Vascular Therapy System
(Compressible Limb Sleeve Device)

Customer Service
Toll Free: 888-508-0712
Email: CustomerService@manamed.net
Web: www.manamed.net
1511 W. Alton Ave, Santa Ana, CA 92704

Manufactured For:
CONTRAINdications

The PlasmaFlow 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, severe congestive heart failure, thrombophlebitis or an active infection;
- 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; on patients with neuropathy; on extremities that are insensitive to pain; where increased venous or lymphatic return is undesirable.

DEFAULT SETTINGs:

- Leg Pressure (not adjustable) 55mmHg
- Cycle time: 60 Seconds
- Mode One: Slow inflation
- Mode Two: Step up technology

Tolerances:

- Pressure 5%

BATTERY CHARGE:

- Takes approximately 3 hours (from depleted state).

BATTERY RUN TIME:

- 7 to 9 hours
QUICK START

1. CALF CUFF APPLICATION
   Wrap the cuff around the calf and secure the Velcro to hold it in place. Make sure the wrap is snug, but not too tight.

2. TURNING THE DEVICE ON
   When the wraps are secured on your legs, press the power button for three seconds until the blue light is illuminated on each unit.

3. INSTRUCTIONS
   **POWER OFF:** Push and hold the Power Button for three seconds and it will turn off.
   **POWER ON:** Press the Power Button for three seconds. The unit powers up with BLUE LED illuminated (RED can be illuminated if battery voltage is low). The unit will be in the first working mode. After a delay, the pumps will allow inflation of the attached wraps to a pre-determined pressure of 55 mmHg. Once the pressure reaches the proper level, the pumps will turn OFF for a 50 second “rest” period.
   **SWITCH MODES:** In order to operate the PlasmaFlow unit in “Mode 2”, simply tap the Power Button once while the unit is powered on. The screen on the left side of the Power Button will display “0”, and the screen on the right side of the Power Button will display “F2”. The unit will start operating in “Mode 2” after a 10-second pause. To switch the PlasmaFlow unit back to “Mode 1”, simply tap the Power Button once.
   
   **Mode 1: Slow Inflation:** Pressure will inflate to 55 mmHg and deflate.
   **Mode 2: Step up Technology:** The PlasmaFlow unit’s pressure will increase at 10 mmHg with a pause at every increment. Once the unit reaches 55 mmHg, it will deflate in the same descending increments.

4. PATIENT DEVICE USE
   Unit will inflate and deflate to the specified mode as directed by your physician.

5. SWITCH MODES
   For instructions on how to switch between modes, please refer to “Instructions” section on this page.

UNIT DESCRIPTION

- Charging Port
- LED Indicator
- Battery Indicator
- Alarm Indicator
- Mode & Timer
- Power Button
- Air Pressure
- Pressure Indicator

BATTERY INDICATOR
In order to properly indicate the state of the battery and charger, there are TWO stages of the BATTERY INDICATOR as follows:

**BLUE:** When unit power is ON and fully operational. Also indicates full charge.

**RED:** When the battery voltage becomes low during the pumping time and rest period. When the light is red, the battery charger must be connected immediately to avoid any interruption.

TIMER INDICATOR
When the PlasmaFlow unit is in use, the screen on the left side of the Power Button operates as a Timer. The screen will display digit “1” for one hour of working time, digit “2” for two hours of working time, etc. When the timer reaches number “99”, it will automatically restart the count from “0” (zero). When PlasmaFlow is not in use, it saves the previously accumulated working time (up to 99 hours). When the power is back on, the Timer will continue the count from the previously saved number.

PRESSURE INDICATOR
When the PlasmaFlow unit is in use, the screen on the right side of the Power Button operates as a Pressure Indicator. As the unit inflates, the numerical digits increase to display the pressure of the PlasmaFlow unit. As the unit deflates, the numerical digits decrease.
WARNINGS AND PRECAUTIONS

WARNINGS

Contact ManaMed™ Customer Service at 888-508-0712 for any questions or to request a replacement.

Do not attempt to repair the device. Do not attempt to open or remove covers.

Do not remove the pump unit from the cuff. Do not attempt to modify or change the device. NEVER attempt any service while the device is in use.

PlasmaFlow™ is a Medical Electrical Device. The following are precautions specific to Medical Electronic Devices:

- Do not operate in a wet environment.
- Do not immerse in any liquid for any reason. For cleaning and disinfecting instructions refer to “Cleaning and Disinfecting” section.
- Do not place the device in autoclave for any reason.
- Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- If exposed to temperatures below 10C (50F) allow the device to warm up to room temperature.
- Do not subject the device to extreme shocks, such as dropping the pump.
- Portable and mobile Radio Frequency Communication Equipment can be affected by Medical Electrical Devices.

CAUTIONS

This device is to be sold by or on the order of the physician.

Operation of the device can be done by the patient.

The PlasmaFlow cuffs are designed for single patient use. The device must be ONLY used for its intended use by the patient prescribed. The device must not be transferred to another patient.

Stop using device if swelling, skin irritation or any other unpleasant or painful sensation occurs and consult a Physician.

Loosen cuffs immediately if pulsation or throbbing occurs as the cuffs may be wrapped too tightly.

Patients with diabetes or vascular disease require frequent skin assessment. Consult a Physician.

Patients who use warming devices in combination with cuffs require frequent assessment as skin irritation may occur. Consult a Physician.

Patients positioned in the supine lithotomy position (with or without cuffs) for an extended period of time require special attention to avoid extremity compartment syndrome. Consult a Physician.

CLEANING AND DISINFECTING

NOTE: Inspect the device 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 during cleaning or disinfecting.

WARNING: DO NOT IMMERSE DEVICE IN ANY LIQUID FOR ANY REASON. DO NOT PLACE DEVICE IN AUTOCLAVE.

Clean the outer surface of the pump unit using a soft cloth, moistened with soapy water or 70% isopropyl alcohol. Air dry only.

Clean the exterior of the cuffs using a soft cloth, moistened with soapy water or 70% isopropyl alcohol. Air dry.

USING THE AC ADAPTER / BATTERY CHARGER

WARNING: Use only the charger provided by ManaMed™. The use of the wrong charger can cause excessive heat, damage to the circuit and shorten the life of the battery.

WHEN DEVICE IS OFF: Plug in the power supply adapter to the wall socket using the plug located at the bottom end of the device. The RED “Charging” LED indicator (located above the Power Button) on the device will illuminate or flash, depending of the state of the charge. When the battery is charging, the LED indicator will be RED. Once the battery if fully charged, the LED indicator will be solid BLUE.

WHEN DEVICE IS ON: The AC adapter can be connected while the device is in use. Whenever the device is ON and the charger is connected and plugged in to the wall socket, the LED indicator on the device will show BLUE.

ALARMS

‘Battery Critical’ – LED indicator located on the device will turn RED if the battery charge drops below critical level. In addition, the cycling will stop and the alarm sound will go on for 10 seconds (unless unit is powered OFF). The device will turn off automatically. Plug in power supply immediately to charge the battery. The device can be used while the battery is charging (see ‘Using the AC Adapter / Battery Charger’ section).

‘Low Pressure or Leak’ – When the device is in use, LED indicator located on the device will flash red, blue, red blue and error code “E 1” will become visible if pressure limit is not reached within 30 seconds. In addition, the cycling will stop and the alarm sound will go on for 10 seconds (unless unit is powered OFF). The device will turn off automatically. Make sure cuff is attached tightly to the leg. Turn the device OFF, and then back ON. If the device continues to alarm after this step, call ManaMed™ Customer Service at 888-508-0712 for a replacement unit. DO NOT ATTEMPT TO FIX THE DEVICE.

Unit must be completely dry prior to use. To ensure that, leave the device in the OFF position and disconnected from the wall outlet for at least 30 minutes (and as long as necessary for the unit to dry completely) after cleaning or disinfecting.

- Do not remove the pump unit from the cuff.
- Do not place cuffs in dryer or microwave.
- Do not use hair dryer to accelerate drying.
- Do not place the device on top of or in front of portable or stationary radiators to accelerate drying.
- Do not use abrasive cleaners.
### Guidance and Manufacturer’s Declaration - Electromagnetic Emissions

The PlasmaFlow is intended for use in the electromagnetic environment specified below. The customer or the user of the PlasmaFlow should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emissions Tests</th>
<th>Compliance</th>
<th>Electromagnetic Environment Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emissions CISPR11</td>
<td>Group I</td>
<td>The PlasmaFlow uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td>
</tr>
<tr>
<td>RF Emissions CISPR11</td>
<td>Class B</td>
<td>The PlasmaFlow is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td>
</tr>
<tr>
<td>Harmonic Emissions</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voltage Fluctuations</td>
<td>Complies</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Guidance and Manufacturer’s Declaration - Electromagnetic Immunity

The PlasmaFlow is intended for use in the electromagnetic environment specified below. The customer or the user of the PlasmaFlow should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic Discharge (ESD)</td>
<td>±8kV contact</td>
<td>±8kV contact</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>IEC 61000-4-2</td>
<td>±15kV air</td>
<td>±15kV air</td>
<td></td>
</tr>
<tr>
<td>Electrical Fast Transient/Burst</td>
<td>±2kV for power supply lines</td>
<td>±2kV for power supply lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC61000-4-4</td>
<td>±1kV for input/output lines</td>
<td>±1kV for input/output lines</td>
<td></td>
</tr>
<tr>
<td>Surge</td>
<td>±1kV differential mode</td>
<td>±1kV differential mode</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC61000-4-5</td>
<td>±2kV common mode</td>
<td>±2kV common mode</td>
<td></td>
</tr>
<tr>
<td>Voltage dips, short interruptions and</td>
<td>&lt;5%Uₗ (&lt;95% dip in Uₗ) for 0.5 cycle</td>
<td>&lt;5%Uₗ (&lt;95% dip in Uₗ) for 0.5 cycle</td>
<td>Mains power quality should be that of a typical commercial or hospital environment. If the user of the PlasmaFlow requires continued operation during power mains interruptions, it is recommended that the PlasmaFlow be powered from an uninterrupted power supply or a battery.</td>
</tr>
<tr>
<td>voltage variations on power supply</td>
<td>40%Uₗ (60% dip in Uₗ) for 5 cycles</td>
<td>40%Uₗ (60% dip in Uₗ) for 5 cycles</td>
<td></td>
</tr>
<tr>
<td>input lines</td>
<td>70%Uₗ (30% dip in Uₗ) for 25 cycles</td>
<td>70%Uₗ (30% dip in Uₗ) for 25 cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt;5%Uₗ (&lt;95% dip in Uₗ) for 5 seconds</td>
<td>&lt;5%Uₗ (&lt;95% dip in Uₗ) for 5 seconds</td>
<td></td>
</tr>
<tr>
<td>Power Frequency (50/60Hz) Magnetic</td>
<td>30 A/m at 50 or 60 Hz</td>
<td>30 A/m at 50 or 60 Hz</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Fields</td>
<td>IEC61000-4-8</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**NOTE:** Uₗ is the a.c mains voltage prior to application of the test level.
ELECTROMAGNETIC COMPATIBILITY (EMC)
TABLES - RF EMISSIONS CLASS B

GUIDANCE AND MANUFACTURER’S DECLARATION – ELECTROMAGNETIC IMMUNITY

The PlasmaFlow is intended for use in the electromagnetic environment specified below.
The customer or the user of the PlasmaFlow should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment Guidance</th>
</tr>
</thead>
</table>
| Conducted RF  | IEC61000-4-6         | 3Vrms            | Portable and mobile RF communications equipment should be used no closer to any part of the PlasmaFlow, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
|               | 150 kHz to 80 MHz    | 3Vrms            | d = 1.2 √P 150 kHz to 80 MHz
|               |                      |                  | d = .35 √P 80 MHz to 800 MHz
|               |                      |                  | d = .70 √P 800 MHz to 2.5 GHz
|               |                      |                  | where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
|               |                      |                  | Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.
|               |                      |                  | Interference may occur in the vicinity of equipment marked with the following symbol: |
| Radiated RF   | IEC61000-4-3         | 3 V/m            | 10 V/m
|               | 80 MHz to 2.5 GHz    |                  | NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
|               |                      |                  | NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

RECOMMENDED SEPARATION DISTANCE BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE PLASMAFLOW

The PlasmaFlow is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PlasmaFlow can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PlasmaFlow as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter W</th>
<th>150 kHz to 80 MHz</th>
<th>80 MHz to 800 MHz</th>
<th>800 MHz to 2.5 GHz</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.01</td>
<td>0.12</td>
<td>0.12</td>
<td>0.23</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
<td>0.38</td>
<td>0.73</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
<td>1.2</td>
<td>2.3</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
<td>3.8</td>
<td>7.3</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
<td>12</td>
<td>23</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.