AIROS 8P
Sequential Compression Device

OPERATING INSTRUCTIONS FOR USE GUIDE

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Indications for Use

The AIROS 8P Sequential Compression Device utilizes gradient pneumatic compression, which is intended for treatment of patients with the following conditions:

- Primary Lymphedema
- Secondary Lymphedema
- Venous insufficiency
- Venous stasis ulcers
- 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:

- Known or suspected Deep Vein Thrombosis (DVT) or pulmonary embolism
- Infections in the limb, including cellulitis
- Presence of lymphangiosarcoma
- Inflammatory phlebitis
- 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

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

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	6.7 lbs. (3.05 kg)
Inflation	User Set
Deflation	Fixed
Cycle Time	User Set
Electrical	100-240VAC, 50/60 Hz, 100VA MAX
Fuse Rated	2.5 AMP, T2.5AH,250V 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 8P 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 pneumatic compression reduces swelling, increases blood flow, and encourages extracellular fluid clearance.

The AIROS 8P system consists of the device and 8-chambered garments. The device provides cycles of compressed air at certain adjustable pressures, and sequentially inflates the garments from distal to proximal. The pressure at each chamber can be individually adjusted to accommodate different therapy needs.

Box Contents

- 1 AIROS 8P Sequential Compression Device
- 1 Power Cord
- 1 Air Blocker (for use during unilateral therapy)
- 1 AIROS 8P Operating Instructions for Use Guide (this booklet)

NOTE: Garments are sold seperately. Refer to Page 23 for garment models.

NOTE: Device set-up, including selection of operating specifications, should be performed by a trained clinician or licensed professional in accordance with the physician's script. Patients may use the device and change operating specifications only as directed by their physician

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:** 3.3 volts DC, max 0.1 AMP, 4 lines x 21 characters per line presentation.

Status Indication

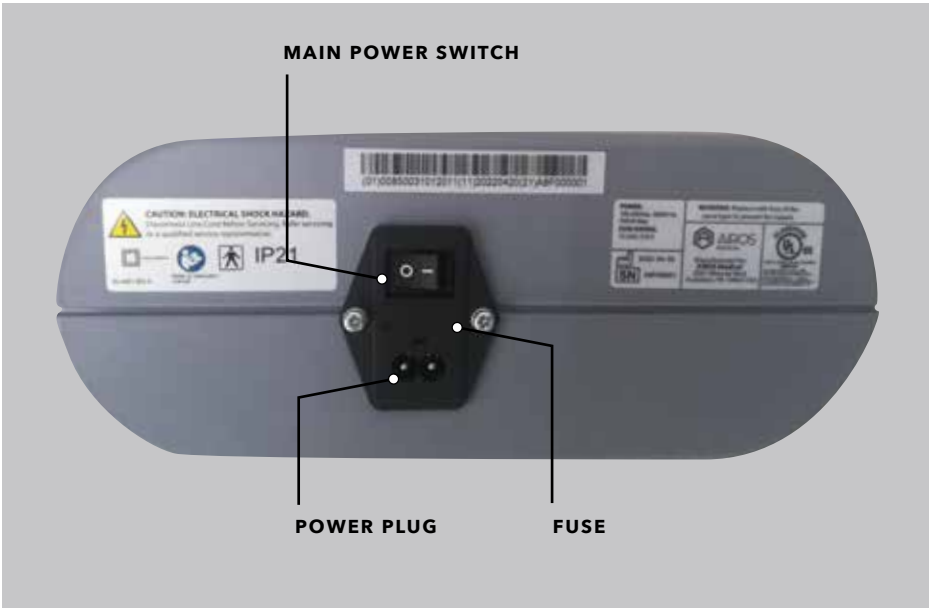
- **Blue LED:** Indicates that treatment is being administered.
- **Green LED:** Indicates that settings are being changed on the device.
- **Yellow LED:** Indicates there is an error in operation.

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.

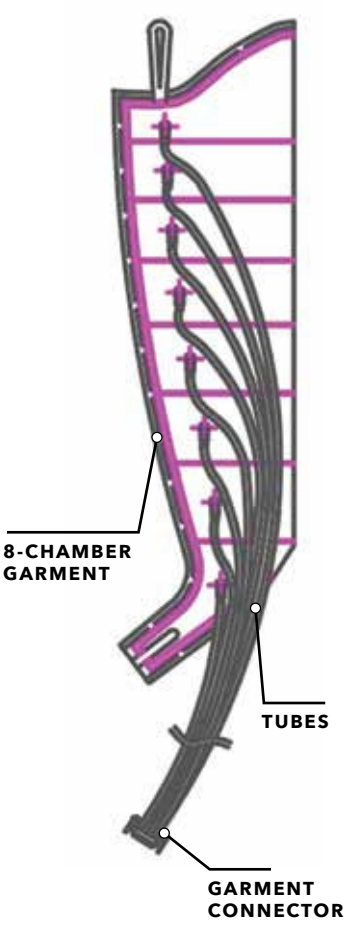
- **FUSE:**
  One (1) time-delayed fuse inside for protection against electrical short circuit.

- **POWER PLUG:**
  Power source.

8-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.



- **8-Chamber Garment:**
  Applied part for treatment. Garment has 8 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 MODE	PERISTALTIC MODE (ARM OR ARM PLUS GARMENT ONLY)
Pressure Range (set in distal chamber)	30-80mmHg (increments of 1mmHg)	35-80mmHg (increments of 1mmHg)	30-80mmHg (increments of 1mmHg)
Cycle Time	40 or 60 seconds	40 or 60 seconds	None
Deflation	12 seconds (18 seconds for Pants)	12 seconds (18 seconds for Pants)	5 seconds
Therapy Time	15, 30, 45 or 60 minutes	15, 30, 45 or 60 minutes	15, 30, 45 or 60 minutes
Gradient	4% (fixed)	4% (default; can be changed by user)	4% (fixed)
Skip Chamber Option	Yes (1 chamber)	Yes (1 chamber)	N/A
Secondary Lymphedema Preparation Treatment (LPT) Mode Option	Focal or Clearing	Focal or Clearing	Clearing
SECONDARY LYMPHEDEMA PREPARATION TREATMENT (LPT) MODE SETTINGS	**FOCAL MODE**	**CLEARING MODE**	
Pressure Options	40, 45 or 50mmHg	15 or 20mmHg	
Chamber Selection	1-4, 2-5, 3-6, 4-7 or 5-8	N/A	
Therapy Time	10 or 15 minutes	N/A	

Primary Operating Modes

The AIROS 8P device can be used in three primary operating modes: **Gradient Mode**, **Pressure Mode**, and **Peristaltic Mode**.

- **Gradient Mode** can be selected for all garment types. The user can set the starting pressure in Chamber 1 on the garment, the most distal chamber near the foot or hand. Pressure decreases at a fixed gradient of 4% distally to proximally. Beginning with Chamber 1, each individual garment chamber inflates to the target pressure and holds that pressure until all chambers have been inflated. Then, all chambers deflate, and the next compression cycle begins.

- **Pressure Mode** can be selected for all garment types. The user can set the pressure in each of the 8 chambers in the garment. The default gradient is 4%. Once a setting is changed in a chamber, the following chamber pressures will automatically be updated to a value equaling a 4% pressure gradient.

- **Peristaltic Mode** is a wave-like operating mode that can be selected for the Arm and Arm Plus garments. The user can set the starting pressure in Chamber 1 on the garment near the hand. Pressure decreases at a fixed gradient of 4% distally to proximally.

  First, Chambers 1 through 3 inflate to their target pressures, sequentially, and then hold their pressure. Then, Chamber 1 deflates, relieving pressure in that area, and Chamber 4 then inflates to its target pressure and holds.

  Chamber 2 then deflates, Chamber 5 inflates, and so on until the entire body area has been compressed.

  This wave-like mode compresses smaller areas of the body at one time and may be selected by physicians for use with certain patients.

Factory Default Settings

User may operate the AIROS 8P using the Factory Default settings. The Factory Default setting is Gradient Mode Operation with 45 mmHg of pressure in the distal chamber and a 4% 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 8P 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 (1-4, 2-5, 3-6, 4-7, or 5-8 selected by the user). Focal Mode can be used **prior** to **Gradient Mode** or **Pressure Mode** therapy.

- **Clearing Mode**: User can utilize this mode to mimic manual lymphatic drainage. Clearing Mode can be used **prior** to **Gradient Mode**, **Pressure Mode**, or **Peristaltic 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.
   - 2.3. Attach GARMENT CONNECTORS of the garment to the GARMENT CONNECTOR PORTS on the Front Panel of the device.

     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. 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.*

Operating Instructions (continued)

2.6. **Directions for Applying Arm Plus Garment**
The Arm Plus garment includes three (3) Garment Extension pieces in the packaging. There is also a fourth larger garment extender available from AIROS Medical that can extend the body circumference further. 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. If the largest piece does not reach, contact your local supplier to acquire the larger garment extender available from AIROS Medical.

2.7. **Directions for Applying Pants Garment**
Unzip both zippers on the garment all about halfway down the legs. Place feet into the bottom of the left and right side of the garment. Utilize pull handles to pull the garment up the body until the top of the garment rests above the waistline. Pull up the zippers while supporting the garment. Ensure that the garment wraps completely around the leg and waist area.

NOTE: Putting on the Pants garment may be easier while lying down.

3. **Treatment Therapy**

NOTE: Device settings can be modified only before or in between therapy sessions. The device will remember the settings from the previous therapy session.

NOTE: Prior to the start of therapy in Gradient Mode, Pressure Mode, or Focal Mode, the garment(s) will briefly "prefill" with air to aid in removing any wrinkles or creases and to allow for minor adjustments in garment positioning. The LCD screen will read "PREFILL". There is no "prefill" session when using the device in Peristaltic or Clearing Modes, or when utilizing the Pants garments.

CAUTION: *The recommended recovery time is 4 hours to warm from the minimum storage temperature between uses (-25°C/-14°F) until the equipment is ready for use when the ambient temperature is 20°C/68°F. The recommended recovery time is 4 hours to cool from the maximum storage temperature between uses (70°C/158°F) until the equipment is ready for use when the ambient temperature is 20°C/68°F.*

Operating Instructions (continued)

3.1	**START-UP SCREEN** AIROS MODEL 8P PRESS START/STOP TO BEGIN TREATMENT NOW	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. 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. If the device has been used before, press the orange **START|STOP BUTTON**. Treatment will begin immediately using settings that have been programmed previously. 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 3.2.
3.2	**MAIN MENU SCREEN** ▸ THERAPY MODES USAGE DATA RESET TO DEFAULT BEGIN TREATMENT	This is the MAIN MENU SCREEN. To select your therapy mode and adjust settings, press **UP** ↑ or **DOWN** ↓ to scroll to THERAPY MODES. Press **SELECT** to confirm and proceed to 3.3 To view device usage data, press **UP** ↑ or **DOWN** ↓ to scroll to USAGE DATA. Press **SELECT** to confirm and proceed to 3.11. 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 3.12. To begin treatment therapy, press **UP** ↑ or **DOWN** ↓ to scroll to BEGIN TREATMENT. Refer to 3.3 for additional instructions to begin treatment.
3.3	**GARMENT SELECTION SCREEN** SELECT GARMENT TYPE: ▸ LEG DOUBLE X-WIDE LEG ← MORE → ← PREVIOUS → ▸ PANTS ARM ARM PLUS	This is the GARMENT SELECTION SCREEN. To select the type of garment or garments being used for therapy, press **UP** ↑ or **DOWN** ↓ to scroll though the garment types. For additional garment types, including PANTS, ARM or ARM PLUS, scroll **DOWN** ↓ to ← **MORE** → to bring you to the next screen. Press **SELECT** to confirm your garment type. If selecting LEG, ARM or DOUBLE X-WIDE LEG, proceed to 3.4. If selecting ARM PLUS, proceed to 3.5. If selecting PANTS, proceed to 3.6.

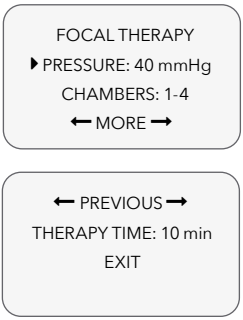
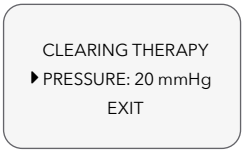
Operating Instructions (continued)

3.4	**GARMENT QUANTITY SCREEN** SELECT # OF SLEEVES FOR USE IN TREATMENT ▸ 1 SLEEVE 2 SLEEVES	**NOTE**: After selecting the type and number of garments for treatment the first time, the device will remember this selection. The user will not need to select the type or number of garments the next time they operate the device. To change the garment type or the number of garments for treatment, the user must reset the device to Factory Default settings. Refer to the instructions in 3.12. Press the **UP ↑** or **DOWN ↓ BUTTONS** 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 and continue to 3.5
3.5	**THERAPY MODE SELECTION SCREEN** ▸ GRADIENT MODE PRESSURE MODE PERISTALTIC MODE BACK TO MAIN MENU	This is the THERAPY MODE SELECTION SCREEN. **NOTE**: PERISTALTIC MODE can only be used with ARM or ARM PLUS garments. To utilize Gradient Mode therapy, press **UP ↑** or **DOWN ↓** to scroll to GRADIENT MODE. Press **SELECT** to confirm and proceed to 3.6. To utilize Pressure Mode, press **UP ↑** or **DOWN ↓** to scroll to PRESSURE MODE. Press **SELECT** to confirm and proceed to 3.10. To utilize Peristaltic Mode, press **UP ↑** or **DOWN ↓** to scroll to PERISTALTIC MODE. Press **SELECT** to confirm and proceed to 3.9. To go back to the MAIN MENU SCREEN, press **UP ↑** or **DOWN ↓** to scroll to BACK TO MAIN MENU. Press **SELECT** to confirm.

Operating Instructions (continued)

3.6	**GRADIENT MODE SET-UP SCREEN** ▸ GRADIENT: 4% PRESSURE: 45mmHg CYCLE TIME: 60 sec ⟵ MORE ⟶ ⟵ PREVIOUS ⟶ THERAPY TIME: 60 min SKIP CHAMBER: OFF ⟵ MORE ⟶ ⟵ PREVIOUS ⟶ LPT MODE: CLEARING BACK TO MAIN MENU BEGIN TREATMENT	**NOTE**: press **UP** ↑ or **DOWN** ↓ to scroll to MORE or PREVIOUS to view additional settings options. **NOTE**: Gradient of pressure cannot be altered. 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. 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. 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 seconds. Press **SELECT** to confirm. The cycle time will be updated and stop blinking. To select a chamber in which to skip pressure, press **UP** ↑ or **DOWN** ↓ to scroll to SKIP CHAMBER. Press **SELECT** to confirm. The skip chamber setting will begin blinking. press **UP** ↑ or **DOWN** ↓ to scroll through the settings, including OFF, 1, 2, 3, 4, 5, 6, 7, or 8. Press **SELECT** to confirm. The skip chamber setting will be updated and stop blinking. 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. If you select FOCAL THERAPY, proceed to 3.7. If you select CLEARING THERAPY, proceed to 3.8. 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. To go back to the MAIN MENU SCREEN, press **UP** ↑ or **DOWN** ↓ to scroll to BACK TO MAIN MENU. Press **SELECT** to confirm. To begin treatment therapy, press **UP** ↑ or **DOWN** ↓ to scroll to BEGIN TREATMENT.

Operating Instructions (continued)

3.7	**FOCAL THERAPY MODE SET-UP SCREEN** 	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. 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 1-4, 2-5, 3-6, 4-7, or 5-8. Press **SELECT** to confirm. The pressure will be updated and stop blinking. 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. To exit and return to a therapy mode set-up screen, press **UP** ↑ or **DOWN** ↓ to scroll to EXIT. Press **SELECT** to confirm
3.8	**CLEARING THERAPY MODE SET-UP SCREEN** 	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. To exit and return to a therapy mode set-up screen, press **UP** ↑ or **DOWN** ↓ to scroll to EXIT. Press **SELECT** to confirm.

Operating Instructions (continued)

3.9	**PERISTALTIC MODE SET-UP SCREEN** ▸ PRESSURE: 45mmHg THERAPY TIME: 60 min ⟵ MORE ⟶ ⟵ PREVIOUS ⟶ LPT MODE: CLEARING BACK TO MAIN MENU BEGIN TREATMENT	NOTE: press **UP** ↑ or **DOWN** ↓ to scroll to MORE or PREVIOUS to view additional settings options. 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. 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 seconds. Press **SELECT** to confirm. The cycle time will be updated and stop blinking. To operate the optional Lymphedema Preparation Treatment (LPT) Clearing Therapy mode before Peristaltic 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 and CLEARING. If you select CLEARING THERAPY, refer to 3.8 before continuing. 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. To go back to the MAIN MENU SCREEN, press **UP** ↑ or **DOWN** ↓ to scroll to BACK TO MAIN MENU. Press **SELECT** to confirm. To begin treatment therapy, press **UP** ↑ or **DOWN** ↓ to scroll to BEGIN TREATMENT.

Operating Instructions (continued)

3.10

PRESSURE MODE SET-UP SCREEN

▸ SET PRESSURE: 1-8
CYCLE TIME: 60 sec
THERAPY TIME: 60 min
← MORE →

← PREVIOUS →
SKIP CHAMBER: OFF
LPT MODE: CLEARING
← MORE →

← PREVIOUS →
BACK TO MAIN MENU
BEGIN TREATMENT

INDIVIDUAL PRESSURE SET-UP SCREEN

▸ CHAMBER 1: 60mmHg
CHAMBER 2: 57mmHg
CHAMBER 3: 54mmHg
← MORE →

← PREVIOUS →
CHAMBER 4: 51mmHg
CHAMBER 5: 48mmHg
← MORE →

← PREVIOUS →
CHAMBER 6: 45mmHg
CHAMBER 7: 42mmHg
← MORE →

← PREVIOUS →
CHAMBER 8: 39mmHg
SAVE/EXIT

NOTE: press **UP** ↑ or **DOWN** ↓ to scroll to MORE or PREVIOUS to view additional settings options.

To set the Pressure in each chamber, press **UP** ↑ or **DOWN** ↓ to scroll to SET PRESSURE. Press **SELECT** to confirm. NOTE: Refer to the INDIVIDUAL PRESSURE SET-UP SCREEN below.

To set the pressure for INDIVIDUAL PRESSURE SET-UP in Chamber 1, press **UP** ↑ or **DOWN** ↓ to scroll to CHAMBER 1. The pressure setting will begin blinking. press **UP** ↑ or **DOWN** ↓ to scroll from X-X%, in increments of 1%. Press **SELECT** to confirm. The percentage will be updated and stop blinking. Repeat these steps to set the pressure in the rest of the chambers.

To save your changes, press **UP** ↑ or **DOWN** ↓ to scroll to SAVE/EXIT. Press **SELECT** to confirm.

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.

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 seconds. Press **SELECT** to confirm. The cycle time will be updated and stop blinking.

To select a chamber in which to skip pressure, press **UP** ↑ or **DOWN** ↓ to scroll to SKIP CHAMBER. Press SELECT to confirm. The skip chamber setting will begin blinking. press **UP** ↑ or **DOWN** ↓ to scroll through the settings, including OFF, 1, 2, 3, 4, 5, 6, 7, or 8. Press **SELECT** to confirm. The skip chamber setting will be updated and stop blinking.

To go back to the MAIN MENU SCREEN, press **UP** ↑ or **DOWN** ↓ to scroll to BACK TO MAIN MENU. Press **SELECT** to confirm.

To operate an optional Lymphedema Preparation Treatment (LPT) mode before Pressure 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.

If you select FOCAL THERAPY, refer to 3.7 before continuing.

If you select CLEARING THERAPY, refer to 3.8 before continuing.

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.

To begin treatment therapy, press **UP** ↑ or **DOWN** ↓ to scroll to BEGIN TREATMENT.

Operating Instructions (continued)

3.11	**USAGE DATA SCREEN** TOTAL USAGE TIME HOURS: 0 MINUTES: 0 ▸ BACK TO MAIN MENU	This screen shows the amount of total time the device has been in used. To go back to the MAIN MENU SCREEN, press **UP** ↑ or **DOWN** ↓ to scroll to BACK TO MAIN MENU. Press **SELECT** to confirm.
3.12	**RESET TO DEFAULT SCREEN** ▸ RESET TO FACTORY DEFAULT SETTINGS CANCEL	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.

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, T2.5AH,250V 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 CT or MRI environments.*

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

CAUTION: *To avoid affective 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 garments are inflated, first disconnect the garments from the device to allow air to flow out of the garment connector. Then unzip the garment and remove it from the body.*

Error Messages/Indicators

High Pressure Error Indicator: 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 yellow LED light will illuminate, and a buzzer will sound.

Low Pressure Error Indicator: 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 yellow LED light will illuminate, and a buzzer will sound.

Software System Error Indicator: This can occur if an internal software system error occurs causing the device to be inoperable. The LCD screen will read **E03**, the yellow LED light will illuminate, and a buzzer 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 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 garment models 8-APLP01 or 8-APRP01) 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, T2.5AH,250V 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.

CAUTION: *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.*

CAUTION: *Use of a fuse, garment, or power supply cord other than those specified or provided by AIROS Medical could result in fire, shock, or improper operation.*

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 submerse 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.
6. Inspect the garment(s) after cleaning. If soiling is still present, repeat steps 2-5.

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

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	8-SL01/8-SL02	Full Leg	8
Small Wide Leg	8-SWL01/8-SWL02	Full Leg	8
Small Extra Wide Leg	8-SXWL01/8-SXWL02	Full Leg	8
Small Double Extra Wide Leg	8-SDXWL01/8-SDXWL02	Full Leg	8
Medium Leg	8-ML01/8-ML02	Full Leg	8
Medium Wide Leg	8-MWL01/8-MWL02	Full Leg	8
Medium Extra Wide Leg	8-MXWL01/8-MXWL02	Full Leg	8
Medium Double Extra Wide Leg	8-MDXWL01/8-MDXWL02	Full Leg	8
Large Leg	8-LL01/8-LL02	Full Leg	8
Large Wide Leg	8-LWL01/8-LWL02	Full Leg	8
Large Extra Wide Leg	8-LXWL01/8-LXWL02	Full Leg	8
Small Pants	8-SP01/8-SP02	Full Leg/Truncal	8
Medium Pants	8-MP01/8-MP02	Full Leg/Truncal	8
Large Pants	8-LP01/8-LP02	Full Leg/Truncal	8
Medium Arm	8-MA01/8-MA02	Arm	8
Large Arm	8-LA01/8-LA02	Arm	8
Arm Plus (Left)	8-APL01/8-APL02	Arm, Shoulder, Chest	8
Arm Plus (Right)	8-APR01/8-APR02	Arm, Shoulder, Chest	8
Arm Plus Pink (Left)	8-APLP01	Arm, Shoulder, Chest	8
Arm Plus Pink (Right)	8-APRP01	Arm, Shoulder, Chest	8
Arm Plus Extender (Left)	APXLL02	Arm, Shoulder, Chest (Extender)	-
Arm Plus Extender (Right)	APXLR02	Arm, Shoulder, Chest (Extender)	-

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 8P 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. 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.

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.

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 plug. Modification of this equipment is not allowed.

Guidance and Manufacturer's Declaration – Electromagnetic Compatibility

1. The AIROS 8P Sequential Compression Device should not be used adjacent to or stacked with other equipment because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

2. Portable and mobile RF communications equipment can affect the AIROS 8P 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 8P Sequential Compression Device as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the AIROS 8P Sequential Compression Device.*

CAUTION: *The AIROS 8P Sequential 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 antennas) should be used no closer than 30 cm (12") to any part of the device, 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 AIROS 8P device is used near electronic equipment such as devices utilizing Radio Frequency Identification (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 AIROS 8P device at least 30cm away from such equipment, otherwise degradation of the performance of this equipment could result.*

3. Guidance & Manufacturer's Declaration – Electromagnetic Emissions

The AIROS 8P Sequential Compression Device is intended for use in the electromagnetic environment specified below. The customer or user of the AIROS 8P 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 8P 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 8P 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 8P Sequential Compression Device is intended for use in the electromagnetic environment specified below. The customer or user of the AIROS 8P Sequential Compression Device should assure that it is used in such an environment.

Immunity Test	IEC 60601-1-2 test level	Compliance level
Electrostatic discharge IEC 61000-4-2	±8kV contact; ±2kV, ±4kV, ±8kV, ±15 kV air	±8kV contact; ±2kV, ±4kV, ±8kV, ±15kV air
Electrical fast transients/bursts IEC 61000-4-4	±2kV AC power supply lines;	±2kV for AC power supply lines
Surges IEC 61000-4-5	±0.5kV, ±1kV lines to lines; ±0.5kV, ±1kV, ±2kV lines to earth	±0.5kV, ±1kV lines to lines
Rated power frequency magnetic fields IEC 61000-4-8	30A/m 50Hz or 60Hz	30A/m 50Hz or 60Hz
Voltage dips IEC 61000-4-11	0% U_T, 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°; 0% U_T, 1 cycle and 70% U_T, 25/30 cycle Single phase: at 0°	0% U_T, 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°; 0% U_T, 1 cycle and 70% U_T, 25/30 cycle Single phase: at 0°
Voltage interruptions IEC 61000-4-11	0% U_T, 250/300 cycle	0% U_T, 250/300 cycle
Proximity magnetic fields IEC 61000-4-39	30 kHz, CW, 8A/m 134,2 kHz, Pulse modulation 2,1 kHz 65 A/m 13,56 MHz Pulse modulation 50 kHz 7,5 A/m	Not applicable

NOTE: U_T 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.

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

Immunity test	IEC 60601-1-2 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 and amateur radio bands 80% AM at 1kHz	3Vrms in 0.15MHz – 80MHz; 6Vrms in ISM and amateur radio bands between 0.15MHz and 80MHz 80% AM at 1kHz	
Radiated RF EM fields IEC 61000-4-3	10V/m 80MHz – 2.7GHz 80% AM at 1kHz	10V/m 80MHz – 2.7GHz 80% AM at 1kHz	
Proximity fields from RF wireless communications equipment	See the following table	Complies	

NOTE 1: The ISM (industrial, scientific and medical) bands between 0,15 MHz 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.

NOTE 2: At 80 MHz and 800 MHz, the higher frequency range applies.

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

Recommended separation distances between portable and mobile RF communications equipment and the AIROS 8P Sequential Compression Device.

The AIROS 8P 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 8P Sequential Compression Device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AIROS 8P 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 of 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.

Test Specifications for ENCLOSURE PORT IMMUNITY to RF Wireless Communications Equipment

Test frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Maximum power (W)	Distance (m)	Immunity Test Level (V/m)
385	380 – 390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9
745						
780						
810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28
870						
930						
1720	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28
1845						
1970						
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28
5240	5100 5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9
5500						
5785						

Test Specifications for ENCLOSURE PORT IMMUNITY to RF Wireless Communications Equipment (continued)

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, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.