

# BodyGuardian® HEART

## **Instructions for Use**



This IFU document is available in other languages upon request.

Hereby, Preventice<sup>®</sup> declares that this remote monitoring device is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC. The declaration of conformity is available at:

3605 Hwy 52 N Rochester, MN 55901 USA

#### QUESTIONS AND CONCERNS

Proper use of this device requires training provided by your health care provider.

If you have questions or encounter problems while you are using the BodyGuardian<sup>®</sup> Heart Remote Monitoring System, contact your health care provider.



Use this space to write down the name and phone number of your health care provider.

Health care provider

Phone number

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# **BodyGuardian Heart kit**



BodyGuardian Heart Instructions for Use

# About BodyGuardian Heart

BodyGuardian<sup>®</sup> Heart Remote Monitoring System is a wearable, remote cardiac monitoring system prescribed by your health care provider. Wearing BodyGuardian Heart allows your doctor to measure your electrocardiography (ECG) data, as well as other physiological information, such as breathing rate, heart rate, and activity level.

BodyGuardian Heart includes the following components:

#### **BodyGuardian Heart monitors**

- 2 monitors
- 1 charging cradle
- 1 charging cradle power cord with adapter

#### BodyGuardian Connect smartphone

- 1 cellular smartphone
- 1 charger

#### Strips or Base and standard ECG electrodes

(supplied by your health care provider)



BodyGuardian Heart does not summon physicians or emergency assistance (911 US, 112 EU, 000 AU) and does not replace direct communication with your health care providers.

#### Warning



Use only the approved power cords supplied with the system when charging the monitors and smartphone. All BodyGuardian Heart components must comply with relevant IEC or ISO safety standards.

#### BodyGuardian Connect smartphone reference



BodyGuardian Connect is configured to work as a component of BodyGuardian Heart. It cannot be used to make phone calls, including calls to 911 (US), 112 (EU), 000 (AU), or perform other smartphone functions.



Figure 1. BodyGuardian Connect smartphone

## How BodyGuardian Heart works

The complete BodyGuardian Heart Remote Monitoring System, as shown in **Figure 2**, consists of components to monitor and collect your physiological data. That data is sent over the Internet and stored in secure databases, available to be accessed and reviewed by your health care professionals.



#### Figure 2. BodyGuardian Heart Remote Monitoring System

# **Getting started**

This chapter will help you set up and start wearing BodyGuardian Heart for the first time.

## Before you begin

Before you begin wearing BodyGuardian Heart:

- Allow time for BodyGuardian Heart and all accessories to reach operating temperature (10 to 45 C).
- Charge your devices, and, if necessary, shave the chest location where you will wear the monitor.
- Use the following instructions to guide you.

## Charge the smartphone

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



charging







## Charge one of the monitors

You must fully charge one of the two monitors before you begin wearing the device:

- 1. Plug the monitor charger into the charging cradle and a power outlet.
- 2. Snap one of the monitors into the cradle.
  - **Tip:** The snaps aren't evenly spaced. The three monitor lights should be adjacent to the power cord that is plugged into the charging cradle.



3. Allow the monitor to charge completely. All lights will go out when it is fully charged.



Charging a monitor just out of the kit can take approximately 2-3 hours.

## **Begin using BodyGuardian Heart**

You are now ready to begin using BodyGuardian Heart.

#### Do you have Strips or the Base?

Your health care provider has supplied you with either BodyGuardian Strips or a BodyGuardian Base (with standard ECG electrodes). Follow the instructions applicable to your equipment.

Strip

Base





#### Attach charged monitor to Strip

Be sure you are using a fully-charged monitor.

1. Line up the monitor and Strip, as shown in Figure 3.



Figure 3. Monitor on Strip

Tip: The snaps aren't evenly spaced. The orientation of the logo on both the monitor and the Strip must be the same.

2. Press firmly so all four snaps are connected.

This section is for BASE patients only

#### Attach charged monitor to Base

Be sure you are using a fully-charged monitor.

1. Line up the monitor and Base, as shown in Figure 4.



Tip: The snaps aren't evenly spaced. The orientation of the logo on both the monitor and the Base must be the same.

#### Figure 4. Monitor alignment on Base

2. Press firmly so all four snaps are connected.

3. Snap the electrodes to the Base.



#### Figure 5. Monitor on Base with electrodes

#### Prepare your skin

- If hair is present on the chest location identified by your health care provider, shave the area.
- Clean the area with soap and water or an alcohol wipe.
- Dry your skin completely.
- Do not apply anything to your skin, such as lotions, oils, sprays.



Do not apply BodyGuardian Heart over open wounds, lesions, infected or inflamed areas. Apply only to intact, clean skin. If you have known skin allergies or hypersensitivities to adhesives, consult your doctor.

## Attach BodyGuardian Heart to your chest

- 1. Peel away the adhesive backing on the Strip or Base electrodes.
- 2. Place the monitor on your chest in one of the placement options shown at right.
- 3. Whether you wear the monitor horizontally or vertically, one of the arrows should be pointing up (Figure 6).



#### Figure 6. Monitor orientation on chest

4. For Strip users, apply finger pressure over the gel pads on the Strip to achieve a tight, smooth connection with the skin. It may take a minute or so to form a good connection with the skin and contours of the chest.



### Preferred placement options (vertical)

✓ Offset slightly to your left side, closer to your heart.





✓ You can angle this placement up to 30° clockwise from true vertical to avoid muscle, fat, and bra.

Orientation



Do not exceed 30° clockwise from vertical

Angle

## Alternate placement options (horizontal)

✓ Two fingers below the collarbone.



✓ You can angle this placement up to 30° clockwise from true horizonal to avoid muscle, fat, and bra.



Do not exceed 30° counterclockwise from horizontal



## **Examples of incorrect placement**







Too low, too far to left side of chest

Too low

## Power on the monitor

- 1. Press and release the center button on the monitor. Do not hold the button down.
- 2. The green center light on the monitor will remain lit or blinking once it has powered on.
- 3. Firmly snap the second monitor into the plugged-in charging cradle to begin charging. The amber battery light will come on.

## Link monitor to the smartphone

 Press and hold the Power / Lock key to turn on the smartphone. The Power / Lock key is located in one of two locations, depending on the model of your phone.



- 2. Once you turn on the smartphone, you will be prompted to view a series of screens that assist you in getting the monitor set up and attached to your chest.
- 3. After you have completed the setup screens and tap **Finish**, the smartphone will automatically connect to the monitor on your chest. This may take up to 2 minutes.
  - Tip: Stay within 3 feet of the phone, remain still, and watch the smartphone for contact errors.

# Using the smartphone



The BodyGuardian Connect smartphone is specifically configured to work with BodyGuardian Heart. It cannot be used make phone calls, including calls to 911 (US), 112 (EU), and 000 (AU), or perform other functions outside of the BodyGuardian Heart.

## Keep the smartphone with you

It is best to keep the phone in the same room with you when wearing the monitor.

# If you are away from the smartphone or the smartphone battery drains:

The monitor will continue to collect your data and automatically send it to the smartphone when the smartphone is available again.

#### If the smartphone goes out of cellular network range: The monitor will continue to collect your data. Once the cellular network is available again, your smartphone will automatically send your cardiac data to your health care provider.

## Charge the smartphone nightly

Plug your smartphone into the charger near your bed each night before you go to sleep.

- 1. If you don't want to be disturbed by alerts while sleeping, tap **Do Not Disturb** on the smartphone.
- 2. Leave the smartphone on.
- 3. Plug the smartphone into the plugged-in smartphone charger in your bedroom.

Continue wearing the monitor while the smartphone charges.

## If the touch screen dims

Even when the smartphone is collecting data, the smartphone turns off the touch screen when you do not use the phone for a specified period. If you need to turn on the screen, press the **Power/Lock key** on the right edge of the smartphone.

## Smartphone display

The smartphone has a dedicated interface to help you monitor system status, record symptoms, and understand indicator light symbols.

#### Smartphone - home screen

The smartphone home screen (**Figure 7**) is displayed when you power on or wake your phone.



Figure 7. Smartphone - home screen

#### **Monitoring Status**

Tap to view monitor status and battery level, strength of skin contact with Strip or Base, as well as current heart rate, breathing rate, and activity level.

#### Pause

Tap to temporarily suspend the collection of data from the monitor. This can be used when you need to remove the monitor for a short time.

Example uses:

- When showering, bathing, or swimming
- While undergoing an MRI

#### **Do Not Disturb**

Tap to turn off sound and vibration alerts associated with the BodyGuardian Connect status monitors.

Example uses:

- Before you go to bed
- While attending church

#### My Tasks

Tap to access screens to record weight, blood pressure, and monitor chest placement.

#### **Help & Settings**

Tap to display information to help you use BodyGuardian Heart. This button does **NOT** call for medical help.

## BodyGuardian Connect - status screen

The BodyGuardian Connect status screen (Figure 8) displays:

- Monitor status and battery level
- Strength of skin contact with Strip or Base electrodes
- Current heart rate, breathing rate, and activity level



Figure 8. BodyGuardian Connect – status screen

The information on this screen refreshes automatically every 60 seconds.

#### Back

Tap to return to the previous screen.

#### Status bar

Displays the current status of the displayed monitor.

#### Monitor toggle

Tap to view your other monitor. Allows you to view the status of your other monitor while it is in the cradle downloading, for example.

#### **Contact strength**

Displays the strength of the ECG signal. A strong connection between the Strip or Base electrodes and your skin is necessary for the monitor to read your ECG information. To achieve strong contact:

- All four monitor snaps must securely fasten the monitor to the Strip or Base.
- For Base users, the standard ECG electrodes must be securely snapped to the Base.
- The Strip or Base electrodes must be securely attached to chest.

#### **Monitor Battery**

Displays the current battery level of the monitor.

#### Heart Rate

(optional feature, may not be activated) Displays your heart beats per minute.

#### **Breathing Rate**

(optional feature, may not be activated) Displays your number of breaths per minute.

#### Activity Level

(optional feature, may not be activated) Displays a relative characterization of your physical activity on a scale of 1-100.

## **Monitoring status**

The status bar displays the monitor status.



Possible statuses are:

#### Monitoring

BodyGuardian Heart is monitoring your cardiac information normally.

#### Searching

The phone is actively looking for a monitor. It is possible that both monitors are powered off or the monitor is out of range.

#### Connecting

The phone has found a monitor that is powered on and is establishing contact.

#### **Re-connecting**

The phone is re-establishing contact with the monitor.

#### **Checking contact**

BodyGuardian Connect is checking to see if contact is strong enough to begin a monitoring session.

#### Connected

BodyGuardian Connect has established contact with a monitor and will begin monitoring momentarily.

#### Downloading data

The phone is downloading your cardiac data from the monitor.

#### Not available

The monitor is not in use. BodyGuardian Heart is actively monitoring with another monitor.

# **Recording symptoms**





This chapter describes the symptoms function. This feature may not be activated for you by your health care provider.

If you experience any symptoms – such as trouble breathing, dizziness, or racing heartbeat – while wearing the monitor, it can be useful for your doctor to be able to identify when you experienced them. This allows your doctor to assess your cardiac information during the time you were feeling particular symptoms.

When symptoms occur, you will be prompted on your BodyGuardian Connect smartphone to select the symptoms you were feeling at that time.

There are two types of triggers that will prompt you to select and record your symptoms:

#### Manual

You click the center button on the monitor on your chest when you are feeling symptoms.

#### Automatic

The monitor automatically detects that you may be experiencing cardiac symptoms, even something mild.

## Manually

Your doctor may ask you to keep track of certain symptoms, such as dizziness or racing heartbeat. When you feel any of these symptoms:

- 1. Press and release the button in the center of the monitor.
- 2. BodyGuardian Heart will record and send your cardiac information to your care team. This helps them understand your symptoms and review your information.

BodyGuardian does not summon physicians or emergency assistance (911 US, 112 EU, 000 AU) and does not replace direct communication with your health care providers.

## Automatically

As BodyGuardian Heart monitors your cardiac information, it detects when you may be experiencing important cardiac events, even mild ones.

If this occurs, your BodyGuardian Connect smartphone will automatically prompt you to select the symptoms you are feeling at that time.

## Selecting your symptoms

When your BodyGuardian Connnect smartphone prompts you, either manually or automatically, select all of the symptoms you are feeling at the time (**Figure 10**).



Figure 10. Selecting symptoms

If you accidentally click the monitor button and are not feeling any symptoms, select:



# Switching monitors with Strips



#### Do you have Strips or the Base?

This chapter applies to patients with BodyGuardian Strips. If you are using the BodyGuardian Base, see **Chapter 6**.

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

- In the morning after you wake up
- At night before you go to bed
- During the day if the battery is low

## Removing a monitor from the Strip

You can switch monitors without removing the Strip from your body. You do not need to perform any tasks on the phone when switching monitors.

- 1. Use finger pressure to hold the Strip against your skin.
- 2. Gently lift a corner of the monitor. Continue lifting gently until all four snaps release.





3. Snap the used monitor into the plugged-in charging cradle.

Do not pause or power off the monitor. The monitor will automatically power off when it is done transferring data.

## Attaching a charged monitor to the Strip

Remain near the phone when switching monitors. You can attach the fully charged monitor while the other monitor is in the charging cradle and transferring data before it powers off.

- 1. Snap the fully-charged monitor to Strip.
- 2. Power on the monitor by pressing and releasing the center button. Do not hold the button down.



3. If prompted by the smartphone, select the location where you positioned the monitor on your chest.

## **Replacing the Strip**

Change the Strip every three days OR when it no longer adheres to the skin.

- 1. Remove the monitor from the Strip.
- 2. Remove the Strip while showering or use a warm, damp cloth to soften the edges of the Strip.
- 3. Slowly peel back and roll the adhesive away from your chest. Continually blot the chest and adhesive with a warm, damp cloth.
  - **Do not rip or tear off the Strip quickly.** Improper removal may cause skin irritation.





Note: Strips are disposable.

# Switching monitors with a Base

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#### Do you have Strips or the Base?

This chapter applies to patients with the BodyGuardian Base. If you are using BodyGuardian Strips, see **Chapter 5**.

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

- In the morning after you wake up
- At night before you go to bed
- During the day if the battery is low

## Removing a monitor from the Base

You can switch monitors without removing the electrodes from your body. You do not need to perform any tasks on the phone when switching monitors.

- 1. Hold the electrodes against your skin.
- 2. Unsnap the Base with monitor attached from the electrodes on your chest.





- 3. Unsnap the monitor from the Base, then snap the monitor into the plugged-in charging cradle.
  - **Do not pause or power off the monitor.** The monitor will automatically power off when it is done transferring data.

Note: Base is reusable for the duration of your study.

## Attaching a charged monitor to the Base

Remain near the phone when switching monitors. You can attach the fully charged monitor while the other monitor is in the charging cradle and transferring data before it powers off.

- 1. While off your body, snap the fully-charged monitor to the Base.
- 2. Snap the Base, with the fully-charged monitor attached, to the electrodes on your chest.
- 3. Power on the monitor by pressing and releasing the center button. Do not hold the button down.
- 4. If prompted by the smartphone, select the location where you positioned the monitor on your chest.

## **Replacing the electrodes**



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

- 1. Slowly peel back and roll the adhesive away from your chest.
- 2. 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.

3. Snap new electrodes to the Base.

# Daily usage

7

Wear your monitor as you go about your normal daily activities, as well as at night while you sleep. However, at times you need to remove the monitor from the Strip (or Base), or remove both the monitor and Strip (or Base and electrodes).

#### Remove only the monitor (or monitor and Base) when:

- Showering, bathing, or swimming
- Traveling on aircraft

# Remove both the monitor and Strip (or Base and electrodes) when:

• Undergoing an MRI

## Showering, bathing, or swimming

Remove the monitor from the Strip (or the monitor and Base) when you shower, bathe, or swim. The monitor and the smartphone are not waterproof, but the Strip (and Base and electrodes) are.

- 1. Remove the monitor from the Strip. For Base users, remove the Base and monitor from the electrodes.
- 2. Tap **Pause** on the phone.
- 3. When you are ready to put the monitor back on, dry off your skin and the Strip (or electrodes) completely.
- 4. Snap the monitor to the Strip. For Base users, snap the Base and monitor to the electrodes.
- 5. On the smartphone, tap **OK** to resume monitoring.
- 6. Verify that the status changes to Monitoring.

## **Traveling on aircraft**

Do not wear the monitor when traveling on aircraft.

Power off your monitor by snapping it into the plugged-in charging cradle. This will automatically power off the monitor, though not necessarily immediately. You can also manually power off the monitor.

To manually power off the monitor:

1. Press and hold down the center button for at least 15-20 seconds until the green light is no longer flashing.



You will know the monitor is off when no lights are flashing every 10 seconds.

## Undergoing an MRI

If you are undergoing an MRI, you must remove both the monitor and the Strip (or the monitor, Base, and electrodes).

- 1. On the phone, tap **Pause**.
- 2. Remove the monitor, then the Strip (or Base and electrodes).

## **Cleaning the monitor**

If you see visible dirt on the monitor:

- Use a sterile 70% isopropyl alcohol (IPA) pad and thoroughly wipe in a circular motion, for a minimum of 30 seconds, all outer surfaces of the monitor. Ensure excess alcohol does not run into or collect in seams or crevices.
- 2. Allow the monitor to air dry.
- 3. If visible soil remains, repeat steps 1-3 using a new, sterile IPA pad until the monitor is visibly clean.

## Storing the monitor and charging cradle

Store the monitor on the charging cradle when not in use or for long-term storage. During travel, store the charging cradle with the snap terminals facing down to prevent moisture or particulate from entering the terminals.

# BodyGuardian Heart monitor lights



The monitor lights indicate status of the monitor only. They do not indicate anything about your health.



# Indications for Use Intended Use



## Indications for Use (US / Canada)

The BodyGuardian System detects and monitors cardiac arrhythmias in ambulatory patients, when prescribed by a physician or other qualified healthcare professional. Not for use with patients requiring attended, in-hospital monitoring for life threatening arrhythmias.

The Preventice BodyGuardian Remote Monitoring System is intended for use with adult patients in clinical and nonclinical settings to collect and transmit health parameters to healthcare professionals for monitoring and evaluation. Health parameters are collected from a variety of commercially available, external plug in devices such as ECG sensors, weight scales, blood pressure meters and pulse oximeters.

The Preventice BodyGuardian Remote Monitoring System does not provide any diagnosis.

## Intended use (EU / AU)

The BodyGuardian Heart Remote Monitoring System detects and monitors biometric parameters in ambulatory patients, when prescribed by a physician or other qualified health care professional. BodyGuardian Heart continuously records, stores and periodically transmits the data for review, storage, or further processing.

# Warnings / Precautions

#### Warnings

 Patients with known skin allergies or hypersensitivities to adhesives or hydrogel may experience reactions. Patients should consult with their health care professional to select a BodyGuardian Strip or alternate electrode option that is most appropriate for their needs.

#### Precautions

- Apply the Strip or electrodes only to intact, clean skin. Do not apply over open wounds, lesions, infected or inflamed areas.
- Do not use lotions, oils or sprays on skin location where you will apply the Strip or electrodes.
- This device is for single patient use only.
- BodyGuardian Heart is not intended for infants weighing less than 10 kg.
- Do not dispose of the monitors. Return monitors to your health care provider.
- Do not use a monitor if the casing is broken or damaged.
- Do not disassemble the monitors. WARNING: Do not modify this equipment without authorization of the manufacturer.
- United States federal law restricts the device to sale by or on the order of a licensed practitioner or therapist.
- Exposure of the wireless communications features of the device, or its accessories, may be interfered with by other devices that operate on the same frequencies.
- Monitors are not defibrillation proof.
- Do not touch the connectors of the power supplies while wearing BodyGuardian Heart.

# Appendix A: Specifications & symbols

## **BodyGuardian Heart monitor specifications**

Expected Service Life	2 years	
Battery Capacity	350mAh minimum 380mAh typical	
Battery Charger Power Requirement	100-240 VAC, 50-60 Hz	
Battery Type	Rechargeable Li-ion	
Battery Voltage	3.7 VDC	
Operating Temperature	+10°C to +45°C	
Storage Temperature (Power Off)	-10°C to +30°C	
Operating Humidity	10% to 95%	
Storage Humidity	30% to 75% (excluding condensation)	
Operating / Storage Pressure	700-1060 hPa	
ECG <ul> <li>Sampling Rate</li> <li>Digital Resolution</li> <li>Input Dynamic range</li> <li>Input Offset Dynamic Range</li> </ul>	256Hz 12 bit ±10mV ±300mV	
Sampling Rates • ECG • Impedance • Accelerometer	256Hz 32Hz 10Hz	
Measurement Ranges <ul> <li>Heart Rate</li> <li>Impedance</li> <li>Respiration</li> <li>Activity</li> </ul>	25 to 240 bpm (±2 bpm) 0 to 120 Ohms 0 to 30 breaths/min (±1 breaths/min) ±2g range in x,y,z directions	
Data Storage • Capacity • Type	24-hour continuous Internal NAND Flash	
Weight	35g	
Communications Type	Bluetooth between monitor and phone	

## **BodyGuardian Heart monitor symbols**

	Refer to instruction manual.
<b>†</b>	Type BF applied part; denotes device is not in direct contact with cardiac muscle.
(((•)))	Wireless transmission symbol
LOT	Lot number
SN	Serial number
REF	Catalogue reference
IPX4	Water splashing against the enclosure from any direction shall have no harmful effect.
Rx only	US law restricts the device to sale by or on the order of a licensed practitioner or therapist.
X	Do not dispose of in trash.
	Class II equipment

# Appendix B: Electromagnetic environment

The BodyGuardian Heart monitor is suitable for use in the specified electromagnetic environment. The purchaser or user of the monitor should assure that it is used in an electromagnetic environment as described below:

#### **Emissions**

Emissions test	Compliance	Electromagnetic Environment
RF emissions CISPR 11	Group 1	The monitor uses RF energy only for its internal function. Therefore, the RF emission is very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The monitor is suitable for use in domestic establishments and in establishments directly connected to the low voltage power supply network which supplies buildings used for domestic purposes.

## Immunity

Immunity Test	IEC 60601- 1-2 Test level	Compliance level	Electromagnetic Environment
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 15 kV air	IEC 60601-1-2 Test level	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines > 3 m	IEC 60601-1-2 Test level	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV differential mode	IEC 60601-1-2 Test level	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$0\% U_{\tau}$ for 0.5 cycles 70% U <sub>{\tau</sub> for 25 cycles 0% U <sub>{\tau</sub> for 250 cycles	IEC 60601-1-2 Test level	Mains power quality should be that of a typical commercial or hospital environment. If the user of the monitor requires continued operation during power mains interruptions, it is recommended that the monitor be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	IEC 60601-1-2 Test level	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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