CircuFlow®

CircuFlow 5200 Series

Sequential Compression Device

Operating Instructions

DEVON
MEDICAL PRODUCTS

www.devonmedicalproducts.com

1.866.446.0092

IFU04.0001 Rev. E 20140313

Intended Use:

The **CircuFlow® 5200 Series Sequential Compression Pump** is a compression device based on sequential pneumatic compression technique which is intended for the treatment of the following conditions:

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

The device is safe for both home and hospital use.

Contraindications:

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

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

Description of Various Symbols:

	ATTENTION: **Consult ACCOMPANYING DOCUMENTS.** This symbol is used to direct the user to refer to the documentations for additional information regarding the system use or description.
	**CAUTION**
	**Type B - applied part.**
	**Electrical shock hazard.** Disconnect LINE CORD before servicing; refer servicing to qualified service personnel.
	**Protective earth** (Ground)
	Federal (USA) law restricts this device to sale by or on the order of a physician
SLO-BLO	Slow acting (time delayed) fuse.
IPx0	Without protection against ingress of water
	Date Of Manufacture
SN	Serial Number
	Waste Electrical Goods Recycled
EC REP	Authorized Representative in the European Community
CE 0123	Conforms with the Medical Device Directive (93/42/EEC) and has been subject to the conformity procedures laid down in the council directive
	Manufacturer
REF	Catalog / Model Number

General Equipment Specifications:

DIMENSION:	12″ (W) × 12″ (D) × 4.5″ (H)
WEIGHT:	12 lbs
INFLATION:	User Set
DEFLATION:	12 seconds
CYCLE TIME:	User Set
ELECTRICAL:	5200: 120 VAC, 60 Hz, 100 VA MAX 5202: 220 VAC - 240 VAC, 50 Hz, 100 VA MAX
FUSE RATED:	250 VAC, 1.0 AMP, SLO-BLO
APPLIED PART:	TYPE B
PROTECTION AGAINST ELECTRICAL SHOCK:	CLASS I
OPERATION MODE:	CONTINUOUS OPERATION
PROTECTION AGAINST WATER:	IPx0

Environmental Conditions:

Temperature:	
Operating Temperature:	41°F (5°C) – 104°F (40°C)
Storage Temperature:	-13°F (-25°C) – 158°F (70°C)
Humidity:	
Operating Humidity:	15% – 93%
Storage Humidity:	< 93%
Atmospheric Pressure:	
Operating Pressure:	70 kPa – 106 kPa
Storage Pressure:	50 kPa – 106 kPa

Device Description and Operating Principle:

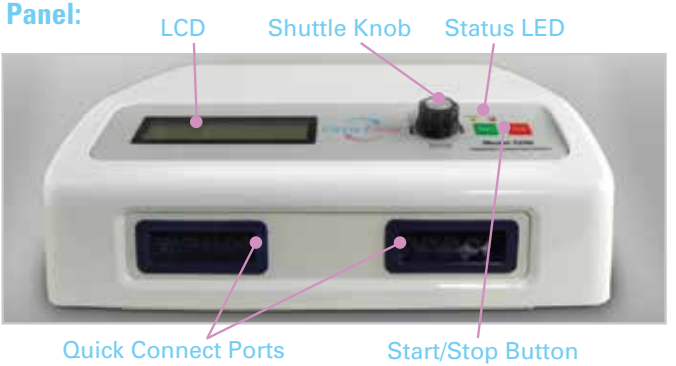
The CircuFlow® 5200 Series Sequential Compression Pump is a gradient compression pneumatic device used for treatment and management of venous or lymphatic disorders. The application of gradient compression is effective by increasing blood flow and encouraging extracellular fluid clearance. The system consists of a device and a pair of four chambered garments. The device provides cycles of compressed air at certain adjustable pressures, and can sequentially inflate the garments from distal to proximal.

Package Contents:

- 1 CircuFlow® 5200 Series Sequential Compression Device
- 1 Power Cord
- 1 CircuFlow® 5200 Series Sequential Compression Device Operating Instructions
- 1 Blocker for use during single garment therapy
- 1 Warranty Registration Form

Device Panels:

1. Front Panel:



Key Function

• **START/STOP KEY:** Through these keys the user can start/end the treatment. In case of an emergency, press "STOP" button to release the air pressure.

Shuttle Knob Function

• Push **SHUTTLE KNOB** realize Mode/Parameter Select Function
• Twist **SHUTTLE KNOB** with clockwise and counterclockwise direction, realizes Adjustment/Change Parameter Function

Display

• **LCD:** Indicating the real-time pressure in each chamber and therapy time
• **LCD SPECIFICATION:** 5 volts DC, max 0.5 amp, 2 lines x 16 characters per line presentation.

Status Indication

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

Quick Connect Port

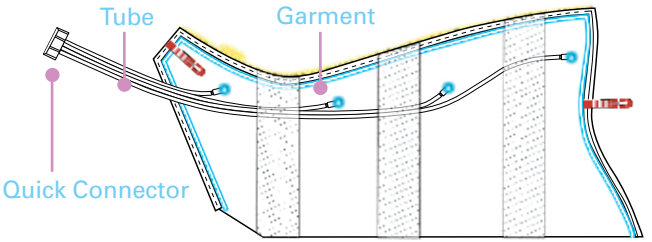
• **LEFT/RIGHT QUICK CONNECT PORT:** Those parts were fixed on the device, and they match with detachable **QUICK CONNECTOR.**
• **AIR BLOCKER:** The **AIR BLOCKER** is used to block the air passage on the unit.

2. Back Panel:

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

3. Four 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 and compliance.



- **QUICK CONNECTOR**: Detachable with the device. Matching with the **QUICK CONNECT PORT** on the front board.
- **TUBE**: Air guidance.
- **GARMENT**: Applied part for treatment. Having four separated chambers.

Operating Instructions:

1. UNPACKING EQUIPMENT

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

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

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

2. PREPARE FOR OPERATING

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

2.2 Gather the power cord and attached to the **APPLIANCE INLET** on the device back panel. Plug the device into a safe, properly grounded outlet. For the 5200, make sure that it is a 120 VAC, 60 Hz outlet. For the 5202, make sure it is a 220 VAC - 240 VAC, 50 Hz outlet.

2.3 Attach left and/or right **QUICK CONNECTORS** of the garment to the **QUICK CONNECT PORTS** which are located on the front panel of device. During a single garment session (i.e. left only or right only) insert the **AIR BLOCKER** into the unused **QUICK CONNECT PORT.**

2.4 Putting the garment on: a) for leg garments, unzip the garment all the way to the end. Place the foot at the bottom end of the garment and pull up the zipper while supporting the garment to wrap around the leg; b) for arm garments, slide the arm through the internal cavity of the garment.

Operating Instructions: *(continued)*

3. TREATMENT

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

There are three operating modes with this device:

- **FACTORY DEFAULT:** Device comes with a factory default setting providing default 45mmHg pressure on distal chamber and a 7% of gradient pressure, a 30 min. treatment time with a 30 sec. cycle time, with no chambers being skipped.
- **GRADIENT MODE:** This mode allows you to set your starting pressure, and the percentage drop of pressure gradient between chambers.
- **PRESSURE MODE:** This mode allows you to set the pressure in each of the four chambers in the sleeve.

3.1 Start

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

Ready... Press <START>

Upon this display, User can directly push < Start > to run the device on Factory Default. If Gradient Mode is desired, continue to 3.2 - 3.10. If Pressure Mode is desired, proceed to 3.10 - 3.16

3.2

Ready... Press <START>

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

3.3

> Factory Default Gradient Mode

This display shows <Therapy Mode Setting>.

Factory Default > Gradient Mode

Turn the **SHUTTLE KNOB** to the right to select Gradient Mode. Then, push the **SHUTTLE KNOB** to select if it is not selected. A selected option will be displayed with an asterisk mark on the right. In the below diagram,

Factory Default > Gradient Mode*

> Pressure Mode Lock Device

Gradient Mode is selected, pressure mode is not. If the option is selected, push the **SHUTTLE KNOB** again will access you to the mode change.

Operating Instructions: *(continued)*

3.4

Pressure 104 mmHg ->

This display shows the first parameter — Pressure. Push the **SHUTTLE KNOB** to select Pressure.

**User can access other parameters by turning the shuttle knob to the right/left at any time.*

104 mmHg

Increase the Pressure by turning the **SHUTTLE KNOB** to the right, decrease the pressure by turning to the left. Offset: 1mmHg

Pressure 107 mmHg ->

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

**Numbers shown are arbitrary and do not reflect appropriate treatment setting.*

3.5

Gradient 7%

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

Gradient 7%

Increase the Gradient by turning the **SHUTTLE KNOB** to the right, decrease by turning to the left. Offset: 1%.

Gradient 9%

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

3.6

Treatment Time <- 30 Min ->

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

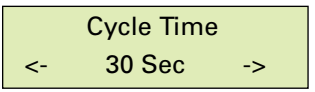
30 Min

Increase the Treatment Time by turning the **SHUTTLE KNOB** to the right, decrease time by turning to the left. Offset: 15 Min.

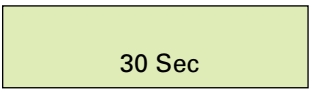
Treatment Time <- 45 Min ->

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

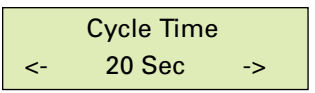
3.7



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

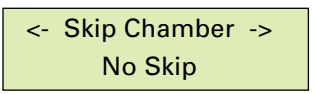


Increase the Cycle Time by turning the **SHUTTLE KNOB** to the right, decrease time by turning to the left. Offset: 10 Sec.

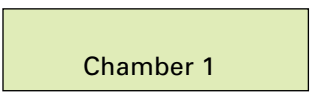


Push the **SHUTTLE KNOB** to confirm the new Cycle Time. This will also take you back to <Parameters>.

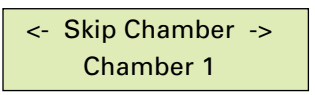
3.8



Access the fifth parameter -- Skip Chamber, by turning the **SHUTTLE KNOB** to the right. Push the S**HUTTLE KNOB** to select Skip Chamber.

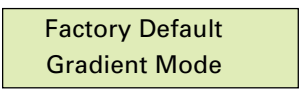


Turn to the chamber you wish to skip by turning the **SHUTTLE KNOB** to the right or left. (Select one only) Chamber 1, Ch. 2, Ch. 3, Ch. 4, or No skip.



Push the **SHUTTLE KNOB** to confirm the Skipped Chamber. This will also take you back to <Parameters>.

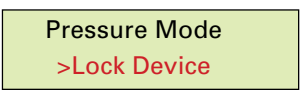
3.9



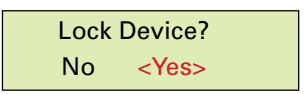
You will be taken to the <Therapy Mode Setting> Screen.

3.10 Lock the Device

This display shows <Therapy Mode Setting>.



Turn the **SHUTTLE KNOB** to the right to select **LOCK DEVICE** option. Push the **SHUTTLE KNOB** to lock the device. A confirmation screen will pop up to ask for confirmation.This is the Lock Device confirmation screen. Turn the **SHUTTLE KNOB** to 'Yes'. Then push the **SHUTTLE KNOB** to lock the device.



Device Locked Password XX	This screen shows a successful locking process. >XX< is the password to unlock the device.
Ready... Press <START>	You will be taken to the <Start> display. Push the green Start button to start your custom treatment.

3.11 Unlock the Device

Ready... Press <START>	This is the <Start> display. Turn/Push the **SHUTTLE KNOB** to unlock the device.
Input Password <00>	This is the <Password Entry> display. Turn the **SHUTTLE KNOB** to change the current character. Current character is highlighted with underline. Push the **SHUTTLE KNOB** to proceed to the next character. After enter both characters, push the **SHUTTLE KNOB** again to confirm the entry.
Password Correct Device Unlocked	This display shows the device has been successfully unlocked.
Ready... Press <START>	You will be taken to the <Start> display. Push the green Start button to start your custom treatment.

3.12

<- Exit	To exit and complete Gradient Mode setup, turn the **SHUTTLE KNOB** to the right. Push to select to Exit.
Ready... Press <START>	Start You will be taken to the <Start> display. Push the green Start button to start your custom treatment.

3.13

Ready...
Press <START>

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

3.14

> Factory Default
Gradient Mode

This display shows <Therapy Mode Setting>.

>Pressure Mode
Lock Device

Turn the **SHUTTLE KNOB** to the right to select Pressure Mode. Then, push the **SHUTTLE KNOB** to select if it is not selected. A selected option will be displayed with an asterisk mark on the right. In the below diagram,

Factory Default
> Gradient Mode*

> Pressure Mode
Lock Device

Gradient Mode is selected, pressure mode is not. If the option is selected, push the SHUTTLE KNOB again will access you to the mode change.

3.15

Pressure Set ->
45 : 42 : 39 : 36

This display shows the first parameter— Pressure. Push the **SHUTTLE KNOB** to select Pressure Set, then push the **SHUTTLE KNOB** on the individual pressures to change them.

**Reference 3.4 for instructions to change Pressure.*

3.16

Treatment Time
<- 30 Min ->

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

**Reference 3.6 for instructions to change Treatment Time.*

3.17

Cycle Time
<- 30 Sec ->

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

**Reference 3.7 for instructions to change Cycle Time.*

3.18

<- Skip Chamber ->
No Skip

Access the fourth parameter -- Skip Chamber, by turning the **SHUTTLE KNOB** to the right. Push the **SHUTTLE KNOB** to select Skip Chamber.

**Reference 3.8 for instructions to change Skip Chamber.*

3.19

<- Exit

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

3.20

Ready... Press <START>

Start

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

4. END OF TREATMENT

4.1 Each treatment will end after its set treatment time has elapsed. The user can also end the treatment at any time during a treatment session by pressing the "STOP" button on the front panel.

4.2 After the treatment, the device will vacuum air from the garment for 1 minute so that it will facilitate the user to easily remove the garment. You will hear a beep sound when the vacuum is completed.

4.3 After vacuum beep, press the **POWER SWITCH** on the backboard to the "OFF" position. Pull out the plug to simultaneously isolate the electrical circuits from the supply mains on all poles.

4.4 Once the power indicator light is off, it is safe to remove the garment.

4.5 The garment should be loose enough by now so you can unzip the garment and remove.

4.6 Press the POWER SWITCH on the backboard to the OFF position and then unplug the power cord.

4.7 Pull out plug to isolate the circuits electrically from the supply mains on all poles simultaneously.

5. NOTE

5.1 After the therapy the device stops and releases air from all four(4) chambers for 60 seconds.

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

Troubleshooting:

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

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

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

Caution: Keep away from environment of CT or MRI

Caution: Keep away from explosive or flammable anesthetic gas

Detaching Quick Connector:

Press down the snap lock on the **QUICK CONNECTOR**, pull out with a light force, the **QUICK CONNECTOR** can be detached from the device with the garment.

The **QUICK CONNECTOR** can also be easily reconnected. Face the ridged side of the snap lock up and aim the **QUICK CONNECTOR** towards the quick connect port. Push the **QUICK CONNECTOR** with a light force towards inside until you hear a click indicating the proper positioning of the connector.

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

Fuse Replacement:

The safety fuse on the back panel of the device can sometimes blow for different reasons such as a power surge or the normal aging of the electronic components. The safety fuse is located in between the **APPLIANCE INLET** and the **POWER SWITCH**.

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

Prior to removal of fuse, disconnect the power cord. While pushing inward on fuse cap, turn counterclockwise to release cap and remove fuse. After placing the new fuse in the cap slot, push cap and fuse inward and turn clockwise to secure.

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

Device Cleaning Instructions:

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

NOTE: Never immerse device in water or apply detergent or water directly.

Garment Care & Cleaning Instructions:

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

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

NOTE: Do not dry clean – Do not Iron

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

Garment Specification:

Several types of garments are available for different size:

Model D-300S	Full Leg	Small Size	4 chambers
Model D-300SW	Full Leg	Small Wide Size	4 chambers
Model D-300SXW	Full Leg	Small Extra Wide Size	4 chambers
Model D-300M	Full Leg	Medium Size	4 chambers
Model D-300MW	Full Leg	Medium Wide Size	4 chambers
Model D-300MXW	Full Leg	Medium Extra Wide Size	4 chambers
Model D-300L	Full Leg	Large Size	4 chambers
Model D-300LW	Full Leg	Large Wide Size	4 chambers
Model D-301H	Half Leg	Regular Size	4 chambers
Model D-301HW	Half Leg	Extra Large Size	4 chambers
Model D-302M	Arm	Medium Size	4 chambers
Model D-302L	Arm	Large Size	4 chambers

Disposal of Device:

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

Warranty & Service Information:

Devon Medical warrants its **CircuFlow® 5200 Series lymphedema compression pumps** (excluding sleeves) (individually each a "Device") to be free from defects in workmanship and materials for a period of three (3) years from the date Device is delivered to the original purchaser ("Warranty Period").

(see next page for further warranty details)

Warranty & Service Information: *(continued)*

Devon Medical Products warrants the sleeves for the Devices to be free from defects in workmanship and materials for a period of one (1) year from the date the sleeves are delivered to the original purchaser. This Limited Warranty is extended only to the original purchaser and is non-transferable. Devon Medical Products' sole obligation under this Limited Warranty shall be, at its sole discretion, to repair or replace a Device which is defective in either workmanship or material. This is the sole remedy of the Purchaser. In addition, this Limited Warranty does not cover any Device which may have been damaged in transit or has been subject to misuse, neglect, or accident; or has been used in violation of Devon Medical Products' instructions, including, without limitation, the instructions contained in the Operation Manual.

THERE ARE NO WARRANTIES THAN THOSE EXPRESSLY STATED HEREIN.

TO THE EXTENT PERMITTED BY LAW, DEVON MEDICAL PRODUCTS DOES NOT MAKE ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE AS TO ANY PRODUCT OR DEVICE, WHETHER OR NOT THAT PRODUCT OR DEVICE IS COVERED BY ANY EXPRESS WARRANTY CONTAINED HEREIN.

IN NO EVENT SHALL DEVON MEDICAL PRODUCTS BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR INDIRECT DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS, USE OR TIME INCURRED BY PURCHASER OR END USER). IN ADDITION, DEVON MEDICAL PRODUCTS SHALL NOT BE LIABLE FOR ANY EXEMPLARY OR PUNITIVE DAMAGES.

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:

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CE 0123

Appendix 1

Product Classification

- According to the type of protection against electrical shock, this device is classified as a Class I Equipment, and Type B Equipment that is powered by an external electrical power source.
- According to the degree of protection against harmful ingress of water this system is classified as Ordinary Equipment (IPx0: without protection against ingress of water)
- According to the methods of sterilization this system does not have any parts or accessories that require sterilization.
- This system is classified as Equipment not Suitable for use in the presence of a Flammable Anesthetic Mixture with Air or Oxygen or Nitrous Oxide.
- According to the mode of operation this system is classified as Equipment that can be used for Continuous Operation.
- **CAUTION:** In the USA, Federal Law restricts this device to sale, by or on the order of a physician.
- Unit is packaged for transportation by common carrier

Appendix 2

Electromagnetic Compatibility Information

Instructions for use

1. **SEQUENTIAL COMPRESSION DEVICE MODEL 5200/5202** needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this document;
2. Portable and mobile RF communications equipment can affect **SEQUENTIAL COMPRESSION DEVICE MODEL 5200/5202.**

Technical description

1. **WARNING** that the use of accessories, transducers and cables other than those specified with the exception of transducers and cables sold by the manufacturer of the **SEQUENTIAL COMPRESSION DEVICE MODEL 5200/5202** as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the **SEQUENTIAL COMPRESSION DEVICE MODEL 5200/5202.**
2. **WARNING** that the **SEQUENTIAL COMPRESSION DEVICE MODEL 5200/5202** should not be used adjacent to or stacked with other equipment.
3.

Guidance and manufacturer's declaration – electromagnetic emissions		
The **SEQUENTIAL COMPRESSION DEVICE MODEL 5200/5202** is intended for use in the electro-magnetic environment specified below. The customer or the user of the **SEQUENTIAL COMPRESSION DEVICE MODEL 5200/5202** should assure that it is used in such an environment.		
Emissions	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The **SEQUENTIAL COMPRESSION DEVICE MODEL 5200/5202** 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 **SEQUENTIAL COMPRESSION DEVICE MODEL 5200/5202** is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

4.

Guidance and manufacturer's declaration – electromagnetic immunity			
The **SEQUENTIAL COMPRESSION DEVICE MODEL 5200/5202** is intended for use in the electromagnetic environment specified below. The customer or the user of the **SEQUENTIAL COMPRESSION DEVICE MODEL 5200/5202** 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 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles) <5 % U_T (>95 % dip in U_T) 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 **SEQUENTIAL COMPRESSION DEVICE MODEL 5200/5202** may be dropped off from normal level, it may be necessary to use uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level			

5.

Guidance and manufacturer's declaration – electromagnetic immunity

The **SEQUENTIAL COMPRESSION DEVICE MODEL 5200/5202** is intended for use in the electromagnetic environment specified below. The customer or the user of the **SEQUENTIAL COMPRESSION DEVICE MODEL5200/5202** should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the **SEQUENTIAL COMPRESSION DEVICE MODEL 5200/5202**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation Distance in metres (m). 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 Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **SEQUENTIAL COMPRESSION DEVICE MODEL 5200/5202** is used exceeds the applicable RF compliance level above, the **SEQUENTIAL COMPRESSION DEVICE MODEL 5200/5202** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **SEQUENTIAL COMPRESSION DEVICE MODEL 5200/5202**.

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

6. Recommended separation distances between portable and mobile RF communications equipment and the **SEQUENTIAL COMPRESSION DEVICE MODEL 5200/5202**

The **SEQUENTIAL COMPRESSION DEVICE MODEL 5200/5202** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **SEQUENTIAL COMPRESSION DEVICE MODEL 5200/5202** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **SEQUENTIAL COMPRESSION DEVICE MODEL 5200/5202** as recommended below, according to the maximum output power of the communications equipment.

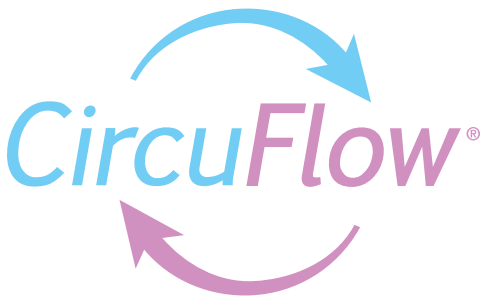
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Notes:



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