

Triple Play VT

Vascular Therapy System (Compressible Limb Sleeve Device)

Manufactured for:
Wildcat Medical, LLC
dba: **Compression Solutions**
817 E. 4th Street
Tulsa, OK 74120 USA

Customer Service
Toll Free:
1-800-994-0464
Email:
info@compressionsolutions.us



Document # TPVT-01A IFU Rev 00
Copyright 2016 Wildcat Medical, LLC

Disposal

- This unit is an electromechanical device that includes printed circuit boards and rechargeable batteries. Do not discard in landfill. Consult local, state, federal and country requirements for proper disposal instructions.
- Sleeves may be discarded in US landfills.
- Pump control unit contains rechargeable batteries. Do not discard the pump unit in regular waste. Bring the unit to your local recycle center or return to Wildcat Medical.

The use of accessories, power supplies and cables other than those specified, with the exception of components sold by the manufacturer of the TriplePlay TPVT-01 as replacement parts, may result in increased emissions or decreased immunity of the TriplePlay TPVT-01.

Class II medical electrical equipment.

The sleeves are single-use devices. One patient may use a sleeve multiple times, but a single sleeve may not be shared between patients.

This unit is an electromechanical device that includes printed circuit boards and rechargeable batteries. Do not discard in landfill. Consult local, state, federal and country requirements for proper disposal instructions.

This symbol designates the degree of protection against electrical shock as being a type BF applied part.

Customer Service

Toll Free: 1-800-994-0464
Email: info@compressionsolutions.us

Wildcat Medical, LLC
dba: **Compression Solutions**
817 E. 4th Street
Tulsa, OK 74120 USA



Technical Data Specifications:

MAIN UNIT:
Dimensions: 6.9 x 4.3 x 1.8 inches (1.75 x 1.1 x 4.6 centimeters)
Weight: Approximately 1.1 lbs. (0.50 kg)
Mode of Operation: Cyclic
Source of Power: 6V 2.2 Ah NiMH or 7.4 V 1.5 Ah Li-Ion Rechargeable Battery

CAUTION: Charge batteries using only the power supply provided by Wildcat Medical.

POWER SUPPLY:
Use only UL/CSA 60601-1 approved power supplies from Wildcat Medical for use in hospital settings

Output: 1.1 - 1.8 A
Mode of Operation: Continuous

SYSTEM OPERATING ENVIRONMENT:
Temperature: +10°C (50°F) to +40°C (104°F)
Humidity: 30 to 75%

DEFAULT SETTINGS:
Calf Pressure (not adjustable) 50 mmHg
Auxiliary Pressure 30 mmHg (adjustable from 30-50 mmHg)
Cycle Time for each output..... 60-70 seconds

TOLERANCES:
Pressure ±5%
Single output run time 6 hours*
Double output run time 5 hours*
Triple output run time 4 hours*

*Battery run time may vary when using the AUX function and/or wraps with higher air bladder capacity than that of Wildcat Medical model TP-3333 calf sleeves. See product label for battery type.

This device is not protected against the ingress of water (ordinary protection, IPX0).

Equipment is not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Intended Uses

The TriplePlay TPVT-01 is intended to be an easy to use portable system, prescribed by a physician, to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (simulating muscle contractions). This device (used with TP-3333 calf sleeves) can be used to:

- Aid in the prevention of DVT;
- Enhance blood circulation;
- Diminish post-operative pain and swelling;
- Reduce wound healing time;
- Aid in the treatment of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in the lower limbs;
- As a prophylaxis for DVT by persons expecting to be stationary for long periods of time.

Contraindications

The TriplePlay TPVT-01 must not be used to treat the following conditions:

- Persons with suspected, active or untreated: deep vein thrombosis, ischemic vascular disease, severe arteriosclerosis, pulmonary edema, congestive heart failure, thrombophlebitis or an active infection;
- On a leg where sleeves would interfere with the following conditions: vein ligation, gangrene, dermatitis, open wounds, a recent skin graft, massive edema or extreme deformity of the leg;
- On patients with neuropathy;
- On extremities that are insensitive to pain;
- Where increased venous or lymphatic return is undesirable;

Default Settings

Calf Pressure Preset Level 50 mmHg
Default AUX Pressure Setting 30 mmHg
Auxiliary Output Pressure Range 30-50 mmHg
Cycle Time (approximate) 60-70 seconds
Internal Safety Valve Relief Pressure 100 mmHg

The rechargeable batteries supplied in this unit are not field replaceable. Return unit to Wildcat Medical if batteries require replacement.

NOTE: Recharge batteries every 60 days when unit is not in use in order to maintain battery integrity. Batteries can be recharged approximately 500 times between replacements.

Battery charge (from depleted state) takes approximately 4 hours and is terminated automatically by the control circuitry.

Warnings and Precautions

WARNING: Do not open or remove covers. No user serviceable parts inside. Direct all service needs to Wildcat Medical, Inc.

WARNING: If pulsations or throbbing occur, the sleeve may be wrapped too tightly. Loosen immediately.

WARNING: Stop using device if swelling occurs; consult physician.

WARNING: Device is to be used only by the patient prescribed, and only for its intended use.

WARNING: Ensure the pump control unit is turned off and unplugged from the wall outlet prior to and while cleaning or disinfecting.

WARNING: Equipment should not be used in the presence of any FLAMMABLE ANESTHETIC MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE.

CAUTION: Do not immerse in any liquid for any reason.

CAUTION: Do not operate device in a wet environment.

CAUTION: Allow sleeves to warm to room temperature if exposed to temperatures below 5°C

CAUTION: Do not subject the unit to extreme shocks, such as dropping the pump unit.

CAUTION: Only use power supply provided by Wildcat Medical, as the unit could overheat with non-approved power supply

CAUTION: Do not place any items in an autoclave.

Description of System Components



ITEMS INCLUDED BUT NOT SHOWN:

- Wall Plug Type Charger (DC Connector mates with control unit charger input)

OTHER ITEMS THAT MAY BE INCLUDED BUT NOT SHOWN:

- Calf Sleeves
- Joint (AUX) Wrap

Environmental Considerations

- Do not operate pump below 0°C (32°F).
- Do not expose to heat exceeding 65°C (149°F).
- Do not operate the pump if it has been stored in freezing conditions. Allow sleeves to warm to room temperature if exposed to temperatures below 5°C (41°F).
- Do not unroll or attach the sleeves in below freezing temperatures (0°C / 32°F) as damage to the air bladders can occur, making them unable to hold pressure.
- Store in a dry location between +10°C (50°F) and +40°C (104°F), 30% -75% relative humidity.
- Limit Transport Temperatures to between -20°C (-4°F) and +60°C (140°F)
- Normal Operating Conditions Temperature Range +10°C (50°F) to +40°C (104°F) Relative Humidity 30% to 75%

Purpose of this Device

The purpose of the TPVT-01 is to aid in the prevention of Deep Vein Thrombosis (DVT) by helping to stimulate blood flow in the legs. This is accomplished by an electronically controlled pump unit delivering a set amount of air to the calf sleeves (model TP-3333) that, in turn, compress the calf or calves to aid blood flow out of the lower extremities.

The TPVT-01 can also provide compression therapy to additional limb or joint sleeves (as may be prescribed by a physician) through the use of the AUX (auxiliary) function and output provided.

The pump unit will inflate the calf sleeves to a specified preset pressure of 50 mmHg, and the auxiliary wrap to a pressure of 30-50 mmHg (set by the user or health care provider), and deflate once that pressure is reached. Cycles are repeated until the unit is turned off. Internal rechargeable batteries allow the system to be completely portable, thus preventing interruptions in treatment.

Set-Up Instructions

- Remove items from packaging and plastic bags.
- Make sure all of the pieces listed on pages 6 are readily available.
- Inspect all components for damage. If any parts appear damaged or are inoperable, contact Compression Solutions Customer Service (front cover).
- Before using, connect the supplied power adapter plug into the jack on the pump and plug into the main wall socket. The LED CHARGE indicator will turn RED during the charge cycle and GREEN when the charge is complete. The unit may be used while connected to the charger.
- Uncoil the sleeve tubing being careful to remove any kinks from tubing due to compression in shipping.
- Apply sleeves to calves(s) (see "Attaching Calf sleeves"), route tubing under clothing or in a manner to prevent a tripping hazard and to avoid kinking.
- Ensure metal thumb tabs on the pump unit and sleeves' air connectors are depressed to allow the air tube connector(s) to engage.
- Connect air tube(s) to pump air outlets.

Attaching the Calf Sleeves

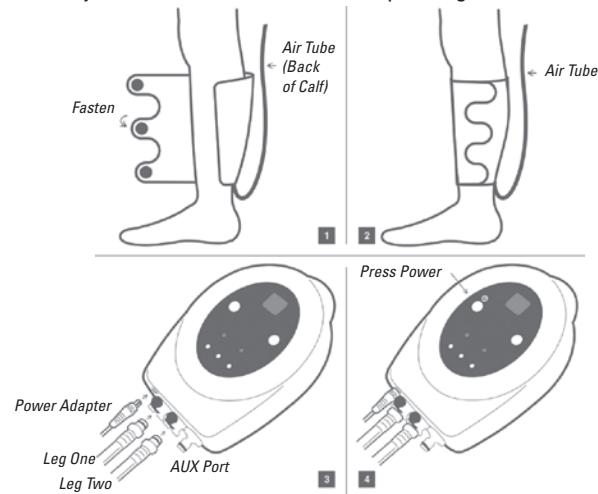
- Make sure that the securing tabs are on the inside of the sleeve relative to your leg.
- Place the sleeve so the middle of the bladder outline is against the back of your calf.
- Wrap the sleeve around your calf *so that it is a snug* fit and fasten the securing tabs. A loose fitting sleeve can cause a low pressure (LO) error alarm.
- Adjust as necessary.

WARNING: If pulsations or throbbing occur, the sleeve is wrapped too tightly. Remove the sleeve and re-wrap for comfort. If pain or swelling occurs, discontinue use and notify your medical professional immediately.

Using the Auxiliary Function

Various additional compression wraps may be prescribed by your physician to aid in therapy. The Auxiliary function and additional (third) output provided on the TriplePlay-VT unit is designed to allow this flexibility.

Before using an auxiliary wrap, ensure that the connector on the wrap is of the type required to fit the mating connector on the TriplePlay-VT unit (contact Compression Solutions Customer Service for assistance or to order any adapters which may be needed for this connection). Place the wrap on the extremity and secure it firmly into place as instructed by your healthcare professional. Connect the end of the air tube to the auxiliary connector on the pump unit. Once the wrap is secure and the tube is connected, turn the unit on; ensure that the AUX function is selected and make any needed pressure adjustments as instructed in the Operating Instructions.



Operating Instructions

- After following the set-up instructions, ensure that the sleeves are wrapped snugly and fastened securely as indicated.
- To turn the system on, press and hold the power button for 1-2 seconds. If the unit will not power on, connect the wall supply to charge the battery. Unit may be used while battery is being recharged.
- The display will show “ON” then “- -” then “00.” The LEG1 and LEG 2 LEDs will be on with a solid light. The pressure of both Calf sleeves is preset to 50 mmHg and cannot be adjusted.

8

User Maintenance

NOTICE: Contains no serviceable parts. Contact Compression Solutions Customer Service.

- Inspect the unit and all components for any damage that may have occurred during shipping or general handling prior to each use (for example, frayed or cut cord, split air tubes, cracked plastic housing, damaged LED display, torn sleeve, etc.). Refer to pages 6 and 7 for a description of all components.
- Do not attempt to connect the wall supply if any damage is noticed.
- Avoid subjecting the unit to shocks, such as dropping the pump unit.
- Notify Wildcat Medical for immediate replacement of any damaged items.
- Do not handle the calf sleeves with any sharp objects. If a bladder is punctured, do not attempt to repair the sleeve. Replacement sleeves (model TP-3333) are available through customer service.
- Roll sleeve for storage transportation; avoid folding or creasing the bladder.
- Battery is not replaceable – return unit to Wildcat Medical if service is needed.
- Contact Compression Solutions to receive replacement instructions for any damaged items. This may include returning the damaged part to Wildcat Medical for service.

Storage

- Store in a dry location between +10°C (50°F) and +40°C (104°F), 30%-75% relative humidity.
- Do not expose to heat exceeding 65°C (149°F).
- Do not store items in direct sunlight.
- Roll sleeve and do not fold, as folding will decrease the life of your product.
- Connect unit to charger for recharge no less than 2 hours every 60 days to preserve integrity of internal batteries.

12

- If using the AUX function, there are three (3) pressure choices – 30, 40 or 50 mmHG. Press the AUX ON button to enable the AUX function. The preset pressure will be 30 mmHg. Repeated pushing of the AUX button will allow you to toggle through to 40 mmHg, 50 mmHg then 00 which turns the port off. **Note: Adjustments can be made at any time when the pump is at “rest” (i.e., before cycling begins or during “rest” periods between sleeve inflations). Initial adjustments (immediately after power ON) must be initiated within 5 seconds of power ON. The unit will begin to cycle through the selected functions 5 seconds after all adjustments have been completed.**
- The pump will start after a short delay (approximately 5 seconds). The Display will show the pressure. The LED for the port in operation will flash slowly while the pump is running.
 - For normal operation:
 - The wrap connected to Leg 1 will inflate (LEG 1 LED flashes slowly) then deflate (LEG 1 LED turns solid), then rests (LEG 1 LED is solid).
 - The wrap connected to Leg 2 will inflate (LEG 2 LED flashes slowly) then deflate (LEG 2 LED turns solid), then rests (LEG 2 LED is solid).
 - If the AUX function is not turned on, the normal operation will cause the pump to cycle between ports LEG1 and LEG2.
 - If the AUX function is turned on and connected to a wrap, the AUX wrap will inflate (AUX LED flashes slowly) then deflate (AUX LED turns solid), then rest (AUX LED is solid) after LEG1 and LEG2 cycles. The typical cycle will be LEG1, LEG 2, AUX then the cycle repeats.
 - The cycle will continue until the pump is turned off manually – by pressing and holding the power button for (2) seconds.
 - If display shows NO, LO or HI, the pump will continue to operate for two (2) cycles to allow the user to correct the issue using the Troubleshooting Guide. At that point, if the issue still exists the pump will automatically shut down the port with the issue, and that port will no longer be included in the ongoing operating cycle.
- The unit will begin to cycle through the selected functions 5 seconds after power is turned on, or 5 seconds after the initial adjustments are completed. **When a sleeve is being inflated, the active outlet is indicated by a slow flashing of the corresponding “function indicator.”** If adjustments are made during a “rest” period, the unit will resume cycling at the end of that rest period. The “rest” time is determined by the number of sleeves selected with the output mode. In a **single sleeve mode** (leg 1,

9

Alarms

“KINKED HOSE” or “HIGH PRESSURE” – If a pressure limit is reached in less than 2 seconds after pump is energized, cycling stops, audible alarm sounds, and display reads “HI”. In addition, the LED indicator coinciding with whichever sleeve was energized when the condition occurred flashes rapidly.

“LEAK” or “LOW PRESSURE” – When a LEG sleeve is activated, if the pressure limit is NOT reached within **20 seconds** after pump is energized (or within **2 minutes** when the AUXILIARY sleeve is activated), cycling stops, audible alarm sounds, and display reads “LO”. In addition, the LED indicator coinciding with whichever sleeve was energized when the condition occurred flashes rapidly. **Note: it is important that the sleeves are fitted to be snug to avoid false low pressure alarms.**

“BATTERY CRITICAL” – If battery voltage drops to a critical level, cycling stops, audible alarm sounds, and display reads “BL”. In addition, the LOW BATTERY LED indicator illuminates.

To reset an alarm condition, the unit must be turned OFF. If not **manually** turned OFF within 2 minutes of an alarm condition occurring, **unit automatically turns itself OFF.**

If you encounter any problems that cannot be resolved by the preceding information, contact Compression Solutions Customer Service

Customer Service

Toll Free: 1-800-994-0464
Email: info@compressionsolutions.us

Wildcat Medical, LLC
dba: **Compression Solutions**
817 E. 4th Street
Tulsa, OK 74120 USA



13

- leg 2 or AUX only modes), the rest period is **60 seconds** from the time that the pressure is reached and the pump is turned off until the time that the sleeve is re-pressurized. In a **dual sleeve mode** (leg 1 + leg 2 or leg 1 + AUX), the rest period is **25 seconds** from the time the pressure is reached and the pump is turned off until the time the next sleeve is pressurized. In the **triple sleeve mode** (leg 1 + leg 2 + AUX), the rest period is **15 seconds** from the time the pressure is reached and the pump is turned off until the time the next sleeve is pressurized. This timing ensures that each sleeve is being deflated for approximately 60 seconds, thus allowing ample rest time between compressions on the affected limb or extremity. It should be noted that the inflated wraps exhaust during the rest period and the display will show “- -” during the rest periods.
- To turn off the pump unit, depress and hold the power button for 1-2 seconds. To reset the pump when an alarm condition occurs simply turn the pump “off” then back “on”.
- For uninterrupted extended operation, connect AC adapter while in use.
- To remove sleeve, pull securing straps and unwrap from leg.
- To disconnect the air tube from pump unit, depress thumb tab on the connector while pulling the tube away.

Low Battery Indicator

In order to ensure that proper pressure is always reached during operation, regardless of the charge state of the battery, there are THREE stages of the LOW BATTERY INDICATOR as follows:

STAGE 1 – The yellow LOW BATTERY INDICATOR illuminates when the pump is NOT RUNNING, turns OFF when the pump starts and illuminates again when the pump is in the REST period. **This is the FIRST indication that a recharge is needed at the earliest opportunity;**

STAGE 2 – The yellow LOW BATTERY INDICATOR will REMAIN ILLUMINATED during both the pumping time and the rest period. **At this stage the battery charger MUST be connected immediately to avoid any interruption in the treatment session;**

STAGE 3 – If the battery voltage drops to a critical level at any time, the yellow LED will illuminate AND the display will show “BL”. In addition, the audible alarm will sound and cycling of the pump will be inhibited. **The unit will then automatically shut off after three seconds.**

10

Troubleshooting

| PROBLEM | SOLUTION |
|--|--|
| Air tube outlet connector will not fit in port | Make sure the metal thumb latch is pressed until it clicks, such that the two ends of the connectors will fit together. |
| Unit will not turn on | Battery charge is too low. Connect unit to a wall supply for a fresh charge and turn on. |
| Cannot feel pressure on leg(s) | <ul style="list-style-type: none"> Sleeve is not wrapped tightly enough Air tubes are not connected Bladder is damaged and will not hold air. Replacement calf sleeves, model TP-3333, are available in pairs by contacting customer service. Tube is damaged Ensure that the sleeve is connected to the proper outlet corresponding to the selected mode |
| Pressure on Auxiliary sleeve is too high | <ul style="list-style-type: none"> Verify settings are correctly set as prescribed Decrease pressure setting. Contact physician. |
| HI alarm (High pressure detected or set pressure detected too soon) | Remove any kinks from line. Be sure the tubes are not tangled or constricted. Start pump again by turning unit OFF and back to ON. If after two (2) attempts the pressure is “high” (Display shows “HI” an audible alarm will sound for 5 seconds and the corresponding LED will flash rapidly), that port (LEG1 or LEG2) will shut down and be bypassed for future cycles during the current operating session. |
| LO alarm (Set pressure not detected within allotted time period) | Ensure tubing is properly connected, sleeves are attached to be snug and there are no air leaks. Start pump again by turning unit OFF and back to ON. If after two (2) attempts the pressure is “low” (the corresponding LED will flash rapidly for 5 seconds), that port (LEG1 or LEG2) will shut down and be bypassed for future cycles during the current operating session. |
| No Display | Display of NO indicates there is no wrap attached to the port that is currently cycling. |
| BL alarm (Pump will not operate) | Battery charge is low. Connect charger. |
| BL alarm (Battery pack has expired.) | Contact Compression Solutions at 800-994-0464 |
| If you encounter any problems that cannot be resolved by the preceding information, contact Compression Solutions Customer Service | Customer Service Toll Free: 1-800-994-0464 Email: info@compressionsolutions.us |

14

Using the AC Adapter / Battery Charger

Insert the supplied power supply plug into the adapter jack on the pump unit and connect the power supply adapter to the main voltage wall socket. The battery charge LED will illuminate RED while charging battery and turn GREEN when charge is complete. When battery fully is charged and connected to wall socket during operation, the battery charge LED will change from GREEN to RED intermittently. It will not be illuminated if the charger is not connected. For extended operation periods, or to charge the battery during treatment sessions, the AC adapter can be connected while the device is in use.

NOTE: In hospital settings, use only a UL/CSA 60601-1 approved power supply provided by Wildcat Medical, Inc. (output of +10 Volts DC @ 1.1 - 1.8 Amperes). Use of alternate power supplies could damage the system.

Cleaning and Disinfecting

NOTE: Inspect the TriplePlay unit and follow the cleaning and disinfecting procedures prior to each use.

WARNING: Device must be turned off and disconnected from the power mains (wall outlet) prior to and while cleaning or disinfecting.

CAUTION: Do not place any items in an autoclave.

CAUTION: Do not immerse pump unit in any liquid for any reason.

- Clean the outer surface of the pump unit using a soft cloth, moistened with soapy water or 70% isopropyl alcohol.
- Do not use bleach on any item.
- Do not use abrasive or volatile cleaners – display or control panel could become scratched and hard to read.
- Do not place sleeve in dryer, as the bladder could melt.
- Hand wash exterior of sleeve using a soft cloth moistened with soapy water or 70% isopropyl alcohol and let air dry.
- Ensure product is completely dry prior to use.

11

15