VITAL CONNECT™ PLATFORM

INSTRUCTIONS FOR USE, VITALPATCH

Device Description

The Vital Connect Platform is a wireless physiological monitoring system. The Vital Connect Platform was developed with an Application Programming Interface intended to allow development of user interface applications enabling healthcare professionals to access collected vital information. The platform consists of:

- Vital Connect Sensor (includes adhesive Patch and Sensor Module)
- Relay Software Library
- Server Software Library (Optional)

The Vital Connect Sensor is a battery-operated adhesive patch with integrated sensors and wireless transceiver, 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 Vital Connect Sensor 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. The encrypted wireless data provided by the Sensor 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. In addition, the wireless data may be transferred to the Vital Connect Secure Server where they are stored for analysis with the deployment of the server.

During normal operation, data are collected on the Vital Connect Sensor and transmitted to the Relay immediately. A continuous connection is needed between the Sensor and the Relay in order to facilitate continuous data transmission. The continuous wireless transmission of the data occurs with a delay or latency of seconds between continuous data collection and transmission. Data can be stored and downloaded from the Relay. Data can continue to be transferred to the Vital Connect Server with a server connection.

Authorized healthcare professionals can configure the system parameters via the API to generate notification of changes in measured data. With the connection to the Secure Server, a notification is triggered when configured physiologic data parameters are exceeded. Notification can be transmitted to a generic display device (i.e. smartphone, tablet, PC or monitor).

The Vital Connect Patch is available in two different adhesive configurations: Active (Hydrocolloid adhesive) and Gentle (Silicone adhesive). Silicone adhesives provide lower skin stress during removal than hydrocolloid. However, in high humidity or perspiration conditions silicone adhesives can cause mild irritation and have reduced adhesion.

Indications for Use

The Vital Connect 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 Vital Connect Sensor for storage and analysis. The Vital Connect 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 Vital Connect 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 device is not intended for use on users who have implanted defibrillators or pacemakers.
- The device is not intended as a stand-alone diagnostic monitor, 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 VitalConnect Sensor module for transfer once connectivity is reestablished.
- The nature of silicone or hydrocolloid adhesives may cause adverse skin reactions. Healthcare providers should advise patients to seek medical attention if a severe adverse event or allergic reaction occur and/or persist beyond 2-3 days.
- Histories of skin irritations should be considered before placing the patch on a patient.
- Do not place device on broken skin.
- This device is not intended to replace appropriate medical supervision and safe practices.
- Clinical validation has not been performed on patients who are pregnant or breastfeeding.
- Do not use this device during an MRI scan or in a location where it will be exposed to strong electromagnetic forces.

Precautions:

- For data to be sent to a healthcare professional for review.
    - The battery must have adequate power for data transmission. Notification will indicate that the battery power is low.
    - The patch must be attached to the patient. Notification will indicate if the patch is off the body or not properly attached.

  - The patient must remain in range of their relay (i.e. smartphone, PC, tablet, body worn cellular modem or wall mount device). Notification will indicate that the sensor has disconnected from the relay.
  - The relay must remain charged and functional for data transmission. Wireless connectivity must be active for transmission of data from the relay to the server.
- Healthcare providers must be aware if uninterrupted continuous data monitoring is necessary for patient safety, treatment in home setting may not be appropriate. If considered medically necessary, additional measures may be taken to ensure appropriate care and monitoring is provided to meet the clinical need.
- If connected to other devices/system through the same user interface (i.e. mobile phone), while connected to the Vital Connect System via a Bluetooth connection, please note that performance of either or both Bluetooth connected devices/system could potentially be affected.
- Similar devices may cause signal interference during data transmission. If you experience this affect, steer clear of interfering devices.
- Do not use the device if the package has been opened, or appears used, damaged, or expired.
- Do not wear device over excessive body hair in the torso area. Excessive body hair should be removed several hours before application.
- Do not use the Silicone adhesive device when showering or bathing.
- Hydrocolloid adhesive device will adhere in moist environments. It will not be damaged while showering. Minimize exposure directly under the shower head, excessive contact with soap, or scrubbing. Gently dry device after showering. Submersing the device or using in a sauna is not recommended. If submersion occurs the duration must be less than 5 minutes and less than 18 inches in depth.
- If discomfort or irritation occurs in patient, device should be removed. If using a Silicone adhesive device, you may transfer it to another recommended torso location. Wear only one device at a time.
- If you experience mild soreness or redness 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 device may cause malfunction or permanent damage.
- Keep the device away from children and pets. The device may be a choking hazard, and may be harmful if swallowed.
- If any component of your Vital Connect System fails to operate after attempting all suggested troubleshooting methods, contact your healthcare provider immediately.
- Clinical validation performed in elderly population, including elderly subjects (Age 59 to 86) with a BMI (Body Mass Index) range of 13.5-59.5 kg/m^2.
- Dispose Vital Connect Patch per local laws, care facility laws or hospital laws.

Storage and Handling

- Storage temperature range: 0 – 40^{o} C
- Storage relative humidity range: 10 – 95% RH
- Ensure your hands are clean and dry before handling the patch and sensor module. Gloves are recommended for healthcare professionals when handling the re-usable module.

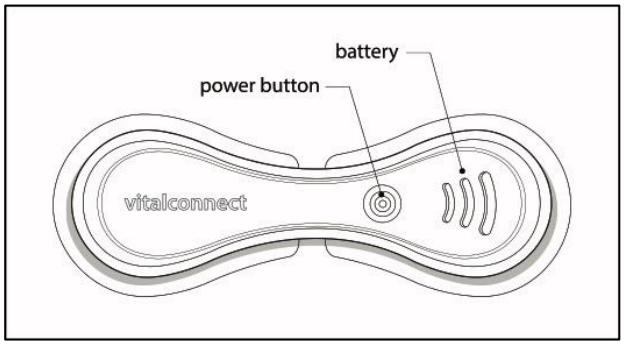
System Interoperability

The Vital Connect platform is developed with an Application Programming Interface (API) intended to allow development of user interface applications enabling healthcare professionals to access collected vital information. Please contact Vital Connect, Inc. to obtain implementation information, including the Vital Connect Platform Integration Manual – Developer Guide.

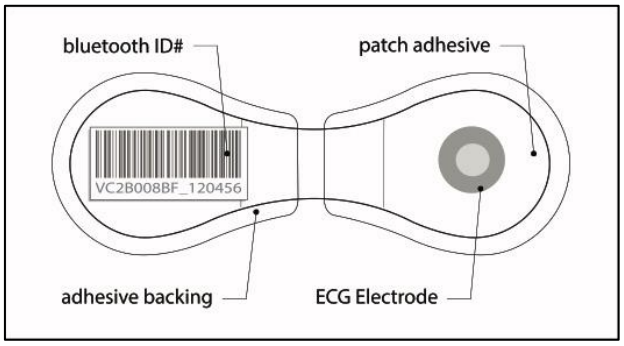
VitalPatch Operational Instructions

VitalPatch Overview

Top



Bottom view

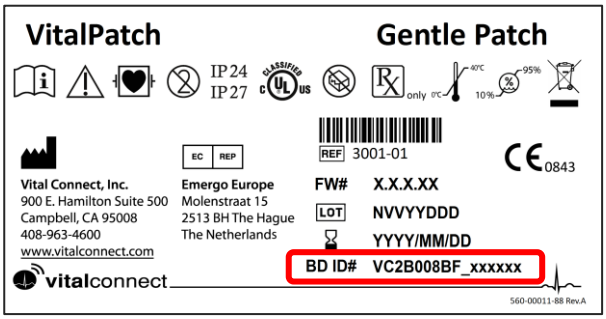


Skin Preparation and Application

1. Remove from pouch

Tear open the pouch and remove the VitalPatch carefully to avoid pressing the Power Button.

Retain the pouch or the adhesive backing with the device Bluetooth ID #. You will need this information to connect to your software application after the patch is applied.

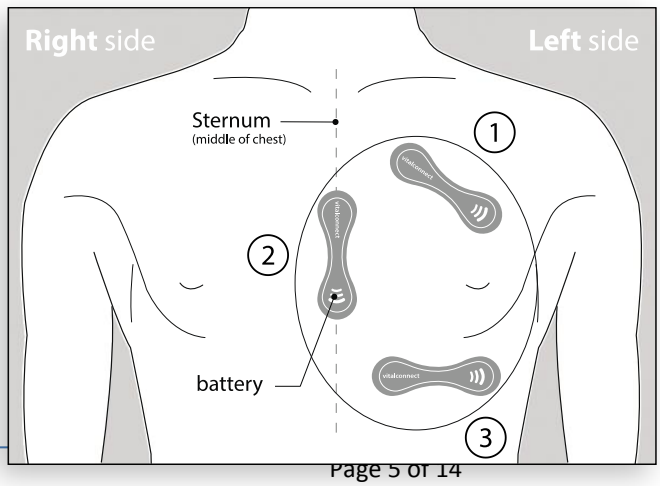


2. Prepare skin

Select a location for patch placement within the oval region (adjust placement away from nipple and armpit):

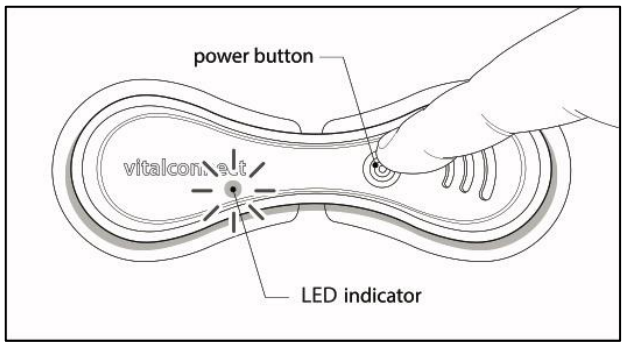
1) **Upper chest at a 45 degree angle**
2) **Center of the chest on the sternum**
3) **Below chest on the rib cage.**

For men, shave chest hair where the patch will be applied. Use isopropyl alcohol to clean skin and allow site to dry.



3. Power on

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



4. Apply to Left Chest

Follow the battery orientation indicated in step 2 for proper patch placement. Remove the adhesive backings from the patch and apply to your prepared skin. Press down on both ends of the patch to ensure it is well adhered to your skin. Avoid exercise for at least 30 minutes after patch application.

Connect

Important: Refer to your software application provider's user manual for more instructions on how to connect to the VitalPatch. A connection is required to establish a start time in the data file. After connecting, walk approximately 30 steps to automatically calibrate posture. For calibrating your VitalPatch manually, refer to your software application provider's user manual.

Removal and Re-application

A. Gentle VitalPatch

Grip one end of the patch and pull away from skin. Place the patch adhesive side up on a clean and dry surface away from reach of children, pets, direct sunlight, and AC/fans, etc. Remove the patch prior to showers and baths.

Gentle VitalPatch can be reapplied up to 3 times during the intended use of the device. Reapply used patch on clean and dry skin.

B. Active VitalPatch

Use of an adhesive tape remover is recommended. Gently sweep the remover pad under the patch and pull away from skin.

Active VitalPatch cannot be reapplied.

For application of a new patch, it is recommended to use a different location within the oval application area.

Disposal

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

It is recommended that healthcare providers advise users to replace a patch after

- **72 hours of continuous monitoring of all Vital Connect Platform measurements or,**
- **96 hours of continuous monitoring of all Vital Connect Platform measurements except ECG (ECG monitoring is turned off).**

Troubleshooting

Basic troubleshooting includes the following:

- Make sure that the "Vital Connect Patch Operational Instruction" have been followed.

- If the Patch is lifting from the skin surface, press down firmly on the areas of the Patch that lifted to reattach it to the skin. If the problem persists, use a new patch.

- For other issues, attempt the following:
    - Restart the application and reconnect to the Vital Connect Sensor. Or if that does not resolve the issue, then
    - Turn off Bluetooth. Turn back on Bluetooth. Start the application and reconnect to the Vital Connect Sensor. Or if that does not resolve the issue, then
    - Power down the relay. Turn back on the relay. Start the application and reconnect to the Vital Connect Sensor.

Issues that need troubleshooting may relate to the user interface application developed by mobile healthcare professionals to use with the Vital Connect Platform. For example, messages such as "Communication not established", "Communication lost", "Battery low", "Bad Battery", may be generated as part of the functionalities of the user interfacing. Please refer to their instructions for use for additional troubleshooting guidance. For additional information regarding the proper use of the Vital Connect Platform and mobile service provider user interface, please contact the prescribing physician, caregiver, or healthcare providers.

Vital Connect Contact Information

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Product Specifications

Measurements	Specifications
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
Skin Temperature	15^0C – 50^0C (≤± 0.3^0C)
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)
System Specifications	
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	72 Hours with all measurements 96 hours with ECG monitoring turned off
Operating Conditions	
Ambient Temperature	10 – 40 ^{o} C
Humidity	10 – 95% RH
Altitude	<3000 m
Barometric Pressure	70 kPa to 102 kPa

Electromagnetic Emission Declaration		
Vital Connect Sensor is intended for use in the electromagnetic environment specified below. The end user of the Vital Connect Sensor should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment**
RF emissions CISPR 11	Group 1	Vital Connect Sensor 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	Vital Connect Sensor 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-VP1**

- This Vital Connect Platform 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.

Canada License-exempt
• **IC ID:11013A-VCIVP1**
• This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device. • Le present appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisee aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioelectrique subi, meme si le brouillage est susceptible d'en compromettre le fonctionnement.

Guidance and declaration – electromagnetic immunity
(For ME equipment ME system that are not life-supporting)

Vital Connect Sensor is intended for use in the electromagnetic environment specified below. The end user of the Vital Connect Platform (including Vital Connect Sensor) 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	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Vital Connect Platform 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 2.5 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: 

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.
[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 Vital Connect Platform is used exceeds the applicable RF compliance level above, the Vital Connect Platform should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Vital Connect Platform. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Guidance and declaration – electromagnetic immunity

(For ME equipment ME system that are not life-supporting)

Vital Connect Sensor is intended for use in the electromagnetic environment specified below. The end user of the Vital Connect Platform (including Vital Connect Sensor) should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment- guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T *is* the a.c. mains voltage prior to application of the test level.			

Recommended separation distance between portable and mobile RF communications equipment and Vital Connect Platform

(For ME equipment ME system that are not life-supporting)

Vital Connect Sensor is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The end user of the Vital Connect Platform (including Vital Connect Sensor) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Vital Connect Platform Sensor 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 kHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 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.

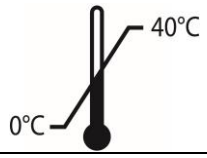
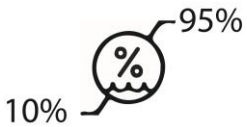
Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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
IP24	Protected against splashing water
IP27	Protected against submerging in water (up to 1 meter for 30 minutes)
	Re-use is not allowed

Symbol	Title
	Read usage instructions
	Properly dispose of EEE (Electrical and Electronic Equipment)
	Non-ionizing radiation
	Defibrillation proof type CF applied part
	MR Unsafe
	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; CAN/CSA-C22.2 No. 60601-1:08; ANSI/AAMI/IEC 60601-2-25, "Medical Electrical Equipment - Part 2-25: Particular Requirements for the Basic Safety and Essential Performance of Electrocardiographs" E358758
	CE Marking conformity
	Manufacturer
	Caution, consult documents
	Not to be used in case package is damaged
	Prescription only
	Authorized Representative in the European Community

Symbol	Title
	Catalogue number
	Batch code
	Use by date
	Temperature limits (Storage)
	Humidity limits (Storage)