cirona™

DVT DEVICE

# *Cirona™ 6300 Series*

## *Deep Vein Thrombosis (DVT)*

## Prevention Therapy System

## **Operating Instructions**

DEVON MEDICAL PRODUCTS

Manufactured for Devon Medical Products
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## Introduction

The Cirona™ 6300 system 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.

## Intended Patient Population

- Age: 18 or above
- Nationality: Irrelevant
- Body weight: Not concern
- Patient state: Normal or anaesthetized
- Health: Check contraindications

## Intended User Profile

- Education/Knowledge: 7th grade+
- Experience Requirement: None
- Language understand: N/A (one button operation)
- Permissible impairments: Except for contraindications

## Indication for Use

The Cirona™ 6300 deep vein thrombosis prevention system 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

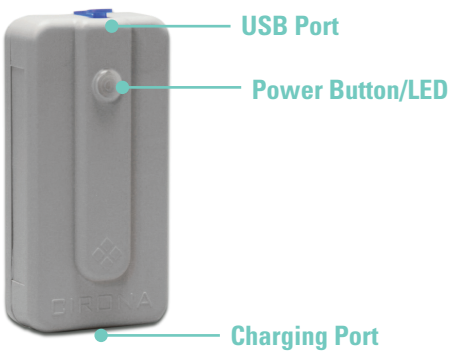
The Cirona™ 6300 series system should NOT be used in the following conditions:

- 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.

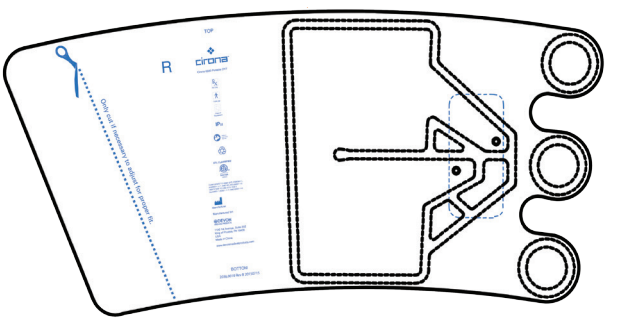
## Device Features:

### Unit Component:




### Cuff Component:

Size (Circumference): Up to 19”



## Operating Instructions:

1. Press the power button located directly below the USB port. The power button should be solid green when powered on.
2. Wrap the cuff snug around the calf, with the inflatable chamber positioned behind it, and press and hold the power button on each unit until the light turns green.
3. After a 5-second delay, the pump will inflate the attached wrap to a pre-determined pressure of 50 mmHg.
4. Once the pressure reaches that level, the pump will turn OFF, deflate for a 50 second "rest" period, and inflate again every 50 seconds.
5. To manually shut off the device, press the power button directly below the USB port. 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 Green indicator on the unit will illuminate or flash, depending on the state of charge.

## 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 yellow 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 Devon Medical Products.
- **Low Battery Error:** User will see a solid yellow 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 a flashing yellow/green LED light accompanied by a beep for 5 seconds before the unit shuts down.
- **To Troubleshoot:** Use only the charger provided by Devon Medical Products.

## Warnings

- Review this manual prior to using the Cirona™ 6300 series system. For any questions please contact Devon Medical Products at 1-866-446-0092.
- 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 the Cirona™ 6300 series system 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 Cirona™ 6300 cuffs are designed for single patient use only as prescribed by a physician.
- The Cirona™ 6300 Series 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 Cirona™ 6300 Series device contains no user serviceable parts inside: Opening or tampering with this device will void the warranty. In the event the Cirona™ 6300 Series System requires repairs, it should be returned to the medical equipment company or to Devon Medical Products 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 a Devon Medical Products 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 |  | Manufacturer |
|  | Serial Number |  | Class II Equipment / Protection against eletrical. |
|  | 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 recharge-able 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 1350mAh (rechargeable) | |
| Charging Time | 3 Hours | |
| Default Pressure Tolerances | 50 mmHg<br>± 5 mmHg | |
| Rest Period | 50s | |
| Operating Conditions | Temperature: +5°C to 40°C (41°F to 104°F)<br>Atmospheric Pressure : 70 kPa to 106 kPa | Humidity : 15% to 93% non-condensing |
| Storage Conditions | Temperature: -25°C to 70°C<br>Atmospheric Pressure : 50 kPa to 106 kPa | Humidity : < 93% non-condensing<br>Keep dry and avoid direct sunlight exposure. |

## Warranty and Service Information:

Devon Medical Products warrants its Cirona™ 6300 Series DVT 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 Devon Medical Products instructions, including, without limitation, the instructions contained in this Manual. Devon Medical Products' sole obligation 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, DEVON MEDICAL PRODUCTS 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 DEVON MEDICAL PRODUCTS 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, DEVON MEDICAL PRODUCTS SHALL NOT BE LIABLE FOR ANY EXEMPLARY OR PUNITIVE DAMAGES.