



Comfortmax Thermax Hot/Cold Water Circulation System

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 Comfortmax Thermax Hot/Cold Water Circulation System

The intended use of the Comfortmax Thermax Hot/Cold Water Circulation System 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.

CONTRAINDICATIONS

When not to use the Comfortmax Thermax Hot/Cold Water Circulation System

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 Comfortmax Thermax Hot/Cold Water Circulation System 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.

<p>WARNING! Read and understand all warnings and Instructions for Use before using this device.</p>	
<p>For Comfortmax Thermax Hot/Cold Water Circulation System (WITH thermometer and temperature control) WARNING! 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.</p>	 
<p>WARNING! 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.</p>	 
<p>WARNING! This device is intended only for single patient use. Secondary use can cause serious injury, including infection.</p>	
<p>WARNING! 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.</p>	

WARNINGS & PRECAUTIONS - (con't)

<p>WARNING! 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.</p>	
<p>WARNING! 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 Comfortmax Thermax Hot/Cold Water Circulation System cold therapy unit hose to the cold pad hose.</p>	
<p>WARNING! Use of the Comfortmax Thermax Hot/Cold Water Circulation System 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.</p>	
<p>WARNING! DO NOT use the Comfortmax Thermax Hot/Cold Water Circulation System near flammable anesthetics, which may result in explosion and serious injury.</p>	

PRECAUTIONS

When to exercise special care when prescribing the Comfortmax Thermax Hot/Cold Water Circulation System






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 Comfortmax Thermax Hot/Cold Water Circulation System

- A physician must prescribe treatment to be rendered by this device, which must state a temperature (for the Comfortmax Thermax Hot/Cold Water Circulation System), 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 Comfortmax cold pads.
- Use only approved Comfortmax cold pads with the Comfortmax Thermax Hot/Cold Water Circulation System cold therapy units.
- To ensure a reliable connection between the Comfortmax Thermax Hot/Cold Water Circulation System and Comfortmax 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. Always use a grounded outlet.
- To avoid the risk of electrical shock, do not disassemble the Comfortmax Thermax Hot/Cold Water Circulation System. If device is not functioning properly, please contact Comfortland product support.
- The Comfortmax Thermax Hot/Cold Water Circulation System is non-sterile and is not intended to be sterilized. Do not attempt to sterilize the unit by any means.
- Rx only.

OPERATING INSTRUCTIONS

<p>1</p>	<p>Add ice to fill line inside the device.</p>	
<p>2</p>	<p>Add cold water to fill line.</p>	
<p>3</p>	<p>Place lid on the device making sure the lip inserts in groove. Then press front of the lid down to close and secure.</p>	
<p>4</p>	<p>Connect the Comfortmax Thermax Hot/Cold Water Circulation System 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.</p>	
<p>5</p>	<p>To turn the device on, insert cord into connection on the back of the device and plug power supply into the wall outlet.</p> <p>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.</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>	

STORAGE 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.

NOMINAL OPERATING ENVIRONMENT

- Ambient Temperature: 10°C - 40°C
- Relative Humidity: 30% - 75%
- Atmosphere Pressure: 700 h Pa - 1060 h Pa



POWER SUPPLY

Comfortmax Thermax Hot/Cold Water Circulation System Domestic Power Supply:
Comfortmax P/N 13-4882-0-00000








WARRANTY

Comfortmax 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 B Equipment	
Ordinary Equipment – IPX0 – Not protected against water ingress.	
With respect to electric shock, fire, and mechanical hazards the Comfortmax Thermax Hot/Cold Water Circulation System complies with UL 60601-1	

LEGEND / SYMBOL DESCRIPTION

Attention / Read Manual	Class II Equipment	Cold Temperature	CE Mark
			
Action Required by User	Rx Only	Type B Equipment	
			

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

- 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.
- Check and clean filter cap located under the pump assembly. First begin by draining the cold therapy unit. Then remove the filter cap located underneath the pump assembly by unsnapping it. Clean the filter cap, removing any material that may be clogging the filter. Finally, reinstall the filter cap before using the device.

Cold pad pressure is low

- Check water level. Add water if necessary.
- Make sure trapped air is out of cold pad.

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.

Water leak at cold pad

- Faulty cold pad, replace.
- Check barrier to ensure it is dry. Replace with dry barrier, if it is wet.

Magnetic or Electromagnetic Interference

- Reorient or relocate the device. Increase the separation between the equipment. Plug the power supply into an outlet on a circuit different from that to which the other device(s) are connected.

PRODUCT SUPPORT

For product support call +(866) 277-3135



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