

BODYGUARDIAN™ MINI PLUS

Instructions for Use



FULLY WATERPROOF

Featuring a waterproof monitor safe for showering, bathing, and submerging in water as deep as 3 feet.

The assembler's declaration of conformity is available at:

2900 37th Street NW
Building 003
Rochester, MN 55901
USA

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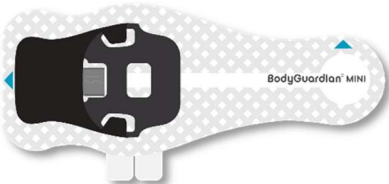
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Equipment included in kit *

BodyGuardian Mini monitor 	BodyGuardian Connect App (installed on included smartphone) CE ECG Plug-in App (installed on included smartphone) 	charging cord  (equipment may differ from pictured)
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OPTIONAL EQUIPMENT

Your kit will include either **Strips, a Bridge (with electrodes)**, or **ECG lead set (with electrodes)**. You will not receive all three. Follow the instructions for the equipment you receive.

BodyGuardian Mini Slide Strip  CE - and - saline wipes  (only included with Strips)	BodyGuardian Mini Bridge  CE - and - ECG electrodes **  CE	ECG lead set types  - or -  - and - ECG electrodes  CE
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* For more information on components of the system that are not included in the kit, see page 38.

** Compatible electrode types with the Bridge:

MANUFACTURER	MODEL / NAME
Covidien	Kendall 455 Standard ECG



Do not use your own personal device chargers. Only use the charger(s) provided to charge Boston Scientific Cardiac Diagnostics devices.

Indications for Use

The BodyGuardian™ Remote Monitoring System detects and monitors cardiac arrhythmias in ambulatory patients, when prescribed by a physician or other qualified healthcare professional.

The BodyGuardian Remote Monitoring System is intended for use with adult and pediatric patients who are at least 29 days old in clinical and non-clinical settings to collect and transmit electrocardiogram (ECG) and other health parameters to healthcare professionals for monitoring and evaluation. Health parameters, such as heart rate and ECG data, are collected from external devices such as ECG sensors.

The BodyGuardian Remote Monitoring System does not provide any diagnosis.

Contraindications

The BodyGuardian Remote Monitoring System is contraindicated for those patients requiring attended, in-hospital monitoring for life threatening arrhythmias. Not for use for detection or notification of hemodynamically unstable or life-threatening arrhythmias or cardiac events requiring urgent medical response.

System overview

The BodyGuardian™ Remote Monitoring System is intended to be used as patient biometric monitoring systems. The BodyGuardian Remote Monitoring System consists of an ECG monitor, various software devices and accessories that can be used to observe a wide variety of patient conditions (e.g., non-lethal cardiac arrhythmias, sinus bradycardia and sinus tachycardia) as prescribed by the healthcare provider.

- The BodyGuardian Remote Monitoring System does not summon physicians nor emergency assistance and does not replace direct communication with your health care provider. **If you are experiencing a medical emergency, dial emergency assistance (911 US).**
- If you have questions or encounter problems while you are using the BodyGuardian Remote Monitoring System, contact your health care provider.
- For indications and contraindications, see **page 2**. For warnings, see **page 29**.

The BodyGuardian Remote Monitoring System consists of the following components:

System Component	Description
Monitor	BodyGuardian Mini Monitor
Monitor Accessories	BodyGuardian Mini Slide Strip
	BodyGuardian Mini Bridge
	ECG lead set
	ECG electrodes
Mobile Applications	BodyGuardian Connect and ECG Plug-in
Server and Website	PatientCare Platform

BodyGuardian Mini Monitor

The BodyGuardian Mini is intended for use in clinical long-term ambulatory ECG monitoring, data transfer and analysis. BodyGuardian Mini is indicated for adult and pediatric patients who require ECG monitoring inside or outside hospital or healthcare facility environments.

BodyGuardian Mini Slide Strip

The BodyGuardian Mini Slide Strip is intended to transfer patient physiological data to the connected ECG monitor. The Mini Slide Strip includes saline wipes. The Mini Slide Strip is optionally included in the kit.

BodyGuardian Mini Bridge

The BodyGuardian Bridge is intended to serve as an interface to transmit physiological signals from body-adhering standard electrodes to the ECG monitor. The Bridge is optionally included in the kit.

ECG lead set

The ECG lead set is intended to serve as an interface to transmit physiological signals from body-adhering standard electrodes to the ECG monitor. The ECG lead set is optionally included in the kit.

BodyGuardian Connect and ECG Plug-in

BodyGuardian Connect is a smartphone application software that serves as the gateway between PatientCare software and the Plug-in software. BodyGuardian Connect provides information to the patient about the status of data transfer to the PatientCare software.

The ECG Plug-In is installed with BodyGuardian Connect on the off-the-shelf smartphone and remains architecturally separate from the BodyGuardian Connect App. The ECG Plug-In communicates directly with connected ECG monitors to configure monitor settings and ECG data transmission. The ECG Plug-In includes a protocol handler that communicates with the PatientCare Platform, and when appropriate, adjusts patient specific monitoring parameters, such as ECG thresholds, to aid healthcare professionals in patient monitoring and diagnostic support.

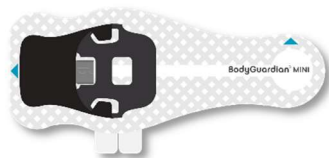
PatientCare Platform

The PatientCare Platform is intended for use by qualified healthcare professionals for the monitoring assessment of the indicated patient populations for biometric measures including arrhythmias using ECG data. The product supports downloading and analyzing data recorded in compatible formats from any device used for the arrhythmia diagnostics such as Holter, cardiac event monitor, mobile cardiac telemetry in 1-3 channels, or other similar devices when assessment of the rhythm is necessary. The PatientCare Platform provides ECG signal processing and analysis, QRS and Ectopic Beat detection, interval measurement, heart rate measurement, and rhythm analysis. The PatientCare Platform is not for use in life supporting or sustaining systems. PatientCare Platform interpretation results are not intended to be the sole means of diagnosis. It is offered to physicians and clinicians on an advisory basis only in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information.

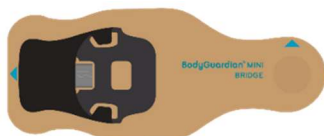
Did you receive Strips, a Bridge, or an ECG lead set?

Your kit will include either Strips, a Bridge (with electrodes), or an ECG lead set (with electrodes). You will not receive all three. Follow the instructions for the kit you receive.

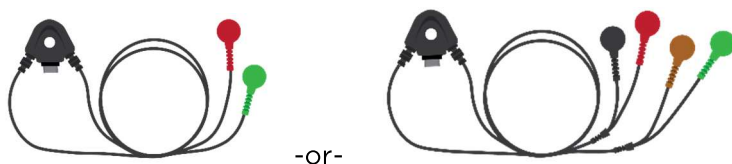
- If your kit came with Strips, see page 5.



- If your kit came with a Bridge, see page 11.



- If your kit came with an ECG lead set, see page 17.



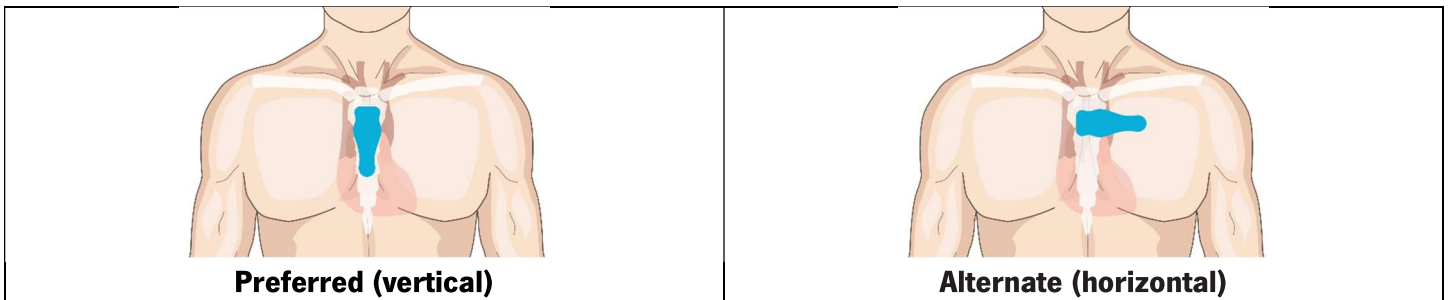
Getting started (using Strips)

If your kit came with Strips, use this section to attach your BodyGuardian Mini PLUS monitor to your chest and begin your monitoring prescription.

- If your kit came with a Bridge, see page 11.
- If your kit came with an ECG lead set, see page 17.

1 Prepare your skin

You can wear BodyGuardian Mini PLUS Strips either vertically or horizontally.

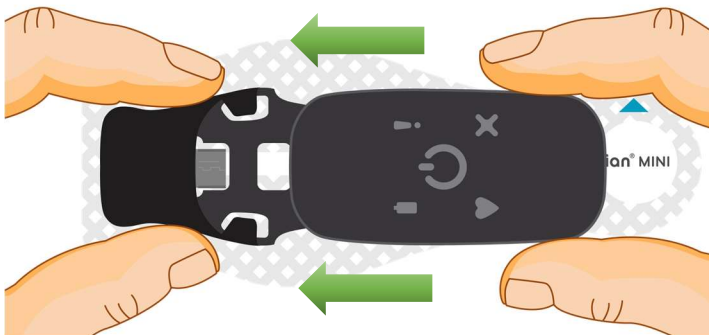


Decide which chest placement you will use before you prepare your skin.

- If hair is present, remove the hair where you will place the monitor.
- Use either the enclosed saline wipe or soap and water to clean the area. Dry the area completely.
- Do not apply lotions, oils, or perfumes. Do not use alcohol. Do not abrade the skin.

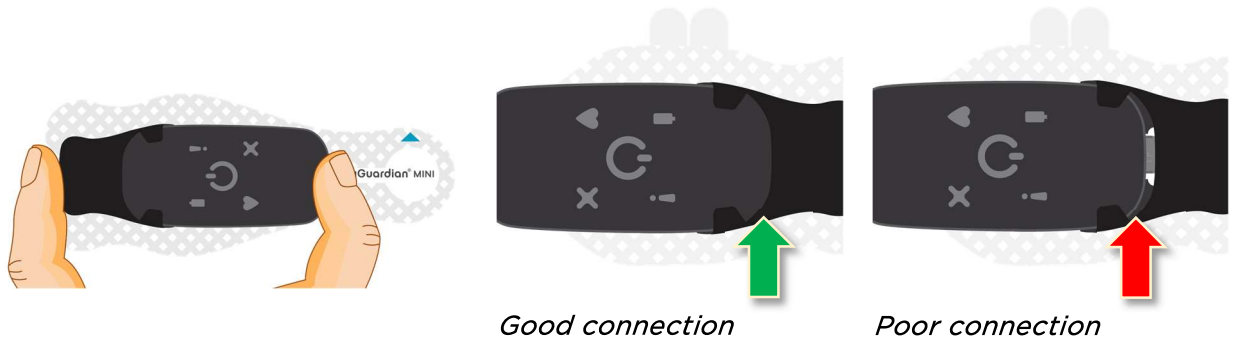
2 Attach the monitor to the Strip

1. Slide the monitor into the black molding on the Strip until the micro-USB connector on the Strip is inserted completely into the monitor.



Tips

- This is most easily accomplished on a flat surface, like a table.
- To line up the micro-USB connector with the port on the monitor, you may need to wiggle the monitor slightly to align.
- To ensure a good connection, pinch together with thumb and index finger:

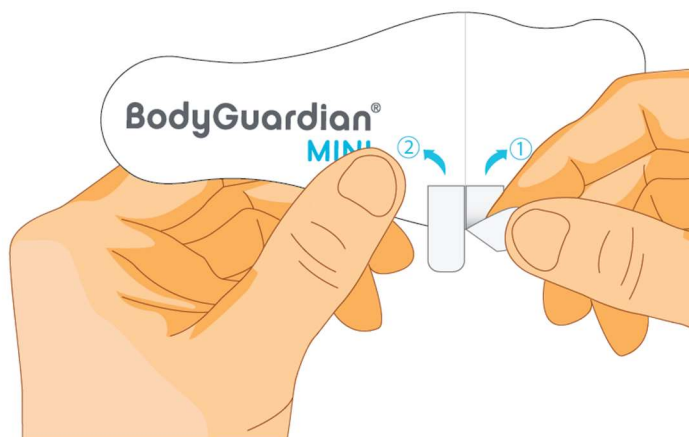


3 Attach to your chest

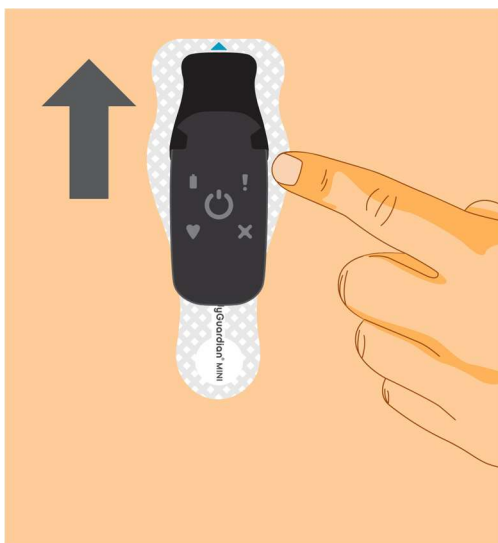


Apply only to intact, clean skin. Do not apply over open wounds, lesions, infected, or inflamed areas. If you have skin allergies, hypersensitivities, or experience skin irritation while wearing the monitor, consult your doctor to select the most appropriate option.

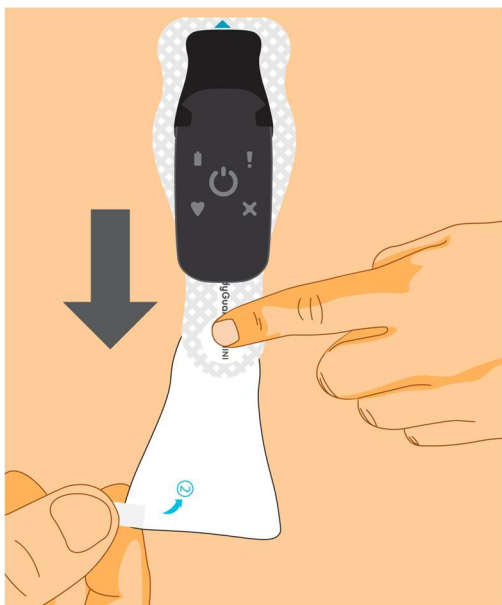
1. Peel away backing 1 from the Strip.



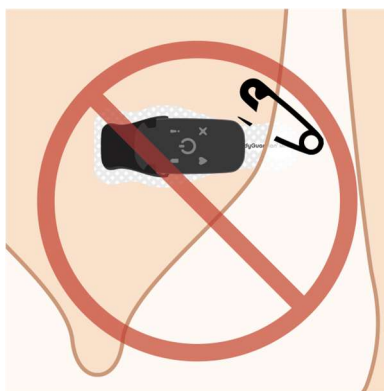
2. Place the portion of the Strip with the adhesive exposed flat on your chest in one of the placement locations (see pages 8-9).



3. Slowly peel away backing 2 from the Strip as you press the Strip flat on your chest. Press the entire surface of the Strip against the skin to ensure it adheres.



Do not wrinkle the Strip.



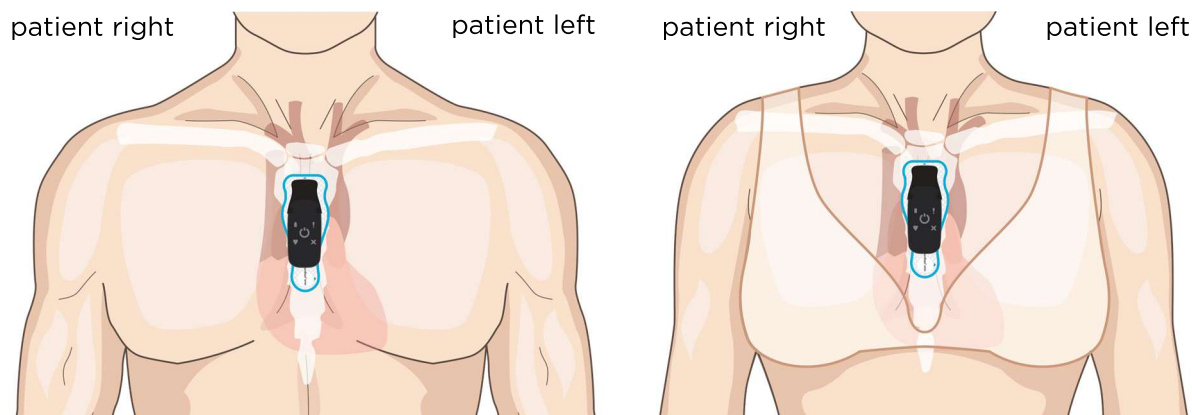
Do not tuck or pin Strip.

Preferred chest placement (vertical)

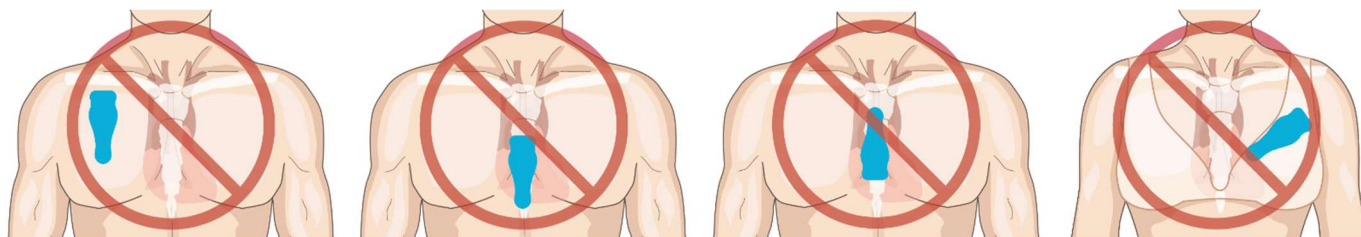


Once the Strip makes contact with your skin, you cannot adjust its position.

Place the top of the Strip just below the jugular notch, which is the bone at the base of the neck at the intersection of the collar bone.



Ensure the uppermost arrow on the Strip on your chest is pointing up.

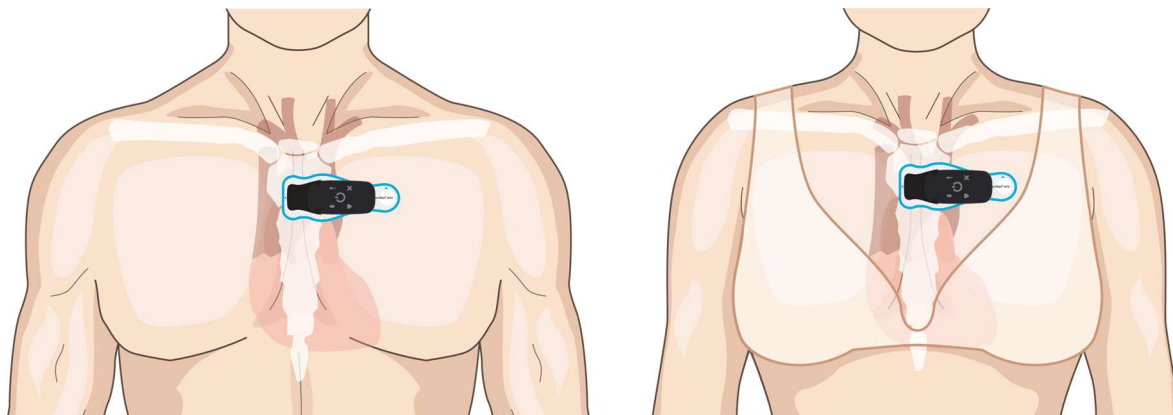


Alternate placement (horizontal)

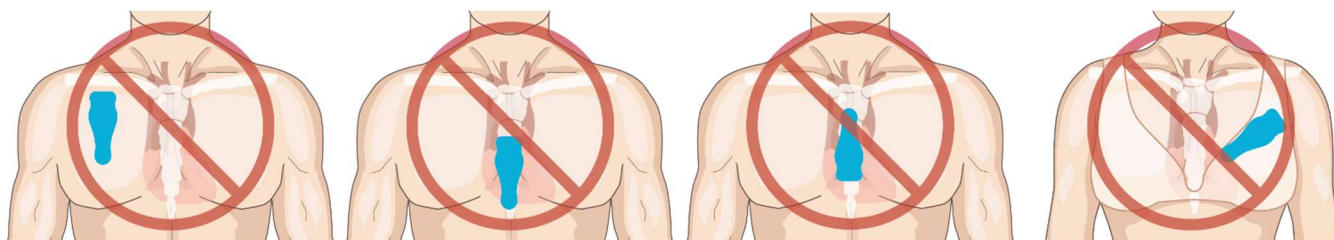


Once the Strip makes contact with your skin, you cannot adjust its position.

Place the right side of the Strip near the center of the chest over the sternum.



Ensure the arrow on the Strip over your left chest, near your left arm, is pointing up.



4 Turn on phone

Press and hold the **Power** key located on the right edge or the back of the phone, depending upon the model. Once powered on, the phone displays the **Action Required** screen.

5 Turn on monitor

Press and release the center button on the monitor once. As the monitor successfully powers on, it will beep periodically as it connects to the phone.



6 Success

Stay within 3 feet of the phone, remain still, and wait for the phone to display a status of **Monitoring**.

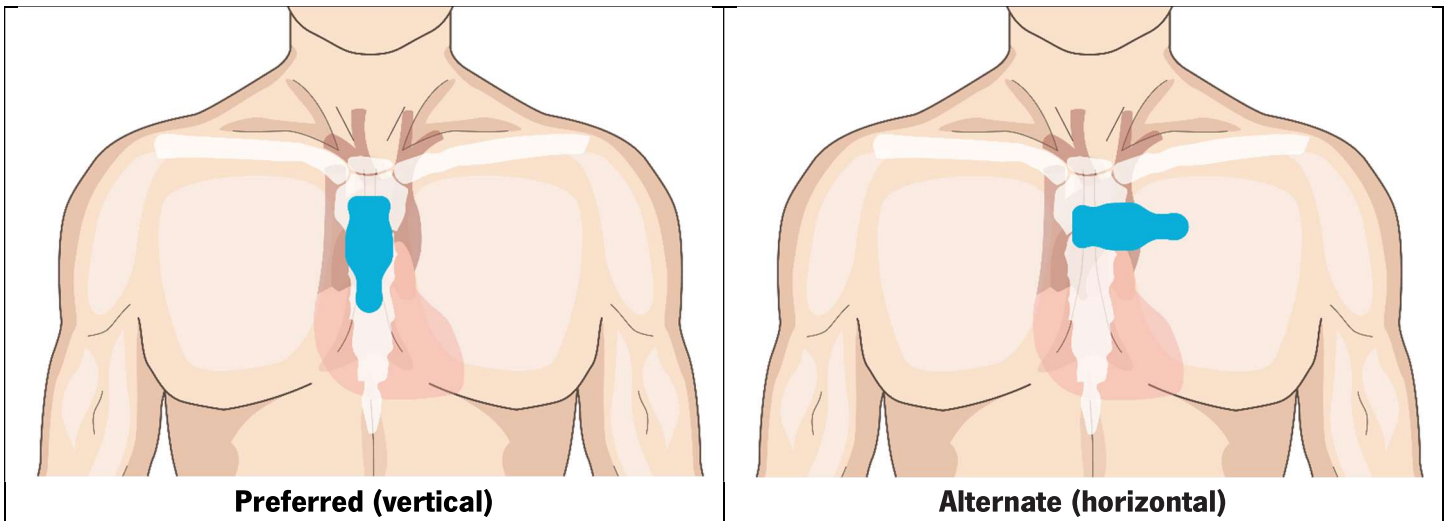
Getting started (using a Bridge)

If your kit came with a Bridge, use this section to get your BodyGuardian Mini PLUS monitor attached to your chest and begin your monitoring prescription.

- If your kit came with **Strips**, see [page 5](#).
- If your kit came with an ECG lead set, see [page 17](#).

1 Prepare your skin

You can wear **BodyGuardian Mini PLUS** Bridge either vertically or horizontally.

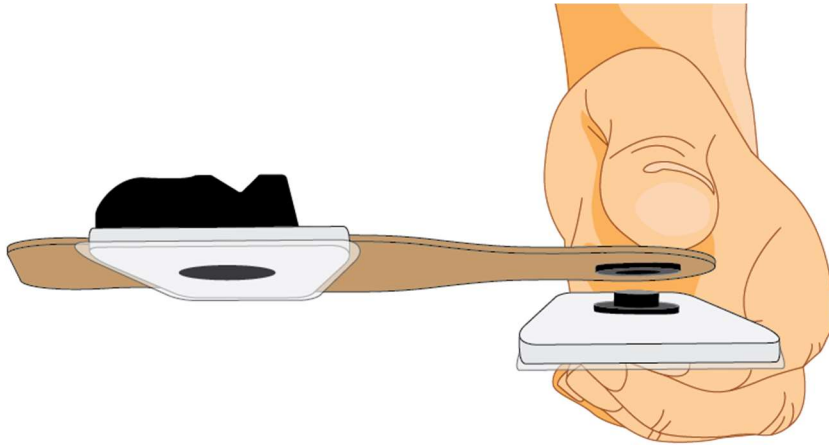


Decide which chest placement you will use before you prepare your skin.

- If hair is present, remove the hair where you will place the monitor.
- Use soap and water to clean the area. Dry the area completely.
- Do not apply lotions, oils, or perfumes. Do not use alcohol. Do not abrade the skin.

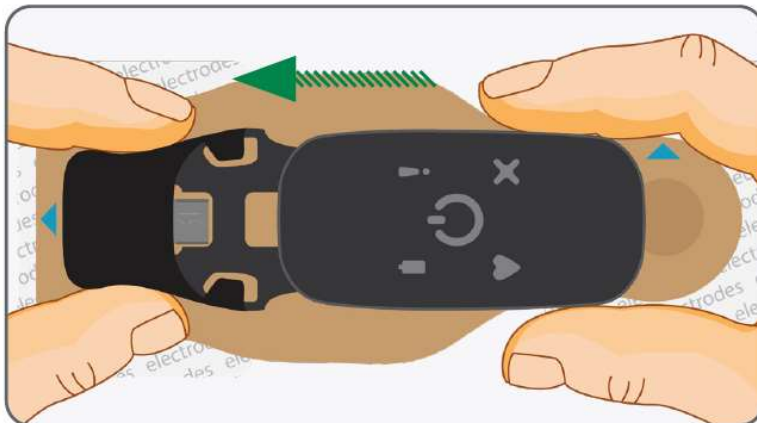
2 Snap the ECG electrodes to the Bridge

1. Press the ECG electrodes firmly onto the Bridge until you hear a snap.



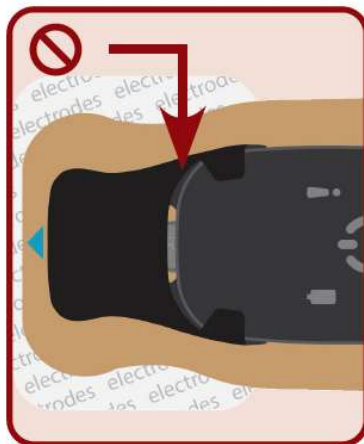
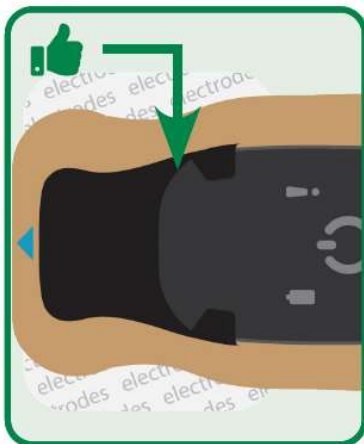
3 Attach the monitor to the Bridge

Slide the monitor into the black molding on the Bridge until the micro-USB connector is inserted completely into the monitor.



Tips

- This is most easily accomplished on a flat surface, like a table.
- To line up the micro-USB connector with the port on the monitor, you may need to wiggle the monitor slightly to align.
- To ensure a good connection, pinch together with thumb and index finger:



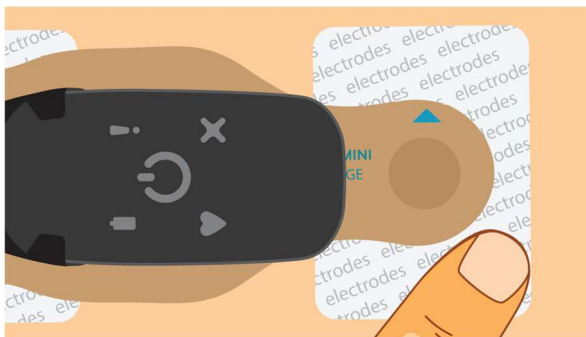
4 Attach to your chest

1. Peel away backing from the electrodes to expose the adhesive.
2. Place on chest in one of the placement locations (see **pages 14-15**).



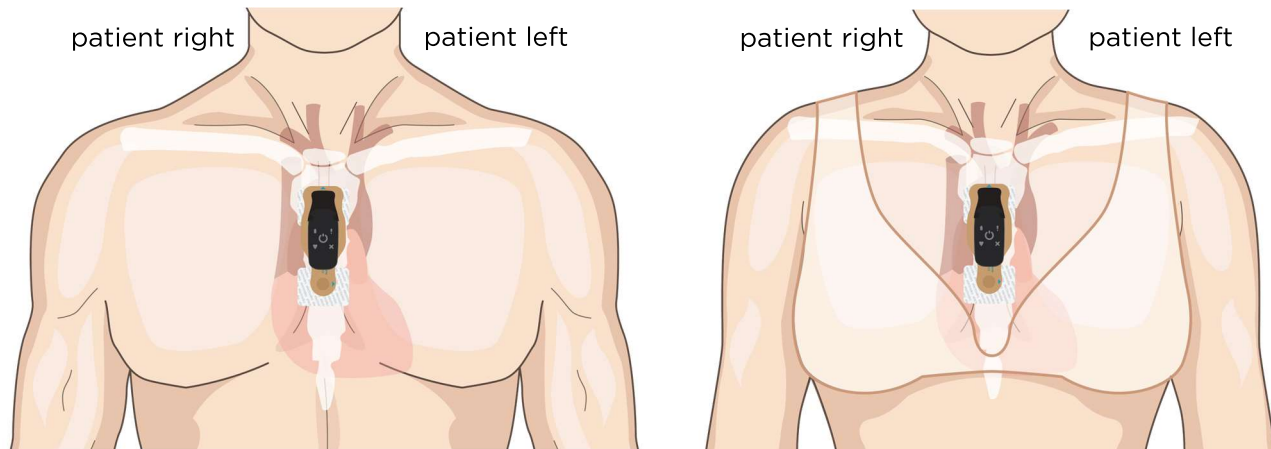
Apply only to intact, clean skin. Do not apply over open wounds, lesions, infected, or inflamed areas. If you have skin allergies, hypersensitivities, or experience skin irritation while wearing the monitor, consult your doctor to select the most appropriate option.

3. Press firmly around the surface of the electrode to ensure adhesion to the skin.

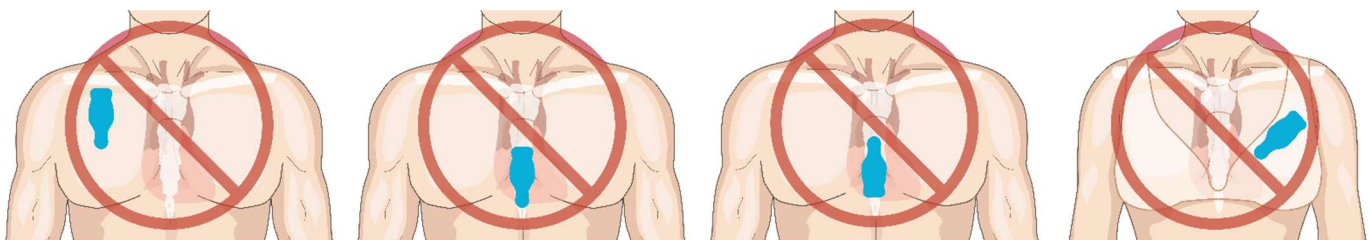


Preferred chest placement (vertical)

Place the top of the Bridge just below the jugular notch, which is the bone at the base of the neck at the intersection of the collar bone.

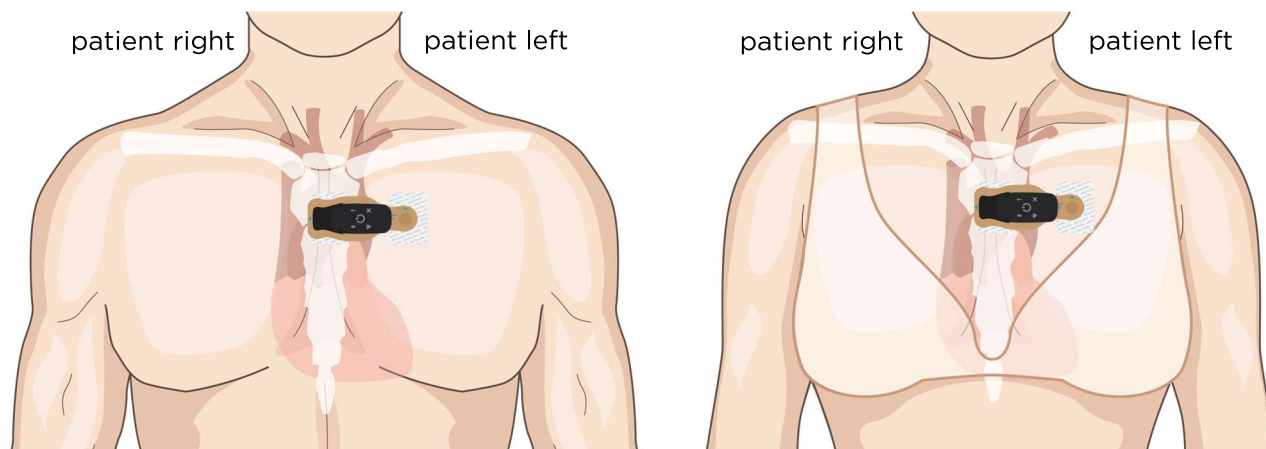


Ensure the uppermost arrow on the Bridge on your chest is pointing up.

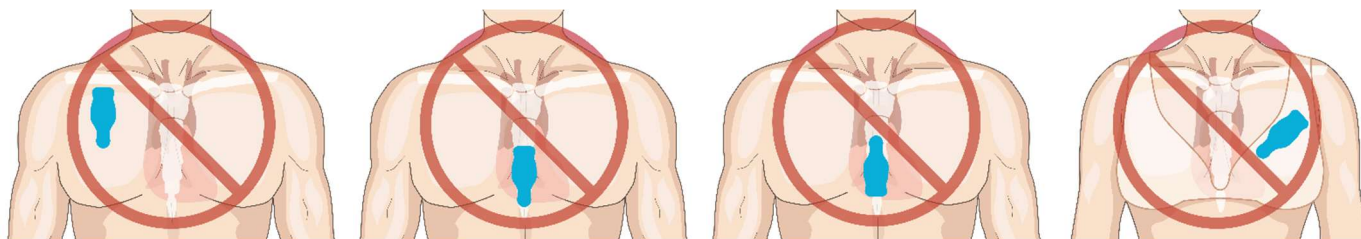


Alternate placement (horizontal)

Place the right side of the Bridge near the center of the chest over the sternum.



Ensure the arrow on the Bridge over your left chest, near your left arm, is pointing up.

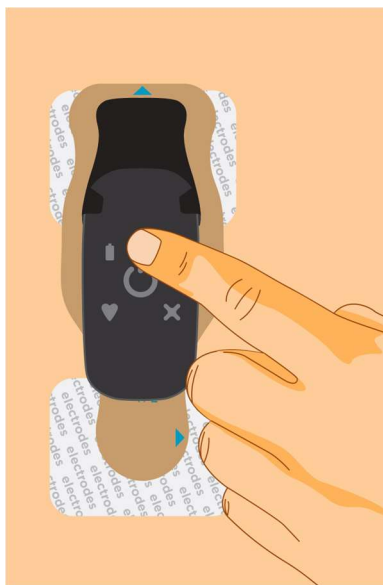


5 Turn on phone

Press and hold the **Power** key located on the right edge or the back of the phone, depending upon the model. Once powered on, the phone displays the **Action Required** screen.

6 Turn on monitor

Press and release the center button on the monitor once. As the monitor successfully powers on, it will beep periodically as it connects to the phone.



7 Success

Stay within 3 feet of the phone, remain still, and wait for the phone to display a status of **Monitoring**.

Getting started (using an ECG lead set)

If your kit came with an ECG lead set, use this section to get your BodyGuardian Mini PLUS monitor attached to your chest and begin your monitoring prescription.

- If your kit came with **Strips**, see [page 5](#).
- If your kit came with a **Bridge**, see [page 11](#).

1 Prepare your skin

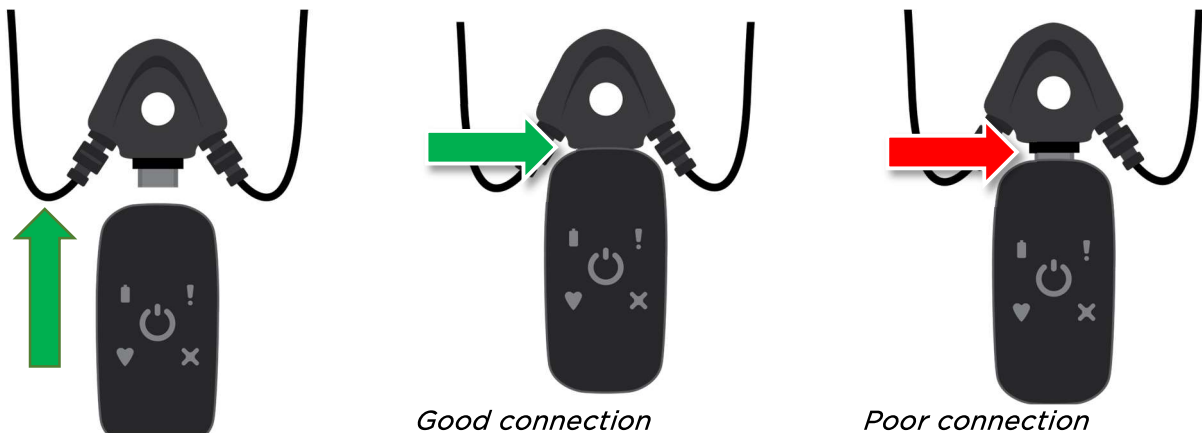
Familiarize yourself with the three chest locations where you will attach ECG electrodes.

See **Attach to your chest** on [page 18](#) for the chest locations where you will place the monitor and ECG electrodes.

- If hair is present, remove the hair where you will place the ECG electrodes.
- Use soap and water to clean the area. Dry the area completely.
- Do not apply lotions, oils, or perfumes. Do not use alcohol. Do not abrade the skin.

2 Attach the monitor and the ECG electrodes

1. Slide the monitor onto the center connector of the lead wires. Ensure the connector is inserted completely into the monitor.



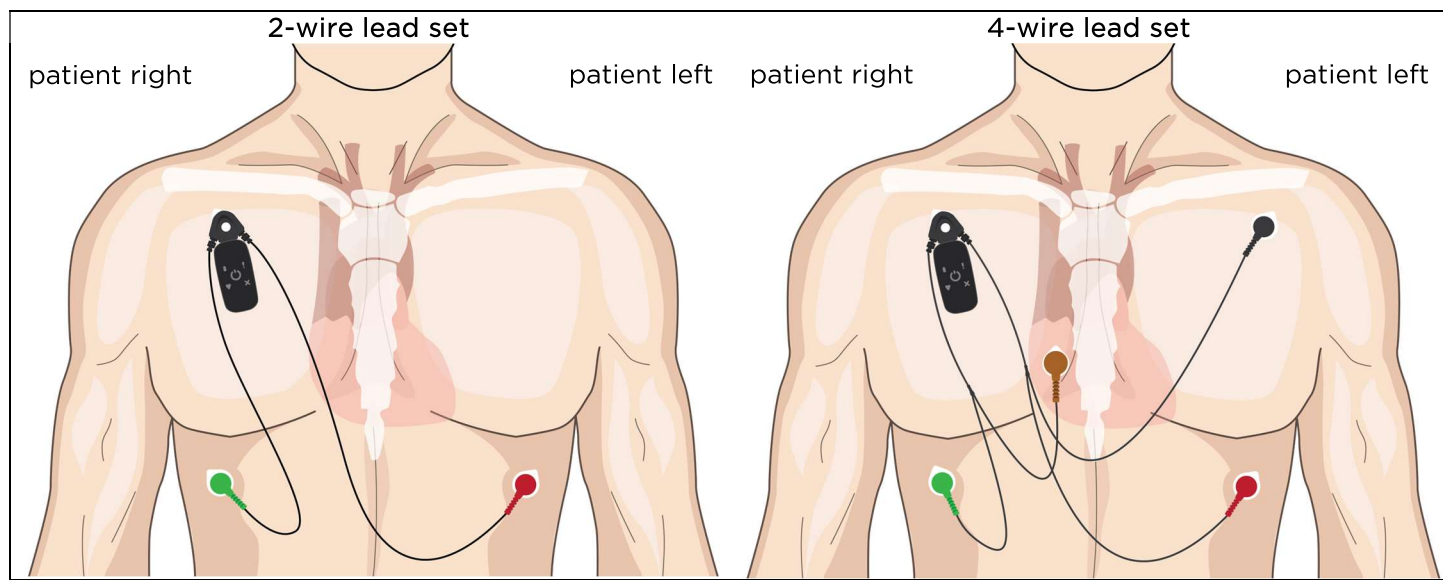
2. Snap an ECG electrode into each of the leads and one into the center monitor connector.

3 Attach to your chest



Apply only to intact, clean skin. Do not apply over open wounds, lesions, infected, or inflamed areas. If you have skin allergies, hypersensitivities, or experience skin irritation while wearing the monitor, consult your doctor to select the most appropriate option.

Remove the adhesive backing from each of the electrodes, then attach them to the following locations:

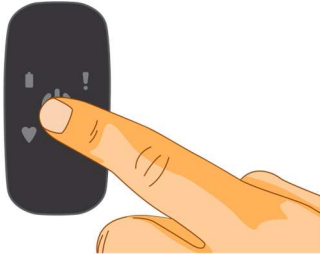


4 Turn on phone

Press and hold the **Power** key located on the right edge or the back of the phone, depending upon the model. Once powered on, the phone displays the **Action Required** screen.

5 Turn on monitor

Press and release the center button on the monitor once. As the monitor successfully powers on, it will beep periodically as it connects to the phone.



6 Success

Stay within 3 feet of the phone, remain still, and wait for the phone to display a status of **Monitoring**.

Using the smartphone



The BodyGuardian Connect smartphone is specifically configured to work with BodyGuardian Mini PLUS. It cannot be used make phone calls, including calls to 911 (US) or perform other functions outside of the BodyGuardian Mini PLUS.

Keep the phone with you at all times

Keep the phone within 10 feet of the monitor on your chest. However, if:

1. You get separated from the phone, or
2. The phone battery depletes

the monitor will continue to collect data and automatically send it to your health care provider when the phone is back in range of the monitor.

If the phone moves out of cellular network range

Your monitoring will continue uninterrupted, but your data won't be sent to your health care provider until you are back in cellular range.

Move to a location with a better cellular signal at your earliest convenience.

Charge the phone nightly

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

The phone displays its battery status as shown below:



Note

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

If the touch screen dims or shuts off

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

To wake the phone screen:

1. Press the Power/Lock key on the right edge of the phone.

Wi-Fi

You can connect the phone to an available Wi-Fi network. This can be particularly useful if you find yourself in an area of poor cellular coverage.

1. On the home screen, tap Wi-Fi.



Wi-Fi is an optional feature that may not be enabled by your health care provider.

2. Ensure the Wi-Fi button is toggled to ON.
3. From the list displayed, tap a network that you trust, then enter the password (if required).

Recording 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. Do not hold the button down.



After you press the center button, it can take up to 60 seconds for the symptoms prompt to appear on the phone.

2. Hold as still as possible for 60 seconds.
3. On the phone, select the symptoms you are feeling. You may select up to 3 symptoms.
4. Tap **Save**.

Tips

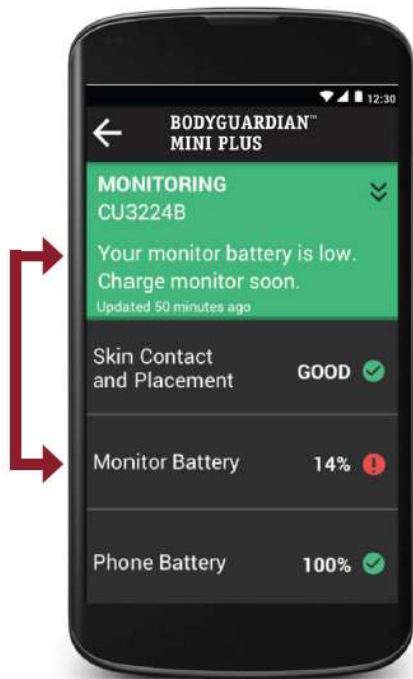
- You must scroll to see the full list of symptoms.
- If you accidentally click the monitor button and are not feeling any symptoms, select: **None or Accidental Push**.

Managing your monitors

Your BodyGuardian Mini PLUS kit comes with either one monitor or two monitors. Use this section to ensure you are always wearing a charged monitor on your chest.

Charging the monitor

When the monitor battery is low, the phone will alert you.



If your kit came with 2 monitors

If you have 2 monitors, switch monitors when the battery of the monitor on your chest is low. **You do not need to remove the Strip, Bridge, or lead set from your chest to switch monitors.** Always wear one of the monitors while the other monitor remains connected to the charger.

1. Detach the monitor from the Strip, Bridge, or lead set on your chest.



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

2. Firmly plug the charger into the monitor.



You must plug the charger into the monitor you just removed from your chest before you attach the other, fully-charged monitor onto your chest.

The monitor takes 1.5-2.5 hours to charge.

3. Attach the charged monitor to the Strip, Bridge or lead set on your chest.
4. Press and release the center button on the monitor to power it on.
 - Do not hold the button down.
 - Remain near the phone when attaching the fully-charged monitor.
 - The phone will automatically detect the new monitor.

If your kit came with 1 monitor

If you have 1 monitor, remove and charge the monitor when the battery is low. You do not need to remove the Strip, Bridge or lead set from your chest when charging the monitor.

If you are using Strips

1. Detach the monitor from the Strip.
2. Plug the charging cord into the monitor. Ensure the other end is plugged into a wall outlet. The monitor takes 1.5-2.5 hours to charge.
3. As soon as the monitor is fully charged, attach the charged monitor to the Strip on your chest.
4. Press and release the center button on the monitor to power it on.
 - Do not hold the button down.
 - Remain near the phone when attaching the fully-charged monitor.
 - The phone will automatically detect the new monitor.

If you are using a Bridge or ECG lead set:

1. Detach the monitor from Bridge or lead set.
2. Plug the charging cord into the monitor. Ensure the other end is plugged into a wall outlet. The monitor takes 1.5-2.5 hours to charge.
3. As soon as the monitor is fully charged, attach the charged monitor to the Bridge or ECG lead set on your chest.
4. Press and release the center button on the monitor to power it on.
 - Do not hold the button down.
 - Remain near the phone when attaching the fully-charged monitor.
 - The phone will automatically detect the new monitor.

Tips for charging the monitor

To charge the monitor, firmly plug the charging cord into the monitor. Ensure the other end is plugged into a wall outlet.



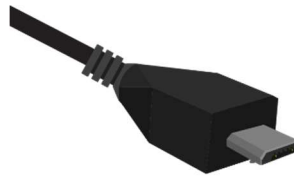
Do not use your own personal device chargers. Only use the charger(s) provided.



The BodyGuardian Mini battery cannot be replaced by the user.

Important

Ensure the micro-USB connector is oriented this way when inserting into the monitor.



front view



side view

Charging time



- While charging, the blue light on the monitor blinks.
- Once fully charged, the blue light on the monitor remains solidly lit.
- Charging time: 1.5-2.5 hours

Replacing the Strip

If your kit came with Strips, change the Strip on your chest when it no longer adheres to the skin. Strips are disposable in the trash. They are not biodegradable or compostable.



To protect signal quality, it's important to not expose the monitor's micro-USB connector directly to water.

1. Remove the monitor from the Strip, then charge the monitor.
2. Slowly peel back and roll the adhesive away from your chest, continually blotting with lukewarm soapy water.
Tip: For easiest removal, start by peeling back the edge of the Strip furthest from the black hub. It is suggested to remove the Strip while showering to limit the potential for skin irritation issues.
3. Use a *new* Strip to reattach BodyGuardian Mini PLUS to your chest.

Replacing the ECG electrodes (for Bridge or ECG lead set)

If your kit came with a Bridge or ECG lead set, change the ECG electrodes on your chest every 3 days OR when they no longer adhere to the skin. Electrodes are disposable in the trash. They are not biodegradable or compostable.

1. Remove the electrodes while showering or use a warm, damp cloth to blot while removing. Slowly peel back and roll the adhesive on the back of the electrodes away from your chest.
2. Remove the leads from the electrodes.
3. Remove the monitor from the center connector, then charge the monitor.
4. Use *new* ECG electrodes to reattach BodyGuardian Mini PLUS to your chest.

Water resistance

The accessories (Strips, Bridge, and ECG lead set) are waterproof and can safely be submerged in water as deep as 3 feet.

The monitor is waterproof when plugged into a body-worn accessory that **does not** leave the micro-USB port exposed. The micro-USB port should **not** be exposed to water.



The phone is NOT waterproof. Keep away from water.

- You do not need to remove BodyGuardian Mini PLUS when showering or bathing.
- If you will be swimming in water deeper than 3 feet, remove the monitor.
- If micro-USB connector on an unattached monitor is exposed to water, open air dry for at least 1 hour before reattaching to a Strip, Bridge, lead set or charger.

After showering, bathing or swimming while wearing BodyGuardian Mini PLUS with a Strip or Bridge:

- Pat the Strip or Bridge with a towel to dry it off.
- Press and hold the Strip or electrodes against your chest to ensure good contact with your skin.

Air travel

BodyGuardian Mini PLUS is safe to wear while traveling on aircraft. You do not need to remove the monitor. If you will be traveling on aircraft:

1. Power off phone after boarding.
2. Power on phone after landing.

MRI

BodyGuardian Mini PLUS cannot be worn while undergoing an MRI.

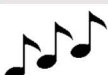
1. On the phone, tap **Pause Monitoring**.
2. Remove the monitor and the Bridge, Strip, or ECG lead set and electrodes.
3. After MRI, re-apply the monitor to your chest.
4. Tap **Resume** on the phone.

Monitor indicators

This section explains the sounds and LED lights on the monitor. The phone communicates this same information and is the best method for understanding the status of your monitoring session.

If you are curious about what the monitors sounds and lights mean, you can use this information as a reference.

Note: The monitor lights are faint. They can best be detected in a dark or dimly lit room.

Sounds		Lights		What it means	Caused by
	and		every 1 sec	Poor skin contact.	Monitor cannot detect good skin contact with skin to begin monitoring.
none			every 5 sec	Poor skin contact.	Monitor cannot detect good contact with skin during already established monitoring session. If this persists for 30 minutes or more, replace your Strip, Bridge or electrodes.
	and		every 5 sec	Poor skin contact.	Monitor has not detected good contact with skin for over 8 hours. Replace your Strip, Bridge or electrodes.
	and		every 5 sec	Monitor battery is low.	Low monitor battery. Charge the monitor.
none	and		every 5 sec	Monitoring successfully.	
none			every 5 sec	Monitoring successfully.	Monitor is communicating with phone over Bluetooth.
		none		Symptom marked.	Press-and-release button push.
	and			Monitor is powering on.	Press-and-release button push.
		   		Monitor is powering off.	Press-and-hold (9-12 sec) button push.
<i>After 9-12 seconds, all four monitor lights illuminate once, followed by a long beep.</i>					
none		    		Device clock error.	Unable to start recording. Contact Boston Scientific Cardiac Diagnostics: 507-218-3437.
<i>Indicators are briefly lit, one at a time, in a rotating pattern.</i>					
none		   		Monitor has halted at internal error handling checkpoint.	Unable to start recording. Contact Boston Scientific Cardiac Diagnostics: 507-218-3437.
<i>Indicators blink</i>					

Liability of healthcare professional

Not all cardiac conditions can be detected by an ECG and many potentially detectable conditions are not always present or may be transitory and not present in specific ECG. The symptoms, physical exam, patient/family history and additional information are critical to the healthcare professional's assessment of patient's cardiac health.

It is liability of the healthcare professional to ensure proper ECG recording, review and interpretation and ultimately make a diagnosis of the individual's cardiac health and/or risk of cardiac events.

Cybersecurity

Boston Scientific Cardiac Diagnostics (CDx) takes measures to ensure that your data is collected, stored, and sent to your health care provider in a secure manner.

- CDx uses secure, encrypted and authenticated connections.
- When the smartphone detects a security issue, monitoring may be discontinued.

CDx recommends patients use security measures when using the smartphone.

- Keep the smartphone with you or in a secure place.
- When using a Wi-Fi network, only connect to trusted networks with strong security that are protected with a password.
- Do not share the smartphone or attempt to install applications on the smartphone or use the smartphone for other purposes beside monitoring.
- Contact your clinic or CDx customer support if the smartphone is lost or stolen.

Warnings

- BodyGuardian Remote Monitoring System does not directly provide diagnosis. A supervising physician is responsible for ECG data interpretation.
- Do not attempt self-diagnosis or self-treatment based on acquired data.
- Do not use the BodyGuardian Remote Monitoring System monitor with high frequency (HF) surgical equipment or with an external defibrillator.
- Do not use the monitor in combination with an external cardiac defibrillator.
- If a patient has been given defibrillation with an external defibrillator while the monitor and applied part are connected to the patient, the monitor and applied part must be sent to manufacturer for checking before continuing device use.
- BodyGuardian Remote Monitoring System monitor cannot be worn while undergoing an MRI or a surgical procedure.
- Patients who have an active implantable medical device (e.g., heart pacemaker or other active implantable device), should consult supervising physician or doctor before use.
- To avoid danger of electrical shock and electromagnetic disturbances, the computer and associated equipment used with the monitor should comply with IEC/EN 62368 (Audio/video, information and communication technology equipment safety) or EN60601-1 (Medical electrical equipment safety) standard. If a computer that does not comply with the IEC/EN 60601-1 requirements is used in the patient environment, the computer and peripherals must be plugged in using an isolation transformer that fulfils the requirements.
- Do not touch parts of the computer, docking station or any non-medical electrical equipment and the patient at the same time when operating the monitor.
- The physician must determine if an artifact caused by radiated interference will have a negative impact on measured ECG signal quality and the subsequent diagnosis.
- Do not disassemble, try to repair, or modify the monitor.
- Prop 65: Warning for California residents. Cancer and reproductive harm. For more information go to: www.P65Warnings.ca.gov.
- BodyGuardian Remote Monitoring System is not intended for monitoring patients during cardiac rehabilitation outside of healthcare facilities.

General safety precautions

- Use ECG sampling rate of 500Hz with pediatric patients weighing less than 10 kg.
- Operating environments: Professional healthcare facility environment and home healthcare environment.
- The monitor IP Classification code is 67 when used with the Strip. When used underwater or showering with Bridge or lead set, the system is safe to wear on-body; however, data output will be temporarily affected. When the monitor is disconnected and exposed to water, the IPX rating is 0.
- EMC disturbances might cause interference and/or noise to data acquisition. To avoid negative effects on the BodyGuardian Mini electromagnetic compatibility, avoid using the monitor next to or stacked with other devices. Avoid using the monitor at a distance of at least 30 cm (12 inches) from portable RF communications equipment. Do not connect the monitor to other devices that are not intended to be connected to it.
- The strong environmental-based vibrations (for example driving on a bumpy road) can reflect on ECG monitor accelerometer data when the subject does not move. Accelerometer data is not differentiated for various physical activities.
- The monitor does not have any electrical stimulation capabilities.
- Do not use a monitor if the casing is broken or damaged.
- Do not dispose of the monitors. Return monitors to your health care provider.
- Use accessories approved by Boston Scientific Cardiac Diagnostics only with compatible devices.
- This device provides an output for ST segment deviation; however, ST segment deviation has not been validated for the intended purpose of ischemia diagnosis.

Notice to user and/or patient:

Any serious incident that has occurred in relation to this device should be reported to Boston Scientific Cardiac Diagnostics and the competent authority of the Member State in which the user and/or patient is established.

Appendix A: Symbols

Symbol	Description
	CE Marking indicating compliance with applicable EU regulations.
	Medical device.
	During transportation: keep package (and contents) away from sunlight.
	Atmospheric pressure limitation. Range: 700 hPa to 1060 hPa
	Federal Communications Commission. Indicates the electronic device, which sold in the United States, is certified and the electromagnetic interference from the device is under the limits that are approved by Federal Communications Commission.
	Serial number. Indicates the manufacturer's serial number so that the medical device can be identified.
	Prescription only. Indicates that the product is a medical device and Federal Law (United States) restricts the device for sale by or on the order of a physician.
	The Mini monitor is equipped with type BF applied parts fulfilling the EN 60601-1 (IEC60601-1) standard.
	The additional electrodes are disposable.
	Consult Instructions for Use.
	The Lot number of the electrodes.
	During transportation: keep package (and contents) dry, protected from rain.
NOTE!	Note text in manual: These statements identify conditions or practices that could result in equipment performance loss or must be otherwise observed.
IP67	IP classification for device. The monitor is waterproof while recording is made with lead set, the Bridge or the Strip fixed to device or with electrode fixed to device. The device is safe although the output is temporarily affected when using the Bridge or lead set during

	exposure to water, in which case the IP classification is temporarily IPX0 during water exposure.
	This equipment contains specified radio equipment that has been certified to the Technical Regulation Conformity Certification under the Radio Law. Bluetooth module BT121 is certified in Japan with certification number 209-J00171.
	Non-ionizing electromagnetic radiation.
	Humidity limitation. Range: 10% to 95%, non-condensing.
	Temperature limitation. Transport: -20 °C to +60 °C (-13 °F to 140 °F) Storage: +0 °C to +25 °C (32 °F to 77 °F) Continuous operating: +0 °C to +45 °C (32° F to 113° F)
REF	Indicates the catalogue number so that the medical device can be identified.
	Manufacturer
	Warning: MR-unsafe! Do not expose the device to a magnetic resonance (MR) environment.
	A data matrix (GS1) code is a two- dimensional barcode consisting of GTIN and PI for ECG sensor.

Appendix B: Technical specifications

Monitor Specifications	SL	EL
1- or 3-channel ECG	Yes	Yes
ECG sampling frequency	250 Hz	250 Hz
ADC precision	24 bits	24 bits
Input Impedance	>10.1Mohms +/- 0.1Mohm	>10.1Mohms +/- 0.1Mohm
Datalogger file format	EDF	EDF
Memory capacity	4 GB	4 GB
Power source	3.7v Li-ion battery	3.7v Li-ion battery
Dimensions	48 x 29 x 12 (mm) weight 18 g	59 x 30 x 13 (mm) weight 22 g
Battery operating time	Up to 8 days (Holter) Up to 3 days (MCT)	Up to 16 days (Holter) Up to 7 days (MCT)
Monitoring period	When using the rechargeable ECG monitor, monitoring period durations are as follows: • MCT/OCT up to 35 days • CEM up to 35 days • Holter up to 15 days	

USB Interface	
Version	USB 2.0
Data throughput	5 MiB/s
Connector interface	Micro-B receptacle

Pacemaker	
Detection performance	BodyGuardian Mini PLUS is capable of recording the activity of an implanted pacemaker according to 60601-2-47:2012 201.12.4.4.109. BodyGuardian Mini PLUS is capable of reporting dual chamber pacing (double pacing) with heart rate of 200 BPM and 150ms interval between the pacemaker pulses. Performance is verified with 2mV pacemaker signal having pulse widths 0.1 ms, 0.5 ms, 1ms and 2 ms.
ECG recording performance	BodyGuardian Mini PLUS is capable of recording ECG signal in the presence of implanted pacemaker pulses according to 60601-2-47:2012 201.12.4.4.109.

Strip/Bridge Specifications	Strip (acrylic)	Strip (long acrylic)	Strip (hydrocolloid)	Electrode (Bridge / lead set)
Dimensions	W: 43.9mm L: 121.6mm	W: 46.2mm L: 171.7mm	W: 46.2mm L: 121.6mm	W: 46.2mm L: 121.6mm
Average wear duration	5-7 days	5-7 days	5-7 days	2-3 days

Boston Scientific Cardiac Diagnostics reserves all rights to improve, change and modify the products and the contents of the Instructions for Use without prior notice.

Appendix C: Electromagnetic Emission

Manufacturer's Declaration - Electromagnetic Emissions		
BodyGuardian Mini PLUS is suitable for use in an electromagnetic environment as described below. The users should ensure that the device is used in such an environment.		
Emission Tests	Compliance	Electromagnetic Environment
RF emissions CISPR11	Group 1	The monitor uses RF energy exclusively for its internal function. Thus the RF emission is very low and it is unlikely that nearby electronic devices would be disturbed.
RF emissions CISPR11	Class B	

Appendix D: Immunity Test Levels

Phenomenon	Basic EMC standard or test method	Immunity Test Levels	
		Professional healthcare facility environment	Home healthcare environment
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See Appendix C	
RATED power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	
Conducted disturbances induced by RF fields	EC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Voltage dips	IEC 61000-4-11	Not applicable	
Voltage interruptions	IEC 61000-4-11	Not applicable	
Surges Line-to-line	IEC 61000-4-5	Not applicable	
Surges Line-to-ground	IEC 61000-4-5	Not applicable	
Electrical fast transients / bursts	IEC 61000-4-4	Not applicable	

Immunity test levels for Proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380 - 390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27
450	430 - 470	GMRS 460, FRS 460	FM $\pm$ 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9
745						
780						
810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0,3	28
870						
930						
1720	1 700 - 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3,4, 25; UMTS	Pulse modulation 217 Hz	2	0,3	28
1845						
1970						
2450	2 400 - 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0,3	28
5240	5 100 - 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9
5500						
5785						

Appendix E: FCC Compliance

The BodyGuardian Mini complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

Consult the dealer or an experienced radio/TV technician for help.



EMERGO EUROPE
Westervoortsedijk 60
6827 AT Arnhem, The Netherlands



MEDENVOY SWITZERLAND
Gotthardstrasse 28
6302 Zug, Switzerland

EMERGO CONSULTING (UK) LIMITED
c/o Cr360 -UL International
Compass House, Vision Park Histon
Cambridge CB24 9BZ United Kingdom



BODYGUARDIAN MINI MONITOR
Bittium Biosignals Ltd
Pioneerinkatu 6
70800 Kuopio Finland



PATIENTCARE PLATFORM
(not included in kit)
Boston Scientific Cardiac Diagnostic Technologies, Inc.
2900 37th Street NW
Building 003
Rochester, MN 55901 USA



ECG PLUG-IN APP
Boston Scientific Cardiac Diagnostic Technologies, Inc.
2900 37th Street NW
Building 003
Rochester, MN 55901 USA



BODYGUARDIAN CONNECT APP
Boston Scientific Cardiac Diagnostic Technologies, Inc.
2900 37th Street NW
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Rochester, MN 55901 USA



BODYGUARDIAN MINI SLIDE STRIP
(optionally included in kit)
Boston Scientific Cardiac Diagnostic Technologies, Inc.
2900 37th Street NW
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BODYGUARDIAN MINI BRIDGE
(optionally included in kit)
Boston Scientific Cardiac Diagnostic Technologies, Inc.
2900 37th Street NW
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**KIT ASSEMBLED &
DISTRIBUTED BY:**

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For manufacturer comments or concerns: 507-218-3437