MCOT®

MOBILE CARDIAC OUTPATIENT TELEMETRY

FLEX

PATIENT EDUCATION GUIDE

BioTel® HEART

Table of Contents

About our Service

Your physician has prescribed **MCOT**™ for you. MCOT 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.

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

* Data will transmit when device is within cellular range.

What to Expect During Service

Contacting You

We may contact you via automated and live messages for the following reasons:

- Confirm insurance information
- Assist with starting service
- Confirm a break-in-service
- Troubleshooting
- On behalf of your physician

(Please note, we will not contact you regarding heart-related findings, unless specifically instructed by your physician.)

Billing for Service

Charges are incurred when you begin monitoring. During or after your service, your insurance company will send you an Explanation of Benefits (EOB). An EOB from your insurance carrier is NOT a bill.

You will be responsible for any out-of-pocket cost associated with deductibles, co-insurances, etc. If there is a balance due, you will receive a statement from BioTel Heart for your portion. If you have any questions regarding the balance due, please refer to your statement for contact information.

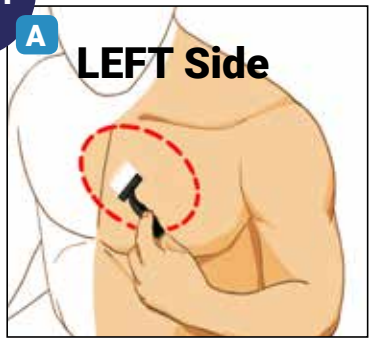
Prompt Return of All Equipment

The device and kit components enclosed are the property of BioTel Heart® and must be returned immediately upon completion of service. Failure to return may result in delayed delivery of the final test results and a bill for the cost of the device.

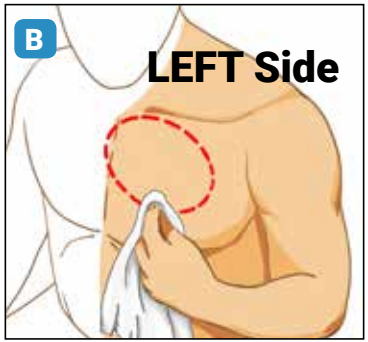
Device Return instructions are located in this guide. Please refer to the Table of Contents for page number.

Getting Started

Step 1



If needed, SHAVE the area where the MCOT Flex will be placed.

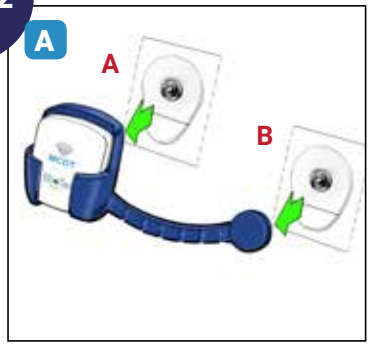


WASH the area with soap and water and DRY thoroughly with a towel.
DO NOT apply lotions or oils.

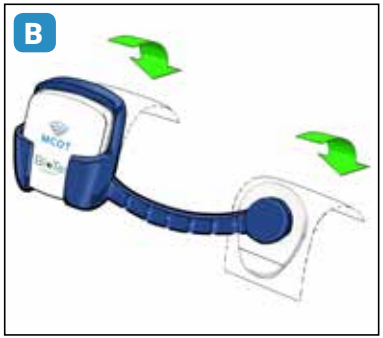
Remove the Flex adapter and MCOT sensor from box 1. Slide the sensor into the Flex. A green light on the sensor will flash briefly when it is completely inserted. It may take up to 15 seconds for the green light to flash.

Remove two electrodes from the electrode pouch. Leave the plastic backing on the electrodes.

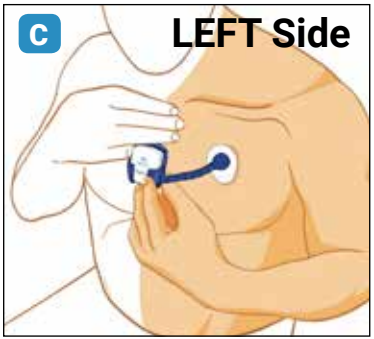
Step 2



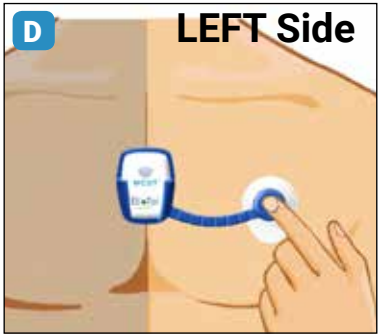
While each electrode is still on the plastic backing, snap it to the back of the MCOT Flex (**A**). Repeat this step by snapping the second electrode onto the back of the arm of the MCOT Flex (**B**).



Remove plastic backing from electrodes.
Be careful not to touch the adhesive.



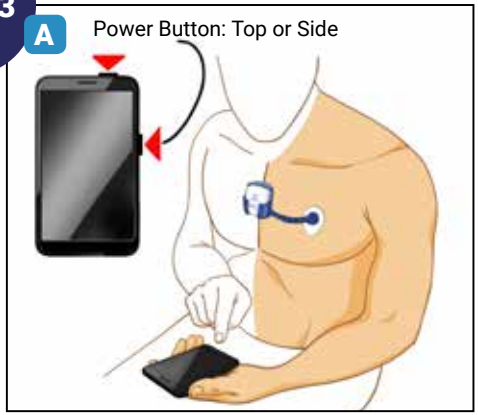
Place the MCOT Flex in the center of your chest approximately three fingerwidths below your collarbone.
Do not place MCOT Flex too low on your chest or this may impact the quality of the signal.



Press the second electrode firmly so that the arm lays flat against your chest.

Step 3

A Power Button: Top or Side



Push Power Button on the monitor (phone) and Follow the on-screen guidance to complete the set-up.

Congratulations!
When you see this screen you've completed the setup process and your heart is being monitored.

Showering and Replacing Electrodes

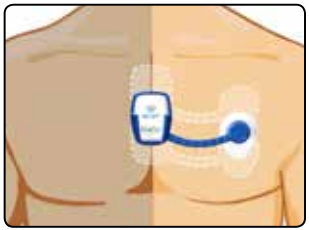
The MCOT sensor worn with the Flex is NOT water-resistant.
It is recommended you change your electrodes every other day or after showering, whichever comes first.
Follow these steps to help you achieve the best results when replacing electrodes.

Before Showering or Removing Electrodes:
1. Turn off monitor.
2. **Remove the sensor from the Flex.**
3. Unsnap the Flex from the electrodes.

Showering/Removing Electrodes:
1. Use soap and water to gently remove the electrodes from skin.
2. Shower normally.

Replacing Electrodes:
1. Dry skin thoroughly
2. Follow the set-up instructions in the Getting Started section of this Patient Education Guide.
3. Wait 10-15 minutes.
4. Turn on monitor.

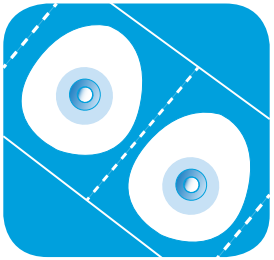
If electrodes are loose, replace them to avoid receiving a "Lead Disconnected " error.



Irritated Skin:
To reduce the risk of skin irritation, or if you develop skin irritation, please follow the steps below:
1. Change electrodes after every shower, or every other day.
2. Ensure skin is clean and dry prior to placing electrodes
3. If your skin is irritated, slightly change the location of the electrodes. View the illustration for alternate placement options.

What to do While Monitoring

The Flex is not waterproof. Remove before showering, bathing or swimming.*



Replace the Electrodes every 48 hours and after every shower.*

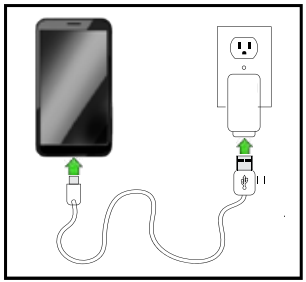
Refer to the Showering and Replacing Electrodes section of this guide for complete instructions.

CHARGING: The Sensor

The monitor will alert you when it is time to charge your sensor. When prompted:

1. Slide the MCOT sensor out of the Flex
2. Insert the sensor into the charger as shown. The light will blink **YELLOW** while the sensor is charging. Charging is complete when the light is **GREEN**.
3. Slide the sensor back into the MCOT Flex.

CHARGING: The Monitor (Phone)

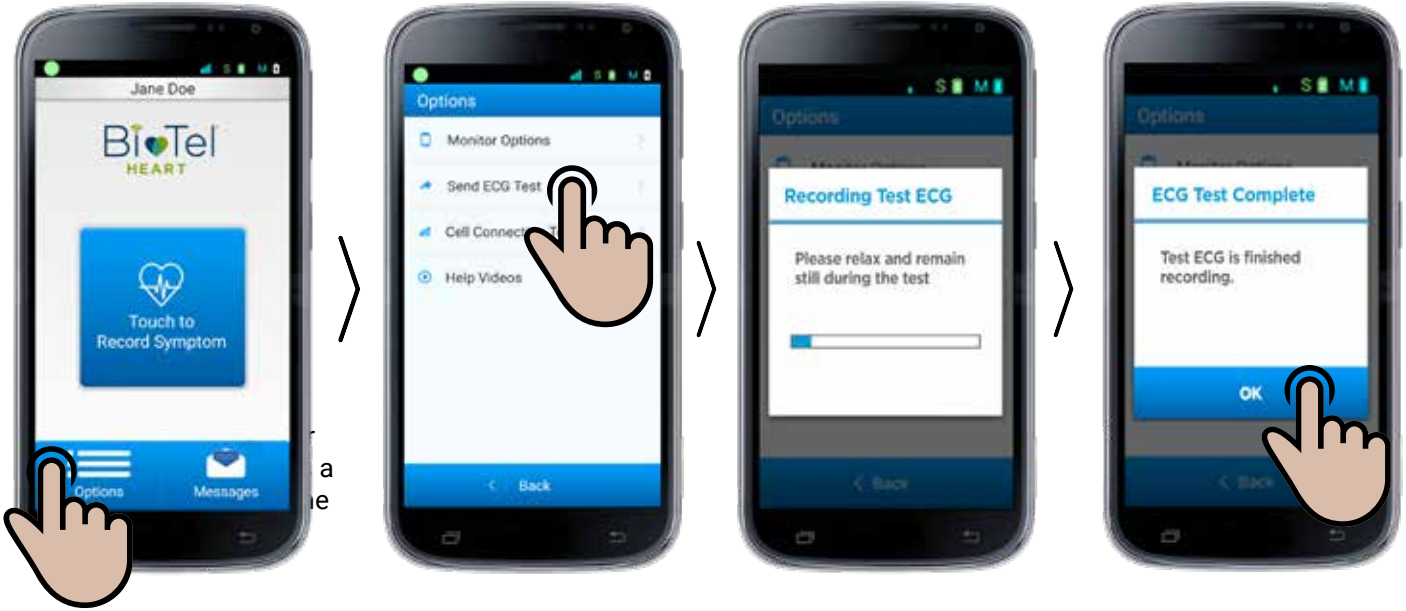


Charge the monitor daily.

To view remaining battery life for the sensor and monitor, swipe down on the screen

Record a Baseline (Manual Recording Option)

When activating MCOT Flex for the first time, sending a baseline should occur automatically, and the data will transmit wirelessly to BioTel Heart. If you do not have cellular coverage, the baseline will store in the monitor until service is available. We may ask you 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

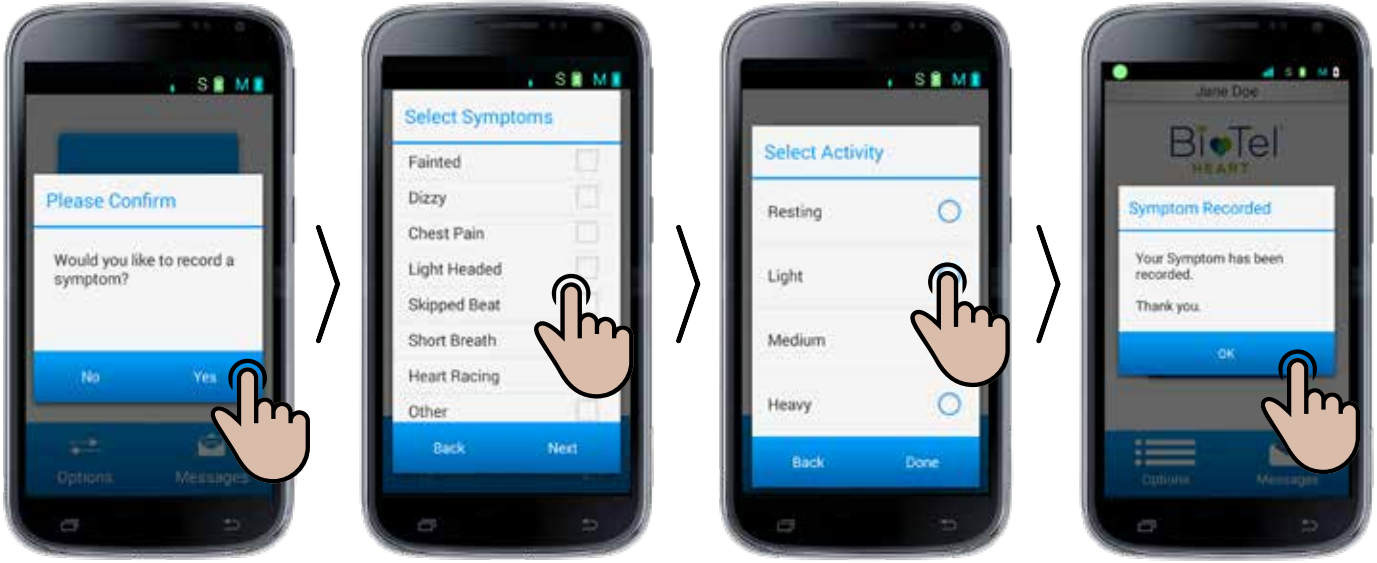
4. Select **OK** to return to the main screen

Record Symptoms

Recording a Symptom

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

Record Symptoms



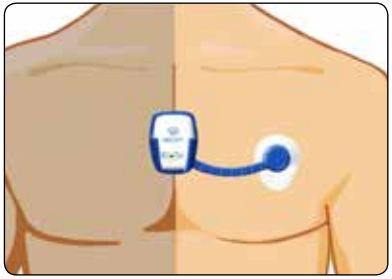
- A dialog box will ask if you would like to record a symptom. Select **Yes** to continue. If you do not wish to record a symptom, select **No**.

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

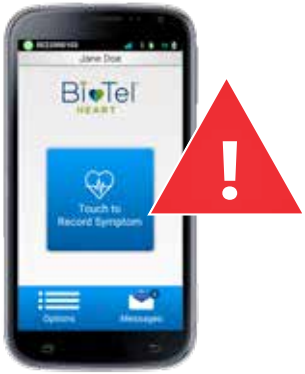
- The **"Select Activity"** screen allows you to record your level of activity when the symptom occurred.
- Select your activity level and press **Done**.

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

Important Information



- Continue to wear MCOT for the duration prescribed by your physician.
- Mild itching or irritation underneath the electrodes 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.



MCOT 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.

Wear and Care Tips:

1. Keep the monitor within 30 feet of you at all times.

2. When you feel a symptom, press the **"Record Symptoms"** button.

3. The Flex accessory is not waterproof. Remove before showering, bathing or swimming.

4. When the battery is low, use the supplied charger. The monitor will show a warning message when the battery is low.

5. Electrodes need to be changed after every shower (daily), or every other day if not showering.

6. Address all alerts on your monitor promptly.

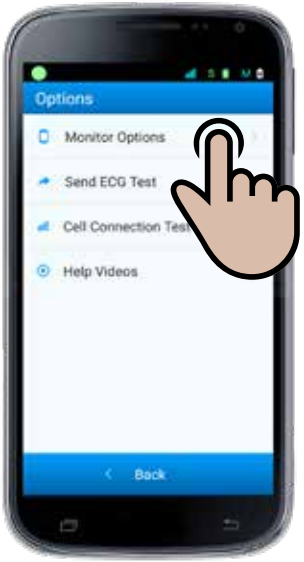
7. A "No Communication" message on your monitor means the sensor is out of range. To resolve the issue, keep the monitor within a range of 30 feet. If the issue persists more than 15 minutes, contact Customer Service at 1.866.426.4401.

8. If you are in an area with no or limited cellular coverage, you may receive a message. To resolve the issue, move to an area with cellular coverage. If you are unable to do so, the monitor will store the data and transmit when service becomes available.

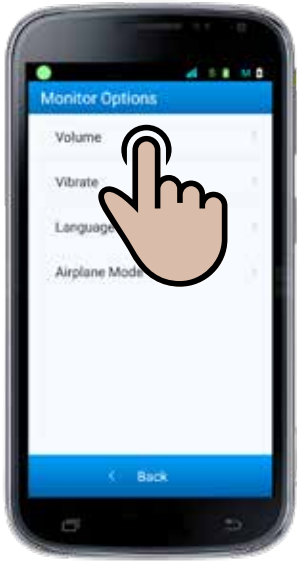
Options

You have the ability to change volume, enable vibrate settings, and airplane mode 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.

Deactivation / Return the Equipment

- When your monitoring service is complete, a message will appear on the monitor to return the equipment.
- Turn off the monitor by pressing the power button.

Steps to Return the Device:

1. Place the sensor, monitor, and chargers into the BioTel Heart kit.
2. Place the kit into the shipping bag and seal closed. The shipping bag is located in the kit.
3. Drop the kit off at any UPS shipping location. If you wish to schedule a pick up, contact UPS at 1-800-742-5877 to schedule a pick-up, inform UPS you have a pre-paid label.
4. Document the tracking number from the return UPS label for your records.

Troubleshooting

Low Battery Messages

- There are two different messages that will display when it is time to charge the sensor or monitor.

Sensor Battery Warning

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

Monitor Battery Warning

A **Battery Warning** ⚠ symbol Indicates that the **monitor battery** is low

- If you receive this warning, charge the monitor using the supplied charging cable and adapter.
- The monitor battery warning can be dismissed by pressing the **OK** button, however the message will appear again.

Troubleshooting

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.

Troubleshooting

Electrodes Disconnected

This warning indicates the Flex or electrodes are not firmly attached to your skin.

Select the **Resolve** button and follow the instructions for correcting the issue.

MOBILE CARDIAC OUTPATIENT TELEMETRY ADDENDUM TO THE PATIENT EDUCATION GUIDE

INDICATIONS FOR USE

The MCOT 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. There is a potential for electromagnetic interference to other devices while using the Braemar Telemetry Patch System Model BTPS-1000.

POTENTIAL FOR ELECTROMAGNETIC INTERFERENCE

If the user needs to complete;y shut down all devices generating an electromagnetic signal, then turn Monitor OFF. Please keep in mind that Bluetooth radio in the Sensor CANNOT be turned OFF.
There is a potential for electromagnetic interference to other devices while using the MCOT Patch System. Additionally, enabling Airplane mode disables cellular modem but Bluetooth radio for both Monitor and Sensor will still be active.

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.

RADIOGRAPHIC USE

The MCOT 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.

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 IP24 only applies to the configuration of the Sensor with Patch when properly inserted. All other configurations (Lead Wire Adapter and Flex Electrode with Sensor) are not water resistant.

- Internally Powered Equipment
- Mode of Operation – Continuous Operation

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.

PRECAUTIONS *coninued*

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

EXTERNAL DEFIBRILLATOR
Remove Sensor and its accessory before using an external defibrillator..

DO NOT TAMPER WITH DEVICE
- Do not use the patch or electrodes if package is tampered or defective.
- There are no serviceable parts in the Sensor. or any of its accessories. Disassembling the Sensor or any accessory 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.
- Only use wall adapters to charge the Monitor that have undergone appropriate safety tests as indicated by a CE or UL marking on label. Use of other wall adapters may damage devices or impact performance.

SINGLE USE / MULTIPLE USES
Both Patch and electrodes used with Flex Electrode and LWA are single use items; do not reuse. All other system components are reusable.
The Patch is a single use item; do not reuse the Patch. All other system components are reusable.

CONNECTION TO COMPONENTS
Only connect the components as described in this manual. Never connect any accessory 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.

WARNINGS

INFANTS and SMALL CHILDREN
The MCOT 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 to the face or cover nose or mouth

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.

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.

REMOVE DEVICE PRIOR TO SHOWER

Remove Sensor and its accessory prior to showering. Device is not intended to be waterproof.

DO NOT LIE DIRECTLY ON THE SENSOR

Do not lie or sleep directly on top of the Sensor as damage may result.

ELECTRODE 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 5°C/41°F to 27°C/80.6°F. Storage of Patch outside these limits may affect longevity of shelf life.

DISPOSAL

The electrode patch is single use. Dispose of electrode patches properly in accordancewith your local ordinances or instructions of your prescribing physician. the electrode 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 - 2600mA-Hr Lithium Ion
Service Life - 3 years

Environmental

IPX Rating: "IP21 Protected from dust and immersion to water between 15cm and 1m."
Operating Temperature: +5°C to +40°C
Non-Operating Temperature: -20°C to +70°C
Operating Humidity: 15% to 93% (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

Flex

General Functional

Number of Electrodes - 2

Environmental

IPX When Sensor is connected to the Flex - "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

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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. 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

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.

BioTel® HEART

1000 Cedar Hollow Road, Malvern, PA 19355

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