MCOT PATCH™

MOBILE CARDIAC OUTPATIENT TELEMETRY

PATIENT EDUCATION GUIDE

BioTel™ HEART

CardioNet & LifeWatch

Need help or have questions? Contact Customer Service Toll Free at 1.866.426.4401 or visit www.gobio.com/patients for online support.

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Video Tutorials

Video instruction is available 24/7 to assist you with set-up.
Monitor - Select Options tab, then press the HELP button.
www.gobio.com - Select Patients tab, select "videos" under MCOT™.

About our Service

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Your physician has prescribed the **MCOT**™ Patch System for you. The MCOT system conducts beat-by-beat analysis of your heart activity and transmits certain abnormal beats to the certified cardiac technicians at BioTel Heart. Trained technicians review data and watch for unusual activity 24 hours a day/ 7 days a week, and in some cases may contact your physician. Clinical reports are made available to your healthcare professional during and at the end of your service.

To get started, review the important information in this guide, or view the instructional videos on the monitor, or visit www.gobio.com/patients.

If you have any questions about your monitoring service or billing, please contact us:

Customer Service: 1-866-426-4401 (toll-free)
email: customerservice@gobio.com
Hours: 24 hours a day, 7 days per week

Billing Department: 1-855-572-3999 (toll-free)
email: billing@gobio.com
Hours: 9:00am - 5:00pm EST

The BioTelemetry Healthcare App

Available on the iPhone App Store

GET IT ON Google Play

Kit Contents

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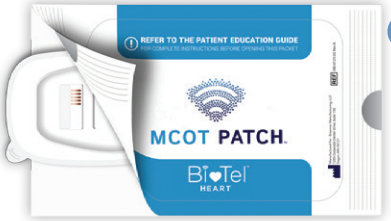

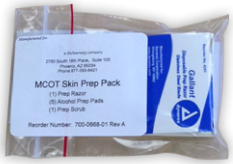

1. Sensor
2. Sensor Charger
3. Patch Pouch
4. Monitor
5. Monitor Case
6. Monitor Charger
7. MCOT Skin Prep Pack
8. Patient Education Guide
9. Return Envelope

STEP 1: Turn On the Monitor

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Power ON the Monitor

- Locate the monitor in your kit. Press and hold the Power button to turn on the monitor. Depending on the model of the monitor, the Power button is located at the top or on the side of the monitor.
- Depending on type of monitor, the buttons at the bottom may be used to wake your monitor from sleep mode.

- The monitor will run through a few screens. It may take up to two minutes to get to the starting screen.

- The text on this screen confirms the monitor is ready for set-up.

STEP 2: Monitor Set-Up

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- Select the appropriate language option and press continue.
- Note: If your screen goes dark now, or anytime throughout your monitoring process, it is in sleep mode. To wake, press and release the power button.

- During the set-up process, you will be required to select a connection type. To view the video, press the blue arrow on the image that says "Patch".

- When you finish watching the video, set the monitor aside and proceed to Step 3: "Attach Sensor to the Patch".

STEP 3: Attach the Sensor to the Patch

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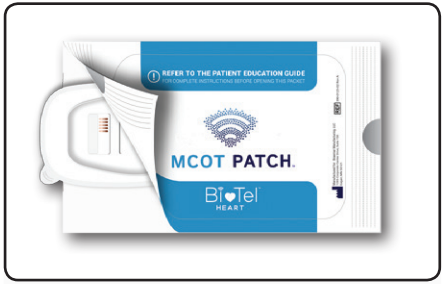
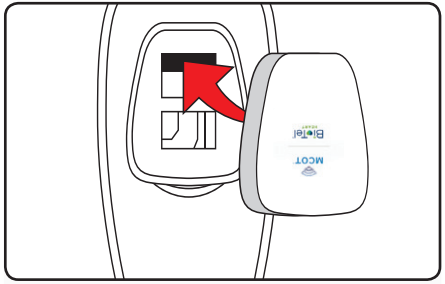


1. Open the pouch.
Tear open one of the pouches and remove the patch.

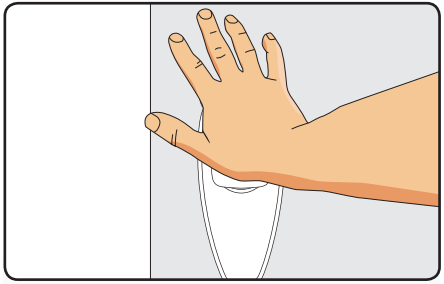
2. Place patch on a flat hard surface.

3. Locate the sensor in your kit.

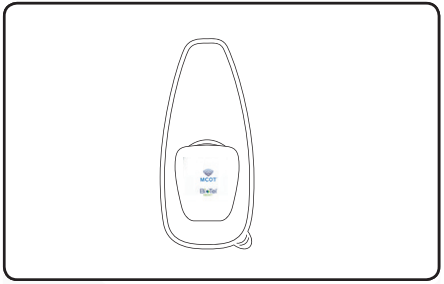
Attach the Sensor to the Patch



4. Place sensor in the patch.

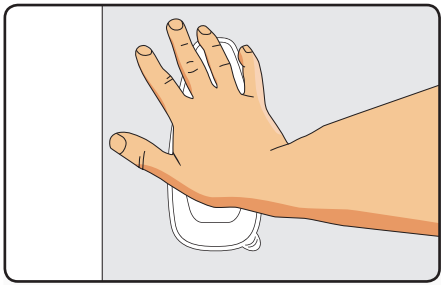


5. While standing, place the palm of your hand on top of the sensor and apply pressure to snap the sensor into the patch. You may hear several clicks.

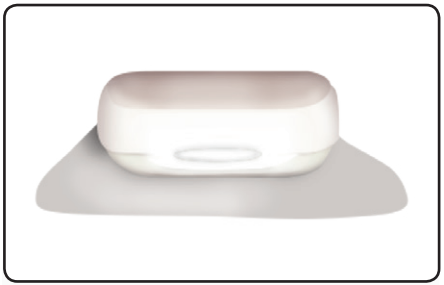


6. Rotate patch 180 degrees. Flashing green lights will appear if connected properly

Attach the Sensor to the Patch



7. With the patch rotated, again place the palm of your hand on top of the sensor and apply pressure to snap the sensor into the patch.

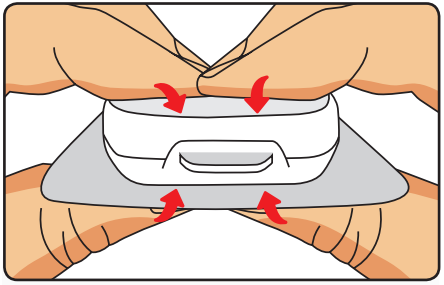


8. Inspect all four sides of the sensor for gaps. The sensor is attached correctly if there are no visible gaps.

9. Correct - No Gap

10. Incorrect - Gap

Attach Sensor to the Patch



11. Apply pressure to any gaps to seal the gap.

12. Ensure that sensor is sealed and there are no gaps. It is very important that all gaps are closed or damage to the sensor could occur.

- Pick up the monitor and press **Continue**.

STEP 4: Pair the Sensor and Monitor

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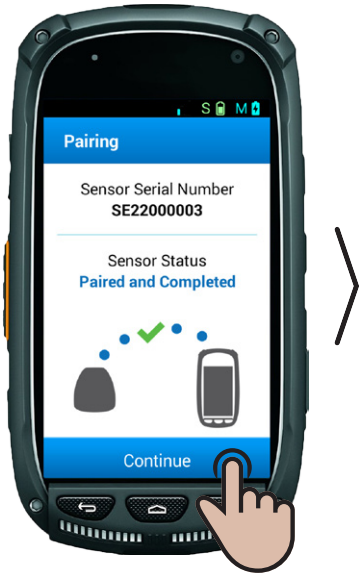
- Pick up the patch so it is near the monitor. The sensor and monitor should automatically link to each other via Bluetooth.
- Some monitor models may differ; if prompted with a Bluetooth pairing request, tap **OK** to start a connection. If the pairing process is successful, a green checkmark will be displayed on the screen. Press **Continue** to move to the next screen.



- You will need to review a series of questions before monitoring can begin.
- Read the text on each screen and select the appropriate response.

STEP 5: Patient Consent

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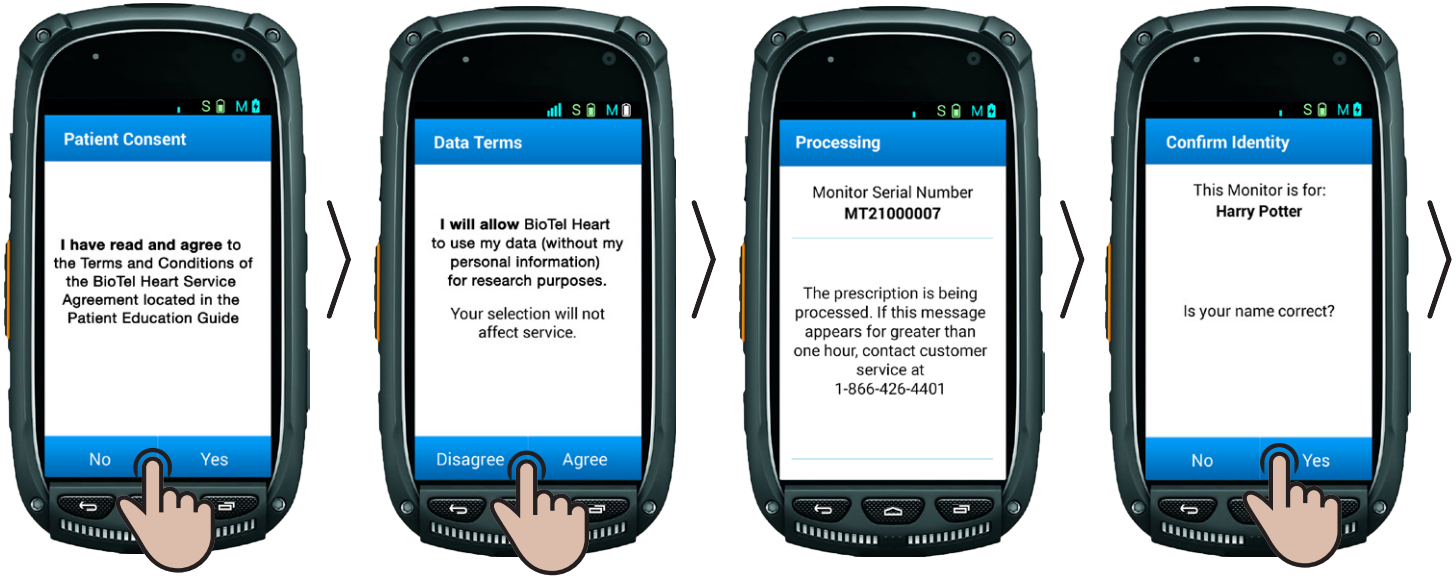

- Consent to the Terms and Conditions of the Service Agreement, located on the "**Patient Consent**" screen, is required to start monitoring.
- If you select **No** the following screen will instruct you to contact BioTel Heart.

- The "**Data Terms**" screen allows BioTel Heart to collect your ECG data for research purposes.
- Select **Agree** to confirm. If you do not agree, select **Disagree**. Your response will not impact service.

- The "**Processing**" screen will appear while your enrollment is being processed through BioTel Heart's internal system.

- The "**Confirm Identity**" screen will ask you to confirm that the name on the screen is yours. If your name appears correctly, select **Yes**.
- If the name is incorrect select **No**. The following screen will instruct you to contact BioTel Heart .

STEP 6: Placement and Skin Preparation

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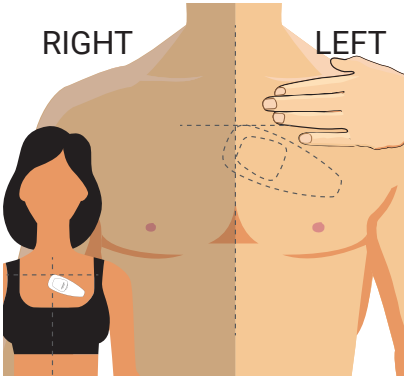
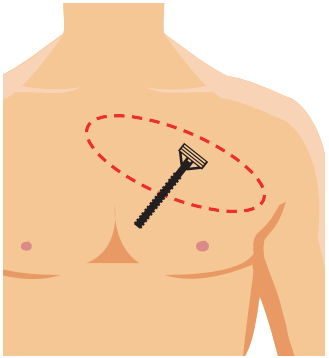
It is important to properly prepare your skin before you apply the patch to your body.

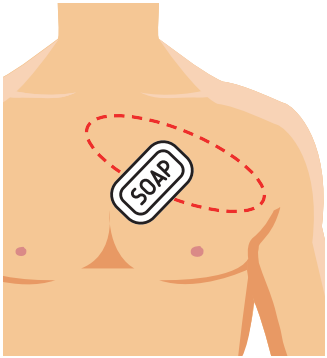
- Now that you've finished the questions, set aside the monitor and proceed to Step 6, 'Placement and Skin Preparation'.



- Determine the area of your chest to prepare by referring to the diagram.
- Locate your collarbone on the **left** side of your body and measure three finger widths.

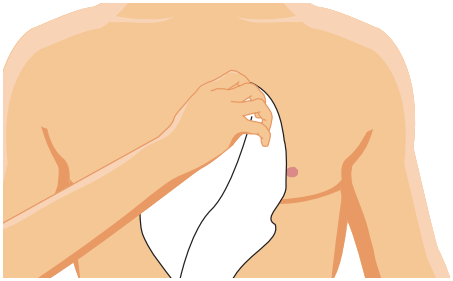


- **Wash / Shave**
  If hair is on your chest, shave the area where the patch will be placed. A razor is available in your MCOT Skin Prep Pack. Start at the center of your chest and shave the entire area marked in the red circle of the diagram.

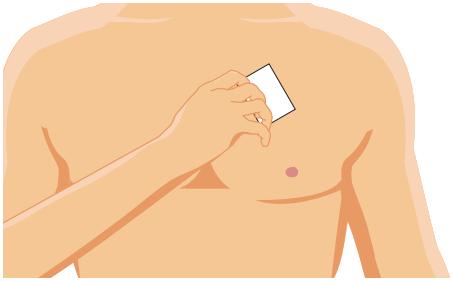


- **Clean Skin**
  Clean the area with soap and water.

Placement and Skin Preparation

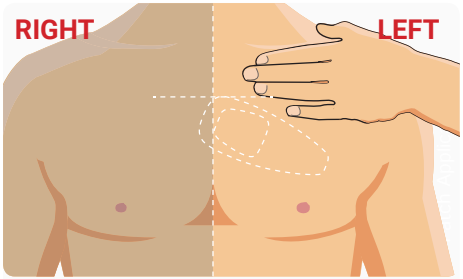


- **Dry Skin**
  Dry skin thoroughly using a towel.

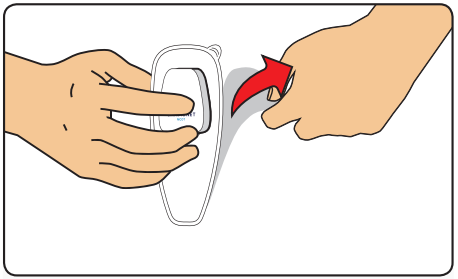


- **Abrade Skin**
  Remove the Prep Scrub Pad from your MCOT Skin Prep Pack. Scrub the cleaned area with firm pressure in a circular motion for one minute. This important step will improve the quality of the recording.
- Do not apply lotions or oils.

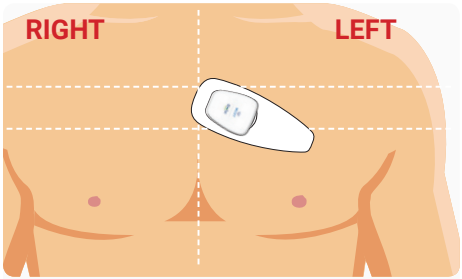
STEP 7: Apply the Patch to Your Skin



1. The top of the patch should be three finger widths down from your collarbone.



2. Pick up the patch with the attached sensor, peel the clear plastic backing off.



3. Place patch on a slight angle as shown in the illustration with the wide end of the patch slightly over the center of your chest.
   - Press all sides of the patch so it will adhere to your skin.

Apply the Patch to Your Skin

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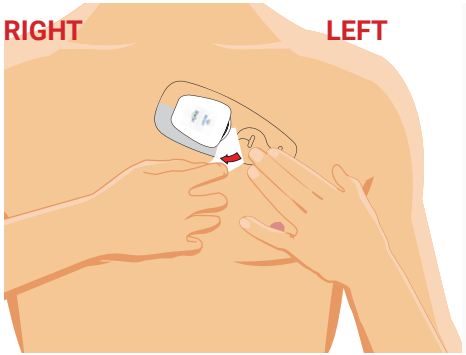

4. **Remove top white paper.** Gently peel off the upper liner by starting with the raised tab.

- After the liner is removed, press all the edges of the patch firmly and on the sensor so the patch will adhere to your skin.
- Smooth out any wrinkles by pressing the patch.
- Wait 10-15 minutes to allow the patch to fully adhere to your skin before proceeding to the next step.

Minor discomfort may occur when the patch is attached to the skin. If you have sensitive skin, this product may not be appropriate for use.

STEP 8: Record a Baseline

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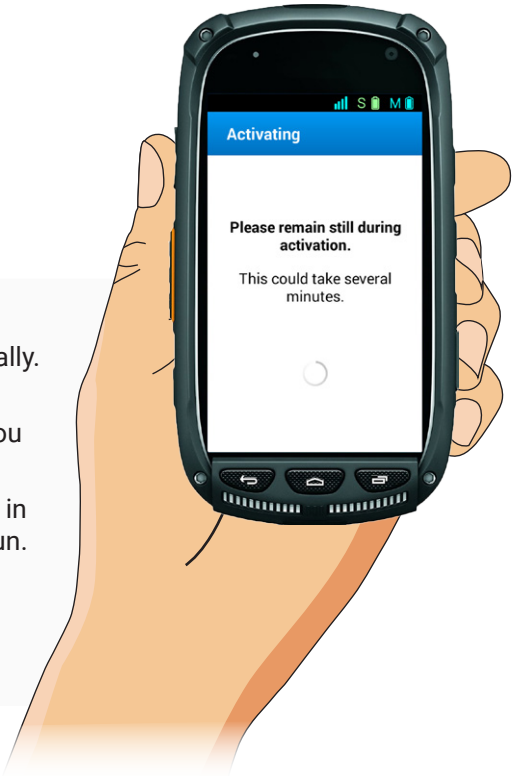
Now that the patch is on your body, pick up the monitor and press **Continue**.



- When you see this screen, a baseline ECG recording will begin. Remain still, preferably seated, and breathe normally.
- Once complete, the main screen (Record Symptom) will appear. This means the baseline ECG is complete and you can go about your normal daily activities.
- The BioTel Heart Monitoring Center will send a text later in the day to confirm that your monitoring service has begun.

Please Note: if you press **Continue** prior to applying the patch to your chest, the **"Activating"** screen may appear for an extended period of time. If this message appears for greater than an hour contact Customer Service.

Record a Baseline (Manual Recording Option)

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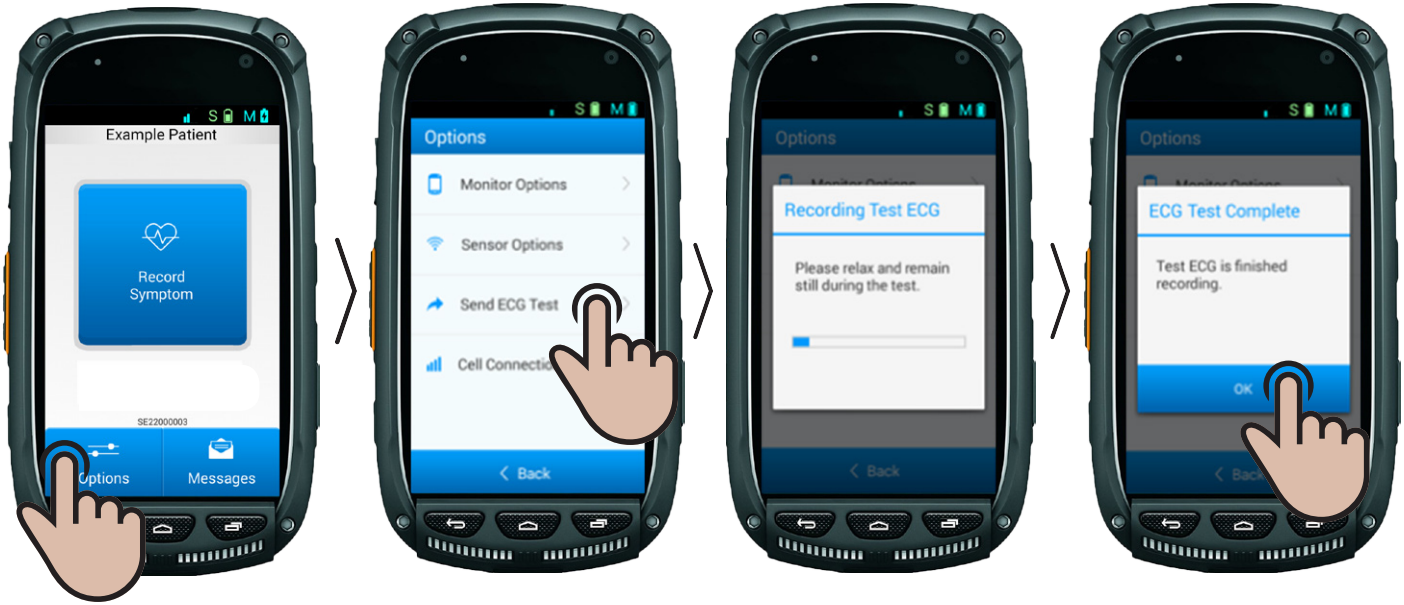
Sending a baseline should occur automatically, and the data will be sent wirelessly to BioTel Heart. If you do not have cellular coverage, the baseline will store in the monitor until service is available. You may be asked to transmit a baseline recording. The steps to complete a manual baseline recording are as follows:



1. Select **Options**

2. Select **Send ECG Test**

3. Test will be recorded

4. Select **OK** to return to the main screen

Record Symptoms

Recording a Symptom

- The MCOT Patch will monitor your heart and send data to the Monitoring Center. However, you can record symptoms as you feel them and your recordings will appear on the reports provided to your physician.
- To record a symptom, press "**Record Symptom**" on the main monitor screen and enter the information.

Record Symptoms

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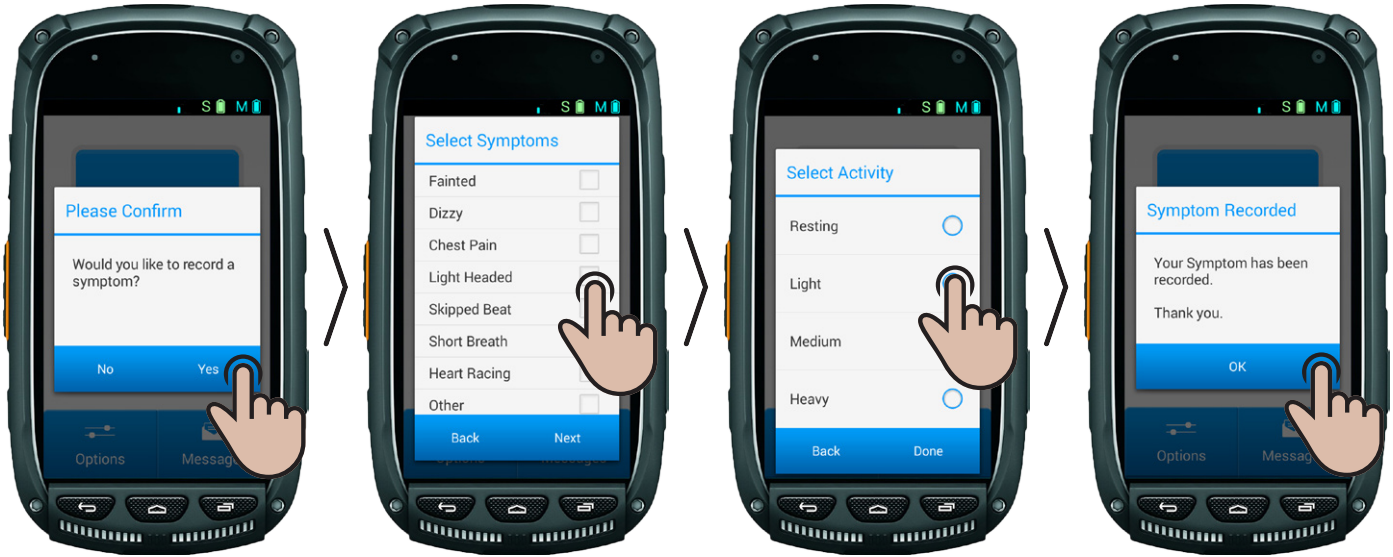

- A dialog box will ask if you would like to record a symptom. Select **Yes** to continue. If you do not wish to record a symptom, select **No**.

- The **"Select Symptoms"** screen allows you to select the symptom(s) you were feeling. Select all that may apply.
- Select **Next** to continue.

- The **"Select Activity"** screen allows you to record your level of activity when the symptom occurred.
- Select your activity level and press **Done**.

- The **"Symptom Recorded"** screen confirms that your symptom was recorded. Press **OK** to return to HOME screen.

Removing the Sensor from the Patch

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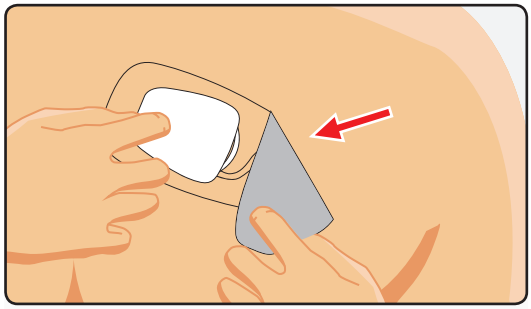
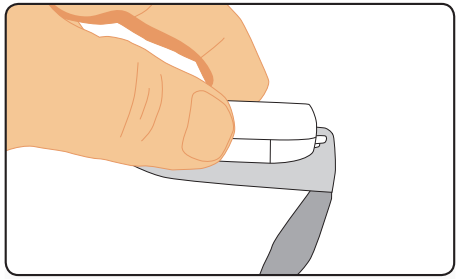
Depending on the duration of your prescription, you may need to change the patch several times throughout your monitoring period. Remove the patch when the sensor battery is low and requires charging, or if the patch is loose and needs to be replaced.

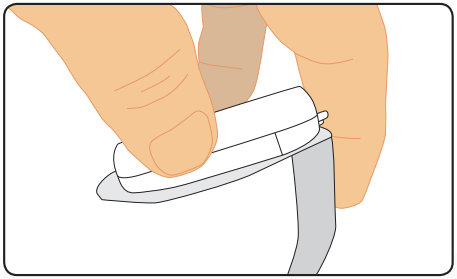
Before removing the MCOT Patch, turn **off** the monitor.



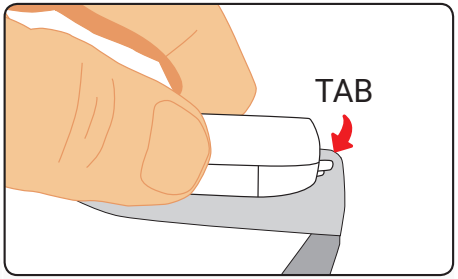
Start at one end and pull the patch material away from your body to remove the patch.



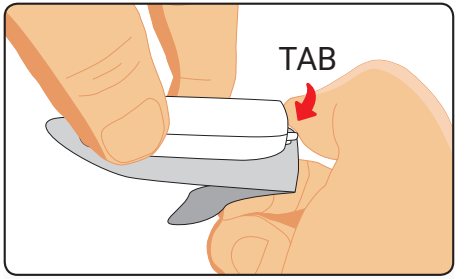
1. **Hold** patch as shown.



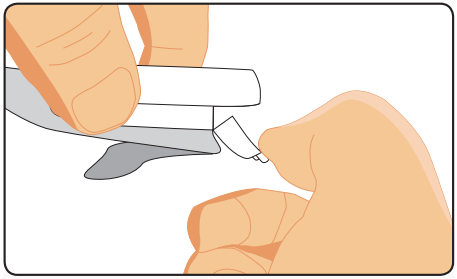
2. **Fold** clear adhesive on top of itself to get out of way for next step.



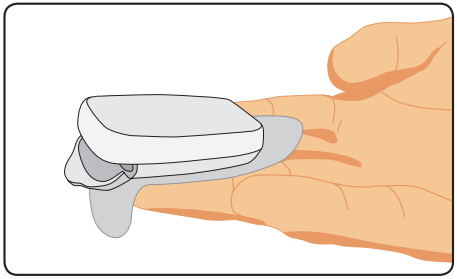
3. Locate patch **Tab**.



4. Apply downward pressure on tab to snap open the tab. This will require some force.

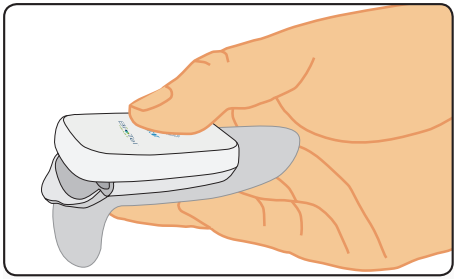


5. Pull down on the tab.

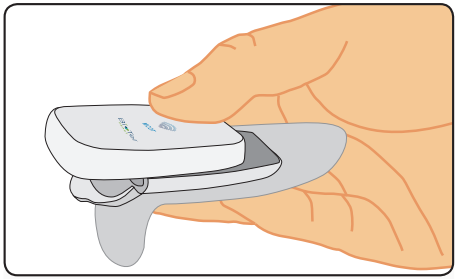


6. Place sensor in hand as shown above.

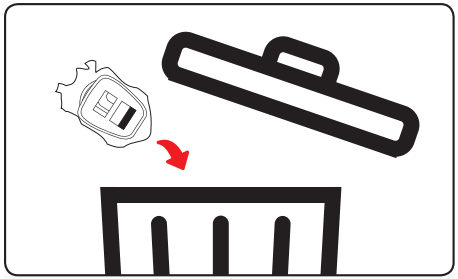
Removing the Sensor from the Patch



7. Place thumb on top of sensor.



8. Push thumb forward to dislodge the sensor from the patch. It may take some force to dislodge the sensor.

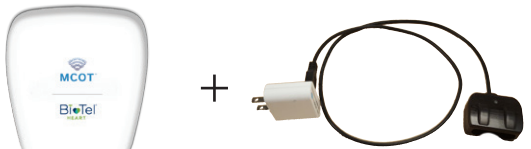


9. Discard the used patch, **NOT the sensor.**

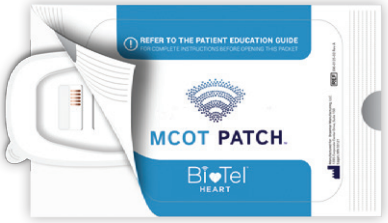
If you need to charge the sensor follow the instructions on page 27.

The sensor is reusable and should not be discarded.

Replacing the Patch

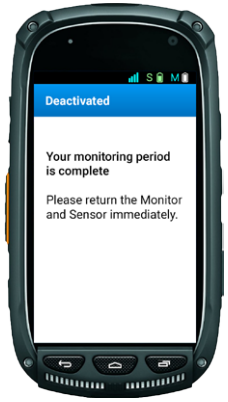


- The sensor must be fully charged before reattaching it to another patch. Follow the instructions on page 27 to charge the sensor. Wait until the sensor is fully charged and the light has turned green before applying another patch to your skin.

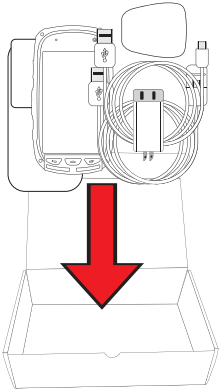


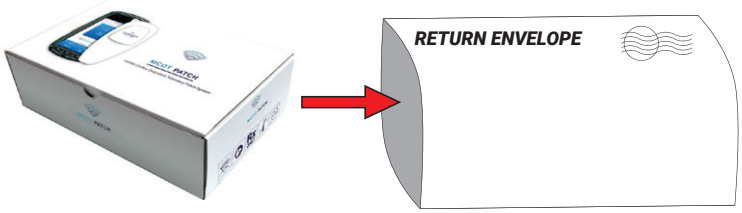
- After the sensor is charged and your skin has been properly cleaned, repeat the steps to attach the sensor to the patch as shown on page 7. Once sensor is attached to the patch follow the steps on page 15 to apply the patch to your skin.

Deactivation / Return the Equipment

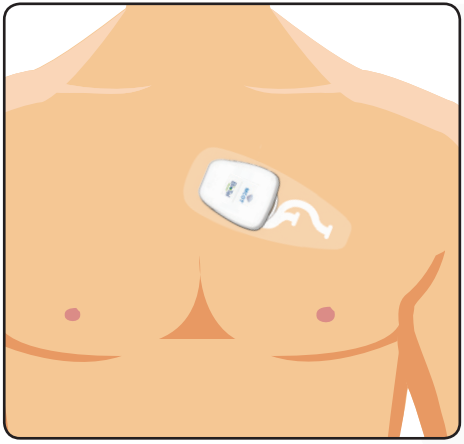


- When your monitoring service is complete, a message will appear on the monitor to return the equipment immediately.
- Turn off the monitor by pressing the power button.
- Remove shipping envelope from kit.
- Pack up the monitor, sensor, chargers, and any extra patch pouches and place into the kit.
- Place the kit into the large, postage-paid envelope and mail back to BioTel Heart, via UPS. There is no cost to you to mail back the equipment.





Important Information

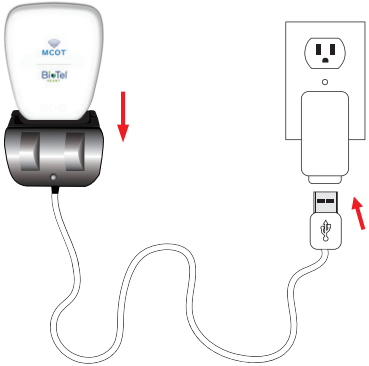


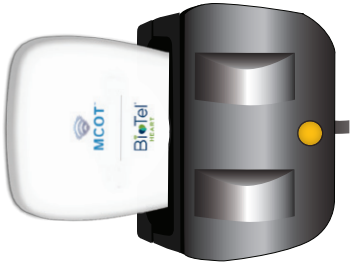
- Continue to wear your MCOT Patch for the duration prescribed by your physician.
- Mild itching or irritation underneath the patch area may occur, and is usually temporary. If more significant itching or irritation develops or persists, contact Customer Service at 1-866-426-4401, they may direct you to contact your physician.
- Keep the monitor and sensor within close range of each other throughout your monitoring period. To avoid getting alert messages on the monitor, keep the monitor within 30 feet of the sensor at all times.
- Record any symptoms as they occur. Promptly respond to any messages or alerts that you receive on the monitor.

The MCOT Patch system is not an emergency response system. The monitor cannot be used to make outgoing calls, even during an emergency. If you experience a symptom that you feel is a medical emergency, call 911 for medical assistance.

Charging The Sensor
The sensor must be charged when the monitor alerts you that the sensor battery is low.

- Locate the charger and cable wire from your kit.
- Only use the supplied charger to charge the sensor.
- Insert sensor into charger as shown in illustration.
- Insert the other end of the cable into the wall charger, and insert the wall charger into a functioning outlet.





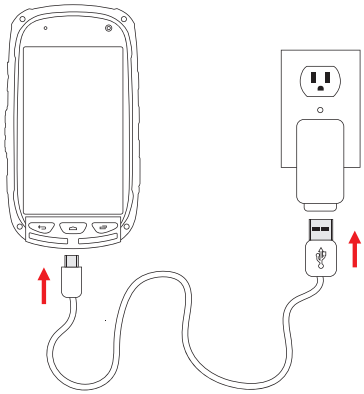
Keep the sensor plugged into the charger until the unit is fully charged and the light turns green. It may take up to 90 minutes to fully charge the sensor.

Charging

Fully Charged

Charging the Monitor
Charge the monitor every night. It may take up to 4 hours to fully charge the monitor.

- Insert the small end of the charging cable into the monitor as shown.
- Insert the other end of the cable into the black charger.
- Insert the charger into a functioning outlet.



Monitor Battery Level

Sensor Battery Level

The monitor is fully charged when the battery symbol turns white.

TIP

Swipe down on the battery images to determine battery level percentages.

Showering

The MCOT Patch components are water-resistant, not waterproof.

You can shower normally; however, for optimal results, **avoid spraying water directly onto the sensor.** While showering, it is recommended to face away from the shower head.

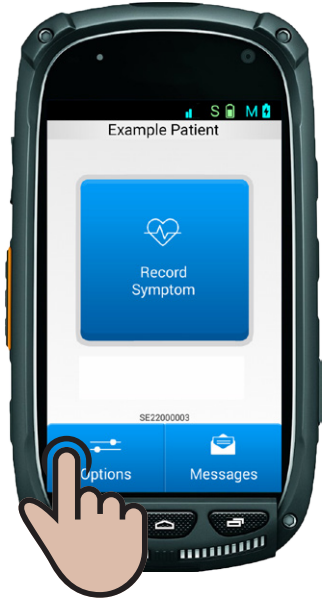
Do not swim, or take baths while wearing the MCOT Patch.

KEEP THE MONITOR AWAY FROM WATER

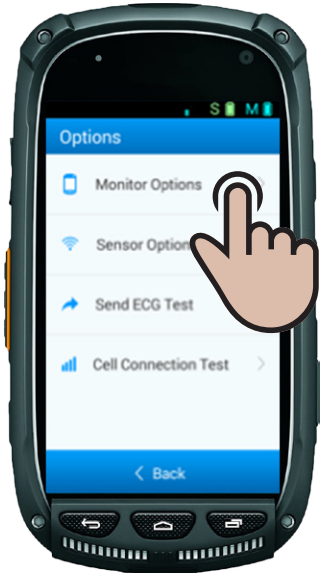
Options

gobio.com/patients

You have the ability to change volume and vibrate settings for the monitor. You can also send a baseline ECG or check cell coverage.



1. Tap **Options**

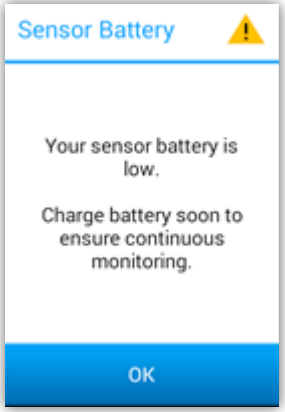


2. Select **Monitor Options**

3. Select **Volume** to adjust volume to either a high, medium or low setting. Select **Vibrate** if you would not like the monitor to ring.

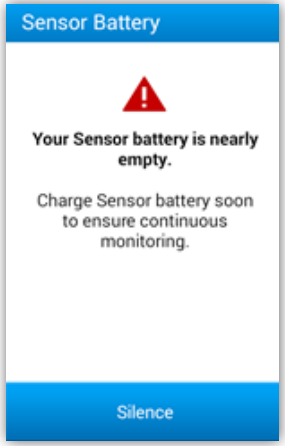
Please Note
Vibrate mode must be on if monitor volume is turned off.

Troubleshooting



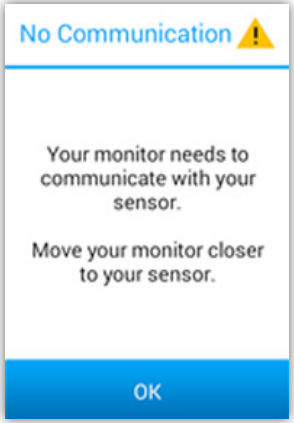
Sensor - Low Battery Messages
There are two different messages that will display when it is time to charge the sensor.

- A **Battery Warning** ⚠ symbol indicates that the sensor battery life is low.
- If you receive this warning message, follow the instructions for removing the patch and charge the sensor.
- The message can be dismissed by pressing the **OK** button, however the message will appear again.



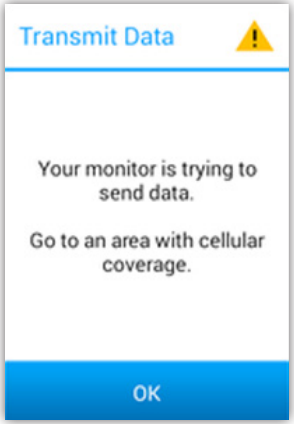
A **Battery Alarm** ⚠ symbol indicates that the sensor battery life is critically low.

- If you receive this alarm, the sensor must be removed from the patch to be charged.
- The battery alarm message can be silenced by pressing **Silence**, but the message will remain on the screen until the sensor battery is charged.



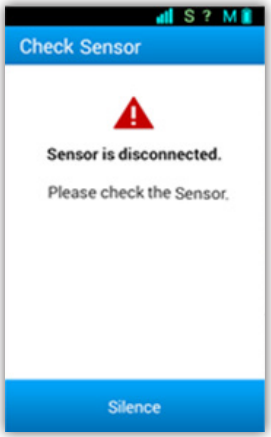
No Communication
This warning appears when the sensor and monitor are out of range from one another. Keep the monitor within 30 feet of you.

- If this message appears when the sensor and monitor are within range, make sure you are not lying on the sensor or blocking its communication to the monitor.



Transmit Data
This warning indicates that the monitor is not able to locate cellular service.

To resolve, move to an area with cellular coverage. If you are unable to locate cellular service, the monitor will store the data and transmit it when cellular service becomes available.



Check Sensor

This warning indicates that the patch is not firmly adhered to your skin. The following are possible reasons for the alarm:

- If it has been more than five days, the patch may be loose and require replacing.
- If the sensor has been removed in order to be charged, the monitor should be turned off as well.

If the above scenarios do not apply, follow the next steps to resolve the issue:

- Press firmly on all of the edges and center of the patch to ensure proper adhesion.
- Wait 5 minutes to see if the issue is resolved. If the error message persists, contact Customer Service for assistance.

MOBILE CARDIAC OUTPATIENT TELEMETRY PATCH ADDENDUM TO THE PATIENT EDUCATION GUIDE

INDICATIONS FOR USE

The MCOT Patch System's 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 arrhythmias (e.g. atrial fibrillation).
5. Patients recovering from cardiac surgery who are indicated for outpatient arrhythmia monitoring.
6. Patients with diagnosed sleep disordered breathing including sleep apnea (obstructive, central) to evaluate possible nocturnal arrhythmias.
7. Patients requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation or atrial flutter.
8. Patients requiring measurement, analysis and reporting of QT interval, excluding patients with a documented history of sustained atrial fibrillation or atrial flutter.
9. Patients who require monitoring for potential arrhythmias based on risk factors (e.g. atrial fibrillation).
10. Patients requiring measurement of ST segment changes. The device is not intended to sound any alarms for ST segment changes.

CONTRAINDICATIONS

The MCOT Patch System is contraindicated as follows:

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 the 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 >160ms or for T wave amplitudes ≤5% of the peak QRS amplitude.

PRECAUTIONS

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. In addition, sources of strong magnetic fields, such as MRI rooms, should also be avoided.

POTENTIAL FOR ELECTROMAGNETIC INTERFERENCE

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

If the user needs to completely shut down all devices generating an electromagnetic signal, as in the case when boarding an airplane.

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 Braemar Telemetry Patch System 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.
- Do not 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.

EXTERNAL DEFIBRILLATOR

Remove MCOT Patch before using an external defibrillator.

RADIOGRAPHIC USE

The MCOT Patch System is not intended for use in radiographic, x-ray, or magnetic resonance imaging (MRI).

PACEMAKER DETECTION

Pacemaker detection is in accordance with AAMI 60601-2-47.

INFANTS and SMALL CHILDREN

The MCOT Patch System should not be used on infants weighing less than 10 kg (22 lbs). The system should be kept away from them due to the following potential hazards.
Cords can be a strangulation hazard to infants and children, keep cords away from infants and children.
Small components which may fit in the mouth, such as the Sensor, may be a choking hazard
Never apply the Patch/Electrode to the face or cover nose or mouth

ADDITIONAL EQUIPMENT CLASSIFICATION INFORMATION REQUIRED BY EN60601-1

EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE

- The water resistance rating of IPX4 applies to the Sensor properly inserted in the Patch/Electrode
- Internally Powered Equipment
- Mode of Operation – Continuous Operation

WARNINGS

FOR USE WITHIN CELLULAR DATA COVERAGE AREA
Any patient whose life may be put at significant risk by the unavailability of a cellular data system should not be monitored by the MCOT Patch System.

NOT AN APNEA MONITOR
The MCOT Patch System is not to be used as an apnea monitor.

NOT AN EMERGENCY RESPONSE SERVICE
The MCOT Patch System is not an emergency response service. If you experience any symptoms that concern you, seek medical help.

DO NOT TAMPER WITH DEVICE
- Do not use the patch if package is tampered or defective.
- There are no serviceable parts in the Patch/Electrode or Sensor. Disassembling the Patch or Sensor will void warranty and may alter performance.
- There are no serviceable parts in the Monitor. Disassembling the Monitor will void warranty and may alter performance.

DO NOT TAMPER WITH MONITOR OR SENSOR BATTERY
The Monitor and Sensor batteries of the MCOT Patch System can present a fire or chemical burn hazard if mistreated. Do not disassemble, heat, incinerate, or recharge using any device other than the supplied power cords.

USE POWER CORDS IN SINGULAR OUTLET
A multiple portable socket outlet or extension cord should not be used with the equipment.

USE ONLY MANUFACTURER APPROVED EQUIPMENT
- Do not use any cables, power cords or other accessories other than the ones provided or replaced from the manufacturer.
- Usage of cables or accessories other than the ones provided may result in increased Radio Frequency (RF) emissions or decreased immunity to electromagnetic interference of the system.

SINGLE USE / MULTIPLE USES
The patch is a single use item; do not reuse. All other system components are reusable.

CONNECTION TO COMPONENTS
Only connect the components as described in this manual. Never connect the Patch to any external electrical item other than the supplied Sensor.

DO NOT STACK
The MCOT Patch System should not be stacked with other equipment. Stacking other equipment on top of the devices may damage enclosure or inner components.

CAUTIONS

DO NOT TAKE THE MONITOR INTO THE SHOWER
The MCOT Patch System Monitor is water resistant, not waterproof; do not take the Monitor into the shower.

AVOID SPRAYING WATER DIRECTLY ONTO THE SENSOR
The MCOT Patch System Sensor is water resistant, not waterproof. Avoid spraying water directly onto the Sensor by keeping it away from all direct water flow and deflecting/shielding with body, a hand, or towel, when showering.

DO NOT LIE DIRECTLY ON THE SENSOR
Do not lie directly on the Sensor as damage may result. Avoid sleeping directly on top of the Sensor.

PATCH STORAGE TEMPERATURE AND SHELF-LIFE
The Patch's storage temperature requirement is narrower than the rest of the components and temperature limits should be taken into account for storage. Shelf like of 18 months from Date of Manufacturer has been tested within the range of +5ºC to +27ºC. Storage of Patch outside these limits may affect longevity of shelf life.

DISPOSAL
The patch is single use. Dispose of the Patch properly in accordance with your local ordinances or instructions of your prescribing physician. The Patch may need to be recycled in accordance with local laws.

All other items provided are reusable and should be returned at the end of your monitoring period.

Specifications

Sensor

General
Channels - 2 channels
Resolution - 12 bits
Sample Rate - 250 Hz

Environmental
IPX Rating When Inserted into Patch/Electrode - IPX4 Resistant to water splashes from any direction"
Operating Temperature * - 10°C to +45°C
Non-Operating Temperature - -20°C to +70°C
Operating Humidity - 10% to 95% (non-condensing)
Non-Operating Humidity - 5% to 95% (non-condensing)

Physical
Size - 2" x 1.6" x 0.36"
Weight - .069 oz. (19g)
Connection to USB - Female Micro USB
Connection to Patch/Electrode - Custom 8 terminal connector
Battery Type - Rechargeable Lithium Ion 3.7 V 500 mA-Hr

Data Transmission
Bluetooth Radio
USB - USB 2.0

Monitor
General
Display - IPS Capacitive Touchscreen
Operating System - Android
Battery Type - 2500mA-Hr Lithium Ion
Service Life - 3 years

Environmental
IPX Rating - "IP67 Protected from dust and immersion to water between 15cm and 1m."
Operating Temperature - 10°C to +45°C
Non-Operating Temperature - -20°C to +70°C
Operating Humidity - 10% to 95% (non-condensing)
Non-Operating Humidity - 5% to 95% (non-condensing)

Physical
Size - 5.06" x 2.69" x .51"
Weight - 5.94 oz.
Battery Type - 2500mA-Hr Lithium Ion
Data Transmission
Cellular Radios - LTE Cat 3, CDMA 1x EVDO, 1x Advanced
Bluetooth - 4.0 + LE/EDR

Patch / Electrode
General Functional
Number of Electrodes - 4

Environmental
IPX When Sensor is connected to Patch/Electrode - "IPX4 Resistant to water splashes from any direction"
Storage Temperature - +5ºC to +27ºC
Storage Humidity - Up to 93% non-condensing
Operating Temperature - +5ºC to +40ºC
Operating Humidity - 15% to 93% non-condensing
Transportation Temperature - 0ºC to 40ºC
Transportation Humidity - Up to 93% non-condensing

Physical
Service life - single use
Size - 2.17" w x 0.24"h x 5.0" l (without release liner)
Weight (sensor in patch) - 0.78 oz (24g)

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 acknowledgement 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's 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 System (sensor, monitor, and accessories), which I am obligated to return to CardioNet upon completion of the service. If I do not immediately return the System, I hereby authorize CardioNet to invoice me for, and agree to pay CardioNet, the value of the Monitoring System and any associated collection costs should collection or legal costs be incurred by CardioNet.

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 BioTel Heart 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., LifeWatch Services, Inc. and Telcare Medical Supply, LLC 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 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 BIOTELEMETRY 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 MEDI-CAL CONDITION OR PERCEIVED CONDITION.

4. LIMITATION OF LIABILITY. TO THE MAXIMUM EXTENT PERMITTED UNDER APPLICABLE LAW: (I) IN NO EVENT SHALL BIOTELEMETRY OR ITS SUBSIDIARIES, AFFILIATES, OFFICERS, DIRECTORS, EMPLOYEES AND AGENTS, 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 BIOTELEMETRY 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.

5. Indemnity. Patient agrees to indemnify and hold harmless BioTelemetry, Inc., it's subsidiaries, and its officers, directors, employees, agents and suppliers from and against all claims of third parties arising out of or related to Patient's use or misuse of the System and/or the Service, or attributable to Patient's breach of this Agreement. BioTelemetry shall control the defense and any settlement of such claim, and Patient shall cooperate with BioTelemetry in defending against such claims.

6. General Provisions. This Agreement may be modified or amended only by a written instrument signed by Patient and BioTelemetry. Any terms and conditions issued by Patient shall not be binding on BioTelemetry, Inc., or it's subsidiaries, officers, directors, employees, agents or suppliers, and shall not modify these Terms and Conditions. No term or provision contained herein shall be deemed waived and no breach excused unless such waiver or consent shall be in writing and signed by the party against whom enforcement thereof is sought. Neither party hereto shall be liable to the other for any failure to perform its obligations under this Agreement due to causes beyond the reasonable control of that party, including, but not limited to, strikes, boycotts, labor disputes, embargoes, unavailability of or failures due to telecommunication networks (including, without limitation, the Internet), acts of God, unavailability of or insufficient utilities, acts of public enemy, acts of governmental authority, floods, riots, or rebellion. This Agreement shall be governed by and construed solely in accordance with the laws of the State of Pennsylvania, without reference to its choice of law rules. Any and all proceedings arising under or in any way relating to this Agreement shall be maintained in the state or federal courts located in Chester County, Pennsylvania, which courts shall have exclusive jurisdiction for such purpose, and Patient hereby consents to the personal jurisdiction of such courts. Patient acknowledges that in the event of an actual or threatened violation of the terms and conditions of this Agreement, BioTelemetry may not have an adequate monetary remedy and shall be entitled to seek injunctive relief without any requirement to post bond, in addition to any other available remedies. If any term or provision of this Agreement is illegal or unenforceable, it shall be deemed adjusted to the minimum extent to cure such invalidity or unenforceability and all other terms and provisions of this Agreement shall remain in full force and effect.

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