DESIGN PHILOSOPHY

Pneumatic compression is a clinically proven modality for reducing the risks associated with deep vein thrombosis[1]. The Defender Vascular Therapy System is a self-contained, compact DVT therapy device that is tubeless, portable, lightweight, and battery-operated. Due to Defender's portability, with no separate pumps and hoses, patients can use it at all times, ensuring maximum mobility during any phase of care. Additionally, Defender incorporates asymmetric compression for the superior emptying of veins[2] that consists of an intermittent pneumatic compression device with sequential, asymmetrical, gradient, graduated compression distal to proximal, duplicating the blood flow of an ambulating patient. Defender provides potentially life-saving mechanical DVT prophylaxis to patients with a continuum of DVT preventative care in the pre-, intra-, and post-surgery phases, expertly designed to provide increased compliance with breathable cuffs that enhance patient experiences.

PURPOSE OF THIS DEVICE

The purpose of the Defender is to aid in the prevention of 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 preset pressure of 55 mmHg and deflate once the pressure is reached. The cycles are repeated on each device until the power is turned off. Internal rechargeable batteries allow the Defender to be completely portable, thus preventing interruptions in treatment.

Indications for Use

The Defender Vascular Therapy System, model 08-0028, 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 of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency, and reduction of edema in the lower limbs.
- As prophylaxis for Deep Vein Thrombosis (DVT) by persons expecting to be stationary for long periods of time.

CONTRAINDICATIONS

The Defender Vascular Therapy System 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 the legs 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 any neuropathy
- On extremities that are insensitive to pain
- Where increased venous or lymphatic return is undesirable

USER MAINTENANCE

Contains no serviceable parts. Contact Precision Medical Products Customer Service at (800) 604-2487

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 Defender for description of all components.

Do not attempt to connect the wall supply if any damage is noticed.

Avoid subjecting the units 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 units.

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

Contact Precision Medical Products to receive replacements instructions for any damaged items.

STORAGE

Store in a dry location between -25°C (-13°F) and +70°C (158°F).

Do not expose to heat exceeding +70°C (158°F).

Prescription only

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

Class II medical electrical equipment

This unit is a electromechanical device that includes printed circuit boards and rechargeable batteries. Do not discard in 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 BF applied part.

Follow the instructions for use.

MR Unsafe

Single Patient

Not manufactured with natural rubber latex.

Store in a dry location within this temperature range.

Non Sterile

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 (800) 604-2487 for a replacement unit.

1. *Labropoulos N, OH D.S, Golts, E, et al.: Improved Venous Return By Elliptical, Sequential and Seamless Air-cell Compression. Loyola University Medical Center, January 2003.*

2. *Kamm R: Unsteady Venous Blood Flow Resulting From Different Modes of External Compression Cambridge, MIT, 1996*

TECHNICAL DATA

Specifications:

Main Unit:
Dimensions: 5.17" X 2.6" X 1.48" (125 X 62.5 X 33.3mm)
Weight: Approx. 0.74 lb (335g)
Mode of Operation: Cyclic
Source of Power: 3.7 volt Li-ion battery

CAUTION: Charge batteries using only the power supply provided by Precision Medical Products.

POWER SUPPLY:

Class II, input: 100 - 240 Vac, 50 - 60 Hz, output: 5 Vdc @ 2.0 Amp

Use only 60601-1 approved power supplies from Precision Medical Products for use in hospital settings.

Output:
Mode of Operation: Continuous

SYSTEM OPERATING ENVIRONMENT:
Temperature: +5 Degrees C (41 Degrees F) to +40 degrees C (104 degrees F)
Humidity: 30%-75%

DEFAULT SETTINGS:
Leg Pressure (not adjustable) 55mmHg
Cycle time: 60 Seconds

TOLERANCES:
Pressure ± 10%

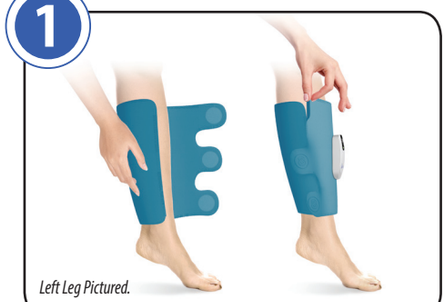
BATTERY CHARGE:
Takes approximately 4 hours (from depleted state).

Defender™

VASCULAR THERAPY SYSTEM
(Compressible Limb Sleeve Device)

QUICK START GUIDE

1



Left Leg Pictured.

CALF CUFF APPLICATION

Wrap the cuff(s) around the calf and secure the fabric fasteners to hold it in place. Make sure the wrap is snug but not too tight. When one or both wrap(s) are secured on the leg(s), the device(s) are ready for operation.

2

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

3

TURNING THE DEVICE ON

When the wraps are secured on your legs, press and hold the white power button on both cuffs for about a second until two beep tones are heard, and the power light is illuminated on each device. To turn the device off, press and hold the white power button for about a second. You will hear two beep tones, and all lights on the device will no longer be illuminated.

4

USING THE DEVICE

The device will make a quiet "humming" sound when inflating and squeezing your leg. This is normal. The wraps will inflate once a minute. IF you feel air releasing around the legs, this is normal. This is a function of the device to keep your legs cool.

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Customer Support: (800) 604-2487 • info@pmpmed.com • www.pmpmed.com • 2217 Plaza Drive, Rocklin, CA

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

SYSTEM COMPONENTS

INSTRUCTIONS

POWER ON

Press and hold the power button for about a second, and the device will turn on. When the device is powered on, C8 is displayed followed by a double digit number, audible alarm beeps twice. Refer to the battery indicator section on below for battery life expectancy.

After a four-second delay, the device is on, and the LED display will always remain on (unless in night mode). The device applies compression to the leg(s) in cycles. During each cycle, the device inflates the cuff to 55mmHg pressure, holds the pressure for four seconds, and then releases the pressure.

Cuff inflation occurs in 6 to 12 seconds. During cuff inflation, the device will display dynamic pressure in five-degree increments 00-05-10-15-20-25-30-35-40-45-50-55. During hold, the device will display "55" and applies pressure for four seconds. Afterward, the pressure is released. The cycle repeats after 50 seconds of idle time. During the 50 seconds of idle time between compression cycles, the display pulses a lower right dash for 48 seconds and will flash "00" quickly for the remaining two seconds before the next inflation of pump activation.

POWER OFF

When the device is operating, press and hold the power button on top of the device for one second

The device is in "sleep" mode—no visible illumination.

ALARMS

Low Pressure or Leak "LP" Power button flashes red and display will flash LP simultaneously following a Low-Pressure event. Audible alarm will sound, and the Power button will flash red. The alarm will continue for 30 seconds (unless the device is powered off) and automatically turn the device off.

Make sure the wrap is attached snuggly to the leg. Turn the device off, and then turn the device back on. If the device continues to alarm after this step, Do not try to fix the device. Call customer service for a replacement device at (800) 604-2487.

High Pressure or Leak "HP" Power button flashes red and display will flash HP simultaneously following a High-Pressure event. Alarm will continue for 30 seconds (unless the device is powered off) and automatically turn the device off. The pump will turn off, and the solenoid will open, releasing the air in the bladder compressing the leg(s).

Turn the device off, and then turn the device back ON. If the device continues to alarm after this step, do not try to fix the device. Call customer service for a replacement device at (800) 604-2487.

Battery Low "BL" – Power button flashes yellow and display will flash BL simultaneously when the battery is low. Plug-in power supply immediately.

Battery Critical "BC" – If the battery voltage drops below a critical level, an audible alarm will sound, display will flash BC and power button will flash red. The alarm will continue for 5 minutes (unless the device is powered off) and automatically turn the device off. Plug-in power supply immediately.

ALARM RESET:

To reset an alarm, the device must be turned off then turned back on. If not manually turned off within 30 seconds of such an alarm condition occurring, the device automatically turns itself off. Once the device is turned back on, the alarm is reset.

OPTIONS

By Prescribing Physician Only

Device use time (amount of time the device is powered ON) is monitored and stored by the MPU (Microprocessor Device) and can be requested by prescribing Physician only.

NIGHT MODE

During normal operation, the device can be turned into night mode by Pressing the power button three times quickly. The light intensity will reduce on the power button, and the LED display will turn off.

To exit night mode Pressing the power button three times quickly. If the power is turned off for any reason, the device will automatically reset and start in normal operation mode.

BATTERY INDICATOR

To correctly indicate the state of the battery and charger, there are SIX stages of the BATTERY INDICATOR as follows:

Battery icon: Remains illuminated at all times during operation.

Solid Green All Three Bars: 100% battery life remaining

Solid Green Two Bars: 68% to 100% battery life remaining, when charging in use or sleep mode, third bar pulses until fully charged.

Solid Green One Bar: 33% battery life remaining, second and third bar pulses alternately until 100% charged when charging in use or sleep mode.

Flashing Yellow Bar: Power button will flash yellow, and "BL" quickly flashes on the LED display. The battery will last 30- 60 minutes or less.

Flashing RED Bar: Battery will last five minutes or less. "BC" will quickly flashes on the LED display until auto shut down or the device(s) are connected to the power supply. Audible alarm will continuously sound until the device powers down, or the power supply adapter is plugged into a wall socket.

USING THE AC ADAPTER / BATTERY CHARGER

CHARGING THE BATTERY: USE ONLY THE CHARGER PROVIDED BY Precision Medical Products.

Use of the wrong charger can cause excessive heat, damage to the charging circuit, and shorten the life of the battery.

THE DEVICE POWERED OFF

Insert the supplied power supply plug into the port at the bottom end of each device and connect the power supply adapter to the wall socket. The battery indicator icon on the LED Display will illuminate three flashing green bars and provide the current charge status. Once the device is fully charged, all three bars will be solid green. A full charge of a depleted battery should take approximately four hours. Refer to the battery indicator on the this page for battery life expectancy.

THE DEVICE POWERED ON

Insert the supplied power supply plug into the port at the bottom end of each device and connect the power supply adapter to the wall socket. 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 Power Button will be illuminated, and the battery indicator icon on the LED Display will illuminate three flashing green bars providing the current charge status. Once the device is fully charged, all three bars will be solid green. Refer to the battery indicator on this page for battery life expectancy.

WARNINGS AND PRECAUTIONS

- The Defender cuffs are designed for single patient use only.
- Medical Electrical Equipment needs special precautions regarding EMC. Portable and mobile RF Communications Equipment can be affected by other Medical Electrical Devices.
- Cuffs used in combination with warming devices may cause skin irritation. Regularly check for patient discomfort, compliance, and skin irritation.
- To prevent extremity compartment syndrome, special attention should be given to patients who are positioned in the supine lithotomy position for extended lengths of time. This includes patients with or without cuffs.
- Do not open or remove covers. No user serviceable parts inside. Direct all unit issues to Precision Medical Products.
- If pulsations or throbbing occur, the cuff may be wrapped too tightly. Loosen Immediately.
- Stop using device if swelling occurs; consult a Physician.
- Device is to be used only by the patient prescribed, and only for its intended use.
- Ensure the pump control unit is turned off and unplugged from the wall outlet prior to and while cleaning or disinfecting.
- Equipment should not be used in the presence of any flammable anesthetic mixture with air, oxygen, or nitrous oxide.
- Do not immerse in any liquid for any reason.
- Do not operate device in a wet environment.
- Allow cuffs to warm to room temperature if exposed to temperatures below 5^{0}C or (41^{0}F).
- Do not subject the unit to extreme shocks, such as dropping the pump.
- Contains no user serviceable parts. Contact Precision Medical Products. Customer Service.
- Do not place any items in an autoclave.
- Operation of this device can be done by the patient.
- No Service is to be attempted while the device is in use.
- This device is not to be altered or modified.

CLEANING AND DISINFECTING

NOTE Inspect the Defender 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 during cleaning or disinfecting.

DO NOT IMMERSE 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 abrasive or volatile cleaners.
- Do not place cuffs in dryer.
- Never remove the unit from the cuff.
- Hand wash the exterior of the cuffs using a soft cloth, moistened with soapy water or 70% isopropyl alcohol and let air dry.
- To ensure the unit IS completely dry prior to use, leave unit in the OFF condition and disconnected from the wall outlet for 30 minutes after cleaning or disinfecting.