

Medical Wearable Platform SDK 01

INSTRUCTIONS FOR USE

LBL 75-06-78 Rev AL

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What's Included



ECG Recorder (the Patch)
x1



Charging Case
x1



Adhesives
x4



USB Charging Cable
x1

Intended Use and Precautions

Intended Use

Medical Wearable Platform SDK-01 is intended to record, store and transfer electrocardiogram (ECG) and accelerometer data. The platform has the capability to provide Heart Rate, Respiratory Rate and R-R Interval using the ECG rhythm. The ECG recorder patch is an ambulatory, continuous recording patch, intended for at-home or hospital, by clinicians or health professionals who intend to monitor their patient's physiological and health conditions for an extended period of time. The device is not intended for patients under 18 years old.

This Instructions for Use is only limited to the use of the hardware and the Software Development Kit (SDK). It does not include any information about the mobile application or user interfacing device as that is outside the scope of the system.

Precautions

1. Any form of modification to this device is forbidden.
2. 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. The Continuous ECG Recorder is to be worn on chest.
5. Do not submerge the Patch in water. Patch may be removed and be reapplied after showering or bathing
6. Pacemakers and implantable cardioverter defibrillator (ICD) are allowed to use with the ECG recorder patch. However, do not use the patch with other defibrillators or other implanted electronic devices.

Intended Use and Precautions

7. Do not wear or use the patch during a magnetic resonance imaging (MRI), or electro-cautery procedures. The Patch is MR Unsafe.
8. 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.
9. Excessive body tissue, hair, or dry skin may affect the signal quality.
10. Do not excessively bend or twist the Patch
11. In case of skin discomfort, remove the Patch immediately.
12. User may only charge the patch via USB cable with the provided charger. No user serviceable part is provided for this product.
13. The performance of the device may be degraded if one or more of the following occur: a) operation outside the manufacturer's stated temperature and humidity range; b) storage outside the manufacturer's stated temperature and humidity range; c) mechanical shock (for example, being dropped)
14. Please contact customer service at support@vivalnk.com if you have any questions.
15. For best results, the Patch must be used with the provided adhesives.
16. No servicing/maintenance required while the device is in use.
17. Not for use in an oxygen rich environment.
18. 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.
19. If the device is not charging or the device is not working, please contact the authorized maintenance personnel.
20. Be careful to potential allergic reactions to Silicone and Hydrogel that are primary materials of the patch and adhesive.
21. The device should be used only with the components recommended for use by the manufacturer.

Intended Use and Precautions

- 22. When not in use, store the device in a dry room and protect it against extreme moisture, heat, lint, dust and direct sunlight.
- 23. Never place any heavy objects on the storage case.
- 24. The device is not intended for measuring and/or analyzing ST segments.
- 25. The device does not analyze the ECG tracing or detect the presence of any arrhythmias. It is simply a Patch.
- 26. In case of interference from other RF emitters in the vicinity, follow Troubleshooting steps listed below.
- 27. When the Patch battery is fully discharged, charge the patch first then reconnect to the SDK via Bluetooth before re-attaching to the body to get Clock Synchronization.
- 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 micro-USB cable into the charging case and connected it to a USB power source to charge the Patch.
- 31. Using strong insertion force or different USB cable will damage the charging port and make the case no longer charging the Patch.
- 32. VivaLNK's email for complaint: support@Vivalink.com.

CYBERSECURITY:

- 1. Device pairing: ensure LOT#/SN returned to the SDK from the Patch matches with the LOT#/SN printed on back of the patch. Do not connect the SDK to any unknown devices.
- 2. All the Patch data is encrypted for security purposes. The SDK needs a decryption key to decrypt the patch data.
- 3. The Patch will not connect or transfer data to any devices that does not use VivaLNK provided SDK package. The bluetooth protocol of the Patch and SDK is proprietary to VivaLNK and cannot be intercepted by other unknown devices.
- 4. Do not attempt to connect any unknown devices to the Patch.

Instructions for Use - Charging the Patch

1. Place the patch in the charger to recharge



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

2. Fully charge the patch before use



Indicates Fully Charged



Indicates Charging

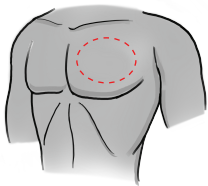
Note: Charging can start when the provided micro-USB cable is properly and carefully inserted into the charging case and connected to a USB power source. Using strong insertion force or different USB cable will damage the charging port and make the case no longer charging the Patch.

3. Once charged, see instructions for "Applying the Patch"

Note: For the charger base, just clean with a dry cloth

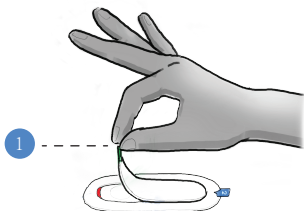
Instructions for Use - Applying the Patch

1. Prepare Skin

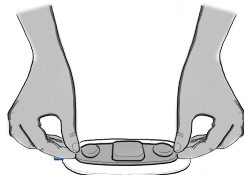


Prepare the left upper middle chest area for device placement. If body hair is present in the area of device placement, shave the area. Thoroughly clean the area with 70% isopropyl alcohol wipe or saturated cloth, using multiple strokes as needed to remove any oils or lotions. Allow area to dry completely.

2. Peel adhesive starting with tab #1



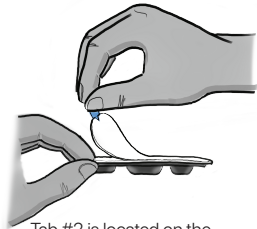
3. Place the Recorder on the adhesive



Before applying a new adhesive, gently wipe both sides of the Recorder with a 70%+ alcohol swab. Be sure to press Recorder firmly onto the adhesive.

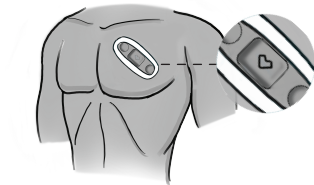
Instructions for Use - Applying the Patch

4. Peel adhesive using tab #2



Tab #2 is located on the bottom side of the patch.

5. Place the Recorder around the middle of upper left chest area at a roughly inclined angle as shown below

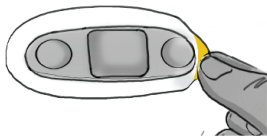


Press the patch firmly on chest and around outer layer of the adhesive. Make sure the heart symbol on the patch is upright.

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

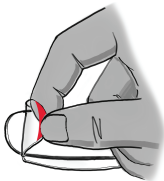
Instructions for Use - Removing and Cleaning the Patch

1. Remove the patch from chest by pulling from the yellow tab of the adhesive
2. Remove the adhesive from the patch itself by peeling from the edge and continue carefully along the full length without excessive bending



Start at the yellow tab of the transparent film to peel off the patch.

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.



Use the red tab to peel the adhesive from the patch. Do not reuse this adhesive.

3. Immediately after each use, gently rub off any adhesive residue with your fingers and any antiseptic alcohol (such as the over-the-counter 70% isopropyl alcohol). Do not submerge the patch in water or alcohol



Before storing the patch into charging case, clean both sides of the patch with any disinfectant below.

- 75% Ethanol
- 70% isopropanol
- chlorhexidine wipes

Instructions for Use - Tips before Showering



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

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

Charging, Storage & Maintenance

Patch Storage & Charging

It is recommended to store the Patch inside the charging case when not in use for better cleanliness. Charging can start when the provided micro-USB 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 Patch.

Adhesives

Each Patch comes with 4 medical grade, disposable adhesives. Adhesives can be used up to 96 hours, but some users may want to change adhesives more often depending on skin type and comfortability. Additional adhesives can be purchased separately as needed.

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

Charger Indicators

WHITE

- When the Patch is placed inside the charger, white light indicates the patch is charging.
- The light should stay on when charging.

GREEN

- When the Patch is placed inside the charger, green light indicates the patch is fully charged.

OFF

- When the Patch is not placed in charger, or the charger is not plugged in via USB cable.

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 patch 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.

Troubleshooting

Symptom	Possible Causes	Solutions
Unusual Data	<ol style="list-style-type: none">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.	<ol style="list-style-type: none">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 data or intermittent data received by SDK No BLE signal or data transmission latency	<ol style="list-style-type: none">1. Bluetooth turned off in the SDK-installed device.2. Out of connection range.3. Interference from other RF emitters, such as RFID, metal detectors, medical equipments etc, in the vicinity	<ol style="list-style-type: none">1. Enable Bluetooth.2. Move the Patch close to the SDK-installed device3. Move far away from any electronic equipment or change rooms or move to an open space.4. Check if the Patch is activated.5. Restart the SDK- installed device.6. The Patch battery is low and charge it.

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 Patch and the device
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 modification not expressly approved by your device provider could void the user's authority to operate the equipment.

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

1. To remove the battery, cut the Patch. The battery is located in the center of the patch.
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)}
<p>a) Continuous ECG Recorder used in aircraft shall meet the RF EMISSIONS requirements 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 Continuous ECG Recorder stored in charger connected to aircraft power.</p> <p>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 ISO 7637-2.</p>		

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 Continuous ECG Recorder and power source with magnetic field of at least 15 cm. If the RISK ANALYSIS shows that the Continuous ECG Recorder 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 Continuous ECG Recorder uses Bluetooth Low Energy (LE) wireless technology (IEEE 802.15.1, managed by Bluetooth Special Interest Group now) to transfer data between the ECG Recorder and the SDK, including ECG, RRI, HR, ACC data, and device information, which complies with the BLE 4.0 and above.

Security Measures:

Low-power Bluetooth wireless communication between patch firmware and SDK, 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 patch firmware and SDK in APP are required to execute these secure controls during data/information exchange. Additionally, AES128 encryption algorithm is added to encrypt the data in the air during BLE transmission.

Technical Specifications ECG Recorder

Product Name: ECG Recorder

Catalog/Model: VV330/VV-330

Patch Size: 90mm x 28mm

Patch Thickness: 7.9 mm

Patch Weight: 7.5 g

Patch Battery: rechargeable

Duration of continuous patch use: 4 Days

Note: Data storage is 24 hours (for Rev 07 and early hardwares) or 96 hours (for Rev 08 and later) on the Recorder during no wireless transmission. To recognize Recorder hardware version, Rev 8 will be marked C8 on the recorder, and also from LOT/SN printed on it.

Heart Rate Detection Range: 40 BPM – 300 BPM

Respiration Rate Detection Range: 5 BrPM – 35 BrPM

Respiration Rate Accuracy: +/- 3 BrPM

Operating Conditions:

Temperature Range: 50° F – 113° F (10° C – 45° C)

Humidity Range: 10% – 95%

Pressure Range: 70 – 106 kPa

Storage Conditions:

Temperature Range: 50° F – 122° F (10° C – 50° C)

Humidity Range: 10% – 95%

Pressure Range: 70 – 106 kPa

Charger Power Source: VV330 Charging Base (micro-USB)

Accelerometer Range: ± -4g in x, y, z

Patch Water Resistance: IPX7

This device complies with Part 15 of the FCC Rules.

Technical Specification

Specification	VV330 ECG Recorder	Specification	VV330 ECG Recorder
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	Latency (from a non-connected state)	6 ms
Max Tx Power	Class 2: 2.5 mW (+4 dBm)		
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



FCC icon



Manufacturer



Polyethylene terephthalate



Keep dry



WEEE icon



Date of Manufacture



Radio emission



CE mark and notified body number



Consult Instructions For Use



Serial Number



Bluetooth® Bluetooth



MR Unsafe



Type-BF applied part



Lot/batch Number



Non Sterile



Caution



Temperature Limitation



Catalog Number



Humidity Limitation



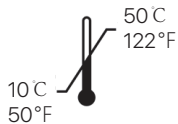
Atmospheric Pressure Limitation



Medical device



Emergo by UL
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands



LBL 75-06-78
Instruction for Use (IFU)-ECG-CE

THANK YOU

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