

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:

- 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 pad while the unit is being operated. 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.
- 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 pad 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.

CAUTION

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

- 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 pads.
- DO NOT operate or store the unit or pads near pets.
- Pads are NOT sterilized. DO NOT place Single Patient Use Pads in an autoclave or attempt to sterilize.
- Before each use, make sure pads are not damaged, punctured or leaking.
- DO NOT puncture the pads.
- 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.
- Single Patient Use Pads are designed for up to 4 weeks of use.
- Single Patient Use Pads are only designed for use by one patient.

CONTRAINDICATIONS

Contraindications for THERMOTHERAPY

Therapy should NOT be used in patients without medical supervision:

- If the patients have decreased skin sensitivity or are insensitive to heat;
- 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.

Contraindications for CRYOTHERAPY

Therapy should NOT be used in patients without medical supervision:

- If the patients have decreased skin sensitivity or are insensitive to cold; and/or
- If the patients are children, elderly, or incapacitated;

Therapy should NOT be used in patients:

- Who have Raynaud's disease; and/or
- Poor circulation



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Quick-Start Guide for Your Thermal Therapy Unit



This Quick-Start Guide is not a substitute for the ThermaZone Instruction and Safety Manual. Review the Instruction and Safety Manual prior to using this device.



The Quick Start user's Manual is also available at www.therma-zone.com.

www.imeconcepts.com

REF Item # 003-99

Easy to Set-Up Easy to Use

Contents:

- (1) ThermaZone Unit
- (1) Tubing Assembly
- (1) AC/DC Adapter / Power Cord
- (1) Instruction Manual

Note: Your choice of pad(s) are packaged separately and included with the shipment.

ThermaZone Unit



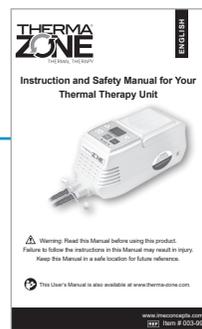
Tubing Assembly



AC/DC Adapter Power Cord



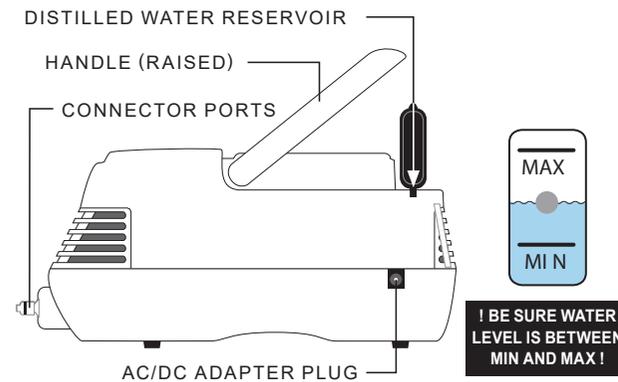
Instruction and Safety Manual



This Quick-Start Guide is not a substitute for the ThermaZone Instruction and Safety Manual. Review the Instruction and Safety Manual prior to using this unit.

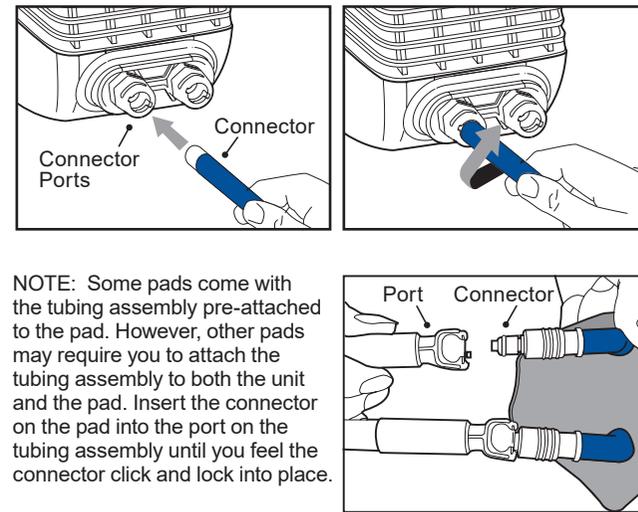
1 Fill the reservoir with distilled water

- 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.



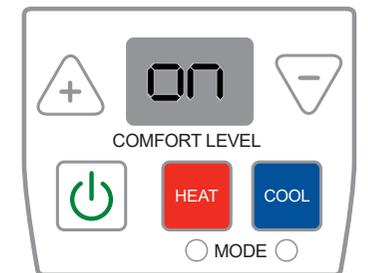
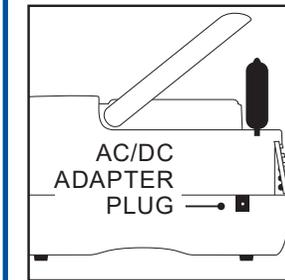
2 Connect a pad

- 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.



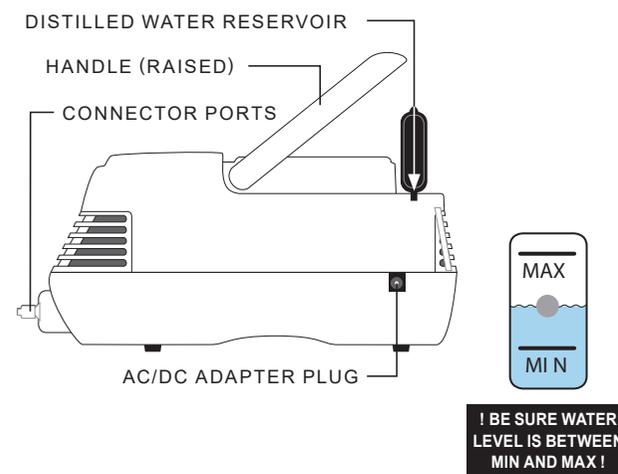
3 Power on your unit

- 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

- Water poured in the reservoir in Step 1 has been pumped into the relief pad.
- Slowly pour additional **DISTILLED WATER** into the reservoir while the unit is still on.
- Monitor water fill level over the next minute to make sure the water level settles between the “MIN” and “MAX” lines.

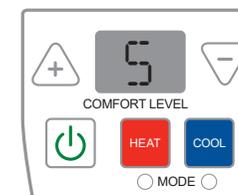


5 Begin thermal therapy

- Power on the unit – on/off
- Select timer mode (optional)
- Select HEAT or COOL mode
- Select comfort level (1-10)

To adjust the temperature during therapy push the + or – button to increase or decrease temperature.

To check the remaining time on the timer, push the heat or cool button and remaining time will appear in the control window for 5 seconds and then return the comfort level setting.



6 Apply your pad

- Choose the appropriate pad.
- Each pad has hook and loop closures with elastic straps for a comfortable fit.
- The straps should be snug enough to hold the pad in place, yet loose enough so that there is no discomfort.
- Sit back and relax.

