

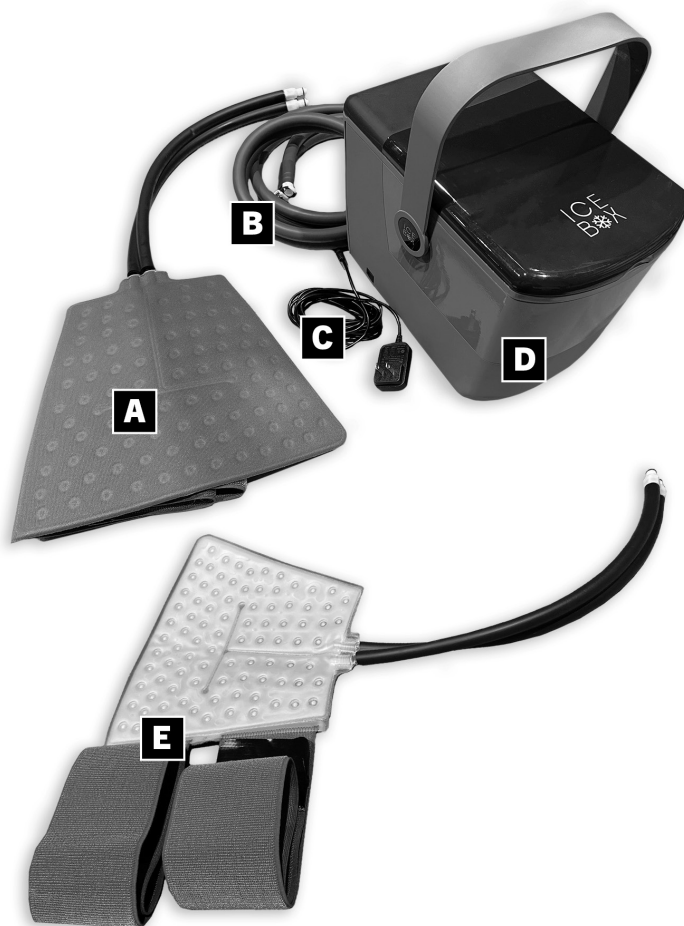


INSTRUCTIONS FOR USE

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List of Components



A – Cooling Pad (*sold separately*)

B – Device Tubing

C – Electrical charge cord

D – ICE BOX® Device

E – Cooling Pad Inside View w/ Velcro Straps (*sold separately*)

Description of Device

The ICE BOX® is a cold therapy device that operates using 12-volt power via the supplied power supply. The components that make up the device include the ICE BOX® device for holding ice and water, cooling pads (*sold separately*), device tubing, velcro straps, and a quiet, brushless motorized pump. Cold water is circulated to the pads that are to be applied to affected areas of the body, to enable cooling which reduces swelling, heat and edema.

Safety Precautions

Please consult your health care provider before using this product to assure you have no conditions that might cause complications from its use. The ICE BOX® device can be cold enough to seriously injure skin. Read all instructions for the device and pads before use. The user must discontinue use if there is any discomfort. This device should never be used when the user is sleeping and should be removed in a timely manner. Always inspect the skin to assure there are no adverse reactions.

CONTRAINDICATIONS

The ICE BOX® Cold Therapy device should not be used on persons with the following conditions:

- Known hematological dyscrasias that predispose to thrombosis (e. g., paroxysmal cold hemoglobinuria, cryoglobulinemia, sickle cell disease, serum cold agglutinins)
- Compromised local circulation (including arteriosclerosis, ischemia)
- Neurologic impairment (including paralysis or localized compromise due to multiple surgical procedures or diabetes) in the affected region, polyneuropathy, or other nerve damage causing decreased skin sensitivity
- Cognition or communication impairments that prevent the user/patient from giving accurate and timely feedback including incapacitated patients with severe cardiovascular disease, anesthetic skin, hypercoagulation disorders, poor circulation,

extremities sensitive to pain, extremely low blood pressure

- Raynaud's disease, phenomenon, or other vasospastic conditions
- Buerger's disease, significant vascular impairment
- Hypersensitivity to cold (cold urticaria) or history of cold related injury (including chilblains or frostbite)
- Severe cardiovascular disease, anesthetic skin, hypercoagulation disorders, poor circulation, extremities sensitive to pain, extremely low blood pressure, incapacitation, decreased skin sensitivity, vein ligation or recent skin grafts, or pheochromocytoma
- Localized unstable skin condition (e. g., dermatitis, vein ligation, gangrene, or recent skin graft) in the affected region or potential impairment of healing in the treatment area, including infection
- Tissues inflamed as a result of recent injury or exacerbation of chronic inflammatory condition

For indoor use only.

ELECTRIC SHOCK HAZARD

Unplug the device before filling it with ice and water and be sure hands are dry before inserting or removing the power supply from wall socket. Avoid getting water or ice on the controls or power adapter. Always unplug the device immediately after each use. Do not use near a tub or sink or any standing water. Do not grab the device if it has dropped into water and be sure it is unplugged safely. Stop use immediately if any damage of the ICE BOX® has occurred or it is not working properly. Do not use near heated surfaces. Great care should be taken when operating an electrical device such as this one.

NOTE: To create the safest operating conditions possible, ICE BOX® has designed the ICE BOX® Cold Therapy System to operate on a 12-volt power supply, significantly reducing the chance of dangerous electric shock. Great care should always be taken when using electricity near water.

WARNING: SKIN INSPECTION AND ADVERSE REACTIONS.

The user or a healthcare provider must check the skin at least every 20 minutes during use of this device, regardless of whether the patient is asleep or awake. The patient must discontinue the use of the ICE BOX® Cold Therapy Unit if he experiences any adverse reaction to the treatment area such as: increase in pain, burning, blistering, itching, increased swelling, discoloration of the skin, increased redness, welts, or any other changes in the appearance of the skin.

WARNING: NO DIRECT CONTACT WITH SKIN: INSULATION BARRIER REQUIRED (NOT INCLUDED)

The ICE BOX® Pad should never make direct contact with the skin. An insulation barrier between the pad and the skin should be used at all times without exception in accordance with advice from a healthcare provider so as to prevent the skin from becoming too cold. The ICE BOX® pad operating temperature is too cold to be placed directly on the skin.

- Unit is not suitable for use in the presence of flammable anesthetic mixture with air, oxygen, or nitrous oxide.
- Follow local ordinances or regulations for proper disposal of device, accessories, and packaging.

WARNING

Read the following treatment warning protocol instructions carefully before operating the ICE BOX® cold therapy system.

- The flow control knob should never be set at the maximum settings ("COLDEST") for more than 20 minutes.
- The ICE BOX® pad should never be applied directly to the user's skin. Do not use the ICE BOX® cold therapy system without first applying an insulation barrier or clothing between the ICE BOX® pad and the user's skin.
- User should never utilize cold therapy while they are asleep or unable to check their skin every 20 minutes unless specifically instructed to do so by the prescribing health care provider.
- Users must check their skin every 20 minutes once steady flow of water through the pad is achieved. Turn the flow control knob counterclockwise to increase the temperature (warmer), and clockwise to decrease the temperature (colder).

- When turning the unit on, turn the flow control knob clockwise to the “Cold” setting and wait 10 minutes to allow the temperature to stabilize before making any additional temperature adjustments.
- The following persons should ALWAYS turn the flow control knob counterclockwise to the warmest setting (“Cold”) when using cold therapy:
 - Persons whose treatment area has been desensitized due to local anesthesia or regional nerve blockers
 - Persons taking prescribed medications that may negatively affect peripheral vascular circulation, including beta adrenergic blockers and local epinephrine use (such as in local anesthetics)
 - Persons suffering from diabetes
 - Persons who have recently undergone hand/wrist or foot/ankle surgery

CAUTION: Contact your healthcare provider immediately and discontinue the use of your ICE BOX® Cold Therapy Unit if you experience any adverse reaction to the treatment area such as: increase in pain, burning, blistering, itching, increased swelling, discoloration of the skin, increased redness, welts or any other changes in the appearance of the skin.

- Make sure that the insulation barrier or clothing is dry.
- Care should be taken during prolonged use for children, diabetics, incapacitated patients and those with decreased skin sensitivity or poor circulation.
- User should consult a licensed healthcare practitioner to determine the correct frequency and duration of treatment for each patient.
- If recommended by a licensed healthcare practitioner for home use, the healthcare practitioner must provide each patient with training for appropriate use and proper application of the ICE BOX® Cold Therapy System.
- User should ask health care practitioner to monitor the person’s use of the device to assure appropriate use and proper application of cold therapy, including but not limited to

application of an insulation barrier between the user's skin and the ICE BOX® Pad.

- The product should never be left unattended when plugged in.
- Never drop or insert any object into any opening or hose.
- Do not operate where aerosol (spray) products are being used or where oxygen is being administered.
- Do not attempt to drag or reposition the ICE BOX® Cold Therapy unit by pulling or tugging on the insulated hoses, as this may cause damage to the unit and/or cause the hoses to disconnect. Use handle when moving the ICE BOX® Cold Therapy unit.
- If you experience disturbance in any other electrical equipment near the ICE BOX® unit, please try to unplug it from the wall socket to verify that it is not the source of disturbance.

SAFETY STANDARDS

ICE BOX®™ Cold Therapy System is tested and certified to comply with the IEC60601-1 standard of electrical safety of medical devices and IEC/ EN60601-1-2, electromagnetic compatibility for medical electrical devices. The company fulfills the requirements of ISO13485.

Intended Use

The ICE BOX® is intended to be used by a single person and has been designed to reduce swelling and pain of areas of the body.

Setup and Operation

1. Ensure ICE BOX® cold therapy device is turned off, turn flow control knob counterclockwise to the off position. Do not plug in to wall socket.

2. Fill reservoir with water to the indicated fill line
3. Add chopped or cubed ice to the reservoir up to the indicated fill line
4. Attach the provided 12V power supply to DC power port, do **NOT** plug into wall circuit.
5. Apply insulation barrier (not included) or clothing over the skin in the area to be treated
6. Apply ICE BOX® Pad over insulation barrier or clothing. The ICE BOX® Pad should never be applied directly over the skin
7. Connect ICE BOX® pad to hose extending from the unit. To ensure proper connection, push couplings together until they snap into place.
8. Plug the provided 12V power supply to wall socket
9. Turn flow control knob clockwise to the first setting, this will turn unit on
10. Wait 10 minutes to allow temperature to stabilize before adjusting the temperature for comfort
11. Turn flow control knob counterclockwise to increase temperature.
12. Turn flow control knob clockwise to lower temperature.
13. To turn the cold therapy unit off, turn flow control knob counterclockwise until it stops.
14. **ALWAYS turn the cold therapy unit off** before disconnecting the ICE BOX® pad or any hoses. To disconnect the hoses, press the release tabs on the coupling and pull the connectors apart.
15. Drain all of the water out of the cold therapy unit after each use.
16. Follow directions before each use.

Maintenance

Do not try to repair your ICE BOX® device unit as this may create a user hazard and set basic safety of the user at risk in regard to

electromagnetic disturbances. An attempt of repairing the device will automatically void warranty. After talking with your healthcare provider, to ensure you are following the operating instructions properly, the unit shall be sent to ICE BOX® for repairs or maintenance. No other company or individual is allowed to service or repair the unit in any way.

CLEANING AND PROLONGED STORAGE

- When you have finished all of your cold therapy usage, prior to prolonged storage, fill the unit with one gallon of water (or enough so the water level is at the ice fill line).
- Add 2 tablespoons of liquid bleach or 3 ounces of 3% hydrogenated peroxide to the water and mix.
- Connect hoses to the ICE BOX® Pad, turn unit on to MAX setting.
- Allow water mixture to circulate for 5 minutes.
- Turn unit off and unplug the power supply.
- Carefully drain the water mixture out of the unit and store in a cool dark place leaving the lid slightly open. (Exposure to sunlight and extreme heat may damage hoses and unit.)
- When reusing the unit after storage, fill the reservoir with clean water and turn the pump on to circulate the water through the hoses and flush the remaining water mixture out of the system (use old pad for this procedure, discard the pad after cleaning is completed).
- Dispose water and refill the reservoir with fresh ice and water combination to begin cold therapy treatment. Follow operating instructions 2–10 before each use.
- Before you use the unit, inspect hoses and new pad for any tears or breaks.
- Clean or replace insulation barrier as recommended by your healthcare practitioner.

Electrical Specifications

POWER SUPPLY

Do not use any other power supply other than the one provided

with the unit.

- Model no: GQ07-120050
- Input: 100-240V
- Input frequency: 50/60 Hz
- Output power: 4.8W
- Output Voltage: 12V
- Output Current: 0.5A Or

ENVIRONMENTAL CONDITIONS

- Operating Temperature: +10 °C to 40 °C
- Operating Humidity: 30% - 75% Relative Humidity
- Atmosphere Pressure: 700h Pa – 1060 h Pa
- Shipping and Storage Temperature: -20 °C to 60 °C

ELECTROMAGNETIC COMPATIBILITY PRECAUTIONS AND WARNINGS

The ICE BOX® Therapy System needs special precautions regarding electromagnetic compatibility (EMC). Specifically, it needs to be installed and put into service according to the EMC information provided as follows:

- The ICE BOX® Therapy System should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the ICE BOX® Therapy System should be observed to verify normal operation in the configuration in which it will be used.
- The ICE BOX® Therapy System may be susceptible to electromagnetic interference from portable and mobile RF communications devices such as mobile (cellular) telephones.
- The ICE BOX® Therapy System may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.

ICE BOX® accessories, various pads, will not negatively affect EMC performance of the ICE BOX® Therapy System. To maintain basic safety, do not use any other power supply other than the one

provided with the unit. ICE BOX® Therapy System is intended for use in EM environment tabulated below.

Guidance and Manufacturer's Declaration

Liability

ICE BOX® does not assume liability for the following:

- Device not maintained as instructed by the instructions for use.
- Device assembled with components from other manufacturers.
- Device used outside of recommended use condition, application, or environment.

Limited Warranty

ICE BOX® warrants, to the original purchaser, that this product is free from defects in materials and workmanship for six (6) months from initial purchase. This warranty does not apply if this product: was not purchased from ICE BOX® or its authorized dealer,; 2 has been altered in any way, or; 3 has not been used in accordance with ICE BOX® Instructions For Use (IFU). This Limited Warranty does not cover damage due to accidents, neglect, misuse, or operation beyond capacity, parts damaged by improper installation, substitution of parts not approved by ICE BOX®, or any other alteration or repair by others that, in ICE BOX® judgment, materially or adversely affects the product or part.

For complete warranty guidelines please visit buyicebox.com

