

VascuComp3-DVT

User Manual



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1. Introduction

Please read the entire manual carefully before trying to operate the VascuComp3-DVT system. It is unsafe to start using the VascuComp3 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 VascuComp3-DVT experience better, please do not hesitate to contact us.

User Assistance Information:

The VascuComp3 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)

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

Icons Used for Warnings and Cautions:



Electrical Shock Risk



Burn Risk



General Caution

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.

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.

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.

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 patient should **NOT** use the VascuComp3-DVT therapy system if the patient is suspected of or observed to have any of the following:

- Presumptive evidence of congestive heart failure
- Suspected / observed pre-existing deep vein thrombosis or pulmonary embolism
- Suspected/observed deep acute venal thrombosis (phlebothrombosis)
- Suspected/observed inflammatory phlebitis process
- Suspected/observed pulmonary edema
- Suspected/observed acute inflammations of the veins (thrombophlebitis)
- Suspected/observed decompensated cardiac insufficiency
- Suspected/observed arterial dysregulation
- Suspected/observed erysipelas
- Suspected/observed carcinoma and carcinoma metastasis in the affected extremity
- Suspected/observed decompensated hypertonia
- Suspected/observed acute inflammatory skin diseases or infection
- Suspected/observed venous or arterial occlusive disease
- Determine venous and lymphatic return is undesirable
- Poor Peripheral Circulation
- Severe Arteriosclerosis, or active infection

3.2. Precautions:

When using the VascuComp3-DVT 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:

3.3. Warnings:



Never push objects of any kind into the therapy unit.



Never spill liquid of any kind on the therapy unit.









If the unit gets wet, unplug the unit from the wall and call ThermoTek service for assistance.



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.

-  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 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.

3.4. Cautions:

Federal law restricts this device to sale by or on the order of a licensed medical practitioner.

-  Follow the prescribed instructions of your medical practitioner for therapy mode, treatment area, duration and frequency of treatment.
If unusual swelling, skin discoloration or discomfort occurs, immediately discontinue use of the VascuComp unit and consult a healthcare professional.
-  Use only ThermoTek approved therapy wraps / garments.
-  Therapy wraps are non-sterile unless specifically labeled as sterile
-  Non-sterile therapy wraps should never be directly applied to an open wound or breached skin.
-  Use only sterile wraps over wounds or breaks in the skin.
-  Do not attempt to sterilize this device by any means.
-  Therapy wraps are to be fitted initially by a healthcare professional that is familiar with the purpose for which the wraps are used.
-  Do not apply the therapy wrap so tightly as to restrict blood or fluid flow.
-  A healthcare professional is responsible for providing wearing instructions and precautions to other healthcare professionals, care providers involved in the patient's care, and the patient.
-  If it is appropriate for the patient to use the wrap with therapy unit at home, the healthcare provider must provide adequate and appropriate instructions for use to the patient.



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



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



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



Clean exposed surfaces of the therapy wrap with either a hospital grade broad spectrum anti-bacterial and anti-microbial 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.



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.



Observe all warning labels. Never remove the warning labels.

4. Indications for Use

The VascuComp3-DVT therapy system is designed to provide 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:

VascuComp™ 3 DVT Mode:

- 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 wound healing time, enhance arterial circulation (blood flow), reduce compartmental pressures, reduce edema (swelling), reduce the need for anticoagulant (blood thinning) medications.

5. VascuComp3-DVT Device Description

The VascuComp3-DVT therapy system is a pneumatic compression system capable of providing intermittent sequential compression therapy.

5.1. Features:

- Compression Modality to Reduce the Risk of DVT Formation on the Calf (45mmHg compression) and Foot (100 mmHg compression)
- Programmable Therapies
- Lightweight and Portable Package
- User-Friendly Interface
- Easy to read Liquid Crystal Display
- Quiet Operation

5.2. General Specifications:

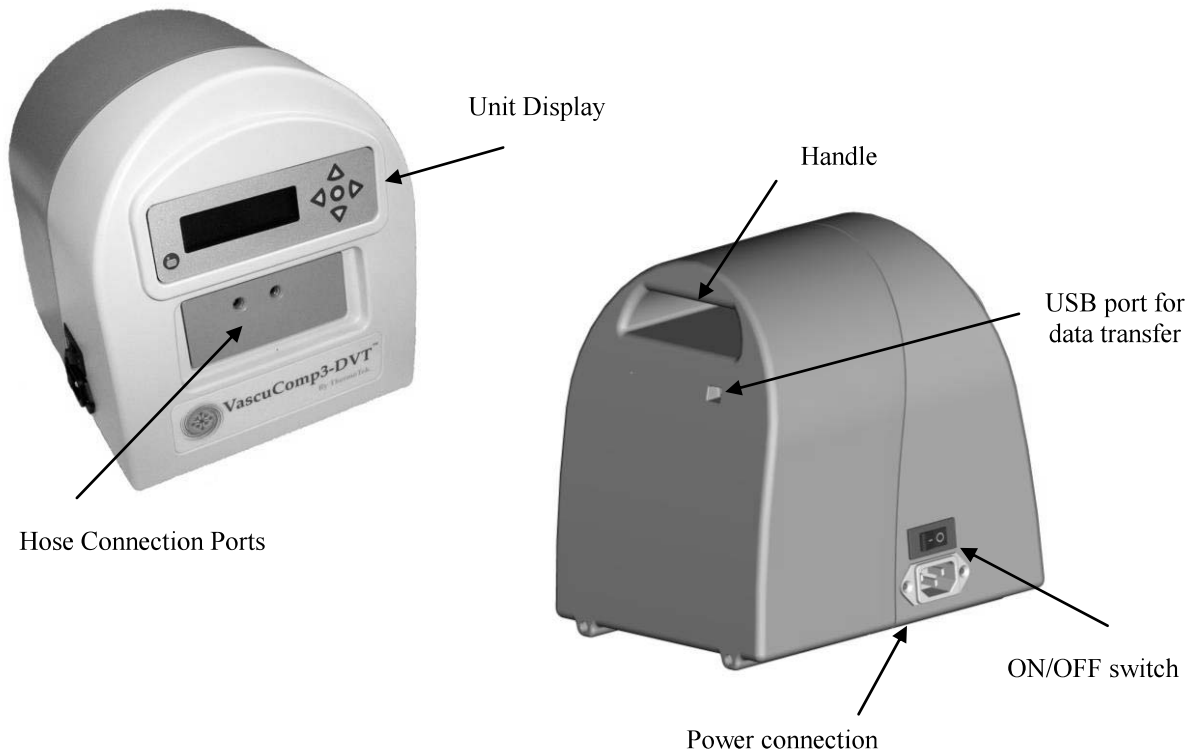
- Weight: 6 lbs.
- Hospital Grade Power Cord
- Dimensions: 7"W x 8"H x 8"D
- Safety: UL Medical Listing 60601-1, CSA 22.2
- IEC 60601-1

5.3. Options:

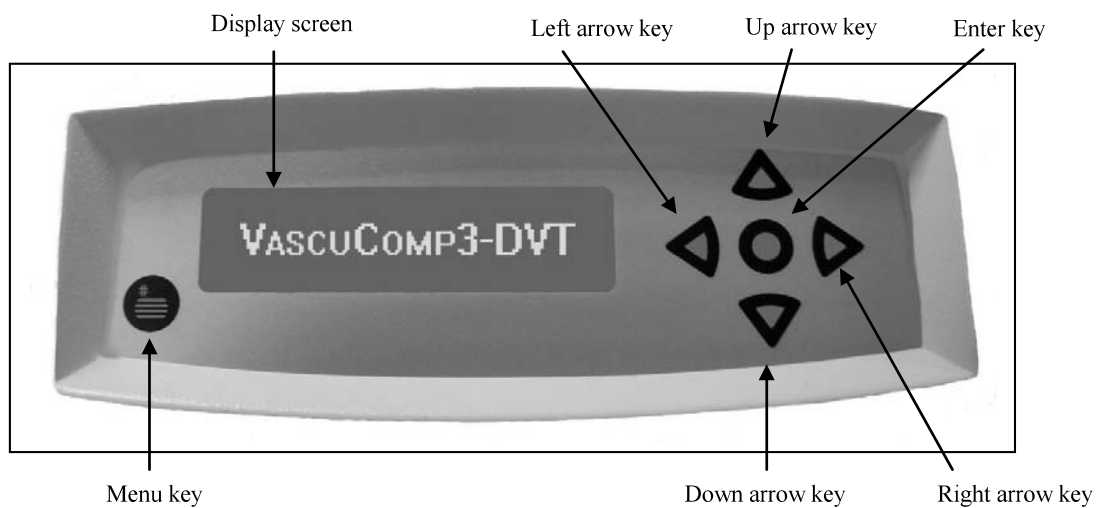
- Sterile Single Patient Use Therapy Wraps
- Non-Sterile Single Patient Use Therapy Wraps
- Bed Hooks
- Carrying Case

5.4. Device Description:

Front Panel Connections

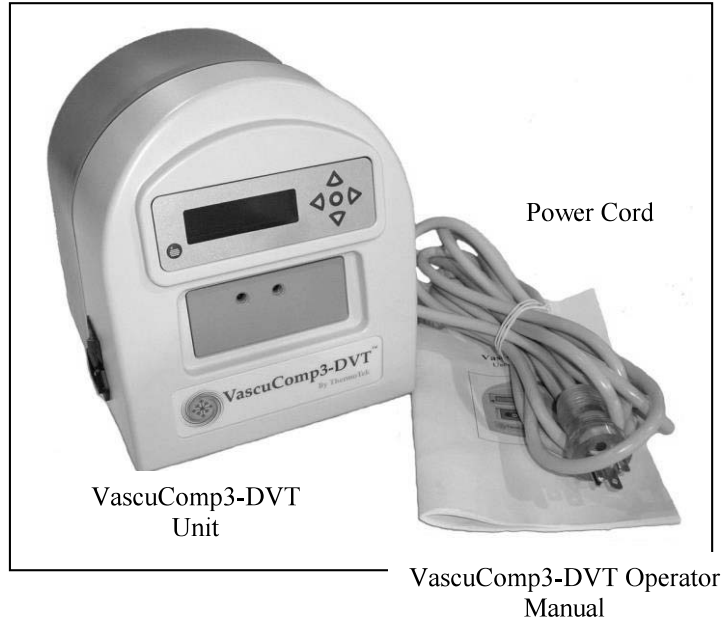


Keypad Interface and Illuminated Display



6. Unpacking Your VascuComp3-DVT Therapy System

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



All of these items are needed for safe system operation. If any of these items are missing from the shipping container, please contact the clinic or hospital that prescribed the unit, the Durable Medical Equipment (DME) provider or ThermoTek Customer Service at 877-242-3232.

Immediately upon unpacking your VascuComp3-DVT 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 VascuComp3-DVT 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. Hoses are integral to the therapy wraps. All wraps have fittings that connect directly to the unit.



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.



If the therapy wrap bag with a sterile wrap has been opened or damaged, Do Not Use, as sterility may have been compromised.

7. Environmental Conditions You Should be Aware of Before Operating Your VascuComp3-DVT Device



The VascuComp3-DVT therapy system is intended for indoor use only.



Do not operate the VascuComp3-DVT system with therapy wraps in or near a wet environment.



The VascuComp3-DVT 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 VascuComp3-DVT system in an ambient environment between 60-80 °F (degrees Fahrenheit) and a relative humidity below 60%.

Failure to meet these operating environment conditions may result in:



Condensate buildup inside the unit.



Overheating or freezing of the unit.



Internal electronics malfunction

- A potential to trip the unit's electrical resettable breaker due to an internal electrical overload.
- 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 VascuComp3-DVT System for Therapy

Now that you have fully unpacked your VascuComp3-DVT Therapy System and verified that all of the necessary equipment is present and not damaged, you may begin to prepare the system for treatment.

1. Place the VascuComp3-DVT unit upright on a level surface and at least 1-foot from any wall or other obstruction.
2. Verify that the power switch (located on the left side of the unit) is in the OFF position.
3. Connect prescribed wrap to the front panel connections. Refer to instructions included with the therapy wrap / garment.
4. The VascuComp3-DVT unit will be delivered with the prescribed treatment pre-programmed within the device.

9. Operating Instructions for Your VascuComp3-DVT System

Refer to Chapter 8 “How to Set Up Your VascuComp3-DVT System” before beginning any application.

9.1. Device Power Up:

1. Place the VascuComp3-DVT unit upright on a level surface and at least 1-foot from any wall or other obstruction that could restrict airflow
2. Verify that the power switch located on the rear panel of the unit is in the OFF position.
3. Verify the unit is plugged into the appropriate AC voltage outlet.
4. Turn the unit to the ON position. The ON/OFF switch is located on the side panel of the unit.
5. When the unit is first powered up, a blue back light will illuminate the display screen located on the front panel of the unit and the fans will turn on. The message **VascuComp3-DVT** will appear on the display screen.



6. The preset treatment mode will be displayed next as either:

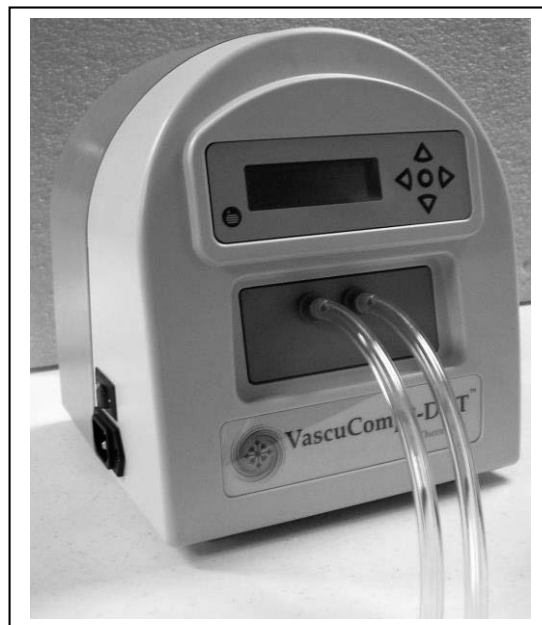


7. Please verify the displayed treatment mode matches the prescription provided by the medical practitioner. If the preset treatment option is different, please contact your healthcare professional.
8. The Main menu will be presented with **RESUME THERAPY** highlighted.

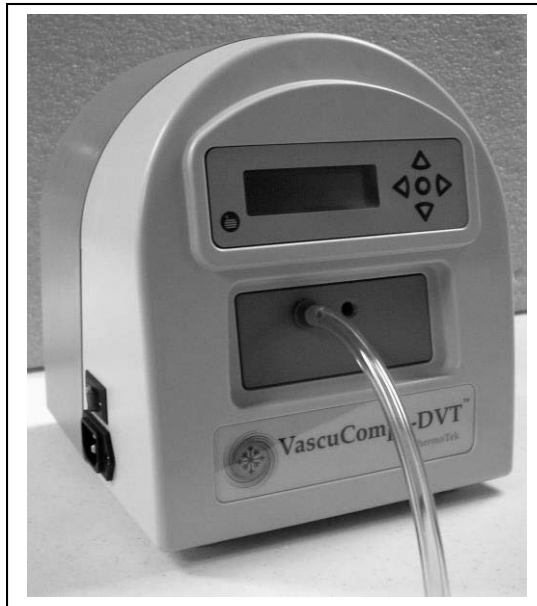
9.2 DVT Treatment (VascuComp3-DVT)

DVT Calf Compression therapy is used in combination with specially designed therapy wraps to transfer pressure to the calf area of the lower leg or the foot using compressed air. The preset inflation and deflation cycle of the VascuComp3-DVT 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.

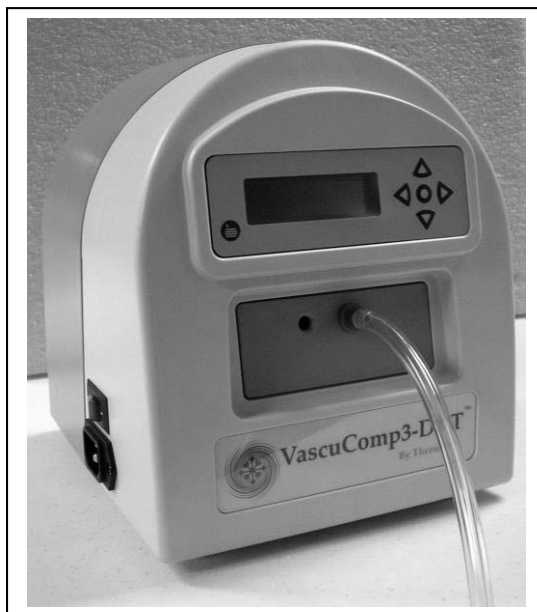
9. Unpack and apply the prescribed therapy wraps to the indicated portions of your body as described on the wrap instructions contained in the wrap packaging.
10. Use of calf therapy on the foot is not an effective or approved treatment to reduce the risk of clot formation.
11. To attach and secure the therapy wrap fittings, connect the hoses from the therapy wraps to the front panel of the unit. For DVT Calf or Foot Bilateral Treatment connect the wrap fittings as shown below:



12. For DVT Left only treatment connect the wrap fittings to the left port as shown below:

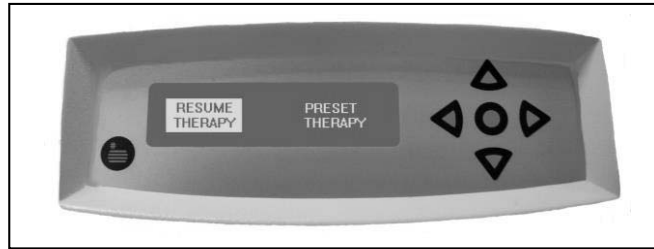


13. For DVT Right only treatment connect the wrap fittings to the right port as shown below:

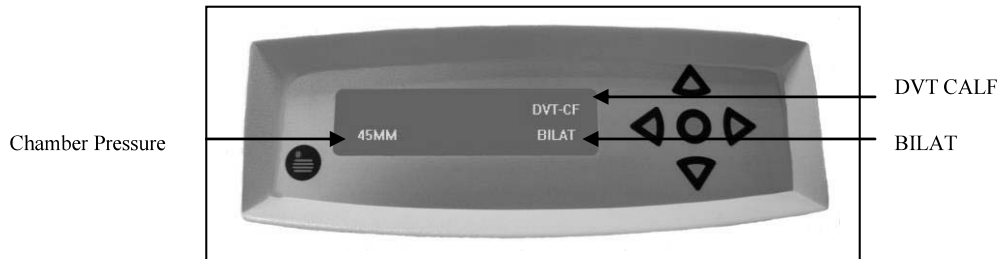


⚠ Make sure the therapy wrap is applied properly before initiating any compression therapy. Allowing the wrap to inflate while unattended or to inflate all the way to a “ballooned” state can cause damage to the wrap and will reduce the life of the wrap.

14. To commence treatment, from the Main menu, highlight RESUME THERAPY option and press the ENTER key.

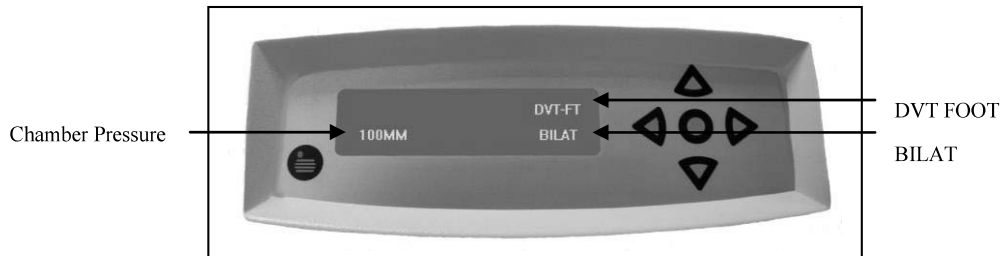


15. The VascuComp3-DVT will commence treatment with the device screen showing the therapy status.
- a. If the DVT treatment is preset for calf compression, the status screen will provide the treatment mode DVT Calf (DVT-CF) and the garment chamber pressure.



With DVT calf compression, the treatment cycle would compress the calf to 45 mmHg and hold for 30 seconds, followed by a relaxation and a rest period of 30 seconds. This sequence constitutes a complete DVT calf treatment cycle.

- b. If the DVT treatment is preset for foot compression, the status screen will provide the treatment mode DVT Foot (DVT-FT) and the garment chamber pressure.



With DVT foot compression, the treatment cycle would compress the foot to 100 mmHg and hold for 30 seconds, followed by a relaxation and a rest period of 30 seconds. . This sequence constitutes a complete DVT foot treatment cycle.

16. If the preset treatment is for bilateral therapy (on both legs) the screen will show BILAT. If the preset treatment is for the left or right leg, then the screen will show LEFT or RIGHT.
17. To stop treatment, press the MENU key. Highlight STOP THERAPY and press the ENTER key.



Note: The treatment should be comfortable and relaxing. In the event there is a warning message or alarm on the screen, please refer to the section 13 for explanation on how resolve the fault conditions.

10. Messages and Alarm Indicators

10.1. Normal Operation

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

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

Bottom Display Line Options:

- **CMP-OFF:** Pneumatic subsystem in idle. System ready to begin prescribed therapy.
- **Timer: H:MM:** Preset Therapy Timer.
- **DVT-FT BILAT:** DVT Foot Bilateral Therapy is active.
- **DVT-FT LEFT:** DVT Foot Left Therapy is active.
- **DVT-FT RIGHT:** DVT Foot Right Therapy is active.
- **DVT-CF BILAT:** DVT Calf Bilateral Therapy is active.
- **DVT-CF LEFT:** DVT Calf Left Therapy is active.
- **DVT-CF RIGHT:** DVT Calf Right Therapy is active.
- **XX mm:** The current compression level in the wrap.

10.2. Warnings, Alarms, and System Errors

The VascuComp3-DVT 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 VascuComp3-DVT unit.

Warnings indicate that an unsafe condition could or is about to occur. Warning notifications combine the use of a flashing description on the upper line of the display and a fast beeping noise.

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 Durable Medical Equipment (DME) provider. If assistance is not available or ineffective, please contact ThermoTek technical assistance toll-free at 1-877-242-3232 during the hours of 8am-5pm Central Time. If technical assistance is needed after these hours, you may contact the 24-hour line at (214) 502-8800.

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

!!WARNING ACTIVE!! CHECK WRAP: 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 a preset time expires before proper inflation was reached this warning activates.

!!WARNING ACTIVE!! BLOCKED AIR FLOW: When using any of the pneumatic compression therapies available, the software monitors the rate of air pressure change. If the rate air pressure change is faster than a preset value in a preset time a warning activates first. If the warning continues and the rate of pressure change is not in a normal range, 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 a preset time expires before proper inflation was reached, a warning activates first. If the warning continues and the wrap is still unable to properly inflate, this 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 wrap inflates too quickly, this alarm activates.






!!ALARM ACTIVE!! KINKED WRAP - H: When using any of the pneumatic compression therapies available on the unit, an independent backup pressure switch 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 pressure safety switch activates. The software monitors and detects that the pressure safety switch has engaged and this alarm activates.

!!ALARM 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.

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 Durable Medical Equipment (DME) provider. If assistance is not available or ineffective, please contact ThermoTek technical assistance toll-free at 1-877-242-3232 during the hours of 8am-5pm Central Time. If technical assistance is needed after these hours, you may contact the 24-hour line at 214-502-8800.

11. Things You Can Do To Keep Your VascuComp3-DVT System Performing

-  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.

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

Cleaning Instructions:

- **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 antimicrobial 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. Storage and Re-Packing the Unit

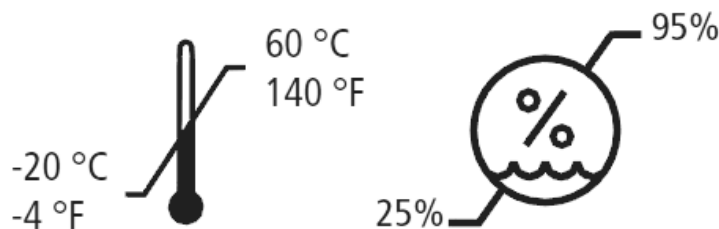
When therapy is complete and it is time to return or store the VascuComp3-DVT therapy system you can use the shipping box.

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. Collect the following items together:
 - VascuComp3-DVT Unit
 - Power Cord
 - User Manual
 - Shipping Box with Package Inserts
5. Store the above items in the original box or in the travel case you received.
6. 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.
7. Store indoors in an ambient environment between 40 °F and 105 °F.

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

 Damage to the unit, hoses and/or wraps.

8. When transporting, follow the guidance as stated below:



13. Troubleshooting Guide

Refer to Chapter 7 “Environmental Conditions You Should Be Aware of Before Operating Your VascuComp3-DVT 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 Durable Medical Equipment (DME) provider. If assistance is not available or ineffective, please contact ThermoTek technical assistance toll-free at 1-877-242-3232 during the hours of 8am-5pm Central Time. If technical assistance is needed after these hours, you may contact the 24-hour line at 214-502-8800.

Problem	Cause	Suggested Actions
Nothing happens when I turn the unit to the ON position.	No AC Power to the unit.	Make sure the unit is plugged into the appropriate electrical outlet. Make sure the power cord is also plugged into the therapy unit.
	Internal fault within the therapy unit.	Turn the power switch off, wait, and turn it back on. Contact ThermoTek customer service if problem persists.

Problem	Cause	Suggested Actions
My unit gives me a CHECK WRAP-BLOCK alarm.	Wrap is loose on the patient.	If the wrap is “ballooned” on the patient, it has been applied loosely. Remove wrap and reapply tightly to fit the patient.
Therapy Wrap is not compressing.	System software 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.

Problem	Cause	Suggested Actions
My unit gives me a CHECK WRAP-LEAK alarm.	Hole in wrap.	Connect a new wrap to the system.
	Wrap not connected.	Make sure the wrap is securely connected to the correct output port.

Problem	Cause	Suggested Actions
My unit gives me a KINKED WRAP - S alarm.	Internal fault within the therapy unit.	Turn the power switch off, wait, and turn it back on. Contact ThermoTek customer service if problem persists.
	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.

Problem	Cause	Suggested Actions
My unit gives me a KINKED WRAP - H alarm.	Internal fault within the therapy unit.	Turn the power switch off, wait, and turn it back on. Contact ThermoTek customer service if problem persists.
	The unit was powered on after being in a hot environment [e.g. trunk of a car]	Make sure the unit is used indoors with an ambient temperature < 80° F. If the alarm activates after power up, let it be in the alarm state until it clears. During this alarm the unit will run with the fans in full power to cool the unit.

Problem	Cause	Suggested Actions
My unit gives me a SYSTEM ERROR XXX alarm.	Reservoir cap is not screwed tightly.	Make sure the unit is unplugged from the AC outlet. Check the reservoir cap and secure it tightly. Connect to AC power and restart unit.

Problem	Cause	Suggested Actions
The wrap is uncomfortable and/or is compressing too tightly.	Internal fault within the therapy unit.	Check the compression level on the display. Compression levels should never exceed 70 mm Hg on the calf wrap and 120 mmHg on the foot wrap. If the unit is displaying a pressure that exceeds these values for the therapies listed, stop compression immediately and contact customer support.

Problem	Cause	Suggested Actions
The wrap is uncomfortable and/or is compressing too tightly.	The wrap is kinked	Check if wrap is kinked as to not allow the air from the wrap to deflate. Readjust or reapply wrap to alleviate the kink.

Problem	Cause	Suggested Actions
The wrap will not deflate	The unit is in Alarms Active state.	Check display for alarm events. If alarms are displayed use the troubleshooting guide to resolve the issue.
	Internal fault within the therapy unit.	Turn the power switch off, wait, and turn it back on. Contact ThermoTek customer service if problem persists.
	Inappropriate therapy selected.	Verify the mode prescribed is the mode currently active. See Chapter 9 for instructions on starting and stopping therapy modes. Allow appropriate amount of time for the unit to cool or heat. Depending on the therapy wrap prescribed, the wrap may take between 10 and 30 minutes to reach preset therapy temperature

Problem	Cause	Suggested Actions
The unit is noisy.	Internal fault within the therapy unit.	Turn the power switch off, wait, and turn it back on. Contact ThermoTek customer service if problem persists.

Problem	Cause	Suggested Actions
The display is not functioning.	Physical damage to unit.	Inspect the unit for physical damage. If the unit shows any cracks or dents, the unit should not be used. Contact ThermoTek Customer Support.
	Internal fault within the therapy unit.	Turn the power switch off, wait, and turn it back on. Contact ThermoTek customer service if problem persists.

Problem	Cause	Suggested Actions
The display is not functioning.	Unit not connected to AC power	Make sure the unit is connected to the AC outlet. Make sure the power switch on unit is switched to the ON position.

Problem	Cause	Suggested Actions
The keypad is not responding	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 ThermoTek Customer Support.
	Internal fault within the therapy unit.	Turn the power switch off, wait, and turn it back on. Contact ThermoTek customer service if problem persists.

EMC Notice

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

MRI Notice

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

Internal Battery

The VasuComp device uses a 3V, 48 AH, Lithium coin cell battery for maintaining its real time clock. The battery is not user replaceable.

14. Device Summary

The VascuComp3-DVT Therapy System is capable of performing therapies for the following:

- **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 aids the blood flow back to the heart.

The wraps for the VascuComp3-DVT 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 VascuComp3-DVT System for Therapy” instructions in Chapter 8.
3. Stop all therapy modes after the prescribed duration is complete.
4. 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 VascuComp3-DVT therapy system for use, please contact the clinic or hospital that prescribed the unit or the Durable Medical Equipment (DME) provider. If assistance is not available or is ineffective, please contact ThermoTek technical assistance toll-free at 1-877-242-3232 during the hours of 8am-5pm Central Time. If technical assistance is needed after these hours, you may contact the 24-hour line at 214-502-8800.

15. Service and Customer Support

ThermoTek, Inc. is committed to servicing our VascuComp3-DVT unit both during and after sale to the customer. If you have any questions concerning the operation of your VascuComp3 unit, please refer to the following to contact us at our Flower Mound, Texas facility:

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

In the event of a Medical Emergency, call:

9-1-1

16. Wraps, Accessories and Replacement Parts

Boxes/Foam:

Part Number	Description
0P2HVC01FM	Packing Foam
0P2HVC01BX	Shipping Box

Replacement Parts:

Part Number	Description
0P3WHG13PC	Cord, PW 10A/125 VAC, Hospital Grade, 12 ft. (Model 0P9PTVSCP4-01)

Available Therapy Wraps:

Part Number	Description
0P9BNDVTFT4	Foot Wrap, DVT, Non-Sterile
0P9BNDVTCA4	Calf Wrap, DVT, Non-Sterile
0P9BNDVTFT4-S	Foot Wrap, DVT, Sterile
0P9BNDVTCA4-S	Calf Wrap, DVT, Sterile

17. Specifications

VascuComp3 Part Number	0P9PTVSCP4-03
VascuComp3 Description	VascuComp3-DVT
Dimensions	7"W x 8"H x 8"D
Ambient Operating Range	60 – 80 °F
Relative Humidity	< 60% RH
Power Consumption (Max)	300 Watts
Input Voltage (Nominal)	100-120 VAC, 60 Hz, Single Phase
Input Current (Max)	3 Amps
USB Interface	Yes, Standard

17.1 Calibration

The VascuComp3-DVT 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 to ThermoTek for testing and calibration.

17.2 Product Listing



The VascuComp3-DVT 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

18. 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 *VascuComp* 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 877-242-3232 for an RMA number. Returned products must be in the ThermoTek approved box and packing material to ensure safe transport. To quickly process your warranty repair request, please have the following product information, which is located on the serial plate located on the back side of ThermoTek products, available: (1) Model Number, (2) Serial Number, (3) Description of Problem, and (4) Contact Name and Telephone Number.

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For customer service information please see Section 15 of this manual.