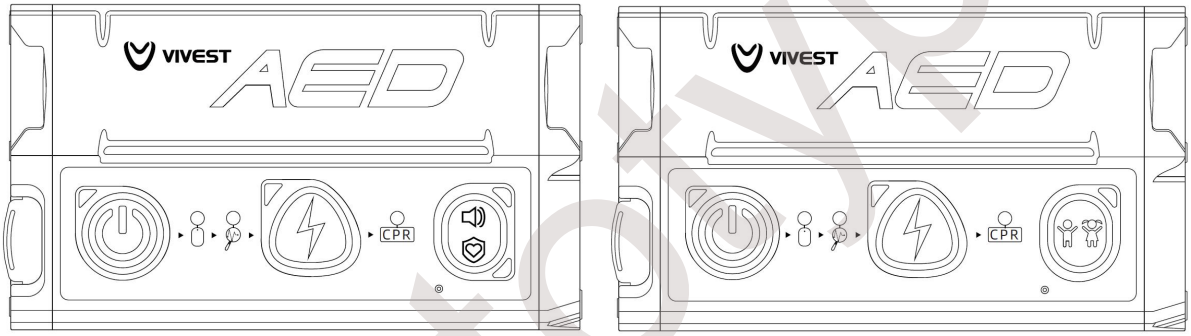
VIVEST

P Series

Automated External Defibrillator

User Manual



ViVest Medical Technology Co., Ltd.

Before Use

Thank you for purchasing the P Series Automated External Defibrillator.

Please read this manual carefully before use. Please keep the device for easy access after use.

Version: 1.3B3
Date: 2025/02/25

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Copyright and Statement

This manual applies to the P Series Automated External Defibrillator.

The company does not assume any responsibility for any injury caused by failing to follow the instructions, precautions, warnings, or usage instructions in this manual.

For information concerning any of our products, please contact VIVEST.

Conventions

This manual uses the following conventions:

Within text, the name and labels for physical buttons and softkeys appear in boldface type (for example, “Press the **Shock** button”).

This manual uses italics for audible prompts (for example, “*Don’t touch patient, Analyzing”*).

Content

1 General Introduction

1.1 Indications

P Series Automated External Defibrillator should be applied only when the patient has the following symptoms at the same time:

- Unconsciousness
- Not breathing or abnormal breathing
- Unresponsiveness

1.2 Contraindications

P Series Automated External Defibrillator can not be use if the patient:

- is conscious,
- is breathing, or
- has a detectable pulse or other sign of circulation

1.3 Intended Use

1.3.1 Intended Purpose

Automated External Defibrillator (AED) is intended for use on patients with suspected Sudden Cardiac Arrest (SCA) who are unconscious, unresponsive and not breathing or breathing abnormally.

1.3.2 Intended Patient Population

The device can be used for adult or pediatric patients. For patients under 8 years of age or less than 25kg, use child mode. For the others, use adult mode. If the age or weight of the patient is uncertain, do not delay the treatment, use adult mode.

1.3.3 Intended Users

The device is intended for use by responders who have been trained in Basic Life Support (BLS), Advanced Life Support (ALS), or another physician-authorized emergency medical response program, or it can be used under the guidance of emergency center's dispatcher.

Note: Compliance with Local Laws. The regulations regarding the use of defibrillators vary by country and region. It is the user's responsibility to ensure compliance with all relevant laws and regulations.

1.3.4 Intended Use Environment

The device can be used in public places and home healthcare environments.

1.4 Service Personnel Requirements

Service personnel must be authorized by the manufacturer, trained and qualified, and have a full knowledge and understanding of the contents of this manual.

1.5 Product Features

The P Series Automated External Defibrillator is divided into 2 models, P1 and P3 (hereinafter referred to ‘the device’). The 2 models have similar functions except below the following:

Model	P1	P3
Function Button	✓	/
Child Button	/	✓

P1 supports 4 operating modes: Standby mode, Rescue mode, Continuous VF/VT identification mode, and Maintenance mode.

P3 supports 3 operating modes: Standby mode, Rescue mode and Maintenance mode.

The mainly used functions and features of the device are shown as follow:

Function \ Model	P1	P3
Voice and Light Guidance	✓	✓
Heart Rhythm Analysis	✓	✓
Defibrillation	✓	✓
Self-test System	✓	✓
Continuous VF/VT Identification Function	✓	/
Child Mode (under 8 years old or weighing less than 25kg)	/	✓
Record	✓	✓
Data Transmission (Bluetooth)	✓	✓
Data Transmission (4G)	Optional	Optional

1.6 Product Limitations

The device is an infrequently-used device, it has certain limitations as outlined below:

- Routine maintenance is needed to ensure the device is ready for use. See Chapter 5 for details.
- This device is not intended for use in patients with implanted and activated ICDS.
- This device should not be used in an MRI environment.

2 Safety Precautions

2.1 Classification of Warning Messages

Warning Messages are generally divided into 3 categories, as described below:

⚠ **Danger**	Warning statements alert you to conditions or actions that can result in personal injury or death.
⚠ **Warning**	Indicates potential risks or risks caused by unsafe operations, which could result in personal injury or property damage if not avoided.
Caution	Used to emphasize instructions or reminders so that users can operate this device safely.

2.2 Warning Messages

⚠ **Danger**

1) The device generates a high voltage electric shock during defibrillation and may cause severe personal injury (such as myocardial damage) or even death. Therefore, defibrillation should be performed by professionally trained layperson.
2) Component replacement can only be performed by the manufacturer. Other personnel must not open the cover to attempt to repair the device or replace components. Otherwise, there is a risk of electric shock.
3) Do not disassemble or modify the device. This could result in personal injury or even death.
4) Other medical equipment which has no defibrillation-proof applied parts should be disconnected from the patient during defibrillation.
5) During defibrillation, keep distance from the patient and remove all metal equipment connected to the patient. Failure to do so may result in an electric shock.
6) There may be a danger of electrocution or injury if the defibrillation energy is not released normally.
7) Do not use the device in an environment with flammable gases or concentrated oxygen to prevent fire or explosion.
8) Do not charge the disposable battery. Charging the disposable battery may cause a fire or explosion.
9) Do not burn or incinerate the battery. Burning or incinerating a battery may cause a fire or explosion. Battery burning, explosion or leakage may cause personal injury.
10) Do not perform maintenance on the device during use.
11) Do not remove the battery when the device enters the rescue mode or when the device is placed in public places.
12) Improper operation may cause the battery to heat up, catch fire, or explode. Please read the warnings carefully before using rechargeable batteries.

Danger

13) If you find that the battery leaks or gives off a bad smell, stay away immediately. If the electrolyte leaks into the skin or clothing, wash it immediately with water. If the electrolyte seeps out and gets into your eyes, do not rub your eyes, wash them immediately with clean water and see a doctor.

14) In order to ensure the expected life of the battery, if the rechargeable battery is not used for a long time, please charge the rechargeable battery at least every three months.

15) When the battery reaches its expiration date, or when the battery is found to be smelly, deformed, discolored or distorted, the battery should be stopped from being used and disposed of in accordance with local regulations.

Warning

1) Only professionally trained personnel who are familiar with the operation of the device can perform emergency defibrillation.

2) Ensure the device is carefully placed to avoid damage to the pads or device, or injury to the patient or operator during use.

3) The device should be placed and affixed in a position that prevents it from falling or dropping. If the device falls or is dropped, it must be checked immediately for any damage.

4) Do not use expired or dry pads as they can not completely adhere to the skin, which will affect the heart rhythm analysis and cause misjudgment.

5) Do not connect the pads to other pads or metal objects in contact with the patient. It is recommended to keep a distance of at least 5 cm. The conductive gel coating on the pads may stick to other objects. Defibrillation with insufficient gel may cause a skin burn under the pads.

6) Before defibrillation, shave any body hair from the patient's chest if necessary. Excessive body hair may cause skin burns.

7) Do not wipe the patient's skin with alcohol. Alcohol wipes will dry the skin and cause skin burns.

8) Sensitivity of the device may be reduced in patients with cardiac pacemakers. A pacemaker may also reduce the detection of all shockable rhythms by the AED. If you know the patient has a cardiac pacemaker, do not place the pads near the implanted device.

9) Do not use the device if the device has been soaked with liquid or lots of water can be seen on the surface of the device. The conductive part of the device must not be in contact with other conductive parts (including the ground).

10) When the device is connected to the patient, do not perform any functional checks to avoid accidental electric shock.

11) Do not use alcohol or other solutions to soak or clean the pads. This may damage the pads and cause the device to malfunction.

12) Moving or carrying the patient during rhythm analysis can cause diagnostic delays or errors.

13) Pads should be placed on a flat skin surface instead of on the wrinkled skin surface, inappropriate placement will affect the heart rhythm analysis, which resulting in misjudgment.

14) When using the device, the operator must keep the patient's body (such as exposed skin or head and limbs) away from touching conductive fluids (such as gel, blood or saline) and metal

Warning

objects (such as a bed frame or a stretcher), to prevent alternate pathways for the defibrillation current.

15) Do not place the device near any apparatus that emits strong Radio-Frequency(RF) signals. Radio frequency emissions can cause incorrect analysis of heart rhythms.

16) Do not use unapproved pads, batteries, and other accessories. The use of unapproved components can cause the device to malfunction. Use accessories only specified by the manufacturer in Appendix 1.

17) The device cannot work if the battery is flat and/or uninstalled. Replace the battery immediately if low battery or battery overdue is detected.

18) If the device is taken out from the highest storage temperature or the lowest storage temperature and put into use immediately, the performance and service life of the device may differ from expectations. The device must not be stored or used outside of the environmental limits specified in this manual.

19) Improper operation may cause runtime errors. Please follow this manual carefully.

20) Only the service personnel should configure the device to use Bluetooth. The use of Bluetooth will not result in any risk to the device or its use.

21) If the status indicator of the device is off, replace the battery to restore the device. This might be due to the battery failure.

22) Be sure not to touch the patient during defibrillation, or it may cause a risk of electric shock.

23) The user should report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user is established.

24) The device cannot be used in MRI environment.

25) Keep the device out of reach of children and pets to avoid the risk of inhalation or swallowing of small parts or strangulation by pads cables.

26) For adult patient, do not perform chest compression over electrodes.

27) Call the emergency rescue number in which the rescuers still don't know how to use the AED after reviewing the Quick Reference Guide.

Caution

1) If any damage occurs to the device, please contact the manufacturer for repair.

2) Please pay attention to all caution and warning signs on the device and accessories.

3) If the device is stored, transported, or used outside the limited range, the performance specification in this user manual may not be reached.

4) The device can be operated at 50°C, but it is recommended to use it below 40°C to avoid patient burns.

5) It is recommended to provide at least one extra battery for each device available in a public place.

2.3 Placement of the Device

The device can be fixed or carried according to user needs:

When fixed, the device should be placed around emergency equipment (such as fire extinguishers, first aid kits, etc.) at a suitable temperature, and keep away from moisture and dust. To ensure correct placement of the device:

1) The ambient temperature at which the device is placed should be between 0°C and 50°C (long term placement). Severe fluctuation of the ambient temperature may significantly shorten the battery's service life and affect the performance of the pads.

2) It should be stored in a dry place with a relative humidity of 0% to 95%.

3) It should be stored away from any direct sunlight. Long-time exposure to direct sunlight will accelerate the aging of the device.

4) To avoid the blockage of the speaker, the device should not be placed in an environment with lint or dust.

5) Do not place the device near a strong magnetic field.

When carrying, the device shall be equipped with specialized portable package, and follow the below contents:

1) The environment temperature should be at 0°C to 50°C, relative humidity environment should be in 0% to 95%, temperature or humidity out of scope may shorten the service life and performance of AED.

2) When carrying, do not close to strong magnetic field.

2.4 Side Effects

Through clinical data from post-market surveillance activity of subject device, there is no side effects reported.

After search the literature of similar device, the result of SOTA evaluation shown that underdesirable effects may include:

- Skin burns.
- Skin reaction.
- Skin rash.
- Interaction with pacemaker.

3 Installation and Preparation

This chapter mainly introduces the components and appearance structure of the device, the functions of the buttons and indicators of the control panel, and the installation of key components.

3.1 Unpacking

To ensure the integrity of the device, carefully take out all components from the packaging case and follow the steps below to check the device:

1) Check the intact of the device shell.

2) Check whether the pads pre-connect to the device.

3) Check the seal and expiration date of the pads.

4) Check the expiration date of the battery.

3.2 Control Panel

The P1 control panel is shown below:

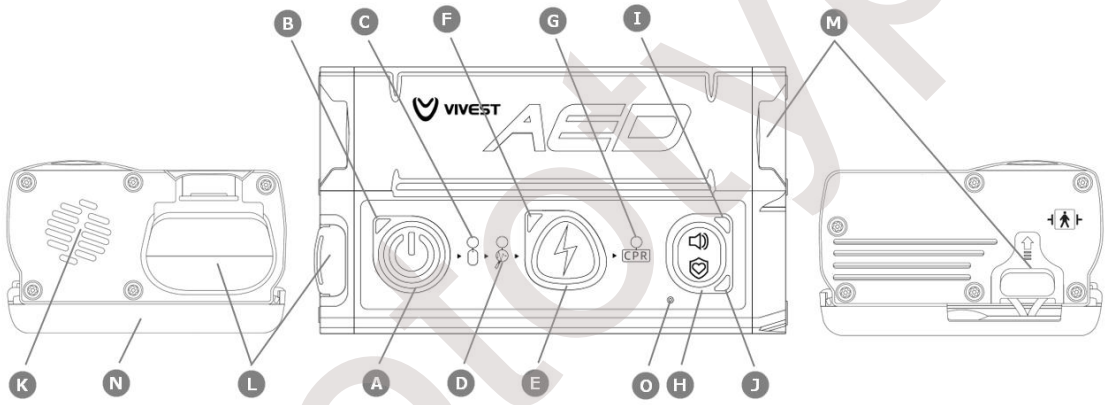


Figure 3- 1 P1 control panel

The graphic description:

Name	Description
A: Power Button	In standby mode, press the power button to enter rescue mode. In rescue mode, press the power button for at least 2 seconds to return to standby mode.
B: Status Indicator	Indicates the current status of the device: ➢ Green light flash shows that the device is in standby mode and ready to use. ➢ Red light flash shows that the device fails to pass the self-test and needs maintenance. ➢ Green lights steady shows that the device is in use. ➢ Light off shows that the battery is not installed or the device is in abnormal situation.
C: Pads Indicator	Indicates the status of pads connection: ➢ Light off shows that the pads are connected with host and patient normally. ➢ Red light flash shows that the pads are not connected with host or patient.

Name	Description
D: Heart Rhythm Analysis Indicator	Indicates the status of heart rhythm analysis: ➢ Green light flash shows that the device is analyzing heart rhythm. ➢ Light off shows that the device is not in analyzing stage.
E: Shock Button	Press the shock button to deliver defibrillation energy after the charge is finished.
F: Shock Indicator	Orange light flash to guide operators to press shock button when charge is finished.
G: CPR Indicator	Indicates the device is in the CPR stage.
H: Function Button	1) Adjust the volume. Press the function button less than 1 second to switch the maximum volume and minimum volume to each other. 2) Switch the mode. Press the function button for at least 3 seconds to switch rescue mode and continuous VF/VT identification mode to each other.
I: Volume Indicator	Blue lights steady indicates that the volume of the device is minimum.
J: Continuous VF/VT Identification mode Indicator	White lights on indicates that the device is in continuous VF/VT identification mode.
K: Speaker	Sends voice prompts and beep sounds, multi-level volume is provided.
L: Battery	Supply power to the device.
M: Pads Cable Connector	Pads connect to the host through the connector.
N: Pads Storage Box	To store the pads.
O: Microphone	Used optionally to record audio during rescue.

The P3 control panel is shown below:

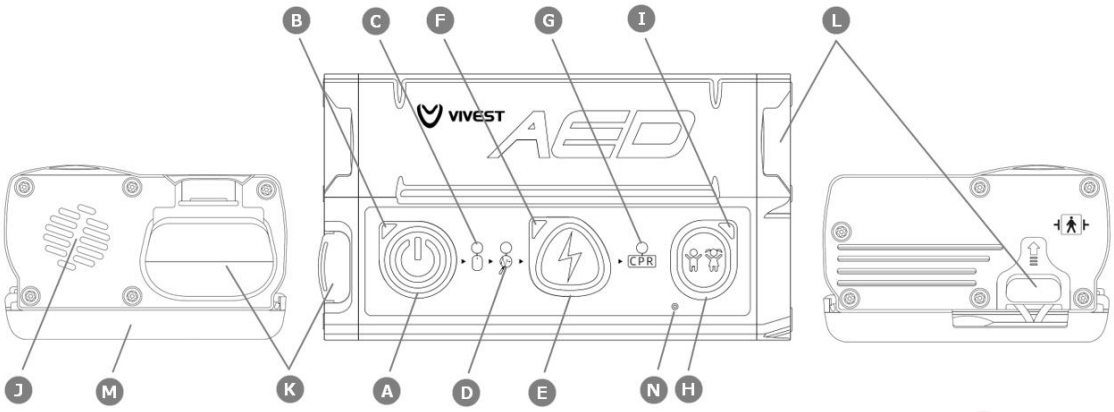


Figure 3- 2 P3 control panel

The graphic description:

Name	Description
A: Power Button	In standby mode, press the power button to enter rescue mode. In rescue mode, press the power button for at least 2 seconds to return to standby mode.
B: Status Indicator	Indicates the current status of the device: ➢ Green light flash shows that the device is in standby mode and ready to use. ➢ Red light flash shows that the device fails to pass the self-test and needs maintenance. ➢ Green lights steady shows that the device is in use. ➢ Light off shows that the battery is not installed or the device is in abnormal situation.
C: Pads Indicator	Indicates the status of pads connection: ➢ Light off shows that the pads are connected with host and patient normally. ➢ Red light flash shows that the pads are not connected with host or patient.
D: Heart Rhythm Analysis Indicator	Indicates the status of heart rhythm analysis: ➢ Green light flash shows that the device is analyzing heart rhythm. ➢ Light off shows that the device is not in analyzing stage.
E: Shock Button	Press the shock button to deliver defibrillation energy after the charge is finished.
F: Shock Indicator	Orange light flash to guide operators to press shock button when charge is finished.
G: CPR Indicator	Indicates the device is in the CPR stage.
H: Child Button	If you need to enter the child mode, press this button, and the device will voice into the child mode. Please hold down the child button for 3 seconds, and hold down this button for 3 seconds to switch the device to the child mode. (To return to the adult mode, the device should shut down and restart).

Name	Description
I: Child mode Indicator	Flash blue indicates long press the child button to enter child mode. Blue lights on indicates that the child energy is active.
J: Speaker	Send voice prompts and beep sounds, multi-level volume is provided.
K: Battery	Supply power to the device.
L: Pads Cable Connector	Pads connect to the host through the connector.
M: Pads Storage Box	To store the pads.
N: Microphone	Used optionally to record audio during an incident.

3.3 Install the Battery

The device accepts the following battery:

- Disposable Battery ($LiMno_2$)
- Rechargeable Battery (Li-ion)

To install the battery:

1) Push the battery tail into the battery compartment.

2) Push the battery to the bottom of the battery compartment.

3) Finally, check whether the buckle of the battery is fully inserted into the battery slot.

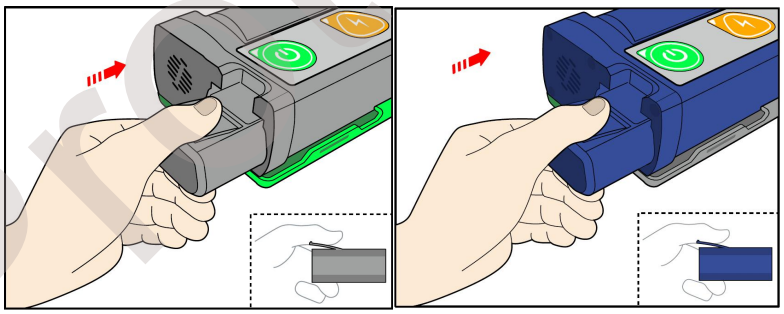


Figure 3- 3 Install the battery

After the battery is installed, the device will run self-test automatically. Refer to Chapter 3.6 for details.

3.4 Remove the Battery

When the 'Low Battery' prompt is indicated, please replace the battery immediately. After removing the battery, please wait for 30 seconds before installing new battery.

To remove the battery:

1) Make sure the machine is in standby mode, if the device is in rescue mode, press the **Power** button for at least 2 seconds to enter standby mode.

2) Press the battery buckle.

3) Immediately remove the battery.

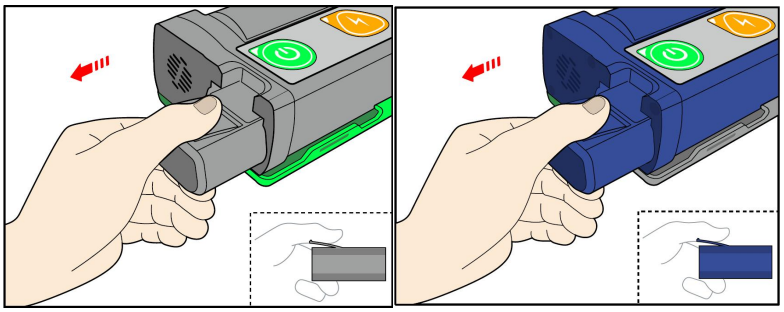


Figure 3- 4 Remove the battery

3.5 Charge

The rechargeable battery is equipped with a dedicated battery charger that can hold two rechargeable batteries for charging at the same time.

- The battery charger is connected to the power supply and the battery is not inserted: The indicator flashes green slowly in the form of a breathing light.
- Battery charger failure: The indicator flashes red.
- Charging: The indicator light flashes green.
- Charge finished: The indicator lights green.

The battery charger shows below:

Figure 3- 5 Battery charger

3.6 Preconnect the Pads

The pads are pre-connected when the device leaves the factory, but it is still necessary to check whether the pads connector is inserted properly before use.

Before using, please check whether the pads package is in good condition and whether expired. If the package is damaged or the electrode is expired, please contact the dealer or manufacturer in time for replacement.

When inserting the pads connector into the socket, be sure to insert tightly.

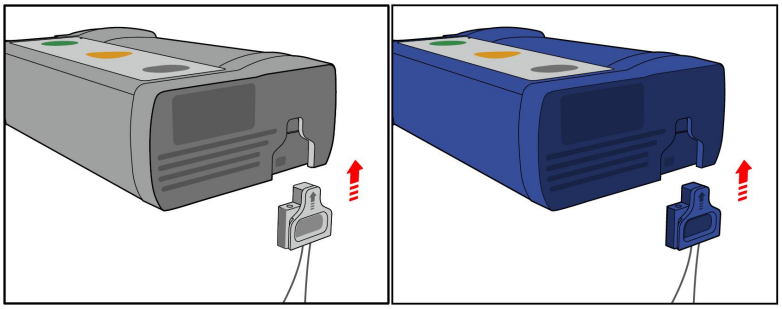


Figure 3- 6 Connect pads to the host

Warning	1) Never use damaged, wrinkled or folded pads, which may result in current leakage and cause burns on skin. 2) Don't reuse the disposable pads. Repeated use may cause performance degradation or cross infection.

3.7 Self-test System

The device performs the following self tests to verify unit integrity and its readiness for emergency use:

- User Self-test
- Battery Installation Self -test
- Power On Self-test
- Periodic Self-test
- Quick status check

User self-test

Service personnel authorized by manufacturer can run user self-test if necessary.

Battery installation self-test

The device performs a self-test whenever batteries are installed. Then the device enters into the standby mode at the end of the battery installation self-test.

- The status indicator blinks green in the standby mode shows that all the tests passed.
- Otherwise, the status indicator flash red, with 5 times of Beep sound, to warning the operator or service personnel.

Power on self-test

The device performs a self test whenever the unit is turned on, this will notify the operator of any failures identified during the self-test.

If detected…	**Voice Prompt**
Pads expired	*Pads Expired*
Pads connector not detected	*Plug in Pads Connector*
Battery expired	*Battery Expired*
Device failure	*Device Failed*
Battery is low	*Low Battery*
Battery is about to run out	*Low Battery, replace battery*

Periodic self-test

Periodic self-test will be carried out daily, weekly, monthly, and quarterly. The default self-test

configuration is weekly self-test, monthly self-test, and quarterly self-test. Service personnel can set daily self-test as required. The default period self-test time is 3 am.

Caution	1) Only in the standby mode when the battery is installed, the device will automatically detect at a preset time. 2) If the device self-test result is normal, the operator can start rescue immediately. 3) If the device self-test result is abnormal, contact the maintenance personnel or the manufacturer for repair.

Quick status check

In standby mode, the device supports a quick status check by pressing the **Function** button of P1 or the **Child** button of P3 to check whether the device is capable of emergency use.

- If the check result is normal, the status indicator blinks green once.
- If the check result is abnormal, the status indicator flashes red once, and the device emits three beeping sounds.

4 Use Automated External Defibrillator

This chapter mainly introduces usage of the device. There are voice and indicator prompt during rescue.

4.1 Brief operation steps

Rescue Mode:

1) Press the **Power** button to turn on the device.
2) Remove any clothing from the patient's chest and take out pads.
3) Attach the pads to the patient according to the figure instruction.
4) Operate according to the voice prompt:
   - If a shockable heart rhythm is detected, press the **Shock** button to defibrillate.
   - If a non-shockable heart rhythm is detected, the device will enter CPR stage.
5) Perform CPR to patient.

Continuous VF/VT Identification Mode (P1 Only):

1) When the device is in the CPR stage and the result of the last heart rhythm analysis is No Shock Advice, while the patient remains conscious (responsive, breathing and pulse), long press the **Function** button for > 3 seconds to enter the continuous VF/VT identification mode
2) During continuous VF/VT identification mode:

   - If a shockable heart rhythm is detected, the device will switch to rescue mode and re-analyzes the rhythm. If the analysis result is 'shock advised', the device will charge to preset energy and defibrillate, and then enters CPR stage.
   - If a non-shockable heart rhythm is detected, the device will re-analyze the rhythm.
   - Press the **Function** button for at least 3 seconds, the device will switch to rescue mode.

Warning	1) The use of this continuous VF/VT identification pattern must be confirmed by a paramedic trained in its use in order to provide a non-diagnostic indication of shockable and non-shockable heart rhythm for patients who are responding to treatment and breathing normally, but may have discomfort in the cardiac area. 2) In the continuous VF/VT identification mode, the device continuously identifies the patient's heart rhythm to evaluate whether the patient has a shockable or non-shockable heart rhythm. In this mode, someone needs to supervise the patient so that if the patient's heart rhythm or health condition changes, the ambulance crew can effectively care for the patient.

4.2 Turn on the Device

Press the power button to turn on the device.

Step	Action	Voice Prompt	Indicator
1	Press the **Power** button (Figure 4-1)	*Call for help*	Status indicator light stays green during all the rescue process.

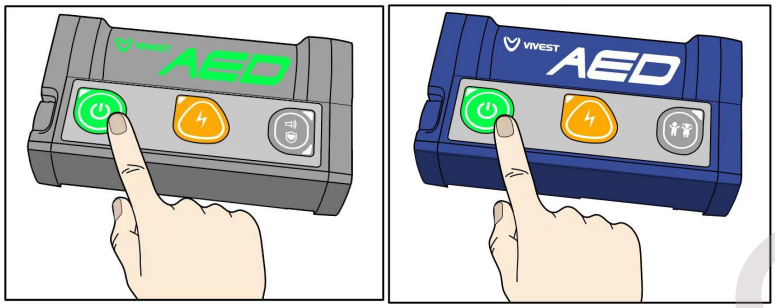


Figure 4- 1 Press the power button

4.3 Apply Pads

To apply pads:

Step	Action	Voice Prompt	Indicator
1	Remove patient's upper body clothing. If necessary, remove the patient's chest hair and dry the patient's skin to ensure good contact between the electrode and the patient's skin. (Figure 4-2)	*Remove clothing*	Pads Indicator flash red till the pads are applied properly.
2	Take out the pads package from the pads storage box at the bottom of the device, then tear open the package and take out the pads. (Figure 4-3)	*Remove Pads Package from Back of AED* *Tear open package, take out the pads*	
3	Remove the liner of the pads and apply the pads on the exposed skin of the patient according to the diagram. The position should be consistent with the diagram on the pads. (Figure 4-4, Figure 4-5)	*Remove Liner from Pads* *Apply Pads to Patient's Chest*	

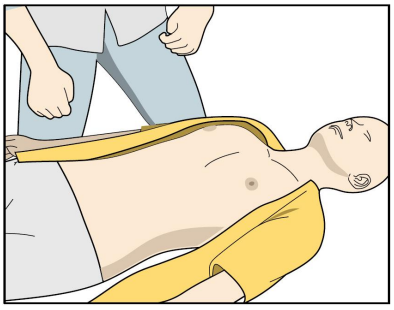


Figure 4- 2 Patient Preparations

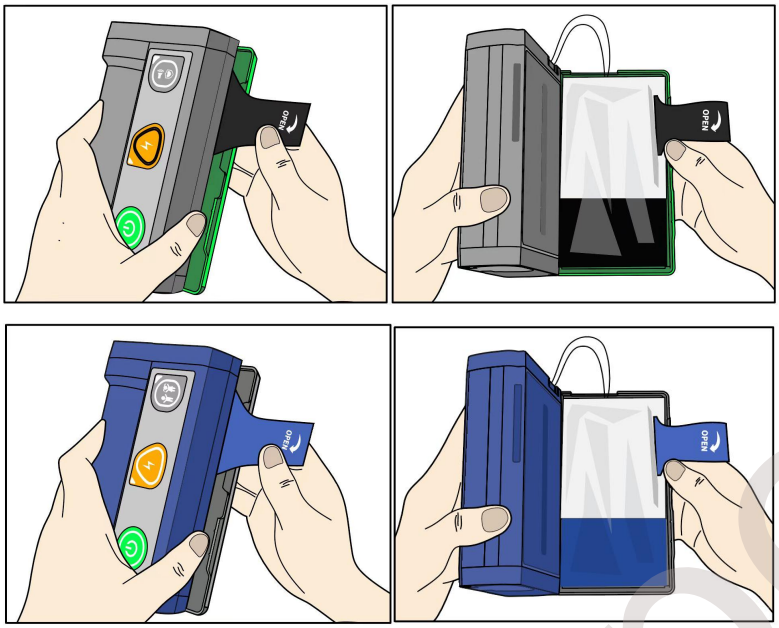


Figure 4- 3 Open pads storage box

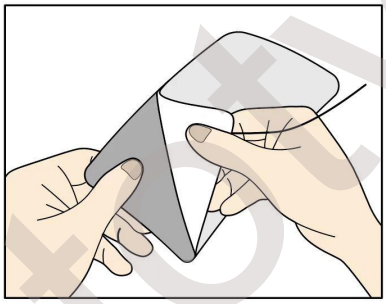


Figure 4- 4 Remove pads liner

When attaching the pads, firmly adhere to one side at first and then press it smoothly to the other side, make it completely attached to the skin to avoid air bubbles. Do this way for both two pads.

Adults and children (P3 only) share the same pads, but it is attached to different parts of the patient's body:

- Attachment position of electrode on child body:

  Place one electrode in the middle of the chest between the nipples and the other in the middle of the back (anterior-posterior).

- Attachment position of electrode on adult body:

  One of the electrodes was applied to the patient’s right chest and below the clavicle as illustrated, and the other electrode was applied to the patient’s left chest and above the rib in the maxillary line.

Those two positions are shown in the figure below:

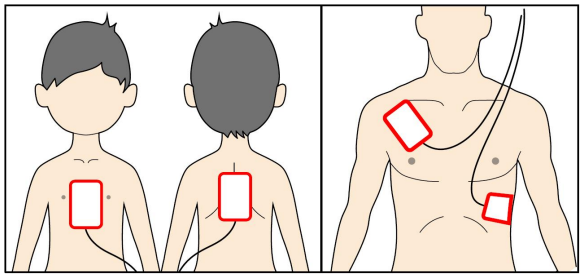


Figure 4- 5 pads position on the patient

Warning	1) The pads must be placed flat on the patient's skin. Not doing so may lead to an incorrect heart rhythm analysis and misjudge of defibrillation. 2) Leaving bubbles between the pads and the patient's skin when attaching the pads may result in burns. 3) Make sure the pads have a good contact with the patient's body, as poor contact might cause skin burns.

4.4 Cardiac Rhythm Analysis

While the pads are applied:

Step	Action	Voice Prompt	Indicator
1	The device will analyze the patient's heart rhythm as long as the pads are attached to the patient correctly.(Figure 4-6)	*Don't Touch Patient, Analyzing*	Heart rhythm analysis indicator flash green.
2	If the pads are not attached properly, the analysis will be interrupted.	*Poor Pads Contact, Check Pads*	Pads indicator flash red.
3	If signal interference is detected...	*Eliminate signal interference*	Heart rhythm analysis indicator flash green.
4	If motion interference is detected...	*Keep Patient Still*	Heart rhythm analysis indicator flash green.

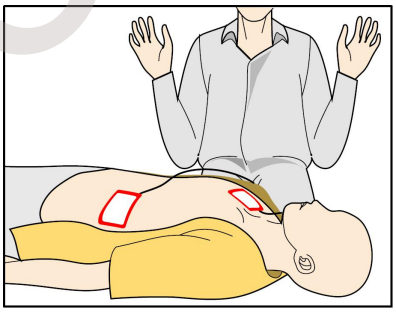


Figure 4- 6 Cardiac Rhythm Analysis

At this point, nobody is allowed to touch the patient or pads. Keep the distance between the patient and the device about 10cm to 90cm, and the distance between the operator and the patient should be less than the distance of one arm.

Warning	Do not touch or shake the patient in the process of cardiac rhythm analysis as it will affect the result.

4.5 Shock Advised

While a shockable rhythm is detected:

Step	Action	Voice Prompt	Indicator
1	If a shockable heart rhythm is detected…	*Shock Advised* *Do not Touch Patient, Charging* *Press the Orange Shock Button*	Shock indicator flash orange.
2	Press the **Shock** button(Figure 4-7)	*Shock Delivered* *Start CPR*	Shock indicator turned off and CPR indicator flash green.
3	If the **Shock** button is not pressed within 30 seconds	*Shock Button is not Pressed*	Shock indicator turned off and CPR indicator flash green.
4	If the patient's heart rhythm turns into a non-shockable rhythm within 30 seconds	*Heart Rhythm Changed, Shock Cancelled*	Shock indicator turned off and CPR indicator flash green.

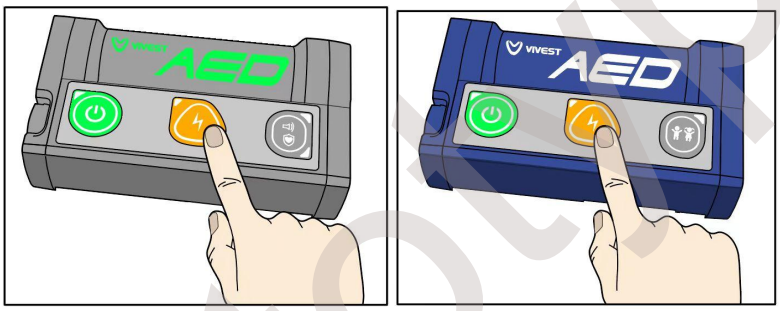


Figure 4- 7 Press the Orange shock button

The device will detect the pads connection continually during charge process, it will stop charge and prompt the operator to check the pads connection if poor contact is detected.

During the whole rescue process, please pay attention to the patient.

Warning	Nobody should touch the patient during defibrillation!

4.6 No Shock Advised

While a non-shockable rhythm is detected:

Step	Action	Voice Prompt	Indicator
1	If a non-shockable heart rhythm is detected…	*No Shock Advised* *Start CPR*	CPR indicator flash green

4.7 Perform CPR

After the defibrillation:

Step	Action	Voice Prompt	Indicator
1	Hands crossed and placed on the patient's chest, and follow the beat sound for chest compressions.(Figure 4-8)	*Beep...Beep...Beep...*	CPR indicator flash green
2	After 30 times of compress, give two breaths.	*Breathe...Breathe*	CPR indicator flash green
3	After 2 minutes of CPR...	*Stop CPR* *Don't Touch Patient,* *Analyzing*	CPR indicator turned off and heart rhythm analyze indicator flash green.

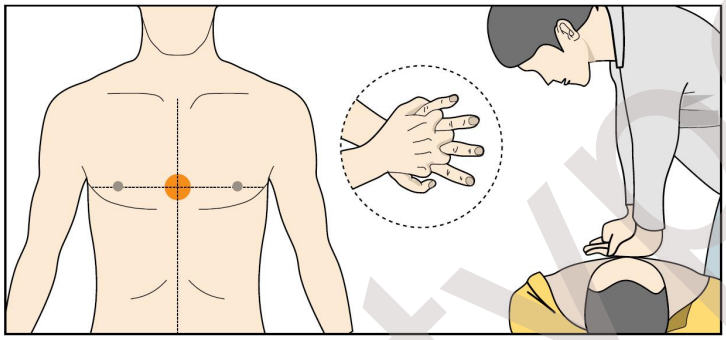


Figure 4- 8 Start CPR

Adult mode contains 2 kinds of compression-to-ventilation ratio, while child mode contains 3 kinds of compression-to-ventilation ratio:

Mode	Compression-to-ventilation ratio
Adult mode	✓ 30:2 (Default) • Only compression
Child mode (P3 only)	• 30:2 ✓ 15:2 (Default) • Only compression

When CPR is over, the device will reanalyze the patient's heart rhythm.

4.8 Operation After Use

After using the device, perform the following steps:

1) Press the **Power** button for at least 2 seconds to enter the standby mode

2) Check the appearance of the device for damage or dirt. If technical support for damage is needed, please contact the manufacturer. If it is dirty, please clean it up, refer to Chapter 5 for details.

3) Dispose of disposable defibrillation electrodes in accordance with local regulations after use, and take out the new defibrillation electrodes (check expiration date), put it into the electrode box of the device.

4) In order to ensure that the device has sufficient power during the next usage, please check the battery power. If the battery power is low, please replace the battery (or charge the battery).

4.9 Pediatric Treatment

For patients less than 25kg (55 lb.) or under 8 years old, most of the patients who have cardiac arrests are not from cardiac problems. The rescue steps shown below:

1) Begin CPR, ask someone to call the emergency center and the nearest AED, and perform CPR till get AED.

2) After obtaining AED, turn it on and press the **Child** button to enter the child mode, the child indicator light starts to flash, the device will issue a voice prompt " *Press the child button for 3 seconds to enter Child mode*", press and hold the child button for 3 seconds, the device will send out The voice prompts "*Child mode*". At this time, the device switches to child Mode. The child mode indicator light is always blue and the defibrillation energy decreases from 150J to 50J.

3) Remove the patient's upper body clothing, expose the front chest and back, and place one electrode in the middle of the chest between the nipples and the other in the middle of the back.

4) Follow the voice prompts. If an electric shock is recommended, press the **Shock** button. Otherwise, the device will directly enter the CPR stage.

Caution	Do not miss the best first aid time just to determine the patient's age. If the patient's age cannot be determined, treat the patient in an adult mode.

5 Maintenance and Troubleshooting

This chapter describes the regular maintenance, transport, disposal, and troubleshooting of the device. Some of those operations should be guided by the authorized service personnel.

5.1 Regular Maintenance

The expected service life of the device is 10 years. In order to ensure the reliability of the device, service personnel should carry out routine maintenance and inspection of the device during the service period. If the machine is more than 5 years old, the frequency of routine maintenance and inspection should be increased appropriately.

The device minimizes required maintenance by using extensive self-tests to simplify the maintenance process. The device will monitor its essential performance automatically during use and run periodic self-test automatically in standby mode. Refer to Chapter 3.5 for details.

By visually checking the status indicator every day, the service personnel can know that whether the device has passed the self-test within the last 24 hours and confirm whether the device is ready for use. To calibrate the impedance and check the accuracy of discharge energy, please contact the manufacturer. By connecting to the device management system, you can remotely manage the device, reducing onsite maintenance. All maintenance work performed must comply with local regulations.

Daily	Monthly	After Rescue	Maintenance Content
✓	✓	✓	Check the status indicator
✓	✓	✓	Check device and accessories
/	/	✓	Replace the pads
/	/	✓	Check battery power and expiration date
/	/	✓	Manual self-test

Warning	P series automated defibrillator has **NO** user-serviceable components. All Components of the device can only be replaced or renewed by the manufacturer. No other person must open the cover to repair the device and replace components, otherwise, there is a risk of electric shock.

5.1.1 Check Pads

The defibrillation pads of the device are disposable. If the pads has been used or the package is damaged, contact local distributor or manufacturer to replace in time.

Please check the date on the package to confirm whether it is expired. Expired electrodes should be disposed of according to local regulations.

In addition, the device can detect the expiration date of the pads through self-test. If the pads expired, the status indicator flashes red in standby mode.

➢ Check whether the pads cable is damaged, if damaged, please replace the pads immediately.

➢ Check whether the pads connector has been inserted. If not, insert it into the conntector socket.

5.1.2 Check Status Indicator

The device standby status indicator is located at the top center of the panel, which indicates the status of device.

➢ The flashing green light indicates that the device is normal state and ready to use.

➢ The flashing red light indicates that the device has failed the self-test and needs to maintenance. Please contact the manufacturer as soon as possible.

5.1.3 Check Integrity and Cleanliness

1) Check the integrity of the device, refer to Chapter 3.

2) Check whether the device is dusty or dirty, especially the pads connector and pads connector socket.

3) Check whether the appearance of device have scratches or other marks of damage, especially near the pads connector and pads connector socket. If any scratches or damage are found, contact the manufacturer for maintenance.

5.1.4 Check Battery

In standby mode or after defibrillation, the battery power may be low.

In standby mode, the device will detect the remain battery power and validity period of the battery through self-test. If expired or low power, the status indicator flashes red and the device sends voice alarm, please review and confirmation in time.

After rescue, service personnel should check the remain battery power and the effective date. If low power or expired, replace the battery (or charge the rechargeable battery) immediately. The replaced battery should be disposed of according to local regulations. After the new battery is installed, the device automatically performs a battery installation self-test.

Caution	After the low battery is prompted for the first time, the battery can still provide at least 30 times defibrillation. To avoid adverse impact on subsequent use, replace the battery immediately after the low battery is prompted.

5.1.5 Cleaning

The cleaning agents available are:

- Water and soap
- Ethanol 96%
- Sodium hypochlorite (chlorine bleach 3% solution in water)

Please remove the dust and dirt on the surface of the device regularly. It is recommended to clean it every three months, or increase the frequency of cleaning according to the usage frequnecy of the machine.

When cleaning, follow these steps:

1) Turn off the power, take out the battery and pull out the defibrillation pads.

2) Use a lint-free cloth or cotton ball to absorb some detergent, and do not splash the detergent on the device.
3) Wipe the shell, handle and screen of the device.
4) Wipe off excessive detergent with a dry cloth.
5) Place the device in a cool and well-ventilated place for at least 30 minutes.
6) Make sure the device is completely dry, then install the battery and pads.

Caution	Do not immerse the device in fluids. Do not clean the accessories (Battery, Pads).

5.2 Transport

If it is necessary to transport the device to a maintenance point, the battery must be removed from the device, and packaged separately and shipped with the device. The device can be transported using general ways, but it must be protected from severe shocks, vibrations and rain and snow during transportation.

5.3 Disposal

The device and its accessories should be disposed of in accordance with local regulations.

5.4 Troubleshooting

Some common failures are listed below. They should be checked one by one in order to troubleshoot the failure. Please contact the manufacturer's designated professional personnel to repair the device.

Failure	**Causes**	**Response**	**Message**
Fail to turn the device on	Battery is not installed	Install the battery	N/A
	Invalid or expired battery	Replace the battery	N/A
	Mainboard error or other factors	Contact the manufacturer for maintenance	N/A
The device suddenly shut down	Invalid or expired battery	Replace battery	N/A
	Mainboard error or other factors	Contact the manufacturer for maintenance	N/A
In standby mode, the device make a Beep sound every 5 seconds, totally 5 times in continuous 25s, cycle once every hour	The device found a failure while performing self-test	Contact the manufacturer for maintenance	The device make a Beep sound every 5 seconds, totally 5 times in continuous 25s, cycle once every hour
Defibrillation charging time is too	Battery/device failure	Stop using the device and contact	*Charging failed*

Failure	Causes	Response	Message
long		manufacturer for maintenance.	
	Insufficient battery	Replace battery	*Charging failed*
Voice prompt "*low battery*"	Insufficient battery	Replace battery	*Low battery*
The device cancels the charging state automatically during charging.	The pads don't stick to the patient's chest.	Attach the pads to the patient's chest	*Poor pads contact, check pads*
	Poor contact between pads and patient	Check pads contact of patient	*Poor pads contact, check pads*
	Damage of pads, cables, or pads connector	Replace pads	*Poor pads contact, check pads*
	Damage of pads socket	Contact the manufacturer for maintenance	*Poor pads contact, check pads*
Status indicator is switched off	Insufficient battery	Replace battery	N/A
	Damage of the status indicator	Contact the manufacturer for maintenance	The device make a Beep sound every 5 seconds, totally 5 times in continuous 25s, cycle once every hour
Data transport failed	Device failure	Contact the manufacturer for maintenance	The device make a Beep sound every 5 seconds, totally 5 times in continuous 25s, cycle once every hour.
	SIM card error	Contact the manufacturer for maintenance	N/A
Power on self-test failed	Defibrillation pads expired	Replace pads	*Pads Expired*
	Low battery/Battery expired/Battery mismatch	Replace battery	*Low battery/Battery Expired/Battery Mismatch*
	Mainboard error or other factors	Contact manufacturer for repair	*Device failed*

6 Cyber Security

This chapter mainly introduces the information about cyber security.

6.1 Runtime Environment

6.1.1 Hardware Environment

- CPU: STM32 series
- RAM: 320 KB
- ROM: 1 MB
- Flash: 128 MB
- Display equipment: LED indicator
- I/O equipment: LED, speaker

6.1.2 Software Environment

- Runtime system: FreeRTOS V10.3.1
- Prerequisite software: File system
- Matching software: No need
- Antivirus Software: No need

6.1.3 Network Environment

P series defibrillator wakes up regularly for self-test under standby mode. After waking up, Bluetooth is turned off and 4G is turned on, and data is uploaded to the cloud server through 4G. In rescue mode and continuous VF/VT identification mode, Bluetooth and 4G are both turned off, there is no network environment. In maintenance mode, Bluetooth and 4G are both turned on, and service personnel can config the device through Bluetooth and 4G.

- Standby mode: 4G
- Maintenance mode: Bluetooth & 4G
- Rescue mode (after the pads are connected to the patient): no network environment
- Continuous VF/VT identification mode: no network environment

	Network Architecture	**Network Type**	**Bandwidth**
4G environment	CS	LTE-CAT1	10kbps
Bluetooth environment	CS	BLE5.1	3kbps

6.2 Data Interface

P series defibrillators have two external data interfaces, which are 4G and Bluetooth.

6.3 User Access

The intended use environment of P series defibrillators is public places or medical places, and must operated by trained professionals or emergency responders.

In addition, the management agency of the AED deployment site needs to manage and maintain the AED device to ensure that the AED can provide treatment capabilities when needed. Therefore, AED users need to be classified.

User role	Responsibility	Require	Access permission
Operator	Rescue with P Series defibrillators.	Professionally trained in defibrillation and first aid	No permission
Service personnel	Install the P series defibrillator device, use the specific toolbox APP to connect to the P series defibrillator device, configure device parameters, upload data, and upgrade the host software.	Received professional training from the manufacturer and obtained authorization from the manufacturer	All parameters can be set

Caution	1) The network interface and data interface of the device are not open to end users. 2) Cyber security related operations can only be carried out by or under the direction of the service personnel!

6.4 Data Exchange Method

6.4.1 Bluetooth Transmission

P series defibrillator is in maintenance mode, the device turns on Bluetooth, and the mobile APP (ViTools) connects to the device via Bluetooth through authorization verification, and mainly completes the following functions through data interaction:

- 4G upload and download control
- Modify AED configuration, read and view AED configuration
- Upgrade software
- View self-test results

6.4.2 4G Transmission

P series defibrillators mainly complete the following functions through 4G under maintenance mode:

- AED configuration upload
- Resource file download and update
- Upload of rescue data

P series defibrillator is in standby mode and performs weekly / monthly / quarterly scheduled self-tests, it mainly completes the following functions through 4G:

- Upload of rescue data

Caution	1) During the rescue data upload process, the power indicator light flashes green and red at the same time, until the rescue data transmission is completed, the power indicator light returns to the normal standby state. 2) If the rescue data upload fails, the device will re-upload it

	after the next self-test until the rescue data is uploaded successfully.

6.5 Device Security Software

No security software is required for P Series defibrillators.

6.6 Cyber Security Update

There are no user-required cybersecurity updates for P Series defibrillators.

6.7 AED Data Storage

The device will store the data during operation in the internal memory. The data type recorded by the device is as shown in the figure below:

Type of data	**Data description**
ECG data	ECG rhythm
Log data	Important events after the device are powered on, mainly include power on and off data, device status, rescue time, pads adhesion, button operation, heart rhythm analysis, charge and discharge, CPR duration, CPR operation and prompt information, discharge times and prompt information.
Self-test data	Data and results of device self-tests, including periodic self-tests, battery installation self-tests, power-on self-tests, and quick status checks.
Recording data	Audio data during rescue

7 Product Warranty

The manufacturer provides a reasonable warranty service during warranty period.

Once requesting a warranty service, you are obliged to provide proof of purchase from the vendor.

And the warranty will be void in the case of:

- Violation of instructions;
- Operation error;
- Improper use or handling;
- Unauthorized personnel have repaired the device;
- Force majeure such as lightning strikes;
- Transport damage due to improper packing when sending back;
- No maintenance;
- Damage due to excessive use (such components include batteries, disposable items, etc.);
- The original accessories were not used.

The manufacturer reserves the right to choose to exclude defects, provide non-defective components, or appropriately lower the purchase price based on product defects.

If the warranty is invalid, the manufacturer will not bear the cost of transportation.

The manufacturer shall not be liable for any accidental injury caused by the operator's violation of user manual, misuse, or improper handling.

Legal warranty requirements are not affected by above situation.

Appendix 1 Package Contents

Components:

Name	Model	Manufacture	Quantity	Unit	Note
Disposable Battery ($LiMno_2$)	BAT-PT01	VIVEST	1	Case	Standard
Rechargeable Battery (Li-ion)	BAT-PT02	VIVEST	1	Case	Optional (Battery charger is recommended to purchased)

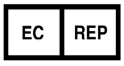
Accompanying documents:

Name	Quantity	Unit
User Manual	1	Copy
Product Certification	1	Copy
Warranty Card	1	Copy
Packing List	1	Copy

Remarks: The components and accompanying documents shall be provided to the customer along with the device, and the accurate contents shall be subject to the provisions in the Packing list.

Appendix 2 Symbols

Symbol	Description	Symbol	Description
IP65	Ingress protection of the device classified as IP65 according to IEC 60529	IP54	Ingress protection of battery charger classified as IP54 according to IEC 60529
	Warning, electricity		Defibrillation-Proof Type BF Applied Part
	General warning sign		Dangerous voltage
	Operating instructions		Follow instructions for use
	Stand-by		Atmospheric pressure limitation
	Return to a collection site intended for Waste Electrical and Electronic Equipment (WEEE). Do not dispose of in unsorted trash		Temperature limitation
	General symbol for recovery/recyclable		Humidity limitation
	Use by date		Date of manufacture
	This way up		Fragile, handle with care
	Use no hooks		Keep away from rain
	Stacking limit by number		Do not dispose of in fire
	Do not re-use		Do not deform or damage

Symbol	Description	Symbol	Description
	Non-sterile		Latex free
	Batch code		Catalogue Number
	Manufacturer		Serial Number
	Authorized representative in the European Union		Comply with the EU 2017/745
	Direct current		Alternating current
	Unique device identifier		Power Button
	Pads Icon		Shock Button
	Analysis Icon		Child Button
	CPR Icon		Function Button:  Adjusting device volume  Switching Device Modes

Appendix 3 Glossaries

Glossary	Description
Standby Mode	When the battery is installed but the device does not turn on, it automatically enters standby mode.
Rescue Mode	This mode performs cardiac rhythm analysis, defibrillation, and cardiopulmonary resuscitation. (Boot default rescue mode)
Continuous VF/VT identification mode	That is, the continuous detection mode, which must be operated by specialized personnel who have received training and qualifications from VIVEST to provide continuous heart rhythm detection for patients who are responsive, breathing, and have a pulse but may have cardiac discomfort. This mode only recognizes shockable and non-shockable rhythms (P1 only).
Pads	Contains defibrillation electrode, cable, and cable connector.
Self-test	The device uses the internal program to perform self-test on the environment where the device is located and each module in the system.
Defibrillation	The method of striking the heart with a certain current to stop ventricular fibrillation.
Pacemaker	An implantable cardiac pacing maker that stimulates the heart with electrical pulses.
Periodic self-test	When the device is in the standby mode, daily self-test, weekly self-test, and monthly self-test are performed automatically to detect batteries, internal circuits, buttons, software, etc.
Cardiac arrest	Ventricular fibrillation is the most common cause of sudden cardiac arrest due to sudden termination of ejection function.
Impedance	The device detected the electrical impedance between two pads attached to the patient's skin.
Shockable rhythm	Pulseless ventricular tachycardia or ventricular fibrillation, which can lead to cardiac arrest.
Non-shockable rhythm	The cardiac rhythm identified by the device as unsuitable for electric shock.
Sensitivity	True positive rate (Sensitivity) is the probability of a positive test result, conditioned on the individual truly being positive.
Specificity	True negative rate (Specificity) is the probability of a negative test result, conditioned on the individual truly being negative.
Motion artifacts	Noise caused by muscle movement, cardiopulmonary resuscitation, or static electricity may interfere with cardiac analysis.

Glossary	Description
New battery	Battery that is well packed, unsealed, and valid.
Manufacturer	Unless otherwise specified, the company described in this manual is VIVEST.
ECG	Electrocardiograph.
CPR	Cardiopulmonary resuscitation, a technique for rescuing patients in cardiac arrest with artificial respiration and chest compressions.
ICD	Implantable cardioverter defibrillator
bpm	Beat per minute
AED	Automated external defibrillator
EMC	Electromagnetic Compatibility
LED	Light emitting diode
AHA	American Heart Association
SCA	Sudden Cardiac Arrest
AAMI	Association for Advancement of Medical Instrument
VF	Ventricular fibrillation
VT	Ventricular tachycardia

Appendix 4 Specifications

Safety Specification Features	
Safety Classification	Internally powered ME equipment
Protection against electric shock	Defibrillation-Proof Type BF Applied Part.
Protection against harmful ingress of water or particulate matter	IP65
Operational mode	Continuous operation
Security Degree	Not AP type or APG type device
ME Equipment Type	Portable
Physical parameters	
Size (height*width*length)	2.09±0.12 in * 3.39±0.12 in * 5.91±0.12 in 5.3±0.3 cm * 8.6±0.3 cm * 15±0.3 cm
Weight (including battery)	1.54 lb. (0.7kg)
Tolerable impact / falling damage	Free to fall from a height of 1.5 m on a hard surface
Environmental parameters	
Operation temperature	-15°C to 50°C (After entering environment of - 20°C from room temperature, it can work for at least 60 minutes)
Storage temperature	0°C to 50°C
Short term storage/ transportation temperature	-40°C to 70°C (< 7 days)
Relative humidity	0% to 95% no condensation
Air pressure	50.4kPa to 106kPa
Altitude	-382m~5000m
Shock	Complies with the requirements of EN1789:2020
Vibration	Complies with the requirements of EN1789:2020
Drop	Complies with the requirements of EN1789:2020, drop height of 1.5m
The time required for the device to warm from the lowest storage temperature between uses until the device is ready	Less than 30 minutes

for its intended use when the ambient temperature is 20°C				
The time required for the device to cool from the highest storage temperature between uses until the device is ready for its intended use when the ambient temperature is 20°C	Less than 30 minutes			
Defibrillation				
Shockable Rhythm	VT/VF			
Waveform	Truncated biphasic exponential waveform			
Energy level	Automatic pre-programmed selection (Adult mode: 150J; Pediatric mode: 50J)			
Output control	Manual operation (In rescue mode, the shock button should be pressed manually).			
Operational impedance limitation of patient	20Ω to 180Ω			
Recovery of ECG input after defibrillation	<2.5s			
Charging time of disposable battery (Time required for charging the defibrillation capacitor to 150J under different battery conditions)	Battery Status (20±2°C)	The time from pressing the power button to the time when the defibrillation can be delivered	The time from the initial heart rhythm analysis to the time when the defibrillation can be delivered	The time from the second heart rhythm analysis to the time when the defibrillation can be delivered
	New Battery	≤19 s	≤ 17 s	≤ 8 s
	New battery, after 6 times of maximum energy discharge	≤19 s	≤ 17 s	≤ 8 s
	New battery, after 15 maximum energy discharge	≤19 s	≤ 17 s	≤ 8 s

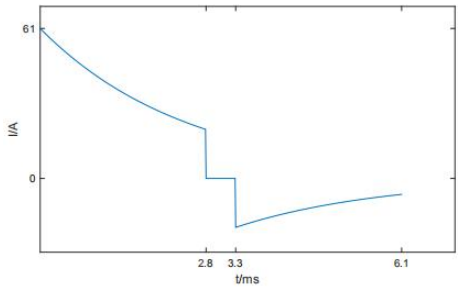
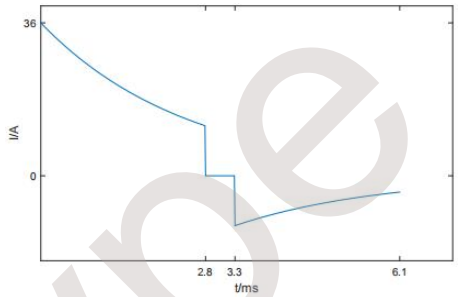
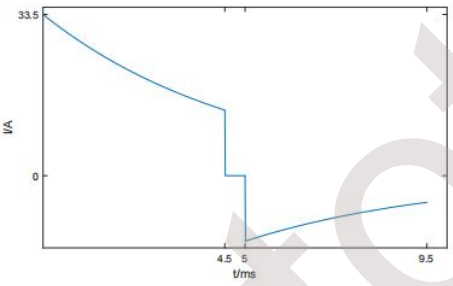
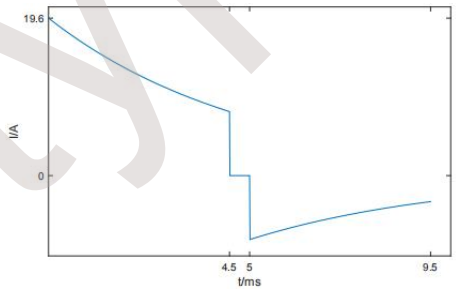
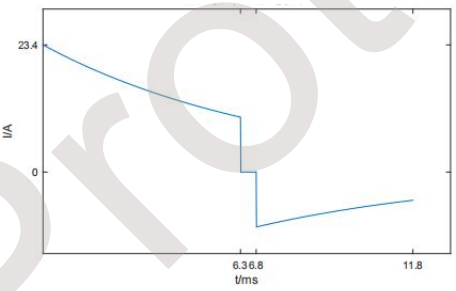
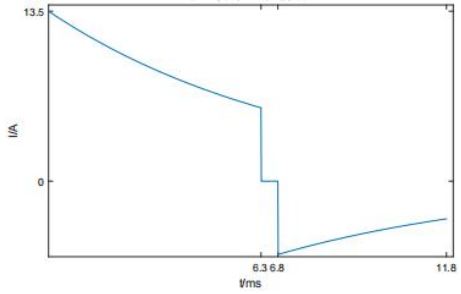
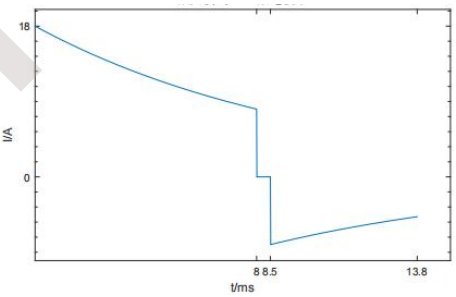
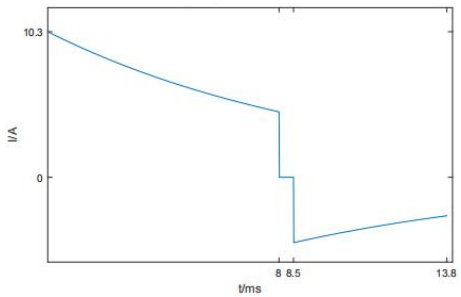
Charging time of rechargeable battery (Time required for charging the defibrillation capacitor to 150J under different battery conditions)	Battery Status (20±2°C)	The time from pressing the power button to the time when the defibrillation can be delivered	The time from the initial heart rhythm analysis to the time when the defibrillation can be delivered	The time from the second heart rhythm analysis to the time when the defibrillation can be delivered
	New, fully charged Battery	≤ 12 s	≤ 10 s	≤ 8 s
	New battery, after 6 times of maximum energy discharge	≤ 12 s	≤ 10 s	≤ 8 s
	New battery, after 15 maximum energy discharge	≤ 12 s	≤ 10 s	≤ 8 s
ECG analysis system				
Analysis accuracy	Comply with IEC60601-2-4 requirements			
Cardiac arrest threshold	<0.2mV			
Artifacts detection	Support If an interfering signal that affects the accuracy of the heart rhythm analysis is detected, the device will delay performing the analysis and give a prompt.			
Pads				
Model	OBS-DE/P		OBS-DE/W	
Target user	Adult		Adult/Child	
Shelf life	5 years			
Specification	Combined by pads connector, wires, and a pair of disposable defibrillation electrodes.			
Length	≥1.0m			
Battery				
Model	BAT-PT01		BAT-PT02	
Type	Disposable battery ($LiMnO_2$ Battery)		Rechargeable battery (Li-ion Battery)	
Capacity	12V/1500mAh		7.2V/3450mAh	

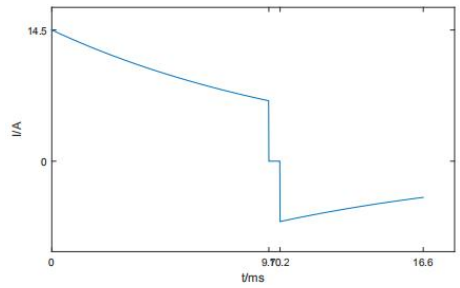
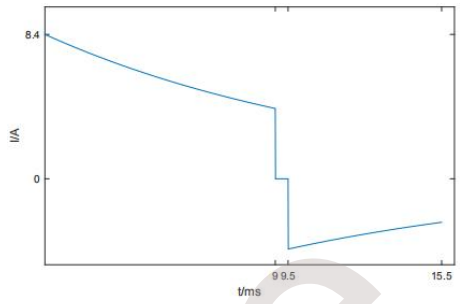
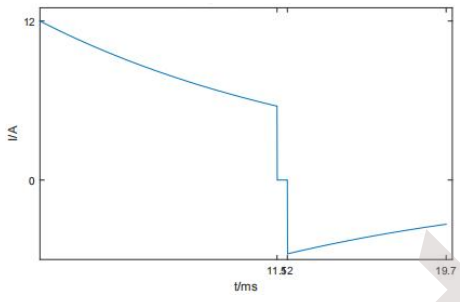
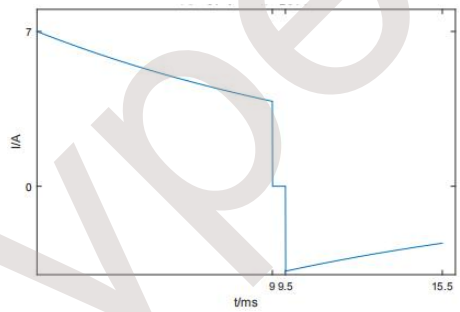
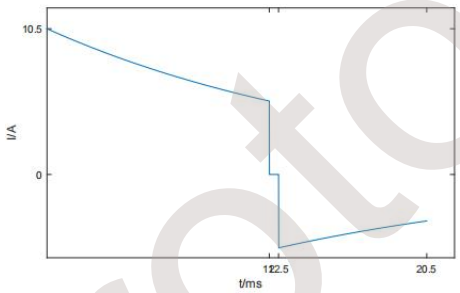
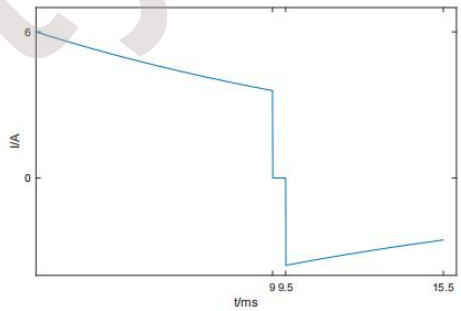
The number of maximum energy discharges which are available from a new and fully charged battery	a) New battery can charge and discharge at least 130 times in rated energy of 150J at 20°C±2°C environment. b) New battery can charge and discharge at least 20 times in rated energy of 150J at -15°C environment. c) New battery, after the first reminder of low battery, can charge and discharge at least 30 times.	a) New fully charged battery can charge and discharge at least 250 times in rated energy of 150J at 20°C±2°C environment. b) New fully charged battery can charge and discharge at least 20 times in rated energy of 150J at -15°C environment. c) New fully charged battery, after the first reminder of low battery, can charge and discharge at least 30 times.
Continuous running time	Ambient temperature 20±5°C (room temperature), new disposable battery, non-shock heart rate analysis and CPR guided circulation continuous running time ≥6 hours, after the first indication of low power can run time ≥1 hour.	Ambient temperature 20±5°C (room temperature), new rechargeable battery, non-shock heart rate analysis and CPR guided circulation continuous running time ≥10 hours, after the first indication of low power can run time ≥1.5 hours.
Continuous VF/VT Mode running time (P1)	Ambient temperature 20±5°C (room temperature), new disposable battery, operating time ≥24 hours in continuous VF/VT mode.	Ambient temperature 20±5°C (room temperature), new fully charged rechargeable battery, operating time ≥45 hours in continuous VF/VT mode.
Standby life	3 years	3 months before recharge
	Ambient temperature 20°C±2°C, standby mode with new battery installed, weekly self-test, do not connect 4G to send self-test results.	
Shelf life	7 years	5 years/ 300 times of charge-discharge cycle
	Ambient temperature 25°C	
Battery Charger (Optional)		
Safety Classification	Class I	
Protection against harmful ingress of water or particulate matter	IP54	
Power Supply	100-240V~ 50Hz/60Hz	
Rated input power	60VA	
Charge time	At 20°C±2°C environment, the battery charger charges 2 rechargeable batteries at the same time, and the fully charged time is not more than 3.7 hours. A single rechargeable battery should take no more than 2.5 hours to fully charged.	
Service Life	10 years	
Device		

Production date	See label on back of device
Service Life	10 years
Record	
Recording function	Immediately after the device is powered on, use the microphone to collect and record ambient sound information. And support to store 3 hours of recording data.
Data Storage	
ECG Data	24 hours of ECG data
Self-test Data	3650 copies
Communication	
Capacity	Support Bluetooth, mobile communication 4G and GPS positioning

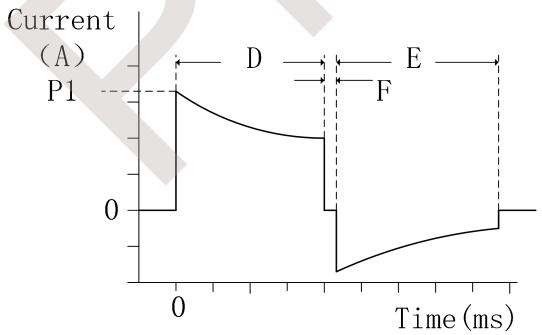
Appendix 5 Defibrillation Waveform

The defibrillation waveform of the device is a truncated biphasic exponential waveform, and the device can automatically adjust the waveform parameters for the patient impedance in the range of 20-180 Ω. The defibrillation waveform parameters under different impedances are as follows:

Load impedance (Ω)	Defibrillation Waveform (Adult mode)	Defibrillation Waveform (Child mode)
25		
50		
75		
100		

Load impedance (Ω)	Defibrillation Waveform (Adult mode)	Defibrillation Waveform (Child mode)
125		
150		
175		

Defibrillation energy output waveform is shown in the figure below:



P1: phase 1 peak current

D: Phase 1 pulse width

E: phase 2 pulse width

F: Time interval between Phase 1 and Phase 2

Energy output under various impedances (Adult mode):

Load impedance (Ω)	Phase 1 pulse width D(MS) ±10%	Phase 2 pulse width E(MS) ±10%	Time interval between Phase 1 and Phase 2 F(MS) ±10%	Peak current P1 (A) ±10%	Energy output (J) ±10%
25	2.8	2.8	0.5	61.0	128
50	4.5	4.5	0.5	33.5	150
75	6.3	5.0	0.5	23.4	155
100	8	5.3	0.5	18.0	157
125	9.7	6.4	0.5	14.5	158
150	11.5	7.7	0.5	12.0	160
175	12	8	0.5	10.5	158

Energy output under various impedances (Child mode):

Load impedance (Ω)	Phase 1 pulse width D(MS) ±10%	Phase 2 pulse width E(MS) ±10%	Time interval between Phase 1 and Phase 2 F(MS) ±10%	Peak current P1 (A) ±10%	Energy output (J) ±10%
25	2.8	2.8	0.5	36.0	43.4
50	4.5	4.5	0.5	19.6	50.0
75	6.3	5.0	0.5	13.5	52.0
100	8.0	5.3	0.5	10.3	52.2
125	9.0	6.0	0.5	8.4	52.3
150	9.0	6.0	0.5	7.0	50.0
175	9.0	6.0	0.5	6.0	49.0

Appendix 6 ECG Analysis System

Summarize

The defibrillator's ECG analysis system, which automatically identifies patient's heart rhythm and provide shock advise to the operator, offers trained operators the possibility of life-saving treatment in treating patients with nausea and arrhythmias. The analysis system has the following functions:

- Judgment of electrode contact
- Recognition and erasure of pacemaker signal
- Recognition of the shockable heart rhythm
- Detection of cardiac arrest
- Detection of Interference

Judgment of electrode contact

The defibrillator will automatically detect the thoracic impedance of the patient. If the impedance value is within the set threshold value, the electrode will be judged to be firmly in contact and the heart rhythm analysis can be started. If the chest impedance value exceeds the set threshold, the electrode is judged to have inadequate contact or to be improperly connected to the defibrillator, at which point the operator is advised to re-insert the electrode.

Recognition and erasure of pacemaker signal

The pulse signal of a buried pacemaker may interfere with the correct identification of arrhythmias. The defibrillator will first identify and erase the pacing signal, and then enter the rhythm analysis. Based on the results of the analysis, the shock or no shock prompt is given.

Recognition of the shockable heart rhythm

According to the requirement for heart rhythm recognition detector consist in clause 201.107 of IEC 60601-2-4:2018, the performance of heart rhythm recognition detector and classification of heart rhythm recognition detector are as follows:

Table A6-1 Performance of heart rhythm recognition detector

Rhythms	Sample Size	Performance Goal of IEC60601-2-4	Observed Performance
Shockable		Sensitivity	
VF	726	>90%	100%
VT	368	>75%	99.7%
Nonshockable		Specificity	
	3350	>99%	99.7%

Table A6-2 Classification of heart rhythm recognition detector

Rhythms	VF and VT	All other rhythms
Shockable	True positive	False positive
	99.7%	0.3%
Nonshockable	False negative	True negative
	0.3%	99.7%

*Data Source: International standards databases and VIVEST clinical collection databases

The results showed that a total of 4444 data were collected, including 3350 nonshockable data, with a specificity of SP-99.7%, and 1094 shockable data, VF with a sensitivity Se-100%, VT with a

sensitivity of Se-99.7%. The positive prediction rate was Pp-99.7%, the false positive rate was Fp-0.3%, and the accuracy was Acc-99.7%. The performance of the heart rhythm recognition detector meets the performance requirements of various rhythm types and quantities in IEC60601-2-4, and the sensitivity or specificity of each rhythm type meet the requirements of IEC60601-2-4.

Detection of cardiac arrest

The Pause threshold is 0.2mV peak-to-peak value. If the electrical signal peak-to-peak value is less than 0.2mV, the system will recognize it as pause, and give a prompt of "*No shock advice*" and move to CPR.

Detection of Interference

The defibrillator's ECG analysis system detects interference, which may be caused by external sources such as posture movements or electrical noise. Postural movement includes patient movement, rescuer movement, vehicle movement, etc.; External sources of electronic noise: e.g., mobile phones, radios, etc. If interference is detected, the system sends a voice warning to the rescuer, at which point the operator should remove the interference as soon as possible to minimize artifacts in the ECG, and the system continues to perform heart rate analysis.

Appendix 7 Electromagnetic Conformity Guide

Warning	1) Use of accessories, transducers and cables not manufactured by the manufacturer could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation. 2) Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this device and the other equipment should be observed to verify that they are operating normally. 3) The EMC of this device needs to be specially protected, and it needs to be installed and repaired in an environment that meets EMC information below. 4) Even if other equipment meets the CISPR emission requirements, they may cause interference to the device. 5) Other equipment that contains RF radio emissions may affect the device (for example, mobile phones, wireless-enabled computers). 6) In the presence of large EM disturbance, the device may unexpectedly prompt “Eliminate Signal Interference”, “Keep Patient Still” or “Poor Pad Contact”, and may not be unable to perform analysis. Please turn off the interference source or move away from it. 7) Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the P1&P3, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

ESSENTIAL PERFORMANCE:

The essential performance of P series AED is to deliver defibrillation therapy and accurately differentiate between shockable and non-shockable rhythms.

Electromagnetic Emissions		
P1/P3 is intended for use in the electromagnetic environment specified in the tables below. The user of the P1/P3 should assure that it is used in such an environment:		
Emission Test	**COMPLIANCE**	**ELECTROMAGNETIC ENVIRONMENT-GUIDANCE**
Radio-frequency emission CISPR 11	Group 1	The P1 /P3 uses RF energy for its internal functions only. Therefore, its RF emissions are low and may not cause any interference in nearby electronic equipment.
Radio-frequency emission CISPR 11	Class B	The P1 /P3 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic distortion IEC61000-3-2	N/A	
Voltage fluctuations and flicker IEC61000-3-2	N/A	

Electromagnetic Immunity			
P1/P3 is intended for use in the electromagnetic environment specified in the tables below. The user of the P1/P3 should assure that it is used in such an environment:			
IMMUNITY TEST	**IEC 60601 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8kV contact ±15kV air	±8kV contact ±15kV air	The relative humidity should be at least 5%
PFMF (50Hz/60Hz) IEC 61000-4-8	30A/m	30A/m	The power frequency magnetic fields should at levels characteristics of a typical location in a typical commercial/hospital environment.

Electromagnetic Immunity			
P1/P3 is intended for use in the electromagnetic environment specified in the tables below. The user of the P1/P3 should assure that it is used in such an environment:			
IMMUNITY TEST	**IEC 60601 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
Radiated RF IEC 61000-4-3	10V/m 80MHz to 2.5GHz	20V/m 80MHz to 2.5GHz	Portable and mobile RF communication equipment should be used no closer to any part of the P1/P3, including cables, than the recommended separation distance calculated from the quation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range. Interference may occur near equipment marked with the following symbols: 
Note 1: At 80MHz and 800MHz, the higher frequency range applies. **Note 2**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the P1/P3 is used exceeds the applicable RF compliance level above, the P1/P3 should be observed to verify normal operation. If abnormal performance is observed additional measures may be necessary, such as reorienting or relocating the P1/P3.			

IMMUNITY to RF wireless communications equipment				
Test frequency (MHz)	**Band [a] (MHz)**	**Service [a]**	**Modulation**	**IMMUNITY TEST LEVEL (V/m)**
385	380 to 390	TETRA 400	Pulse modulation [b] 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM [c] ±5 kHz deviation 1 kHz sine	28
710	704 to 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	28
870				
930				
1720	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3,4,25; UMTS	Pulse modulation [b] 217 Hz	28
1845				
1970				
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	9
5500				
5785				
If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.				
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50% duty cycle square wave signal. c) As an alternative to FM modulation, the carrier may be pulse modulated using a 50% duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.				

IMMUNITY to proximity magnetic fields		
Test frequency	**Modulation**	**IMMUNITY TEST LEVEL (A/m)**
30 kHz [a)]	CW	8
134.2 kHz	Pulse modulation [b)] 2.1 kHz	65 [c)]
13.56 MHz	Pulse modulation [b)] 50 kHz	7.5 [c)]
a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT. b) The carrier shall be modulated using a 50% duty cycle square wave signal. c) r.m.s., before modulation is applied.		

Appendix 8 Additional Information

Clinical Benefits

Provide the analysis of shockable rhythm or non-shockable rhythm and deliver the shock with the shockable rhythm to improve the survival for patients with SCA.

Incident Reporting

If the user or patient needs to report any serious incidents in relation to the device, can contact the manufacturer and the competent authority of the Member State where the user and / or patient is established.

Information Available to The User

The user manual is provided with the device in a paper format.

The SSCP will be available on EUDAMED.

https://ec.europa.eu/tools/eudamed

Regulatory Compliance

VIVEST solemnly declares that P series Automated External Defibrillator complies with the relevant provisions of the relevant medical equipment standards:

IEC 60601-1:2005+A1:2012+A2:2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance,

IEC 60601-2-4:2010+AMD1:2018 Medical electrical equipment – Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators,

IEC 60601-1-2:2014+A:2020 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests,

IEC 60601-1-12:2014+A1:2020 Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment.

IEC 60601-1-11:2015+A1:2020 Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Appendix 9 Compatible Accessories

Those accessories are compatible to P series AED:

Name	Model	Manufacture
Pads (P1)	OBS-DE/P	Baisheng Medical Co.,Ltd.
Pads (P3)	OBS-DE/W	Baisheng Medical Co.,Ltd.
Battery Charger	MAC01	VIVEST