

# PT9 Precision Chiller



## User Manual

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## 2 INTRODUCTION

Read the entire guide before attempting to connect or operate this product. Keep this guide for future reference.

The PT9 is a solid-state thermoelectric heating and cooling system. It is designed to maintain a set temperature of the working fluid that is circulated between the thermal management application and itself.

This guide provides the information required to setup and use the PT9 precision temperature control system.

### 2.1 How to Contact ThermoTek Inc.

If you have questions about the PT9 system, or require service, please contact ThermoTek Inc. at:






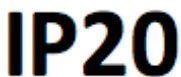
1200 Lakeside Parkway, #200

Flower Mound, TX 75028





Tel: 972-874-4949 (8:00am – 5:00 pm CT)

ThermoTek Website: [www.thermotekusa.com](http://www.thermotekusa.com)

### 2.2 Explanation of Symbols

|   |  |
|---|--|
|  | <b>IMPORTANT:</b> Read Instructions before Use<br>Before operating the device, please read the entire instruction guide. Keep the guide available for future reference.        |
|  | <b>CAUTION.</b> Consult user manual to determine potential hazards prior to operating the device.  |
|  | Manufacturer's Part Number   |
|  | Device Serial Number   |
|  | AC Power   |
|  | Ingress Protection Of the Device. Solid Particles > 12.5 mm will be protected from access to hazardous parts. The device does not have any ingress protection against liquids. |



|   |   |
|---|---|
|   | Do NOT Dispose with General Household Waste<br>Please consult local government / city laws on acceptable method of disposal of electro-mechanical systems in compliance with the Waste Electric and Electronic Equipment Directive (WEEE) 2001/96/EC. |
|  | Device Manufacturing location   |
|  | Device Manufacture Date Code  |
|  | RoHS Compliant  |

## 2.3 EMC Precautions

The PT9 precision temperature control system is an Electrical Equipment that requires installation precautions regarding electromagnetic compatibility (EMC). Installation is to be completed as specified in the Technical Information Section.

## 2.4 Glossary of Terms:

|                                |  |
|--------------------------------|--|
| <b>Arterial Dysregulation:</b> | A physiological impairment of the arteries.  |
| <b>Arteriosclerosis:</b>       | A chronic disease in which thickening, hardening and loss of elasticity of the arterial walls result in impaired blood circulation.  |
| <b>Constant Compression:</b>   | Continuous, regulated and compressive force applied to the skin surface for the manipulation of subcutaneous compartment pressures.  |
| <b>Carcinoma Metastasis:</b>   | A malignant new growth having potential to spread.   |
| <b>Contraindication:</b>       | A reason that makes it inadvisable to prescribe a particular drug or employ a particular procedure or treatment to a patient.  |
| <b>Contrast:</b>               | A pain management therapy consisting of repeatedly heating and cooling of the subcutaneous muscle tissue.  |
| <b>Edema:</b>                  | An accumulation of an excessive amount of watery fluid or blood in cells, tissues or serous cavities of the body.  |
| <b>Erysipelas:</b>             | An acute superficial form of cellulitis; a spreading inflammation of subcutaneous or connective tissue.  |
| <b>Hypertonia:</b>             | Extreme tension of the muscles or arteries.  |
| <b>Non-Ambulatory:</b>         | To be in a resting or immobile state; not moving.  |
| <b>Phlebothrombosis:</b>       | Thrombosis of a vein without prior inflammation of the vein; associated with sluggish blood flow or with rapid coagulation of the blood. Usually caused by prolonged bed-rest, pregnancy or surgery. |
| <b>Pulsating Compression:</b>  | Also called intermittent or undulating compression, is the manipulation of subcutaneous compartment pressures in a high-to-low repeating cycle.  |
| <b>Stasis Dermatitis:</b>      | A common inflammatory skin disease that occurs on the lower extremities in patients with chronic venous insufficiency with venous hypertension.  |
| <b>Thrombophlebitis:</b>       | An acute inflammatory reaction of a vein due to thrombus presence.   |

|                       |   |
|-----------------------|---|
| <b>Thrombus:</b>      | A clot formed in a blood vessel or in a chamber of the heart.   |
| <b>Vein Ligation:</b> | The presence of veins that have been surgically rejoined.   |
| <b>Venous Stasis:</b> | Slowing of blood flow typically caused by venous valve failure or the existence of clots in the vein. |

## 2.5 Contraindications for Pneumatic Compression Therapy:

*The patient should not use the PT9 therapy system if the patient is suspected of or observed to have any of the following:*

- Presumptive evidence of congestive heart failure,
- Pre-existing DVT condition,
- Deep acute venal thrombosis (phlebothrombosis),
- Inflammatory phlebitis process,
- Episodes of pulmonary embolism,
- Pulmonary edema,
- Acute inflammations of the veins (thrombophlebitis),
- Decompensated cardiac insufficiency,
- Arterial dysregulation,
- Erysipelas,
- Carcinoma and carcinoma metastasis in the affected extremity,
- Decompensated hypertonia,
- Acute inflammatory skin diseases or infection,
- Venous or arterial occlusive disease,
- Venous or lymphatic return is undesirable,
- Poor peripheral circulation,
- Severe arteriosclerosis or active infection.

## 2.6 Contraindications for Heat and Cold Therapy:

*The following patients must use the PT9 therapy system for temperature contact therapy under the supervision of a physician if they are:*

- Individuals with extremities not sensitive to pain,
- Individuals with extremely low blood pressure,
- Individuals with Raynaud's disease,
- Hypersensitivity to cold,
- Children,
- Diabetics,
- Incapacitated patients,
- Individuals with decreased skin sensitivity,
- Individuals with poor circulation,
- Patients with vein ligation or recent skin grafts.

## 2.7 Precautions:

*When using the PT9 system, basic safety precautions should always be followed to reduce the risk of fire, electric shock and personal injury. Please read the entire manual carefully before trying to operate the unit.*

- ⚠ Never push objects of any kind into the therapy unit through the air filter or frame.
- ⚠ Never spill liquid of any kind into the therapy unit.
- ⚠ Do not overfill the reservoir of the unit.
- ⚠ If the unit gets wet, unplug the unit from the wall and allow the unit to dry before use.
- ⚠ The unit must be operated with the supplied power cord and plugged into a 3-prong grounded outlet.
- ⚠ Do not operate the unit if it has any noticeable or physical damage or is leaking fluid.
- ⚠ Do not operate the unit with a damaged or frayed power cord.
- ⚠ The therapy unit is not intended to be used in a wet environment or when relative humidity is greater than 60%.
- ⚠ Do not spray the unit with any water solvents or cleaners.
- ⚠ Do not drop the therapy unit or cause impact to the unit.
- ⚠ Do not pull or otherwise put undue stress on the hoses.
- ⚠ Do not use this device without the supplied air filter.
- ⚠ Do not use near equipment that generates electromagnetic or other interferences as this may be harmful to the therapy unit.
- ⚠ Do not smoke while using therapy wraps or use wraps by an open flame.
- ⚠ Do not touch the heat sink fins on the sides of the unit during or immediately after operation.
- ⚠ Do not stick a finger or any other foreign objects into the reservoir.
- ⚠ Do not drink or ingest the coolant.

## 2.8 Cautions:

- ⚠ Follow the prescribed instructions of your physician for therapy settings, area, frequency and duration of treatment.
- ⚠ Prolonged exposure to cold has a potential to cause injury to tissue. There is a potential for cold injury even when providing cooling within the prescribed treatment settings.
- ⚠ If unusual swelling, skin discoloration or discomfort occurs, immediately discontinue use of the PT9 unit and consult a healthcare professional.
- ⚠ Use only ThermoTek approved therapy wraps.
- ⚠ Therapy wraps are non-sterile unless specifically labeled as sterile.
- ⚠ Non-sterile therapy wraps should never be directly applied to an open wound or breached skin.
- ⚠ Use only sterile wraps over wounds or breaks in the skin.
- ⚠ Do not attempt to sterilize this device by any means.
- ⚠ A licensed healthcare practitioner must select the correct temperature setting for hot or cold therapy use.
- ⚠ Patients vary in sensitivity to cold. Make a regular check of the patient's temperature once established.

- ⚠ Therapy wraps are to be fitted initially by a healthcare professional that is familiar with the purpose for which the wraps are used.
- ⚠ Do not apply the therapy wrap so tightly as to restrict blood or fluid flow.
- ⚠ A healthcare professional is responsible for providing wearing instructions and precautions to other healthcare professionals, care providers involved in the patient's care, and the patient.
- ⚠ If it is appropriate for the patient to use the wrap with therapy unit at home, the healthcare provider must provide adequate and appropriate instructions for use to the patient.
- ⚠ The healthcare provider must monitor the patient's use of the therapy unit, assuring appropriate use and application of all therapies.
- ⚠ Disposable therapy wraps are designed for single patient use only and may only be used on the same patient for the length of treatment.
- ⚠ The therapy wrap should be periodically cleaned if it is used on the same patient for an extended period of time.
- ⚠ Clean exposed surfaces of the therapy wrap with either a mild anti-bacterial soap and water solution or an isopropyl alcohol and water solution. Do not use bleach on therapy wraps.
- ⚠ Dressings used under the therapy wrap should be applied lightly.
- ⚠ Do not use pins to secure the therapy wraps or hoses.
- ⚠ Do not allow the therapy wrap or hoses to contact sharp objects that could puncture it.
- ⚠ All therapies using compression must be turned OFF when the unit is not in use or the wrap is removed from the patient for prolonged periods or for repositioning of the wrap.
- ⚠ Immediately stop compression therapy if you experience any sense of discomfort, numbness or tingling of the limb.
- ⚠ Use only approved coolant in the PT9 unit.
- ⚠ Slots and openings in the cabinet are provided for ventilation to protect the unit from overheating. These openings must not be blocked or covered at any time except by the supplied air filter.
- ⚠ Observe all warning labels. Never remove the warning labels.

## 2.9 Indications for Use:

The PT9 therapy system is designed to provide fluid heating, cooling and compression as specified in this manual. If the system is used in a manner other than as specified, its operation or the safety protection may be impaired.

### ***Indications for Use:***

- Treatment of disorders associated with vascular or lymphatic insufficiency such as Chronic Venous Insufficiency (CVI), venous stasis ulcers, post-mastectomy edema and chronic lymphedema.
- Reduction of edema associated with soft tissue injuries such as burns, postoperative edema and ligament sprains.
- Localized thermal therapy (hot or cold) for post-traumatic and post-surgical medical and/or surgical conditions.

## 2.10 Unpacking Instructions

When the PT9 system arrives, it is important that you carefully unpack the contents and ensure that you have all the equipment required for operation. Please retain the shipping carton for storage and future transportation of the device.

Included in the box, you should find the following:

- User Manual
- PT9 Control Unit
- Power Cord
- Umbilical Hose
- Fluid Bottle



All of these items are needed for safe system operation. If any of these items are missing from the shipping carton, please contact the clinic or hospital that prescribed the unit, or ThermoTek Customer Service at 972-874-4949.

Immediately upon unpacking your PT9 therapy system, inspect your unit. If the unit shows shipping damage, contact the transportation company and file a freight damage claim. Be sure to retain all packing material and the original box or case.

Along with the PT9 therapy system, you should have received all therapy wraps necessary for your prescribed treatment in individually sealed, unopened bags. These wraps may be marked “Sterile” or “Non-Sterile” depending on the type of treatment recommended by your physician.

- ⚠ Non-sterile premium therapy wraps are designed for use in a PT clinic under the supervision of the healthcare provider. The healthcare provider shall take appropriate care to clean the wrap between patient use.
- ⚠ Disposable therapy wraps are designed for single patient use only. If you received a therapy wrap in a non-sealed bag or container, the wrap should not be used. Please contact the clinic or hospital that prescribed the unit or the Durable Medical Equipment (DME) provider immediately to obtain a new, sealed therapy wrap.
- ⚠ Non-sterile therapy wraps should never be directly applied to an open wound or breached skin.
- ⚠ Use only sterile wraps over wounds or breaks in the skin.

⚠ Disposable therapy wraps are designed for single patient use only and may only be used on the same patient for the length of treatment.

### 3 DEVICE DESCRIPTION

The PT9 therapy system is an electronic heating, cooling and compression system. The PT9 therapy system provides precisely controlled hot or cold fluid that never has to directly contact the skin during therapy. The system is also capable of providing calibrated compressed air all in one convenient unit. This lightweight, portable system utilizes solid-state thermoelectric heat pumps that heat and cool with electricity in a safe and environmentally friendly manner.

#### 3.1 Features

- Fluid Therapy Temperature Range between 37°F – 49°F and 100°F - 105°F
- Treatment for Edema and Lymphedema in the Upper and Lower Extremities with alternating compressions of Low (15 mmHg), Med (30 mmHg) and High (50 mmHg)
- Pain Management
- Programmable Therapies
- Lightweight and Portable Package
- User-Friendly Interface
- 110-240 VAC, 50/60 Hz Operation
- Easy to use and read Touch Screen Display
- Quiet Operation

*\*The ability to achieve 37°F will depend on the wrap size and ambient temperature and may not be possible in every situation.*

#### 3.2 General Specifications

- Weight: 18.75 lbs.
- Hose Length: 7 ft.
- Hospital Grade Power Cord
- Dimensions: 6.6"W x 12"D x 13.2"H
- Operating Fluid: 90% Distilled Water/10% Isopropyl Alcohol
- Safety: IEC 60601-1

#### 3.3 Options

- Non-Sterile Premium Therapy Wraps
- Carrying Case

3.4 Device Illustration





## 4 ENVIRONMENTAL CONDITIONS YOU SHOULD BE AWARE OF BEFORE OPERATING YOUR PT9 DEVICE

- ⚠ The PT9 therapy system is intended for indoor use only.
- ⚠ Do not operate the PT9 system with therapy wraps in or near a wet environment.
- ⚠ The PT9 therapy system is not to be used in a confined space. Adequate air flow distance from the unit sides must be maintained during operation.
- ⚠ Inadequate air flow can result in overheating of internal electrical components and undesirable or excessive noise.

Only use the PT9 system in an ambient environment between 60-80°F (degrees Fahrenheit) and a relative humidity below 60%.

Failure to meet these operating environment conditions may result in:

- ⚠ Condensate buildup inside the unit.
- ⚠ Overheating or freezing of the unit.
- ⚠ Internal electronics malfunction.
  - A reduction in the heating or cooling capabilities of the unit.
  - A potential to blow the unit's electrical fuse due to an internal electrical overload.
  - The inability of the unit to properly regulate and administer fluid temperature during heat or cold therapies.
  - The inability of the unit to properly regulate and administer pneumatic compression as specified in the indications for use.

## 5 PT9 SYSTEM SETUP

### 5.1 Setting up the PT9 System for Therapy

Follow the steps outlined below:

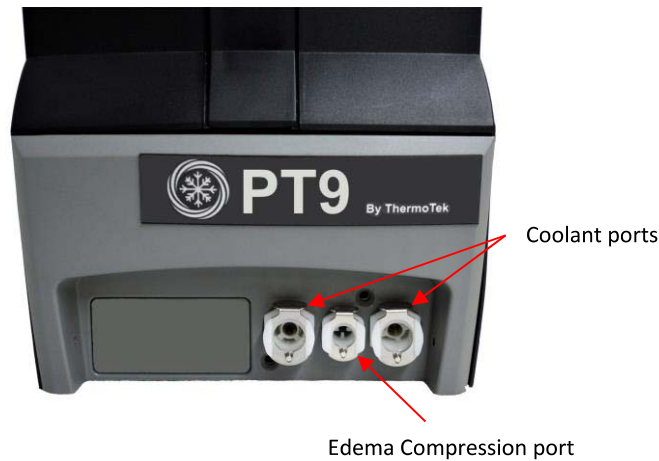
1. Place the PT9 control unit upright on a level surface and at least 1-foot from any wall or other obstruction on all sides that could restrict airflow through the unit.
2. Verify that the power switch located on the right side panel of the unit is in the OFF position.

#### **For Heat, Cool, Lymphedema or Edema Treatment Only:**

3. Unscrew and remove the coolant reservoir cap from the top of the unit. Using the coolant bottle supplied with the therapy system, fill the reservoir to the bottom of the reservoir neck. See the coolant mixing instructions label located on the coolant bottle.
4. Unpack a prescribed therapy wrap and place the wrap flat on a surface lower than the PT9 unit.
5. Connect the clear and grey hoses of the umbilical to the therapy wrap used for treatment. The fittings should make a “click” sound when inserted to indicate a secure connection.



6. On the front panel of the unit, locate the fittings for the coolant and edema compression connections.
7. Connect the clear hoses to the coolant ports of the unit (flow direction does not matter on this unit). The fittings should make a “click” sound when inserted to indicate a secure connection.
8. Connect the gray hose to the compression port. The fitting should make a “click” sound when inserted to indicate a secure connection.



9. Plug the supplied power cord into the unit and into a grounded AC outlet.
10. Turn ON the unit. The power switch is located on the right panel of the unit. When first powered up, the unit will power up and present the START menu screen on the display after a few seconds.



Figure 5-1: Start Menu

11. Open the reservoir cap and check the fluid level in the reservoir. If it is low, add the provided coolant from the coolant bottle into the reservoir until the level is at the base of the neck.
12. Press the START key on the display to begin priming the pump and filling the wrap.
13. Check the coolant level in the reservoir periodically over a 3-minute priming period and add coolant to the reservoir as necessary. If a "Check Flow/Fluid" alarm shows on the display, press ACCEPT to return to the START menu and press the START key to re-start the priming process.
14. Once coolant is flowing into the therapy wrap and there are no large bubbles in the clear tubing to the wrap, the system is ready for treatment. Screw the reservoir cap back on to complete the priming process.
15. Refer to the Operation Instructions in the next chapter for details on your specific prescribed treatment.

If you experience difficulty in setting up your PT9 therapy system for use, please contact the clinic or hospital that prescribed the unit. If you are unable to contact the provider, please contact the ThermoTek service line at (214) 502-8800 for assistance.

## 6 OPERATING INSTRUCTIONS FOR YOUR PT9 SYSTEM

Refer to Chapter 5 “PT9 System Setup” before beginning any therapy.

- ⚠ The patient must be familiar with all warnings and cautions listed in Chapter 2 before attempting to operate the unit.
- ⚠ The wraps for the PT9 system are designed to maximize the effectiveness of the therapies listed above. Only use wraps in combination with therapy modes as prescribed.

***The PT9 Therapy System is capable of performing therapies for the following:***

**Pneumatic Compression Therapy for Edema and Lymphedema:** Compression therapy provides compressed air to the therapy wrap and transfers pressure to the treatment site. This added external pressure aids in reducing the pooling of blood and lymphatic fluid in the targeted extremity. The compression treatment provided by the unit uses a preset pressure setting and cycle time.

**Cool Therapy:** Cool therapy passes cool fluid through the wrap for the management of pain, discomfort and swelling. If prescribed, Cool therapy can be used in combination with Pneumatic Compression therapy.

**Heat Therapy:** Heat therapy passes warm fluid through the wrap for the management of pain and discomfort. If prescribed, Heat therapy can be used in combination with Pneumatic Compression therapy.

**Thermal Contrast Therapy:** Thermal Contrast Therapy passes fluid through the wrap in an alternating cycle of Cool-Heat-Cool-Heat for the management of pain, discomfort and swelling. During Thermal Contrast Therapy, the unit will cool down the circulating fluid to 49°F for twenty (20) minutes and then heat up to 105°F for ten (10) minutes. This cycle is repeated until the prescribed duration of treatment is completed.

### 6.1 Pre-Programmed Therapy Operation:

The equipment provider will have programmed the PT9 controller with a specific prescribed therapy based on clinician instruction. To set up the unit for therapy, follow the instructions below:

1. Turn on the unit. The power switch is located on the right side panel of the unit.
2. When first powered up, after the initial boot-up sequence, the unit will display the START screen.

3. Press the Start key on the lower menu bar.
4. The THERAPY ACTIVE screen will be displayed as shown below.

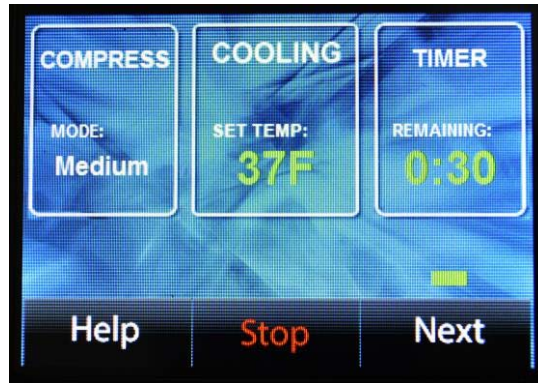


Figure 6-1: THERAPY ACTIVE screen

5. The Therapy Active screen shows the following information:
  - a. The therapies that have been programmed by the provider.
  - b. The window labeled COMPRESS shows the edema compression state and setting.

In this example, the edema compression is set to the Medium setting (30 mmHg). Other available settings are LOW (15 mmHg), HIGH (50 mmHg) and OFF. In the OFF mode, edema compression therapy is not active.

- c. The window labeled COOLING shows the thermal therapy state and setting.

In this example, the therapy mode is COOL with a setting of 37F. In cool mode, the temperature setting can be within 37F to 49F. Other available modes are HEAT, CONTRAST and OFF. In HEAT mode, the setting is 105F. In CONTRAST mode, the temperature will alternate between 20 minutes of COOL at 49F and ten minutes of HEAT at 105F. In OFF mode, the thermal therapy is not active.

- d. The window with TIMER shows the thermal therapy timer.
  - e. There are two TIMER options: CONTINUOUS and TIMED. If the timer is set for CONTINUOUS, the Therapy Active screen will show time elapsed. If the timer is set for TIMED, the Therapy Active Screen will show time remaining.
  - f. When you want to stop all therapies, press the STOP key and the unit will return to the START screen.
  - g. You can then power the unit OFF via the power switch located on the right side panel.

## 6.2 Changing Pre-Programmed Thermal Therapy Operation:

1. If you want to change COOL or HEAT therapy, select the NEXT key.
2. Select the COOL/HEAT Therapy key.

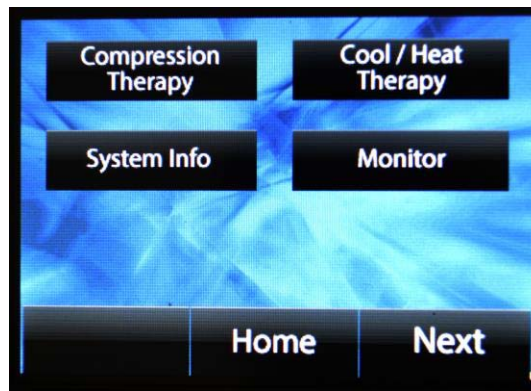


Figure 6-2: Menu Options screen

3. Press the COOL Mode key and then the Up/Down keys to adjust the cooling temperature from 49F down to 37F in 1F increments. Continue pressing the Down key to turn cooling OFF. Press the ACCEPT key.

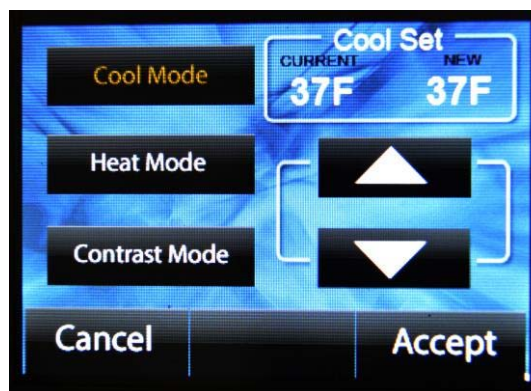


Figure 6-3: Cool Mode

4. Press the HEAT Mode key and then Up/Down keys to adjust the heating temperature from 105F to 100F in 1F increments. Continue pressing the Down key to turn heating OFF. Press the ACCEPT key.

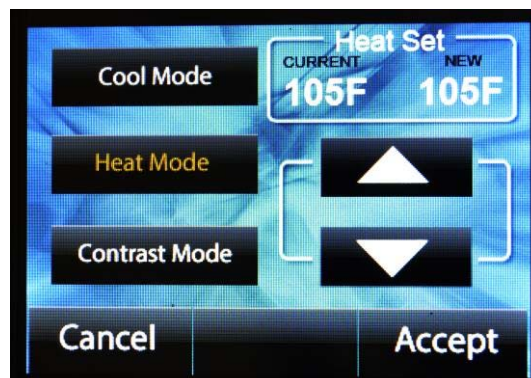


Figure 6-4: Heat Mode

5. Press the CONTRAST Mode key to set the device into Contrast Mode, to cycle from 49F to 105F. Press the ACCEPT key.



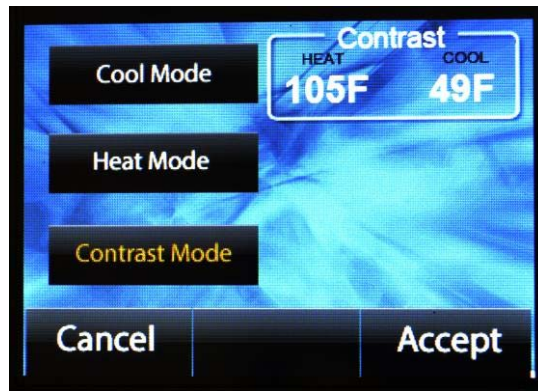


Figure 6-5: Contrast Mode

### 6.3 Changing Pre-Programmed Edema Compression Operation:

1. If you want to change EDEMA COMPRESSION therapy, select the NEXT key.
2. Select the Compression Therapy key.

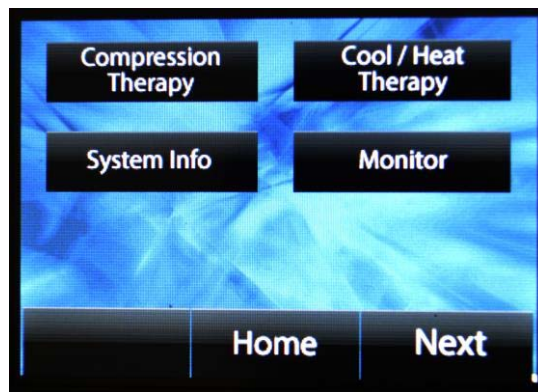


Figure 6-6: Menu Options

3. Select the Low, Medium or High key, or select OFF to discontinue compression therapy. Press the ACCEPT key.

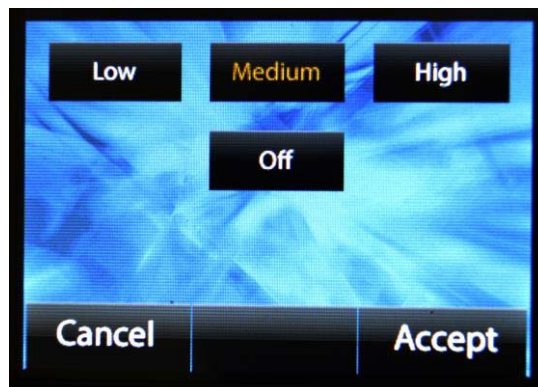


Figure 6-7: Compression Options

### 6.4 Changing Timer Operation:

1. From the START screen, press the NEXT key.
2. The MENU screen will be displayed as shown below.





Figure 6-8: Main Menu Options

3. Select the Timer Setting key.
4. Select the Continuous key to run therapy continuously. Press the Accept key.

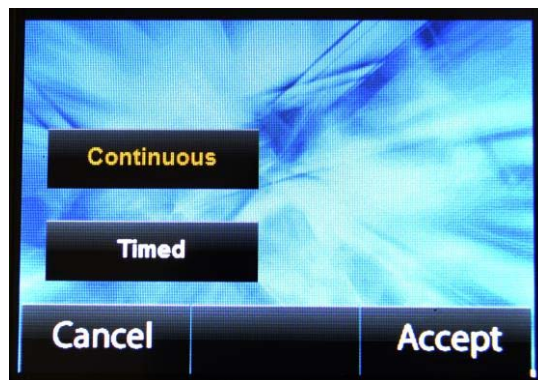







Figure 6-9: Timer Continuous

5. Select the Timed key to set the therapy time from 5 minutes to 1 hour and 30 minutes in 5 minute increments, using the Up/Down arrows. Press the Accept key.



Figure 6-10: Timer Timed

## 7 THINGS YOU CAN DO TO KEEP YOUR PT9 SYSTEM PERFORMING

-  Do not use abrasive or solvent-based cleaners on the unit.
-  There are no user serviceable internal parts. The system warranty is voided if the tamper seals are breached or removed.
-  Keep water away from vents, power ON/OFF switch and the power cord connection of the unit.
-  To avoid possible electric shock, do not remove the cover of the unit.
-  Do not immerse the unit in water or any liquid.

- **Check the fluid level weekly.**

If the coolant mixture ever becomes discolored or offensive to smell, contact the clinic or hospital that prescribed the unit or the Durable Medical Equipment (DME) provider for assistance. If microbial growth is present, the unit should not be used.

If you are unable to contact the provider, please contact the ThermoTek service line at (214) 502-8800 for assistance.

- **Wipe the exterior of the unit with a damp cloth.**

Do not use abrasive or solvent-based cleaners on the unit.

- **Clean off the therapy wrap if used for longer than 2-weeks or when noticeably dirty.**


Clean the exposed surfaces of the therapy wrap with either a mild antibacterial soap and water solution or an isopropyl alcohol and water solution.

Do not use bleach on the therapy wraps. This will weaken the plastic material and can cause either an air or coolant leak.

- **Cleaning the filter:**

1. Remove the six screws on the filter cover, located on the right side panel, to access the air filter.
2. Use warm, soapy water to clean the filter.
3. Allow the filter to air dry completely before re-installing to the unit.

- **Re-installing the filter:**

-  The air filter must be completely dry before installing on the unit. Using a wet air filter has a strong risk of causing an internal electrical short and is hazardous to both the user and the unit.

1. Turn the unit OFF and disconnect the power cord.
2. Place the filter inside the filter housing and re-install the filter cover with the six screws.

## **8 DRAINING THE FLUID FROM THE UNIT**

Periodically between uses or if the unit is going to be stored for a long period of time, the system should be drained of fluid.




1. Turn the unit OFF and unplug from electrical source.
2. Disconnect all of the hoses from the unit.
  - a. Firmly press the metal tabs of the fitting attached to the hose.
  - b. Gently pull back the hose from the unit to release.
3. Remove the reservoir cap from the unit by twisting the cap counter-clockwise.
4. Lift the unit on both ends and tip backward to empty the fluid from the reservoir into a bucket or sink.
5. Continue to tip the unit until the reservoir is completely empty of all fluid.

## 9 STORAGE AND RE-PACKING THE UNIT

When therapy is complete and it is time to return or store the PT9 therapy system, you can use the transport box.

1. Turn the unit OFF and unplug from the electrical source.
2. Remove all therapy wraps.
3. Disconnect all fittings from the rear panel of the unit.
4. If you have an umbilical hose assembly with your unit, disconnect the therapy wrap from the umbilical assembly.
5. Follow the “Draining the Fluid from the Unit” instructions in Chapter 8.
6. Do not screw the units’ reservoir cap on, but rather leave it off to allow the unit to dry completely. This helps avoid the risk of microbial growth in the unit during storage or long transport.
7. Collect the following items together:
  - PT9 Unit
  - Reservoir Cap
  - Umbilical Hose
  - Power Cord
  - User Manual
  - Coolant Mixing Bottle
8. Store the above items in the original packing box or in the travel case you received.
9. All therapy wraps are for single patient use only. If the patient is going to restart therapy later with a non-sterile wrap, retain the wrap with the unit. If the patient is going to restart therapy with a sterile wrap or is discontinuing therapy, the wrap can now be discarded.
10. Store indoors in an ambient environment between 40°F and 105°F.

Failure to properly store the unit, wraps and umbilical hose may result in the following:

-  Damage to the unit, hoses and/or wraps.
-  Catastrophic system damage if the unit is not properly drained.
-  Microbial growth inside the unit if not properly drained.

## 10 DEVICE SUMMARY

The PT9 Therapy System is capable of performing therapies for the following:

1. **Cool Therapy:** the unit passes cool (37°F – 49°F) fluid through the wrap for the management of pain, discomfort and swelling. If prescribed, Cool therapy can be used in combination with Pneumatic Compression Therapy.
2. **Heat Therapy:** the unit passes warm (100°F-105°F) fluid through the wrap for the management of pain and discomfort. If prescribed, Heat therapy can be used in combination with Pneumatic Compression Therapy.
3. **Pneumatic Compression Therapy for Edema and Lymphedema:** the unit uses a preset cycle time to inflate compressed air into the therapy wrap. This added external pressure aids in reducing the pooling of blood and lymphatic fluid in the targeted extremity.

The wraps for the PT9 system are designed to maximize the effectiveness of the therapies listed above. Only use wraps in combination with therapy modes as prescribed.

### Basic Instructions for Use:

The instructions listed here are not intended to replace the complete user instructions listed in Chapters 5 and 6. The user should read this entire manual before attempting to operate the device.

1. Attach the therapy wraps as described in the instructions located in the wrap packaging.
2. Prepare the unit for operation using the “PT9 System Setup” instructions in Chapter 5.
3. Initiate the prescribed therapy of Heat, Cool or Thermal Contrast with or without Pneumatic Compression for the duration advised on the prescription.
4. Stop all therapy modes after the prescribed duration is complete.
5. If Pneumatic Compression was utilized, make sure to stop the compression therapy before removing the therapy wrap.

If you experience difficulty in setting up your PT9 therapy system for use, please contact the clinic or hospital that prescribed the unit. If you are unable to contact the provider, please contact the ThermoTek service line at (214) 502-8800 for assistance.

## 11 SERVICE AND CUSTOMER SUPPORT

ThermoTek, Inc. is committed to servicing our PT9 unit both during and after sale to the customer. If you have any questions concerning the operation of your PT9 unit, please refer to the following to contact us at our Flower Mound, Texas facility:

- **Sales Organization:** (972) 874-4949
- **ThermoTek Website:** [www.thermotekusa.com](http://www.thermotekusa.com)
- **Service Line (after hours):** (214) 502-8800

 **Do not drink or ingest the coolant mixture.**

# 12 WRAPS, ACCESSORIES AND REPLACEMENT PARTS

## Boxes/Foam:

| Part Number | Description            |
|-------------|------------------------|
| OP2H257DFM  | Packing Foam           |
| OP2H257DBX  | Shipping Box           |
| OP9KVT5TCS  | Traveling Case, Single |

## Replacement Parts:

| Part Number | Description                                  |
|-------------|--|
| OP2CT255AF  | Washable Air Filter                          |
| OP2DCAPBTL  | Reservoir Cap                                |
| OP3C12MGCP  | Cord, PW 10A/125 VAC, Hospital Grade, 12 ft. |
| OP2DNANTFB  | Mixing Bottle, Thermoflow                    |

## Available Premium Therapy Wraps:

| Part Number   | Description   |
|---------------|---|
| OP9BLARMMR1   | Arm Wrap, Half, Non-Segmental                                 |
| OP9BFARMMR1   | Arm Wrap, Full  |
| OP9BBACKMR1   | Back Wrap   |
| OP9BLCRVMR1   | Cervical Wrap, Lower  |
| OP9BTCRVMR1   | Cervical Wrap, Total  |
| OP9BUCRVMR1   | Cervical Wrap, Upper  |
| OP9BFTAKMR1   | Foot/Ankle Wrap (Elbow, Half-Leg, Non-Segmental)              |
| OP9BANKLMR1   | Foot/Ankle Wrap, Open-Heel                                    |
| OP9BHEADMR1   | Head Wrap   |
| OP9BHPSBMR1   | Hip Wrap, Standard w/Harness                                  |
| OP9BSFKNMR1   | Knee Wrap, Standard, Half-Leg, Non-Segmental                  |
| OP9BKNEEMR1   | Knee Wrap, Large, Half-Leg, Segmental, Gradient Pressure      |
| OP9BCFKNMR1   | Leg Wrap, Full, Segmental, Gradient Pressure, Circumferential |
| OP9BCFKNMR1-L | Leg Wrap, Full, Segmental, Circumferential, 4" Extender       |
| OP9BLFKNMR1   | Knee Wrap, Medium, Half-Leg                                   |
| OP9BMNWAMR1   | Mini Wrap   |
| OP9BSSHLMR1   | Shoulder Wrap, Standard w/Straps                              |
| OP9BSSWHMR1   | Shoulder Wrap, Standard w/Harness                             |
| OP9BMSHDMR1   | Shoulder Wrap, Medium w/Straps                                |
| OP9BMSWHMR1   | Shoulder Wrap, Medium w/Harness                               |
| OP9BUKNEMR1   | Universal U Wrap  |

## Hose Assemblies:

| Part Number | Description                    |
|-------------|--------------------------------|
| OP9APT9UMB  | Assembly, Hose, Umbilical, PT9 |

## 13 TECHNICAL SPECIFICATIONS

### 13.1 PT9 System Technical Specification

|  |  |
|--|--|
| PT9 Part Number                          | 0P9PT09SYS   |
| Operating Environment                    | 50°F – 80°F [10°C – 27°C]                              |
| Relative Humidity                        | 30% to 60%, Non Condensing                             |
| Thermal Therapy Temperature Range        | 37°F – 105°F [6°C – 40.5°C]                            |
| Edema Compression Therapy Pressure Range | 15-mmHg to 50-mmHg                                     |
| Dimensions                               | 13.2”H x 12.00”D x 6.6”W<br>[335mmH x 305mmD x 167mmW] |
| Weight                                   | 18.75 lbs. [8.5 kg]                                    |
| Circulatory Pump                         | 12 VDC Centrifugal Pump                                |
| Reservoir Fluid Capacity                 | 8.5 floz. [250 ml]                                     |
| Temperature Accuracy                     | ±2°F [±1.1°C]  |
| Input Voltage                            | 100-240 VAC, 50/60 Hz                                  |
| Input Current (Max)                      | 6.0A   |
| Recommended Coolant                      | 90% Distilled Water, 10% Isopropyl Alcohol             |
| Transport & Storage Environment          | 32°F – 122°F [0°C – 50°C]<br>10% - 95%, Non Condensing |

### 13.2 Calibration

The PT9 therapy unit is comprised of components that are of high accuracy and low drift. Under normal operation, the therapy unit does not require calibration. The end user has the option to send the unit back to ThermoTek, Inc. for testing and calibration.

### 13.3 Product Listing



The PT9 therapy unit has been tested and listed by ETL to meet or exceed the requirements for UL Medical Listing 60601 Standards. This product is classified as a Type B Medical Equipment, Class II.



## 14 WARRANTY

**Limited Warranty Terms:** ThermoTek, Inc. (“ThermoTek”) warrants to the immediate purchaser from ThermoTek or an immediate purchaser of an unused unit from an authorized distributor of ThermoTek products, that any PT9 system will be free from defects in workmanship and material under normal use for one year after the date of purchase. ThermoTek warrants to the immediate purchaser from ThermoTek, or an immediate purchaser of an unused wrap from an authorized distributor of ThermoTek products, that ThermoTek single patient use wraps will be free from defects in workmanship and material under normal use for only the first use of the wrap.

This Limited Warranty covers only defects in material or workmanship. Therefore, it does not cover any other claim, service, defect, condition, or damage, including: installation, set-up, or instructions or recommendations on use; accidents, tampering, improper product selection, misuse, neglect, or abnormal use; use of parts, accessories or fluids that are incompatible or adversely affect operation, performance, or durability; unauthorized service, repair or alteration; excessive moisture or humidity; normal wear and tear; cleaning or any condition caused by any dirt or foreign substance on or in the product; or damages resulting from shipping. **Installation or use of the product or any portion thereof in a manner that does not comply with the Operating Instructions voids the warranty. Any alteration or modification that changes the product’s effectiveness or intended use voids the warranty.**

ThermoTek will, at its option, repair or replace within a reasonable time any product that is found to have a defect in material or workmanship under normal use during the applicable warranty period. This is the immediate purchaser’s sole remedy. Any warranty on a repair or replacement expires at the same time as the warranty expires or would have expired on the original product. The product must be returned at the immediate purchaser’s expense to an authorized ThermoTek Service Center for warranty service. ThermoTek will pay for the expense of returning the product receiving warranted service to the immediate purchaser. The immediate purchaser is responsible for and will be assessed a fee for test and calibration if no defects are found with the product.

Because ThermoTek updates and advances its products and technology, ThermoTek reserves the right to modify or improve the design of any product without assuming any obligation to modify any product previously manufactured.

Any product returned for warranty must have a Returned Materials Authorization (“RMA”) number on the outside of the container or package. Please call ThermoTek Customer Service at 877-242-3232 for an RMA number. A ThermoTek unit must be drained of all fluids before return. Returned products must be in the ThermoTek approved box and packing material to ensure safe transport. To quickly process your warranty repair request, please have the following product information, which is located on the serial plate located on the back side of ThermoTek products, available: (1) Model Number, (2) Serial Number, (3) Description of Problem, and (4) Contact Name and Telephone Number.

**Disclaimer of Warranties:** ThermoTek disclaims all other warranties, express or implied, including any warranty of merchantability or fitness for a particular purpose. The product is sold “as is” and NO WARRANTY OR AFFIRMATION OF FACT, OTHER THAN AS SET FORTH IN THE LIMITED WARRANTY ABOVE, IS MADE OR AUTHORIZED BY THERMOTEK (whether in the past or future). Thermotek has not made any affirmation of fact or promise relating to the product being sold that has been relied upon or become the basis of a bargain. This limited warranty is not transferable or made to any person other than the original purchaser of the product from ThermoTek OR THE ORIGINAL PURCHASER OF THE PRODUCT FROM AN AUTHORIZED DISTRIBUTOR OF THERMOTEK. To the extent any disclaimer is not permitted by applicable law, any warranty shall expire upon the expiration of the limited warranty provided above, and recourse is limited to repair or replacement as provided above.

**DISCLAIMER AND Limitation of Liability:** the foregoing sets forth Thermotek’s only obligations and the exclusive claim and remedy against Thermotek, regardless of whether such claims are based on warranty, contract, tort or any other theory. ThermoTek Disclaims and is not responsible for direct, special, incidental, consequential, or other damages, costs or loss. ThermoTek’s liability is limited to repair or replacement as provided above. In the event the repair or replacement warranty above is determined to fail OF its essential purpose, the foregoing terms and provisions apply except that, instead of repair or replacement, the exclusive remedy is Thermotek’s repayment of the purchase price less an amount equal to eight percent of the product’s purchase price multiplied by the number of months that the product was available to or in use by the purchaser.

**Other Limitations:** ThermoTek assumes no responsibility for the accuracy or completeness of the information presented, which is subject to change without notice. Any mention of non-ThermoTek products or services is for informational purposes only and is not an endorsement, recommendation or representation. If any provision of this Limited Warranty is held to be invalid or unenforceable, such provision shall be fully severable and the remaining portions of the Limited Warranty shall remain in full force and effect.





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