



Shenzhen Oceanus Medical Device Co.,Ltd.

O-Wave-I Operating manual

OCE-ESWT-002



Shenzhen Oceanus Medical device Co., Ltd

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1 Product brief introduction

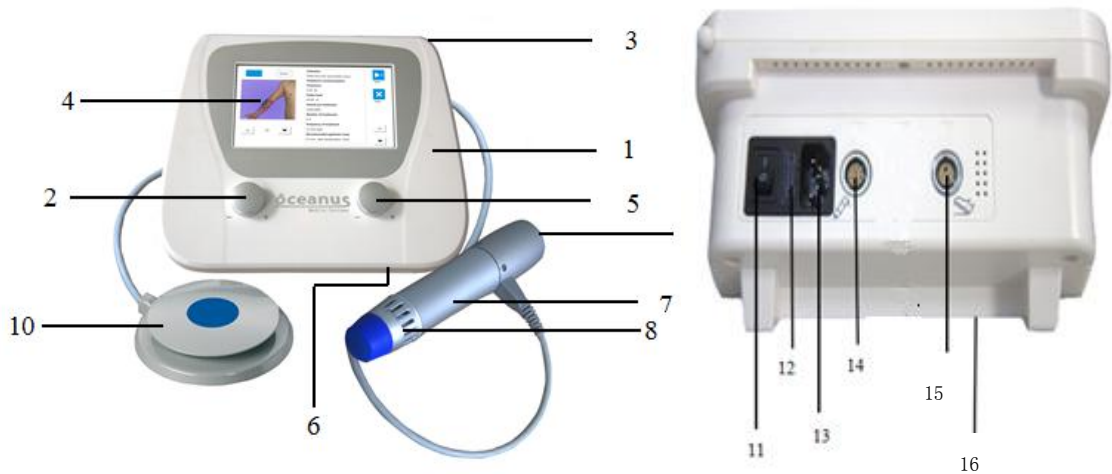
The O-Wave I is a medical device produced by Shenzhen Oceanus Medical Device Co., Ltd, its main utilizes the energy generated by the solenoid drive actuate bullet body inside therapeutic handle, so that the impact of the bullet body to pulse colliding the therapeutic head, the acoustic pulse will be converted to the exact ballistic shock wave, have a good therapeutic effect for musculoskeletal disorder and other. It brings the hope to the life of skeletal muscle disease patients, please read the manual carefully when using the product.

2 Product intended use

The O-wave I used in the area of adjuvant therapy of chronic joint pain and muscular pain and be used by medical staff

3 Primary structure of the product

The product mainly consists of host, therapeutic handle and foot switch, which hosts including upper and lower case, power supply, main board and touch screen. Accessories include power line, handwriting pen, handle bottom case, keys and aluminium alloy suitcase. Supplies accessories include silicone cap and therapeutic handle/therapeutic handle and foot switch belongs to exchange component. The product structure chat is as follows:



No.	Part name
1	Host
2	Energy knob
3	Handwriting pen
4	Display screen
5	Frequency knob
6	SD card slot
7	Therapeutic handle (therapeutic head)
8	Air outlet

No.	Part name
9	Air intake and fan
10	Foot switch
11	Power switch
12	Fuse wire
13	Power port
14	Handle port
15	Foot switch port
16	Product nameplate

4 Product main features

The main product features of O-Wave I as follow:

- a) The human engineering design provides setting and operates conveniently;
- b) 7 inches color crystal Chinese and English touch screen design, intuitive and clear;
- c) Import power source, to ensure instant shock output effect;
- d) Energy and frequency selection, conform to treatment demand;
- e) Single or dual output is optional, and provides a various professional probe;
- f) There are 7 adjustable preset reference solutions;
- g) Adopt a portable design.

5 Product requirements and main parametric description

5.1 Product requirements

1) Working power supply: 100-240VAC, frequency: 50/60Hz

2) Environmental requirements

Item	Temperature requirement	Humidity requirement	Atmospheric pressure
Work environment requirement	20°C-32°C	25%-75%RH	700hPa-1060hPa
Storage/ Transport environment requirement	0°C-40°C	10%-93%RH	700hPa-1060hPa

5.2 Product main technical parametric description

●Pulse energy levels:

60 - 185 mJ (at the applicator),freely adjustable in 10 mJ increments

at 22 Hz max. 90 mJ

at 16 Hz max. 120 mJ

at 10 Hz max. 185 mJ; The output tolerance is $\pm 40\text{mJ}$, The CV is $\pm 5\%$

●Working frequency

1~22 Hz,adjustable in 1 Hz increments

●Work pattern

4 continuous capture modes (shots /4/8/12 pulses)

●Reference operating version

7 preset operation versions, can be adjustable

●Suggestion for treatment parts

Exceeds 25 preset treatment suggestion

●Control function

All function implemented by touching operation; rotary knob controls energy and frequency; multi-directional foot switch coordinates with therapeutic handle operation.

●Product boundary dimension

290×240×130mm (length/width/height)

●Product weight

2.07kg (do not contain therapeutic handle and foot switch)

●The description of therapeutic handle/therapeutic head to shock wave

The therapeutic handle design conforms to human engineering, combines anodized aluminium shell with fan cooling, produces electromagnetic force drive projectile working by means of coil electrical over. The boundary dimension is 23cm, diameter is 5cm (the maximum); the minimum service life of therapeutic handle is 2,000,000 times (the calculation according to a number of strokes); only need to do some daily maintenance and nursing for appearance, it is recommended to use cleaning with medicinal alcohol; the therapeutic head divided into 3 specifications: 6/15/25mm (diameter); the minimum service life of each therapeutic head is 150,000 times (the calculation according to a number of strokes).

●Power consumption

100/240VAC 50/60 Hz, 300VA

●The fuse (wire fuse) specification

250V/10A

●The requirement of therapeutic head temperature

The external temperature of therapeutic head of the O-wave I is not greater than 48°C.

●Electrical safety classification

Type BF applied parts



6 Application method of product

6.1 The information needs to understand before the use of product

1) Graphical interfaces introductions

1.1) Beginning interface



Remarks:

- 1-Settings button: click on this icon, the display screen will jump to the settings interface
- 2-Beginning button: click on this icon, the display screen will jump to treatment/scheme

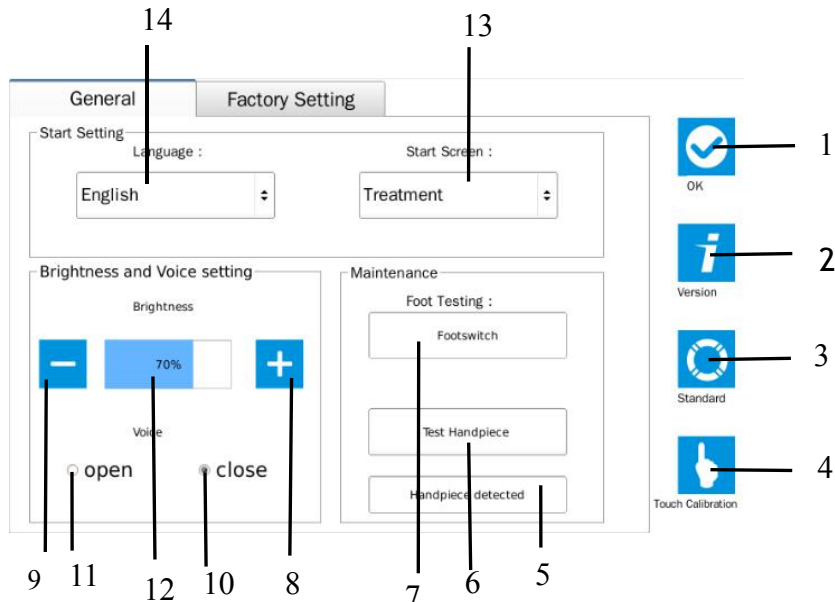
interface

1.2) Settings interface

1.2.1) General settings interface

General settings view:

●Single-end



Remarks:

- 1-“Confirm” button: click on this icon, the display screen will jump to the beginning interface.
- 2-“Versions” button: click on this icon, the screen will pop up a version dialog box; you can see the product software information in this dialog box.
- 3-“Standard” button: click on this icon, the general settings will return the default.
- 4-“Touch calibration” button: click on this icon, the display screen will pop up a prompt box, indicating whether you need to calibrate the touch screen.
- 5-Handle state bar: if the connection state is not normal, and the state bar turns blue, it means that the handle is not found.
- 6-“Test handle” button: click on this icon, the handle will work once. It is use for testing the handle whether is normal work.
- 7-Foot switch state bar: it displays the working state to foot switch. If treading the foot switch, the state bar will turn blue and it means the working performance is normal.
- 8-Luminance increased button: click on this icon, the luminance of display screen will increase, and the value of the 12th item on the interface will corresponding increase.
- 9-Luminance decreased button: click on this icon, the luminance of display screen will decrease, and the value of the 12th item on the interface will corresponding decrease.
- 10-Voice shutdown button: click on this icon, the voice will shut down.
- 11-Voice booting button: click on this icon, the voice will boot.
- 12-Luminance item: the value of luminance represents the luminance of display screen.
- 13-Booting screen of pull-down menu: click on this menu value of this button, select which

opening mode, the retrospective interface will automatic jump to the corresponding working interface.

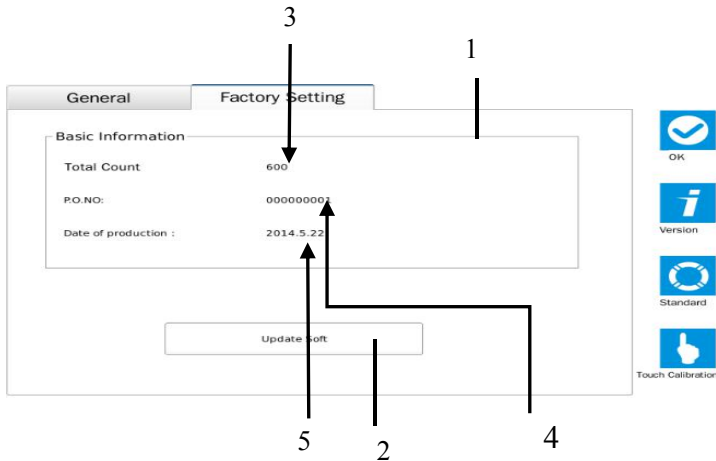
1— Language pull-down menu: click on this button, this menu will choose your needed language.

1.3) Factory settings

Factory settings view

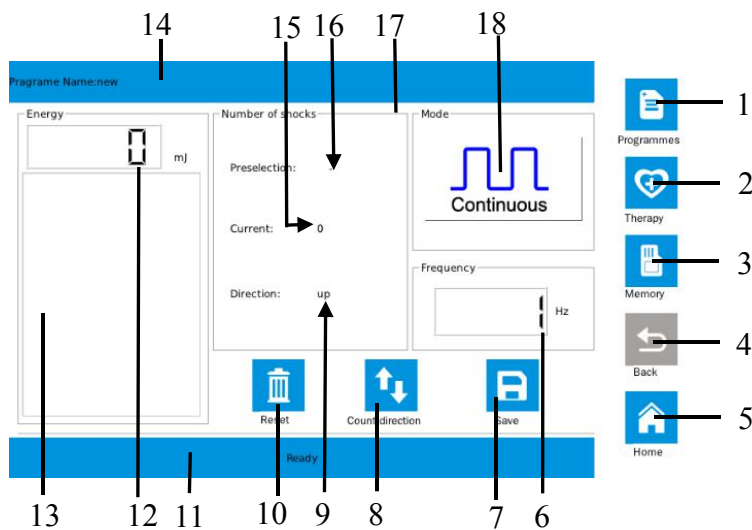


Remarks:



- 1-Basic information box: it displays some key information of this product. If you click on this box, it will pop up the following password dialog box: the operation authorization of this dialog box belongs to manufacturer owned, is use for monitoring the product and be closed to visitors.
- 2-“Update software” button, is use for updating software, usually by the manufacturer to use.
- 3-Counter, summarizing the working grand total data of the product.
- 4-SN number, the product SN brings into correspondence with machine SN.
- 5-Date of manufacture

3) Treatment interface

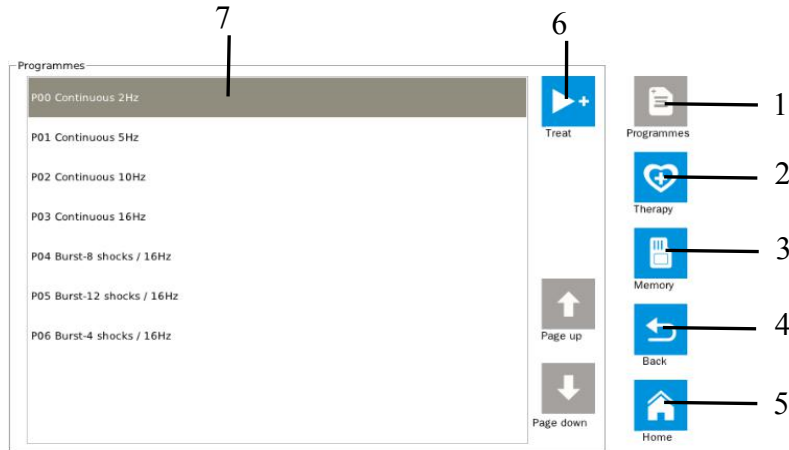


Remarks:

- 1-“Scheme” button: click on this icon, the display screen will jump to the scheme interface.
- 2-“Therapy” button: click on this icon, the display screen will jump to the treatment interface.
- 3-“RAM” button: click on this icon, the display screen will jump to the RAM interface.
- 4-“Return” button: click on this icon, the display screen will jump to the working interface.
- 5-“Homepage” button: click on this icon, the display screen will jump to the beginning interface.
- 6-Frequency display bar: adjust the knob on the shell; the frequency of display value will change.
- 7-“Save” button: click on this icon, it will pop up a dialog box to save the current treatment data.
- 8-“Count direction” button: click on this icon, the count value will become display value of the maximum or minimum.
- 9-Count direction
- 10-“Reset” button: click on this icon, when the count direction displays upward, the value is 0; when displays down of setting value.
- 11-Handle working state bar
- 12-Energy display bar: adjust knob on the shell can display current energy value.
- 13-Energy display bar: adjust knob on the shell can display with energy to change the graphics.
- 14-Treatment scheme title: with the change in treatment programs to change themselves.
- 15-Current count value: it records the current number of strokes of handle. If the number of strokes equal to the setting value, the handle will stop work, and the current count value will flash all the time.
- 16-Setting value: the maximum value is 10,000 times number of strokes, such as display “-” and it represents the current setting value is 10,000 times.

- 17-Settings treatment data box: click on this box, it will pop up a dialog box to set the treatment data.
- 18- Working mode button: click on this box, it will pop up a dialog box to choose a working mode.

3) Scheme interface

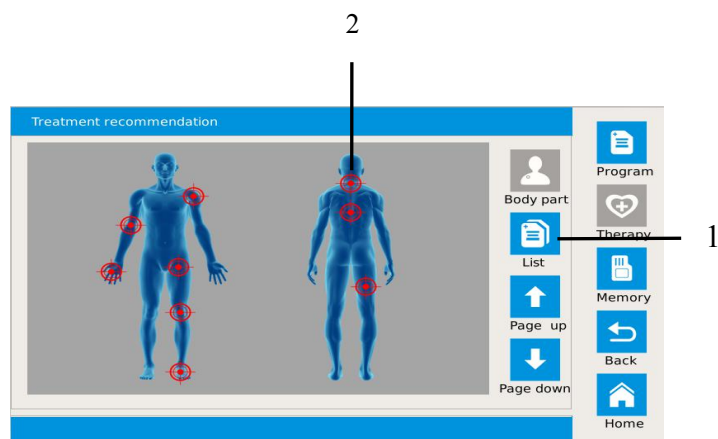


Remarks:

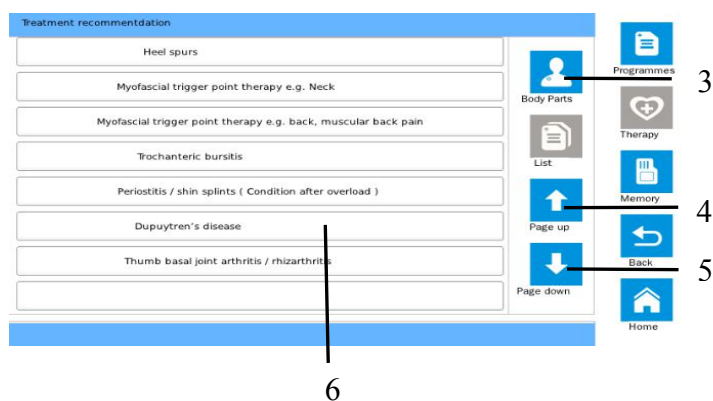
- 1-“Scheme” button: click on this button, the display screen will jump to the scheme interface, after entering the scheme interface, this button will automatically become grey and it cannot operate for the moment. You can enter the next level menu to operate. The following 2/3 items are same as it.
- 2-“Therapy” button: click on this button, the display screen will jump to the treatment interface.
- 3-“RAM” button: click on this button, the display screen will jump to the RAM interface.
- 4-“Return” button: click on this button, the display screen will jump to the working interface.
- 5-“Homepage” button: click on this button, the display screen will jump to the beginning interface.
- 6-“Treatment” button: click on this button, the display screen will jump to the treatment interface; setting value, frequency, mode these parameters will also be transfer to the working interface.
- 7-Treatment scheme selected menu: as the reference choose of treatment scheme, you can select by yourself according to different schemes.

4) Therapy interface

Body parts view:

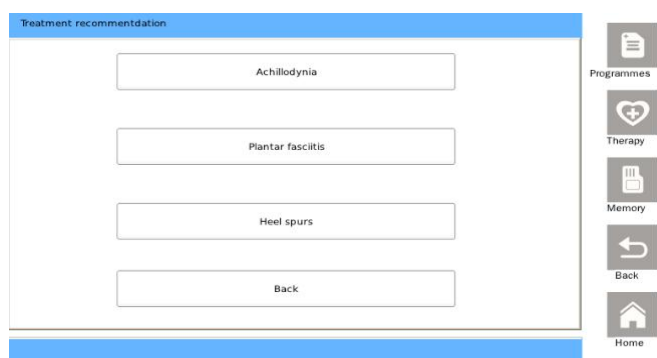


List view:



Remarks:

- 1-“List” button: if press this button, the treatment part will display in form of the list.
- 2-One of treatment part: if press this button, the display screen will jump to an interface, this interface will display the detailed description of this treatment part. In additional, a part may be several diseases, the screen will pop up the following dialog box that what kind of disease let you choose, the picture as shown:

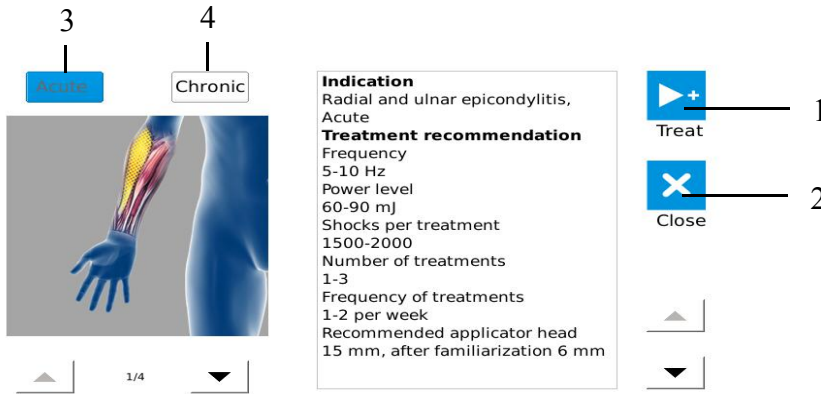


Click on other buttons except “Return”, the display screen will jump to an interface, and this interface will display the detailed description of this treatment part. If press the “Return” button that the dialog box will be cancelled.

- 3-Body parts button: if press this button, the body treatment part will display by means of the picture.

- 4-“Previous page” button: if press this button, it will turn to the content of the front page in the list.
- 5-“Next page” button: if press this button, it will turn to the content of the rear page in the list.
- 6-Body parts of disease button: if press the button, the display screen will jump to an interface, this interface will display the detailed description of this treatment part.

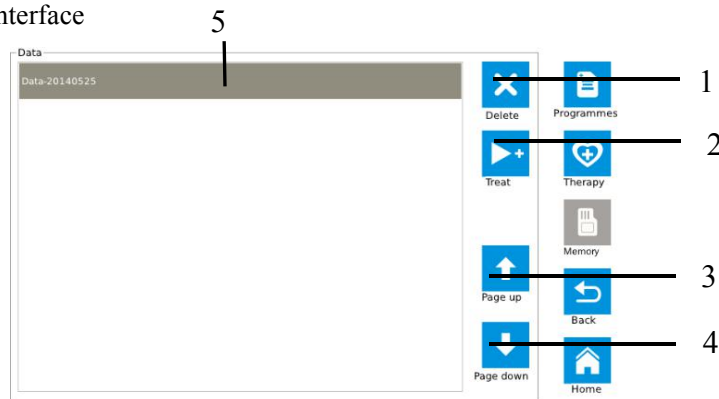
5) Treatment described interface



Remarks:

- 1-“Treatment” button: if press this button, the display will jump to the treatment interface; frequency, energy, setting value these will also be transfer to the working interface.
- 2-“Cancel” button: if press this button, this dialog box will be cancelled.
- 3-“Acute disease” button: if you are a patient with acute disease, you can click on this button; this interface will give an only treatment suggestion for you. If the button is blue that represents the button has been selected and cannot click again.
- 4-“Chronic disease” button: if you are a patient with chronic disease, you can click on this button; this interface will give an only treatment suggestion for you. If the button has been selected and cannot click again.

6) RAM interface



Remarks:

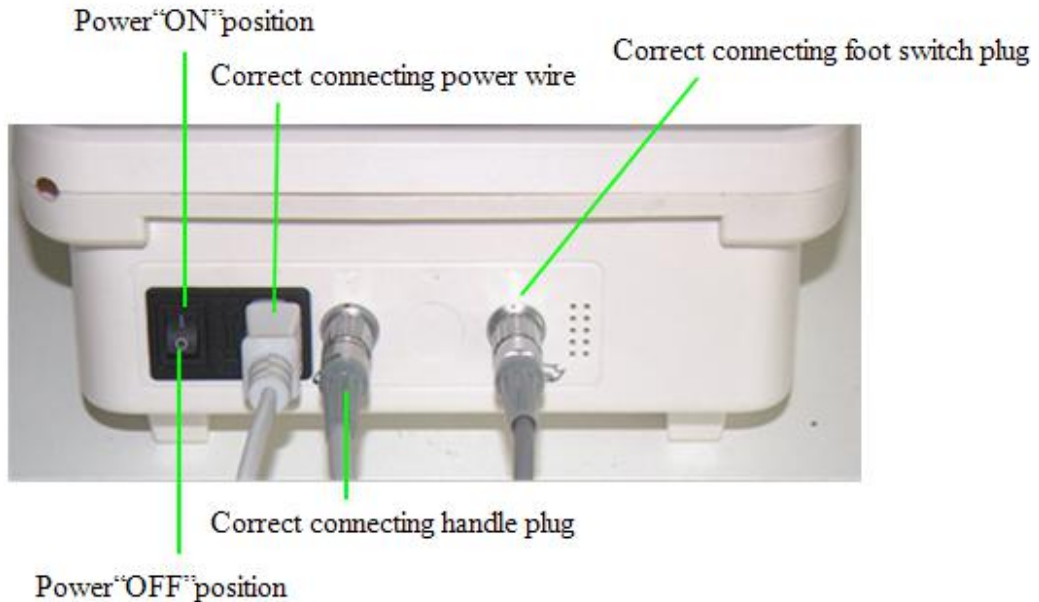
- 1-“Delete” button: if press this button, it will delete the selected item.

- 2-“Treatment button”: if press this button, the display screen will jump to the treatment interface, the data saved by yourselves will be selected and that will be read and transmitted to the working interface, including energy, setting value, mode and frequency.
- 3-“Previous page” button: if press this button, it will turn to the content of the front page in the list.
- 4-“Next page” button: if press this button, it will turn to the content of the rear page in the list.
- 5-Option item: the data saved by yourselves in the selected one.

6.2 Product specific operating method

1) Booting

After plugging in the power wire, foot switch and therapeutic handle, the power switch to the “ON” position, the device is booting, about 17 seconds into the beginning interface.



2) Shutdown

Dial the power switch to the "off" position, the device off, automatic shutdown, but the power wire must pull out after the device is completely shut down.

3) Normal work

The detection before normal work

Click on the Settings icon into the general settings interface, check the sound and luminance bar, is the sound in the open mode, is the display luminance suitable for operator, and it can be adjusted.

① Handle connection examination

The handle status bar is mainly used to displaying the connection state of handle, normal display is white, handle is not found shown in blue, and please check handle plug connection

② Foot switch and handle test

Click on the handle test button, frame color will become dark, if the handle will work once (heard snapped), said the handle with a normal working condition, otherwise the handle will not work. Depress the foot switch, foot switch test bar becomes blue, indicating that the foot switch is operating normally, such as discoloration need to check the connection plug connection is good.

③ Into the treatment interface

Click on the "Confirm" button to return to the beginning interface, then click on the "Boot" button to enter treatment interface, if not treatment interface, you can click on the "Return" button to enter treatment interface.

④ Start work

If the energy value is 0, you need to adjust the energy knob on the left side of the shell to change its value, while clicking count dialog box to set the number of treatment which you want and save it. As shown below:



Then attaching the therapeutic head of handle to the site in need of treatment, foot switch is depressed to begin treatment, as follows:



⑤ User-defined choice

Before starting work, you can also change the settings value, frequency and mode to choose your favorite way for treatment. For detailed operation, please refer to the 6.1 treatment interface description.

4) Interface switching

There are 3 situations about the jump between interfaces:

① Jump directly between interfaces

Under this situation, you need to click on the button associated with the interface. For example: in the treatment of screen, click the "program" button, you can jump directly to the scheme interface.

② Jump from the beginning interface to the intended interface.

You can set the value of booting screen interface as the intended interface in the settings interface. For example, set the value of the booting screen is "RAM"; click on the "Start" button will jump to the RAM interface. Of course, do not do the above settings, click on the "Start" button, if you did not enter a intended interface can also jump to a intended interface according to situation ①.

③ Fixed direction Jump

The settings interface jump to the other interfaces can only be through the "Confirm" button to the booting screen, and then do the next jump. Treatment description interface via the "Cancel" button to jump to the therapy interface, through the "treatment" button to jump to the treatment interface.

5) Save and read data

Only in the working interface, you can save the data. Click on the "Save" button in the working interface, the screen will pop up a dialog box in this dialog box, you must enter a name for the data you want to save, and then click on the "Save" and you will complete the preservation of data. Jump to the RAM interface, you can see the names of all the data you saved, select one you want to read out, click on the "treatment" button, the display screen will jump to the treatment interface, the energy, settings value, frequency, and mode will be transmitted to the treatment interface, now you can use them to work.

6) The use of scheme

In the scheme interface, select one you want, then clicking on the "treatment" button, the display screen will jump to the treatment interface. In the treatment interface, if the energy value is 0, you must adjust the housing knob to change its value, and then depressing the foot switch.

7) View the treatment recommendations and use for treatment

First, jump to the treatment interface, you can click the button in the list view or click on parts of the body inside view. In addition, if a site may have several diseases, the screen will pop up a dialog box that allows you to go by clicking on the button above to select one of them. After clicking, you will see on this site for a detailed description of the treatment of selected diseases. Finally, you can click on the "treatment" button to jump to the working interface, frequency, power, mode and setting values of these parameters will be passed to the working interface.

Now, you can depress the foot switch, and use them to go to work.

6.3 Product precautions for use

6.3.1 Error message

- Error temperature

The temperature alarm appears that the current handle temperature exceeds the settings parameter of software, must be stopped until cooling fan stops running, and then starting up. The description of appeared position:



The picture is at the bottom of the treatment interface (handle work status bar).

- Handle is not found

The occurrence of handle is not found, the alarm represents that the device cannot scan the handle, pull out the handle and re-insert the handle and check whether you can easily pull out it, if they cannot pull out and the alarm signal to eliminate said the handle has a good connection. Appeared position has a same wrong with “error temperature”.

- SD card is not found

The occurrence of SD card is not found the alarm represents that the SD card cannot insert or damaged, if the card had been in the slot but still has this problem, you can reboot the device to solve, you cannot find the SD card after rebooting, it may mean this card is damaged, it is recommended to replace another one to continue to use. The description of appeared position:



The picture appears in the factory setting of settings interface, only occur when upgrading software.

- The new software cannot be found

This alarm indicates that the software is not downloaded to the SD card or incorrect download way. Re-download the new software to the SD card images directory can solve this problem. Appeared position is the same as "NO SD-card found".

- The service life of handle is expired

This alarm indicates that the current life of the handle has expired, you can replace the new handle, to avoid because of the handle using a maturity not been promptly replaced, the proposed operator checked regularly in use, inspection methods: Click the Settings button --- select factory mode --- Check the total value can be. Appeared position is the same as "temperature error".

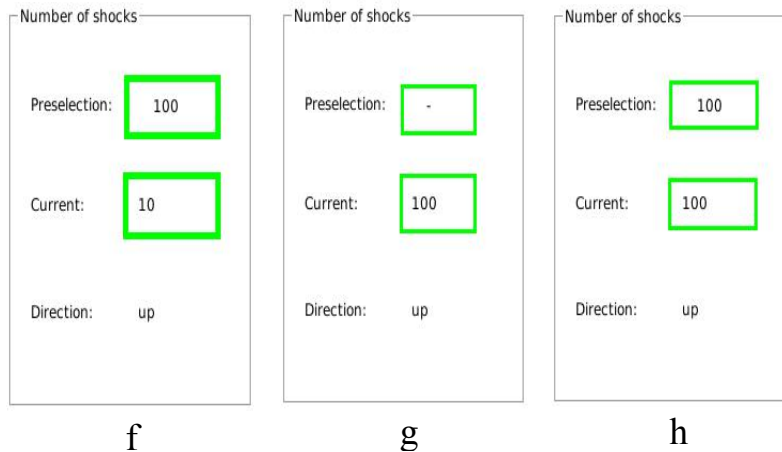
6.3.2 Operating interface icon introductions

Icon	Introduction	Icon	Introduction	Icon	Introduction	Icon	Introduction
	Version information		Back to the previous level		Love treatment recommendations		Downward
	Save		Back to the booting interface		Treatment list		Settings
	Standard or default		Increase		Delete		Body parts
	Click and touch by hand		Decrease		Confirm		Up and down direction
	RAM management		Start up		Cancel		Selected work head 1
	Scheme detailed description		Treatment		Upward		Selected word head 2

6.3.3 Sing information explanation

- Working interface of count

There are 3 situations in the working interface of count value; the following three pictures represent three cases:



In the case of f, the set value is 100, and the current count is 10, which means the current count before reaching 100, the handle can also be hit 90 times.

In the case of g, the set value displays "-" and indicates a value of 10,000, the current count displays 100, the handle can be worked until 9,900 of the current count is displayed.

In the case of h, the set value displays 100, and the current count displays 100, then the value of the count value will always blink. At this point the handle will not work, said that it has completed the designated. Release the foot switch, reset the data, or is cleared and then set the data.

●Count direction on the working interface

If the value of the count direction is displayed as "up", the current count value will increase from zero to the set value. When it reaches the set value, the current count will flash, and the handle does not work.

If the value of the count direction is displayed as "down", the current count value from the set value will start decreasing until it is 0, when is 0, the current count will flash, and the handle does not work.

●Treatment description interface of button colors

There are 3 colors on the treatment description interface of button colors: blue, grey and white. For example is the following view.



As shown in this interface icon of background is blue, has defaulted as the treatment mode by the software. If this interface icon of background is grey that represents this function cannot use at the same time. If this interface icon of background is white that represents this function can switch work from blue background icon.

●silk-screen shell

Silk-screen	Explanation	Silk-screen	Explanation
	Minus identification of frequency/energy adjusting knob on the O-wave I		Plus identification of frequency/energy adjusting knob on the O-wave I
	The Therapeutic headle port label of O-wave I		Foot switch identification of foot switch on the O-wave I

7 Product installation and trouble removal

7.1 Product installation

Please check the power outlet should have a good grounding wire before installing, and this machine is strictly prohibited without ground power to use. The machine requires away from water installation.

The instrument has its own embedded software, and the software has been installed at the factory. Machine installation does not require professionals to delegate user at installation.

7.2 Common trouble removal

1) Fault phenomenon: it is unable to boot.

Solution:

- Check whether the power wire has been properly connected, the interface is loose.
- Check the power switch whether is already appropriated for "open" position.
- Check whether the fuse has burned out, and replace the same specification as burned fuse.
- If the cause of the above checks still cannot boot, please replace the power wire of the same interface.

Tip: After power on the device, you can see the logo information on the display screen at least 5~7 seconds.

2) Fault phenomenon: touch inaccurate

Solution:

Click on the "Touch Calibration" button on the Settings interface, and in once to recalibrate the touch screen.

3) Fault phenomenon: the therapeutic handle does not work

3.1) If in the treatment interface, the therapeutic handle does not work after treading the foot switch, the solution is:

- The therapeutic handle is not connected, or not even close.

You can see the blue state bar will show “not found the therapeutic handle” at the bottom of working interface, check the connector to therapeutic handle whether connect well, after unplugging reinstall expressed readiness has been connected properly. If the handle is still not found or the therapeutic handle is problem, need to replace the handle.

- Temperature

If the handle temperature is too high, the handle will not work. Blue status bar at the bottom of the working interface will show "temperature error", because the handle temperature exceeds the set temperature, it can be continue to use until the fan operation stops on its own. Otherwise, the

temperature is not the cause of the problem.

- The energy on the working interface

In the working interface, if the energy is shown as "0", the handle cannot work. You must adjust the knob on the housing to change its value, and then depress the foot switch. If the handle can work, and the energy that is causing this problem, otherwise it is not.

- The current count value on the working interface

In the working interface, if the current count keeps flashing, the handle also does not work. You can click the "Reset" button or change the setting value to solve this problem. Otherwise, it is not the cause of the problem.

- Mode on the working interface

If you choose the other one mode expect the “continuous” mode, the handle can only hit four times or 8 or 12 times after treading the foot switch. If you want to continue to handle the work, you must release the foot switch and foot switch is treaded again. Otherwise, it is not the reason.




- Other reasons



If the described above you have been checked on and without any problems, please skip to the settings interface and tread the foot switch to see the color of its information display bar whether turns blue, if there is no discoloration, need to replace the foot switch.






8 Safety precautions

■The manual said that the purpose of warning sign and legend is safe and proper using the product by yours, and prevents the harm to you and others.

■The warning sign and legend as well as their meaning is as follows:

Warning sign	Meaning
 using contraindication	It shows that it will appear the dangerous of casualties or serious injury in the error use.
 warning	It shows that it will appear the possibility of casualties or serious injury in the error use.
 attention	It shows that it will appear the possibility of personal injury or damaged goods in the error use.

 Warning	
<p>① The therapeutic apparatus cannot be used with the HF apparatus to avoid burns or damaged apparatus</p> <p>② If the patient himself uses the therapeutic apparatus and HF apparatus at the same time, the part of massage plate may be cause burns on apparatus, it may also damage the apparatus; If</p>	

<p>use the apparatus near (1 meter) the short wave or microwave therapeutic apparatus, the output of apparatus may be instability.</p> <p>③ It will increase a danger of heart fibrillation by using electrode close to the chest.</p> <p>④ Do not modify this equipment without authorization of the manufacturer</p> <p>⑤ Serious twist injury within 24 hours, prohibiting the use of treatment of shock wave.</p> <p>⑥ The product will produce certain heat when used (when in the process of ultimate working, The safe working temperature has built-in 68°C, and the therapeutic head's temperature will Reach to 68°C), please always pay attention to monitor patient's condition.</p> <p>⑦ All accessories and replaceable parts of the products (silicone cap, therapeutic head/therapeutic handle and foot switch) are not belong to interchangeable part, any change you must contact manufacturer to purchase.</p> <p>⑧ When operating this product, the operators use therapeutic handle to treat patients but they must be medical staff and need to wear nosocomial medical gloves.</p>	
 Contraindication	
<p>●General factors:</p> <ol style="list-style-type: none"> 1) Serious heart attack, arrhythmia and high blood pressure; 2) The patient with a cardiac pacemaker; 3) Not curative hemorrhagic disease of coagulation disorders of patient; 4) The use of immunosuppressants; 5) All kinds of cancer patients; 6) Patient with thrombosis; 7) Pregnant woman. 8) Growing children <p>●Local factors:</p> <ol style="list-style-type: none"> 1) The patient with local infection and skin burst; 2) Tendon and fascia of acute injury; 3) The patient with synovial fluid leakage; 4) The therapeutic parts in the brain/lung and spinal cord organizer; 5) Atrophy and infectious nonunions; 6) Massive defective bone nonunions. 	 
 Precautions	
<ol style="list-style-type: none"> 1) Before treatment, you should tell patients the feeling during treatment, eliminating the patients' concerns and obtaining cooperation. 2) Before treatment, ask and check the skin of therapeutic parts has or not the hypaesthesia, 	

- large scar or damaged.
- 3) Treatment should be removing metal items of therapeutic parts, such as wrist watch, hairpin, jewelry, etc.
 - 4) Please turn off the power when not in use.
 - 5) The product cannot be used in any location for treatment head.
 - 6) It is not allowed to use the therapeutic head direct contact with the skin treat in the treatment.
 - 7) The product will produce certain noise and heat during use, please pay attention to the surroundings whether fitness for use.
 - 8) For security reasons, the energy and frequency of the device will not reach the maximum at the same time.
 - 9) The product will produce feeble electromagnetic field during use, please keep away from strong magnetic environment.
 - 10) There is a long term effect on the device and therapeutic handle, the handle for a long-term use can cause ballistic wear, may wear out ballistic and cause internal short circuit. The device components for a long-term use will be aging phenomenon.
 - 11) The device cannot squeeze, may cause display screen broken when drop; the device does not receive any data input in the working state, can avoid artificial misoperation harm to patients in the work.
 - 12) When connecting the device, the connector of work handle and the connector of foot switch are different (one is 2PIN, one/two are 10PIN), there will be no fault phenomena; the plug has hooks structure, not loose to slide.
 - 13) Please use the matching handwriting pen when device operation on the touch screen, click on the touch screen are not allowed to use other sharp object.
 - 14) When device is abnormal, if they cannot handle by themselves, please contact our after-sales service; it is not allowed to take apart shell privately or flash other software, the resulting damage will be borne by the customers themselves.

9 Product maintenance and nursing

- Energy conservation

After treatment, please shutdown the power, save the energy and protect the device.

- Cleaning

With a clean cloth and 75% alcohol to clean the host shell, the interior does not require cleaning. It requires that with a paper or cloth to clean surface coupling agent after completed at the same time. Please use 75% medicinal alcohol to clean the surface of treatment caps before pre-treatment again.

- Consumables

All accessories and replaceable parts of the product are not belong to general parts, if need to replace, you must contact the manufacturer to buy.

- Coupling agent

In the treatment, use the coupling agent and special medical coupling agent of ultrasonic transducer.

- Calibration

The basic operation of the product is by means of touch screen, it may cause touching off normal because of a long term operation, and the recalibrate can by means of touching calibration function of settings interface, then can continue to use.

- Service life

The minimum service life of the complete machine is 2,000,000 times (calculation according to the number of strokes)

The minimum service life of each therapeutic head is 150,000 times (calculation according to the number of strokes)

- Scrap processing

After confirming the product has been scrapped, the product cannot be thrown away and by the hospital or nursing institutions unified scrap processing.

10 EMC declarations





1、 This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.

2、 * Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit.

This may result in incorrect operation of the unit.



3、 Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!

4、 * Caution: this machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

 Warning  The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the MANUFACTURER of the AMBULATORY O-wave I as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the O-wave I.

Guidance and manufacture’s declaration – electromagnetic emission		
The OCE-ESWT-002 O-wave I is intended for use in the electromagnetic environment specified below. The customer of the user of the OCE-ESWT-002 O-wave I should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions EN 55011	Group 1	The OCE-ESWT-002 O-wave I use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission EN 55011	Class A	The OCE-ESWT-002 O-wave I 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 emissions EN 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions EN 61000-3-3	Complies	

Guidance and manufacture's declaration – electromagnetic immunity			
The OCE-ESWT-002 O-wave I is intended for use in the electromagnetic environment specified below. The customer or the user of OCE-ESWT-002 O-wave I should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) EN 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst EN 61000-4-4	±2 kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	± 1kV differential mode ± 2kV common mode	± 1kV differential mode ± 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles 5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the OCE-ESWT-002 O-wave I requires continued operation during power mains interruptions, it is recommended that the OCE-ESWT-002 O-wave I be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field EN 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity			
<p>The OCE-ESWT-002 O-wave I is intended for use in the electromagnetic environment specified below. The customer or the user of OCE-ESWT-002 O-wave I should assure that it is used in such an environment.</p>			
Immunity test	EN 60601 test level	Compliance level	Electromagnetic environment - guidance
<p>Conducted RF EN 61000-4-6</p>	<p>3 V_{rms} 150 kHz to 80 MHz</p>	<p>3 V</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the OCE-ESWT-002 O-wave I, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in metres (m).^b</p> <p>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.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div>
<p>Radiated RF EN 61000-4-3</p>	<p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 V/m</p>	<p>Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in metres (m).^b</p> <p>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.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div>
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p>			
<p>NOTE 1 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^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 OCE-ESWT-002 O-wave I is used exceeds the applicable RF compliance level above, the OCE-ESWT-002 O-wave I should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the OCE-ESWT-002 O-wave I</p>			
<p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

**Recommended separation distances between
portable and mobile RF communications equipment and the OCE-ESWT-002 O-wave I.**

The OCE-ESWT-002 O-wave I is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the OCE-ESWT-002 O-wave I can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the OCE-ESWT-002 O-wave I as recommended below, according to the maximum output power of the communications equipment.










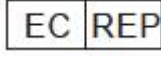

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 KHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for 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.

11 The paraphrase of graphic symbol

Label	Explanation	Label	Explanation
	Serial number		This symbol is used to direct the user to refer to documentation for additional information regarding the system use or description.
	The name and address of the manufacturer		Keep dry
	Date of manufacture		CE identification + noticed code
	Contact its local authorities to determine the proper method of disposal of potentially bio hazardous parts and accessories.		Anti-electromagnetic radiation
	Type BF anti-shake		The name and address of the EU representative
	Fragile		

12 Executive standards

The product conforms to the following standards and laws:

EN 60601-1: 2006/A1:2013 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance

EN 60601-1-2: 2007 /AC: 2010 Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests

13 Accessories and parts

No.	Object	Material code	Quantity	Picture
01	Host	OCE-ESWT-002-01	1	
02	Therapeutic handle	OCE001010101Z	1	
03	Foot switch	OCE001020102Z	1	
04	Therapeutic head	OCE001010101Z-07 OCE001010101Z-08 OCE001010101Z-09	Diameter of 6/15/25mm each 1	
05	Power line	OCE00102040401	1	
06	Handle pedestal	OCE001010101Z-04	1	
07	Handwriting pen	OCE00101010405	1	
08	Silicone cap	OCE001010101Z-06	10	
09	Aluminium alloy suitcase	OCE00103040101	1	
10	Product manual	OCE00103040402	1	Omit

14 Guarantee card

Warranty card

Customer name: _____ Contact number: _____

Address: _____

Product name: _____ Product model: _____

Date of purchase: _____ year _____ month _____ day

Warranty regulations:

1. First of all thank you for choose our products, for more convenient for you, please carefully read the regulations.
2. The card is the warranty certificate, the user for safe keeping, if lost, will not be returned.
3. This product is only entitled to one year free warranty to the host, within a year, if the host go wrong, the product can be sent to the manufacturer will repair free of charge rely on this card, other parts can contact the manufacturer to purchase a replacement.
4. The host failure caused by man-made accidents, misuse, abuse or irresistible natural factors, the Company does not assume warranty obligations.
5. Before the host maintenance, please back up your data yourself, the Company has no obligation for you to back up your data; if cause data loss in the process of maintenance, the company does not undertake any responsibility.
6. Unauthorized change and disassemble, the company is not under warranty.
7. Other issues shall be negotiated between the parties to resolve, the final interpretation of the Company.

Signed by the manufacturer:

Name: Shenzhen Oceanus Medical Device Co., Ltd Contact number: +86.755.8659-9459

Aftermarket address: No.2,East side,Floor 2,Yinjin Building, Liuxian Road 3,Xin'an Zone 71 ,
Xin'an Subdistrict, Baoan District,Shenzhen,China

For more information about the product or accessories, please consult the manufacturer, or please visit the website: <http://www.oceanuswave.com>