

VitalPatch Instructions for Use

VitalPatch RTM
VitalPatch Green

Have questions or need help?

For help with VitalPatch and general support, please call 800-219-3000.

CALL 911 if you are having an emergency!

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Related Documents

For video instructions or language-translated documentation, please refer to the **Patient Resources** section of the **vitalconnect.com** website.

Relay devices from VitalConnect are typically distributed with a printed *QuickStart Guide*. Each guide provides simplified instructions that are tailored for the type of monitoring to be performed. If a QuickStart Guide is not available, contact your care provider, or refer to the **Patient Resources** section of the **vitalconnect.com** website.

Contact Information

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Revision History

Rev. M	Initial production release of this document.
Rev. N	Added instructions for posture calibration. Revised instructions for temperature calibration.
Rev. P	Added instruction for 120 or 168 hours of battery life. Minor changes to position of VitalPatch on the body for clarity.
Rev. R	Added support email to contacts page.
Rev. S	Removed CE and EC rep symbols in general symbols table. Removed EC rep address from contact info.
Rev. T	Added the CE mark and EC rep address and symbols.
Rev. U	Added note indicating that Secondary position is not supported for cardiac monitoring. Added instruction to pause for 2 minutes after removing the VitalPatch from the pouch. Added new "VitalPatch Not Adhering" topic. Added instructions for Adhesive Overlay. Added Table of Contents.
Rev. V	Removed pacemaker contraindication.
Rev. W	Added an Adverse Event Reporting section. Added the Manufacturer, EC Rep, and Medical Device symbols to the General Symbols section.
Rev. Y	Updated VitalConnect address.
Rev. Z	Added dimension and weight specifications. Added additional IFU symbol and Japan MIC Certification to to the General Symbols section.
Rev. AA	Added information about automatic calibration. Added instructions to cut VitalPatch in half after removal. Removed information about 120 hour (5-Day) VitalPatch.
Rev. AB	Revised explanation of IP24/IP27 symbols to clarify that these ratings are for ingress protection only and do not indicate support for submersion or swimming.
Rev. AC	Added information about VitalPatch Green (previously documented in IFU-034), including patch return instructions. Added description of VItalPatch pouch label. Updated recommended maximum range between VitalPatch and relay devices. Corrected adverse event statement to clarify that adverse events can be reported for both VitalPatch and the adhesive overlay.

Section 1: Device Description

The VitalPatch® device (VitalConnect Sensor) is a component of the VitalConnect Platform. The VitalPatch device is a wireless, battery-operated wearable biosensor, worn on the torso to record heart rate, electrocardiography (ECG), heart rate variability, R-R interval, respiratory rate, fall detection, activity (including step count) and posture (body position relative to gravity including fall detection). The **VitalPatch RTM** model records body temperature and skin temperature. The **VitalPatch Green** model does not record body temperature and skin temperature.

The VitalPatch device continuously gathers physiological data from the person being monitored and then transmits encrypted data via bi-directional communication to the Relay device when in range of the Relay device. The encrypted wireless data provided by the VitalPatch device may be downloaded from the Relay device for storage, or integrated into a Third-Party Relay Application via the APIs of the Relay Software Library. Additionally, wireless data may be transferred to and stored on an optional Secure Server for future analysis if there is an active server connection. The data provided by the VitalPatch device is intended to aid caregivers in making diagnoses by providing additional information to standard of care patient monitors.

During normal operation, data is collected by the VitalPatch device and transmitted immediately to the Relay device. A continuous connection is needed between the VitalPatch device and the Relay device in order to facilitate continuous data transmission. The continuous wireless transmission of data occurs with a latency of seconds between data collection and transmission.

Section 2: Indications for Use

The VitalConnect Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings. This can include heart rate, electrocardiography (ECG), heart rate variability, R-R interval, respiratory rate, body temperature, skin temperature, activity (including step count), and posture (body position relative to gravity including fall). Data are transmitted wirelessly from the VitalConnect Sensor for storage and analysis. The VitalConnect Platform can include the ability to notify healthcare professionals when physiological data fall outside selected parameters.

The device is intended for use on general care patients who are 18 years of age or older as a general patient monitor, to provide physiological information. The data from the VitalConnect Platform are intended for use by healthcare professionals as an aid to diagnosis and treatment. The VitalPatch device can be used on patients with pacemakers that comply with ISO 14117:2012 and ANSI/AAMI PC69:2000 without deviations. Heart rate, electrocardiography (ECG), heart rate variability, R-R interval, and respiratory rate are not intended for patients with pacemakers. The device is not intended for use on critical care patients.

Contraindications

The VitalPatch device is not intended as a stand-alone diagnostic monitor, but the data may be applicable for use in diagnosis.

Warnings

- The VitalPatch device is a secondary, adjunct patient monitor and is not intended to replace existing standard-of-care patient monitoring practices.
- Depending on wireless connectivity, a temporary interruption of data transmission is possible, which may impact continuous or real-time monitoring. Data will be stored on the device for transfer once connectivity is reestablished.
- The nature of hydrocolloid adhesives may cause adverse skin reactions. Healthcare providers should advise patients to seek medical attention if either of the following occurs:
  - A severe adverse event
  - An allergic reaction persisting beyond 2-3 days
- Histories of skin irritations should be considered before placing the VitalPatch device on a patient.
- Do not use the VitalPatch device during an MRI scan or in a location where it will be exposed to strong electromagnetic forces.
- Only place the VitalPatch device on intact skin.
- Clinical validation has not been performed on patients who are pregnant or breastfeeding.

Precautions

- For data to be sent to a healthcare professional for review:
  - The VitalPatch device must be properly adhered to the patient.
  - The patient must remain in range of their Relay device. The range will vary by device type. The recommended maximum range from the VitalPatch to the VistaTablet is 30ft (10m). The recommended maximum range from the VitalPatch to the VistaPhone (all models) is 10ft (3m). The quoted ranges are "line of sight" and may be reduced by walls, adjacent furniture, electrical interference, and body position relative to the relay.
  - The VitalPatch device must have adequate power for data transmission. Notification of the VitalPatch device battery level will indicate when the battery power is low.
  - The Relay device must remain charged and functional for data transmission. Wireless connectivity must be active for transmission of data from the Relay device to the server.
- If uninterrupted continuous data monitoring is necessary for patient safety, remote monitoring in home settings using the VitalPatch device may not be appropriate.
- Data collected by the VitalPatch device for patients experiencing cardiac arrhythmia may indicate slightly higher or lower respiratory rate values, compared to visual observation, for the duration of the active arrhythmic episode.
- The VitalPatch device is Single Use Only. Do not reapply the device once it is removed.
- Wireless electronic devices may cause signal interference during data transmission. Avoid close proximity with interfering devices.
- Medical electrical equipment or electrical stimulators attached to the patient's body may degrade VitalPatch signal quality or produce erroneous results from the biosensor. The potential interaction must be evaluated and authorized by the responsible organization.
- Do not use the VitalPatch device if the package has been opened, or appears used, damaged, or expired.
- The VitalPatch device may be used while showering. Minimize exposure directly under the shower head, excessive contact with soap, or scrubbing. Gently dry the device after showering. Do not submerge the device or use in a sauna.
- Wear only one VitalPatch device at a time.
- If discomfort or irritation occurs, the VitalPatch device should be removed. If mild soreness or redness is experienced after removing the device, do not apply a new device in the same location. Choose another recommended location.
- Incorrect handling, excessive force, or dropping the VitalPatch device may cause malfunction or permanent damage.
- Keep the VitalPatch device away from children and pets. The device may be a choking hazard, and may be harmful if swallowed.
- If VitalPatch fails to operate, contact your healthcare provider immediately.
- Dispose of the VitalPatch device per local laws, care facility laws or hospital laws for routine/non-hazardous electronic waste.

Product Storage

- Storage temperature range: 0°C to 40°C
- Storage relative humidity range: 10% to 95%

System Interoperability

The VitalPatch device is compatible with Relay devices and software developed with the VitalConnect Application Programming Interface (API). Please contact VitalConnect, Inc. to obtain implementation information.

Section 3: Product Identification

The VitalPatch biosensor is packaged in a sealed, airtight pouch. The back side of the pouch has a label with important product information.

- For VitalPatch RTM, see **Figure 1** below.
- For VitalPatch Green, see **Figure 2** below.

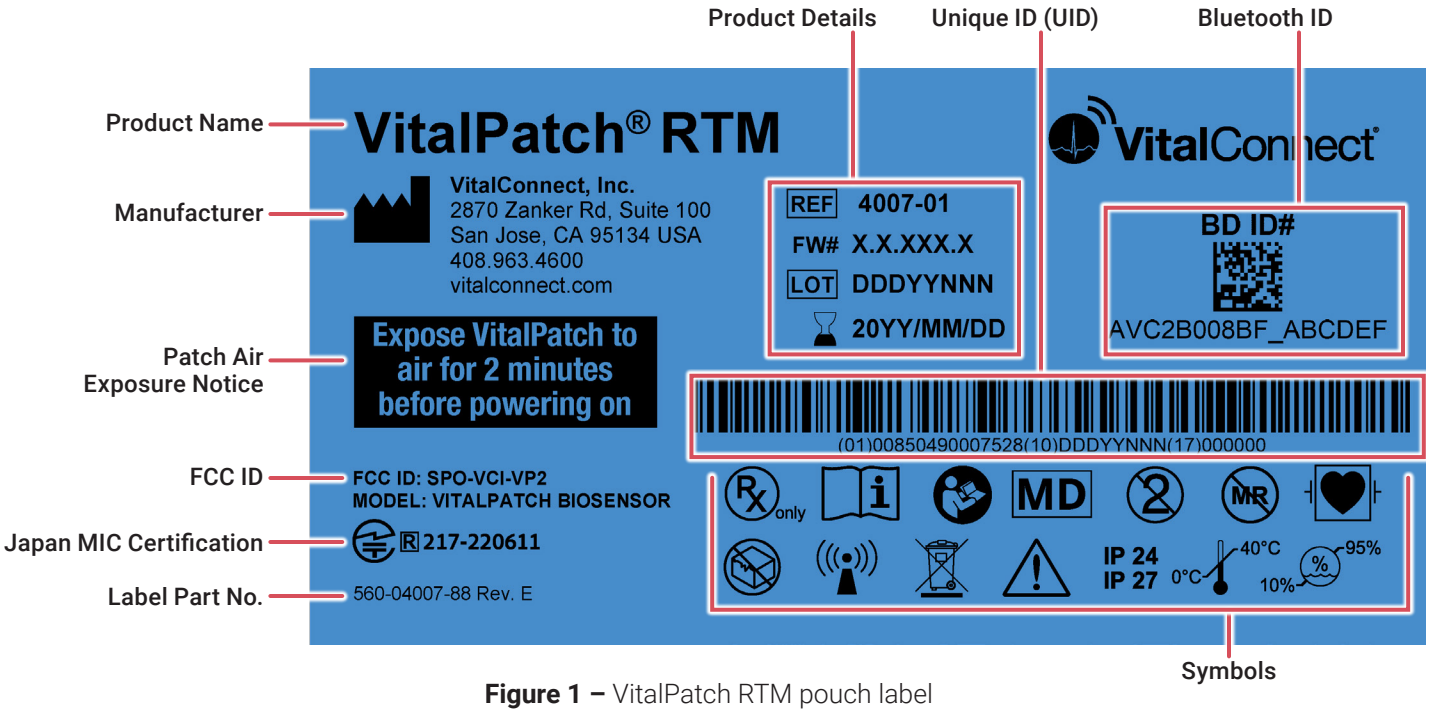


Figure 1 – VitalPatch RTM pouch label

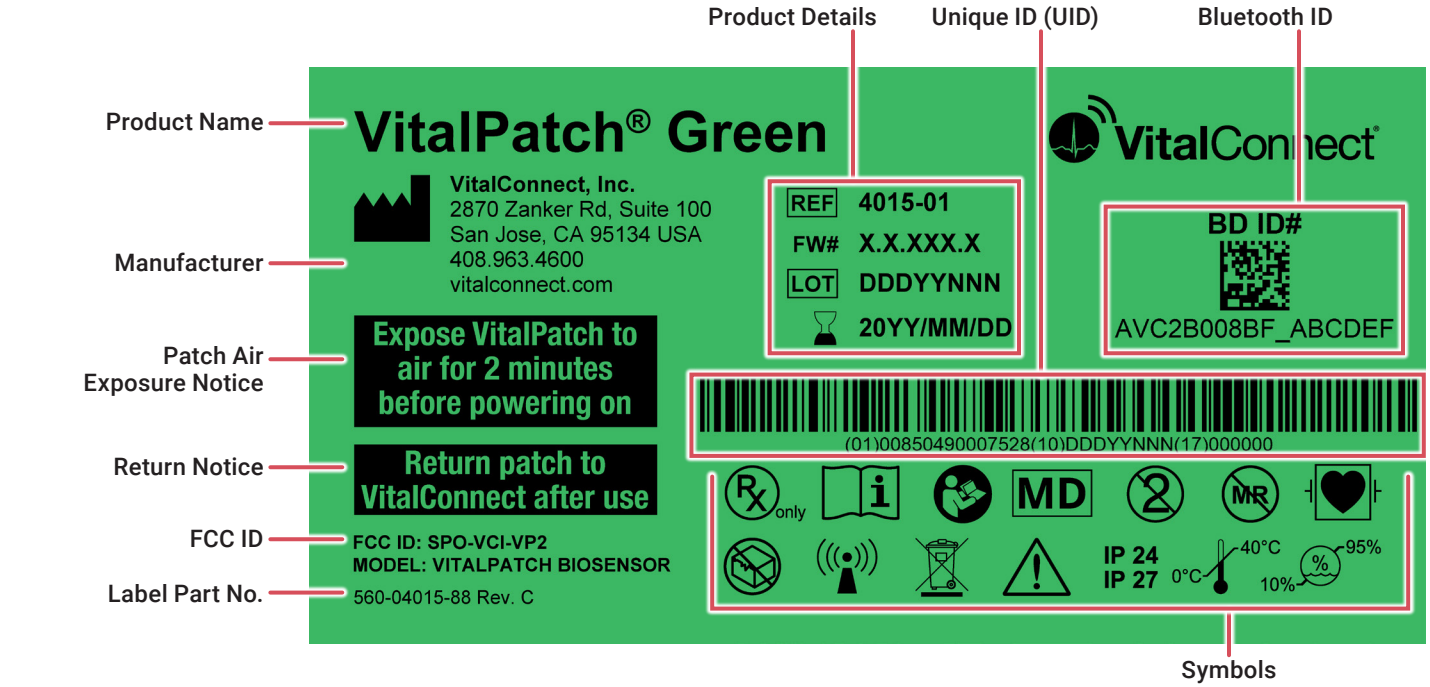


Figure 2 – VitalPatch Green pouch label

The pouch label shows the following information:

- **Product Name** — This should be "VitalPatch RTM" or "VitalPatch Green". Note that the VitalPatch Green does not record body temperature and skin temperature, and is therefore not suitable for applications such as remote patient monitoring where temperature monitoring is required.
- **Manufacturer** — This is the name, address, and phone number of the manufacturer (VitalConnect, Inc.).
- **Patch Air Exposure Notice** — This is a reminder to the user that the VitalPatch must be exposed to air for a minimum of 2 minutes before powering on.
- **Return Notice** — This is a reminder to the user that this model of VitalPatch (VitalPatch Green) must be returned to VitalConnect after use.
- **FCC ID** — This is a unique identifying code confirming that the VitalPatch meets FCC standards for radio frequency emission.
- **Label Part No.** — This is the part number for the pouch label (not the VitalPatch).
- **Product Details** — This area of the label includes the following data fields:
  - **REF** — Device catalog number
  - **FW#** — VitalPatch firmware revision
  - **LOT** — Manufacturing lot date
  - **Expiration** — Product use-by date
- **Unique ID (UID)** — This is a set of numbers in human-readable and barcode format that uniquely identifies this device. The UID includes the manufacturer identifier (VitalConnect), REF, product use-by date, and serial number.
- **Bluetooth ID** — This is the unique Bluetooth ID of the device in human-readable form and scannable QR code. The ID is also printed on the patch release liner. Note that for pairing with a relay device, only the last 6 characters vary from device to device.
- **Symbols** — These symbols communicate precautionary information, handling guidelines, and usage instructions for the VitalPatch. For more information about the meaning of these symbols, refer to **Section 11 on page 20**.

Section 4: Applying the VitalPatch

These instructions describe how to handle the VitalPatch, prepare the skin for VitalPatch application, position the VitalPatch, and apply the VitalPatch to the skin.

Note: It is recommended that healthcare providers advise users to replace the VitalPatch device after 168 hours (7 days) of use. To preserve data, the VitalPatch device must be connected to the Relay device prior to the end of battery life (168 hours). The device will no longer be usable after 168 hours.

VitalPatch Overview

The orientation of the **Logo Side** and **Battery Side** are important when placing the device on the patient. See **Figure 3** for the top view of the VitalPatch device, showing the logo side (left) and battery side (three lines on the right).

See **Figure 4** for a view of the following components on the bottom side of the device:

- **Adhesive Backing (2x)** — These are clear, removable films on the left and right sides of the device. These are removed during the device application process.
- **Bluetooth ID Label** — This is a label on the adhesive backing that displays the Bluetooth ID of the device. The ID is in human-readable form and scannable QR code. Note that for pairing with a relay device, only the last 6 characters vary from device to device.
- **No Adhesive** — This is a region on the underside of the device where there is no adhesive. When handling the device with the adhesive backings removed, hold the device only in this region.
- **Patch Adhesive (2x)** — These are the adhesive regions on the left and right sides device. Do not handle these directly during the application process.
- **ECG Electrode (2x)** — These are the sensors for detection of ECG signal on the left and right sides of the device.

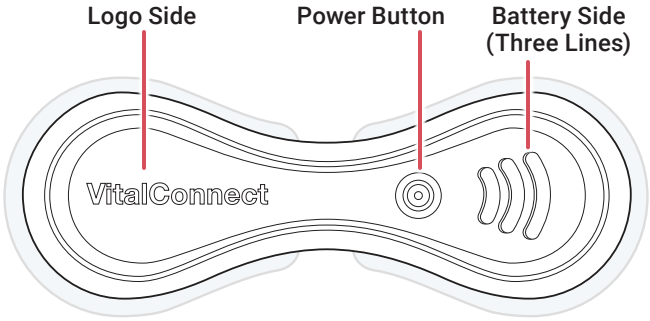


Figure 3 – VitalPatch Top View

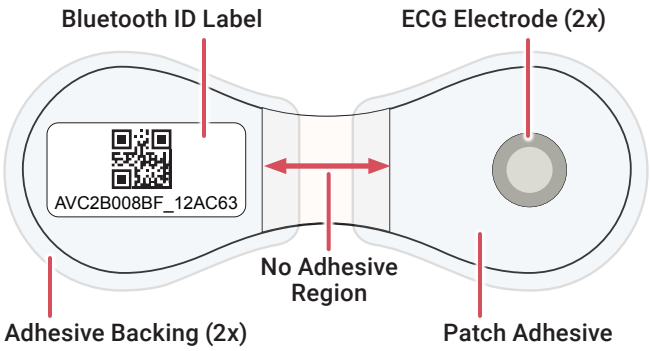


Figure 4 – VitalPatch Bottom View

Product Handling

Ensure hands are clean and dry before handling the VitalPatch device. When handling the VitalPatch device, do not touch the adhesive. See **Figure 5.** The steps below should minimize the chance of touching the

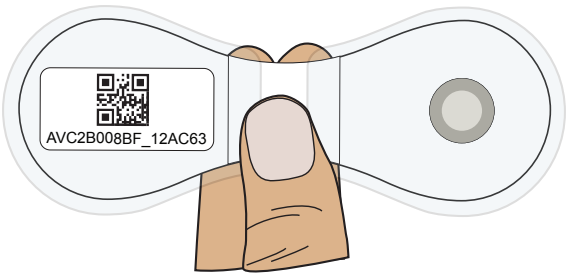


Figure 5 – Grasp device in the no-adhesive region

adhesive. If the liners have been removed it is best to hold the device in the center with your thumb and fingers. Contact with the adhesive prior to application to the patient will deteriorate the adhesive and compromise wear duration.

Step 1: Remove VitalPatch from pouch

Tear open the pouch using the notch mark and remove the VitalPatch device carefully to avoid pressing the Power Button. See **Figure 6.**

After removing the VitalPatch from the pouch, **wait at least 2 minutes** before powering-on the device. This pause ensures optimal performance of the VitalPatch battery. Skin preparation (next step) can be performed while waiting.

DO NOT remove the adhesive backings until instructed.

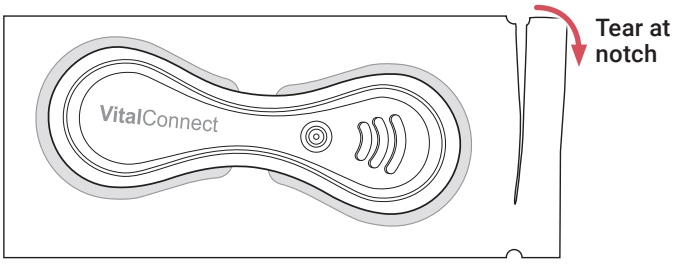


Figure 6 – Remove VitalPatch from pouch and wait 2 minutes

Step 2: Prepare skin

Prepare the skin on the left side of the chest in either the Primary location or the Secondary location. See **Figure 7**.

- The **Primary** location is on the upper left chest. This is the preferred location. You must use this site for cardiac monitoring or if using **VitalPatch Green**.
- The **Secondary** location is just left of the centerline, below the chest on the rib cage, positioned horizontally in an area with minimal body curvature. Use this location only if the Primary location cannot be used. This location is not recommended for obese persons and cannot be used for cardiac monitoring.

For a good connection and proper operation, the VitalPatch device should NOT be worn over body hair. Remove (shave) body hair in the area of device placement before applying.

Use an alcohol wipe to clean the location and allow to dry. The location should be free of oils and lotions to maximize adhesion.

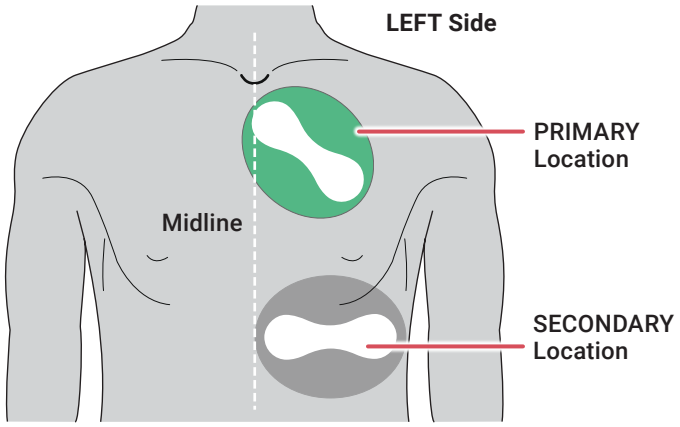


Figure 7 – Prepare the left side of the chest

Step 3: Power-on VitalPatch

Place the VitalPatch on a flat surface. Locate and press the power button. Look for a green light to flash temporarily to confirm the device is powered on. See **Figure 8**.

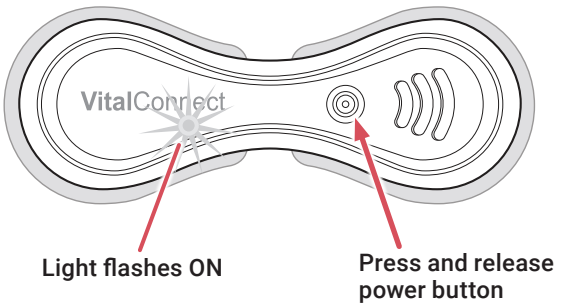


Figure 8 – Power-on VitalPatch

Step 4 for PRIMARY location: Position VitalPatch on the body

See **Figure 9**. With the adhesive backings still adhered, place the VitalPatch device on a flat body surface on the left chest, with the logo side of the device two fingers below the suprasternal (jugular) notch. Angle the device downward at a 45-degree angle across the chest, with the three lines pointing downwards.

It is more important to locate the flattest surface of the chest for the VitalPatch device placement to minimize movement during the monitoring session.

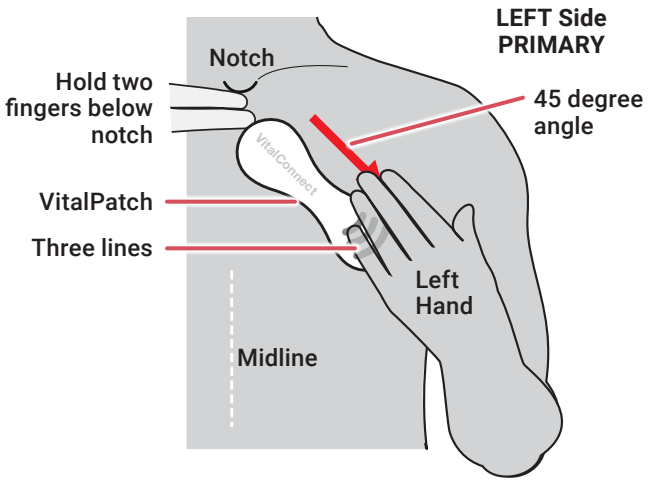


Figure 9 – Hold VitalPatch against chest in the PRIMARY location

Step 4 for SECONDARY location: Position VitalPatch on the body

IMPORTANT: Do not use the Secondary location for cardiac monitoring.

See **Figure 10**. With the adhesive backings still adhered, place the VitalPatch device on a flat body surface on the left chest, just left of the midline, below the chest on the rib cage, positioned horizontally in an area with minimal body curvature.

It is more important to locate the flattest surface of the chest for the VitalPatch device placement to minimize movement during the monitoring session.

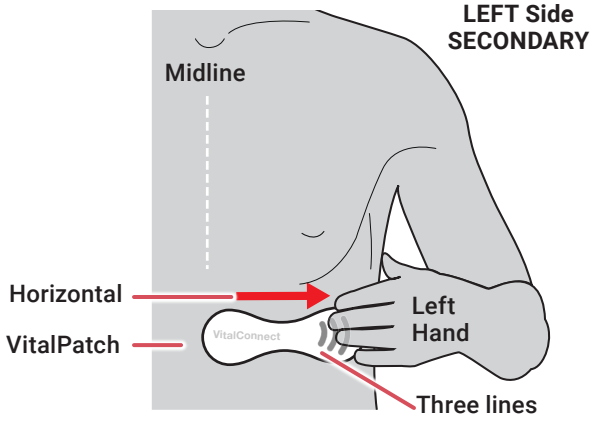


Figure 10 – Hold VitalPatch against chest in the SECONDARY location

Step 5: Apply VitalPatch to body

See **Figure 11.** Hold one end of the VitalPatch against the chest. Lift the other side and grab the adhesive backing tab located near the center of the VitalPatch. Without touching the adhesive, pull the tab to remove the adhesive backing and press the VitalPatch down to apply. Repeat this process to apply the other side of the VitalPatch.

Press down on both ends of the device to ensure it is well-adhered to skin. Avoid exercise for at least 30 minutes after application.

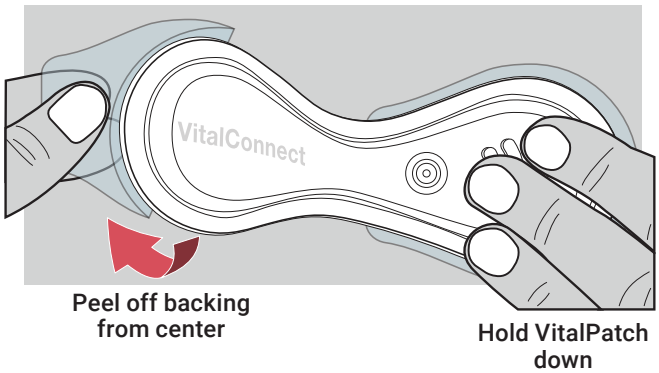


Figure 11 – Peel off adhesive backing while holding VitalPatch down against chest

Section 5: Connecting VitalPatch

After applying the VitalPatch, retain the pouch or the adhesive backing with the device Bluetooth ID number. You will need this information to connect to your software application after the VitalPatch device is applied. The Bluetooth ID number can be found on the pouch label or on the adhesive backing in both human readable and barcode formats. See **Figure 12**.

Refer to your software application provider's user manual for more instructions on how to connect to the VitalPatch device. A connection is required to establish a start time in the data file. For calibrating your VitalPatch device, refer to your software application provider's user manual.

If using a VistaPhone or VistaTablet relay device, refer to the VistaPoint *instructions for Use* for your device.

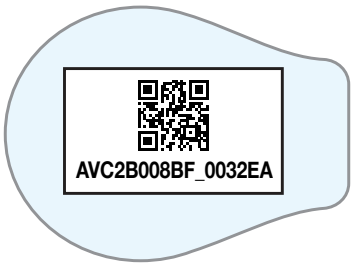


Figure 12 – Adhesive backing with Bluetooth ID label

Step 1: Calibrate body posture

Perform the following steps to calibrate body posture, as directed by the software application:

1. Note the position of the VitalPatch on the chest.
2. Select the VitalPatch position in the software application.
3. Note the position of the patient. The position must be one of the following:
   - **Standing or Sitting** (preferred) – the patient must stand or sit as upright as physically capable.
   - **Supine** – the patient must lie down in a supine position as flat as physically capable.
   - **Elevated** – the patient must be laying on a bed that can be elevated. Position the bed angle at 30°. Note that the Elevated posture may not be supported by your software application. If it is not provided as an option, you must reposition the patient to be in either the standing, sitting or supine positions.
4. Enter the patient position in the software application.

Note: The VitalPatch has an automatic calibration feature that is activated if the patient walks with the VitalPatch before connecting to the relay device. If automatic calibration occurs, the software application on the relay device may not require the user to indicate VitalPatch position and patient posture. The VitalPatch will operate normally after automatic calibration.

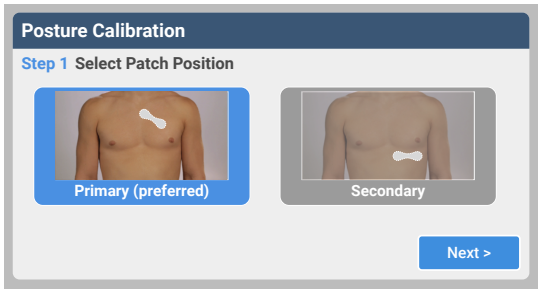


Figure 13 – Select patch position on chest

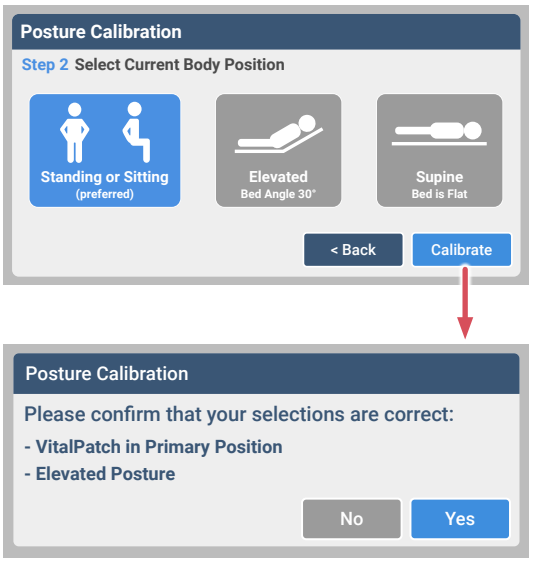


Figure 14 – Select and confirm body position

Step 2: Calibrate body temperature

Note: Perform this step only if the body temperature measurement feature is supported by both the VitalPatch and your software application. VitalPatch Green does not support body temperature.

Perform the following steps to calibrate body temperature, as directed by the software application:

1. Wait at least 30 minutes after applying the VitalPatch before performing the initial temperature calibration. This allows the temperature of the VitalPatch to stabilize. If the software application requires you to perform the initial calibration before 30 minutes, repeat the body temperature calibration after at least 30 minutes have elapsed.
2. Take a body temperature measurement using a clinical-grade thermometer.
3. Ensure the software application is configured for the measurement units of your thermometer (Celsius or Fahrenheit).
4. Enter the measured body temperature in the software application.
5. Repeat the body temperature calibration each day between the hours of 09:00 and 21:00 to ensure continued accuracy and to accommodate natural variation in body temperature due to circadian rhythms.

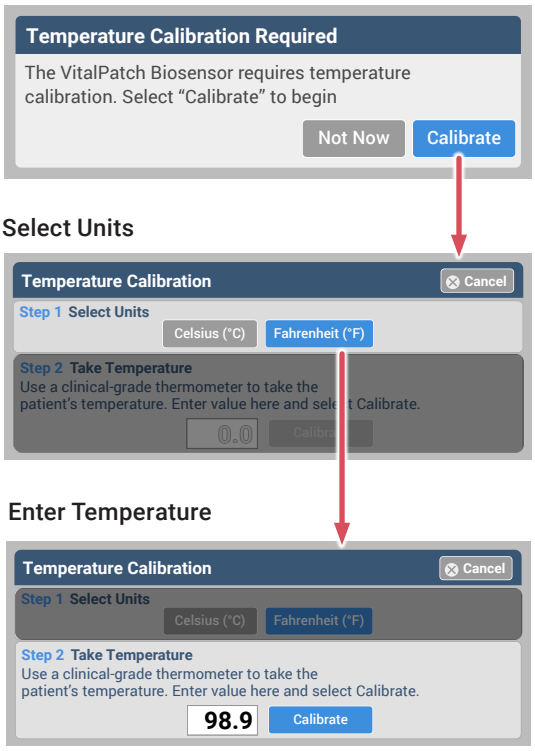


Figure 15 – Calibrate body temperature

Section 6: Troubleshooting

Use the steps in this section to identify and resolve potential issues with the VitalPatch device.

VitalPatch Not Connected to Relay Device

The VitalPatch device may lose contact with the relay device for the following reasons:

- **Patch is out of range of relay device** — The VitalPatch must remain within Bluetooth transmission range of the relay device to ensure continuous connection and data transmission.
  - The recommended maximum range from the VitalPatch to the VistaTablet is 30ft (10m). The recommended maximum range from the VitalPatch to the VistaPhone (all models) is 10ft (3m). The quoted ranges are "line of sight" and may be reduced by walls, adjacent furniture, electrical interference, and body position relative to the relay. Other relay devices may have shorter or longer maximum ranges
  - Body position may reduce this distance (for example, if the body is turned away from the relay device).
  - Interior walls and electrical interference may also reduce the connection range.
  - When the VitalPatch returns within range of the relay device, connection will automatically be reestablished.
- **Patch suffocation** — The VitalPatch uses an air-zinc battery that requires continuous exposure to air.
  - If the VitalPatch "suffocates" (loses exposure to air), the device will automatically shut off. To restart the VitalPatch, press the power button.
  - To prevent suffocation, avoid tight-fighting and/or non-breathable clothing on the chest.
  - Do not cover the VitalPatch with tape, bandages, or non-approved adhesive overlays.
  - Do not submerge the VitalPatch in water (for example, by swimming or taking a bath). Showering with the VitalPatch is OK.

VitalPatch Not Adhering (Patch-Off Condition)

If the relay device indicates a "Patch off" event has been detected, but visual inspection shows the patch has not been removed, check if the patch has lifted from the skin. If the patch has partially lifted from the skin but remains attached, press the patch down firmly against the skin to re-adhere. If one or both sides of the patch has completely lifted off the skin, remove the patch and replace with a new one following the Skin Preparation and Application steps described previously. If multiple "Patch Off" notifications are received in a short period of time, remove the patch and replace with a new one.

If the VitalPatch has partially lifted from the skin, or if the VitalPatch will be exposed to conditions where lifting and patch-off may occur, apply the optional VitalConnect adhesive overlay to help keep the VitalPatch adhered to the skin. Use only the approved adhesive overlay described in **Section 7 on page 13**.

The overlay may be used if the VitalPatch begins to peel up at the edges but has not lost contact with the skin. DO NOT use the adhesive overlay if the VitalPatch has already lifted off the skin.

The use of other adhesives or tape to adhere the VitalPatch to the skin is not recommended, will prevent proper operation of the VitalPatch, and will void the warranty of the VitalPatch.

Skin Irritation

If discomfort or irritation occurs, the VitalPatch device should be removed. If mild soreness or redness is experienced after removing the device, do not apply a new device in the same location. Shift the new device to another location.

Section 7: Applying the Adhesive Overlay

Adhesive Overlay Indications for Use

The Adhesive Overlay is an adhesive for use in conjunction with the VitalPatch device. This is an optional accessory that may be used when the VitalPatch device does not adhere for the full monitoring session period. Other adhesives or overlays not specifically made for the VitalPatch device are not recommended and could void the warranty of the VitalPatch device when used. Follow the instructions below when applying and removing the Adhesive Overlay.

Adhesive Overlay Overview

Figure 16 shows the adhesive overlay being positioned over the VitalPatch.

Figure 17 shows the final appearance of the VitalPatch after application of the adhesive overlay.

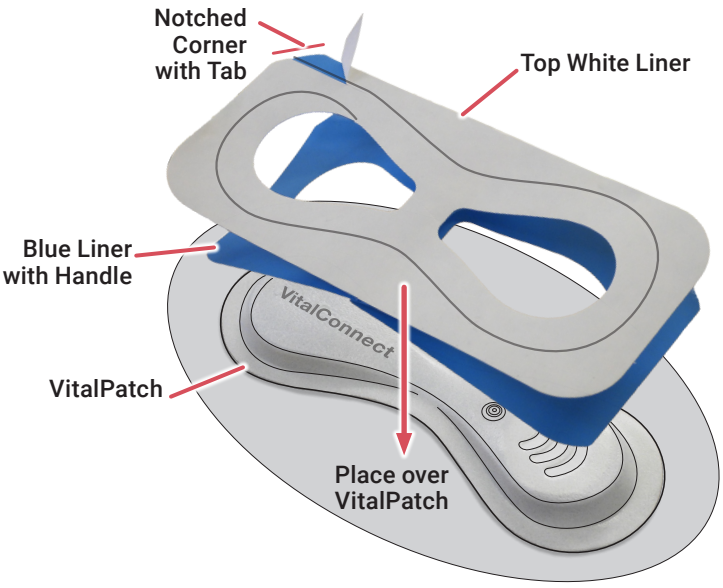


Figure 16 – Adhesive overlay application and features

Adhesive Overlay Warnings and Precautions

The adhesives in this product may cause adverse skin reactions. Healthcare providers should advise patients to seek medical attention if either of the following occurs:

- A severe adverse event.
- An allergic reaction persisting beyond 2-3 days.
- If discomfort or irritation occurs, the adhesive overlay should be removed

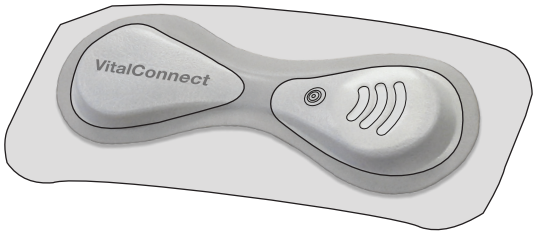


Figure 17 – Adhesive overlay after application

Adhesive Overlay Application Steps

For an instructional video, see vitalconnect.com/docs/overlay-video.html.

Note: It may be helpful to look in a mirror when doing the following steps.

Step 1: Prepare Skin

For people with dense chest hair, it is advised to trim the chest hair before application of the VitalPatch and the adhesive overlay.

Clean the skin around the VitalPatch device with an alcohol prep-pad. See **Figure 18**. Avoid touching the VitalPatch with the pad. Allow the skin to dry.

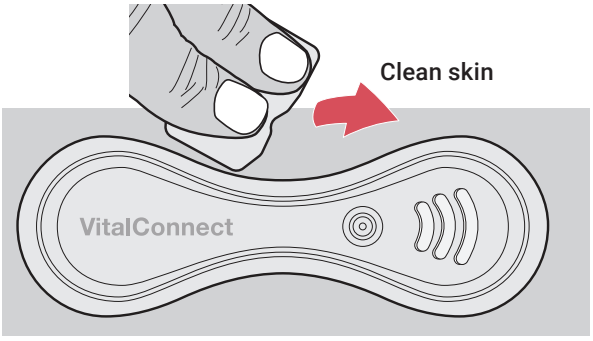


Figure 18 – Clean skin around VitalPatch

Step 2: Bend Tab

a. Before applying the adhesive overlay, find the notched corner. See **Figure 19**.

b. Bend the tab up approximately half an inch to match figure on the right. This creates a bent tab that will help you remove the white top liner later.

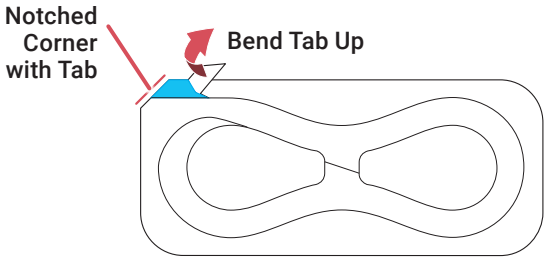


Figure 19 – Bend tab up on adhesive overlay

Step 3: Place Over VitalPatch

a. Place the adhesive overlay over the VitalPatch such that the white liner is facing up away from the skin. See **Figure 20**.

b. Align the two cutouts of the adhesive overlay with the raised portions of the VitalPatch.

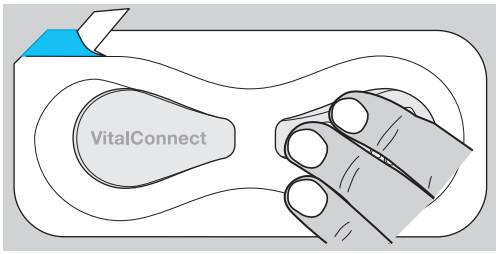


Figure 20 – Place over VitalPatch

Step 4: Remove First Blue Liner

a. With one hand hold one end of the adhesive overlay firmly in place. See **Figure 21**.

b. With the other hand find and grab onto the blue liner. Slowly peel away and remove the blue liner as shown in the image.

c. Then press the adhesive overlay to adhere it to the skin and VitalPatch.

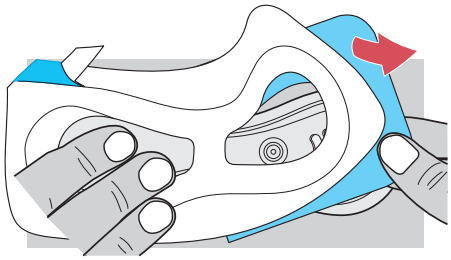


Figure 21 – Remove blue liners

Step 5: Remove Second Blue Liner

Repeat previous step for the remaining blue liner.

Step 6: Press Down

Press down the adhesive overlay to adhere it to the skin and VitalPatch.

Step 7: Peel Off Top White Liner

a. Peel off the top white liner starting with the bent tab. See **Figure 22**.

b. Press the overlay against the skin and VitalPatch with your other hand as you continue to remove the whole white liner.

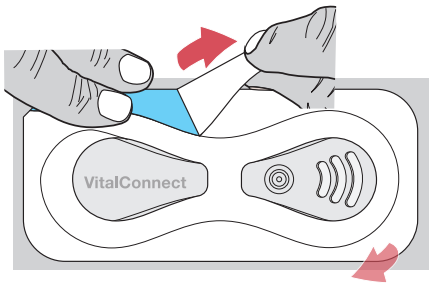


Figure 22 – Peel off top white liner at tab

Step 8: Seal Edges

Press down on the adhesive overlay to seal all the edges against the skin and VitalPatch. See **Figure 23**.

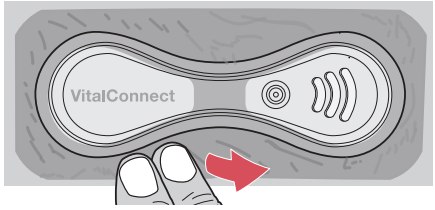


Figure 23 – Press down on overlay to seal all edges

Removing the Adhesive Overlay

To remove the adhesive overlay and the VitalPatch:

a. Grasp a corner of the overlay and pull it off the skin by stretching it horizontally to help release it from the skin. See **Figure 24**.

b. Continue peeling off the adhesive overlay and the VitalPatch.

If the VitalPatch does not come off with the overlay, remove the VitalPatch by peeling it from one end. See next section for more information on removing VitalPatch.

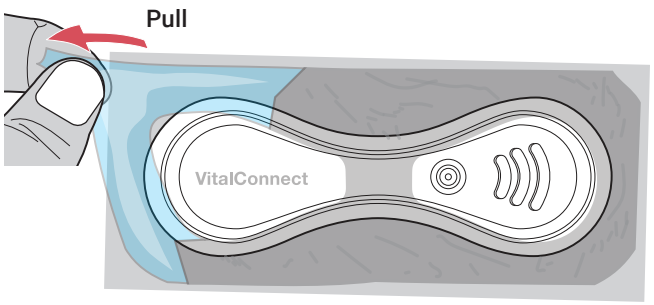


Figure 24 – Grasp corner of overlay and pull horizontally

Section 8: Removing and Returning the VitalPatch

Removing the VitalPatch

Disconnect the VitalPatch device according to your software application provider's user manual prior to removing the device from the patient.

When removing the VitalPatch device, use of an adhesive removal pad is recommended. Gently sweep the removal pad under the patch and pull away from skin. See **Figure 25**.

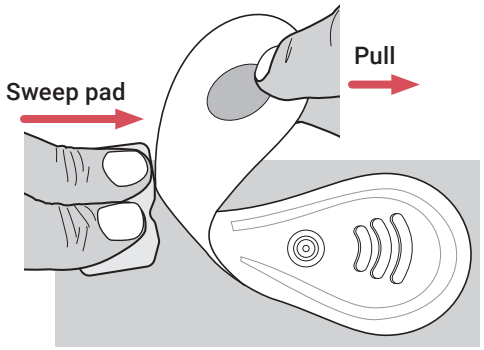


Figure 25 – Sweep adhesive removal pad while pulling off

Returning a Used VitalPatch Green

Note: The VitalPatch RTM does not need to be returned and can be disposed according to local laws for routine electronic waste.

The VitalPatch Green contains recyclable electronics and must be returned to VitalConnect along with the relay device. To return the VitalPatch Green:

1. Fold the patch in half so that the left and right sides are stuck together. See **Figure 26**.

2. Use scissors to cut the folded end of the patch. This step ensures the device is no longer operational.

3. Place the folded and cut patch into the recycle bag provided with the monitoring kit. Seal the bag closed. See **Figure 27**.

4. When finished with the monitoring period, place the recycle bag with all used patches into the monitoring kit for return.

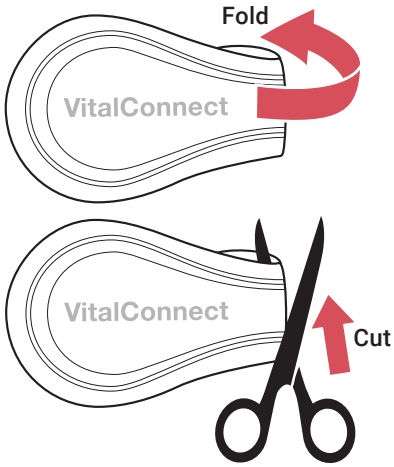


Figure 26 – Fold patch in half and cut with scissors

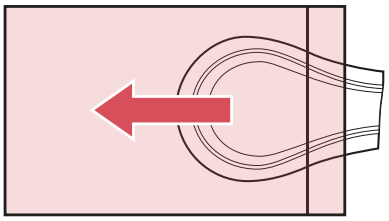


Figure 27 – Place in recycle bag

Section 9: Adverse Event Reporting

Adverse events and/or potential patient injury complications that are reasonably associated with the use of the VitalPatch and/or the Adhesive Overlay should be reported, as follows:

Region	Where to Report
USA	1. VitalConnect, Inc. 2. Users and patients can report to FDA at: https://www.accessdata.fda.gov/scripts/medwatch/
EU	1. VitalConnect, Inc. 2. The Competent Authority of the Member State in which the user and/or patient is established

Section 10: Product Specifications

VitalPatch Basic Specifications

Measurements	ECG Dynamic Range	-10mV to +10mV
	Heart Rate (stationary and ambulatory)	30 – 200 Beats per Minute (<±5 or 10% Beats per Minute, whichever is greater)
	Respiration Rate	• 10-30 Breaths per Minute with a mean absolute error of less than 3 Breaths per Minute, validated by clinical studies • 4-42 Breaths per Minute with a mean absolute error of less than 1.5 Breaths per Minute, validated by simulation studies
	Fall Detection	Fall or No Fall (> 90% Sensitivity and >98% Specificity)
	Step Count	< 5% Absolute Error Compared to Manual Count Step count is reset to 0 after step count 65535 is reached.
	Posture Detection	Lying down, Upright, Walking, Running, or Leaning (>70% Accuracy Compared to Visual)
	Body Temperature (VitalPatch RTM only)	32°C - 42°C (≤1°C, mean absolute error)
	Skin Termperature (VitalPatch RTM only)	15°C – 50°C (≤0.3°C)
Communications	Bluetooth (BT4.1)	• VistaTablet: Maximum 10m (30ft) line of sight • VistaPhone: Maximum 3m (10ft) line of sight
	Radio Modulation	FSK (Frequency Shift Keying)
	Radio Frequency	2.4 – 2.5GHz
	Transmit power	≤10dbm
	Security	AES-CCM 128 Bit Encryption (Advanced Encryption Standard-CCM mode)

Battery	Battery Type	Zinc Air
	Battery Voltage	DC 1.4V
	Battery Life	168 Hours
Operating Conditions	Ambient Temperature	10 – 40°C
	Humidity	10 – 95% RH (noncondensing)
	Altitude	<3000 m
	Barometric Pressure	70 kPa to 102 kPa
Physical Characteristics	Dimensions	120mm x 41mm x 9.5mm (4.7” x 1.6” x 0.38”)
	Weight	13g (0.46 ounces)

Electromagnetic Emission Declaration

The VitalPatch device is intended for use in the electromagnetic environment specified below. The end user of the device should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment
RF emissions CISPR 11	Group 1	The VitalPatch device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The VitalPatch device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

FCC Compliance (FCC ID: SPO-VCI-VP2)

The VitalPatch device 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 (FCC Title 47, Subpart A, Part 15.19(3)).

Changes or modifications not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment (FCC Title 47, Subpart A, Part 15.21)

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 (FCC Title 47, Subpart B, Part 15.105(b)):

- 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.

Guidance and Declaration – Electromagnetic Immunity (For ME equipment ME system that are not life-supporting)

The VitalPatch device is intended for use in the electromagnetic environment specified below. The end user of the device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment- guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the VitalPatch device than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.17\sqrt{P}$ (80 MHz to 800 MHz) $d = 2.33\sqrt{P}$ (800MHz to 2.7 GHz) where $\boldsymbol{P}$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $\boldsymbol{d}$ is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Note 3: UT is the a.c. mains voltage prior to application of the test level.

(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distance between portable and mobile RF communications equipment and VitalPatch (For ME equipment ME system that are not life-supporting)

The VitalPatch device is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The end user of the device can help prevent electromagnetic interference by maintaining a minimum

distance between portable and mobile RF communications equipment (transmitters) and the VitalPatch device as recommended below, according to the maximum output power of the communications equipment.

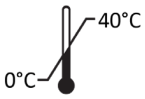
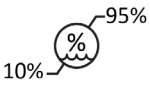
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**	
	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	**800 MHz to 2.7 GHz** $d = 2.33\sqrt{P}$
0.01	0.17	0.23
0.1	0.37	0.74
1	1.17	2.33
10	3.69	7.38
100	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance $\boldsymbol{d}$ in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where $\boldsymbol{P}$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. The VitalPatch device complies with the applicable requirements and relevant provisions of the Radio Equipment Directive 2014/53/EU (RED).

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Section 11: General Symbols

Symbol	Title	Symbol	Title
IP24 IP27	**IP24:** Protected against access by 12.5mm diameter solid object and splashing water. **IP27:** Protected against access by 12.5mm diameter solid object and submerging in water (up to 1 meter for 30 minutes). Note that the IP27 rating refers only to protection from solid and water ingress. The VitalPatch Bluetooth and batteries will not operate when submerged, so the VitalPatch is not approved for submersion or swimming.		
	Read instructions for use		Refer to instruction manual/booklet
	Properly dispose of EEE (Electrical and Electronic Equipment)		Non-ionizing radiation
	Defibrillation-proof type CF applied part		MR Unsafe
	Prescription only		Manufacturer
	Caution, consult documents		Not to be used in case package is damaged
	Catalogue number Batch code		Re-use is not allowed
	Use by date		Temperature limits (Storage)
	Humidity limits (Storage)		Contents (Numeral represents quantity of units inside)
	Medical Device		
	Underwriters Laboratories MEDICAL — PATIENT MONITORING EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005), "Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance; ANSI/AAMI/IEC 60601-2-25, "Medical Electrical Equipment - Part 2-25: Particular Requirements for the Basic Safety and Essential Performance of Electrocardiographs" E358758		