cirona™

DVT DEVICE

Cirona™ 6100 Series

Deep Vein Thrombosis (DVT)

Prevention Therapy System

Operating Instructions

DEVON
MEDICAL PRODUCTS
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Device Descriptions and Operating Principle:

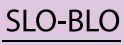
The Cirona™ 6100 Series deep vein thrombosis prevention system is a pneumatic compression device that noninvasively helps reduce the incidence of deep vein thrombosis, a potentially life threatening condition.

The Cirona™ 6100 Series system consists of a device and a pair of soft compression garment(s) (sleeves) and the extension tubing set for the calf, calf-thigh, and foot. The device will alternatively inflate the two garments and mimic the natural walking pace in order to enhance circulation. The device-supplied compression provides a 60-second automatically timed cycle consisting of an approximately 12-second inflation period followed by a 48-second period of relaxation. A pressure of 40mmHg is used for the calf, calf-thigh, and foot pressure treatments. This pressurization enhances venous flow and fibrinolytic activity in order to ultimately prevent early blood clotting.

Intended Use:

The Cirona™ 6100 Series system is a prescription device intended to be used preventatively to increase venous blood flow in patients at risk of deep vein thrombosis due to the associated risk factors for thrombus formation during: trauma, critical care, general medicine, general surgery, as well as neurological, orthopedic, urologic, obstetric conditions and treatments.

Description of Various Symbols:

	ATTENTION: **Consult ACCOMPANYING DOCUMENTS.** This symbol is used to direct the user to refer to documentation for additional information regarding the system use or description.
	Class II Equipment
	**Dangerous Voltage** **Electrical shock hazard.** Disconnect LINE CORD before servicing; refer servicing to qualified service personnel.
	Type B. Applied Part
	Prescription Use Only
	Slow acting (time delayed) fuse
	Without protection against ingress of water
	Date of Manufacture
	Serial Number
	Button: Start/Pause
	Button: Switch between one/two leg mode
	Keep Dry
	Waste Electrical Goods Recycled
 0123	Conforms with the Medical Device Directive (93/42/EEC) and has been subject to the conformity procedures laid down in the council directive
	Authorized Representative in the European Community
	Manufacturer
	Catalog / Model Number

Contraindications:

The **Cirona™ 6100 Series system** should NOT be used in the following conditions:

- Severe atherosclerosis or other ischemic vascular diseases
- Suspected or known acute deep vein thrombosis
- Severe congestive cardiac failure
- Existing pulmonary edema
- Existing pulmonary embolisms
- Extreme deformity of the limbs
- Any local skin or tissue condition in which the garments would interfere:
    - Gangrene
    - Untreated or infected wounds
    - Recent skin graft
    - Dermatitis
- Known presence of malignancy in the legs
- Limb infections, including cellulitis, that have not received antibiotic coverage
- Presence of lymphangiosarcoma

Cautions:

- **CAUTION:** In the USA, federal law restricts this device to sale, by or on the order of a physician.
- Ensure that there are no kinks in the tubing and that connectors are firmly locked in.
- Regularly check the system while it is in operation and ensure the garment fits.
- Garment should be removed if the patient experiences pain, numbness, or tingling.
- Never put on or take off the garments when inflated as it may cause damage to the sleeves.
- Do not interrupt the compression system for a substantial amount of time.

Device Panels and LCD Displays:

Device Panels:

Button: Start/Pause

Button: Switch Between One/Two Leg Mode

LCD: Display real-time pressure and treatment mode

Garments:

Garment Specification:

Model	Application	Circumference	Patient Sizing
D-110	Calf	Up to 17″	Standard
D-120	Calf	Up to 23″	Large
D-125	Calf	Up to 32″	Extra Large
D-135	Calf - Thigh	Up to 22″	Small
D-130	Calf - Thigh	Up to 28″	Standard
D-140	Calf - Thigh	Up to 36″	Large
D-145	Calf - Thigh	Up to 42″	Extra Large
F-15	Foot	Up to 13″	Small
F-10	Foot	Up to 16″	Standard
Extension Tubing Set	6′ tube extender to connect the garments to the device.		

Operating Instructions:

1. UNPACK EQUIPMENT

1.1 Open the shipping box and lift the device up and out of the box.
1.2 Remove the protective foams and take the device from the plastic bag.
1.3 Remove the sleeve(s) from packaging.

2. PREPARE FOR OPERATION

2.1 Plug the device into the proper electrical outlet. For 6100, plug into a safe 120VAC, 60Hz outlet. For the 6102, plug into a safe, 220 VAC - 240 VAC, 50 Hz outlet. **DO NOT SWITCH ON YET**.
2.2 Position the device on a flat surface or use the hooks/bed brackets to suspend it at the foot of the bed or any place convenient for use.
2.3 The garments can be used on either leg or foot depending on conditions.
2.4 Attach the tube set to the device by connecting the male connectors into the device connectors until a click is heard. Device connectors are located on the right side of the device.
2.5 Attach the garments to the tube set using the snap lock connectors. Put on the garments and make sure that they are snug and the inflatable chambers are in the appropriate position.

a. Calf Garment: Unfold and position the inflatable chamber directly behind the patient's calf.
b. Calf-Thigh Garment: Unfold and position the inflatable chambers directly behind the patient's calf and thigh.
c. Foot Garment: Fully unfold and position the inflatable chamber against the base of the patient's foot with the tube set facing upward. Wrap the tab firmly over top of the foot. Pulling the remaining long tab around the heel and firmly secure to the top of the foot.

3. START AND STOP THERAPY

3.1 Switch on the device. Treatment will start automatically after 10 seconds.

3.2 During the initial 10-second waiting period, press the button continuously to select from either one or two-leg mode and the LCD screen will display the chosen mode.
As shown in Figure 1, one garment is selected. For single garment treatment, the garment must be inserted into the top connector labeled “1”.
As shown in Figure 2, two garments are selected.

Press the button to start the treatment immediately.

Figure 1

Figure 2

3.3 During regular therapy, the screen will show the current operating mode (1 or 2) and the operating real time pressure. For example Fig. 2 shows two garments selected at 40 mmHg.

3.4 Press and hold the button for 2 seconds to pause the treatment at any time as shown in Figure 3.
Resume the treatment by pressing the button.

Figure 3

3.5 The treatment mode can be changed at anytime by holding down the button for 2 seconds.

3.6 When deflating, LCD screen will display as in Figure 4(a,b,c) below.

Figure 4a

Figure 4b

Figure 4c

4. END OF TREATMENT

4.1 The user can end the treatment at any time during a treatment session by pressing the button and turning off the device with the power switch.

4.2 Once the power is off, it is safe to remove the garment which should be loose enough by now.

4.3 Pull the plug out of the wall outlet to isolate the circuits electrically from the supply mains on all poles simultaneously.

Troubleshooting:

If the system fails to operate when plugged in and switched ON, check the fuse on the back of the housing. Unplug the device and remove the fuse holder or contact your local authorized dealer for further information or advice.

Important: To protect against a fire hazard, replace blown fuses with identical type and rating (1.0AMP 250VAC SLO-BLO). If the fuse blows again, return the device to dealer for service.

Caution: There are no user serviceable parts inside the system. There is an electrical shock hazard if the device assembly is disassembled. Refer all service to qualified personnel.

Caution: Keep away from CT or MRI environments.

Caution: Keep away from explosive or flammable anesthetic gas.

Alarm:

When an error occurs, the device will deflate. Meanwhile an audible alarm will sound and an error code will flash on the screen. There are two possible error codes:

1. Hi

Error code “Hi” indicates the pressure is too high.

Figure 5

2. Lo

Error code “Lo” indicates the pressure is too low.

Figure 6

Error Code Resolutions			
Error Code	Possible Cause	Mitigation	Still not functional?
Hi	Kink or obstruction in tubing connecting the garments	Make sure all tubing is not kinked or tangled.	Call for service.
Lo	A leak may be present in the tubing or connections.	1. Verify that the connectors are firmly in place and not loose by reconnecting all connections and tubing. 2. Replace garments if defective due to puncture or other causes.	Call for service.

Detaching Quick Connectors:

Press the snap lock down on the quick connector, pull out with a light force, and the quick connector can be detached from the device.

The quick connector can also be easily reconnected. Push the male end of the quick connector inside the female end with a light force until you hear a click indicating proper connection.

NOTE: The quick connectors should only be detached for maintenance of the garments. This activity should generally be handled by medical professionals. Home users are not recommended to operate on the quick connectors.

Fuse Replacement:

The safety fuse on the back panel of the device can sometimes blow for different reasons such as a power surge or the normal aging of the electronic components. The safety fuse is located to the right of the back label.

If fuse damage does happen, a medical professional can replace the fuse as long as a part that has the following parameters is ordered
(1.0 AMP 250VAC SLO-BLO).

While pushing inward on the fuse cap, turn counterclockwise to release the cap and remove the fuse. After placing the new fuse in the cap slot, push the cap and fuse inward and turn clockwise to secure.

NOTE: The outer safety fuse is the only item serviceable by someone other than a Devon Medical Products technician. Devon Medical Products technicians have been trained specifically for the manufacture and repair of all Devon Medical Products including this device.

Device Cleaning Instructions:

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

The outside device casing is made of plastic and can be cleaned using a soft damp cloth and a mild detergent. Allow device surface to thoroughly dry after cleaning.

Never apply hypocarbonate and phenol based cleaning agents as plastic deterioration may occur.

Never immerse device in water or apply detergent or water directly on the device.

Garment Care and Cleaning Instructions:

Garments are for single patient reusable and can only be used on a single person for the entire course of the treatment.

Dispose the garments when the treatment is completed.

If the garment gets soiled and immediate replacement is not available, patients can use a soft cloth dampened with water to wipe off the soilage and do not use it until it is thoroughly dry. Please try to obtain the replacement garment as soon as it becomes available.

Excessive fluid should be avoided.

Disposal of Device:

Medical equipment and devices should be disposed of in proper containers that meet Environmental Protection Agency standards. Check with local State Laws & Regulations to see what is required in your state or contact your local representatives.

General Equipment Specifications:

Dimension	110x180x270 (mm) / 4x7x11 (in)
Weight	2.5kg / 5.5lbs
Electrical Rating	6100: 120 VAC, 60 Hz, 45 VA MAX 6102: 220 VAC - 240 VAC, 50 Hz, 45 VA MAX
Fuse Rating	250 VAC, 1.0 AMP (SLO-BLO)
Mode of Operation	Continuous Operation
Applied Part	Type B
Air Output	40 mmHg
Cycle Time	60 s
Protection Against Electrical	Class II
Protection Against Water	IPXO

Environmental Conditions:

Environmental operating conditions:

Temperature Range	+41°F (+5 °C) to +104 °F (+40°C)
Relative Humidity	15% to 93% (Non-condensing)
Atmospheric Pressure Range	70 kPa to 106 kPa

Environmental Storage Conditions:

Temperature Range	-13°F (-25 °C) to +158°F (+70°C)
Relative Humidity	<93% (Non-condensing)
Atmospheric Pressure Range	50 kPa to 106 kPa

Warranty and Service Information:

Our warranty service to the machine offers the following coverage

- Compression devices: 1 year

Devon Medical Products warrants its **Cirona™ 6100 Series DVT Device** (excluding sleeves) ("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 extended only to the original purchaser and is non-transferable. 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 does not cover any Device which may have been damaged in transit or has been subject to misuse, neglect, or accident; or has been used in violation of Devon Medical Products instructions, including, without limitation, the instructions contained in the Operation Manual.

- **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.**

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CE 0123

Appendix 1:

Product Classification

- According to the type protection against electrical shock, this device is classified as a Class II Equipment, and Type B Equipment that is powered by an external electrical power source.
- According to the degree of protection against harmful ingress of water, this system is classified as the ordinary equipment (IPXO: without protection against ingress of water).
- According to the methods of sterilization, this system does not have any parts or accessories that require sterilization.
- This system is classified as equipment not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide.
- According to the mode of operation, this system is classified as the equipment that can be used for continuous operation.
- Unit is packaged for transportation by common carrier.

Appendix 2:

Electromagnetic Compatibility Information

1. The use of **Cirona™ 6100 Series deep vein thrombosis (DVT) therapy device** requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying table.

2. Portable and mobile RF communications equipment can affect the normal functioning of the **Cirona™ 6100 Series device**.

Technical Description

1. **Warning:** The use of accessories, transducers and cables other than those specified and sold by Devon Medical as replacement parts for internal components may result in increased emissions or decreased immunity of the **Cirona™ 6100 Series device**.

2. **Warning:** The **Cirona™ 6100 Series device** should not be used adjacent to or stacked with other equipment.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The **Cirona™ 6100 Series Deep Vein Thrombosis (DVT) Prevention Therapy Device** is intended for use in the electromagnetic environment specified below. The customer or the user of the **Cirona™ 6100 Series device** should ensure that it is used in such an environment.

Emissions	Compliance	Electromagnetic environment-- guidance
RF emissions CISPR 11	Group 1	The **Cirona™ 6100 Series device** 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 CISPR 11	Class B	The **Cirona™ 6100 Series device** 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/ flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Cirona™ 6100 Series Deep Vein Thrombosis (DVT) Prevention Therapy Device is intended for use in the electromagnetic environment specified below. The customer or the user of the Cirona™ 6100 Series device should ensure 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	±6 kV contact ±8 kV air	±6 kV contact ±8 kV 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 IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) and neutral	±1 kV line(s) and neutral	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 IEC 61000-4-11	<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 5s	<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 5s	Mains power quality should be that of a typical commercial or hospital environment. If a dips or an interruption of mains power occurs, the current of the Cirona™ 6100 Series device may be dropped off from normal level, it may be necessary to use uninterruptible power supply or a battery.
Power frequency (60 Hz) magnetic field IEC 61000-4-8	3 A/m	3A/m	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 AC's main voltage prior to application of the test level

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Cirona™ 6100 Series Deep Vein Thrombosis (DVT) Prevention Therapy Device is intended for use in the electromagnetic environment specified below. The customer or the user of the Cirona™ 6100 Series device should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 Hz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Cirona™ 6100 Series device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz 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, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 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 fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Cirona™ 6100 Series device is used exceeds the applicable RF compliance level above, Cirona™ 6100 Series device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Cirona™ 6100 Series device.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Cirona™ 6100 Series Device

The Cirona™ 6100 Series Deep Vein Thrombosis (DVT) Prevention Therapy Device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Cirona™ 6100 Series device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Cirona™ 6100 Series device 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 $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
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 d 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.

Notes:

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