

# BodyGuardian® HEART

# Patient Instruction Manual



Preventice Services, LLC and Preventice Technologies, Inc., are independent, wholly owned subsidiaries of Preventice Solutions, Inc.

Return your monitor on: \_\_\_\_\_ / \_\_\_\_ / \_\_\_\_

#### Did you receive your monitor at home?



If you are receiving the monitor at home and require assistance, call Preventice Services at: **888.500.3522** 

#### **Patient services**

- 888.500.3522 (press 1, 1)
- 24 hours a day, 7 days a week
- monitortroubleshooting@preventice.com

#### **Returning your monitor**

- 888.500.3522 (press 1, 5)
- O 7:00 a.m. 7:00 p.m. CST, M-F
- monitorrecovery@preventice.com

#### **General information**

www.preventicesolutions.com/patients/body-guardian-heart



Preventice Services is not an emergency response service. Contact your doctor immediately if your symptoms worsen. If you are experiencing a medical emergency, dial 911.



The BodyGuardian Connect smartphone cannot be used to make phone calls, including calls to 911, or perform other smartphone functions. Viewing the smartphone is prohibited while driving, operating heavy machinery or in situations that may jeopardize your safety.

#### **Billing assistance**

- **3** 888.747.4701
- 2 8:00 a.m. 5:00 p.m. CST, M-F
- reimbursementinfo@preventice.com

#### **Patient benefit quotes**

- **388-747-4760**
- 8:00 a.m. 4:00 p.m. CST, M-F
- patientbenefitquotes@preventice.com

# Patient financial obligations and billing information



On behalf of your physician, you are being provided with a heart monitor from Preventice Services. This test will be billed in two parts:

- 1. Your medical professional will bill your insurance for the in-office hook-up and the final reading of the test results.
- 2. Preventice Services will bill your insurance for the use of the monitor along with providing the physician with 24/7 monitoring center service and all requested data and reports.



Your insurance company will usually send you an Explanation Of Benefits (EOB) describing the amount paid and the amount you owe Preventice. An EOB is not a bill.

Our goal is to help your physician diagnose your heart condition without delay or concerns about billing. We offer patient-friendly payment options, including a discounted rate at the time of service or a reduced rate when your insurance indicates a large fee payable by you for our services or the physician's services.



All equipment is the sole property of Preventice Services. To avoid financial liability and to ensure that you do not receive a bill for the value of the equipment in your possession (up to \$2,400), please return the equipment immediately after your service ends. Any request for an extension of your study beyond your prescribed study needs to come from your physician through a new order sent to Preventice Services. Be aware that the second study may not be covered by all insurance providers and you may be responsible for those charges.

### Welcome to BodyGuardian Heart



Your physician has prescribed you the **BodyGuardian Heart Remote Monitoring System** and monitoring center service provided by **Preventice Services** to detect irregular heart rhythms. You must wear the monitor for the length of time your doctor has prescribed.

### When your study concludes



**Remove BodyGuardian Heart as soon as your physician or qualified health care professional ends your service.** Any data or information transmitted or received by Preventice after your physician or qualified health care professional has ended your service will not be processed, reviewed or analyzed by Preventice, and Preventice shall have no liability for any such information or data.

### Air travel



The monitor cannot be worn while traveling on an aircraft. This monitor does not operate outside the United States. Contact **Patient Services** if you plan to travel outside the United States.

### **Resources and assistance**



If you are receiving the monitor at home and require assistance, call Preventice Services at: **888.500.3522** For the manufacturer's Instructions for Use, visit: **www.preventicesolutions.com/docs/BGH-IFU.pdf** 



Instructional videos with subtitles and online help are available on BodyGuardian Heart smartphone to help you use your monitor. From the Home screen, tap Help and Settings → Videos. For additional resources, visit: www.preventicesolutions.com/patients/body-guardian-heart

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

# Equipment

Ensure that the following equipment is included in the box.



**Note** Your equipment may vary from the components pictured. Preventice reserves the right to modify, change, or discontinue products or accessories at any time.



# Charge the smartphone

Plug the charger into the smartphone and a wall outlet. The smartphone is fully charged when the battery indicator on the screen is solid green.

Charging the smartphone can take up to 4 hours.



### Charge one of the monitors

With one monitor firmly snapped into the charging cradle, plug the charging cradle into a wall outlet. All monitor lights will go out when the monitor is fully charged.



# Prepare your skin

- If hair is present, remove the hair where you will 1. place the monitor (see **p.9** for chest locations).
- 2. Thoroughly clean the area with soap and water. Dry the area completely.
- 3. Do not apply lotions, oils, or perfumes.



# Snap the charged monitor to the Base for the first time

- 1. Line up the snaps on the monitor and the Base. The snaps aren't evenly spaced. To make sure the snaps are lined up, the orientation of the logo on both the monitor and the Base must be the same.
- 2. Snap the monitor to the Base. Press firmly to securely connect all four snaps one by one.
- 3. Snap the electrodes to the Base.
- 4. Firmly snap the second monitor into the plugged-in charging cradle so it is charged and ready when you switch monitors.
  - The amber battery light on the monitor will come on while it is charging.
  - All monitor lights will go out when the monitor is fully charged.

# **Warning**

Apply only to intact, clean skin. Do not apply over open wounds, lesions, infected, or inflamed areas.

If you have skin allergies or hypersensitivities to adhesives, consult your doctor to select the appropriate option. If you experience adhesive irritation, apply on unaffected skin or contact Preventice for alternative options.

To request additional or alternative supplies:

Phone: 888.500.3522 (press 1, 1, 3) Email: inventory@preventice.com

**Note** Wear one of the two monitors at a time. One monitor should be in the charging cradle while you wear the other on your chest.

# Attach BodyGuardian Heart to your chest

1. Peel away the backing, including the flap, from the electrodes.



2. Place on your chest in one of the locations shown at right. Make sure one of the two arrows on the Base is pointing up.



3. Ensure the Base is spread out evenly.





#### **Preferred chest placement**



#### Placement

Horizontally, or nearly horizontally, on the upper chest Two fingers below the clavicle

∠ Placement can be angled to avoid muscle and fatty tissue and to achieve tight adhesion to skin





# **Turn on smartphone**

- 1. Press and hold the power key.
- 2. Wait 60 seconds for the phone to establish a network connection.



# Turn on monitor

- 1. Press and release the center button on the monitor. Do not hold the button down. The green center light on the monitor will remain lit or blinking once it has powered on.
- 2. Once the monitor is powered on, it will automatically connect to the smartphone.
- Stay within 3 feet of the phone, remain still, and watch the phone for electrode contact errors. If you receive a *Poor Contact* message, see p.16.



# Congratulations

Once you see the Monitoring Status on the smartphone change to *Monitoring*, you have successfully set up your monitor.

# DAILY USAGE



# Keep the smartphone within 10 feet of the monitor at all times

Keep the smartphone with you. However, if (1) you get separated from the smartphone, (2) the smartphone battery depletes or (3) you go out of cellular network range, the monitor will continue to collect data and automatically send it when the smartphone is back in range.



# Charge the smartphone nightly

Ensure the smartphone is within 10 feet of the location where you sleep. Leave the smartphone turned on and plug it into the smartphone charger and into a wall power outlet.

The smartphone is fully charged when the battery indicator on the screen is completely solid green.

**Note:** If you don't want to be disturbed by alerts while sleeping or while at an event, tap **Do Not Disturb** on the smartphone.

**Tip** The smartphone supports multiple languages. Tap **Help and Settings**  $\rightarrow$  **Settings**  $\rightarrow$  **Change Language**.

# **Switching monitors**

Wear one of the monitors on your chest while the other remains in the charging cradle. Switch the monitor on your chest:

First thing in the morning At night before you go to sleep At any time if the battery is low



### Removing the monitor from the Base

Tip: You can switch monitors without removing the Base and electrodes from your chest.

#### To remove the monitor on your chest from the Base:

- Hold the Base and electrode against your skin, then unsnap the monitor from the Base. To make it easier to reattach the fully-charged monitor, leave the Base snapped to the electrodes on your chest
- 2. Snap the monitor into the plugged-in charging cradle.
  - ▲ Do not power off the monitor. It will automatically power off when it is done transferring data.



### Switching monitors (continued)





2





# Attaching the charged monitor to the Base

#### To attach the fully-charged monitor to the Base:

- 1. Slip a finger or thumb behind the Base on your chest, between the electrodes.
- 2. With your finger or thumb behind the Base, align and snap the monitor to the Base one snap at a time.
- 3. Power on the monitor by pressing and releasing the center button.
  - ▲ Do not hold the button down. The phone will automatically detect the new monitor.
- Stay within 3 feet of the smartphone, remain still, and watch the smartphone for contact errors. If you receive a *Poor Contact* message, see p.16 of this manual.

# DAILY USAGE





# **Recording your symptoms**

If you begin to feel symptoms related to the reason your monitor was prescribed such as **dizziness**, **chest pain** or **shortness of breath**, you can manually record these events.

- 1. Press and release the center button on the monitor.
- 2. Hold as still as possible for 60 seconds.
- 3. On the smartphone, select the symptoms you are feeling. You may select up to 3 symptoms.
- 4. Tap **Save**.

# DAILY USAGE

# When do I need to remove BodyGuardian Heart from my chest?

### Showering, bathing, swimming

**Remove**: monitor The monitor is **NOT** waterproof.



#### **Pausing and removing**

- 1. On the smartphone, tap **Pause**. Then tap **Yes**.
- 2. Remove **Base** from electrodes on chest.
- 3. When you are ready to reattach, dry off your skin and electrodes completely. Then snap the monitor back onto the Base on your chest.
- 4. On the smartphone, tap **OK** to resume monitoring.

### Airline travel, MRI

Remove: monitor, Base, electrodes



#### **Pausing and removing**

- 1. On the smartphone, tap **Pause**. Then tap **Yes**.
- 2. Remove Base, monitor, electrodes from chest.
- 3. When you are ready to reattach BodyGuardian Heart, snap new electrodes to the Base and place on your chest.
- 4. On the smartphone, tap **OK** to resume monitoring.

Important: Only use the Pause button when you shower, bathe, swim, travel on an airplane, or undergo an MRI.



### **Replacing the electrodes**

Change the electrodes when they no longer adhere to the skin. Electrodes are disposable.

- 1. Remove the monitor and Base from your chest.
- Slowly peel back and roll the adhesive on the back of the electrode away from your chest.
  Tip: Dampen with water to ease removal from your skin or remove while in the shower.

Do not rip or tear off the electrodes quickly. Improper removal may cause skin irritation.



# Poor Contact message appears on the smartphone

#### CAUSE

This message indicates poor contact between your skin, the monitor and electrodes. It is NOT related to the Bluetooth or cellular connection of the smartphone.

#### RESOLUTIONS

] Tap OK

Tap **OK** on the smartphone to dismiss the message.

# Check the monitor snaps

Ensure all snaps are securely fastened between the monitor and the Base.

# Check the chest application

#### a. Skin preparation

Ensure that the skin on the placement location on your chest has been prepared appropriately:

- Remove hair, excess oils, lotions, perfumes, etc. The placement location should be clean and dry.
- Wash the placement location with soap and water. Use alcohol if soap and water are not available.







#### b. Chest placement location

Ensure that BodyGuardian Heart is positioned properly on the chest. See **p.9** of this manual for chest placement locations. Ensure one of two arrows on the Base is pointing up.

**Tip** For the **horizontal position**, some patients acquire a better signal when BodyGuardian Heart is placed higher up on the chest, closer to the collarbone, to avoid fleshy tissue areas. BodyGuardian Heart receives a higher quality signal when placed over firmer areas.

#### c. Electrode-to-skin adhesion

Ensure that the electrodes are securely adhered to the skin without wrinkles or bubbles. When applying the electrodes, apply pressure to ensure good contact with the skin.

### Replace the electrodes

- 1. Ensure that the chest placement location is properly prepared. See *3a. Skin preparation*.
- 2. Snap new electrodes to the Base, remove the backing on the electrodes, then place on your chest.

If the message persists, contact Preventice: 888.500.3522 (press 1, 1, 4).





### The Pause button on the smartphone is disabled OR Monitoring Status on the smartphone is '*Searching*'

#### CAUSE

These conditions occur when the smartphone is not connected to one of your monitors. This problem is often caused when neither monitor is powered on. This occurs most often when switching monitors.

#### RESOLUTION

#### Check to see if the monitor is powered on.

- ➡ If no monitor lights are lit, the monitor is not powered on. To power on the monitor:
  - 1. Press and release the center button on the monitor. Do not hold the button down.
  - 2. Once the monitor powers on and the smartphone connects to the monitor, Monitoring Status will change to *Monitoring*.

**Note:** If there is data on the monitor, the smartphone will download that data before it moves to a status of *Monitoring*. This could take several minutes.







#### → If any monitor lights are lit, the monitor is powered on.

If the monitor is powered on, check to see if the smartphone is downloading data.

- 1. On the smartphone, tap Monitoring Status.
- 2. Tap the blue arrows to display both monitors.
- If the smartphone displays a monitoring status of *Downloading data* that means data is being downloaded from the monitor to the smartphone. Tap the white *Downloading data* entry. This will display orange radiating rings that indicate that downloading is active.

**Note**: If the smartphone does NOT display *Downloading data*, contact Preventice: **888.500.3522 (press 1, 1, 4)**.

Once the smartphone has finished downloading, the status on the smartphone will change to *Monitoring*. This could take several minutes.
 Note: The smartphone must be within 3 feet of the monitor on your chest to efficiently complete the downloading process.

If the issue persists, contact Preventice: **888.500.3522** (press 1, 1, 4).



## When switching monitors, the smartphone displays 'Downloading data' for an extended time

#### CAUSE

This occurs when there is a large amount of collected data on the monitor that is currently being downloaded to the smartphone.

#### RESOLUTION

#### Wait for the smartphone to finish downloading.

- 1. Keep the smartphone within 3 feet of the monitor you just placed on your chest to allow the downloading process to complete.
- 2. Once the smartphone has finished downloading, the status on the smartphone will change to *Monitoring*. This could take several minutes to several hours depending on the amount of data to be downloaded from the monitor.



# A number pad prompting for a passcode appears on the smartphone

#### CAUSE

The smartphone may display a security passcode screen from time to time.

#### RESOLUTION

**This screen can be dismissed.** Tap the white arrow in the upper-left corner of the screen.



# The smartphone touch screen dims or shuts off automatically

#### CAUSE

Even when the smartphone is collecting data, the smartphone turns off the touch screen to conserve battery when you do not use the phone for a specified period. This is normal. The smartphone is still performing its monitoring functions. It has simply turned off the touch screen display.

#### RESOLUTION

#### No action is necessary. If you would like to wake the smartphone screen:

1. Press the **Power/Lock key** on the right or top edge of the smartphone, depending upon your model.

# **RETURNING EQUIPMENT**



# **Returning your equipment**

Return the BodyGuardian Heart equipment to Preventice Services immediately after your service ends.

- 1. Turn off the smartphone by pressing and holding the power button.
- 2. Turn off the monitor by pressing and holding the center button for 15 seconds. Release the center button when all lights on the monitor are off.
- 3. Place the monitors, smartphone, charging cradle, unopened electrodes and all charging accessories into the padded packs provided, then into the box. See p.5 for the list of equipment.
- 4. Remove the adhesive strip from flap on the shipping box and seal securely. **The prepaid return label is already affixed to the bottom of the box.**
- 5. Drop package off at the shipping carrier listed on the prepaid return label.

For assistance, call Preventice at **888.500.3522**.

**Note:** If you have lost or damaged the equipment, Preventice will mail you an invoice for the cost of the item. We appreciate your feedback. Please return this survey inside the box once your study is completed. This survey can also be completed online at: **www.preventicesolutions.com/patients/patient-survey.html** 

Patient name	City		State	
Doctor's office / hospital	Contact me via: Dhone			
My hook-up took place at: Home Physican's office	Email			
BodyGuardian <sup>®</sup> HEART	Excellent	Average	Poor	Not applicable
Rate our service level	1	2	3	4
General satisfaction with Preventice Services				
Ability to get through on the phone				
Attention given to your comments				
Knowledge, professionalism and courtesy of representatives				
Explanations given to hook up your monitor				
Amount of time the representative spent with you				
Rate the contents of the materials	1	2	3	4
Printed instruction manual included in your box				
Educational videos on the Preventice website (www.preventicesolutions.com/patients.html)				

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# PATIENT SURVEY

BodyGuardian® HEART	Excellent	Average	Poor	Not applicable
Rate your experience using the monitor and its accessories	1	2	3	4
Setting up the monitor				
Wearing and changing the monitor daily				
Charging the battery				
Comfort of the Base				
Shipment of supplies for the length of your study				
Comments				

I hereby authorize Preventice Solutions, Inc. to use, reuse, publish or republish my name in light of any communication I made and photographic likeness in all forms and all media for advertising, marketing, and any other lawful purposes. I release and discharge Preventice Solutions, Inc. from any and all claims and demands that may arise out of or in connection with the use of photographs, name or likeness, including without limitation any and all claims for libel or violation of any right of publicity or privacy. I have read this release and fully understand its contents, and I reserve the right to revoke this release upon written request to: Preventice Solutions, Inc. 1717 N. Sam Houston Parkway West, Suite 100 Houston, Texas 77038