

PHILIPS

Bi♥Tel[®]
HEART

MCOT[®]

Mobile Cardiac Outpatient Telemetry

Patient education guide



Scan the QR code to view how to set up your MCOT

Need help or have questions?

Contact Customer Support toll-free at 1.866.426.4401 or visit myheartmonitor.com for online support.



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About our service

Your physician has prescribed the **MCOT®** System for you to assist with your diagnosis. MCOT conducts beat-by-beat analysis of your heart activity and transmits certain abnormal beats to the certified cardiac technicians at Philips 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) or 833-396-2626 (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: 9:00 am - 5:00 pm EST

* The data will transmit when device is within cellular range.

What to expect during service

Contacting you

Before, during or after your service, we may contact you for any of the following reasons:

- Confirm insurance information
- Assist in starting 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 Philips 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

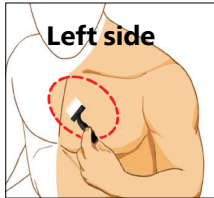
The device and kit components enclosed are the property of Philips BioTel Heart and must be returned immediately upon completion of service. Failure to return may result in delayed delivery of the final test results and a bill for the cost of the device.

Device return instructions are located in this guide. Please refer to the table of contents for the page number.

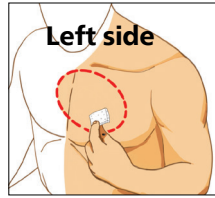
Getting started

Remove box 1 from your kit to get started

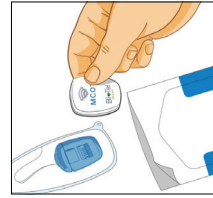
Step 1



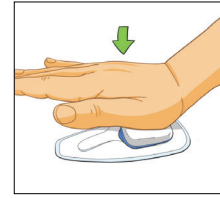
Shave (if needed), then **wash and dry** area shown in diagram thoroughly.



Once skin is dry, **scrub** area with the **scrub pad** for 60 seconds. **Do not** apply lotions or oils.



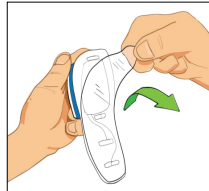
Remove a **patch** from the patch pouch. Place **sensor** into patch and **press down firmly** to snap it in place.



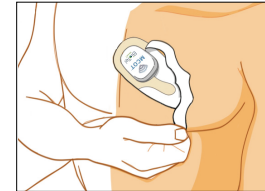
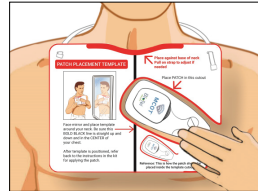
Step 2



Locate the patch placement template under **Box 1** and follow its instructions for use.

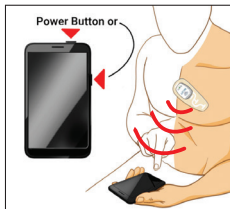


Remove clear backing and apply the patch to your chest using the template as a guide, as shown. Use a mirror for guidance. Then remove the template.

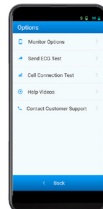


Press patch firmly against your skin. **Remove top white paper.**

Step 3



Push power button on the monitor (phone) and follow the on-screen guidance to complete the set up.



Congratulations!
You completed
the set-up process.

Note, save the box – you will need to repeat steps 1 and 2 when applying a new patch.

Please note: if you have sensitive skin, the patch may not be ideal. Call our help desk to learn what options you may have.

Need help? Call 1.866.426.4401 or visit us online at myheartmonitor.com.

For assistance setting up your monitor, scan the QR code on the cover to view an instructional video.

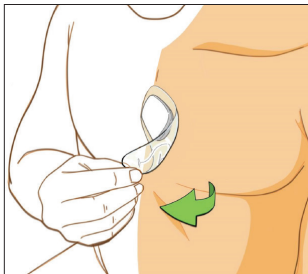
Monitoring

When you are ready to change your patch, charge the sensor and monitor (phone).

Remove box 2 (monitoring) from your kit

Step 1

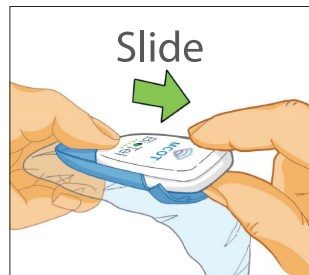
How to remove the sensor from the patch



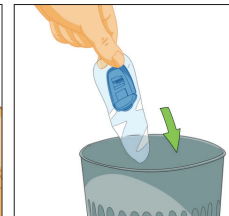
Power **off** monitor. Remove the patch by pulling the clear adhesive away from your body.



Apply downward pressure on the tab to snap/break it off. This will require some force.



Hold the sensor as shown and slide the sensor forward to remove it from the patch.

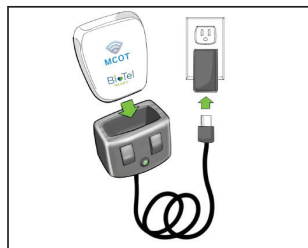


Discard the used patch, **not the sensor.**

Re-use the sensor on a new patch after the sensor is recharged.

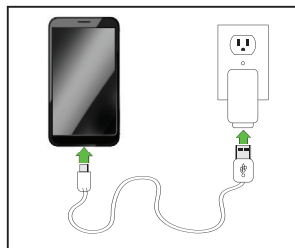
Step 2

Charging the sensor



Locate charger and cable wire in Box 2. Refer to the illustration to connect the sensor to charger and plug into an outlet. Charging may take up to 90 minutes and is complete when the light turns **solid green**.

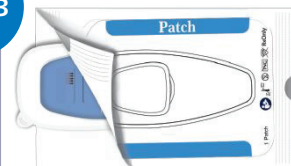
Charging the monitor (phone)



Locate charger and cable in **Box 2**. Refer to illustration to connect wire to **monitor** (phone) and charger to a wall outlet. Charging can take up to 90 minutes.

Step 3

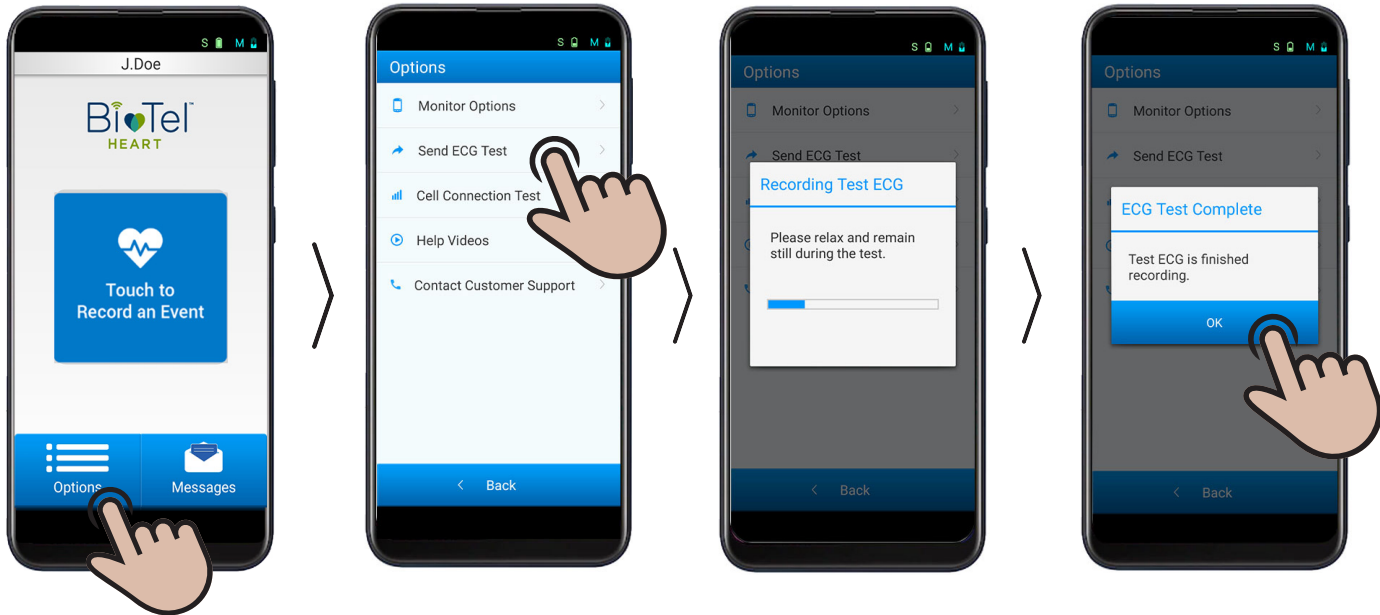
Apply a new patch



Remove a patch from a new pouch. Patch pouches are located in Box 2.

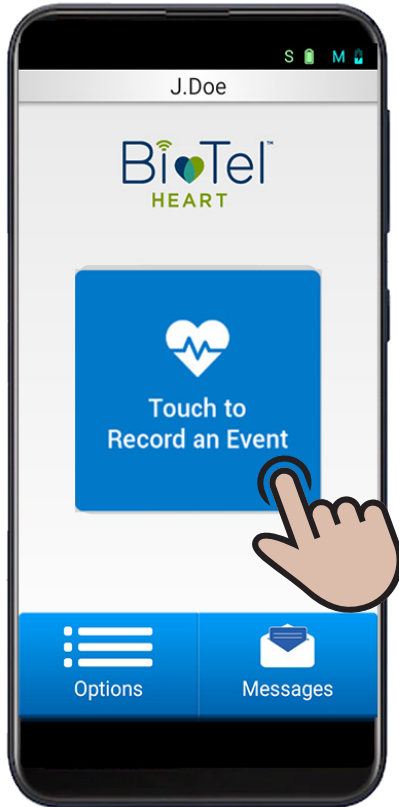
Record a baseline ECG (manual recording option)

When activating MCOT for the first time, sending a baseline ECG data recording should occur automatically, and the data will transmit wirelessly to Philips 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 an ECG test recording. The steps to complete a manual ECG test recording are as follows:



- Select "**Options**".
- Select "**Send ECG Test**".
- Test will be recorded.
- Select "**OK**" to return to the home screen.

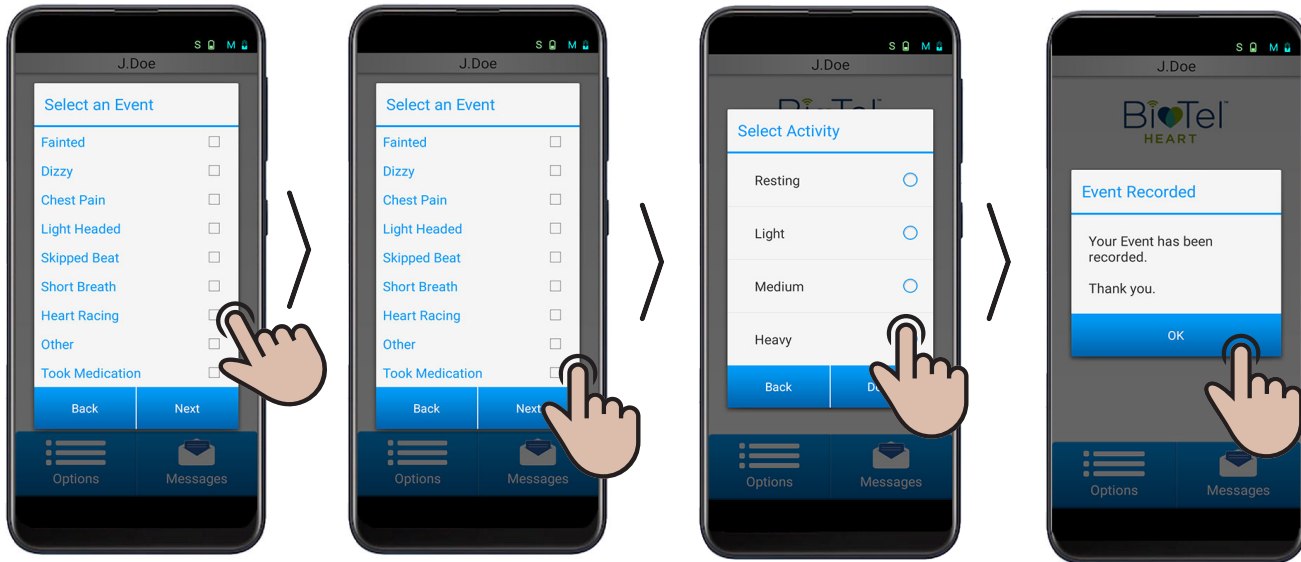
Record events



Record an event

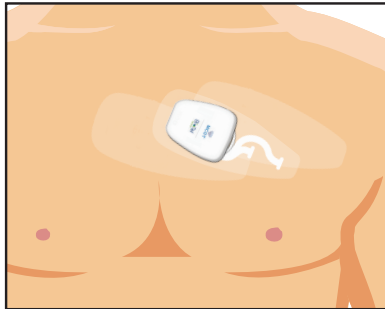
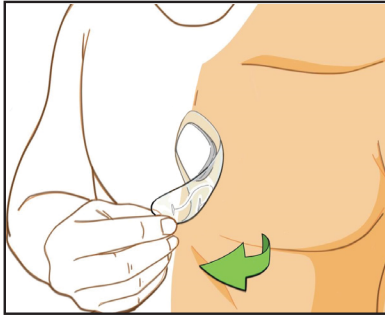
- MCOT will monitor your heart and send data automatically to the Philips BioTel Heart Monitoring Center. You can also record symptoms as you feel them, and your recording will appear on the reports provided to your physician.
- To record an event, press "**Touch to Record an Event**" on the home screen.

Record events



- The "Select an Event" screen allows you to select the event(s) you wish to log.
- Select all that apply.
- If an event occurred while taking a medication, check the box "Took Medication" in addition to the event.
- Select "Next" to continue.
- The "Select Activity" screen allows you to record your level of activity when the symptom you were feeling occurred.
- Select your activity level and press "Done."
- The "Event Recorded" screen confirms that the event(s) you selected were recorded.
- Press "OK" to return to the home screen.

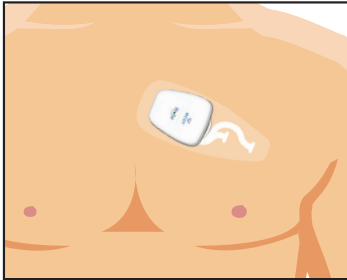
Changing the patch



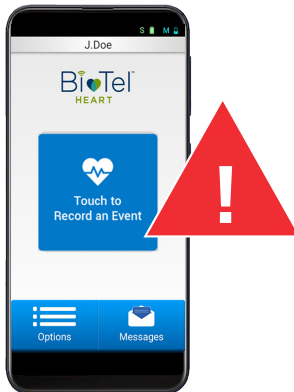
- Change the patch if instructed by the monitor or if the patch begins to loosen. Patches should last approximately 5 days*.
- Follow the instructions on page 6 to charge the sensor before applying a new patch.
- Once the sensor is fully charged and its light is green, remove a new patch from its pouch (located in box 2) and reapply. Refer to the instructions on page 5 for assistance.
- **Note: If applying the patch in the same area, please do not scrub the skin with a prep scrubber before applying a new patch.**
- If skin is broken or irritated, select an area on your skin in a slightly different location or position. Please refer to the illustration.

* Depending on how long your service lasts, you will need to change your patch every 5 days or sooner.

Important information



- Continue to wear MCOT until service is completed.
- Mild itching or irritation of skin underneath the patch area may occur and is usually temporary. If more significant itching or irritation develops or persists, contact Customer Support at 1-866-426-4401, they may direct you to contact your physician.
- Record any events or symptoms you may feel. If instructed by your physician, record when you took medication.
- Promptly respond to any messages or alerts that you receive on the monitor.
- This device will not transmit data outside of the United States.



The MCOT 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.

For assistance setting up your monitor, scan the QR code on the cover to view an instructional video.

Wear and care tips:



1. Keep the monitor and sensor in close proximity at all times.



2. When you feel a symptom or would like to record taking medication as indicated by your physician, press the "**Tap to Record an Event**" button.



3. Shower or exercise as normal while wearing the MCOT patch.



Do not swim or take a bath.

The sensor is water-resistant, not waterproof. Do not submerge in water.



4. When the battery of the monitor (phone) is low, use the supplied charger. The monitor will show a warning message when the battery is low. For best practice, charge the monitor daily.



5. Do not remove the patch from your skin after you begin monitoring. With normal wear, each patch should last about 5 days.



6. The monitor will alert you when your service is complete.



7. Address all alerts on your monitor (phone) promptly.



8. A **"No Communication"** message on the monitor means the sensor is out of range of the monitor. To resolve the issue, keep the monitor in close proximity of the sensor. If the issue persists more than 15 minutes, contact Customer Service at 1.866.426.4401.



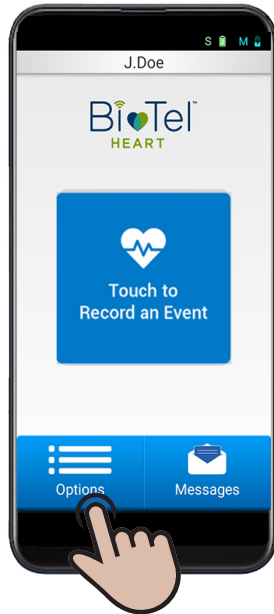
9. If you are in an area with no or limited cellular coverage, you may receive a message. To resolve the issue, move to an area with cellular coverage. If you are unable to do so, the monitor will store the data and transmit when service becomes available.



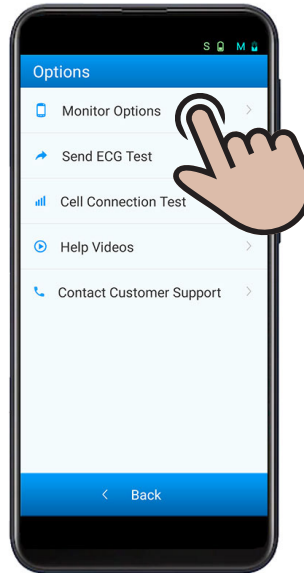
10. If you experience discomfort with the patch anytime during monitoring, a lead wire adapter is available in the kit for alternate use.

Options

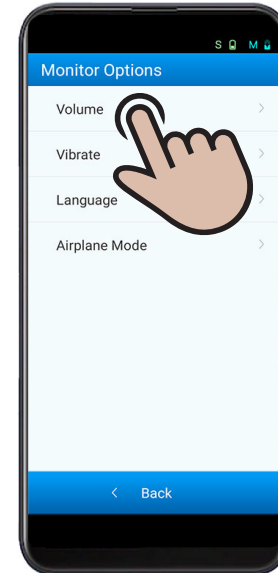
The "**Options**" screen allows you to change monitor settings (such as "**Volume**, **Vibrate Mode**, **Language** or **Airplane Mode**"), as well as record and send an ECG test, check cell coverage, watch help videos or get information to contact Customer Support.



- Tap "**Options.**"



- Select "**Monitor Options.**"



- Select the option you wish to adjust. Select "**Volume**" to adjust the 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.
- Power off the monitor by pressing down the power button until a power off message appears, and follow the instructions on the screen.

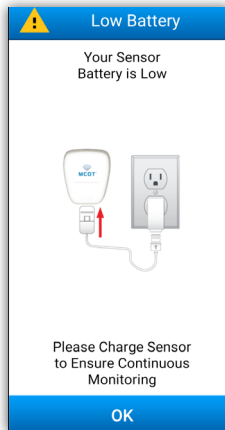
Steps to return the device:

1. Place the sensor, monitor, monitor case, unused patches and chargers back into the Philips BioTel Heart kit.
2. Place your packed kit into the pre-paid shipping envelope provided in your kit and then follow the return instructions to ship back to Philips BioTel Heart.

Troubleshooting

Warning messages ⚠

You may receive different warning messages, which would guide you through any issue requiring your attention. A warning can be dismissed by pressing the "OK" button; however, the message will appear again until the issue is resolved.



"Low Battery" (sensor) warning

If you receive this warning message, follow the instructions for removing the patch and charging the sensor. To increase battery life in the sensor, keep the monitor and sensor in close proximity at all times.



"Low Battery" (monitor) warning

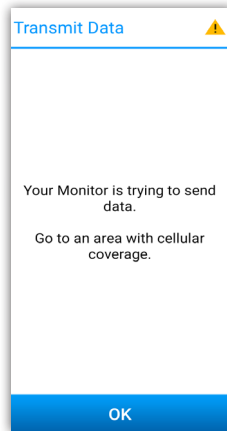
If you receive this warning, charge the monitor using the supplied charging cable and adapter.

Troubleshooting



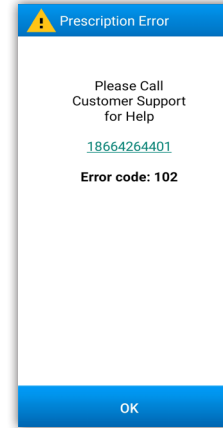
"No Communication" warning

This warning appears when the sensor and monitor are out of range from one another. Keep the monitor and sensor with you at all times and make sure you are not lying on the sensor or blocking its communication to the monitor.



"Transmit Data" warning

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.



"Prescription Error" 102 (warning)

This warning indicates that Philips has not received your prescription, but your heart ECG is still being recorded. Try moving to an area with cellular coverage. Once the connection has been made, you will be notified that your prescription has been received.

Troubleshooting

Alert messages:

There are different alert messages you may receive, which would require your immediate attention. Press the "**Resolve**" button to receive additional guidance, or "**Silence**" if guided to do so on the screen.

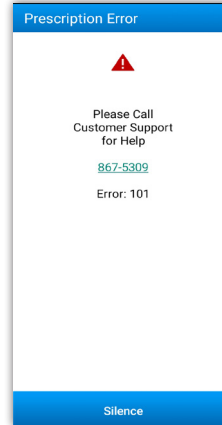


"Patch Disconnected" error

This warning indicates the patch is not firmly adhered to your skin. Possible reasons include:

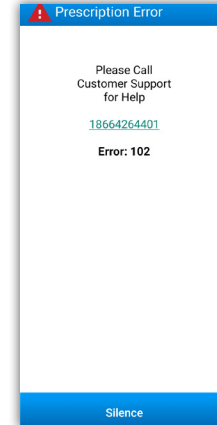
- The patch may be loose or needs to be changed.
- If the sensor/patch are removed to charge, power off the monitor.

If the scenarios above do not fix the issue, select the "**Resolve**" button and follow the instructions.



"Prescription Error" 101

This warning indicates that your prescription details do not match the device supplied. You must contact Customer Support for assistance.



"Prescription Error" 102 (alert)

This error message indicates that Philips has not received your prescription, but your heart ECG is still being recorded. You must contact Customer Support for assistance.

Troubleshooting

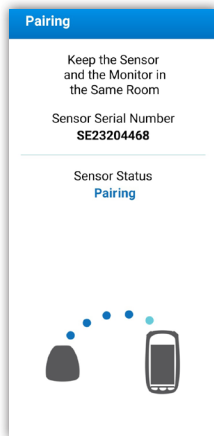
Sensor and Monitor Pairing Unsuccessful

If either the "**Pairing**" screen or "**Insert Sensor**" screen is continuously displayed, then the monitor is not able to detect and pair with the sensor provided.

Press down on all four corners of the sensor to ensure it is fully in the patch.

If a red light is visible on the sensor, remove the patch and charge it with the supplied charger. Once charged, place the sensor in a new patch (see page 5 for guidance) and continue pairing the monitor with the sensor.

If the issue continues, contact Customer Support.



"Pairing"



"Insert Sensor"

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 life of 18 months from Date of Manufacturer has been tested within the range of +5°C to +27°C. 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 Samsung A10e

General Functional

Display S5.83" HD+ PLS Touchscreen

Operating System Android

Battery Type 3000mA-Hr Lithium Ion Polymer

Service Life 3 years

Hearing Aid Compatibility (HAC) Samsung A10e:

M3 (RF Emissions Category)

T3 (Signal to Noise Category)

Environmental

IPX Rating IP68

Dust tight protection, Can be submerged in water up to 1.5m deep for <30 min

Operating Temperature 10°C to +45°C

Non-Operating Temperature -20°C to +70°C

Atmospheric Pressure 700 hPa to 1060 hPa

Operating Humidity 10% to 95% (non-condensing)

Non-Operating Humidity 5% to 95% (non-condensing)

Physical

Size 147.3 x 69.6 x 8.4mm

Weight 141g

Data Transmission

Cellular Radios LTE Cat 4 150/50 Mbps, CDMA 800/1900, HSDPA 850/900/1700

(AWS)/1900/2100

Monitor Samsung J3 2017

General Functional

Display Super AMOLED Touchscreen

Operating System Android

Battery Type 2600mA-Hr Lithium Ion

Service Life 3 years

Hearing Aid Compatibility (HAC) Samsung J3

M3 (RF Emissions Category)

T3 (Signal to Noise Category)

Environmental

IPX Rating IP22

Protected from particles >12.5mm and dripping water when tilted up to 15°

Operating Temperature 10°C to +45°C

Non-Operating Temperature -20°C to +70°C

Atmospheric Pressure 700 hPa to 1060 hPa

Operating Humidity 10% to 95% (non-condensing)

Non-Operating Humidity 5% to 95% (non-condensing)

Physical

Size 142.3 x 71.0 x 7.9mm

Weight 138g

Battery Type 2600mA-Hr Lithium Ion

Data Transmission

Cellular Radios LTE Cat 3, CDMA 1x EVDO, 1x Advanced

Bluetooth 4.2, A3DP, LE

Monitor Samsung J3 2018

General Functional

Display IPS LCD capacitive touchscreen

Operating System Android

Battery Type 2600mA-Hr Lithium Ion

Service Life 3 years

Hearing Aid Compatibility (HAC) Samsung J3

M3 (RF Emissions Category)

T3 (Signal to Noise Category)

Environmental

IPX Rating IP22

Protected from particles >12.5mm and dripping water when tilted up to 15°

Operating Temperature 10°C to +45°C

Non-Operating Temperature -20°C to +70°C

Atmospheric Pressure 700 hPa to 1060 hPa

Operating Humidity 10% to 95% (non-condensing)

Non-Operating Humidity 5% to 95% (non-condensing)

Physical

Size 142.3 x 71.0 x 7.9mm

Weight 152g

Battery Type 2600mA-Hr Lithium Ion

Data Transmission

Cellular Radios LTE Cat 3, CDMA 1x EVDO, 1x Advanced

Bluetooth 4.2, A3DP, LE

Patch / Electrode

General Functional

Number of Electrodes - 4

AC Impedance 500 ohm typical

DC Offset Voltage 2 mV

Combined Offset Instability and Internal Noise <40 µV

Defibrillation Overload Recovery 15 mV

Bias Current Tolerance 6 mV (8 h)

Service Life Single-use only

Environmental

IPX VWhen Sensor is Connected to Patch/Electrode IPX4

Resistant to water splashes from any direction

Storage Temperature +5°C to +27°C

Storage Humidity Up to 93% non-condensing

Operating Temperature +5°C to +40°C

Operating Humidity 15% to 93% non-condensing

Atmospheric Pressure 700 hPa to 1060 hPa

Transportation Temperature 0°C to 40°C

Transportation Humidity Up to 93% non-condensing

Shelf Life 18 Months from Date of Manufacturer

Physical

Size (W x H x D) 61 mm x 7 mm x 132 mm

55* mm x 6* mm x 126* mm

*Without release liner

Weight (after removal from pouch) 5 g

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

TERMS AND CONDITIONS OF THE BIOTELEMETRY SERVICE AGREEMENT.

PLEASE READ THIS DOCUMENT CAREFULLY BEFORE ACTIVATING THE MONITOR.

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

PRIVACY AND CONFIDENTIALITY.

By signing this document and/or accepting these terms electronically, you acknowledge that you have received a copy of BioTelemetry's Notice of Confidentiality and Privacy Practices, which is incorporated in this agreement below. This 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., Geneva Healthcare, LLC, BioTel INR, LLC, 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: Under certain circumstances, we may disclose your health information to researchers when their research has been approved by an institutional review board or privacy board that has reviewed the research proposal and protocols to ensure the privacy of your health information.

Research; Death; Organ Donation: We may disclose your health information to a coroner, medical examiner, funeral director or organ procurement organization for certain purposes as necessary for each to carry out their duties. For example, if you are an organ donor, we may disclose your health information to an organ procurement organization as necessary to facilitate organ donation or transplantation. We may disclose your health information to a coroner or medical examiner to identify a deceased person or determine the cause of death.

Public Health and Safety: We may disclose your health information in connection with certain public health reporting activities. For example, we may disclose your health information to a public health authority authorized to collect or receive such information such as state health departments and federal health agencies. 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. We may also disclose your health information to the Food and Drug Administration (FDA) or a person subject to the jurisdiction of the FDA for the purpose of activities related to the quality, safety or effectiveness of an FDA-regulated product or activity.

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, protection of the President and authorized persons or foreign heads of state 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.

Health Oversight: We may disclose your health information in connection with certain health oversight activities of licensing and other agencies, such as audit, investigation, inspection, licensure, or disciplinary actions, and civil, criminal, or administrative proceedings.

National Instant Criminal Background Check System: We may use or disclose your health information for purposes of reporting to the National Instant Criminal Background Check System the identity of an individual who is prohibited from possessing a firearm under 18 U.S.C. 922(g)(4).

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 communications confidentially of your protected health information as further explained in this section. 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 submit a complaint to us using the information listed at the end of this notice. You may also submit a complaint 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: September 3, 2020

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 to 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., its 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 its 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

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