

# Capiflo

## Owners Manual



### Manufactured By:

K & L Distributors, Inc.

8403 Benjamin Rd. Suite A

Tampa FL, 33634

Vascular Therapy System

(Compressible Limb Sleeve Device)

### Customer Service

Phone: (813) 243-2222

Email: [Sales@capiflo.com](mailto:Sales@capiflo.com)

Web: Capiflo.com

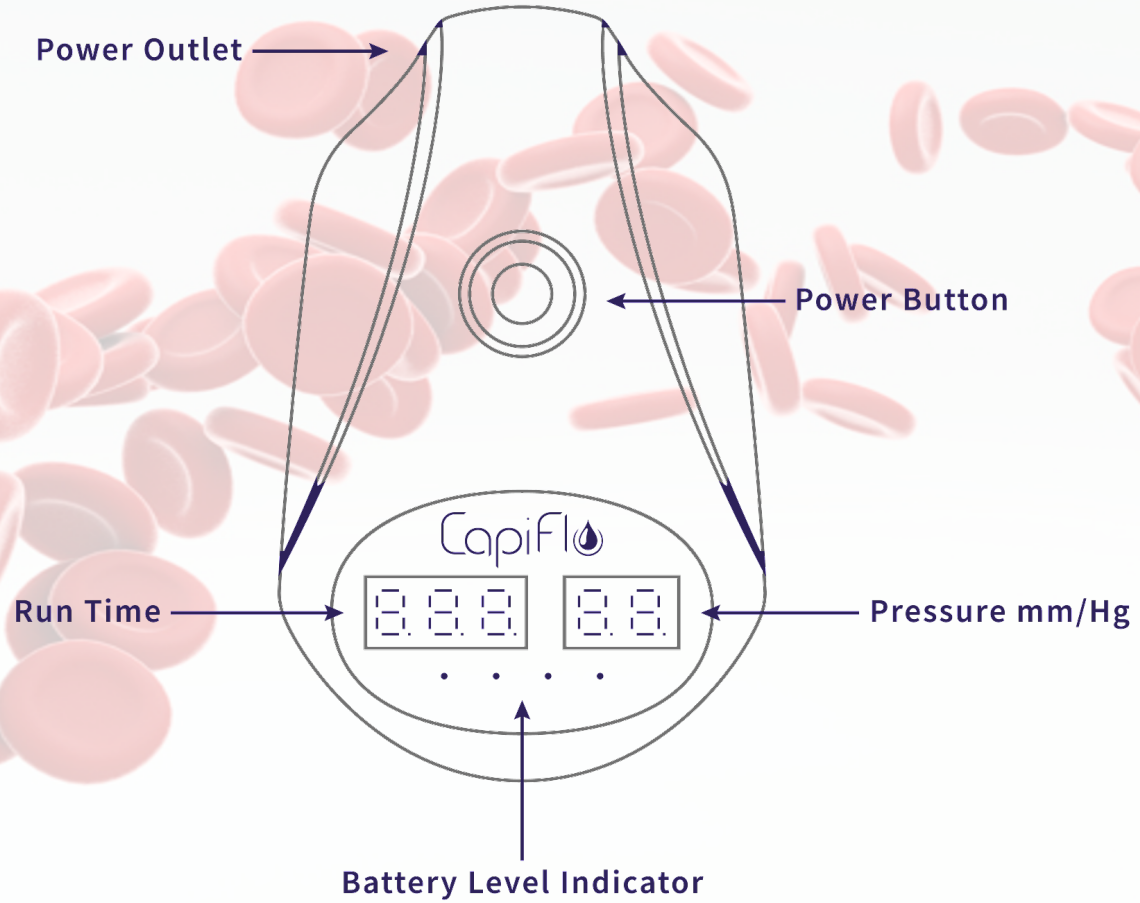
**Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner**

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# SYSTEM COMPONENTS



# QUICK START GUIDE



**POWER OFF:** Unit is in "sleep" mode. No visible LED illumination.

## **POWER ON:**

When the unit powers up, 3 green LEDs will be illuminated to indicate the charge level of the device (3 green LEDs is a fully charged unit, 1 green LED means low battery). After a 5 second delay, the pumps will allow inflation of the attached wrap to a pre-determined pressure of 55 mmHg. Pressing the power button one more time will adjust the pressure setting to 50 mmHg. An additional press will decrease the pressure to 40 mmHg. The chosen pressure level is shown by the number on the right of the control unit. Once the pressure reaches the proper level, the pump will turn OFF for a 50 second "rest" period, and the cuff deflates through the vent port to cool the leg or legs. After the "rest" period, the wrap is again inflated, and will do so every 50 seconds until the unit is powered off or loses charge.

## **BATTERY INDICATOR:**

In order to properly indicate the state of the battery and charger, there are three stages of the battery indicator as follows:

With the machine firmly attached to the leg, the machine can be turned on by pressing the power button for up to 5 seconds. The red power indicator will be illuminated to indicate the unit is powered on. A fully charged CapiFlo unit will have 3 green lights illuminated, a partially charged CapiFlo unit will have 2 green lights illuminated, and a CapiFlo unit with low battery will have only one of the green lights illuminated. The CapiFlo with a low battery charge will continue to operate for a short amount of time but charging should be performed soon.

The battery will run for approximately 24 hours continuously when the unit is fully charged.

## **PURPOSE OF THIS DEVICE:**

The CapiFlo is the world's best portable Deep Vein Thrombosis (DVT) unit, model NS-9000. This is a medical device, prescribed by a physician for use in a clinical or home settings to aid in the prevention and the onset of DVT in patients. This is done by stimulating blood flow in the extremities simulating muscle contractions.

## **HOW IT WORKS:**

The purpose of Capiflo DVT is to assist in helping to prevent Deep Vein Thrombosis (DVT). The Capiflo helps stimulate blood flow in the legs when the unit is activated. The device is an electronically controlled unit with a built-in air pump to inflate air bags encompassed in each individual unit, one for each leg. When turned on, the pump will deliver the preprogrammed set amount of air to the cuffs. When the legs are squeezed on the calves it aids in increasing the blood flow in the lower extremities.

The units will inflate separately with each cuff inflating to a preset pressure of 55mmHg, 50mmHg, or 40 mmHg depending on the user's initial selection. The unit will inflate to the desired pressure for 15 seconds, deflate once the desired pressure is reached, and will stay deflated for approximately 45 seconds. After completion, the run cycle will be repeated until the unit is turned off or the battery loses charge. Built in rechargeable batteries allow the Capiflo to be fully portable, allowing uninterrupted treatment.

## **POTENTIAL USES:**

- Assist and aid in the prevention of DVT (Deep Vein Thrombosis).
- As a prophylaxis for Deep Vein Thrombosis (DVT) by persons expecting to be stationary for long periods of time.
- To increase blood circulation in the lower limbs.
- Help reduce post-operative swelling and pain.
- Cut down on wound healing time.
- Capiflo can assist in the treatment of chronic venous insufficiency and the reduction of edema in the lower limbs, venous stasis ulcers, arterial and diabetic leg ulcers, and stasis dermatitis.

## INDICATIONS FOR USE

Capiflow can be used in the treatments of the following conditions:

- Stasis Dermatitis
- Venous Stasis Ulcers
- Arterial and Diabetic Leg Ulcers
- Chronic Venous Insufficiency
- Reduction of Edema in the Lower Limbs

## CONTRAINDICATIONS

Capiflow must NOT be used to treat the following conditions:

- Persons with suspected, active or untreated:
  - Deep Vein Thrombosis (DVT)
  - Ischemic Vascular Disease
  - Severe Arteriosclerosis
  - Pulmonary Edema
  - Severe Congestive Heart Failure
  - Thrombophlebitis
  - Active Infections
- On the legs where cuffs would interfere with the following conditions:
  - Vein Ligation
  - Gangrene
  - Dermatitis
  - Open Wounds
  - Recent Skin Grafts
  - Massive Edema
  - Extreme Deformity of the Leg.
- Do NOT use on any neuropathy.
- Do NOT use on extremities that are insensitive to pain.
- Do NOT use where increased venous or lymphatic return is undesirable.

# INSTRUCTIONS FOR USE



## PLACE THE CAPIFLO:

- Place the unit on the calf wrapping the sleeve around the shin. Secure the unit with the Velcro straps. Ensure the fit is firm but not too tight.
- *Both units should be used simultaneously unless otherwise instructed by a medical professional.*



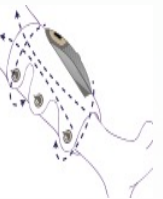
## TURN THE DEVICE ON:

- When the devices are secured on your legs, press and hold the power button for approximately 3 seconds until the red light is illuminated. *Each of the Capiflo cuffs operates independently and both need to be turned on.*
- When the Capiflo is turned on the default pressure is set to 55 mmHg.
- A second press of the power button will change the pressure to 50 mmHg.
- A third press of the power button will decrease the pressure to 40 mmHg.
- Notes regarding normal operation of the devices:
  - It is normal for the device to make a humming sound when inflating and applying pressure to your legs.
  - The wraps will inflate approximately one time per minute.
  - It is normal to feel air releasing around your legs. This a function of the Capiflo designed to help keep your legs cool during use.



## CONTROLS:

- The first series of numbers (left side) on the control module represents the cumulative run hours for the machine.
- The second series of numbers (right side) is the amount of pressure being applied by the machine measured in mmHg.



## CLEANING AND DISINFECTING:

Inspect the Capiflo unit and follow the cleaning and disinfecting procedures prior to each use. The Capiflo device must be powered off and disconnected from the wall outlet prior to and during cleaning or disinfecting

**DO NOT IMMERSIVE THE UNIT IN ANY LIQUID FOR ANY REASON**

- Clean the outer surface of the pump using a soft cloth moistened with soapy water or 70% isopropyl alcohol.
- Do not use harsh or abrasive cleaners.
- Do not place cuffs in the dryer. Air dry on a flat surface only.



# CHARGING THE BATTERY

## CHARGING:

- When the unit is turned off and the battery is charging the red light will be flashing. Once the battery is fully charged, the red light will remain solid, and the three green lights will be illuminated as well.

## USING THE AC ADAPTER/BATTERY CHARGER:

- With the unit powered off, insert the supplied power adapter into the port at the bottom end of the unit and connect the power supply plug to the wall socket.
- The RED charging indicator on the unit will illuminate or flash depending on the level of the battery charge.
- To fully charge the battery takes approximately 4 hours.
- When the unit is turned off and plugged in this means the battery is charging and the power button will flash red.
- Once the battery is fully charged the power button will stop flashing and remain illuminated in solid red with all three green lights illuminated as well.

## CHARGING WHILE POWERED ON:

- For extended operation periods or to charge the battery during treatment sessions, the AC adapter can be connected while the device is in use.
- The unit will be charging while in use.
- When the unit is powered on while connected to the charger the LED indicators will illuminate green.

## CHARGER:

- Only use the charger provided by K & L Distributors, Inc.
- Using the incorrect charger may cause excessive heat, damage to the charging circuit, and shorten the life of the battery.



# ALARM FUNCTIONS

## **ALARM: BATTERY CRITICAL**

If the battery voltage drops below the critical level the run cycle will stop, an audible alarm will sound, and the unit will flash yellow. The alarm will continue for 30 seconds and automatically turn the unit off unless it is manually powered off before the 30 seconds passes. The power supply should be plugged in immediately to charge the unit.

## **ALARM: LOW PRESSURE OR LEAK**

If the pressure limit is not reached within 30 seconds after the pump is activated the run cycle will stop, an audible alarm will sound, and the unit LEDs will flash blue. The alarm will continue for 30 seconds and automatically turn the unit off unless it is manually powered off before the 30 seconds passes. To troubleshoot this issue please turn the unit off, make sure the wrap is snugly attached to the leg, then turn the unit back on. If the alarm continues to sound after troubleshooting, do NOT try to fix the device. Please call customer service for a replacement unit at (813) 243-2222.

## **ALARM RESET:**

When the alarm sounds, normal operating functions of the device are inhibited for safety. When this occurs, the unit must be powered off manually or it will automatically power itself off within 30 seconds of the alarm sounding. Once the unit is powered on again, the alarm is reset.

## **USER MAINTENANCE:**

This unit does not have any serviceable parts. Contact K & L Distributors, Inc. Customer Service at (813) 243-2222 for assistance.

After receipt, inspect the unit including all components for damage that may have occurred during shipping. Examples of damage include frayed or cut charging cords, cracked housings, torn cuffs, etc. Refer to the image of the CapiFlo for a description of the components.

Do not plug into the power outlet if any damage is noticed. Be careful and do not damage the unit by dropping or stepping on it as this may cause damage to the pumps.

Stay away from sharp objects as they may puncture the leg cuffs. If the air bladder is punctured or leaks, do not attempt to repair. Call the customer service line and a replacement unit will be sent.

Do not fold or crease the air bladder during use or transportation. The battery is not replaceable. If there is a problem, replacement units are available through customer service. Contact K & L Distributors, Inc. to order your replacement.

## **STORAGE:**

Store in a dry location between 50 °F (10 °C) and 100 °F (40 °C), bathroom storage is not recommended. Do not store in temperatures above 150 °F (65 °C). Storing in direct sunlight can cause damage to the units. Do not store or transport the units in humidity that is greater than 60% or barometric pressure greater than 29.0.

## **DISPOSAL:**

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

The CapiFlo pump control units contain rechargeable batteries. Do not discard the pump unit in the trash.

## PRECAUTIONS AND WARNINGS:

- The CapiFlo cuffs are designed for single patient use only.
- Medical electrical equipment needs special precautions. Please read and understand all precautions regarding EMC.
- Portable and mobile RF communications equipment can be affected by other medical electrical devices.
- Cuffs should not be used in conjunction with heat packs or other warming devices as this may cause skin irritation.
- Regularly check patient for discomfort or skin irritation during use.
- To prevent extremity compartment syndrome, attention should be given to patients who are positioned in the supine lithotomy position for extended lengths of time.
- Do not open or remove covers. There are no user serviceable parts inside. Direct all unit issues to K & L Distributors, Inc.
- If any discomfort occurs, the cuff may be wrapped too tightly and should be loosened immediately.
- If swelling occurs, consult a physician.
- Device is to be used only by the patient as prescribed by a doctor and only for its intended use.
- Make sure the unit is turned off and unplugged prior to cleaning or disinfecting.
- Unit should not be used in the presence of any flammable anesthetic mixture with air, oxygen, or nitrous oxide.
- Do not immerse in any liquid.
- Do not operate in a wet environment.
- Allow unit to warm to room temperature if it is exposed to temperatures below 40 °F (4 °C)
- Do not expose unit to extreme shocks such as dropping or crushing the pump.
- The adapter plug is used as the isolation from the supply mains. When charging the battery, please do not position the device so that it is difficult to operate the disconnection device.
- This medical device may create electromagnetic interference. Do not operate around or at the same time as other electronic devices that may be subject to electromagnetic interference.
- To avoid electromagnetic interference, the device should be installed at the medical site which meets the requirement of EMC.
- Do NOT place any items in an autoclave.
- Operation of this device can be performed by the patient with proper instruction and training.
- Do not attempt to service while the device is in use.
- This device is NOT to be altered or modified.
- This device contains no user serviceable parts. If you have any issues, please contact K & L Distributors, Inc. customer service at (813) 243-2222.



Do not use accessories, other than those provided by CapiFlo. Power supplies and cables other than those specified, with the exception of components sold by the manufacturer of the CapiFlo as replacement parts, may result in defective operation of the CapiFlo.



Class II (2)

Class II medical electrical equipment.



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



This symbol designates the degree of protection against electrical shock from the wrap as being a type B applied part

**Please carefully read and follow all instructions for use.**

**This device is not waterproof. The CapiFlow is not suitable for use around flammable anesthetic mixtures with air, oxygen, or nitrous oxide. The rechargeable batteries supplied in this unit are not field replaceable. If you have any issues, please contact (813) 243-2222 for a replacement unit.**

# TECHNICAL DATA



## SPECIFICATIONS:

Base Unit:  
Dimensions: 2. 6" X 5. 2" (66 mm X 131 mm)  
Weight: Approx. 0. 5 lb. (0.227 kg)  
Mode of Operation: Cyclic  
Source of Power: 7.4 Volt Li-ion batter pack (consisting of two 3.7 Volt cells)

## CAUTION:

Charge batteries using only the power source provided by K & L Distributors, Inc.

## POWER SUPPLY:

Class II  
Model JZB012-050100UX  
Input: 100-240 Vac, 50-60 Hz  
Output: 7.4 Vdc @ 1.1 Amp  
Manufacturer: Shenzhen Jiuzhou Power Technology Co LTD  
*Only use UL/60601-1 approved power supplies from K & L Distributors, Inc. for use in a hospital setting.*

## OUTPUT:

Mode of Operation: Continuous

## SYSTEM OPERATING ENVIRONMENT:

Temperature: 50 °F (10 °C) and 104 °F (40 °C)  
Humidity: 30%-75%

## DEFAULT SETTINGS:

Leg Pressure 55mmHg (40mmHg and 50mmHg available by adjustment)  
Cycle time: 60 Seconds

## TOLERANCES:

Pressure: 5%

## BATTERY CHARGE:

Fully charges in approximately 4 hours.