VascuTherm 5

Therapy System

Patient User Manual

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2 INTRODUCTION

This Instructions for Use – Patient User Manual applies to the VascuTherm™ 5 for the treatment of swelling, pain and to reduce the risk of blood clots in the legs, as prescribed by the physician.

The VascuTherm 5 Patient User Manual contains general safety and operating information. It is intended for patients using the VascuTherm 5 under the care and direction of their healthcare professional.

Please read the entire user manual 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.

If you have any medical questions or concerns, please discontinue use of the VascuTherm 5 device, and contact your healthcare provider, immediately.

If it is a medical emergency call 9-1-1 or visit your nearest emergency room for evaluation and treatment.

If you have any questions about how to use the VascuTherm 5 or if the device is not functioning or displaying an alarm, please contact your local provider or prescribing clinic for assistance. You should have received the contact information when you were provided the VascuTherm 5 device. If this information is not available, please contact ThermoTek and we will assist you with your questions or help locate your local provider.

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.

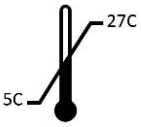
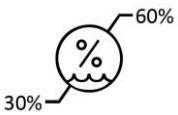
2.1 How to Contact ThermoTek Inc.

If you have questions about the VascuTherm 5 system, or require service, please contact ThermoTek Inc. at:

1200 Lakeside Parkway, #2
Flower Mound, TX 75028
Tel: 972-874-4949 (8:00am – 5:00 pm CT)
Service Line After Hours: (214) 502-8800

ThermoTek Website: www.thermotekusa.com

2.2 Explanation of Symbols

	IMPORTANT: Read Instructions before Use Before operating the device, please read the entire instruction guide. Keep the guide available for future reference.
	CAUTION. Consult user manual to determine potential hazards prior to operating the device.
	The use of this device shall be prescribed by a healthcare professional
	AC Power
	Type B Applied Part
	Recommended ambient temperature for using the VT5 system
	Recommended ambient humidity for using the VT5 system
	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.
	Use this device in a dry place. Do not get it wet
	Do not smoke when using the device and accessories.
	Do not use near open flames, like fireplaces, candles,
	Do NOT Dispose with General Household Waste 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.
	Manufacturer's Part Number

	Device Serial Number
	Device Manufacturing location
	Device Manufacture Date Code

2.3 Glossary of Terms:

Arterial Dysregulation:	A physiological impairment of the arteries.
(Arterial/Venous) occlusive disease:	A condition where narrowed or blocked blood vessels block blood flow to the limbs.
Arteriosclerosis:	A chronic disease in which thickening, hardening and loss of elasticity of the arterial walls result in impaired blood circulation.
Constant Compression:	Continuous, regulated and compressive force applied to the skin surface for the manipulation of subcutaneous compartment pressures.
Carcinoma Metastasis:	A malignant new growth having potential to spread.
Cardiac insufficiency/Congestive heart failure:	Decreased capacity of the heart to pump blood.
Contraindication:	A reason that makes it inadvisable to prescribe a particular drug or employ a particular procedure or treatment to a patient.
Contrast:	A pain management therapy consisting of repeatedly heating and cooling of the skin and underlying muscle tissue.
Deep Venous Thrombosis (DVT):	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.
Edema:	Swelling due to excess fluid trapped in the body's tissues.
Erysipelas:	An acute superficial form of cellulitis; a bacterial infection affecting the skin.
Hypertonia:	Motor neuron disease/disruption that causes issues inflexibility and movement.
Non-Ambulatory:	To be in a resting or immobile state; not moving.
Phlebothrombosis:	Thrombosis of a vein without prior inflammation of the vein; associated with sluggish blood flow. Usually caused by prolonged bed-rest, pregnancy or surgery.
Pulmonary Embolism:	A blood clot in the lungs.
Pulsating Compression:	Also called intermittent or undulating compression, is the manipulation of subcutaneous compartment pressures in a high-to-low repeating cycle.
Raynaud's disease/phenomenon:	Disease where small arteries constrict more than they should in response to cold thus limiting blood supply to the affected areas.
Thrombophlebitis:	An acute inflammatory reaction of a vein due to thrombus presence.
Thrombus:	A clot formed in a blood vessel or in a chamber of the heart.
Venous Stasis:	Slowing of blood flow typically caused by venous valve failure or the existence of clots in the vein.

2.4 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.

2.5 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,
- Hypersensitivity to cold,
- Children,
- Diabetics,
- Incapacitated patients,
- Individuals with decreased skin sensitivity,
- Individuals with poor circulation,

2.6 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.

- ⚠ Do not open the device for any reason. There are high voltage electrical components and moving parts inside the device, that can be cause electric shock or harm.
- ⚠ Do not use the device in a sterile environment, such as an operating room.
- ⚠ Never push objects of any kind into the therapy unit through the air filter or frame.
- ⚠ Do not drop any objects into the reservoir
- ⚠ 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.
- ⚠ 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.
- ⚠ Connect the power cord to a 115VAC wall power. Without AC power, the unit cannot provide prescribed treatment.
- ⚠ 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 near equipment that generates electromagnetic or other interferences as this may be harmful to the therapy unit.
- ⚠ Do not use the device in a car, or airplane.
- ⚠ Do not smoke while using the device or use near an open flame, such as candles, fireplace, space heaters.
- ⚠ Do not stick a finger or any other foreign objects into the reservoir.
- ⚠ Do not place the VascuTherm 5 power cord near your neck. Strangulation risk.
- ⚠ Do not place the VascuTherm 5 DVT compression tubes near your neck. These garments are to be worn on your calf or foot. Strangulation risk.
- ⚠ Only use the coolant mixture provided with the device.
- ⚠ Do not drink or ingest the coolant.

2.7 Cautions:

- ⚠ Follow the prescribed instructions of your physician for therapy settings, treatment 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, irritation, skin discoloration or discomfort occurs, immediately discontinue use of the VascuTherm 5 unit and consult your healthcare professional.**
- ⚠ Use only ThermoTek approved therapy wraps.
- ⚠ **Therapy wraps are for single patient use only. Do not reuse therapy wraps on more than one patient. Potential patient harm due to cross contamination and /or treatment efficacy.**
- ⚠ Therapy wraps are non-sterile.
- ⚠ Do not use non-sterile therapy wraps applied directly to an open wound or breached 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. If the treatment setting is painful, or you do not feel any sensation, discontinue use and consult your healthcare professional.**
- ⚠ **Patients vary in sensitivity to heat. If the treatment setting is painful, or you do not feel any sensation, discontinue use and consult your healthcare professional.**
- ⚠ 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 use 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.
- ⚠ 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 VascuTherm 5 unit.
- ⚠ Do not warm the coolant or add hot coolant to the reservoir.
- ⚠ 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.
- ⚠ This device does not have an internal battery. When the device is powered off via the power switch or unplugged from wall power, it will stop delivery of treatment.

2.8 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.

2.9 Unpacking Instructions

When the VascuTherm 5 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
- VascuTherm 5 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, or the unit shows shipping damage, please contact the clinic or hospital that prescribed the unit, the Durable Medical Equipment (DME) provider or ThermoTek Customer Service at (214) 502-8800.

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 are specific to the

treatment area depending on the type of treatment recommended by your physician. The wraps are labeled Non-Sterile.

- ⚠ If the device shows shipping damage, do not use the device.
- ⚠ 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.
- ⚠ 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 VascuTherm 5 therapy system is an electronic heating, cooling and compression system that 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 43°F – 49°F for cold therapy and 105°F for heat therapy
- Compression Modality to reduce the risk of DVT formation on the Calf (45mmHg compression) and Foot (100mmHg compression)
- Treatment for Edema and Lymphedema in the Upper and Lower Extremities with alternating compressions of Low (15mmHg), Med (30mmHg) and High (50mmHg)
- Pain Management
- Programmable Therapies
- Lightweight and Portable Package
- User-Friendly Interface
- 110 VAC, 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, ambient temperature/humidity, and may not be possible in every situation.*

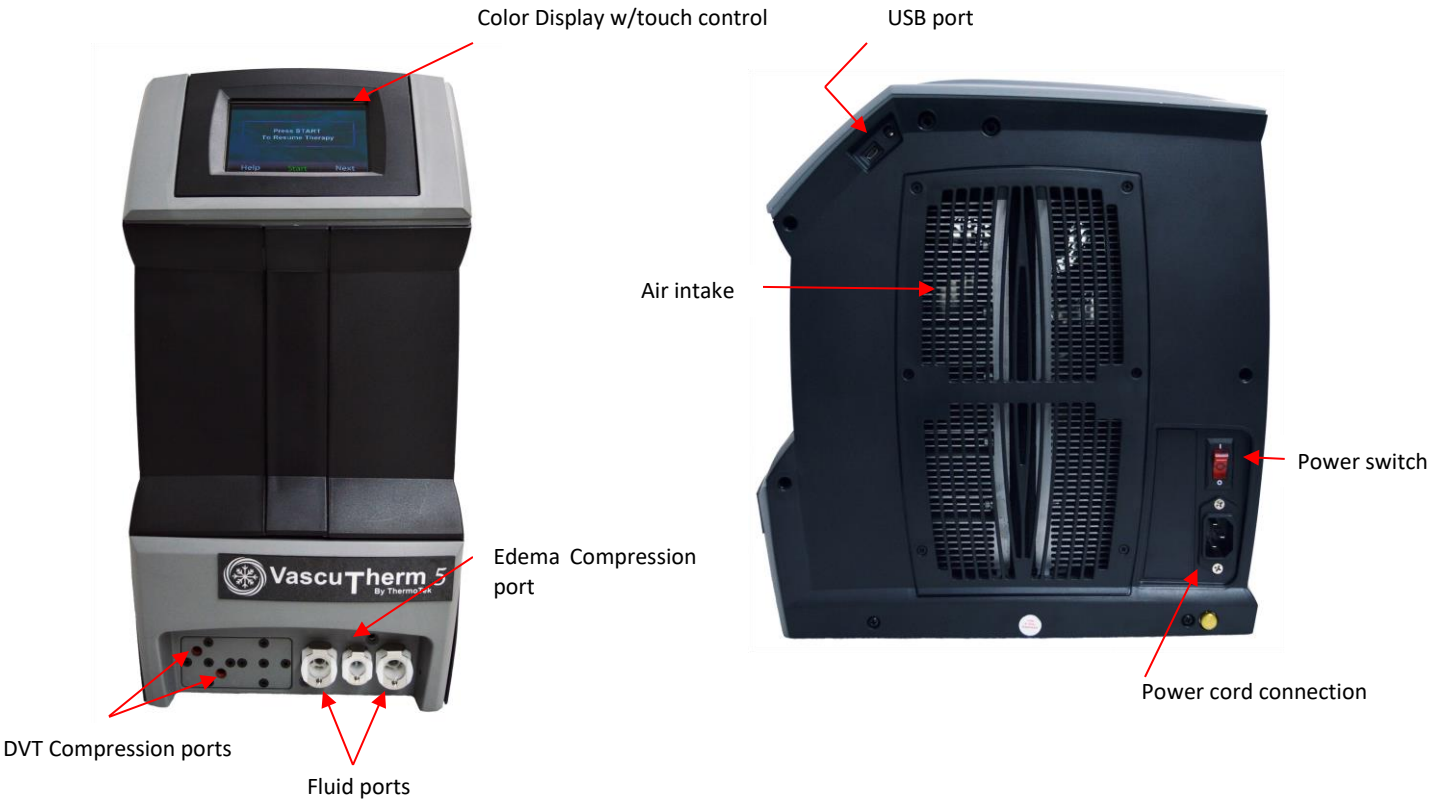
3.2 General Specifications

- 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

3.3 Options

- Non-Sterile Single Patient Use Therapy Wraps

3.4 Device Illustration



4 Environmental Conditions You Should Be Aware Of Before Operating Your VascuTherm 5 Device

⚠ The VascuTherm 5 therapy system is intended for indoor use only.
⚠ The VascuTherm 5 therapy system is intended to be used in an environmentally controller indoor environment with an ambient temperature of 5 – 27°C [41 – 80°F], with a relative humidity below 60%, non-condensing.
⚠ 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 of minimum 1-foot 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.

Failure to meet these operating environment conditions may result in:

⚠ Overheating or freezing of the unit.
- A reduction in the heating or cooling capabilities of the unit.
- 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 VASCUTHERM 5 SYSTEM SETUP

5.1 Setting up the VascuTherm 5 System for Therapy

Follow the steps outlined below:

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 AC power cord connector and the power switch located on the right side panel of the unit is in the OFF position.
3. Position the VascuTherm 5 control unit such that you have easy access to turn off the switch and disconnect the AC power cord in the event of a fault condition with the control unit.
4. If the VascuTherm 5 has been in storage or has been transported at temperatures outside of 5 – 27°C [41 – 80°F], please allow the device to acclimate to its intended use environment for minimum 60 minutes, prior to initiating treatment.

If you were prescribed DVT Prevention Therapy Only: follow steps 5-7. For all other therapies, skip to step 9.

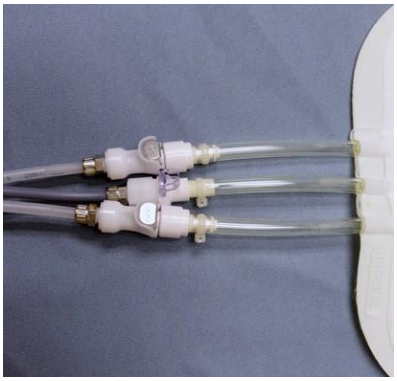
5. Unpack and apply the prescribed therapy wraps to the indicated portions of your body as described on the wrap instructions contained in the wrap packaging.
6. On the front panel of the unit, locate the ports for the DVT wrap(s) as shown below:
7. To attach and secure the therapy wrap fittings, insert (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.

Figure 5.1: DVT Ports

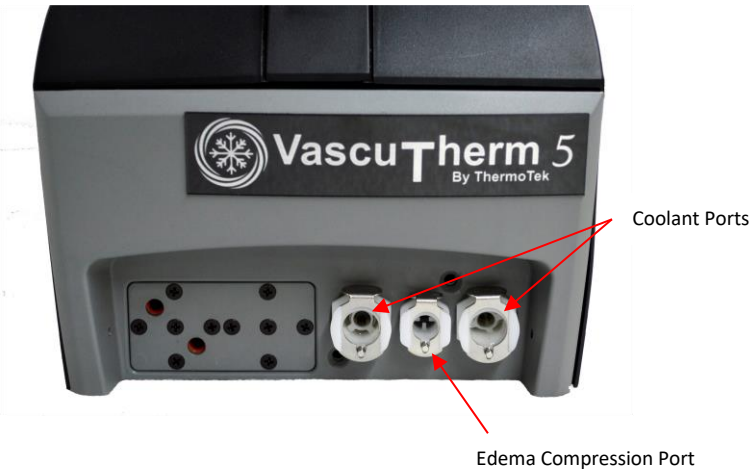
8. Plug the supplied power cord into the unit and into a grounded AC outlet. The VascuTherm 5 therapy system is now ready for DVT prevention therapy. Refer to the Operation Instructions in Chapter 6.

For Heat, Cool, Lymphedema or Edema Treatment Only:

9. Unscrew and remove the coolant reservoir cap from the top of the unit. Check the fluid level. If the fluid level is below the neck, using the coolant bottle supplied with the therapy system, fill the reservoir to the bottom of the reservoir neck.
10. Unpack a prescribed therapy wrap and place the wrap flat on a surface lower than the VascuTherm 5 unit.
11. 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.
12. The clear tubes from the umbilical are the fluid circulating tubes, and they connect to the two outer ports of the wrap. The gray tube of the umbilical is the edema compression line, and it connects to the center port of the wrap.



13. On the front panel of the unit, locate the fittings for the coolant and edema compression connections.
14. 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.
15. Connect the gray hose to the compression port. The fitting should make a "click" sound when inserted to indicate a secure connection.



16. Plug the supplied power cord into the unit and into a grounded AC outlet.
17. 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 5-4: Start Menu

18. Press the START key on the display to begin priming the pump and filling the wrap.
19. If a "Check Flow/Fluid" low priority alarm shows on the display, locate the supplied coolant bottle, open the reservoir cap and add fluid to the base of the neck.
20. Acknowledge the alarm to return to the Active Therapy screen.
21. 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.
22. 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.

6 OPERATING INSTRUCTIONS FOR YOUR VASCUTHERM 5 SYSTEM

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

⚠ If AC power is lost during treatment, the device will power off. Reconnect to AC power and resume treatment.

The VascuTherm 5 Therapy System provides the following therapies:

Pneumatic Compression Therapy for the prevention of DVT: 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 thermal (hot / cold) 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 stopped by the patient.

6.1 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. Connect the provided therapy wraps as shown in the wrap instruction label or how the health care provider instructed you.
3. When first powered up, after the initial boot-up sequence, less than 15 seconds, the unit will display the START screen.

Figure 6-1: START screen

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

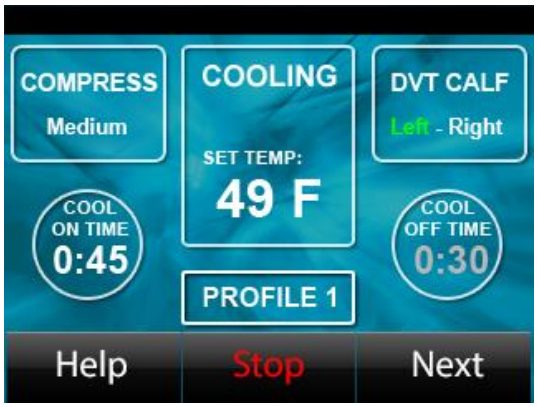


Figure 6-2: THERAPY ACTIVE screen

6. 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 (30mmHg). Other available settings are LOW (15mmHg), HIGH (50mmHg) 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 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 can be within 100F to 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.

6.2 Pausing Pre-Programmed Thermal Therapy Operation:

1. If this option is allowed by the clinician and 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.
2. The setting will change to OFF in red letters.
3. To re-initiate thermal therapy, press and hold the COOLING or HEATING title on the screen for 2 seconds.
4. The therapy will be restated with the previous setting.

6.3 Pausing Pre-Programmed Edema Compression Operation:

1. If this option is allowed by the clinician and 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.
2. The setting will change to OFF in red letters.
3. To re-initiate edema compression therapy, press and hold the COMPRESS title on the screen for 2 seconds.
4. The therapy will be restated with the previous setting.

6.4 Pausing Pre-Programmed DVT Compression Operation:

1. If this option is allowed by the clinician and if you want to temporarily pause DVT COMPRESSION therapy while thermal and/or EDEMA therapies are active, PRESS and HOLD the DVT title on the screen for 2 seconds.
2. The setting will change to OFF in red letters.
3. To re-initiate DVT compression therapy, press and hold the DVT title on the screen for 2 seconds.
4. The therapy will be restated with the previous setting.

6.5 Changing Therapy Profiles:

1. 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.
2. The THERAPY CHANGE screen will be displayed as shown below.

Figure 6-3: THERAPY CHANGE screen

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

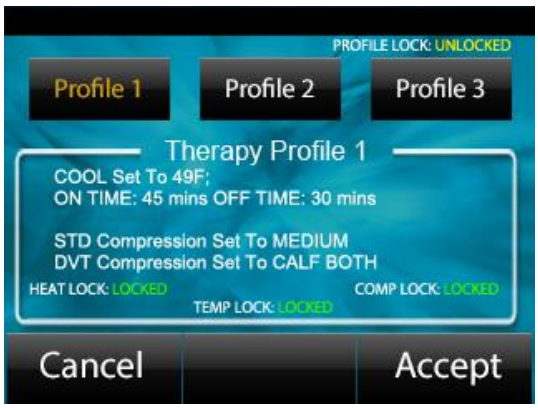


Figure 6-4: PROFILE SELECT screen

5. 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.
6. Select the profile number instructed by the provider. Review the profile settings to match the information provided by the provider.
7. Press the ACCEPT key to accept the new treatment profile.
8. 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.

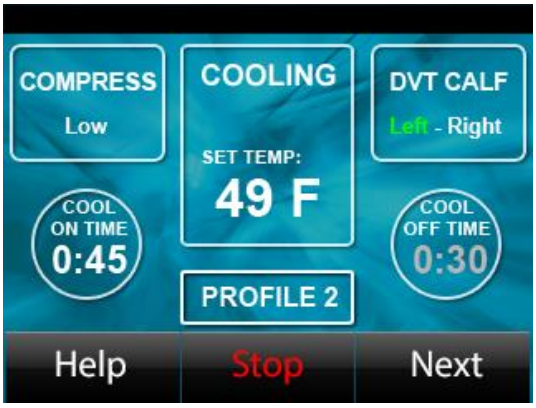


Figure 6-5: THERAPY ACTIVE screen

6.6 Quiet Mode Operation:

1. The VascuTherm 5 controller has a mode, if enabled by the equipment provider, to set the fans in QUIET mode.
2. 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.

Figure 6-6: QUIET MODE option

3. Press on the Quiet Mode key.
4. 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.

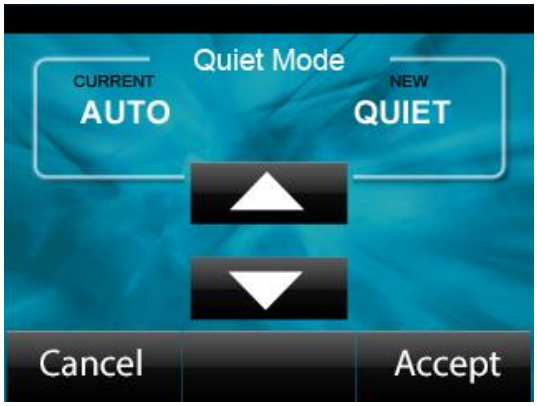


Figure 6-7: QUIET MODE option

5. 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.

7 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 serviceable internal parts. Dangerous voltages and moving parts are present inside the device. 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.

- **Remove any spilled cooling fluid with a soft dry cloth.**
- **Wipe the exterior of the unit with a damp soft cloth or an anti-microbial wipe.**
  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.

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.
    c. If the hoses are attached to the DVT air fittings, simply press in on the fitting and pull 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.

Figure 8-1: Draining the fluid

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 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 front 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 for minimum 6 hours. This helps avoid the risk of microbial growth in the unit during storage or long transport.
7. Reinstall the reservoir cap
8. Collect the following items together:

    - VascuTherm 5 Unit
    - Umbilical Hose
    - Power Cord
    - User Manual
    - Coolant Bottle

9. Store the above items in the original packing box or in the travel case you received.
10. All therapy wraps are for single patient use only. Discard the therapy wraps per local government / city laws on acceptable method of disposal.
11. Follow the instructions provided by the clinic or hospital that prescribed the unit or the Durable Medical Equipment (DME) provider on how to return the VascuTherm 5 system. If you are unable to contact the provider, please contact the ThermoTek service line at (214) 502-8800 for assistance.

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

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

10 TROUBLESHOOTING

The VascuTherm 5 has many internal software safeguards to help protect the user and the device from unsafe operation. This section contains a list of possible system warnings and alarms presented to inform the user of the potential unsafe condition where therapy efficacy may be affected.

The VascuTherm 5 alarm system uses visual notifications. There are no special pre-checks required by the user to confirm device alarm operation. The visual notification is via the multifunction display on the device, which is active and visible after a device power up.

The visual notification is presented on the LCD located on the front of the device. The user is required to be in front of the device to read the alarm message and take appropriate action(s) to resolve the fault condition.

Low Priority Alarms indicate a potential condition that may allow continued operation without redundant checks or operate at a reduced capacity, while providing cooling temperatures within the prescribed treatment range. The low priority alarm state does not halt or discontinue therapy delivery and therapy will continue. Low priority alarm notification has a of 5 to 120 seconds delay, to minimize false alarms.

Alarm notification combines the use of “ALARM ACTIVE – LOW PRIORITY” text on the upper line and an alarm description on the lower line of the display. Press the acknowledge button on the low priority alarm and continue with treatment, as desired. You can also choose to terminate the therapy session and contact customer service for assistance.

Once acknowledged by the user, most low priority alarms will not be presented for the remaining treatment time. Some low priority alarms will repeat, however, if there is a higher risk of a patient’s therapy being interrupted. If the issue that triggered the low priority alarm is not resolved, the fault state could escalate to the medium priority alarm event, at which point therapy is halted and the medium priority message is presented to the user.

Medium Priority Alarms indicate that a potentially unsafe condition is currently present or that a low priority alarm has persisted too long and halts all current therapies to protect the patient. The medium priority alarm state must be corrected before any therapy can be restarted. Medium priority alarm notification has a 5 to 600 second delay, to minimize false alarms.

Alarm notification combines the use of “ALARM ACTIVE – MED PRIORITY” text on the upper line and an alarm description on the lower line of the display. Press the acknowledge button to clear the active alarm. If the alarm state is still present, the alarm message will reappear and prevent the start of any therapy.

Below is a list of common notifications and alarms that may occur during therapy operation of the unit.

10.1 Alarm Message – Medium Priority

Problem	Cause	Suggested Actions
My unit gives me an ALARM Medium Priority **Low coolant level**	Reservoir is low on coolant. This check is performed continuously when the system is powered and operational Treatment halted when this alarm is active.	Press Accept Key to clear the alarm. Open the reservoir cap. Check the fluid level and if necessary, add fluid to the base of the neck with the provided coolant bottle. Close the cap. From the start screen, press Start to resume therapy. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me an ALARM Medium Priority **Not Cooling / No Fluid Flow Alarm** **Not Heating / No Fluid Flow Alarm**	The therapy temperature is outside of prescribed range. This check is performed continuously when the system is powered and delivering cold or heat therapy. Treatment halted when this alarm is active.	Press Accept Key to clear the alarm. Make sure the air intake side (right side of the device) is clear of any objects. Make sure the room ambient is less than 85F. Make sure all fluid ports are connected. To be sure, disconnect the ports on the gray tubes from the unit and reconnect them. You should hear a click when then ports are fully engaged. Repeat at the hose connections to the wrap. Make sure the wrap tubing or the thermal wrap is not kinked. Remove the wrap from the body and place it flat next to the unit. From the start screen, press Start to resume therapy.

		Check the clear tubes on the wrap to see if fluid Is circulating. If fluid is circulating, reapply the wrap to the body, making sure there are no kinks when applied. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me an ALARM Medium Priority **UI IC Reset (WDT)** **SYS IC Reset (DT)** **Brown-out Detected** **ADC Reset Failure** **ADC Calibration Failure** **ADC Conversion Failure** **I2C Bus Read Error** **EE Memory Read Error** **Clock Read Error** **IPC Failure**	Internal subsystem fault event. This check is performed continuously when the system is powered and operational. Treatment halted when this alarm is active. Power cycle of the device is required to restart treatment.	Turn the unit off by turning the power switch, located on the right side of the device, to the OFF position. This disconnects AC power to the unit. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me an ALARM Medium Priority **2.5V Ref High Limit** **2.5V Ref Low Limit** **5.0VDC High Limit** **5.0VDC Low Limit** **3.3VDC High Limit** **3.3VDC Low Limit** **PS1A Current High Limit** **PS1B Current High Limit**	Internal subsystem fault event. This check is performed continuously when the system is powered and operational. Treatment halted when this alarm is active.	Press Accept Key to clear the alarm. Turn the unit off by turning the power switch, located on the right side of the device, to the OFF position. This disconnects AC power to the unit. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me an ALARM Medium Priority **I2C Bus Read Alarm** **EE Memory Read Alarm** **EE Memory Write Alarm** **Clock Read Alarm** **Clock Write Alarm** **IPC Mode Mismatch Alarm**	Internal subsystem fault event. This check is performed continuously when the system is powered and operational. Treatment halted when this alarm is active.	Press Accept Key to clear the alarm. Turn the unit off by turning the power switch, located on the right side of the device, to the OFF position. This disconnects AC power to the unit. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me an ALARM Medium Priority **Supply Sensor Open** **Supply Sensor Short** **Supply Sensor Locked**	Primary temperature measurement sensor within the cooling engine hardware fault. This check is performed continuously when the system is powered and operational Treatment halted when this alarm is active.	Press Accept Key to clear the alarm. Turn the unit off by turning the power switch, located on the right side of the device, to the OFF position. This disconnects AC power to the unit. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me an ALARM Medium Priority **Manifold Sensor Open** **Manifold Sensor Short**	Secondary temperature measurement sensor within the cooling engine hardware fault. This check is performed continuously when the system is powered and operational Treatment halted when this alarm is active.	Press Accept Key to clear the alarm. Turn the unit off by turning the power switch, located on the right side of the device, to the OFF position. This disconnects AC power to the unit. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me an ALARM Medium Priority **Heatsink Sensor Open** **Heatsink Sensor Short**	Heatsink temperature measurement sensor within the cooling engine hardware fault. This check is performed continuously when the system is powered and operational Treatment halted when this alarm is active.	Press Accept Key to clear the alarm. Turn the unit off by turning the power switch, located on the right side of the device, to the OFF position. This disconnects AC power to the unit. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me an ALARM Medium Priority **Supply Sensor High Limit** **Manifold Sensor High Limit** **Heatsink Sensor High Limit**	A temperature measurement sensor(s) within the cooling engine is detecting a high temperature fault limit. This check is performed continuously when the system is powered and operational Treatment halted when this alarm is active.	Press Accept Key to clear the alarm. Make sure the air intake side (right side of the device) is clear of any objects. Make sure the room ambient temperature is less than 85F. Make sure the device is not near a heat source such as a fireplace. Make sure all fluid ports are connected. Turn the unit off by turning the power switch, located on the right side of the device, to the OFF position. This disconnects AC power to the unit. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me an ALARM Medium Priority **Supply Sensor Low Limit** **Manifold Sensor Low Limit** **Heatsink Sensor Low Limit**	A temperature measurement sensor(s) within the cooling engine is detecting a low temperature fault limit. This check is performed continuously when the system is powered and operational Treatment halted when this alarm is active.	Press Accept Key to clear the alarm. Make sure the air intake side (right side of the device) is clear of any objects. Make sure the room ambient temperature is greater than 50F. Make sure all fluid ports are connected. Turn the unit off by turning the power switch, located on the right side of the device, to the OFF position. This disconnects AC power to the unit. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me an ALARM Medium Priority **HW Safety Temp Protection Active**	Hardware safety temperature detection activated due to supply temperature sensor readings is outside save therapeutic range. This check is performed continuously when the system is powered and operational Treatment halted when this alarm is active. Power cycle of the device is required to restart treatment.	Press Accept Key to clear the alarm. Turn the unit off by turning the power switch, located on the right side of the device, to the OFF position. This disconnects AC power to the unit. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me an ALARM Medium Priority **HW Temp Lockout Failure**	Hardware safety temperature detection activated when supply temperature sensor readings are within range as reported by the software. This check is performed continuously when the system is powered and operational Treatment halted when this alarm is active.	Press Accept Key to clear the alarm. Turn the unit off by turning the power switch, located on the right side of the device, to the OFF position. This disconnects AC power to the unit. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me an ALARM Medium Priority **Standard Wrap Not Venting**	Internal pressure monitoring system has detected that the thermal compression wrap is not venting to its low-pressure state. This check is performed continuously when the system is powered and operational Treatment halted when this alarm is active.	Press Accept Key to clear the alarm. Check for any kinks in the thermal compression wrap. Remove the wrap from the body and reapply and make sure there are no kinks or folds that may block airflow. Restart therapy. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me an ALARM Medium Priority **Standard Wrap Not Inflating**	Internal pressure monitoring system has detected that the thermal compression wrap is not inflating to its high-pressure state. This check is performed continuously when the system is powered and operational Treatment halted when this alarm is active.	Press Accept Key to clear the alarm. Check the connection ports on the gray tube of the therapy hose are securely connected to the unit and the thermal compression wrap. Restart therapy. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me an ALARM Medium Priority **Standard Wrap Not Holding**	Internal pressure monitoring system has detected that the thermal compression wrap is not able to maintain its high-pressure state. This check is performed continuously when the system is powered and operational Treatment halted when this alarm is active.	Press Accept Key to clear the alarm. Check the connection ports on the gray tube of the therapy hose are securely connected to the unit and the thermal compression wrap. Restart therapy. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me an ALARM Medium Priority **Standard Comp Over Pressure – SW**	Internal pressure monitoring system has detected that the thermal compression wrap's pressure is rising too fast during the inflation phase. This check is performed continuously when the system is powered and operational Treatment halted when this alarm is active.	Press Accept Key to clear the alarm. Check for any kinks in the thermal compression wrap. Remove the wrap from the body and reapply and make sure there are no kinks or folds that may block airflow. Restart therapy. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me an ALARM Medium Priority **DVT Wrap Not Venting**	Internal pressure monitoring system has detected that the DVT therapy wrap is not venting to its low-pressure state. This check is performed continuously when the system is powered and operational Treatment halted when this alarm is active.	Press Accept Key to clear the alarm. Check for any kinks in the DVT wrap tubing or application of the wrap to the body. Remove the wrap from the body and reapply and make sure there are no kinks or folds that may block airflow. Restart therapy. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me an ALARM Medium Priority **DVT Wrap Not Inflating**	Internal pressure monitoring system has detected that the DVT wrap is not inflating to its high-pressure state. This check is performed continuously when the system is powered and operational Treatment halted when this alarm is active.	Press Accept Key to clear the alarm. Check the connection ports on the DVT wraps are securely connected to the device. Restart therapy. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me an ALARM Medium Priority **DVT Wrap Not Holding**	Internal pressure monitoring system has detected that the DVT wrap is not able to maintain its high-pressure state. This check is performed continuously when the system is powered and operational Treatment halted when this alarm is active.	Press Accept Key to clear the alarm. Check the connection ports on the DVT wraps are securely connected to the device. Restart therapy. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me an ALARM Medium Priority **DVT Comp Over Pressure – SW**	Internal pressure monitoring system has detected that the DVT compression wrap's pressure is rising too fast during the inflation phase. This check is performed continuously when the system is powered and operational Treatment halted when this alarm is active.	Press Accept Key to clear the alarm. Check for any kinks in the thermal compression wrap. Remove the wrap from the body and reapply and make sure there are no kinks or folds that may block airflow. Restart therapy. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me an ALARM Medium Priority **DVT Comp Over Pressure – SW**	Internal pressure monitoring system has detected that the DVT compression wrap's pressure is rising too fast during the inflation phase. This check is performed continuously when the system is powered and operational Treatment halted when this alarm is active.	Press Accept Key to clear the alarm. Check for any kinks in the thermal compression wrap. Remove the wrap from the body and reapply and make sure there are no kinks or folds that may block airflow. Restart therapy. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me an ALARM Medium Priority **Comp Over Pressure - HW**	Hardware safety pressure detection activated due to the device's pressure sensor reading outside therapy range This check is performed continuously when the system is powered and operational Treatment halted when this alarm is active.	Press Accept Key to clear the alarm. Check for any kinks in the thermal compression wrap. Remove the wrap from the body and reapply and make sure there are no kinks or folds that may block airflow. Turn the unit off by turning the power switch, located on the right side of the device, to the OFF position. This disconnects AC power to the unit. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me an ALARM Medium Priority **HW Comp Lockout Failure**	Hardware safety pressure detection activated when pressure sensor readings are within range as reported by the software. This check is performed continuously when the system is powered and operational Treatment halted when this alarm is active.	Press Accept Key to clear the alarm. Turn the unit off by turning the power switch, located on the right side of the device, to the OFF position. This disconnects AC power to the unit. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists.

10.2 Alarm Message – Low Priority

Problem	Cause	Suggested Actions
My unit gives me an ALARM Low Priority **Low coolant Warning**	The coolant in the reservoir is getting low when heat / cool therapy is active. This check is performed continuously when the system is powered and operational Treatment is not interrupted when this alert is active.	Press Accept Key to clear the alert. The run therapy information screen will be displayed. While therapy is running, open the reservoir cap and add coolant to the base of the neck with the provided coolant bottle. Close the cap. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me an ALARM Low Priority **Ambient Sensor Open** **Ambient Sensor Short**	Ambient measurement sensor hardware fault. This check is performed continuously when the system is powered and operational Treatment is not interrupted when this alert is active.	Press Accept Key to clear the alert. The run therapy information screen will be displayed. If you choose, turn the unit off by turning the power switch, located on the right side of the device, to the OFF position. This disconnects AC power to the unit. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me an ALARM Low Priority **Ambient Sensor High Limit**	Internal ambient temperature measurement sensor(s) within the cooling engine is detecting a high temperature fault limit. This check is performed continuously when the system is powered and operational Treatment is not interrupted when this alert is active.	Press Accept Key to clear the alert. The run therapy information screen will be displayed. Make sure the air intake side (right side of the device) is clear of any objects. Make sure the room ambient temperature is less than 85F. Make sure the device is not near a heat source such as a fireplace. If you choose, turn the unit off by turning the power switch, located on

		the right side of the device, to the OFF position. This disconnects AC power to the unit. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me an ALARM Low Priority **Ambient Sensor Low Limit**	Internal ambient temperature measurement sensor(s) within the cooling engine is detecting a high temperature fault limit. This check is performed continuously when the system is powered and operational Treatment is not interrupted when this alert is active.	Press Accept Key to clear the alert. The run therapy information screen will be displayed. Make sure the air intake side (right side of the device) is clear of any objects. Make sure the room ambient temperature is greater than 50F If you choose, turn the unit off by turning the power switch, located on the right side of the device, to the OFF position. This disconnects AC power to the unit. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me an ALARM Low Priority **PS1A Current Low Limit** **PS1B Current Low Limit**	Potential internal subsystem fault event. This check is performed continuously when the system is powered and operational. Treatment is not interrupted when this alert is active.	Press Accept Key to clear the alert. The run therapy information screen will be displayed. If you choose, turn the unit off by turning the power switch, located on the right side of the device, to the OFF position. This disconnects AC power to the unit. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists.

10.3 General Questions

Problem	Cause	Suggested Actions
Nothing happens when I turn the unit on	No power to the device. Potential internal subsystem fault event.	Make sure the device is plugged in to a 120 VAC AC power outlet in your home. Turn the unit off by turning the power switch, located on the right side of the device, to the OFF position. This disconnects AC power to the unit. Wait 10 minutes and re-connect. Try an alternate AC outlet. Contact customer service if problem persists.

Problem	Cause	Suggested Actions
The wrap is leaking fluid.	The wrap connectors are not connected / seated properly. Condensation on the wrap may be mistaken for a fluid leak. Physical damage to the wrap.	During cold therapy, the patient contact side of the wrap can condensate based on the room environment. This is normal. Remove the wrap, wipe the condensate, and reapply the wrap. Disconnect and reconnect the therapy hose and wrap. If the Cooling Wrap is leaking, discontinue treatment and remove the wrap. Inspect the wrap for physical damage. If the wrap shows any signs of puncture or tear, the wrap should not be used. Contact your provide or customer service to obtain a new wrap.

11 TECHNICAL INFORMATION

The VascuTherm 5 Therapy System provides the following therapies:

1. **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.
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.
4. **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.

The VascuTherm 5 Therapy System is intended to be used in hospitals and healthcare facilities as prescribed by a healthcare professional. The system is designed for indoor use, within the temperature, pressure and humidity specifications stated below.

11.1 VascuTherm 5 System Technical Specification

VascuTherm 5 Part Number	0P9PTVT500
Operating Environment	41°F – 80°F [5°C – 27°C]
Relative Humidity	30% to 60%, Non-Condensing
Operating Altitude	< 2000 meters
Thermal Therapy Temperature Range	43°F - 49°F [6°C – 9.6°C] and 100°F - 105°F [37.8°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 fl oz. [250 ml]
Temperature Accuracy	±2°F [±1.1°C]
Input Voltage	120 VAC, 60 Hz
Input Current (Max)	6.0A

Recommended Coolant	93% Distilled Water, 7% Isopropyl Alcohol
Transport & Storage Environment	-13°F – 158°F [-25°C – 70°C] 10% - 90%, Non-Condensing

11.2 VascuTherm 5 Classification Information

US FDA Medical Device	21 CFR 878.4360
Protection Against Electric Shock Hazard	Class I per UL/EN/IEC 60601-1
Applied Protection Against Fluid Ingress	IP 20
Applied Part	Type B

11.3 VascuTherm 5 Conformance Information

Quality Assurance	FDA 21 CFR 820 QSR, ISO 13485
Safety	IEC 60601-1
Electromagnetic Compatibility (EMC)	IEC 60601-1-2

11.4 VascuTherm 5 Guidance and Manufacture's Declaration – Electromagnetic Emissions

Emission Test	**Compliance**	**Electromagnetic Environment - Guidance**
Radiated Emissions EN 55011	Complies to Group 1, Class B	The VascuTherm 5 System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference to nearby electronic equipment. The VascuTherm 5 System is suitable for use in all hospitals, health service clinics and homes connected to the public low voltage power adapter network that supplies buildings used for domestic purposes.
Conducted Emissions EN 55011	Complies to Group 1, Class B	
Harmonics Emission EN 61000-3-2	Complies	
Voltage fluctuations / flicker emissions EN 61000-3-3	Complied	

11.5 VascuTherm 5 Guidance and Manufacture's Declaration – Electromagnetic Immunity

Immunity Test	**IEC 60601 Test Level**	**IEC 60601 Test Level**	**Electromagnetic Environment - Guidance**
Electrostatic Discharge EN 61000-4-2	± 8kV contact ± 156kV air	± 8kV contact ± 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered in synthetic material, the relative humidity should be at least 30%
Electrical Fast Transient / Burst EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/	± 2 kV for power supply lines ± 1 kV for input/	Mains power quality should be that of a typical commercial or hospital environment.

	output lines	output lines	
Surge EN 6100-4-5	± 1 kV line to line ± 2 kV line to earth	± 1 kV line to line ± 2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power adapter lines EN 61000-4-11 (per EN60601-1-2, 4th ed)	<5% UT, (95% dip in UT) for 0.5 cycle 40% UT, (60% dip in UT) for 5 cycles 70% UT, (30% dip in UT) for 25 cycles < 5% UT, (95% dip in UT) for 5 sec	<5% UT, (95% dip in UT) for 0.5 cycle 40% UT, (60% dip in UT) for 5 cycles 70% UT, (30% dip in UT) for 25 cycles < 5% UT, (95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) Magnetic field EN 61000-4-8	30 A/m (60 Hz)	30 A/m (60 Hz)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF EN 61000-4-6 Radiated RF EN 6100-4-3	3Vrms 0.15MHz to 80 MHz 3V/m 80 MHz – 2.7 GHz	3Vrms 0.15MHz to 80 MHz 3V/m 80 MHz – 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the VascuTherm 5 system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

11.6 EMC Notice

This equipment generates, uses, and can radiate radio frequency energy. If not installed and used in accordance with the instructions in this manual, electromagnetic interference may result. The equipment has been designed to provide reasonable protection against electromagnetic interference when operated in the intended use environments described in this manual.

11.7 MRI Notice

This equipment contains electronic and ferrous components whose operation can be affected by intense electromagnetic fields. Do not operate the system in an MRI environment or in the vicinity of high-frequency surgical diathermy equipment, defibrillators, or shortwave therapy equipment. Electromagnetic interference could disrupt the operation of the device.

11.8 Internal Battery

The device uses a 3V, 48 mAH, Lithium coin cell battery for maintaining its real-time clock. This battery is not user replaceable or serviceable.

11.9 Calibration

VascuTherm 5 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 for testing and calibration.

11.10 Electromagnetic Interference

This device has been tested and found to comply with the limits for Medical Devices according to IEC60601-1-2. These limits are designed to provide reasonable protection against harmful interference in typical medical installations. This equipment generates and radiates radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. There is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user can try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the physical separation between the equipment and other device(s).
- Connect the equipment into an outlet or circuit different from the one where the other device(s) are connected.

12 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
- **Service Line** (after hours): (214) 502-8800

13 PACKAGING

Boxes/Foam:

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

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 VascuTherm 5 system will be free from defects in workmanship and material under normal use for two years after the date of purchase (domestic only). 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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