

Instruction and Safety Manual for Your Thermal Therapy Unit



Warning: Read this Manual before using this product.
Failure to follow the instructions in this Manual may result in injury.
Keep this Manual in a safe location for future reference.

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. [Instruction Manual.
- 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.

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CAUTION

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

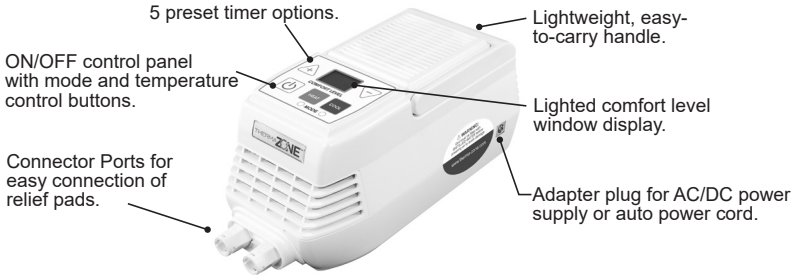
Therapy should NOT be used in patients:

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

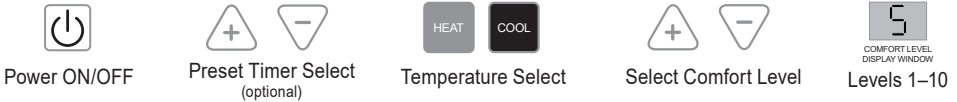
THERMAZONE INTENDED USE

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.

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.



CONTROL PANEL



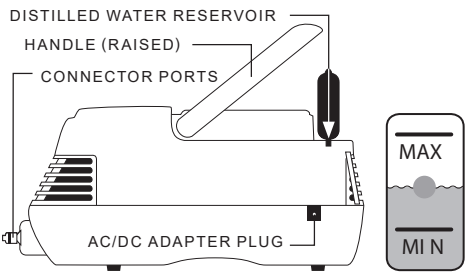
GETTING STARTED

We recommend you setup and familiarize yourself with operating the ThermaZone unit before you need to use it. Open the carton and remove the packaging material around the unit. Place the unit on a solid, flat surface. Ensure that the top, front and back vents on your unit have six inches of space surrounding them.

NOTE: Water from your tap or water in a bottle labeled as Spring or Purified water is not the same as distilled water. Tap water, spring water, purified water and even water filtered in your home filtration system may still contain many types of suspended pollutants, microscopic chemicals, toxins and other contaminants. Distilled water is necessary to prevent any damage caused by minerals present in tap water and most bottled waters.

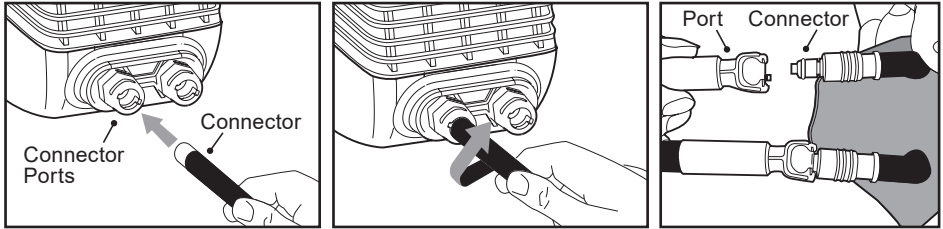
1 FILL THE RESERVOIR WITH DISTILLED WATER

- 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 RELIEF PAD

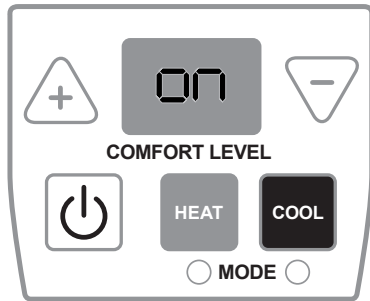
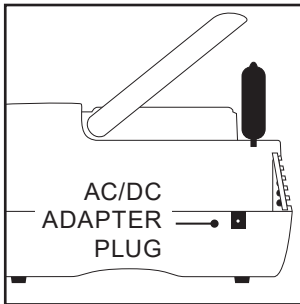
- Remove the white caps from the end of the white connectors on the tubing assembly.
- Attach the white connectors to the connector ports on the front of the unit, by aligning the tabs and turning clockwise.



NOTE: Some pads come with the tubing assembly pre-attached to the pad. However, other pads may require you to attach the tubing assembly to both the unit and the pad. Insert the connector on the pad into the port on the tubing assembly until you feel the connector click and lock into place.

3 POWER ON YOUR THERMAZONE 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

If this is the first time you are using the unit, or the first time you have connected a relief pad, the water from the reservoir will be pumped into the chambers of the pad during Step 3. At this time, you will need to refill your unit with distilled water.

- Pour additional **distilled water** into the reservoir.
- Monitor water fill level over the next minute to make sure the water level settles between the "MIN" and "MAX" lines.
- Close the black rubber fill cap.



! BE SURE WATER LEVEL IS BETWEEN MIN AND MAX !

5 SELECT PRESET TIMER MODE (OPTIONAL)

Your unit comes equipped with 5 Preset Timer Modes. If you do not want to select a Preset Timer Mode for your current therapy session, bypass Step 5 and move onto Step 6. If you do want to select a Preset Timer Mode you must select the timer option before you select the temperature mode.

Be sure to review the General Precautions in the ThermaZone Instruction and Safety Manual Section 6 before selecting a Temperature Mode and Comfort Level.

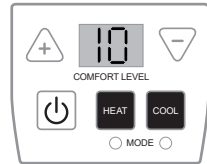
Push the  button to set the timer.

There are five preset timer options.

The option will be displayed in the comfort level window.

Push the button up to five times to get to desired option.

The preset options are as follows:



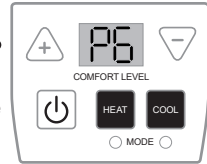
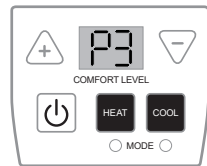
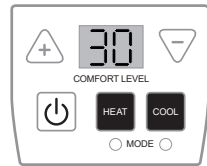
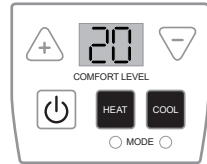
Preset 1: Window displays "10"
10 minutes in selected mode, then unit turns off automatically.

Preset 2: Window displays "20"
20 minutes in selected mode, then unit turns off automatically.

Preset 3: Window displays "30"
30 minutes in selected mode, then unit turns off automatically.

Preset 4: Window displays "P3"
30 minutes in selected mode, then 30 minutes in Program Pause (PP)* mode. (Repeats continuously until unit is manually turned off)

Preset 5: Window displays "P6"
30 minutes in selected mode, then 60 minutes in Program Pause (PP)* mode. (Repeats continuously until unit is manually turned off)



*In Program Pause ("PP") mode, your unit will remain powered on. However, no power will be applied to the heating/cooling component of the unit and the water will begin returning to the ambient temperature. You will need to manually power off the unit at the conclusion of your therapy.

SPECIAL NOTES ON TIMER OPTIONS

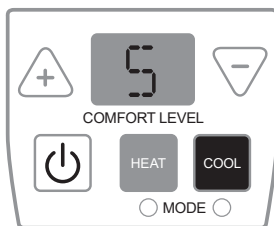
Presets 4 and 5 are automatic settings that provide continuous therapy until you **manually** power off the unit or switch modes. The unit counts down and automatically restarts in the original selected mode.

Note: You must set the timer before you select the temperature mode if you want to use any of the preset timers.

Once you have selected the temperature mode you can check the remaining time on the timer by pushing the currently selected "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 CHOOSE YOUR DESIRED TEMPERATURE MODE AND COMFORT LEVEL

HEAT: To use the heating function, press the red “HEAT” button on the control panel. Adjust the temperature by pushing the plus (+) and minus (–) buttons. Temperature level 1 will provide minimum heat, and temperature level 10 will provide maximum heat. We suggest that you start the unit at level 5 and make adjustments depending on your comfort level.



COOL: To use the cooling function, press the blue “COOL” button on the control panel. You can adjust the temperature by pushing the plus (+) and minus (–) buttons. Temperature level 1 will provide minimum cooling effect while temperature level 10 will provide the maximum cooling effect.

Note: Temperature levels can vary based on the ambient temperature.

As a safety precaution the pad temperature will not rise above 125° F (51.7° C), the unit has a thermal cut-off to prevent overheating. We suggest that you start the device at level 5 and make adjustments depending on your comfort level.

FOR BEST RESULTS: Once you have set up your unit and are ready to begin therapy, you will achieve the best results if you follow these simple tips:

IF APPLYING **COOL** THERAPY:

Select and attach your desired relief pad and turn on your unit. Set the cool comfort level to ‘10’ and leave the pad open on a flat surface for 10 minutes before applying to your body. This will enable the unit to get cool without fighting the body’s natural temperature of 98° F (36.7° C).

IF APPLYING **HEAT** THERAPY:

Select and attach your desired relief pad and turn on your unit. Choose your desired comfort level and place the pad on the body to begin therapy immediately. Your body heat will actually help the unit reach your desired heat temperature more rapidly.

IF GOING FROM **HEAT** THERAPY TO **COOL** THERAPY:

To initiate contrast therapy from the HEAT mode, it is recommended that you remove the pad from the body and leave flat on a surface for approximately 10 minutes. Simply push the COOL button and the device will begin to count down (from 60) for 3 minutes and then begin in the alternate mode. Removing the pad from the body will enable the cool temperatures to be achieved more rapidly.

IF GOING FROM **COOL** THERAPY TO **HEAT** THERAPY:

To initiate contrast therapy from the COOL mode, it is **not** necessary to remove the pad from the body. Simply push the HEAT button and the device will begin to count down (from 60) for 3 minutes and then begin the alternate mode.

GENERAL PRECAUTIONS:

Tolerance to thermal therapy differs according to tissue type (body part and tissue density), temperature, and exposure time. This is patient specific and each patient must exercise caution and judgment when using the ThermaZone and cease use if therapy becomes uncomfortable or skin damage is noticed or suspected.

⚠ WARNING: 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.

⚠ WARNING: Decreased sensation from the body's natural adaptation to heat may cause you to tolerate a 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)

⚠ WARNING: ThermaZone pads are intended to be used without any additional ointments, crèmes, 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.

The following recommendations may help prevent thermal injury to specific tissues*:

Temperature (C°) Max	Temperature (F°) Max	Maximum Suggested Time
40	104	Safe for prolonged use (2 hours or longer)
45	113	30 minutes
46	115	20 minutes
47>	116	⚠ WARNING: May cause skin burn if used greater than 10 minutes. Recommended: 1) Use of towel or thin barrier between the skin and pad to protect the skin. 2) Frequently monitor skin to avoid tissue damage if maximum temperature settings are desired.

*Data on file

ThermaZone HEAT Mode Temperatures**

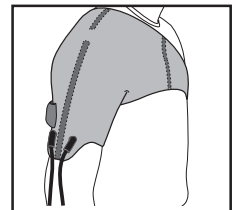
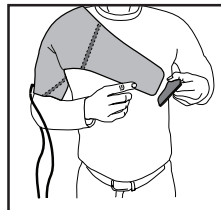
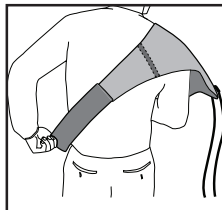
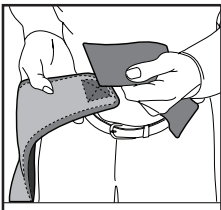
Comfort Level	1	2	3	4	5	6	7	8	9	10
Temperature (C°)	24.4	28.3	31.1	33.9	36.7	39.4	42.8	46.1	49.4	51.7
Temperature (F°)	76	83	88	93	98	103	109	115	121	125

**Temperatures represented are from the smallest ThermaZone pad and may be slightly lower on larger pads.

7 APPLY YOUR 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 without discomfort. Place the pad in a comfortable position so it does not move around easily. Pads can be applied to intact skin, used over clothing or over a thin barrier.

NOTE: When pads are applied directly to skin, the temperature will feel more intense.





EXAMPLE SHOWN FROM "SHOULDER PAD" INSTRUCTION MANUAL.
EACH INDIVIDUAL RELIEF PAD COMES WITH A FULL SET OF INSTRUCTIONS.

8 SIT BACK AND RELAX

You are now ready to enjoy the comfort and convenience of your thermal therapy unit. If the therapy becomes uncomfortable, remove the pad immediately and adjust the temperature level. Allow the pad temperature to reset for 10–15 minutes before reapplying. To adjust temperature during therapy, push the (+) or (–) buttons to increase or decrease the temperature. To check the remaining time in a preset timer mode, push the currently selected “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.

9 ADDITIONAL OPERATING INSTRUCTIONS

AFTER INITIAL USE – SAME PAD: After following the  Quick-Start Guide, or the 8 steps in this manual for initial setup of the unit, each subsequent use with the SAME PAD is a simple 6 step procedure: 1) Plug in the unit, 2) monitor the water level indicator to make sure the current distilled water level is between “MIN” and “MAX,” 3) press the ON/OFF  button to turn the unit on, 4) set timer (optional), 5) set your desired temperature level, 6) apply the pad to the appropriate area requiring relief.

CHANGING TEMPERATURE MODES/CONTRAST THERAPY: Some users find both heat and cool treatments beneficial in relieving their pain. Changing the cooling and heating modes during the same use requires a 3 minute delay to prevent damage to the components of the unit. When the unit is in either mode, and you press the button on the control panel corresponding to the other mode, a timer will immediately be displayed on the control panel that will count down from 60 to 0. Once the timer reaches zero, the other mode will automatically start. At this time, you can select the temperature level you prefer and continue using as previously directed. Refer to Step 6 for best results when using contrast therapy.

DURING USE: WE DO NOT RECOMMEND USING THE UNIT FOR LONGER THAN 30 MINUTES AT A TIME. After 30 minutes, take a break and then reapply. If the therapy becomes uncomfortable, remove the pad and adjust the temperature level. Allow the pad temperature to reset for 10–15 minutes before reapplying. For safety reasons, the pad is not meant to be worn while sleeping, bathing or showering. Please read the safety instructions thoroughly before using the unit (see page 2).

ENDING THERAPY: Once your surface therapy is complete, or if you would like to discontinue using the unit, press the on/off button and allow the pad to return to room temperature before storing it. Always unplug the unit after each use.

THERMAL THERAPY PADS

Individual pads work in conjunction with the ThermaZone Therapy technology and are interchangeable with the unit. Pads are made of a soft, flexible material for maximum comfort.

Once the unit is plugged in, the power is turned on, the pad is attached, you've selected your desired time mode, and you've selected your desired temperature, touch the inside of the pad (the channels will be showing) with your hand to ensure the temperature is not too warm or cold. When you are satisfied with the pad temperature, fit the desired pad per the instructions that accompanied the pad. The straps should be snug enough to hold the pad in place, yet loose enough so that there is no discomfort. The goal is to have the pad in a comfortable position so it does not move around easily.

FRONT AND SIDE HEAD PAD



EYE PAD



OCCIPITAL (BACK OF HEAD) PAD



UNIVERSAL PAD



SHOULDER PAD



BACK PAD



KNEE PAD/ELBOW PAD



ANKLE PAD



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 Preventive 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 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 pads with warm tap water and dry with a clean, lint-free cloth.

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 ThermaZone Unit or Pads:

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 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 uses with different patients.

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

Clean Single Patient Use Pad anytime it becomes dirty.

SERVICE LIFE

As long as the Unit is operated and maintained in accordance with this ThermaZone Safety & Instruction Manual, the service life can last up to three (3) years. Service life is not to be confused with the Standard Warranty.

TROUBLESHOOTING

FAIL SAFE SWITCH FUNCTION: If you find that the cooling or heating system is not working properly on your unit, it is possible that the safety switch has been activated because the unit was getting too hot. This may be caused by a blockage of the air intake vent that is used to cool the pump. If this occurs, turn the unit off and make sure that there are no objects (e.g. clothing) within six inches of the unit. The switch will automatically reset after a few minutes. Upon resuming use, ensure that the power of the unit is set to a lower level temporarily (level 5). NEVER use a power adapter other than the one provided with the unit.

ENSURE MAXIMUM HEAT OR COOL: Some users have noticed that wearing the pad too tightly can reduce the maximum heat and cool that the unit can achieve. If this happens, try loosening the pad and resuming use.

IF UNIT IS NOT COOLING: Check the water level and lay the pad flat. Make sure the water is flowing properly into the pad and the pad channels are firm to the touch.

OVERFILLING THE RESERVOIR: When filling the unit with distilled water, make sure to pour water into the water reservoir portion of the unit only (under the rubber cap). If too much water is poured in at once, it may not drain properly into the unit's reservoir. If this happens, either tip the unit to one side or soak the excess water up with a towel to expose the air hole. Then, resume filling the unit with water.

ADAPTER MALFUNCTION: If the AC / DC adapter does not turn on, the adapter could be defective or overused.*

PAD DISCOLORATION: Pads may become discolored over time. Discoloration is due to the water running through a small portion of copper tubing within the device, which causes the pad to become discolored over extended periods of time. Discoloration is not bacteria, fungi, or algae, and is not harmful to the user.

POWER FUSE FAILURE: There is a possibility that, over time, the power fuse to your unit may need to be replaced.*

YOU SHOULD NOT ATTEMPT TO FIX THE UNIT YOURSELF OR ALLOW SOMEONE TO FIX IT. ATTEMPTING TO REPAIR THE UNIT YOURSELF WILL RESULT IN AN INVALID WARRANTY.

PREVENTIVE MAINTENANCE

FLUSHING THE THERMAZONE SYSTEM:

Under normal use, the internal water can become contaminated with dust and water precipitant. This is a normal occurrence and periodic flushing of the system may help alleviate potential clogging of the water reservoir and internal plumbing system. Flushing of the system once a month is adequate, but heavy use may require more frequent flushing.

PREPARING THE SYSTEM TO BE FLUSHED:

Follow steps 1-3 from the GETTING STARTED section of this guide.

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

After steps 1-3 are complete, the ThermaZone system is ready to begin the flushing process.

NOTE:

- Do not apply heat or cooling during the flushing process
- Fill the system with only distilled water
- Ensure the system is properly grounded

STEP 4: DISCONNECT TUBE

- Turn the power off but leave the unit plugged in. With the unit facing you, disconnect the blue tube connected to the right-side connector port.



DISCONNECT TUBE

STEP 5: OPEN VALVE

- Please note, the blue tubing connector contains a spring-loaded valve. The valve will need to be pressed in during the flushing process. Simply press the valve against the flat surface of a sink or basin to open valve so that it will drain.



SPRING-LOADED VALVE



PRESS THE VALVE AGAINST A FLAT SURFACE TO OPEN IT.

STEP 6: SYSTEM FLUSH

- You are now ready to flush the system. With the connector pressed against the surface, press the ON/OFF button to turn on the ThermaZone unit. The pump and fan will begin to operate and the display window will read ON. Once the pump begins to operate, water will begin flowing out of the depressed connector. When full, the reservoir holds approximately 60 mls of distilled water and the pump should expel the water within 1 minute.

WARNING: Do not consume water removed from the ThermaZone device.

- After the water stops flowing, release the valve and press ON/OFF to turn the power off. At the back of the unit, the red ball within the reservoir should be at or below the MIN level indicator.
- It is advisable to flush the system multiple times.

STEP 7: REATTACH TUBE

- Once the flushing process is complete, attach the unattached pad/tubing connector to the right port connector, and refill the reservoir with distilled water. The system is ready for use.

STANDARD WARRANTY

ThermaZone Unit & Pads

Limited 1 YEAR WARRANTY on the ThermaZone Thermal Therapy Unit

Limited 3 Month WARRANTY on ThermaZone Pads

Innovative Medical Equipment, LLC warrants the ThermaZone Unit, if properly used as stated above, will be free from defects in material and workmanship for a period of (6) months after the date the ThermaZone unit is purchased. Innovative Medical Equipment, LLC warrants the ThermaZone pads, if properly used as stated above, will be free from defects in material and workmanship for a period of (3) months after the date the ThermaZone Pad is purchased.

Innovative Medical Equipment, LLC does not authorize anyone, including, but not limited to, retailers, the subsequent consumer purchaser of this product from a retailer or remote purchaser, to obligate Innovative Medical Equipment, LLC in any way beyond the terms set forth herein.

This warranty does not cover damage caused by misuse or abuse, accident; the attachment of unauthorized accessories; alteration of the unit; improper installation; unauthorized repairs or modifications; improper use of electrical/ power supply; loss of power; dropped unit; malfunction or damage of an operating part from failure to provide manufacturer's recommended maintenance, transportation damage; theft; neglect; vandalism; or environmental conditions; loss of use during the period the product is at the repair facility or otherwise awaiting parts or repair; or any other condition whatsoever that are beyond the control of Innovative Medical Equipment, LLC.


This warranty is effective only if the product is operated in the country from which the product was purchased. If the product is modified in any way, including but not limited to, altering the power supply, it will not be covered under this warranty.

THIS WARRANTY PROVIDED HEREIN SHALL BE THE SOLE AND EXCLUSIVE WARRANTY. THERE SHALL BE NO OTHER WARRANTIES EXPRESSED OR IMPLIED INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS OR ANY OTHER OBLIGATION ON THE PART OF INNOVATIVE MEDICAL EQUIPMENT, LLC WITH RESPECT TO PRODUCTS COVERED BY THIS WARRANTY. INNOVATIVE MEDICAL EQUIPMENT, LLC SHALL HAVE NO LIABILITY FOR ANY INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES. IN NO EVENT SHALL THIS WARRANTY REQUIRE MORE THAN THE REPAIR OR REPLACEMENT OF ANY PART OR PARTS WHICH ARE FOUND TO BE DEFECTIVE WITHIN THE EFFECTIVE PERIOD OF THE WARRANTY. NO REFUND WILL BE GIVEN. IF REPLACEMENT PARTS ARE DEFECTIVE MATERIALS ARE NOT AVAILABLE, INNOVATIVE MEDICAL EQUIPMENT RESERVES THE RIGHTS TO MAKE PRODUCT SUBSTITUTIONS IN LIEU OF REPAIR OR REPLACEMENT. UNLESS OTHERWISE AGREED TO IN WRITING BY INNOVATIVE MEDICAL EQUIPMENT, LLC, THIS LIMITED WARRANTY SHALL APPLY ONLY TO THE ORIGINAL PURCHASER OF THE THERMAZONE UNIT AND PADS AND IS NON-TRANSFERABLE.

This warranty does not extend to the purchase of opened, used, repaired, repackaged, and/or resealed products, including but not limited to sale of such products on internet auction sites and/or sale of such products by surplus or bulk re-sellers. Any and all warranties or guarantees shall immediately cease or terminate as to any products or part thereof which are repaired, replaced, altered, or modified, without the prior express and written consent of Innovative Medical Equipment, LLC. This warranty provides you with specific legal rights. Due to individual country regulations, some of the above limitations and exclusions may not apply to you.

SAFETY & INSTRUCTION LABEL ON THE UNIT (SEE BOTTOM)

REF 003-99

 Before using device, read Instruction Manual and Quick-Start Guide for important instructions and safety information.

INPUT: 12V  , 6A  Use ThermaZone with power supply Specified by Manufacturer

  PADS  IP22











WARNING

- UNDER PENALTY OF LAW DO NOT REMOVE THIS TAG
- READ THE INSTRUCTION AND SAFETY MANUAL BEFORE USING
- PRODUCT SHOULD NOT BE USED BY PERSONS INSENSITIVE TO HEAT
- FAILURE TO FOLLOW THE INSTRUCTIONS AND SAFETY MANUAL MAY RESULT IN THE RISK OF FIRE AND INJURY - INCLUDING DEATH
- BURNS CAN RESULT FROM IMPROPER USE
- NEVER USE WHILE SLEEPING, UNDER BLANKETS OR OTHER MATERIALS
- DO NOT USE FOR MORE THAN 30 MINUTES AT A TIME
- DO NOT USE NEAR WATER OR WHEN WET
- REMOVE IF TEMPERATURE BECOMES UNCOMFORTABLE
- NOT TO BE USED BY CHILDREN WITHOUT MEDICAL SUPERVISION
- DO NOT USE THIS PRODUCT AS A SUBSTITUTE FOR MEDICAL ATTENTION.

U.S. Patent No. 9,283,109

203-102v5

GENERAL SYMBOLS & SAFETY SIGNS

Symbol	Title
	Direct Current
	Alternating Current
	Warning/Caution
	Operating Instructions
	Type BF Applied Part. Classification required for medical devices that come in direct contact with the patient.
	Manufacturer
	Reference symbol for specific product or catalog number.
	Type of power outlet required to properly operate the device.
IP 22	Protection against solid objects greater than 12.5mm and against drops of liquid falling for short periods of time.
	Class II Equipment
	Waste Electrical and Electronic Equipment (WEEE) Symbol Product owners should refer to their specific state and government regulatory guidelines for proper disposal.

CAUTION: ThermaZone therapy units are classified by the FDA as class II medical devices that must be prescribed by a Physician or Licensed Healthcare Professional.

THERMA[®]
ZONE
THERMAL THERAPY

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#103-32 v7 04/2020