

Range of Motion (ROM) Knee Brace

with Advanced Heat or Cool Therapy

- Adjustable, one size fits most
- Fits up to 26", 3" above the patella.
- Comfortable and lightweight
- Fits right or left knee
- Includes 2 Polycentric hinges to limit Flexion or Extension.



This is not a substitute for the ThermaZone Instruction and Safety Manual. Review the Instruction and Safety Manual prior to using this pad/brace and unit.

 This User's Manual is also available at www.therma-zone.com in English.



(01)00854682001950(10)1714320

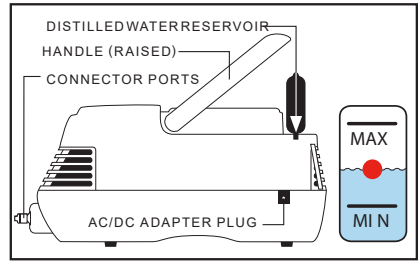
Individual Pads/Braces work in conjunction with the ThermaZone Thermal Therapy technology and are interchangeable with the unit.



www.therma-zone.com

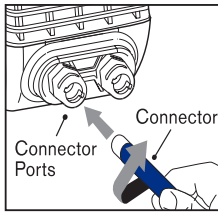
1 FILL THE RESERVOIR WITH DISTILLED WATER

- Lift the handle.
- Gently peel back black rubber fill cap.
- Slowly pour DISTILLED WATER into the reservoir under the fill cap (water should drain through hole in the center of the reservoir).
- Ensure you have filled between “MIN” and “MAX” levels on the water level indicator to maintain optimal performance.

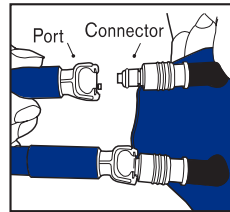


2 INSTALL A BRACE

- Remove the white caps from the end of the white connectors on the tubing assembly.



- Attach the white connectors to the connector ports on the front of the unit, by aligning the tabs and turning clockwise by 90°.

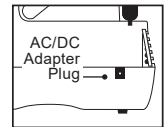



- Insert the connector on the brace into the port on the tubing assembly until you feel the connector click and lock into place.

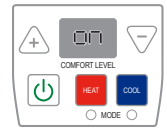
3 BEFORE POWERING ON

THE BRACE MUST BE AT ROOM TEMPERATURE AND LAYING FLAT. ENSURE THE BRACE CHAMBER IS UNRESTRICTED, FOLDED OR BLOCKED. BLOCKAGE COULD CAUSE THE BRACE TO LEAK OR BREAK DUE TO THE WATER PRESSURE!

- Plug one end of the power cord into the electric outlet, and plug the other end into the AC/DC adapter plug on the unit (the control panel will illuminate).



- Press the ON/OFF  button (the fan and pump will start and the digital display will now say “ON”).

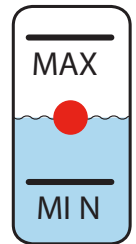


4 REFILL THE RESERVOIR





If this is the first time you are using the unit, or the first time you have installed a brace, the water from the reservoir will be pumped into the chambers of the brace during step 3. At this time, you will need to re-fill your unit with Distilled Water.

- With unit running, pour additional **DISTILLED WATER ONLY** into the reservoir.
- Monitor water fill level over the next minute to make sure the water level settles between the “MIN” and “MAX” lines.

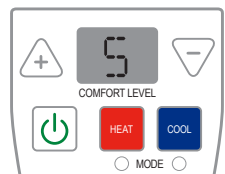
! BE SURE WATER LEVEL IS BETWEEN MIN AND MAX !



5 CHOOSE THERAPY SETTINGS

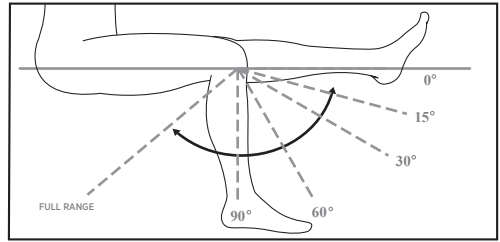
- Select a pre-set timer mode. (optional) 
- Choose your desired temperature mode HEAT or COOL.  
- Select comfort level (1-10) 

The temperature can be adjusted during therapy by pushing the (+) or (-) button to increase or decrease temperature. You can also check the remaining time on the timer (optional) by pushing the previously chosen HEAT or COOL button. The remaining time will appear in the comfort level window for 5 seconds and then the display will return to the comfort level setting.

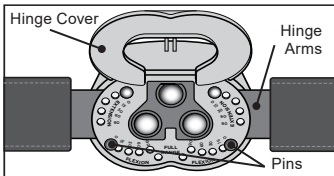


6 DETERMINE DESIRED RANGE OF MOTION SETTING

Range of Motion instructions should be provided by your physician. Refer to the image to the right to understand the calculation of the angle for Flexion.



7 SET THE RANGE OF MOTION HINGES



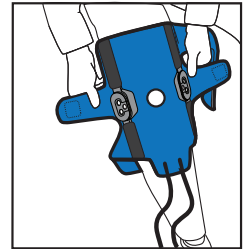
- Open the hinge cover and remove the pins on the Flexion side of the hinge.
- Move the hinge arms until the desired Flexion angle is reached. There will be an opening through both layers of the hinge in the hole next to the desired Flexion angle. Drop pins into desired setting, pushing them firmly into place.
- Set both sides of the hinge (top and bottom) to the same angle.
- Repeat process for both the left and right hinge.

8 APPLY YOUR BRACE

Braces can be applied directly to intact skin or can be used over clothing or a thin barrier.

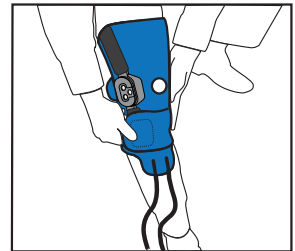
Note: When braces are applied directly to the skin, the temperature will feel more intense.

- To attach the knee pad align the circle in the center of the brace with the knee cap.
- The tubing connectors will be at the bottom of the brace.



9 SECURE THE STRAPS

- Wrap the center straps behind the knee with the right strap under the left strap and secure with the hook and loop closure.
- Wrap the bottom strap across the front of the brace just above the tubing connectors and secure the hook and loop closure.

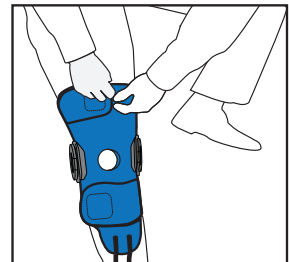


10 BEGIN THERMAL THERAPY

- Wrap the top strap behind the leg, just above the knee cap. Secure the hook and loop closure to the front of the brace.

Sit back and relax. You are now ready to enjoy the comfort and convenience of your continuous thermal therapy unit. If the therapy becomes uncomfortable, remove the brace immediately and adjust the temperature. Allow the brace temperature to reset for 10-15 minutes before reapplying.

Note: For best results when switching from Heat mode to Cool mode, remove the brace from your body for 10 minutes.



SAFETY INSTRUCTIONS

READ THIS FIRST • SAVE THESE INSTRUCTIONS • IMPORTANT SAFEGUARDS

READ ALL INSTRUCTIONS CAREFULLY BEFORE USING THE THERMAL THERAPY DEVICE

WARNING

Avoid these potentially hazardous situations which, if not avoided, may result in death or serious injury:

- ThermaZone therapy units are classified by the FDA as class II medical devices that must be prescribed by a Physician or Licensed Healthcare Professional.
- DO NOT use the unit for any reason other than its intended use.
- DO NOT use for more than 30 minutes at a time.
- DO NOT use while sleeping.
- DO NOT lie on the brace while the unit is being operating. Doing so may create excessive pressure between the brace and patient skin that can increase the likelihood of thermal injury.
- DO NOT use this product as a substitute for medical attention.
- ALWAYS follow the protocol provided by the attending physician.
- DO NOT apply ThermaZone Pads to breached or wounded skin.
- ThermaZone pads are intended to be used without any additional ointments, cremes, salves, moisturizers, or similar topical applications between ThermaZone pads and the body area to be treated. Use of these types of topical applications may result in undesired tissue effect.
- DO NOT apply pads so tightly as to restrict blood or fluid flow. Dressings used under pads should be applied lightly.
- Pads are NOT sterilized. DO NOT place Single Patient Use Pads in an autoclave or attempt to sterilize.
- DO NOT operate in an operating room.
- DO NOT operate when intended user is connected to life support equipment, cardiac device, and/or electrophysiology device.
- DO NOT plug into an electrical outlet that is already supporting an appliance.
- DO NOT use unit with an extension cord unless the cord has been checked and tested by a qualified technician.
- DO NOT leave unsupervised when the unit is being used near children or infirm persons.
- DO NOT operate in a wet or moist condition.
- DO NOT use while bathing or in the shower.
- DO NOT leave unattended while in use.
- DO NOT use while smoking or place on or near a hot gas flame, flammable products, electric element or a heated oven.
- DO NOT obstruct vents on the top, front, or back of the unit.
- DO NOT operate if the cord appears damaged or if you have dropped or damaged the unit. Inspect the unit and its cord beforehand to be sure that it is in good working condition.
- DO NOT use the unit outdoors. The unit is for indoor use only.
- DO NOT operate where aerosol (spray) products are being used.
- DO NOT operate the unit under a blanket, pillow or other such items as excessive heat may cause fire, electrical shock or other injury.
- DO NOT reach for the unit if it falls into water – unplug it immediately.
- DO NOT drop or insert any object or body part into any opening of the unit.
- DO NOT allow unit, accessories or cord to touch hot surfaces.
- DO NOT run the cord under carpeting or cover it with throw rugs, runners, or the like.
- DO NOT attempt to disassemble or repair your unit as such action may cause a risk of electric shock or injury.
- DO NOT modify equipment.
- DO NOT use with power supplies other than those specified by manufacturer.
- DO NOT consume water removed from the ThermaZone device.
- DO NOT use HEAT mode in ambient temperatures above 85 degrees Fahrenheit (29.4 degrees Celsius).
- Prolonged exposure to heat greater than 46° C (115° F) may cause skin injury to certain tissues. The user must exercise caution and monitor discomfort and skin condition accordingly. Remove the brace if pain or discomfort from the temperature is experienced.
- Decreased sensation from the body's natural adaptation to heat may cause you to tolerate heat that might cause a skin burn. Use caution when setting the unit to maximum heat settings and do not use for prolonged periods at these settings (20 minutes or longer, must be adjusted according to patient tolerance).
- Due to individual differences in sensitivity and susceptibility to cold or heat, the patient's skin should be frequently observed. Prolonged exposure to cold or heat has a potential to cause injury to tissue. Follow the instructions of the attending physician for length, frequency, and duration of treatment. DO NOT use COOL mode in ambient temperatures below 60 degrees Fahrenheit (16 degrees Celsius).
- To avoid adverse effects to the skin, shut off the ThermaZone unit if patient begins to feel uncomfortable.
- Discontinue use if dizziness, severe pain, or severe skin reaction occurs.
- Be sure to disconnect the unit from electrical outlet when filling or emptying water. Turn off unit before unplugging from an outlet.
- After operation of the unit, always wait for the unit to return to room temperature before storing.
- As with any product with a cord, there is a risk of strangulation. Take care in storing and using the unit around children.
- Be sure to review the General Precautions in the ThermaZone Instruction and Safety Manual Section 6 before selecting a Temperature Mode and Comfort Level.

SAFETY INSTRUCTIONS

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READ ALL INSTRUCTIONS CAREFULLY BEFORE USING THE THERMAL THERAPY DEVICE

CAUTION

Avoid these potentially hazardous situations which, if not avoided, may result in minor or moderate injury, or damage to the ThermaZone Unit or Brace:

- DO NOT position the unit so that it is difficult to operate the disconnection device (plug of the Power supply).
- DO NOT unplug by pulling on the cord.
- DO NOT pull or carry the unit by the cord.
- Unplug from the electrical outlet before cleaning or storing.
- Arrange the blue tubing and cord away from traffic areas and where it will not be tripped over.
- DO NOT drop the unit or brace.
- DO NOT operate or store the unit or brace near pets.
- Before each use, make sure braces are not damaged, punctured or leaking.
- DO NOT puncture the braces.
- To avoid any adverse effects to your health or skin, shut off the unit if you begin to feel discomfort.
- If you are sensitive to hot or cold temperatures, consult your doctor before use.
- Consult the temperature setting warnings and precautions in the instructions when using this unit.
- The application instructions for the ROM Knee Brace are intended for the use of qualified professionals only. It is not recommended for patients to attempt to apply or adjust this device unless otherwise instructed to do so by an orthopedic professional. Any questions regarding further adjustment or frequency / duration of wear should direct to your orthopedic professional who understands the individual condition for which this device was prescribed.

INTENDED USE

ThermaZone is intended to provide heating or cooling effect at controlled temperatures through water-circulating, anatomically designed pads for the application of noninvasive localized thermal therapy. The Range of Motion (ROM) Knee Brace provides stability and support for chronic knee pain and instability. ThermaZone is not meant to replace the program that medical professionals have prescribed for their patients. Physician consultation before changing or discontinuing a recommended therapy or treatment plan is strongly recommended. ThermaZone pads are not intended to come in contact with breached or wounded skin.

CONTRAINDICATIONS

Absolute Contraindications for **THERMOTHERAPY**

Therapy should **NOT** be used in patients without medical supervision:

- If the patients have decreased skin sensitivity;
- If the patients are children, elderly, or incapacitated; and/or
- If the patients have poor circulation, vein ligation, recent skin grafts, or extremely low blood pressure.

Therapy should **NOT** be used in patients:

- Who are insensitive to Heat.

Absolute Contraindications for **CRYOTHERAPY**

Therapy should **NOT** be used in patients:

- Who have Raynaud's disease.
- Who are children.

Absolute Contraindications for us of **RANGE OF MOTION (ROM) BRACE**

ROM Brace should **NOT** be used in patients:

- Who have moderate to severe ligament instabilities.

TRANSPORT, STORAGE & DISPOSAL

Temperature; 4.5-50C

Humidity: 0-90%

Atmospheric Pressure: 50 kPa to 106 kPa

ALWAYS unplug the unit immediately after use and before storing.

ALWAYS drain the unit before Storage, according to the Preventative Maintenance instructions on page 13. "Storage" means non-use for over three months.

DO NOT STORE or store where it can fall into a bathtub, shower, sink, water or other liquid.

Store the unit and pads in a cool, clean, dry space.

AVOID EXPOSURE to sunlight and high heat conditions for extended periods. Keep away from flames.

When removing and storing the pads or tubing assemblies, replace the caps on the end of the blue tubes.

Dispose of the unit and pads in a manner that is consistent with your federal, state, and local laws and regulations.

OPERATION

Temperature: 16C-29.4C.

Humidity: 15-90%

Atmospheric Pressure: 70.0 kPa to 106.0 kPa

CLEANING

BEFORE CLEANING:

ALWAYS power off the unit and unplug the AC / DC power cords from the outlet and the unit before cleaning. **DISCONNECT** the brace from the unit. Remove hinges from the brace.

TO CLEAN:

Unit can be cleaned with a neutral disinfectant wipe.

Braces can be cleaned with a neutral disinfectant wipe, soap-water or mild detergent. Rinse brace with warm tap water and dry with a clean, lint-free cloth. Hinges can be hand washed in cold water with mild detergent. Allow parts to air dry before re-assembly.

When used in accordance with the cleaning & disinfectant wipe manufacturer's instructions for use, the following cleaning & disinfection wipes do not adversely affect the appearance or performance of the TheraZone Unit or Brace:

Cleaning & Disinfectant Wipe	Manufacturer
CaviWipes™	Metrex Research
Super Sani Cloth® Germicidal Disposable Wipe	Professional Disposables Internation, Inc. (PDI)

DO NOT:

- use ANY chemical cleaning agents or products containing alcohol on unit, braces or hinges, except as outlined above.
- wash the unit or hold under running water.
- spray the unit, braces or hinges with cleaning or degreasing sprays.
- scrub the unit, braces or hinges with brushes. **DO NOT** place unit or braces in autoclave sterilizer.
- attempt to sterilize the unit or braces
- clean the unit, braces or hinges using a laundry machine. Hand wash **ONLY**.
- dry unit, braces or hinges in machine dryer. Hang or line dry **ONLY**.

FREQUENCY:

Clean Unit anytime it becomes dirty or between uses with different patients.

Clean Brace anytime it becomes dirty or between uses on different patients.

Clean Hinges anytime they become dirty.