



**ARTAIRA Arterial
Compression Device**

OPERATING INSTRUCTIONS FOR USE GUIDE

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Indications for Use

The ARTAIRA Arterial Compression Device is an intermittent pneumatic compression device intended for treatment of patients with the following conditions:













- Intermittent claudication
- Rest pain
- Diabetic Foot
- Ischemic neuritis
- Arterial ulcers
- Gangrene
- Poor runoff

Contraindications

Contraindications for the ARTAIRA Arterial Compression Device include:

- Inflammatory phlebitis or pulmonary embolism
- Deep Vein Thrombosis (DVT)
- Congestive Heart Failure (CHF)
- Infection in treatment area
- Worsening skin tissue condition in treatment area

Overview & Description of Symbols

	<p>General Warning Sign</p>
	<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>
	<p>Non-ionizing Radiation</p>

General Equipment Specifications

Dimension	28cm W x 28cm D x 15cm H
Weight	7.5 lbs. (3.4 kg)
Compression Sequences	<p>Foot/Ankle: 3 seconds compression, 17 seconds non-compression</p> <p>Calf: 3 seconds compression, 17 seconds non-compression</p> <p>Calf compression sequence begins 1 second after the Foot/Ankle compression sequence</p>
Electrical	<p>Input: AC 100-240V, 50/60Hz, Max 0.5A</p> <p>Output: DC 12V, 2.0A, 24W</p>
Applied Part	TYPE BF
Protection Against Electrical Shock	Class II
Operation Mode	CONTINUOUS
Protection Against Water	IP21

Environmental Conditions

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

Device Description & Operating Principles

Overview

The AIROS ARTAIRA Arterial Compression Device is an intermittent pneumatic compression device intended to increase blood flow and increase circulation in the lower extremities by providing timed compression to the foot/ankle and calf.

The device connects through air tubing to a pair of compression garments (left and right leg), each with two air chambers: one on the underfoot, and one on the calf area of the patient. One garment can be used with the device if needed, and an air blocker would connect into the other port in this case (unilateral therapy).

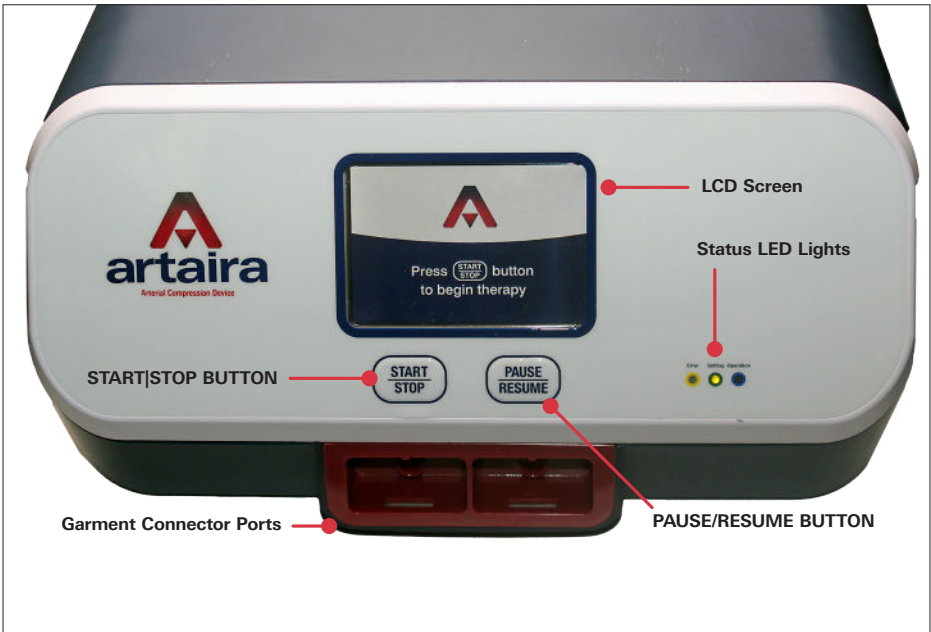
Box Contents

- 1 ARTAIRA Arterial Compression Device
- 1 Power Adapter
- 1 Air Blocker (for use during unilateral therapy)
- 1 ARTAIRA Operating Instructions Booklet



NOTE: Garments are sold separately

Device Panels: Front Panel



Button Functions

- **START|STOP BUTTON:** Allows user to begin and end treatment.
- **PAUSE|RESUME BUTTON:** Allows user to Pause treatment, Resume treatment or access Usage Data.

Display

- **LCD Screen:** Shows user settings information, chamber pressure, treatment time remaining, and other real-time device information.
- **LCD Specification:** 3.5" TFT, 320 x 3RGB x 480 pixels.

Status Indication

- **Blue LED:** Indicates that treatment is being administered.
- **Green LED:** Indicates that settings are being changed on the device.
- **Yellow LED:** Indicates that there is a problem with the device.

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 and Side Panel



- **MAIN POWER SWITCH:**
Power switch used to turn the Device on or off. Found on the Side panel of the ARTAIRA device.

- **POWER INPUT PORT:**
Power source found on the back panel of the ARTAIRA device. To be connected by the power adapter.

ARTAIRA Garment Overview

The garment shall consist of 2 independent air chambers inside a soft outer layer and integrated with hook and loop fasteners to allow secured placement on the patient's lower extremity.



ARTAIRA Garment:
Applied part for treatment. Garment has 2 Chambers, (Foot/Ankle) and (Calf)

Tubes:
Guide the air to the two chambers of the ARTAIRA garment.

Connector:
Detachable from the device. Matches with Connector Port on the Front Panel.

Applying the Garments

Below are instructions for applying the garment to the leg. **Ensure that the device is placed securely on a flat, even surface near where the user will utilize therapy. Connect the garment(s) to the device before applying the garment to the leg.**

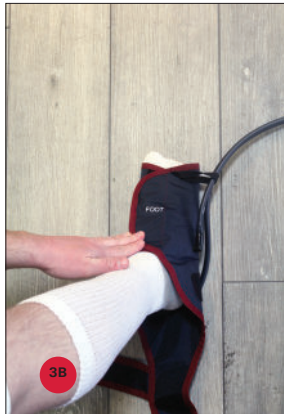
Step 1: Lay the garment flat with all the hooks and fasteners facing up.



Step 2: Place the foot in the garment such that the sole of the foot is directly over the air chamber.



Step 3: Place the left flap with the hooks and fasteners on top of the foot. Then place the right flap over the foot and connect to the left flap to ensure a snug fit. Ensure the writing on the garment that reads "FOOT" is facing up.



Applying the Garments (continued)

Step 4: With both hands, grab both flaps of the top part of the garment. Place the garment on the back of the upper calf area just below the knee. Pull the left flap over the leg. Then place the right flap over the leg and connect to the left flap to ensure a snug fit.



Step 5: With both hands, grab both flaps of the middle part of the garment. Place the garment on the back of the lower calf area. Pull the left flap over the leg. Then place the right flap over the leg and connect to the left flap to ensure a snug fit.



Applying the Garments (continued)

Step 6: Grab the ankle strap with the writing, “PLACE ACROSS ANKLE” and pull it over the ankle. Fasten to the lower part of the garment by attaching the hook and fasteners. Ensure a snug fit.



Once the garment is fully secured to the leg as shown below, treatment can begin.



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 on an even surface.

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 ADAPTER to the POWER INPUT PORT on the Back Panel of the device. Secure the other end of the POWER ADAPTER to a safe, properly grounded outlet.
- 2.3. Attach CONNECTOR(S) of the garments to the CONNECTOR PORT(S) on the Front Panel of the device. **Note:** For unilateral therapy (applying treatment to only one leg), place the AIR BLOCKER in the unused CONNECTOR PORT.
- 2.4. **Directions for Applying Leg Garment(s).** Refer to “Applying the Garment” section of this guide on page 8.



CAUTION: *The detachable Power Adapter may pose a risk of strangulation. Do not allow children or pets to touch or play with the device power cord or garment tubing that could cause strangulation*




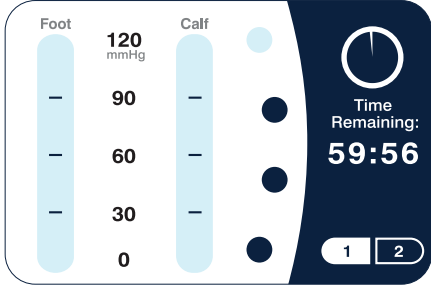

CAUTION: *Prolonged Treatment may lead to injury. Only use the device for the amount of treatment time directed in the physician’s script*

3. Treatment Therapy


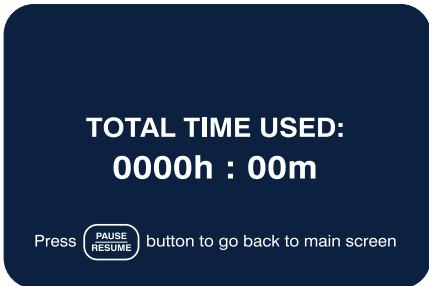
The ARTAIRA Arterial Compression Device can only be used in one operating mode for pneumatic compression. There are no settings that can be changed on the ARTAIRA Arterial Compression Device.

- **Treatment Time:** 1 Hour (60 Minutes)
- **Sequence Time:** 20 Seconds (per chamber)
 - 3 seconds of compression
 - 17 seconds of non-compression
 - 1 second delay between start of Foot/Ankle chamber to start of Calf chamber
- **Chamber Pressure:** 120 mmHg

Operating Instructions (continued)

3.1	<p>MAIN SCREEN</p>  <p>Press START STOP button to begin therapy</p>	<p>Press the MAIN POWER SWITCH located on the Side Panel of the device to the “I” position. The device’s screen will illuminate. The MAIN SCREEN will appear.</p> <p>To use the device and begin treatment immediately press the START STOP BUTTON.</p>
3.2	<p>THERAPY SCREEN</p>  <p>Foot 120 mmHg 90 60 30 0</p> <p>Calf 90 60 30 0</p> <p>Time Remaining: 59:56</p> <p>1 2</p>	<p>This is the THERAPY SCREEN.</p> <p>This screen will appear after the START STOP BUTTON has been pressed.</p> <p>Note: Unit will first fill the reservoir with air for 16-seconds before the countdown begins.</p> <p><i>Note: Settings for the ARTAIRA Arterial compression device cannot be changed.</i></p> <p>The treatment can be paused at any point by pressing the PAUSE RESUME BUTTON. The device will remain paused until the PAUSE RESUME BUTTON is pressed, which will resume the treatment.</p> <p>To stop treatment, press the START STOP BUTTON. This will initiate the deflation process as shown in 3.3 DEFLATION SCREEN.</p>
3.3	<p>DEFLATION SCREEN</p>  <p>Deflation in progress...</p> <p>25 seconds remaining</p>	<p>This is the DEFLATION SCREEN.</p> <p>This will appear either after treatment has ended or after the START STOP BUTTON has been pressed during treatment.</p>

Operating Instructions (continued)

3.4	<p>REMINDER SCREEN</p>  <p>Please connect a garment or blocker in Connector Port 1, then press the START STOP button to begin therapy.</p>	<p>If the ARTAIRA device is being used unilaterally (1 garment connected) then an Air Blocker must be connected to the opened Garment Connector Port.</p> <p>If a garment or an Air Blocker is not connected the REMINDER SCREEN will be shown to request one be connected.</p>
3.5	<p>USAGE DATA SCREEN</p>  <p>TOTAL TIME USED: 0000h : 00m</p> <p>Press PAUSE RESUME button to go back to main screen</p>	<p>This screen shows the amount of total time the device has been used.</p> <p>To enter this page the user must press and hold the PAUSE/RESUME BUTTON for 5 seconds.</p>

Operating Instructions (continued)

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 (30 seconds).
- 4.3. Upon completion of treatment and deflation session, press the **MAIN POWER SWITCH** located on the Side Panel of the device to the "O" position. The device's screen will go dark.
- 4.4. Unfasten the areas of the garment with hook and loop fasteners.
- 4.5. Remove the garment(s) from the Front Panel of the device.
- 4.6. Unplug the power adapter from the wall.



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 device away from CT or MRI environments.*



CAUTION: *Operating the equipment near explosive and flammable gas may cause fire. Keep away from explosive and flammable anesthetic gas.*



CAUTION: *To avoid affecting the life and normal function of the equipment, do not expose the device to direct sunlight and protect the device against dirt and moisture.*



CAUTION: *If there is a power outage during treatment and the garment(s) are inflated, first disconnect the garment(s) from the device to allow air to flow out of the garment connector. Then pull the Velcro apart on the garment and remove it from the body.*

Error Messages/Indicators



If the device functions improperly, the LCD screen shall display one of the following error codes (E01, E02, E03.X, where X denotes the source of fault) and a prompt to go back to the Main Screen.

If the user presses the “PAUSE|RESUME” button the LCD will display the Main Screen.

- **E01** = Error High Pressure: This can occur if there is a kink or other obstruction in the garment tubing, or if there is an air obstruction in the device.
- **E02** = Error Low Pressure: This can occur if there is a leak, and the garments cannot fill properly. A leak may be caused by a hole in the garment, or if the garment connectors are improperly connected.
- **E03** = Software Error: This can occur if there is any sign of a faulty component, or a software error is found by the device itself. There are four types of software errors:
 - **E03.1** = The main control unit inside the device crashes or the software fails.
 - **E03.2** = The air pump or its drive circuit is damaged.
 - **E03.3** = The pressure sensor is damaged.
 - **E03.4** = The air valve or its drive circuit is damaged.

Attaching and Detaching Connector

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

Plug the prongs on the Garment Connector into the holes on the Garment Connector Port on the device.

The Garment Connector can also be easily detached from the device. Simply pull out the Garment Connector with a light force and the garment will detach from the device.

Garment Care & Device Maintenance

The ARTAIRA compression garments are for single patient use only. To clean, disconnect the garment(s) from the device. Unzip the garment and spread it out on an even, flat surface. Hand wash the inside and outside surfaces of the garment with warm, soapy water. DO NOT submerge the tubing or tubing parts in water. Use a clean, dry cloth to wipe the garment. Leave the garment open to air dry until it is dry on all surfaces. DO NOT place the garments in a drying machine, dry clean, or blow-dry.



NOTE: Please clean the garment(s) as needed if the garment is soiled.



NOTE: Garment(s) 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 garment(s) and contact AIROS Medical or an authorized AIROS Medical dealer to obtain new garments.

Device Maintenance

The ARTAIRA device is not field-serviceable. Patients should not perform any maintenance. Tampering with or dismantling the device in any way will void the warranty. If you have any questions or need assistance, please contact AIROS Medical or your authorized dealer.

Device Disposal

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

Warranty & Service Information:

AIROS Medical, Inc. warrants its ARTAIRA Arterial 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, Inc. 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 Operation Manual.

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.

Manufactured for:

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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: 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.



NOTE: In the USA, Federal Law restricts this device to sale, by or on the order of a physician.



NOTE: Unit is packaged for transportation by common carrier. The device must be operated by qualified and trained personnel only.



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

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

1. The ARTAIRA Arterial 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 ARTAIRA Arterial 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 ARTAIRA Arterial Compression Device as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the ARTAIRA Arterial Compression Device.*



CAUTION: *The ARTAIRA Arterial Compression Device should not be used adjacent to or stacked with other equipment.*



CAUTION: *Portable RF communications equipment (including peripherals such as antenna cables and external antenna(s)) should be no closer than 30cm (12" to any part of the product, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.*



CAUTION: *The potential for electromagnetic interference in all environments cannot be eliminated. Use caution if the ARTAIRA device is used near electronic equipment such as devices utilizing Radio Frequency Identification Device (RFID), Wireless Power Transfer (WPT) devices, anti-theft equipment, metal detectors, high-frequency surgical devices, or medical equipment such as diathermy and electrocautery equipment. Please keep the ARTAIRA device at least 30cm away from such equipment, otherwise degradation of the performance of this equipment could result.*

Essential Performance

The Essential Performance of the ARTAIRA Arterial Compression Device is that the device maintains its pressure specification of 120+10mmHg in the garment chambers when fully inflated and the unit deflates as intended during each therapy sequence and when therapy is stopped by the user.

Guidance & Manufacturer's Declaration – Electromagnetic Emissions

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


EMISSIONS	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Conducted and Radiated RF emissions CISPR 11	Group 1	The ARTAIRA Arterial 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 ARTAIRA Arterial Compression Device is suitable for use in all establishments, including professional/domestic and those not directly connected to the public low-voltage power supply network that supplies buildings used for professional/domestic purposes except for near active HF surgical equipment and the RF shielded room for magnetic resonance imaging.
Radiated RF emissions CISPR 11	Class B	
Harmonic emissions IEC 6100-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 6100-3-3	Complies	

Guidance & Manufacturer's Declaration – Electromagnetic Immunity

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

Immunity Test	IEC 60601-2 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge IEC 61000-4-2	±8kV contact; ±2kV, ±4kV, ±8kV, ±15 kV air	±8kV contact; ±2kV, ±4kV, ±8kV, ±15kV 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	±2kV AC power supply lines; ±1kV DC power/Signal lines. 100 kHz repetition frequency	±2kV for AC power supply lines 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5kV, ±1kV lines to lines; ±0.5kV, ±1kV, ±2kV lines to earth	±0.5kV, ±1kV lines to lines	Mains power quality should be that of a typical commercial or hospital environment.
Rated power frequency magnetic fields IEC 61000-4-8	30A/m 50Hz or 60Hz	30A/m 50Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips IEC 61000-4-11	0% UT, 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°; 0% UT, 1 cycle and 70% UT, 25/30 cycle Single phase: at 0°	0% UT, 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°; 0% UT, 1 cycle and 70% UT, 25/30 cycle Single phase: at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the product requires continued operation during power mains interruptions, it is recommended that the Electronic Stimulator for Pain Relief be powered from an uninterruptible power supply or a battery.
Voltage interruptions IEC 61000-4-11	0% UT, 250/300 cycle	0% UT, 250/300 cycle	
<p>NOTE: UT is the a.c. mains voltage prior to application of the test level. E.g.: 25/30 means 25 periods at 50 Hz or 30 periods at 60 Hz. 250/300 means 250 periods at 50 Hz or 300 periods at 60 Hz</p>			

Guidance & Manufacturer's Declaration – Electromagnetic Immunity (continued)

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted disturbances induced by RF fields IEC 61000-4-6	3Vrms in 0.15MHz – 80MHz; 6Vrms in ISM bands between 0.15MHz and 80MHz (Professional healthcare facility environment), 6Vrms in ISM and amateur radio bands between 0.15MHz and 80MHz (Home healthcare environment) 80% AM at 1kHz	3Vrms in 0.15MHz – 80MHz, 6Vrms in ISM and amateur radio bands between 0.15MHz and 80MHz (Home healthcare environment) 80% AM at 1kHz	Portable and mobile RF communications equipment should be used no closer to any part of these devices, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation Distance $d=3.5\sqrt{1/(p)}$ $d=12\sqrt{2/(p)}$ $d=3.5/E1\sqrt{1/(p)}$ $d=7/E1\sqrt{1/(p)}$ 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 meters(m)b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, and should be less than the compliance level in each range.c Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF EM fields IEC 61000-4-3	3V/m (Professional healthcare facility environment); 10V/m (Home healthcare environment), 80MHz – 2.7GHz 80% AM at 1kHz	10V/m (Home healthcare environment) 80MHz – 2.7GHz 80% AM at 1kHz	
Proximity magnetic fields IEC 61000-4-39	30 kHz , CW,8A/m 134,2 kHz, Pulse modulation 2,1 kHz 65f A/m 13,56 MHz Pulse modulation 50 kHz 7,5f A/m	134,2 kHz , Pulse modulation 2,1 kHz 65f A/m 13,56 MHz Pulse modulation 50 kHz 7,5f A/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. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz
 The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz

b. 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 ARTAIRA Arterial Compression Device is used exceeds the applicable RF compliance level above, the ARTAIRA Arterial 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 ARTAIRA Arterial Compression Device.

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

d. This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT.

e. The carrier shall be modulated using a 50 % duty cycle square wave signal.

f. r.m.s., before modulation is applied.

Guidance & Manufacturer's Declaration – Electromagnetic Immunity

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

Immunity Test	IEC 60601-2 test level	Compliance level	Electromagnetic environment-guidance
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See the following table	Complies	

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band a) (MHz)	Service a)	Modulation	Immunity Test Level (V/m)
385	380 – 390	TETRA 400	Pulse modulation b) 18 Hz	27
450	430 – 470	GMRS 460, FRS 460	FM c) \pm 5 kHz deviation 1 kHz sine	28
710	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	9
745				
780				
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	28
870				
930				
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	28
1 845				
1 970				
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	28
1 845				
1 970				
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	9
5 500				
5 785				
NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.				
a) For some services, only the uplink frequencies are included.				
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.				
c) As an alternative to FM modulation, the carrier may be pulse modulated using a 50 % duty cycle square wave signal at 18 Hz. while it does not represent actual modulation, it would be worst case.				

Guidance & Manufacturer’s Declaration – Electromagnetic Immunity

Recommended separation distances between portable and mobile RF communications equipment and the **ARTAIRA Arterial Compression Device**.

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

Maximum output power rating of the transmitter W	Separation distance according to frequency of transmitter (m)			
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	150kHz ^ 80MHz $d=2\sqrt{(p)}$	80MHz ^ 800MHz $d=0.35\sqrt{(p)}$	800MHz ^ 2.5GHz $d=0.7\sqrt{(p)}$
0.01	0.12	0.2	0.04	0.07
0.1	0.38	0.63	0.11	0.22
1	1.2	2.0	0.35	0.7
10	3.8	6.3	1.11	2.21
100	12	20	3.5	7

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.



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