



# VascuTherm™ 5

## User Manual



ThermoTek™



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# Chapter 1

## Introduction:

Please read the entire manual carefully before trying to operate the VascuTherm 5™ system. It is unsafe to start using the VascuTherm™ 5 system before reading the entire user manual. Please keep this user manual for future reference.

At ThermoTek, we pledge to provide the highest quality product with excellent support and service. If we can do anything to make your VascuTherm™ 5 experience better, please do not hesitate to contact us.

## User Assistance Information:

The VascuTherm™ 5 Therapy System is manufactured by:

ThermoTek, Inc.

1200 Lakeside Parkway #200, Flower Mound, Texas 75028

Hours of Operation: Monday-Friday 8 a.m. to 5 p.m. CT

## Phone/Fax Numbers:

Telephone: (972) 874-4949

Fax: (972) 874-4945

Toll-free Telephone: (877) 242-3232 (U.S. only)

24-hour service line: (214) 502-8800

## ThermoTek Website:

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

## Icons Used for Warnings and Cautions:



Electrical Shock Risk



Burn Risk



General Caution



Frostbite or Cryogenic Burn Risk



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

In the event of a Medical Emergency, call:

# 9-1-1

# Chapter 2

## 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>Deep Venous Thrombosis (DVT):</b>	A type of phlebothrombosis; the formation of a clot in the deep veins of the extremities typically due to slowing or halting of blood return to the heart.
<b>Edema:</b>	A 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.

# Chapter 3

## General Warnings and Cautions:

### 3.1 Contraindications for Pneumatic Compression Therapy:

***The patient should not use the VascuTherm™ 5 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.

### 3.2 Contraindications for Heat and Cold Therapy:

***The following patients must use the VascuTherm™ 5 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,
- Hypersensitive to cold,
- Children,
- Diabetics



- Incapacitated patients,
- Individuals with decreased skin sensitivity,
- Individuals with poor circulation,
- Patients with vein ligation or recent skin grafts.

## 3.3 Precautions:

***When using the VascuTherm™ 5 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.***

## 3.4 Warnings:



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.

## 3.5 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 VascuTherm 5 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 the 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 the approved coolant in the VascuTherm 5 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.

# Chapter 4

## Indications for Use:

The VascuTherm™ 5 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.
- Decrease the risk of deep venous thrombosis (DVT).
- Aids the blood flow back to the heart.
- Treat and assist healing of cutaneous ulceration (wounds), reduce healing time, enhance arterial circulation (blood flow), reduce compartmental pressures, reduce edema (swelling), reduce the need for anticoagulant (blood thinning) medications.

# Chapter 5

## VascuTherm™ 5 Device Description:

The VascuTherm™ 5 therapy system is an electronic heating, cooling and compression system. The VascuTherm™ 5 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.

### 5.1 Features:

- Fluid Therapy Temperature Range between 43°F - 49°F to 105°F
- Compression Modality to reduce the risk of DVT formation on the Calf (45mmHg compression) and Foot (100 mmHg compression)
- 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 43°F will depend on the wrap size and ambient temperature and may not be possible in every situation.*

### 5.2 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

## 5.3 Options:

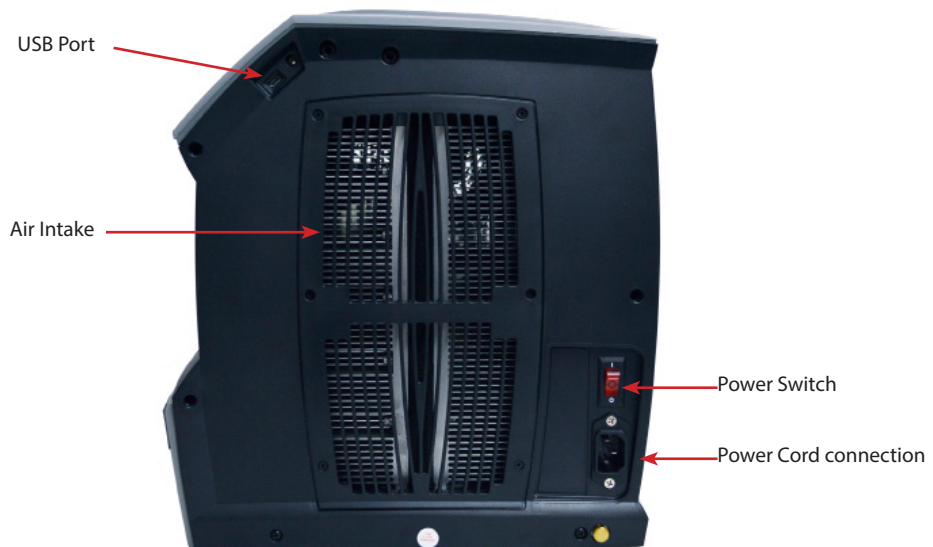
- Non-Sterile Single Patient Use Therapy Wraps
- Sterile Single Patient Use Therapy Wraps
- Carrying Case

## 5.4 Device Description:

### Front View



### Right Side View



**Left Side View**

Air Exhaust



**Top Side View**

Coolant Reservoir Opening

Handle



# Chapter 6

## Unpacking Your VascuTherm™ 5 Therapy System:

*When you first unpack the carrying case you should have the following items:*



All of these items are needed for safe system operation. If any of these items are missing from the shipping container, please contact the clinic or hospital that prescribed the unit, the Durable Medical Equipment (DME) provider or ThermoTek Customer Service at 972-874-4949.

Immediately upon unpacking your VascuTherm™ 5 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 VascuTherm™ 5 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.





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.

# Chapter 7

## Environmental Conditions You Should Be Aware Of Before Operating Your VascuTherm™ 5 Device:



The VascuTherm™ 5 therapy system is intended for indoor use only.



Do not operate the VascuTherm™ 5 system with therapy wraps in or near a wet environment.



The VascuTherm™ 5 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 VascuTherm™ 5 system in a 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.

# Chapter 8

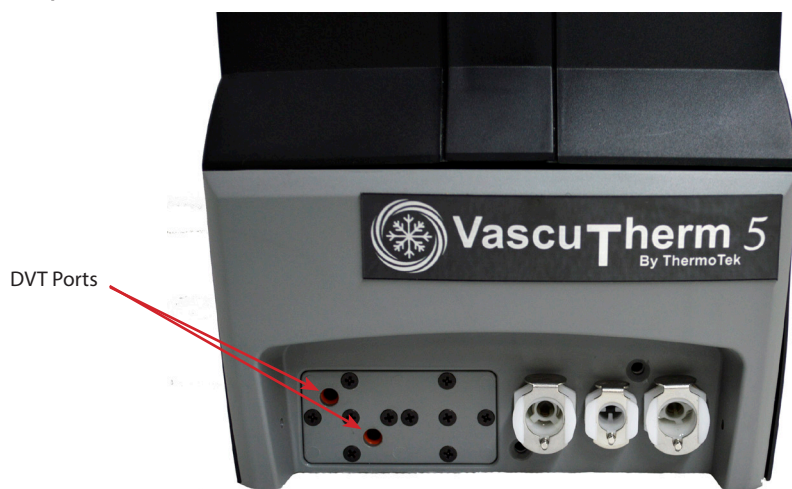
## How to Set Up Your VascuTherm™ 5 System for Therapy:

Now that you have fully unpacked your VascuTherm™ 5 Therapy System and verified that all of the necessary equipment is present and not damaged, you may begin to prepare the system for treatment.

1. Place the VascuTherm™ 5 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.

*If you were prescribed DVT Prevention Therapy Only: follow steps 3-6. For all other therapies, skip to step 7.*

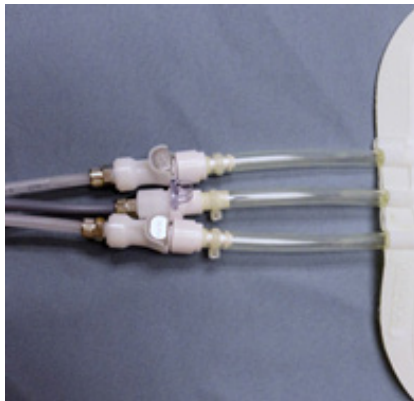
3. Unpack and apply the prescribed therapy wraps to the indicated portions of your body as described on the wrap instructions contained in the wrap packaging.
4. On the front panel of the unit, locate the ports for the DVT wrap(s) as shown below:
5. To attach and secure the therapy wrap fittings, insert (push) the blue wrap fitting into the port. The O-ring within the port will create a leak-free seal. Do this for both the Left and Right wraps.



6. Plug the supplied power cord into the unit and into a grounded AC outlet. The VascuTherm 5 therapy system is now ready for DVT prevention therapy. Refer to the Operation Instructions in Chapter 9.

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

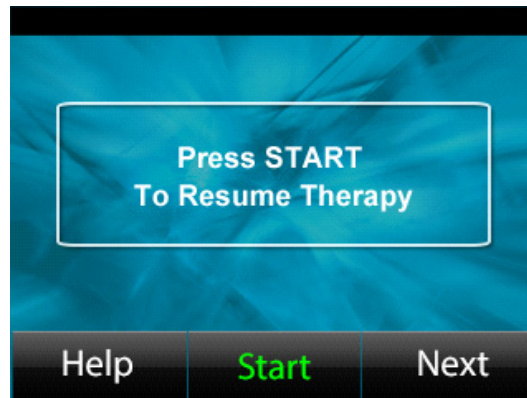
7. Unscrew and remove the coolant reservoir cap from the top of the unit. Using the coolant bottle supplied with the therapy system, fill the reservoir to the bottom of the reservoir neck. See the coolant mixing instructions label located on the coolant bottle.
8. Unpack a prescribed therapy wrap and place the wrap flat on a surface lower than the VascuTherm 5 unit.
9. 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.



10. On the front panel of the unit, locate the fittings for the coolant and edema compression connections.
11. 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.
12. Connect the grey hose to the compression port. The fitting should make a "click" sound when inserted to indicate a secure connection.



13. Plug the supplied power cord into the unit and into a grounded AC outlet.
14. 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.



15. 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.
16. Press the START key on the display to begin priming the pump and filling the wrap.
17. 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.
18. Once coolant is flowing into the therapy wrap and there are no large bubbles in the clear tubing or the wrap, the system is ready for treatment. Screw the reservoir cap back on to complete the priming process.
19. Refer to the Operation Instructions in the next chapter for details on your specific prescribed treatment.

If you experience difficulty in setting up your VascuTherm 5 therapy system for use, please contact the clinic or hospital that prescribed the unit or the Durable Medical Equipment (DME) provider. If you are unable to contact the provider, please contact the ThermoTek service line at (214) 502-8800 for assistance.

# Chapter 9

## Operating Instructions for your VascuTherm™ 5 System:

*Refer to Chapter 8 “How to Set Up Your VascuTherm™ 5 System” before beginning any therapy.*



The patient **MUST** be familiar with all warnings and cautions listed in Chapter 3 before attempting to operate the unit.



The wraps for the VascuTherm™ 5 system are designed to maximize the effectiveness of the therapies listed above. Only use wraps in combination with therapy modes as prescribed.

*The VascuTherm™ 5 Therapy System is capable of performing therapies for the following:*

**Pneumatic Compression Therapy for the prevention of DVT and PE:** DVT Compression therapy is used in combination with specially designed therapy wraps to transfer pressure to the calf or foot using compressed air. The preset inflation and deflation cycle of the VascuTherm 5 therapy system simulates natural walking action. This increases blood flow to the heart through the veins of the lower extremities to reduce the risk of clot formation.

**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.

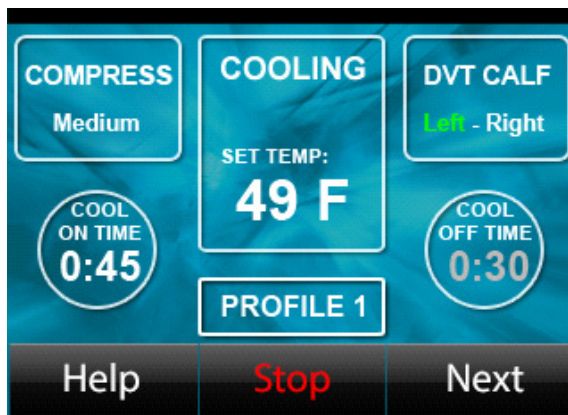
**Heat Therapy:** Heat Therapy passes warm fluid through the wrap for the management of pain and discomfort. If prescribed, Heat therapy can be used in combination with Pneumatic Compression therapy.

**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.

## 9.1 Pre-Programmed Therapy Operation:

The equipment provider will have programmed the VascuTherm 5 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.



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 therapy 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 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 49F. In cool mode, the temperature setting can be within 43F 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 labeled DVT CALF shows the DVT compression state and setting.

In this example, the DVT compression mode is set to CALF with compression on both left and right legs. In CALF mode, the settings can be Both Legs (Bilateral), Left Leg only, Right Leg only or OFF. Other available modes are DVT FOOT compression with settings identical to CALF mode.

- e. The window with COOL ON TIME and COOL OFF TIME shows the thermal therapy timers.

The COOL ON TIME is the time the COOL therapy is active. The time shown is the remaining cool time. The COOL OFF TIME is the time the COOL therapy is off. In COOL mode, the active timer is white and the in-active timer is gray. When the COOL ON TIME expires, the unit will automatically pause cooling for the COOL OFF TIME duration. When the COOL OFF TIME expires, the unit will automatically resume COOL mode and be active for the prescribed time interval. In HEAT mode, the timers operate similar to COOL mode with HEAT ON TIME and HEAT OFF TIME. In CONTRAST mode, the timers will show the alternating COOL TIME and the HEAT TIME for therapies.

- f. The window with PROFILE1, shows the active profile programmed by the equipment provider.
- g. When you want to stop all therapies, press the STOP key and the unit will return to the START screen.
- h. You can then power the unit OFF via the power switch located on the right side panel.

## 9.2 Pausing Pre-Programmed Thermal Therapy Operation:

6. If you want to temporarily pause COOL or HEAT therapy while compression therapy is active, PRESS and HOLD the COOLING or HEATING title on the screen for 2 seconds.
7. The setting will change to OFF in red letters.
8. To re-initiate thermal therapy, press and hold the COOLING or HEATING title on the screen for 2 seconds.
9. The therapy will be restated with the previous setting.

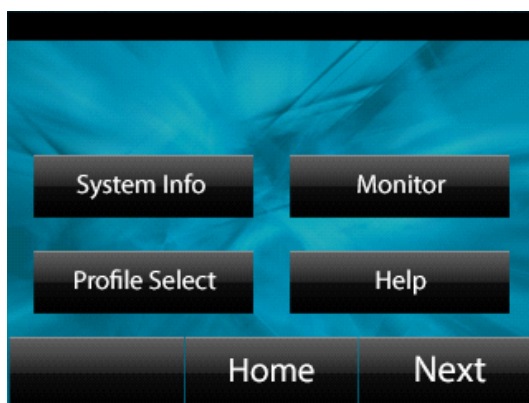


## 9.3 Pausing Pre-Programmed Edema Compression Operation:

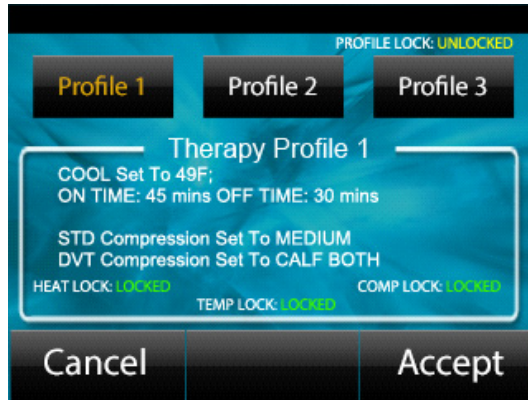
10. If you want to temporarily pause EDEMA COMPRESSION therapy while thermal and/or DVT therapies are active, PRESS and HOLD the COMPRESS title on the screen for 2 seconds.
11. The setting will change to OFF in red letters.
12. To re-initiate edema compression therapy, press and hold the COMPRESS title on the screen for 2 seconds.
13. The therapy will be restated with the previous setting.

## 9.4 Changing Therapy Profiles:

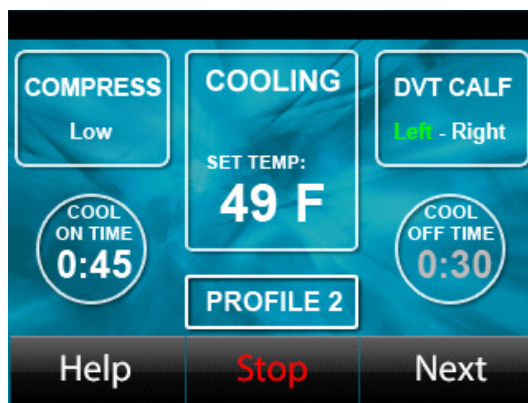
14. If the equipment provider has instructed you to change the treatment profile after some period of therapy duration, from the ACTIVE THERAPY screen, press the NEXT key.
15. The THERAPY CHANGE screen will be displayed as shown below.



16. Press the Profile Select key.
17. The PROFILE SELECT screen will be displayed as shown below.

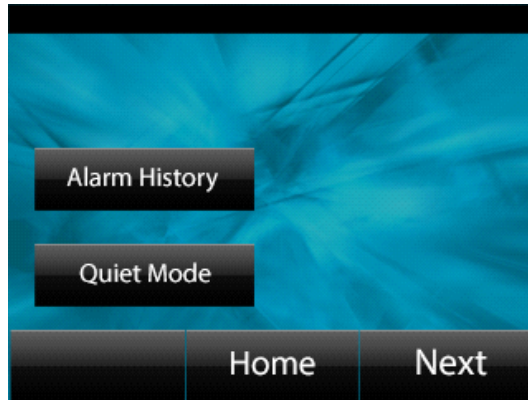


18. The controller can store up to three therapy profiles. The current active profile will be displayed in gold color with its settings below in white.
19. Select the profile number instructed by the provider. Review the profile settings to match the information provided by the provider.
20. Press the ACCEPT key to accept the new treatment profile.
21. The Profile window in the THERAPY ACTIVE screen will update to show the new profile section. In the example below, the profile was changed from “Profile 1” to “Profile 2” to change the EDEMA COMPRESSION Therapy setting from Medium to Low. This profile will be used for treatment from now on.



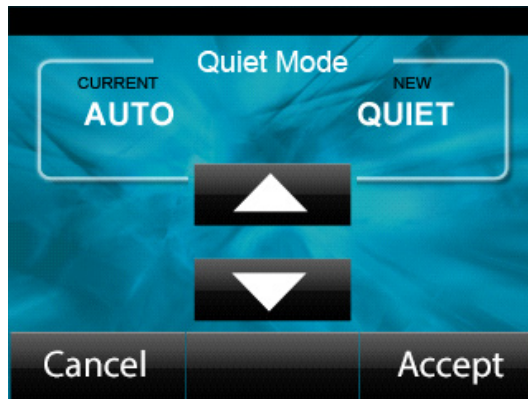
## 9.5 Quiet Mode Operation:

22. The VascuTherm 5 controller has a mode, if enabled by the equipment provider, to set the fans in QUIET mode.
23. To access this mode, from the THERAPY ACTIVE SCREEN, press the Next key twice. If the QUIET MODE has been enabled by the equipment provider, the option to set it will be visible on the screen as shown.



24. Press on the Quiet Mode key.

25. The Quiet Mode selection screen will be displayed. Press the UP or DOWN arrows to set the "New Setting" to Quiet. Press the Accept key.



26. You will notice the fans operating in quiet mode. Please note, the controller will continue to monitor the thermal therapy temperature, and if required will enter the high fan speed mode to provide the prescribed treatment.

# Chapter 10

## Things You Can Do To Keep Your VascuTherm 5 System Performing:



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



There are no user servicable 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 wrap with either a mild antibacterial soap and water solution or an isopropyl alcohol and water solution.

Do not use bleach on the 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.

# Chapter 11

## 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.
  - c. If the hoses are attached to the DVT air fittings, simply press in on the fitting while twisting counter-clockwise to release it from the unit.
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.

# Chapter 12

## Storage and Re-Packing the Unit:

When therapy is complete and it is time to return or store the VascuTherm™ 5 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 a 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 11.
6. Do not screw the unit’s 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:
  - VascuTherm™ 5 Unit
  - Reservoir Cap
  - Hose
  - Power Cord
  - User Manual
  - Coolant Mixing Bottle
8. Store the above items in the original packaging 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 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.



# Chapter 13

## Device Summary:

*The VascuTherm™ 5 Therapy System is capable of performing therapies for the following:*

- **Cool Therapy:** the unit passes cool (43°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.
- **Heat Therapy:** the unit passes warm (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.
- **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.
- **Pneumatic Compression Therapy to reduce the risk of DVT Formation:** the unit uses a preset cycle time to inflate compressed air into the therapy wrap. This action increases blood flow return through the veins of the lower extremities to the heart and reduces the risk of clot formation.

The wraps for the VascuTherm™ 5 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 8 and 9. 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 “How to Set-Up Your VascuTherm™ 5 System for Therapy” instructions in Chapter 8.
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 VascuTherm 5 therapy system for use, please contact the clinic or hospital that prescribed the unit or the Durable Medical Equipment (DME) provider. If you are unable to contact the provider, please contact the ThermoTek service line at (214) 502-8800 for assistance.

# Chapter 14

## Service and Customer Support:

ThermoTek, Inc. is committed to servicing our VascuTherm™ 5 unit both during and after sale to the customer. If you have any questions concerning the operation of your VascuTherm™ 5 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.**

# Chapter 15

## Wraps, Accessories and Replacement Parts:

### Boxes/Foam:

Part Number	Description
0P2H257DFM	Packing Foam
0P2H257DBX	Shipping Box
0P9KVT5TCS	Traveling Case, Single

### Replacement Parts:

Part Number	Description
0P2CT255AF	Washable Air Filter
0P2DCAPBTL	Reservoir Cap
0P3C12MGCP	Cord, PW 10A/125 VAC, Hospital Grade, 12 ft.
0P2DNANTFB	Mixing Bottle, Thermoflow

### Available Therapy Wraps:

Part Number	Description
<b>Thermal Compression Wraps:</b>	
0P9BANKLMR3	Wrap, Foot/Ankle, Open Heel, SPU
0P9BANKLMR3-U	Wrap, Foot/Ankle, Open-Heel, SPU, Unfilled
0P9BBACKMR3	Wrap, Back, SPU
0P9BBACKMR3-U	Wrap, Back, SPU, Unfilled
0P9BBSW3XL	Wrap, Shoulder w/Brace, 3XL
0P9BBSW4XL	Wrap, Shoulder w/Brace, 4XL
0P9BBSWLRG	Wrap, Shoulder w/Brace, Large
0P9BBSWMED	Wrap, Shoulder w/Brace, Medium
0P9BBSWSML	Wrap, Shoulder w/Brace, Small
0P9BBSWXLG	Wrap, Shoulder w/Brace, XLG
0P9BBSWXSM	Wrap, Shoulder w/Brace, X-Small
0P9BBSWXXL	Wrap, Shoulder w/Brace, XXL
0P9BBTB2XL	Wrap, Back w/Brace, 2XL
0P9BBTB3XL	Wrap, Back w/Brace, 3XL
0P9BBTB4XL	Wrap, Back w/Brace, 4XL
0P9BBTBLRG	Wrap, Back w/Brace, Large
0P9BBTBMED	Wrap, Back w/Brace, Medium
0P9BBTBSML	Wrap, Back w/Brace, Small

0P9BBTBXLG	Wrap, Back w/Brace, X-Large
0P9BCFKNMR3	Wrap, Knee, Full Leg, Seg, Grad, Circumferential, SPU
0P9BCFKNMR3-L	Wrap, Knee, Full Leg, Seg, Grad, Circumferential, 4" Extender, SPU
0P9BCFKNMR3-U	Wrap, Knee, Full Leg, Seg, Grad, Circumferential, SPU, Unfilled
0P9BFACEMR3	Wrap, Face, SPU
0P9BFACEMR3-U	Wrap, Face, SPU, Unfilled
0P9BFARMMR3	Wrap, Full Arm, SPU
0P9BFARMMR3-U	Wrap, Full Arm, SPU, Unfilled
0P9BFTAKMR3	Wrap, Foot/Ankle, SPU
0P9BFTAKMR3-U	Wrap, Foot/Ankle, SPU, Unfilled
0P9BHEADMR3	Wrap, Head, SPU
0P9BHPSBMR3	Wrap, Hip, Standard, SPU
0P9BHPSBMR3-U	Wrap, Hip, Standard, SPU, Unfilled
0P9BJWWSMR3-U	Wrap, Jaw w/Strap, SPU, Unfilled
0P9BKNEEMR3	Wrap, Large Knee, Half Leg, SPU
0P9BKNEEMR3-U	Wrap, Large Knee, Half Leg, SPU, Unfilled
0P9BLARMMR3	Wrap, Arm, SPU
0P9BLARMMR3-U	Wrap, Arm, SPU, Unfilled
0P9BLCRVMR3	Wrap, Lower Cervical, SPU
0P9BLCRVMR3-U	Wrap, Lower Cervical, SPU, Unfilled
0P9BLFKNMR3	Wrap, Knee, Medium, SPU
0P9BLFKNMR3-SC	Wrap, Knee, Medium, Segmental, SPU
0P9BLFKNMR3-SCU	Wrap, Knee, Medium, Segmental, SPU, Unfilled
0P9BLFKNMR3-U	Wrap, Knee, Medium, SPU, Unfilled
0P9BLSB2XL	Wrap, Back w/Brace, LSO, 2XL
0P9BLSB3XL	Wrap, Back w/Brace, LSO, 3XL
0P9BLSB4XL	Wrap, Back w/Brace, LSO, 4XL
0P9BLSBLRG	Wrap, Back w/Brace, LSO, Large
0P9BLSBMED	Wrap, Back w/Brace, LSO, Medium
0P9BLSBSML	Wrap, Back w/Brace, LSO, Small
0P9BLSBXLG	Wrap, Back w/Brace, LSO, X-Large
0P9BMNWAMR3	Wrap, Mini, SPU
0P9BMNWAMR3-U	Wrap, Mini, SPU, Unfilled
0P9BMSHDMR3	Wrap, Shoulder, Medium, SPU
0P9BMSWHMR3	Wrap, Deluxe, Shoulder, Half Arm, SPU
0P9BMSWHMR3-U	Wrap, Medium Shoulder w/Harness, SPU, Unfilled
0P9BRM2X13	Wrap, Knee, ROM Brace, XXL, 13"
0P9BRM2X17	Wrap, Knee, ROM Brace, XXL, 17"
0P9BRMLX13	Wrap, Knee, ROM Brace, L-XL, 13"
0P9BRMLX17	Wrap, Knee, ROM Brace, L-XL, 17"
0P9BRMSM13	Wrap, Knee, ROM Brace, S-M, 13"

0P9BRMSM17	Wrap, Knee, ROM Brace, S-M, 17"
0P9BSFKNMR3	Wrap, Knee, Standard, Half Leg, SPU
0P9BSFKNMR3-U	Wrap, Knee, Standard, Half Leg, SPU, Unfilled
0P9BSFNMR3	Wrap, Knee, No Compression, SPU
0P9BSFNMR3-U	Wrap, Knee, No Compression, SPU, Unfilled
0P9BSHLMR3	Wrap, Shoulder, Large, SPU
0P9BSHLMR3	Wrap, Shoulder, Standard, SPU
0P9BSWHMR3	Wrap, Shoulder, Half Arm w/Harness, SPU
0P9BSWHMR3-U	Wrap, Shoulder, Half Arm w/Harness, SPU, Unfilled
0P9BTCRVMR3	Wrap, Total Cervical, SPU
0P9BTCRVMR3-U	Wrap, Total Cervical, SPU, Unfilled
0P9BUCRVMR3	Wrap, Upper Cervical, SPU
0P9BUCRVMR3-U	Wrap, Upper Cervical, SPU, Unfilled
0P9BUKNEMR3	Wrap, Universal U, SPU
0P9BUKNEMR3-U	Wrap, Universal U, SPU, Unfilled
0P9BWITHDMR3	Wrap, Wrist/Hand, SPU
0P9BWITHDMR3-U	Wrap, Wrist/Hand, SPU, Unfilled
<b>Pneumatic Compression Wraps:</b>	
0P9BNDVTCA4	Wrap, DVT, Calf Set, Push, SPU
0P9BNDVTFT4	Wrap, DVT, Foot Set, Push SPU

**\*Sterile Therapy Wrap options available (example: 0P9XXXXXXXX3-S)**

#### **Hose Assemblies:**

<b>Part Number</b>	<b>Description</b>
0P9AVT5UMB	Hose, Therapy Umbilical, Standard, 7 ft., VT5

# Chapter 16

## Specifications:

VascuTherm™ 5 Part Number	0P9PTVT500
Operating Environment	50°F - 80°F [10°C - 27°C]
Relative Humidity	30% to 60%, Non Condensing
Thermal Therapy Temperature Range	43°F - 105°F [6°C - 40.5°C]
Edema Compression Therapy Pressure Range	15-mmHg to 50-mmHg
DVT Compression Therapy Pressure Range	45-mmHg to 100-mmHg
Dimensions	13.2"H x 12.00"D x 6.6"W [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] 10% - 95%, Non Condensing

## 16.1 Calibration

The VascuTherm™ 5 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.

## 16.2 Product Listing



The VascuTherm™ 5 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.

# Chapter 17

## Warranty and Disclaimer Information:

**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 VascuTherm™ 5 will be free from defects in workmanship and material under normal use for two years 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 of 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 VascuTherm or NanoTherm 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 VascuTherm and NanoTherm products, available: (1) Model Number,



(2) Serial Number, (3) Description of Problem, and (4) Contact Name and Telephone Number.

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1200 Lakeside Parkway #200

Flower Mound, TX 75028

Ph: 972-874-4949, Fax: 972-874-4945

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

For customer service information, please see Section 14 of this manual.

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