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Attention

- In order to use this device safely and correctly, please read the manual carefully before you use it.
- Warning marks, illustrations and meanings in this manual are as follows:

Legend	
	Symbol means prohibition (things mustn' t be done). The content prohibited shows in the form of Characters in or near.
	Symbol means compulsion (things must be obeyed). The specific content prohibited shows in the form of characters or picture in or near.
	The symbol means important message.

 Notice	
It is dangerous for patients to conduct self-judgment and self-treatment just based on treatment outcome, so please follow doctors' advice. <ul style="list-style-type: none">• It' s possible to exacerbate the condition because of self-judgment.	
The device mustn' t be used by babies and those who can' t express their thoughts freely. <ul style="list-style-type: none">• It' s possible to lead to accidents or disputes.	
The device can' t be employed out of other purposes except realizable function or purpose. <ul style="list-style-type: none">• It' s possible to lead to accidents or disputes.	
Please do not disassemble, repair or rebuild the device or accessories of the negative pressure device. <ul style="list-style-type: none">• Probably functions of the device cannot be exerted or even the device would be damaged.	
Be careful	<ul style="list-style-type: none">• Do not stick or drop the device.• Use it horizontally, instead of tipsily or upside down.

 Notice	<p>The actual application effect of the device is closely related to the seal condition of the wound. Thus, if the seal condition is not good, the actual application effect of the device will decrease; extremely poor seal condition will lead the device to give an alarm and stop working.</p> <p>It cannot be used in air mixed with flammable anesthetic gas or in flammable anesthetic gas mixed with oxygen or Nitrous Oxide.</p>
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Summary

1. Product composition

Negative pressure wound therapy device (hereinafter referred to as NPWT device)consists of NPWT negative pressure pump and NPWT drainage bottle.

NPWT device belonging medical negative pressure wound therapy equipment with medium negative pressure and low flow rate can only be employed by trained medical professionals.



Warning: those who are not trained shouldn't employ the device. And please follow the instructions and doctors' advice because any unintended use easily leads to risks.

2. Mechanism of product

With the help of negative pressure pump exhausting air, the negative pressure will be produced in NPWT drainage bottles and wounds so as to have a condition of negative pressure to treat the wound.

The device could generate continuous or dynamic negative pressure and form a condition of negative pressure in accordance with the requirements of the setting in the wound. In the end, the mechanism of negative pressure on the wound will ultimately promote wound healing.

3. Scope of application

NPWT device is merely used by the hospital or family to conduct ordinary negative pressure suction for patients, not suitable for abortion.

4. Contraindication

If the patients has one of the following symptoms, the device mustn't be used to conduct negative pressure therapy.

- Exposure of blood vessels, nerves, anastomoses or organs.
- Eschar necrotic tissue.
- Untreated osteomyelitis.
- Fistula due to unexplained reasons in other parts except intestinal tract.
- A malignant tumor in the wound.

5. Package content and configuration list

Package content of NPWT device consists of:

- NPWT dedicated adapter
- NPWT device
- NPWT user manual


Configuration list:

Accessory Name	Specification/Model	Quantity	Unit
NPWT Machine	/	1	PCS
NPWT disposable canister	RH-140/RH-450	1	PCS
The manual	/	1	PCS
Qualified certificate	/	1	PCS
Adaptor	DC18V/2A	1	PCS

Specification of adaptor: input AC 100–240VAC,50/60Hz,0.9-0.45A output DC18V, 2A.

Voltage: DC18V.

Volume of NPWT disposable canister: 140ml and 450 ml.

 Attention	<p>NPWT device has automatic overflow protection function, so when NPWT disposable canister is installed and applied correctly, the device could automatically monitor the condition of overflow and give an alarm symbolizing blocking before overflow. More detailed information is available in Chapter “Running warning” of this manual.</p> <p>Equipped with a built-in filter, NPWT disposable canister belongs to the medical material and it cannot be cleaned and replaced.</p>
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6. Technical parameter

The performance indicators for NPWT device are referred to as follows:

1. Adjustable range of negative pressure: -50~-225mmHg.
2. Accuracy of stable negative pressure: Between 50~225mmHg, the absolute error between actual measurement value and set value should be less than or equal to ± 5 mmHg.
3. Noise due to normal work: shouldn't exceed 40dB.
4. Battery lifetime: shouldn't be less than 6h.
5. Ultimate negative pressure: Shouldn't exceed 235mmHg.
6. Free-air flow: shouldn't exceed 6L/min.
7. Parameters of drainage bottle:
 - 7.1. Maximum allowable negative pressure of drainage bottle: 225mmHg;
 - 7.2. Sealing: when the negative pressure in the drainage bottle is 225 ± 10 mmHg, seal the bottle, After 3min measure the negative pressure in the bottle and leakage of negative pressure should be controlled within 20mmHg.
 - 7.3. Volume: the drainage bottle can be loaded with an exudate that is not less 90% of the standard capacity.
 - 7.4. Stop overflowing: during the use, the exudate in the drainage cannot be absorbed into negative pressure pump.
8. Display function:
 - 8.1. The monitor of negative pressure device should display the value of the negative pressure and the unite is mmHg.
 - 8.2. During the treatment, the monitor of negative pressure device should graphically display the leaking rate.
9. Warning function: The device can give an alarm if there is leakage, low battery level and blocking.


7.Application environment

The device could be expectedly used in the following normal working environment

- a) Temperature: 5°C-35°C
- b) Humidity: ≤80% R.H

Basic operation

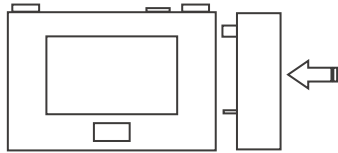
1.Power installation

Connect the power output plug of the power adapter to the power socket on the back of the device .

2.Install/uninstall canister

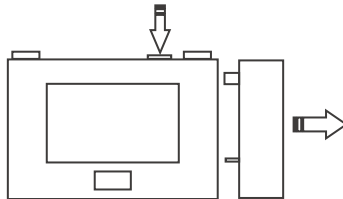
Warning: remember to use the special canister and sucker drainage tube from Guangzhou Rainhome Pharm & Tech Co.,Ltd. Please follow the requirements of this manual because any unexpected use would lead to security risk.


1. Install NPWT canister:



Use hand to push the canister, when the sound of “Click” is heard, the installation of NPWT canister is completed.

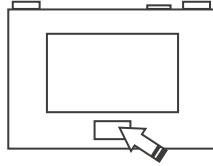
2. Uninstall NPWT canister:




Press the button  on the top of the device, hold the canister with another hand and pull it out to remove the drainage bottle.

3.Operation

1.ON:




Boot-strap diagram

Press the key  for 1.5 seconds, NPWT device will be turned on.

Attention: if there is no operation after NPWT device is turned on, it will be automatically shut down after 5 minutes.

2.OFF:

Press the key  around 3 seconds, the NPWT device will be turned off.

4.Display operation

4-1.Welcome to enter the main display:



Welcome to the main display

After press the key  for a while, it enters to the main display.

4-2.Set/start the continuous therapy.

After turn on the device, it lasts for a few seconds and it will automatically enter the main setting interface, such as below:



The main setting interface

On the main setting interface select “Continuous Therapy”, enter to the setting interface of Continuous Therapy.



The setting interface of Continuous Therapy

Click “+” or “-” on the continuous therapy setting interface to adjust the pressure value of continuous pressure therapy. The adjustment step is 25mmHg. The maximum value is 225mmHg and the minimum value is 50mmHg. Click the value display box on the continuous treatment setting interface to input the keyboard, and use the method of the keyboard box to set the treatment pressure value, the negative pressure value is an integer and the system default value is 125mmHg.



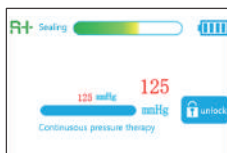
When using the keyboard to input, if it exceeds the maximum and falls below the minimum value, it will display a cross-border reminder. After adjusting the value of negative pressure, click the key ‘Enter’ and then return to the main interface. Click the key “Submit” to enter the continuous therapy interface. If click “Cancel” ,the system default value as 125mmHg will be restored.



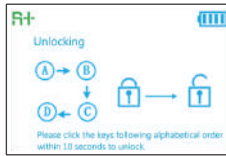
In the continuous pressure therapy interface, click the set to input the pressure value and time of the current mode arbitrarily, and click "Cancel" on the setting interface to restore the system default value. Click the key “▶” on the continuous therapy interface, it will be started continuous therapy. Such as below:



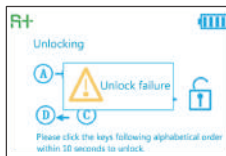
In this interface, it is showed the cumulative treatment time. Start the treatment, Start treatment, start timing (display time accuracy is min, hour value is up to 999, minute value is up to 59), stop treatment, and time is cleared. Click the back button on the startup interface to return to the previous setting page, Click the key “Locking” to lock the working state that can be prevented accidental touch. Such as:



Click “unlock” to enter unlock interface. Such as below:



To unlock, please click the keys following alphabetical order within 10 seconds. If there is no operation within 10 seconds, it will automatically exit the unlock interface. If you do not follow the sequence of taps, the unlock failure prompt will pop up, and then exit the unlock interface.



Unlock failure interface

After unlocking, click “ || ” to pause or end this treatment.。

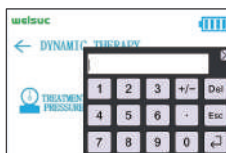
4-3.Setting/start dynamic therapy.

After start NPWT device, click “setting” on continuous therapy interface to enter the main setting interface. On the main setting interface, select “DYNAMIC THERAPY” to enter the dynamic therapy interface 1.



Dynamic therapy setting interface 1

Click “+” or “-” on the dynamic therapy setting interface 1 to adjust the pressure value of dynamic therapy, the adjustment step is 25mmHg. The maximum value is 225mmHg and the minimum value is 50mmHg. Or click the value display box on the dynamic therapy setting interface to pop up the keyboard, and use the input method of the keyboard to set the therapy pressure value, the negative pressure value is an integer, such as:

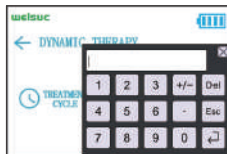


When using the keyboard to input, if it exceeds the maximum value and falls below the minimum value, the keyboard display box will display an out-of-bounds reminder. After adjusting the pressure value, click the return button to return to the main interface, and click the "next" button to enter the dynamic therapy setting interface 2. If click "Cancel", the system default value of 125mmHg will be restored.



Dynamic therapy setting interface 2

Click "+" or "-" on the dynamic therapy setting interface 2 to adjust the cycle of dynamic pressure therapy, and the adjustment step is 2 minutes. The maximum value is 98min and the minimum value is 2min. Or click the value display box on the dynamic treatment setting interface to pop up the keyboard, and use the keyboard input method to set the treatment period. The time period is limited to an even number, such as:



When using the keyboard to input, if it exceeds the maximum value and falls below the minimum value, the keyboard display box will display an out-of-bounds reminder. After adjusting the treatment period, press the return key to return to the previous setting page. Click the "Submit" button to enter the dynamic pressure therapy mode interface. If you click "Cancel", the system default value 10min will be restored.

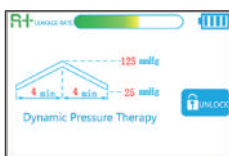


Dynamic Pressure therapy interface

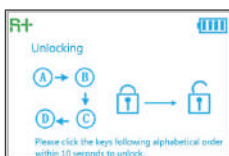
In the dynamic pressure therapy mode interface, click the set to enter the parameter setting interface, you can set the pressure value and time of the current mode arbitrarily, and click "Cancel" on the setting interface to restore the system default value. Click the back button to return to the previous setting interface. Click the start button “▶” in the dynamic pressure therapy mode interface to start dynamic pressure therapy. After startup the interface will be as shown below:



Click the return button on the startup interface to return to the previous setting interface. Click the “lock” button to lock the current working state in order to prevent accidental touch. The locked interface will be shown such as below:



Click the button “UNLOCK” to enter the UNLOCK interface.



To unlock, please touch in alphabetical order within 10 seconds. If there is no operation within 10 seconds, it will automatically exit the unlock interface; if you do not follow the sequence, it will pop up an unlock failure prompt, and then exit the unlock interface.



Unlock failure interface

After unlock, click the button “ || ” to end the therapy operation.

4-4.set and start Intermision therapy.

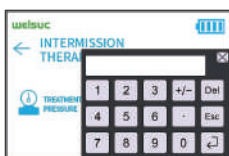
In the main setting interface, click the "INTERMISSION THERAPY" button to enter intermission therapy interface

1. The intermission therapy interface is shown in the figure below.



intermission therapy interface 1

Click "+" or "-" on the intermission therapy setting interface 1 to adjust the pressure value of intermission pressure therapy, and the adjustment step is 25mmHg. The maximum value is 225mmHg and the minimum value is 50mmHg. And also click on the value display box on the intermittent therapy setting interface 1 to pop up the keyboard, and use the keyboard input to set the therapy pressure value, and the negative pressure value is an integer, such as:

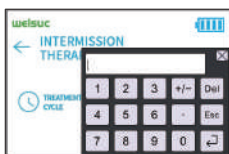


When using the keyboard to input, if it exceeds the maximum value and falls below the minimum value, the keyboard display box will display an out-of-bounds reminder. After adjusting the pressure value, click the return button to return to the main interface, and click the "next" button to enter the intermission therapy setting interface 2. If you click "Cancel", the system default value of 125mmHg will be restored.



Intermission therapy setting interface 2

Click "+" or "-" on the setting interface 2 to adjust the therapy time, and the adjustment step is 1 min. The maximum value is 99min, and the minimum value is 1min. You can also click on the value display box on the intermission treatment setting interface 2 to pop up the keyboard, and use the keyboard to set the treatment time, and the setting value is an integer. The keyboard input interface is shown in the figure below.

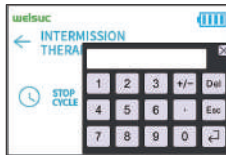


When using the keyboard to input, if it exceeds the maximum value and falls below the minimum value, the keyboard display box will display an out-of-bounds reminder. After adjusting the treatment time, click the back button to return to the previous setting page. Click the "Next" button to enter the intermission pressure therapy mode interface 3. If you click "Cancel", the system default value 5min will be restored.

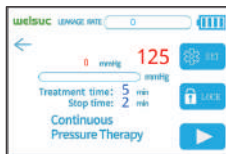


Intermission therapy setting interface 3

Click "+" or "-" on the intermission therapy setting interface 3 to adjust the stop time of intermission therapy, and the step length is 1min. The maximum value is 99min and the minimum value is 1min. Or click the value display box on the intermission therapy setting interface 3 to pop up a keyboard, and use the keyboard to set the stop time, and the set value is an integer. The keyboard input interface is shown in the figure below.



When using the keyboard to input, if it exceeds the maximum value and falls below the minimum value, the keyboard display box will display an out-of-bounds reminder. After adjusting the stop time, click the return button to return to the previous setting page, and click the "Submit" button to enter the intermission pressure therapy mode interface. If you click "Cancel", the system default value of 2min will be restored.



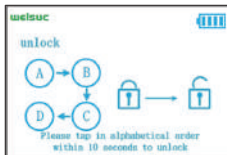
In the intermission pressure therapy mode interface, click Set to enter the parameter setting interface. The pressure value and time of the current mode can be set arbitrarily, and the system default value will be restored by clicking "Cancel" on the setting interface. Click the back button to return to the previous setting interface. Click the start button “▶” to start intermission pressure therapy. The interface after startup is as shown below:



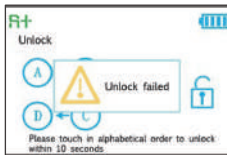
Click the return button in the startup interface to return to the previous setting interface, and click "lock" to lock the current working state to prevent accidental touch. The locked interface is as shown below:




Click "Unlock" to enter the unlock interface.



Please touch in alphabetical order to unlock within 10 seconds. If there is no operation within 10 seconds, it will automatically exit the unlock interface; if you do not follow the sequence, it will pop up an unlock failure prompt, and then exit the unlock interface.



After unlock, click the button "  " to end the therapy.

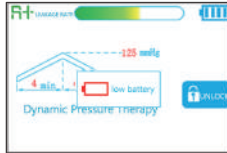
4-5.Help interface of the system.

In the main setting interface, click the button "Call us" to enter the information interface such as the figure below.



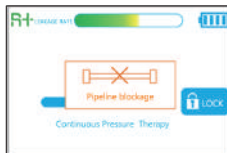
4-6.Low charge alarm.

When the power of the system is too low, the LCD screen of the therapy device will pop up a warning that the battery is too low and accompanied by an alarm sound. As shown below. At this time, the power adapter should be connected to the therapy device to charge the therapy device.



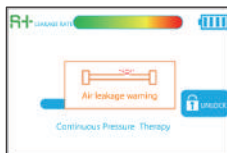
4-7.Blocked pipes alarm.

When the device is working in continuous treatment mode or dynamic treatment mode, the pipeline is blocked, and the LCD screen will pop up a warning of pipeline blockage with an alarm sound. As shown below. At this time, the treatment should be suspended, and the location of the pipeline blockage should be found and solved before restarting the treatment device.







4-8.Air leakage alarm.

When the device is working in continuous treatment mode or dynamic treatment mode, air leakage occurs in the pipeline, and the LCD screen will pop up an air leakage warning with an alarm sound. As shown below. At this time, the treatment should be suspended, and the location of the pipeline leak should be found and solved before restarting the treatment device.

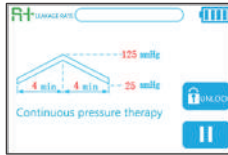


4-9.Tightness.

When the treatment device works in continuous treatment mode or dynamic treatment mode, it will monitor the air leakage of the pipeline in real time and display it on the LCD screen. If it shows the rate during “” and “”, it means that the tightness of pipelines is on the good situation. If it shows the rate during “” and “” it means the tightness of pipelines is not good, at this situation, it needs to check the tightness of pipeline.

10.Recharge.

Use a dedicated charger to charge the treatment device. Connect the charging connector to the treatment device to charge, and the LCD screen will display the icon that the therapy is charging, such as below:

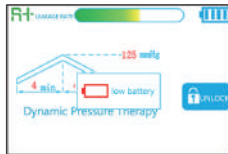


Exception handling

During the use of the device, a low battery alarm, blockage alarm, and air leak alarm may be happened. The alarm level is medium and the alarm volume is not less than 50dB.

1.Running alarm

During operation, when the device uses the internal battery and the internal battery power is too low, the device makes a low battery alarm:



Low battery warning

At this time, the device will issue a "di..." alarm. When using the device without the adapter, it can be observed that the internal battery power of the device gradually decreases until a low battery alarm occurs.

When the device detects that there may be a blockage in the system pipeline after the treatment is started, or when the liquid in the drainage bottle is full and the overflow protection is activated, the device will stop running and issue a blockage alarm:



Pipeline blocked alarm

At this time, the device will send out an alarm of "Di di di...". When the device is running, clamp off the drainage tube connected to the device, and the device will generate a blockage alarm within 1 minute.



Attention: When the dynamic negative pressure alarm is blocked due to the overflow protection, you can press the return key to return to the main interface of the device, and replace the dynamic negative pressure drainage bottle, and then restart the device operation.

When the device detects that there may be a system leak after starting the treatment, it will give an air leak alarm. Such as below:



Help interface of air leak warning

At this time, the device will send out an alarm of "Dididi...". Disconnect the connection between the drainage bottle and the suction cup drainage tube, start the device, and the device will alarm for air leakage within 1 minute.

After the alarm occurs, the user can cancel the alarm sound by pressing the "set" key and return to the system working interface where the treatment stops.

2. Fault handling

Failure phenomenon	Possible Causes	Solution
Low battery warning	The battery is too low	Adopt the power adapter to supply power, which can charge the device and it does not affect normal use
Air leakage warning	There is an air leak at the wound seal	Observe the seal of the wound, find the leak and reseal
Pipeline blocked warning	The drainage bottle is full	Replace a new canister
	Pipeline blocked	Replace a new pipeline
The power adapter is red	The power adapter is not connected to the power source	Check whether the power supply connected to the adapter is connected power or whether the adapter wiring is normal



If any abnormalities and faults cannot be eliminated, please do not open the device by yourself, please contact the supplier or customer service to get support as soon as possible.

Maintenance

1.Regular maintenance

Drainage bottles and dressing kits used with the device are all disposable consumables and do not require maintenance. After use, they must be properly disposed of in accordance with the requirements of medical waste. Do not dispose of them at will. The dynamic negative pressure device must be maintained after each clinical use. The maintenance steps are as follows:

- The power adapter should be unplugged: after turning off the power to the device, unplug the adapter plug at the back of the device.
- Remove the dynamic negative pressure drainage bottle from the device. Use 70% isopropanol or medical alcohol to wipe and release the side of the device, especially the right side of the device and the buckle of the drainage bottle.
- Use 70% isopropanol or medical alcohol to wipe the front display and keys of the device. After using a mild detergent or a damp cloth to clean the rest of the equipment housing, use another soft cloth to dry the equipment housing.
- Avoid directly contact with the device such as oil and other organic solvents during maintenance. After completing the maintenance, place the device in a dry and clean environment.
- After the device reaches the end of its service life, it does not need to be maintained, and it can be handled in the same way as general medical electronic device.

The risks that exist after the device reaches the end of its useful life.:

- The air pump is aging and the device cannot be started.
- The internal components are aging and the device cannot be treated normally.
- The touch screen of the device may be insensitive and risk of touch failure.

Recommendations to reduce risk:

- Perform regular maintenance on the product in accordance with the requirements of this manual.
- Please use it horizontally, do not use the device tilted or upside down.
- Handle the device carefully during use, and do not hit or drop the device.
- In the event of a malfunction or abnormality during the use of the device, please do not disassemble it by yourself, and contact the manufacturer in time.



Avoid any liquid dripping on the surface of the equipment or placing the device in any high-concentration humidity environment at any time. It is strictly forbidden to immerse the equipment in water or be sprayed by water or other liquids. It is strictly forbidden to disassemble the equipment by yourself during equipment maintenance. If you need service, please contact our company or an authorized supplier.

2.About the internal battery

This product contains a rechargeable lithium ion battery pack. When the device can work with an adapter power supply, the adapter should be preferentially selected as the power input of the negative pressure pump. The internal battery pack is used as a backup power source and is only used when the device environment cannot be connected to the adapter power source.

Please make sure to use the adapter power supply specially equipped by Guangzhou RainHome Pharma & Tech Co., Ltd. to charge the internal battery.

The internal battery does not need to be maintained or maintained during the product life cycle. Do not disassemble the battery pack of the device privately. If you need to repair the product, please contact the manufacturer or the manufacturer's designated after-sales unit.

After the product life has expired, please do not discard the device casually. It can be handed over to a local hazardous waste treatment station for disposal, or the product can be mailed to the manufacturer for disposal.

Transportation and storage requirements

1.Transportation

- 1.Avoid vibration, collision, knock, and drop during transportation of this device.
2. The device should be kept at room temperature and pressure during transportation, and avoid exposure to sunlight.
- 3.The equipment cannot be transported with high-concentration volatile corrosive gases, liquids, etc. during transportation.

2.Storage requirements

- Storage temperature: -10°C~50°C
- Storage humidity: 5%~85% R.H
- Atmospheric pressure: 700hPa~1060hPa
- Others non-corrosive gases, good ventilation.

Service life and warranty period

The service life of this product (dynamic negative pressure) is 2 years. See the label attached to the back of the product for the production date.

This product is guaranteed for the whole machine (two years) from the date of leaving the factory. For after-sales service contact information, see product after-sales service information.



Failures caused by the customer's own disassembly of the device are not covered by the warranty. If liquid or solid is sucked into the device, please contact Guangzhou RainHome Pharm&Tech Co., Ltd. for product maintenance. Do not disassemble and repair the product privately.

Electromagnetic Compatibility



Attention:

- The dynamic negative pressure device complies with the relevant requirements of YY 0505 standard electromagnetic compatibility.
- The user should install and use it according to the electromagnetic compatibility information provided by the accompanying documents.
- Portable and mobile radio frequency communication equipment may affect the performance of dynamic negative pressure device. Avoid strong electromagnetic interference when using it, such as close to mobile phones, microwave ovens, etc.;
- The guidelines and manufacturer's declaration are detailed in the attachment.



Warning:

- The device or system should not be used close to or stacked with other equipment. If it must be used close or stacked, it should be observed to verify that it can operate normally under the configuration used.
- Except for cables sold by equipment or system manufacturers as spare parts for internal components, the use of accessories and cables other than those specified may result in an increase in the emission of the device or system or a decrease in immunity.

Symbol interpretation

The service life of this product (dynamic negative pressure) is 2 years. See the label attached to the back of the product for the production date.

This product is guaranteed for the whole machine (two years) from the date of leaving the factory. For after-sales service contact information, see product after-sales service information.



Important prompt message



B-type application part



Information of manufacturer



Production date



product ID



Classified number of product



Disposable product



Do not use the device when the package is damaged



Maximum stacked layer (4layers)



Maximum stacked layer (6layers)



Fragile



Up



Sunscreen



Obsolete instructions for electronic products



Keep dry



Ambient temperature of device operation



Expiration date



II class device



Please read random appendix