

1- Lead Holter

User manual



Model : VSH101

Please read the instruction manual carefully and follow the instructions before use.

Important safety instructions

■ Warning

01. The record and interpretation of this product is only for clinical evaluation and reference, and cannot be directly used as the diagnosis result. Please consult a doctor for advice.
02. Before using this product, please confirm that the equipment indicator lights in the environment can be clearly identified and operated.
03. When using this product, please use the special "ECG patch" of this product. If you use other brands of patches, it may affect the interpretation of the equipment. Please do not use damaged or defective patches.
04. People who are allergic to hydrogel or patch adhesive materials should not use this product.
05. When you want to use this product in a hospital or other medical institutions, please confirm with the medical staff first, so as not to affect the operation of other medical equipment, such as computer tomography (CT), magnetic resonance imaging (MRI), X-ray machine (X-RAY) is used together with related medical equipment such as automatic external cardiac defibrillator (AED).
06. This product ensures that for patients with an artificial pacemaker, the operation of the artificial pacemaker will not be affected, and the 2 millisecond pacing signal can be measured.
07. When this product is measuring, in order to prevent electromagnetic interference, please avoid using other electronic products nearby. If electromagnetic interference is found, please change the measurement location or turn off the product that can cause electromagnetic interference, so as not to affect the interpretation of the equipment.
08. This product should be placed in a dry, non-corrosive gas and no strong electromagnetic field interference environment.
09. This product contains a lithium battery. Do not leave the device in a high temperature environment or throw it into a fire for a long time to avoid the danger of explosion.
10. If you do not use the product for a long time, please charge the battery to 100%, and recharge the device to 100% every month to avoid excessive discharge of the battery and damage to the battery due to long-term storage without use. It cannot be turned on.
11. Do not use this product when it is connected to a power supply (charging).
12. This product is a precision medical instrument. Do not drop, beat, or smash the device to avoid damage to the device. The user is not allowed to disassemble the equipment without authorization, and must be repaired by professional maintenance personnel.
13. This product is intended for infants weighing less than 10 kg.
14. That conductive part of electrodes and associated connectors for type BF applied parts or type CF applied including the neutral electrode should not contact other conductive parts including earth.

■ Matters needing attention

01. Please read the manual carefully before using this product.
02. During the period of using this product, users can carry out general daily life activities, but do not use it during high-intensity exercise (such as marathons, etc.). A lot of sweat on the surface of the skin may cause the ECG patch of this product to deteriorate or fall off, which will affect the accuracy of signal measurement.
03. The 1-lead Holter of this product meets the IP42 dustproof and waterproof rating. Please do not take showers, baths, swimming and other underwater activities during use.
04. When it is necessary to use this product for a long time for measurement, at least every 8 hours to confirm whether the position of the ECG patch of this product is displaced or falling off, and at the same time check whether the skin is allergic.
05. If there is any skin discomfort during use, such as itching, rash, redness, etc., please remove the product immediately (stop the measurement) and consult a doctor.
06. Do not use this product when there is a wound or swelling or inflammation on the skin (where the ECG patch of this product is expected to be attached).
07. Do not use corrosive and abrasive cleaners to clean or wipe this product.
08. Please recycle this product and its related patches in accordance with local laws and regulations.
09. Children under 12, pregnant women and breastfeeding women should consult their physicians before using this product.
10. 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.

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.

—Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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Product Introduction

■ Product description

The ECG signal is collected by the sensor, the device processes and calculates the signal, and the analysis can obtain the ECG data. Finally, the data is wirelessly transmitted to each functional module of the mobile phone APP for display through Bluetooth. This 1-lead Holter monitor complies with the international standard IEC-60601-2-47.

■ Scope of product application

This product is mainly suitable for ECG monitoring of home and community medical institutions. This product can collect, process, store, and transmit 1-lead ECG, heart rate and other information safely, reliably and in real time. The collected information can be transmitted via Bluetooth.

■ Intended use of the product

This product is suitable for the ECG detection and monitoring of the following people :

- People with heart discomfort, such as heart palpitations.
- People with arrhythmia, cardiovascular disease, and heart disease drugs.
- People who need long-term close follow-up observation.

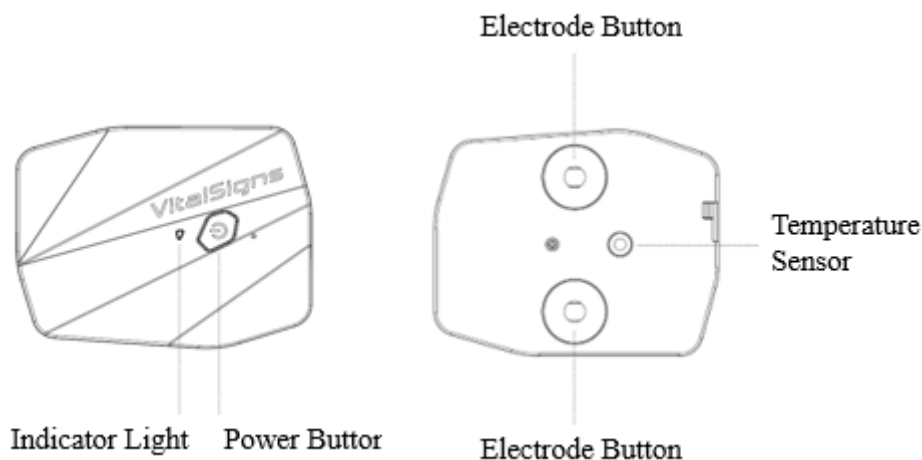
■ Product function

This product provides users with the following functions :

- 24-hour real-time continuous 1-lead ECG monitoring
- It can store and view historical ECG data

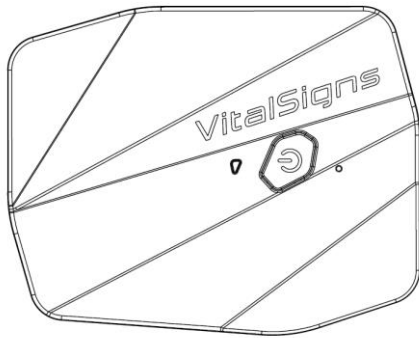
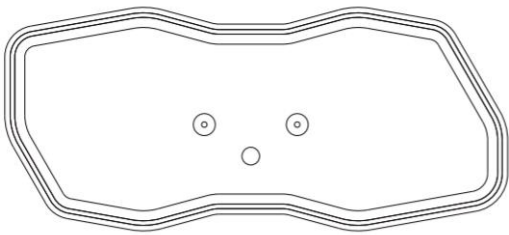
Product content

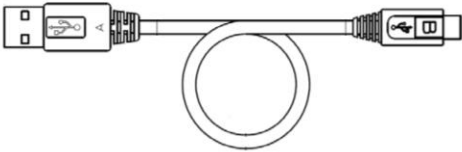
■ Product appearance



* The illustrations used in this manual may be slightly different from the appearance of the actual product.

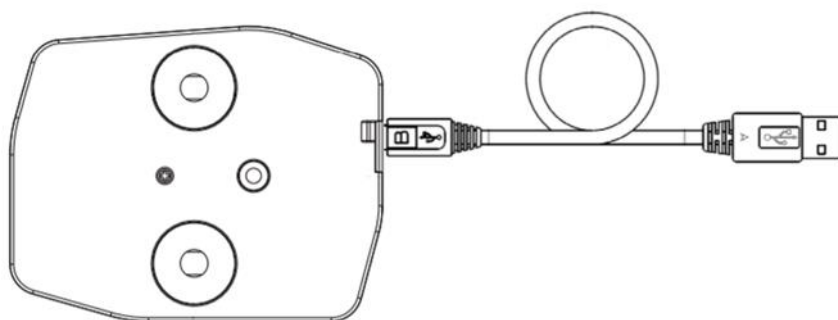
■ The main contents of the package

Equipment	Description
1-Lead Holter 【Host】	
Applicable ECG patch	 Remark : The ECG patch is a consumable, repeated use may cause skin irritation or affect the accuracy of signal measurement.

Equipment	Description
Micro-USB Cable	

* The illustrations used in this manual may be slightly different from the appearance of the actual product

■ Host charging method



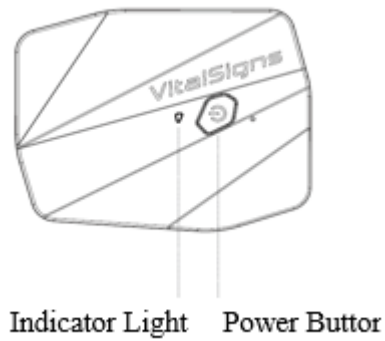
1. Please combine the MICRO-USB cable with the charging terminal of the 1-lead Holter recorder.
2. Please plug the other end into the USB charger interface .
3. When the indicator light is off, it means charging is complete (100%) .

Reminder: The device is not allowed to be used while charging.

VSH101	Instruction	1-lead Holter	Remark
Recharge	NA	Indicator light Constant bright green light	charging
		Indicator light Turn off the off state	Fully charged

* This product has passed EN 60601-1, IEC/EN 60601-1-2, IEC 60601-1-11 certification.

■ How to turn on and turn off the host



VSH101	Instruction	1-lead Holter	Remark
Boot up	Long press the host “power button” 3 second	Indicator light Flashing green	Indicates that the device has been turned on successfully
Close up	Long press the host “power button”3 second	Indicator light Turn off the off state	Indicates that the device has been shut down successfully

Instructions

■ Preparations before use

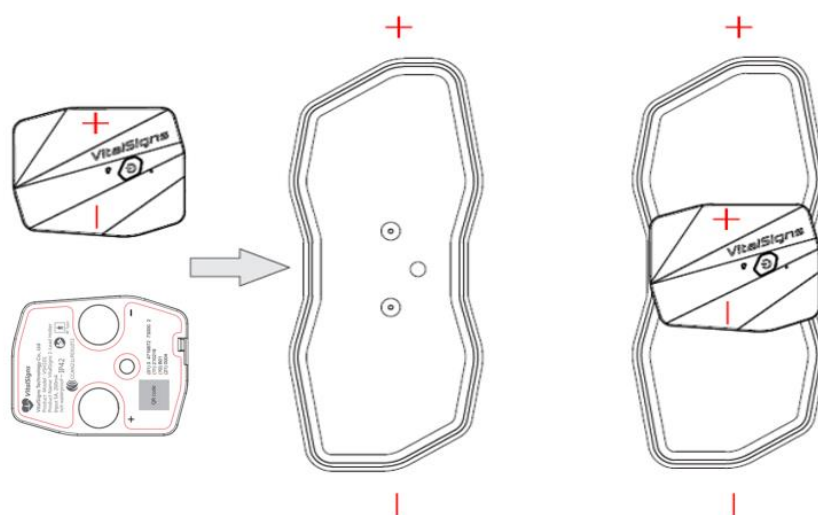
Please perform the following steps before using this product :

1. Please charge the 1-lead Holter recorder to 100% at first.
2. Please install the exclusive application app on smart devices (such as smart phones and tablets).
3. Please follow the instructions on the app to complete the registration and related initial settings. °

■ Get started

After completing the above pre-use preparations, please follow the steps below to start measuring with the 1-lead Holter recorder :

1. ECG patch preparation and installation



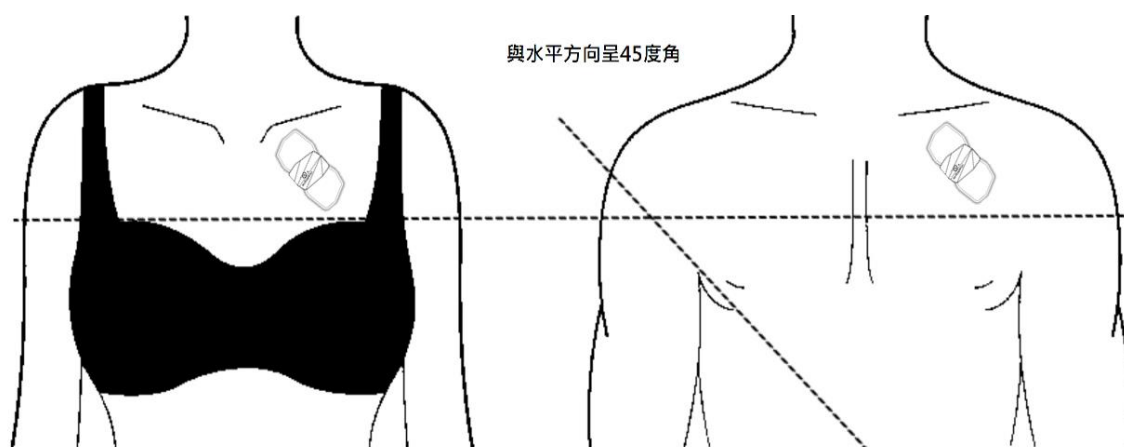
- I. Please clean the chest where the ECG patch is expected to be attached first, and remove oil and skin debris as much as possible. If necessary, shave the body hair in this area. Do not use alcohol when cleaning, as this will increase the resistance of the skin.
- II. Take out the ECG patch from the package, please do not uncover the protective film on the back.
- III. The buckles (male/convex) at both ends of the ECG patch are fastened to the main unit (female/concave). Please make sure that the positive pole (+) of the label sticker on the chassis must be in the same position as the positive pole (+) of the ECG patch. The negative pole (−) of the label sticker must be in the same position as the negative pole (−) of the ECG patch diagram, and press lightly to ensure that the ECG patch is firmly combined with the host.

2. Host and APP connection

- I. When the host is turned on, the Bluetooth function of the host will be turned on automatically.
- II. After the user opens the APP on the smart device, please make sure that the Bluetooth of the device is turned on, and set the connection to the host on the APP.
- III. Wait for the indicator light of the host to be steady blue, indicating that the connection is successful.

VSH101	Instruction	1-lead Holter	Remark
Boot up	Long press the host "power button" 3 second	Indicator light Flashing green	Indicates that the device has been turned on successfully.
Connect	Please start the APP, turn on the Bluetooth function on the smart device and set up the connection with the host	Indicator light Constant Bright Blue	Indicates that the device has been successfully connected.

3. Host wear



- I. Hold both sides of the main unit, uncover and remove the ECG patch protective film from one end.
- II. Stick the host and ECG patch on the position between the chest and the collarbone, and make sure that the direction of the device is as shown in the figure above (switch button/USB hole downward). The positive pole (+) is on the bottom, and the negative pole (-) is on the top. Paste them at a mitre angle.
- III. Gently press both sides of the ECG patch with your fingers to ensure that the ECG patch is fully attached to your body. Please avoid touching the switch button during the pressing process.

4. Connection considerations

- I. Please keep the distance between the host and the smart device within 10 meters. Too far or too much shielding may affect the Bluetooth transmission function.
- II. The recording time of each piece of data takes 5 minutes. If the host is removed within 5 minutes of starting the measurement, the piece of data has no reference significance.
- III. After the host is close up, the APP on the smart device will automatically disconnect from the host.

VSH101	Instruction	1-lead Holter	Remark
Close up	Long press the host “power button”3 second	Indicator light Turn off the off state	Indicates that the device has been close up successfully.

Product information and specifications

■ Product specifications

Project	Specification and description
1-lead Holter	<ul style="list-style-type: none"> ● Working power : 160mAh Rechargeable lithium battery ● Charging power supply : 5V , 200mA ● Dynamic input range 10% or 50μV ● Input impedance 10 MΩ ● Common mode rejection 45 dB ● Gain accuracy : Tolerance $\pm 10\%$ ● Gain stability : No more than 3% within 24hr ● System noise 50μV ● Frequency response ± 3dB ● Measuring range and accuracy of heart rate : The error of 30bpm ~ 200bpm does not exceed $\pm 10\%$ of the input heart rate or within 5bpm.
Measurement signal input	<ul style="list-style-type: none"> ● Via ECG patch
Data transfer	<ul style="list-style-type: none"> ● Bluetooth 4.2 ● Tx : 9.33 dBm ● Transmission range : 10 Meters (without shielding space)

Project	Specification and description
LED display	<ul style="list-style-type: none"> ● Boot up : Press and hold the main unit " power button " for 3 seconds, the indicator light flashes green, indicating that the device has been successfully powered on. ● Connection : Please start the APP, turn on the Bluetooth function on the smart device and set up the connection with the host. The indicator light is steady blue, indicating that the device has been successfully connected. ● Close up : Press and hold the main unit's " power button " for 3 seconds, the indicator light turns off and goes out, indicating that the device has been shut down successfully.
1-lead Holter battery	<ul style="list-style-type: none"> ● Built-in lithium battery : 3.7V / 160mAh ● Battery usage : Test mode use time is 24 hours (Continuously send data to the server) (Note: new battery)
Product normal working conditions	This equipment should be placed in a dry, non-corrosive environment, and no strong electromagnetic field interference. It should not be worn when swimming or bathing.
Operating environment	<ul style="list-style-type: none"> ● Working temperature : 5℃ ~ 40℃ ● Working humidity : 10% ~ 80%RH , Non-condensing ● Working altitude : 70kPa ~ 106kPa, 3000 m
Transportation and storage environment	<ul style="list-style-type: none"> ● Storage/transport temperature : -20℃ ~ 55℃ ● Storage/transport humidity : 10% ~ 85%RH , Non-condensing ● Storage/transportation altitude : 70kPa ~ 106kPa
Dimension	<ul style="list-style-type: none"> ● 1-lead Holter : 54*42.96*8 mm ● ECG patch : 130*62*4.4 mm ● Micro-USB Cable : 80*40*12 mm(34+950+25 mm)
Weight	<ul style="list-style-type: none"> ● 1-lead Holter : 8.5 g ● ECG patch : 4.5 g ● Micro-USB Cable : 7 g
Waterproof level	<ul style="list-style-type: none"> ● 1-lead Holter : IP 42

Project	Specification and description
Maximum operating frequency	● 40MHz
Applicable standards	This product complies with 《Ministry of Health and Welfare Taiwan Food and Drug Administration Second level general medical equipment inspection》 (Be applicable “Pharmaceutical Good Manufacturing Practice Regulations” Part 3 Chapter 2 Standard Mode)

■ Other information

Light description

VSH101	Instruction	1-lead Holter	Remark
Recharge	NA	Indicator light Constant bright green light	charging
		Indicator light Turn off the off stat	Fully charged
Boot up	Long press the host “power button” 3 second	Indicator light Flashing green	Indicates that the device has been turned on successfully.
Connect	Please start the APP, turn on the Bluetooth function on the smart device and set up the connection with the host	Indicator light Constant bright blue light	Indicates that the device has been successfully connected.
Close up	Long press the host “power button” 3 second	Indicator light Turn off the off stat	Indicates that the device has been shut down successfully.

Troubleshooting

Problem	Reason	Solution
The host cannot be turned on	The battery voltage is too low, causing the machine to fail to turn on.	<ul style="list-style-type: none"> ● Please charge the host. ● For related precautions, please refer to "Host charging method".
Host cannot connect	The connection fails continuously, the transmission distance between the host and the smart device has exceeded the upper limit, or there is a shielding that causes the connection to be abnormal.	<ul style="list-style-type: none"> ● Please restart the APP on the smart device and connect to the host. ● At the same time, confirm that the distance between the host and the smart device is within 10 meters, and the shielding has been removed. ● For related precautions, please refer to "Host and APP Connection" and "Connection considerations".
The pairing between the smart device and the host is abnormal	<ul style="list-style-type: none"> ● The Bluetooth function on the smart device is not turned on 	<ul style="list-style-type: none"> ● Please make sure that the Bluetooth function is turned on
ECG data disappeared	The battery is exhausted or the host is not properly connected to the smart device.	<ul style="list-style-type: none"> ● Please confirm the power of the host. When the host presents a low voltage, please charge it as soon as possible. ● At the same time, please confirm the connection between the host and the APP. ● For related precautions, please refer to "Host charging method" and "Host and APP connection".

Problem	Reason	Solution
The recorded waveform has a lot of noise	It means that there is interference to the signal during the measurement. The interference may come from poor contact of the ECG patch, excessive body movement, and strong electromagnetic interference in the environment... etc.	<ul style="list-style-type: none"> ● Make sure to use a new ECG patch and the correct electrode sticker installation method. ● Please avoid excessive body movements when using it, and do not use it when performing high-intensity exercises (such as marathons, etc.). ● Please change the measurement location or turn off the product that can cause electromagnetic interference source. ● For related precautions, please refer to " Preparations before use " and " Host wear ".

■ 1-lead Holter cleaning method

Item	Cleaning method
1-lead Holter	Wipe with dry cloth
ECG patch	The ECG patch is a consumable, if it needs to be replaced, the user can purchase it by himself
Micro-USB Cable	Wipe with dry cloth

■ ECG patch

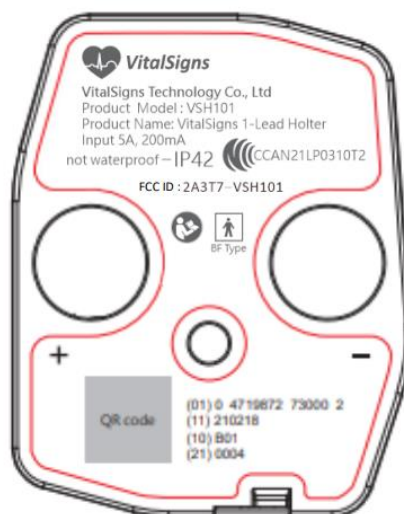
Users can contact Vital Signs Technology Co., Ltd. or go to medical equipment stores to purchase ECG patches approved by the Ministry Of Health And Welfare.




The specifications of the ECG patch are as follows,

1. Approved by the Ministry Of Health And Welfare, or in line with FDA or CE certification.
2. Pass the biocompatibility test (ISO 10993).
3. The size of the male buckle is 4 mm, and the distance between the two male buckles is 25 mm.

* Reminder: If you use patches from other brands, it may affect the interpretation of the equipment.

■ Chassis label illustration



VSH101	Reference	Description
	National Communications Commission	Inspection certificate number : CCAN21LP0310T2
	ISO 7010-M002	Please refer to instruction manual / booklet
	IEC 60417-5333	BF type body parts
IP42	This product has passed IEC 60601-1-11 certification.	4: Isolate most wires from extending in and small sharp-pointed tools, or ants, etc. from crawling in. 2: Protection against dripping water at an angle of 15°