



INSTRUCTIONS FOR USE

VasoPress[®] External Pneumatic Compression System OPERATING INSTRUCTIONS

Distributed by SterilMed, Inc.
11400 73rd Avenue North
Maple Grove, MN 55369
Toll Free 1-888-541-0078/Fax 763-488-3350
www.sterilmed.com

Caution: Federal law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE

The VasoPress garment is recommended for use in patients for whom external compression therapy is indicated to reduce the incidence of deep vein thrombosis and resulting pulmonary embolism due to the presence of risk factors for thrombosis formation.

DEVICE DESCRIPTION

The VasoPress DVT is an intermittent pneumatic compression system that aids in the prevention of deep vein thrombosis (DVT) a potentially life threatening condition which can lead to pulmonary embolism. The VasoPress DVT is a non-invasive mechanical prophylactic system that helps decrease the incidence of deep vein thrombosis.

The system consists of an air pump and a soft pliable compression garment(s) (sleeves) for the foot, calf or thigh. The controller supplied compression on a pre-set timing cycle (12 seconds inflation followed by 48 seconds of deflation) at a suggested pressure setting of 40 mmHg for the Leg or 80mmHg for the Foot (unless otherwise prescribed by the licensed caregiver). The pressure in the garments is transferred to the extremity augmenting venous blood flow when the leg is compressed, reducing stasis. This process also stimulates fibrinolysis, thus reducing the risk of early clot formation.

SYSTEM SET UP AND OPERATING INSTRUCTIONS

The VasoPress DVT System is easy to set up. The following steps should be followed:

1. Once the pump and garments have been removed from their packaging plug the pump into an electrical outlet. **Do Not Switch On.**
2. Position the pump on any flat surface or suspend the pump at the foot of the bed using the swing-out hooks.
3. The garments may be used on either leg or either foot (depending on the garment).
4. Unfold the garments and position according to the instructions for use.

5. Snugly wrap the garment making sure the inflatable bladder is in the correct position, then secure with the tabs. The garment should fit securely but not tightly around the patient extremity.
6. Repeat the procedure for the other garment.
Note: If only one garment is to be used, simply leave the unused air outlet on the pump free (no tubing attached).
7. Air tubing is required to connect the garment to the pump and is provided separately. Attach the garments to the air tubing using the white snap lock connectors. Each tube has a male end connector at one end and a female end connector at the other. The female end (large white connector) will fit to the male end (small white connector) that is on the garment. Make certain that a “click” sound is heard to ensure a solid connection.
8. Attach the other end(s) of the air tubing (male end) to the large white female connector(s) on the pump. Make certain that a click is heard with each snap lock connection. If you need disconnect the tubing, press the silver colored tab on large white (female) connector and pull apart.
9. Adjust the pump pressure to the recommended pressure setting, unless otherwise specified/ordered by a physician.
10. Press the on/off switch to turn pump on.
11. Disconnect Device: Disconnect by plug.

Additional Recommendations:

- Ensure that there are no kinks in the tubing and the connectors are properly locked. Treatment pressure should never be changed without the direct order of a physician.
- Ensure that the garments are fully secure.
- Never apply or remove the garments while inflated as this may cause damage to the sleeve.

CONTRAINDICATIONS FOR USE

The use of the VasoPress DVT is not recommended in the following conditions:

1. Severe congestive cardiac failure.
2. Severe arteriosclerosis or other ischemic vascular disease.
3. Extreme deformity of the limbs.
4. Known or suspected deep vein thrombosis.
5. Any local condition in which the garments would interfere:
6. Gangrene
7. Dermatitis
8. Untreated or infected wounds
9. Recent skin Grafts

CLEANING

Garments:

The garment should be cleaned weekly using a damp soft cloth and mild detergent. (Never use phenol based cleaning solutions). After patient use, save garments for reprocessing and place in designated collection containers. SterilMed is an authorized vendor that reprocesses VasoPress DVT garments.

Reprocessing these garments will maximize device usage and minimize environmental impact. SterilMed is an FDA regulated reprocessor and utilizes validated procedures to reprocess these DVT compression garments. Please contact your SterilMed Customer Service Associate for more information.

NOTE: DO NOT DISCARD the air tubing hose with the garments

Pump:

SWITCH OFF THE ELECTRICAL SUPPLY TO THE PUMP AND DISCONNECT THE POWER CORD FROM THE MAIN SUPPLY BEFORE CLEANING AND INSPECTION.

The casing of the pump is manufactured from high impact ABS plastic and if soiled, it can be wiped down with a sodium hypochlorite solution to dilution of 1000ppm or any EPA-approved hospital grade disinfectant.

Do not use phenol based cleaning solution.

STORAGE AND CARE OF PUMP

1. Check the power cord and plug for abrasions or excessive wear.
2. Plug in the unit and verify air flows from the ports. To accomplish this, a tube set will have to be inserted due to the auto shut-off outlet ports.
3. Place in plastic bag for storage

MAINTENANCE AND TROUBLESHOOTING

No daily maintenance is required. It is intended that properly qualified, authorized technical personnel only should service equipment.

Symptom	Possible Solution
Pump not functioning	<ol style="list-style-type: none"> 1. Check plug 2. Tighten or replace fuse 3. Return to BioMed or central storage location for pumps
Pump functioning, but no air output	<ol style="list-style-type: none"> 1. Reconnect air tubes 2. Check and secure tubing 3. Return to BioMed or central storage location for pumps
Low pressure light and or audible alarm activates	<ol style="list-style-type: none"> 1. Reconnect air tubing 2. Check garment 3. Return to BioMed or central storage location for pumps

CALIBRATION AND SERVICING

Pressure should be checked and adjusted if necessary every six (6) months. The back of the pump has a filter which should be replaced as needed.

To adjust pressure, remove dial and follow instructions below:

1. Before removing the dial, note the pressure using an in-line mercury manometer with the dial placed at Leg pressure setting (40mm Hg). The cycle time is 12 seconds on and 48 seconds off. Adjust the pressure when the mercury manometer has reached its maximum (approximately 4 seconds after air has entered the manometer.)
2. With the mercury manometer, attached in-line, turn screw under dial and adjust the pressure. Turn the screw clockwise to increase the pressure and counter clockwise to decrease the pressure.

RECOMMENDED TREATMENT GUIDELINES¹

External Pneumatic Compression (EPC) is designed for patients who are assessed to be at risk for the development of DVT.

Following is a list of risk factor known to increase the incidence of DVT. All risk factors have a value of one (1) unless otherwise noted. A recommended treatment pressure of 40mm Hg or 80mm Hg has been established depending on the garment of choice. In all cases the recommendation is a guideline and is not a substitute for clinical judgment and experience.

When using the VasoPress DVT no concomitant anti-embolism compression hosiery is required for clinical effectiveness.

RISK FACTORS

	Age 40 to 60 years old	Pregnancy or postpartum < 1 month
	Age 60+ to 70 years old (2 factors)	Cancer / Malignancy
	Age over 70+ (3 factors)	Estrogen / Hormone therapy
	Previous history of DVT/PE (3 factors)	Sepsis / Severe infection
	Immobilization	Inflammatory bowel disease
	Obesity, >20% of ideal body weight	Stroke
	Surgical procedures over 30 minutes	Hypercoagulable states: e.g., plaminogen disorder
	Pelvic surgery or total joint replacement	Protein S, Protein C, and Antithrombia III deficiencies
	Myocardial infarction	Trauma
	Congestive heart failure	History of previous major surgery
	History of pelvic or long bone fracture	Venous stasis, leg edema. Venous ulcers
	Severe COPD	Varicose veins
(low risk = 0-1 factor)	(moderate risk = 2-4 factors)	(high risk = > 4 factor)



TECHNICAL SPECIFICATIONS

Reorder #	CTCVP500
Size	10.75" L. 3.5" W, and 7.5" H
Weight	6.4 Pounds
Input Rating	120V/60 Hz, 18W
Fuse Rating	1A 250V
Classification (UL60601-1)	Class I, Type BF
Humidity	Operation 30 - 75%; Storage & transportation 30 - 95%
Air Pressure	75 – 106kPa
Temperature	Operation 15° - 35C; Storage & transportation 15° - 70°C
Safety Standard	UL, CE, TUV
Pressure Range	40-80 mmHg +/- 10%
Cycle Time	Inflation 12 seconds +/-10%; Deflation 48 seconds +/-10%
Indicator Light	Green illuminated power on, red LED for low pressure or continuous pressure
Audible Alarm	Low pressure or continuous pressure will activate the alarm

GARMENT DETAILS

Model	Application	Size	Patient Sizing
CTCVP501P	Calf	Pediatric, Small	Up to 14" calf circumference
CTCVP501M	Calf	Medium	Up to 18" calf circumference
CTCVP501L	Calf	Large	Up to 24" calf circumference
CTCVP501B	Calf	X-Large	Up to 30" calf circumference
CTCVP520	Foot	Standard	Up to size 13
CTCVP520L	Foot	Large	Over size 13
CTCVP530M	Thigh	Medium	Up to 29" thigh circumference
CTCVP530L	Thigh	Large	Up to 36" thigh circumference
CTCVP530B	Thigh	X-Large	Up to 42" thigh circumference

The garment and tubing are 100% latex free
Garments may be sterilized using ETO

1. Moser KM Pulmonary thromboembolism – Your challenge is prevention. The Journal of Respiratory Diseases Volume 10 Number 10, October 1989.

Instructions for Use can be found at www.sterilmed.com. Further questions or concerns by the health practitioner can be addressed directly by contacting your SterilMed Customer Service Associate at 1-888-541-0078.

Vasopress® is a registered trademark of Compression Therapy Concepts or an affiliate.