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, skin temperature, fall detection, activity (including step count) and posture (body position relative to gravity including fall detection). 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.

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, 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 device is not intended for use on critical care patients.

Contraindications

- The VitalPatch device is not intended for use on users who have implanted defibrillators or pacemakers.
- 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:
  o A severe adverse event
  o 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:
  o The VitalPatch device must be properly adhered to the patient.
  o The patient must remain in range of their Relay device.
  o 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.
  o 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.

• Patients with known sensitivities to metals may experience irritation or discomfort when using the VitalPatch device. If this occurs, the VitalPatch device should be removed.

• Patients with known sensitivities to metals may experience irritation or discomfort when using the VitalPatch device. If this occurs, the VitalPatch device should be removed.

• 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 – 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 hours (5 days) of use. To preserve data, the VitalPatch device must be connected to the Relay device prior to the end of battery life (120 hours). The device will no longer be usable after 120 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. 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.

**Note:** 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 angled diagonally toward the heart. The exact angle is not critical; 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 battery side of the VitalPatch device should be pointed to the left side of the patient's chest. See image to the right.

**Note:** The VitalConnect logo should be oriented such that it is readable by someone facing the patient when it is applied. The battery 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.
**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.

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**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.
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, refer to separate instructions for use for the interface and for additional troubleshooting guidance.

**Contact Information**

**VitalConnect, Inc.**
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San Jose, CA 95110 USA
Phone: (408) 963-4600
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30175 Hannover
Germany
Tel: +49 511 6262 8630
Fax: +49 511 6262 8633
## Product Specifications

<table>
<thead>
<tr>
<th>Measurements</th>
<th>ECG Dynamic Range</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>-10mV to +10mV</td>
</tr>
</tbody>
</table>

| 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 |

| Skin Temperature       | 15°C – 50°C (± 0.3°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) |

| 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 ≤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 Hours |

| Operating Conditions   | Ambient Temperature 10 – 40 °C |
|                       | Humidity 10 – 95% RH |
|                       | 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.

<table>
<thead>
<tr>
<th>Emission test</th>
<th>Compliance</th>
<th>Electromagnetic environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>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.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class B</td>
<td>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.</td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment- guidance</th>
</tr>
</thead>
</table>
| Radiated RF IEC 61000-4-3   | 10 V/m 80 MHz to 2.5 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:

\[
d = \begin{cases} 
1.17\sqrt{P} & \text{80 MHz to 800 MHz} \\
2.33\sqrt{P} & \text{800 MHz to 2.5 GHz}
\end{cases}
\]

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 should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

| Electrostatic discharge (ESD) | ± 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%.

\[±8\text{kV}\] \[±15\text{kV}\]
Power frequency magnetic field
IEC 61000-4-8

<table>
<thead>
<tr>
<th>Power frequency (50/60 Hz) magnetic field</th>
<th>30 A/m</th>
<th>30 A/m</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter (W)</th>
<th>Separation distance according to frequency of transmitter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>80 MHz to 800 MHz</td>
</tr>
<tr>
<td>0.01</td>
<td>0.17</td>
</tr>
<tr>
<td>0.1</td>
<td>0.37</td>
</tr>
<tr>
<td>1</td>
<td>1.17</td>
</tr>
<tr>
<td>10</td>
<td>3.69</td>
</tr>
<tr>
<td>100</td>
<td>11.67</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Title</th>
<th>Symbol</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>IP24</td>
<td>Protected against splashing water</td>
<td>IP27</td>
<td>Protected against submerging in water (up to 1 meter for 30 minutes)</td>
</tr>
<tr>
<td>🚩</td>
<td>Re-use is not allowed</td>
<td>📚</td>
<td>Read usage instructions</td>
</tr>
<tr>
<td>🚬</td>
<td>Properly dispose of EEE (Electrical and Electronic Equipment)</td>
<td>📡</td>
<td>Non-ionizing radiation</td>
</tr>
<tr>
<td>🚫</td>
<td>Defibrillation proof type CF applied part</td>
<td>📡</td>
<td>MR Unsafe</td>
</tr>
<tr>
<td>🏫1434</td>
<td>CE Marking conformity</td>
<td>📡</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>🙁</td>
<td>Caution, consult documents</td>
<td>🚫</td>
<td>Not to be used in case package is damaged</td>
</tr>
<tr>
<td>🇲️ RX</td>
<td>Prescription only</td>
<td>🇲️ EC</td>
<td>Authorized Representative in the European Community</td>
</tr>
<tr>
<td>📕</td>
<td>Catalogue number</td>
<td>🍀</td>
<td>Batch code</td>
</tr>
<tr>
<td>🕒</td>
<td>Use by date</td>
<td>🌡️</td>
<td>Temperature limits (Storage)</td>
</tr>
<tr>
<td>🌡️</td>
<td>Humidity limits (Storage)</td>
<td>🌡️</td>
<td>Contents (Numeral represents quantity of units inside)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>🌡️</td>
<td></td>
</tr>
<tr>
<td>🍀 only</td>
<td></td>
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Underwriters Laboratories