VIVALNK

Medical Wearable Platform

℞ Only

INSTRUCTIONS FOR USE

LBL 75-06-132 Rev 01

Contents

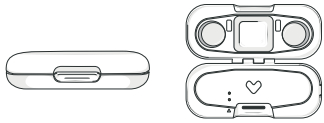
Medical Wearable Platform Description

This document provides instructions for the Medical Wearable Platform. The Medical Wearable Platform is an end-to-end solution for multi-parameter monitoring, including continuous recording, display, and analysis of multiple physiologic parameters by healthcare professionals in a home or healthcare setting.

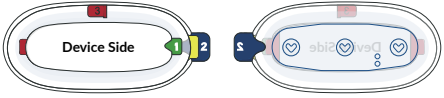
The Platform consists of the following:
1) a Multi Vital Sensor (aka. the Recorder), rechargeable or single-use.
2) single use, disposable Hydrogel Adhesive Patch.
3) a Charging Case and USB cable.
4) Software Library for Authorized Persons to build their own app.
5) a Mobile App, built upon the Software Library (4) as an option for end-users.
6) Cloud Data Services.
7) Web Portal.
The platform does not make any independent diagnosis or determinations; it provides data, preliminary analyses, and data visualizations to healthcare professionals for interpretation.
The Medical Wearable Platform's Software Library is developed as an Application Programming Interface (API), intended to be used as a programming platform to allow Authorized Persons (i.e. health care services providers) to develop applications enabling target users (i.e. physicians, caregivers, patients) to view or access collected vital information.
The device provides operational alarms, shown as an audible chime and a text notification, for lead on/off status detection, battery monitoring. Over the Air (OTA) updates, real time clock, and power management. The operational alarms are intended to notify users of any interruption in data and of the overall operation status of the device. The device does not provide any alarms based on physiological data setting.

What's Included

Multi Vital Sensor
x1



Charger
x1



Liner #3 only available on part of adhesive models

Adhesive
x4

USB Charging Cable
x1

Intended Use and Precautions

Intended Use

The Medical Wearable Platform is a wireless monitoring system intended for use by healthcare professionals for recording and displaying multi-parameter physiological data within healthcare settings or at home. This includes electrocardiogram (ECG), accelerometer and gyroscope data (activity), heart rate, respiratory rate, and skin temperature. Data is transmitted wirelessly to a separate location (such as mobile phones and web applications) for storage and display.

The Medical Wearable Platform can be configured by Authorized Persons developing their own applications utilizing the software library and application programming interfaces provided.

The Medical Wearable Platform is not intended to be used on critical care patients and is intended to supplement vital sign monitoring by healthcare professionals, not to replace current standards of care. The Medical Wearable Platform is an ambulatory, continuous recording system intended for use on general care patients and on patients who are 18 years of age or older.

Precautions

1. Any form of modification to this device is forbidden.
2. The Multi Vital Sensor is to be worn on chest. Do not use this device if it cannot stay in contact with the skin and do not use on wounded or irritated skin.
3. This device is non-sterile.
4. Do not submerge the device in water. The device may be removed and re-applied after showering or bathing with a new adhesive.
5. Pacemakers and implantable cardioverter defibrillator (ICD) are allowed to use with the Multi Vital Sensor. However, do not use the Multi Vital Sensor with other defibrillators, or other implanted electronic devices. The Multi Vital Sensor is contraindicated for use during defibrillation.
6. Do not wear or use the device during a magnetic resonance imaging (MRI), or electro-cautery procedures. The Multi Vital Sensor is MR Unsafe.

Intended Use and Precautions

7. Exposure of the wireless communications features of the device, or its accessories, may be interfered with by other devices that operate on the same frequencies.

8. Excessive body tissue, hair, or dry skin may affect the signal quality.

9. Do not excessively bend or twist the device.

10. In case of skin discomfort, remove the device immediately.

11. User may only charge the device via USB cable with the provided charger. No user serviceable part is provided for this product.

12. The performance of the device may be degraded if one or more of the following occur: a) operation outside the manufacturer's stated temperature, humidity and pressure range; b) storage outside the manufacturer's stated temperature, humidity and pressure range; c) mechanical shock (for example, being dropped).

13. Please contact customer service at support@vivalink.com if you have any questions.

14. For best results, the Multi Vital Sensor must be used with the provided adhesives.

15. No servicing/maintainance required while the device is in use.

16. Not for use in an oxygen rich enviroment.

17. Before every use, check the device. Do not use the device if it is damaged. The continuous use of a damaged unit may cause improper results.

18. If the device is not charging or the device is not working, please contact the authorized maintenance personnel.

19.Be careful to potential allergic reactions to Silicone and Hydrogel that are primary materials of the Multi Vital Sensor and adhesive.

20.The device should be used only with the components recommended for use by the manufacturer.

21. When not in use, store the device in a dry room and protect it against extreme moisture, heat, lint, dust and direct sunlight.

22. Never place any heavy objects on the storage case.

23. The device is not intended for measuring and/or analyzing ST segments.

Intended Use and Precautions

24. The device does not analyze the ECG tracing or detect the presence of any arrhythmias. It is simply an Recorder.

25. In case of interference from other RF emitters in the vicinity, follow Troubleshooting steps listed below.

26.When the device battery is fully discharged, charge it first then reconnect to the Mobile app via Bluetooth before re-attaching to the body to get Clock Synchronization.

27. Caution: Federal law restricts this device to sale by or on the order of a physician.

28. Do not remove the adhesives by pulling on the dome circles on top of the electrodes or by peeling the edge of the device. Doing so may break the device, and render it nonfunctional.

29. Immediately after each use, gently wipe the device with alcohol until all adhesives residue are removed. Excessive cleaning or strong scrub or using non-recommended solvents may damage the electrodes and render the device unfunctional.

30. Properly and carefully insert the provided USB type-C cable into the charging case and connect it to a USB power source to charge the device.

31. Using strong insertion force or different USB cable will damage the charging port and make the case no longer charging the device.

32. VivaLNK's email for complaint: support@vivalink.com.

YBER SECURITY:

1. Device pairing: ensure LOT#/SN returned to the Mobile app from Multi Vital Sensor matches with the LOT#/SN printed on back of the device. Do not connect the Mobile app to any unknow devices.

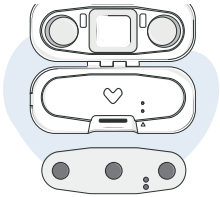
2. Do not attempt to connect any unknown devices to Multi Vital Sensor or Authorized Persons

3. All Multi Vital Sensor data is encrypted for security purposes. The Software Library needs a decryption key to decrypt the data, and then send the data to Mobile app to display.

4. The Multi Vital Sensor will not connect or transfer data to any devices that does not use VivaLNK provided Software Library package. The Bluetooth protocol of Multi Vital Sensor firmware and Software Library is proprietary to VivaLNK and cannot be intercepted by other unknown devices.

Instructions for Use - Charging the Recorder

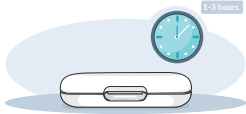
1. Place the Recorder in the charger to recharge



Align the two dots on the Recorder with the two pins on the charger to properly charge the Recorder.

2. Fully charge the Recorder before use

Solid Green Light Indicates Fully Charged



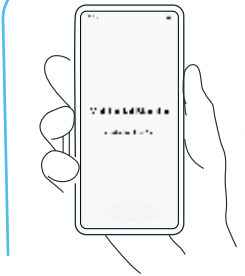
Solid White Light Indicates Charging

3. Once charged, please pair the Recorder to your mobile app first for synchronous clock, then follow the instructions for "Applying the Recorder"

Note: For the charger, just clean with a dry cloth, if needed.

Note: Charging can start when the provided USB type-C cable is properly and carefully inserted into the charging case and connected to a USB power source. Using strong insertion force or different USB cable will damage the charging port and make the case no longer charging the Recorder.

Instructions for Use - Download the Mobile App and Pairing via Bluetooth



1) Contact support@vivalink.com, download and install the Multi Vital Monitor App (aka. MVM App, v4.0.0) from link provided or app stores and follow instructions to create an account and set up your profile.

2) Make sure Bluetooth is turned ON in your phone settings and then click the product image to “Start Pairing”.

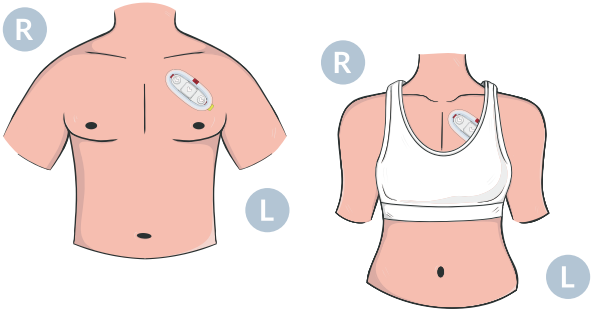
3) Select the Recorder SN that matches with the SN listed on the packaging or back of your Recorder. If device not found, select “Troubleshoot” and follow the instructions.

4) Once pairing is successful, you should see the Recorder battery and the firmware version. The Recorder is now connected to the MVM App and you are set to view your ECG and other vital signs.

Note: refer to the separate Instruction for Use for more clear procedures on Mobile App operation, the file ID is LBL 75-06-114. Please contact VivaLNK Customer Service to obtain if need.

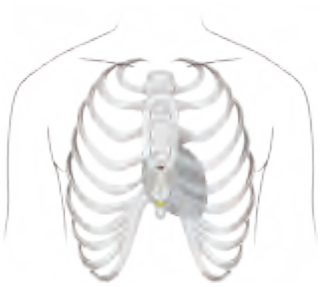
Instructions For Use - Device Wear Positions

Position #1



Applicable Adhesive Models: A13, A34, A35, A50, A60
Applying Procedures: Refer to Pages 10-16

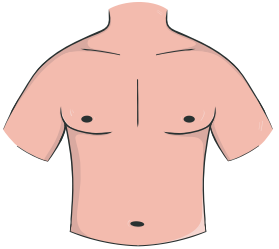
Position #2



Applicable Adhesive Model: A51
Applying Procedures: Refer to Pages 17-23

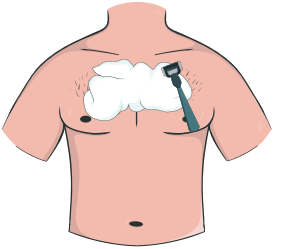
Instructions For Use - Skin Preparation (Position #1)

1. Remove clothing



Remove your shirt and bra so your upper chest is exposed.

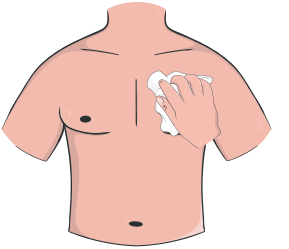
2. Shave application area



Shave the area on the sternum or middle of your chest, as shown in the pictures. Chest hair can interfere with the contact between the hydrogel and your skin, affecting the Recorder's performance.

Avoid Open Wounds:
Do not apply the Recorder on open wounds or broken skin.

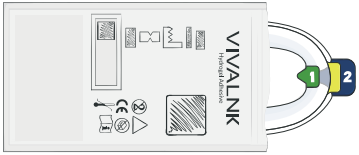
3. Clean your skin



Clean the designated area on your chest with a 70% isopropanol wipe and let it dry for one to two minutes.
This removes any lotion or oil, ensuring better Recorder performance and reducing skin irritation.

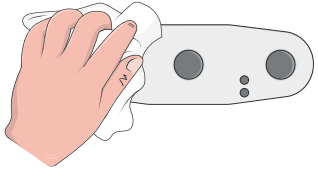
Instructions for Use - Applying Adhesive (Position #1)

1. Prepare the adhesive



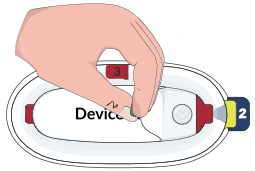
Open a bag of adhesives for the Recorder and remove the adhesive.

2. Clean the Recorder



Use a 70% isopropanol wipe to clean the Recorder before and after each use.

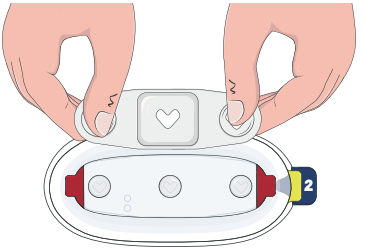
3. Remove liner 1
(Green Tab)



On a clean, flat surface, peel off the liner strip (Green Tab) from the top of the adhesive.

Instructions for Use - Applying Adhesive (Position #1)

4. Place the Recorder on the adhesive

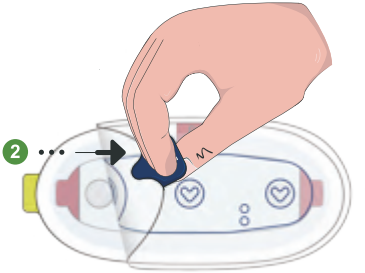


Place the Recorder onto the exposed adhesive surface, aligning the hearts on the device and the adhesive.

When positioned correctly, the heart symbols should face upward.

Press down firmly to attach it securely.

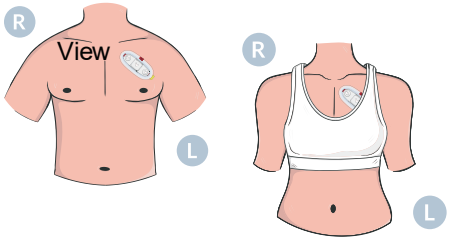
5. Remove liner 2 (Blue Tab)



On a clean, flat surface, peel off the liner strip (Blue Tab) from the top of the adhesive.

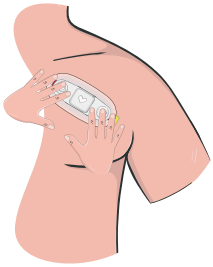
Instructions for Use - Applying the Recorder (Position #1)

1. Position Recorder



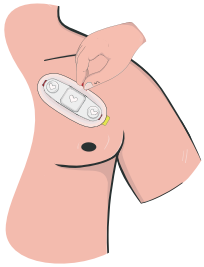
Apply it 2 to 3 finger widths below the left collar bone (over your heart on your upper left chest)

2. Secure the Recorder



Press down on the Recorder firmly and trace the edge of the adhesive with your finger to ensure a firm hold.

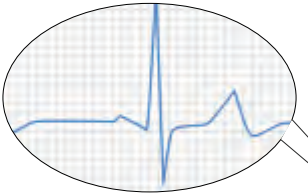
3. Remove liner 3 (Red Tab)



A60: Peel off the liner strip (Red Tab) from the edge of the adhesive.

' For optimal adhesion, stretch chest outward (moving shoulders back with a full inhalation), to ensure the skin is at maximum stretch.

Instructions for Use - View Live ECG on MVM App



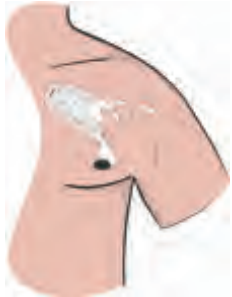
Note: refer to the separate Instruction for Use for more clear procedures on Mobile App operation, the file ID is LBL 75-06-114. Please contact VivaLNK Customer Service to obtain if need.

View your live ECG and the current vital signs on the home page after the Recorder is paired.

BATTERY section provides information about the Recorder's battery or if the Recorder is connected.

Instructions for Use - Remove Your Recorder (Position #1)

1. Applying adhesive remover

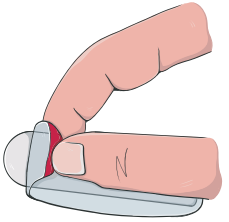


Use the Uni Solve Adhesive Remover wipe. Hold the wipe at the edge of the adhesive tape and squeeze gently so the fluid flows between the skin and the adhesive.

2. Slowly remove the Recorder

Slowly peel the yellow tab of the adhesive to remove the Recorder from your chest.

3. Remove the adhesive from the Recorder

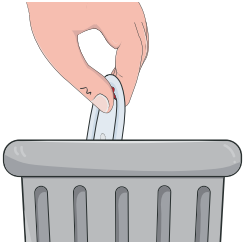


Peel the adhesive from the Recorder starting from the edge or red tab. Removing the adhesive on a flat surface may be easier. Not to bend the Recorder.

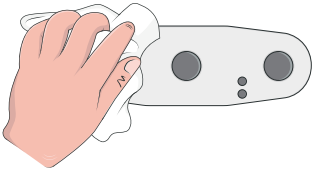
Note: Do not use the adhesive remover on cuts or scrapes.
Note: Do not remove the adhesives by pulling on the dome circles on top of the electrodes or by peeling the edge of the device. Doing so may break the device, and render it unfunctional.

Instructions for Use - Cleaning (Position #1)

4. Discard the used adhesive



5. Cleaning the Recorder



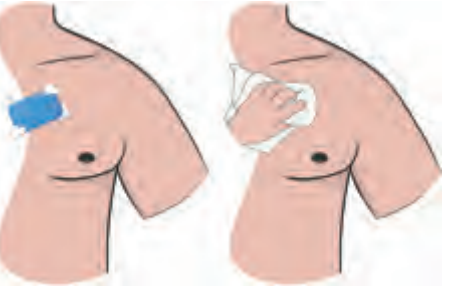
After discarding the adhesive, use a 70% isopropanol wipe to remove any adhesive residue from the Recorder.

Clean the Recorder with a 70% isopropanol wipe before and after each use. If adhesive residue has dried on the Recorder, apply 70% isopropyl alcohol to soften it. Then, gently wipe it off using a paper towel.

Clean both sides of the patch with any disinfectant below.

- 75% Ethanol
- 70% isopropanol
- Chlorhexidine wipes

6. Cleaning your skin

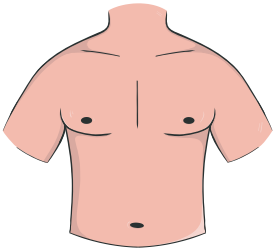


Wash the skin where the Recorder was applied using soap and water.

Rinse and pat dry.

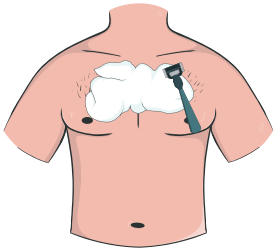
Instructions For Use - Skin Preparation (Position #2)

1. Remove clothing



Remove your shirt and bra so your upper chest is exposed.

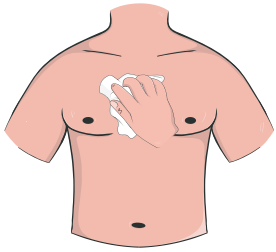
2. Shave application area



Shave the area on the sternum or middle of your chest, as shown in the pictures. Chest hair can interfere with the contact between the hydrogel and your skin, affecting the Recorder's performance.

Avoid Open Wounds:
Do not apply the Recorder on open wounds or broken skin.

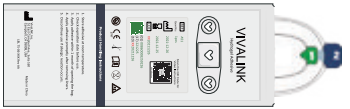
3. Clean your skin



Clean the designated area on your chest with a 70% isopropanol wipe and let it dry for one to two minutes.
This removes any lotion or oil, ensuring better Recorder performance and reducing skin irritation.

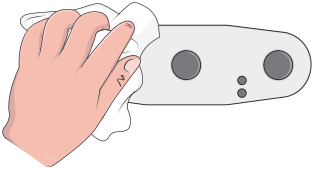
Instructions for Use - Applying Adhesive (Position #2)

1. Prepare the adhesive



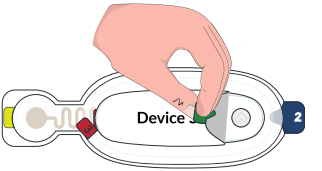
Open a bag of adhesives for the Recorder and remove the adhesive.

2. Clean the Recorder



Use a 70% isopropanol wipe to clean the Recorder before and after each use.

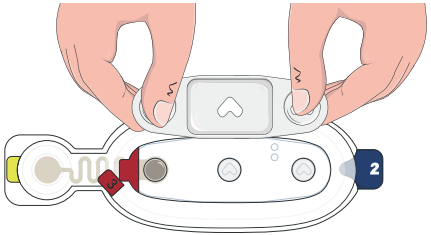
3. Remove liner 1
(Green Tab)



On a clean, flat surface, peel off the liner strip (Green Tab) from the top of the adhesive.

Instructions for Use - Applying Adhesive (Position #2)

4. Place the Recorder on the adhesive

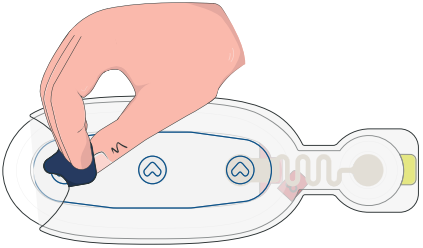


Place the Recorder onto the exposed adhesive surface, aligning the hearts on the device and the adhesive.

When positioned correctly, the heart symbols should face upward, and the adhesive tail should point to the right.

Press down firmly to attach it securely.

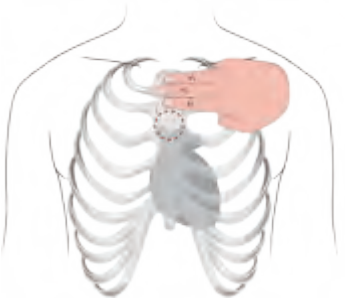
5. Remove liner 2 (Blue Tab)



Lift the combined Recorder and peel off the backing (Blue Tab) from the adhesive.

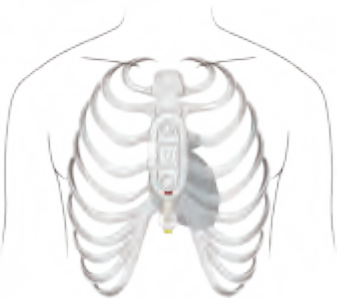
Instructions for Use - Applying The Recorder (Position #2)

1. Position Recorder



Position the Recorder two to three finger-widths below your jugular notch.

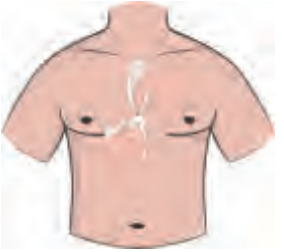
2. Secure the Recorder



First press the device side of the Recorder onto your skin, then press down the adhesive tail, making sure it points downward.

Press down on the Recorder firmly and trace the edge of the adhesive with your finger to ensure a firm hold.

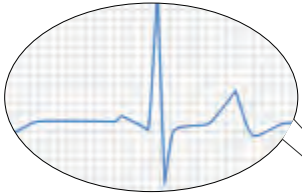
3. Remove liner 3 (Red Tab)



Peel off the liner strip 3 (Red Tab) from the edge of the adhesive.

* For optimal adhesion, stretch chest outward (moving shoulders back with a full inhalation), to ensure the skin is at maximum stretch.

Instructions for Use - View Live ECG on MVM App



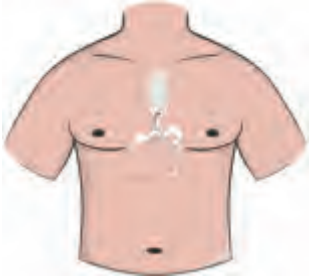
Note: refer to the separate Instruction for Use for more clear procedures on Mobile App operation, the file ID is LBL 75-06-114. Please contact VivaLNK Customer Service to obtain if need.

View your live ECG and the current vital signs on the home page after the Recorder is paired.

BATTERY section provides information about the Recorder's battery or if the Recorder is connected.

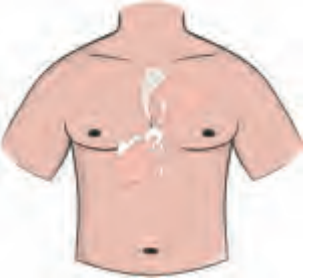
Instructions for Use - Remove Your Recorder (Position #2)

1. Applying adhesive remover



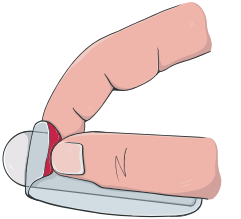
Use the Uni Solve Adhesive Remover wipe. Hold the wipe at the edge of the adhesive tape and squeeze gently so the fluid flows between the skin and the adhesive.

2. Slowly remove the Recorder



Slowly peel the yellow tab of the adhesive to remove the Recorder from your chest. Use the adhesive remover to remove any remaining adhesive.

3. Remove the adhesive from the Recorder

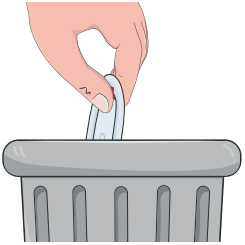


Peel the adhesive from the Recorder starting from the edge or red tab. Removing the adhesive on a flat surface may be easier.
Not to bend the Recorder.

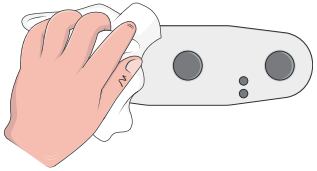
Note: Do not use the adhesive remover on cuts or scrapes.
Note: Do not remove the adhesives by pulling on the dome circles on top of the electrodes or by peeling the edge of the device. Doing so may break the device, and render it unfunctional.

Instructions for Use - Cleaning (Position #2)

4. Discard the used adhesive



5. Cleaning the Recorder



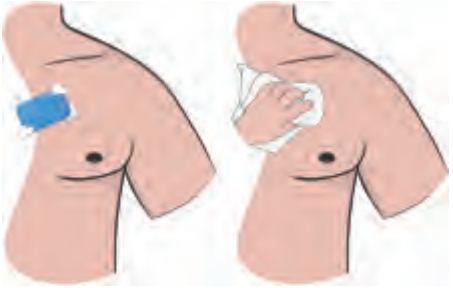
After discarding the adhesive, use a 70% isopropanol wipe to remove any adhesive residue from the Recorder.

Clean the Recorder with a 70% isopropanol wipe before and after each use. If adhesive residue has dried on the Recorder, apply 70% isopropyl alcohol to soften it. Then, gently wipe it off using a paper towel.

Clean both sides of the patch with any disinfectant below.

- 75% Ethanol
- 70% isopropanol
- Chlorhexidine wipes

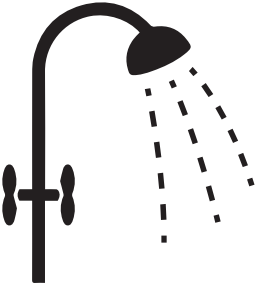
6. Cleaning your skin



Wash the skin where the Recorder was applied using soap and water.

Rinse and pat dry.

Instructions for Use - Tips before Showering



Note: While the Recorder is water resistant, avoid excessive exposure to water as it can affect the adhesive and device.

1. Avoid prolonged or hot showers.
2. Avoid soap or rubbing around the Recorder.
3. Dry Recorder with towel.
4. If the Recorder dislodges after a shower, or you notice a problem with the sensor signals, see instructions for “Removing and Cleaning the Recorder”.

Charging, Storage & Maintenance

Storage

It is recommended to store the Recorder inside the charger when not in use for better cleanliness.

Adhesives

Each Recorder comes with 4 medical grade, disposable adhesives. Adhesives can be used up to 14 days (please contact VivaLNK for the latest adhesive options), but some users may want to change adhesives more often depending on skin type and comfortability. Additional adhesives can be purchased separately as needed. After each use, discard the used adhesive. The actual wear duration may vary based on real-world conditions and may need to be replaced more frequently depending on:

- Skin type and oiliness
- Level of physical activity or sweating
- Showering or water exposure
- Skin preparation and placement

Note: After adhesive bag is open, use within one month. Otherwise, the water evaporation of the adhesive tape may affect performance.

Traveling

When passing through the airport security, if wearing the device, take it off from your body and allow TSA officers to screen the device. To charge the device in other countries, make sure to use a standard USB (Universal Serial Bus) outlet.

Cleaning

To prevent patient cross infection, it is recommended to use a new adhesive before each use. Before applying a new adhesive, gently clean both sides of the Recorder with any disinfectant below:

- 75% Ethanol
- 70% isopropanol
- chlorhexidine wipes

Note: Excessive cleaning or strong scrub or using non-recommended solvents may damage the electrodes and render the device unfunctional.

Charging and Battery Handling

The device will not work until the battery has enough power.

Charging, Storage & Maintenance

• When the Recorder needs charging, please connect the Recorder to a power source.
• Charging can start when the provided USB type-C cable is properly and carefully inserted into the charging case and connected to a USB power source. Using strong insertion force or different USB cable will damage the charging port and make the case no longer charging the Recorder.
• You should charge the battery when the battery is less than 10% charged.
• When in charging mode, the charging status will be displayed on the charger box. See the table below for details.

Recorder Status	Status Indicator
Charging	The charger box's WHITE light will remain solidly lit.
Fully charged	The charger box's GREEN light will remain solidly lit.
Not in charging	The light is OFF when the Recorder is not placed in charger, or the charger is not plugged in via USB cable.
Battery low	Notification from mobile app if connected via BLE.

⚠ Disassemble and replace the battery is not allowed. If the battery can no longer be charged, please contact Customer Service.

⚠ Overcharging the battery may reduce its lifetime.

⚠ Over discharging the battery may reduce its lifetime.

⚠ The battery will enter over-discharge state when the Recorder is not used for more than 8 months. When charging an over-discharged battery, the charger box's white and green LED lights will be alternately flashing during the first one minute of charging.

⚠ Do not use the Recorder while charging.

⚠ The battery has limited charge cycles. Battery life and charge cycles vary by use and settings.

⚠ Do not plug or unplug the charging cable into the AC charger adapter, or the AC charger adapter's power cord into the electrical outlet with wet hands. If the AC adapter is abnormal, please change the adapter.

Instructions for Authorized Persons

- Authorized Persons (i.e. healthcare services providers) must sign the Developer License agreement with VivaLNK to be able to use the Software Library to create their own application, which provides any user interface functionality along with any fault alarms.
- Authorized Persons must adhere to the Application Programming Interface (API) in the Software Library while developing their applications, and provide their Instruction for Use accordingly based on the information below.
- Authorized Persons are required to maintain compliance with the intended use of the Medical Wearable Platform.
- Should the Authorized Persons choose to expand the intended use of the device in any way, such as any of the following in their application, the Authorized Persons are responsible to comply with the healthcare rules, applicable FDA regulations, local regulations and safety compliance requirements of their target country.
    - Introduction of additional features or notifications that impact the intended use, and are different from that provided in the VivaLNK's device.
    - Introduction of additional data analysis or data generation intended for any diagnostic purpose.
    - Use of the Platform as a part of a larger system having more functions and features with a different Intended Use.
    - Generation of their own Instructions for Use due to changes above.
- Authorized Persons are allowed to modify the following if desired:
    - the view or the display of physiological data in the app without any altering of such data.
    - the removal or combination or cosmetic look of the alerts provided in the Software library.
- Authorized Persons are not allowed to modify the Recorder, the Charger, and the physical content of this Platform in anyway.

Instructions for Authorized Persons - continued

- Authorized Persons must follow applicable FDA regulations below to determine if a new submission is needed or if the modification is acceptable.
  - "Deciding When to Submit a 510(k) for a Change to an Existing Device" issued on October 25th 2017, which is available at https://www.fda.gov/media/99812/download,
  - "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" issued on October 25th 2017, which is available at https://www.fda.gov/media/99785/download,
  - "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" issued on July 28th 2014, which is available at https://www.fda.gov/media/82395/download,
  - "General/Specific Intended Use" issued on November 4th 1998, which is available at https://www.fda.gov/media/71966/download.
- The device provides operational alarms, shown as an audible chime and a text notification, for lead on/off status detection, battery monitoring, Over the Air (OTA) updates, real time clock, and power management. The operational alarms are intended to notify users of any interruption in data and of the overall operation status of the Recorder. The device does not provide any alarms based on physiological data setting.
- Authorized Persons are allowed to modify or merge or ignore any of these operational alerts, but Authorized Persons are not allowed to set new alerts by configuring the physiological data without considering a new 510(k) submission.

Instructions for Authorized Persons - continued

1. Join the VivaLNK Developer Program (https://www.vivalnk.com/developer/) by signing the Developer License / Terms and Conditions

2. A VivaLNK representative will send you an invitation to the Box.com folders (https://vivalnk.account.box.com/login) with the Software Development Kit (SDK).

3. Accept the invitation to Box.com (create a free account if you don't have one already), and Download the SDK. The SDK includes:
   - Software Library
   - Developer Guide and API Specification, SAS 73-01-04 for Android and SAS 73-01-12 for iOS
   - Demo app

4. Integrate the Library into your application according to the Developer Guide and API Specification.

5. Prepare and provide end-user with instructions specific to your use case.

Troubleshooting

Symptom	Possible Causes	Solutions
Unusual Data	1. This device might be damaged. 2. This device might not be worn correctly. 3. The operation temperature is too high or too low. 4. Improper or no skin preparation. 5. Incorrect attachment of adhesive.	1. Contact your device provider. 2. Recheck device's location or contact with skin. 3. Use this device under instructed operation temperature. 4. Prepare the skin before application. 5. Follow the instructions to attach the adhesive.
No BLE signal can be scanned out, or continuous pairing failure. No data or intermittent data received by Mobile App, or data transmission latency.	1. Bluetooth turned off in the Mobile app-installed device. 2. The device was paired with another Mobile app-installed device. 3. Mobile (Android or iOS) OS error. 4. Out of wireless connection range. 5. Interference from other RF emitters, such as RFID metal detectors, medical equipment etc., in the vicinity.	1. Enable Bluetooth. 2. To charge the Recorder via charger box for 5 seconds, to activate it. 3. To check the possible pairing between current Recorder and other Mobile app-installed devices. 4. Typically, disabling and re-enabling the Bluetooth on the Mobile app-installed device or restarting the device resolves the issue. 5. The Recorder battery is low and charge it. 6. Move the Recorder close to the Mobile app-installed device. 7. Move the Recorder far away from any electronic equipment or change rooms or move to an open space.

Certification & Disclaimer

Notes:
This device 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 device does cause harmful interference to radio or television reception, the user is encouraged to try to correct the interference by one or more of the following measures.
1. Increase the separation between the Recorder and the other devices.
2. Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
3. Consult an experienced radio / TV technician for help.
4. Reorient or relocate the receiving antenna.

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.

Changes or modifications not expressly approved by your device provider could void the user's authority to operate the equipment.

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:
(1) This device may not cause interference.
(2) This device must accept any interference, including interference that may cause undesired operation of the device.

l'appareil contient des émetteurs/récepteurs exempts de licence qui sont conformes aux CNR exempts de licence d'Innovation, Sciences et Développement économique Canada. L'exploitation est soumise aux deux conditions suivantes :
(1) l'appareil ne doit pas produire de brouillage,
(2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Certification & Disclaimer

For private households: Information on Disposal for Users of WEEE

Disposing of this product correctly will help save valuable resources and prevent any potential negative effects on human health and the environment, which could otherwise arise from inappropriate waste handling. Please contact your local authority for further details of your nearest designated collection point. Penalties may be applicable for incorrect disposal of this waste, in accordance with your national legislation.

This symbol  on the product(s) and / or accompanying documents means that used electrical and electronic equipment (WEEE) should not be mixed with general household waste. For proper treatment, recovery and recycling, please take this product(s) to designated collection points where it will be accepted free of charge.

Alternatively, in some countries, you may be able to return your products to your local retailer upon purchase of an equivalent new product.

Battery Removal

The Recorder contains a lithium battery. Refer to proper disposal instructions below:

1. To remove the battery, cut the Recorder. The battery is located in the center of the Recorder. .
2. All batteries / accumulators should be disposed separately from the municipal waste stream via designated collection facilities appointed by the government or the local authorities. The correct disposal of your old batteries/accumulators will help to prevent potential negative consequences for the environment, animal, and human health.

Electromagnetic Compatibility (EMC) Tables

Table 1

Emission Test Levels		
Phenomenon	**Professional Healthcare Facility Environment (E.g. physician offices, dental offices, clinics etc.)**	**Home Healthcare Environment (E.g. restaurants, cafes, shops, etc.)**
	IEC 60601 Test Level	IEC 60601 Test Level
Conducted and radiated RF EMISSION	CISPR 11	CISPR 11 [a) b)]

a) The Multi Vital Sensor used in aircraft shall meet the RF EMISSIONS reguirements of RTCA DO-160G: 2010 and EUROCAE ED-14G: 2011. Therefore, use of Section 21 (and category M) of a more recent edition, e.g. [39] or [40], should be considered. The conducted FR EMISSIONS test is also applicable to The Multi Vital Sensor stored in charger connected to aircraft power.

b) In other intended modes or in EM ENVIRONMENTS of transportation, applicable standards shall apply. Examples of standards that might be applicable include CISPR 25 and IS0 7637-2.

Electromagnetic Compatibility (EMC) Tables

Table 2

Immunity Test Levels		
Phenomenon and Basic EMC standard or test method	**Professional Healthcare Facility Environment (E.g. physician offices, dental offices, clinics etc.)**	**Home Healthcare Environment (E.g. restaurants, cafes, shops, etc.)**
Electrostatic discharge IEC 61000-4-2	± 8 kV contact ± 2 kV , ± 4 kV, ±8 kV, 15 kV air	
Radiated RF EM fields IEC 61000-4-3	3 V/m 80 MHz - 2.7 GHz 8% AM at 1kHz	10 V/m 80 MHz - 2.7 GHz 8% AM at 1kHz
Rated power frequency magnetic fields IEC 61000-4-8	30 A/m [c)] 50Hz or 60Hz	

c) This test level assumes a minimum distance between the Multi Vital Sensor and power source with magnetic field of at least 15 cm. If the RISK ANALYSIS shows that the Multi Vital Sensor will be used closer than 15 cm to power source with magnetic field, the IMMUNITY TEST LEVEL shall be adjusted as appropriate for the minimum expected distance.

Wireless Technology

VivaLNK Multi Vital Sensor (the Recorder) uses Bluetooth Low Energy (LE) wireless technology (IEEE 802.15.1, managed by Bluetooth Special Interest Group now) to transfer data between the Recorder firmware and the Mobile app, including ECG, RRI, HR, ACC data, and device information, which complies with the BLE 5.0 and above.

Security Measures:
Low-power Bluetooth wireless communication between the Recorder firmware and Mobile app, in line with Bluetooth 4.0+ low-power Bluetooth protocol, works in the 2.4GHZ ISM radio frequency band, and belongs to general information technology equipment. Through security mechanism in wireless Bluetooth communication protocol stack ensured by Bluetooth Special Interest Group, both the Recorder firmware and Mobile app are required to execute these secure controls during data/information exchange. Additionally, AES128 encryption algorithm is added to encrypte the data in the air during BLE transmission.

Technical Specifications

Hardware Product Name: Multi Vital Sensor
Catalog/Model: VV360/VV370/VV380
Recorder Size: 90mm x 28mm
Recorder Thickness: 11 mm
Recorder Weight: 17 g
Recorder Battery: rechargeable

Duration of continuous recording use: up to 30 days
Note: The above duration of continuous recording use is including battery lifetime and onboard memory data storage size during no wireless transmission..

To recognize the hardware version of the Recorder, the below ICON will be printed on the surface of the device.
- VV360 Rev 01 will be marked F3
- VV370 Rev 01 will be marked G3
- VV380 Rev 01 will be marked H3

Operating Conditions:
Temperature Range: 41 ℉ - 113 ℉ (5 ℃ - 45 ℃)
Humidity Range: 10% - 95%
Pressure Range: 70 - 106 kPa

Storage Conditions:
Temperature Range: -4 ℉ - 131 ℉ (-20 ℃ - 55 ℃)
Humidity Range: 10% - 95%
Pressure Range: 70 - 106 kPa

Charger Power Source: USB type C Charging Case
Accelerometer Range: +/- 16g
Gyroscope Angular Rate: +/- 250dps
Dust and Water Resistance: IP67 for the Recorder, IP21 for Charging Case

This device complies with Part 15 of the FCC Rules

Technical Specifications

Product Model	VV360	VV360	VV370	VV380
Product Label				
Regulation	US FDA	CE, Health Canada	Global	Global
LED Light	No	No	Yes	Yes
Physical Button	No	No	Yes	Yes
Rechargeable?	Yes	Yes	Yes	No
Single-use?	No	No	No	Yes
Heart Rate Detection Range /Accuracy	40 BPM - 300 BPM / ±5%			
Respiratory Rate Detection Range /Accuracy	No	5 BrPM – 35 BrPM / ±3BrPM		
Skin Temperature Detection Range / Accuracy	No	No	86 ℉ -109.4 ℉ (30 ℃ – 43 ℃)/ ±32.18 ℉ (±0.1 ℃)	

Technical Specifications

Specification	Multi Vital Sensor	Specification	Multi Vital Sensor
Frequency Band	2.4GHz ISM Band (2.402 – 2.480 GHz Utilized)	Channel Usage	Frequency-Hopping Spread Spectrum (FHSS)
Channels	40 channels with 2 MHz spacing (3 advertising channels/37 data channels)	Power Consumption	~0.01x to 0.5x of reference (depending on use case)
Modulation	GFSK	Application throughput	0.27–1.37 Mbit/s
Data Rate	LE 1M PHY: 1 Mb/s, 2 Mb/s	Latency (from a non-connected state)	6 ms
Max Tx Power	1.32mW (1.19dBm), between Class 2 to 1.		
Network Topologies	Point-to-Point (including piconet) Broadcast	Robustness	Adaptive frequency hopping, Lazy Acknowledgement, 24-bit CRC, 32-bit Message Integrity Check
Security	128-bit AES with Counter Mode CBC-MAC and application layer user defined	Minimum total time to send data (det. battery life)	3 ms

Definition of Symbols

Prescription Use Only


Manufacturer

Polyethylene terephthalate

Serial Number


Date of Manufacture


Radio emission


Caution


Consult Instructions For Use

Lot/batch Number

Non Sterile


Keep Dry


Type-CF applied part

Catalog Number

MR Unsafe


WEEE icon


Temperature Limitation

Bluetooth

Medical device


FCC icon


Atmospheric Pressure Limitation

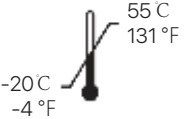
Humidity Limitation

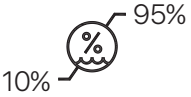
CE mark and notified body number

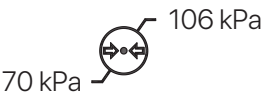
EC REP

Emergo Europe B.V.
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

CE
2797







THANK YOU

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