VascuTherm™ 4
User Manual

ThermoTek™

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Chapter 1

Introduction:

Please read the entire manual carefully before trying to operate the VascuTherm 4™ system. It is unsafe to start using the VascuTherm™ 4 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™ 4 experience better, please do not hesitate to contact us.

User Assistance Information:

The VascuTherm™ 4 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

Icons Used for Warnings and Cautions:

 Dangerous Voltage

 General Caution

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

In the event of a Medical Emergency, call:

9-1-1

Chapter 2

Glossary of Terms:

Arterial Dysregulation:	A physiological impairment of the arteries.
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.
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 subcutaneous 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:	A accumulation of an excessive amount of watery fluid or blood in cells, tissues or serous cavities of the body.
Erysipelas:	An acute superficial form of cellulitis; a spreading inflammation of subcutaneous or connective tissue.
Hypertonia:	Extreme tension of the muscles or arteries.
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 or with rapid coagulation of the blood. Usually caused by prolonged bed-rest, pregnancy or surgery.
Pulsating Compression:	Also called intermittent or undulating compression, is the manipulation of subcutaneous compartment pressures in a high-to-low repeating cycle.
Stasis Dermatitis:	A common inflammatory skin disease that occurs on the lower extremities in patients with chronic venous insufficiency with venous hypertension.
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.
Vein Ligation:	The presence of veins that have been surgically rejoined.
Venous Stasis:	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™ 4 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™ 4 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™ 4 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 Cautions:


Never push objects of any kind into the therapy unit through the exterior case.


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 power supply; Autec Power Systems model DT-M250-48-BE2, 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 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 therapy wraps by an open flame.

Do not stick a finger or any other foreign objects into the reservoir.

Do not drink or ingest the coolant.

3.5 Warnings:

If unusual swelling, skin discoloration or discomfort occurs, immediately discontinue use of the VascuTherm 4 unit and consult a healthcare professional.

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 potential for cold injury even when providing cooling within the prescribed treatment settings.

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.

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.

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.

Do not attempt to sterilize this device by any means.

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 4 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.

The power cord could be a potential tripping hazard. Use caution while walking over the power cord.

Observe all warning and caution labels. Never remove the caution/warning labels.

Chapter 4

Indications for Use:

The VascuTherm™ 4 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™ 4 Device Description:

The VascuTherm™ 4 therapy system is an electronic heating, cooling and compression system. The VascuTherm™ 4 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 - 50°F [6.0°C - 10.0°C] and 105°F [40.5°C]
- 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
- 100-240 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.***

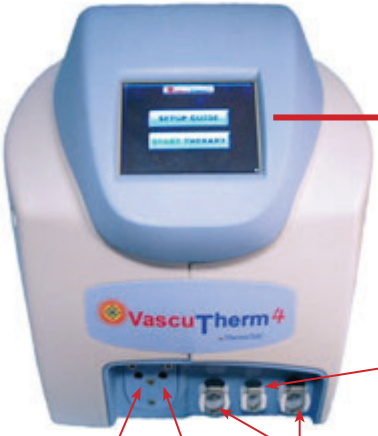
5.2 General Specifications:

- Weight: 9.5 lbs.
- Hose Length: 5 ft.
- Hospital Grade Power Cord
- Dimensions: 9.81"W x 9.88"H x 8.75"D
- Operating Fluid: 90% Distilled Water/10% Isopropyl Alcohol
- Safety: IEC 60601-1 and IEC 60601-1-2

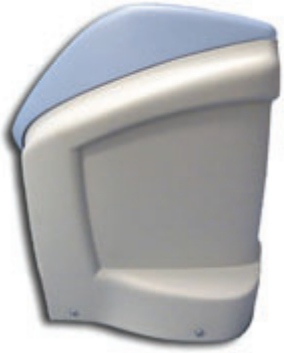
5.3 Options:

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

5.4 Device Description:



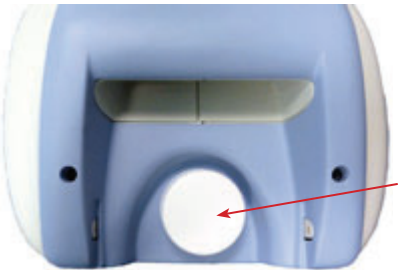
Touch Screen User Interface



RIGHT SIDE

LEFT SIDE

Air Exhaust Vent


Coolant Reservoir Opening

TOP


Air Intake
Caution label
Serial Number label
USB Connection
Marking label
Power Connection

BACK

Chapter 6

Unpacking Your VascuTherm™ 4 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 877-242-3232.

Immediately upon unpacking your VascuTherm™ 4 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™ 4 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™ 4 Device:

The VascuTherm™ 4 therapy system is intended for indoor use only.

Do not operate the VascuTherm™ 4 system with therapy wraps in or near a wet environment.

The VascuTherm™ 4 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™ 4 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.
- 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™ 4 System for Therapy:

Now that you have fully unpacked your VascuTherm™ 4 Therapy System and verified that all of the necessary equipment is present and not damaged, you may begin to prepare the system for treatment.

- Place the VascuTherm™ 4 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.

- Connect the output connector and the power supply to the back of the unit.

Follow steps 3-12 on the touch screen display for a complete setup guide prior to beginning any treatment.

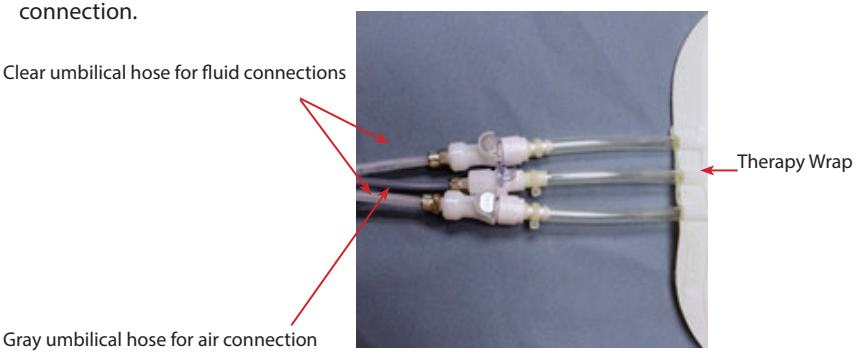
- Connect the power cord to the power supply input connector and connect the opposite end of the power cord to a grounded wall outlet.

- The unit will power-up and the Start Screen will be presented.

- 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.

- Unscrew and remove the coolant reservoir cap from the top of the unit. To prevent any seepage into the device, block the handle area as shown. Using the coolant bottle supplied with the therapy system, fill the reservoir to the bottom of the reservoir neck (see section 5.4 Coolant Reservoir Fill Location). See the coolant mixing instructions label located on the coolant bottle. Close the cap tightly.

- Connect the clear and grey hoses from the umbilical hose to the therapy wrap used for treatment. The fittings should make a "click" sound when inserted to indicate a secure connection.



- On the front of the unit, connect the clear and gray hoses from the umbilical as shown. The fittings should make a "click" sound when inserted to indicate a secure connection.

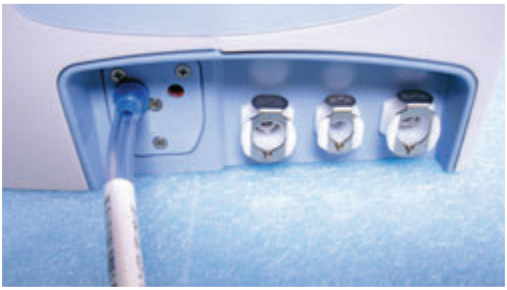
Umbilical connections to VascuTherm 4 front panel

- If DVT Compression wraps are provided, un-wrap them and connect to the front of the unit as shown in the picture below.

- For bi-lateral operation, connect each of the wraps into the two available ports.

DVT connections for bi-lateral therapy

- For a left DVT operation, connect the wrap into the left port. For right DVT operation, connect the wrap into the right port.



DVT connection for left DVT therapy

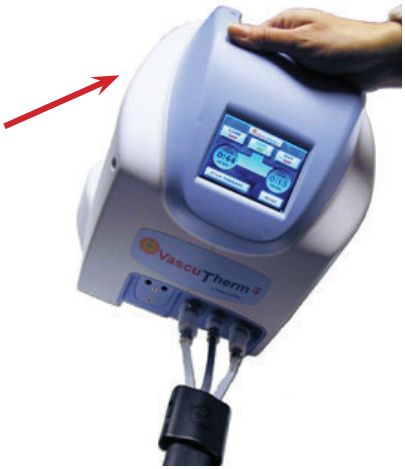
- A quick start guide is also available on the unit from the start therapy screen. Select SETUP GUIDE to review the information.

Priming your Unit:

1. Follow the instructions in Chapter 9 for turning on Cool Therapy.

NOTE: Remove the reservoir cap from the unit.

2. After turning on Cool Therapy, lower the wrap about 1.5 ft. [0.5 m] below the unit and tilt the unit to the right for no more than 10 seconds at initial start up as to release the air bubbles trapped in the system.



Tilt unit to the right to release air bubbles trapped in the system.

3. Stop therapy. Check the reservoir fluid level after stopping the fluid pump and fill the reservoir as necessary.

NOTE: you may get a Check Flow/Fluid Alarm or Low Temp Alarm if the unit remains with the therapy running and with the fluid pump ON without having a good flow of fluid through the system and the wraps. To avoid these alarms, make sure you STOP therapy about 30 seconds after you START therapy while you are trying to prime your unit and achieve a good fluid flow.

4. Start therapy again while tilting the unit to the right for about 30 seconds.

5. Shake the wrap so as to help it release the bubbles it may have inside.

6. Stop therapy. Check the reservoir fluid level one more time and fill the reservoir as necessary.

7. Repeat steps 4-6 until you can verify there is fluid moving through the clear fluid tubes, there are little to no air bubbles in the tubes or wraps.

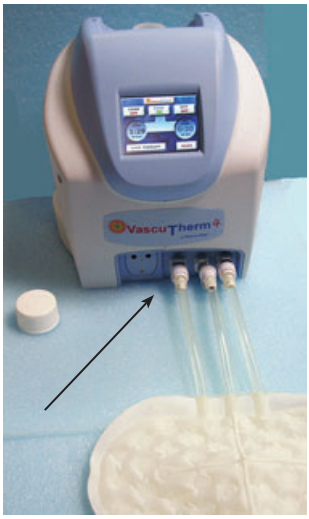
8. Priming your unit will take approximately 5 to 10 minutes to complete.

9. After you see that enough fluid has filled up the wrap and a good flow is going from the unit to the wrap and back into the unit, you have completed the priming process for the VascuTherm™ 4 and you are ready to begin therapy.

10. If steps 1 through 9 are ineffective, try the following options:

- Disconnect the umbilical hose from the unit and connect the therapy wrap directly to the unit.

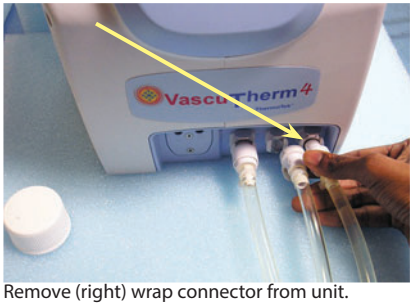
Disconnect umbilical from unit.

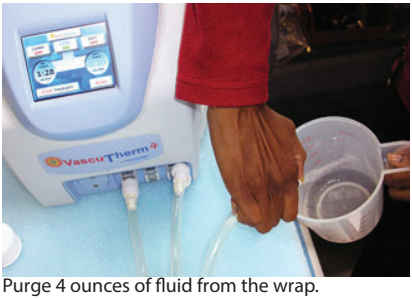


Connect therapy wrap directly to unit.

- From the front of the unit, remove the (right) wrap connector from the unit. Press the connector end to purge 4 ounces of fluid from the wrap into a cup.

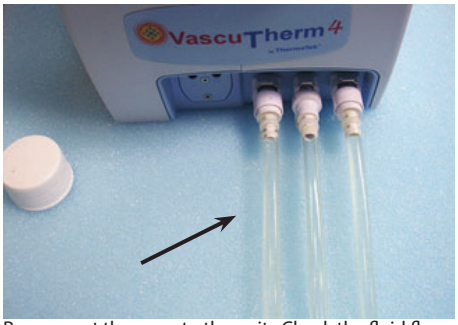
NOTE: Do not spill any fluid onto the unit.


Remove (right) wrap connector from unit.



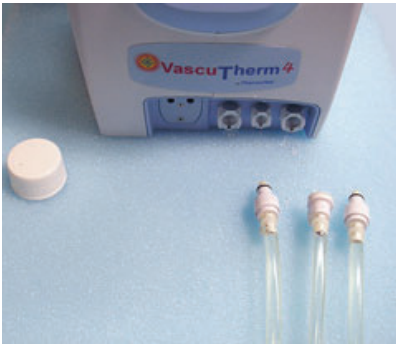
Purge 4 ounces of fluid from the wrap.

- Re-connect the therapy wrap to the unit and visually check the fluid flow for air bubbles. Let the system run for 1 minute or so to cool the wrap which determines fluid flow. Verify all air bubbles have been purged from the fluid lines of the wrap.

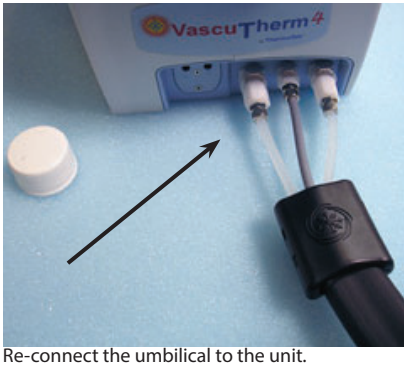


Re-connect the wrap to the unit. Check the fluid flow and verify all air bubbles have been purged.

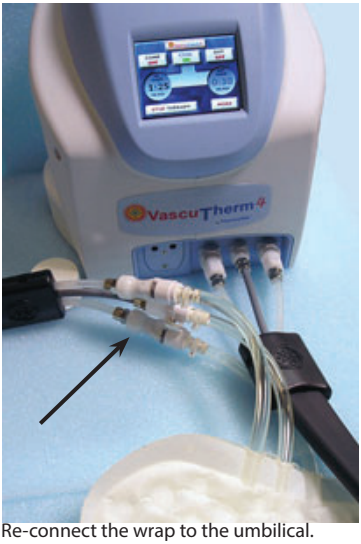
- Disconnect the therapy wrap from the unit completely. Re-connect the umbilical to the unit and re-connect the wrap to the umbilical. Visually check fluid flow. Let the system run for 1 minute or so to cool the wrap which determines fluid flow.



Disconnect therapy wrap from unit completely.



Re-connect the umbilical to the unit.



Re-connect the wrap to the umbilical.

- Replace the reservoir cap. Screw onto the reservoir tightly.

- The VascuTherm™ 4 needs to be primed only when it is first set-up or when a new unfilled wrap is connected. Once correctly primed, the system should operate for 2-3 weeks until you may need to add fluid and possibly prime the system again.

Air bubbles trapped in the unit's system may affect your unit's performance.

Chapter 9

Operating Instructions for your VascuTherm™ 4 System:

Refer to Chapter 8 "How to Set Up Your VascuTherm™ 4 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™ 4 system are designed to maximize the effectiveness of the therapies listed above. Only use wraps in combination with therapy modes as prescribed.

The VascuTherm™ 4 Therapy System is capable of performing therapies for the following:

- Cool Therapy,
- Heat Therapy,
- Pneumatic Compression Therapy for Edema and Lymphedema,
- Pneumatic Compression Therapy to reduce the risk of DVT (Deep Venous Thrombosis).

9.1 Turning the Unit ON for the First Time:

The VascuTherm™ 4 therapy system is capable of being programmed with a specific prescribed therapy by the equipment provider. Your therapy unit may have been programmed in such a manner or may be intended to be used with manually initiated therapies. To set up the unit for therapy, follow the instructions below.

- Connect the external power supply to the unit and connect the power supply to a grounded AC power outlet.
- When first powered up, the unit will beep briefly and the VascuTherm™ 4 and ThermoTek logos will briefly appear while the unit is starting up.
- The selections are "**SETUP GUIDE**" (a guide on how to setup the unit and the wraps before use), "**START THERAPY**" to begin the therapy.
- The menu selections can be selected by touching the keys on the touch screen pad in the Setup Screen.

Automatic Pre-Programmed Therapy

- If the device has been pre-programmed, then by selecting "**START THERAPY**" on the Start Screen, the pre-programmed therapy is initiated and the Main Therapy Screen will appear.

- To stop therapy, select "**STOP THERAPY**" on the Main Therapy Screen.

START SCREEN

MAIN THERAPY SCREEN

- The unit will notify you of a mode change by a sustained audible beep. If you happen to change the unit from automatic to manual mode, you must disconnect the unit from the power supply and reconnect the unit to turn it back on again to restart automatic therapy and the therapy timer. Any therapy time used on the timer will not be retained and therapy will restart from the beginning to ensure proper treatment.

- The set temperature may be pre-programmed and locked. If the set temperature is pre-programmed and locked, you will not have the option to change the set temperature during cool therapy.

- With the unit running in Cool Mode, open the reservoir cap and check the coolant level. Add coolant if necessary. Close the cap tightly.

Manually Controlled Therapy

If the device has not been pre-programmed to set therapy, follow the instructions on how to control the unit manually detailed in the following chapters 9.2 to 9.5.

9.2 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 (see the instructions in Chapter 9.5).

- To initiate Cool Therapy, select "**COOL**", the Therapy Setup Screen will appear. The Cool Therapy can be turned ON or OFF by selecting "**COOL ON**" or "**COOL OFF**" and selecting "**SAVE**".

MAIN THERAPY SCREEN

THERAPY SETUP SCREEN

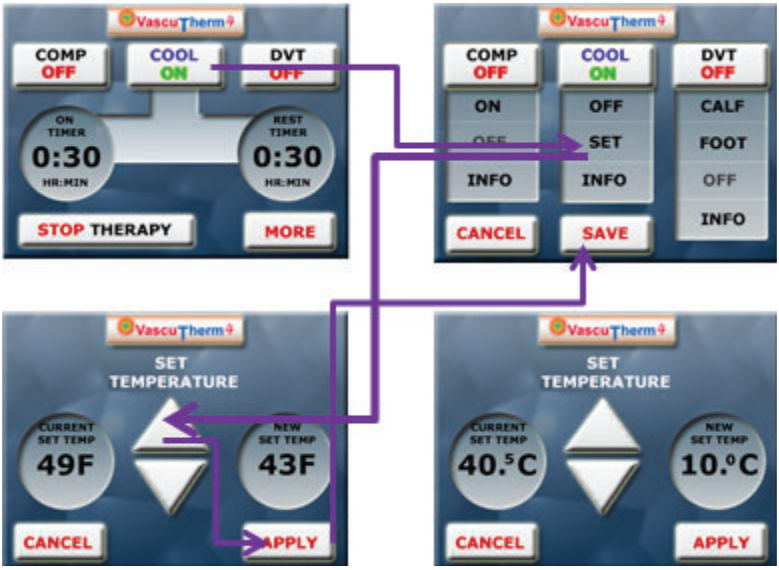
MAIN THERAPY SCREEN

THERAPY SETUP SCREEN

- The temperature can be set to the desired setting by selecting "**COOL**" then selecting "**SET**". The Temperature Set Screen will appear. On the left, the current set temperature is displayed. Select the "**UP**" or "**DOWN**" arrows to achieve the desired temperature setting. The new temperature will be displayed on the right. Temp will scroll from *43°F to 50°F, and then it will jump to 105°F. If set to 105°F, the therapy mode will be set to heat and the label will change to "**HEAT**".

- In degree Celsius scale, the temp will scroll from 6°C to 10°C, and then it will jump to 40.5°C.

**The ability to achieve 43°F will depend on the wrap size and ambient temperature and may not be possible in every situation.*



- Once the desired temperature setting is achieved, select "**APPLY**". The Therapy Setup Screen will re-appear. Select "**SAVE**" to save the new set temperature selected or select "**CANCEL**" to cancel the set temperature changes and cancel Therapy Setup Screen and go back to the Main Therapy Screen.

- If you want to show the current therapy setting, select "**INFO**" under Cool Menu. The system will show the following information, therapy setting, therapy temperature and time settings.

- Select "**RETURN**" to return to the Therapy Setup Screen. Select "**SAVE**" or "**CANCEL**" to return to the Main Therapy Screen.

- Once treatment is initiated, the Main Therapy Screen will display the current therapy settings:

MAIN THERAPY SCREEN

- For the current therapy duration, the "**ON TIMER**" will display the minutes remaining for therapy and appear "Bold" and the "**REST TIMER**" will appear "Faded Out". When the therapy has stopped, the "**REST TIMER**" will display the minutes remaining before the therapy can start again and it will appear "Bold" and the "**ON TIMER**" will appear "Faded Out".

- To stop therapy, select "**STOP THERAPY**". Display will return to the Start Screen.

When the prescribed therapy duration is complete:

- If the display is in the Main Therapy Screen, select "**STOP THERAPY**" from the Main Therapy Screen. The Cool Therapy will stop and the display will return to the Start Screen.

- To disable Cool Therapy and continue with other active therapy modalities, and prevent it from running on the next start up, from the Therapy Setup Screen, select "**COOL**" followed by "**OFF**". The unit will return to the Main menu and Cool Therapy will be disabled until re-enabled by the user.

- If no additional therapies are to used, it is recommended to turn the unit OFF. Once the unit is OFF, you may now remove your therapy wraps.

⚠ Compression should be turned OFF when the therapy wrap is not on the patient. Allowing the wrap to inflate while unattended or to inflate all the way to a "ballooned" state can cause damage to the wrap and will reduce the life of the wrap.

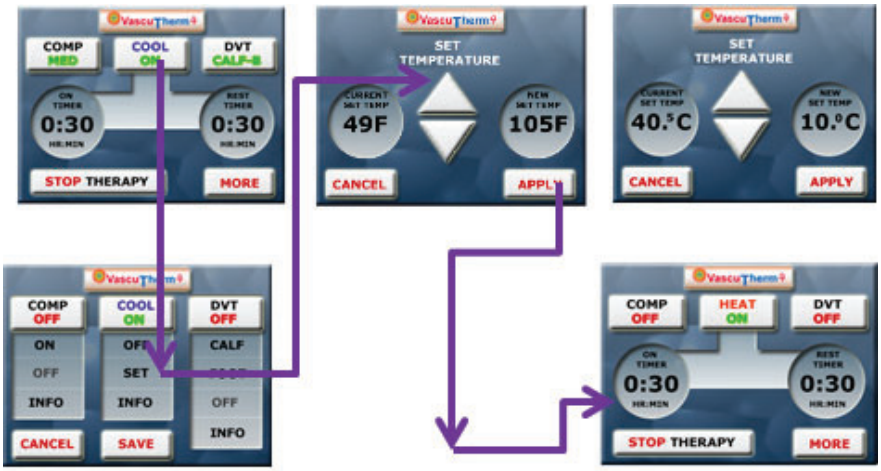
9.3 Heat Therapy:

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 (see the instructions in Chapter 9.4).

- To initiate Heat Therapy, select "**COOL**" on the Main Therapy Screen. The Therapy Setup Screen will appear. The Heat Therapy can be turned ON or OFF by selecting "**SET**". Increase the temperature by selecting the "**UP**" arrow until it reaches 105°F (40.5°C). Select

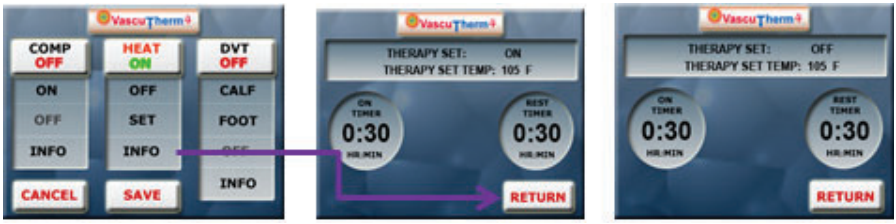
"**APPLY**" and then select "**SAVE**". The Main Therapy Screen will re-appear.

- If the Heat Mode is OFF, select "**HEAT**" and select "**ON**" on the Therapy Setup Screen and select "**SAVE**" to initiate Heat Therapy.



- If set to 105°F, the label will change to "**HEAT**". In degree Celsius scale, the temp will scroll from 6°C to 10°C, and then it will jump to 40.5°C.

- If you want to show the current therapy setting, select "**INFO**" under the Heat Menu. The system will show the following information; therapy setting, therapy temperature and time settings.



- Select "**RETURN**" to return to the Primary Therapy Screen. Select "**SAVE**" or "**CANCEL**" to return to the Main Therapy Screen.

- Once treatment is initiated, the Main Therapy Screen will display the current therapy settings.

MAIN THERAPY SCREEN

- For the current therapy duration; the "**ON TIMER**" will display the minutes remaining for therapy and appear "Bold" and the "**REST TIMER**" will appear "Faded Out". When the therapy has stopped, the "**REST TIMER**" will display the minutes remaining before the therapy can start again and it will appear "Bold" and the "**ON TIMER**" will appear "Faded Out".

When the prescribed therapy duration is complete:

- If the display is in the Main Therapy Screen, select "**STOP THERAPY**" from the Main Therapy screen. The Cool therapy will stop and the display will return to the Start screen.

- To disable Heat therapy and continue with other active therapy modalities, and prevent it from running on the next start up, from the Therapy Setup Screen, select "**HEAT**", followed by "**OFF**". The unit will return to the Main menu and Heat therapy will be disabled until re-enabled by the user.

- If no additional therapies are to be used, it is recommended to turn the unit OFF. Once the unit is OFF, you may now remove your therapy wraps.

⚠ Compression should be turned OFF when the therapy wrap is not on the patient. Allowing the therapy wrap to inflate while unattended or to inflate all the way to a "ballooned" state can cause damage to the wrap and will reduce the life of the wrap.

9.4 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.

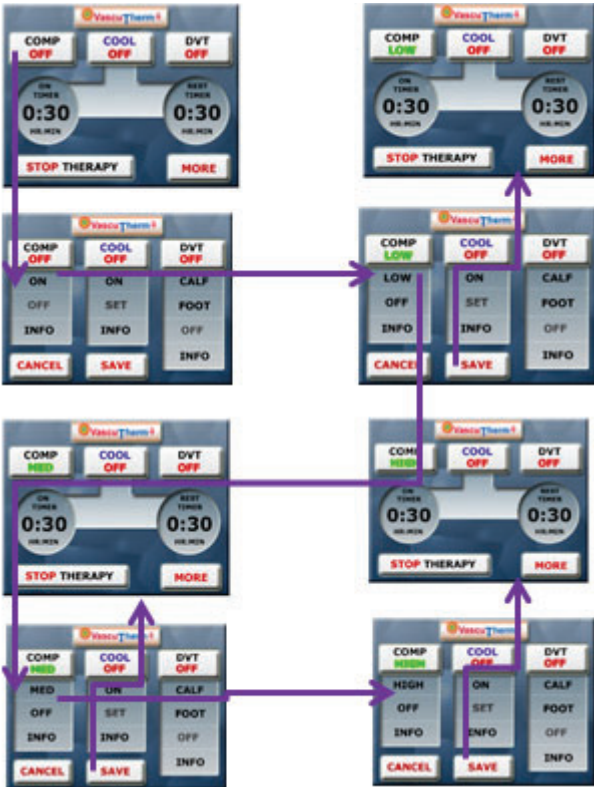
To help ease discomfort during compression treatments, pneumatic compression therapy can be used in combination with Cool or Heat. See the instructions in Chapters 9.2 and 9.3 for additional details on Cool or Heat therapies.

Make sure the therapy wrap is applied properly before initiating any compression therapy. Allowing the wrap to inflate while unattended or to inflate all the way to a "ballooned" state can cause damage to the wrap and reduce the life of the wrap.

- To initiate Compression Therapy, select "**START THERAPY**" from the Start Menu and the Main Therapy screen will appear.

- To turn "**ON**" the Compression Therapy for Edema, also known as Standard Compression, select "**COMP**" from the Main Therapy screen. The Primary Therapy screen will appear. Standard Compression has three compression levels; Low (15 mmHg), Med (30 mmHg) and High (50 mmHg).

- Select "**ON**" for the "**COMP LOW**" to appear. To change from Low Level to Med Level, select "**LOW**", the pressure setting will change to "**COMP MED**". To change from Med Level to High Level, select "**MED**" and the screen will show "**COMP HIGH**". To return to Low Level, select "**HIGH**" and the screen will show "**COMP LOW**" again. Select "**SAVE**" to save the compression settings desired. Select "**CANCEL**" to cancel the changes and return to the Main Therapy screen.



- If you want to show the current therapy setting for compression, select "**INFO**" under the "**COMP**" menu. The system will show the following information; therapy setting and therapy pressure.

- Select "**RETURN**" to return to the Therapy Setup screen. Select "**SAVE**" to return to the Main Therapy screen.

When the prescribed therapy duration is complete:

- If the display is in the Main Therapy screen, select "**STOP THERAPY**" from the Main Therapy screen. The compression therapy will stop and the display will return to the Start screen.

- To disable Compression therapy and prevent it from running on the next start up, from the Therapy Setup screen, select "**COMP**", then select "**OFF**". Select "**SAVE**" to save the changes made. The unit will return to the Main menu and the Compression Therapy will be disabled until re-enabled by the user.

- If no additional therapies are to be used, it is recommended to turn the unit OFF. Once the unit is OFF, you may now remove your therapy wraps.

⚠ Compression should be turned OFF when the therapy wrap is not on the patient. Allowing the wrap to inflate while unattended or to inflate all the way to a "ballooned" state can cause damage to the wrap and will reduce the life of the wrap.

9.5 DVT Calf Compression Therapy:

⚠ The use of Calf therapy on the Foot is not an effective or approved treatment to reduce the risk of clot formation.

⚠ Make sure the therapy wrap is applied properly before initiating any compression therapy. Allowing the wrap to inflate while unattended or to inflate all the way to a "ballooned" state can cause damage to the wrap and will reduce the life of the wrap.

The use of Calf Compression therapy is for bilateral use. If for any reason only the Left DVT wrap will be used, connect the wrap to the left port or connect the wrap to the right port if only the Right DVT wrap will be used.

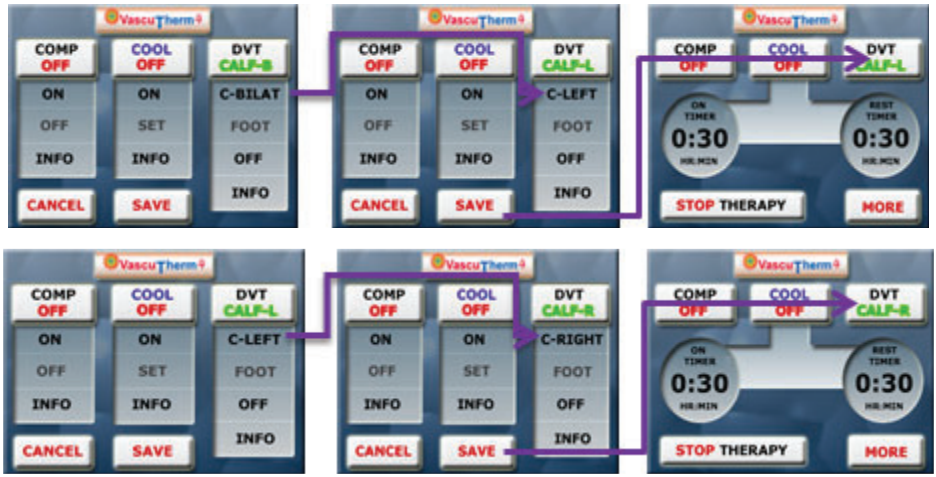
DVT Calf Compression therapy is used in combination with specially designed therapy wraps to transfer pressure to the calf area of the lower leg using compressed air. The preset inflation and deflation cycle of the VascuTherm 4™ therapy system simulates natural walking action. This increases blood flow return to the heart through the veins of the lower extremities to reduce the risk of clot formation.

- To initiate DVT Calf Compression, select "**START THERAPY**" from the Start Menu and the Main Therapy screen will appear.

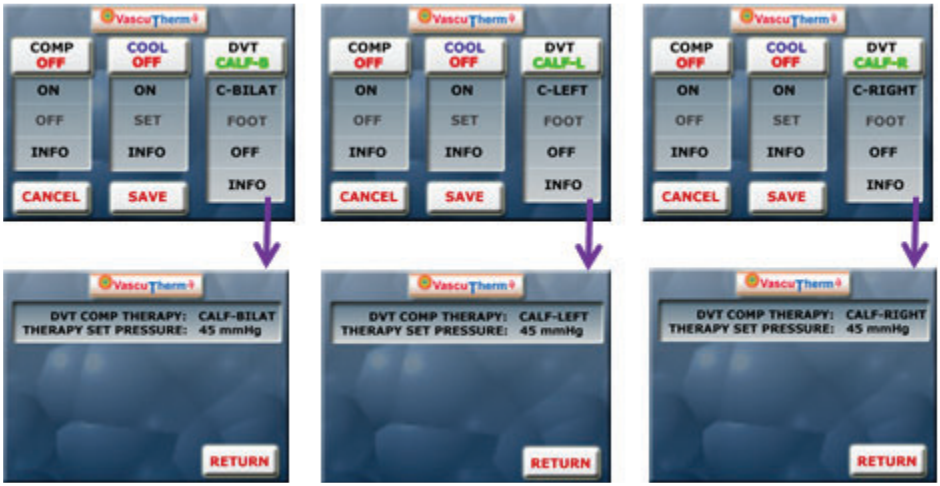
- On the Main Therapy screen (COMP/COOL/DVT) select "**DVT**" and you will be taken to the Primary Therapy screen.

- Select "**CALF**" from the Primary Therapy screen, the display will change and now read "**C-BILAT**". Bilateral compression will automatically alternate compression cycles between the left and the right calf wraps. Select "**SAVE**" to save the settings. The next screen will be the Main Therapy screen.

- If your prescribed therapy is for left calf or right calf only, keep on tapping "**CALF**", the display will continue to change and now read "**C-LEFT**" or "**C-RIGHT**". Select "**SAVE**" to save the settings. The next screen will be the Main Therapy screen.



- To show the current therapy setting for DVT, select "**INFO**" under the "**DVT**" menu. The system will show the following information; therapy setting and therapy pressure.

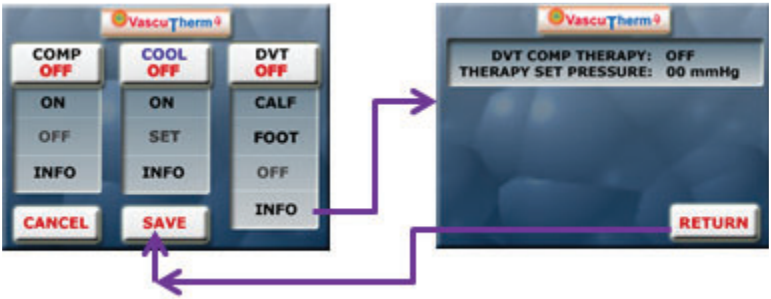


- Select "**RETURN**" from the Info screen to return to the Primary Therapy screen. Select "**SAVE**" or "**CANCEL**" to return to the Main Therapy screen.

When the prescribed therapy duration is complete:

- If the display is in the Main Therapy screen, select "**STOP THERAPY**" from the Main Therapy screen. The compression therapy will stop and the display will return to the Start screen.

- To disable DVT Compression therapy and prevent it from running on the next start up, go to the "**DVT**" menu. From the Main screen, select "**DVT**", then select "**OFF**". Select "**SAVE**" to save the changes made. The unit will return to the Main menu and DVT Compression will be disabled until re-enabled by the user.



- If no additional therapies are to be used, it is recommended to turn the unit OFF. Once the unit is OFF, you may now remove your therapy wraps.

⚠ Compression should be turned OFF when the therapy wrap is not on the patient. Allowing the wrap to inflate while unattended or to inflate all the way to a "ballooned" state can cause damage to the wrap and will reduce the life of the wrap.

9.6 DVT Foot Compression Therapy:

⚠ Use of foot therapy on the calf or any other wrap treatment area other than the foot may cause harm to the patient.

Make sure the therapy wrap is applied properly before initiating any compression therapy. Allowing the wrap to inflate while unattended or to inflate all the way to a "ballooned" state can cause damage to the wrap and will reduce the life of the wrap.

The use of Foot Compression Therapy is for bilateral use. If for any reason only the Left DVT wrap will be used, connect the wrap to the left port or connect the wrap to the right port if only the Right DVT wrap will be used.

DVT Foot Compression therapy is used in combination with specially designed therapy wraps to transfer pressure to the foot using compressed air. The preset inflation and deflation cycle of the VascuTherm 4™ therapy system simualtes natural walking action. This increases blood flow to the heart through the veins of the lower extremities to reduce the risk of clot formation.

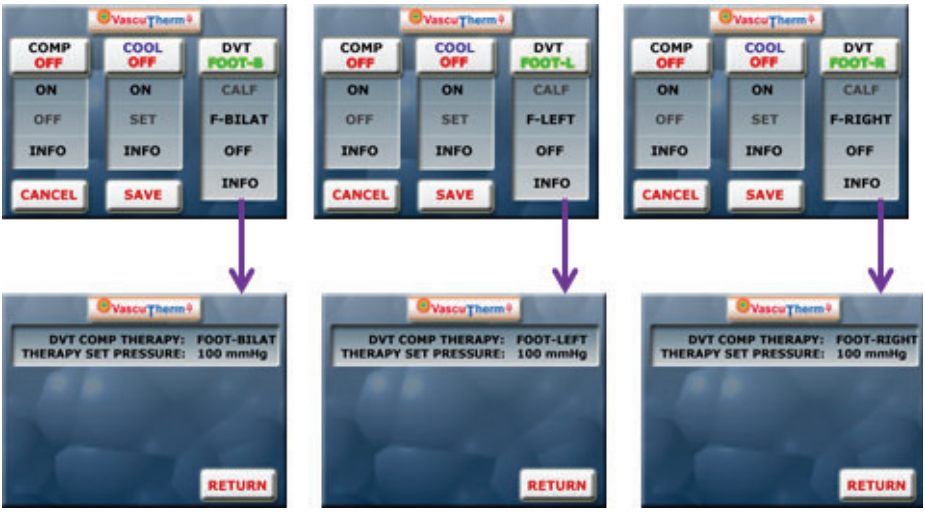
- To initiate DVT Foot Compression, select "**START THERAPY**" from the Start screen and the Main Therapy screen will appear.

- On the Main Therapy screen (COMP/COOL/DVT), select "**DVT**" and you will be taken to the Primary Therapy screen.

- Select "**FOOT**" from the Primary Therapy screen, the display will change and now read "**F-BILAT**". Bilateral compression will automatically alternate compression cycles between the left and the right calf wraps. Select "**SAVE**" to save the settings. The next screen will be the Main Therapy screen.

- If your prescribed therapy is for left foot or right foot only, keep on tapping "**FOOT**"; the display will continue to change and now read "**F-LEFT**" or "**F-RIGHT**". Select "**SAVE**" to save the settings. The next screen will be the Main Therapy screen.

- To show the current therapy setting for DVT, select "**INFO**" under the "**DVT**" Menu. The system will show the following information; therapy setting and therapy pressure.

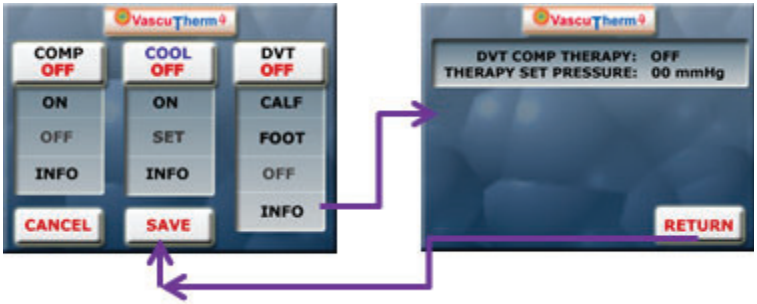


- Select "**RETURN**" from the Info screen to return to the Primary Therapy screen. Select "**SAVE**" or "**CANCEL**" to return to the Main Therapy screen.

When the prescribed therapy duration is complete:

- If the display is in the Main Therapy screen, select "**STOP THERAPY**" from the Main Therapy screen. The compression therapy will stop and the display will return to the Start screen.

- To disable DVT compression therapy and prevent it from running on the next start up, go to the "**DVT**" menu. From the Main screen, select "**DVT**", select "**OFF**", then select "**SAVE**" to save the changes made. The unit will return to the Main menu and DVT Compression will be disabled until re-enabled by the user.



- If no additional therapies are to be used, it is recommended to turn the unit OFF. Once the unit is OFF, you may now remove your therapy wraps.

⚠ Compression should be turned OFF when the therapy wrap is not on the patient. Allowing the wrap to inflate while unattended or to inflate all the way to a "ballooned" state can cause damage to the wrap and will reduce the life of the wrap.

9.7 Pneumatic Compression Therapy and DVT Calf Therapy:

⚠ At any time, Pneumatic Compression or DVT Therapy may be turned OFF separately. Turning OFF either compression mode while a wrap is inflated will deflate the respective wrap.

⚠ Make sure the therapy wrap is applied properly before initiating any compression therapy. Allowing the wrap to inflate while unattended or to inflate all the way to a "ballooned" state can cause damage to the wrap and will reduce the life of the wrap.

Follow the instructions as follows to set Pneumatic Compression Therapy and DVT Calf Compression Therapy:

⚠ Use of calf therapy on the foot is not an effective or approved treatment to reduce the risk of clot formation.

DVT Calf Compression therapy is used in combination with specially designed therapy wraps to transfer pressure to the foot using compressed air. The preset inflation and deflation cycle of the VascuTherm 4™ 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.

- Follow the instructions for STD Compression and DVT Calf Compression Therapy. Select "**ON**" for the STD COMP therapy and select the appropriate compression pressure of "**LOW**", "**MED**" or "**HIGH**". Next, select "**C-BILAT**", "**C-LEFT**" or "**C-RIGHT**" for the DVT Calf therapies. Select "**SAVE**" to save the changes made.

When the prescribed therapy duration is complete:

- Select "**STOP THERAPY**" from the Main Therapy screen. The STD Compression and DVT Calf therapy will stop and the display will return to the Start screen.

- To disable STD Compression and DVT Compression therapy and prevent it from running on the next start up, from the Main Therapy screen select "**DVT**" to go to the Primary Therapy screen. From that menu, select "**OFF**" for the DVT and "**OFF**" for the STD Comp. Select "**SAVE**" and the unit will return to the Main Therapy screen. STD Compression and DVT Calf Compression will be disabled until re-enabled with the Set Therapy procedure.

- If no additional therapies are to be used, it is recommended to turn the unit OFF. Once the unit is OFF, you may now remove your therapy wraps.

⚠ Compression should be turned OFF when the therapy wrap is not on the patient. Allowing the wrap to inflate while unattended or to inflate all the way to a "ballooned" state can cause damage to the wrap and will reduce the life of the wrap.

9.8 Pneumatic Compression Therapy and DVT Foot Therapy:

⚠ At any time, Pneumatic Compression or DVT Therapy may be turned OFF separately. Turning OFF either compression mode while a wrap is inflated will deflate the respective wrap.

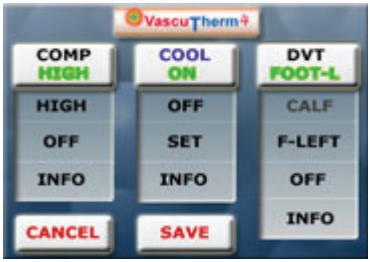
⚠ Make sure the therapy wrap is applied properly before initiating any compression therapy. Allowing the wrap to inflate while unattended or to inflate all the way to a "ballooned" state can cause damage to the wrap and will reduce the life of the wrap.

Follow the instructions as follows to set Pneumatic Compression Therapy and DVT Foot Compression Therapy:

⚠ Use of foot therapy on the calf or any other wrap treatment area other than the foot may cause harm to the patient.

DVT Foot Compression therapy is used in combination with specially designed therapy wraps to transfer pressure to the foot using compressed air. The preset inflation and deflation cycle of the VascuTherm 4™ 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.

- Follow the instructions for STD Compression and DVT Foot Compression Therapy. Select "**ON**" for the STD COMP therapy and select the appropriate compression pressure of "**LOW**", "**MED**" or "**HIGH**". Next select "**F-BILAT**", "**F-LEFT**" or "**F-RIGHT**" for the DVT Foot therapies. Select "**SAVE**" to save the changes made.



When the prescribed therapy duration is complete:

- Select "**STOP THERAPY**" from the Main Therapy screen. The STD Compression and DVT Calf therapy will stop and the display will return to the Start screen.

- To disable STD Compression and DVT Compression therapy and prevent it from running on the next start up, from the Main Therapy screen select "**DVT**" to go to the Primary Therapy screen. From that menu, select "**OFF**" for the DVT and "**OFF**" for the STD Comp. Select "**SAVE**" and the unit will return to the Main Therapy screen STD Compression and DVT Calf Compression will be disabled until re-enabled with the Set Therapy procedure.

- If no additional therapies are to be used, it is recommended to turn the unit OFF. Once the unit is OFF, you may now remove your therapy wraps.

Compression should be turned OFF when the therapy wrap is not on the patient. Allowing the wrap to inflate while unattended or to inflate all the way to a "ballooned" state can cause damage to the wrap and will reduce the life of the wrap.

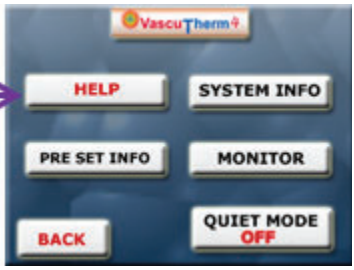
Chapter 10

System Screen:

To access the System screen, from the Primary Therapy screen select "**MORE**" and the System screen will appear. The System screen will provide information about the unit that will be helpful to the user.

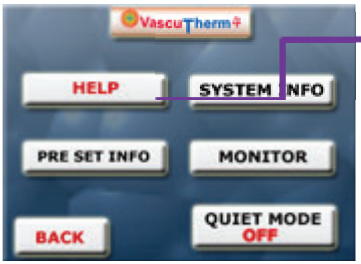
MAIN THERAPY SCREEN

SYSTEM SCREEN



- Select "**HELP**" to access the unit's information about who to contact if there are any questions or concerns regarding the VascuTherm 4. Select "**RETURN**" to return to the previous screen. Select "**BACK**" to return to the Main Therapy screen.

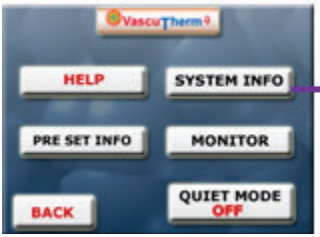
SYSTEM SCREEN



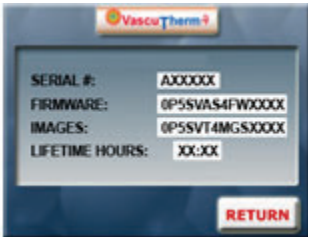
HELP SCREEN

- Select "**SYSTEM INFO**" to access the unit's information about its firmware and serial number. Select "RETURN" to return to the previous screen. Select "**BACK**" to return to the Main Therapy screen.

SYSTEM SCREEN

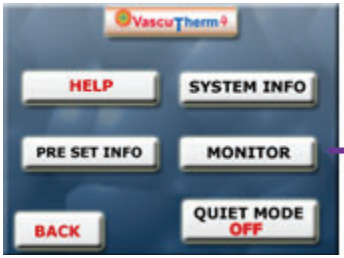


SYSTEM INFO SCREEN



- Select "**MONITOR**" to access the unit's information about its performance regarding temperature and pressure. Select "**RETURN**" to return to the previous screen. Select "**BACK**" to return to the Main Therapy screen.

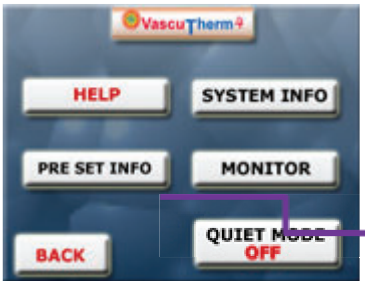
SYSTEM SCREEN



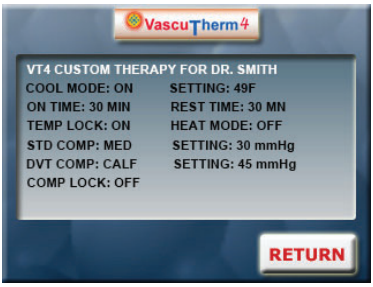
MONITOR INFO SCREEN

- Select "**PRE SET INFO**" to access the unit's information about the pre-programmed therapy information. Select "**RETURN**" to return to the previous screen. Select "**BACK**" to return to the Main Therapy screen.

SYSTEM SCREEN

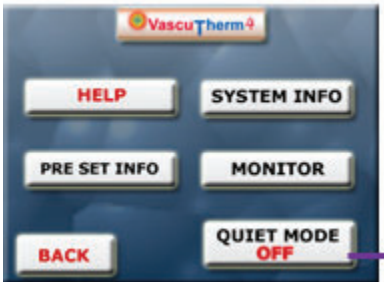


PRE PROG INFO SCREEN

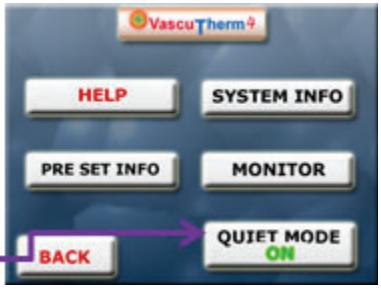


- Select "**QUIET MODE**" to turn it "ON" or "OFF" and reduce the system's noise output.

SYSTEM SCREEN



FAN SPEED CONTROL



Turning "ON" the system's "QUIET MODE" will reduce the cooling system's efficiency, especially if the unit has been recently turned on and has not reached the programmed temperature.

If you experience difficulty in setting up your VascuTherm 4 therapy system for use, please contact the clinic or hospital that prescribed the unit or the Durable Medical Equipment (DME) provider. If assistance is not available or is ineffective, please contact ThermoTek technical assistance toll-free at 1-877-242-3232 during the hours of 8am-5pm Central Time. If technical assistance is needed after these hours, you may contact the 24-hour line at (214) 502-8800.

Chapter 11

Things You Can Do To Keep Your VascuTherm™ 4 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 assistance is not available or is ineffective, please contact ThermoTek technical assistance toll-free at 1-877-242-3232 during the hours of 8am-5pm Central Time. If technical assistance is needed after these hours, you may contact the 24-hour line at 214-502-8800.

- **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.

Chapter 12

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 pull on the fitting 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 13

Storage and Re-Packing the Unit:

When therapy is complete and it is time to return or store the VascuTherm™ 4 therapy system, you can use the shipping 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 12.

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™ 4 Unit
- Reservoir Cap
- Hoses
- Power Cord
- Power Supply
- User Manual
- Coolant Mixing Bottle
- Shipping Box with Package Inserts

8. Store the above items in the original 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, power supply 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 14

Troubleshooting Guide:

The VascuTherm™ 4 Therapy System has many internal software safeguards to help protect the patient and the unit from unsafe operation. In this section, you will find a list of possible system warnings and alarms that may occur if a potentially unsafe situation arises while using the VascuTherm™ 4 unit.

Refer to Chapter 7 "Environmental Conditions You Should Be Aware of Before Operating Your VascuTherm™ 4 Device" for a list of acceptable environmental conditions for safe operation.

Neither the unit nor the wraps are intended for field repair. Do not attempt to service the unit in any way other than using the instructions listed in this guide.

If the unit is displaying an alarm, warning or system error not listed in the below Troubleshooting Guide, contact Customer Support. See the Customer Support contact information below.

Alarms indicate that an unsafe condition is currently present and halts all current therapies to protect the patient. The alarm state must be corrected before any therapy can be restarted. Alarm notification combines the use of "ALARM ACTIVE" text on the upper line and an alarm description on the lower line of the display. An audible notification is also initiated by a slow beeping noise. Press any 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.

System Errors indicate that an internal software or hardware error has occurred and that an unsafe condition is currently present and all current therapies are halted to protect the patient. An example of this is when there is a problem reading from one of the internal sensors. System errors typically require service to the unit to identify and correct the problem. If you encounter a system error, please write down what is indicated on the display and contact the clinic or hospital that prescribed the unit or the Durable Medical Equipment (DME) provider. If assistance is not available or ineffective, please contact ThermoTek technical assistance toll-free at 1-877-242-3232 during the hours of 8am - 5pm Central Time. If technical assistance is needed after these hours, you may contact the 24-hour line at (214) 502-8800.

Below is a list of common user-related warnings and alarms that may occur during therapy operation of the unit.

Problem/Alarm Screen	Cause	Suggested Actions
Nothing happens when I turn the unit to the ON position.	No power to the unit.	Make sure the unit is connected to the power supply and that the power supply is connected to an appropriate AC outlet.
	Internal fault within the therapy unit.	Check if the power supply LED is green. Turn the unit off by disconnecting the power supply. Wait 10 minutes and re-connect the power supply. Try an alternate AC outlet. Contact ThermoTek customer service if problem persists.

Problem/Alarm Screen	Cause	Suggested Actions
The unit is leaking.	The coolant ports are not connected/ seated properly.	Make sure the unit is unplugged from the AC outlet. Check the coolant connections; disconnect and reconnect the ports to make sure they are seated properly.
	Physical damage to the unit.	Inspect the unit for physical damage. If the unit shows any cracks or dents and is leaking, the unit should not be used. Contact the clinic or DME for assistance.
	Condensation on the wrap.	If the patient is utilizing cool therapy, remove the wrap and wipe it down with a clean, dry cloth. Moisture buildup could be condensation rather than a leak. If water returns immediately, discard the wrap and contact customer support.

Problem/Alarm Screen	Cause	Suggested Actions
The wrap is leaking fluid.	The coolant ports are not connected/seated properly.	Disconnect and reseat all fluid connections on the umbilical/ hose assembly.
	Physical damage to the unit.	If the wrap is leaking, turn the unit off and remove the wrap from the patient immediately. If the patient is utilizing a sterile wrap, the wound site may need to be cleaned. Consult a physician for proper wound care. Inspect the wrap for physical damage. If the wrap shows any signs of puncture or tear, the wrap should not be used. Discard the wrap and contact the clinic or DME for assistance.

Problem/Alarm Screen	Cause	Suggested Actions
The wrap is uncomfortable and/or is compressing too tightly.	The wrap is kinked.	Check if wrap is kinked as to not allow the air from the wrap to deflate. Readjust or reapply wrap to alleviate the kink.
	The wrap may be installed too tightly.	Stop compression therapy. Remove and reapply following Therapy Wrap instruction.
	Internal fault within the therapy unit.	Check the compression level on the "Monitor Screen". Compression levels should never exceed 50mmHg for Standard Compression and 100mmHg for DVT Compression. If the unit is displaying a pressure that exceeds these values for the therapies listed, stop compression immediately and contact ThermoTek customer support.

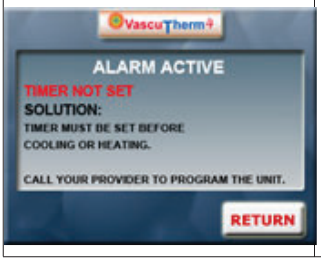
Problem/Alarm Screen	Cause	Suggested Actions
The unit is heating when it should be cooling (or cooling when it should be heating).	The unit is in Alarms Active state.	Check display for the type of alarm event. If alarms are displayed, use the troubleshooting guide to resolve the issue.
	Internal fault within the therapy unit.	Check if the power supply LED is green. Turn the unit off by disconnecting the power supply. Wait 10 minutes and reconnect the power supply. Try an alternate AC outlet. Contact ThermoTek customer service if problem persists.

Problem/Alarm Screen	Cause	Suggested Actions
Unit turns on, but it is not heating or cooling.	Heat/Cool therapy not selected.	Check the display to see if therapy mode is selected. See Chapter 9 for instructions on starting and stopping therapy modes.
	Physical damage to unit.	Inspect the unit for physical damage. If the unit shows any cracks or dents, the unit should not be used. Contact the clinic or DME for assistance.
	Coolant ports not properly connected.	Check the connections on your unit and wraps.
	Internal fault within the therapy unit.	Check if the power supply LED is green. Turn the unit off by disconnecting the power supply. Wait 10 minutes and reconnect the power supply. Try an alternate AC outlet. Contact ThermoTek customer service if problem persists.

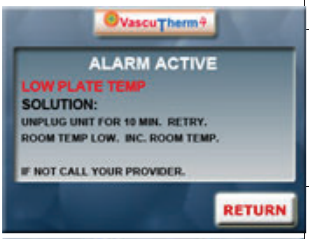
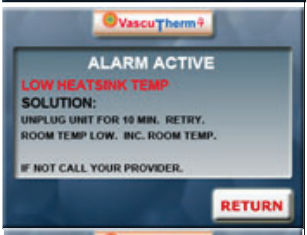
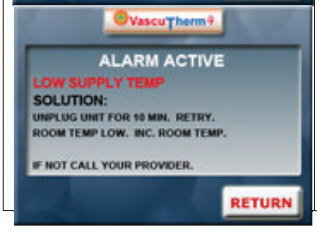
Problem/Alarm Screen	Cause	Suggested Actions
The unit is noisy. **(cont'd on next page)**	Unit is not in quiet mode.	Turn on the Quiet Mode in the System Menu on your unit.
	External material lodged in fan blade.	Check for foreign objects or material caught in inner fan blade.

	Internal fault within the therapy unit.	Check if the power supply LED is green. Turn the unit off by disconnecting the power supply. Wait 10 minutes and reconnect the power supply. Try an alternate AC outlet. Contact ThermoTek Customer Service if problem persists.

Problem/Alarm Screen	Cause	Suggested Actions
The touch screen is not functioning.	Physical damage to unit.	Inspect the unit for physical damage. If the unit shows any cracks or dents, the unit should not be used. Contact the clinic or DME for assistance.
	Unit not connected to AC power.	Make sure the unit is connected to the power supply and that the power supply is connected to an appropriate AC outlet.
	Internal fault within the therapy unit.	Check if the power supply LED is green. Turn the unit off by disconnecting the power supply. Wait 10 minutes and re-connect the power supply. Try an alternate AC outlet. Contact ThermoTek customer service if problem persists.

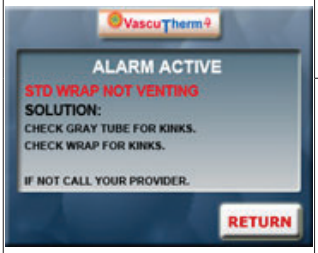
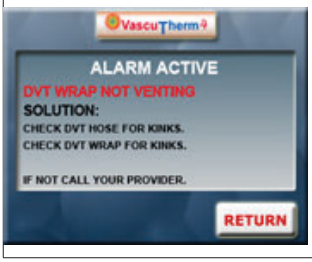
Problem/Alarm Screen	Cause	Suggested Actions
My unit gives me a TIMER NOT SET alarm. 	The timer on your unit has not been set to run cool or heat therapy.	Contact your provider so they can program your unit.

Problem/Alarm Screen	Cause	Suggested Actions
My unit gives me a CHECK FLOW/FLUID alarm. 	Reservoir is low on coolant.	Make sure the therapy mode is set to COOL mode. Open the reservoir cap. Check the fluid level and if necessary, add fluid to the bottom of the neck. Run the system with the cap open for one minute. Close cap tightly.
	Coolant ports not connected properly.	Turn the unit OFF. Check if coolant ports are connected to the wrap. To make sure proper connection, disconnect and reconnect the ports at the wrap. You should hear a "click" sound when the connectors are mated correctly. Turn ON the unit and restart therapy.
	There is a kink in the wrap.	Turn the unit OFF. Check for any folds or kinks on the wrap. Readjust wrap to alleviate blockage. Turn ON the unit and restart therapy.
	Air bubbles trapped within the unit.	Make sure the therapy mode is set to COOL mode. Check the clear tubing on the wrap for air bubbles. If air bubbles are present, refer to Chapter 8 for priming the unit. Run the system with the cap open for minutes. Tapping the clear tubing on the wrap with a finger will also aid in the release of the air bubbles. Close cap tightly. Start and stop therapy several times to clear bubbles from the pump. Give the unit a few seconds between starting and stopping therapy.

Problem/Alarm Screen	Cause	Suggested Actions
My unit gives me a LOW HEAT SINK TEMP, LOW SUPPLY or LOW PLATE TEMP alarm.   	Unit is operated in a cold ambient environment.	Make sure the unit is operated indoors in an ambient > 60°F.
	The unit was filled with cold coolant.	Make sure the unit is filled with room temperature fluid.
	The unit was powered on after being in a cold environment [e.g. trunk of a car].	Make sure the unit is used indoors with an ambient temperature > 60°F. Turn the unit OFF for 30 minutes and restart the unit. Resume therapy.
	Internal fault within the therapy unit.	Check if the power supply LED is green. Turn the unit off by disconnecting the power supply. Wait 10 minutes and reconnect the power supply. Try an alternate AC outlet. Contact ThermoTek customer service if problem persists.

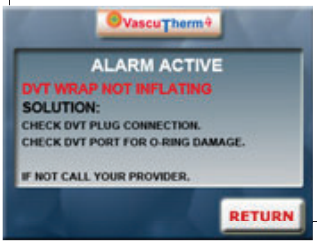
Problem/Alarm Screen	Cause	Suggested Actions
My unit gives me a HIGH HEAT SINK TEMP, HIGH SUPPLY or HIGH PLATE TEMP alarm. **(cont'd on next page)** 	Fan failure.	Check that you can hear the fan working. If it is not working, please call your provider.
	Unit operated in a place with restricted airflow.	Make sure the unit is operated in a location with adequate airflow from all sides. Make sure there is at least 6" of clearance around the unit.
	The unit was filled with hot coolant.	Make sure the unit is filled with room temperature fluid.
	Unit is operated in a hot ambient environment.	Make sure the unit is operated indoors with an ambient < 80°F.

 	The unit was powered on after being in a hot environment [e.g. trunk of a car]. The hot environment raised the coolant temperature within the unit to alarm limits of > 113°F.	Make sure the unit is used indoors with an ambient temperature < 80°F. Turn the unit OFF for 30 minutes and restart the unit. Resume therapy.
	The wrap is kinked.	Remove the therapy wrap and allow the unit to run without compression. Reapply the therapy wrap and continue.
	Internal fault within the therapy unit.	Check if the power supply LED is green. Turn the unit OFF by disconnecting the power supply. Wait 10 minutes and reconnect the power supply. Try an alternate AC outlet. Contact ThermoTek Customer Service if problem persists.

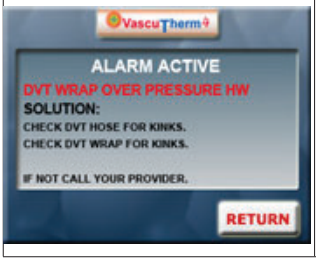
Problem/Alarm Screen	Cause	Suggested Actions
My unit gives me a STD WRAP NOT VENTING or DVT WRAP NOT VENTING alarm.  	System software detected a kink in the wrap or airline.	Make sure the patient is not asserting excessive force on the wrap or airline. This will cause the wrap pressure to spike and trip this alarm. Stop current therapy, remove and reapply wrap. Make sure hoses are not kinked.
	Internal fault within the therapy unit.	Check if the power supply LED is green. Turn the unit off by disconnecting the power supply. Wait 10 minutes and reconnect the power supply. Try an alternate AC outlet. Contact ThermoTek customer service if problem persists.

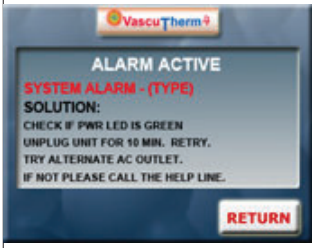
Problem/Alarm Screen	Cause	Suggested Actions
My unit gives me a STD WRAP NOT HOLDING PRESSURE or DVT WRAP NOT HOLDING PRESSURE alarm.	Leak in DVT port due to O-ring damage.	Check for O-ring damage in DVT port. O-ring damage will cause a leak, not allowing wrap to hold pressure.
	Leak through STD compression airline connector O-ring.	Check the O-ring that is on the STD compression connector fitting going to the unit.
	Internal fault within the therapy unit.	Check if the power supply LED is green. Turn the unit off by disconnecting the power supply. Wait 10 minutes and reconnect the power supply. Try an alternate AC outlet. Contact ThermoTek customer service if problem persists.

Problem/Alarm Screen	Cause	Suggested Actions
My unit gives me a STD WRAP NOT INFLATING or DVT WRAP NOT INFLATING alarm.	Wrap is loose on the patient.	If the wrap is "ballooned" on the patient, it has been applied loosely. Remove wrap and reapply tightly to fit the patient.
	The correct therapy is not selected.	Make sure you have selected the correct therapy and that the therapy is active.
	Wraps not connected to unit.	Make sure the wraps are connected to your unit.
	Leaky wrap.	Make sure your wraps are not leaking air.
	Internal fault within the therapy unit.	Check if the power supply LED is green. Turn the unit off by disconnecting the power supply. Wait 10 minutes and reconnect the power supply. Try an alternate AC outlet. Contact ThermoTek customer service if problem persists.



Problem/Alarm Screen	Cause	Suggested Actions
My unit gives me a STD WRAP OVER PRESSURE SW or DVT WRAP OVER PRESSURE SW alarm.  	System hardware detected a kink in the wrap.	Make sure the patient is not asserting excessive force on the wrap. This will cause the wrap pressure to spike and trip this alarm. Stop current therapy, remove and reapply wrap. Make sure hoses are not kinked.
	Kinked hose.	Make sure there are no kinks in the Standard and DVT hoses.
	Internal fault within the therapy unit.	Check if the power supply LED is green. Turn the unit off by disconnecting the power supply. Wait 10 minutes and reconnect the power supply. Try an alternate AC outlet. Contact ThermoTek customer service if problem persists.

Problem/Alarm Screen	Cause	Suggested Actions
My unit gives me a STD WRAP OVER PRESSURE HW or DVT WRAP OVER PRESSURE HW alarm.  	System hardware detected a kink in the wrap.	Make sure the patient is not asserting excessive force on the wrap. This will cause the wrap pressure to spike and trip this alarm. Stop current therapy, remove and reapply wrap. Make sure hoses are not kinked.
	Kinked hose.	Make sure there are no kinks in the Standard and DVT hoses.
	Internal fault within the therapy unit.	Check if the power supply LED is green. Turn the unit off by disconnecting the power supply. Wait 10 minutes and reconnect the power supply. Try an alternate AC outlet. Contact ThermoTek Customer Service if problem persists.

Problem/Alarm Screen	Cause	Suggested Actions
My unit gives me a SYSTEM ALARM - (TYPE)  "TYPE" defined as: TSH SHORT TSH OPEN TSS SHORT TSS OPEN TSP SHORT TSP OPEN PSENSOR EXT ADC INT ADC BK AIR 12C 5DC U 5DC O 3.3DC U 3.3DC O BROWNOUT DETECTED WATCH DOG TIMER RESET	Internal fault within the therapy unit.	Check if the power supply LED is green. Turn the unit off by disconnecting the power supply. Wait 10 minutes and reconnect the power supply. Try an alternate AC outlet. Contact ThermoTek customer service if problem persists.

Chapter 15

Device Summary:

The VascuTherm™ 4 Therapy System is capable of performing therapies for the following:

- **Cool Therapy:** the unit passes cool (*43°F - 50°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™ 4 system are designed to maximize the effectiveness of the therapies listed above. Only use wraps in combination with therapy modes as prescribed.

**The ability to achieve 43°F will depend on the wrap size and ambient temperature and may not be possible in every situation.*

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™ 4 System for Therapy" instructions in Chapter 8.

3. Initiate the presscribed therapy of Cool, Heat, 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 4 therapy system for use, please contact the clinic or hospital that prescribed the unit or the Durable Medical Equipment (DME) provider. If assistance is not available or is ineffective, please contact ThermoTek technical assistance toll free at 1-877-242-3232 during the hours of 8am - 5pm Central Time. If technical assistance is needed after these hours, you may contact the 24-hour line at 214-502-8800.

Chapter 16

Service and Customer Support:

ThermoTek, Inc. is committed to servicing our VascuTherm™ 4 unit both during and after sale to the cutomer. If you have any questions concerning the operation of your VascuTherm™ 4 unit, please refer to the following to contact us at our Flower Mound, Texas facility:

- **Sales Organization:** (972) 874-4949
- **Toll Free Number:** (877) 242-3232
  (between 8:00am and 5:00pm CST, Monday through Friday)
- **ThermoTek Website:** www.thermotekusa.com
- **Service Department (after hours):** (214) 502-8800

Do not drink or ingest the coolant mixture.

In the event of a Medical Emergency, call:

9-1-1

Chapter 17

Wraps, Accessories and Replacement Parts:

Replacement Parts:

Part Number	Description
0P2DCAPBTL	Reservoir Cap
0P3WHG13PC	Power Cord, PW 10A/125 VAC, Hospital Grade, 12 ft.
0P5WEXT36V	Power Supply, Ext, Med, 250W
0P2DNANTFB	Mixing Bottle, Thermoflow

Available Therapy Wraps:

Part Number	Description
Thermal Compression Wraps:	
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
0P9BSFNCMR3	Wrap, Knee, No Compression, SPU
0P9BSFNCMR3-U	Wrap, Knee, No Compression, SPU, Unfilled
0P9BSHLDMR3	Wrap, Shoulder, Large, SPU
0P9BSSHLMR3	Wrap, Shoulder, Standard, SPU

0P9BSSWHMR3	Wrap, Shoulder, Half Arm w/Harness, SPU
0P9BSSWHMR3-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
0P9BWTHDMR3	Wrap, Wrist/Hand, SPU
0P9BWTHDMR3-U	Wrap, Wrist/Hand, SPU, Unfilled
Pneumatic Compression Wraps:	
0P9BNDVTCA4	Wrap, DVT, Calf Set, Push, SPU
0P9BNDVTFT4	Wrap, DVT, Foot Set, Push SPU

***Sterile Therapy Wrap options available (example: 0P9XXXXXXX3-S)**

Hose Assemblies:

Part Number	Description
0P9AVT4UMB	Hose, Therapy Umbilical, Standard, 5ft.

Optional Equipment:

Part Number	Description
0P2AVT4BHB	Bed Hook

Chapter 18

Specifications:

VascuTherm™ 4 Part Number	0P9PTVT400
Dimensions	9.81”W x 9.88”H x 8.75”D
Ambient Operating Range	60 - 80°F
Relative Humidity	< 60% RH
Therapy Temperature Range	Between *43°F - 50°F [6.0°C - 10.0°C] and 105°F [40.5°C]
Centrifugal Pump	12-Volt Brushless DC
Weight without fluid	10-pounds
System Fluid Capacity	11 ounces [320 mL]
Power Consumption (Max)	250 Watts
Input Voltage (Nominal)	100-240 VAC, 50/60 Hz, Single Phase
Input Current (Max)	2.5 Amps
Accuracy	± 2°F
Refrigerant	None
USB Interface	Yes, Standard
Recommended Coolants	90% distilled water, 10% alcohol

**** The ability to achieve 43°F will depend on the wrap size and ambient temperature and may not be possible in every situation.***

18.1 Calibration

The VascuTherm™ 4 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 or repair to original manufacturing specifications.

18.2 Product Listing

The VascuTherm™ 4 Therapy Unit has been tested and listed by ETL to meet or exceed the requirements for IEC 60601-1, UL 60601 Safety Standards and IEC 60601-1-2 EMC Standards. This product is classified as a Type B Medical Equipment, Class II.

MRI Notice

This equipment contains electronic and ferrous components whose operation can be affected by intense electromagnetic fields. Do not operate the VascuTherm 4 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 VascuTherm 4 system.

Internal Battery

The VascuTherm 4 uses a 3V, 48 mAH, Lithium coin cell battery for maintaining its real time clock. The battery is not user replaceable.

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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™ 4 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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For customer service information, please see Section 16 of this manual.

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