

# VascuTherm4-M

by ThermoTek, Inc.

## User Manual





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# 1. Introduction

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Please read the entire manual carefully before trying to operate the VascuTherm4-M system. It is unsafe to start using the VascuTherm4-M system before reading the entire user manual.

At ThermoTek, we pledge to provide the highest quality product with excellent support and service. If we can do anything to make your VascuTherm4-M experience better, please do not hesitate to contact us.

## User Assistance Information:

The VascuTherm4-M Therapy System is manufactured by:

ThermoTek, Inc.  
1200 Lakeside Parkway #200  
Flower Mound, TX 75028  
(972) 874-4949  
(877) 242-3232 (toll free service number)  
or visit us on the web at [www.thermotekusa.com](http://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, please call your nearest healthcare professional.

## 2. Glossary of Terms

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**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 and regulated 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** – an 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.

## 3. General Warnings and Cautions

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### 3.1. Contraindications for Pneumatic Compression Therapy:

The patient should **NOT** use the VascuTherm4-M 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 VascuTherm4-M 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 VascuTherm4-M 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. Precautions include:

### **3.4. Caution:**



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



Never spill liquid of any kind on 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 use therapy wraps or use 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. Warning:**



If unusual swelling, skin discoloration or discomfort occurs, immediately discontinue use of the VascuTherm4-M unit and consult a healthcare professional.



Follow the prescribed instructions of your physician for area, frequency and duration of treatment.



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 VascuTherm4-M unit.



Slots and openings in the cabinet are provided for ventilation to protect the unit from overheating. These openings must not be blocked or covered at any time except by the supplied air filter.



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



## 4. Indications for Use

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The VascuTherm4-M 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 are to:

- 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.

## **5. VascuTherm4-M Device Description**

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The VascuTherm4-M therapy system is an electronic heating, cooling and compression system. The VascuTherm4-M 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 6.0°C – 18.0°C [43°F – 64°F] and 40.5°C [105°F]
- Compression Modality to Reduce the Risk of DVT Formation on the Calf (45mmHg compression) and Foot (100 mmHg compression)
- Treatment for Edema and Lymphedema in the Upper and Lower Extremities with alternating compressions of Low (15 mmHg), Med (30 mmHg) and High (50mmHg)
- 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

### **5.2. General Specifications:**

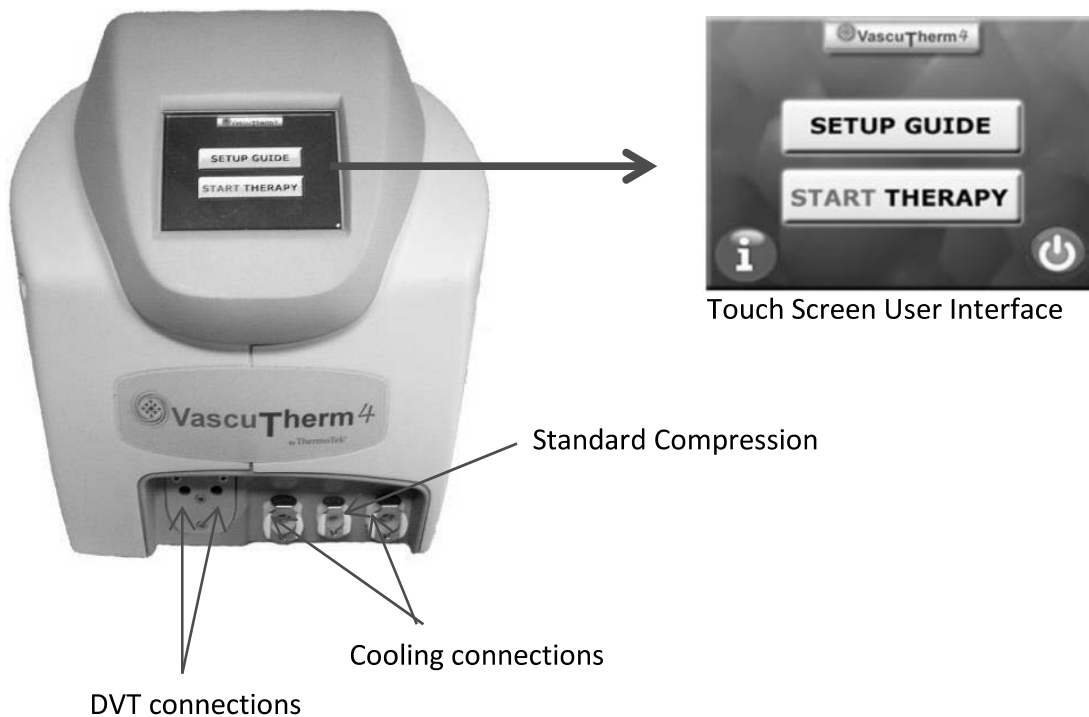
- Weight: 4.3 kg [9.5 lbs.]
- Hose Length: 1.5 m [5 ft.]
- Hospital Grade Power Cord

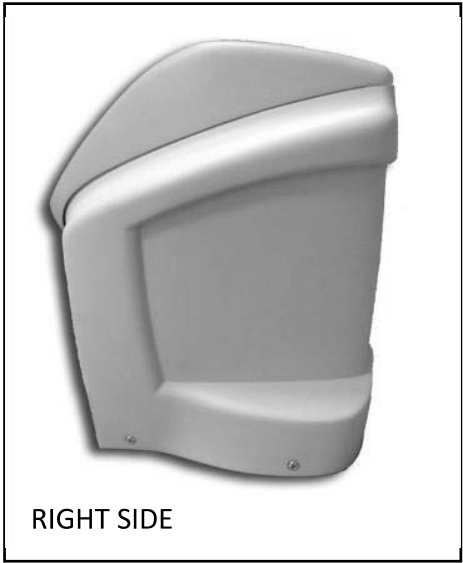
- Dimensions: 25.0 cm W x 25.1 cm H x 22.2 cm D [9.81"W x 9.88"H x 8.75"D ]
- Operating Fluid: 90% Distilled Water/10% Isopropyl Alcohol
- Safety: IEC 60601-1 and IEC 60601-1-2

### 5.3. Options:

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

### 5.4. Device Description:

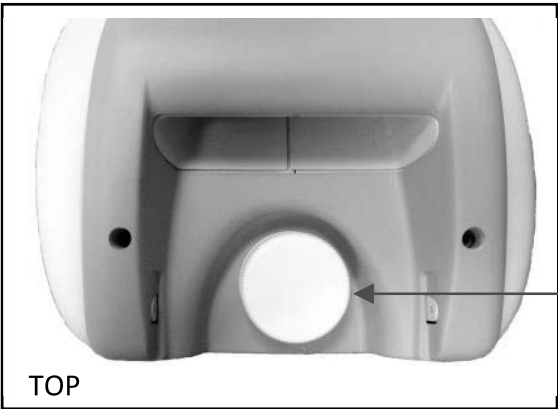




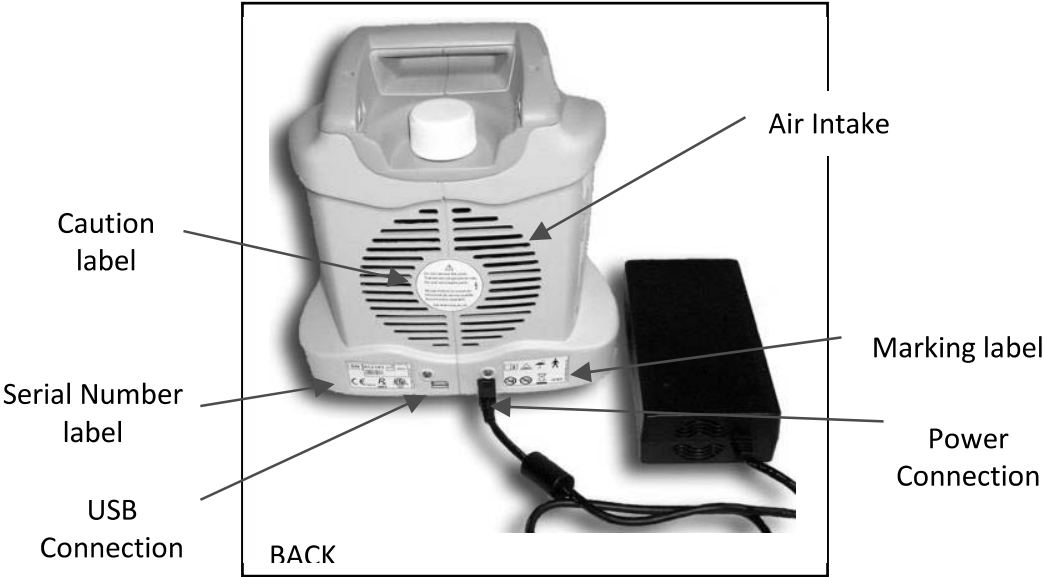
Device  
Information label



Air Exhaust Vent



Coolant Reservoir  
Opening



Air Intake

Caution  
label

Serial Number  
label

USB  
Connection

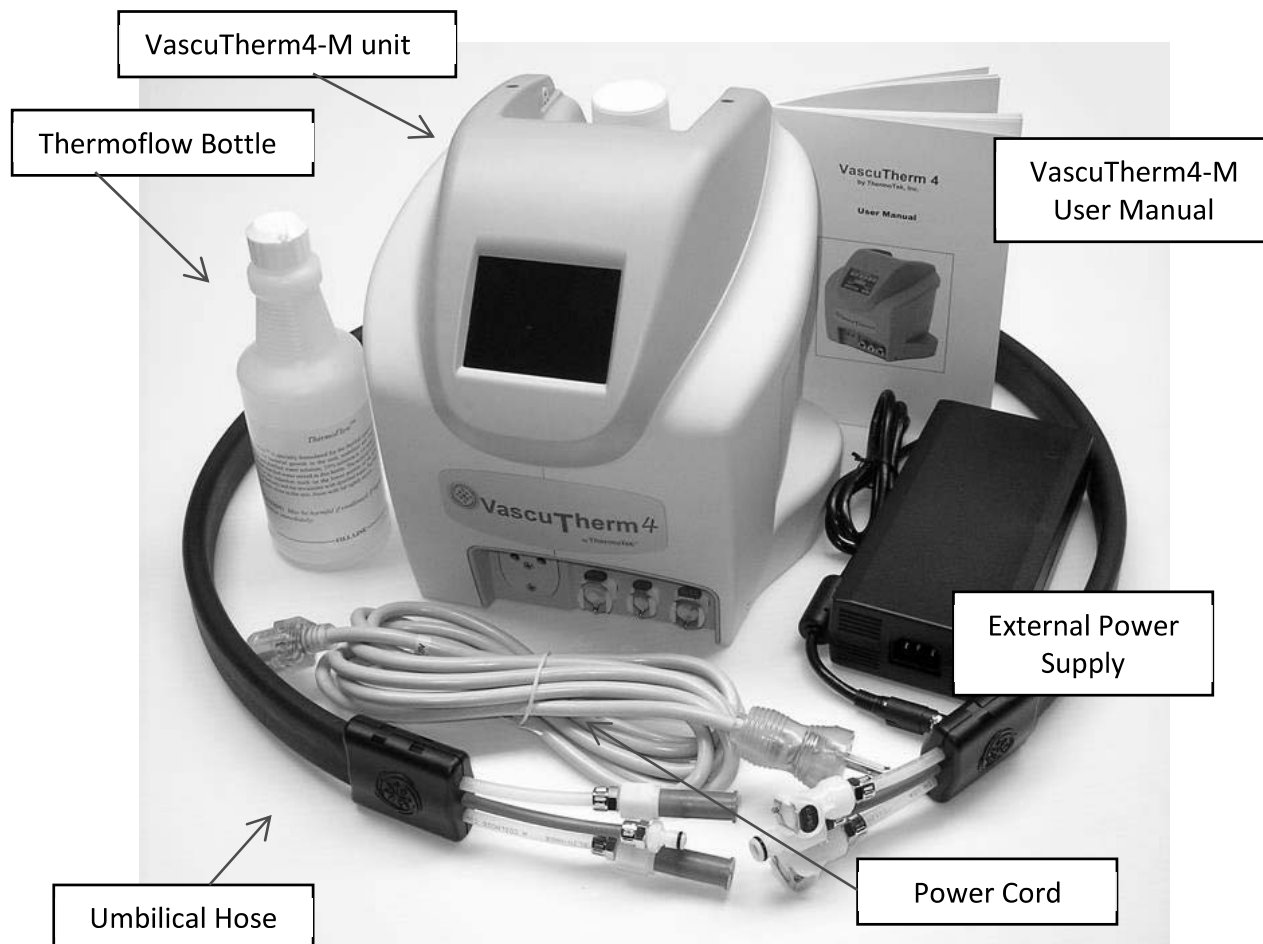
Marking label

Power  
Connection

## 6. Unpacking Your VascuTherm4-M Therapy System

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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 VascuTherm4-M 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 VascuTherm4-M 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 the treatment.

## 7. Environmental Conditions You Should be Aware of Before Operating Your VascuTherm4-M Device

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The VascuTherm4-M therapy system is intended for indoor use only.



Do not operate the VascuTherm4-M system with therapy wraps in or near a wet environment.



The VascuTherm4-M 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 VascuTherm4-M system in an ambient environment between 15.5-26.5 °C [60-80 °F] 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.

## 8. How to Set Up Your VascuTherm4-M System for Therapy

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Now that you have fully unpacked your VascuTherm4-M 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 VascuTherm4-M unit upright on a level surface and at least 30.5 cm [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.**

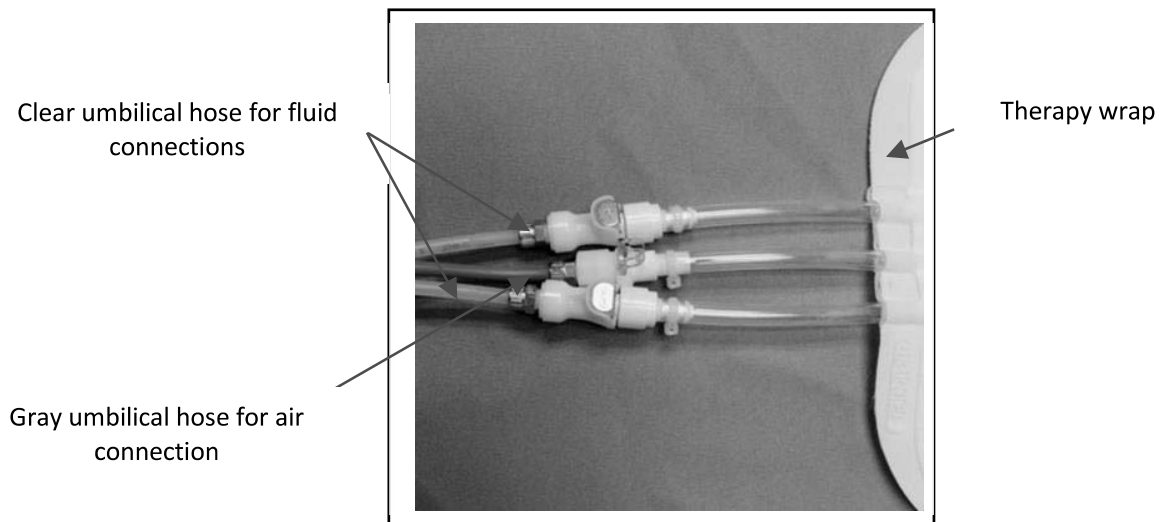
- Connect the power cord to the power supply input connector and connect the opposite end of the power cord to a grounded wall outlet.



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



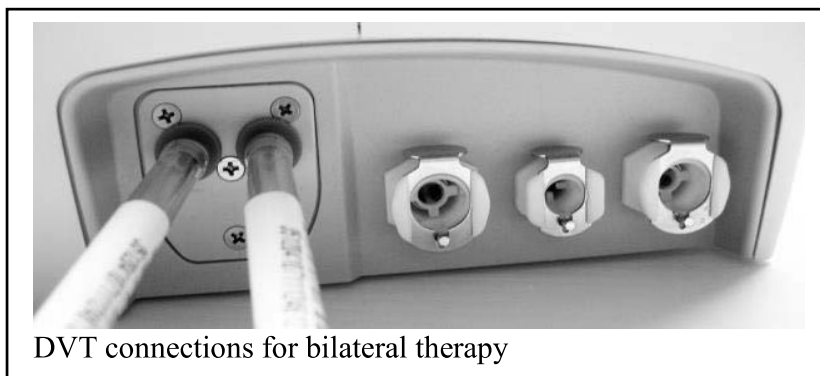
- Unpack and apply the prescribed therapy wraps to the indicated portions of your body as described on the wrap instructions contained in the wrap packaging.
- Unscrew and remove the coolant reservoir cap from the top of the unit. Using the coolant bottle supplied with the therapy system, fill the reservoir 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.



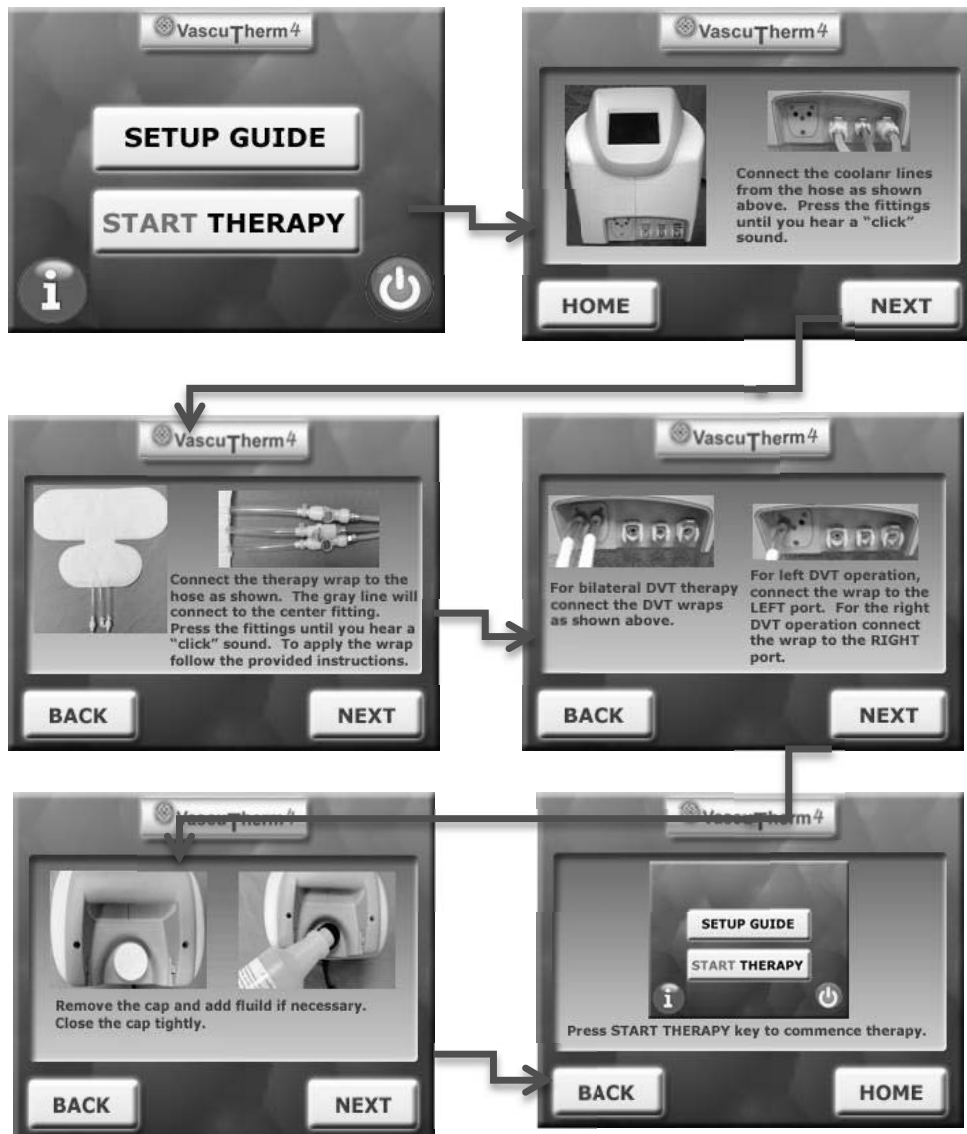
- If DVT Compression wraps are provided, un-wrap them and connect to the front of the unit as shown in the picture below.
- For the bilateral operation, connect each of the wrap into the two available ports.



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

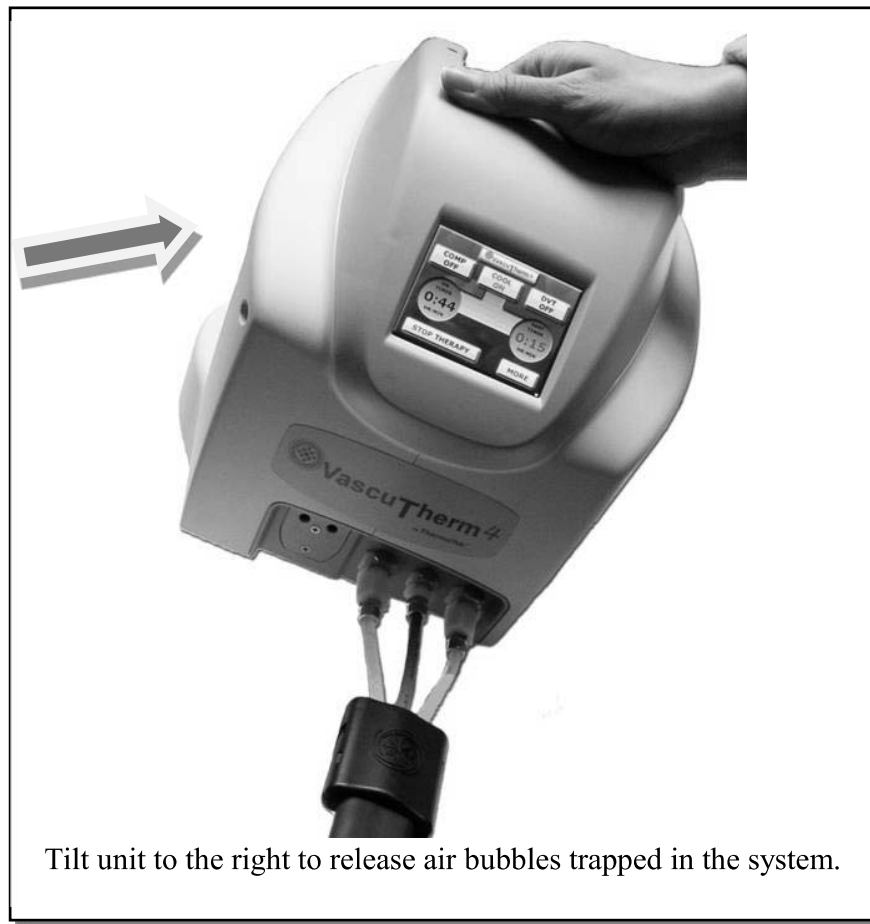


- A quick start guide is also available on the unit from the start therapy Screen. Select SETUP GUIDE to review the information.



## Priming your unit:

1. Follow the instructions on Chapter 9 in the User Manual for turning ON the Cool Therapy.
2. After turning ON Cool Therapy, lower the wrap about 0.5 m below the unit and tilt the unit to the right as to release the air bubbles trapped in the system.



3. Stop therapy. Check the reservoir fluid level after stopping the fluid pump and fill 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 and with the wrap about 0.5 m below the unit, tilt the unit to the right.
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 2-6 until you have 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 VascuTherm4 and you are ready to begin therapy.
10. The VascuTherm4 needs to be primed only when it is first setup 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.

## 9. Operating Instructions for Your VascuTherm4-M System

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Refer to Chapter 8 “How to Set Up Your VascuTherm4-M System for Therapy” 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 VascuTherm4-M system are designed to maximize the effectiveness of the therapies listed above. Only use wraps in combination with therapy modes as prescribed.

The VascuTherm4-M Therapy System is capable of performing therapies for the following:

- Cool Therapy,
- Heat Therapy,
- Pneumatic Compression Therapy for Edema and Lymphedema, and
- Pneumatic Compression Therapy to reduce the risk of DVT.

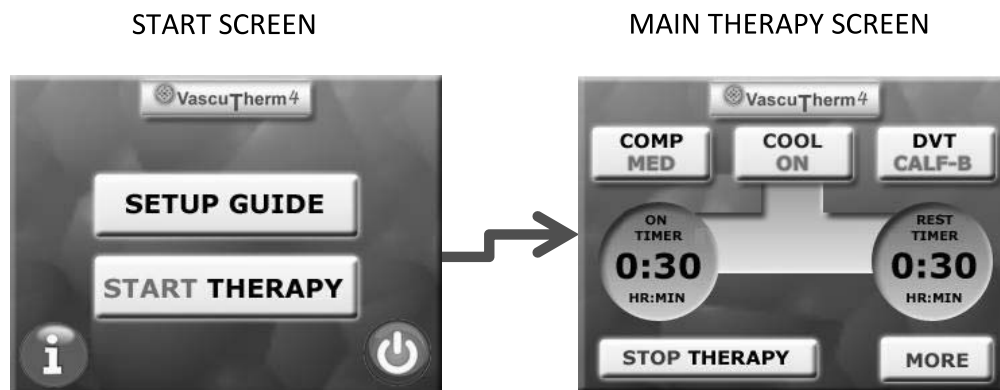
### 9.1. Turning the Unit ON for the First Time:

The VascuTherm4-M 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 VascuTherm4-M 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.



- 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.

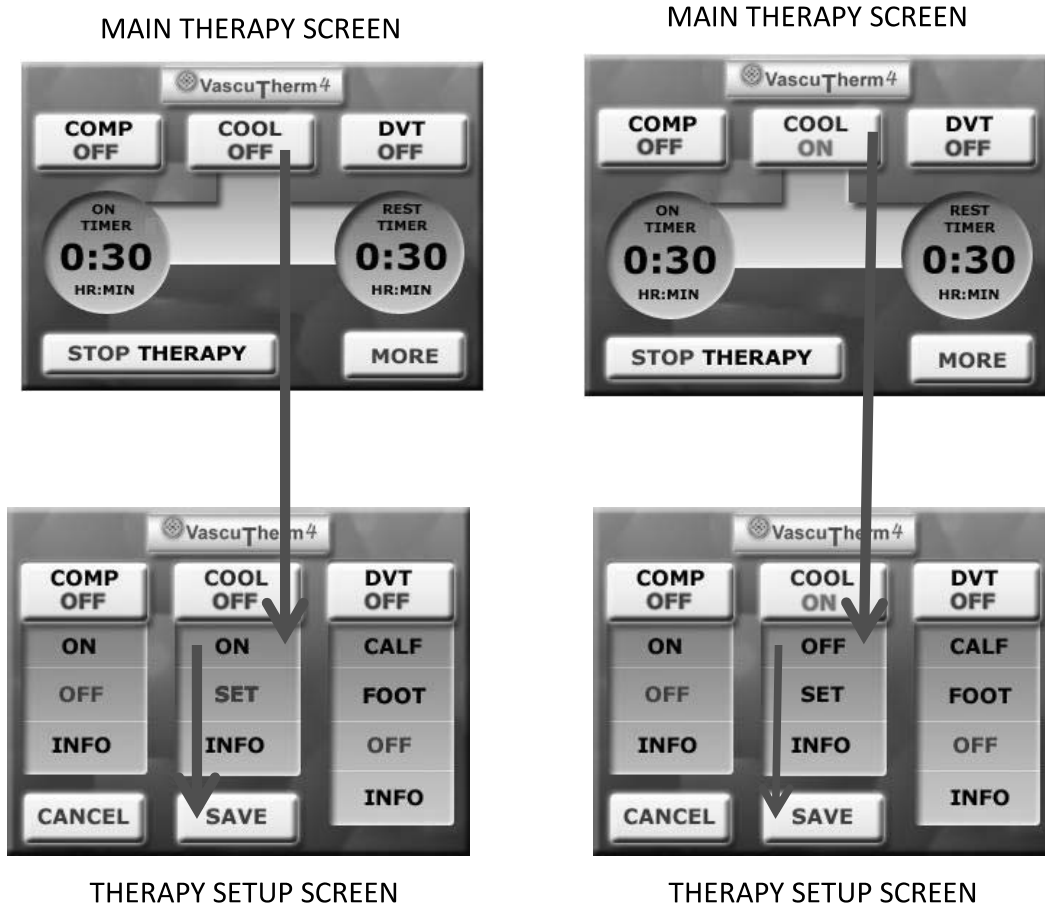
### **9.2. Cool Therapy:**

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).

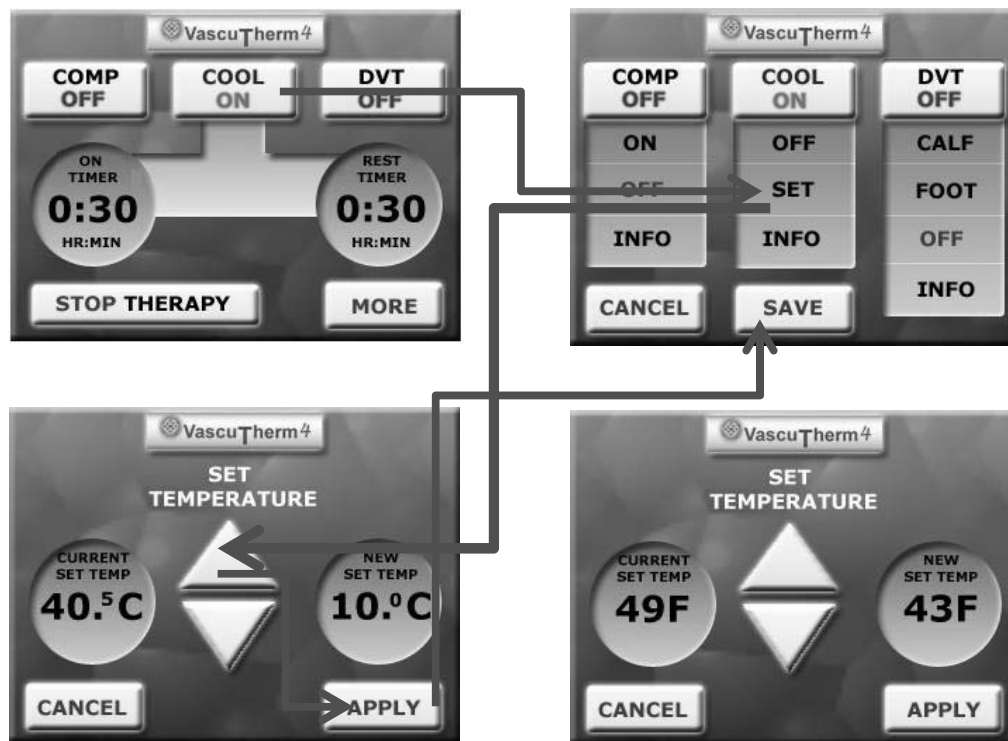
- To initiate Cool Therapy, select “**COOL**”, the Therapy Setup Screen will appear. The Cool Therapy can be turned



ON or OFF by selecting **“COOL ON”** or **“COOL OFF”** and selecting **“SAVE”**.



- 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 6.0°C – 18.0°C [43°F - 64°F], and then it will jump to 40.5° C [105°F]. If set to 40.5° C [105°F] the therapy mode will be set to heat and the label will change to **“HEAT”**.



- 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 be used, it is recommended to turn the unit OFF. Once the unit is OFF, you may now remove your therapy wraps.

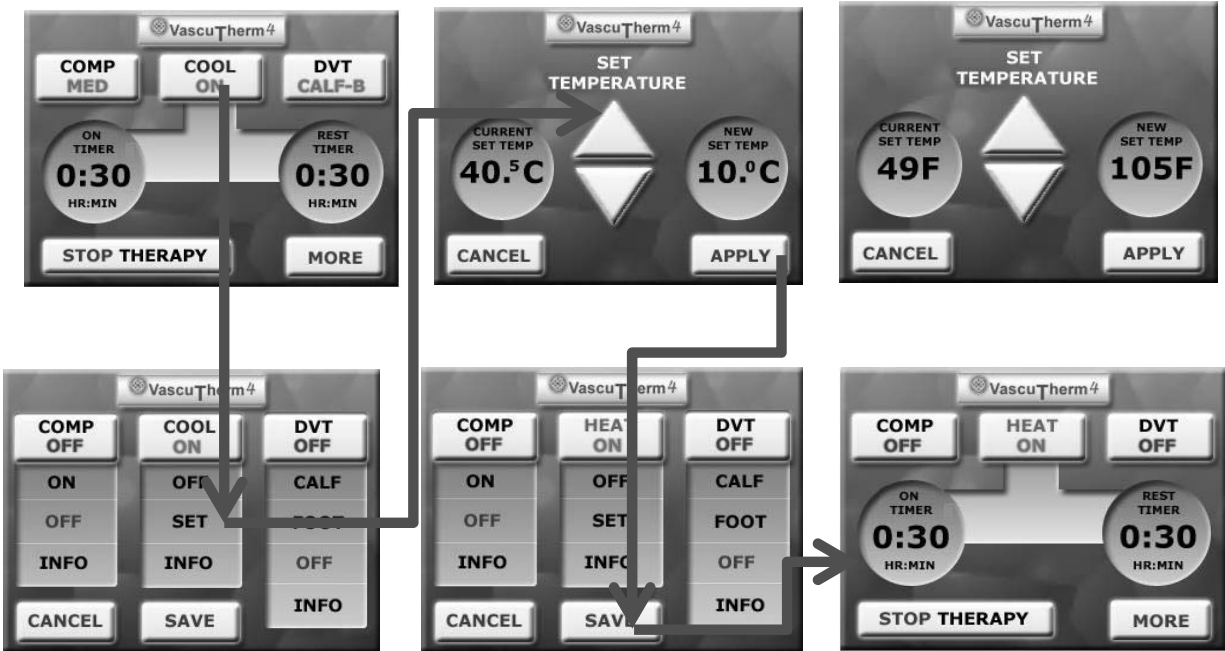


Compression should be turned OFF when the therapy wrap is not on the patient. Allowing the wrap to inflate while unattended or to inflate all the way to a “ballooned” state can cause damage to the wrap and will reduce the life of the wrap.

### 9.3. 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 40.5°C [105°F]. 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 40.5°C [105°F] the label will change to **“HEAT”**. In degree Celsius scale, the temp will scroll from 6°C to 18°C, and then it will jump to 40.5°C.
- If you want to show the current therapy setting, select **“INFO”** under 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 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 will reduce the life of the wrap.

- To initiate Compression Therapy, select **“START THERAPY”** from the Start Menu and the Main Therapy Screen will appear.

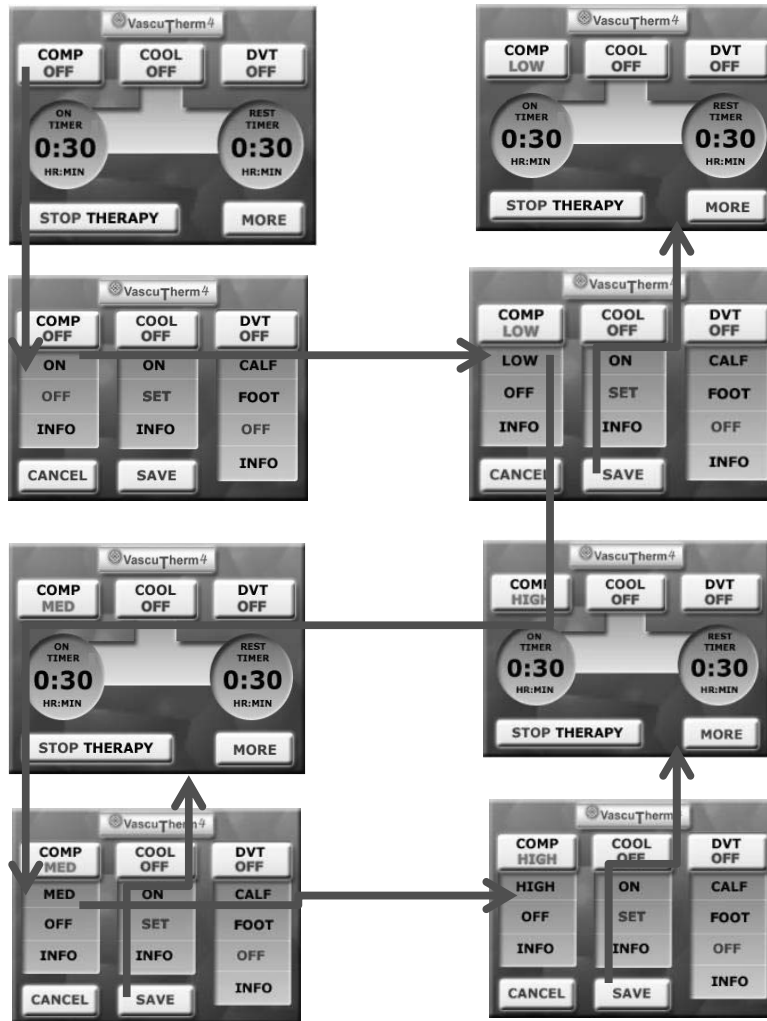


- To turn “**ON**” the Compression Therapy for Edema, also known as Standard Compression, select “**COMP**” from the Main Therapy Screen. The Primary Therapy Screen will appear. Standard Compression has three compression levels; Low (15mmHg), Med (30 mmHg) and High (50 mmHg).

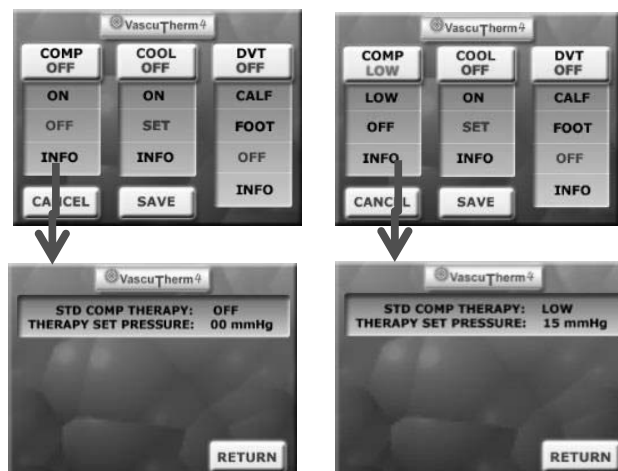


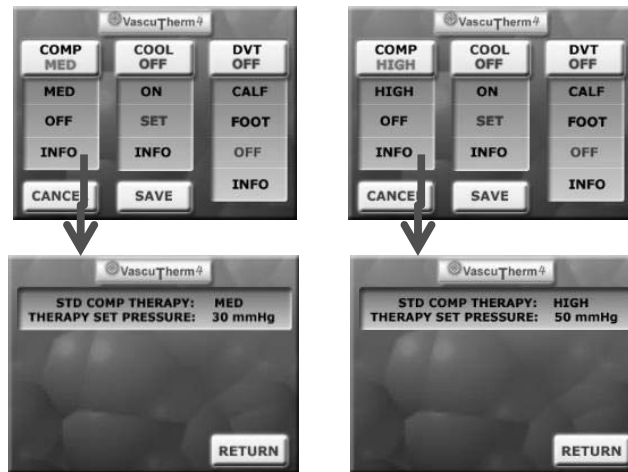
- Select “**ON**” for the “**COMP LOW**” to appear. To change from Low Level to Med level, select “**LOW**”, the pressure setting will change to “**COMP MED**”. To change from Med Level to High Level, select “**MED**” and the screen will show “**COMP HIGH**”. To return to Low Level, select “**HIGH**” 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 “**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 VascuTherm4-M 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.

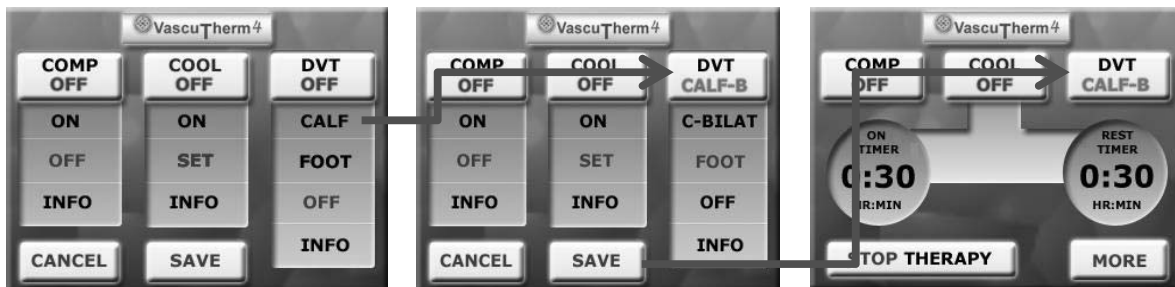
- To initiate DVT Calf Compression, select “**START THERAPY**” from the Start Menu and the Main Therapy Screen will appear.



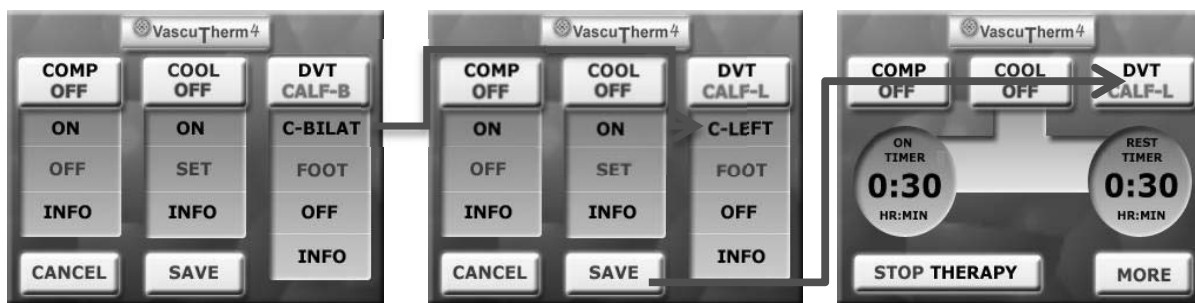
- On the Main Therapy Screen (COMP/COOL/DVT) select **“DVT”** and you will be taken to the Primary Therapy Screen.

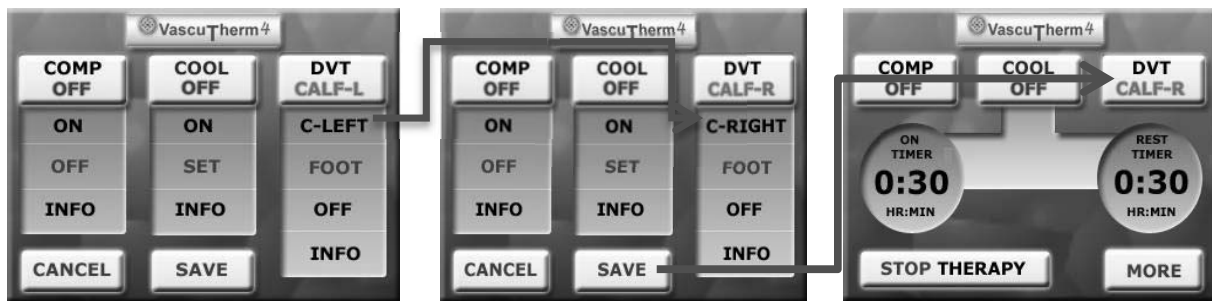


- Select **“CALF”** from Primary Therapy Screen,, the display will change and now read **“C-BILAT”**. Bilateral compression will automatically alternate compression cycles between the left and the right calf wraps. Select **“SAVE”** to save the settings. The next screen will be the Main Therapy Screen.

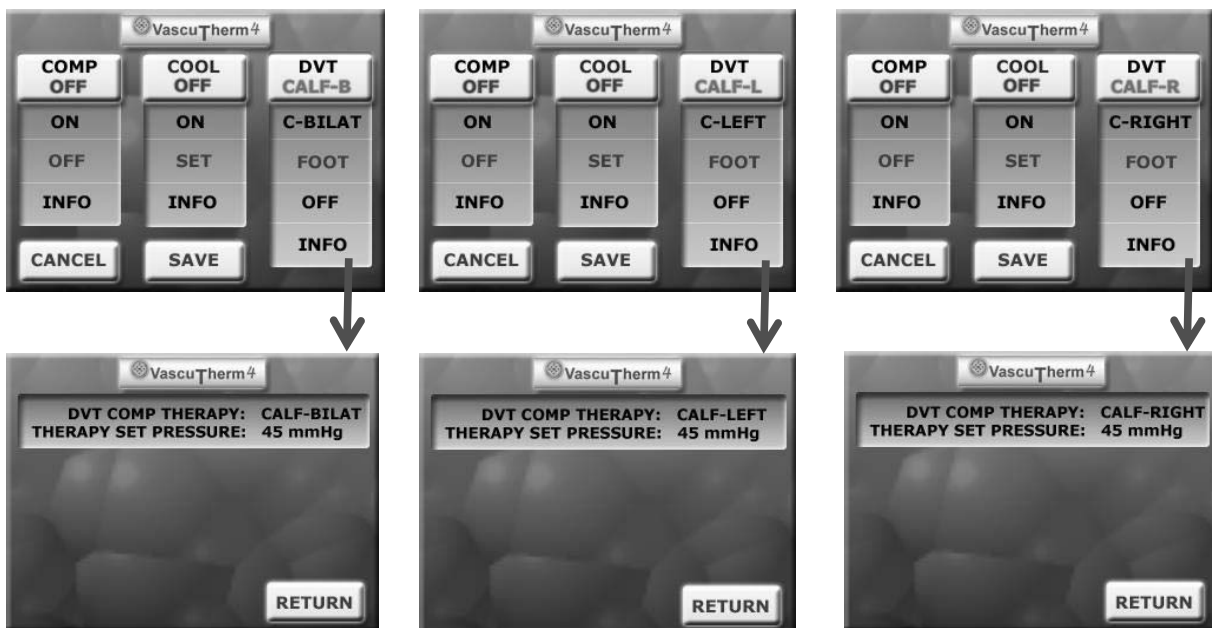


- If your prescribed therapy is for left calf or right calf only, keep on tapping **“CALF”**, the display will continue to change and now read **“C-LEFT”** or **“C-RIGHT”**. Select **“SAVE”** to save the settings. The next screen will be the Main Therapy Screen.

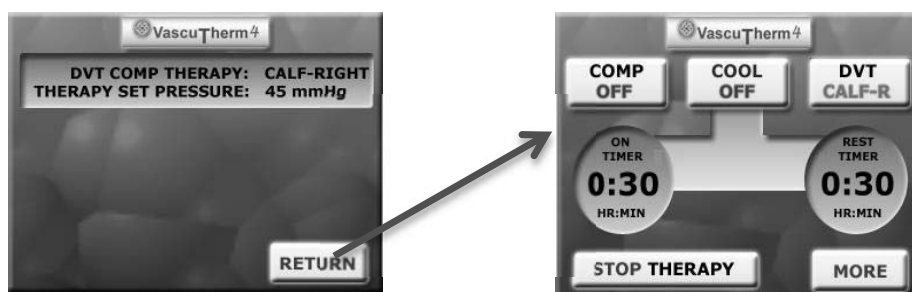




- To show the current therapy setting for DVT, select **"INFO"** under the **"DVT"** Menu. The system will show the following information; therapy setting and therapy pressure.

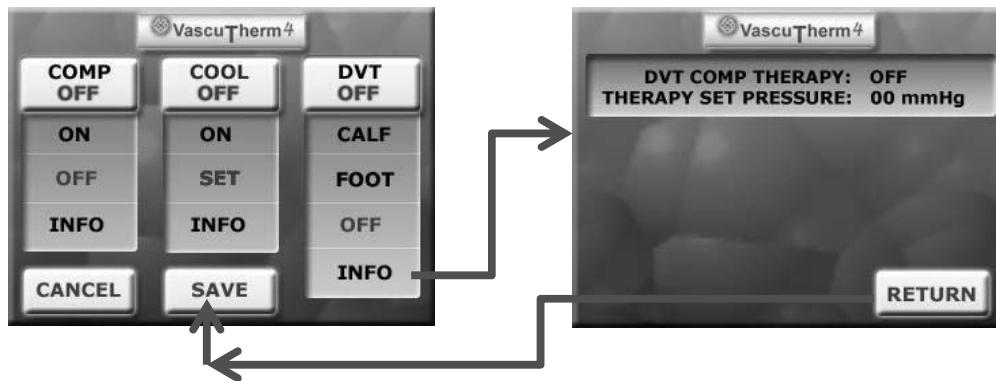


- Select **"RETURN"** from the Info Screen to return to the Primary Therapy Screen. Select **"SAVE"** or **"CANCEL"** to return to the Main Therapy Screen.



## 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 VascuTherm4-M 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.

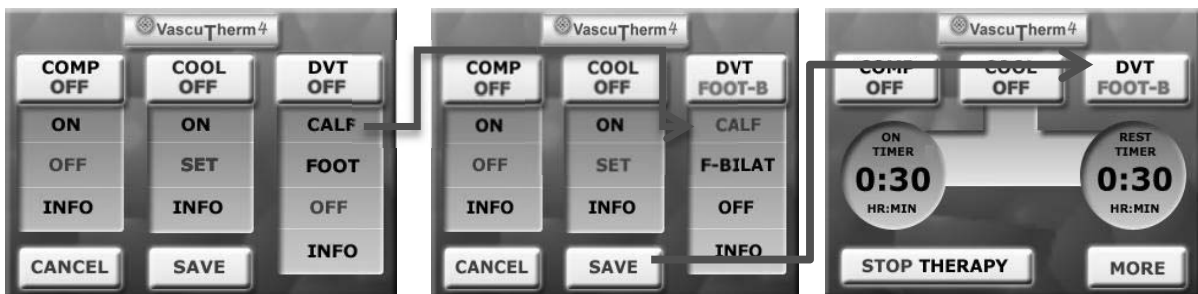
- To initiate DVT Foot Compression, select “**START THERAPY**” from the Start Screen and the Main Therapy Screen will appear.



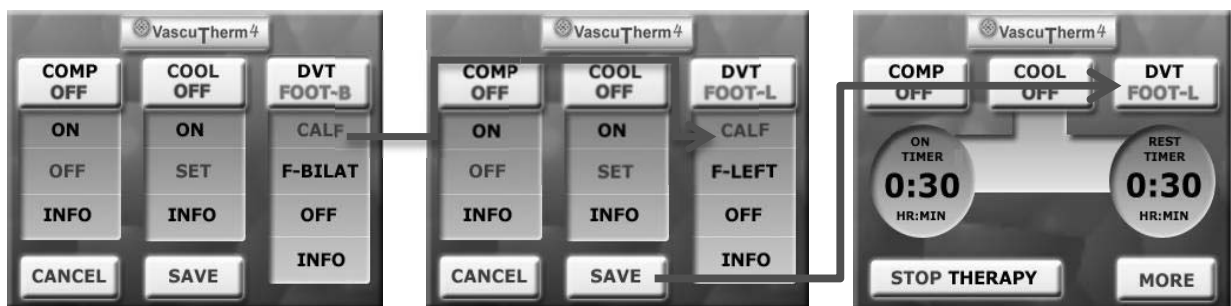
- On the Main Therapy Screen (COMP/COOL/DVT) select **“DVT”** and you will be taken to the Primary Therapy Screen.



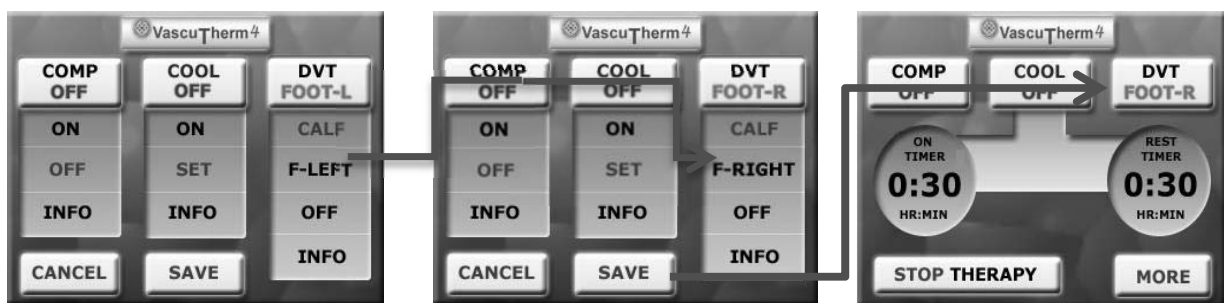
- Select **“FOOT”** from Primary Therapy Screen,, the display will change and now read **“F-BILAT”**. Bilateral compression will automatically alternate compression cycles between the left and the right calf wraps. Select **“SAVE”** to save the settings. The next screen will be the Main Therapy Screen.



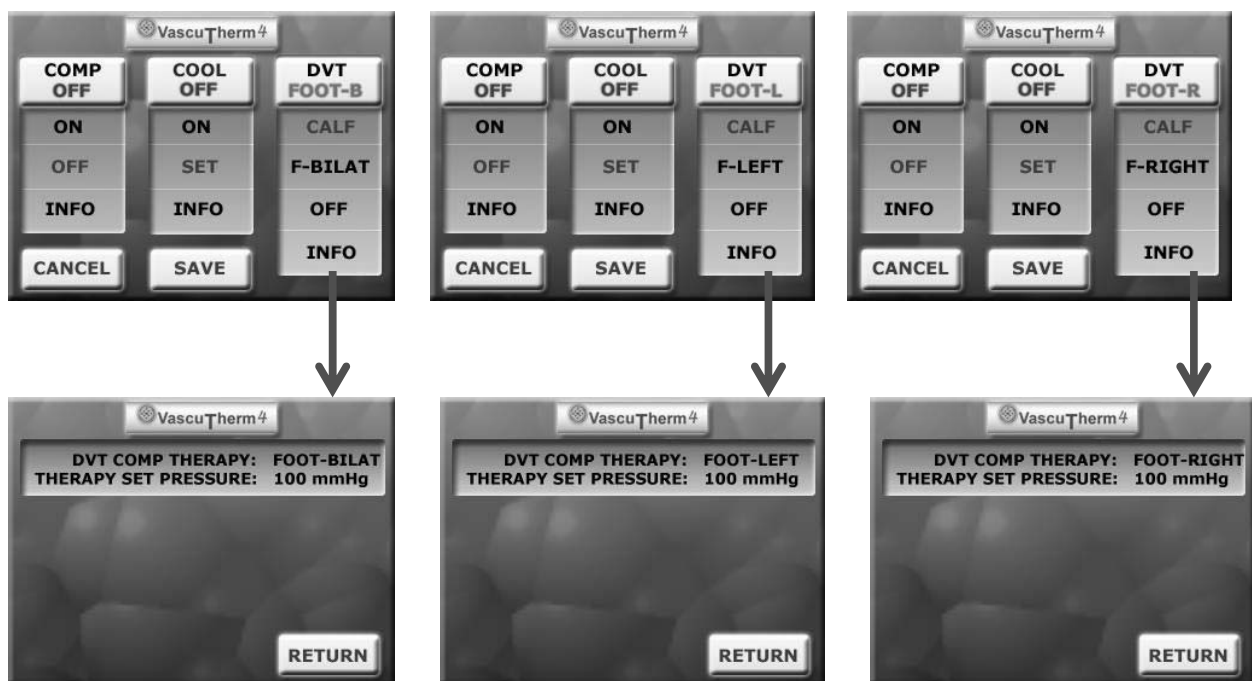
- If your prescribed therapy is for left foot or right foot only, keep on tapping **“FOOT”**; the display will continue to change and now read **“F-LEFT”** or **“F-RIGHT”**. Select **“SAVE”** to save the settings. The next screen will be the Main Therapy Screen.



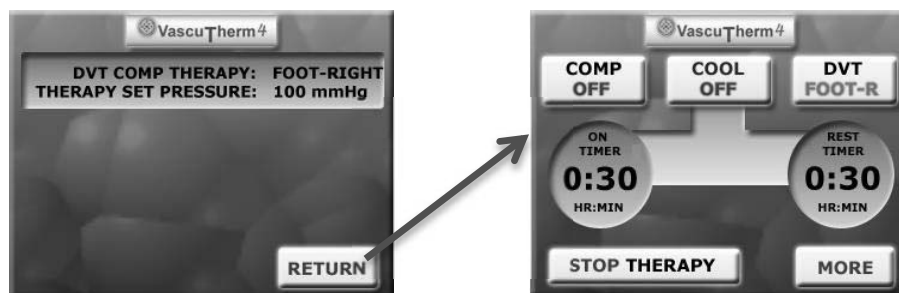




- To show the current therapy setting for DVT, select **"INFO"** under the **"DVT"** Menu. The system will show the following information; therapy setting and therapy pressure.

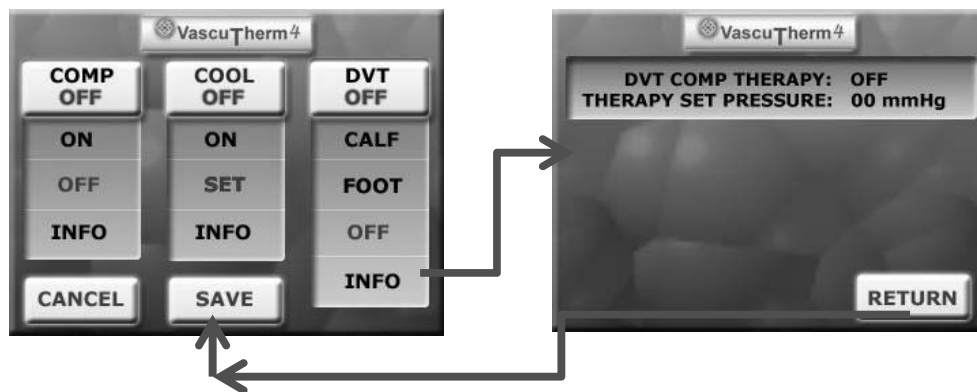


- Select **"RETURN"** from the Info Screen to return to the Primary Therapy Screen. Select **"SAVE"** or **"CANCEL"** to return to the Main Therapy Screen.



## 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.

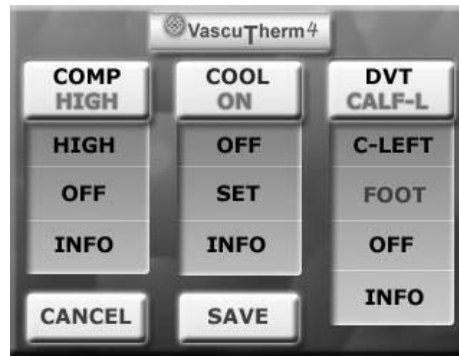
### Follow the instructions as follows to set Pneumatic Compression Therapy and DVT Calf Compression Therapy:



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 calf area of the lower leg using compressed air. The preset inflation and deflation cycle of the VascuTherm4-M 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.

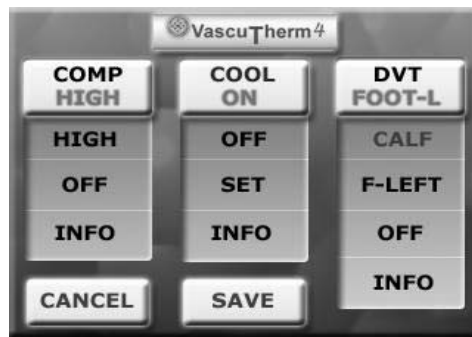
### Follow the instructions as follows to set Pneumatic Compression Therapy and DVT Foot Compression Therapy:



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 VascuTherm4-M 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.



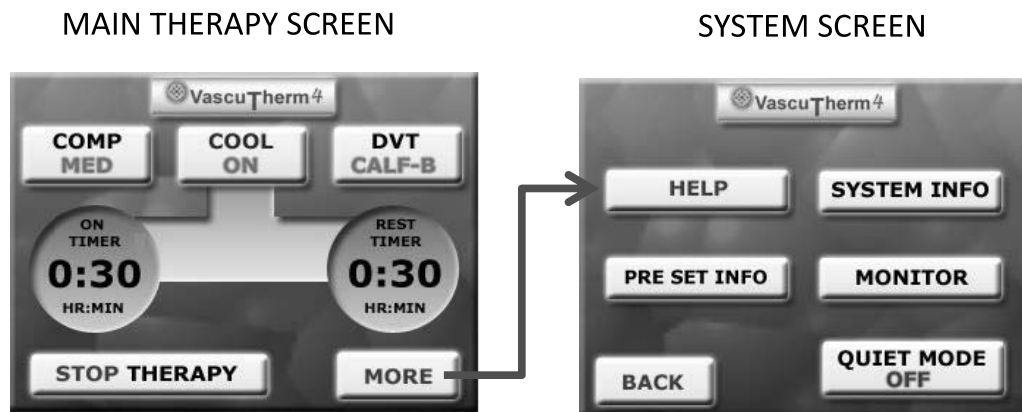
### When the prescribed therapy duration is complete:

- 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.

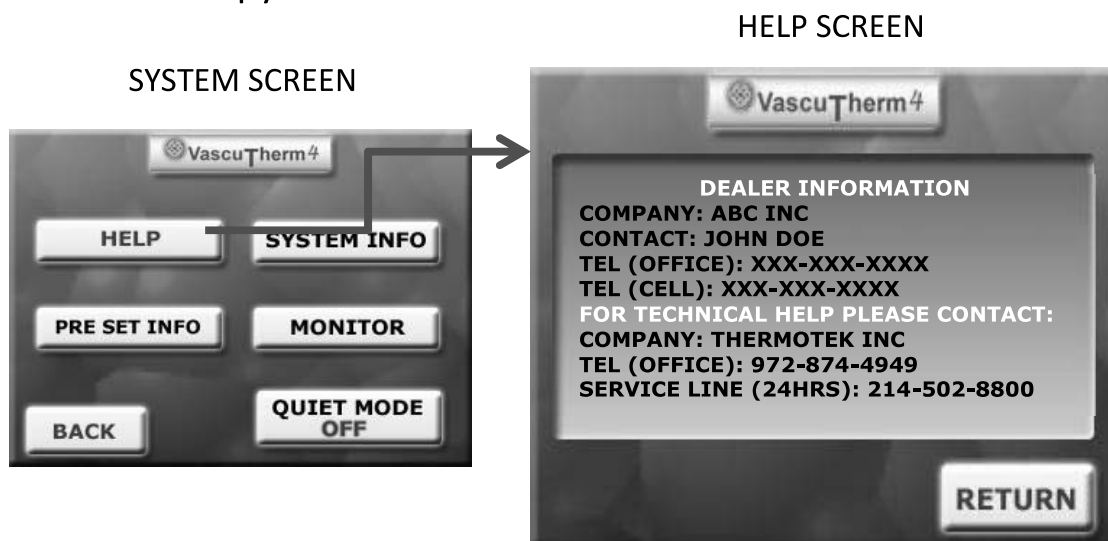
## 10. System Screen

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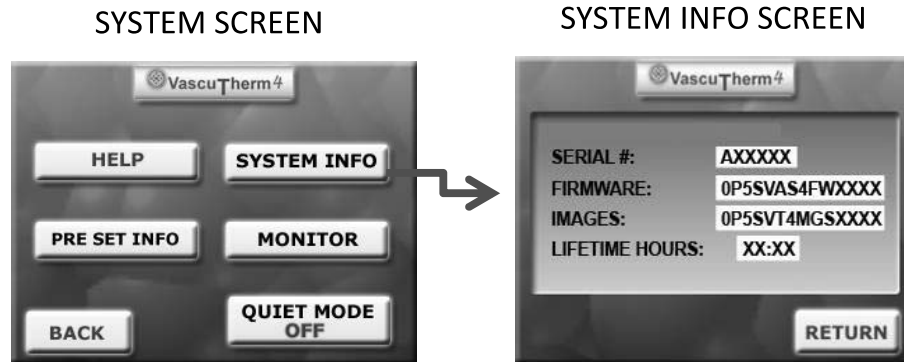
To access the System Screen, from the Primary Therapy Screen select “MORE”, and the System Screen will appear. The System Screen will provide information about the unit that will be helpful to the user.



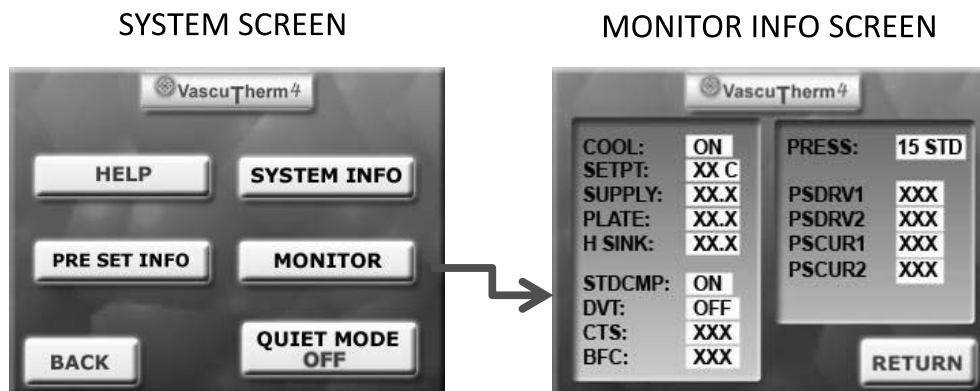
- Select “**HELP**” to access the unit’s information about who to contact if there are any questions or concerns regarding the VascuTherm4-M. Select “**RETURN**” to return to the previous screen. Select “**BACK**” to return to the Main Therapy Screen.



- 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.



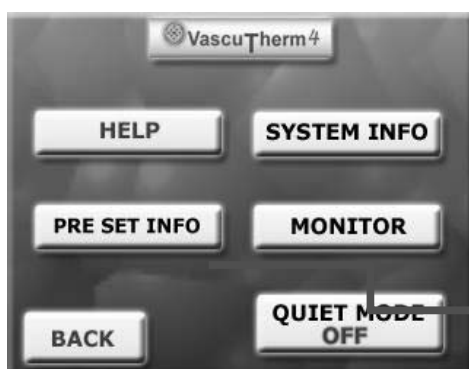
- Select “**MONITOR**” to access the unit’s information about its performance regarding temperature and pressure. Select “**RETURN**” to return to the previous screen. Select “**BACK**” to return to the Main Therapy Screen.



- 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

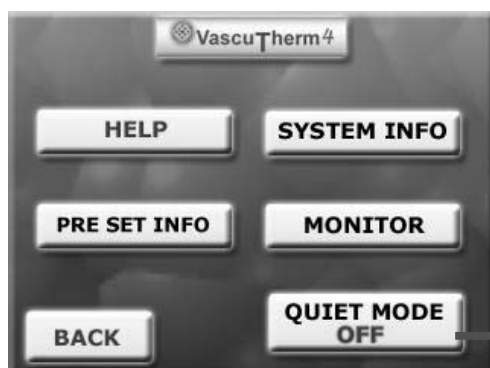


PRE PROG INFO SCREEN

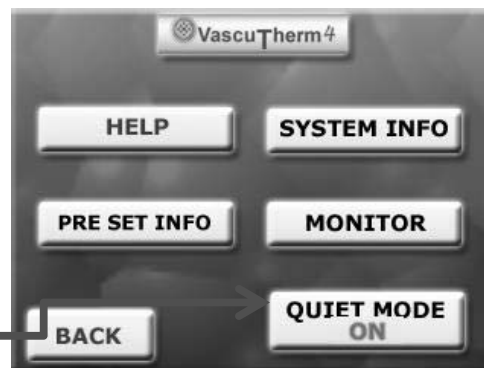


- Select **“QUIET MODE”** to turn it **“ON”** or **“OFF”** and reduce the system’s noise output.

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 VascuTherm4-M 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 U.S. Central Time.

## 11. Things You Can Do To Keep Your VascuTherm4-M System Performing

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



There are no user serviceable internal parts. The system warranty is voided if the tamper seals are breached or removed.



Keep water away from vents, power ON/OFF switch and the power cord connection of the unit.



To avoid possible electric shock, do not remove the cover of the unit.



Do not immerse the unit in water or any liquid.

- **Check the fluid level weekly.**

If the coolant mixture ever becomes discolored or offensive to smell, contact the clinic or hospital that prescribed the unit or the Durable Medical Equipment (DME) provider for assistance. If microbial growth is present and 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 U.S. Central Time.

- **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.

## **12. Draining the Fluid from the Unit**

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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 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.

## **13. Storage and Re-Packing the Unit**

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When therapy is complete and it is time to return or store the VascuTherm4-M 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 hose assembly umbilical 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:
  - VascuTherm4-M 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 4.5° C [40 °F] and 40.5°C [105 °F].
11. 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.

## 14. Troubleshooting Guide

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The VascuTherm4-M 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 VascuTherm4-M unit.

Refer to Chapter 7 “Environmental Conditions You Should Be Aware of Before Operating Your VascuTherm4-M 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.

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

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



		problem persists.
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<b>Problem/ Alarm Screen</b>	<b>Cause</b>	<b>Suggested Actions</b>
<b>The unit is leaking.</b> <b>(cont'd on next page)</b>	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

		<p>condensation rather than a leak.</p> <p>If water returns immediately, discard the wrap and Contact Customer Support.</p>
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Problem/ Alarm Screen	Cause	Suggested Actions
<p><b>The wrap is leaking fluid.</b> <b>(cont'd on next page)</b></p>	<p>The coolant ports are not connected / seated properly.</p>	<p>Disconnect and reseal all fluid connections on the umbilical/hose assembly.</p>
	<p>Physical damage to the unit.</p>	<p>If the wrap is leaking, turn the unit off and remove the wrap from the patient immediately.</p> <p>If the patient is utilizing a sterile wrap, the wound site may need to be cleaned. Consult a physician for proper wound care.</p> <p>Inspect the wrap for physical damage. If the wrap shows any</p>

		signs of puncture or tear, the wrap should not be used. Discard the wrap and contact the clinic or DME for assistance.
--	--	--

<b>Problem/ Alarm Screen</b>	<b>Cause</b>	<b>Suggested Actions</b>
<b>The wrap is uncomfortable and/or is compressing too tightly. (cont'd on next page)</b>	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 50 mm Hg for Standard Compression and 100 mm Hg for

		<p>DVT Compression.</p> <p>If the unit is displaying a pressure that exceeds these values for the therapies listed, stop compression immediately and ThermoTek contact customer support.</p>
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Problem/ Alarm Screen	Cause	Suggested Actions
<p><b>The unit is heating when it should be cooling (or cooling when it should be heating)</b></p> <p><b>(cont'd on next page)</b></p>	<p>The unit is in Alarms Active state.</p>	<p>Check display for the type of alarm event. If alarms are displayed use the trouble-shooting guide to resolve the issue.</p>
	<p>Internal fault within the therapy unit.</p>	<p>Check if the power supply LED is green.</p> <p>Turn the unit off by disconnecting the power supply. Wait 10 minutes, and re-connect the power supply.</p> <p>Try an alternate AC outlet.</p>

		Contact ThermoTek customer service if problem persists.
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<b>Problem/ Alarm Screen</b>	<b>Cause</b>	<b>Suggested Actions</b>
<b>Unit turns on, but it is not heating or cooling. (cont'd on next page)</b>	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


		<p>by disconnecting the power supply. Wait 10 minutes, and re-connect the power supply.</p> <p>Try an alternate AC outlet.</p> <p>Contact ThermoTek customer service if problem persists.</p>
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<b>Problem/ Alarm Screen</b>	<b>Cause</b>	<b>Suggested Actions</b>
<b>The unit is noisy.</b> <b>(cont'd on next page)</b>	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 that for foreign objects or material caught in inner fan blade.
	Internal fault within the therapy unit.	<p>Check if the power supply LED is green.</p> <p>Turn the unit off by disconnecting the power supply. Wait 10 minutes, and re-connect the power supply.</p> <p>Try an alternate</p>

		AC outlet.  Contact ThermoTek customer service if problem persists.
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Problem/ Alarm Screen	Cause	Suggested Actions
<b>The touch screen is not functioning.</b> <b>(cont'd on next page)</b>	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 connect 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,

		<p>and re-connect the power supply.</p> <p>Try an alternate AC outlet.</p> <p>Contact ThermoTek customer service if problem persists.</p>
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Problem/Alarm Screen	Cause	Suggested Actions
<p><b>My unit gives me a TIMER NOT SET alarm.</b></p> 	<p>The timer on your unit has not been set to run cool or heat therapy.</p>	<p>Contact your provider so they can program your unit.</p>




Problem/Alarm Screen	Cause	Suggested Actions
<p><b>My unit gives me a CHECK FLOW/FLUID alarm.</b></p> <p><b>(cont'd on next page)</b></p> 	<p>Reservoir is low on coolant.</p>	<p>Make sure the therapy mode is set to COOL mode.</p> <p>Open the reservoir cap. Check the fluid level and if necessary add fluid to the bottom of the neck.</p> <p>Run the system</p>





		<p>with the cap open for one minute.</p> <p>Close cap tightly.</p>
	Coolant ports not connected properly.	<p>Turn the unit OFF.</p> <p>Check if coolant ports are connected to the wrap.</p> <p>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.</p> <p>Turn ON the unit and restart therapy.</p>
	There is a kink in the wrap.	<p>Turn the unit OFF.</p> <p>Check for any folds or kinks on the wrap.</p> <p>Readjust wrap to alleviate the blockage.</p> <p>Turn ON the unit and restart</p>


		therapy.
	Air bubbles trapped within the unit.	<p>Make sure the therapy mode is set to COOL mode.</p> <p>Check the clear tubing on the wrap for air bubbles.</p> <p>If air bubbles are present, refer to Ch. 8 of this manual for Priming your VascuTherm 4-M.</p> <p>Run the system with the cap open for 5 minutes.</p> <p>Tapping the clear tubing on the wrap, with a finger, will also aid in the release of the air bubbles.</p> <p>Close cap tightly.</p> <p>Start and Stop therapy several times to clear bubbles from pump. Give the unit a few seconds between starting and stopping</p>

		therapy.
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Problem/Alarm Screen	Cause	Suggested Actions
<p><b>My unit gives me a LOW HEAT SINK TEMP, LOW SUPPLY or LOW PLATE TEMP alarm.</b></p> <p><b>(cont'd on next page)</b></p>   	<p>Unit is operated in a cold ambient environment.</p>	<p>Make sure the unit is operated indoors in an ambient <math>&gt; 15.5^{\circ}\text{C}</math> [<math>60^{\circ}\text{F}</math>].</p>
	<p>The unit was filled with cold coolant.</p>	<p>Make sure the unit is filled with room temperature fluid.</p>
	<p>The unit was powered on after being in a cold environment [e.g. trunk of a car].</p>	<p>Make sure the unit is used indoors with an ambient temperature <math>&gt; 15.5^{\circ}\text{C}</math> [<math>60^{\circ}\text{F}</math>].</p> <p>Turn the unit OFF for 30 minutes and restart the unit.</p> <p>Resume therapy.</p>
	<p>Internal fault within the therapy unit.</p>	<p>Check if the power supply LED is green.</p> <p>Turn the unit off by disconnecting the power supply. Wait 10 minutes, and re-connect</p>

		<p>the power supply.</p> <p>Try an alternate AC outlet.</p> <p>Contact ThermoTek customer service if problem persists.</p>
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Problem/Alarm Screen	Cause	Suggested Actions
<p><b>My unit gives me a HIGH HEAT SINK TEMP, HIGH SUPPLY or HIGH PLATE TEMP alarm.</b></p> <p><b>(cont'd on next page)</b></p>	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.	<p>Make sure the unit is operated in a location with adequate airflow from all sides.</p> <p>Make sure there is at least 6" of clearance around the unit.</p>
	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 in an ambient < 26.5° C

		[80° F].
	<p>The unit was powered on after being in a hot environment [e.g. trunk of a car].</p> <p>The hot environment raised the coolant temperature within the unit to alarm limits of &gt; 45°C [113° F].</p>	<p>Make sure the unit is used indoors with an ambient temperature &lt; 26.5° C [80° F].</p> <p>Turn the unit OFF for 30 minutes and restart the unit.</p> <p>Resume therapy.</p>
	The wrap is kinked.	Remove the therapy wrap and allow the unit to run without compression. Re-apply the therapy wrap and continue.
	Internal fault within the therapy unit.	<p>Check if the power supply LED is green.</p> <p>Turn the unit off by disconnecting the power supply. Wait 10 minutes,</p>



		<p>and re-connect the power supply.</p> <p>Try an alternate AC outlet.</p> <p>Contact ThermoTek customer service if problem persists.</p>
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Problem/Alarm Screen	Cause	Suggested Actions
<p><b>My unit gives me a STD WRAP NOT VENTING or DVT WRAP NOT VENTING alarm.</b></p> <p><b>(cont'd on next page)</b></p>  	<p>System software detected a kink in the wrap or airline.</p>	<p>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 re-apply wrap. Make sure hoses are not kinked.</p>
	<p>Internal fault within the therapy unit.</p>	<p>Check if the power supply LED is green.</p> <p>Turn the unit off by disconnecting the power supply. Wait 10 minutes,</p>

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


		<p>the power supply.</p> <p>Try an alternate AC outlet.</p> <p>Contact ThermoTek customer service if problem persists.</p>
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Problem/ Alarm Screen	Cause	Suggested Actions
<p><b>My unit gives me a STD WRAP NOT INFLATING or DVT WRAP NOT INFLATING alarm.</b></p> <p><b>(cont'd on next page)</b></p>  	<p>Wrap is loose on the patient</p>	<p>If the wrap is “ballooned” on the patient, it has been applied loosely.</p> <p>Remove wrap and reapply tightly to fit the patient.</p>
	<p>The correct therapy is not selected</p>	<p>Make sure you have selected the correct therapy and that the therapy is active.</p>
	<p>Wraps not connected to unit.</p>	<p>Make sure the wraps are connected to your unit.</p>
	<p>Leaky Wrap</p>	<p>Make sure your wraps are not leaking air.</p>




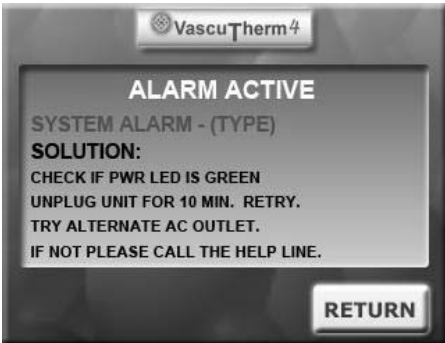
	Internal fault within the therapy unit.	<p>Check if the power supply LED is green.</p> <p>Turn the unit off by disconnecting the power supply. Wait 10 minutes, and re-connect the power supply.</p> <p>Try an alternate AC outlet.</p> <p>Contact ThermoTek customer service if problem persists.</p>
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Problem/ Alarm Screen	Cause	Suggested Actions
<p><b>My unit gives me a STD WRAP OVER PRESSURE SW or DVT WRAP OVER PRESSURE SW alarm.</b></p> <p><b>(cont'd on next page)</b></p> 	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 re-apply 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.	<p>Check if the power supply LED is green.</p> <p>Turn the unit off by disconnecting the power supply. Wait 10 minutes, and re-connect the power supply.</p> <p>Try an alternate AC outlet.</p> <p>Contact ThermoTek customer service if problem persists.</p>

Problem/ Alarm Screen	Cause	Suggested Actions
<p><b>My unit gives me a STD WRAP OVER PRESSURE HW or DVT WRAP OVER PRESSURE HW alarm.</b></p> <p><b>(cont'd on next page)</b></p> 	System hardware detected a kink in the wrap.	<p>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 re-apply wrap. Make sure hoses are not kinked.</p>

	Kinked hose	Make sure there are no kinks in the Standard and DVT hoses.
	Internal fault within the therapy unit.	<p>Check if the power supply LED is green.</p> <p>Turn the unit off by disconnecting the power supply. Wait 10 minutes, and re-connect the power supply.</p> <p>Try an alternate AC outlet.</p> <p>Contact ThermoTek customer service if problem persists.</p>

Problem/ Alarm Screen	Cause	Suggested Actions
<p><b>My unit gives me SYSTEM ALARM – (TYPE)</b></p> <p><b>(cont'd on next page)</b></p> 	Internal fault within the therapy unit.	<p>Check if the power supply LED is green.</p> <p>Turn the unit off by disconnecting the power supply. Wait 10 minutes, and re-connect the power supply.</p> <p>Try an alternate</p>

“TYPE defined as: TSH SHORT TSH OPEN TSS SHORT TSS OPEN TSP SHORT TSP OPEN PSENSOR EXT ADC INT ADC BK AIR I2C 5DC U 5DC O 3.3DC U 3.3DC O BROWNOUT DETECTED WATCH DOG TIMER RESET		AC outlet.  Contact ThermoTek customer service if problem persists.
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## 15. Device Summary

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The VascuTherm4-M Therapy System is capable of performing therapies for the following:

- **Cool Therapy:** the unit passes cool (6.0° C - 18.0° C [43°F - 64°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 (40.5° C [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 reduce the risk of clot formation.

The wraps for the VascuTherm4-M system are designed to maximize the effectiveness of the therapies listed above. Only use wraps in combination with therapy modes as prescribed.

### Basic Instructions for Use:

The instructions listed here are not intended to replace the complete user instructions listed in Chapters 8 and 9. The user should read this entire manual before attempting to operate the device.

1. Attach the therapy wraps as described in the instructions located in the wrap packaging.
2. Prepare the unit for operation using the “How to Set-Up Your VascuTherm4-M System for Therapy” instructions in Chapter 8.
3. Initiate the prescribed 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 VascuTherm4-M 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.

## 16. Service and Customer Support

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ThermoTek, Inc. is committed to servicing our VascuTherm4-M unit both during and after sale to the customer. If you have any questions concerning the operation of your VascuTherm4-M 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 U.S. Central Standard Time, Monday through Friday)
- **ThermoTek Website:** [www.thermotekusa.com](http://www.thermotekusa.com)



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

In the event of a Medical Emergency, please call your nearest healthcare professional.

## 17. Wraps, Accessories and Replacement Parts

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**Boxes/Foam:**

**Replacement Parts:**

Part Number	Description
OP2DCAPBTL	Reservoir Cap
OP3W10A8EU	Power Cord, 10A/250VAC, 2.5M, EU, Hospital Grade.
OP5WEXT36V	Power Supply, Ext, Med, 250W
OP2DNANTFB	Mixing Bottle, Thermoflow

**Available Therapy Wraps:**

Part Number	Description
OP9BNDVTFT	DVT Foot Wrap Set, Non-Sterile
OP9BNDVTCA	DVT Calf Wrap Set, Non-Sterile
* Sterile Therapy Wrap options available (example: OP9XXXXXXXX3-S)	
OP9BSFKNMR3	Standard Knee Wrap, Single Patient Use
OP9BLFKNMR3	Medium Knee Wrap, Single Patient Use
OP9BKNEEMR3	Large Knee Wrap, Single Patient Use
OP9BCFKNMR3	Circumferential Knee Wrap, Single Patient Use
OP9BSFNMR3	Knee Wrap w/o compression, Single Patient Use
OP9BUKNEMR3	Universal U Wrap, Single Patient Use
OP9BSSHLMR3	Standard Shoulder Wrap w/ Straps, Single Patient Use
OP9BSSWHMR3	Standard Shoulder w/Harness, Single Patient Use
OP9BMSHDMR3	Medium Shoulder Wrap w/ Straps, Single Patient Use
OP9BMSWHMR3	Medium Shoulder Wrap w/Harness, Single Patient Use
OP9BSHLMR3	Large Shoulder Wrap, Single Patient Use
OP9BLARMMR3	Arm Wrap, (Half Arm)Single Patient Use
OP9BFARMMR3	Arm Wrap, (Full Arm)Single Patient Use
OP9BFTAKMR3	Foot/Ankle Wrap, Single Patient Use
OP9BANKLMR3	Open Heel Foot/Ankle Wrap, Single Patient Use



0P9BHPSBMR3	Hip Wrap w/ Harness, Single Patient Use
0P9BBACKMR3	Back Wrap, Single Patient Use
0P9BUCRVMR3	Upper Cervical Wrap, Single Patient Use
0P9BLCRVMR3	Lower Cervical Wrap, Single Patient Use
0P9BTCRVMR3	Total Cervical Wrap, Single Patient Use
0P9BMNWAMR3	Mini Wrap, Single Patient Use
0P9BFACEMR3	Face Wrap, Single Patient Use
0P9BHEADMR3	Head Wrap, Single Patient Use

#### **Hose Assemblies:**

<b>Part Number</b>	<b>Description</b>
0P9AVT4UMB	Hose, Therapy Umbilical, Standard 5 ft. [ 1.5 m]

#### **Optional Equipment:**

<b>Part Number</b>	<b>Description</b>
0P2AVT4BHB	Bed Hook

## 18. Specifications

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VascuTherm4-M Part Number	OP9PTVT40M
Dimensions	25.0 cm W x 25.1 cm H x 22.2 cm D [9.81"W x 9.88"H x 8.75"D]
Ambient Operating Range	15.5–26.5 °C [60 – 80 °F ]
Relative Humidity	< 60% RH
Therapy Temperature Range	6.0 – 40.5° C [43 – 105 °F]
Centrifugal Pump	12-volt Brushless DC
Weight without Fluid	4.5 kg [10-lbs]
System Fluid Capacity	320 mL [11-ounces]
Power Consumption (Max)	250 Watts
Input Voltage (Nominal)	100-240 VAC, 50/60 Hz, Single Phase
Input Current (Max)	2.5 Amps
Accuracy	± 1 °C [± 2 °F]
Refrigerant	None
Heating/Cooling Function	Heating Optional
USB Interface	Yes, Standard
Recommended Coolants	90% distilled water, 10% alcohol

### 18.1 Calibration

The VascuTherm4-M 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 VascuTherm4-M 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 VascuTherm4-M 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 VascuTherm4-M system.

### **Internal Battery**

The VascuTherm4-M 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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## **20. Warranty and Disclaimer Information**

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**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 VascuTherm4-M will be free from defects in workmanship and material under normal use for one (1) year after the date of purchase. ThermoTek warrants to the immediate purchaser from ThermoTek, or an immediate purchaser of an unused wrap from an authorized distributor of ThermoTek products, that ThermoTek single patient use wraps will be free from defects in workmanship and material under normal use for only the first use of the wrap.

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

**ThermoTek will, at its option, repair or replace within a reasonable time any product that is found to have a defect in material or workmanship under normal use during the applicable warranty period. This is the immediate**

**purchaser's sole remedy.** Any warranty on a repair or replacement expires at the same time as the warranty expires or would have expired on the original product. The product must be returned at the immediate purchaser's expense to an authorized ThermoTek Service Center for warranty service. ThermoTek will pay for the expense of returning the product receiving warranted service to the immediate purchaser. The immediate purchaser is responsible for and will be assessed a fee for test and calibration if no defects are found with the product.

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

Any product returned for warranty must have a Returned Materials Authorization ("RMA") number on the outside of the container or package. Please call ThermoTek Customer Service at 877-242-3232 for an RMA number. A ThermoTek 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.

**DISCLAIMER OF WARRANTIES: THERMOTЕК 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**

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**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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For customer service information please see Section 17 of this manual.

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Rev: X1 02/13