VascuTherm3-M

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1. Introduction

Please read the entire manual carefully before trying to operate the VascuTherm3-M system. It is unsafe to start using the VascuTherm3-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 VascuTherm3-M experience better, please do not hesitate to contact us.

User Assistance Information:

The VascuTherm3-M Therapy System is manufactured by:

ThermoTek, Inc.
1200 Lakeside Parkway #200
Flower Mound, TX 75028
001-(972) 874-4949
001-(877) 242-3232 (toll free service number)

For 24-hour Service, call 001-(214) 502-8800
or visit us on the web at www.thermotekusa.com

Icons Used for Warnings and Cautions:


Electrical Shock Risk


Burn Risk


Frostbite or Cryogenic Burn Risk


General Caution

Do not drink or ingest the coolant mixture.

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 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

3.1. Contraindications for Pneumatic Compression Therapy:

The healthcare professional should not use the VascuTherm3-M on patients that are 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 healthcare professional should use the VascuTherm3-M on the following patients that require temperature contact therapy 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 VascuTherm3-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 air filter or frame.

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 plugged into a 3-prong grounded outlet.

Do not operate the unit if it has any noticeable or physical damage or is leaking fluid.

Do not operate the unit with a damaged or frayed power cord.

The therapy unit is not intended to be used in a wet environment or when relative humidity is greater than 60%.

Do not spray the unit with any water solvents or cleaners.

Do not drop the therapy unit or cause impact to the unit.

Do not pull or otherwise put undue stress on the hoses.

Do not use this device without the supplied air filter.

Do not use near equipment that generates electromagnetic or other interferences as this may be harmful to the therapy unit.

Do not smoke while use therapy wraps or use wraps by an open flame.

Do not touch the heat sink fins on the sides of the unit during or immediately after operation.

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

3.5. Warnings:


Follow the prescribed instructions from 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.


If unusual swelling, skin discoloration or discomfort occurs, immediately discontinue use of the VascuTherm3-M unit and consult a healthcare professional.


Use only ThermoTek approved therapy wraps.


Therapy wraps are non-sterile unless specifically labeled as sterile


Therapy wraps should never be directly applied to an open wound or breached skin.


Do not attempt to sterilize this device by any means.


Patients vary in sensitivity to cold. Make a regular check of the patient's temperature once established.


Therapy wraps are to be fitted initially by a healthcare professional that is familiar with the purpose for which the wraps are used.


Do not apply the therapy wrap so tightly as to restrict blood or fluid flow.


A healthcare professional is responsible for providing wearing instructions and precautions to other healthcare professionals, care providers involved in the patient's care, and the patient.


A licensed healthcare professional is responsible for evaluating the usage of the VascuTherm3-M on pregnant women, nursing women or children, assuring appropriate use and application of all therapies.


If it is appropriate for the patient to use the wrap with therapy unit at home, the healthcare provider must provide adequate and appropriate instructions for use to the patient.


The healthcare provider must monitor the patient's use of the therapy unit, assuring appropriate use and application of all therapies.


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

The therapy wrap should be periodically cleaned if it is used on the same patient for an extended period of time.

Clean exposed surfaces of the therapy wrap with either a mild anti-bacterial soap and water solution or an isopropyl alcohol and water solution. Do not use bleach on therapy wraps.

Dressings used under the therapy wrap should be applied lightly.

Do not use pins to secure the therapy wraps or hoses.

Do not allow the therapy wrap or hoses to contact sharp objects that could puncture it.

All therapies using compression must be turned OFF when the unit is not in use or the wrap is removed from the patient for prolonged periods or for repositioning of the wrap.

Immediately stop compression therapy if you experience any sense of discomfort, numbness or tingling of the limb.

Use only the approved coolant in the VascuTherm3-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 labels. Never remove the warning labels.

Do not drink or ingest the coolant.

There is a potential for fluid to overflow from the reservoir if the thermal wrap is positioned above the VascuTherm3-M™ and the device is powered off.

DO NOT open the reservoir cap with the <u>unit power turned OFF</u> or when it is in <u>Resume Therapy Mode,</u> with the thermal wrap connected to the device.

4. Indications for Use

The VascuTherm3-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:

- Localized thermal therapy (hot or cold) for post traumatic and post-surgical medical and/or surgical conditions,
- Reduction of edema associated with soft tissue injuries such as burns, postoperative edema, and ligament sprains,
- Treatment of disorders associated with vascular or lymphatic insufficiency such as Chronic Venous Insufficiency (CVI), venous stasis ulcers, post-mastectomy edema and chronic lymphedema,
- 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. VascuTherm3-M Device Description

The VascuTherm3-M therapy system is an electronic heating, cooling and compression system. The VascuTherm3-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 6.0º C – 10.0ºC for Cool therapy and 40.5ºC for Heat Therapy
- 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 compression from 10 mmHg to 30 mmHg
- Pain Management
- Programmable Therapies
- Lightweight and Portable Package
- User-Friendly Interface
- Universal (100 – 240) VAC Power Input
- Easy to read Liquid Crystal Display
- Quiet Operation

5.2. General Specifications:

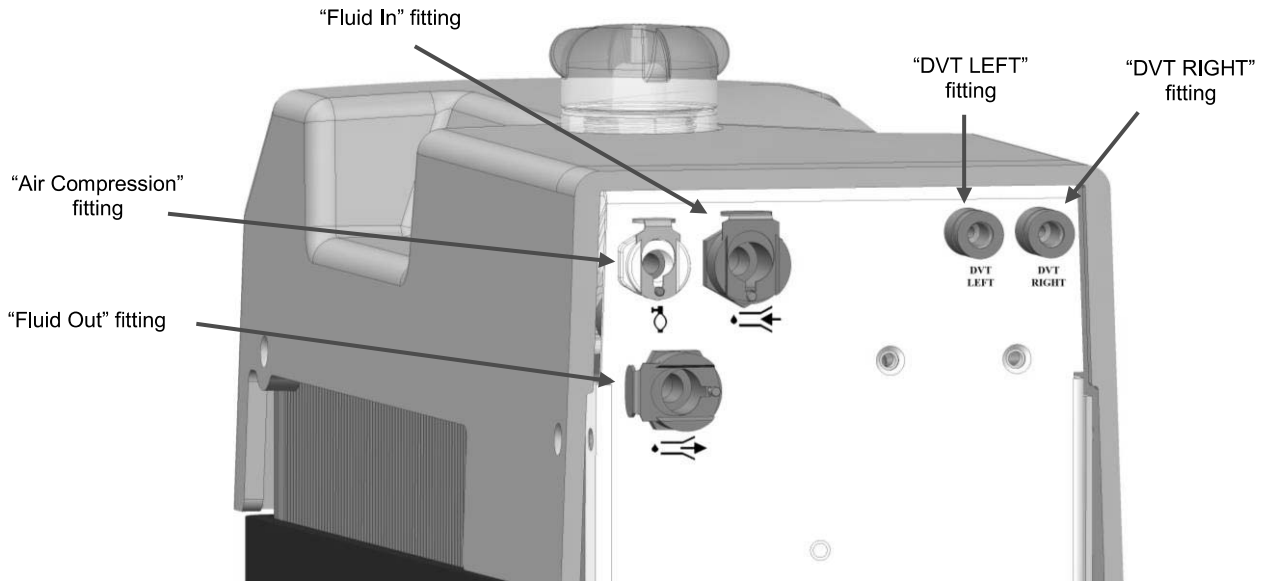
- Weight: 6.80 kg.
- Hose Length: 213.4 cm.
- Grounded Power Cord
- Dimensions: 13.33 cm W x 22.22 cm H x 36.19 cm D
- Operating Fluid: 90% Distilled Water/10% Isopropyl Alcohol
- Safety: IEC60601-1 ed.3

5.3. Options:

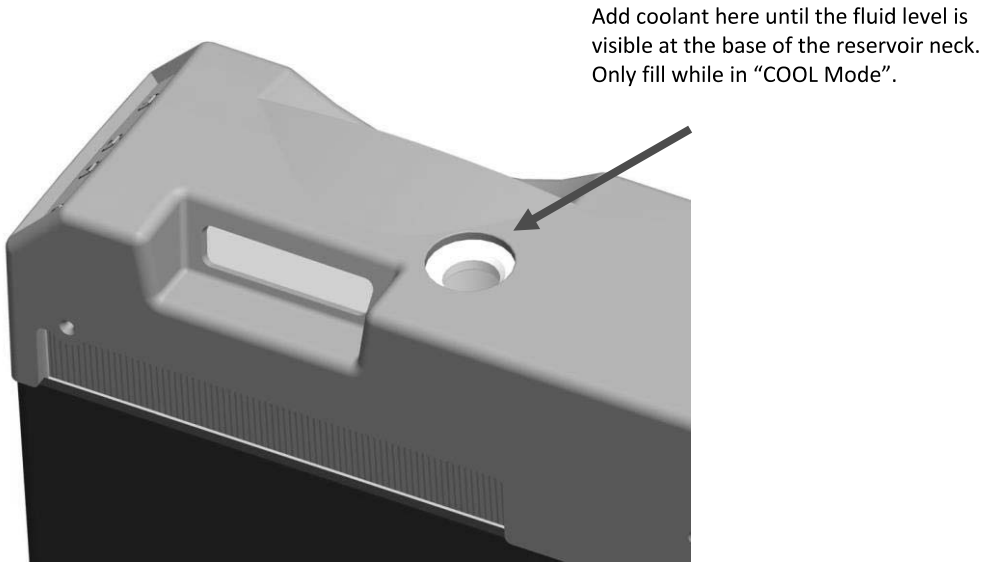
- Single Patient Use Therapy Wraps
- Carrying Case
- Rolling Stand

5.4. Device Description:

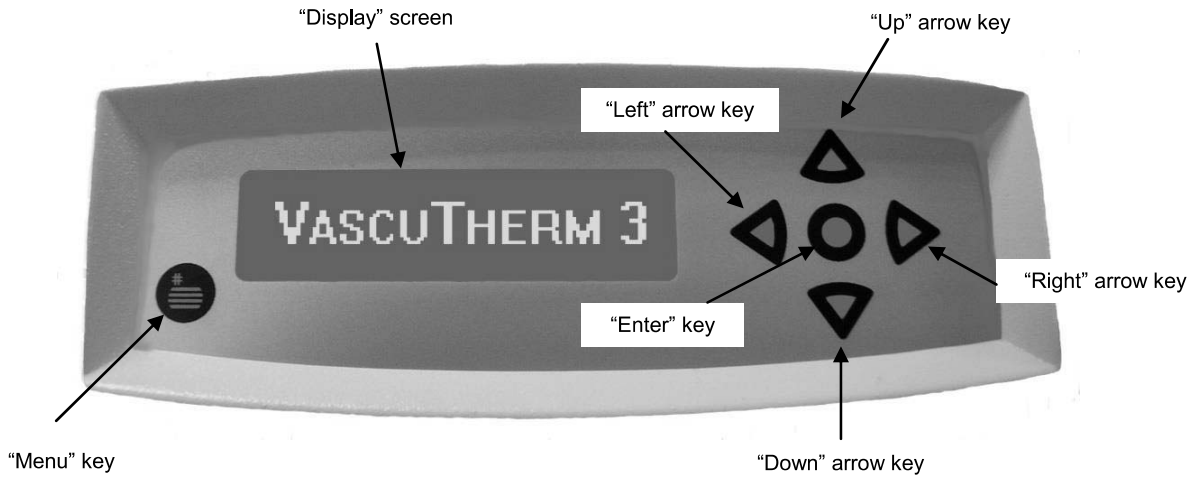
Rear Panel Connections



Coolant Reservoir Fill Location

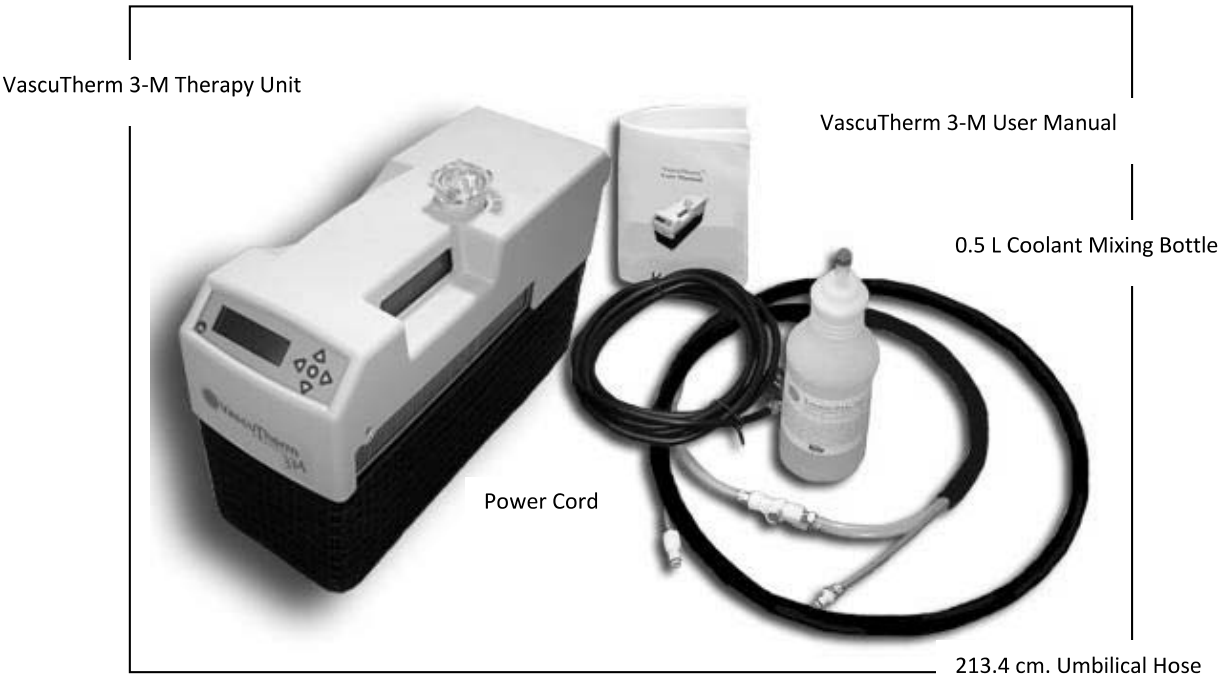


Keypad Interface and Illuminated Display



6. Unpacking Your VascuTherm3-M Therapy System

When you first unpack the device 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 or ThermoTek Customer Service at 001-(877)-242-3232.

Immediately upon unpacking your VascuTherm3-M Therapy System, inspect your unit. If the unit shows shipping damage, contact the transportation company and file freight damage claim. **Be sure to retain all packing material and the original box or case.**

Along with the VascuTherm3-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 immediately to obtain a new, sealed therapy wrap.

Therapy wraps should never be directly applied to an open wound or breached skin.

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

7. Environmental Conditions You Should be Aware of Before Operating Your VascuTherm3-M Device

The VascuTherm3-M therapy system is intended for indoor use only.

Do not operate the VascuTherm3-M system with therapy wraps in or near a wet environment.

The VascuTherm3-M therapy system is not to be used in a confined space. For optimal operation a clearance of 30.5 cm is required on all sides of the system. Inadequate air flow can result in overheating of internal electrical components and undesirable or excessive noise.

Only use the VascuTherm3-M system in an ambient environment between 15.5-26.7 ºC (degrees Celsius) and a relative humidity below 60%.

Failure to meet these operating environment conditions may result in:

Condensation buildup inside the unit.

Overheating or freezing of the unit.

Internal electronics malfunction

- A reduction in the heating or cooling capabilities of the unit
- A potential to trip the unit's electrical breaker (thermal switch) due to an internal electrical overload.
- The inability of the unit to properly regulate and administer fluid temperature during heat or cold therapies.
- The inability of the unit to properly regulate and administer pneumatic compression as specified in the indications for use.

8. How to Set Up Your VascuTherm3-M System Prior to Therapy

Now that you have fully unpacked your VascuTherm3-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.

1. Keep unit upright and on a level surface.

2. Make sure there is a 30.5 cm clearance and free path for airflow entry and exit around the unit prior to operation.

3. Verify the power switch is in the OFF position.

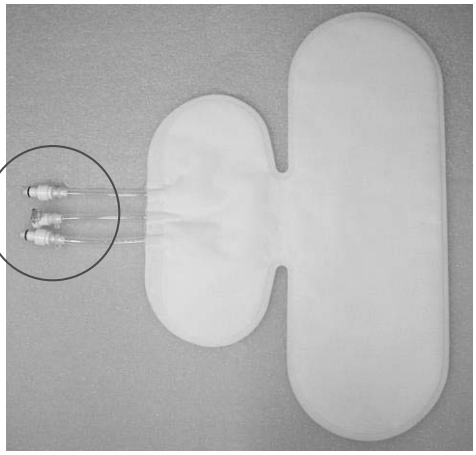
4. Remove the coolant reservoir cap from the top of the unit. Using the coolant bottle supplied with the therapy system, fill the reservoir to the bottom of the reservoir neck. Close the cap back securely on the reservoir

   Note: If the coolant bottle is empty, please refer to the mixing instructions label located on the coolant bottle.

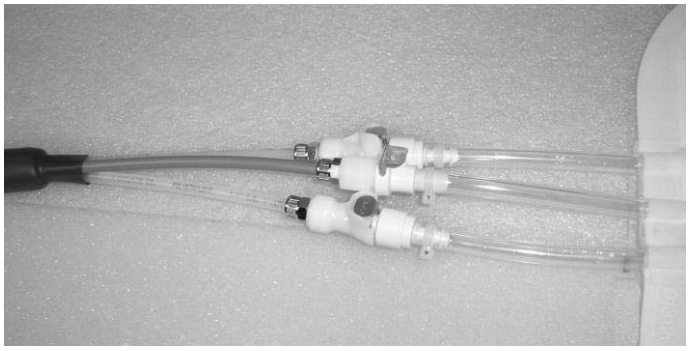
5. **DO NOT** over fill reservoir.

6. Unpack a prescribed therapy wrap and place the wrap flat on a surface lower than the VascuTherm3-M unit.

7. Connect the clear and grey hoses to the therapy wrap used for treatment. The fittings should make a “click” sound when inserted to indicate a secure connection.



Therapy Wrap connections



Wrap connections to umbilical hose.

8. On the rear panel of the unit, locate the fittings marked by the symbols for "Fluid Out", for "Fluid In", and for "Air Compression".

9. Connect the clear hoses to the and ports on the rear panel of the unit (flow direction does not matter on this unit). The fittings should make a "click" sound when inserted to indicate a secure connection.

10. Connect the grey hose to the port. The fitting should make a "click" sound when inserted to indicate a secure connection

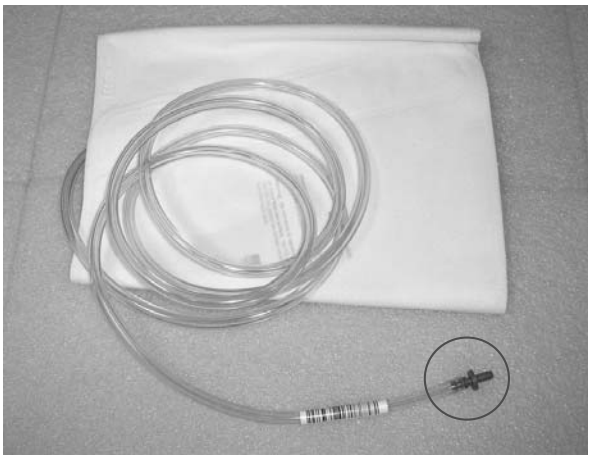
11. You might need to add fluid to the reservoir after starting treatment. Refer to section **8.2** for instructions on how to add fluid to the reservoir and fill the fluid wrap.

Note: DO NOT open the reservoir cap with the **unit power turned OFF** or when it is in **Resume Therapy Mode,** with the thermal wrap connected to the device.

12. If DVT therapy wraps were provided with the unit, install the wraps as shown below. To attach and secure the therapy wrap fittings, insert the wrap fitting into the rear panel connector and secure it by pushing it all the way in.

- For **bilateral** operation, do this for both the Left and Right wraps.

- For **unilateral** operation, inset the wrap to the connector labeled LEFT.



DVT wrap connection

DVT Bilateral connection to unit.

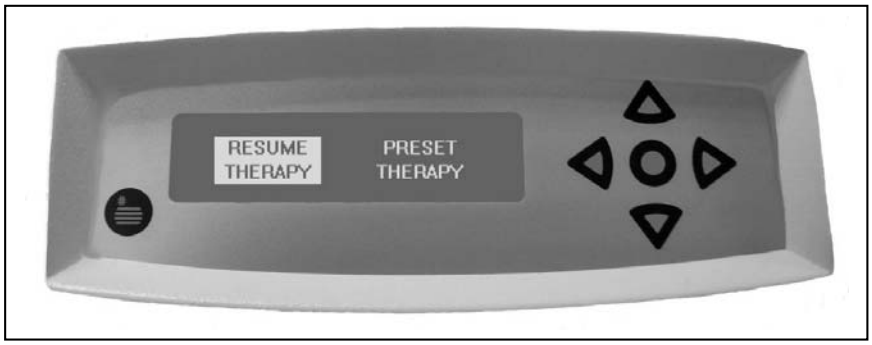
DVT Unilateral connection to unit.

13. Install the appropriate end of the power cord into the unit. Plug the male end into a grounded AC voltage source, within the specified voltage range.

8.2 Adding Fluid to the Reservoir

1. Turn on the unit. The power switch is located on the rear panel of the unit. When first powered up, the unit will beep briefly and a blue light will illuminate the display screen.

2. After a brief boot-up sequence, the display will show the Main Menu screen:



3. The menu selections can be selected using the LEFT and RIGHT keys. Once the desired menu is highlighted, press the ENTER key to accept the selection.

4. Select “SET THERAPY” or “PRESET THERAPY”, then select “HEAT/COOL”, select “COOL” and select “ON”. After this selection, the display will show the main menu displayed above. Select “RESUME THERAPY” to initiate cooling so that the unit begins to fill wraps with fluid.

5. While the wraps are being filled, the coolant level in the reservoir may go down. Check periodically over a 3-minute initiation period and add coolant to the reservoir as necessary. If a “Check Flow/Fluid” alarm shows on the display, press the MENU key to clear the alarm message; add coolant if necessary; re-select “RESUME THERAPY” to continue.

6. When you see a fluid stream without any air bubbles flowing in the clear tubes, screw the cap onto the reservoir. The VascuTherm3-M therapy system is now ready for therapy. Refer to the Operation Instructions in the next chapter for details on your specific prescribed treatment.

If you experience difficulty in setting up your VascuTherm3-M therapy system for use, please contact the clinic or hospital that prescribed the unit or the healthcare provider. If assistance is not available or is ineffective, please contact ThermoTek technical assistance toll-free at 001-(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 001-(214)-502-8800.

9. Operating Instructions for Your VascuTherm3-M System

Refer to Chapter 8 “How to Set-Up Your VascuTherm 3-M System Prior to 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 VascuTherm3-M system are designed to maximize the effectiveness of the therapies listed above. Only use ThermoTek approved wraps for single therapy and / or combination therapy modes as prescribed.

The VascuTherm 3-M Therapy System is capable of performing therapies for the following:

- Cool Therapy,
- Heat Therapy,
- Thermal Contrast Therapy,
- Pneumatic Compression Therapy for Edema and Lymphedema,
- Pneumatic Compression Therapy for the prevention of DVT,
- Combination Therapies:
    - Thermal (Heat / Cool / Contrast) Therapy with Pneumatic Compression Therapy for Edema and Lymphedema,
    - Thermal (Heat / Cool / Contrast) Therapy with Pneumatic Compression Therapy for prevention of DVT,
    - Thermal (Heat / Cool / Contrast) Therapy with Pneumatic Compression Therapy for Edema and Lymphedema and for prevention of DVT,
    - Pneumatic Compression Therapy for Edema and Lymphedema and for prevention of DVT.

9.1. Turning the Unit ON for the First Time:

The VascuTherm3-M therapy system is capable of being programmed manually or having an automatic pre-programmed therapy with a specific prescribed therapy for the patient by the healthcare professional.

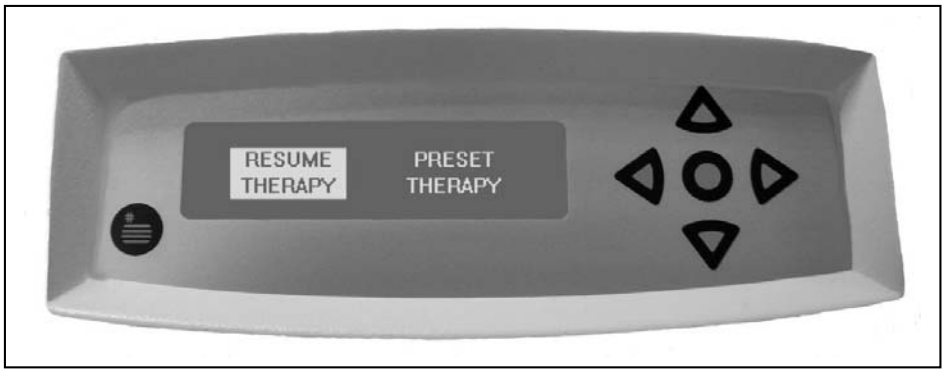
9.1.1 Automatic Pre-Programmed Therapy

1. Verify the unit is plugged into the appropriate AC voltage outlet.

2. Turn the unit ON. The power switch is located on the rear panel of the unit.

3. When first powered up, the unit will beep briefly and the VascuTherm3 and ThermoTek logos will briefly appear while the unit is starting up.

4. After a brief boot-up sequence, the display will show the Main Menu Screen. If the unit has not been pre-programmed the options will be RESUME THERAPY and PRESET THERAPY to indicate, the device has been programmed.



5. To initiate the prescribed therapy, highlight RESUME THERAPY option, using the LEFT or RIGHT keys and press CENTER key to accept the selection.

   - **DO NOT press and hold any of the keys during automatic therapy**. Doing so will halt the automatic therapy timer and change the unit into manual mode. 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 turn the unit off at the rear panel switch and back on again to restart automatic therapy and the therapy timer. Any therapy time used on the timer will not be retained and therapy must restart from the beginning to ensure proper treatment.

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

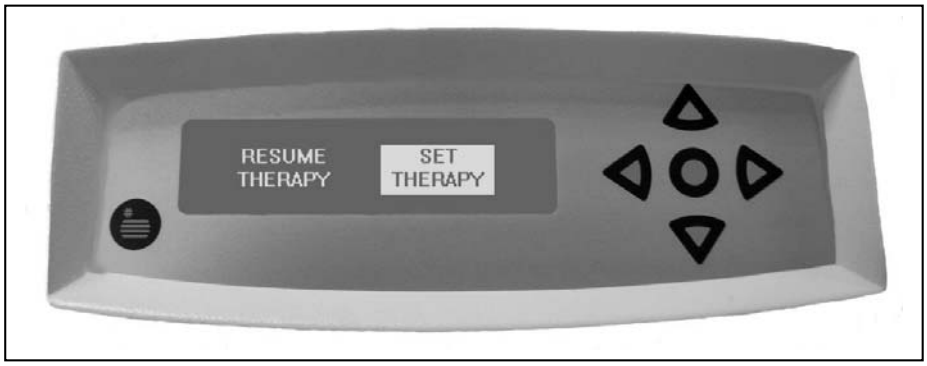
9.1.2. Manual Therapy

1. Instructions on how to control the unit manually are detailed in the following chapters 9.2 thru 9.8.

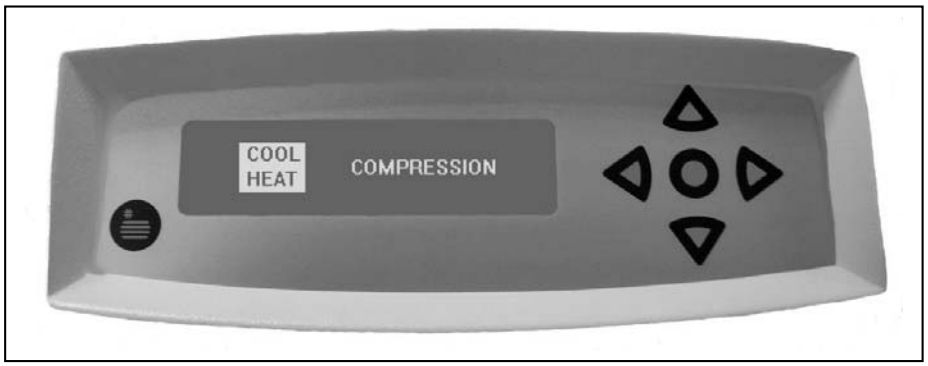
9.2. Cool Therapy:

Cool Therapy passes cool fluid through the wrap for the management of pain, discomfort and swelling. Cool Therapy can be used in combination with Pneumatic Compression Therapy and DVT Therapy (see the instructions in Chapter 9.8).

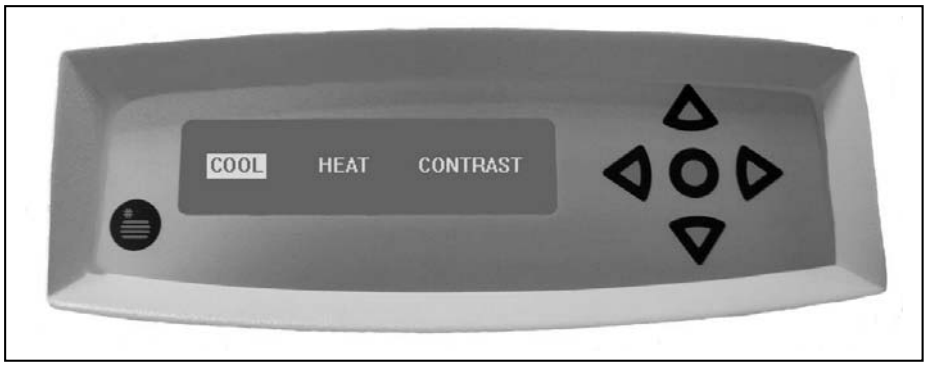
1. To initiate Cool Therapy, select “SET THERAPY”.



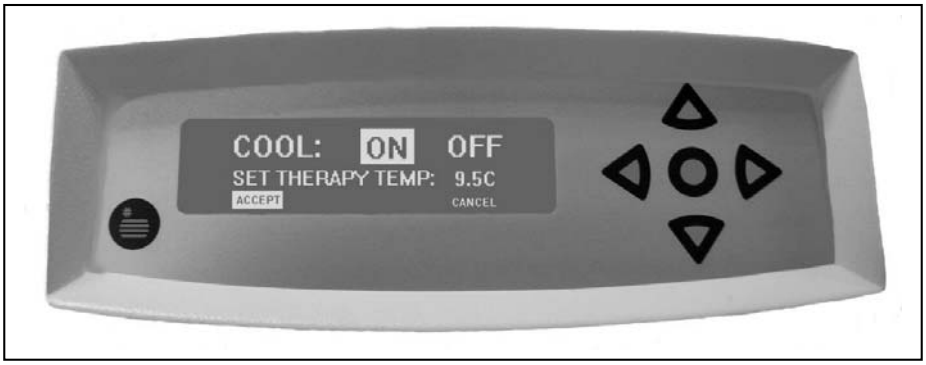
2. Select “COOL/HEAT”.



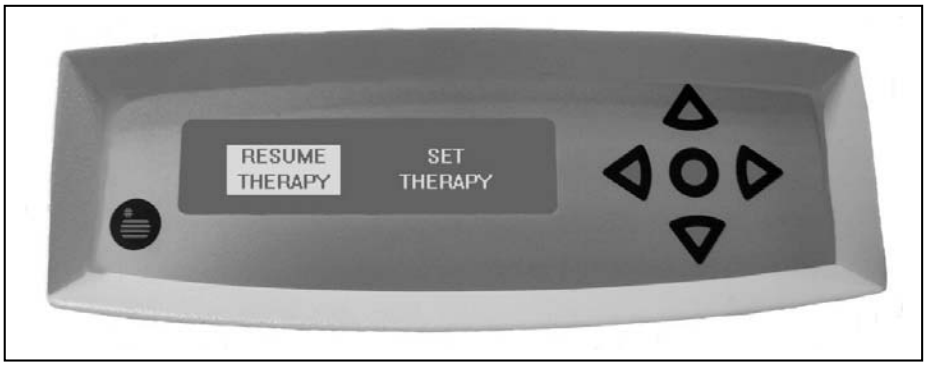
3. Select “COOL”.



4. Select COOL: “ON”. Press the down arrow to change or adjust the temperature. Once the desired temperature is selected, press the ENTER key and select “ACCEPT”.



5. Select “RESUME THERAPY”.



6. Once treatment is initiated, the status menu will display the current therapy settings:

7. If the therapy was initiated manually, then to stop therapy press the MENU key and select “STOP THERAPY”.

8. To disable STD Compression therapy and prevent it from running on the next start-up, select “SET THERAPY” to go to the “COMPRESSION MODE” menu. From that menu, select “STD”, then select “OFF”. The unit will return to the Main

menu and STD Compression will be disabled until re-enabled with the “SET THERAPY” procedure.

When the prescribed therapy duration is complete:

9. If times between treatments are more than one hour, it is recommended to turn the unit OFF to prevent condensation from building up on the therapy wrap.

   If continuous daily treatments are prescribed, it is best to leave the unit:

   - Turned ON,
   - Connected to the therapy wrap, and
   - Controlling to the desired temperature

⚠ 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.

⚠ If Compression therapy is being used in combination with Cool therapy, allow the wrap to fully deflate before removing it from the patient.

Note: Condensation time may vary based on the operating environment. Condensation time may be shorter for extremely cool environments. Watch for condensation build-up on the wraps during cool therapy. If condensation forms, remove condensation from therapy wraps with a clean, dry cloth prior to patient use.

9.2.1 Thermal Therapy Timer

1. When COOL Therapy is active a treatment duration timer [ON TIME] and a treatment rest timer [OFF TIME] will also be active.

2. This timer has been set by the equipment provider and is not user adjustable.

3. When COOL therapy is initiated, the device will indicate the remaining therapy time. This time will decrease until it reaches 0:00hrs, at which point the COOL therapy will stop.

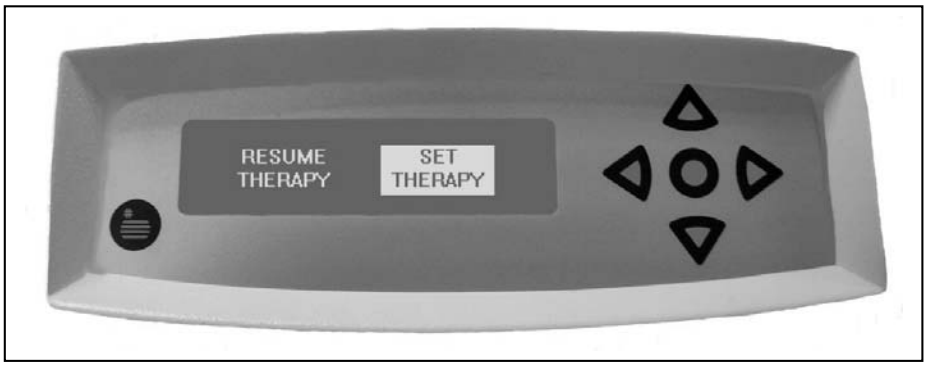
4. After the COOL therapy has stopped, the unit will go into a Rest state until the "Off" time counts down to 0:00hrs, at which point the COOL therapy will re-initiated.

5. The timer feature is only applicable to COOL, HEAT and CONTRAST therapies. Pneumatic compression therapies will operate continuously.

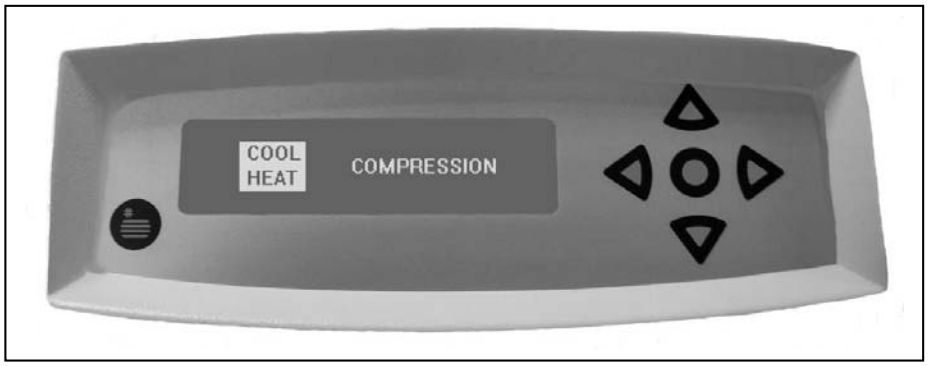
9.3. Heat Therapy:

Heat Therapy passes warm fluid through the wrap for the management of pain and discomfort. Heat therapy can be used in combination with Pneumatic Compression Therapy and DVT Therapy (see the instructions in Chapter 9.8).

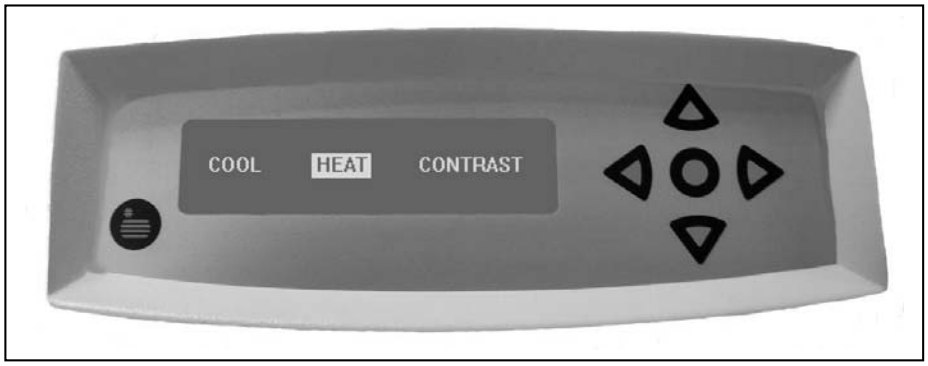
1. To initiate heat therapy, select "SET THERAPY".



2. Select “COOL/HEAT”.

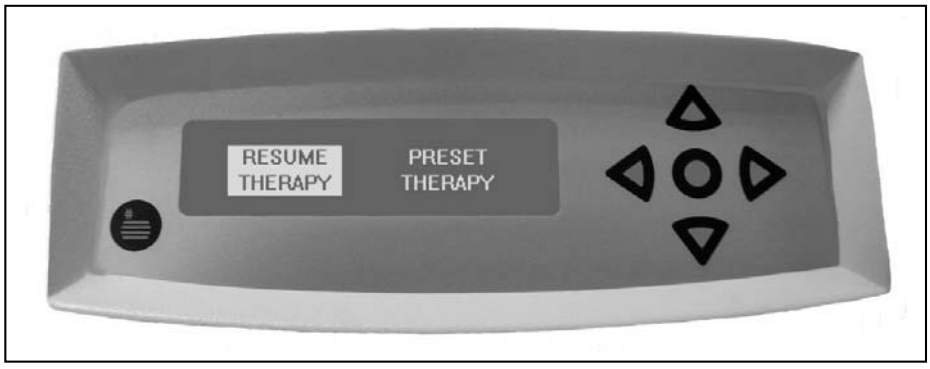


3. Select “HEAT”.



4. Select HEAT: “ON”.

5. Select “RESUME THERAPY”.



6. Once treatment is initiated, the status menu will display with the current therapy settings.

7. If the therapy was initiated manually, then to stop therapy press the MENU key and select “STOP THERAPY”.

8. To disable STD Compression therapy and prevent it from running on the next start-up, select “SET THERAPY” to go to the “COMPRESSION MODE” menu. From that menu, select “STD”, then select “OFF”. The unit will return to the Main menu and STD Compression will be disabled until re-enabled with the “SET THERAPY” procedure.

When the prescribed therapy duration is complete:

9. If times between treatments are more than one hour, it is recommended to turn the unit OFF. Once the unit is OFF, you may now remove your therapy wraps. If continuous daily treatments are prescribed, it is best to leave the unit:

    - Turned ON,
    - Connected to the therapy wrap,
    - Controlling to the desired temperature, and
    - Compression turned OFF.

⚠ 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.

⚠ If Compression therapy is being used in combination with Heat therapy, allow the wrap to fully deflate before removing it from the patient.

9.3.1 Thermal Therapy Timer

1. When HEAT Therapy is active, a treatment duration timer and a treatment rest timer will also be active.

2. This timer has been set by the equipment provider and is not user adjustable.

3. When HEAT therapy is initiated, the device will indicate the remaining therapy time. This time will decrease and when it reaches 0:00hrs, the HEAT therapy will stop.

4. The HEAT therapy will be in a Rest state until the Rest time reaches 0:00hrs, at which point the HEAT therapy will be re-initiated.

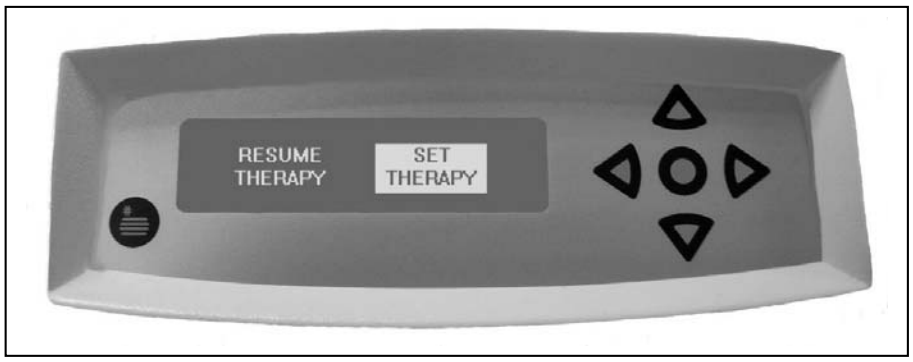
5. If the treatment is manually stopped or the VascuTherm3-M's power is disconnected, the active timer information will not be stored. When treatment is re-initiated the timers will be reset to the preset values.

6. The timer feature is only applicable to COOL, HEAT, and CONTRAST therapies. Pneumatic compression therapies will operate continuously.

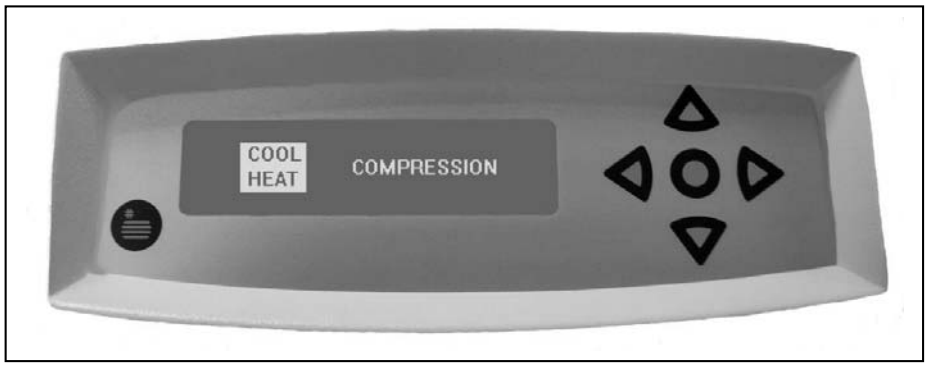
9.4. Thermal Contrast Therapy:

Thermal Contrast Therapy passes fluid through the wrap in an alternating cycle of Cool-Heat-Cool-Heat for the management of pain, discomfort, and swelling. During Thermal Contrast Therapy, the unit will cool down the circulating fluid to 9.5ºC for twenty (20) minutes and then heat up to 40.5ºC for ten (10) minutes.

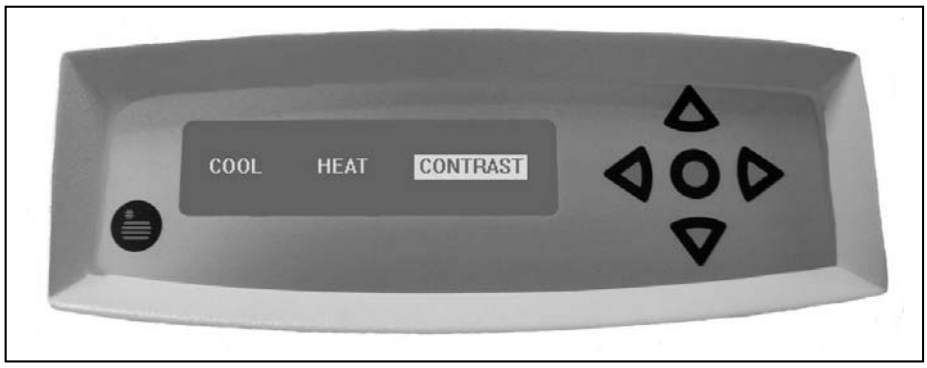
1. To initiate thermal contrast therapy, select “SET THERAPY”.



2. Select “COOL/HEAT”.

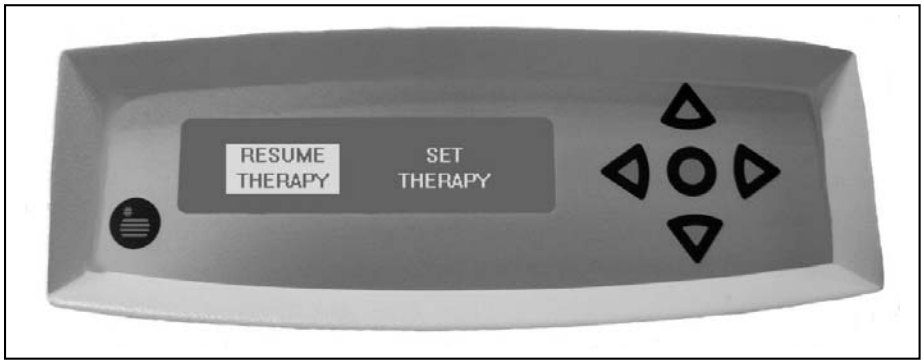


3. Select “CONTRAST”.



4. Select “ON”

5. Select “RESUME THERAPY”.



6. Once treatment is initiated, the status menu will display with the current therapy settings:

7. If the therapy was initiated manually, then to stop therapy, press the MENU key and select “STOP THERAPY”.

8. To disable STD Compression therapy and prevent it from running on the next start-up, select “SET THERAPY” to go to the “COMPRESSION MODE” menu. From that menu, select “STD”, then select “OFF”. The unit will return to the Main menu and STD Compression will be disabled until re-enabled with the “SET THERAPY” procedure.

When the prescribed therapy duration is complete:

9. If times between treatments are more than one hour, it is recommended to turn the unit OFF. Once the unit is off, you may now remove your therapy wraps.

   If continuous daily treatments are prescribed, it is best to leave the unit:

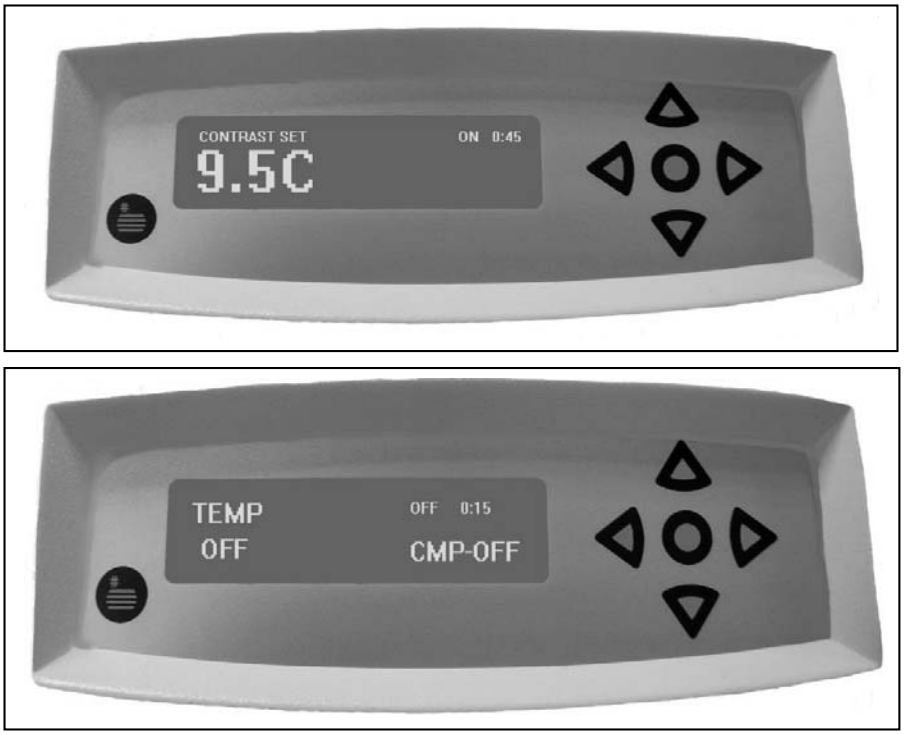
   - Turned ON,
   - Connected to the therapy wrap,
   - Controlling to the desired temperature, and
   - Compression turned OFF.

⚠ 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.

⚠ If Compression therapy is being used in combination with Heat therapy, allow the wrap to fully deflate before removing it from the patient.

9.4.1 Thermal Therapy Timer

1. When CONTRAST Therapy is active, a treatment duration timer and a treatment rest timer will also be active.



2. This timer has been set by the equipment provider and is not user adjustable.

3. When CONTRAST Therapy is initiated, the device will indicate the remaining therapy time. This time will decrease and when it reaches 0:00hrs, the CONTRAST therapy will stop.

4. The CONTRAST therapy will be in a Rest state until the Rest time reaches 0:00hrs, at which point the CONTRAST therapy will be re-initiated.

5. If the treatment is manually stopped or the VascuTherm3-M's power is disconnected, the active timer information will not be stored. When treatment is re-initiated the timers will be reset to the preset values.

6. The timer feature is only applicable to COOL, HEAT and CONTRAST therapies. Pneumatic compression therapies will operate continuously.

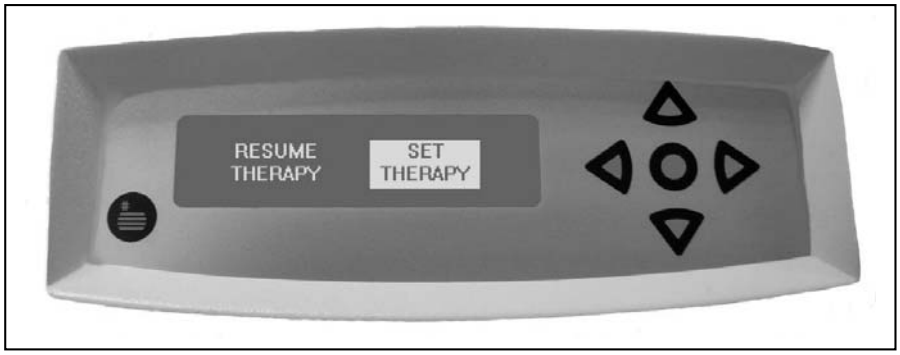
9.5. Pneumatic Compression Therapy for Edema and Lymphedema:

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, Heat, or Thermal Contrast therapy. See the instructions in Chapters 9.2 to 9.4 for additional details.

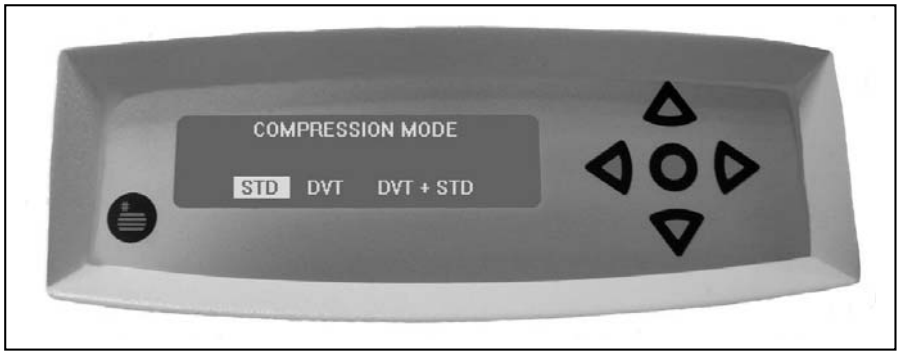
Make sure the therapy wrap is applied properly before initiating any compression therapy. Allowing the wrap to inflate while unattended or to inflate all the way to a "ballooned" state can cause damage to the wrap and will reduce the life of the wrap.

1. To change the unit into Pneumatic Compression Therapy mode, also known as Standard Compression or STD mode, select "SET THERAPY" from the Main menu.

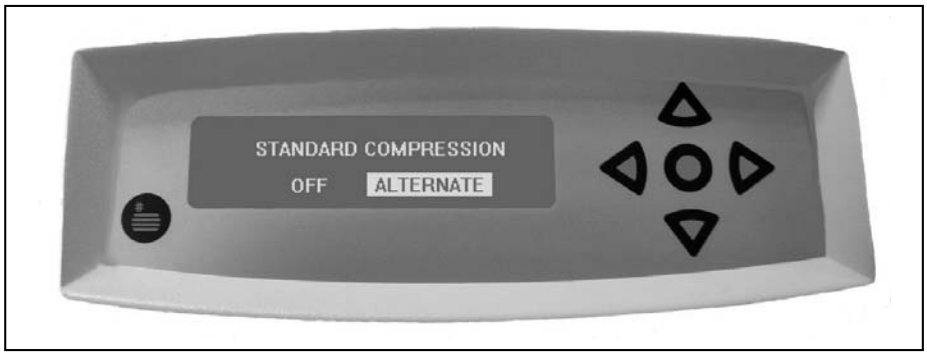


2. On the next screen select “COMPRESSION” and you will be taken to the following screen “COMPRESSION MODE”.

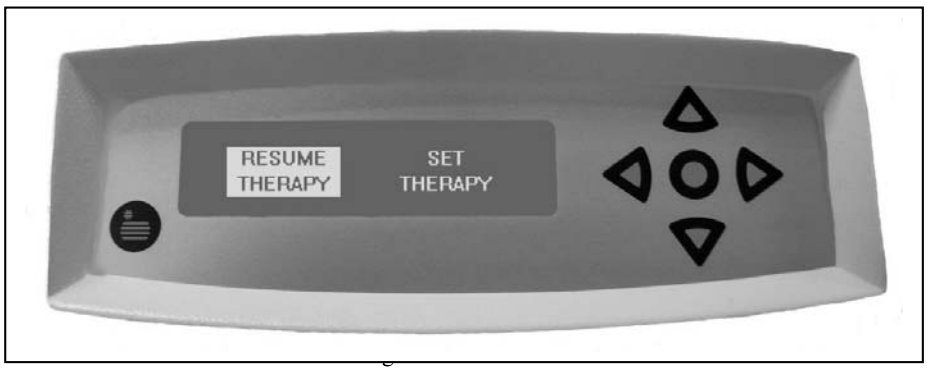
3. Select “STD”, for Standard Pneumatic Compression.



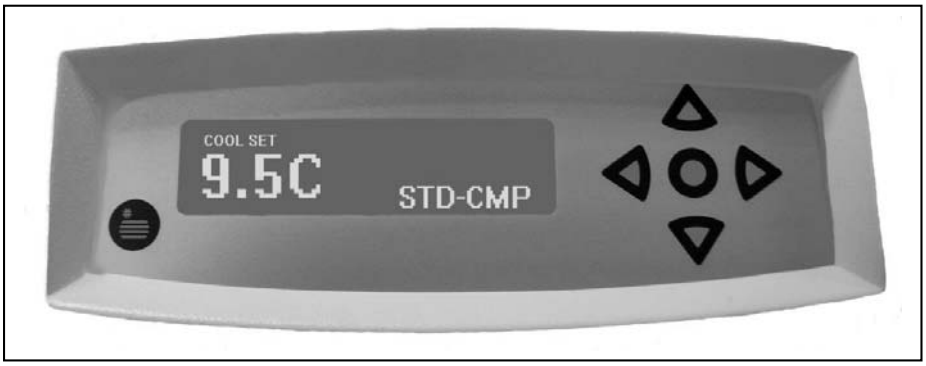
4. Select “ALTERNATE”.



5. Select “RESUME THERAPY”.



6. Once treatment is initiated, the status menu will display the current therapy settings:



The wrap will begin to inflate and deflate in a preset time and pressure setting.

7. If the therapy was initiated manually, then to stop therapy press the MENU key and select “STOP THERAPY”.

8. To disable STD Compression therapy and prevent it from running on the next start-up, select “SET THERAPY” to go to the “COMPRESSION MODE” menu. From that menu, select “STD”, then select “OFF”. The unit will return to the Main menu and STD Compression will be disabled until re-enabled with the “SET THERAPY” procedure.

When the prescribed therapy duration is complete:

9. If the display is in the Status screen, tap the MENU key to return to the Main menu.

10. Select “STOP THERAPY” from the Main menu. The Compression therapy will stop and the display will return to the “RESUME THERAPY” screen.

11. To disable STD Compression therapy and prevent it from running on the next start-up, select “SET THERAPY” to go to the “COMPRESSION MODE” menu. From that menu, select “STD”, then select “OFF”. The unit will return to the Main menu and STD Compression will be disabled until re-enabled with the “SET THERAPY” procedure.

12. 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.

⚠ If Compression therapy is being used in combination with Cool, Heat or Contrast Therapy, allow the wrap to fully deflate before removing it from the patient.

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.

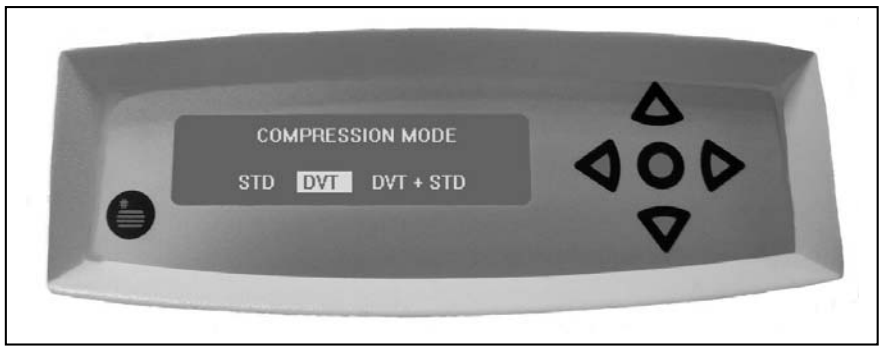
⚠ Make sure the therapy wrap is applied properly before initiating any compression therapy. Allowing the wrap to inflate while unattended or to inflate all the way to a “ballooned” state can cause damage to the wrap and will reduce the life of the wrap.

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 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.

1. To initiate DVT Foot Compression, select “SET THERAPY” from the Main menu.

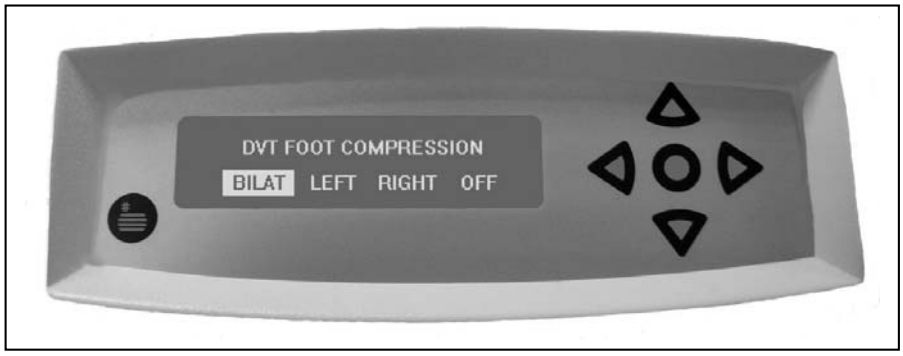
2. On the next screen (Heat/Cold/Compression) select “COMPRESSION” and you will be taken to the “COMPRESSION MODE” screen.

3. Select “DVT” from this menu and press ENTER. The next screen is the FOOT/CALF selection screen.



4. Select “FOOT”.

5. The DVT Foot (Bilateral, Left, Right, Off) selection screen will appear. Make the desired selection.



6. Bilateral compression therapy will automatically alternate compression cycles between the left and right foot wraps.

7. If your prescribed therapy is for the left foot or right foot only, select “LEFT” or “RIGHT”.

8. The Main menu will appear. Select “RESUME THERAPY” to start therapy. The wrap will begin to inflate and deflate in a preset time and pressure setting.

When the prescribed therapy duration is complete:

9. If the display is in the Status screen, press the MENU key to return to the Main menu.

10. Select “STOP THERAPY” from the Main menu. The Compression therapy will stop and the display will return to the “RESUME THERAPY” screen.

11. To disable DVT Foot Compression therapy and prevent it from running on the next start up, select “SET THERAPY” to go to the “COMPRESSION MODE” menu. From that menu, select “DVT”, then either “FOOT”, then select “OFF”. The unit will return to the Main menu and DVT Foot Compression will be disabled until re-enabled with the Set Therapy procedure.

Note: Current therapy **must** be terminated before a new or different mode of therapy can be initiated. The new mode of therapy will be ready to begin when the current compression cycle is complete.

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. DVT Calf Compression Therapy:

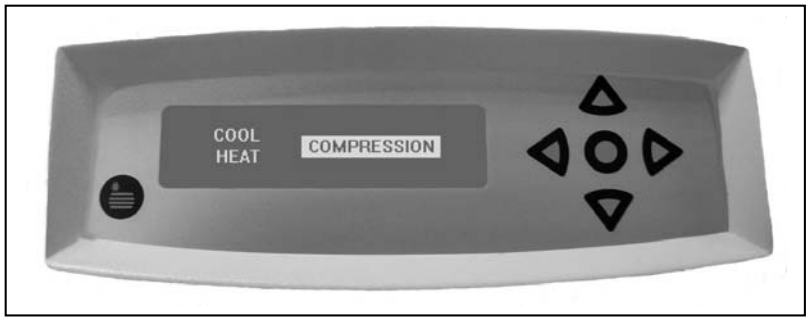
The use of Calf therapy on the Foot is not an effective or approved treatment to reduce the risk of clot formation.

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.

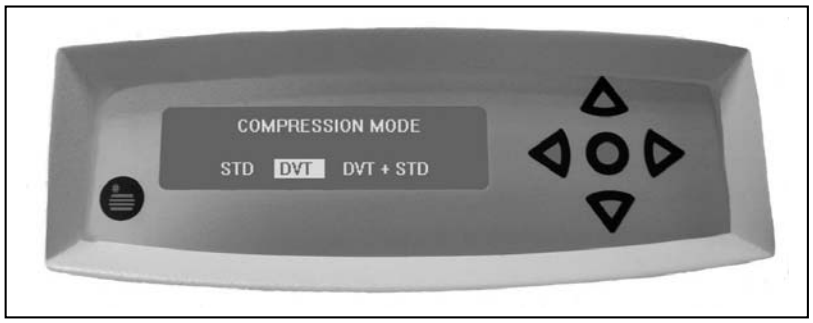
DVT Calf Compression therapy is used in combination with specially designed therapy wraps to transfer pressure to the calf area of the lower leg using compressed air. The preset inflation and deflation cycle of the VascuTherm therapy system simulates natural walking action. This increases blood flow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

1. To initiate DVT Calf Compression, select “SET THERAPY” from the Main menu.

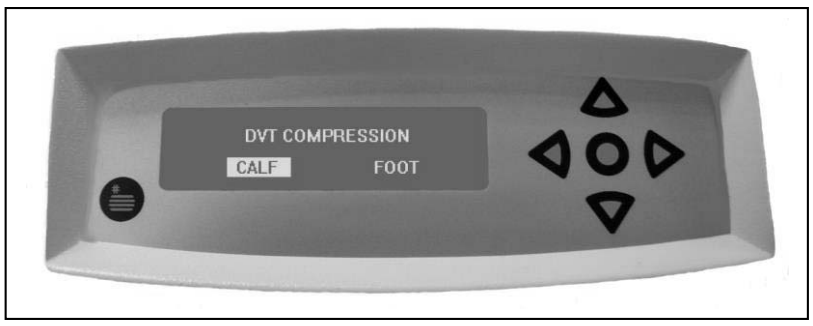
2. On the next screen (Heat/Cool/Compression), select “COMPRESSION” and you will be taken to the “COMPRESSION MODE” screen.



3. Select “DVT” from this Menu and press ENTER.



4. The next screen is the FOOT/CALF selection screen. Select “CALF”.



5. The DVT Calf BILATERAL, LEFT, RIGHT, OFF selection screen will appear. Make the desired selection.

6. Bilateral Compression therapy will automatically alternate compression cycles between the left and right foot wraps.

   If your prescribed therapy is for the left or right calf only, select “LEFT” or “RIGHT”.

7. The Main menu will appear. Select “RESUME THERAPY” to start therapy. The wrap will begin to inflate and deflate in a preset time and pressure setting.

When the prescribed therapy duration is complete:

8. If the display is in Status screen, press the Menu key to return to the Main menu.

9. Select “STOP THERAPY” from the Main menu. The Compression therapy will stop and the display will return to the “RESUME THERAPY” screen.

10. To disable DVT Compression therapy and prevent it from running on the next start up, select “SET THERAPY” to go to the “COMPRESSION MODE” menu. From that menu, select “DVT”, then either “CALF”, then select “OFF”. The unit will return to the Main menu and DVT Calf Compression will be disabled until re-enabled with the “SET THERAPY” procedure.

11. 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.

    Note: Current therapy **must** be terminated before a new or different mode of therapy can be initiated. The new mode of therapy will be ready to begin when the current Compression cycle is complete.

⚠ 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. Combination Therapies:

The following are therapies that can be used in combination and simultaneously with one another:

9.8.1. Thermal (Cool/Heat / Contrast) Therapy in Combination with Pneumatic Compression Therapy for Edema and Lymphedema:

⚠ 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 activate combination therapies of Thermal and Pneumatic compression:

1. Follow the instructions for the appropriate Thermal (Cool/Heat/Contrast) Therapy in Section 9.2, 9.3, or 9.4.

2. Follow the instructions for Pneumatic Compression Therapy in Section 9.5.

When the prescribed therapy duration is complete:

3. If the display is in the Status screen, press the Menu key to return to the Main menu.

4. Select "STOP THERAPY" from the Main menu.

5. To disable a specific therapy and prevent it from running on the next start up, follow the directions stated in Sections 9.2 to 9.4 or 9.5

⚠ 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.

9.8.2. Thermal (Cool/Heat/Contrast) Therapy in Combination with DVT Therapy:

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.

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

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

DVT Compression therapy is used in combination with specially designed therapy wraps to transfer pressure to the calf or foot area using compressed air. The preset inflation and deflation cycle of the VascuTherm 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 activate combination therapies of Thermal and DVT compression:

1. Follow the instructions for the appropriate Thermal (Cool/Heat/Contrast) Therapy in Section 9.2, 9.3, and 9.4.

2. Follow the instructions for DVT Foot/Calf Compression Therapy in Section 9.6 or 9.7.

When the prescribed therapy duration is complete:

3. If the display is in the Status screen, press the Menu key to return to the Main menu.

4. Select "STOP THERAPY" from the Main menu.

5. To disable a specific therapy and prevent it from running on the next start up, follow the directions stated in Sections 9.2 to 9.4, or 9.6 to 9.7.

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.

9.8.3. Thermal (Cool/Heat/Contrast) Therapy in Combination with Pneumatic Compression Therapy for Edema and Lymphedema and DVT Therapy:

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.

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

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

DVT 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 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 activate combination therapies of Thermal, Standard Compression and DVT compression:

1. Follow the instructions for the appropriate Thermal (Cool/Heat/Contrast) Therapy in Section 9.2, 9.3, and 9.4

2. Follow the instructions for Pneumatic Compression Therapy in Section 9.5

3. Follow the instructions for DVT Foot/Calf Compression Therapy in Section 9.6 or 9.7

When the prescribed therapy duration is complete:

4. If the display is in the Status screen, press the Menu key to return to the Main menu.

5. Select "STOP THERAPY" from the Main menu.

6. To disable a specific therapy and prevent it from running on the next start up, follow the directions stated in Sections 9.2 to 9.7

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.

9.8.4. Pneumatic Compression Therapy and DVT Therapy:

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.

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

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

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 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 activate combination therapies of Standard Compression and DVT compression:

1. Follow the instructions for Pneumatic Compression Therapy in Section 9.5

2. Follow the instructions for DVT Foot and DVT Calf Compression Therapy in Sections 9.6 or 9.7

When the prescribed therapy duration is complete:

3. If the display is in the Status screen, press the Menu key to return to the Main menu.

4. Select “STOP THERAPY” from the Main menu.

5. To disable a specific therapy and prevent it from running on the next start up, follow the directions stated in Sections 9.5 to 9.7

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. Display Messages and Alarm Indicators

10.1. Normal Operation

The following list contains display messages that you may encounter during normal therapy operation:

- **VascuTherm Rev: Vascu_xx_yy**: Boot-up screen displayed temporarily.

- Default display screen is Status screen with the left side showing Thermal Therapy operation mode and the right side showing Compression Therapy operation mode.

Left Side Display Options:

- **TEMP OFF:** Thermal subsystem in idle.

- **COOL SET XX ºC:** Preset cool mode therapy temperature is active. (XX in 6.0-10.0 ºC range).

- **HEAT SET 40.5 ºC:** Preset heat mode therapy temperature is active.

- **CONTRAST SET XX ºC:** Preset cycling between cool and heat therapy temperatures (XX = 9.5 or 40.5).

Right Side Display Options:

- **CMP-OFF:** Pneumatic subsystem in idle. System ready to begin prescribed therapy.

- **STD-CMP:** Compression Therapy for Edema and Lymphedema (standard) is active.

- **DVT- FTB:** DVT Foot therapy mode is active and currently providing alternating compression treatment between the left and right feet by the preset cycle.

- **DVT- FTL:** DVT Foot therapy mode is selected and currently providing compression cycles to the left foot only.

- **DVT- FTR:** DVT Foot therapy mode is active and currently providing compression cycles to the right foot only.

- **DVT- CFB:** DVT Calf therapy mode is active and currently providing alternating compression treatment between the left and right feet by the preset cycle.

- **DVT- CFL:** DVT Calf therapy mode is selected and currently providing compression cycles to the left foot only.

- **DVT- CFR:** DVT Calf therapy mode is active and currently providing compression cycles to the right foot only.

10.2. Alarms and System Errors

The VascuTherm3-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 VascuTherm3-M unit.

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 the 3-digit number indicated on the display and contact the clinic or hospital that prescribed the unit or the Healthcare provider. If assistance is not available or ineffective, please contact ThermoTek technical assistance toll-free at 001-(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 001-(214)-502-8800.

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

!!ALARM ACTIVE!! CHECK FLOW/FLUID: When using either the COOL or HEAT temperature therapies available on the unit, the software monitors the units ability to change the coolant temperature. If the software suspects that the unit was not able to properly alter the coolant temperature due to a **low coolant level** or **blocked flow condition** this alarm will activates.

!!ALARMS ACTIVE!! HIGH TEMP ALARM: Anytime the unit is turned ON, the software constantly monitors the temperature of the internal coolant media. If the software determines that the temperature of the coolant is hotter than a safe level, this alarm activates.

!!ALARM ACTIVE!! LOW TEMP ALARM: Anytime the unit is turned ON, the software constantly monitors the temperature of the internal coolant media. If the software determines that the temperature of the coolant is colder than a safe level, this alarm activates.

!!ALARM ACTIVE!! HIGH H-SINK TEMP: Anytime the unit is turned ON, the software constantly monitors the temperature of the heat sink fins visible on either side of the unit. If the software determines that the heat sink fin temperature is hotter than a safe level this alarm activates.

!!ALARM ACTIVE!! LOW H-SINK TEMP: Anytime the unit is turned ON, the software constantly monitors the temperature of the heat sink fins visible on either side of the unit. If the software determines that the heat sink fin temperature is colder than a safe level this alarm activates.

!!ALARM ACTIVE!! CHECK WRAP-LEAK: When using any of the pneumatic compression therapies available on the unit, the software monitors the amount of time taken to properly inflate the wrap. If the wrap does not inflate in a pre-determined time interval, an air leak is suspected and the alarm activates.

!!ALARM ACTIVE!! CHECK WRAP-BLOCK: When using any of the pneumatic compression therapies available on the unit, the software monitors the amount of time taken to properly inflate the wrap. If the air pressure rises faster than a predetermined rate, an air blockage is suspected and the alarm activates.

!!ALARMS ACTIVE!! KINKED WRAP – S: When using any of the pneumatic compression therapies available on the unit, the software monitors the current air pressure value by way of an internal pressure sensor in the event that unsafe high pressure is detected by the pressure sensor, the software executes an emergency pressure vent and this alarm activates to notify the patient of the therapy termination.

!!ALARMS ACTIVE!! KINKED WRAP - H: When using any of the pneumatic compression therapies available on the unit, an independent backup pressure sensing circuitry constantly monitors the system air pressure value. This alarm activates if the software controlled pneumatic solenoids fail to properly activate during an emergency pressure vent and the backup over pressure detection circuitry activates. The software monitors and detects that the pressure safety circuitry has engaged and this alarm activates.

SYSTEM ERROR XXX: This alarm indicates that an internal software or hardware error has occurred. The unit potentially requires service by an authorized technician. If you encounter a system alarm, please write down the 3-digit number indicated on the display and contact the clinic or hospital that prescribed the unit or the Healthcare provider. If assistance is not available or ineffective, please contact ThermoTek technical assistance toll-free at 001-(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 001-(214)-502-8800.

11. Taking Care of Your Vascu-Therm3-M

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 Healthcare 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 001-(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 001-(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.**

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

  The therapy wrap should be periodically cleaned if it is used on the same patient for an extended period of time.

  Clean exposed surfaces of the therapy wrap with either a mild anti-bacterial soap and water solution or an isopropyl alcohol and water solution. Do not use bleach on therapy wraps.

When treatment is complete, dispose of the single patient use wrap according to hospital, clinical or local standards.

- **Cleaning the filter:**

1. The filter is attached to the unit with Velcro strips. Carefully remove (separate) the filter from the Velcro strips installed to the unit.

2. Use warm, soapy water to clean the filter.

3. Allow the filter to air dry completely before re-installing to the unit.

- **Re-installing the filter:**

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

1. Turn the unit OFF and disconnect the power cord.

2. Starting at the rear of either side of the unit, begin attaching one end of the air filter towards and around the front of the unit using the Velcro strips.

3. Continue attaching the air filter around to the opposite side of the unit.

4. The filter should be taught without bulge across the top and bottom of the filter to prevent bypassing of air.

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.

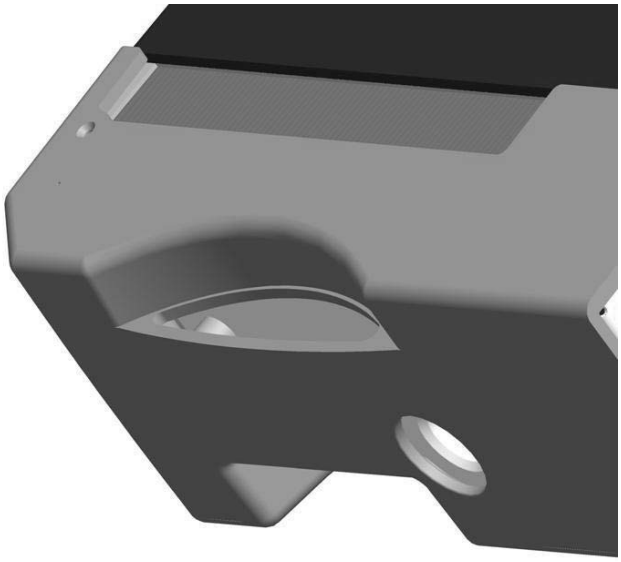
1. Turn the unit OFF and unplug from electrical source.

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 press in on the fitting while twisting counter-clockwise to release it from the unit.

3. Remove the reservoir cap from the unit by twisting the cap counter-clockwise.

4. Lift the unit on both ends and tip backward to empty the fluid from the reservoir into a bucket or sink.



5. Continue to tip the unit until the reservoir is completely empty of all fluid.

13. Storage and Re-Packing the Unit

When therapy is complete and it is time to return or store the VascuTherm3-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:
    - VascuTherm3-M Unit
    - Reservoir Cap
    - Hoses
    - Power Cord
    - 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 single patient use wrap, retain the wrap with the unit. If the patient is going to discontinuing therapy, the wrap can now be discarded.
10. Store indoors in an ambient environment between 4.4ºC and 40.5 ºC.

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

 Damage to the unit, hoses and/or wraps.

 Catastrophic system damage if the unit is not properly drained.

 Microbial growth inside the unit if not properly drained.

14. Troubleshooting Guide

Refer to Chapter 7 “Environmental Conditions You Should Be Aware of Before Operating Your VascuTherm3-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 above Troubleshooting Guide, contact Customer Support. See the Customer Support contact information below.

If your issue cannot be resolved with the following scenarios, first contact the clinic or hospital that prescribed the unit or the Healthcare provider. If assistance is not available or ineffective, please contact ThermoTek technical assistance toll-free at 001-(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 001-(214)-502-8800.

15. Device Summary

The VascuTherm3-M Therapy System is capable of performing therapies for the following:

- **Cool Therapy:** the unit passes cool (6.0ºC – 10.0ºC) 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 (40.5ºC) 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 and deflate compressed air into the therapy wrap. This added external intermittent pressure cycle 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 and deflate 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 VascuTherm system are designed to maximize the effectiveness of the therapies listed above. Only use ThermoTek approved wraps for single therapy and / or combination 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 VascuTherm3-M System Prior to Therapy” instructions in Chapter 8.
3. Initiate the prescribed therapy of Heat, Cool or Thermal Contrast with or without Pneumatic Compression for the duration advised on the prescription.
4. Stop all therapy modes after the prescribed duration is complete.
5. If Pneumatic Compression was utilized, make sure to stop the compression therapy before removing the therapy wrap.

If you experience difficulty in setting up your VascuTherm3-M therapy system for use, please contact the clinic or hospital that prescribed the unit or the Healthcare provider. If assistance is not available or is ineffective, please contact ThermoTek technical assistance toll-free at 001-(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 001-(214)-502-8800.

16. Service and Customer Support

ThermoTek, Inc. is committed to servicing our VascuTherm3-M unit both during and after sale to the customer. If you have any questions concerning the operation of your VascuTherm3-M unit, please refer to the following to contact us at our Flower Mound, Texas facility:

- **Sales Organization:** 001-(972) 874-4949
- **Toll Free Number:** 001-(877) 242-3232
  (between 8:00am and 5:00pm CST, Monday through Friday)
- **ThermoTek Website:** www.thermotekusa.com
- **Service Department** (after hours): 001-(214) 502-8800

Do not drink or ingest the coolant mixture.

17. Wraps, Accessories and Replacement Parts

Boxes/Foam:

Part Number	Description
0P2HNTFSET	Packing Foam
0P2HNTSBX0	Shipping Box
0P9KNTCKS0	Traveling Case, Single

Replacement Parts:

Part Number	Description
0P2CDMARFT	Washable Air Filter
0P9PTDVTFA	Filter Assembly with Velcro loop
0P2DDMRSPG	Reservoir Cap
0P3W10A8EU	Power Cord, 10A/250VAC, 2.5M, EU, Hospital Grade.
0P2DNANTFB	Mixing Bottle, Thermoflow

Available Therapy Wraps:

Part Number	Description
0P9BNDVTFT	DVT Foot Wrap Set
0P9BNDVTCA	DVT Calf Wrap Set
* Sterile Therapy Wrap options available (example: 0P9XXXXXXX3-S)	
0P9BSFKNMR3	Standard Knee Wrap, Single Patient Use
0P9BLFKNMR3	Medium Knee Wrap, Single Patient Use
0P9BKNEEMR3	Large Knee Wrap, Single Patient Use
0P9BCFKNMR3	Circumferential Knee Wrap, Single Patient Use
0P9BSFNCMR3	Knee Wrap w/o compression, Single Patient Use
0P9BUKNEMR3	Universal U Wrap, Single Patient Use
0P9BSSHLMR3	Standard Shoulder Wrap w/ Straps, Single Patient Use
0P9BSSWHMR3	Standard Shoulder w/Harness, Single Patient Use
0P9BMSHDMR3	Medium Shoulder Wrap w/ Straps, Single Patient Use
0P9BMSWHMR3	Medium Shoulder Wrap w/Harness, Single Patient Use
0P9BSHLDMR3	Large Shoulder Wrap, Single Patient Use
0P9BLARMMR3	Arm Wrap, (Half Arm)Single Patient Use
0P9BFARMMR3	Arm Wrap, (Full Arm)Single Patient Use
0P9BFTAKMR3	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:

Part Number	Description
0P9ANANUMB	Hose, Therapy Umbilical, Standard 213.4 cm.

Optional Equipment:

Part Number	Description
0P9KNVPMKT	Kit, Unit Pole Mount, Nano/Vascu

18. Specifications

VascuTherm3-M Part Number	0P9PTVTM3M
Dimensions	13.33 cm W x 22.22 cm H x 36.19 cm D
Ambient Operating Range	15.56 - 26.67 ºC
Relative Humidity	< 60% RH
Therapy Temperature Range	6.0 – 40.5 ºC
Centrifugal Pump	12-volt Brushless DC
Weight without Fluid	6.80 kg
System Fluid Capacity	0.95 L
Power Consumption (Max)	450 Watts
Input Voltage (Nominal)	100-240 VAC, 50/60 Hz, Single Phase
Input Current (Max)	4.5 Amps
Accuracy	± 1 ºC
Refrigerant	None
Heating/Cooling Function	Yes, Standard
RS232 Interface	Yes, Standard
Recommended Coolants	90% distilled water, 10% alcohol

18.1 Calibration

The VascuTherm3-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 and calibration.

18.2 Product Listing

- The VascuTherm3-M therapy unit has been tested and listed by ETL to meet or exceed the requirements for IEC60601-1 ed.3, and IEC 60601-1-2 EMC Standards.

19. Index

20. 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 VascuTherm3-M will be free from defects in workmanship and material under normal use for one year after the date of purchase. ThermoTek warrants to the immediate purchaser from ThermoTek, or an immediate purchaser of an unused wrap from an authorized distributor of ThermoTek products, that ThermoTek single patient use wraps will be free from defects in workmanship and material under normal use for only the first use of the wrap.

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

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

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

Any product returned for warranty must have a Returned Materials Authorization ("RMA") number on the outside of the container or package. Please call ThermoTek Customer Service at 001-(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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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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