

LSO Heating & Cooling Back Brace

- 003-48 Base Model Brace
- 003-50 Base Model Brace +
Lateral Supports
- 003-51 Base Model Brace +
Lateral Supports +
Abdominal Support

- Adjustable, 25" - 68" waist
- Support for lumbar back



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

 This User's Manual is also available at www.thermazone.com

Individual pads, caps and braces work in conjunction with the ThermaZone Thermal Therapy technology and are interchangeable with the unit.

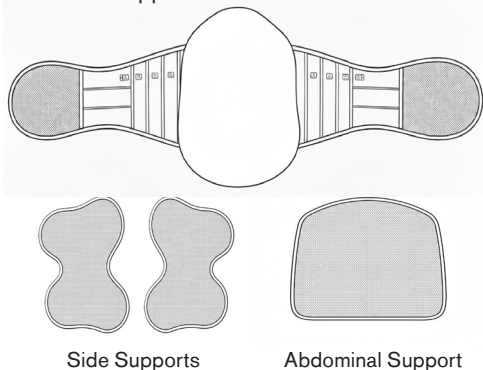


www.thermazone.com

1 REMOVE SUPPORTS

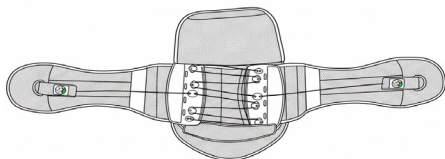
CAUTION: These application instructions are intended for the use of qualified professionals only. It is not recommended for patients to attempt to apply or adjust this brace unless otherwise instructed to do so by an orthopedic professional.

- Lay back brace flat with the interior side facing up.
- If included, remove side supports and abdominal support.



2 ADJUST BACK BRACE TO FIT

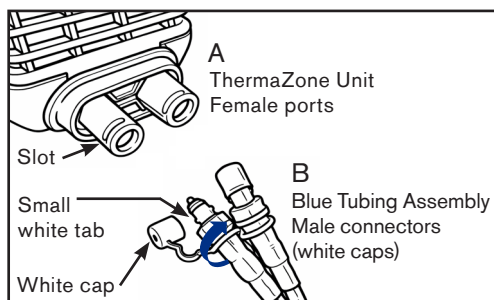
- Turn the brace over, laying it flat with the exterior side facing up. Open flap and remove both side belts.



- Size indications are marked on each side belt. Reattach the side belts at the waist size indicators as needed. Simply fold the excess fabric and tuck it under the back of the panel and reattach the flap.
- If included, reattach the side supports and abdominal support.

5 ATTACH BLUE TUBING TO THERMAZONE UNIT

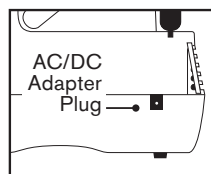
- Remove the white caps from the male connectors on the Blue Tubing Assembly (B).
- Attach the male connectors of the blue tubing (B) to the female ports on the front of the ThermaZone unit (A), by aligning the small white tabs with the slots on the ports and turning clockwise by 90°.



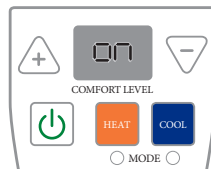
6 BEFORE POWERING ON

THE PAD MUST BE AT ROOM TEMPERATURE AND LAYING FLAT. ENSURE THE PAD CHAMBER IS UNRESTRICTED, FOLDED OR BLOCKED. BLOCKAGE COULD CAUSE THE PAD 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).

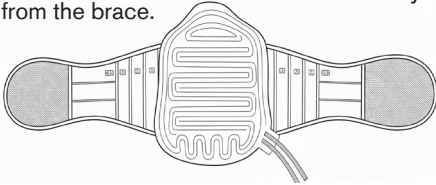


- Press the ON/OFF button (the fan and pump will start and the digital display will now say "ON").

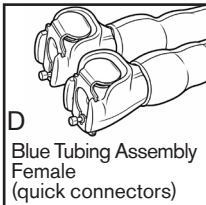
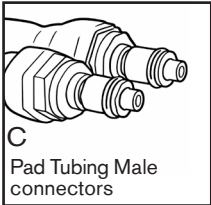


3 ATTACH WATER PAD TO BACK BRACE

- Lay back brace flat with the back support up. Position the pad Velcro side down in the center of the back support and press the Velcro tabs against the support to secure. Position the white ends of the tubes away from the brace.

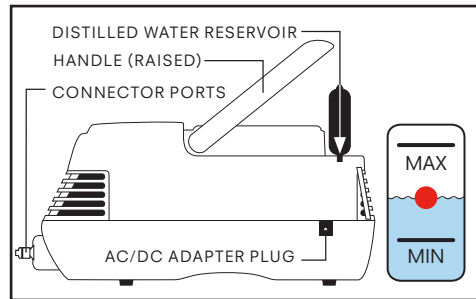


- Insert both male connectors of the Pad Tubing (C) into the female quick connectors of the Blue Tubing Assembly (D) until you feel the connectors click and lock in place.



4 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.



7 REFILL THE RESERVOIR

If this is the first time you are using the unit, or the first time you have installed a pad, the water from the reservoir will be pumped into the chambers of the pad during Step 6. At this time, you will need to refill your unit with distilled water.

- Power off the unit. Disconnect AC/DC adapter plug from unit.
- Repeat Step 4 to add DISTILLED WATER ONLY to the reservoir.
- Once water level settles between the "MIN" and "MAX" levels, connect the AC/DC adapter plug to the unit and power on the unit.
- Monitor the water fill level over the next minute to make sure the water level settles between the "MIN" and "MAX" lines.
- Repeat Step 7 until water level settles between the "MIN" and "MAX" lines.



**BE SURE WATER
LEVEL IS BETWEEN
MIN AND MAX !**

8 APPLY BACK BRACE & PAD

- Position the back brace and secure across your abdomen as directed by a medical professional.



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

Note: For best results when switching from Heat mode to Cool mode, remove the pad 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 UNIT

WARNING

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

- DO NOT use ThermaZone without a prescription. ThermaZone therapy units are classified by the FDA as class II medical devices and 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 pad while the unit is operating. Doing so may create excessive pressure between the pad 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 pads in an autoclave or attempt to sterilize.
- DO NOT operate unit in an operating room.
- DO NOT operate unit 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 people.
- 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 allow unit, accessories or cord to touch hot surfaces.
- 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 run the cord under carpeting or cover it with throw rugs, runners, or similar floor coverings.
- 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 the manufacturer.
- DO NOT consume water removed from the ThermaZone unit or pad.
- 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 pad if pain or discomfort from the temperature is experienced.
- Decreased sensation from the body's natural adaptation to heat may enable the user to tolerate heat that might otherwise cause a skin burn. Use caution when setting the unit to maximum heat levels and do not use for prolonged periods (20 minutes or longer) at these levels. Adjust temperature 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 the 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

READ THIS FIRST • SAVE THESE INSTRUCTIONS • IMPORTANT SAFEGUARDS

READ ALL INSTRUCTIONS CAREFULLY BEFORE USING THE THERMAL THERAPY UNIT

CAUTION

Avoid these potentially hazardous situations which, if not avoided, may result in minor or moderate injury, or damage to the ThermoZone unit or pad:

- DO NOT position the unit in such a way that it is difficult to operate the disconnection apparatus (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.
- Position the blue tubing and cord away from traffic areas and where it will not create a tripping hazard.
- DO NOT drop the unit or pad.
- DO NOT operate or store the unit or pad near pets.
- Before each use, make sure pad is not damaged, punctured or leaking.
- DO NOT puncture the pad.
- DO NOT refrigerate or freeze the pad.
- DO NOT microwave the pad.
- For Full Headcap users only: DO NOT USE if gel cap is punctured.
- 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 ThermoZone Instruction and Safety Manual Section 6 when using this unit.
- For Range of Motion (ROM) Knee Brace and LSO Heating & Cooling Back Brace users only: The application instructions for these braces are intended for the use of qualified professionals only. It is not recommended for patients to attempt to apply or adjust unless otherwise instructed to do so by an orthopedic professional. Any questions regarding further adjustment or frequency / duration of wear should be directed to your orthopedic professional who understands the individual condition for which these braces were prescribed.

INTENDED USE

ThermoZone 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. ThermoZone 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. ThermoZone 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.

TRANSPORT, STORAGE & DISPOSAL

Temperature: 4.5° -50° C

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 Preventive Maintenance instructions on page 13 of the Instruction and Safety Manual. "Storage" means non-use for over three months.

DO NOT 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: 16° C-29.4° C.

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 pad from the unit.

TO CLEAN:

Unit can be cleaned with a neutral disinfectant wipe.

Pads can be cleaned with a neutral disinfectant wipe, soap-water or mild detergent. Rinse pad with warm tap water and dry with a clean, lint-free cloth.

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

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

FOR LSO HEATING & COOLING BACK BRACE: Remove the rigid components. The rigid components can be wiped clean with a damp cloth. Soft goods can be hand washed in warm water with a mild detergent. Triple rinse and air dry. Avoid twisting the material to remove water.

DO NOT:

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

FREQUENCY:

Clean unit anytime it becomes dirty or between use with different patients.

Clean pad anytime it becomes dirty or between use on different patients.

THERMAZONE ALSO OFFERS OPTIONAL ACCESSORIES.



BLUE TUBING ASSEMBLY

One blue tubing assembly is included with every ThermaZone unit. It is also sold separately as a replacement component for lost or damaged tubing.

The blue tubing assembly is 6' feet in length and comes complete with quick connectors to attach orthopedic pads, full headcaps and braces to the ThermaZone unit.



AUTO POWER CORD

The ThermaZone Auto Power Cord allows the ThermaZone unit to be used in any motor vehicle equipped with a 12-Volt DC power outlet. Convenient to power ThermaZone unit when traveling.



CARRY & STORAGE BAG

The ThermaZone Duffel comes with a foam insert to secure and protect the ThermaZone unit. The main compartment has a U-shaped zipper opening for easy access. The compact and easy-to-carry duffel has a padded shoulder strap and is sized to hold the ThermaZone unit and a minimum of four additional pads.

The duffel has additional outside storage zipper pockets to hold accessories. A custom foam insert provides cut-outs to hold the bottle of distilled water required to operate ThermaZone.



HOSPITAL BED BRACKET

This metal, powder-coated bracket securely holds the ThermaZone unit and attaches to patients' hospital bed rail or standard 1" diameter Equipment IV pole. Made in the U.S.A.



IV POLE WITH BASKET

48" Equipment IV pole has a 1" diameter pole with 5-point low center-of-gravity base with heavy-duty locking casters. Includes a chrome-plated basket with mounting hardware. Made in the U.S.A.

Basket Dimensions: 12" wide X 5 3/4" deep X 8" tall

Hospital Bed Bracket (shown in photo) is sold separately.



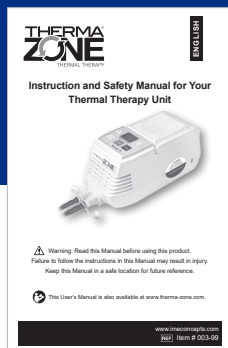
BEFORE YOU BEGIN:

Read Instruction and Safety Manual included with your ThermaZone unit.

The ThermaZone Instruction and Safety Manual is also available at www.thermazone.com.

STANDARD WARRANTY:

Limited 3-month warranty on ThermaZone pads, caps and braces. See Instruction and Safety Manual for full warranty details.



AVAILABLE THERMAL THERAPY PADS



**SHOULDER
PAD**



**BACK / HIP
PAD**



**KNEE /
ELBOW PAD**



**RANGE OF
MOTION (ROM)
KNEE BRACE**



**ANKLE
PAD**



**UNIVERSAL
PAD**



**FRONT & SIDE
HEAD PAD**



**OCCIPITAL
PAD**



**FULL HEAD
CAP**



EYE PAD



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