DVTCare™

Personal Circulation Assistant

Customer Service

See Service Provider Documentation

Document #1012; rev 13; 7/14/10

CA5 USER MANUAL
Table of Contents

Manufactured by:
Michigan Medical Innovations
481 Pettis Ave. NE Ada, Michigan 49301 USA
www.michmedical.com

Please Fill in for Future Reference

Date Purchased: _____ Serial Number: _____

General Warnings

WARNING: Electric shock hazard. Do not remove cover.
WARNING: Do not attempt to service the pump control unit for any reason. Contact DVT*Care* for replacement instructions (page 56).
WARNING: If pulsations or throbbing occur, the cuff is wrapped too tight. Loosen immediately.
WARNING: Stop using device if swelling occurs; consult physician.

WARNING: Device 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 power mains (wall outlet) prior to and while cleaning or disinfecting.
WARNING: Equipment not suitable for use in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE.
WARNING: Leg cuffs are not to be used in direct contact with the skin.
CAUTION: Do not immerse in any liquid for any reason.
CAUTION: Do not operate device in a wet environment.
CAUTION: Allow cuffs to warm to room temperature if exposed to temperatures below 5° C
CAUTION: Do not subject the unit to shocks, such as dropping the pump unit.
CAUTION: Contains no serviceable parts. Contact provider for service (page 2)
CAUTION: Do not place any items in an autoclave.
CAUTION: This unit needs to be installed according to information provided in EMC sec. 38.

CAUTION: Portable and mobile RF communications equipment can affect the operation of this device.

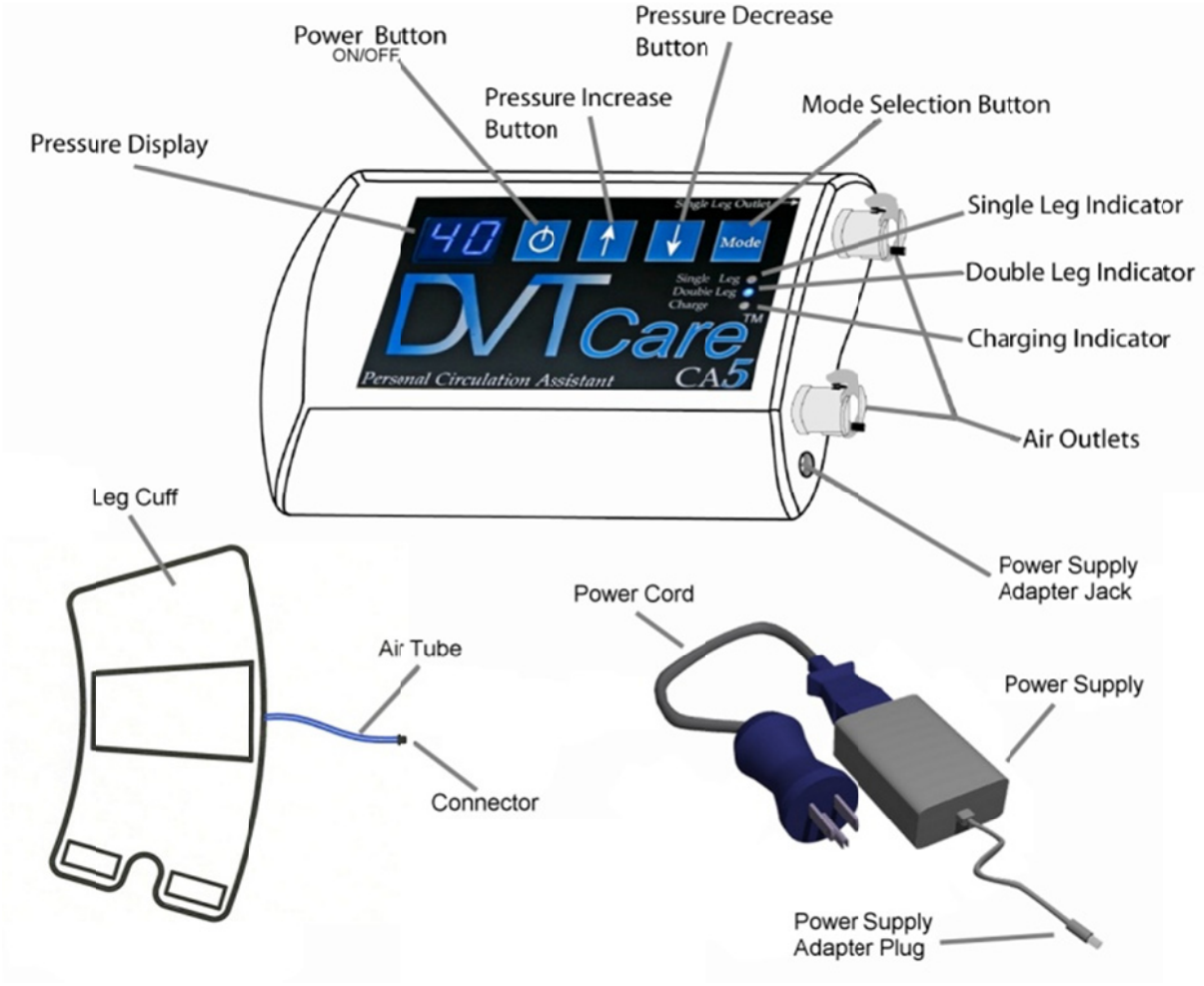
Purpose of Device

The purpose of the CA5 personal circulation assistant is to aid in the prevention of Deep Vein Thrombosis (DVT) by helping to stimulate blood flow in the legs. This is accomplished by the electronically controlled pump unit delivering a set amount of air to the leg cuffs that, in turn, compress the calf(s) to aid blood flow out of the lower extremities.
This pump unit will inflate to a specified pressure, set by the user or health care provider, and deflate once that pressures is reached. Cycles are repeated until the unit is turned off. In addition to having single and double leg modes, the CA5 also incorporates adjustable cycle times (adjusted by healthcare providor) to accommodate a wide range of treatment profiles. The hold and cycle times can only be adjusted by a healthcare provider. Internal rechargeable batteries allow the system to be completely portable, thus preventing many interruptions in treatment.

Intended Uses

The DVTcare™ CA5 is intended to be an easy to use, portable system that is prescribed by healthcare professionals, to help prevent the onset of DVT in patients, by stimulating blood flow in the legs (simulating muscle contractions). Furthermore, the unit can be used as an aid in the prophylaxis for DVT by persons traveling, or those expecting to be stationary for long periods of time (greater than 4 hours). The designed portability allows patients to wear the unit during many hospital stay related activities, such as physical therapy sessions, wheel chair transportation, cafeteria sittings, and during general mobility throughout the facility. This device can also be used by patients to: aid in the prevention of DVT, enhance blood circulation, diminish post-operative pain and swelling, reduce wound healing time, and aid in the treatment and healing of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency, and reduction of edema in the lower limbs.

Description of Device



Default Settings

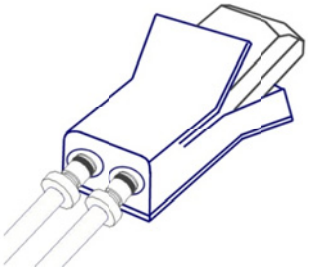
Pressure Set Point	50 mmHg
Pressure Limit	50 mmHg
Pressure Adjustment Range	20-50 mmHg
Hold Time	1 second
Cycle Time	1 minute

Set-Up Instructions

NOTE: The DVT*Care* CA5 requires EMC precautions, and needs to be installed and put into service according the EMC information provided at www.michmedical.com/ca5emcdata

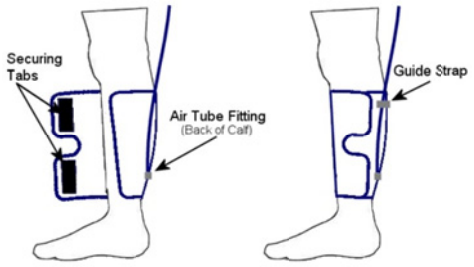
NOTE: Portable and mobile radio frequency communications can affect the DVT*Care* CA5

1. For future reference, enter the date of purchase and unit Serial Number found on the rear label of each pump unit) in the spaces provided on page 2.
2. Remove items from packaging and plastic bags (if present).
3. Make sure all of the pieces listed on page 4 are readily available.
4. Inspect all components for damage. If any parts appear damaged or are inoperable, contact Provider Customer Service (page 1)
5. Uncoil the tubing attached to the cuff(s).
6. Apply garments to leg calf (see Donning Leg Cuffs on page 6), route tubing under clothing or in a manner to prevent a tripping hazard and to avoid kinking.
7. Ensure metal thumb tabs on the pump units air outlets are depressed to allow the air tube connector to engage.
8. Insert pump in pouch and align the pump air outlets with the two access holes in the pouch.
9. Connect air tube(s) to pump air outlets by routing them through the carry pouch air access holes.
10. Secure carry case as desired using the strap or belt loop provided.



Donning the Leg Cuffs

1. Make sure that the securing Velcro is on the inside of the sleeve relative to your leg.
2. Place the cuff so the middle of the bladder outline is against the back of your calf with the air tube fitting facing out.
3. Wrap the cuff around your calf so that it is a snug fit.
4. Adjust as necessary.
   WARNING: If pulsations or throbbing occur, the cuff is wrapped too tightly. Loosen immediately.



AC Adapter

Insert the supplied power supply plug into the adapter jack in the pump and connect the power supply adapter to a 100-240V~ wall socket. The batter charge LED will illuminate while charging battery and remain turn off when charge is complete. It will not be illuminated if the charger is not connected. To maximize performance during extended operation, connect AC adapter while in use. Full charge is approximately 7.0 volts.

NOTE: Use power supply provided ITE FJ-SW1280c029
Input: 110-240V~, 50/60Hz, 0.5A
Output: +12V - - - 1.2 A

NOTE: To isolate unit, unplug from AC adapter/power supply.

Operating Instructions

1. After following the set-up instructions on page 5, ensure leg cuffs are wrapped firmly around legs as indicated on page 5.
2. To turn the system on, press and hold the power button for 2 seconds.
3. The system will self diagnose and the display will show the remaining battery voltage followed by the current set pressure. If battery voltage is below 5.8, connect the power supply prior to use. Any error codes will be displayed as well (see page 7). If the unit will not power on, connect the wall supply to charge battery. Unit may be used while plugged into wall outlet.
4. Set pressure by using the ↑ and ↓ buttons, to either increase or decrease the set pressure.

5. Press the “Mode” button to change between single and double leg modes.
6. While in “Double Leg” mode, only one leg cuff fills at a time. The leg bladders vent immediately after filling and continue to vent until the next cycle.
7. Healthcare providers please reference supplemental instructions for entering the “Health care provider access code” to adjust the upper pressure limit and access the reset function.
8. Pressure adjustments can be made at any time during the cycle, by pressing the ↑ or ↓ arrow keys. Each press will change the pressure in 1mmHg increments. Press and hold either key for 1 second to scroll in 5mmHg increments.
9. To turn off the pump unit, depress and hold the power button for approximately 2 seconds.
10. To maximize performance during extended operation, connect AC adapter while in use.
11. To remove cuff, pull securing straps and unwrap from leg.
12. To disconnect the air tube from pump unit, depress thumb tab on pump unit while pulling the tube away.

User Maintenance

WARNING: Do not attempt to service the pump control unit for any reason.

- Inspect the unit and components for any damage that may have occurred during shipping or general handling prior to each use (ie: cut cord, split air tubes, cracked plastic housing, torn cuff, etc). Refer to Description of Device (pg 5) for 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 provider for immediate replacement of any kinked or damaged tubes.
- Do not handle the leg cuffs with any sharp objects. If bladder is punctured, do not repair.
- Roll cuff for storage transportation; avoid folding or creasing the bladder.
- Battery is not replaceable – return unit to provider.
- This device is not protected by a protective earth ground.

Environmental Conditions

- Do not expose device to direct sunlight.
- 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 cuffs to warm to room temperature if exposed to temperatures below 5 ° C (41° F).
- Do not unroll or don the leg cuff in below freezing temperatures (0° C / 32° F) as damage to the air bladder can occur, making it unable to hold pressure.
- Do not expose device to a direct heat source with temperatures exceeding 50° C (122 ° F) for extended periods of time.
- Store in a dry location between +10 ° C (50 ° F) and +40 ° C (104 ° F), 30% -75% relative humidity.
- Transport temperature and relative humidity: Temperature Range -20° C (-4° F) to +60° C (140° F); Relative Humidity 30% tp 75%; Keep Dry
- Normal Operating Conditions: Temperature Range +10° C (50° F) to +40° C (104° F); Relative Humidity 30% o 75%

Trouble Shooting

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 tube connector will enter the air outlet fitting.
Unit will not turn on		Batter charge is too low. Connect unit to a wall supply for a fresh charge and turn on.
Cannot feel pressure on leg(s)		Cuff is not wrapped tightly enough
		Air tubes are not connected
		Bladder is damaged and will not hold air
		Tube is damaged
		Ensure “Double Leg” mode is selected when using both cuffs
Pressure is too high on leg		Verify settings are correct as prescribed by physician
		Decrease pressure setting. Contact physician.
HI 	Control unit detected high pressure	Remove any kinks from line. Be sure all tubes are not tangled or constricted. Start pump again.
LO 	Pressure cuff(s) is under-inflated	Make sure tubing is properly connected. Listen and look for air leaks.
Lb 	Pump will not operate	Battery charge is low. Connect charger.
	Battery pack has expired.	Contact DVT*Care*
Er 	Pump will not operate.	Contact DVT*Care* for return information.

If problems persist, contact your equipment provider as per page 1.

Contraindications

The DVT*Care* CA5 should **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.
- It is not recommended for use on a leg where cuffs would interfere with the following conditions: vein ligation, gangrene, dermatitis, open wounds, a recent skin graft, massive edema or extreme deformity of the leg.
- Not for use with patients with neuropathy.
- Do not use on extremities that are insensitive to pain.
- Do not use where increased venous or lymphatic return is undesirable.
- Leg cuffs are not to be used in direct contact with skin.

Storage

- Store in a dry location between +10 ^{o} C (50 ^{o} F) and +40 ^{o} C (104 ^{o} F), 30% -75% relative humidity.
- Do not expose to heat exceeding 65^{o} C (149^{o} F).
- Do not store items in direct sunlight.
- Ensure zipper/covers of the carry pouch/storage bags are firmly closed to prevent dust and damage.
- Roll cuff and do not fold, as folding will decrease the life of your product.
- Connect unit to charger for recharge no less than 6 hours every 30 days to preserve integrity of internal batteries.

Cleaning and Disinfecting

Note: Inspect the DVT*Care* unit and follow the cleaning and disinfecting procedures prior to each use.

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

CAUTION: Contains no serviceable parts. Contact equipment provider for service.

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 could become scratched and hard to read.
- Do not place cuff or carry pouch in dryer, as the bladder could melt.
- Hand wash exterior of cuff and carry pouch using a soft cloth moistened with soapy water or 70% isopropyl alcohol and let air dry.
- To ensure product is completely dry prior to use, leave unit in the off condition and disconnected from power (wall outlet) for 30 minutes after cleaning or disinfecting.

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

Technical Data – DVT*Care* Model CA5

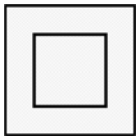
Electro Magnetic Compatibility Data available at www.michmedical.com/ca5emcdata

Refer to user manual for further instructions.

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

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.

The use of accessories, transducers and cables other than those specified, may result in increased emissions or decreased immunity of the DVT*Care* CA5.



Designates Class II medical electrical equipment.

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

Alternating Current

Direct Current

Fragile

This end up

Temperature Limits

Keep away from rain

General (Technical Data Continued)
Size: 5.9 x 3.9 x 1.6 inches (15 x 10 x 4 centemeters)
Weight: 1.1 lbs (0.50 kg)

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.

Power
This device is internally powered and operates under continuous loading. This device is not protected by a protective earth ground.

Power Supply: ITE FJ-SW1280c029
Input: 110-240V~, 50/60Hz, 0.5A
Output: +12VDC 1.2 A

NOTE: This power supply is not approved for hospital, oxygen rich use.

Battery*:

Single-leg mode run time:	17 hours
Double-leg mode run time:	8 hours
Recharge time:	3-4 hours
Approximate number of charges:	500 Cycles

* Based on default settings

NOTE: Recharge batteries using only the power supply supplied with this system. Batteries are best cycled a minimum of once every 60 days to sustain 500 cycle life.

NOTE: This unit is provided with rechargeable batteries and are not replaceable. Return to provider for service (see page 1).

Default Settings

Pressure	50mmHg
Hold Time	1 second
Cycle Time	60 seconds

Feature Adjustment Range

Pressure	20-65 mmHg
Hold Time	Not adjustable
Cycle Time	60-75 seconds

Tolerances

Pressure	±4 mmHg
Cycle Time	±1 second
Displayed battery charge	±0.1 V
Recharge Time	3-4 hours
Single-leg run time	17 hours
Double-let run time	8 hours

Explanation of button functions

1. **Power**
   Depress and hold to turn unit on. Depress and hold to turn unit off.
2. **Up Arrow**
   Depress briefly to increase pressure by 1mmHg. Depress and hold to increase pressure by 5mmHg increments.
3. **Down Arrow**
   Depress briefly to decrease pressure by 1mmHg. Depress and hold to decrease pressure by 5mmHg increments.
4. **Mode**
   Depress briefly to change from single-leg mode to double-leg mode and vice versa. Confirm garment connections to “single-leg” fitting when in single-leg mode and garment connections to both fittings when in double-leg mode.

Explanation of LED indicators

1. Single-leg mode Indicates unit is operating in single-leg mode.

2. Double-leg mode Indicates unit is operating in double-leg mode.

3. Charge status If charge light is on, unit is charging. If charge light is off, charging, while connected to power supply and plugged into wall power supply, charge is complete.

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.

Cuffs may be discarded in US landfills.

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See Service Provider Documentation for Service and Technical Support Information.