PHILIPS

Extended Holter

ePatch

Lead wire adapter

# Patient education guide


Need help or have questions? Call Patient Services toll-free: 1.877.593.6421 or visit **myheartmonitor.com** for online support.

Scan the QR code to view how to setup your ePatch Lead Wire Adapter. visit **myheartmonitor.com.**

# Table of contents

# About our service

Your physician has prescribed the Philips extended Holter – ePatch for you. ePatch continuously records and stores heartbeats that are analyzed by cardiac technicians at Philips. Clinical reports are made available to your healthcare provider at the end of service.

**To get started, review the important information in this guide or visit myheartmonitor.com.**

**If you have any questions, please contact us:**

Patient Services: 1-877-593-6421 (toll-free)
email: customerservice@gobio.com
Hours: Mon–Fri: 8am–8:30pm ET; Sat–Sun: 8am–4:30pm ET

# 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.

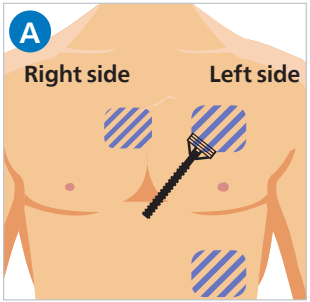
**You will be responsible for any out-of-pocket cost associated with deductibles, co-insurances, etc. If there is a balance due, you will receive a statement from Philips for your portion. If you have any questions regarding the balance due, please refer to your statement for contact information.**

## Prompt return of all equipment

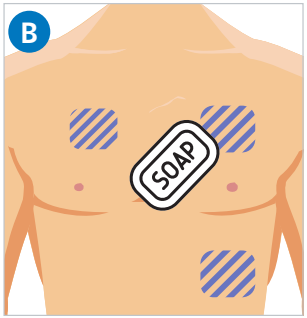
The device and kit components enclosed are the property of Philips and must be returned immediately upon completion of service. **Failure to return may result in delayed delivery of the final test results and a bill for the cost of the device.**

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

## Step 1




- Locate the shaded areas. If hair is on your chest, you will need to shave.

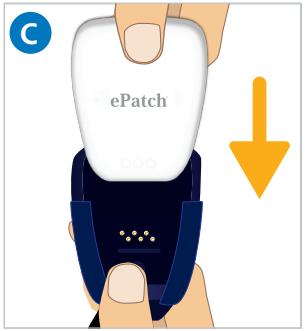



- Clean the area with soap and water.
- Dry your skin using a towel.

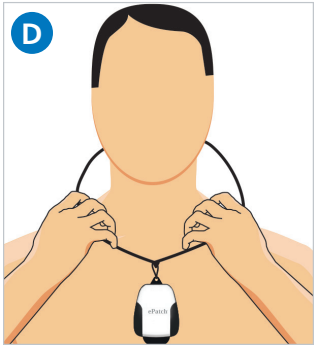
**Important Notes:**

– Wait for 2-3 minutes until the skin is completely dry before proceeding to the next step.

– Do not apply lotion or oils after skin preparation.




- Remove the lead wire adapter with lanyard from the kit.
- Push the sensor* through the top of the Philips Lead Wire Adapter until it is **firmly** in place.
- To confirm recording, a **solid green light** is displayed. The green light will blink for a period of time and then turn off.

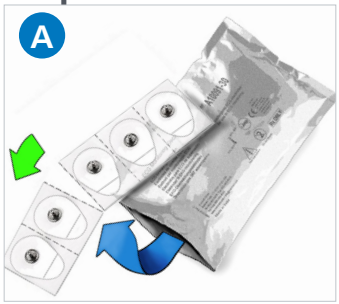



- Place the lanyard over your head and around your neck.

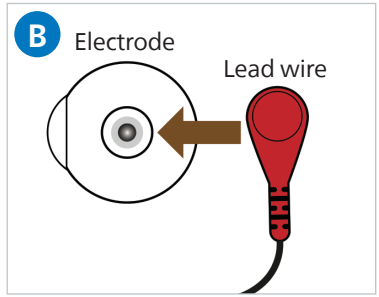
**Not seeing the green light sequence?**
**Contact Patient Services at 1-877-593-6421 or visit myheartmonitor.com.**

* Logo design on device in this guide may differ from the logo on the actual device supplied in kit.

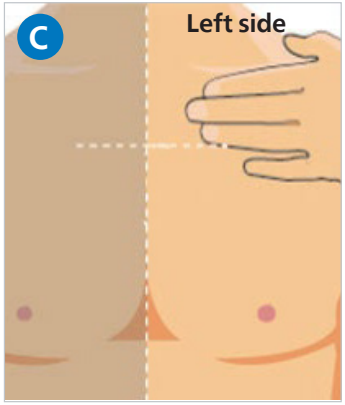
## Step 2



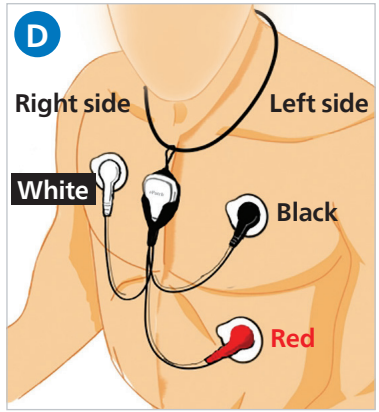

- Remove a packet of electrodes from the kit. Tear off three electrodes, one for each lead wire.




- Snap each lead wire onto an electrode.




- Before attaching each electrode, peel the adhesive liner off the back of it.
- Attach the black lead electrode approximately 3 fingers width below your collarbone, on the left side of your chest.
- Next, do the same on the right side of your chest with the white lead electrode.




- Attach the red lead electrode on your lower rib on the left.
- The Lead Wire Adapter is now correctly placed. Congratulations, you are now recording with ePatch!
- **Note:** The ePatch recording will stop after the predefined recording time or when the sensor is removed from the Lead Wire Adapter.

# Showering and replacing electrodes

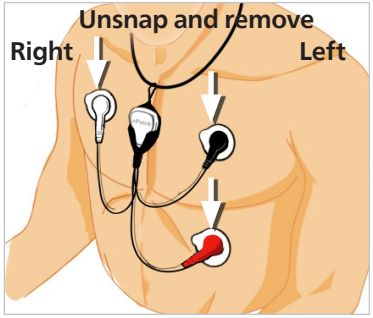
## Showering

The Lead Wire Adapter is **not** water-resistant; therefore, swimming or bathing should be avoided while wearing the sensor with the Lead Wire Adapter. Remove the Lead Wire Adapter (and the sensor) from the body and set aside.

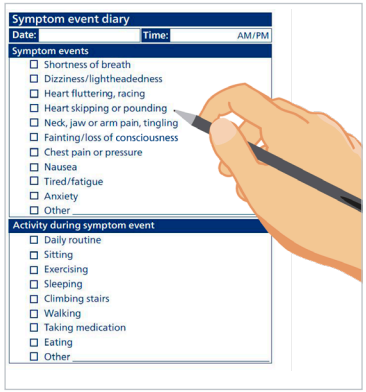
## Replacing electrodes:

Gently push the sensor out of the Lead Wire Adapter and then remove leads and electrodes from the body.

**Important Note:** Refer to the information provided with the surface electrodes for replacement instructions.

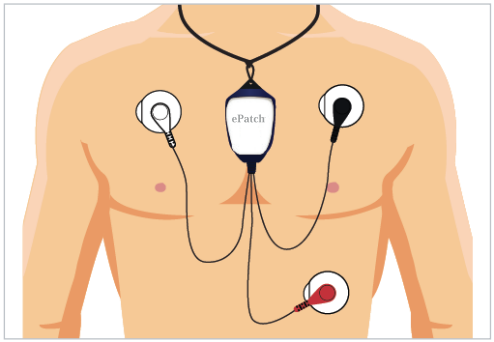



# Record symptoms




- Whenever you feel a heart-related symptom record the symptom in the event diary included in the kit.
- Make sure to write that symptom and how you are feeling in the diary.
- Locate the diary in your kit and fill in your name, address, physician's name, and the start date. After your monitoring period has ended, fill in the date you removed ePatch.
- Do not forget to include the date and time of each symptom.

# Important information

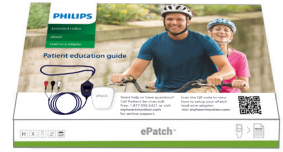



- Continue to wear your device for the duration prescribed by your physician.
- Minor discomfort is expected when the Lead Wire Adapter with electrodes are attached to the skin. The materials selected for these accessories are biocompatible and are purposed for this use. However, if severe skin irritation does occur and becomes uncomfortable for continued use then remove the Lead Wire Adapter with electrodes and contact your physician or Patient Services department at 1-877-593-6421.
- Record any events or symptoms you may feel in the patient diary (see directions on page 8).
- When you begin the ePatch setup process, make sure that you insert the sensor FIRMLY into the Lead Wire Adapter until you see a green light to ensure that ePatch is properly connected to record your data.
- If you do not see a green light when you insert the sensor into the Lead Wire Adapter, your ePatch may not be recording, so contact the Patient Services department at 1-877-593-6421.

# Returning the equipment

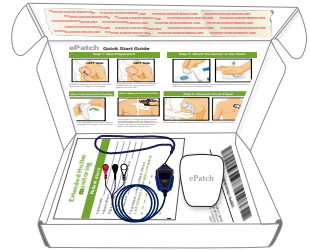
## Step 1

**Important:** Do not throw the box away. You will need to use it to return the equipment and supplies.




## Step 2

When you are ready to return ePatch, pack up the sensor, Lead Wire Adapter, unused electrodes, diary and any other supplies, and place into the kit.




## Step 3

Remove the protective strip to expose the adhesive.
Seal the kit shut and then follow the return instructions to ship the kit back to Philips. There is no cost to you to mail back the equipment.

# Travel information

Patient name: _____

1. You are being monitored using an Philips extended Holter – ePatch—a prescription-only, continuously recording and non-transmitting cardiac device that contains a rechargeable lithium-ion battery.
2. If you plan to travel by aircraft while wearing the ePatch, please show TSA authorities this card at the security checkpoint and let them know this cardiac monitoring device:
   - is attached to your skin and cannot be removed or else it will prematurely end your service.
   - does not transmit data wirelessly.
   - contains a lithium-ion battery that can be carried on to the plane per FAA regulations regarding lithium-ion batteries.*

If you are traveling outside the U.S. anytime during your monitoring period, contact the Patient Services at (1-877-593-6421) for assistance, Mondays–Fridays from 8am–8:30pm ET and Saturdays–Sunday from 8am–4:30pm ET.

If you need assistance during your monitoring period, contact the Patient Services at 1-877-593-6421 for assistance, Monday–Friday: 8am–8:30pm ET and Saturday–Sunday: 8am–4:30pm ET.

*For more information, visit https://www.faa.gov/

## ePatch addendum to the patient education guide

Indications for use
ePatch is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety.

ePatch is intended for use by adolescents 18-21 and adults.

Contraindications
The sensor is not intended for use on:
- Patients with implanted pacemakers.
- The compatible lead wire adapter is not intended for use in the following cases:
  - On patients with known allergies to adhesive materials or hydrogel.
  - The compatible lead wire adapter should not be placed on broken, damaged, or irritated skin.

$R_x$only
Caution: Federal law restricts this device to sale by or on the order of a physician.

Precautions
Avoid contact with the eyes or mucus membranes of gels, alcohol, acetone, or any substance used in the placement or removal of the electrodes. This can damage the eyes or mucus membranes of the patient.

Do not use an obviously broken sensor. This can cause electric discharge or decrease the quality of the acquired ECG signals.

Do not touch the terminals at the backside of the sensor or let them touch other conductive parts or earth. This may damage the sensor.

Minimize the number of devices connected to the patient. Otherwise, there is a risk of accumulation of leakage current.

Store and use the sensor within temperature, pressure, and humidity ranges specified in the specifications section. Avoid exposing any part of the sensor to heat sources, heat radiators and fireplaces, direct exposure to sunlight, nebulizers, or electrical steam kettles. Temperature changes cause condensation and moisture that can lead to malfunction of the sensor. Before using the sensor, allow the sensor to acclimate to ambient temperature. For reference, if the temperature difference between the sensor and the environment is above 10ºC, a 20 minutes wait time in an intermediate temperature is recommended.

The sensor is NOT water resistant when worn with the lead wire adapter; therefore, do not bathe or swim while wearing the sensor in the lead wire adapter set-up.

Do not expose the internal parts of the sensor to any liquids.

Mobile phones, transmitters, and similar equipment generating radio frequency (RF) emissions should not be used or placed next to the sensor during recordings. This can affect the to sensor. Follow the recommendations regarding the separation distance specified in the manufacturer's declaration for EMC in this Instruction Manual, see Annex 1 of the ePatch Sensor IFU.

Warnings
The sensor is not intended for use on infants, or on pregnant and/or breastfeeding women.
The sensor is not intended for use on patients with implanted pacemakers.
Do not use the sensor in an X-ray, computed tomography (CT), or magnetic resonance imaging (MRI) environment. This may affect the scanning results, may lead to malfunction of the sensor, and it may injure the patient.
Remove sensor prior to defibrillation.
Do not tamper with, disassemble or modify sensor or accessories, as this may affect functionality or performance. A slight electrical sensation may be experienced.

Use the sensor with compatible accessories supplied by the manufacturer. Otherwise, electrical shock or damage to the sensor may occur. In addition, the ECG signal quality could be affected.

Use of other equipment or accessories not specified in this Instructions For Use document might lead to skin irritations, allergy, electrical shock, and malfunction of the sensor. Use of other chargers may damage the device and/or the accessories.

Keep products out of reach of infants, children and pets, as this could potentially cause a choking hazard or cause suffocation if placed over face or mouth. There is a danger of strangulation if the provided USB Cable and/or lead wires are misused.

Please refer to the Instructions for Use associated with the compatible accessory for their specific Warnings.

## Specifications
## ePatch sensor

| | |
|---|---|
| Device classification (EN 60601-1): Class: | Internally Powered, Type BF applied parts, not protected against defibrillator, no functional earth terminal |
| Data acquisition: | 1, 2, or 3 channels ECG, Event Marker[a] |
| Recording time: | Up to 14 days[b] (the recording time is configurable by manufacturer) |
| Sampling rate: | 128, 256, 512, or 1024 Hz[a] |
| Resolution: | 12 bit or 16 bit, depending on customer presence |
| Frequency response: | 0.05 to 55 Hz High Pass |
| Input range ECG Channels: | 180 mVpv (Peak-to-Valley) CMRR (common mode rejection ratio): >60 dB @ 50/60 Hz |
| Input impedance: | 10 MΩ |
| Connections: | 1 ePatch Specific 8-Terminals Connector for connection to a compatible electrode |
| Storage medium: | 2 GB internal storage |
| Maximum data file size: | 2 GB EFS-file (ePatch File System) |
| Expected service life: | Minimum 300 uses or two years, whichever occurs first |

[a] The number of recorded ECG channels and the sampling frequency depends on the configuration of your sensor. Note that not all combinations of channels and sampling frequencies are possible.

[b] The maximum recording time for a configuration with one ECG channel and a sampling frequency of 256Hz is 14 days but other configurations are possible.
The maximum possible recording time is increased when the number of recorded ECG channels and/or the sampling frequency is decreased. Likewise, the maximum possible recording time is decreased when the number of recorded ECG channels and/or the sampling frequency is increased. Note that the recording time of the sensor may be be configured to be less than the maximum possible recording time.

### Battery (sensor)
The sensor is powered by an integrated battery with the following specifications. The battery is not replaceable:

| | |
|---|---|
| Type: | Rechargeable lithium-ion battery |
| Nominal capacity: | 500 mAh (Nominal) |
| Battery life: | 300 charge cycles |
| Maximum charge current: | 500 mA |

### Dimensions and weight (sensor):

| | |
|---|---|
| Dimensions (W x H x D): | 40 x 49 x 12 mm |
| Weight | 20 g |

### Environmental Conditions and Device Life (sensor):

| | |
|---|---|
| Enclosure protection degree: | IP24 (when the sensor is firmly connected to a compatible patch/electrode) |

### Operating conditions

| | |
|---|---|
| Temperature: | +5°C to +40°C |
| Pressure: | 700 – 1060 hPa |
| Relative humidity: | 15% - 90% (non-condensation) |

### Transport and storage conditions (including between uses)

| | |
|---|---|
| Temperature: | - 25°C to +50°C |
| Relative humidity: | 15% - 93% (non-condensation) |
| Device Life: | Non-perishable, battery charge level to be maintained. |

**CAUTION:** Exceeding the recommended operating, storage, and transportation conditions may result in reduction of the performance of the sensor and/or accessories.

**NOTE:** For environmental conditions for the compatible accessories, refer to the instructions for use specific to the accessory.

**Lead wire adapter environment specifications**

Enclosure protection degree: IP21 (when the sensor is connected to a compatible lead wire adapter)

Operating conditions:

| | |
|---|---|
| Temperature: | +5°C to +40°C |
| Pressure: | 700 – 1060 hPa |
| Relative humidity: | 15% - 93% (non-condensation) |

Storage conditions (including between uses):

| | |
|---|---|
| Temperature: | 5°C to +27°C |
| Relative humidity: | Up to 93% (non-condensation) |

Transportation conditions:

| | |
|---|---|
| Temperature: | 0°C to +40°C |
| Relative humidity: | Up to 93% (non-condensation) |

Glossary of Symbols for ePatch sensor

| Symbol | Description |
|---|---|
| CE 2797 | CE mark Indicates that the product conforms with standards for products sold within the European Union |
|  | WEEE (Waste Electrical and Electronic Equipment) Directive (2002/96/EC) |
|  | Type BF Applied Part |
|  philips.com/IFU | Electronic instructions for use |
|  | Refer to instruction manual |
|  | Protect from moisture |
| ℞ only | Prescription use only (U.S. Federal Law) |
| REF | Catalogue number |
|  | Manufacturer |
| SN | Serial number |
| 20XX | Year of Manufacture |
| EC REP | European Authorized Representative |
| MR | MR Unsafe |

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

## Terms and conditions of the Philips BioTelemetry service agreement.

PLEASE READ THIS DOCUMENT CAREFULLY BEFORE ACTIVATING THE MONITOR.

Activating monitoring service is your acceptance of the terms of this Agreement. If you do not agree with the terms of this document please notify Customer Service at 1-866-426-4401 immediately.

PRIVACY AND CONFIDENTIALITY

Activating monitoring service serves as your electronic signature indicating you acknowledge that you have received a copy of BioTelemetry's Notice of Confidentiality and Privacy Practices, which is incorporated in this agreement below. This acknowledgment is required by the Health Insurance Portability and Accountability Act (HIPAA) to ensure that you have been made aware of your privacy rights. You give BioTelemetry your consent and permission to communicate with other members of your household, if necessary, with regard to your BioTelemetry service. You also authorize BioTelemetry to provide your monitoring data to your physician and his / her staff and to Emergency Medical Services by phone, e-mail, fax or through secure Internet access. You 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 activating monitoring services serves as my electronic signature, and that 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 acknowledgment 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.

**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.

**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.

**Required by the Secretary of Health and Human Services:** We may be required to disclose your health information to the Secretary of the United States Department of Health and Human Services to investigate or determine our compliance with certain legal requirements.

**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 certain communications confidentially. That means you can request that we communicate with you by alternative means or to an alternative location by submitting a request to us in writing using the information listed at the end of this notice. We will accommodate your request if it is reasonable and specifies the alternative means or location. We may also condition this accommodation by asking you for information as to how payment will be handled.

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

Paper Notice: IIf 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 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 MEDICAL CONDITION OR PERCEIVED CONDITION.

4. LIMITATION OF LIABILITY. TO THE MAXIMUM EXTENT PERMITTED UNDER APPLICABLE LAW: (I) IN NO EVENT SHALL BIOTELEMETRY OR ITS 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.

PATIENTS' RIGHTS AND RESPONSIBILITIES

**This document describes a summary of the rights and responsibilities of the patient using Philips' ECG diagnostic services. This document may not be comprehensive: please refer to the labeling or your clinical provider for further information or questions.**

Rights:

- The patient has the right, within the law, to personal and information privacy, as manifested by the right to:
  - Make recording and submit transmissions in surroundings designed to assure privacy.
  - Expect that any discussion involving the patient will be conducted discreetly.
  - Medicare records will only be read by individuals directly involved in the patient's care or the monitoring of its quality.
  - Expect that all communications and other records pertaining to care, including the source of payment of treatment be treated as confidential.
  - Expect appropriate services without discrimination based upon race, color, religion, sex, handicap, sexual preference, or national origin.
  - Expect that their psychosocial, spiritual, and cultural values are respected and that they may express their spiritual beliefs and cultural practices that do not harm others.
- The patient has the right to expect safety in so far as Philips practices and environment are concerned.
- The patient has the right to obtain complete and current information concerning his care from his/her physician. Philips provides a service to the patient and the physician. It is the responsibility of the physician to discuss diagnosis, treatment & any known prognosis. Please understand that Philips is not legally able to disclose the results of the recordings.
- The patient has the right to expect a well-trained staff knowledgeable in areas related to medical procedure and equipment used in these procedures. The staff is trained and skilled in taking into consideration individual beliefs and values.
- All patients complaints will be addressed in accordance with the existing complaints/grievance procedure.
- Patients under legal age have the right to have a surrogate decision maker properly informed and educated.
- The patient has the right to access the company's policy regarding charges and payment responsibilities.
- The patient has the right to access the company's Notice of Privacy Practices.

Responsibilities:

- The patient is responsible for making it known whether they clearly comprehend the service and what is expected of them.
- The patient is responsible for following the instructions provided by Philips technicians.
- The patient is responsible for their actions if they refuse to use the service as prescribed by physician.
- The patient is responsible to ask for explanations if you do not understand how the service works or how to use the device.
- The patient is responsible to advise Philips of any dissatisfaction you may have regarding the service.
- The patient is responsible to be considerate of the rights of Philips personnel.
- The patient is responsible to assure that the financial obligations associated with the service are fulfilled.
- The patient is responsible for returning the assigned equipment to Philips, in proper working order, upon completion of the service.

Patients' rights and responsibilities

If you have any questions about your monitoring service or billing, please contact Patient Services: 1-877-593-6421 (toll-free) or customerservice@gobio.com

Hours: Mon-Fri 8 am - 8:30 pm ET; Sat-Sun 8 am - 4:30 pm ET

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 indicates a medical emergency, you should immediately dial 911 for medical assistance.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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: 1-877-593-6421 • customerservice@gobio.com • www.myheartmonitor.com