



MOBILE BLOOD CLOT PREVENTION

Instructions For Use

Manufacturer

Xiamen Weiyou Intelligent Technology Co.,Ltd

ADD

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Introduction

The VU recovery™ DVT Prevention Device is intended for patients at risk for deep vein thrombosis and pulmonary embolism due to the associated risk factors for thrombus formation during and following various surgical situations. The application of this device can effectively increase venous flow velocity so as to reduce unexpected stasis and upregulate the fibrinolytic activities in order to prevent early blood clotting.

Purpose

The purpose of the VU recovery™ 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 60mmHg 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 VU recovery™ to be completely portable, thus preventing interruptions in treatment.

Indication for Use

VU recovery™ is intended to be an easy to use portable system, prescribed by a physician, to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (simulating muscle contractions).

This device can be used in the home or clinical settings 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 a prophylaxis for DVT by persons expecting to be stationary for long periods of time

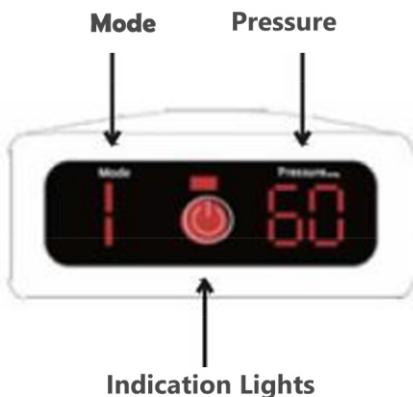
Contraindications

The VU recovery™ Therapy System should NOT be used in the following conditions:

- Severe arteriosclerosis or other ischemic vascular diseases
- Acute or active deep vein thrombosis
- Existing pulmonary edema, pulmonary embolisms, and/or congestive cardiac failure
- On patients with neuropathy, active infections, and/or thrombophlebitis
- On extremities that are extremely deformed, insensitive to pain, or where increased venous or lymphatic return is undesirable
- Any local skin or tissue condition in which the garments would interfere including but not limited to:
 - Vein ligation
 - Gangrene
 - Open wounds
 - Recent skin graft
 - Dermatitis
 - Massive edema

Caution: Federal law restricts this device to sale by or on the order of physician.

Device Features



**To Power On, Press and Hold the Power Button until the Device begins to inflate. Inflation will begin within 4 seconds of holding the Power Button.*

Operating Instructions:

1. Wrap the cuff snug around the calf, with the inflatable chamber positioned behind it.
2. Press and hold the power button on each unit until the device powers on and begins inflating. When the power button is held, the indicator light will flash with alternating Red and Blue lights. While the indicator lights are flashing, continue to hold the power button until the device begins inflating. The device will begin inflating within 4 seconds of holding the power button.
3. After a brief delay, the pump will inflate the attached wrap to a pre-determined pressure of 60 mmHg.
4. Once the pressure reaches that level, the pump will turn OFF, deflate for a 50 second "rest" period, then inflate again every 50 seconds.
5. To manually shut off the device, press and hold the Red power button. If the unit is off, no LED light will be illuminated.

Note: When the chamber is inflating, it is completely normal to hear a humming noise and feel a squeezing sensation around your leg.

Charging:

Insert the supplied power supply plug into the port at the bottom end of the unit and connect the power supply adapter provided to the wall socket. The Red indicator light on the unit will illuminate when the charge has begun. A solid red light will indicate that the battery is still charging and has not reached maximum capacity. When the battery has achieved a full charge, a flashing Blue indication light will appear. The Blue indicator light will continue to flash until the unit is disconnected from the power supply plug.

Device Cleaning Instructions:

SWITCH OFF AND DISCONNECT THE POWER CORD FROM THE MAIN SUPPLY BEFORE CLEANING AND INSPECTION.

- The unit casing is made from plastic and can be cleaned using a soft damp cloth and a mild detergent free from harsh chemicals to avoid deterioration.
- Cuffs are designed for single patient use and cleaning is not recommended.

Error Indicators

- **Pressure Error:** User will see a flashing Red LED light accompanied by a beep for 30 seconds before the unit shuts down.
- **To Troubleshoot:** Ensure wrap is snug around calf, power unit off and on. Use only the charger provided by Xiamen Weryou Intelligent Technology Co.,Ltd.
- **Low Battery Error:** User will see a flashing Red LED light accompanied by a beep for 30 seconds before the unit shuts down.
- **To Troubleshoot:** Plug power cord into a wall socket immediately.
- **Adapter Error:** User will see an intermittent flashing Red and Blue LED light accompanied by a beep for 5 seconds before the unit shuts down.
- **To Troubleshoot:** Use only the charger provided by Xiamen Weiyou Intelligent Technology Co.,Ltd.

Warnings

- Review this manual prior to using the VU recovery™ Vascular Therapy system. For any questions please contact (86)-592-6252495.
- During use, regularly check the system and ensure the cuff is fitted properly. If pain and tingling occur, remove cuff immediately as it may be wrapped too tightly.
- Never apply or remove cuffs when inflated as it may cause damage.
- Do not use VU recovery™ around explosive or flammable material, in an MRI environment, in a hyperbaric chamber, or near a fireplace or radiant heater.
- Disconnect prior to defibrillation.
- The VU recovery™ cuffs are designed for single patient use only as prescribed by a physician.
- The VU recovery™ Therapy System is to be used only by the patient prescribed, and only for its intended use.
- There is a risk of strangulation if one gets tangled in the cables or tubing.
- Use the device in a clean environment; one that is free from dirt, dust, pets, hair, etc.

- To prevent extremity compartment syndrome, special attention should be given to patients, with or without cuffs, who are lying on their back for extended lengths of time.
- Do not immerse in any liquid for any reason or subject the unit to extreme shocks, such as dropping the pump.
- If battery swells, gets hot, or smokes while charging, disconnect the charger immediately. This may cause the battery to leak, and the reaction with air may cause the chemicals to ignite, resulting in fire.
- Use a properly rated charger to charge the lithium battery.
- Incorrect voltage and/or current can cause fire.
- Do not position the device that makes it difficult to unplug the power cord.
- Keep away from babies and children.

Maintenance and Replacement Parts

The VU recovery™ Vascular Therapy System contains no user serviceable parts inside: Opening or tampering with this device will void the warranty. In the event the VU recovery™ Therapy System requires repairs, it should be returned to the medical equipment company or to Xiamen Weiyou Intelligent Technology Co.,Ltd. directly. Modification of any kind is prohibited.

Battery: Do not attempt to open, disassemble, or service the battery pack. Do not crush, puncture, short external contacts, or dispose of in fire or water. Use only an VU recovery™ approved 3.7V rechargeable lithium battery and charger to avoid fire. If the device will not be in use for an extended period of time, the battery should be maintained by recharging regularly and storing in a safe, dry place.

Description of Various Symbols

	Warning/Caution: See instructions for use		On/Off Button
	Date Of Manufacture		Manufacture Lot Number
	Type BF Applied Part. Internally powered electrical device		Manufactured for
	Serial Number		Class II Equipment / Protection against electrical.
	Keep Dry / Never immerse device in water directly, never apply water directly and allow to dry thoroughly when cleaning.		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 that meet EPA standards and comply with laws in your area.
	Prescription Use Only		Refer to instruction manual.
IP22	Protected against foreign objects equal to or greater than 12.5mm and against falling drops of water when enclosure tilted up to 15°		Conforms to AAMI STD. ES60601-1, HA60601-1-11 and IEC STD. 60601-1-6 Certified to CSA STD. C22.2 No. 60601-1, 60601-1-11 and 60601-1-6

General Equipment Specifications

Dimension	65*130*30 (mm) / 2.6*5.1*1.2 (in)	
Weight	0.3 kg / 0.66 lbs	
AC/DC Adapter	AC Input: 100~240 Volts, AC 50/60Hz, 500mA MAX DC Output: 5V 2A (2 Plugs)	
Mode of Operation/ Operating Time	Continuous / 8 hours	
Battery Type	Lithium Battery 3.7V 3000mAh (rechargeable)	
Charging Time	4.5 Hours	
Default Pressure Tolerances	60 mmHg ± 5 mmHg	
Rest Period	50s	
Operating Conditions	Temperature: +5°C to 40°C (41°F to 104°F) Atmospheric Pressure : 70 kPa to 106 kPa	Humidity : 15% to 93% non-condensing
Storage Conditions	Temperature: -25°C to 70°C Atmospheric Pressure : 50 kPa to 106 kPa	Humidity : < 93% non-condensing Keep dry and avoid direct sunlight exposure.

Warranty and Service Information:

Xiamen Weiyou Intelligent Technology Co.,Ltd warrants its VU recovery™

Vascular Therapy Device ("Device") to be free from defects in workmanship and materials for a period of one (1) year from the date Device is delivered to the original purchaser ("Warranty Period"). This Limited Warranty is only for the original purchaser, is non-transferable, and does not cover any Device that may have been damaged in transit, subject to misuse, neglect, or accident; or has been used in violation of Xiamen Weiyou Intelligent Technology Co.,Ltd's instructions, including, without limitation, the instructions contained in this Manual. The sole obligation of Xiamen Weiyou Intelligent Technology Co.,Ltd under this Limited Warranty shall be, at its sole discretion, to repair or replace a Device which is defective in either workmanship or material. This is the sole remedy of the Purchaser.

In addition, this Limited Warranty

- THERE ARE NO WARRANTIES THAN THOSE EXPRESSLY STATED HEREIN.
- TO THE EXTENT PERMITTED BY LAW, Xiamen Weiyou Intelligent Technology Co.,Ltd DOES NOT MAKE ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE AS TO ANY PRODUCT OR DEVICE, WHETHER OR NOT THAT PRODUCT OR DEVICE IS COVERED BY ANY EXPRESS WARRANTY CONTAINED HEREIN.
- IN NO EVENT SHALL Xiamen Weiyou Intelligent Technology Co.,Ltd BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR INDIRECT DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS, USE OR TIME INCURRED BY PURCHASER OR END USER). IN ADDITION, Xiamen Weiyou Intelligent Technology Co.,Ltd SHALL NOT BE LIABLE FOR ANY EXEMPLARY OR PUNITIVE DAMAGES.

FCC Caution:

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

FCC RF Radiation Exposure Statement:

1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

2. This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.