
# User Manual

Version 24

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# 1. Introduction

Thank you for choosing Cryo Dynamics ARC™, an advanced motorized cold therapy device designed to provide targeted treatment for your health condition. Please read this manual thoroughly and consult with your physician with any questions before using the device to ensure safe and effective operation.

# ⚠ 2. Safety Precautions, Contraindications, and Limitations on Special Patient Populations

Before using this device, consult your healthcare practitioner  to ensure it is appropriate for your condition. Below are safety precautions to consider before use of the ARC™:

⚠ Inform your physician if you have any of the following conditions: arthritis, peripheral vascular disease, decreased skin sensitivity, poor or impaired local circulation, hypercoagulation disorders, diabetes, or neuropathies.

⚠ The treatment administered by this device requires a physician's prescription, specifying the ideal temperature (of the ARC™), the duration and frequency of usage, as well as the intervals between use. You are obliged to adhere to the specific instructions given to you by your healthcare practitioner.

⚠ This device has the potential to reach temperatures that can inflict serious harm, such as deep skin damage (tissue necrosis). You should ensure you can regularly monitor the state of your skin beneath the therapy wrap. Should you be unable to do so every hour at minimum, refrain from using the device. Different individuals may have varying sensitivity to cold and can react differently to cold therapy.

⚠ You must continually check for symptoms like heightened pain, burning sensation, numbness, tingling, increased redness, discoloration, itchiness, enlarged swelling, blisters, irritation, or any other alterations in skin condition under the therapy wrap or around the treated area. In case you encounter any of these symptoms, stop using the ARC™ immediately and consult your physician.

⚠ Ensure you monitor the barrier between your skin and the cold pad for moisture. If you feel any, immediately stop usage of this device.

⚠ Do not place casts or bandages over ARC™ therapy wraps.

⚠ ONLY use with approved Cryo Dynamics parts & accessories.

⚠ To ensure a reliable connection between the ARC™ and the therapy wrap, secure the umbilical hoses until they “snap” or “click” into place. The fit should be snug. Always check the umbilical hose connections during use.

⚠ This device is intended for single patient use.

⚠ Use the following precautions to avoid electrical shocks, fires, burns, or other personal injuries from electrical power:

- ONLY operate the device indoors, with dry hands, and in a dry location.
- Ensure all electrical connections stay clear of water or excessive moisture.

⚠ Never use this device if the power supply or plug have been damaged.

⚠ The ARC™ is non-sterile and is not intended to be sterilized. Do not attempt to sterilize the unit by any means.

⚠ ONLY use with a protective barrier placed between the pad and the user’s skin.

⚠ DO NOT modify the device or pads in any way.

⚠ DO NOT use the device if you have any of the following Contraindications unless expressly directed by your healthcare practitioner.

- Open wounds or sores
- Reduced sensation in the treatment area
- Cold-induced urticaria (hives)
- Raynaud’s phenomenon or other vasospastic conditions
- Buerger’s disease
- Cold allergy or hypersensitivity
- Cryoglobulinemia
- Paroxysmal cold hemoglobinuria or other cold agglutinin disorders
- Pheochromocytoma
- Sickle cell anemia
- Susceptibility to cold injury

⚠ **Limit the use of ARC™ with these patients:** This device should be used with caution among patients who lack responsiveness, are incapacitated, or have had changes in their mental status or pain perception. Those who have recently undergone surgery and are under the influence of sedatives, analgesics, or anesthetics, or those who are taking hypnotics, anxiolytics, or antidepressants should be regularly monitored while using this device.

- You must continually check for symptoms like heightened pain, burning sensation, numbness, tingling, increased redness, discoloration, itchiness, enlarged swelling, blisters, irritation, or any other alterations in skin condition under the therapy wrap or around the treated area. In case you encounter any of these symptoms, immediately turn off the device, remove the therapy wrap, and check with your physician.

⚠ Ensure the device is positioned such that the power source can be easily disconnected.

⚠ To prevent the risk of strangulation, keep all hoses and cables away from the neck and ensure they are properly secured and out of reach during use.

⚠ Keep out of reach of children, pets, and pests. The sealed coolant contains glycol which is toxic and will cause injury if ingested.

## 3. Product Components

- Heat exchanger
- Controller assembly
- Power supply
    - The ARC™ is only to be used with the provided power supply (MFG# GQ12-120100-AU).
- Insulation case
- Handle
- Control unit umbilical assembly
- Applicable therapy wrap:
    - Knee therapy wrap (S/M or L/XL) or
    - Hip therapy wrap (S/M or L/XL) or
    - Shoulder therapy wrap (S/M or L/XL)
- Packaging
    - Foam inserts
    - Black rubber connector caps
    - Fill port wrapping
    - Plastic bag containing wraps
    - Plastic bag containing power supply
- Detachable components*
    - Heat exchanger assembly
    - Therapy Wrap
        - Knee
        - Hip
        - Shoulder

- Therapy wrap bladder
  - Knee
  - Hip
  - Shoulder

# 4. Operating Instructions (See Quick Start Guide for Illustrations)

1. Place the CryoCore into the freezer.
2. Remove the CryoCore from the freezer after a minimum of 4 hours.
3. Be sure to remove all protective materials from both CryoCores before use.
4. Insert the CryoCore into the insulation case, ensuring both connectors are facing upwards.

⚠ CryoCore heat exchanger should **not** be in direct contact with other items while in the freezer.

5. Ensure the metal tab on the female connector is pushed in before attempting to connect the components.
6. Connect the controller assembly to the CryoCore by sliding forward until each tab clicks.
7. Connect the power supply.
8. Attach the applicable therapy wrap as directed, being sure to avoid direct skin contact by placing a cloth like protective layer between your skin and the wrap.
    1. Knee Therapy Wrap
    2. Hip Therapy Wrap
    3. Shoulder Therapy Wrap
9. Connect the therapy wrap to the control unit umbilical assembly via the connectors, being sure to check for leaks.
10. Press the button once to start a 30-minute cycle. Press and hold the button for 3 seconds to start a continuous cycle.
11. After a 30-minute cycle, the ARC™ will power down.
12. After use, place the CryoCore back into the freezer for the next use unless all therapy sessions have been completed.

⚠ Remember, do not exceed the recommended usage frequency without proper medical advice.

⚠ Caution when removing CryoCore cartridge after being placed in the freezer as it may be cold and sensitive to the touch.

## 5. Cleaning and Maintenance

The ARC™ requires irregular maintenance to ensure optimal performance, this maintenance is not to be performed while the ARC™ is in operation. Once working fluid level within the CryoCore becomes low, lay the CryoCore in horizontal position with the fill port cap facing upward, unscrew the fill port cap and fill the reservoir with a mixture containing 45% Propylene Glycol and 55% water to the base of the fill port cap opening. Wipe off any excess liquid after securing the fill port cap.

To clean the device, use a soft, damp cloth and a mild cleanser. Do not immerse any part of the device in water or other liquids. Standard hospital cleaning procedures may be followed utilizing Cidex, Clorox Clean-Up, or "Green Soap". Standard hospital cleaning procedures such as steam sterilization are not to be used on the ARC™ or its related accessories.

## 6. Troubleshooting

If you are facing issues with your device, please refer to the following troubleshooting tips. If the problem persists, contact customer support.

- Problem: Pump not running, fluid not flowing to pad, or pad not cold
    - Check that the device is plugged in.
    - Allow 5 minutes for flow and pressure to stabilize.
    - Ensure heat exchanger is cold to the touch.
    - Ensure that the umbilical cord is attached to the proper connector.
    - Disconnect and reconnect the power supply.
- Problem: Unit is leaking fluid
    - Remove the power cord from the electrical outlet
    - Disconnect all connectors and reconnect as outlined in item 6 of the Quick Start Guide.
    - If the problem persists, remove the power cord, cease all use of the unit and contact customer support.
- Problem: Heavy Condensation
    - Small amounts of condensation are normal in high humidity environments.
    - Ensure the protective layer between the therapy pad and your skin is adequately covering the therapy pad.
    - Protect all open wound sites with a sterile dressing and a waterproof barrier.
- Problem: Connectors not securely connecting

- Ensure the metal tab on the female connector is pushed in before attempting to connect the components.
- Ensure the seal on each end of the connector fits correctly within its housing.

# 7. Product Specifications

- Operating Temperature Range: 0°C – 35°C
- Storage Temperature:
  - Shipping Storage Temperature: -20°C - 70°C (-4°F - 158°F)
  - User Storage Temperature: 4°C - 70°C (39.2°F - 158°F)
- Relative Humidity Range: 15%-100% RH
- Operating Pressure Range: 1.00atm - .80atm
- Weight: ≤10 lbs. fully operational
- Umbilical Cord Length from Control Unit: 152 cm.
- Umbilical Cord Length from Therapy Wrap: 15.24 cm.
- Dimensions: 10 ¼ in. W x 15 in. H x 5 ¾ in. D
- Working Fluid: Propylene Glycol
- Working Fluid Flow Rate: ≥50mL ≤600mL/min.
- Working Fluid Pressure: 20 psi.
- Safety: IEC 60601.1
- Maximum Pump Pressure: 37 psi.
- Cooling Temperature Range: ≤ 55°F
- User Operating Temperature: 0 – 135°F
- Audible Noise Level: ≤60 dBA
- Expected Service Life: ≥600 Operating Cycles
- Expected Service Life of ARC™ Therapy Wraps: ≥600 Operating Cycles
- Voltage: 12Vdc, 1.0A

**Regulatory Requirements:**

- The ARC™ is designed for sale in the United States.
- The ARC™ has been designed to meet the requirements of a Class II 510k exempt medical device.
- The ARC™ shall be designed to meet IEC 60601 approval.
- The ARC™ has been designed in accordance with FDA 21CFR820 and ISO 13485 requirements.

# 8. Warranty Information

Your product comes with a warranty effective from the date of purchase. For complete warranty information, please refer to the customer support number below.

## 9. Customer Support

For assistance with setup, usage, maintenance, or to report any unusual operation or events, please contact Cryo Dynamics directly.

Should you require any further assistance, our dedicated customer support team is here to help. Please reach out to us at:

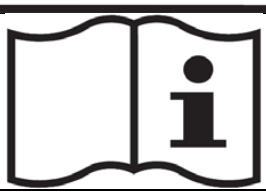
- Phone: (404) 434-4546
- Email: lwright@cryod.com

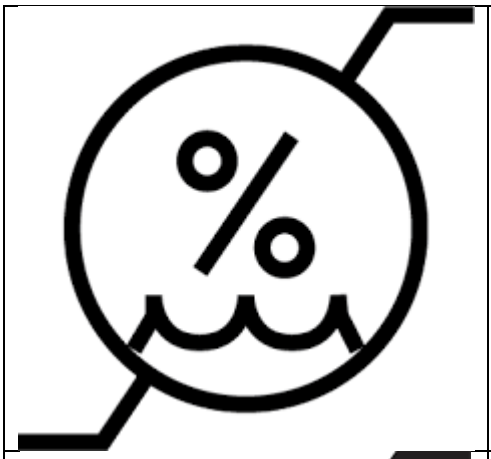
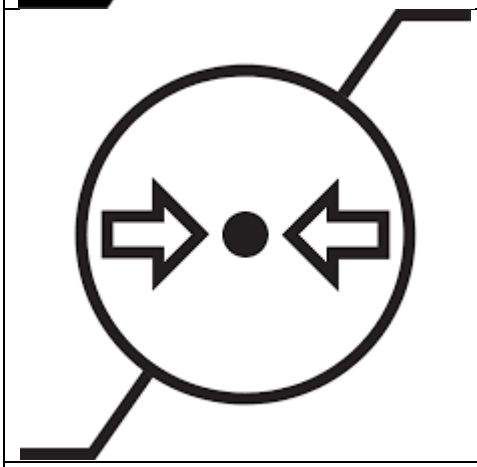
Always remember to have your product model and purchase details on hand when contacting customer support.

## 10. Additional Information

The ARC™ is manufactured by E-Power Corp. at No. 10, Fenghuangshan Road, Yantian Village, Fenggang Town, Dongguan City, Guangdong Province, China

| Symbol | Title of Symbol |
|---|---|
|  | Manufacturer |
|  | Use-by Date |
|  | Batch Code |

| | |
|---|---|
|   | Catalog Number |
|   | Medical Device |
|   | Global Trade Item Number |
|  | Consult Instructions for Use |
|  | Caution |
|   | Single patient multiple use |
|  | Temperature Limits |

| | |
|---|---|
|  | Humidity Limits |
|  | Pressure Limits |
|  | Non-pyrogenic |
|  | Type BF applied part |
|  | Keep dry |
| **110V** | 110 volts |

| | |
|---|---|
| IP22 | IP rating |