ArterioFlow™

ArterioFlow® 7500

Arterial Compression Device

Operating Instructions

DEVON
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Intended Use:

The **ArterioFlow® 7500** is intended as an adjunctive therapy for patients with ischemic disease of the lower extremities, due to one or more of the following causes:

• Amputations (minor) • Angioplasty/stent failure • Arteriopathic wounds
• Graft failure • Intermittent claudication • Ischemia • Night Pain
• Rest Pain • Small vessel disease • Ulcers

Description of Various Symbols:

	**ATTENTION: Consult ACCOMPANYING DOCUMENTS.** This symbol is used to direct the user to refer to the documents for additional information regarding the system use or description.
	**Type B - applied part.** The part attached to the patient (the garment to be applied on the patient extremity) is of TYPE B.
	**Electrical shock hazard.** Disconnect LINE CORD before servicing; refer servicing to qualified service personnel.
	**Protective earth** (Ground)
Rx ONLY	Federal (USA) law restricts this device to sale by or on the order of a physician.
SLO-BLO	Represent a kind of slow acting (time delayed) fuse.

Contraindications:

Compression **IS NOT** recommended in the following conditions:

• Infections in the limb, including cellulites without appropriate antibiotic coverage
• The presence of lymphangiosarcoma
• Deep vein thrombosis (DVT)
• Inflammatory phlebitis or episodes of pulmonary embolism
• Congestive heart failure (CHF)

Any local conditions in which garments would interfere, for example:

• Untreated, infected wounds
• Intermittent Claudication
• Small Vessel Disease
• Arteriopathic Wounds
• Angioplasty/Stent Failure

General Equipment Specifications:

DIMENSION:	12″ (W) × 12″ (D) × 4.5″ (H)
WEIGHT:	11 lbs
INFLATION:	Less than 4 seconds
CYCLE TIME:	User Set
ELECTRICAL:	120 VAC, 60 HZ, 100VA MAX
FUSE RATED:	250 VAC, 1.0 AMP, SLO-BLO
APPLIED PART:	TYPE B
PROTECTION AGAINST ELECTRICAL SHOCK:	CLASS I
OPERATION MODE:	CONTINUOUS OPERATION WITH INTERMITTENT LOADING
PROTECTION AGAINST WATER:	IPXO

Environmental Conditions:

Temperature:	
Operating Temperature:	50°F (10°C) – 104°F (40°C)
Storage Temperature:	-4°F (-20°C) – 131°F (55°C)
Humidity:	
Operating Humidity:	30% – 75%
Storage Humidity:	10% – 100%
Atmospheric Pressure:	
Operating Pressure:	70 kPa – 106 kPa
Storage Pressure:	50 kPa – 106 kPa

Device Description and Operating Principle:

The **ArterioFlow 7500® Pump** is designed to deliver bilateral pressures of 25–125mmHg for two to three treatments per day. It applies a unique form of pneumatic compression to the foot, ankle and calf to increase arterial blood flow to the lower limbs. It also helps many patients who suffer from poor circulation and who are not good surgical candidates.

Device Panels:

1. Front Panel:

Key Function

- **START/STOP KEY:** Through these keys the user can start/end the treatment.

SHUTTLE KNOB Function

- Push **SHUTTLE KNOB** to realize mode/parameter select function
- Twist **SHUTTLE KNOB** in a clockwise and counterclockwise direction to realize adjustment/change parameter function

Display

- **LCD:** Indicating the real-time pressure in each chamber and the total therapy time left.

Status Indication

- The Operation LED (green) shows the machine is on and receiving power.
- The Setting LED (yellow) shows that you are in the setup menu.
- The Error LED (red) shows there was a problem while running the machine.

QUICK CONNECT PORT

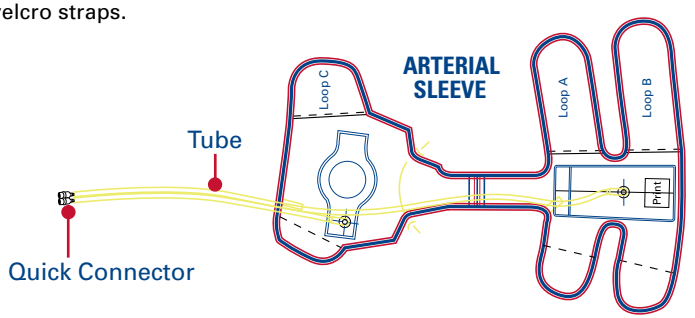
- **LEFT/RIGHT GROUP CONNECTOR FITTINGS:** The garment extends tubes with two pairs of connectors. Each pair has male and female connector fittings that correspond with the connector fittings on the unit itself.

2. Back Panel:

- **POWER PLUG:** Power source.
- **FUSE:** Two(2) slow acting (time delayed) fuses inside for protection against electrical short circuit.
- **POWER SWITCH:** Power can be turned on or turn off by this switch.

3. Two Chamber Garment:

This garment is designed to fit the foot and calf comfortably, with easily adjustable velcro straps.



- **QUICK CONNECTOR:** Detachable with the device. Matching with the **CONNECTOR FITTINGS** on the front board.
- **TUBE:** Air guidance.
- **GARMENT:** Article the patient wears to undergo treatment.

Operating Instructions:

1. UNPACKING EQUIPMENT

1.1 Open the shipping box and lift the device up and out of the box.

1.2 Remove the protective foams and remove the device from the plastic bag.

1.3 Remove the garment from the plastic bag and unroll the tubes that are wrapped around the folded garment. Unfold the garment and spread it flat.

2. PREPARE FOR OPERATING

2.1 Place the device on a flat and stable surface in close proximity to where the patient will be resting.

2.2 Gather the power cord and attach to the **POWER PLUG** on the device back panel. Plug the device into a safe, properly grounded, 120 VAC, 60 Hz outlet.

2.3 Attach the **QUICK CONNECTORS** of the garment to the **QUICK CONNECT PORTS** which are located on the front panel of the device.

2.4 Putting the garment on: First put the arch of the foot over the inflation area by LOOP C (see garment diagram), then snugly secure the Velcro straps over the bridge of the foot. Second wrap LOOP A and LOOP B (see garment diagram) snugly around the calf.

Operating Instructions: *(continued)*

3. TREATMENT

*Settings can only be modified or restored before or in between treatments.

There are two operating modes with this device:

- **Factory Default:** Device comes with a factory default setting providing a compression pressure at 120mmHg with a one second delay between the foot and calf; 20 second cycle time; 30 minute treatment time.
- **Customer SET:** This mode allows you to set your pressure, treatment time and cycle time.
- **Ex.** For a 20 second cycle, there is one(1) second inflation, with a three(3) (+/-1) second holding period on foot and calf, and a thirteen(13) to sixteen(16) second resting period. There also is a one(1) (+/-0.5) second **DELAY** between the foot and the calf. For a different cycle time setting, these time values are proportionate to the cycle time.

3.1 Start

Press Main **POWER SWITCH** up to "ON" position which is located on the rear panel. The green power indicator on the front panel will then illuminate.

Ready... Press <START>	Upon this display, User can directly push < Start > to run the device on Factory Default. If Customer Set Mode is desired, continue to 3.2

3.2

Ready... Press <START>	Upon this display, User can access Customer Set Mode by pushing the **SHUTTLE KNOB** that will take you to <Therapy Mode Setting>.

3.3

> Factory Default Customer Set	This display shows <Therapy Mode Setting>.
Factory Default > Customer Set	Turn the **SHUTTLE KNOB** to the right to select Customer Set. Then push the **SHUTTLE KNOB** to access all parameters.
Pressure 120 mmHg ->	This display shows the first parameter — Pressure. Push the **SHUTTLE KNOB** to select Pressure.
120 mmHg	Increase the Pressure by turning the **SHUTTLE KNOB** to the right, decrease the pressure by turning to the left. Offset: 1mmHg
Pressure 100 mmHg ->	Push the **SHUTTLE KNOB** to confirm the new Pressure. This will also take you back to <Parameters>.

Operating Instructions: *(continued)*

3.4

Treatment Time
<- 30 Min ->

Access the second parameter -- Treatment Time, by turning the **SHUTTLE KNOB** to the right. Push the **SHUTTLE KNOB** to select Treatment Time.

30 Min

Increase the Treatment Time by turning the **SHUTTLE KNOB** to the right, decrease time by turning to the left. Offset: 5 Min.

Treatment Time
<- 45 Min ->

Push the **SHUTTLE KNOB** to confirm the new Treatment Time. This will also take you back to <Parameters>.

3.5

Cycle Time
<- 20 Sec ->

Access the third parameter -- Cycle Time, by turning **SHUTTLE KNOB** to the right. Push the **SHUTTLE KNOB** to select Cycle Time.

20 Sec

Increase the Cycle Time by turning the **SHUTTLE KNOB** to the right, decrease time by turning to the left. Offset: 1 Sec.

Cycle Time
<- 15 Sec ->

Push the **SHUTTLE KNOB** to confirm the new Cycle Time. This will also take you back to <Parameters>.

3.6

<- Exit

To exit and complete, turn the **SHUTTLE KNOB** to the right. Push to select to Exit.

Ready... Press <START>

Start

You will be taken to the <Start> display. Push the green Start button to start your custom treatment.

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4. END OF TREATMENT

4.1 When you press the "STOP" key during treatment, or when your treatment time is completed after setting time, the device will stop working.

4.2 Before the buzzer sounds, the device will vacuum air from garment for 3 seconds so that it will be easy to take off the garment.

4.3 Next, you can press the **POWER SWITCH** on the backboard to the "OFF" position and unplug the **POWER CORD**.

4.4 Once the Status LED light has shut off, it is safe to remove the garment.

4.5 The garment should be loose enough so you can remove the garment.

4.6 Press the lock of the **CONNECTOR FITTING**, pull outward away from device if necessary.

NOTE: An internal buzzer gives reminders when device is ready to start or stop and when treatment is finished.

Troubleshooting:

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

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

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

Caution: Keep away from environment of CT or MRI

Caution: Keep away from explosive or flammable anesthetic gas

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 in between the **POWER PLUG** and the **POWER SWITCH**.

When occasional 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)**.

Prior to removal of fuse, disconnect the **POWER CORD**. While pushing inward on fuse cap, turn counterclockwise to release cap and remove fuse. After placing the new fuse in the cap slot, push 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. Our technicians have been trained specifically for the manufacture and repair of all Devon Medical Products' devices including this device.

Device Cleaning Instructions:

The outside pump casing is made from plastic and can be cleaned using a soft cloth and mild detergent or water.

NOTE: Never immerse device in water.

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 is required in your state.

Garment Care & Cleaning Instructions:

1. Disconnect the **QUICK CONNECTOR** from the device. Unzip the garment and spread it on an even flat surface.
2. Wash both interior and exterior surfaces of the garment with a mild liquid soap.
3. After washing use a clean, dry cloth to initially dry the garment. Then leave the garment open to air dry.

NOTE: Never use abrasive materials such as scrubbing pad, clearing chemicals or detergents containing bleach, as they may cause damage to the garments exterior.

NOTE: Do not dry clean – Do not Iron

Sterilization: Sterilization of the garments and the pump system is not required. However, if sterilization of the garment is desired in a hospital setting, gas sterilization is suitable. The temperature must NOT exceed 125ºF (51ºC).

Garments and Accessories:

The available sizes of garments and accessories are listed below, subject to updates:

Model D-303R	Regular size for leg garment	2 chambers
Quick Connector Air Blockers	Used for unilateral treatment	Set of 2
Sleeve Expander	Attach to Loop A or Loop B to expand the sleeve	

Warranty & Service Information:

Devon Medical Products warrants its **ArterioFlow® 7500** arterial compression pumps (excluding sleeves) (individually each a "Device") to be free from defects in workmanship and materials for a period of three (3) years from the date Device is delivered to the original purchaser ("Warranty Period"). Devon Medical Products warrants the sleeves for the Devices to be free from defects in workmanship and materials for a period of one (1) year from the date the sleeves are delivered to the original purchaser. 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.

(see next page for further warranty details)

Warranty & Service Information: *(continued)*

TO THE EXTENT PERMITTED BY LAW, DEVON MECIAL 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 MECIAL 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 MECIAL PRODUCTS SHALL NOT BE LIABLE FOR ANY EXEMPLARY OR PUNITIVE DAMAGES.

NOTE: This unit is not field serviceable. Tampering with or dismantling this unit in any way will void warranty. If you have questions or need assistance, please contact your local authorized dealer.

Manufactured By:

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Appendix 1
Product Classification:

- According to the type of protection against electrical shock, this device is classified as a Class I 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 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 Equipment that can be used for Continuous Operation.
- **CAUTION:** In the USA, Federal Law restricts this device to sale, by or on the order of a physician.
- Unit is packaged for transportation by common carrier
- **WARNING:** To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- Do not position the device in a way that makes it difficult to unplug the power plug.
- Modification of this equipment is not allowed.

Appendix 2
Accompanying Documents:

A. Instructions for use

1. **MODEL 7500** needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS;
2. Portable and mobile RF communications equipment can affect **MODEL 7500**.

B. Technical description

1. Warning that the use of accessories, transducers and cables other than those specified with the exception of transducers and cables sold by the manufacturer of the **MODEL 7500** as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the **MODEL 7500.**
2. Warning that the **MODEL 7500** should not be used adjacent to or stacked with other equipment.
3.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The **MODEL 7500** is intended for use in the electromagnetic environment specified below. The customer or the user of the **MODEL 7500** should assure that it is used in such an environment.

Emissions	Compliance	Electromagnetic environment-- guidance
RF emissions CISPR 11	Group 1	The **MODEL 7500** 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 **MODEL 7500** 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 **MODEL 7500** is intended for use in the electromagnetic environment specified below. The customer or the user of the **MODEL 7500** 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	±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 **MODEL 7500** may be dropped off from normal level, it may be necessary to use uninterruptible power supply or a battery.
Power frequency (50/60 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 **MODEL 7500** is intended for use in the electromagnetic environment specified below. The customer or the user of the **MODEL 7500** should assure 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 **MODEL 7500** 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 **MODEL 7500** is used exceeds the applicable RF compliance level above, the **MODEL 7500** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **MODEL 7500**.

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 MODEL 7500

The **MODEL 7500** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **MODEL 7500** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **MODEL 7500** as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	**Separation distance according to frequency of transmitter (m)**		
(W)	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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