) Analysis of heart rate

The average heart rate is calculated on the basis of the mean R to R interval in the last 6 seconds or 8 R to R intervals (whatever is shorter). For the MIT-BIH ECG database, the average RMS error for the calculated HR was 1.07%, and for the AHA ECG database, the RMS error for the HR calculated was 2.08% (see table below).

AHA ECG Database HR measurements

Record	ErrSum	RefSum	Nmeas	MeanRefHR	RMSerror(%)
Sum	130111.6913	2167402.8283	26706		
Gross				81.1579	2.7197
Average				81.4511	2.0762

Summary of results from 78 records

MIT-BIH ECG Database HR measurements

Record	ErrSum	RefSum	Nmeas	MeanRefHR	RMSerror(%)
Sum	25694.4788	1016331.6122	13030		
Gross				77.9994	1.8003
Average				78.0769	1.0691

Summary of results from 44 records

2) Analysis of rhythm Disturbances

The CardioNet System detects the arrhythmias and other ECG abnormalities shown in the CardioNet Event Thresholds Table. These include the following:

- Bradycardia
- Tachycardia
- Irregular heart rate to detect possible Atrial Fibrillation / Flutter
- Frequent PVCs
- Ventricular Tachycardia
- Ventricular Fibrillation
- Pauses

Disclosure of Technical Performance Specification (con't)

3) Analysis of ST alteration
The CardioNet System does not currently address ST analysis.

4) Recognition and measurement of the QRS morphology and duration
QRS morphology classification (such as labeling of each detected beat as normal or ventricular, etc.) is provided by the Mortara Arrhythmia Analysis Library, as part of the ECG analysis. The CardioNet System does not report measurements of the QRS duration.

5) Learning Phase
A learning phase occurs for one minute during the initial analysis of the patient's baseline ECG. A learning phase also occurs for one minute each time the Monitor is powered up and after a leads off detection has been detected and reset.

6) Measurement of PR intervals
The CardioNet System does not provide measurements of PR intervals.

7) Recognition of paced rhythms
The CardioNet supports recognition of pacer pulses. The CardioNet System detects pacer pulses and calculates pacemaker non-fire, non-capture rates.