



Instructions for Use, VitalPatch® Biosensor



Device Description

The VitalPatch[®] device is a component of the patient monitoring 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, body temperature, skin temperature, fall detection, activity (including step count) and posture (body position relative to gravity including fall detection). The VitalPatch device can perform analysis of arrhythmia events including detection of ventricular ectopic beats, pause, atrial fibrillation or flutter, sinus rhythms (normal sinus rhythm, sinus bradycardia, sinus tachycardia), second degree AV block, supraventricular tachycardia, idioventricular rhythm, ventricular bigeminy, and ventricular trigeminy, and measurement of heart rate, PR interval, QT interval, corrected QT intervals (Bazett formula and Fridericia formula), and QRS duration for each rhythm. 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. The data provided by the VitalPatch device may also be intended for trained technicians at a Remote Site to review the ECG waveforms and determine if they concur with the analysis made by the algorithm in the VitalPatch device. 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.

Indications for Use

The VitalPatch device is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in 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). The device can perform analysis of arrhythmia events including detection of ventricular ectopic beats, pause, atrial fibrillation or flutter, sinus rhythms (normal sinus rhythm, sinus bradycardia, sinus tachycardia), second degree AV block, supraventricular tachycardia, idioventricular rhythm, ventricular bigeminy, and ventricular trigeminy, and measurement of heart rate, PR interval, QT interval, corrected QT intervals (Bazett formula and Fridericia formula), and QRS duration for each rhythm. The analysis of arrhythmia events is performed on the device.

The VitalPatch device is intended to be integrated with a patient monitoring platform. Data are transmitted wirelessly from the device to the patient monitoring platform for storage and analysis.

The VitalPatch 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 device are intended for use by healthcare professionals as an aid to diagnosis and treatment. The 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), analysis of arrhythmia events, 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.

The optional arrhythmia analysis feature is intended for use by healthcare professionals trained in the identification and treatment of arrhythmia events. Automated arrhythmia analysis is an adjunct to clinical assessment; clinician review of the analysis should precede any therapeutic intervention.

Contraindications

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

Warnings

- 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.
- Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon heart rate signals of the VitalPatch device. Keep pacemaker patients under close surveillance.
- Heart rate, ECG, arrhythmia events, heart rate variability, R-R interval, and respiratory rate will not be transmitted or stored if you select that the patient has a pacemaker.
- Pacemaker spikes are not rejected by the VitalPatch device and heart rate values may be inaccurate for patients with pacemaker. Do not rely entirely upon heart rate signals of the VitalPatch device for patients with pacemaker. Keep pacemaker patients under close surveillance.
- Respiratory rate values may be inaccurate for patients with pacemaker. Do not rely entirely upon respiratory rate signals of the VitalPatch device. Keep pacemaker patients under close surveillance.
- Disturbances to ECG signal including distortions due to pacing artifacts may occur when pacemaker is used simultaneously with the VitalPatch device.
- Paced cardiac rhythms are not detected by the VitalPatch device and arrhythmia monitoring may be compromised by other equipment, such as pacemakers or other stimulators, when used simultaneously with the VitalPatch device.
- Automated interpretation of arrhythmia by the VitalPatch device is a valuable tool when used properly. However, no automated interpretation is completely reliable, and a qualified physician shall review the interpretations before treatment, or non-treatment, of any 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 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.
- The healthcare professional will be notified when there are interruptions in data connectivity.
- 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 device. 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.

Additional Warnings and Precautions for Emergency Use Authorization (EUA)

The following additional warning and precautions apply when using the VitalPatch device under the Emergency Use Authorization for QT monitoring:

- The VitalPatch has neither been cleared or approved for remote monitoring and detection of changes in the QT interval of an ECG in patients who are undergoing treatment in a hospital setting for COVID-19 with drugs that can prolong QT intervals and may cause life threatening arrhythmias (e.g., hydroxychloroquine or chloroquine, especially when used in combination with azithromycin). Such remote monitoring may reduce HCP (health care personnel) exposure to SARS-CoV-2;
- The VitalPatch has been authorized for the above emergency use by FDA under an EUA;
- The VitalPatch has been authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
- **WARNING:** When used for drug-induced QT monitoring, the VitalPatch device is for hospital-use only.
- **WARNING:** The VitalPatch device is NOT to be used for drug-induced QT monitoring not related to COVID-19.
- **WARNING:** The VitalPatch device calculates QT intervals from single-lead ECG recordings. It is expected that QT intervals estimated from single-lead ECG recordings are likely to be equal or shorter than those derived from 12-lead ECG recordings. The clinician should consider this when interpreting the VitalPatch QTc measurements and setting the threshold for notification.
- **WARNING:** When interpreting the VitalPatch QTc measurement, single-channel ECG recordings should be reviewed for artifacts, T wave morphology changes, or lengthened QTc. QT measurements with the VitalPatch are unreliable in the presence of noise or artifacts. Relevant changes in morphology (e.g., the appearance of U waves) or QTc measurements should be further investigated using a standard 12-lead ECG.
- **WARNING:** QT measurements with the VitalPatch device may be unreliable in cases of motion or changes to heart rate. Consider taking QT measurements when the patient is at rest.
- VitalConnect recommends that a 12-lead ECG QT measurement be obtained to screen for QT prolongation and establish the baseline difference before initiation of corrected QT (QTc)-prolonging drug therapy for treatment of COVID-19. The described baseline should be used to track changes to the QT interval.
- The accuracy of the VitalPatch device for measuring QTc intervals has only been tested in healthy individuals. The device has not been validated to detect drug-induced QT prolongation.
- The accuracy of the VitalPatch device for measuring QTc has only been tested for a 1-minute average. The VitalPatch QT measurement for averaging periods of 2, 5, or 10 minutes has not been validated.
- Using the VitalPatch to measure QT intervals has only been tested with the recommended patch placement. The accuracy of QT measurement with nonstandard patch placement is unknown.
- Users have the option to disable additional types of arrhythmia detection that are provided by the monitoring software, but are not FDA cleared. For example, disable the following non-cleared arrhythmia types for detection:

- Sinus Bradycardia
- Sinus Tachycardia
- Second Degree AV Block
- Supraventricular Tachycardia
- Atrial Fibrillation
- Ventricular Bigeminy
- Ventricular Trigeminy
- Idioventricular Rhythm
- Pause
- Prolonged PR Interval
- Wide QRS Complex

Product Storage

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

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, including the *MAN-001, VitalConnect Platform Integration Manual – Developer Guide*.

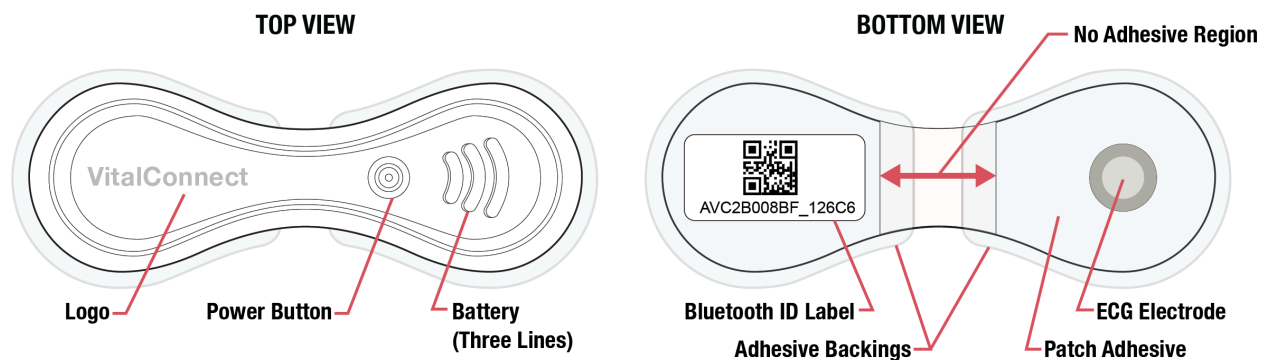
VitalPatch Operating Instructions

Note: It is recommended that healthcare providers advise users to replace the VitalPatch device after 120 or 168 hours (5 or 7 days) of use. To preserve data, the VitalPatch device must be connected to the Relay device prior to the end of battery life (120 or 168 hours). The device will no longer be usable after 120 or 168 hours.

VitalPatch Overview

Note: Orientation of the Logo Side and Battery Side are important when placing the device on the patient.

See image below for a view of the VitalPatch device, showing the logo side and battery side.



Product Handling

Ensure hands are clean and dry before handling the VitalPatch device. Gloves are recommended when handling the device.

When handling the VitalPatch device, do not touch the adhesive. The steps below should minimize the chance of touching the 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. See image to the right.



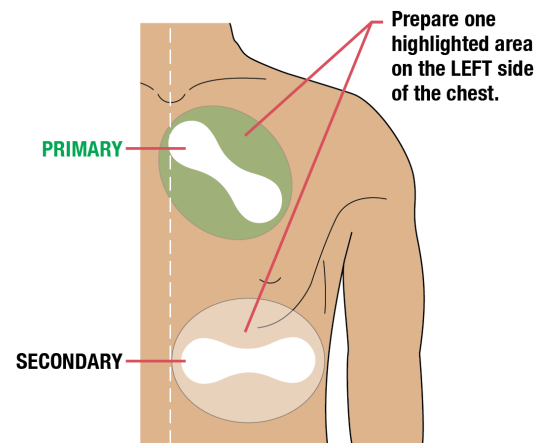
Skin Preparation and Application

Step 1: Prepare skin.

The primary application site is located on the upper left chest. If the device cannot be placed on the primary application site, use the secondary application site instead. The secondary application site is located just left of the centerline, below the chest on the rib cage. Do not use the secondary application site if arrhythmia detection is ordered. Consult your healthcare provider for additional guidance on the preferred application site.

For a good connection and proper operation, the VitalPatch device should NOT be worn over areas with a high concentration of body hair. Remove body hair in the area of device placement before applying the device. See image to the right.

For all patients, use an alcohol wipe to clean skin where the entire device will contact skin and allow site to dry. The application site should be free of oils and lotions to maximize adhesion.



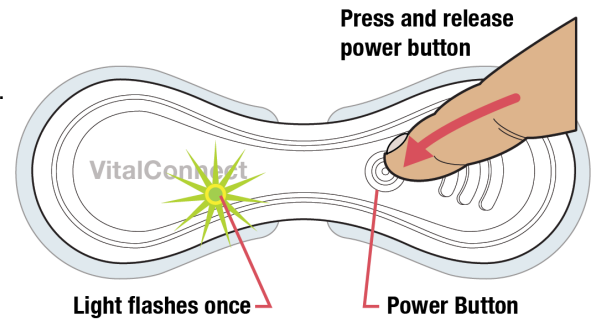
Step 2: Remove VitalPatch from pouch.

Tear open the pouch using the notch mark and remove the VitalPatch device carefully, to avoid pressing the Power Button.

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 to the patient. The Bluetooth ID number can be found on the pouch label or on the adhesive backing in both human readable and barcode formats. See image to the right.

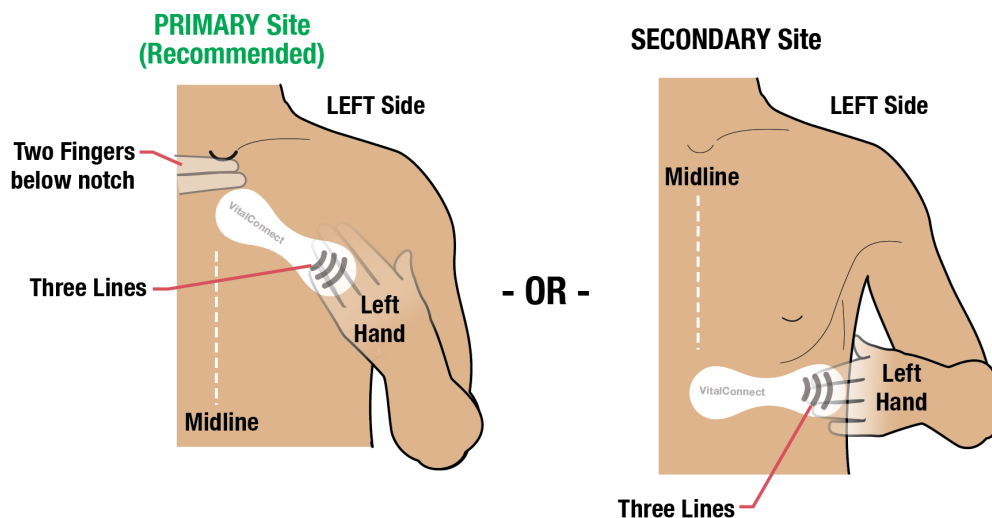
Step 3: Power-on VitalPatch.

Locate and press the Power Button. Look for a green light illuminating temporarily to confirm the device is powered on. See image to the right.



Step 4: Position VitalPatch on the body.

With the adhesive backings still adhered, place the VitalPatch device on a flat body surface on the left chest, with one electrode two fingers below the suprasternal (jugular) notch, and, ideally at a 45-degree angle. It is more important to locate the flattest surface of the chest for the VitalPatch device placement in order to minimize movement during the monitoring session. The three lines of the VitalPatch device should be pointed to the left side of the patient's chest. See image below.



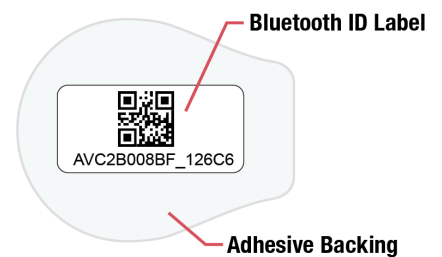
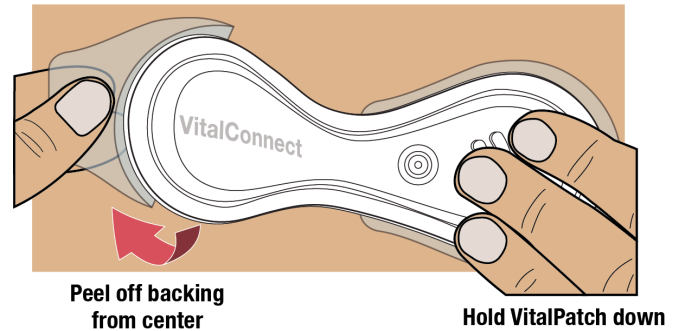
Note: The VitalConnect logo should be oriented such that it is readable by someone facing the patient when it is applied. The three lines will be closest to the left side of the chest.

If the device cannot be placed in the Primary Location use the Secondary Location instead. The Secondary Location is located just left of the centerline, below the chest on the rib cage, positioned horizontally in an area with minimal body curvature. This location is not recommended for obese persons. Do not use the secondary application site if arrhythmia detection is ordered. Consult your healthcare provider for additional guidance on the preferred application site.

Step 5: Apply VitalPatch to body.

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.



Step 6: Connect VitalPatch.

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.

Should the software application indicate that a "Patch off" event has been detected but the patch has not been removed – check if the patch has lifted from the skin. If it has noticeably lifted, remove the patch and replace with a new one following the Skin Preparation and Application steps described previously. Additionally, if multiple "Patch Off" notifications are received in a short period of time, remove the patch and replace with a new one.

Step 7: Calibrate Body Posture

Refer to your software application provider's user manual for instructions on how to calibrate the body posture. Perform the following steps as directed by the software application:

- Note the position of the VitalPatch on the chest (**Primary** or **Secondary**).
- Enter the VitalPatch position in the software application.
- 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.
- Enter the patient position in the software application.

Step 8: Calibrate Body Temperature

Note: Perform this step only if the body temperature measurement feature is supported by both the VitalPatch and your software application. Some versions of the VitalPatch and/or the software application may not support this feature.

Refer to your software application provider's user manual for instructions on how to calibrate the body temperature measurement feature. Perform the following steps as directed by the software application:

- 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.
- Take a body temperature measurement using a clinical-grade thermometer.
- Ensure the software application is configured for the measurement units of your thermometer (Celsius or Fahrenheit).
- Enter the measured body temperature in the software application.
- 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.

Step 9: Calibrate Pacemaker Status

Refer to your software applications provider's user manual for instructions on how to select whether or not the patient has a pacemaker. Perform the following steps as directed by the software application:

- If the patient has a pacemaker, enter the "Yes" option when prompted.
- If the patient does not have a pacemaker, enter the "No" option when prompted.

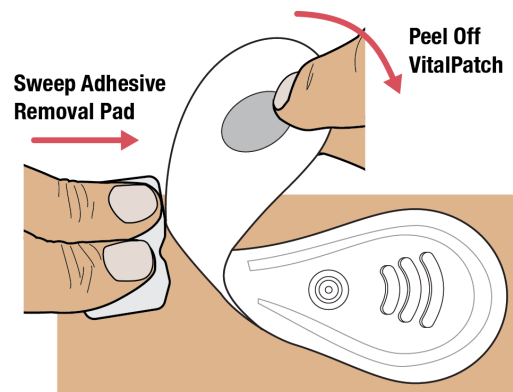
VitalPatch Removal and Disposal

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

Note: If the VitalPatch device has not been disconnected prior to removal, it will continue to generate and stream data until it is disconnected.

When removing the VitalPatch device, use of an adhesive tape remover is recommended. Gently sweep the remover pad under the device and pull away from skin. See image to the right.

Note: The VitalPatch device is Single Use Only. Do not reapply the device once it is removed.



Please observe local laws for disposal of battery-operated electronic products.

Troubleshooting

For issues related to a user interface application and for additional troubleshooting guidance, refer to separate Instructions for Use for the interface.

Contact Information

VitalConnect, Inc.

224 Airport Parkway, Suite 300

San Jose, CA 95110 USA

Phone: (408) 963-4600

www.vitalconnect.com

Customer Support

support@vitalconnect.com

855-757-9086

Product Specifications

Measurements	ECG Dynamic Range	Not available for patients with pacemakers. -10mV to +10mV
	Heart Rate (stationary and ambulatory)	Not available for patients with pacemakers. 30 – 200 Beats per Minute (± 5 or 10% Beats per Minute, whichever is greater)
	Respiration Rate	Not available for patients with pacemakers. <ul style="list-style-type: none"> ○ 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
	Body Temperature	32°C - 42°C ($\leq 1^\circ\text{C}$, mean absolute error)
	Skin Temperature	15°C – 50°C ($\leq 0.3^\circ\text{C}$)
	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)
	Arrhythmia	Not available for patients with pacemakers.
	Arrhythmia: Atrial Fibrillation (persists for ≥ 15 seconds)	Episode sensitivity and episode positive predictivity $\geq 70\%$
	Arrhythmia: Sinus rhythms (normal sinus rhythm at 60 to 100 beats per minute, sinus bradycardia ≤ 60 beats per minute, sinus tachycardia ≥ 100 beats per minute)	Episode sensitivity and episode positive predictivity $\geq 60\%$
	Arrhythmia: Second degree AV block (Sinus P wave not followed by a QRS/ more P waves than QRS)	Episode sensitivity and episode positive predictivity $\geq 60\%$
	Arrhythmia: Supraventricular tachycardia (≥ 5 consecutive premature supraventricular beats ≥ 100 beats per minute)	Episode sensitivity and episode positive predictivity $\geq 60\%$
	Arrhythmia: Idioventricular rhythm (≥ 4 consecutive Ventricular ectopic beats ≤ 100 beats per minute)	Episode sensitivity and episode positive predictivity $\geq 60\%$
	Arrhythmia: Ventricular bigeminy (≥ 3 pattern cycles)	Episode sensitivity and episode positive predictivity $\geq 60\%$
	Arrhythmia: Ventricular trigeminy (≥ 3 pattern cycles)	Episode sensitivity and episode positive predictivity $\geq 60\%$

	Arrhythmia: Pause (≥ 2 seconds without a QRS complex, and $< 4s$)	Sensitivity and positive predictivity $\geq 60\%$
	Arrhythmia: Ventricular ectopic beats (ventricular premature and escape beats)	Sensitivity and positive predictivity $\geq 60\%$
	Arrhythmia: Measurement of rhythm heart rate, PR interval, QT interval, corrected QT intervals (Bazett formula and Fridericia formula), and QRS duration for each rhythm	Detection Sensitivity and Positive predictivity $\geq 70\%$. Mean and standard deviation of absolute timing error $\leq 50ms$
	Pacemaker spikes	<ul style="list-style-type: none"> ○ VitalPatch device does not detect or display pacemaker spikes. ○ Disturbances to ECG signal including distortions due to pacing artifacts occur when tested per IEC 60601-2-47:2012. ○ Heart Rate values do not meet specifications for patients with pacemaker when tested per IEC 60601-2-27:2011 (± 2 mV to ± 700 mV amplitude, 0.1 ms to 2.0 ms pulse width). ○ Respiratory Rate values do not meet specifications for patients with pacemaker per simulation studies (± 2 mV to ± 700 mV amplitude, 0.1 ms to 2.0 ms pulse width).
Communications	Bluetooth (BT4.1)	Max. 10 Meters (30 Feet Line of Sight)
	Radio Modulation	FSK (Frequency Shift Keying)
	Radio Frequency	2.4 – 2.5GHz
	Transmit power	$\leq 10dbm$
	Security	AES-CCM 128 Bit Encryption (Advanced Encryption Standard-CCM mode)
Battery	Battery Type	Zinc Air
	Battery Voltage	DC 1.4V
	Battery Life	120 or 168 Hours
Operating Conditions	Ambient Temperature	10 – 40°C
	Humidity	10 – 95% RH (noncondensing)
	Altitude	< 3000 m
	Barometric Pressure	70 kPa to 102 kPa

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 P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and 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)














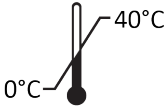
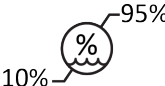


The VitalPatch device is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The end user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) 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 d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where 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.

General Symbols

Symbol	Title	Symbol	Title
IP24	Protected against splashing water	IP27	Protected against submerging in water (up to 1 meter for 30 minutes)
	Re-use is not allowed		Read usage instructions
	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
	Use by date		Temperature limits (Storage)
	Humidity limits (Storage)		Contents (Numeral represents quantity of units inside)
	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		

Document History

Revision	Description
Rev. 01	Initial release of this document.
Rev. 02	Modified IFU to include only non-lethal arrhythmias. Also, modified precaution statement on data connectivity.
Rev. 03	Updated precaution statements for data connectivity.
Rev. 04	Updated to include software option that allows user to select if the patient has a pacemaker. Updated to include ECG, HRV, and R-R interval as excluded if the patient has a pacemaker. Added statements indicating that arrhythmia detection is only supported in the primary position.
Rev. 05	Removed reference to 10 seconds with notification delay. Updated list of arrhythmias in device description, and indications for use. Updated product specifications for arrhythmia with performance metrics.
Rev. 06	Revision to intended use to answer FDA questions.
Rev. 07	Incorporate EUA verbiage