

TEMPERATURE THERAPY PROTOCOLS

| Treatment Period: | Frequency/ Duration: | Type of Barrier: | Inspect Skin Every: | Inspection Method: |
|-------------------------|----------------------|------------------|---------------------|--------------------|
| Day: Through Day: | | | | |
| Day: Through Day: | | | | |
| Day: Through Day: | | | | |

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User Guide

RX Only  Single Patient Use Only



7700 Hot/Cold Temperature Therapy Unit



INDICATIONS FOR USE – WHEN TO USE TEMPERATURE THERAPY

Cold Therapy. Use of cold therapy is intended to be prescribed by a properly licensed practitioner to temporarily reduce pain and swelling resulting from injury to or surgery to areas such as the shoulder, knee and back.

Hot Therapy. Use of hot therapy is intended to be prescribed by a properly licensed practitioner to temporarily increase blood circulation and lessen muscle soreness or stiffness during rehabilitation.

Any other uses of this product are not recommended.

Ask your doctor whether you can use compression or mild exercise to ensure adequate blood flow to the affected area before, during and/or after use of this unit.

DO NOT use until you have completely read this User Guide.

SAFETY ALERT FOR HEALTHCARE PROVIDERS! THIS UNIT CAN CAUSE THERMAL INJURY, INCLUDING SERIOUS HEAT OR COLD-INDUCED INJURIES, IF NOT PROPERLY PRESCRIBED. DO NOT

prescribe this unit if you have not read and understood all unit and therapy blanket warnings, contraindications and the *User Guide* or if you do not feel you are appropriately trained on the use of this unit. **ALWAYS** consider the individual patient's medical history in comparison to the warnings and contraindications prior to prescribing this unit. **ALWAYS** provide the patient with specific written instructions on the (1) frequency and duration of use during individual therapy sessions, (2) mandatory use of a skin barrier, (3) correct therapy blanket application, (4) methods and frequency of skin inspection, (5) total length of treatment and, when appropriate, (6) use of compression or mild exercise to ensure adequate blood flow before, during and/or after use of this unit. **ALWAYS** review your patient-specific instructions and all product information with the patient. **IMMEDIATELY DISCONTINUE** use of this unit if your patient experiences, at the treatment site, any change in skin condition

or appearance, including burning, numbness, tingling, discoloration, itching, blisters, welts, irritation; temporary loss of normal motor function; or increased pain, redness or swelling.

SAFETY ALERT FOR PATIENTS! THIS UNIT CAN CAUSE THERMAL INJURY, INCLUDING SERIOUS HEAT OR COLD-INDUCED INJURIES. DO NOT use this unit without a prescription from your healthcare provider. **DO NOT** use this unit if you have not read and understood all unit and therapy blanket warnings, contraindications and the *User Guide* or if you do not feel you are appropriately trained on the use of this unit. **DO NOT** use this unit if your healthcare provider has not provided you with specific written instructions on (1) how long and how often to use this unit during individual therapy sessions, (2) mandatory use of a wrap to serve as a barrier between the skin and therapy blanket, (3) correct therapy blanket application, (4) how and when to inspect skin, and (5) total length of treatment with the unit. **DO NOT** use this unit if you do not understand the instructions or product information provided by your healthcare provider. **DO NOT** use this unit if you are not able to inspect the condition of your skin underneath the therapy blanket on at least an hourly basis or as otherwise recommended by your healthcare provider. **IMMEDIATELY DISCONTINUE** use of this unit and **CONTACT YOUR HEALTHCARE PROVIDER** if you experience, at the treatment site, any change in skin condition or appearance, including burning, numbness, tingling, discoloration, itching, blisters, welts, irritation; temporary loss of normal motor function; or increased pain, redness or swelling.

CONTRAINDICATIONS – WHEN NOT TO USE COLD THERAPY

DO NOT use cold therapy on patients with any of the following contraindications:

- History of cold injury, frostbite or adverse reactions to cold therapy.
- Incoherent due to sedation, anesthesia, coma or sleep.
- Decreased skin sensitivity or localized circulation or wound healing problems, including those caused by multiple surgical procedures.
- Circulatory syndromes due to Raynaud's disease, Buerger's disease, peripheral vascular disease, vasopastic disorders, or hypercoagulable clotting disorders.
- Hand/wrist or foot/ankle surgery exhibiting polyneuropathy.
- Hypersensitivity to cold.
- Children 12 and under.
- Local tissue infection.
- Diabetes.

If you have any of the above contraindications, ask your healthcare provider for alternate treatments.

CONTRAINDICATIONS – WHEN NOT TO USE HOT THERAPY

DO NOT use hot therapy on patients with any of the following contraindications:

- History of heat injury or adverse reactions to hot therapy.
- Incoherent due to sedation, anesthesia, coma or sleep.
- Decreased skin sensitivity or localized circulation or wound healing problems.
- Arteriosclerosis or atherosclerosis.
- Abdomen of women who are pregnant.
- Localized malignancy in treatment area.
- Hypersensitivity to heat.
- Local tissue infection, swelling or inflammation.

If you have any of the above contraindications, ask your healthcare provider for alternate treatments.

PRECAUTIONS

- Condensation on therapy blankets and couplings may occur when in use depending on the air temperature and temperature at the treatment site. This is normal; however, **DO NOT** continue use if skin barrier becomes moist. Change to dry barrier as necessary.
- Avoid pouring water directly over the power receptacle located on back of the unit.
- Unplug unit when not in use.
- Use proper country electrical adapter.

WARNINGS

- Read and understand all unit and therapy blanket warnings, contraindications, precautions and the *User Guide* prior to using this unit.
- This unit can cause thermal injury, including serious heat or cold-induced injury. **IMMEDIATELY DISCONTINUE** use of this unit and **CONTACT YOUR HEALTHCARE PROVIDER** if you experience, at the treatment site, any change in skin condition or appearance, including burning, numbness, tingling, discoloration, itching, blisters, welts, irritation; temporary loss of normal motor function; or increased pain, redness or swelling.
- This unit is prescription (Rx) only. **DO NOT** use this unit without a prescription from a healthcare provider. Use of this unit without a prescription or failure to follow or understand the prescription may result in serious injury, including frostbite and tissue necrosis.
- **DO NOT** use this unit if you are not able to inspect the condition of the skin underneath the therapy blanket on at least an hourly basis. However, due to individual differences in sensitivity and susceptibility to cold and hot temperatures, **ALWAYS** observe the treatment area as recommended by your healthcare provider.
- **DO NOT** apply therapy blanket underneath a fiberglass or plaster cast or other dressing, wrapping or bracing that would prevent the patient from checking the skin under the therapy blanket.
- **DO NOT** let any part of the therapy blanket touch the skin or an open wound. **ALWAYS** use a barrier between the skin and the therapy blanket. If a sterile dressing has been applied to the treatment site that does not completely cover the skin under the therapy blanket, use an additional barrier. Application of the therapy blanket directly on the skin may result in serious injury, including frostbite and tissue necrosis.
- **ALWAYS** check for moisture on the barrier between the skin and the therapy blanket. Because moisture on the barrier may create colder temperatures on the skin and result in serious injury, immediately discontinue use of this unit if moisture is present on the barrier. Change to dry barrier as necessary.
- **DO NOT** use a therapy blanket that is leaking water as this may result in serious injury, including infection and tissue necrosis. **ALWAYS** check for a secure connection between the unit and therapy blanket. **ALWAYS** check for any leaks at the start of every individual therapy session.
- **DO NOT** use this unit with any therapy blanket other than a DeRoyal brand therapy blanket. Other therapy blankets may be colder, increasing the risk of serious injury.
- **ALWAYS** follow the healthcare providers directions for (1) how long and how often to use this unit during individual therapy sessions, (2) mandatory use of a wrap to serve as a barrier between the skin and therapy blanket, (3) correct therapy blanket application, (4) how and when to inspect skin, and (5) total length of treatment with the unit. Failure to follow or understand the directions may result in serious injury, including frostbite and tissue necrosis.
- This unit is intended for single-patient use. Secondary use can cause serious injury, including infection.
- **DO NOT** use in the presence of flammable anesthetics or other flammable materials. Such use may result in serious injury due to the risk of explosion.
- **DO NOT** plug or unplug adapter from wall outlet with wet hands or handle or use this unit in a wet location. The electrical connections of this unit are not waterproof and must be kept dry. Failure to follow this warning may result in electrical shock and serious injury.
- **DO NOT** use any power adapter other than the one provided with this unit.
- **DO NOT** operate this unit with an extension cord or if the power adaptor is damaged.
- **ALWAYS** use a properly grounded AC electrical wall outlet.
- No Modifications of this equipment allowed.
- Cables and hoses may cause strangulation hazard. Keep out of reach of children.




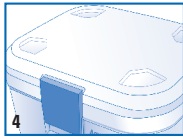


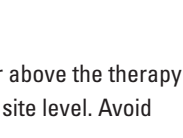
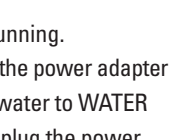
COMPONENTS

- **Reservoir** holds water and/or ice for circulating chilled or hot water.
- **Circuit Board** (inside unit) controls pump motor, regulating water flow from unit reservoir to therapy blanket.
- **Pump Motor** circulates water between unit reservoir and therapy blanket.
- **Motor Cage** is located inside the unit and secures the pump motor.
- **Therapy Blanket** covers the treatment site allowing water to flow through and return back to unit (sold separately or as a combo unit).
- **Latched Lid** allows user to securely close lid.
- **Carrying Strap** can be used to transport unit and store the hose.
- **Hose** (attached to the unit/reservoir) circulates cold or hot water through the therapy blanket and returns water back to the unit.
- **Power Adapter** provides 12.0V electrical voltage to unit.
- **Drain Plug** allows water to drain from the unit.

Operating Instructions

Cold Therapy



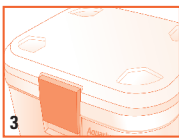


Note: Before filling reservoir, ensure the drain plug located on the front of the unit is twisted on tightly. **Operating Temperature/Conditions:** 41°F to 104°F (5°C to 40°C); 15-90% Humidity; and Atmospheric Pressure: 700-1050 hPa.

1. Open latch and lid. 
2. Fill reservoir with cold tap water to WATER FILL LINE marked on the side of the unit's motor cage. 
3. Next, add ice to ICE FILL LINE marked on the top of the unit's motor cage. **Note:** DO NOT overfill unit. Condensation may collect on top of unit if ice/water level is above ICE FILL LINE. Larger pieces or amounts of ice will equal longer cooling times. 
4. Close and lock lid. 
5. Attach the therapy blanket fittings to the unit hose by inserting ends of blanket tubes into hose fittings. Push each fitting together firmly until you hear a "click." Check for secure connection by lightly tugging on each hose. 
6. After all connections are made, first plug the power adapter into the back of the unit. Then, plug the power adapter into a properly grounded AC electrical wall outlet. **Note:** Place unit within user's reach so user can unplug power adapter with ease. 
7. Place the therapy blanket over treatment area with clear side towards covered skin and secure. Follow directions included with the therapy blankets and wraps sold separately or included in cold therapy unit/blanket combo sets. 
8. To maximize water flow efficiency, place unit at or above the therapy blanket (**Note:** no more than 3 feet) and treatment site level. Avoid twisting or kinking hoses when unit is running. 
9. A green light will illuminate, signaling the unit is running.
10. If the unit needs additional water and/or ice, unplug the power adapter from the wall, empty any remaining water and add water to WATER FILL LINE and ice to ICE FILL LINE. With dry hands, plug the power adapter into a properly grounded AC electrical wall outlet and restart the unit.

Hot Therapy

Note: Before filling reservoir, ensure the drain plug located on the front of the unit is twisted on tightly. **Operating Temperature/Conditions:** 41°F to 104°F (5°C to 40°C); 15-90% Humidity; and Atmospheric Pressure: 700-1050 hPa.

1. Open latch and lid
2. Fill reservoir with hot tap water (not to exceed 120°F/48.9°C) to the ICE FILL LINE marked on the top of the unit's motor cage.

- Note:** DO NOT overfill reservoir.
3. Close and lock lid. 
 4. Attach the therapy blanket fittings to the unit hose by inserting ends of blanket tubes into hose fittings. Push each fitting together firmly until you hear a "click." Check for secure connection by lightly tugging on each hose. 
 5. After all connections are made, first plug the power adapter into the back of the unit. Then, plug the power adapter into a properly grounded AC electrical wall outlet. **Note:** Place unit within user's reach so user can unplug power adapter with ease. 
 6. Place the therapy blanket over treatment area with clear side towards covered skin and secure. Follow directions included with blankets and wraps sold separately or included in cold therapy unit/blanket combo sets. 
 7. To maximize water flow efficiency, place therapy unit at or above the therapy blanket (**Note:** no more than 3 feet) and treatment site level. Avoid twisting or kinking hoses when unit is running. 
 8. A green light will illuminate, signaling the unit is running.
 9. If the unit needs additional hot water, unplug the power adapter from the wall, empty any remaining water and add hot water to the ICE FILL LINE marked on the top of the unit's motor cage. With dry hands, plug the power adapter into a properly grounded AC electrical wall outlet and restart the unit.

To Disconnect Unit

1. First, unplug the power adapter from the electrical wall outlet. Then, unplug the power adapter from the back of the unit.
2. Next, disconnect hose tubes from the unit and therapy blanket by pushing each metal button at connection points.

Cleaning and Storage

1. Disconnect unit and remove from patient.
 2. Drain water/ice from reservoir by either **a)** opening the latch and lid and dumping out, or **b)** opening latch and lid and unscrewing drain plug to allow water to flow out automatically.
 3. Next, use a dry towel to collect any remaining moisture. **Tip:** When storing unit, leave a few dry towels in unit to collect any condensation that may not have been removed when cleaning.
- Transport and Storage Temperature:** -13°F to 158°F (-25°C to 70°C); 93% Maximum Humidity; and Atmospheric Pressure: 700-1060 hPa
4. To prevent hose kinking, wrap hose with the hook and loop closure located on the carrying strap.

Disposal

1. Dispose of product according to local regulations.

Light Display Information

Solid Green Light: Indicates the unit is operating properly. The temperature in cold mode is between 40-50°F/4.4-10.0°C and in hot mode between 80-120°F/26.7-48.9°C.

Blinking Green Light: Indicates the unit is operating properly. This is an indication that the blanket temperature has risen above 51°F/10.6°C in cold mode and that the ice level in the reservoir may need to be checked soon.

Solid Amber Light: Indicates the unit is operating properly. However, in cold mode the temperature is above 65°F/18.3°C and in hot mode the temperature is below 80°F/26.7°C.

Solid Red Light: Indicates the unit is operating properly. However, in hot mode the temperature is above 120°F/48.9°C. Add cool water to the reservoir to lower the temperature **Note: DO NOT** overfill unit.

Blinking Red Light: Indicates there may be a kink in the black hose or the therapy blanket may be folded over or elevated too high above the bucket, thereby restricting the water from properly flowing. Unplug unit, check and adjust as needed, then reconnect. If blinking red light continues please contact DeRoyal.

Note: The motor will stop running when the temperature is below 43°F/6.1°C in the cold mode or above 120°F/48.9°C in the hot mode. The motor will start again when the temperature rises above 42°F/5.6°C in the cold mode or below 120°F/48.9°C in the hot mode. This is a feature of automatic temperature control (ATC™).




WARRANTY

DEROYAL PRODUCTS ARE WARRANTED FOR NINETY (90) DAYS FROM THE DATE OF SHIPMENT FROM DEROYAL AS TO PRODUCT QUALITY AND WORKMANSHIP. DEROYAL'S WRITTEN WARRANTIES ARE GIVEN IN LIEU OF ANY IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

TROUBLESHOOTING

| Problem | Solution |
|------------------------------------|--|
| Unit will not turn on | Check all adaptor and therapy blanket connections and ice/water level. |
| No water flow to therapy blanket | Check for hose kinks or folds in therapy blanket. |
| Unit runs continuously at a speed | Check water/ice level and add if low. |
| Unit continuously stops and starts | Unit is maintaining optimal temperature. Refer to "Light Display Information." |
| Red light stays illuminated | Refer to "Light Display Information." |
| Motor stops running | During normal operating mode, unit motor will pause as needed to maintain correct temperature. Length of the pause may vary. |

EXPLANATION OF SYMBOLS

| Symbol | Description |
|---|---|
|  | Safety symbol to highlight specific warnings associated with this device located in the instructions for use. |
|  | Type BF, Applied Part |
|  | Class II Equipment |

IP21

IP2X - Protected against solid foreign objects of 12.5mm diameter and greater

IPX1 - Protected against vertically falling water drops



Improving Care. Improving Business.™



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