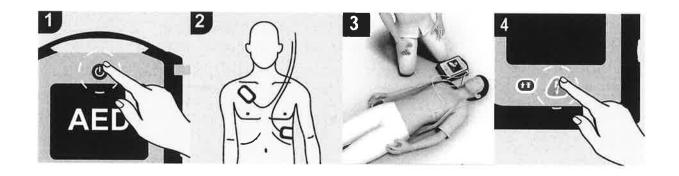


PowerBeat X Series Automated External Defibrillator QUICK REFERENCE MANUAL



ViVest Medical Technology Co., Ltd.

Information in this document is subject to change without notice.

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Before Use

Please be familiar with the content and various safety warnings list in this manual.

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1 Product Information and Safety

Product models

This manual is for PowerBeat X Series Automated External Defibrillator, including 2 models, PoweBeat X1 and PowerBeat X3 (hereinafter referred to 'device/the device ').

	PowerBeat X1	Powerbeat X3
LED Lights	✓	✓
Graphic Panel	✓	
Voice Prompt	✓	✓
LCD Color Display		✓
Animation		✓
Text Prompts		✓

Intended Use

PowerBeat Series 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.

For patients under 8 years of age or less than 25kg (55 lb.), use child mode. For patients at 8 years of age or older, use adult mode.

The AED is intended for use by responders who have been trained in its operation and 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.

The AED can be used in public places such as schools, airports and stations.

Essential Performance

The essential performance of the device is to deliver defibrillation therapy and accurately differentiate between shockable and non-shockable rhythms.

Safety terms and definitions

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

⚠ Danger	Indicates urgent risks, immediate hazards that will lead to personal injury or even death.
⚠ Warning	Indicates potential risks or risks caused by unsafe operations, it could result in personal injury or property damage if not avoided.
Caution	Used to emphasize instructions or reminders so that users can use this device better.

Safety message

- 1) The device generates high voltage during defibrillation and may cause severe personal injury or even death. Therefore, defibrillation should be performed by professionals.
- 2) Components replacement can only be performed by the manufacturer. Other personnel must not open the cover to attempt to repair the device and replace components. Otherwise, there is a risk of electric shock.
- 3) Do not disassemble or modify the device, otherwise it may result in personal injury or even death.
- 4) Other ME EQUIPMENT which has no DEFIBRILLATION-PROOF applied parts shall be disconnected from the PATIENT during defibrillation.
- 5) During defibrillation, stay away from the patient and all metal equipments connected to the patient, otherwise there is a danger of electric shock.
- 6) There maybe a danger of electrocuted or injury if the defibrillation energy is not released normally.
- 7) Do not use the equipment in an environment with flammable gases or concentrated oxygen to prevent fire or explosion.
- 8) Do not charge the battery. Charging the battery may cause a fire or explosion .
- Do not burn or incinerate the battery. Burning or incinerating a battery may cause a fire or explosion.
- 10) Do not maintain the device during use.
- 11) Do not remove the battery when the machine enters the rescue mode or when the machine is placed in public places.

♠ Warning

- 1) Only those technicians who are professionally trained and familiar with the operation of the device can perform first aid defibrillation operations.
- 2) Carefully place the device and cables to avoid dragging the pads, avoid tripping and entanglement of the patient, and avoid device or personnel injury during dragging.
- 3) Place and fix the device to prevent it from falling or dropping. If the device has a falling incident, be sure to check the device for damage.
- 4) Do not use expired or dry pads as they can not completely adhere to the skin.
- 5) Do not repeatedly and rapidly charge and discharge the device except as necessary during emergency treatment of patient. If the device test requires repeatedly internal discharges, wait at least one minute after every three discharges.
- 6) 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 skin burned under the pads.
- 7) Before defibrillation, shave body hair from the patient's chest if necessary. Excessive body hair may cause skin burns.
- 8) Do not wipe the patient's skin with alcohol. Alcohol wipes will dry the skin and cause skin burns.
- 9) In patients with cardiac pacemakers, the sensitivity of the device may be reduced and may not detect all shockable rhythms. If you know the patient has an cardiac pacemaker, do not place pads near by the implanted equipment.
- 10) 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).
- 11) When the device is connected to the patient, no functional checks can be performed to avoid accidental electric shock.
- 12) Do not use alcohol or other solutions to soak or clean the pads. These behaviors may damage the pads and cause improperly operation to the device.
- 13) Moving or carrying the patient during rhythm analysis can cause diagnostic delays or errors.
- 14) The pads should be placed on a flat skin surface instead of on the folded skin surface. If the pads is not placed in the right place, it will affect the heart rhythm analysis and cause misjudgment.
- 15) 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

⚠ Warning

- saline) and metal objects (such as a bed frame or a stretcher), which may provide unwanted pathways for the defibrillation current.
- 16) Do not place the device near any apparatus that emits strong Radio-Frequency(RF) signals. Radio frequency emissions can cause incorrect result or misjudgement of heart rhythms analysis.
- 17) Do not use unapproved pads, batteries, and other accessories. The use of unapproved components can cause malfunction to the device. Use accessories only specified by the manufacturer.
- 18) The device cannot work when the battery is exhausted and uninstalled. If the battery is low power or overdue, replace the battery immediately.
- 19) If the device is taken out from the highest storage temperature or the lowest storage temperature and put into use immediately, the performance of the device may differ from expectations. Device must not be stored or used outside of the environmental limits specified in this manual.
- 20) Improper operation may cause runtime errors. Please follow manual carefully.
- 21) Only the service personnel could configure the device by Bluetooth and special tools. The use of Bluetooth will not bring any risk to the use of the device.
- 22) When the status indicator of the device is found to be off, the service personnel could try to replace the battery pack to restore the device to normal. This might be due to the overcurrent protection or other battery failure.

- 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 specifications in 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) At least one extra battery is recommended to provide for each device in a public place.

2 **Getting Started**

Unpacking

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

- 1. Check the intact of the device shell
- 2. Check the seal and validity period of the pads, and
- 3. Check the validity period of the battery.

Product Overview

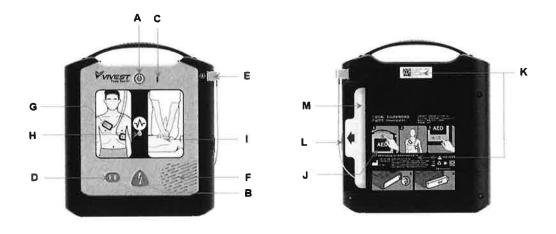


Figure 1 PowerBeat X1

NO.	Name	NO.	Name	NO.	Name
Α	Power Button	F	Speaker	K	Device Label
В	Shock Button	G	Pads Indicator	L	USB Interface
С	Status Indicator	Н	Rhythm Analysis Indicator	М	Pads
D	Child Button	1	CPR Indicator	1	1
E	Pads Cable Connector	J	Quick Operation Guide	1	1

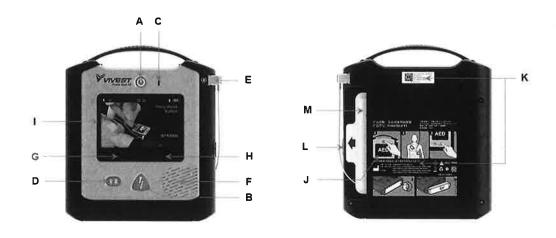


Figure 2 PowerBeat X3

NO.	Name	NO.	Name	NO.	Name
Α	Power Button	F	Speaker	K	Device Label
В	Shock Button	G	Info Soft Button (Left)	L	USB Interface
С	Status Indicator	Н	Language Soft Button (Right)	М	Pads
D	Child Button		LCD Screen	1	1
Ε	Pads Cable Connector	J	Quick Operation Guide	1	1



Figure 3 PowerBeat X3 display screen

NO.	Name	NO.	Name	NO.	Name
Α	Number of shocks	С	Language switching Icon	E	Patient type
В	Info Icon	D	Battery power	F	Running Time

Battery

Specification	Description
Battery type	LiMnO₂ Non-rechargeable
The number of maximum energy discharges which are available from a new battery	New battery can charge and discharge 200±10 times in rated energy of 150J at 20°C±2°C environment.
Battery standby mode operation time	5 years
Battery life	5.5 years
Low battery condition	The device can deliver at least 10 shocks after the low battery indication is first displayed.

Install Battery

To install the battery:

- 1. Put the end of battery pack into the device battery slot
- 2. Push the battery pack into the battery slot
- 3. Finally check if the buckle of the battery pack is fully inserted into the battery slot.

After the battery pack is installed, the device will run self-test automatically.

Replace Battery

When the low battery prompt is indicated, please replace the battery pack immediately.

To replace the battery, please follow the steps below:

- 1. Turn off the device to enter standby mode,
- 2. Press the buckle of the battery, and pull it out, and
- 3. Wait for 30 seconds, and then install a new battery.

- 1) Battery can only be replaced in standby mode. If the device is not in rescue mode, press the power button for at least 2 seconds to turn it off.
- 2) The device will run a self-test automatically after install battery.

Pads

⚠ Warning:

- 1) Never use a damaged, wrinkled and folded pads, or it may cause dangerous such as leakage current and unwanted burns on skin.
- 2) Don't reuse the disposable pads. Repeated use may cause performance degradation or cross infection.
- 3) The pads should be placed on the patient's flat skin surface, otherwise, it may lead to a wrong heart rhythm analysis and even cause a misjudgment of defibrillation!
- 4) Do not leave bubbles between the pads and the patient's skin when attaching the pads, otherwise the skin may be burned by the electric discharge.
- 5) Make sure the pads have a good contact with the patient's body, a poor contact might cause skin burns.

Preconnected the Pads

Check whether the pads connector is preconnected to the socket. If not, follow the steps below to connect the pads:

- 1. Check the integrity of the pads package,
- 2. Check the expiration date on the pads package, and
- 3.Insert the pads connector into the socket.



Replace Pads

Replace the pads immediately when:

- -after rescue,
- -expired, and
- -the pads package is damaged.

Follow these steps to replace pads:

- 1. Turn off the device to enter standby mode,
- 2. Pinch the pads connector tightly and pull it out,
- 3. Repalce a new pads and insert the pads connector into the socket,
- 4. Turn on the device to run a self-test, and

5. If no error message occurs, turn off the device.

Child Mode

The device provides a child button to switch patient type.

If the patient is less than 25kg (55 lb.) or under 8 years old:

- 1.Press the child button, and the device will prompt "To enter the Child mode, press the child button for 3 seconds", and
- 2. Press this button for 3 seconds, and the device will switch to the child mode.

- 1) If you need to switch from child mode to adult mode, shut down and restart the device.
- 2) After enter the analysis stage for 5 seconds, patient type switching will be prohibited.

3 Using the Device

Step 1: Assess the patient

PowerBeat X1/PowerBeat X3 can be used only when the patient has the following symptoms at the same time:

- Unconscious.
- > No breathing or abnormal breathing, and
- Unresponsiveness

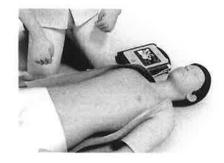
The intended user must have been trained in its operation and in Basic Life Support (BLS), Advanced Life Support (ALS), or another physician-authorized emergency medical response program.

Contraindications

PowerBeat X1/PowerBeat X3 should not be used if the patient is responsive or conscious.

Step 2: Prepare the patient





- 1. Place the device next to the patient, and press the power button.
- 2. Follow the instruction of the device to remove patient's clothing.

Caution:

- 1) Shave excessive hair of patient's chest if necessary.
- 2) Clean patient's chest to ensure a well contact between the pads and the skin.
- 3) For child patient, remove all clothing of upper body, and press the child button to enter child mode.

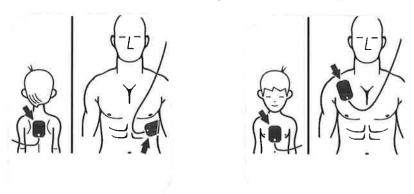
\triangle Warning:

Do not delay the treatment for determine patient's type. If doubt, use adult mode.

Step 3: Attach pads

AED prompts	Action	Figure
"Remove Pads Package from Back of AED"	Take the pads package out from the back of the device, and check: -the date, and -the integrity.	
"Tear open package, take out the pads"	If the pads package is integrity and within expiry date, tear open the package and take out pads, check: -whether damaged, and -no impurities.	
"Remove Liner from Pads"	Remove bule liner from pads.	
	For adult patient, one of the electrodes was applied to the patient's right chest and below the clavicle, and the other electrode was applied to the patient's left chest and above the rib in the maxillary line.	3
"Apply Pads to Patient's Chest"	For child patient, place one electrode in the middle of the chest between the nipples and the other in the middle of the back (front and back).	

Adults and children share the same pads, but the position is different:



Step 4: Cardiac rhythm analysis

AED prompts	Action
"Do not Touch Patient, Analyzing	Do not touch the patient.
Heart Rhythm"	Wait for the next prompt.

During the analysis phase, you may hear one or more of these prompts:

AED prompts	Problem	Action
"Poor Pads Contact, Check	The pads are not attached	Check and ensure the pads
Pads"	properly.	attach properly to the patient.
"Eliminate signal interference"	Signal interference occurs.	Check and eliminate the signal
		interference.
" Keep the patient still "	The patient cannot remain	Check and keep patient still.
	still due to external forces.	

Step 5: Require Defibrillation

AED prompts	Action
"Shock Advised"	Check and ensure that nobody is touching the patient.
	Wait for the next prompt.
"Do not Touch Patient, Charging"	Check and ensure that nobody is touching the patient.
	Wait for the next prompt.
"Press Flashing Shock Button"	Check and ensure that nobody is touching the patient.
	Press the flashing shock button.
"Shock Delivered"	Wait for the next prompt.

- 1) If a non-shockable heart rhythm is detected, the device will send a voice prompt "No Shock Advised" and turn to CPR stage.
- 2) When the device is charged, it continues to analyze the patient's heart rhythm. If the

rhythm changes and a shock is no longer needed, the device prompts, "Heart Rhythm changed. Shock cancelled" and then prompts to start CPR.

Step 6: CPR

After the AED delivers a shock or detects a non- shockable rhythm, it enters CPR stage.

AED prompts	Action	
"Begin CPR"	Place heel of one hand on center of chest between nipples, be sure to keep your fingers up off the chest wall. Keep your arms straight and shoulders over your hands. Vertical force produced by the upper part of the body.	
Веер	Follow the beep sound for chest compressions. Push hard, and push fast. Depth: more than 5cm/2inchs.	
"Breathe", "Breathe"	Pinch the person's nose with your finger tips and start mouth to mouth breathing. Place your mouth over the patient's mouth and exhale. Give two full breaths.	
"Stop CPR"	Wait for the next prompt.	

Step 7: Prepare for the next rescue

After rescue, perform the following steps:

- 1. Press the power button for 3 seconds to enter the standby mode.
- 2.Clean the device if necessary.
- 3.Replace new pads.
- 4. Check the remained battery power and replace new battery if necessary,
- 5. Put the device back in its original location for easy use.

4 Maintenance and troubleshooting

Self-test system

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. The device provides manual self-test, battery installed self-test, power-on self-test and periodic self-test.

1. Manual self-test

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

2. Battery installed self-test

As soon as the battery is installed, the device will run a self-test. Then the device enters the standby mode after all the checks are completed.

3. Power-on self-test

The device will run a self-test before use when the power is on. This self-test is important because the system will prompt malfunction of the device to remind operator or service personnel if failed the self-test.

4. Periodic self-test

Periodic self-test including daily, weekly, monthly and quarterly self-test. The device will run self-test automatically according to the default self-test time. The default time of daily self-test is 3 am.

Caution:

The device only run self-test automatically at the preset time in standby mode when the battery is installed.

Routine maintenance

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

Export data by USB device		✓

⚠ Warning:

PowerBeat series automated defibrillator has NO user-serviceable components. ALL Components of the device can only be replaced or renewed by the manufacturer. Other person must not open the cover to repair the device and replace components. Otherwise, there is a risk of electric shock.

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 frequency of the machine.

Disposal

After the expiration date of this device, it should be disposed according to local regulations. If in doubt, contact the local distributor or recycling company.

Disposal of the pads and batteries shall also comply with the relevant regulations and be recycled or disposed as required. If in doubt, contact the local distributor or recycling company.

Troubleshooting

Failure	Causes	Response	Message
The device cannot be turned 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

Failure	Causes	Response	Message
The device and entropy	Invalid or expired battery	Replace battery	N/A
The device suddenly shut down	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	N/A
Voice prompt "low battery"	Insufficient battery	Replace battery	N/A
	Insufficient battery	Replace battery	N/A
Status indicator is not on	Damage of the status indicator	Contact the manufacturer for maintenance	N/A
	Defibrillation pads expired	Replace pads	"Pads overdue"
Power-on self-test failed	Low battery	Replace battery	"Low battery"
	Mainboard error or other factors	Contact manufacturer for repair	"Device failure"

Appendix 1 Symbols

Symbol	Description	Symbol	Description
IP55	The dust and water proof levels of the device are 5 and 5 respectively.		Temperature limit.
\triangle	Caution. Consult accompanying documentation.	%	Humidity limitation.
- <u>*</u>	Defibrillation-Proof Type BF Applied Part. The device, when connected to the patient's chest by the pads, can withstand the effects of an externally applied defibrillation shock.	~~	Date of manufacture.
A	Warning, electricity.	SN	Serial Number
	Battery alarm indication.	<u>11</u>	This way up.
	Stand-by.	圣	Use no hooks.
X	Return to a collection site intended for Waste Electrical and Electronic Equipment (WEEE). Do not dispose of in unsorted trash.	X 9	Stacking limit by number.
<u></u>	Atmospheric pressure limitation.	1	Fragile, handle with care.
*	Keep away from rain.	4	Dangerous voltage.

(Do not deform or damage.		Direct current.
	Do not dispose of in fire.	[]i	Operating instructions.
83	General symbol for recovery/recyclable.		Follow instructions for use,
2	Do not re-use.	<u>^</u>	General warning sign.
	Use-by date.	•~	USB.
LOT	Batch code.	**	Child button
	Manufacturer.	P	Shock button
REF	Catalogue Number.	NON	Non-sterile.

Appendix 2 Specification

Physical		
Size (including handle)	232±1mm(H)* 209±1mm(W)* 59±0.5mm(D)	
	9.13in(H)* 8.23in(W)* 2.32in(D)	
Weight (including battery)	Approx. 1.5kg (3.3 lb.)	
Tolerable impact / falling damage	Free to fall from a height of 1.5 m on a hard surface	
Service life	10 years	
Environmental		
	Temp: -10℃~+50℃	
Operation condition	Relative humidity: 5%~95%, no condensation	
	Atmospheric pressure range: 59.4kPa ~ 106kPa	
	Short-term Temp: -40°C∼+70°C(Within one week)	
Characterist condition	Long-term Temp: 5℃~50℃	
Storage and Transportation condition	Relative humidity: 5%~95%, no condensation	
	Atmospheric pressure range: 59.4kPa~106kPa	
Defibrillation		
Shockable Rhythm	VF/VT	
Waveform	Truncated biphasic exponential waveform	
E	150J for adult mode	
Energy level	50J for child mode	
Operational impedance limitation of patient	20Ω \sim 180Ω (The device will inhibit its output when the patient impedance is outside the limit.)	
Charging time	a) less than 18 seconds with a new battery.	
	b) less than 18 seconds with a new battery depleted by	

· · · · · · · · · · · · · · · · · · ·	maximum energy discharge.
	c) less than 18 seconds with a new battery depleted by 15 maximum energy discharge.
	d) less than 22 seconds from initially switching power on to readiness for maximum energy discharge with a new battery.
	e) less than 22 seconds from initially switching power on to readiness for maximum energy discharge with a new battery depleted by 6 maximum energy discharge.
	f) less than 22 seconds from initially switching power on to readiness for maximum energy discharge with a new battery depleted by 15 maximum energy discharge.
Display (for PowerBeat X3 only)	
Туре	Liquid crystal display (LCD)
Size	105.5mm (H)×65.3mm (W)
Resolution	800 pixels×480 pixels
Cyber Security	
Cyber Security	CPU: STM32F767II
Cyber Security	CPU: STM32F767II RAM: 2 MB
Cyber Security Hardware Environment	
	RAM: 2 MB
	RAM: 2 MB ROM: flash, 64MB
	RAM: 2 MB ROM: flash, 64MB Display equipment: LED indicator, LCD display
Hardware Environment	RAM: 2 MB ROM: flash, 64MB Display equipment: LED indicator, LCD display I/O equipment: LED、speaker
	RAM: 2 MB ROM: flash, 64MB Display equipment: LED indicator, LCD display I/O equipment: LED、speaker Runtime system: FreeRTOS V9.0.0
Hardware Environment	RAM: 2 MB ROM: flash, 64MB Display equipment: LED indicator, LCD display I/O equipment: LED、speaker Runtime system: FreeRTOS V9.0.0 Prerequisite software: File system
Hardware Environment	RAM: 2 MB ROM: flash, 64MB Display equipment: LED indicator, LCD display I/O equipment: LED、speaker Runtime system: FreeRTOS V9.0.0 Prerequisite software: File system Matching software: NO NEED
Hardware Environment	RAM: 2 MB ROM: flash, 64MB Display equipment: LED indicator, LCD display I/O equipment: LED、speaker Runtime system: FreeRTOS V9.0.0 Prerequisite software: File system Matching software: NO NEED Antivirus Software: NO NEED

Interface	USB Bluetooth
User Type	Operator: Responsibility: Perform rescue using PowerBeat X1/ PowerBeat X3. Requirement: Have been professionally trained.
	Service personnel: Responsibility: Install the PowerBeat X1/PowerBeat X3, connect the device using the specified software to configure parameters, export data, and upgrade.
	Requirement: Have been professionally trained and authorized by manufacturer.
	Access Rights: Configure all the parameters.

Appendix 3 Glossaries

Glossary	Description
Standby Mode	The device will turn to standby mode after the battery installed.
Rescue Mode	The device will turn to rescue mode when the power button was pressed.
Self-test	The device uses internal procedures to conduct self-detection of the device's oGl0wn environment and each module of the system.
Defibrillation	The method of striking the heart with a certain current to stop ventricular fibrillation.
Pads	Contains defibrillation electrode, cable and cable connector.
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, and 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.
New battery	Battery pack 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.

Glossary	Description
AED	Automated external defibrillation
LED	Light emitting diode
AHA	American Heart Association
SCA	Sudden Cardiac Arrest
USB	Universal serial bus

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