

Patient education guide







MCOT is not an emergency response system. The monitor (phone) 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.

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About our service

Your physician has prescribed MCOT for you to assist with your diagnosis. MCOT conducts beat-by-beat analysis of your heart activity and transmits certain abnormal beats to the cardiac technicians at Philips. 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:

Patient Services: 1-866-426-4401 or 1-833-396-2626

Email: customerservice@gobio.com Hours: 24 hours a day, 7 days a week

^{*} 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 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

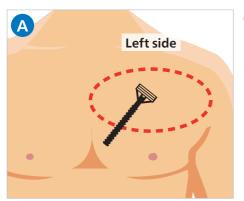
The device and kit components enclosed are the property of Philips and must be returned immediately upon completion of service.

Failure to return may result in delayed delivery of the final test results and a bill for the cost of the device.

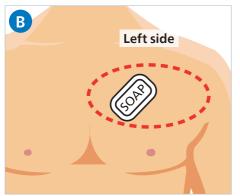
Device return instructions are located in this guide. Please refer to the table of contents for the page number.

Getting started

Step 1: Prepare your skin



• It is important to prepare your skin before applying the device. If hair is on your chest in the indicated area (red circle), shave hair using a razor.



- Wash the area with soap and water.
- Dry thoroughly with a towel.
- Do not apply lotions or oils.

Step 2: Attach electrodes to the Flex Adapter

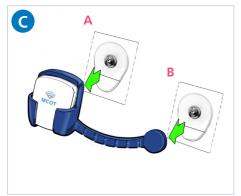


- Remove the Flex Adapter and MCOT sensor from Box 1.
- Slide the sensor into the Flex Adapter.
- A green light on the sensor will flash briefly when completely inserted.
- It may take up to 15 seconds for the green light to flash.



- Locate the package of electrodes in Box 2 of the kit.
- Remove two electrodes from the electrode pouch. Leave the plastic backings on.

Step 2: Attach electrodes to the Flex Adapter, continued



- (A) While the electrode is still on the plastic backing, snap it to the back of the Flex Adapter as shown in the diagram.
- (B) Repeat this step by snapping the second electrode onto the back of the Flex Adapter arm.

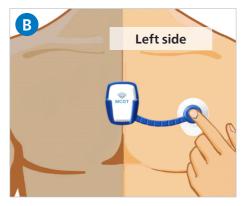


• Remove the plastic backing strips from the electrodes.

Step 3: Attach MCOT Flex Adapter to your chest

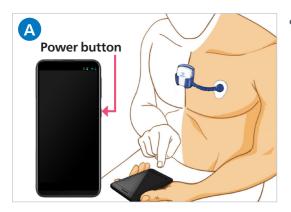


- Place the Flex Adapter in the center of your chest approximately three finger-widths below your collarbone.
- Do not place too low, or this may impact the quality of the signal.

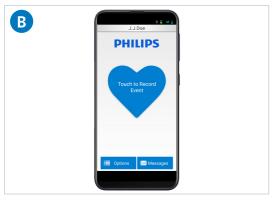


 Press the second electrode firmly on the left side of your chest, so that the arm lays flat against your chest.

Step 4: Activate the monitor



• Push the power button on the monitor and follow the guidance to complete the setup.



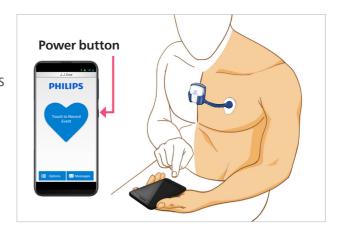
 Congratulations! When you see this screen, you've completed the setup process and your heart is being monitored.

Showering and replacing electrodes

It is recommended that electrodes be changed every 48 hours or after every shower (if showering daily).

Before showering or removing electrodes:

- 1. Turn off monitor.
- 2. Unsnap Flex Adapter from the electrodes.
- 3. Remove the sensor from the Flex Adapter (this prevents the sensor from wasting battery).
- 4. Use warm soap and water to remove the electrodes.
- 5. Shower normally.



Replacing electrodes:

- 1. Dry skin thoroughly.
- 2. Follow Steps 1-3 in the setup instructions in the getting started section of this patient education guide.

If electrodes are loose, replace them to avoid receiving an error message.

It is recommended that you change your electrodes every other day or after showering, whichever comes first.

MCOT worn with the Flex Adapter is not water-resistant.

Remove before showering, bathing or swimming.



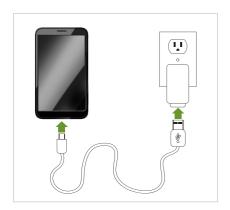


Charging the sensor



- You will receive an alert on the monitor when it is time to charge the sensor.
- Locate the charger and the cable wire in Box 2.
- Refer to the illustration to connect the sensor to the charger and plug it into an outlet.
- Charging may take up to 90 minutes and is complete when the light turns solid green.
- Once the sensor is fully charged, repeat the setup process. Refer to the Getting Started section of this patient education guide for the steps.

Charging the monitor

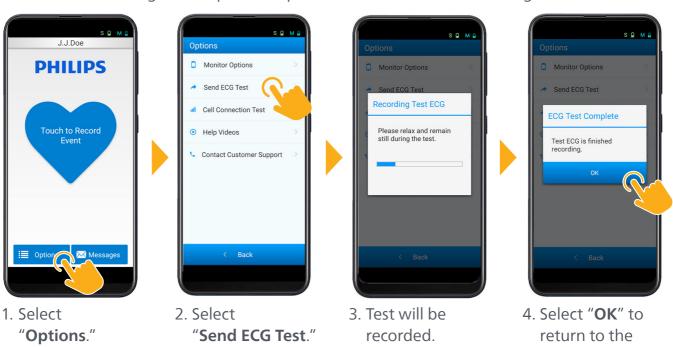


Charge the monitor daily, preferably at night

- Locate the charger and the cable wire in Box 2. Refer to the illustration to connect wire to monitor and charger to a wall outlet.
- It may take up to 4 hours to fully charge the monitor.

Record a baseline (manual recording option)

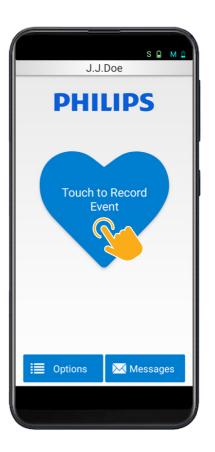
When activating MCOT for the first time, a baseline ECG test data recording should occur automatically and data will transmit wirelessly to Philips. If you do not have cellular coverage, the baseline will store in the monitor until service is available. You may be asked to transmit an ECG test recording. The steps to complete a manual ECG test recording are as follows:



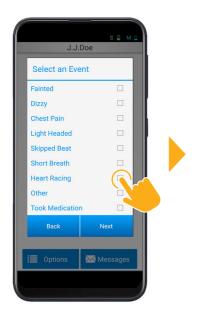
home screen.

Record events

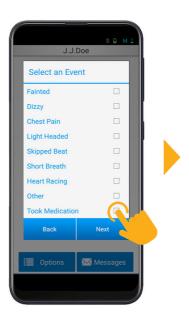
- MCOT monitors your heart and sends data automatically to the Philips monitoring center.
 You can also record symptoms as you feel them or indicate taking medication. When doing so, a timestamp indicator will appear on the reports provided to your physician.
- To record an event, press "**Touch to Record Event**" on the home screen.



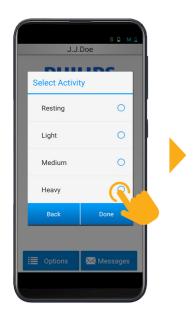
Record events, continued



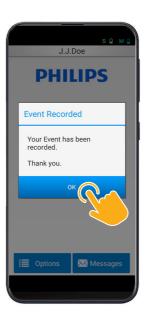
- 1. The "**Select an Event**" screen allows you to select the event(s) you wish to log.
- 2. Select all that apply.



- If an event occurred while taking a medication, check the box "Took Medication" in addition to the event.
- 4. Select "Next" to continue.

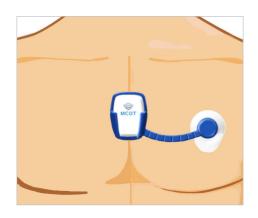


- 5. The "**Select Activity**" screen allows you to record your level of activity when the symptom occurred.
- 6. Select your activity level and press "**Done**." 8. Press "**OK**" to return to the home screen.



- 7. The "**Event Recorded**" screen confirms that the event(s) you selected were recorded.

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 Patient Services 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.

Wear and care tips



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



 When you feel a symptom or would like to record taking medication as indicated by your physician, press the "Touch to Record Event" button on the home screen.



3. MCOT worn with the Flex Adapter is not waterproof. Remove before showering, bathing or swimming. Replace the electrodes every 48 hours or after every shower.



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



5. Charge monitor daily with the charger provided.



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



7. Address all alerts on your monitor promptly.



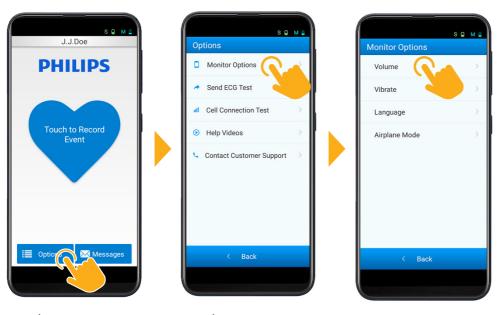
8. A "No Communication" message on the monitor means the sensor is out of range of the monitor. Keep the monitor near the sensor to resolve the issue. If the issue persists for more than 15 minutes, contact Patient Services at 1-866-426-4401.



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.

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 Patient Services.



1. Select "Options."

Select "Monitor Options." 3. 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



Return all MCOT equipment promptly to avoid charges.

The MCOT device and kit components are the property of Philips. Failure to return may result in a bill for the cost of 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.

Returns are simple:

- 1. Place the sensor, monitor, chargers and any unused electrode pouches into the Philips kit.
- 2. Place your packed kit into the pre-paid shipping envelope provided with your kit and ship back to Philips.

Instructions for patients traveling within the United States

Patient name:	

- 1. You are being monitored using the MCOT system a patient-worn, prescription-only medical device containing electronic components, and a rechargeable lithium-ion battery.
- 2. If you travel by aircraft while wearing this monitoring system, tell TSA authorities at the security checkpoint that:
 - The device cannot be removed from your skin or it will interrupt your cardiac monitoring service.
 - The device contains a lithium-ion battery that can be carried on to the plane per FAA regulations.*
- 3. Enable "Airplane Mode" on your monitor for the duration of the flight by doing the following:
 - Select "Options" and then select "Monitor Options," select "Airplane Mode," select "On," select "OK" and then confirm the "Enabled" message by selecting "OK."
 - When airplane mode is enabled, an image of an airplane () will show on the top portion of the monitor screen. The communication between the sensor and monitor will remain in airplane mode until it is manually turned off. If you are asked about the monitor by the flight attendant, please inform them that airplane mode is enabled and show them the monitor.
 - To turn off airplane mode, repeat the same previous steps with the exception of selecting "Off" after "Airplane Mode."

MCOT is NOT approved for use outside the United States

The MCOT system cannot transmit data wirelessly to the monitoring center outside of the U.S. Before traveling outside the United States, contact Philips Patient Services at 1-866-426-4401 for assistance.

* https://www.faa.gov/hazmat/packsafe/resources/media/Airline_passengers_and_batteries.pdf

Warning messages



You may receive different warning messages on your monitor to alert you to an issue requiring attention.



"Low Battery" sensor warning

If you receive this warning message, remove the sensor from the adapter and charge. To increase battery life keep the monitor and sensor in close proximity at all times.

A warning can be dismissed by pressing the "**OK**" button; however, the message will appear again until the issue is resolved.

Warning messages 1





"Low Battery" monitor warning

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



"No Communication" warning

This warning appears when the sensor and monitor are out of range from each other. Keep the monitor and sensor with you at all times.

Warning messages 1





"Transmit Data" warning

This warning indicates that the monitor cannot locate cellular service. To resolve, move to an area with cellular coverage. If you are unable to locate service, the monitor will store the data and transmit it when cellular service becomes available

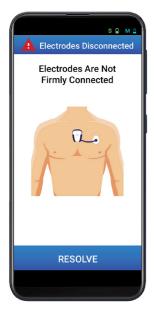


"Prescription Error" **102 (warning)**

This warning indicates that Philips has not received your prescription, but your heart ECG is still being recorded. Please contact Patient Services at 1-866-426-4401 for support.

Alert messages

There are different alert messages you may receive, which would require your immediate attention. Select the "**Resolve**" button for assistance to resolve the error, or "**Silence**" if guided to do so on the screen.

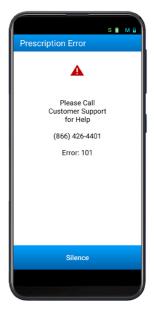


"Electrodes Disconnected" error

This alert indicates the electrodes are not firmly adhered to your skin.

 If the sensor has been removed to charge or you removed the electrodes and Flex Adapter from your chest, the monitor should be turned off.

If this does not fix the issue, select the "Resolve" button and follow the instructions



"Prescription Error" 101

This message indicates additional information is needed. Contact Patient Services for support at 1-866-426-4401.

Sensor and monitor pairing unsuccessful

If either the "Pairing" screen or "Insert Sensor" screen is continuously displayed, the monitor is not able to connect with the sensor. Press down on the sensor to ensure it is fully inserted. If a red light is visible on the sensor, remove the sensor and charge with the supplied charger. Once charged and the light turns solid green, place the sensor into the Flex Adapter.

If the issue continues, contact Patient Services.



"Pairing"



"Insert Sensor"

Mobile Cardiac Outpatient Telemetry (MCOT) System with Flex Adapter Addendum to the patient education guide

Indications for use

The MCOT System is designated as Rx only and its indications for use are as follows:

- 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.
- 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 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.
- 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 OT interval changes.
- The device does not annotate QT interval for QRS durations >160ms or for T wave amplitudes ≤5% of the peak QRS amplitude.

Warnings

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.

EXTERNAL DEFIBRILLATOR

Remove MCOT System and Sensor before using an external defibrillator.

INFANTS and SMALL CHILDREN

The MCOT System should not be used on infants weighing less than 22 lbs (10 kg). The system should be kept away from infants and small children 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 electrodes to the face or cover nose or mouth

Precautions

DO NOT TAMPER WITH DEVICE

CAUTION:

- Do not use electrodes if package is tampered or defective.
- There are no serviceable parts in the Sensor and Flex Adapter. Disassembling the Sensor or accompanying Flex Adapter 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

CAUTION: The Monitor and Sensor batteries of the MCOT 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 and chargers.

USE POWER CORDS IN SINGULAR OUTLET

 ${\sf CAUTION: A multiple \ portable \ socket \ outlet \ or \ extension \ cord \ should \ not \ be \ used \ with \ the \ equipment.}$

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 accessories or components 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

CAUTION: The electrodes are a single use item; do not reuse the electrodes. All other system components are reusable.

CONNECTION TO COMPONENTS

CAUTION: 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

CAUTION: The MCOT System with Flex Adapter system should not be stacked with other equipment. Stacking other equipment on top of the devices may damage enclosure or inner components.

FLEX ADAPTER STORAGE TEMPERATURE AND SHELF LIFE

CAUTION: The Flex Adapter's storage temperature requirement is narrower than the rest of the components and temperature limits should be taken into account for storage. The Flex adapter has been tested and is within the range of +5°C to +27°C. The Flex adapter has a shelf life of 2 years. Storage of the Flex Adapter outside these limits may affect longevity of shelf life.

ASSEMBLED DEVICE

CAUTION: Do not attempt to charge Sensor while assembled into any accessory. The Sensor should be charged on its own as an isolated unit.

FOR USE WITHIN CELLULAR DATA COVERAGE AREA

CAUTION: The device is not designed for high-risk patients and ECG analysis is not meant to be real-time.

A loss of cellular data coverage may prevent Monitor from sending medically significant
events to Remote Site for review. For optimal monitoring service please stay in an area with
cellular coverage.

NOT AN APNEA MONITOR

CAUTION: The MCOT System is not to be used as an apnea monitor.

AVOID ELECTROMAGNETIC INTERFERENCE

CAUTION: 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

CAUTION: There is a potential for electromagnetic interference to other devices while using the MCOT System. If the user needs to completely shut down all devices generating an electromagnetic signal, then turn the Monitor OFF. The Bluetooth radio in the Sensor CANNOT be turned OFF. Additionally, enabling Airplane Mode disables cellular modem but Bluetooth radio for both Monitor and Sensor will still be active.

USE WITH IMPLANTED PACEMAKERS

CAUTION: If you have an implanted pacemaker, the manufacturer may have recommended certain precautions when using a cellular phone. Since the MCOT System contains a cellular phone, you should take the same precautions when carrying and using the Monitor. In general, most pacemaker manufacturers recommend the following:

- You should keep a distance of at least 6 inches (15 cm) between the cellular phone and a pacemaker.
- You should hold the cellular phone on the opposite side of the body from the pacemaker.
- 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.
- You should refer to the manufacturer's information for guidance regarding your pacemaker and interference issues.

PACEMAKER DETECTION

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

ICDs DEFIBRILLATORS

CAUTION: Use with an ICD defibrillator is prohibited.

RADIOGRAPHIC USE

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

ADDITIONAL EQUIPMENT CLASSIFICATION INFORMATION REQUIRED BY EN 60601-1 CAUTION:

- EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE.
- The Flex Electrode with Sensor is not water resistant.
- Internally Powered Equipment.
- Mode of Operation Continuous Operation.

CHANGES OF PERFORMANCE

CAUTION: In the event there's a change in performance of the MCOT System with Flex Adapter system, reference the Instructions For Use or call Patient Services at 1-866-426-4401.

EXPOSURE TO ENVIRONMENTAL CONDITIONS

CAUTION: In the event the system is subjected to environmental conditions which may affect performance, such as high magnetic fields, as is the case in a MRI room, external electrical influences, electrostatic discharge (ESD), or other similar situations the user is requested to consult the Instructions For Use or call Patient Services at 1-866-426-4401.

PHYSICAL ACTIVITIES AND EXPOSURE TO ENVIRONMENTAL EFFECTS SHOULD BE LIMITED

CAUTION: Physical activities leading to involuntary muscle spasm may cause artifacts while recording ECG signals. These activities should be avoided for the duration of use. Additionally, environmental effects, such as cold ambient temperature, may also generate muscle tremors and should also be avoided.

DO NOT TAKE THE MONITOR INTO THE SHOWER

CAUTION: The MCOT System Monitors (cell phones) are water resistant, not waterproof; do not take the Monitor into the shower.

DO NOT LIE DIRECTLY ON THE SENSOR

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

CHARGING THE MONITOR

CAUTION: Do not touch pins on the charger while connected to power outlet.

 \Re **ONLY** U.S. Federal law restricts this device to sale by or on the order of a physician.

Specifications

Sensor

General functional

General ranctional		
Channels	2 channels	
Resolution	12 bits	
Sample rate	250, 500, or 1000 sps	
Frequency response	0.05 – 55 Hz	
CMMR	71 dB	
Input range	+/- 7.5 mV @ Gain 70 +/- 3.75 mV @ Gain 140 +/- 3.0 mV @ Gain 175	
Recording time	30 days at 250Hz, 2 Channels	
Service life	3 years	
Sensitivity	The device does not have a set minimum amplitude or value for ECG measurement. Minimum requirements are to maintain leads attached to the skin. When this condition is not met, a 'Leads-OFF' alert is triggered and resulting ECG data is flagged as 'leads-off' and not used for ECG analysis.	
Environmental		
IPX rating When inserted into Patch	IP24 Resistant to water splashes from any direction	
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	2" x 1.6" x 0.36"	
Weight	0.69 oz	
Weight (Sensor + Patch)	0.78 oz	
Connection to Patch	Custom 8 terminal connector	
Battery type	Internal Rechargeable Lithium Ion 3.7 V 500 mAh with LiNiMnCoO ₂ (NMC) as cathode and graphite as anode.	
Data transmission		
Bluetooth radio	BT 2.0 or 2.1	

^{*} Practical operating temperature range for using the system is limited by the Patch's temperature limitations. Together, operating temperature range is +10°C to 40°C.

USB 2.0

Samsung J3 2017 and J3 2018 Monitor specifications

	Samsung J3 2017	Samsung J3 2018
General functional		
Display	Super AMOLED Touchscreen	IPS LCD capacitive touchscreen
Operating system	Android	Android
Battery type	2600 mAh Lithium Ion with LiCoO ₂ (LCO) as cathode and graphite as anode	2600 mAh Lithium Ion with LiCoO ₂ (LCO) as cathode and graphite as anode
Service life	3 years	3 years
Hearing aid compatibility (HAC)	Samsung J3 M3 (RF Emissions Category) T3 (Signal to Noise Category)	Samsung J3 M3 (RF Emissions Category) T3 (Signal to Noise Category)
Environmental		
IPX rating	IP22 Protected from particles >12.5 mm and dripping water when tilted up to 15°	IP22 Protected from particles >12.5 mm and dripping water when tilted up to 15°
Operating temperature	10°C to +45°C	10°C to +45°C
Non-operating temperature	-20°C to +70°C	-20°C to +70°C
Atmospheric pressure	700 hPa to 1060 hPa	700 hPa to 1060 hPa
Operating humidity	10% to 95% (non-condensing)	10% to 95% (non-condensing)
Non-operating humidity	5% to 95% (non-condensing)	5% to 95% (non-condensing)
Physical		
Size	142.3 x 71.0 x 7.9 mm	142.3 x 71.0 x 7.9 mm
Weight	138 g	152 g
Battery type	2600mA-Hr Lithium Ion	2600mA-Hr Lithium Ion
Data transmission		
Cellular radios	LTE Cat 3, CDMA 1x EVDO, 1x Advanced	LTE Cat 3, CDMA 1x EVDO, 1x Advanced
Bluetooth	4.2, A3DP, LE	4.2, A3DP, LE

USB

Samsung A10e specifications

General functional	
Display	PLS TFT capacitive touchscreen
Operating system	Android
Battery type	3000 mAh battery
Service life	3 years
Hearing aid compatibility (HAC)	M3 (RF Emissions Category) T3 (Signal to Noise Category)
Environmental	
IPX rating	IP68 Dust resistant and can be immersed in 1.5 meters of freshwater for up to 30 minutes
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 8.4 mm
Weight	141 g
Data transmission	
Cellular radios	LTE Band 13(700), 25(1900), 26(850), 41(2500) CDMA- Band 27(800)
Bluetooth	5.0, A2DP, LE

Samsung A13 specifications

General functional	
Display	6.6" FHD + LCD, 1080x2408
Operating system	Android
Battery type	5000 mAh
Service life	3 years
Hearing aid compatibility (HAC)	M3 (RF Emissions Category) T3 (Signal to Noise Category)
Environmental	
IPX rating	No IPX Rate
Operating temperature	0°C to +35°C
Non-operating temperature	-20°C to +50°C
Atmospheric pressure	4,572m, Equivalent air pressure above 57.3 kPa
Operating humidity	00% to 95% (non-condensing)
Non-operating humidity	5% to 95% (non-condensing)
Physical	
Size	165.1 x 76.2 x 8.8 mm
Weight	195.6 g
Data transmission	
Cellular radios	LTE Band B1(2100), B2(1900), B3(1800), B4(AWS), B5(850), B7(2600), B12(700), B13(700), B14(700), B20(800), B25(1900), B26(850), B29(700), B30(2300), B66(AWS-3), B71(600), B38(2600), B41(2500), CDMA-B1(2100), B2(1900), B4(AWS), B5(850), B8(900)
Bluetooth	5.0, A2DP, AVRCP, DI, HFP, HID, HOGP, HSP, MAP, OPP, PAN, PBAP, SAP

Flex Electrode

Tested to IP21 to ensure basic safety; devices are not water resistant
+5°C to +27°C
Up to 93% non-condensing
+5°C to +40°C
15% to 93% non-condensing
700 hPa to 1060 hPa
0°C to 40°C
Up to 93% non-condensing

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 Patient Services 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 copayments, 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.gobic.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 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 OUIET ENJOYMENT, AS WELL AS ANY IMPLIED WARRANTIES OTHERWISE ARISING OUT OF COURSE OF DEALING, COURSE OF PERFORMANCE OR TRADE USAGE, PATIENT FURTHER ACKNOWLEDGES AND AGREES THAT BIOTELEMETRY SHALL NEITHER BE RESPONSIBLE NOR LIABLE FOR PATIENT'S INABILITY TO ACCESS OR USE THE SERVICE AS A RESULT OF ANY DEFICIENCY IN THE INTERNET, THE TELEPHONE SERVICE, OR OTHER CONNECTION BETWEEN BIOTELEMETRY AND PATIENT, PATIENT EXPRESSLY ACKNOWLEDGES AND AGREES THAT NEITHER THE SYSTEM, NOR THE SERVICE (AS WELL AS ANY SUPPORT GIVEN BY ANY BIOTELEMETRY SUPPORT STAFF), NOR ANY MATERIAL AVAILABLE THROUGH PATIENT'S USE OF THE SYSTEM OR SERVICE IS INTENDED TO PROVIDE PATIENT WITH MEDICAL ADVICE. A DIAGNOSIS OR TREATMENT, PATIENT MUST ALWAYS SEEK THE ADVICE OF PATIENT'S

PHYSICIAN OR OF ANOTHER QUALIFIED MEDICAL PRACTITIONER WITH ANY QUESTIONS PATIENT MAY HAVE REGARDING A SPECIFIC MEDI-CAL CONDITION OR PERCEIVED CONDITION.

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

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

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



Important reminder:

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

1000 Cedar Hollow Road, Suite 102, Malvern, PA 19355
Toll free: 1 (866) 426-4401 | customerservice@gobio.com | www.philips.com/ECGSolutions