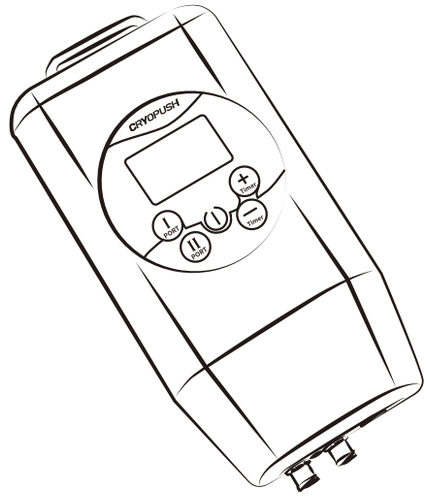
140.00 mm

CRYOPUSH



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www.cryopush.com

info@cryopush.com

USER MANUAL

Cryopush Cold Compression Device
Model No.:AO2-P-001
Version: A/3

200.00 mm

技术要求:
1.157g铜板
2.无覆膜
3.膜印
4.骑马钉
5.尺寸：展开尺寸：200*140mm
成品尺寸：100*140mm

01.08.02.118
Version：A/3
冷敷气压按摩仪-510K-说明书

CONTENT

Intended Use

The Cryopush Cold Compression Device is indicated for the temporary relief of minor muscle aches and pains.

The device is indicated for temporary increase in circulation of the treated areas in people who are in good health, and simulates kneading and stroking of tissues using by an inflatable wrap.

The cold pack is indicated for localized therapy in situations where cold temperature therapy is necessary or desirable.

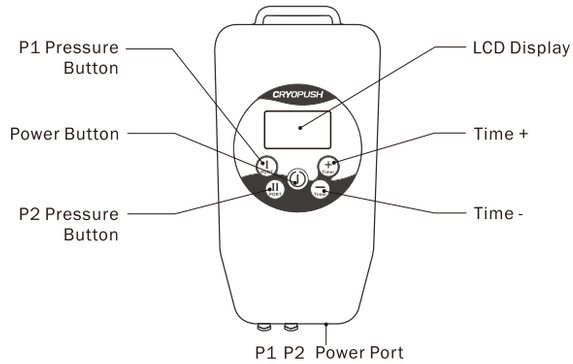
Contraindications

Do NOT use the device if any of the below condition applies:

* Suspected, active or untreated: deep vein thrombosis, ischemic vascular disease, severe arteriosclerosis, pulmonary edema, congestive heart failure, thrombophlebitis or an active infection;
* On a limb where wraps would interfere with the following conditions: vein ligation, gangrene, dermatitis, open wounds, a recent skin graft, massive edema or extreme deformity of the affected area;
* Those with Neuropathy;
* Those who are extremely insensitive to pain;
* Where increased circulation is undesirable;
* Those who have significant vascular impairment in the affected area such as prior frostbite, diabetes and ischemia;
* Those who have known hematological dyscrasias which affect thrombosis such as paroxysmal cold hemoglobinuria, cryoglobulinemia, sickle-cell disease and serum cold agglutinins.

Product Introduction

The Cryopush Cold Compression Device consists of a main unit and wraps. Main unit inflates the wrap to a specified pressure of 20 mmHg, 40 mmHg, 60 mmHg, 80 mmHg or 100 mmHg (set by the user), and once the pressure reached the targeted level, it will hold for 10 seconds before releasing, then decompresses and the air pressure drops. The cycle begins again. Default working time is 30 minutes. Built-in rechargeable lithium batteries allow the system to be completely portable for use anytime and anywhere.



Display Interface

I How To Use

If you want compression treatment with cold therapy, follow steps 1.1 and 1.2 to prepare the cold pack; For compression therapy alone, start from step 1.3.

1.Prepare Wrap

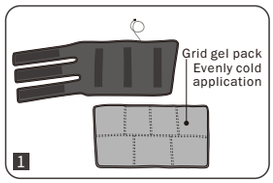
1.1 Freeze the gel pack for around 6 hours in a freezer or a refrigerator (temperature-18℃±2℃).

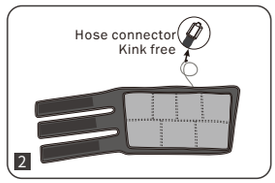
1.2 Place the external wrap flat with Velcro facing up, attach gel pack to wrap, see Pic 1 & 2 below.

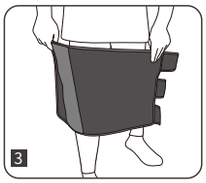
1.3 Secure wrap on the knee, adjust to snug fit through Velcro and straps bottom up, Pic 3 &4.

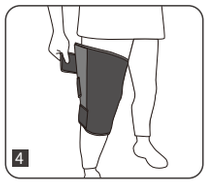
Note: Do not use the cold wrap on exposed skin, apply over clothing or barrier cloth. For replacement gel pack, please contact the after-sale service.

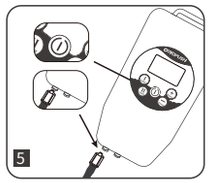
1.4 Connect the air hose of wrap to main unit, Pic 5.











2. Operate the device

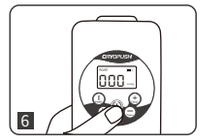
2.1 Turn It On: Long press the power button to turn it on, LCD display will light up as Pic 6.

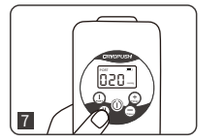
If not responding, connect the main unit with power supply to charge; It is advised not to use it when charging.

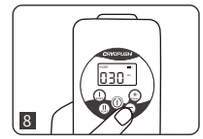
2.2 Set Pressure: Press “PORT I” or “PORT II” button (according to P1/P2 port wrap is connecting with) to set desired pressure as Pic 7. three seconds afterwards without further action, it will start working. Pressure is adjustable when it is in operation.

2.3 Set Time: Press “Timer +” or “Timer -” button to switch interface to set working time as Pic 8, 3 seconds afterwards without further action, it will start working. The default setting is to automatically shut down after 30 minutes operation.

2.4 Turn it Off: When LCD display is on, long press power button to turn it off.







Notice:

1. When main unit is working, the pressure displayed is real time value.

2. When using, ensure the wrap is properly connected with port P1/P2; If targeted pressure level is not reached in several minutes, the pump unit will alarm and corresponding port indicator flashes. Pump will stop working and please check if wrap is properly connected or if the wrap is leaking.

Cautions

1. Indoor use only.
2. Main unit contains small parts, only professionals are allowed to disassemble.
3. Avoid sharp objects contacting the wrap in case of damage or gel leakage.
4. Main unit is only applicable to Cryopush inflatable wraps.
5. Charge the main unit every 2 or 3 months to maintain battery integrity if you do not use it for a long time.
6. Use this device only at its intended body part and according to instructions.
7. Do not use the product in high temperature environment.
8. Keep away from water, do not use if water or other liquid permeated main unit.
9. Do not use cold wrap on exposed skin, use the wrap only over barrier cloth.
10. Allow at least one hour interval before repeating cold therapy.

Warnings

1. Contains built-in lithium battery, dispose properly.
2. Do not throw the device in fire in case of explosion.
3. Use only the power adaptor provided by the manufacturer.
4. If pulsations, numbness, or throbbing occurs, the wrap may be wrapped too tightly, loosen immediately.
5. Ensure the main control unit is turned off and unplugged from the wall outlet prior to and while cleaning.
6. To avoid the risk of electrical shock, do not remove any panels from the main unit.
7. Stop using device if swelling occurs; consult physician.

Performance Characteristics

Model	A02- P-001
Main unit Size	173*82*40 mm
Main unit Weight	340g
Adaptor Input	100-240V~50/60Hz
Adaptor Output	12V 2A
Pressure Levels	20 mmHg, 40 mmHg, 60 mmHg, 80 mmHg, 100 mmHg (±15mmHg)
Working Time	10min, 20 min, 30 min, 40 min, 50 min, 60 min, 70 min, 80 min, 90 min, 100 min, 110 min, 120 min
Battery Capacity	2600mAh
Charge Time	Around 4 hours
Battery Life	Around 10 hours
Noise Level	≤55dB
Pressure holding time	10 seconds
Pressure release time	20 seconds

NOTE:

· Default time setting is 30 minutes.

· Anti kink Luer connector is used for quick connection/disconnection and avoid kinked tube.

Troubleshooting

Device cannot turn on	Battery is low, connect the main unit to power source to charge
Cannot feel pressure	1. Check if hose is properly connected to main unit. 2. Wrap is not snug fit, adjust wrap fit. 3. Check if wrap is leaking or damaged.
Pressure abnormal	In normal use, the display shows the pressure value has reached target level while the main unit keeps inflating; the pressure sensor malfunctions and stop using immediately. Return the device for repair or exchange.
PORT 1" or "PORT 2" flashes with buzzer sound	1. "PORT 1" flash means the PORT 1 wrap pressure cannot reach targeted level; Short press PORT I button to stop alarm and check the connection between main unit and wrap. 2. "PORT 2" flash means the PORT 2 wrap pressure cannot reach targeted level; Short press PORT II button to stop alarm and check the connection between main unit and wrap.
Device shuts down during charging	Battery temperature protection: when battery temperature is higher than set value during charging, device will shut down. It will back to normal when battery temperature lowers to normal level.
Device shuts down during working	1. Load over current protection: When load increases and the current exceed the set protection threshold, device will shut down. Use the device when current is back to normal; Return the device for repair. 2. Battery temperature is too high, wait and use till it lowers to normal level.

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 BF applied part

UDI — Unique Device Identifier, Indicates a carrier that contains Unique Device Identifier information

Manufacturer

Date of manufacturer

LOT — Batch code

SN — Serial number

For indoor use only

Direct current

Disposal of product according to local regulations.

IP21 — Ingress Protection Marking of IP21: Protected from touch by hands greater than 12 millimeters, Protected from condensation.

This side up

Fragile

Keep Dry

Maximum number of packages that may be stacked is 6

Standards Compliance

This device adheres to the following standards: IEC 60601-1; ANSI AAMI ES60601-1; EN 60601-1; IEC 60601-1-2; AAMI/IEC60601-1-2; EN 60601-1-2; IEC 60601-1-11; ANSI/AAMI HA60601-1-11; EN 60601-1-11;

Electromagnetic Compatibility

The device satisfies the EMC requirements of the international standard IEC 60601-1-2. The requirements are satisfied under the conditions described in the table below. The device is an electrical medical product and is subject to special precautionary measures with regard to EMC which must be published in the instructions for use.

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
RFemissionsCISPR11	Group1	The product is only for its internal function. There fore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RFemissionsCISPR11	Class B	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	Class A	
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	SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER		
OUTPUT POWER OF TRANSMITTER W	150KHz TO 80MHz $D = 1.2\sqrt{P}$	80MHz TO 800MHz $D = 1.2\sqrt{P}$	800MHz TO 2 .5GHz $D = 2.3\sqrt{P}$
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.

NOTE1: At 80MHz and 800MHz,the separation distance for the higher frequency range applies.

NOTE2: 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	IEC60601TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
Electrostatic discharge (ESD) IEC61000-4-2	±8kV contact ±2、4、8、15kV air	±8kV 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	±2kV for Power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5、1kV line(s) to line(s)	±0.5、1kV line(s) to line(s)	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 0.5cycle 40% UT (60%dip in UT) for 5cycles 70% UT (30% dip in UT)for 25 cycles <5% UT (>95%dip in UT) for 300 cycles	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60%dip in UT) for 5cycles 70% UT (30%dip in UT) for 25cycles< 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 (50/60Hz) magnetic field IEC61000-4-8	30A/m	30A/m	Power frequency magnetic fields should beat levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity fields from RF wireless communications equipment IEC 61000-4-3	Complies	Complies	/
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	IEC60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
Conducted RF IEC61000-4-6	3Vrms 150kHz to 80MHz	3Vrms	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 $d = 1.2\sqrt{P}$
	6 Vrms 150kHz to80MHz ISM frequency band	6Vrms	
Radiated RF IEC61000-4-3	80MHz To 2.7GHz	10V/m	$d = 1.2\sqrt{P}$ $d = 2.3\sqrt{P}$ 800MHzto2 .7GHz where P is the maximum output Power rating of the transmitter in watts(W) according to the transmitter manufacturer and d is the recommended Separation distance in meters(m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80MHz and 800MHz, the higher frequency range applies. **NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures,objects and people.			

FCC Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Caution: Any changes or modifications to this device not explicitly approved by manufacturer could void your authority to operate this equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation. RF Exposure Information

The device has been evaluated to meet general RF exposure r equirement. The device can be used in portable exposure condition, compliance with exposure requirements.

Main Materials

Main Unit: Acrylonitrile Butadiene Styrene;

Wrap: Polyvinyl chloride and nylon composite

Cold pack: Thermoplastic polyurethanes, the gel is made from Glycerin, resin and water.

Environment Requirements

Operating:

Temperature: 5℃～40℃(41°F～104°F)

Relative humidity: 10%～90%

Atmospheric pressure: 700~1060hpa

Transport & Storage:

Temperature: -25℃~55℃（-13°F～131°F）

Relative humidity: 10%～90%

Atmospheric pressure: 700~1060hpa

Cleaning

Caution: Main unit must be turned off and disconnected from power mains (wall outlet) prior to cleaning or disinfection.

Caution: No modification of this equipment is allowed.

* Use soft cloth or towel to wipe to clean.

Software Version

KRP-A02-P-001-A. V1

Service Life

Main unit: 1000 hours

Inflatable wrap: 250 hours

Disposal

Main unit contains rechargeable batteries. Do not discard it in regular waste; The device and packaging must be disposed of in accordance with respective local or national environmental regulations.

Warranty Information

Cryo-Push warrants that A02-P-001, 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 wrap 6 months after the date of original purchase.

If the product, which is the subject of this Limited Warranty, malfunctions during the warranty period for reasons covered by this Limited Warranty, Cryo-Push, at its options, may elect to replace or repair the returned product with either a new or reconditioned product. This limited warranty exists only to the original purchaser of the product and are non-transferable.

This limited warranty does not cover damages due to external causes, including, without limitation, accident, usage not in accordance with product instructions, misuse, neglect, alteration, normal wear and tear or unauthorized repairs.

Warranty Registration Card

(Please fill out and return upon purchase of Cryo-Push Product.)

Your Name: _____

Phone No.: _____

Email Address: _____

Company/Organization: _____

Purchase From: _____

Purchase Date: _____

Model No.: _____

Series No.: _____

Statement

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 6 of 16 Use one of the methods below to submit voluntary adverse event reports to the FDA:

Report Online at www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home 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 MedWatchLearn. The form is available atwww.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf

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

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