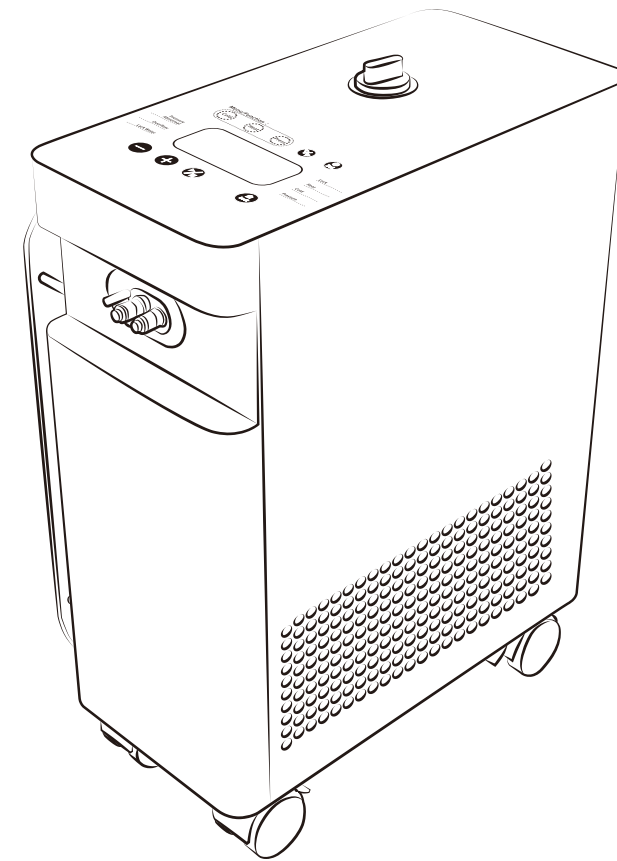


280.00 mm

210.00 mm

dr.aktive
**CRYO
DUO**



Rx ONLY

United States Federal Law restricts this device to sale by,
or on the order of, a licensed health care practitioner.



Chengdu Cryo-Push Medical Technology Co., Ltd
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USER MANUAL

Hot and Cold Compression System

Model A02-C-032

Version: A/0

成品尺寸:140*210mm(展开尺寸:280*210mm)

物料编码:01.08.02.213

Version: A/0

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1. Product Introduction

The device adopts thermoelectric technology to chill and heat the liquid, no refrigerant is required. It offers 5 therapy options: cold only, heat only, compression only, cold and compression, heat and compression; operators can choose different function for treatment. It is to control the temperature of circulating liquid and circulate it to the cuff, which is secured on a body part, to apply cold or heat to target area. Compression therapy can be used alone, or used along with cold/heat therapy. Compression is achieved by alternative inflating and deflating of the cuff.

2. Indication for Use

The device combines cold, heat and compression therapies. It is indicated to treat post-surgical and acute injuries to reduce edema, swelling and pain for which cold and compression are indicated; and it is to treat post traumatic and post surgical medical and/or surgical conditions for which localized thermal therapy (hot or cold) are indicated.

It is intended to be used by, or on the order of, licensed healthcare professionals in rehabilitation facilities, outpatient clinics, and athletic training settings.

3. Safety Warnings

- 1) Follow the prescribed instructions of your healthcare professional for treatment temperature, pressure, frequency and duration.
- 2) A layer of clothing between skin and the cuff is required during use, do not use cuff on exposed skin.
- 3) Improper or prolonged use of this product may cause tissue damage.
- 4) Pay extra caution during immediate postoperative period, especially when sedated or on any medication that could alter normal pain sensation, Check the skin of the treated region frequently.
- 5) During use, patients should monitor the skin of treated region, the surrounding area and digits of extremities of treated limb (if applicable) for any excessive redness, blistering, signs of burning, light-headedness, generalized sweating, itching, increased swelling or pain. If any of the mentioned signs are present, or any changes in skin appearance occur (such as blister, discoloration), patients are advised to discontinue use and consult a physician.

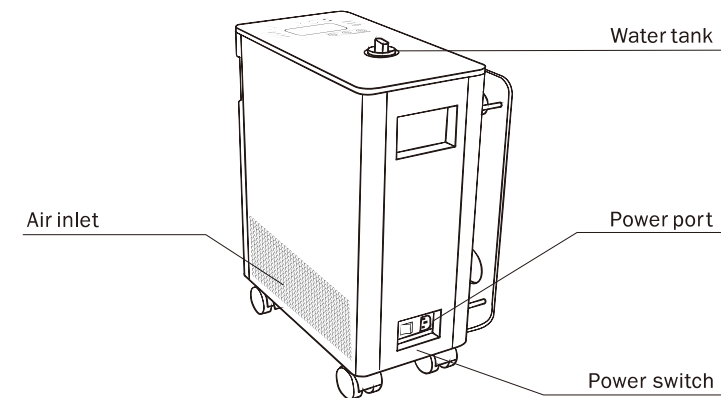
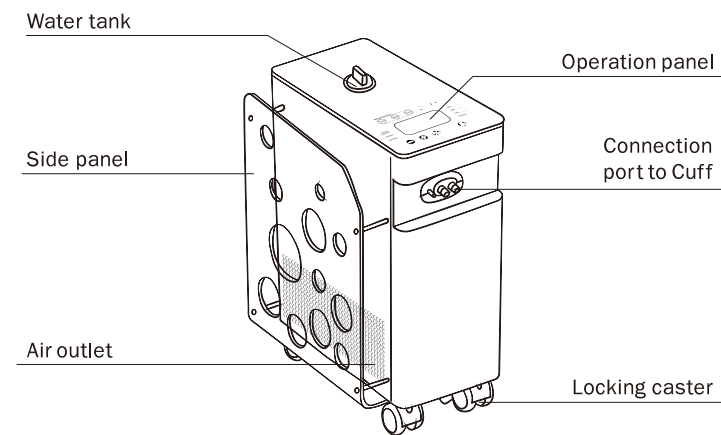
- 6) Be careful when using heat therapy, monitor the skin of treated area frequently, choose cooler temperature settings or leave more time between treatments, if necessary.
- 7) When using heat therapy, protective measures should be taken for the skin of heat-sensitive or high-risk patients, especially in areas of sensory deficits.
- 8) Use extra caution if you are currently on any medication or have an underlying medical condition that predisposes to excessive bleeding or bruising.
- 9) Heating of the gonads and developing fetus should be avoided.
- 10) To avoid electrical shock, product malfunction or damage, never operate the system with damaged power cords or connection hose, or other mechanical damage, or if the unit is otherwise not fully operational.
- 11) To avoid the risk of electrical shock, product must only be connected to a power supply with protective earth.
- 12) To avoid the risk of electrical shock, do not remove any circuit boards from the main unit.
- 13) To avoid injury, be careful not to trip over the power cord or connection hose.
- 14) Keep the product including cuff and power cord away from children and pets.
- 15) Warning: no modification of this device is allowed, any modification of modification attempts could be hazardous.
- 16) Unsupervised use of this product by children or incapacitated persons could be dangerous.
- 17) Use only distilled water as the circulating liquid.
- 18) Follow the user instructions to perform routine disinfection and cleaning.
- 19) Do not operate the system when main unit is tilted
- 20) The product is not for use in sterile environment; Do not use this device in the presence of flammable anesthetics.
- 21) The product is not suitable for use with anesthetics.
- 22) The product is not waterproof, to avoid electrical shock and device malfunction or damage, do not use the product where water may enters the device, do not place water at top of main unit.
- 23) Do not spill corrosive liquids on the surface of the main unit or cuff.
- 24) Disconnect from power source prior to move, maintain or repair the product.
- 25) In case of any product malfunction, repair should be performed by or under instruction of authorized professionals.
- 26) Use the product within its valid service life.
- 27) When water amount is low and bubble may occur, it may be misjudged for water shortage, add suitable amount of water.
- 28) Loosen the cuff straps immediately if pain, swelling or any discomfort occurs.
- 29) Use only the power cord supplied by the manufacturer, to change a damaged power cord, please contact the local dealer or the manufacturer.
- 30) The cuff is re-usable, for single patient use.
- 31) If the product gets wet, unplug from the wall, wipe the outer surface with a dry cloth, and allow it to dry before use.

- 32) Ensure that the side vents of the product are not blocked. Use compressed air to remove dust from the air vents once a year.
- 33) Do not smoke or use cuffs by an open flame.
- 34) Follow the prescribed instructions of your healthcare professional for treatment regimen(s), area, frequency, and duration.
- 35) A licensed healthcare practitioner must select the correct regimen for use.
- 36) Use only the approved therapy cuffs.
- 37) Do not apply the therapy cuff so tightly as to restrict blood or fluid flow.
- 38) Therapy cuffs are non-sterile unless specifically labeled as sterile.
- 39) Non-sterile therapy cuffs should never be directly applied to an open wound or breached skin.
- 40) Do not allow the therapy cuff or connection hose to contact sharp objects that could puncture them.
- 41) The product is not to be used in a confined space; ensure that adequate air flow can be maintained through the side of the unit.
- 42) A Cuff (comprised of an inner air bladder and water bladder and an outer sleeve) must be attached to the main unit to begin treatment. Each cuff is also sold separately and choose the suitable cuff for specific body parts. Use only Cryopush cuff with the system. Using products other than those manufactured or provided by Cryopush with the system may void the warranty.
- 43) Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and other equipment should be observed to verify that they are operating properly.
- 44) Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm(12inches) to any part of the product. Otherwise, degradation of the performance of the product could result.
- 45) The emissions characteristics of this product make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the product.
- 46) Use carefully, May cause serious burns. Do not use over sensitive skin areas or in the presence of poor circulation. The unattended use of this device by children or incapacitated persons may be dangerous.
- 47) Sources of electromagnetic disturbance may affect this product (e.g. MRI, electrocautery equipment, diathermy equipment, radiofrequency ablation devices, high-frequency electrosurgical units, radiofrequency physiotherapy devices, in-hospital 5G base stations, RFID, EAS, metal detectors, near-field communication systems and wireless power transmission), please try to stay away from such environments during use.
- 48) The device is shipped out without side panel installation; side panel must be installed prior use, refer to the section 16 Installation Guidance of Side Panel, you may also contact the local dealer or manufacturer for help.

4. Components and Specification

4.1 Product Components

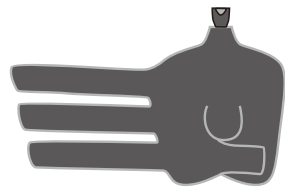
It mainly composed of a main unit, a power cord, various of cuffs and a connection hose. The cuff is the applied part which is to be secured on a body part and a barrier cloth between the cuff and the skin is required. Refer to the section 13 Surface Materials to avoid any allergic reactions.



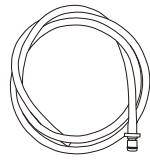
4.2 Replacement parts

Note: Accessories and replacement parts can be purchased through local dealer or contact the manufacturer.

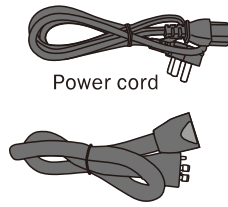
Warning: Use of accessories or power cord other than those specified by the manufacturer of this product could result in safety issue or improper operation.



Therapy cuff (Knee as example)



Drainage tube



Power cord

Connection hose

4.3. Specifications

4.3.1 Product specifications

Transportation & storage Environment		Temperature:1°C ~ 50°C Relative humidity:10%~90% Atmospheric pressure:700hPa-1060hPa			
Operating Environment		Environment Temperature:10°C~27°C Relative humidity:30%~90% Non-condensing Atmospheric pressure:0-3,000m			
Anti-electric Type	Class I	Anti-electric Shock Level	Type B		
Power supply	100~240V AC 50/60Hz	Operating mode	Continuous		
IP ratings	IPX0	Power	480VA		
Capacity of water tank	Max 550ml (operation)	Operating fluid	Distilled water		
Main unit weight	Around 16.5kg	Main unit size	38x27.7x53cm	Hose length	Around 165cm
Safety classification for the use with flammable anesthetic gases mixed with air		Product can not be used in the presence of flammable anesthetic gas mixed with air or with oxygen or nitrous oxide.			

4.3.2 Function Introduction

Function	Temperature	Time	Pressure
Heat	Adjustable range: 38~45°C, 1°C increment.	Adjustable range: 10-40 min, 5 min increment.	Adjustable range: 0~75 mmHg, 15mmHG increment.
Cold	Adjustable range: 4~16°C, 1°C increment.	Adjustable range: 20~60 min, 5 min increment.	Adjustable range: 0~75 mmHg, 15mmHG increment.
Compression	-	Adjustable range: 10~60 min, 5 min increment.	Adjustable range: 15~75 mmHg; 15mmHg increment.
Measured Skin Temperature	Maximum Temperature: Skin temperature measured as high as 44.2°C when set to maximum Heat therapy set point; Minimum Temperature: Skin temperature measured as low as 5.1 °C when set to minimum Cold therapy set point;		
Water tank temperature	Maximum water tank temperature for heat therapy: 45 °C Minimum water tank temperature for cold therapy: 4°C Water temperature accuracy: ±1.5°C		

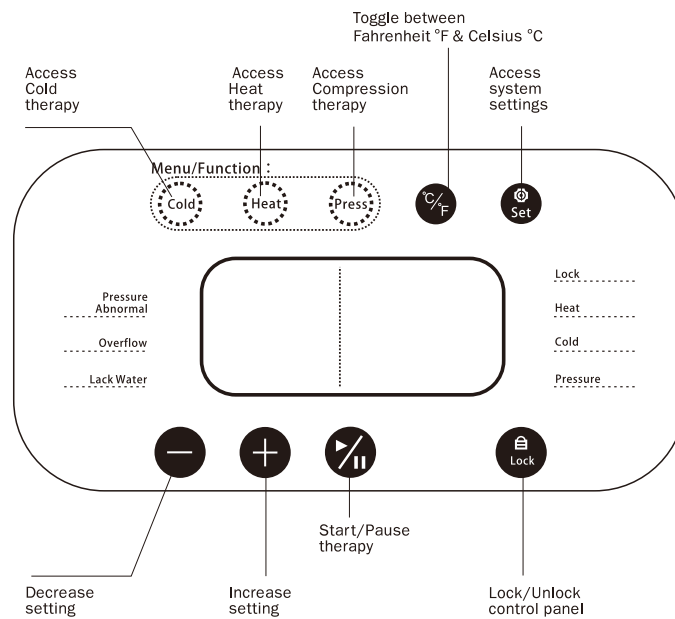
4.3.3 Cuff Specifications

Sizes of therapy cuffs (length x width)			
Universal cuff	800x470mm	Elbow cuff	650x430mm
Wrist cuff	540x460mm	Back cuff	1340x330mm
Right shoulder cuff	1160x980mm	Ankle cuff	25x430mm
Thigh cuff	920x450mm	Left shoulder cuff	1160x980mm
Hip cuff	cuff body: 880 X 510mm; waist belt: 1250 X 85mm		

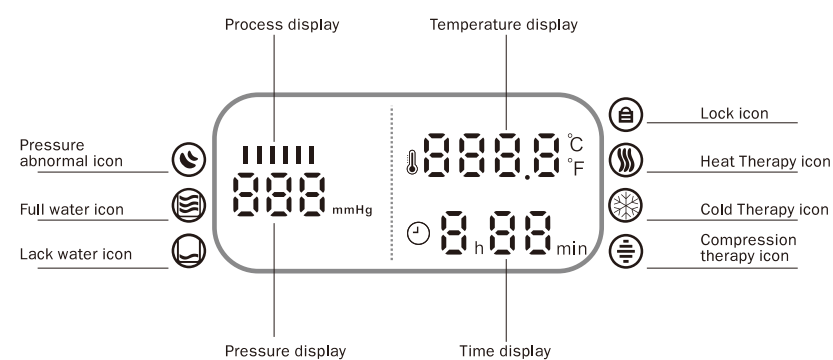
Note: the cuff size error is ±20mm, the size measured includes the extended strap and largest size is taken. The cuffs are in irregular shape to anatomically fit different body part, please contact the local dealer or manufacturer for size details when selecting the suitable cuff.

5. How To Use

5.1 Button introduction



5.2 Icons and Display Introduction



5.3 Preparation Prior Use

Ensure the side panel is installed prior to use, refer to the section 17 for installation instructions.

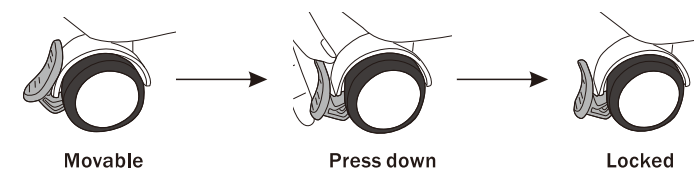
5.3.1 Place the main unit in proper location:

- within 2 meters distance from power socket, which offers 480W power with protective earth;
- Indoor and on flat ground;
- Dry environment, ensure air inlet and outlet areas are unobstructed;
- Avoid the risk of tripping on power cord.

Note: Keep at least 30cm distance between the device air inlet/outlet and the wall.

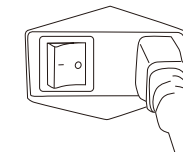
5.3.2 Lock Main Unit Casters

When main unit is in proper position, press down 4 casters to lock and fix the main unit in place.



5.3.3 Power On

- Connect power cord to main unit;
- Plug the power cord into an appropriate power outlet;
- Press the power switch to turn main unit on;
- Main unit beeps once and the screen lights up.



IMPORTANT: Place the power cord in a safe location to prevent tripping hazards or inadvertent disconnection.


5.3.4 Fill Water



- Screw the water tank cap to open, add water carefully.
- when icon Overflow (⊕) lights on, stop filling and the device is ready to operate. (When icon Lack Water (⊖) light is on, cold or heat therapy can not be activated.)
- Tighten the water tank cap.

Important Notice:



Product is shipped out with empty water tank, for first use, water filling is required; Use only distilled water, adding tap water could shorten the service life of main unit; The main unit is not waterproof, avoid splashing water on it when filling.

Lack water icon

When liquid in water tank is insufficient, lack water icon  lights on, then cold/ heat therapy can not be activated; Fill water till it lights off before use.

During cold/heat therapy, if water shortage of water tank is detected in continuous 1S, Lack water icon  lights on; If it detected water shortage in continuous 1min, error code "EA" displays with time icon flashing, and present function stops. Long press start/pause button  3S to turn off the function.

Overflow icon

When there is sufficient liquid in water tank, Overflow icon  light is on to indicate full water status. Therefore, stop filling water in case of overflow when the icon  lights on.

Note: if too much water is added, drain part of the water out through device drainage function.

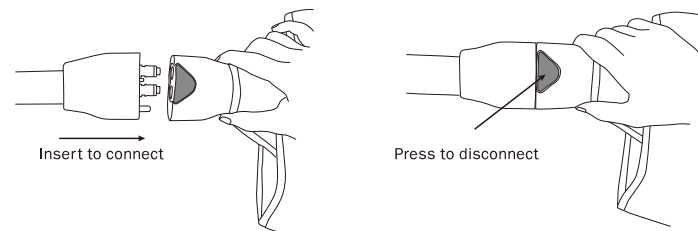
Note: Drain and change circulation water from main unit and cuff every 2 weeks. If the device will be out of use for a long time, drain water out.

5.4 Secure the Cuff

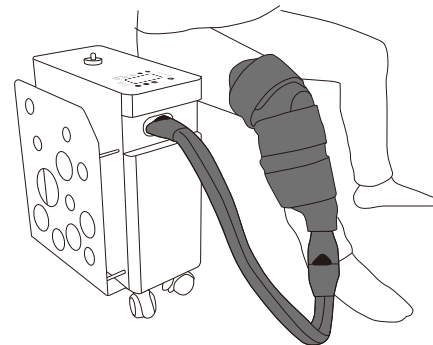
Secure the cuff on target body part through straps and velcros. Refer to Section 15 for wear instruction of all available cuffs.

Note: do not use the cuff on exposed skin, a layer of barrier cloth is required.



The connector works as below:






Connect the Cuff to the main unit through hose:







5.5 Cold Therapy


A, Short press Cold button , icon  light up. LED displays default settings as: pressure 15mmHg, target temperature 8°C, time 40 min;

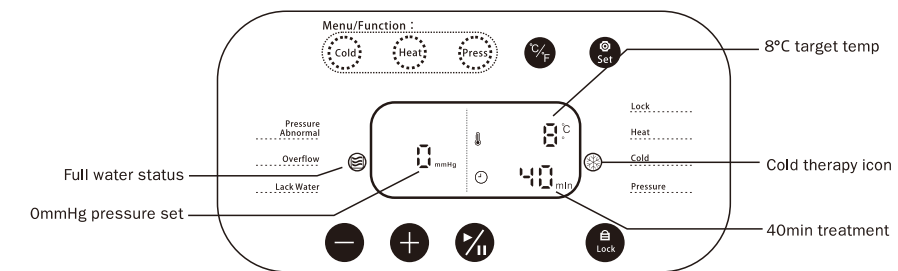
Then pressure display is flashing, press   button to set pressure, 0-75mmHg adjustable range and 15mmHg increment;


B, Short press Set button , temperature display flashes, press   buttons to adjust temperature; 4-16°C adjustable range and 1°C increment.

C, Short press Set button  again, time display flashes, press   buttons to adjust time; 20-60min adjustable range and 5min increment.


D, Short press Set button  again, now pressure display flashes, user can adjust pressure level;


By pressing Set button , user can access settings of pressure, temperature and time in turn. Below is an example of cold therapy setting interface:






E, Short press  button to switch temperature display between Fahrenheit and Celsius.



F, Short press Start/Pause button  to start cold therapy.



G, During cold therapy, to pause and re-start treatment, short press Start/Pause button  ; If the device was paused for over 10 minutes, main unit will automatically turn off Cold function.




H, During cold therapy, only 2 buttons are operational: Start/Pause  and Lock button  ; other buttons are invalid.




I, Press and hold Lock button  for 3S, lock icon  lights on, all other buttons are invalid. To unlock, long press the Lock button  again.


5.6 Heat Therapy


A. Short press Heat button , heat therapy icon  lights on; LED displays default settings as: Pressure 15mmHg, temperature 40°C and time 20 min.

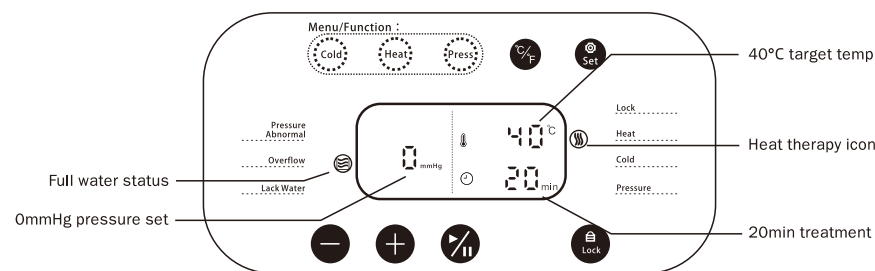
Then pressure display is flashing, adjust pressure by pressing   buttons; adjustable range 0-75mmHg with 15mmHg increment.

B. Short press Set button , temperature display flashes, set temperature by pressing   buttons; adjustable range 38-45°C with 1°C increment.

C. Short press Set button  again, time display flashes, adjust time by pressing   button, adjustable range 10-40min with 5min increment.


D. Short press Set button  again, pressure display flashes, pressure is adjustable then.



User can access settings of pressure, temperature and time separately through Set button . Below is an example of heat therapy setting interface:






E. Short press  button to switch temperature display between Fahrenheit and Celsius.



F. Short Start/Pause button  to start heat therapy.



G. During heat therapy, short press start/pause button  to pause or re-start treatment; If the device was paused for over 10 minutes, main unit will automatically turn off Heat function.




H. During heat therapy, only 2 buttons are operational: start/pause  and Lock ; all other buttons are invalid.


I. Press Lock button  and hold for 3S, icon Lock  lights on, all buttons except Lock button are invalid. To unlock, long press Lock button  again.


5.7 Compression Therapy

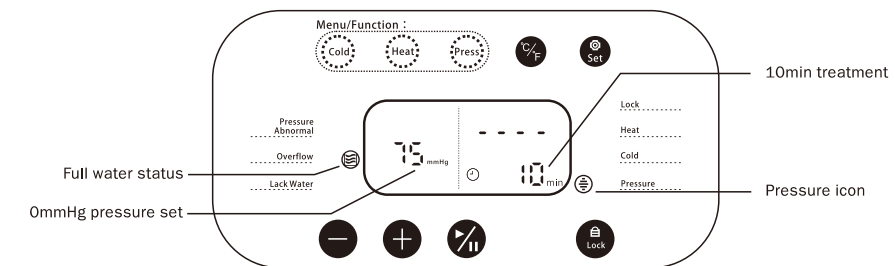
A. Short press Press button , compression icon  lights on; LED displays default settings as: pressure 15mmHg and time 10min.


Then pressure display is flashing, adjust pressure by pressing   buttons, adjustable range 15-75mmHg with 15mmHg increment.


B. Short press Set button , time display icon flashes, set time by pressing   buttons, adjustable range 10-60min with 5min increment.


C. Short press Set button  again, pressure display icon flashes and progress icon lights on, pressure is adjustable now.

User can access settings of pressure and time through Set button . Below is an example of compression therapy setting interface:





D. Short press Start/Pause button , compression function starts with progress icon lighting on. Screen displays present pressure value and remaining time. When it reaches set level, pressure will be held for 15S and then released for 15S, which runs as a cycle.



E. To pause treatment during therapy, short press Start/Pause button , compression function stops and light of progress icon keeps on;

User can re-set pressure level and time through Set button ; If the device was paused for over 10min, main unit turns off compression function automatically.

To continue using, press Start/Pause button  again.


F. During therapy, only Lock button  and start/pause button  are operational, all others are invalid.

Note: Pressure Abnormal Icon 

During compression, when set pressure is not reached in 3min, pressure abnormal icon  lights on; if it is not reached in continuous 6min, error code "EB" is displayed with time icon flashing, and present function stops; Long press start/pause button  3S to turn function off.

5.8 End of Therapy

When the set time completes, time area on the LED displays “-”, device stops working automatically.

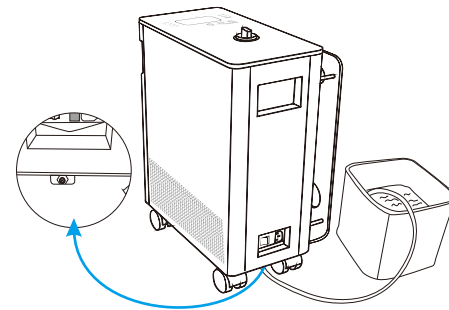
During treatment, the user can end the therapy by pressing and holding Start/Pause button  for 3S.

After using, press the power button to turn device off and unplug from the power source.

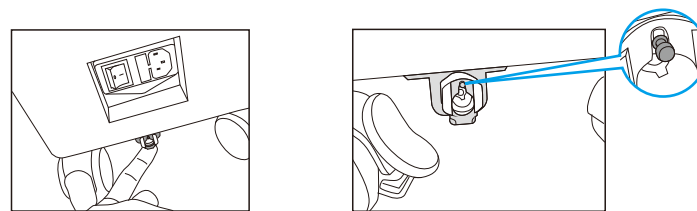
5.9 How To Drain Water









To drain water out from Cuff and main unit, follow below steps first:

- A. Ensure main unit and Cuff are well connected;
- B. Ensure water tank cap is screwed tightly;
- C. Take an empty water bucket with at least 1.2L capacity, connect the drainage tube to drainage port of main unit.



- D. Press the lower part of the drainage port upwards, insert the drainage tube to the port and you will hear a click.

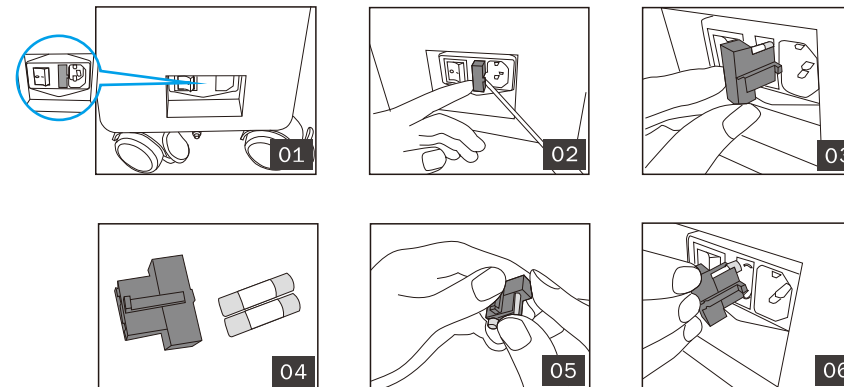


- 1) Press and hold Press button  for 3S, time area on LED displays “3min” (defaulted function time, not adjustable), LED displays “-” in other area. All icons remain off light.
- 2) Short press Start/Pause button , device starts drainage function, Progress display lights on and screen displays remaining function time. When it completes 3min function time, drainage stops automatically.
- 3) To turn off drainage function during operation, long press Start/Pause button  for 3S. During drainage, only Lock button  and Start/Pause button  are operational, all others are invalid.
- 4) To lock the control panel, long press the Lock button  3S; lock icon  lights on and all other buttons become invalid. Long press Lock button  again to unlock.

Notice: The drainage function can not completely drain cuff and main unit, slight water will still remain inside. After drainage, close water outlet otherwise main unit will have some water flowing out.

5.10 How to Replace Fuses

- A. Turn device off and unplug the power cord from main unit; the fuse holder is located between power button and power port. Pic 01.
- B. Use a screwdriver to open the fuse holder through the buckle at power port side; and take the fuse holder out. Pic 02-03.
- C. Remove blown fuses from fuse holder and insert with replacement fuses. Pic 04-05. Fuse size: 5x20mm; specifications: T8AH 250V.
- D. Install the fuse holder back to main unit, you will hear a click and then it is properly installed. Pic 06.



6. Factory Defaulted Settings

Item	Defaulted settings		
	Temperature	Treatment time	Compression level
Cold Therapy	8	40min	15mmHg
Heat therapy	40	20min	15mmHg
Compression therapy	/	10min	15mmHg
Temperature display	°C		
Language	English		

7. Troubleshooting

Problem	Cause	Solutions
Can not turn device on	Power is not connected Fuse is blown	1. Check if power cord is well connected. 2. Check if power switch is on.
	Fuse is blown	Replace the fuse, please unplug the power before operation.
Error code "E1"	Water temperature is too high.	1. Turn off the device, check if hose and cuff is properly connected, check if hose is kinked or folded. 2. Re-start the device to operate.
Error code "E2"	Water temperature is too low.	1. Turn off the device, check if hose and cuff is properly connected, check if hose is kinked or folded. 2. Re-start the device to operate.
Error code "E5"	Temperature of Temperature Control Module is too high.	1. Check the heat dissipation, do not block the air inlet and outlet. 2. Check if foreign body enters water tank. 3. Turn off power, wait for it to cool down before powering on again.
Error code "E6"	Temperature of Temperature Control Module is too low.	1. Check the heat dissipation, do not block the air inlet and outlet. 2. Check if foreign body enters water tank. 3. Turn off power, wait for it to cool down before powering on again.
Error code "E7"	Fan stops	Check if foreign body enters main unit at the air inlet area.
Error code "E8"	Fan stops	Check if foreign body enters main unit at the air inlet area.
Error code "E9"	Pressure is too high	Check if Cuff is well connected, no folding or bending.
Error code "EA"	Lack water	1. Check if main unit leaks water 2. Check if water outlet leaks.
Error code "EB"	Insufficient pressure	Check if Cuff is well connected, no air leakage.

Problem	Cause	Solutions
Can not feel the temperature	No water circulated to Cuff	1. Check if Cuff is well connected, no folding or bending. 2. Check if system completes pre-cooling or pre-heating time.
Can not reach set temperature	Under power	1. Check if the ambient temperature is out of required range. 2. Check the heat dissipation, do not block the air inlet and outlet. 3. Check if correct settings are made.
Displayed temperature fluctuates greatly	Abnormal connection	Check if hose is kinked or folded.

Note: Contact local dealer or manufacturer if above methods can not solve your problem.
When set temperature of cold therapy is higher than environment temperature, cold function can not be activated.

8. Maintenance

8.1 Main unit and cuffs

It is important to keep main unit and cuff clean and as dust free as possible, to clean the system:

-Use a soft cloth dipped in ethanol to wipe the outer surface of the main unit.

-Use a wet towel, or soft cloth damped with 70% isopropyl alcohol, to wipe the surface of cuff and other accessories.

Note:

Do not pour the cleaning agent directly on the surface of the product and wipe with a cloth.

Do not use oxides, alkaline detergents, banana water, volatile oils or other organic solvents to clean the product.

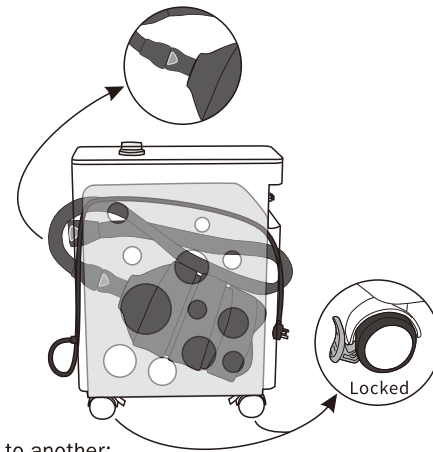
8.2 Maintenance of water tank:

Drain and change circulation water from main unit and cuff every 2 weeks; If the system will be out of use for a long time, drain the water thoroughly; details on how to drain water, refer to section 5.9.

8.3 Transporting the system

8.3.1 To move the system indoor shortly:

- Press the power switch to turn the device off, unplug from the power source;
- Disconnect cuff from main unit and place cuff and power cord behind the side panel (be careful not to fold the cuff joint).
- Unlock the casters and push to move (keep water tank cap tightened);
- When the system is in appropriate place, lock the casters and fix it in place.



8.3.2 To transport the product from one place to another:

- Drain water from main unit and cuff first, follow section 5.9 How to Drain water.
- Press the power switch to turn device off, unplug from power source.
- Disconnect cuff and power cord from main unit and place them behind the side panel.
- Lock the casters and properly package the product before transporting.

9. Contraindications

Read complete indications, contraindications and warnings before use. Follow the recommendation of your health care practitioner for frequency and duration of use for this product; A health care practitioner should set up and supervise the use of the product for the patient.

	Therapy Mode		
	Heat therapy	Cold Therapy	Compression Therapy
X = Absolute Contraindication -Therapy in these situations should not be used in patients who have. R = Relative Contraindication -therapy in these situations should only be used under supervision of a licensed health care practitioner in patients who have.			
Current clinical signs in the affected region of significant peripheral edema (e.g., deep vein thrombosis, chronic venous insufficiency, acute compartment syndrome, systemic venous hypertension, congestive heart failure, cirrhosis/liver failure, renal failure).	X	X	X
Significant vascular impairment in the affected region(e.g., from prior frostbite, arteriosclerosis, arterial insufficiency, diabetes, vascular dysregulation, or other vascular ischemic disease)	X	X	X
Known hematological dyscrasias that predispose to thrombosis (e.g., paroxysmal cold hemoglobinuria, cryoglobulinemia, sickle-cell disease, serum cold agglutinins).		X	R

	Therapy Mode		
	Heat therapy	Cold Therapy	Compression Therapy
X = Absolute Contraindication -Therapy in these situations should not be used in patients who have. R = Relative Contraindication -therapy in these situations should only be used under supervision of a licensed health care practitioner in patients who have.			
Tissues inflamed as result of recent injury or exacerbation of chronic inflammatory condition.	X	R	
Extremities with diffuse or focal impaired sensitivity to pain or temperature that prevent the patient from giving accurate and timely feedback.	X	R	
Compromised local circulation or neurologic impairment (including paralysis or localized compromise due to multiple surgical procedures) in the affected region.	R	R	R
Cognition or communication impairments that prevent them from giving accurate and timely feedback.	X	R	
An acute, unstable (untreated) fracture in the affected region.	X		R
Local malignancy.	X		R
Areas of skin breakdown or damage (damaged or at-risk skin) producing uneven heat conduction across the skin (e.g., open wound, scar tissue, burn or skin graft). Any open wound must be dressed prior to use of the product.	X	R	R
Actively bleeding tissue or hemorrhagic conditions.	X		
Recently radiated tissues or areas affected by heat-sensitive skin diseases (e.g., eczema, psoriasis, vasculitis, dermatitis).	X		
Localized unstable skin condition (e.g., dermatitis, vein ligation, gangrene, or recent skin graft) in the affected region.	R	R	R
Any active local or systemic infection.	X		X
Current clinical signs of inflammatory phlebitis, venous ulcers, or cellulitis.	R	X	X
A pregnancy	X		
Any significant risk factors or current clinical signs of embolism (e.g. pulmonary embolus, pulmonary edema, cerebral infraction, atrial fibrillation, endocarditis, myocardial infarction, or arteromatous embolic plaque).		X	X
A condition in which increased venous or lymphatic return is not desired in the affected extremity (e.g., lymphedema after breast cancer or other local carcinoma and/or carcinoma metastasis in the affected extremity).		X	X
Raynaud's disease or cold hypersensitivity (cold urticaria).		X	
Hypertension, Cardiac failure, extreme low blood pressure, or decompensated cardiac insufficiency.	R	R	X
Children under 18 years old.	R	R	R
Had recent toe surgery in the affected region.		R	R
Obtunded or with diabetes mellitus, multiple sclerosis, poor circulation, spinal cord injuries, and rheumatoid arthritis.	R	R	X
Decompensated hypertonia in the affected region.		X	


10. Other Information



- 10.1 Cryo-Push warrants that the product, if properly used, will be free from defects in materials or workmanship for a limited period, main unit is warranted for one (1) year and cuff 6 months after the date of original purchase.
Warranty does not cover damages due to external causes, nor human caused damages during use such as scratches, air or water leakages.
- 10.2 No modification of this equipment is allowed; repair can only be carried out by professionals designated by the manufacturer.
- 10.3 Expected service life: main unit: 3 years; cuff: 6 months.
- 10.4 Software version: A02_C_032_A_V1

11. Disposal

Do not discard the product in regular waste; The device and packaging must be disposed of in accordance with respective local or national environmental regulations.

12. Symbol Index

 Caution
Indicates that important cautionary information, such as warnings and precautions, cannot be presented on the medical device itself and are Presented in the instructions for use.



 Refer to instruction manual  Type B applied part

 Manufacture  Unique device identifier



 Serial number  Batch code


 Model number


 Date of manufacture, country of manufacture


 Caution, risk of electric shock  Warning, hot surface

Rx only Prescription devices  Medical Device

 Consult instructions for use.  For indoor use only

 Temperature limit the device can be safely exposed.

 Humidity limitation the device can be safely exposed.

 Disposal of product according to local regulations.

13. Surface Materials

Main unit shell: Aluminum alloy
Control buttons: Acrylic
Side panel: Acrylic
Connection hose: Nylon
Connector: PC+ABS

Therapy cuffs: Nylon
Power cord: PVC
Power switch: Nylon

14. Standard Compliance

The device adheres to the following standards: IEC 60601-1:2005, IEC 60601-1: 2005/AMD1: 2012, IEC 60601- 1:2005/AMD2:2020, IEC 60601-1-2:2014 + A1:2020, EN 60601-1-2:2015 + A1:2021, IEC TS 60601-4-2:2024.

15. Electromagnetic Compatibility

Electromagnetic Compatibility Information According to IEC/EN 60601-1-2

Table 1 for Emissions

GUIDANCE AND MANUFACTURER'S DECLARATION ELECTROMAGNETIC EMISSIONS		
The product is intended for use in the electromagnetic environment specified below. The customer or the user of the product should assure that it is used in such an environment.		
EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
RF emissions CISPR11	Group1	The product is 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 emissions CISPR11	ClassA	The product 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 IEC61000-3-2	ClassA	
Voltage fluctuations/flicker emissions IEC61000-3-3	Complies	


Table 2 for RF Immunity

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE PRODUCT			
The product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the product 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		
	150 KHZ TO 80 MHZ $d = 1.2 \sqrt{P}$	80 MHZ TO 800 MHZ $d = 1.2 \sqrt{P}$	800 MHZ TO 2.5 GHZ $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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.			

Table 3 for Transient Electromagnetic Immunity

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The product is intended for use in the electromagnetic environment specified below. The customer or the user of the product should assure that it is used in such an environment.			
IMMUNITY TEST	IEC60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
Electrostatic discharge (ESD) IEC61000-4-2	± 8 kV contact ± 2, 4, 8, 15kV air	± 8 kV contact ± 2, 4, 8, 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative Humidity should be at least 30%.
Electrical fast transient/burst IEC61000-4-4	± 2 kV	± 2 kV 100KHz	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	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 IEC61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5s	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the product requires continued operation during power mains interruptions, it is commended that the product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the AC mains voltage prior to application of the test level.			

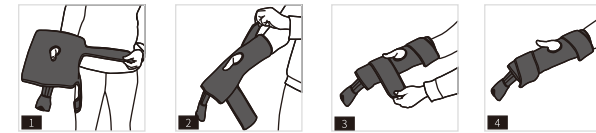
Table 4 for RF Electromagnetic Immunity

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The product is intended for use in the electromagnetic environment specified below. The customer or the user of the product should assure that it is used in such an environment.			
IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz	3 Vrms 150KHz to 80MHz	Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 2.3 \sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
	6V rms 150KHz to 80MHz ISM frequency band 80% am 1KHz	6V rms 150KHz to 80MHz ISM frequency band 80% am 1KHz	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 Ghz	3 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, 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.			

16. Wear Instructions For Available Cuffs

Note: do not use the cuff on exposed skin, a layer of barrier cloth between the skin and the cuff is required.

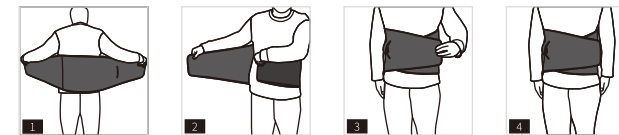
Hand/wrist Cuff
A02-C-032-G



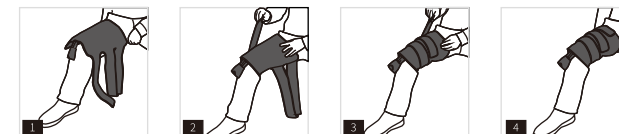
Elbow Cuff
A02-C-032-F



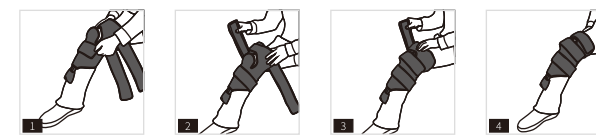
Back Cuff
A02-C-032-E1



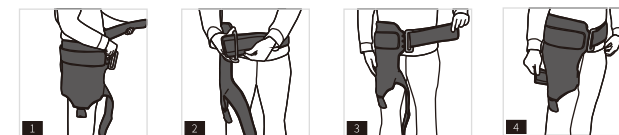
Thigh Cuff
A02-C-032-C



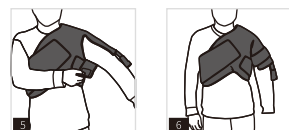
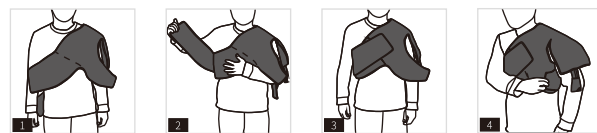
Universal Cuff
A02-C-032-T



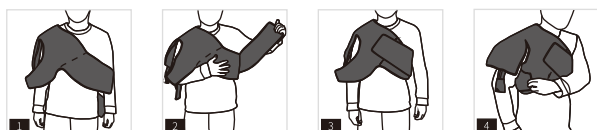
Hip Cuff
A02-C-032-E2



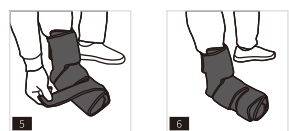
Left Shoulder Cuff
A02-C-032-B1



Right Shoulder Cuff
A02-C-032-B2



Ankle Cuff
A02-C-032-A



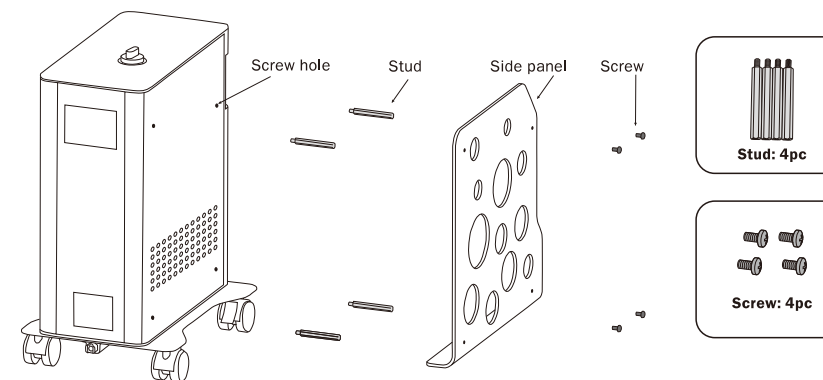
17. Installation Guidance of Side Panel

Important notice:

- 1.The device is shipped out with the acrylic side panel not installed, which must be installed prior to use.
- 2.The side panel is to keep the air outlet of the device free from obstructions and ensure the proper heat dissipation. If the side panel is not installed, the device could be damaged or malfunction.

Below is the structure and preview of the installation.

Below is the preview of the structure and installation:

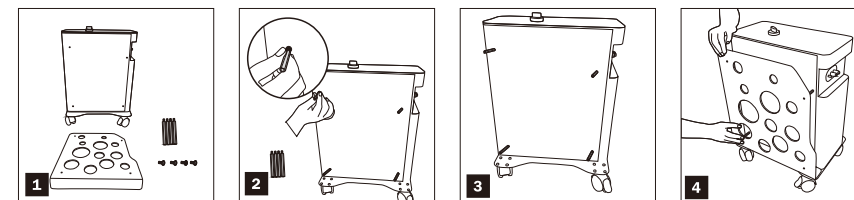


How to install the side panel:

Step 1: Take the main unit and side panel out from the packaging. Take the studs and screws provided out, there will be 4 pieces of each. Keep the main unit upright and in proper position, press down 4 casters to lock and fix the main unit in place. (Fig.1)

Step 2: Refer to the Fig. 1 to find the location of the screw holes on the left panel of the main unit. Screw the studs separately to the screw holes by hand. (Fig. 2-3)

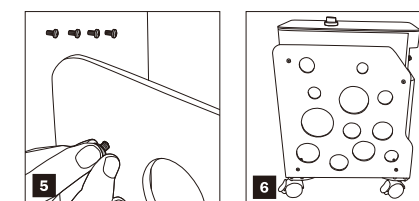
Step 3: Carefully align the screw holes positioned on the four corners of the acrylic slide panel to the studs. (Fig. 4)



Step 4: Install the screws separately to the acrylic side panel and tighten by hand. (Fig. 5)

Installation complete. (Fig. 6)

Note: For help and more installation information, please contact local dealer or the manufacturer.



18. Warranty Registration Card

Please fill out and return upon purchase of the Product.

Your Name: _____

Phone No.: _____

Email Address: _____

Company/Organization: _____

Purchase From: _____

Purchase Date: _____

Model No.: _____

Series No.: _____

19. Guidance on reporting adverse events

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

If you think you or someone in your family has experienced a serious reaction to a medical product, you are encouraged to take the reporting form to your doctor. Your health care provider can provide clinical information based on your medical record that can help FDA evaluate your report.

However, we understand that for a variety of reasons, you may not wish to have the form filled out by your health care provider, or your health care provider may choose not to complete the form. Your health care provider is NOT required to report to the FDA. In these situations, you may complete the Online Reporting Form yourself.

You will receive an acknowledgement from FDA when your report is received. Reports are reviewed by FDA staff. You will be personally contacted only if we need additional information.

Submitting Adverse Event Reports to FDA

Use one of the methods below to submit voluntary adverse event reports to the FDA:

a. Report Online at

www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home

b. Consumer Reporting Form FDA 3500B. Follow the instructions on the form to either fax or mail it in for submission. For help filling out the form, see MedWatch Learn. The form is available at

www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf

c. Call FDA at 1-800-FDA-1088 to report by telephone

Reporting Form FDA 3500 commonly used by health professionals. The form is available at www.fda.gov/downloads/aboutFDA/reportmanualsforms/forms/ucm163919.pdf