

Instructions-For-Use (IFU) & Information Guide

IFU-01

Instructions For Use (IFU) & Information Guide

This document provides instructions and information for the VitalConnect Platform, also referred as Wireless physiological monitoring system. VitalConnect platform is developed as an Application Programming Interface (API), intended to be used as a programming platform to allow mobile health care services providers to develop user interface applications enabling the users (i.e. physician, caregiver, patients) to view and/or access collected vital information. The platform consists of:

1. VitalConnect Sensor
2. VitalConnect Relay Software Library
3. VitalConnect Secure Server Software Library

User Assistance information

For additional information regarding the proper use of the VitaConnect Platform and mobile service provider user interface, please contact the prescribing physician, caregiver, or health care provider.

Device Description

The VitalConnect Platform consists of the VitalConnect Sensor, Relay Software Library, and Server Software Library. The VitalConnect Platform is accessible via an application program interface (API) that allows authorized persons to receive data and notifications generated by the system.

The VitalConnect 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, respiratory rate, skin temperature, fall detection, step count and posture. The sensor continuously gathers physiologic data and then transmits the data via a Relay Software Library managed bi-directional relay device to a central server controlled by the Server Software Library, where the data is stored for analysis by healthcare professionals and researchers.

Authorized healthcare professionals can configure the system parameters via the API to generate notification of changes in measured data. 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).

VitalConnect Platform sub-systems include:

1. VitalConnect Sensor
 - a) Patch

The Patch is designed as a low cost disposable self-adhesive interface to the body.

- b) Sensor Module

Residing within the patch, the sensor module performs processing functions related to capture of physiologic data and also performs bi-directional communication with the relay device.

2. VitalConnect Relay Software Library
The Relay Software Library manages bi-directional communication between the Sensor Module and the Server Software Library and is installed on a relay device.
3. VitalConnect Server Software Library
The Server Software Library is installed on a central server, manages the upload, processing and storage of sensor data, as well as real-time configuration of and notifications from the VitalConnect Platform.

Antenna Description

The VitalConnect Sensor Module utilizes a Fractus Micro Reach Xtend 2.4GHz Chip Antenna (part #FR05-S1-N-0-110) in order to communicate via Bluetooth low energy to the relay. This antenna is a linear, omnidirectional, monopole antenna that operates in the 2.4-2.5GHz range. The antenna is connected to the Bluetooth transceiver through a 2 inductor matching network that has been optimized to maximize the power radiated by the antenna and minimize the voltage standing wave ratio (VSWR). The product is for use with BT 4.0 only.

Indications for Use

- The VitalConnect Platform is a wireless monitoring system intended for use by healthcare professionals and researchers for unattended surveillance of patient physiologic data. This includes heart rate, electrocardiography (ECG), heart rate variability, respiratory rate, skin temperature, fall detection, step count and posture. Data is transmitted wirelessly to a central location where it is stored for analysis. The VitalConnect Platform can be configured by Authorized Persons to notify healthcare professionals when physiologic data falls outside selected parameters.
- The VitalConnect Platform is intended for use on general care patients which are at least 18 years of age. It is not intended for use on critical care in-patients. It is not intended as a diagnostic or alarm device.

Information Guide:

General Warnings and Precautions:

Warning:

- No modification to the VitalConnect Sensor is permitted.
- No modification to the relay is permitted.
- Do not wear VitalConnect Sensor if you are under the age of 18.
- Do not wear VitalConnect Sensor, without the consent of your healthcare provider, if you have implanted defibrillators.
- Do not wear VitalConnect Sensor, without the consent of your healthcare provider, if you have implanted pace-makers.
- Do not wear VitalConnect Sensor if you are Pregnant or breastfeeding
- If you are wearing a VitalConnect Sensor and plan on traveling on an airplane, contact your service provider for instruction.
- All components of VitalConnect Sensor should be kept out of the reach of children, pets, or anyone who may swallow components or otherwise be at risk of being harmed by components. If any component is swallowed, seek emergency medical attention immediately.
- Do not share your patch or sensor components with others to avoid damage to your device, potential harm to others, and/ or risk of contamination.
- Do not use a patch if the container has been opened or appears to have been used or damaged.
- Do not make any modifications to any components of the VitalConnect System, unless otherwise instructed by Vital Connect Inc. and its approved affiliates.
- If connected to other devices/system through the same user interface (i.e. mobile phone), while connected to the VitalConnect System via a Bluetooth connection, please note that performance of either or both Bluetooth connected devices/system could potentially be affected.

Caution:

- Do not wear a “previously used” patch beyond its recommended life cycle of three (3) days.
- You may experience slight discomfort and/or itchiness as a result of wearing silicone or acrylic adhesive materials. If you experience discomfort or irritation, beyond mildly tolerated symptoms, please remove patch immediately.
- It is possible to experience mild soreness and/or redness after the removal of a patch. If you experience this affect, do not wear the patch in the same area.
- Adverse skin reactions may occur due to the nature of this product containing silicone or acrylic adhesives. Should event of adverse or allergic reactions occur and persist beyond two to three (2-3) days, contact your healthcare provider for further consultation.
- Do not wear patch and module while swimming.
- Protect the silicone adhesive patch and sensor module units from excessive moisture and/or sweating to avoid product malfunction and lack of proper adhesion.
- Module and patch will not be damaged while showering or bathing if properly sealed. Do not submerge in more than 18 inches of water.
- Patient / end user physiological signal values shall be set within the allowable configured minimum and maximum range.
- Connectivity and data transmission of device may be interrupted while under water. Reconnect your device once you are out of the water after allowing for drying time.
- Handle the VitalConnect System with care and according to instruction of use.
- Incorrect handling, use of excessive force, or dropping of any components of the VitalConnect System may cause malfunction and/or permanent damage to the patch and sensor module.
- Keep VitalConnect Sensor components away from excessive heat exposure, as this may cause damage.
- To ensure optimal performance of the VitalConnect System, avoid wearing the VitalConnect Sensor while undergoing any medical imaging procedures such as MRI, CT, X-ray, PET, etc.
- If any component of your VitalConnect System fails to operate after attempting all suggested troubleshooting methods, contact your product provider immediately.
- Do not dispose the patch and battery in a household trash bin. Dispose per local laws, care facility laws or hospital laws.
- If the patch or sensor module becomes un-responsive and unable to link, remove the module from the patch and replace it in a new patch. If it is still un-responsive and unable to link, replace the module. User will be notified of the failure via a text message on the relay (i.e. phone).
- When traveling in a car, vital data collected by the sensor module may not be transmitted to the server, due to the unavailability of Bluetooth (the amount of data collected by the module is depends on the sensor module memory size).
- When traveling on an airplane, vital data collected by the sensor module will not be transmitted to the server, due to the unavailability of Bluetooth (the amount of data collected by the module is depends on the sensor module memory size).

General Information:

- VitalConnect Sensor is tested by UL for electrical safety in accordance with IEC 60601-1-1
- VitalConnect Sensor is tested by UL for electromagnetic compatibility in accordance with IEC 60601-1-2
- Vital Connect Sensor complies with the Essential Performance defined in 60601-1, amendment 1: “performance of a clinical function, other than that related to BASIC SAFETY, where loss or degradation beyond the limits specified by the MANUFACTURER results in an unacceptable RISK”, either with applicable testing or via user documentation.
- VitalConnect system is tested by UL for FCC in accordance with ANSI C63.10-2009, FCC CFR 47 Part 2, FCC CFR 47 Part 15, RSS-GEN Issue 3, and RSS-210 Issue 8.
- Electronic components are RoHS compliant.
- Patch top layer and adhesive is medical grade.
- Software failure, firmware failure or battery failure has no adverse effect on the end-user. The failure would vital data collection and transmission. In the event this occurs, the end-user or service provider will be notified as applicable.
- VitalConnect Sensor is:
 - Type BF applied part
 - Not reusable
 - IPX4, protected against water spray
 - IPX7, protected against water submersion
- No installation or maintenance is required.
- The patch is intended for a one-time use, for up to 3 days.
- The battery is not rechargeable. It’s intended for a one-time use for the life of the patch which is up to 3 days.
- The system does not display any messages
- Start-up process is not included in this manual. This IFU is not intended for the end-user.
- Shutdown procedure is not included in this manual. This IFU is not intended for the end-user.
- No cable or physical connection required. The only connection is the Sensor Module to the Patch (as shown in General Description below).
- Vital Connect Sensor should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, Vital Connect Sensor should be observed to verify normal operation in the configuration in which it will be used.
- Packaging label is legible within 90 degree viewing angle of the label.
- Packaging label is legible within distance of 50 cm (20 inches)
- Packaging label is legible within 500 lux – 1000 lux lighting (i.e. foot-candles)

Recommendations:

- For a good connection and proper operation, the VitalConnect Sensor should NOT be worn over areas with a high concentration of body hair in the torso area. Removal of body hair on the torso area is recommended before placing the VitalConnect Sensor.
- Recommend gently wiping the sensor module with a damp cloth, after every use
- Recommended operating temperature range: 10 - 43 deg C
- Recommended shipping and storage temperature range: 0 – 50 deg C
- Recommended shipping and storage relative humidity range: 10 – 95% RH
- Recommended operating relative humidity range: 10 – 95% RH
- Recommended operating altitude: < 2000 m
- Recommended barometric pressure: 80 kPa

Data Accuracy:

Data accuracy for the following attributes is measured through various bench testing test cases in compliance with ANSI/AAMI/IEC 60601-2-47: 2012. They include:

- clause 201.12.4.4.101, Linearity and Dynamic Range,
- clause 201.12.4.4.102, Input Impedance
- clause 201.12.4.4.103, Common Mode Rejection
- clause 201.12.4.4.104, Gain Accuracy
- clause 201.12.4.4.105, Gain Stability
- clause 201.12.4.4.106, System Noise
- clause 201.12.4.4.108, Frequency Response
- clause 201.12.4.4.110, Timing Accuracy
- clause 201.12.1.101.3.1, Heart Rate
- clause 201.12.1.101.3.7, ECG Hard Copy

Error Codes/ Description:

VitalConnect Platform is capable of generating the following user error message:

- Communication not established
- Communication lost
- Battery low
- Bad battery

Service Provider:

- In the event the Internet is interrupted, Service Provider should notify the end-user (patient) that patient vital data is not being transmitted.
- Provide detail use instruction and information on the user interface application.

FCC:

FCC ID : SPO-VCI-Module

IC: 11013A-VCIMODULE

- This 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.

Electromagnetic Compatibility (EMC):

- Vital Connect Sensor may need special precautions regarding EMC and should be used according to the EMC information provided in the “Warning” and “Caution” sections of this document.
- Portable and mobile RF communications equipment can affect Vital Connect Sensor. See Medical Electrical Equipment user manual for RF communication precautions.
- Type of radio modulation, frequency and antenna power is follows:
 - Radio modulation: FSK (frequency shift keying)
 - Frequency: 2.4 – 2.5GHz
 - Antenna power: 4dbm.


Electromagnetic Emission Declaration

Vital Connect Sensor (i.e. patch model #: 545-00006-00 and module model #: 600-0001-00) is intended for use in the electromagnetic environment specified below. The patient or 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.

**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	<p>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.</p> <p>Recommended separation distance</p> <p>$d = 1.81 \sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 3.69 \sqrt{P}$ 800MHz to 2.5 GHz</p> <p>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).</p> <p>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.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

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	0.3 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	800 kHz to 2.5 GHz
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

The following marking information will be placed on the package:



Description:

VitalConnect Sensor Patch, (Patch Model No.: 545-00006-00, Sensor Model No.: 600-00001-00)

CAUTION:

- Do not place device on broken skin. If irritation develops, discontinue use
- For individual use only
- Do not use if package has been opened
- Do not use if you have an implanted device such as a pacemaker

For detail information, see Instructions for use

Manufactured by:
Vital Connect, Inc.
2105 S. Bascom Ave
Campbell, CA 95008
408-963-4600
www.vitalconnect.com



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

Recommended shipping and storage temperature range: 0 – 50 deg C
Recommended shipping and storage relative humidity range: 10 – 95% RH

VitalConnect Platform

VitalConnect platform consists of the following sub-systems:

1. VitalConnect Sensor
2. VitalConnect Relay Software Library
3. VitalConnect Secure Server Software

Instruction for use for the Mobile Healthcare Service Provider

1. VitalConnect Secure Server Software Library
 - a) Download Software
 - 1) Goto www.vitalconnect.com
 - 2) Select Download
 - 3) Select Server Software
 - 4) Select Media (location to download the software application)
 - 5) Login using Vital Connect provided user ID, and user assigned password
 - 6) Select “Start Download”
 - b) Ensure that applicable software tools, drivers, etc. have been properly installed to allow communication between the “server software library”, “service provider user interface application” and the “relay software library”.
 - c) Configure user parameters as required (relay software library and server library).
 - d) Prepare and provide user with additional user instruction as applicable.
2. Ensure that VitalConnect Relay intended to collect end user vital data is functional.

Instruction for use for the end-user

1. Unpack the relay module and plug into a 110-120Vac outlet.
2. Confirm that the green LED light is “on” on the module.
3. Follow VitalConnect Sensor assembly and use instruction below.

Start-up process:

Note: this process only applies to the end user.

1. Unpack the VitalConnect Sensor box.
2. Follow the assembly instruction provided in the VitalConnect Sensor box.
3. If the VitalConnect Sensor is assembled and placed on the torso per the IFU, physiologic data should be automatically collected and transmitted to the server designated by the Service Provider.

Shut-down process:

1. Remove VitalConnect Sensor from torso.
2. Remove sensor module (see IFU).
3. Physiologic data collection and transmission will stop.
4. To use a new patch, follow steps 2 and 3 of the “Start-up process”.

VitalConnect Sensor - Assembly Instruction (bottom entry):

Sensor Module

Module
Connector



Figure 1: Front logo side

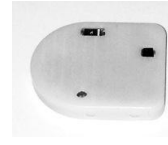
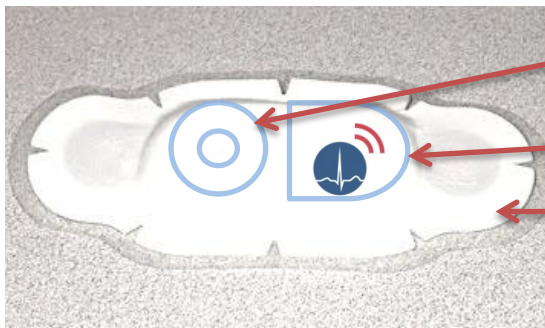


Figure 2: Back side

Patch

* Blue outline shown on Figure-3 below is for visualization and may not be indicated on the patch

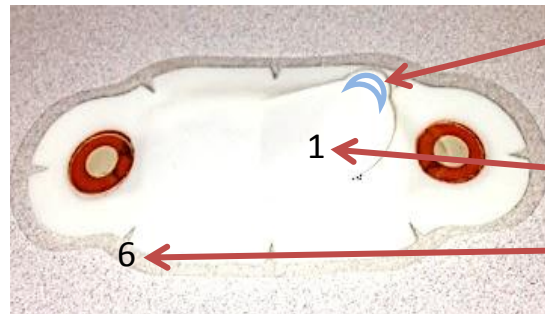


* Battery side

* Module side

Wing side

Figure 3: Front of patch

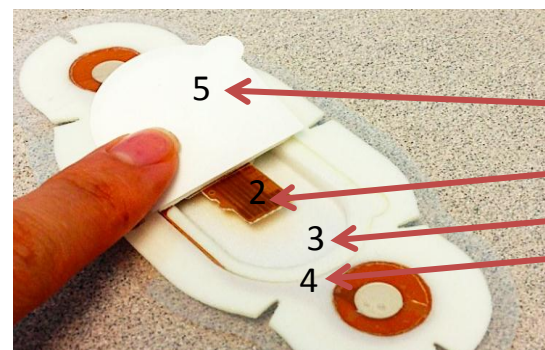


* Crescent shaped tab located at the edge is designed to help you grip and move the flap.

Back Flap (1)

Clear Release Liner (6)

Figure 4: Adhesive Side



Paper Liner of Back Flap (5)

Connector Tongue (2)

Module compartment/ cavity (3)

Module cavity adhesive rim (4)

Figure 5: Inside patch

Please read before use:

1. Please ensure hand is clean, dry, and non-greasy before handling patch and sensor.
2. It is recommended for men with long chest hair to trim or shave at least several hours before application.
3. It is recommended that you stand or sit upright and use a mirror when applying patch to chest.

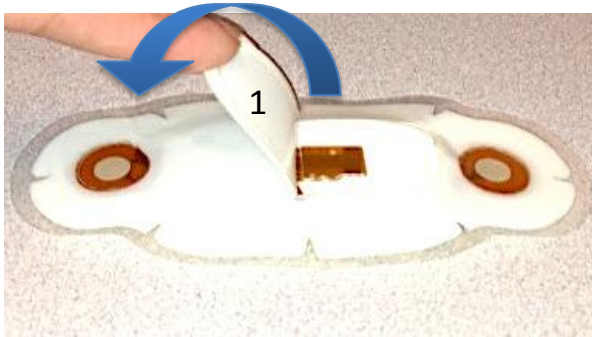


Figure 1: Lift back flap (1) over to opposite side. Use your finger to hold back flap down.

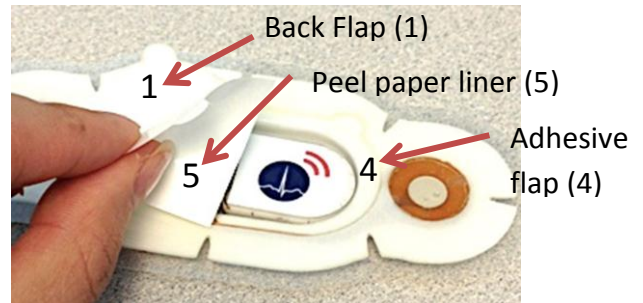


Figure 4: Peel paper liner (5) off back flap (1). Fold back flap (1) onto module cavity adhesive rim (4) lining up the edges as much as possible.

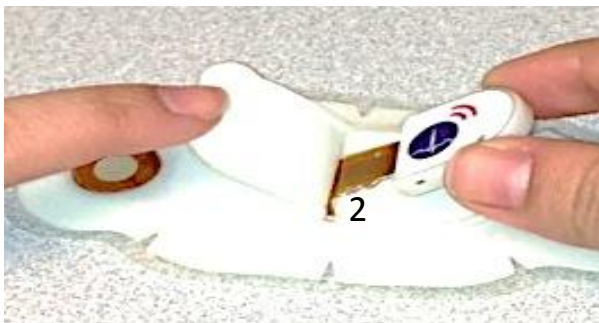


Figure 2: Insert module into connector tongue (2). Push module pass a slight resistance until it can no longer move inward. (Green LED light will blink with functioning module and patch)

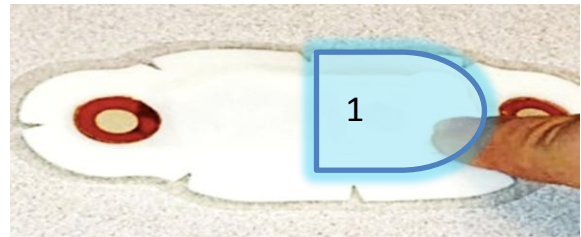


Figure 5: Press down firmly on the edge of back flap (1) to ensure it is sealed.

Please prep skin with alcohol wipe if you have not done so prior to removing the release liner.

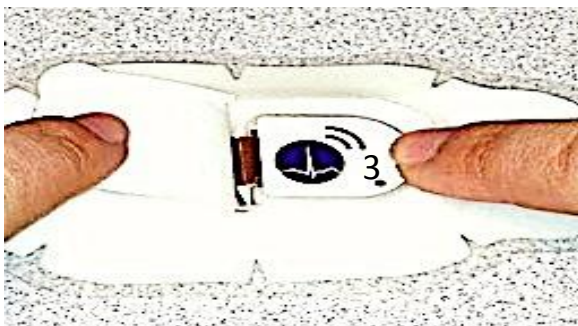


Figure 3: Press module into cavity (3).

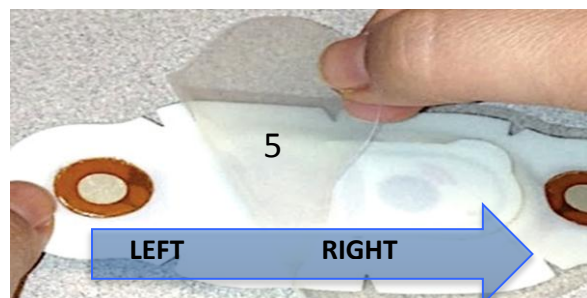


Figure 6: Separate patch from clear release liner by carefully peeling off clear liner (6). Start from left (battery side) to right (module side).

Removing Module from Patch



Figure 7: Hold patch in one hand with adhesive side facing you.

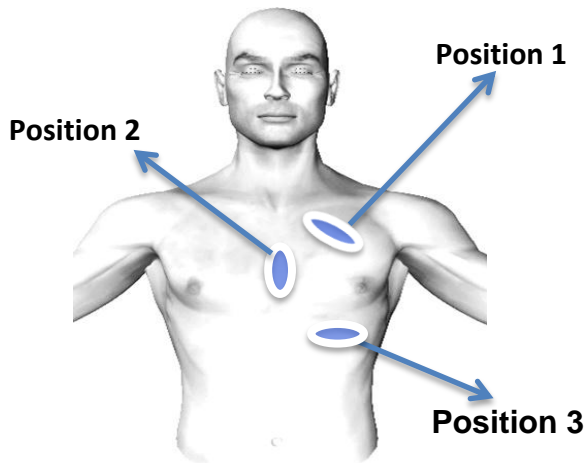


Figure 8: Please sit upright or stand in front of a mirror to ensure proper placement of patch on your chest. Place patch on the left chest in 1 of 3 recommended positions:

1. Upper chest at 45 degree angle pointing towards the center
2. Center of chest at the sternum
3. Under chest over ribcage pointing to center of body

**** To take patch off, lift the edge off one wing and slowly peel it off skin.**

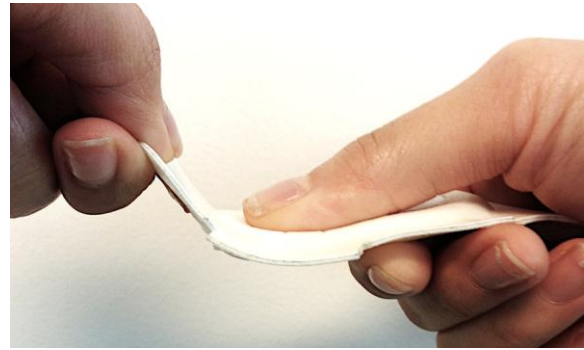


Figure 9: Hold patch securely by the wing side with 1 hand (pulling upward position). With the other hand, place thumb on top edge of the module side.



Figure 10: Pull the wing up while pushing thumb down on module side until sealed cavity is popped open and module is revealed. This hand gesture is similar to “popping” a pill or gum out of a foil packet.

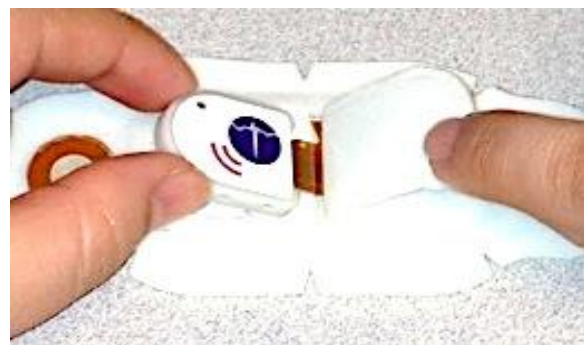


Figure 11: Remove any patch material that may be stuck to module and pull module from connector tongue.

Tips for Best Use

Connection

- Check module to ensure logo is facing up before connecting to the patch.
- Ensure that sensor module is firmly connected
- Green LED light will blink several times if module is properly connected AND patch has sufficient battery life to operate.
- After showering or bathing, system may lose connection. Please allow 15 minutes to air-dry and retry connecting to Apps

Troubleshooting

For trouble shooting, contact product manufacturing







Manufacturing contact information:

Vital Connect Inc.

2105 S. Bascom Ave., Suite 316, Campbell, CA 95008

Phone: 408 (963) 4600. www.vitalconnect.com

General symbols

Symbol	Title
IP24	Protected against splashing water
IP27	Protected against submerging in water (up to 1 meter for 30 minutes)
	Do not reuse
	Operating instruction
	Follow operating instruction
	Non-ionizing radiation
	Defibrillation proof type CF applied part
	<p>Underwriters Laboratories</p> <p>MEDICAL — PATIENT MONITORING EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH</p> <p>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</p>