Non-invasive Hemodynamic Blood Pressure Monitor

Discovery 1

User Manual

Vita-Course Technologies Co., Ltd.

User Notes:

Thank you for using the Non-invasive Hemodynamic Blood Pressure Monitor.

Please read the instruction manual carefully before using the product.

Vita-Course shall not take corresponding responsibility for any abnormality or any personal or machine damage caused by the irregular use, maintenance and reposition without the guidance of the instruction, and shall not provide free maintenance for such failures.

This manual is only applicable to Discovery 1 type Non-invasive Hemodynamic Blood Pressure Monitor (hereinafter referred to as "equipment")

Contraindications: unclear

Copyright and Disclaimer

File Updating

This instruction was finally revised by Vita-Course Technologies on February 22, 2017.

Safety Announcements:

☒ **Warning: The patient or the operator may die or be seriously injured when the equipment is operated mistakenly.**

🔔 **Caution : The damage may happen to people or equipment when the equipment is employed incorrectly.**

⚠ **Note : Important tips on operation and use**

☒ Warning

1. Before the use of the equipment, users need to check the equipment so as to ensure its safe use and normal work.
2. Do not use the equipment in these places full of the flammable gas and explosion.
3. Allergic reactions may occur in very few other users. If it happens, please stop using the equipment immediately.
4. When users connect other equipment to their bodies, please be cautious: the total leakage current may exceed the permissible limitation, causing potential damage to the user.
5. Equipment accessories, such as pulse wave probes and cables whose materials have been tested for biocompatibility, cannot be replaced at will. Please use the accessories provided by our company in case it may lead to some adverse consequences related to safety and biocompatibility etc.
6. All the connections of applications should be away from the user's neck so as not to choke the user's neck.
7. Before carrying out maintenance, please turn off the equipment.
8. The scrap of this equipment and parts shall comply with local laws and regulations.
9. This equipment belongs to professional medical equipment, and only the professionals appointed by the factory are responsible for the maintenance.
10. Apply to those who are 16~70 years old.
11. Please close the equipment and evacuate the sensor during magnetic resonance imaging MRI scanning; if not, it may cause burns or affect the accuracy of MRI images as well as equipment.
12. Please make sure children can't touch it when you keep it.
13. Please do not use the high frequency operation equipment at the same time so as not to affect the measurement accuracy of the equipment.

Caution

1. Please keep and use the equipment within the regular range of temperature, humidity and atmospheric pressure; if not, it would lead to damage of the equipment and inaccurate measurement results.
2. Please do not directly open the equipment after it is affected with damp to avoid damaging the equipment, and use it after it is dried.
3. The equipment is limited to one user at the same time.
4. Please be away from equipment with strong electromagnetic interference, such as microwave ovens, large printers, induction cooker, etc. when using it.
5. When using high frequency surgical equipment, close the equipment and evacuate the sensor.

Note

1. When common arrhythmias, such as atrial fibrillation, premature ventricular fibrillation, and atrial fibrillation, occur, they may affect the accuracy of output results.
2. Professionals shall interpret the measuring results of the equipment.
3. The value of blood pressure measured by this equipment is equivalent to that measured by auscultation, and the error is in line with the requirements specified in YY 0667-2008.
4. If those who are equipped with heart pacemaker, a stent and beyond the measurement range use the equipment, the accuracy of the output results will be affected.
5. Please remove your callus of your hands and nail polish before using the equipment.
6. Check the battery power after each use. When the battery is less than 1 cell, you must charge the battery, and ensure sufficient storage of electricity.
7. Please stop using the equipment if there is any indication of malfunction.
8. Signal input and output interfaces can only be connected to the required devices.

Table of Content

Chapter 1 Summary

1.1 Characteristics of products

- ✓ Noninvasive and cuff-less equipment
- ✓ The self-contained screen to monitor blood pressure measurement data; real-time clock to display the time.
- ✓ Rapid measurement of blood pressure and pulse rate.
- ✓ Automatic measurement.
- ✓ Dynamic continuous measurement can keep 24 hours.
- ✓ Real-time power display, low battery alert and auto sleep for power save.
- ✓ Wireless connection via display terminal, such as Bluetooth and intelligent mobile phone, etc.

1.2 Intended Use/Instruction for use

The Discovery 1 - Non-invasive blood pressure trending device is a small, lightweight, handheld, device intended for measuring and display of Blood Pressure trending (systolic and diastolic) and spot-check of Peripheral pulse rate (PPR) and Peripheral pulse wave (PPW). Measurement is performing on capillary fingertip tissue (other than the thumb). The ring finger is the recommended site. The results of each measurement are stored in the system memory.
It is intended to be used by any person aged above 18 years old.

1.3 The scope of products

Apply to medical institutions or families to monitor the blood pressure and pulse rate of the human body.

1.4 Structure

The cuff-less equipment consists of a host, mobile APP software and accessories.
Accessories include : Pulse wave probe and cable, arm band (optional), power adapter, data transmission line / charging line.

1.5 Product classification

According to the classification of medical device management categories: Class II

According to the type of protection against electric shock: class II internal power supply equipment
According to the degree of protection against electric shock: BF-type equipment
According to the degree of protection against harmful liquid into: ordinary equipment (the closed equipment that cannot stop the liquid into)
According to the safety degree related to a mixture of flammable anesthetizing gas and air or oxygen or Nitrous Oxide: not applicable in the place existing flammable anesthetizing gas.
According to the work system: continuous operation of equipment

1.6 Operating environment

1．Operating temperature：5 ℃～45 ℃；
Relative humidity：10%～95%(non-condensing)；
Atmospheric pressure：70.0 kPa～106.0 kPa；
2．Working mode: internal power supply: DC 3.7, V/2200, mAh;
Charging mode: power adapter input voltage: 220 V, 50Hz.

1.7 Safety

1. Comply with IEC 60601-1:2012 "Medical electrical equipment; Part 1: General requirements for safety"
2. Comply with IEC 60601-1-2:2014 "Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests"
3. Comply with ISO 80601-2-61 "Particular requirements for basic safety and essential performance of pulse oximeter equipment"

Chapter 2 Wearing and Connecting

2.1 Out of box audit

1、Open the packing box and take out the equipment and accessories.
2、Open the random file and check accessories according to the packing list:
1) Check whether the equipment has any mechanical damage.
2) Check whether all accessories including plug, wires and sensor have scoring or shortness.
3) Before using the equipment, check whether the equipment and accessories are in danger or have abnormality; if it has abnormality (such as patients' cable rupture, shell cracking, etc.), do not carry out measurement.)
If you have any questions, please contact the seller or contact us. We will provide you with satisfactory service in time.

2.2 Appearance presentation

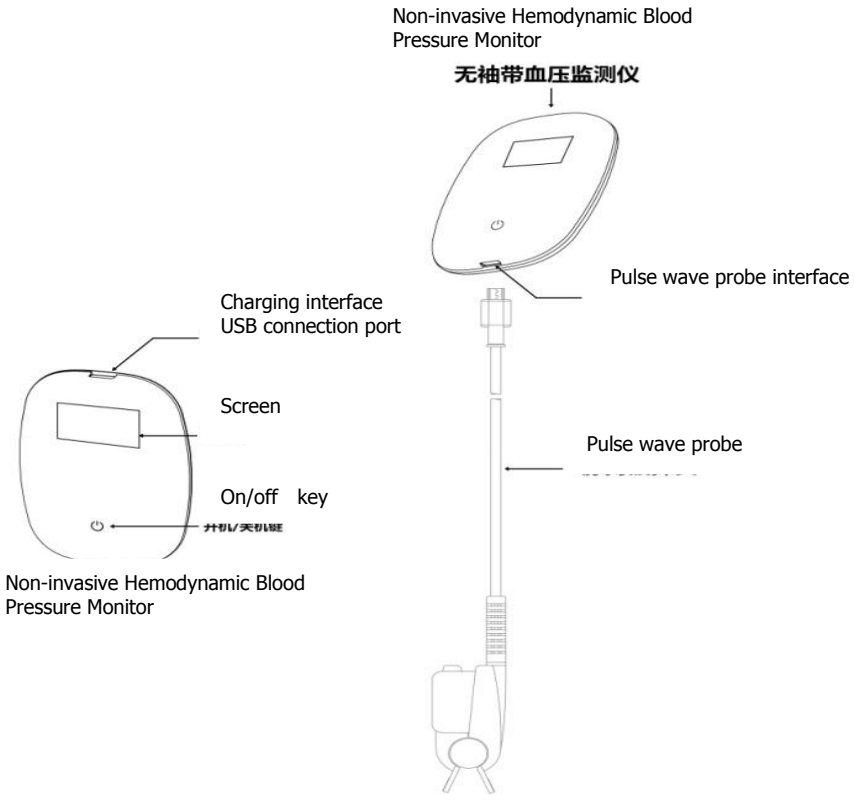

Figure 2.1 product drawing

Content	Description

On/off key	Press the power on / off button for 1 second to turn on the equipment Press the power on / off button for 4 seconds to turn off the battery
Screen	Display interface content
USB connection port	Connect line USB to charge upgrade the program and export data
Pulse wave probe interface	Connect pulse wave probe

2.3 Marks

Content	Description
	Be careful ! Consult the random file
	USB connection port
PPG	Pulse wave probe
	BF applied part
	On /off button
	Non-Ionizing Radiation

2.4 Wearing

Please wear arm belt as shown in Figure 2.2

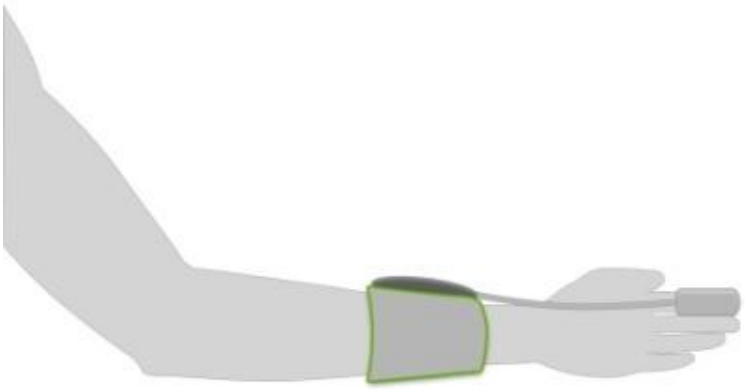

Figure 2.2 wearing arm belt

2.4.1 The connection of pulse wave probe

Connect the plug of the pulse wave probe to the interface corresponding to the equipment.
When you connect them, you could hear "Kaka".
As shown in Figure 2.3, the finger of the person to be measured (using the index finger of the left hand) is extended into the probe.

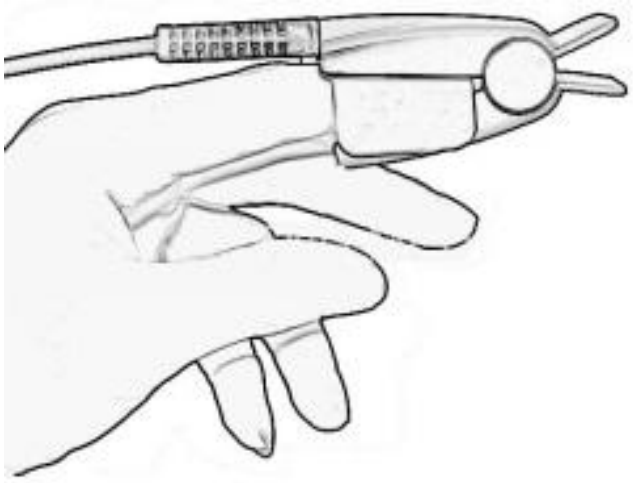

Figure 2.3 the finger position of wearing the clip pulse wave probe

Safety attentions for pulse wave measurement

☒Before the use, please check the pulse wave probe and if there is worn cable or abnormality, please immediately stop using the equipment.

☒Do not place the pulse wave probe on the limb with an artery or venous infusion tube because such circumstance will affect the accuracy of measuring results.

☒Do not look directly at the pulse wave probe when using it in order to avoid the damage to eyes.

☒Please stop using the probe if you find out its temperature is obviously increasing.

☒Please do not use the pulse wave probe for a long time when the ambient temperature is above 40 degrees in order to avoid burns.

☒ Normally, at least once every 3 hours, change the wearing position. Inspect the worn area every 1 to 2 hours to ensure good skin condition is aligned with the correct light. If local skin condition changes, please change the position of the pulse wave probe in time.

☒ Constant use of the pulse wave probe can cause discomfort or tenderness, especially in patients with microcirculatory disturbances, so preferably change the wearing position once every 2 hours.

☒ As for some special patients, the measuring part of the pulse wave probe should be checked carefully and do not place the sensor in a edematous or fragile tissue!

🔔Those who are measured should not have long fingernails and apply nail polish, etc.

🔔If those who are measured have thick callus of fingers, the finger with less callus is preferred.

🔔 Do not bend, twist cable.

🔔 The blood pressure cuff and pulse wave sensor that need to be pressurized cannot be used on the same limb because measuring the blood pressure on the same limb will affect the monitor of pulse wav.

🔔Do not use the broken pulse wave probe.

🔔Do not completely put the probe into the water, solution or cleaning agent because the probe is lack of waterproof function.

🔔Please hold the forepart of the plug to pull the plug.

🔔The pulse wave probe can be used repeatedly. Before that, the probe needs cleaning. The specific methods are described in a chapter related to maintenance.

🔔In order to ensure the safety and effectiveness, it' s necessary to use the pulse wave probe provided by our company and stop the interface of the pulse wave probe from being connected to other things.

Chapter 3 Interface Introduction and Operation

3.1 Boot

Press the button of switch machine for 1 second. The system enters the boot interface successfully, as shown in figure 3.1.

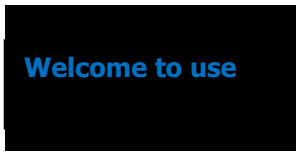

Figure 3.1 boot interface

⚠ Check the battery power after each use. When the battery is less than 1 cell, you must charge the battery, and ensure sufficient storage of electricity.

⚠ If there are indications or signs of broken function, please stop using the equipment immediately and directly contact with seller or our company.

3.2 Connecting APP

Before the measurement, the equipment needs to connect to terminal equipment via Bluetooth and intelligent mobile phone as shown in figures 3.2 and 3.3. Users need to download APP "Discovery 1", which is related to terminal devices. And mobile APP software can be downloaded from the company's official website.

Running environment of software:

Software running environment:

IOS8.0 and above software version, support iPhone 5, iPhone 5S and above hardware

Android 4.3 and above software version

Bluetooth supports 4.0BLE protocol

Displaying pictures and introduction of measurement results of physiological data could be seen from the APP operation assistant!

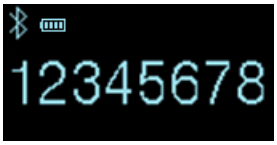

Figure 3.2 the equipment is not connected.

Content	Name	Meaning
	Bluetooth signal icon	Indicating that Bluetooth is on
	Power icon	Displaying the situation of the use of battery
12345678	sequence code	The sequence code consists of 8 digits and letters.

Figure 3.3 the equipment is connected

Content	Name	Meaning
	Bluetooth signal icon	Indicating that Bluetooth connects with APP
14:37	Time	Displaying the current synchronization time

3.3 Calibration

The equipment must be calibrated before being measured for the first time and specific procedure should be:

1. Wearing the equipment that needs to be connected to APP

2. Select the calibration function of the mobile App and start calibration measurement. In this process, the interface of the equipment is shown in figure 3.4:

Figure 3.4 calibration measurement

3. After the finish of calibration measurement, it is necessary to use mercury equipment or other equipment to measure the user blood pressure value, and input the measurement result into the corresponding window of APP.

Attention ：

1. For the sake of pursuing more accurate measuring results of blood pressure.

2. Desktop equipment and other equipment that used for calibration must be qualified products, which are approved by the National Metrology Department and periodically calibrated. Methods of blood pressure measurement refer to Guidelines for Chinese blood pressure measurements.
Input methods refer to App operation guide.

3.4 Measurement

1. Set up the measurement mode and then carry out measurement as shown in figure 3.5;
If you want the equipment to enter automatic measurement and dynamic continuous measurement mode, please ensure that the battery power is more than 3 squares
2. After the equipment enters dynamic continuous measurement mode, you could look at the present situation of measurement by connecting mobile phone APP to the equipment and after the mobile phone APP is disconnected, the dynamic continuous measurement of the equipment is not affected.

Figure 3.5 measurement interface

Content	Name	Meaning
H	Dynamic continuous measurement mode	Indicating that the equipment is in dynamic continuous measurement mode
A	Mark of dynamic measurement mode	Indicating that the equipment is in dynamic measurement mod
	Power Icon	Displaying the condition of using the battery
Zhang Aihua	Name	Representing patients' name
120/80 mmHg	Blood pressure value	Representing a systolic / diastolic pressure value
70 bpm	Pulse rate value	Representing pulse rate value

3.5 Measuring result

After the finish of measurement, the value of measuring results will be displayed. If the result is normal, it would be like the figure; the blood pressure analysis report can be printed through mobile phone APP and the specific operating procedure can be seen in guidance of APP operation;

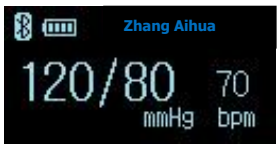

Figure 3.6 the interface of measuring result

3.6 Prompt in measurement

3.6.1 Prompt of starting the measurement

1. In the dynamic continuous mode, if the interval of day ≥ 30minutes, within five minutes before the measurement, prompt will start in the form of vibration; in addition to that, it will display such indication "Going to start the measurement". It is like the figure 3.7.

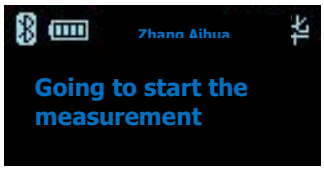

Figure 3.7 start the prompt during the day

2. If the interval of day < 30 minutes, there is no prompt.
3. Within five minutes before the start of the measurement, prompt will start in the form of vibration; in addition, it will display "Start the measurement during the night". It is like the figure 3.8.

Figure 3.8 start the prompt during the night

3.6.2 Abnormal prompt of the connection of the pulse wave probe

In calibration mode, single mode, automatic mode, dynamic mode, the pulse wave probe falls off or connects abnormally, and the screen shows "abnormal connection ". The equipment will generate a vibration reminder. As shown in figure 3.9:

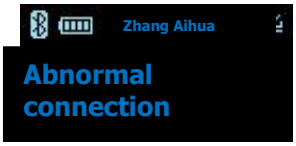

Figure 3.9 Abnormal connection

If you want to withdraw from the automatic mode and dynamic mode, you need to connect your mobile phone to the product and then make APP enter the corresponding mode, and eventually click Cancel Measurement to achieve the final withdrawal. If it is being measured, you need to wait until the measurement is over before you can exit the measurement mode.

3.6.3 Measuring influencing factors

During measurement, the following factors may affect the accuracy of measurement:

1. The ambient light is too strong or there is a strobe light or a flash light (such as a fire light). (Hint: cover the area of the blood oxygen probe with opaque material.)

2. Excessive movement of users, excessive vibration.

3. Severe cough, laughter, anger and other emotional fluctuations occurred during the measurement.

4. Effect of electromagnetic field, such as nuclear magnetic resonance equipment--microwave ovens, large printers, induction cooker and so on.

5. The impact of high frequency surgical equipment and electrosurgical devices

6. Wrong position of placing the pulse wave probe or the incorrect use of accessories.

7. Hypovolemic shock due to blood loss, burns, trauma, etc., shock caused by infection, allergies, nerves, cardiogenic diseases and ischemia and hypoxia in surrounding tissues caused by various causes.

8. The existence of certain cosmetics, such as nail polish, cosmetics and so on.

3.7 Battery level

1. The information of battery status is shown on all screens fixedly. These battery icons tell you the current battery status (see the following table)

Icon	Description
	The electricity=100%
	The electricity≤75%
	The electricity≤50%
	The electricity≤25%
	The electricity≤10%
When the power is switched on, the power icon is always blinking.	

2. Prompt of low battery: when the electricity is less than 25%, there will be a hint of low battery as shown in Figure 3.10. It will return to the original interface after 10 seconds. When the electricity is less than 5%, it will show a low battery. As shown in Figure 3.11, the device will automatically turn off after 10 seconds.

;

Figure 3.10 prompt of low power 25%

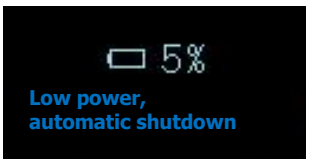

Figure 3.11 prompt of low power 5%

3. When the battery is off and charged, the battery icon on the screen flashes in turn, showing the percentage of the electricity, as shown in figure 3.12;

Figure 3.12 the interface of the battery being off and charged

- The time of charge once: 4~6 hours
- During the charge, please pull the pulse wave probe.
- Given a built-in battery in the equipment, regardless of whether the use or the boot, the built-in battery will be charged when the equipment is connected with alternating current. If the battery is full, please disconnect the AC immediately because charging time should not exceed 12 hours.
- Please use the power adapter configuration provided by our company; stop any other objects from being into the charging interface.

Chapter 4 Structural Features and Working Principle

4.1. Overall structure framework chart

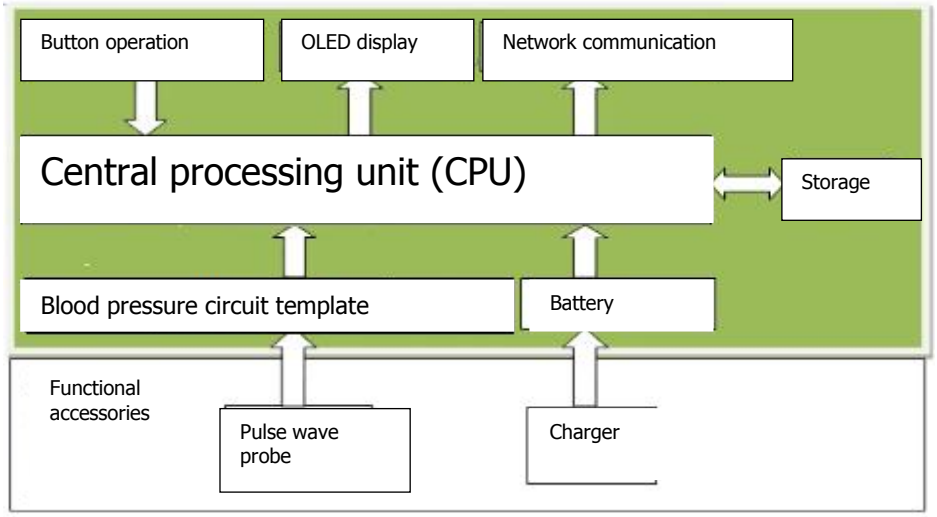

Figure 4.1 Overall structure framework chart

4.2 Principle of blood pressure measurement

The product is designed to calculate the blood pressure I terms of conduction time of pulse and wave parameters of pulse. This method is proposed based on interdependent characteristics between conduction time of the pulse wave along the arterial as well as characteristic parameters of the pulse wave and arterial pressure. Through the determination of the PPG signal, conduction time of the pulse wave along thee arterial and other correlation variables would be obtained and accordingly the systolic and diastolic pressures of the body are gotten by fitting operation. The pulse rate can be obtained by calculating the pulse wave signal.

Chapter 5 Technical Characteristics

5.1 Blood pressure

1. Measuring range of blood pressure

Systolic pressure 50 mmHg ~200 mmHg

Arterial pressure 40 mmHg ~160 mmHg

2. Stability of measurement results

Average deviation≤3 mmHg。

3. Accuracy of measurement

Within the range of systolic pressure 70 mmHg～180 mmHg、Arterial pressure 40 mmHg～130 mmHg：Mean difference≤±0.67 kPa(±5 mmHg)，standard deviation≤1.067 kPa(8 mmHg)

4. Display resolution of blood pressure：1 mmHg

5.2 Pulse wave

5.2.1 Sensor

1. Type：Photodiode；

2. Wavelength：infrared：905 nm，red light：660 nm；

3. Maximum average optical output power：≤2 mW；

4. Update cycle of data：1 s。

5.2.2 Range and accuracy

1. Pulse range：40 bpm～240 bpm；

2. Accuracy：±2% or ±2 bpm，choose the big value；

3. Resolution ：1 bpm。

5.3 Size and weight

Host size： 90 mm x 64 mm x 17 mm

Host net weight：about 150 g

Chapter 6 Maintenance, Preservation, Storage and Transportation

In order to ensure the equipment will run normally and extend its life in use, maintenance and preservation of equipment should not be neglected. The warranty period of this equipment and fittings could be seen in the detailed provisions of the contract of sale.

☒If the responsible hospital or unit using the equipment fails to realize maintenance and preservation, unexpected equipment malfunction may occur and then bring the damage to health.

If you find any problems of equipment and need to get circuit diagrams, drawings, notes, or technical support, please contact with maintenance personnel, Vita-Course Technologies or your authorized supplier.

6.1. Cleaning of equipment

The equipment should be kept clean. It is recommended to clean the outer surface and display screen regularly and in a timely manner using non erosion cleaning liquid, such as clean water. The surface of the equipment and sensors can be cleaned by medical alcohol, dried naturally or cleaned with dry cloth

☒ You must turn off the power before cleaning equipment.

🔔**Do not let the cleaning liquid be into connecting socket of the equipment in order to avoid damaging the equipment.**

🔔**Do not let any part of the equipment be soaked in the liquid.**

🔔**After the use, please keep it clean and put it away.**

🔔**Do not use such things that have strong friction (such as steel wool and sandpaper) to clean the equipment.**

🔔**Do not use such things that have strong corrosiveness such as bleaching powder to clean the equipment and accessories.**

6.2 Cleaning of accessories

After the use of accessories, you could immerse the clean and dry gauze in medical alcohol with the concentration of 75% or in isopropanol solution with the concentration of 70% and then use this gauze to clean the surface of the used accessory (including sensor and plug).

🔔 Do not fully immerse accessories of the equipment in water solution, accessories or detergents.

6.3. Maintenance test

6.3.1 Routine test

Before using the equipment, you need to carry out the following inspection:

- Check whether the host has any mechanical damage;
- Check whether the structure performance of all accessories (including plug and sensor) is complete;
- Check all available measurement function to make sure that the equipment can work well;
  If there is any obvious indication of the damage of the equipment, please stop using it and contact with supplier.

6.3.2 Periodic test

Every year or after the maintenance every time, a thorough inspection, including function and safety, of the equipment must be carried out by qualified personnel.

☒ If y the hospital using the equipment cannot implement a satisfactory maintenance project, it will result in equipment failure, and may endanger the health of human body.

☒ If the pulse wave sensor and the cable are damaged or deteriorated, stop using it and replace new cables.

6.3.3 Battery maintenance

☒ This equipment adopts the built-in battery, which cannot be arbitrarily removed from it;

☒ Does not charge the battery using other power device, so as not to damage the battery;

☒ The aging battery cannot be thrown away in the fire, so as to avoid the explosion;

☒ Do not use the battery to supply power for other electronic devices;

☒ Destruction of battery should comply with local laws and regulations;

🔔In order to extend the useful life of battery, please use battery properly and regularly carry out the maintenance and preservation. The equipment should be charged regularly for maintenance though it is not used for a long time. Generally, it should be charged once a month and 4~6 hours each time;

🔔Please contact with our company directly if battery is already broken;

🔔 This equipment is equipped with a built-in battery. Regardless of whether the boot for the use, as long as alternating current (AC) is connected with the equipment, the process of charging is working. When the battery is full, please disconnect the AC because charging time should not exceed 12 hours;

🔔 Please use the power adapter configuration provided by our company.

Chapter 7 Storage and Transportation of Equipment

7.1 Storage

If the equipment is not used for a long time, it should be cleaned, put into the packing box and stored in a dry, dust-free, and well ventilated room without corrosive gas.

7.2 Transportation

It can be transported by car, train or plane. Take care to handle gently during transit.

Environment of transportation and storage:

Temperature: -20 ~ 55 DEG c;

Relative range of humidity: 10%~ 95% (non condensing);

Range of atmospheric pressure: 53 kPa to 106 kPa.

Chapter 8 Troubleshooting

8.1 Check the equipment and accessories

A visual inspection should be carried out before each use when the power is disconnected:

1. Check the outside of the equipment to see if it is clean and the general physical condition. Make sure the outer skin is not broken, all parts are in place, and there is no dumping of liquid as well as no signs of abuse.

2. Check whether all accessories (such as cables, sensors, sensory unit, etc.) are in good condition. If there is any sign of damage, please stop using it.

8.2 Check cable and charging line

1. Check whether the power plug and the power cord are damaged, and make sure the plug is fixed and not moved in the outer skin. If there is any damage, please contact the maintenance personnel, Vita-Course Technologies or your authorized supplier.

2. Check the user's cable and its corresponding stress relief device in general to confirm that the insulating layer is undamaged and that both ends of the connector are firmly connected to prevent rotation or other stresses.

3. Clamp the pulse wave sensor on the user's finger and open the equipment and gently pull the cable line near the ends of the cable to make sure there is no interruption.

8.3 Troubleshooting

If you suspect a measurement results, please read the instruction manual and confirm several times that the measurement is properly set.

If you have any problems with the equipment, please call the maintenance staff.

Phenomenon	Possible reason	Solution
The equipment is power-off.	Depletion of internal lithium battery	Plug in the power adapter to charge the battery.
	Possible damage	Send the product to the designated repair shop or sales shop for repairs
No reaction when pushing	Work abnormally	The equipment turns off if you push button no less than 10 seconds; it will

the button		turn on if you push button about 1 second.

Figure 8.3 analysis of common fault

8.4 Disposal of equipment

☒In order to avoid the pollution and infecting others, other equipment and environment, the equipment should be cleaned before the disposal of equipment and according to local regulation (regulations on disposal of electronic and electrical components and equipment) it can be disposed. If there is no related regulation, please dispose of it in accordance with the rules of the disposal of waste in the local hospital.

Do not throw away battery randomly and knock it down, and then contact with the local supplier.

This product must be recycled and processed in accordance with local law.

Please do not treat obsolete electrical or electronic equipment as unclassified municipal waste. Collected separately, the equipment can be safely, properly reused, treated, and recycled.

⚠

Chapter 9 Appendix

Appendix EMC manufacturer's statement and guidance

Electromagnetic compatibility

⚠ **Note：**

- The equipment complies with IEC 60601-1-2:2014 standard and electromagnetic compatibility requirements
- The user shall install and use the equipment according to the electromagnetic compatibility information provided by the random files.
- Portable and mobile RF communications devices may affect device performance, so in order to avoid strong electromagnetic interference, please keep away mobile phones and microwave ovens.
- The guide and detailed manufacturer's statement are in the appendix.
- This device is bound by Bluetooth and APP software. Bluetooth operating frequency: 2.400~2.4835 GHz, radiation power: -20~4 dBm. Pay attention to the effect on the equipment that is sensitive to.

Warning：

- Equipment or systems shall not be accessible or stacked for use with other equipment. If it must be approached or folded for use, it shall be observed and verified to be in operation under the configuration used.
- In addition to the regulated transducer and cable, the use of specified accessories, transducers, and cables may result in an increase in equipment or system emissions or a decrease in immunity.
- The use of specified accessories, transducers, or cables in conjunction with equipment and systems may result in an increase in equipment or system emissions, or a decrease in immunity.
- Using the value that is below the minimum amplitude or minimum specified in this specification may lead to inaccurate results.

Appendix：

The guidance and manufacture’ s statement--electromagnetic emission		
Users or buyers of the equipment should make sure that it is used in such following electromagnetic environment:		
Emission test	**Conformity**	**electromagnetic environment–guidance**
GB4824 RF emission	1group	The device uses RF energy only for its internal functions. As a result, its RF emission is very low and may not cause any interference to nearby electronic devices.
GB4824 RF emission	B type	The equipment is suitable for use in all facilities, including homes and public low voltage power grids connected directly to homes.
Gb17625.1 Harmonic emission	Inadequacy	
GB17625.2 Voltage fluctuation / scintillation emission	Conformity	

The guidance and manufacture’ s statement–electromagnetic immunity			
Users or buyers of the equipment should make sure that it is used in such following electromagnetic environment:			
Immunity test	**IEC 60601 test level**	**Accord with level**	**Electromagnetic immunity–guidance**
Electrostatic discharge （ESD） **GB/T 17626.2**	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	The ground shall be wood, concrete or tile, and if the ground is covered with synthetic material, the relative humidity shall be at least 30%.
EFT--electrical fast transient **GB/T 17626.4**	+ 2kV to power line + 1kV to input / output line	±2kV to power line	The network power shall have typical quality used in the commercial or hospital environment.
Surge **GB/T 17626.5**	+ 1 kV differential mode voltage + 2 kV common mode voltage	±1 kV differential mode voltage	The network power shall have typical quality used in the commercial or hospital environment.

Voltage sags, short interruptions and voltage variations on the power input line **GB/T 17626.11**	<5 % U_T, continuing 0.5 weeks (on U_T, a temporary drop >95%) 40 % U_T, lasting 5 weeks (on U_T, a temporary drop 60%) 70 % U_T , lasting 25 weeks (on U_T, a temporary drop 30%) <5 % U_T, lasting 5s (on U_T, a temporary drop >95%)	<5 % UT, lasting 0.5 weeks(on UT, a temporary drop >95%) 40 % UT, lasting 5 weeks (on UT, a temporary drop 60%) 70 % UT , lasting25 weeks (on UT a temporary drop 30%) <5 % UT, lasting 5s (on UT, a temporary drop >95%)	The network power shall have typical quality used in the commercial or hospital environment. If the equipment's users need to run continuously during power outages, the recommended equipment is powered by an uninterruptible power supply or uses battery.
Power frequency magnetic field (50Hz) **GB/T 17626.8**	3A/m 50Hz	3A/m 50Hz	The power frequency magnetic field shall have the horizontal characteristics in a typical commercial or hospital environment.
Note: U_T refers to AC network voltage before test voltage is applied.			

The guidance and manufacture’ s statement–electromagnetic immunity			
Users or buyers of the equipment should make sure that it is used in such following electromagnetic environment:			
Immunity test	**IEC 60601 test level**	**Accord with level**	**Electromagnetic immunity–guidance**
RF conduction GB/T 17625.6	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to	3 Vrms 3 V/m	Portable and mobile RF communications devices shall not be used closer to any part of the equipment (including the cable) than the recommended isolation distance. The distance shall be calculated by the formula corresponding to the transmitter frequency. **Recommended isolation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz Among them, P refers to the maximum output power rating of the transmitter, which is provided by its manufactures. Watt (W) is a unit, D is recommended isolation distance, and meters (m)is a unit.

RF radiation GB/T 17626.3	2,5 GHz		The field strength of the fixed RF transmitter is determined by the electromagnetic field survey a, and in each frequency range the B should be lower than the level required. Interference may occur near the equipment that marks the following symbols.

Note 1：On the 80MHz and 800MHz, formulas of higher frequency bands are employed.

Note 2：The guidance may not apply to all the situations because electromagnetic transmission is influenced by the absorption and reflection of buildings, objects, and the human body.

a The field strength of the fixed transmitter, such as wireless (cellular / cordless) telephone, the base station of ground mobile radio, amateur radio, AM as well as FM radio and television broadcasting, cannot be theoretically predicted. In order to evaluate the electromagnetic environment of a fixed RF transmitter, the investigation of electromagnetic field should be conducted. If the field strength of the device is higher than the RF level of the above-mentioned application, the equipment shall be observed to verify its normal operation. If abnormal performance is observed, supplementary measures may be necessary, including reorientation or repositioning of the equipment.

b In the whole frequency range of 150 kHz to 80 MHz, the field strength should be less than 3 V/m.

Recommended isolation distance between portable and mobile RF communications devices and Discovery 1

The device is expected to be used in a controlled electromagnetic environment where radiated RF is disturbed. On the basis of the maximum output power of communication equipment, purchasers or users of Discovery 1 can maintain the minimum distance between Discovery 1 and portable and mobile RF communication equipment (transmitter) and accordingly prevent electromagnetic interference.

Rated maximum output power of transmitter /W	**Isolation distance corresponding to different frequencies of transmitter**		
	150 kHz ~ 80 MHz $d = 1.2\sqrt{P}$	**80 MHz ~ 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz ~ 2,5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Rated maximum output power of transmitter can be defined by related formulas of transmitter frequency bar. Recommended isolation distance could be represented by d and the unit is meter. *P* represents Rated maximum output power of transmitter, which is provided by its manufactures. Watt (W) is a unit.

Note 1: on a frequency range of 80 MHz and 800 MHz, a formula with a higher frequency range is adopted

Note 2 : The guidance may not apply to all the situations because electromagnetic transmission is influenced by the absorption and reflection of buildings, objects, and the human body.

The warranty ordinance of the product

1. Product warranty card is a certificate of warranty service;
2. The warranty period of the host of the equipment is 1 year and of battery and other accessories is 3 months. The warranty start date is the invoice purchase date.
3. Due to the following circumstances, product failure does not belong to the warranty category.
1) Users disassemble, refit products and use other accessories that are not provided by the company;
2) Machine failure or damage because users do not obey the safety or operating method described in this specification;
3) Damage caused by improper use or other factors, or by natural disasters.
4. if the repair service is beyond the warranty range, the maintenance would not be free and the warranty period of the same failure lasts 3 months.

Warranty card		
Users' information		
Name of the equipment		
Type of the equipment		
Number of the equipment		
Purchase date		
Users' name		
Telephone		
Warranty record :		
Warranty date	Failure and processing method	Repairer /date

FCC Caution

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. 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:

-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.

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

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled Environment and can be use without any restrictions.

Contact information

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WeChat public number：维他驿站
Registration number / technical requirement number:
Production license number:
Product life: 3 years
Production date: detailed information in the host nameplate