

In the European Community:

BODYGUARDIAN™ MINI PLUS | BODYGUARDIAN™ MINI PLUS

Procedure Pack

Instructions for Use



FULLY WATERPROOF

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

The Procedure Pack assembler's declaration of conformity is available at:

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

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February 2026
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LA1026-A LL-60060-Q

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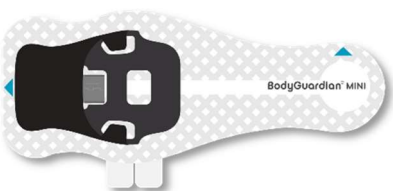
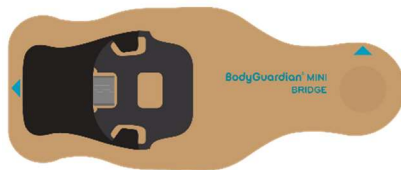
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Equipment included in Pack *

BodyGuardian Mini monitor  CE 0537	BodyGuardian Connect App (installed on included smartphone) ECG Plug-in App (installed on included smartphone) CE 2797 	charging cord  (equipment may differ from pictured)
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OPTIONAL EQUIPMENT

Your equipment 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 pack, see **page 38**.

** Registered as an accessory to the sensor under CE 0537.

*** Compatible electrode types with the Bridge:

<u>MANUFACTURER</u>	<u>MODEL / NAME</u>
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 / Intended Purpose

BodyGuardian Mini PLUS Procedure Pack

The BodyGuardian™ Remote Monitoring System is intended to be used as patient biometric monitoring systems. The BodyGuardian Mini PLUS procedure pack 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) and parameters (e.g., activity, weight, blood pressure, and oxygen level) as prescribed by the healthcare provider.

- BodyGuardian Mini PLUS (in the EU called BodyGuardian Mini PLUS Procedure Pack) 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, 112 EU).**
- If you have questions or encounter problems while you are using BodyGuardian Mini PLUS (in the EU called BodyGuardian Mini PLUS Procedure Pack), contact your health care provider.
- For a complete list of indications, contraindications, and warnings, see **pages 28-29**.

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 provides the detection and reporting features appropriate for the indications below:

- Evaluation of patients with symptoms related to rhythm disturbances or symptoms suggesting arrhythmias.
- Evaluation of patients for ST segment changes
- Evaluation of patients with a pacemaker
- Evaluation of patient rest and stress ECG
- Reporting of heart rate variability analysis
- Wireless transmission of patient ECG data and arrhythmia events for further analysis.

Interpretation algorithm provides a computer-generated analysis of potential patient cardiac abnormalities, which must be confirmed by a physician with other relevant clinical information. The BodyGuardian Mini does not provide interpretive statements. BodyGuardian Mini is contraindicated for:

- Those patients requiring attended, in-hospital monitoring for life threatening arrhythmias
- Pediatric patients weighing less than 10 kg

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.

BodyGuardian Connect App

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.

ECG Plug-in App

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.

BodyGuardian Mini Bridge

The 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 procedure pack.

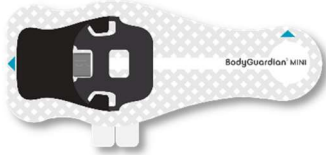
BodyGuardian Mini Slide Strip

The 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 procedure pack.

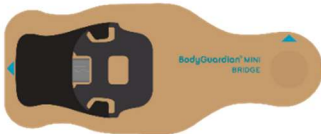
Did you receive Strips, a Bridge, or an ECG lead set?

Your equipment 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 equipment you receive.

- If your equipment came with **Strips**, see page 4.



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



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



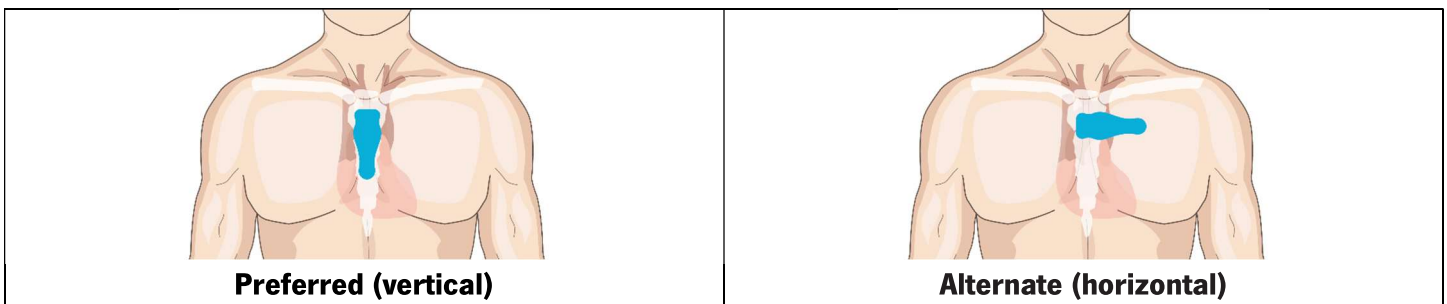
Getting started (using Strips)

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

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

1 Prepare your skin

You can wear BodyGuardian Mini PLUS either vertically or horizontally.



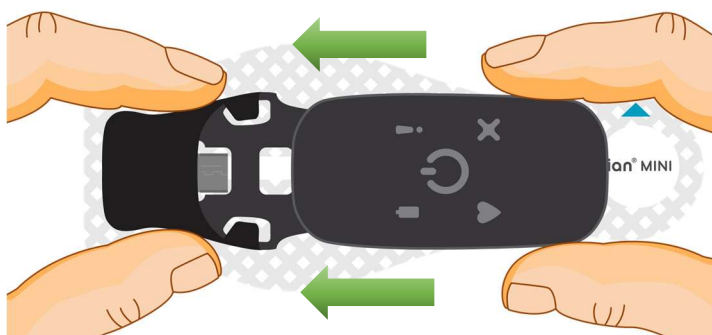


Decide which chest placement you will use before you prepare your skin.

- 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.

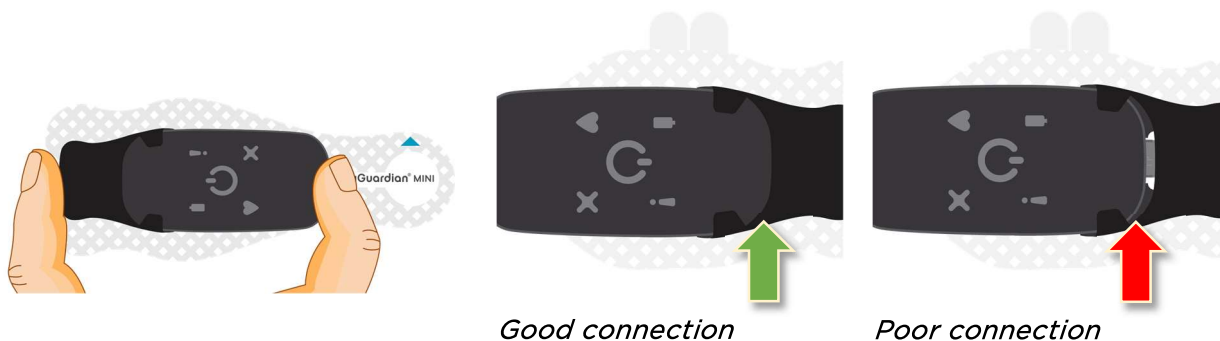
2 Attach the monitor to the Strip

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:

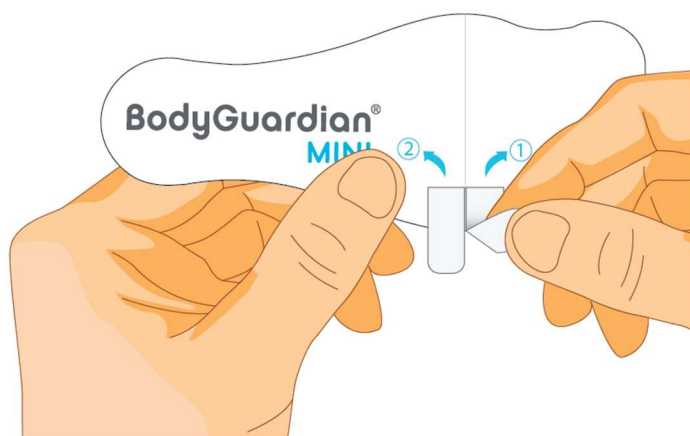


3 Attach to your chest

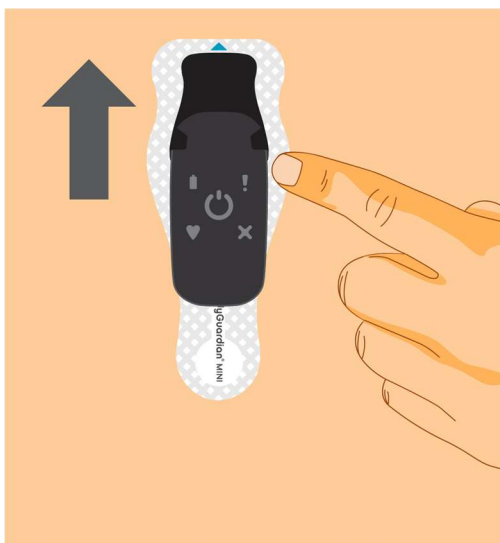


Apply only to intact, clean skin. Do not apply over open wounds, lesions, infected, or inflamed areas. If you have skin allergies or hypersensitivities, or experience skin irritation while wearing the monitor, consult your doctor to select the appropriate option.

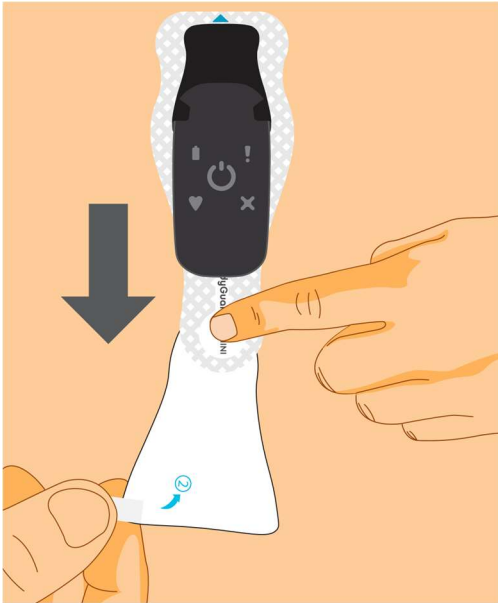
1. Peel away backing 1 from the Strip.



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.



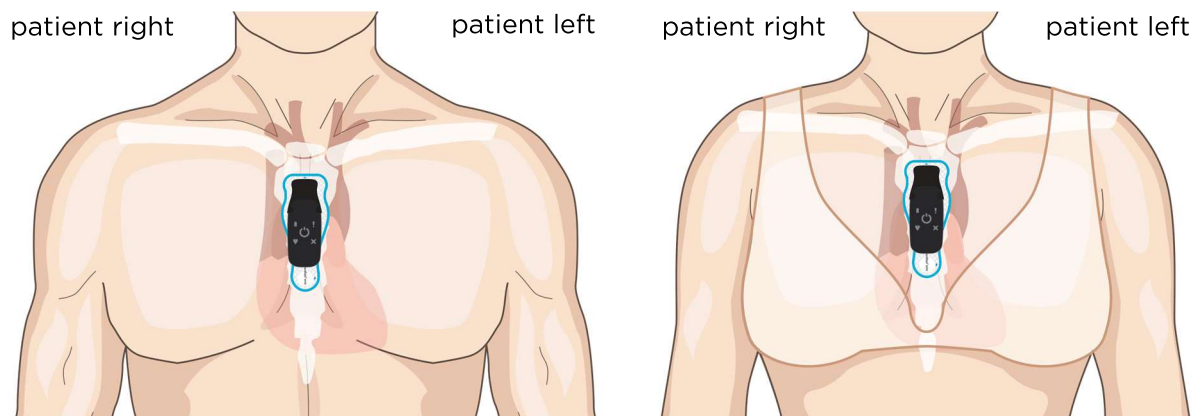
Do not tuck or pin Strip

Preferred chest placement (vertical)

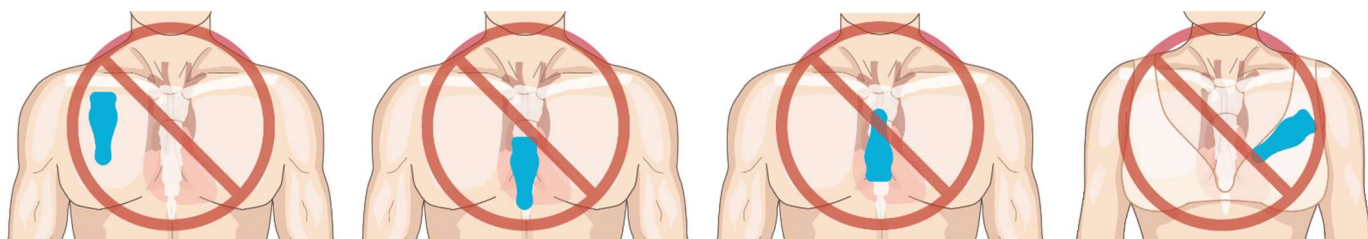


Once the Strip makes contact with your skin, you cannot adjust its position.

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.

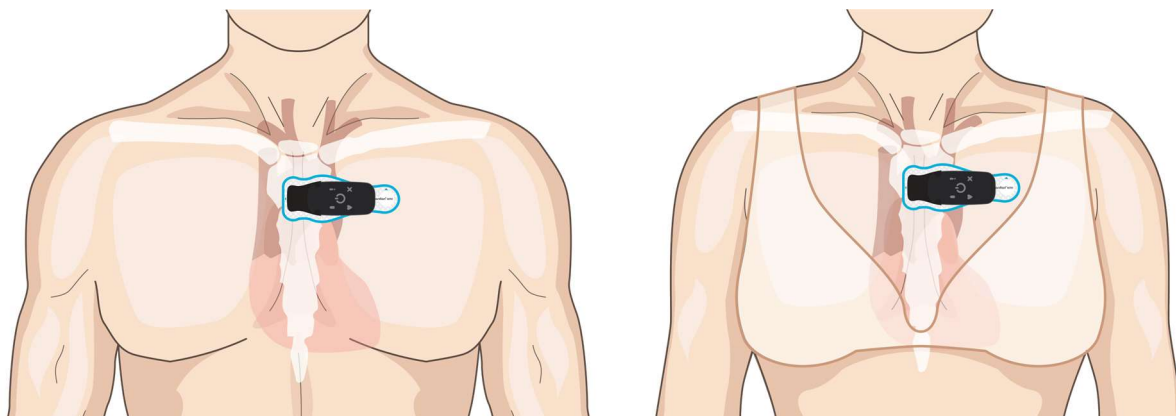


Alternate placement (horizontal)

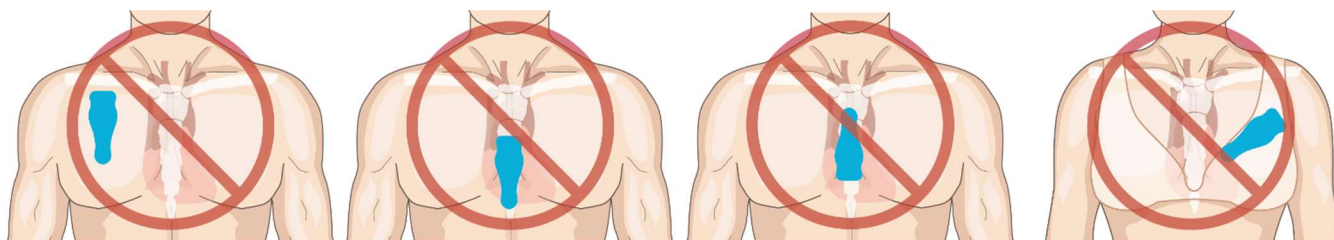


Once the Strip makes contact with your skin, you cannot adjust its position.

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.

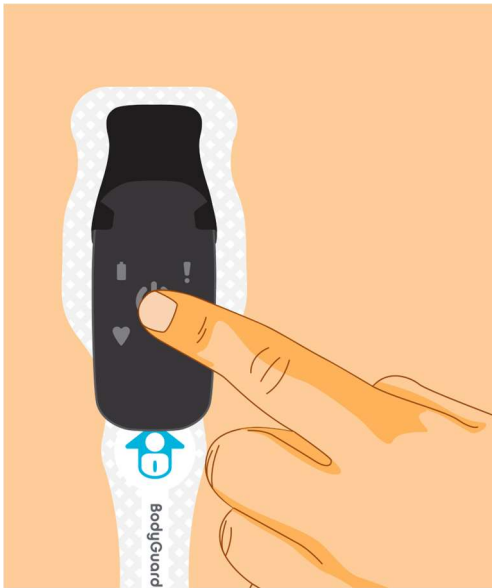


4 Turn on phone

Press and hold the power key until the phone turns on.

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.

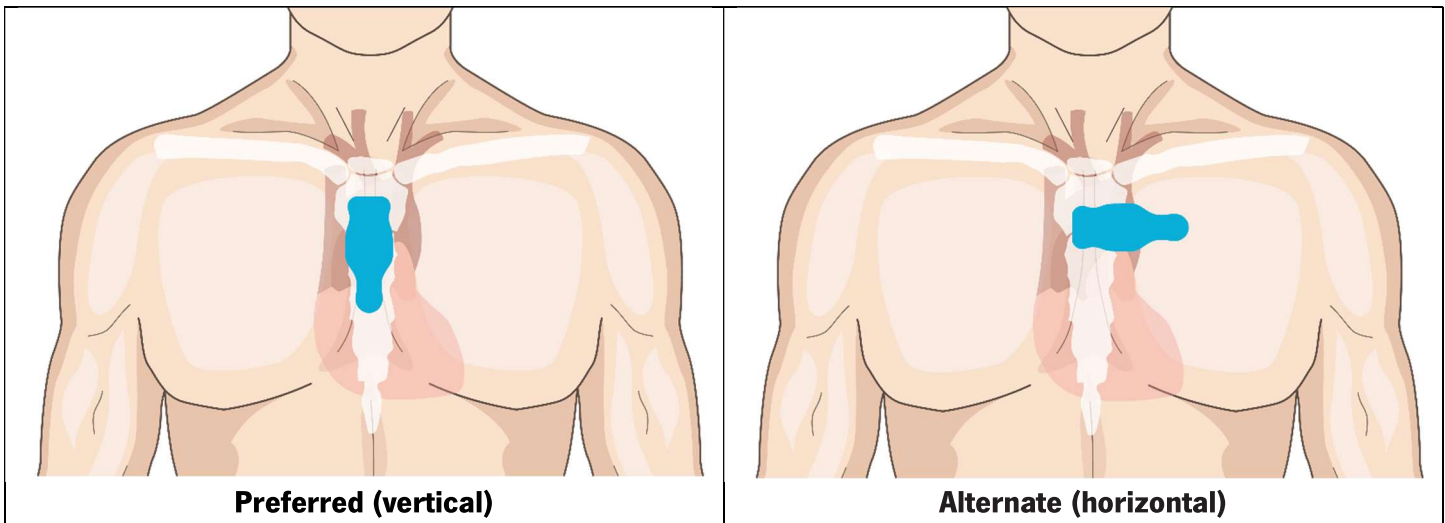
Getting started (using a Bridge)

If your equipment 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 equipment came with **Strips**, see **page 4**.
- If your equipment came with an **ECG lead set**, see **page 17**.

1 Prepare your skin

You can wear BodyGuardian Mini PLUS either vertically or horizontally.

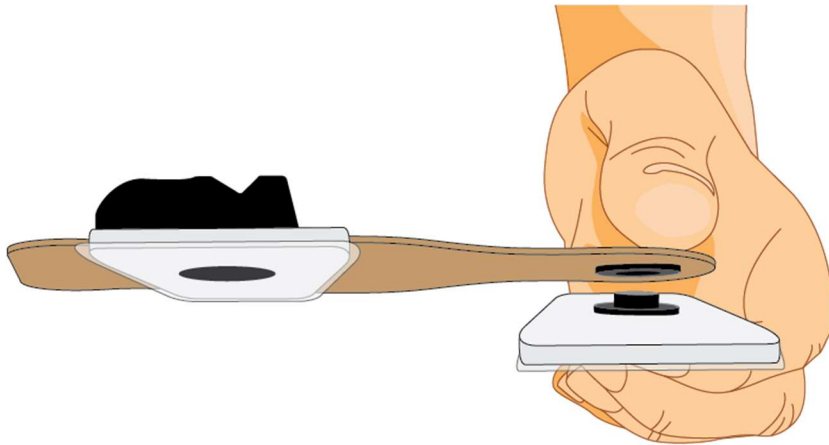


Decide which chest placement you will use before you prepare your skin.

- 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.

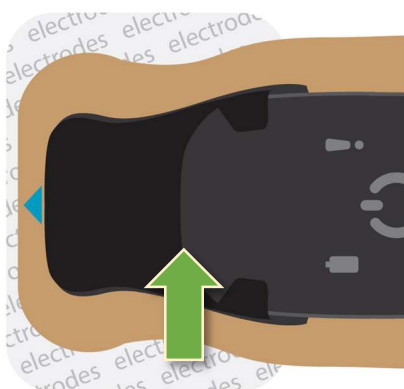
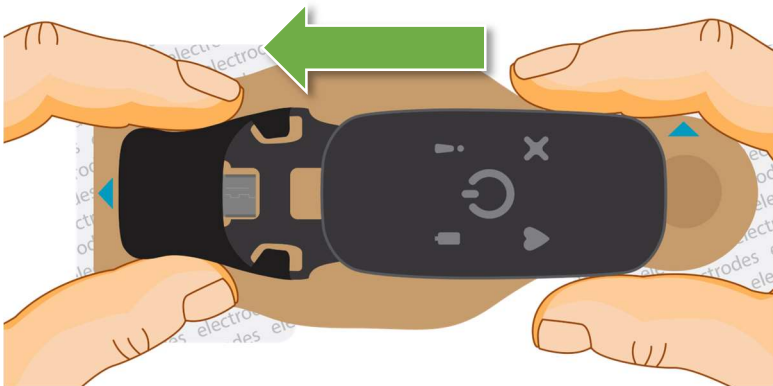
2 Snap the ECG electrodes to the Bridge

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

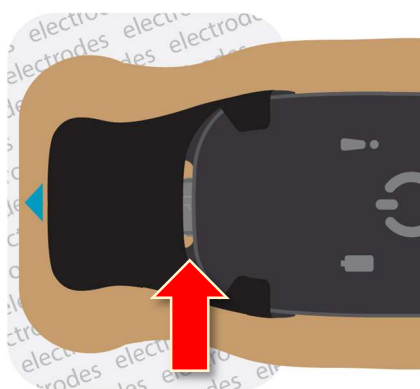


3 Attach the monitor to the Bridge

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



Good connection



Poor connection

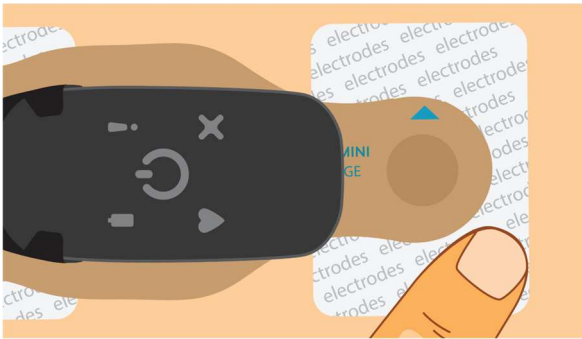
4 Attach to your chest

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**).



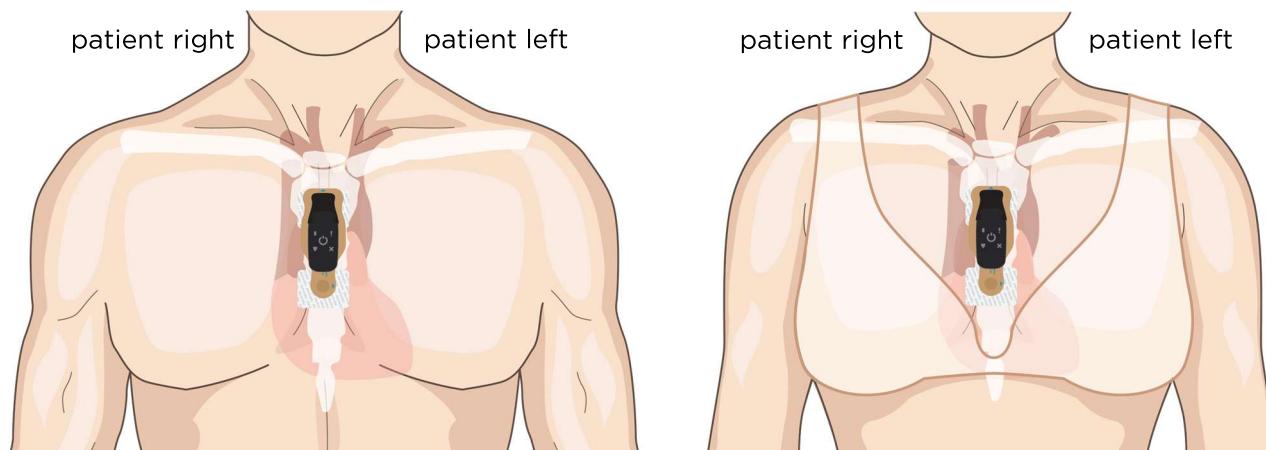
Apply only to intact, clean skin. Do not apply over open wounds, lesions, infected, or inflamed areas. If you have skin allergies, hypersensitivities, or experience skin irritation while wearing the monitor, consult your doctor to select the appropriate option.

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

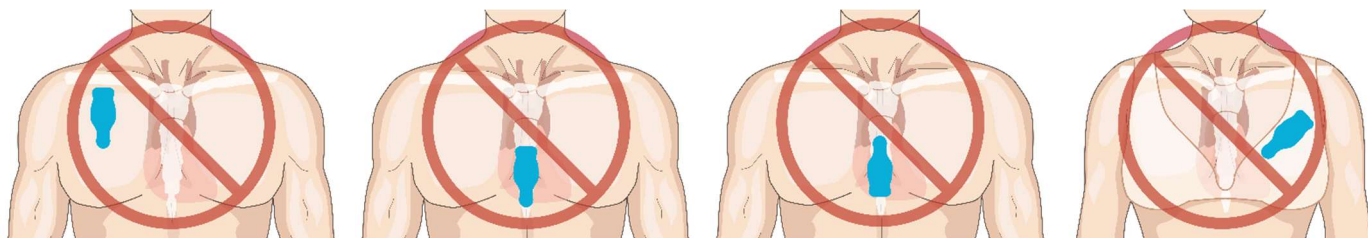
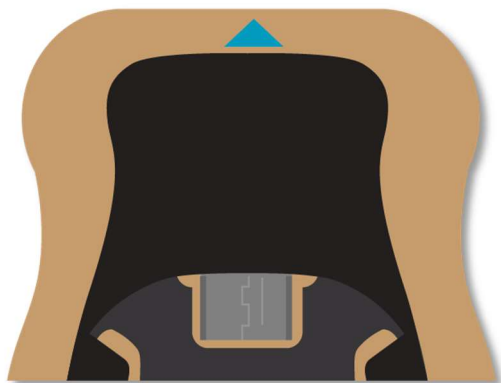


Preferred chest placement (vertical)

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.

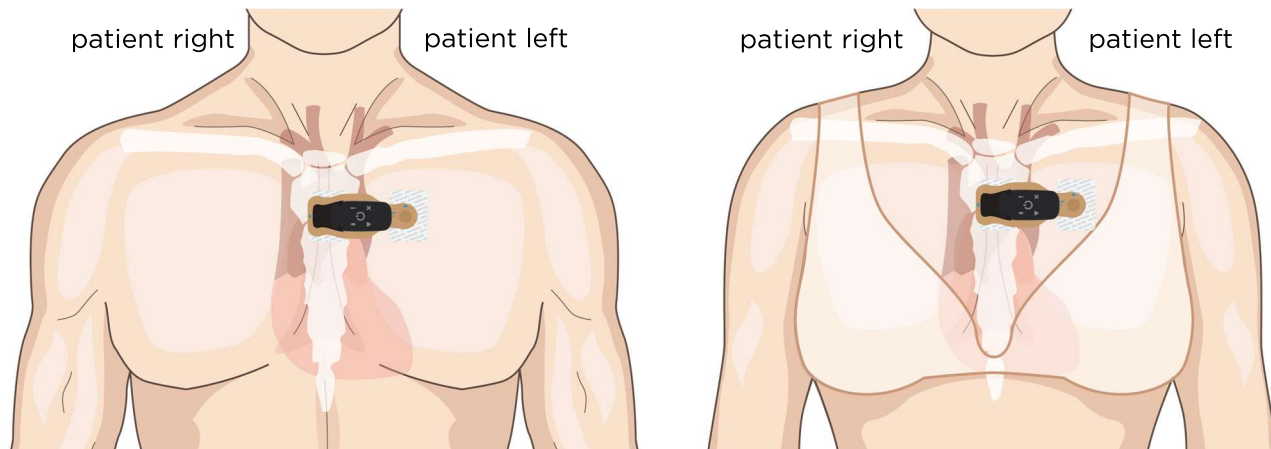


Ensure the uppermost arrow on the Bridge on your chest is pointing up.

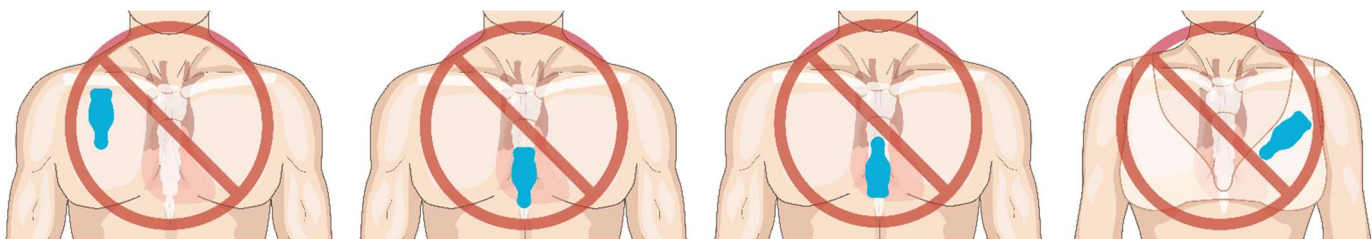


Alternate placement (horizontal)

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.

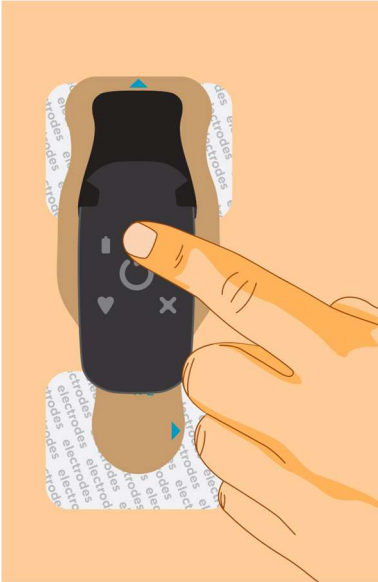


5 Turn on phone

Press and hold the power key until the phone turns on.

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 equipment 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 equipment came with **Strips**, see **page 4**.
- If your equipment came with a **Bridge**, see **page 11**.

1 Prepare your skin

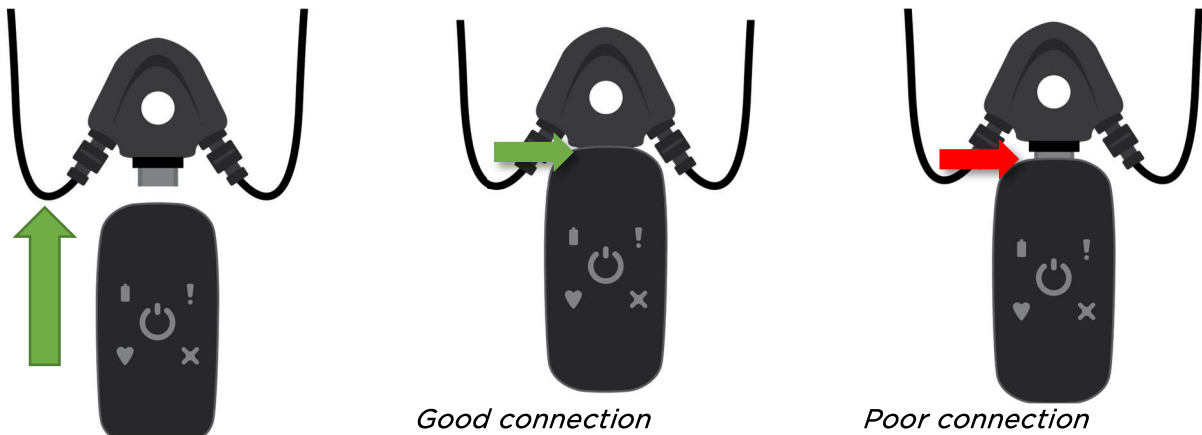
Familiarize yourself with the three chest locations where you will attach ECG electrodes.

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.



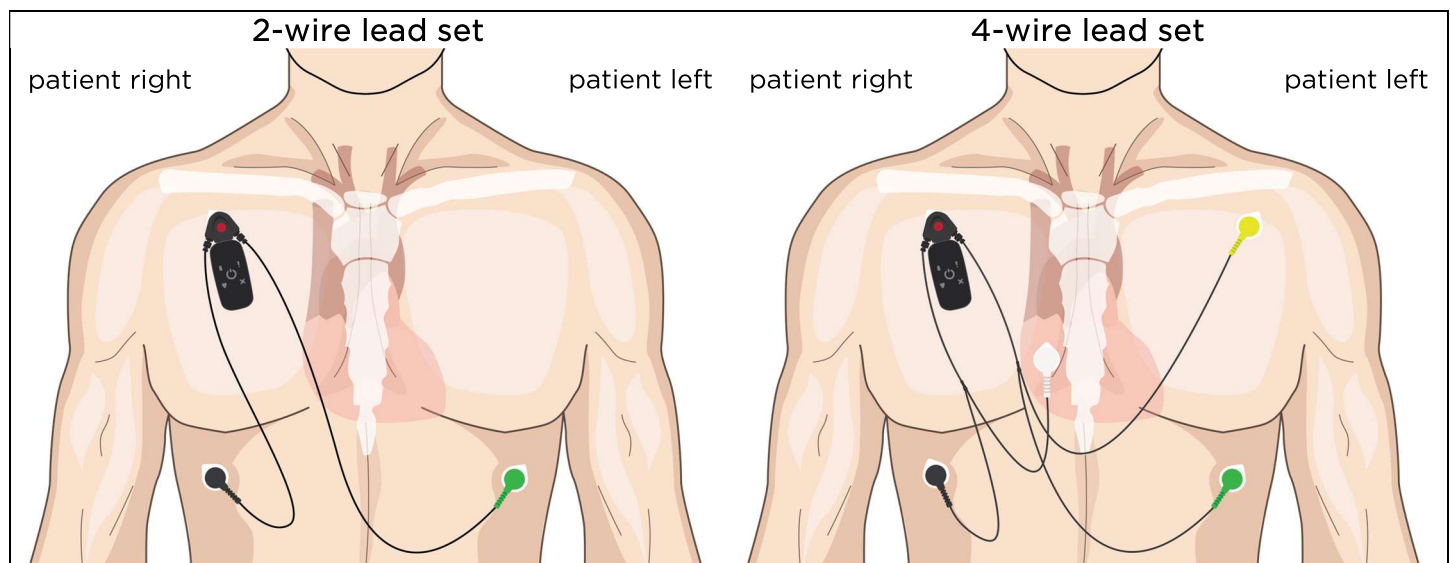
2. Snap an ECG electrode into each of the leads and one into the center monitor connector.

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 appropriate option.

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

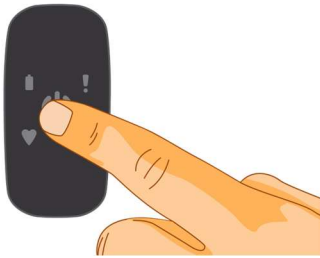


4 Turn on phone

Press and hold the power key until the phone turns on.

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) and 112 (EU), 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.
4. Tap **Save**.

Tips

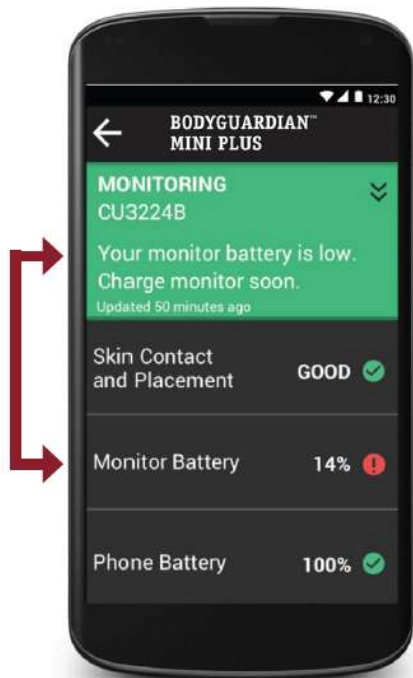
- You must scroll to see the full list of symptoms.
- If you accidentally click the monitor button and are not feeling any symptoms, select: **None or Accidental Push**.

Managing your monitors

Your BodyGuardian Mini PLUS equipment 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 equipment 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.



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

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.
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 equipment 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.



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

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:

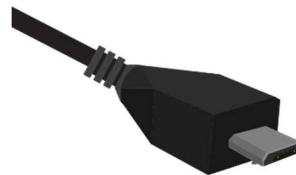
1. Detach the monitor from Bridge or lead set.
2. Plug the charging cord into the monitor. Ensure the other end is plugged into a wall outlet. The monitor takes 1.5-2.5 hours to charge.
3. As soon as the monitor is fully charged, attach the charged monitor to the Bridge or ECG lead set on your chest.
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.

Important

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



front view



side view

- 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 equipment came with Strips, change the Strip on your chest when it no longer adheres to the skin. Strips are disposable.



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 re-attach BodyGuardian Mini PLUS to your chest.

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

If your equipment 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.

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 re-attach 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, lead set or charger.

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

- Pat the Strip with a towel to dry it off.
- Press and hold the Strip 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 flash 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>					

Contraindications

System Level

The BodyGuardian Mini PLUS (in the EU called BodyGuardian Mini PLUS Procedure Pack) is not intended to provide diagnoses. The web portal and reports should not be used without supervision and review by a qualified physician.

The BodyGuardian System and BodyGuardian Mini Monitor are contraindicated for those patients requiring attended, in-hospital monitoring for life threatening arrhythmias.

Warnings

System Level

- Do not attempt self-diagnosis or self-treatment based on acquired data.
- 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 Strip or alternate electrode option that is most appropriate for their needs.
- Use BodyGuardian Mini PLUS with accessories provided by Boston Scientific Cardiac Diagnostics. Other cables and accessories may negatively affect sensor performance.

BodyGuardian Mini Monitor

- The device is not intended to be used at the same time with high frequency (HF) surgical equipment or with a defibrillator.
- Patients who have active implantable medical device (like heart pacemaker and so on), should consult supervising physician or doctor before use.
- 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.
- To avoid danger of electrical shock and electromagnetic disturbances, the computer and associated equipment used with the monitor should comply with IEC/EN 60950 (IT and office 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.
- EMC disturbances might cause interference and/or noise to data acquisition
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the monitor, including cables specified by Boston Scientific Cardiac Diagnostic Technologies, Inc. Otherwise, degradation of the performance of this equipment could result.

General safety precautions

System Level

- United States federal law restricts the device to sale by or on the order of a licensed practitioner or therapist.
- Always follow instructions for disposable electrodes which are used for recordings.
- Apply 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.
- The procedure pack is for single patient use only.

BodyGuardian Mini Monitor

- Use ECG sampling rate of 500Hz with pediatric patients weighing less than 10 kg.
- 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.
- Do not disassemble, try to repair, or modify monitor.
- Monitor does not have any electrical stimulation capabilities.
- Monitor does not directly provide diagnosis as a supervising physician is responsible for ECG data interpretation.
- Accelerometer data is not analyzed within the monitor or differentiated between various physical activities.
- Operating environments: Professional healthcare facility environment and Home healthcare environment.
- If a patient has been given defibrillation, 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 Mini cannot be worn while undergoing an MRI.
- 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.

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
	The monitor is CE-marked for the conformity to Council Directive 93/42/EEC regarding medical devices.
	Medical device.
	The 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.
	For EU only: This symbol indicates that this device shall be disposed according to European Union directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE).
	During transportation: keep package dry, protect 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
	Wireless Transmission Symbol.

	A relative humidity range of 15 % to 90 %, non-condensing
	Transport and storage conditions -20 °C to + 60 °C (transport) -20 °C to + 60 °C at a relative humidity up to 90 %, non- condensing (storage)
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

1-channel ECG	Yes
ECG sampling frequency	250 Hz
ADC precision	24 bits
Input Impedance	>10.1Mohms +/- 0.1Mohm
Datalogger file format	EDF
Memory capacity	4 GB
Power source	3,7 V Li-ion battery
Dimension	48 x 29 x 12 (mm) Weight 18 g
Dimension (EL)	59 x 30 x 13 (mm) Weight 22 g
Operating time	Up to 7 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 2	
RATED power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	
Conducted disturbances induced by RF fields	IEC 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	

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 ± 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						



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ECG PLUG-IN APP
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BODYGUARDIAN CONNECT APP
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BODYGUARDIAN MINI SLIDE STRIP
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BODYGUARDIAN MINI BRIDGE
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**PROCEDURE PACK
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