USER GUIDE

Scan QR Code to watch Instructions for Use

MANAMED

PlasmaFlow™

Vascular Therapy System

(Compressible Limb Sleeve Device)

PlasmaFlow™

Do not use this product before reading this manual. If you have any questions, please call your physician or ManaMed Customer Service at 888-508-0712.
To learn more about ManaMed, visit www.manamed.com

MANAMED®

PlasmaFlow Label Symbol Descriptions

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

Designates Class II medical electrical equipment.

This unit is an electromechanical device that includes printed circuit boards and rechargeable batteries. Do not discard in landfill. Consult local county 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.

Consult instructions for use.

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

Caution

Federal Law (U.S.A.) restricts this device to sale, distribution or use by or on the order of a physician or properly licensed practitioner. PlasmaFlow is only intended for the use by the individual for whom it was prescribed. The device is ONLY for single patient use.

THIS DEVICE IS NON-STERILE
PlasmaFlow does not require sterilization before use.

Technical Data

Device Box Components
PlasmaFlow Take-Home DVT Device (2)
PlasmaFlow Charger

Power Supply
Class II Input: 100 – 240 Vac, 50-60 Hz. Output: 5 V at 1 Amp
Use only UL/60601-1 approved power supplies
from ManaMed for use in hospital settings.
Output: Mode of Operation Continuous

Specifications
Dimension: 23’ x 10.25” x 1.5’ (58cm x 26cm x 4 cm)
Weight: Approximately 1.43 lb (.65 kg)
Modes of Operation: Mode 1 and Mode 2
Source of Power: DC 5 V or Inner Battery
(3.7volt Lithium-Ion Battery)

System Operating Environment:
Temperature: 50oF (10oC) and 104oF (40oC)
Humidity: 30%-75%. Keep dry.

Default Settings
Leg Pressure (not adjustable): 55mmHg
Cycle time: 60 Seconds
Mode One: Slow Inflation
Mode Two: Set Up Technology

Tolerance
Pressure 5%

PlasmaFlow Labeling Information

Indications for Use

PlasmaFlow model PF0001 is intended to be an easy-to-use portable system, prescribed by a physician, for use in the home or in a clinical setting to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (simulating muscle contractions). This device 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 and healing of stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in the lower limbs.
- The unit can also be used as an aid in the prophylaxis for DVT by persons expecting to be stationary for long periods of time.

Contraindications

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 the 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.
- On patients with neuropathy.
- On extremities that are insensitive to pain.
- Where increased venous or lymphatic return is undesirable.

Warnings

Do not attempt to repair the device or 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 50oF (10oC), 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 b affected by Medical Electrical Devices.

Cautions

The 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 the device if swelling, skin irritation or any other unpleasant or painful sensation occurs. Consult your 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 your physician. Patients who use warming devices in combination with cuffs require frequent assessment as skin irritation may occur. Consult your 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 system. Consult your physician.

PlasmaFlow Overview

Purpose and Description of PlasmaFlow - What is DVT?
Deep vein thrombosis (DVT) occurs when a blood clot (thrombus) forms in one or more of the deep veins in your body, usually in the legs. This can cause pain or swelling.
Causes of DVT:

- Certain blood clotting medical conditions.
- Immobility for extended periods of time.
- Damage to a vein from surgery or trauma.
- Inflammation due to infection or injury.

The purpose of the PlasmaFlow™ is to aid in the prevention of DVT. The device stimulates blood flow within the legs with an electrically- controlled pump that delivers a set amount of air to the leg cuffs. The air compresses the calf or calves to aid blow flow out of the lower extremities.

The pump will inflate each leg cuff to a pre-set pressure of 55mmHG and deflate once that pressure is reached. These cycles are repeated on each unit until the power is turned off. The internal, rechargeable batteries allow the PlasmaFlow to be completely portable, thus preventing interruptions in treatment.

PlasmaFlow System Features and Components

Two portable, tubeless and lightweight cuffs:
Each cuff features a house control unit that contains a Power Button, Charging Port and an LCD Screen to monitor patient usage and device air pressure. The control units are not removeable from PlasmaFlow.

Each house control unit contains a battery and internal electronics to ensure the pump is inflating and delivering air to the leg cuffs.

PlasmaFlow control unit displays the mode, timer, and air pressure of the device while turned on. Refer to "Getting Started" section on page 4.

The house control on each cuff has a charging port to charge the device. PlasmaFlow will not communicate with other electrical devices.

Battery and Charger:

Battery Run Time: 7 to 9 hours.

PlasmaFlow is powered by a rechargeable battery. The charger is included with PlasmaFlow upon receiving the device box.

CAUTION: Only use the charger that was supplied by ManaMed. Do not plug other chargers into PlasmaFlow as it may damage the device or charger.

The port plug end of the cord plugs into the charging port on the housing unit on the PlasmaFlow device and the other end plugs into an electrical wall outlet.

Battery Charge Time: Takes approximately 3 hours to charge (from depleted state).
Read more about the battery and how to charge PlasmaFlow in the "Getting Started" section on page 4.

Getting Started

Charging PlasmaFlow

PlasmaFlow has a rechargeable lithium-ion battery that provides approximately 7-9 hours of treatment before needing to be recharged. It takes approximately 3 hours to charge from depleted state. To ensure PlasmaFlow is functioning properly, the device monitors battery voltage and electrical signal. Important: Charge both device cuffs before first use.

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 on the bottom end of the device. The RED "Charging" LED indicator (located above the Power Button) on the device will illuminate or flash, depending on the state of the charge. When the battery is charging, the LED indicator will be RED. Once the battery is fully charged, the LED indicator will be solid BLUE.

When Device is ON: The AC Adaptor can be connected while the device is in use. Plug the charger into the bottom of the controller on the device. Plug the end of the charger into an electrical wall outlet.

1. Find the charger port on the PlasmaFlow device.

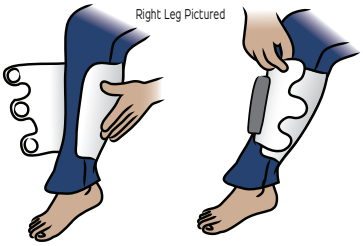
2. Plug the charger into the charging port on the PlasmaFlow device. Plug the power supply end of the charger into an electrical wall outlet.

3. The charging LED indicator will illuminate RED when the battery is charging. When the batter is fully charged, the indicator will be BLUE.

4. If the device is on and charging, the LED indicator on the device will be BLUE.

Quick Start Instructions for Wearing and Operating PlasmaFlow

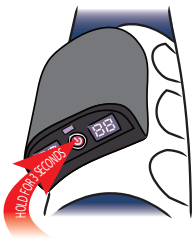
Step 1



Step 1: Calf Cuff Application

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

Step 2



Step 2: Turning the Device On

When the cuffs are secured on your each of your calves, press the Power Button for three seconds until the blue light is illuminated on each unit. The unit will be in the first working mode.

Step 3

Step 3: Starting Treatment

After a couple seconds, pumps inside the unit will cause the cuff sleeves to inflate to a pre-set pressure of 55 mmHG. Once the pressure reaches the proper level, the pumps will turn OFF for a 50 second 'rest' period.

The unit will inflate and deflate to the specified mode as directed by your physician. For instructions on how to switch between modes, refer to the "Switching Modes" section on page 5.

Switching Modes

The PlamsaFlow unit is pre-set to "Mode 1." Only switch to "Mode 2" if instructed by your physician.

In order to operate the PlasmaFLow unit in "Mode 2", tap the Power Button once while the unit is powered on. The screen on the left side of the Power Button will display "O" 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 1

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

Mode 2

PlasmaFlow Use and Care

Contains no serviceable parts. 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 charging cord, cracked plastic housing unit, torn cuffs, etc). Refer to image of PlasmaFlow for description of the system components. Do not attempt to connect the wall supply if any damage is noticed. Avoid subjecting the unit to shocks such as dropping the pumps. Do not handle leg cuffs with any sharp objects. If a bladder is puncture or you notice a leak, do not attempt to repair the unit or cuffs. Replacement units are available by contacting customer service. Avoid folding or creasing the bladder during use and transportation of the unit. Battery is not replaceable. Replaceable units are available by contacting customer service.

WARNING: This device is not protected against water. Equipment not suitable for use in the presence of flammable anesthetic mixture with air, oxygen, or nitroux oxide. Contact ManaMed Customer Service at 888-508-0712 to receive replacement instructions for any damaged items.

Operating Conditions
Temperature: 50°F (10°C) and 104°F (40°C).
Humidity: 30%-75%. Keep dry.
If PlasmaFlow is stored or transported in temperatures and humidity outside of this range, allow the device time to come to room temperature.

Storage
Store in a dry location between 50°F (10°C) and 104°F (40°C).
Do not expose to heat exceeding 122°F (50°C) for extended periods of time.
Do not store items in direct sunlight.

Cleaning and Disinfecting

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

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

DO NOT IMMERSE DEVICE IN ANY LIQUID. 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 only.

Unit must be completely dry prior to use. To ensure unit is completely dry, 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 the dryer or microwave.
- Do not use a 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 cleans.

Battery and Charging Safety

Battery

Do not attempt to replace the lithium-ion battery.

Do not attempt to replace the battery with non-approved batteries. Incorrect replacement of batteries could result in damage to the device. The battery should only be replaced by ManaMed.
Be sure to only use the USB battery charger (Part Number PFCHG) provided with the system. Other chargers may cause the battery to overheat and damage the battery, PlasmaFlow or the user.
Do not use an extension cord with the battery charger as it may cause overheating.
Do not use the battery charger with other devices as it may cause damage to the device or battery charger.
If the battery area on the PlasmaFlow system becomes overheated, discontinue using and contact ManaMed Customer Service at 888-508-0712.

Charging

Important: Charge both devices before first use.
The battery will charge whether PlasmaFlow is turned on or off.
If the battery power decreases quickly even after recharging for four or more hours, contact Customer Service.

Do not recharge the battery in any of the following locations:

- Where the temperature is below 50°F (10°C) or above 104°F (40°C).
- Anywhere near water.
- Outdoors.
- Within reach of small children.
- Any areas where people could walk on the charger cable or trip over the charger cable.

Disposal

PlasmaFlow is an electromechanical device that includes printed circuit boards and rechargeable batteries. Do not discard in landfill. For details on how to dispose of PlasmaFlow correctly, consult local requirements for proper disposal instructions. Pump control units contain rechargeable batteries. Do not discard the pump in regular waste. Bring the unit to your local recycle center or contact ManaMed Customer Service at 888-508-0712.
Warning: Do not throw any part of PlasmaFlow into fire.

Alerts and Alarms

E1-Low Battery: When the device is in use and error code "EI" appears, it means the battery is low. Charge the device for a full 4 hours before resuming use.

"Low Pressure or Leak": EI may also appear if the pressure limit is not reached within 80 seconds. The cycling will stop and the alarm will sound for 10 seconds (unless unit is powered off). Turn the device OFF and then back ON. If the device continues to alarm after this step, plug both devices into the wall for a full four hours and resume use after charge.

E2-"Battery Critical" Alarm: When the code "E2" appears on the device, the device must be plugged in and charged. You can continue to use the device if it is plugged in and charging. If the device continues to alarm, call ManaMed Customer Service at 888-508-0712. DO NOT ATTEMPT TO FIX THE DEVICE.

Limited Warranty

ManaMed, Inc warrants to the original purchaser of its PlasmaFlow Vascular Therapy System purchased by the purchaser directly from ManaMed, Inc that the PlasmaFlow System conforms to ManaMed, Inc's manufacturing specifications. This warranty will be in effect for a period of 120 days from the date of purchase.

In the event of a material breach of this warranty, upon timely written notice, ManaMed, Inc will either repair or replace the PlasmaFlow Vascular Therapy System or refund the original purchase price. This will constitute the Purchaser's sole remedy. This limited warranty does not extend to any resale or other transfer of the PlasmaFlow System by Purchaser to any other person or entity.

MANAMED, INC EXPRESSLY DISCLAIMS ANY AND ALL OTHER WARRANTIES, EITHER EXPRESSED OR IMPLIED, RELATING TO THE SYSTEM OR ITS PERFORMANCE, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY AND ANY IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE.

Customer Service

Manamed is available to answer any questions regarding the use of the PlasmaFlow System.
To contact Customer Service:
Call: 888-508-0712 (toll free) or
E-mail: CustomerService@ManaMed.Net

For General Information: Visit www.ManaMed.Net

Mail: ManaMed PlasmaFlow Customer Service
5240 W Charleston Blvd., Las Vegas, NV 89146

PlasmaFlow™

Compliance Statements & Declarations Electromagnetic Compatibility (EMC) Tables

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.		
Emissions Tests	**Compliance**	**Electromagnetic Environment Guidance**
RF Emissions CISPR11	Group 1	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.
RF Emissions CISPR11	Class B	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.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations IEC 61000-3-3	Complies	

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.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±8kV contact ±15kV air	±8kV contact ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC61000-4-4	±2kV for power supply lines ±1kV for input/ output lines	±2kV for power supply lines ±1kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5%UT (>95% dip in UT) for 0.5 cycle 40%UT (60% dip in UT) for 5 cycles 70%UT (30% dip in UT) for 25 cycles <5%UT (>95% dip in UT) for 5 seconds	<5%UT (>95% dip in UT) for 0.5 cycle 40%UT (60% dip in UT) for 5 cycles 70%UT (30% dip in UT) for 25 cycles <5%UT (>95% dip in UT) for 5 seconds	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.
Power Frequency (50/60Hz) Magnetic Fields IEC61000-4-8	30 A/m at 50 or 60 Hz	30 A/m at 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c mains voltage prior to application of the test level.			

Compliance Statements & Declarations Electromagnetic Compatibility (EMC) Tables

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.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC61000-4-6	3Vrms 150 kHz to 80 MHz	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 $d = 1.2\sqrt{P}$ 150 KHz to 80 MHz $d = .35\sqrt{P}$ 80 MHz to 800 MHz $d = .70\sqrt{P}$ 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[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	

NOTE 1: At 80 MHz and 800 MHz, 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.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to the fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PlasmaFlow is used exceeds the applicable RF compliance level above, the PlasmaFlow should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PlasmaFlow.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

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.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 KHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = .35\sqrt{P}$	800 MHz to 2.5 GHz $d = .70\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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.

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PlasmaFlow™

Scan QR Code to watch
Instructions for Use

Manufactured By:

MANAMED®

5240 W Charleston Blvd.,
Las Vegas, NV 89146

888-508-0712 (toll free)
CustomerService@manamed.net
www.manamed.com