

MCOTTM_{OS}

Patient Education Guide



Contact Us:

Toll Free: 1-866-426-4401

Email: CustomerService@gobio.com

Online Chat: gobio.com/Patients

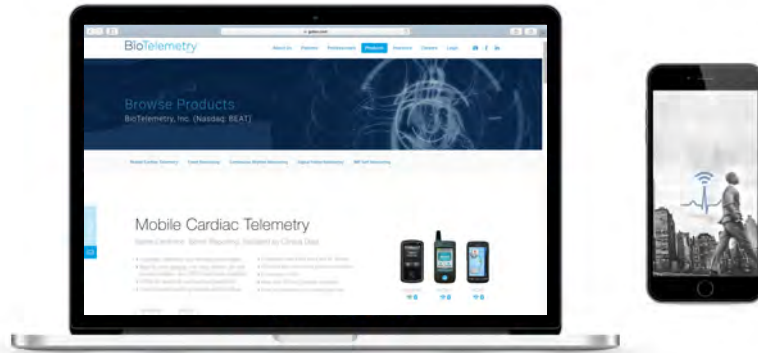


CardioNet & LifeWatch

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Online Video Tutorials

For helpful video instruction, select the **Patients** tab on our website at **www.gobio.com*** or download the **BioTel Heart App** select Videos, then MCOTos.



Share Your Thoughts

Please share how we are doing by filling out our survey at www.gobio.com

*devices in online videos may be different

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IMPORTANT REMINDER:

This device provides a diagnostic test. It is not an emergency response service. If at any time you experience a symptom that you feel is a medical emergency, you should immediately dial 911 for medical assistance.

1

Before you Begin

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1

About our Service

MCOT^{es} - Before you Begin

The MCOTs service was developed to help doctors detect and treat heart problems that may not happen often enough to be found during a routine ECG in the physician's office. Using a sensor worn around your neck and a monitor that transmits your heart rhythms to our monitoring center, we can help physicians detect problems that may infrequently occur, whether you feel them or not, even while you are sleeping.

Our goal is to work as a team with patients and physicians to help people receive the best possible care.

If you have any questions or concerns, please contact us.

Customer Service: 1-866-426-4401 (24 Hours)

Billing: 1-855-572-3999 (Weekdays 9:00am - 5:00pm EST)

Email: CustomerService@gobio.com

Online Chat: gobio.com/Patients or via the BioTelemetry Healthcare App/Contact Us



The BioTelemetry Healthcare App



1

Getting to Know the Monitor

MCOT^{ce} - Before you Begin



Touch Screen

To operate monitor, touch the screen where indicated. Monitor is still functioning when dark. (Screen will go dark after 1 minute.)

Wake Button

Press Wake button to view the screen.

Charging Light

Orange = Charging
Green = Fully Charged

Battery Strength Indicator

Status Light

Solid Green = Communication with sensor
Red = Read the screen for instructions

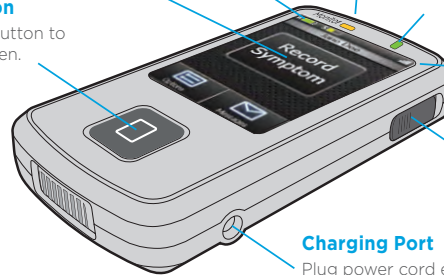
Cell Strength Indicator

Power Switch

Slide to power monitor
On (White) / Off (Black)

Charging Port

Plug power cord end here to charge the monitor.

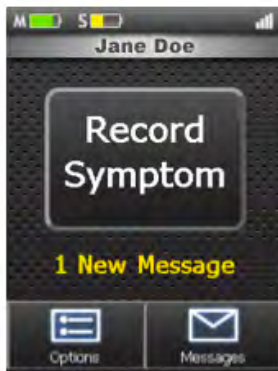


The MCOTs Monitor is a small portable device that gathers data from the sensor and sends the information to our 24 hour monitoring center. The monitor automatically transmits data using a built-in cell phone. Although the monitor will transmit ECG's from your heart automatically, it is important to record symptoms as you feel them. This will provide additional information on the reports received by your physician.

1

Getting to Know the Monitor

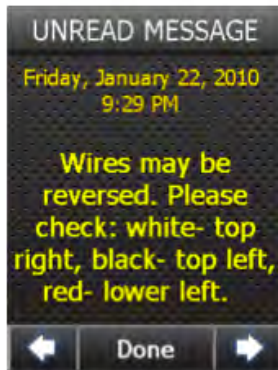
MCOT^{CS} - Before you Begin



Home Screen:

This is the main monitoring screen that will appear throughout your monitoring period.

- Options: Used to adjust monitor settings.
- Messages: Displays text messages from monitoring center.
- Record Symptom: Allows you to record a symptom and activity level that will appear on reports sent to your physician.



Text Messaging:

Our monitoring center may send you text messages from time to time. The monitor's main screen will show how many new messages are waiting for your review.

- Select "Message" to read new messages.
- Select "Done" when finished reading the message.
- Use the arrows on the bottom of the screen to scroll through additional (previous) messages.
- The text will turn white once the message has been read.

About the Sensor

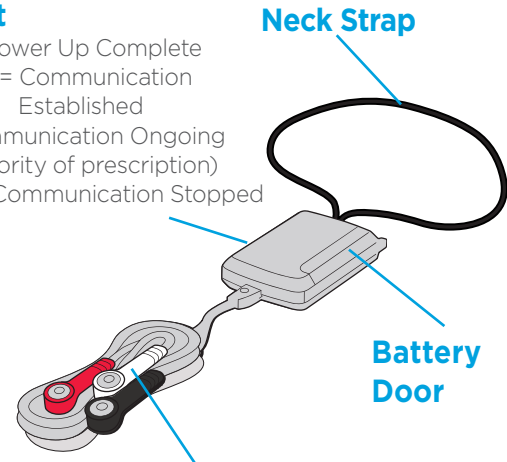
- The sensor is a small device worn around your neck.
- Three lead wires gather data from your heart.
- The sensor can gather and store up to five hours of data.
- The sensor communicates the data from your heart constantly to the monitor.
- It is recommended that you keep the sensor and monitor in the same room at all times to eliminate loss of communication between the devices.

Sensor Light

Solid Green = Power Up Complete
Flashing Green = Communication
Established

No Light = Communication Ongoing
(majority of prescription)

Flashing Red = Communication Stopped



Lead Wires

Each wire will snap to an electrode that will be attached to your body.

2

Things to Know

In this Section:

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- Monitor Battery 9
- Sensor Battery 10
- Replacing Electrodes 11
- Showering, Bathing, Swimming 12
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2 Recording a Symptom

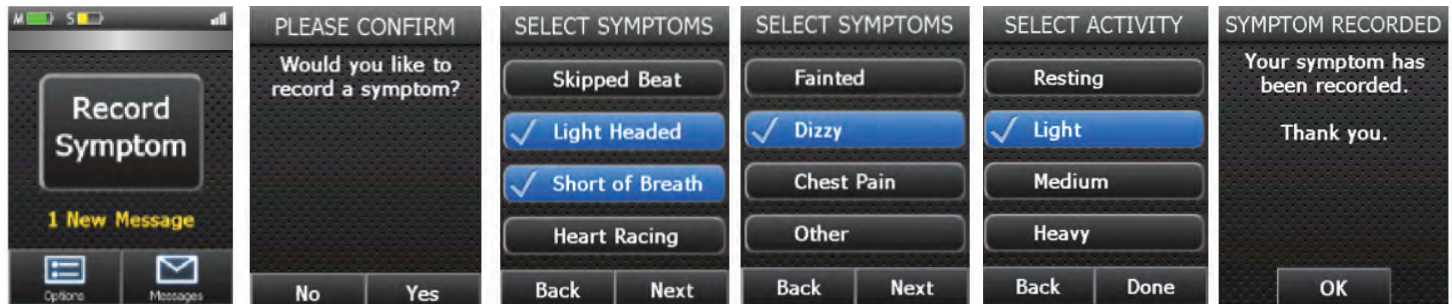
The monitor and sensor work together to transmit important ECG data to the monitoring center. You also have the ability to record ECG data associated with symptoms you are feeling.

To Record a Symptom:

1. Select **Record Symptom** on the monitor screen. Select **Yes** to record symptom.
2. Select corresponding symptom(s); select **Next** for additional symptoms options. If you make a selection in error press the option again to deselect.
3. Select **Next**, and then select your level of activity.
4. Select **Done** to complete. If you do not complete all steps your symptom will not be submitted to the monitoring center.
5. You will receive a confirmation message indicating your symptom was recorded. Select **OK**.

Please Note:

If you select **Fainted**, the monitor will ask “**Did you faint?**” You will then need to confirm that you lost consciousness. The monitoring center may contact you if **Fainted** was submitted as a symptom.



2

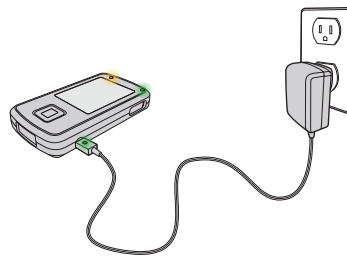
Monitor Battery

MCOT^{es} - Things to Know

Charging the Monitor Using the Power Cord

- Charge the monitor daily. A depleted battery could take up to 4 hours to charge.
- The MCOTos monitor battery lasts up to 10 hours on a full charge.
- There are several variables that can affect how quickly the monitor's charge is depleted. These include but are not limited to, data transmission, cell signal, and data gathering.
- The "Charge Monitor" alarm will sound when the battery is critically low.

Direct Power Cord Charging



Charging Light: Green indicates functional power source.

Checking Battery Power

To check the battery levels in both the sensor and monitor, tap on the battery icons on top left of the monitor screen. These will give you an estimate of how much battery life remains for each device.

M = Monitor **S = Sensor**

Battery Strength Indicator



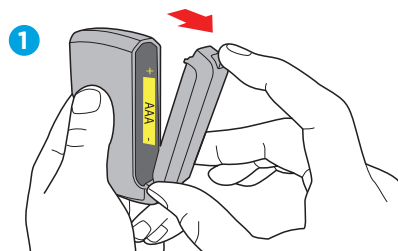
Sensor Battery

- The sensor battery will last 24 hours.
- The battery in the sensor must be replaced at approximately the same time each day.

Changing the Sensor Battery

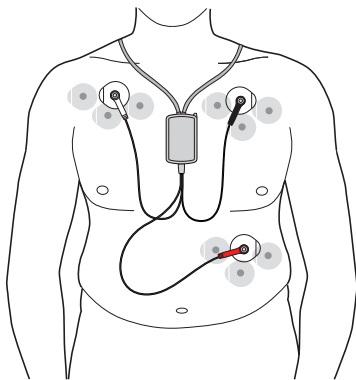
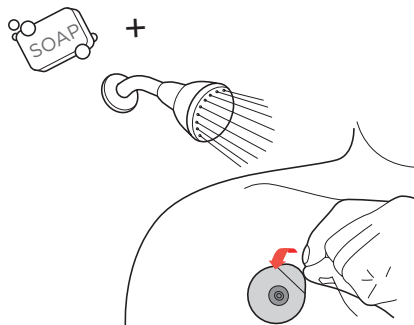
- Turn off monitor.
- Open battery door (Fig. 1).
- Remove and discard old battery.
- Insert new battery (Fig. 2).
- Close battery door.
- You will hear a chime indicating that the battery was inserted correctly.
- Turn on monitor.

Changing the Battery



2 Replacing Electrodes

MCOT^{es} - Things to Know



Change your electrodes every other day, following these steps:

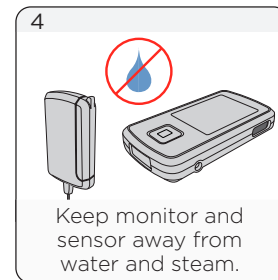
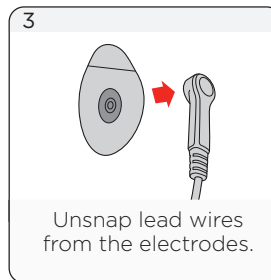
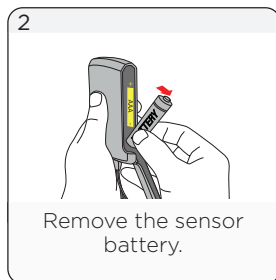
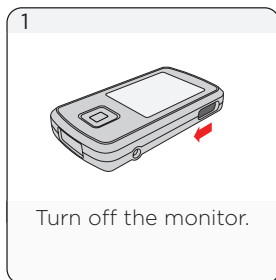
- Turn off monitor.
- Remove battery from sensor.
- Unsnap lead wires from the electrodes.
- Gently remove electrodes from skin (Use soap, water, or adhesive remover if necessary.)
- Wash and dry skin thoroughly.
- Snap new electrodes to lead wires.
- Place electrode on skin in a slightly different location. (Refer to illustration for alternate locations.)
- Allow 10-15 minutes for electrodes to adhere to skin.
- Insert sensor battery and turn on monitor.

Please Note:

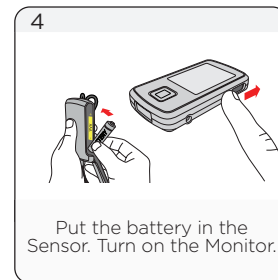
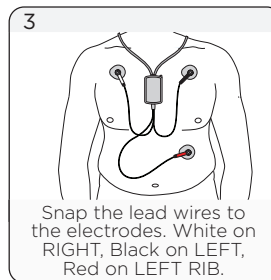
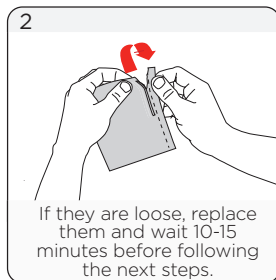
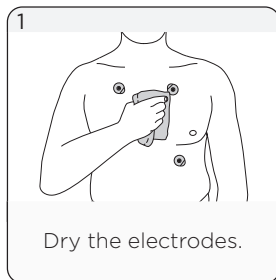
If you have a Pacemaker implanted, do not place the electrode directly on top of it.

2 Showering, Bathing, Swimming

BEFORE showering, bathing or other water activities:



AFTER showering, bathing or other water activities:



Please Note: The electrodes are water resistant. You may wear them for showering and bathing.

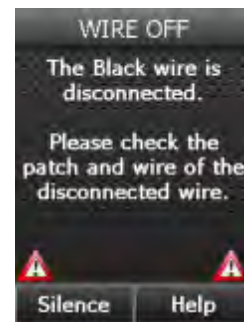
2

Skin Care - Issues

MCOT^{es} - Things to Know**Electrodes Not Sticking**

Occasionally, some patients experience issues with electrodes not adhering to their skin. As a result, they may experience the “WIRE OFF” Alert. This can happen even if the electrodes appear firmly connected. To reduce this risk please make a note of the following:

- Skin should be cleaned and dried thoroughly before applying or replacing electrodes.
- “Hydrating” and “moisturizing” soaps and body washes may make it more difficult for electrodes to adhere to skin.
- Using medical tape to keep the electrodes adhered may help.
- Change the electrodes more often, if needed.

**Please Note:**

- If you need additional supplies, Email: **CustomerService@gobio.com**. Include your full name, date of birth, delivery address, supplies needed and supplies remaining. Please allow 3-4 business days for delivery.
- If you continue to have issues, please contact **Customer Service at 1-866-426-4401**.

Irritated Skin

Minor skin irritation is common when wearing any type of electrode for extended periods. We provide each patient with hypo-allergenic and latex free electrodes.

To reduce the risk of skin irritation, ensure that you do the following:

- Change the electrodes every other day.
- Slightly change the location of each electrode.
- Ensure skin is clean and dry prior to applying electrode.
- The kit contains an alternative brand of electrodes if you experience issues.

Please Note:

- We have provided you with alternative electrodes in case of sensitivity.
- Alternative electrodes are not guaranteed to resolve skin irritation.
- If your skin irritation intensifies beyond minor itching, contact customer service. We may direct you to contact your physician.
- Customer Service cannot authorize you to end service, only your physician can discontinue service.

2

Ending Service Indicator

MCOT^{es} - Things to Know



Deactivation Message

When your monitoring is complete, a message will appear on the monitor. You do not need to call us. It is your responsibility to return the kit as soon as possible so that other patients can benefit from using this valuable service. **You will be billed for the kit if it is not returned promptly.**

Please follow these steps when you receive the message that your prescription is complete:

- Take off the sensor and remove the sensor battery.
- Turn off the monitor using the power switch on the side of the monitor.
- Refer to the Kit Return Instructions.

3

Frequently Asked Questions

Service FAQ

- What can I expect while on service? (p.17)
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Features & Troubleshooting FAQ

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Reporting FAQ

- When will my physician get my results? (p.20)
- Will Customer Service call me if I have an arrhythmia? (p.20)
- Can I have my reports sent to me or another physician? (p.20)

3

MCOT Service FAQ

What can I expect while on service?

Reports will be generated and sent to your physician for review.

We may contact you for the following:

- A break in service greater than 24 hours
- Troubleshooting
- Physician request

Do I have to record symptoms?

It is not mandatory to record symptoms. Recording symptoms when you feel them will provide additional information on the reports sent to your physician. When a symptom is recorded the monitor gathers and transmits the data associated with the symptom, as well as ECG data that occurred before and after the symptom was recorded. There is no need to call to confirm the receipt of your recording.

How do I order more supplies?

Email: CustomerService@gobio.com

Phone: **1-866-426-4401**

Include your full name, date of birth, delivery address, supplies needed and supplies remaining. Please allow 3-4 business days for delivery.

Can I shower while monitoring?

Yes, please refer to page 12 for instructions.

How far away can I be from the monitor?

Please refer to page 6 for information.



Am I required to wear the monitor all the time?

You are encouraged to wear the monitor at all times. The more you wear the monitor, the more information will be presented to your physician for accurate diagnosis. However, you must remove the monitor while bathing or participating in water activities. If you choose to remove the monitor for more than 24 hours, email **CustomerService@gobio.com**. Include your full name, date of birth, and be as specific as possible with the time frame you will not be monitoring. If you do not have access to email, contact Customer Service at 1-866-426-4401.

Will traveling while monitoring affect my monitor transmissions?

The monitor can be worn anywhere in the US. If you are flying, remove the monitor and sensor and pack it in your carry-on luggage, reconnect once you land. If you are travelling out of the country, you can wear the monitor, but data will NOT transmit to the monitoring center until you return to the US. If you plan to travel outside of the country contact Customer Service at 1-866-426-4401, they will provide you with pertinent information.

How long will the monitor last, when fully charged?

The monitor may last up to 10 hours. Variables such as cell strength, data gathering, and data transmission will impact the battery life.

Should I wear the monitor while exercising?

Yes, unless otherwise directed by your physician.

If I end service early, will my estimated cost be reduced?

No, the monitoring service is billed at a flat rate. Ending service early will not reduce the amount billed to your insurance, or your patient responsibility.

3

MCOT Service FAQ

Why is the monitor beeping?

Read and follow the message on the monitor. If no message exists, the issue has been resolved. If beeping continues, contact Customer Service.

The monitor screen is non-responsive, what do I do?

Turn off monitor, wait 20 seconds, and turn on monitor. If monitor is still non-responsive, contact Customer Service.

The monitor indicates “move to a better cell coverage area.” Why am I getting this message?

The monitor has information that it is attempting to transmit. Check the cell strength indicator on the monitor, and relocate to an area with a stronger signal. If message persists, turn off monitor, wait 20 seconds, and turn on monitor. If this is unsuccessful, contact Customer Service.

How do I change the volume setting?

1. Select **Options**.
2. Select **Monitor** or **Sensor**.
3. Select **Volume**.
4. Select appropriate volume.
5. Select **OK**.

Please Note: If the vibrate setting is turned off, and you choose to turn the monitor’s volume off, it will default to “low” volume, even though you selected to turn it off.

Will the monitor alert me if there is something wrong with my heart?

No. The monitor will only send alerts regarding technical maintenance, i.e. charge battery, wire off, etc. The monitoring center may send you a text message with instructions.

Can I reply to a text message on my monitor?

No. Open the message and follow the directions and prompts.



When will my physician get my results?

Once you begin service your physician will receive reports throughout your monitoring period. At the conclusion of service your physician will receive a summary report.

Will Customer Service call me if I have an arrhythmia?

The monitoring center will contact you if a specific request is made by your physician.

Reminder: MCOT^{es} is not an emergency service. If at any point you are having a medical emergency please dial 9-1-1.

Can I have my reports sent to me or another physician?

Yes, we can provide you or another physician copies of your reports upon completion of service with your consent. To receive copies of your reports, email **CustomerService@gobio.com**. Include your name, date of birth, and service date, Customer Service will send you an Authorization for Release. Complete and return as directed on the form. Reports should arrive within 7-10 business days.

Mobile Cardiac Outpatient Telemetry

Addendum to the Patient Education Guide – Model CN1006 (C5)

Indications for Use:

The 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; and 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 arrhythmia (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.

Contraindications:

- 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.

FOR USE ON ADULT AND PEDIATRIC PATIENTS ONLY The MCOT System is intended for use on adults and children. It is not intended to be used on infants weighing less than 10 kg (22 lbs.).

Precautions

DISPOSE OF BATTERIES PROPERLY

Observe all local laws for the disposal of alkaline batteries.

WHEN NOT IN USE, REMOVE Sensor BATTERY

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

AVOID ELECTROMAGNETIC INTERFERENCE

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

POTENTIAL FOR ELECTROMAGNETIC INTERFERENCE

There is a potential for electromagnetic interference to other devices while using the MCOT System.

USE WITH IMPLANTED PACEMAKERS AND ICDs (DEFIBRILLATORS) If you have an implanted pacemaker or defibrillator (ICD), the manufacturer may have recommended you take certain precautions when using a cellular phone. Since the Monitor contains a cellular phone, you should take the same precautions when carrying and using the Monitor. In general, most manufacturers recommend the following:

- You should keep a distance of at least six inches (15 cm) between the cellular phone and a pacemaker or defibrillator.
- You should hold the cellular phone on the opposite side of the body from the pacemaker or defibrillator.

- Don't carry a cellular phone in a breast pocket or on a belt if that would place the phone within six inches of the pacemaker or defibrillator.
- You should refer to the manufacturer's information for guidance regarding your pacemaker or ICD and interference issues.

Cautions

POWER DOWN Monitor AND Sensor BEFORE SHOWERING

Power down the Monitor and remove the Sensor before showering. The Sensor/Monitor is water resistant, not waterproof.

DO NOT GET THE Monitor AND Sensor WET

Make sure the Monitor and Sensor stay dry at all times.

CLEANING

Use a soft cloth to clean the equipment. In case of a spill on equipment, please disconnect the equipment and return it using the return shipping instructions provided in your kit.

LIMITATIONS OF COVERAGE

BioTel Heart's ability to obtain information regarding a cardiac event and to contact you or your physician in a timely manner is limited by a number of factors including:

- Transmission of information about a cardiac event to our 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 we are able to make contact with you or your physician.
- If you or your physician are not accessible by telephone, we will not succeed in making contact with you or your physician.

MAINTAIN MINIMUM DISTANCE FROM Base

Due to RF exposure, maintain a minimum distance of 7.87 inch (20cm) from the Base.

Warnings

FOR USE WITH TELEPHONE SYSTEM

Any patient whose life may be put at significant risk by the unavailability of the telephone system should not be Monitored by the MCOT System.

NOT AN APNEA Monitor

The Monitor is not to be used as an apnea Monitor.

USE ONLY WITH SUPPLIED ELECTRODES

While wearing the Sensor, use only electrodes provided in service kit.

NOT AN EMERGENCY RESPONSE SERVICE

The MCOT System is not an emergency response service. If you experience any symptoms that concern you, seek medical help.

DO NOT TAMPER WITH DEVICE

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

DO NOT TAMPER WITH Monitor BATTERY

The Monitor battery can present a fire or chemical burn hazard if mistreated. Do not disassemble, heat, incinerate, or recharge using any device other than the Base or the supplied power cord.

USE ONLY THE SUPPLIED POWER CORD IN SINGULAR OUTLET

Do not use any power cord for the Base other than the one provided in the service kit. A multiple portable socket outlet or extension cord should not be used with the equipment.

DO NOT USE NEAR FLAMMABLE ANESTHETIC

Units are not to be used in the presence of flammable anesthetic.

Specifications**PHYSICAL**

Sensor 3 inches x 1.9 inches x 0.7 inches; Weight: 3.0 oz. with battery

Monitor 4.7 inches x 2.6 inches x 0.9 inches; Weight: 6.0 oz.

Display 2.27 inches x 1.7 inches; Touch screen: color

Base 4.3 inches x 3.7 inches x 1.0 inch; Weight: 6.0 oz.

FUNCTIONAL

Sample Rate 250 samples per second

ECG Resolution 12 bits

Dynamic range of ECG +/- 5 mV

Bandwidth 0.05 to 40 HZ Channels 2

Battery Life: Monitor Up to 10 hrs (with cleared memory & fully recharged battery)

Battery Life: Sensor 24 hrs (1 AAA Alkaline)

Leakage Current Less than .1 Q A Electrodes

TRANSMISSION

Sensor to Monitor 900 MHz ISM band RF transmission, digital error corrected.

Minimum 150 foot range. Retransmission if data is corrupted.

Monitor to Center CDMA (PCS and cellular) wireless, digital error corrected. Telephone line modem, digital error corrected.

OPERATING CONDITIONS

Operating Temperature- 0 - 45°C

Operating Humidity 10% - 95% noncondensing

Storage Temperature -20 - 65°C noncondensing

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, 1.0A; or 15V, 1.67A

Note: Both the Monitor and Sensor are internally powered

STANDARDS COMPLIANCE

Monitor EN60601-1; AAMI EC-38; FCC Part 15

Sensor EN60601-1; AAMI EC-38; FCC Part 15

Base IEC60950; FCC Part 15, 68

AECG Equipment Type I

Note: This equipment has been tested and found to comply with the limits for medical devices to the IEC 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

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

This device complies with part 15 and 68 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference and, (2) This device must accept interference received including interference that may cause undesired operation.

FCC ID

Sensor ISM QBI-1011

Monitor ISM QBI-1012 or QBI-1014

Monitor Cell Modem R17CC864-DUAL or R17CE910-DUAL

FCC RULES PART 15

The Model CN1006 has been tested and complies with the limits for Part 15 of the FCC Rules for a class B digital device. 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 LLC COULD VOID THE USER'S AUTHORITY TO OPERATE THE EQUIPMENT FCC RULES PART 68 REGISTRATION

Model CNI006 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 CNI006 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 or an authorized agent. It is the responsibility of users requiring service to report the need for service to CardioNet or to one of our authorized agents. Service can be facilitated through our office at: CardioNet 1000 Cedar Hollow Road, Suite 102, Malvern, PA 19355
Tel #1 610-729-7000.

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

The Model CNI006 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 CNI006 disrupts the telephone network, the telephone company can discontinue your service temporarily. If possible, the telephone company will notify you in advance. If advance notice is not practical, they will notify you as soon as possible. You are also informed of your right to file a complaint with the FCC.

TELEPHONE COMPANY FACILITY CHANGES

The telephone company can make changes in its facilities, equipment, operations, or procedures that can affect the operation of your equipment. If they do, you should be notified in advance so you have an opportunity to maintain uninterrupted telephone service.

FCC RADIO FREQUENCY EXPOSURE INFORMATION

In August 1996, the Federal Communications Commission (FCC) of the United States, with its action in Report and Order FCC 96-326, adopted an updated safety standard for human exposure to radio frequency (RF) electromagnetic energy emitted by FCC regulated transmitters. Those guidelines are consistent with the safety standard previously set by both U.S. and international standards bodies. The design of this device complies with the FCC guidelines and these international standards. Use only the supplied antenna. Unauthorized antennas, damaged antennas, modifications, or attachments could impair call quality, damage the device, or result in violation of FCC regulations. Please contact us if damage to the unit is apparent.

BODY-WORN OPERATION

This device was tested and was found to comply with the FCC exposure requirements. The device was also tested and found to comply with SAR (Specific Absorption Rate) testing. For more information about RF exposure, please visit the FCC website at www.fcc.gov.

Electrodes

Conductive parts of Electrodes and associated connectors, including NEUTRAL ELECTRODE, should not contact other conductive parts including earth.

For questions on electrodes, contact:

S&W Healthcare - www.swhealthcare.com or 1-800-843-1201

Vermed - www.vermed.com or 1-800-245-4025

Monitor, Sensor and Base are property of CardioNet and should be returned to CardioNet 1E Beacon Light Lane, Suite G, Chester, PA, 19013 USA.

CardioNet, LifeWatch, and BioTel Heart are trademarks of BioTelemetry, Inc.

TERMS AND CONDITIONS OF THE BIOTELEMETRY SERVICE AGREEMENT.

PLEASE READ THIS DOCUMENT CAREFULLY BEFORE ACTIVATING THE MONITOR.

To activate your monitor and begin service you will be asked to accept the terms of this Agreement. Answering “Yes” to the questions on the monitor’s touch screen prior to activation is your acceptance of the terms listed in this document. If you do not agree with the terms of this document please notify Customer Service at 1-866-426-4401 immediately.

PRIVACY AND CONFIDENTIALITY

By signing this document and/or accepting these terms electronically, you acknowledge that you have received a copy of BioTelemetry's Notice of Confidentiality and Privacy Practices, which is incorporated in this agreement below. This acknowledgment is required by the Health Insurance Portability and Accountability Act (HIPAA) to ensure that you have been made aware of your privacy rights. You give BioTelemetry your consent and permission to communicate with other members of your household, if necessary, with regard to your BioTelemetry service. You also authorize BioTelemetry to provide your monitoring data to your physician and his /her staff and to Emergency Medical Services by phone, e-mail, fax or through secure Internet access. You will also be asked to give BioTelemetry permission to use your monitoring data, without your identity, in clinical research and case studies. This is an option and not required to continue to receive BioTelemetry monitoring service (“Service”). You consent to receiving calls from BioTelemetry and its affiliates or authorized agents on your landline or cellular telephone related to the service or payment related to the service. For example, BioTelemetry or its affiliate or authorized agent may contact you in order to obtain the loaned BioTelemetry Monitoring System (“System”) or seek payment for the value of the System. You understand that such communications may include the use of prerecorded voice messages and/or automatic telephone dialing systems.

ASSIGNMENT OF BENEFITS

I request that payment of authorized health insurance benefits, including Medicare benefits, if I am a Medicare beneficiary, to be made on my behalf to CardioNet, LLC. (a subsidiary of BioTelemetry, Inc.) for any medical services provided to me by CardioNet. I authorize any holder of medical and/or insurance information about me to release to CardioNet, my health insurance carrier, or the Centers for Medicare and Medicaid Services (CMS) any information needed to determine these benefits or the benefits payable for related services provided under this agreement. This assignment includes all dates of services rendered by CardioNet for all insurance plans. A copy of this authorization will be sent to CMS or my health insurance carrier if requested. The original will be kept on file by CardioNet. I understand that I am fully responsible to CardioNet for any co-payments, co-insurance, deductibles, payments made directly to me by my health insurance carrier for CardioNet services, and, when allowed by law, services not-covered or payable under my health insurance plan. I also understand that by signing this form and/or accepting these terms electronically, I am accepting financial responsibility as explained above for all payment for services received from CardioNet. By signing this document and/or accepting these terms electronically, I acknowledge that I have received a copy of CardioNet's Notice of Privacy Practices. This acknowledgement is required by the Health Insurance Portability and Accountability Act (HIPAA) to ensure that I have been made aware of my privacy rights.

SERVICE AGREEMENT

Financial Terms I understand that I am fully responsible and agree to pay for any co-payments, co-insurance, deductibles, all payments made directly to me by my insurer for CardioNet services, and when allowed by law, services not-covered (not payable) under my health insurance plan. I acknowledge that I am financially responsible for the loaned Monitoring System (sensor, monitor, and accessories), which I am obligated to return upon completion of the service. If I do not immediately return the Monitoring System, I hereby authorize BioTelemetry to invoice me for, and agree to pay BioTelemetry, the value of the Monitoring System and any associated collection costs should collection or legal costs be incurred by BioTelemetry.

OPERATIONAL NOTICES

I hereby acknowledge that, given the variance in cellular phone coverage and signal strength, the System may not always provide continuous transmission of my ECG rhythm to the Monitoring Center. In the event that there is no cellular phone coverage or adequate signal strength to transmit recorded events, I will move to an area to optimize transmission capability or connect the monitor and base to a direct telephone line as requested. I hereby acknowledge that the System is intended to aid in diagnosis only, and is not designed for prevention or treatment of any event or condition. I agree to immediately discontinue use of the System upon any sign of discomfort or other problems directly related to the System, and to promptly report such discomfort or other problems to BioTelemetry. I give BioTelemetry and its subsidiaries my consent and permission to communicate with other members of my household, if necessary, with regard to my service. I also authorize BioTelemetry and its subsidiaries to provide my monitoring data to my physician and his /her staff and to Emergency Medical Services by phone, e-mail, fax or through secure Internet access. I will also be asked to give BioTelemetry and its subsidiaries permission to use my monitoring data, without my identity, in clinical research and case studies. This is an option and not required to continue to receive monitoring services.

NOTICE OF CONFIDENTIALITY AND PRIVACY PRACTICES

This notice describes how medical information about you may be used and disclosed and how you can get access to this information. Please review it carefully.

PROTECTING YOUR HEALTH INFORMATION

BioTelemetry, Inc., together with its family of companies including CardioNet, LLC, Heart-Care Corporation of America, Inc., and LifeWatch Services, Inc. understands the importance of keeping your health information private. We are required by law to maintain the privacy of health information that identifies you or can be used to identify you. We are also required to provide you with this notice of our privacy practices, our legal duties and your rights concerning your health information. We are required to abide by the terms of this notice currently in effect. We may modify or change our privacy practices described in this notice from time to time, particularly as new laws and regulations become effective. Any changes will be effective for all the health information that we maintain, even information in existence before the change. If we materially modify our privacy practices, you may obtain a revised copy of this notice by contacting us using the information listed at the end of this notice, or by accessing our website at www.gobio.com/patients.

USES AND DISCLOSURES OF YOUR HEALTH INFORMATION

USES AND DISCLOSURES THAT MAY BE MADE WITHOUT YOUR AUTHORIZATION OR OPPORTUNITY TO OBJECT

We may use and disclose your health information, without your authorization, in the following ways:

Treatment: We may use and disclose your health information to provide, coordinate or manage your treatment. For example, we may disclose your health information to a provider who requests this information to treat you.

Payment: We may use and disclose your health information to bill and get payment for health services we provide to you. For example, we may disclose your health information to your health insurance plan to obtain payment for services provided to you.

Health Care Operations: We may use and disclose your health information in order to support our business activities. For example, we may use your health information to conduct quality improvement activities, to engage in care coordination and case management, to conduct business management and general administrative activities, and other similar activities.

Health & Wellness Information: We may use your health information to contact you with information about health related services or appointment reminders. If you do not wish to receive this type of information, you may request to opt-out of receiving this information by sending an email to privacy@biotelinc.com or calling the phone number provided at the end of this notice.

Research; Death; Organ Donation: We may use or disclose your health information for research purposes in limited circumstances. We may disclose your health information to a coroner, medical examiner, funeral director or organ procurement organization for certain purposes.

Public Health and Safety: We may use and disclose your health information to the extent necessary to avert a serious and imminent threat to your health or safety or the health or safety of others. We may disclose your health information to appropriate authorities if we reasonably believe that you are a possible victim of abuse, neglect, domestic violence or other crimes.

Required by Law: We will use or disclose your health information when we are required to do so by law.

Process and Proceedings: We may disclose your health information in response to a court or administrative order, subpoena, discovery request or other lawful process.

Law Enforcement: We may disclose your health information, so long as applicable legal requirements are met, to a law enforcement official, such as for providing information to the police about the victim of a crime.

Inmates: We may disclose your health information if you are an inmate of a correctional institution and we created or received your health information in the course of providing care to you.

Military and National Security: We may disclose your health information to military authorities if you are a member of the Armed Forces. We may disclose your health information to authorized federal officials for lawful intelligence, counterintelligence and other national security activities.

Workers' Compensation: We may disclose your health information as authorized by and to the extent necessary to comply with laws relating to workers' compensation or other similar programs, established by law, that provide benefits for work-related injuries or illness without regard to fault.

Business Associates: We may disclose your health information to persons who perform functions, activities or services to us or on our behalf that require the use or disclosure of your health information. To protect your health information, we require the business associate to appropriately safeguard your information.

To You: We will disclose your health information to you, as described in the Individual Rights section of this notice.

USES AND DISCLOSURES THAT MAY BE MADE EITHER WITH YOUR AGREEMENT OR THE OPPORTUNITY TO OBJECT

Unless you object, we may disclose to a member of your family, a relative, a close friend or any other person you identify, orally or in writing, your health information that directly relates to that person's involvement in your health care. If you are unable to agree or object to such disclosure, we may disclose such information as necessary if we determine that it is in your best interest based on our professional judgment. We may use or disclose your health information to notify or assist in notifying a family member, personal representative or any other person that is responsible for your care of your location or general condition.

USES AND DISCLOSURES BASED ON YOUR WRITTEN AUTHORIZATION

Marketing: We must obtain your written authorization to use and disclose your health information for most marketing purposes.

Sale of Health Information: We must obtain your written authorization for any disclosure of your health information which constitutes a sale of health information.

Other Uses: Other uses and disclosures of your health information will be made only with your written authorization, except as described in this notice or as otherwise required or allowed by applicable law. In the event that we ask for your authorization to use or disclose your health information, we will provide you with an appropriate authorization form. Once you've given us a written authorization, you can revoke that authorization at any time, except to the extent that we have taken action in reliance on your authorization.

INDIVIDUAL RIGHTS

Access: You have the right to see or get an electronic or paper copy of your health information by submitting a request to us in writing using the information listed at the end of this notice. There are certain exceptions to your right to obtain a copy of your health information. For example, we may deny your request if we believe the disclosure will endanger your life or that of another person. Depending on the circumstances of the denial, you may have a right to have this decision reviewed. We will charge you a fee to cover the costs incurred by us in complying with your request.

Disclosure Accounting: You have the right to an accounting of disclosures of your health information made by us by submitting a request to us in writing using the information listed at the end of this notice. This right only applies to instances when we or our business associates disclosed your health information for purposes other than treatment, payment, health care operations, upon your written authorization, and certain other activities. The right to receive this information is subject to certain exceptions, restrictions and limitations. You must specify a time period, which may not be longer than 6 years. You may request a shorter timeframe. You have the right to one free request within any 12-month period, but we may charge you for any additional requests in the same 12-month period. We will notify you about any such charges, and you are free to withdraw or modify your request in writing before any charges are incurred.

Restriction Requests: You have the right to request restrictions on the use and disclosure of your health information by submitting a request to us in writing using the information listed at the end of this notice. Your request must state the specific restriction requested and to whom you want the restriction to apply. We are not required to agree to these additional restrictions, except we must agree not to disclose your health information to your health plan if the disclosure (1) is for payment or health care operations and is not otherwise required by law, and (2) relates to a health care item or service which you paid for in full out of pocket. If we agree to a restriction, we will abide by our agreement (except in an emergency).
Confidential Communication: You have the right to receive certain communications confidentially. That means you can request that we communicate with you by alternative means or to an alternative location by submitting a request to us in writing using the information listed at the end of this notice. We will accommodate your request if it is reasonable and specifies the alternative means or location. We may also condition this accommodation by asking you for information as to how payment will be handled.

Amendment: You have the right to amend your health information in our records for as long as we maintain the information. You must make a request in writing, using the information listed at the end of this notice, to obtain an amendment. Your written request must explain why the information should be amended. If we agree to amend your health information we will make reasonable efforts to inform others of the amendment and to include the changes in any future disclosures of that information. We may deny your request if, for example, we determine that your health information is accurate and complete. If we deny your request, we will send you a written explanation and allow you to submit a written statement of disagreement to be appended to the information you want amended.

Paper Notice: If you receive this notice electronically you are entitled to receive this notice in written form. Please contact us using the information listed at the end of this notice to obtain this notice in written form.

Breach: You have the right to be notified if you are affected by a breach of unsecured health information.

QUESTIONS AND COMPLAINTS

If you want more information about our privacy practices or have questions or concerns, please contact us using the information listed at the end of this notice. If you are concerned that we may have violated your privacy rights, or you disagree with a decision we made about your rights to your health information you may complain to us using the information listed at the end of this notice. You may also complain to the U.S. Department of Health and Human Services. We support your right to protect the privacy of your health information. We will not retaliate against you in any way if you choose to file a complaint with us or with the U.S. Department of Health and Human Services.

CONTACT INFORMATION

BioTelemetry, Inc.
Privacy Officer
1000 Cedar Hollow Road, Suite 102
Malvern, PA 19355
Telephone: 610.729.7000
Email: privacy@biotelinc.com

Update Effective date: August 30, 2017

I CERTIFY THAT I UNDERSTAND AND AGREE TO THE FOREGOING TERMS AND TO THE FOLLOWING STANDARD TERMS AND CONDITIONS.

1. Use of Cardiac Monitoring System ("System") and Access to and Use of BioTelemetry Monitoring Service ("Service"). Subject to Patient's compliance with the terms and conditions indicated within this Patient Education Guide (the "Agreement"), BioTelemetry hereby grants Patient a personal, nonexclusive, nontransferable license to use the System and to access and use the features and functions of the Service solely for purposes of monitoring Patient's heart rate as prescribed by Patient's physician. Patient expressly acknowledges and agrees that the Service, which is available only by physician prescription, is used solely to assist physicians in diagnosis and treatment, and is not intended for use as an emergency response system for patients who may experience serious or life-threatening medical problems. Patient is aware that cell phone coverage limitations and delays in land-line telephone communications could significantly delay transmission and analysis of patient monitoring data. Patient agrees to contact BioTelemetry immediately if problems are experienced using the system or if signs of physical discomfort occur, and to discontinue use of the system if the physician or BioTelemetry believe service discontinuation is advisable. Patient shall not, in whole or in part, sublicense, provide access to, tamper with, modify, distribute, use in a service

bureau or time-sharing capacity, export in violation of applicable laws and regulations, rent, loan, transfer, disassemble, or reverse engineer or create a derivative work of the System or Service. Patient shall not, in whole or in part, transfer or assign this Agreement or any right granted hereunder, except upon the prior written consent of BioTelemetry. Any prohibited transfer or assignment shall be null and void. Subject to the licenses granted herein, as between BioTelemetry and Patient, BioTelemetry holds all right, title and interest in and to the System and the Service including, without limitation, any patents, trademarks, trade secrets, copyrights or other intellectual property rights therein. BioTelemetry reserves all rights not expressly granted to Patient under this Agreement.

2. Term and Termination. This Agreement shall commence on the date that BioTelemetry accepts Patient's enrollment hereunder, and shall continue until terminated by either party as set forth herein. Either party may terminate this Agreement, for any or no reason, upon thirty (30) days' written notice to the other party, except that this Agreement shall immediately terminate if Patient breaches Paragraph 1 above. Upon any termination of this Agreement, Patient shall immediately discontinue all use of the Service, and shall promptly return the System to BioTelemetry. The limitations in Paragraph 1, and Paragraphs 3-6 shall survive any termination of this Agreement.

3. NO WARRANTY. THE SYSTEM AND THE SERVICE ARE PROVIDED BY BIOTELEMETRY HEREUNDER SOLELY ON AN "AS-IS" AND "AS AVAILABLE" BASIS WITHOUT WARRANTY OF ANY KIND. TO THE MAXIMUM EXTENT PERMITTED UNDER APPLICABLE LAW, BIOTELEMETRY HEREBY DISCLAIMS ANY AND ALL WARRANTIES, EXPRESS, IMPLIED OR STATUTORY, INCLUDING, BUT NOT LIMITED TO, ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE, NON-INFRINGEMENT AND/OR QUIET ENJOYMENT, AS WELL AS ANY IMPLIED WARRANTIES OTHERWISE ARISING OUT OF COURSE OF DEALING, COURSE OF PERFORMANCE OR TRADE USAGE. PATIENT FURTHER ACKNOWLEDGES AND AGREES THAT BIOTELEMETRY SHALL NEITHER BE RESPONSIBLE NOR LIABLE FOR PATIENT'S INABILITY TO ACCESS OR USE THE SERVICE AS A RESULT OF ANY DEFICIENCY IN THE INTERNET, THE TELEPHONE SERVICE, OR OTHER CONNECTION BETWEEN CARDIONET AND PATIENT. PATIENT EXPRESSLY ACKNOWLEDGES AND AGREES THAT NEITHER THE SYSTEM, NOR THE SERVICE (AS WELL AS ANY SUPPORT GIVEN BY ANY BIOTELEMETRY SUPPORT STAFF), NOR ANY MATERIAL AVAILABLE THROUGH PATIENT'S USE OF THE SYSTEM OR SERVICE IS INTENDED TO PROVIDE PATIENT WITH MEDICAL ADVICE, A DIAGNOSIS OR TREATMENT. PATIENT

MUST ALWAYS SEEK THE ADVICE OF PATIENT'S PHYSICIAN OR OF ANOTHER QUALIFIED MEDICAL PRACTITIONER WITH ANY QUESTIONS PATIENT MAY HAVE REGARDING A SPECIFIC MEDICAL CONDITION OR PERCEIVED CONDITION.

4. LIMITATION OF LIABILITY. TO THE MAXIMUM EXTENT PERMITTED UNDER APPLICABLE LAW: (I) IN NO EVENT SHALL BIOTELEMETRY OR ITS LICENSORS OR SUPPLIERS BE LIABLE TO PATIENT FOR ANY INDIRECT, INCIDENTAL, SPECIAL, CONSEQUENTIAL OR PUNITIVE DAMAGES ARISING OUT OF OR RELATED TO THIS AGREEMENT INCLUDING, WITHOUT LIMITATION, LOST PROFITS, COSTS OF DELAY, ANY FAILURE OF DELIVERY, BUSINESS INTERRUPTION, COSTS OF LOST OR DAMAGED DATA, UNAUTHORIZED DISCLOSURE TO OR ACCESS OF PATIENT DATA, OR LIABILITIES TO THIRD PARTIES ARISING FROM ANY PERSONAL INJURY OR PROPERTY DAMAGE CLAIM OR ANY OTHER TYPE OF CLAIM, EVEN IF BIOTELEMETRY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES; AND, (II) IN NO EVENT SHALL BIOTELEMETRY'S AGGREGATE LIABILITY UNDER THIS AGREEMENT EXCEED THE AMOUNT PAID BY PATIENT TO CARDIONET UNDER THIS AGREEMENT. THE PARTIES AGREE THAT THE ALLOCATION OF LIABILITY SET FORTH IN THIS SECTION 5 FORMS AN ESSENTIAL BASIS OF BIOTELEMETRY'S WILLINGNESS TO GRANT PATIENT THE USE OF THE SYSTEM AND ACCESS TO AND USE OF THE SERVICE AND IS INDEPENDENT OF EACH AND EVERY LIMITED REMEDY THAT PATIENT MAY HAVE.

IMPORTANT REMINDER:

This device provides a diagnostic test. It is not an emergency response service. If at any time you experience a symptom that you feel is a medical emergency, you should immediately dial 911 for medical assistance.



1000 Cedar Hollow Road, Suite 102, Malvern, PA 19355

Toll free: 1-866-426-4401 • CustomerService@gobio.com • www.gobio.com

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