

AIROS 6
Sequential Compression Device

OPERATING INSTRUCTIONS FOR USE GUIDE

www.airosmedical.com
1.866.991.6956



AIROS[®]
SIX

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Indications for Use

The AIROS 6 Sequential Compression Device utilizes gradient pneumatic compression, which is intended for treatment of patients with the following conditions:

- Lymphedema
- Venous stasis ulcers
- Venous insufficiency
- Peripheral edema











The device is safe for both home and hospital use.

Contraindications

Pneumatic compression **IS NOT** recommended for use in patients with the following conditions:

- Infections in the limb, including cellulitis without appropriate antibiotic coverage
- 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, including: Untreated wounds, infected wounds, gangrene, recent skin graft, or dermatitis

Overview & Description of Symbols

	<p>NOTE: Refer to Accompanying Documents for more information regarding the system use or description.</p>
	<p>Type BF - Applied Part</p>
	<p>Dangerous Voltage - Electrical Shock Hazard Disconnect Line Cord before servicing. Refer servicing to a qualified service representative.</p>
	<p>Class II Equipment</p>
<p>IP21</p>	<p>Protected against solid foreign objects of 12.5mm Ø and greater. Protection against vertically falling water drops.</p>
	<p>Date of Manufacture</p>
	<p>Serial Number</p>
	<p>Prescription Use Only</p>
	<p>Model/Catalog Number</p>
	<p>Manufacturer</p>
	<p>Waste Electrical Goods Recycled</p>

General Equipment Specifications

Dimension	10.2" W x 10.5" D x 4.3" H (260 mm W x 267 mm D x 110 mm H)
Weight	6.4 lbs. (2.88 kg)
Inflation	User Set
Deflation	12 Seconds
Cycle Time	User Set
Electrical	120 VAC, 60 Hz, 100VA MAX
Fuse Rated	2.5 AMP T250VACH SLO-BLO
Applied Part	Type BF - Applied Part
Protection Against Electrical Shock	Class II
Operation Mode	CONTINUOUS
Protection Against Water	IP21

Environmental Conditions

TEMPERATURE	
Operating Temperature	41°F (5°C) - 104°F (40°C)
Storage Temperature	-13°F (-25°C) - 158°F (70°C)
Transportation Temperature	-13°F (-25°C) - 158°F (70°C)
HUMIDITY	
Operating Humidity	15 - 93% RH
Storage Humidity	<93% RH
Transportation Humidity	<93% RH
ATMOSPHERIC PRESSURE	
Operating Pressure	70kPa - 106kPa
Storage Pressure	50kPa - 106kPa
Transportation Pressure	50kPa - 106kPa

Device Description & Operating Principles

Overview

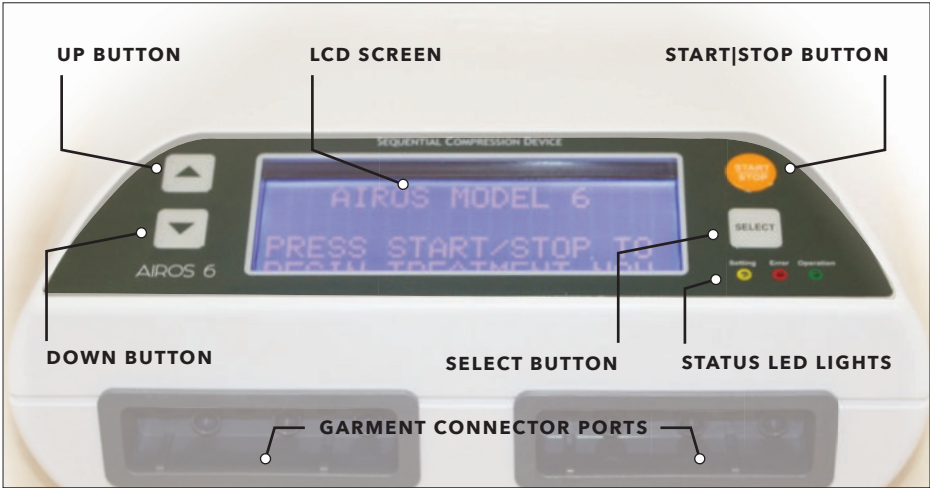
The AIROS 6 Sequential Compression device is a gradient pneumatic compression device. The device is used for treatment and management of venous or lymphatic disorders. The application of gradient sequential compression increases blood flow and encourages extracellular fluid clearance.

The AIROS 6 system consists of the device and 6-chambered garments. The device provides cycles of compressed air and sequentially inflates the garments from distal to proximal.

Box Contents

- 1 AIROS 6 Sequential Compression Device
- 1 Power Cord
- 1 Air Blocker (for use during unilateral therapy)
- 1 AIROS 6 Operating Instructions for Use Guide

Device Panels: Front Panel



Button Functions

- **START|STOP BUTTON:** Allows user to begin and end treatment.
- **SELECT BUTTON:** Allows user to select options displayed on the LCD screen.
- **UP BUTTON:** Allows user to scroll up to options displayed on the LCD screen.
- **DOWN BUTTON:** Allows user to scroll down to options displayed on the LCD screen.

Display

- **LCD Screen:** Shows user settings information, chamber pressure, treatment time remaining, and other real-time device information.
- **LCD Specification:** 5 volts DC, max 0.5 amp, 4 lines x 20 characters per line presentation.

Status Indication

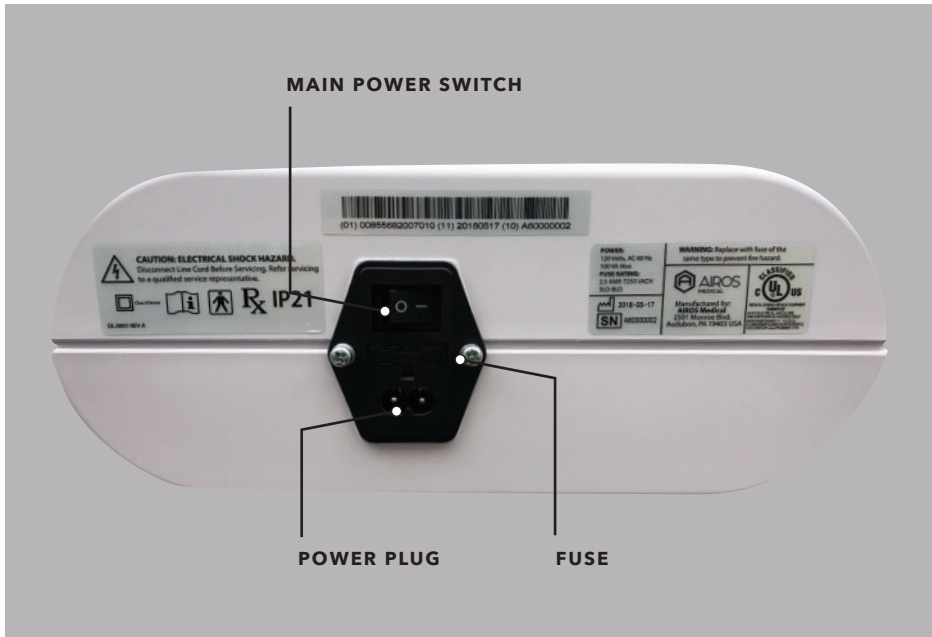
- **Green LED:** Indicates that treatment is being administered.
- **Yellow LED:** Indicates that settings are being changed on the device.
- **Red LED:** Indicates there is an error in operation.

Garment Connector Ports

The Garment Connector Ports are fixed on the device and match with the Garment Connectors on the detachable garments used with this system.

- **Air Blocker:** The Air Blocker is used to block air passage to the unit.

Device Panels: Back Panel

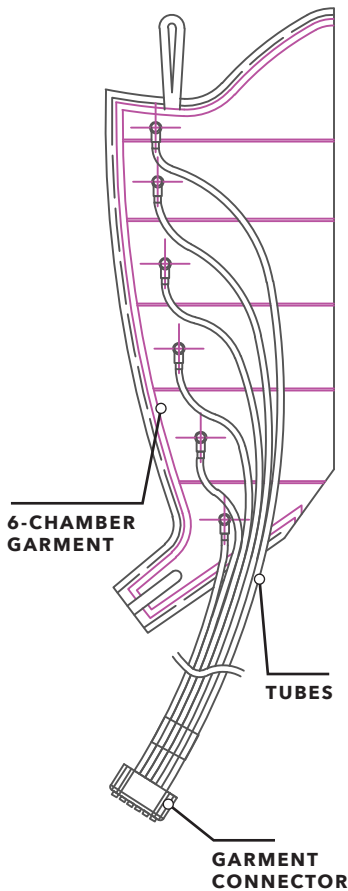


- **MAIN POWER SWITCH:**
Power can be turned on or off.
- **FUSE:**
One (1) time-delayed fuse inside for protection against electrical short circuit.
- **POWER PLUG:**
Power source.

6-Chamber Garment

The segments within the garments are constructed to prevent 'ridging.' (Ridging occurs if there is a gap between two compressed areas of tissue. Tissue is forced towards the gap causing a creased area with restricted blood flow.)

The design of the garments ensures high patient comfort.



- **6-Chamber Garment:**
Applied part for treatment. Garment has 6 separate chambers.
- **Tubes:**
Guide the air.
- **Garment Connector:**
Detachable from the device.
Matches with the Garment Connector Port on the Front Panel.

Device Operation Specifications

Overview

PRIMARY OPERATING MODE SETTINGS	GRADIENT MODE	
Pressure Range (set in distal chamber)	30-80mmHg (increments of 1mmHg)	
Cycle Time	40 or 60 seconds	
Deflation	12 seconds	
Therapy Time	15, 30, 45 or 60 minutes	
Gradient	5% (fixed)	
Secondary Lymphedema Preparation Treatment (LPT) Mode Option	Focal or Clearing	
SECONDARY LYMPHEDEMA PREPARATION TREATMENT (LPT) MODE SETTINGS	FOCAL MODE	CLEARING MODE
Pressure Options	40, 45 or 50mmHg	15 or 20mmHg
Chamber Selection	1-3, 2-4, 3-5 or 4-6	-
Therapy Time	10 or 15 minutes	-

Primary Operating Mode

The primary operating mode in which the AIROS 6 can be used is **Gradient Mode**. The user can set the starting pressure in Chamber 1 on the garment, the most distal chamber. Pressure decreases at a fixed gradient of 5% moving distally to proximally.



NOTE: User may operate the AIROS 6 using the Factory Default settings. The Factory Default setting is Gradient Mode Operation with 45 mmHg of pressure in the distal chamber and a 5% gradient pressure reduction moving towards the proximal chamber; a 60-minute therapy time; a 60-second cycle time; and Lymphedema Preparation Treatment/LPT Mode set to OFF.

Secondary Operating Modes

The AIROS 6 can also be used in two secondary Operating Modes: **Focal Mode** or **Clearing Mode**.

- **Focal Mode:** User can choose to utilize this mode to tenderize the tissue in a limb or limbs affected by Lymphedema Fibrosis. Treatment can be applied using three specific chambers in the garment (1-3, 2-4, 3-5 or 4-6, selected by the user). Focal Mode can be used **prior** to Gradient Mode therapy.
- **Clearing Mode:** User can utilize this mode to mimic manual lymphatic drainage. Clearing Mode can be used **prior** to Gradient Mode therapy.

Operating Instructions

1. Unpacking the Equipment

- 1.1. Open the shipping box and remove the device.
- 1.2. Remove the protective foams and bag.
- 1.3. Remove the garments from the bag.
- 1.4. Unroll the tubes and unroll the garment by spreading it out flat.

2. Preparing for Operation

- 2.1. Place the device on a flat, sturdy surface in close proximity to where the user will utilize therapy.
- 2.2. Secure the proper end of the POWER CORD to the POWER PLUG on the Back Panel of the device. Secure the other end of the POWER CORD to a safe outlet. Outlet should be 120 VAC, 60 Hz.
- 2.3. Attach GARMENT CONNECTORS of the garment to the GARMENT CONNECTOR PORTS on the Front Panel of the device.



NOTE: For unilateral therapy (applying treatment to only one arm or one leg), place the AIR BLOCKER in the other GARMENT CONNECTOR PORT that is unused.

2.4. Directions for Applying Leg Garment(s)

Unzip the garment all the way. Place foot at the bottom end of the garment and pull up the zipper while supporting the garment. Ensure that the garment wraps completely around the leg.

2.5. Directions for Applying Arm Garment(s)

Slide the arm through the internal part of the garment.



CAUTION: The detachable power supply cord may pose a risk of strangulation.

2.6. Directions for Applying Arm Plus Garment

The Arm Plus garment includes three (3) Garment Extension pieces in the packaging. Utilize the smallest Garment Extension piece that ensures a snug fit. Zip the appropriate-sized Garment Extension piece to the back section of the Arm Plus garment. Slide the arm through the internal part of garment. Fasten the back section of the garment with the zipper to the front section of the garment. Ensure a snug fit. If the back section does not reach the front section, unzip the Garment Extension piece and utilize the next largest piece.

3. Treatment Therapy



NOTE: Device settings can only be modified or restored before or in between treatment sessions.



NOTE: Prior to the start of therapy, the garment(s) will briefly "prefill" with air to aid in removing any wrinkles or creases and to allow for any minor adjustments in garment positioning. The LCD screen will read "PREFILL".

Operating Instructions (continued)

<p>3.1</p>	<p>START-UP SCREEN</p> <div data-bbox="165 264 400 384" style="border: 1px solid gray; border-radius: 10px; padding: 10px; text-align: center;"><p>AIROS MODEL 6 PRESS START/STOP TO BEGIN TREATMENT NOW</p></div>	<p>Press the MAIN POWER SWITCH located on the Rear Panel of the device to the "ON" position. The device's screen will illuminate. The START-UP SCREEN will appear.</p> <p>To use the device for the first time and begin treatment immediately with Factory Default settings, press the orange START STOP BUTTON. Proceed to 3.2 for further instructions to begin treatment.</p> <p>If the device has been used before, press the orange START STOP BUTTON. Treatment will begin immediately using settings that have been programmed previously.</p> <p>To view or change settings before treatment, access the MAIN MENU SCREEN by pressing and holding down the SELECT BUTTON for 5 seconds. Proceed to 3.4.</p>
<p>3.2</p>	<p>SLEEVE TYPE SELECTION SCREEN</p> <div data-bbox="165 898 400 1038" style="border: 1px solid gray; border-radius: 10px; padding: 10px; text-align: center;"><p>SELECT SLEEVE TYPE ▶ LEG ARM ARM PLUS</p></div>	<p>NOTE: After selecting the sleeve type for treatment the first time, the device will remember this selection. The user will not need to select the sleeve type the next time they operate the device.</p> <p>For leg treatment: Press the UP ↑ or DOWN ↓ button to move the arrow on the screen to "LEG". Press the SELECT button. Proceed to 3.3.</p> <p>For arm treatment: Press the UP ↑ or DOWN ↓ button to move the arrow on the screen to "ARM". Press the SELECT button. Proceed to 3.3.</p> <p>For arm/shoulder/chest treatment: Press the UP ↑ or DOWN ↓ button to move the arrow on the screen to "ARM PLUS". Press the SELECT button. Treatment will begin immediately.</p>

Operating Instructions (continued)

<p>3.3</p>	<p>SLEEVE NUMBER SELECTION SCREEN</p> <p>SELECT # OF SLEEVES FOR USE IN TREATMENT</p> <ul style="list-style-type: none">▶ 1 SLEEVE2 SLEEVES	<p>NOTE: After selecting the number of sleeves for treatment the first time, the device will remember this selection. The user will not need to select the number of sleeves the next time they operate the device. To change the number of sleeves for treatment, the user must reset the device to Factory Default settings. Refer to the instructions in 3.9.</p> <p>Press the UP ↑ or DOWN ↓ button to move the arrow on the screen next to "1 Sleeve" for unilateral treatment with one leg or arm, or "2 Sleeves" for bilateral treatment with two legs or arms. Press the SELECT button to confirm your selection. Treatment will begin immediately.</p>
<p>3.4</p>	<p>MAIN MENU SCREEN</p> <ul style="list-style-type: none">▶ THERAPY OPTIONSUSAGE DATARESET TO DEFAULTBEGIN TREATMENT	<p>This is the MAIN MENU SCREEN.</p> <p>To adjust therapy settings, press UP ↑ or DOWN ↓ to scroll to THERAPY OPTIONS. Press SELECT to confirm and proceed to 3.5.</p> <p>To view usage data, press UP ↑ or DOWN ↓ to scroll to USAGE DATA. Press SELECT to confirm and proceed to 3.8.</p> <p>To reset the settings on the device to Factory Default settings, press UP ↑ or DOWN ↓ to scroll to RESET TO DEFAULT. Press SELECT to confirm and proceed to 3.9.</p> <p>To begin treatment therapy, press UP ↑ or DOWN ↓ to scroll to BEGIN TREATMENT. Refer to 3.2 for additional instructions to begin treatment.</p>

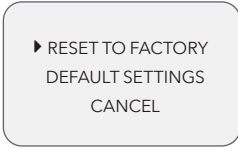
Operating Instructions (continued)

<p>3.5 GRADIENT MODE SET-UP SCREEN</p> <div data-bbox="165 280 396 427"><p>GRADIENT: 5% ▶ PRESSURE: 45mmHg CYCLE TIME: 60 sec ← MORE →</p></div> <div data-bbox="165 453 396 600"><p>← PREVIOUS → THERAPY TIME: 60 min LPT MODE: CLEARING ← MORE →</p></div> <div data-bbox="165 625 396 772"><p>← PREVIOUS → BACK TO MAIN MENU BEGIN TREATMENT</p></div>	<p>NOTE: Press UP ↑ or DOWN ↓ to scroll to MORE or PREVIOUS to view additional settings options.</p> <p>The gradient cannot be changed and is fixed at 5%.</p> <p>To set the Pressure, press UP ↑ or DOWN ↓ to scroll to PRESSURE. Press SELECT to confirm. The pressure will begin blinking. Press UP ↑ or DOWN ↓ to scroll from 30-80 mmHg, in increments of 1 mmHg. Press SELECT to confirm. The pressure will be updated and stop blinking.</p> <p>To set the Cycle Time, press UP ↑ or DOWN ↓ to scroll to CYCLE TIME. Press SELECT to confirm. The cycle time will begin blinking. Press UP ↑ or DOWN ↓ to scroll to 40 or 60 seconds. Press SELECT to confirm. The cycle time will be updated and stop blinking.</p> <p>To set the Therapy Time, press UP ↑ or DOWN ↓ to scroll to THERAPY TIME. Press SELECT to confirm. The therapy time will begin blinking. Press UP ↑ or DOWN ↓ to scroll to 15, 30, 45, or 60 minutes. Press SELECT to confirm. The cycle time will be updated and stop blinking.</p> <p>To operate an optional Lymphedema Preparation Treatment (LPT) mode before Gradient Mode therapy, press UP ↑ or DOWN ↓ to scroll to LPT MODE. Press SELECT to confirm. The LPT Mode option will begin blinking. Press UP ↑ or DOWN ↓ to scroll through the settings, including OFF, CLEARING, and FOCAL.</p> <p>If you select FOCAL THERAPY, proceed to 3.6.</p> <p>If you select CLEARING THERAPY, proceed to 3.7.</p> <p>If you do not wish to run an LPT Mode option, scroll to OFF. Press SELECT to confirm. The LPT Mode setting will be updated and stop blinking.</p> <p>To go back to the MAIN MENU SCREEN, press UP ↑ or DOWN ↓ to scroll to BACK TO MAIN MENU. Press SELECT to confirm.</p> <p>To begin treatment therapy, press UP ↑ or DOWN ↓ to scroll to BEGIN TREATMENT. NOTE: If this is the first time the device is being used, you may be asked to select the number of sleeves to be used for therapy. Refer to 3.2 for additional instructions.</p> <p>If this is not the first time the device is being used, you may not be asked to select the number of sleeves. Treatment will begin immediately.</p>
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Operating Instructions (continued)

<p>3.6</p>	<p>FOCAL THERAPY MODE SET-UP SCREEN</p> <div style="border: 1px solid gray; border-radius: 10px; padding: 10px; margin-bottom: 10px;"> <p>FOCAL THERAPY</p> <p>▶ PRESSURE: 40 mmHg</p> <p>CHAMBERS: 1-3</p> <p>← MORE →</p> </div> <div style="border: 1px solid gray; border-radius: 10px; padding: 10px;"> <p>← PREVIOUS →</p> <p>THERAPY TIME: 15 min</p> <p>SAVE/EXIT</p> </div>	<p>To set the Pressure, press UP ↑ or DOWN ↓ to scroll to PRESSURE. Press SELECT to confirm. The pressure will begin blinking. Press UP ↑ or DOWN ↓ to choose from 40, 45, or 50 mmHg. Press SELECT to confirm. The pressure will be updated and stop blinking.</p> <p>To select the number of Chambers for therapy, press UP ↑ or DOWN ↓ to scroll to CHAMBERS. Press SELECT to confirm. The pressure will begin blinking. Press UP ↑ or DOWN ↓ to choose from 1-3, 2-4, 3-5, or 4-6. Press SELECT to confirm. The pressure will be updated and stop blinking.</p> <p>To set the Therapy Time, press UP ↑ or DOWN ↓ to scroll to THERAPY TIME. Press SELECT to confirm. The pressure will begin blinking. Press UP ↑ or DOWN ↓ to choose from 10 or 15 minutes. Press SELECT to confirm. The pressure will be updated and stop blinking.</p> <p>To exit and return to a therapy mode set-up screen, press UP ↑ or DOWN ↓ to scroll to EXIT. Press SELECT to confirm.</p>
<p>3.7</p>	<p>CLEARING THERAPY MODE SET-UP SCREEN</p> <div style="border: 1px solid gray; border-radius: 10px; padding: 10px;"> <p>CLEARING THERAPY</p> <p>▶ PRESSURE: 20 mmHg</p> <p>SAVE/EXIT</p> </div>	<p>To set the Pressure, press UP ↑ or DOWN ↓ to scroll to PRESSURE. Press SELECT to confirm. The pressure will begin blinking. Press UP ↑ or DOWN ↓ to choose from 15 or 20 mmHg. Press SELECT to confirm. The pressure will be updated and stop blinking.</p> <p>To exit and return to a therapy mode set-up screen, press UP ↑ or DOWN ↓ to scroll to EXIT. Press SELECT to confirm.</p>
<p>3.8</p>	<p>USAGE DATA SCREEN</p> <div style="border: 1px solid gray; border-radius: 10px; padding: 10px;"> <p>TOTAL USAGE TIME</p> <p>HOURS: 0</p> <p>MINUTES: 0</p> <p>▶ BACK TO MAIN MENU</p> </div>	<p>This screen shows the amount of total time the device has been in used.</p> <p>To go back to the MAIN MENU SCREEN, press UP ↑ or DOWN ↓ to scroll to BACK TO MAIN MENU. Press SELECT to confirm.</p>

Operating Instructions (continued)

3.9	RESET TO DEFAULT SCREEN 	To reset the device to the Factory Default settings, press UP ↑ or DOWN ↓ to scroll to RESET TO FACTORY DEFAULT SETTINGS . Press SELECT to confirm. To cancel and return to the MAIN MENU SCREEN , press UP ↑ or DOWN ↓ to scroll to CANCEL . Press SELECT to confirm.
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4. End of Therapy

- 4.1. Therapy will end after the treatment time has elapsed. The user can also stop therapy at any time during a treatment session by pressing the **START|STOP BUTTON**
- 4.2. When therapy is ended, the device will vacuum air out of the garment for three minutes (180 seconds).
- 4.3. At the end of this deflation session, the screen will display: "DO YOU WANT TO EXTEND DEFLATION?" If there is still air in the garment making it difficult to remove, press **UP ↑** or **DOWN ↓** to scroll to YES. Press **SELECT** to confirm. The device will run another deflation session for five minutes (300 seconds). At the end of this deflation session, the START-UP SCREEN will appear.
- 4.4. If you do not need to run another deflation selection, press **UP ↑** or **DOWN ↓** to scroll to NO. Press **SELECT** to confirm. The START-UP SCREEN will appear.
- 4.5. If you do not make a selection within one minute (60 seconds), the START-UP SCREEN will appear.
- 4.6. Upon completion of treatment and deflation sessions, press the **MAIN POWER SWITCH** located on the Rear Panel of the device to the "OFF" position. The device's screen will go dark.
- 4.7. Unzip your garment(s) and remove.
- 4.8. Remove the garment(s) from the Front Panel of the device.
- 4.9. Unplug the power cord from the wall

Troubleshooting

If the device does not operate when plugged in and the MAIN POWER SWITCH is in the "ON" position, check the fuse on the rear panel of the device. Unplug the device and remove the fuse from its housing, or contact your local authorized dealer for further information.

Important: When replacing a blown fuse, to protect against fire hazard replace the fuse with one of the identical type and rating (2.5 AMP T250VACH SLO-BLO). If the fuse blows again, return the pump to your dealer for servicing.



CAUTION: *There are no parts inside the device that are user-serviceable. 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.*

Error Messages/Alarms

High Pressure: This can occur if there is a kink or other obstruction in the tubing connecting the garments, or if the connector port is blocked. The LCD screen will read **E01**, the red LED light will illuminate, and an alarm will sound.

Low Pressure: This can occur if the garment is not properly secured to the connector port or there is a hole in the garment causing a leak. The LCD screen will read **E02**, the red LED light will illuminate, and an alarm will sound.

Software System Error: This can occur if an internal software system error occurs causing the device to be inoperable. The LCD screen will read **E03**, the red LED light will illuminate, and an alarm will sound.



NOTE: If you receive any of these error messages, press the **START|STOP BUTTON**, which will begin deflation of the garments. Then, contact your local authorized dealer or AIROS Medical.

Attaching and Detaching Garment Connector

The Garment Connector on the garment connects easily to the Garment Connector Port on the Front Panel of the device.

While holding the Garment Connector in front of the device, the hose that is colored black (or dark gray, for the Arm Plus garment) should be on the right hand side. Plug the prongs on the Garment Connector into the holes on the Garment Connector Port on the device.

Holding the Garment Connector, simply press down gently on the middle ridged section of the connector with your thumb and pull out the Garment Connector from the device using light force.

Home users are not recommended to plug the garments into the device. It is recommended to have a medical professional plug the garments into the device.

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 MAIN 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 (2.5 AMP T250VACH 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 an AIROS Medical trained technician. AIROS Medical trained technicians have been trained specifically for the manufacture and repair of all AIROS Medical devices.

Garment Care & Cleaning Instructions

1. Disconnect the garment(s) from the device. Unzip the garment and spread it out on an even, flat surface.
2. Hand wash the inside and outside surfaces of the garment with warm, soapy water.
3. DO NOT submerge tubing or tubing parts in water.
4. Use a clean, dry cloth to wipe the garment. Leave the garment open to air dry until it is dry on all surfaces.
5. DO NOT place in a drying machine, dry clean, or blow-dry.



NOTE: Garments are single patient use only and are NOT to be used by multiple persons.



NOTE: DO NOT use abrasive materials such as a scrubbing pad, cleaning chemicals, or detergents containing bleach, as they may cause damage to the garment.



NOTE: If directed methods for cleaning the garments do not remove all soiling, discard the garments and contact AIROS Medical or an authorized AIROS Medical dealer to obtain new garments.

Garment Sizes

Contact AIROS Medical or your dealer to learn more about how to determine sizing.

MODEL	MODEL NUMBER	TYPE	CHAMBERS
SMALL LEG	6-SL01	Full Leg	6
SMALL WIDE LEG	6-SWL01	Full Leg	6
SMALL EXTRA WIDE LEG	6-SXWL01	Full Leg	6
MEDIUM LEG	6-ML01	Full Leg	6
MEDIUM WIDE LEG	6-MWL01	Full Leg	6
MEDIUM EXTRA WIDE LEG	6-MXWL01	Full Leg	6
LARGE LEG	6-LL01	Full Leg	6
LARGE WIDE LEG	6-LWL01	Full Leg	6
HALF LEG	6-HL01	Half Leg	6
HALF WIDE LEG	6-HWL01	Half Leg	6
MEDIUM ARM	6-MA01	Arm	6
LARGE ARM	6-LA01	Arm	6
ARM PLUS (LEFT)	6-APL01	Arm, Shoulder, Chest	6
ARM PLUS (RIGHT)	6-APR01	Arm, Shoulder, Chest	6
ARM PLUS PINK (LEFT)	6-APLP01	Arm, Shoulder, Chest	6
ARM PLUS PINK (RIGHT)	6-APRP01	Arm, Shoulder, Chest	6

Device Disposal

Medical equipment and devices should be disposed of in proper containers that meet Environmental Protection Agency standards. Check with state laws and local regulations to see what is required in your state.

Warranty & Service Information:

AIROS Medical, Inc. warrants its AIROS 6 Sequential Compression Devices (excluding garments, and 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").

AIROS Medical warrants the garments for the Devices to be free from defects in workmanship and materials for a period of one (1) year from the date the garments are delivered to the original purchaser.

This Limited Warranty is extended only to the original purchaser and is non-transferable. AIROS Medical's sole obligation under this Limited Warranty shall be, at its sole discretion, to repair or replace a Device that 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 that may have been damaged in transit or has been subject to misuse, neglect, or accident; or has been used in violation of AIROS Medical instructions, including, without limitation, the instructions contained in the Operating Instructions for Use Guide.

THERE ARE NO WARRANTIES THAN THOSE EXPRESSLY STATED HEREIN.

TO THE EXTENT PERMITTED BY LAW, AIROS MEDICAL 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 AIROS MEDICAL 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, AIROS MEDICAL 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 for:

AIROS Medical, Inc.
2501 Monroe Blvd., Suite 1200
Audubon, PA 19403
1-866-991-6956
www.airosmedical.com



Product Classification

According to the type of protection against electrical shock, this device is classified as a Class II Equipment, and Type BF 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 (IP21: Protected against solid foreign objects of 12.5mm Ø and greater. Protection against vertically falling water drops.)

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.



NOTE: 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.
The device must be operated by qualified and trained personnel only.



Do not position the device in a way that makes it difficult to unplug the power plug. Modification of this equipment is not allowed.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

1. The AIROS 6 Sequential Compression Device needs special precautions regarding EMC and needs to be installed and put into service according to EMC information provided in the Operating Instructions.
2. Portable and mobile RF communications equipment can affect the AIROS 6 Sequential Compression Device.

Technical Description



CAUTION: *The use of accessories, transducers, and cables other than those specified with the exception of transducers and cables sold by the manufacturer of the AIROS 6 Sequential Compression Device as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the AIROS 6 Sequential Compression Device.*



CAUTION: *The AIROS 6 Sequential Compression Device should not be used adjacent to or stacked with other equipment.*

3. Guidance & Manufacturer’s Declaration - Electromagnetic Emissions

The AIROS 6 Sequential Compression Device is intended for use in the electromagnetic environment specified below. The customer or user of the AIROS 6 Sequential Compression Device should assure that it is used in such an environment.


EMISSIONS	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
RF emissions CISPR 11	Group 1	The AIROS 6 Sequential Compression 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 AIROS 6 Sequential Compression 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 6100-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 6100-3-3	Complies	

4. Guidance & Manufacturer's Declaration - Electromagnetic Immunity

The AIROS 6 Sequential Compression Device is intended for use in the electromagnetic environment specified below. The customer or user of the AIROS 6 Sequential Compression Device 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 AIROS 6 SEQUENTIAL COMPRESSION DEVICE 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	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE! UT is the a.c. mains voltage prior to application of the test level			

5. Guidance & Manufacturer's Declaration - Electromagnetic Immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic Environment - Guidance
Conducted RF IEC 6100-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the AIROS 6 Sequential Compression Device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P} \text{ 80MHz to 800MHz}$ $d = 2.3\sqrt{P} \text{ 800MHz to 2.5GHz}$ <p>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 metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, (A) should be less than the compliance level in each frequency range (B).</p>
Radiated RF IEC 6100-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	<p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

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 AIROS 6 Sequential Compression Device is used exceeds the applicable RF compliance level above, the AIROS 6 Sequential Compression 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 AIROS 6 Sequential Compression Device.

6. Guidance & Manufacturer’s Declaration - Electromagnetic Immunity (continued)

Recommended separation distances between portable and mobile RF communications equipment and the AIROS 6 Sequential Compression Device.

The AIROS 6 Sequential Compression Device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AIROS 6 Sequential Compression Device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AIROS 6 Sequential Compression 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 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.





www.airosmedical.com
1.866.991.6956