

DONJOY®

**IceMan® CLEAR³
IceMan® CLASSIC &
IceMan® CLASSIC³
Cold Therapy Units**

Instructions for Use

THIS DEVICE CAN BE COLD ENOUGH TO CAUSE SERIOUS INJURY. SERIOUS ADVERSE REACTIONS AND SAFETY HAZARDS MAY OCCUR WHEN USING THIS DEVICE.

INDICATIONS FOR USE

When to use the IceMan®

The intended use of the IceMan® CLEAR³, IceMan® CLASSIC, and IceMan® CLASSIC³ is for the temporary reduction of swelling and pain after surgery or injury. This is a non-sterile prescription device for single patient use to provide localized external application of cold therapy. This device may not be used for any other purpose.

OPERATING PRINCIPLE

The DonJoy® IceMan® devices provide cold therapy by flowing cold water, from an ice bath through an applied therapy pad.

INTENDED USER PROFILE

The intended user should be a licensed medical professional, the patient, the patient's caretaker, or a family member providing assistance. The user should be able to:

- Read, understand and be physically capable to perform all the directions, warnings and cautions provided in the information for use.

CONTRAINDICATIONS

When not to use the IceMan® DO NOT use this device on patients with 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 or history of cold injury.

LIMITATIONS ON SPECIAL PATIENT POPULATIONS

Limit the use of the IceMan® with these patients Limit the use of this device with patients who are unresponsive, incapacitated, have altered mental status or altered pain perception. Post-surgical patients under sedation or on analgesics or anesthetics, as well as patients taking hypnotics, anxiolytics, or antidepressants, must be monitored frequently during use of this device. These patients may not be able to perceive pain, burning, numbness, tingling or decreased sensation and may be susceptible to injury. Discontinue cold therapy immediately at the first sign of cold injury.

WARNINGS & PRECAUTIONS



WARNING

- **THIS DEVICE CAN BE COLD ENOUGH TO CAUSE SERIOUS INJURY. SERIOUS ADVERSE REACTIONS AND SAFETY HAZARDS MAY OCCUR WHEN USING THIS DEVICE.**



- Read and understand all warnings and Instructions for Use before using this device.
- **For IceMan® CLEAR³ or IceMan® CLASSIC³ (WITHOUT thermometer and temperature control) DO NOT** use this device without a prescription from a physician. Rx only. Your prescription must state how long and how often the device should be used and the length of breaks between uses. **DO NOT** use this device if a prescription has not been provided to you or if you do not understand the prescription. Use of this device without a prescription or failure to follow the prescription may result in serious injury, including tissue necrosis.

R_x
only

- **For IceMan® CLASSIC (WITH thermometer and temperature control) DO NOT** use this device without a prescription from a physician. Rx only. Your prescription must state a temperature, how long and how often the device should be used and the length of breaks between uses. **DO NOT** use this device if a prescription has not been provided to you or if you do not understand the prescription. Use of this device without a prescription or failure to follow the prescription may result in serious injury, including tissue necrosis.

R_x
only

- This device can be cold enough to cause serious injury, including tissue necrosis. You must be able to check your skin condition under the cold pad frequently (at least every hour). **DO NOT** use this device if you cannot check your skin condition frequently (at least every hour). Check for increased pain, burning, numbness, tingling, increased redness, discoloration, itching, increased swelling, blisters, irritation or other changes in skin condition under the cold pad or around the treatment area. If you experience any of these conditions, immediately discontinue use of this device and contact your physician.
- This device is intended only for single patient use. Secondary use can cause serious injury, including infection.
- Application of the cold pads directly on the skin may result in serious injury, including tissue necrosis. **DO NOT** let any part of the cold pad touch your skin. **ALWAYS** use with a barrier between your skin and the cold pad.



WARNINGS & PRECAUTIONS (con't)

- The barrier between your skin and the cold pad may develop moisture during use, which may create colder temperatures on the skin. Temperatures that are too cold may result in serious injury, including tissue necrosis. **ALWAYS** check for moisture on the barrier between your skin and the cold pad. If moisture is present on the barrier, immediately discontinue use of this device.
- Poor connections between hoses may cause leaking, which may result in serious injury, including infection and tissue necrosis. **ALWAYS** listen for a "snap" or "click" when connecting the IceMan® cold therapy unit hose to the cold pad hose. Use only IceMan® cold pads.
- Use of the IceMan® with wet hands or in a wet location may result in electrical shock and serious injury. **DO NOT** handle transformer or power cord with wet hands or in a wet location. The power supply unit is the mains power disconnect. Do not position the equipment to make access to the disconnect difficult. Only connect equipment to the power supply provided for this product.
- **DO NOT** use the IceMan® near flammable anesthetics or oxygen enriched environment, which may result in explosion and serious injury.
- Keep power cord, hose, small parts, and packaging materials away from children and animals. These items pose a risk for suffocation or strangulation.
- It could be unsafe to use accessories, detachable parts and materials, or interconnect to other equipment not described in these instructions, or otherwise modify the equipment.
- Care must be taken when operating this device adjacent to other equipment. Potential electromagnetic or other interference could occur to this or other equipment. Try to minimize this interference by not using other electronic equipment in conjunction with this device.
- To avoid the risk of electrical shock, do not disassemble the IceMan®. If device is not functioning properly, please contact DonJoy product support.

PRECAUTIONS

When to exercise special care when prescribing the IceMan®






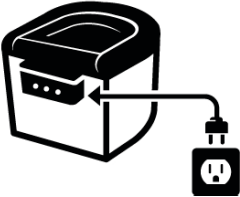
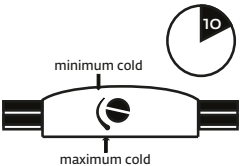
Exercise special care prescribing this device for the following patients: those with arthritic conditions; peripheral vascular disease; children under the age of 12; those with decreased skin sensitivity; poor circulation, or compromised local circulation; hypercoagulation disorders; diabetes or neuropathies.

PATIENT INFORMATION

Directions for use of the IceMan®

- A physician must prescribe treatment to be rendered by this device, which must state a temperature (for the IceMan® CLASSIC), how long and how often the device should be used and the length of breaks between uses. You must follow the individual prescription provided to you by your physician.
- This device can be cold enough to cause serious injury, including tissue necrosis. You must be able to check your skin condition under the cold pad. DO NOT use if you cannot check your skin condition frequently (at least every hour). People are sensitive to cold in diverse ways and may react differently to cold treatment.
- Check for increased pain, burning, numbness, tingling, increased redness, discoloration, itching, increased swelling, blisters, irritation or other changes in skin condition under the cold pad or around the treatment area. If you experience any of these conditions, immediately discontinue use of this device and contact your physician.
- Inform your physician if any of the following apply to you: arthritic conditions; peripheral vascular disease; under the age of 12; decreased skin sensitivity; poor circulation or compromised local circulation; hypercoagulation disorders; diabetes or neuropathies.
- Check for moisture on the barrier between your skin and cold pad. If moisture is present on the barrier, immediately discontinue use of this device.
- Do not cast or bandage over IceMan® cold pads.
- Use only approved IceMan® cold therapy pads with the IceMan® units.
- To ensure a reliable connection between the IceMan® and IceMan® cold pad, “snap” or “click” hoses together into place so that the fit is tight and snug. Monitor hose connections during use.
- This device is intended for single patient use.
- Follow all precautions necessary to avoid electrical shock, fire, burns, or other personal injury from electrical power by using the device indoors, with dry hands, and in a dry location. Keep all electrical connections away from water.
- Never use this device if the power cord or plug is damaged.
- The IceMan® is non-sterile and is not intended to be sterilized. Do not attempt to sterilize the unit by any means.
- Rx only.

OPERATING INSTRUCTIONS

1	Add ice to fill line inside the device.	
2	Add cold water to fill line.	
3	<p>3a. CLEAR³ Lid – Place lid on the device making sure the lip inserts into the groove. Then press the lid down to close and secure.</p> <p>3b. CLASSIC and CLASSIC³ Lid – With the handle down, place lid on device making sure the label is facing up. Secure the lid by raising the handle, which will engage the lid locking mechanism.</p>	<div>  <p>3a</p> </div> <div>  <p>3b</p> </div>
4	Connect the IceMan [®] hose to the cold pad hose. To ensure a reliable connection, “snap” or “click” hoses together into place so that the fit is tight and snug.	
5	<p>To turn the device on, insert cord into connection on the back of the device and plug power supply into the wall outlet. (To turn off the device unplug it.) WARNING! When applying the cold pad, DO NOT let any part of the cold pad touch your skin. Always use with a barrier between your skin and the cold pad. Apply cold pad to patient. Refer to application instructions provided with cold pad.</p> <p>Check for moisture on the barrier between the patient's skin and cold pad. If moisture is present on the barrier, immediately discontinue use of this device.</p>	
6	<p>For IceMan[®] CLASSIC</p> <p>Set temperature control on the hand console starting at the white dot. Allow 10 minutes after the cold pad is placed on the patient for the temperature to stabilize. Then adjust the temperature to the range prescribed by the physician.</p> <p>DO NOT use if you do not have a prescription.</p>	

STORAGE & CLEANING INSTRUCTIONS

- Unplug the power supply from the electrical outlet.
- **TO AVOID DANGER OF ELECTRICAL SHOCK, DO NOT UNPLUG THE POWER SUPPLY WITH WET HANDS.**
- Disconnect pad from hose.
- Drain cooler and wipe dry.
- Drain pad by holding so that the hose is hanging downward.
- Press in the buttons at the end of the hose and allow all water to drain out of the pad.
- If cleaning is necessary: wipe down device and hand wash pads and wraps with mild soap and warm water. Air dry.

ENVIRONMENTAL & SERVICE LIMITS

- Operating Temperature Range: 5°C - 40°C
- Operating Relative Humidity Range: 15% - 90%
- Storage and Transportation Temperature: -25°C - 70°C
- Storage and Transportation Relative Humidity Range: up to 90%
- Atmospheric Pressure Range: 700 hPa - 1060 hPa
- Shelf Life: 10 Years
- Service Life: 400 Operating Hours



POWER SUPPLY

- To order a replacement power supply contact DJO Global Customer Support.
- DonJoy® IceMan® CLASSIC & CLEAR³ Power Supply: DJO P/N 25-4882
- DonJoy® IceMan® CLASSIC³ Power Supply: DJO P/N 25-4041













WARRANTY

DJO, LLC will repair or replace all or part of the unit and its accessories for material or workmanship defects for a period of six months from the date of sale.

SAFETY CLASSIFICATIONS

Mode of Operation – Continuous Operation	
External Electrical Power Source – Class II Equipment	
Degree of Protection Against Electric Shock – Type BF Equipment	
International Protection Marking Code which indicates that the device has been tested to Standard IEC 60529 for ingress protection.	IP21

LEGEND / SYMBOL DESCRIPTION

Attention / Read Manual	Class II Equip- ment	Cold Temperature	Warning Sign
			
Manufacturer	Rx Only	Type BF Equip- ment	Temperature Limits
			
Safety Mark	Humidity Limits	Atmospheric Pressure Limits	This device must be separated from household waste and recycled as electronic waste
			

Blue – Action Required by User
Yellow – Proceed With Caution
Orange – Warning

TROUBLESHOOTING

Pump will not turn on

- Check all electrical connections and make sure the wall plug has power.

Cold pad will not cool down/Cold pad pressure is low

- Make sure trapped air is out of cold pad once power is applied.
- Make sure cooler is filled with ice and water.
- Check all hose connections and make sure cold pad is wrapped properly to allow water to flow.

No water flow

- Check water level. Add water if necessary.
- Check and clean filter cap located under pump assembly.
- Cold pad and hose are wrapped too tightly or the hose is kinked. Unwrap and rewrap the cold pad with cold therapy unit running, making sure water is circulating freely throughout the cold pad and the hose is not kinked.
- Make sure connection between the cold therapy unit hose and cold pad hose is properly connected.

Water leak at connector

- Connector between cold therapy unit hose and cold pad hose is not properly connected. Stop machine, disconnect hose, and reconnect hose listening for a “snap” or “click”, and restart the unit.
- Check barrier to ensure it is dry. Replace with dry barrier, if it is wet.
- Check o-rings.

WEBSITE

For more details please refer DJO Global website: djo-global.com

PRODUCT SUPPORT

Contact manufacturer if assistance is needed in setting up, using or maintaining the equipment or to report unexpected operation or events.

For product support call +1-888-405-3251 or +1-760-727-1280.

ACCESSORIES

Contact DJO Global product support at the above number or visit www.djo-global.com for information and availability of any of the following accessories:

- Cold Pads*
- Cold Wraps*
- Dressings*

* Sterile options available.

COMPLIANCE STATEMENTS

ELECTROMAGNETIC COMPATIBILITY (EMC)

Iceman has been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical devices to IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

Caution: Medical electrical equipment requires special precautions regarding EMC and must be installed and operated according to these instructions. It is possible that high levels of radiated or conducted radio-frequency electromagnetic interference (EMI) from portable and mobile RF communications equipment or other strong or nearby radio-frequency sources, could result in performance disruption of the system. Evidence of disruption may include equipment ceasing to operate, or other incorrect functioning. If this occurs, survey the site of disruption, and take the following actions to eliminate the source(s).

- Turn equipment in the vicinity off and on to isolate disruptive equipment.
- Relocate or reorient interfering equipment.
- Increase distance between interfering equipment and your system.
- Manage use of frequencies close to the system frequencies.
- Remove devices that are highly susceptible to EMI.
- Lower power from internal sources within the facility control (such as paging systems).
- Label devices susceptible to EMI.
- Educate clinical staff to recognize potential EMI-related problems.
- Eliminate or reduce EMI with technical solutions (such as shielding).
- Restrict use of personal communicators (cell phones, computers) in areas with devices susceptible to EMI.
- Share relevant EMI information with others, particularly when evaluating new equipment purchases which may generate EMI.
- Purchase medical devices that comply with IEC 60601-1-2 EMC Standards (3V/meter EMI immunity, limit interference level to 0.0014 V/meter).

ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES – RF EMISSIONS CLASS B

Guidance and Manufacturer’s Declaration – Electromagnetic Emissions		
Iceman is intended for use in the electromagnetic environment specified below. The customer or the user of Iceman should assure that it is used in such an environment.		
Emissions Tests	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1	Iceman uses RF energy 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 CISPR 11	Class B	
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations IEC 61000-3-3	Complies	Iceman 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.


ELECTROMAGNETIC COMPATIBILITY (EMC)

TABLES – RF EMISSIONS CLASS B (*con't*)

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
Iceman is intended for use in the electromagnetic environment specified below. The customer or the user of Iceman should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV 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 IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	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 IEC 61000-4-11	Voltage dips of >95% for 0.5 cycles 30% for 25 cycles 60% for 5 cycles >95% for 250 cycles (5s)	Voltage dips of >95% for 0.5 cycles 30% for 25 cycles 60% for 5 cycles >95% for 250 cycles (5s)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Cold Therapy Unit requires continued operation during power mains interruptions, it is recommended that Iceman be powered from an uninterrupted power supply or a battery.
Power Frequency (50/60Hz) Magnetic Fields IEC 61000-4-8	Inductive loop at 50 Hz and 60 Hz, to 30 amps (rms) per meter	Inductive loop at 50 Hz and 60 Hz, to 30 amps (rms) per meter	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the ac mains voltage prior to application of the test level.			

ELECTROMAGNETIC COMPATIBILITY (EMC)

TABLES – RF EMISSIONS CLASS B (con't)

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
Iceman is intended for use in the electromagnetic environment specified below. The customer or the user of Iceman 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	150 kHz - 80 MHz at 3 Vrms 1 kHz 80% amplitude modulated	150 kHz - 80 MHz at 3 Vrms 1 kHz 80% amplitude modulated	Portable and mobile RF communications equipment should be used no closer to any part of the Cold Therapy Unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = [3.5/V_1] \sqrt{P}$ 150 KHz to 80 MHz $d = [3.5/E_1] \sqrt{P}$ 80 MHz to 800 MHz $d = [7/E_1] \sqrt{P}$ 800 MHz to 2.5 GHz where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manu-facturer and <i>d</i> 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. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	Radiation field strength of 3 V/m from 80 - 2500 MHz (80% AM 1 kHz)	Radiation field strength of 3 V/m from 80 - 2500 MHz (80% AM 1 kHz)	
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.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Iceman is used exceeds the applicable RF compliance level above, Iceman should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Cold Therapy Unit. ^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$ V/m.			

ELECTROMAGNETIC COMPATIBILITY (EMC)

TABLES – RF EMISSIONS CLASS B (con't)

Recommended separation distances between portable and mobile RF communications equipment and the Cold Therapy Unit			
Iceman is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Iceman can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Iceman 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 m		
	150 KHz to 80 MHz $d = [3.5/\sqrt{P}] \sqrt{P}$	80 MHz to 800 MHz $d = [3.5/E_1] \sqrt{P}$	800 MHz to 2,5 GHz $d = [7/E_1] \sqrt{P}$
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.			