PlasmaWave™

INSTRUCTIONS FOR YOUR NEW PLASMAWAVE

Vascular Therapy System
(Compressible Limb Sleeve Device)

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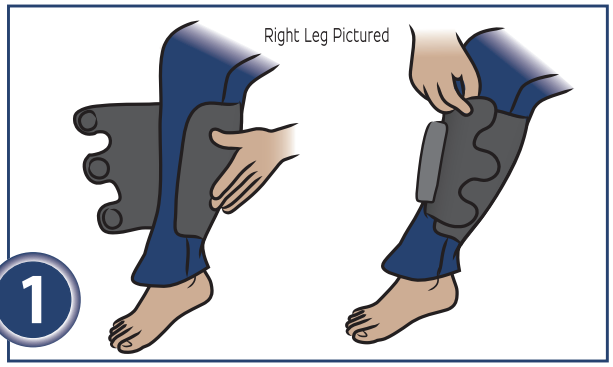
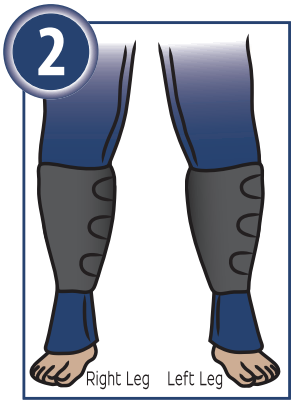
QUICK START



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.



When both wraps are secured on your legs, they should look like the picture above.

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.

PATIENT DEVICE USE

Unit will inflate and deflate to the specified mode as directed by your physician.

UNIT DESCRIPTION

INSTRUCTIONS

POWER ON: Power On: Press the Power Button for three seconds. The unit powers up with a battery indicator, three-digit usage meter, and the default mode.

Start Treatment: Before the device is powered on, make sure that both calf sleeves are plugged into the bottom of the unit and properly fit around the calf. The wraps begin to inflate 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. To enter a different mode, tap the M button to cycle to the next mode.

Power Off: Push and hold the Power button for three seconds, it will turn off.

Switch Modes: In order to operate the PlasmaWave unit in a different mode, simply tap the M button. The LCD will alert the user that the mode has been switched. Default mode is 1. Mode is determined by your prescribing physician.

Mode 1: Slow Inflation: Pressure will inflate to 55 mmHg and deflate. A one minute pause between cycles.

Mode 2: "Step Up Technology": The PlasmaWave unt's pressure will increase at 10 mmHg with a pause at ever increment. Once the unit reaches 55 mmHg, it will deflate.

Mode 3: "Quick Cycle Inflation": Inflation to 55 mmHg over 10 seconds and then deflate. No pause between cycles.

Mode 4: "5 Second Hold": Inflation to 55 mmHg with a five second hold. One minute between cycles.

BATTERY INDICATORS

In order to properly indicate the state of the battery and charger, there are two primary indicators.

LCD Screen: In the top left a battery icon shows the level of charge. When charging this icon moves from right to left.

Charging light indicator: light will illuminate when receiving a charge.

Charging Time: The device may take approximately 4 hours to fully charge.

Battery Life: The device is capable of running over 24 hours when not plugged in. Fully charge device before contacting your supplier.

DIGITAL NUMERIC DISPLAYS

Timer Indicator: Timer Indicator: When the PlasmaWave unit is in use, the timing display section of the LCD screen indicates hours of working time. The screen will display 001 for one hour of working time.

Pressure Indicator: When the PlasmaWave unit is in use, the Pressure section of the LCD screen indicates the pressure of the sleeve. If the number fluctuates, this is normal and part of the settings.

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USER MAINTENANCE

Contains no serviceable parts. Contact ManaMed Customer Service at 888-508-0712.

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 housings, torn cuffs, etc). Refer to image of PlasmaWave 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 pumps.

Do not handle the leg cuffs with any sharp objects. If a bladder is punctured or you notice a leak, do not attempt to repair the unit or cuffs. Replacement units are available through customer service.

Avoid folding or creasing the bladder during use and transportation of the unit.

Battery is not replaceable; replacement units are available through customer service.

Contact ManaMed to receive replacements instructions for any damaged items.

STORAGE

Store in a dry location between +10°C (50°F) and +40°C (104°F).

Do not expose to heat exceeding 50°C (122°F) for extended periods of time.

Do not store items in direct sunlight.

DISPOSAL

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.

Pump control units contain rechargeable batteries. Do not discard the pump unit in regular waste. Bring the unit to your local recycle center or contact ManaMed.

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

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 BF applied part.

Consult instructions for use.

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

WARNING: This device is not protected against water. Equipment is not suitable for use in the presence of flammable anesthetic mixture with air, oxygen, or nitrous oxide. The rechargeable batteries supplied in this unit are not field replaceable. If you have any issues please contact 888-508-0712. for a replacement unit.

PURPOSE OF DEVICE

The purpose of the PlasmaWave™ 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 delivering a set amount of air to the leg cuffs that, in turn, compress the calf or calves to aid blood flow out of the lower extremities.

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

INDICATIONS FOR USE

The PlasmaWave is intended to be an easy to use portable system, prescribed by a physician, for use in the home or 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

The PlasmaWave 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.

TECHNICAL DATA

Specifications:

Dimensions: 8.7" x 2.75" x 2" (221mm x 70mm x 48.3mm)
Weight: Approx. .62 lb (280g)
Modes of Operation: Mode 1, Mode 2, Mode 3, Mode 4
Source of Power: 100-240VAC, 50-60Hz

CAUTION: Charge batteries using only the power source provided by ManaMed.

POWER SUPPLY:

Class II, input: 100 - 240 Vac, 50 - 60 Hz, output: 12 V @ 2 Amp)
Use only UL/60601-1 approved power supplies from ManaMed for use in hospital settings.

Output:

Mode of Operation: Continuous

SYSTEM OPERATING ENVIRONMENT:

Temperature: +10°C (50°F) to +40°C (104°F)
Humidity: 30%-75%. Keep dry.

DEFAULT SETTINGS:

Leg Pressure (not adjustable) 55mmHg Cycle time: 60 Seconds
Mode 1: Slow inflation to peak, keep 10 secs then deflation.
Mode 2: Step up technology.
Mode 3: Quick inflation and deflation.
Mode 4: Slow inflation to peak, keep 5 seconds then deflation.

TOLERANCES:

Pressure 10%.

BATTERY CHARGE:

Takes approximately 4 hours

BATTERY RUN TIME:

24 hours

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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.

PlasmaWave™ 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 PlasmaWave 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.

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

Low Battery: When the device is in a battery critical state, the unit will illuminate the alarm light and notify the user with a buzzer sound. Device will turn off automatically.

Low Pressure or Leak: When the product detects an air leak, the alarm light will indicate it with a buzzer. Device will turn off automatically.

Troubleshoot Alarms: Before contacting customer service or your supplier, charge the device for a full period of 4 hours before resuming use. If the unit continues to alarm, call your supplier or ManaMed Customer Service at 888-508-0712.

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.

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.

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ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES - RF EMISSIONS CLASS B

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS		
The PlasmaWave is intended for use in the electromagnetic environment specified below. The customer or the user of the PlasmaWave should assure that it is used in such an environment.		
Emissions Tests	**Compliance**	**Electromagnetic Environment Guidance**
RF Emissions CISPR11	Group 1	The PlasmaWave 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 PlasmaWave 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 PlasmaWave is intended for use in the electromagnetic environment specified below. The customer or the user of the PlasmaWave 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%U_T (>95% dip in U_T) for 0.5 cycle 40%U_T (60% dip in U_T) for 5 cycles 70%U_T (30% dip in U_T) for 25 cycles <5%U_T (>95% dip in U_T) for 5 seconds	<5%U_T (>95% dip in U_T) for 0.5 cycle 40%U_T (60% dip in U_T) for 5 cycles 70%U_T (30% dip in U_T) for 25 cycles <5%U_T (>95% dip in U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the PlasmaWave requires continued operation during power mains interruptions, it is recommended that the PlasmaWave 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: U_T is the a.c mains voltage prior to application of the test level.			

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ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES - RF EMISSIONS CLASS B (continued)

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY

The PlasmaWave is intended for use in the electromagnetic environment specified below.
The customer or the user of the PlasmaWave 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 PlasmaWave, 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 PlasmaWave is used exceeds the applicable RF compliance level above, the PlasmaWave should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PlasmaWave.

[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 PlasmaWave

The PlasmaWave is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PlasmaWave can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PlasmaWave 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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