Cirvo Compression System
Patient User Manual

Caution: Federal law restricts this device to sale by or on the order of a physician

Company Information

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Mountain View, CA 94040
United States

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Email: customerservice@radialmedical.com

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Figure 1: Packaging

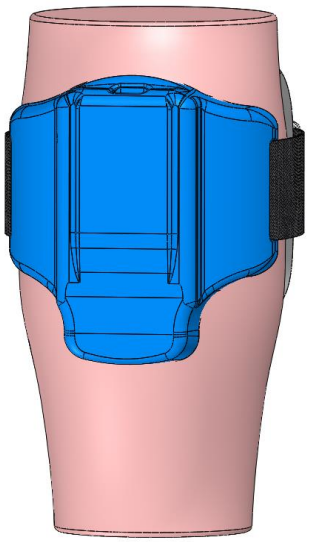


Figure 2: Cirvo Device – Back View (Calf)

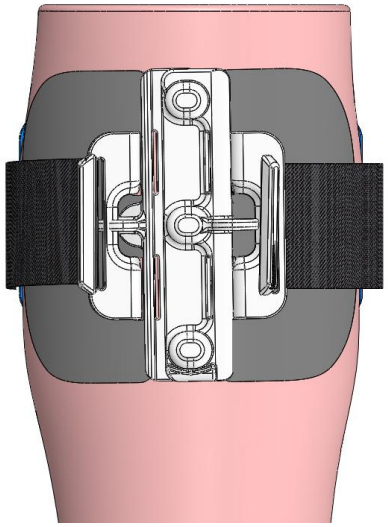


Figure 3: Cirvo Device – Front View (Shin)

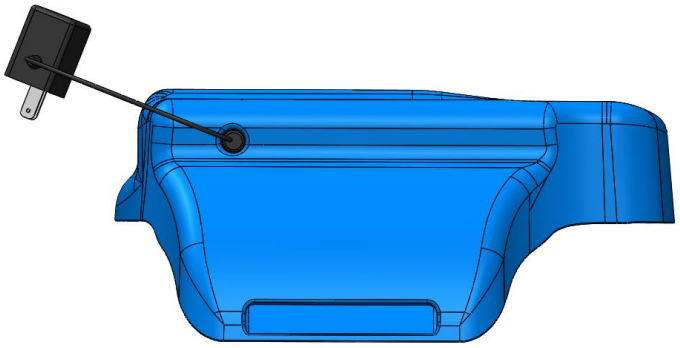


Figure 4: AC Charger

Section 1 - Contents

FA-00430 Cirvo Compression Device and AC Charger – Qty: 2 ea.
IFU-00387 Physician Instruction For Use (IFU) – Qty 1 ea.
IFU-00444 Patient User Manual – Qty 1 ea.

Section 2 - General Information

The Cirvo Compression System

The Cirvo Compression System consists of a compression device, the Cirvo Compression Device (**Figures 2 & 3**) and an AC Charger (**Figure 4**). The system is designed to provide compression to the calf area to assist blood flow in the venous or arterial system.

Physician Reference

This IFU provides detailed information about the Cirvo Compression System, prescription programming, device setup, operation and data acquisition capabilities.

What is Compression Therapy?

Compression therapy has been shown to be effective in the prevention of Deep Venous Thrombosis (DVT) in patients after surgery and in the management of venous leg ulcers (VLU). Intermittent sequential compression is a standard of care for the prevention of deep venous thrombosis[1,2]. Post-operative sequential compression in the home is supported by a randomized study comparing usual care (standard stockings and anticoagulation) with or without sequential compression. A DVT occurred in 4% (3/75) in the sequential compression group compared to 19% (14/75) in the usual care group[3].

Treatment of venous leg ulcers using compression therapy is based on mechanically applying pressure to the limb to counteract venous hypertension. Typical initial treatment focuses on sustained pressure with different types of stockings or compression bandage systems. If conservative therapy fails after a 6-month trial, the standard of care consists of sequential compression therapy. Specifically, guidelines from the Society for Vascular Surgery recommend

[1] Ho KM, Tan JA. Stratified meta-analysis of intermittent pneumatic compression of the lower limbs to prevent venous thromboembolism in hospitalized patients. Circulation. 2013;128(9):1003-20.
[2] Gould MK, Garcia DA, Wren SM, Karanicolas PJ, Arcelus JI, Heit JA, et al. Prevention of VTE in nonorthopedic surgical patients: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest. 2012;141(2 Suppl):e227S-e77S
[3] Sobieraj-Teague M, Hirsh J, Yip G, Gastaldo F, Stokes T, Sloane D, et al. Randomized controlled trial of a new portable calf compression device (Venowave) for prevention of venous thrombosis in high-risk neurosurgical patients. J Thromb Haemost. 2012;10(2):229-35.

sequential compression therapy when other compression options are not available, cannot be used, or have failed to aid in venous leg ulcer healing after prolonged compression therapy[4].

The Cirvo Compression System has been specifically designed to address the limitations of existing sequential compression systems. The Cirvo Compression Device is portable, quiet, and does not have tubes and cables, allowing the patient to remain mobile during therapy and potentially enhancing compliance with the therapy. The Cirvo can monitor compliance and pressure cycles to facilitate monitoring treatment, adjusting the therapy, or reinforcing compliance as necessary.

How does the Radial Medical Compression System work?

The Cirvo Device uses a small motor to sequentially tighten the system around the leg. It also includes the Cirvo App that allows customization of the prescribed therapy and the ability to track your therapy progress

What data is collected by the Cirvo Device?

The Cirvo Device has the ability to measure the amount and duration of compression received during a therapy session. The Cirvo Device has the capability to locally store and transmit data regarding therapy compliance and dosage to the prescribing physician using high-level encryption technology.

Section 3 - Indications for Use

The Cirvo Compression System is indicated for use in:

- Preventing deep vein thrombosis (DVT)
- Enhancing blood circulation
- Diminishing post-operative pain and swelling
- Reducing wound healing time
- Treatment and assistance in healing: stasis dermatitis; venous stasis ulcers; arterial and diabetic leg ulcers
- Treatment of chronic venous insufficiency
- Reducing edema
- Treatment of Restless Leg Syndrome (Willis-Ekbom Disease)

[4] O'Donnell TF, Jr., Passman MA, Marston WA, Ennis WJ, Dalsing M, Kistner RL, et al. Management of venous leg ulcers: clinical practice guidelines of the Society for Vascular Surgery (R) and the American Venous Forum. J Vasc Surg. 2014;60(2 Suppl):3S-59S.

Section 4 - Contraindications

The Cirvo Compression System is contraindicated in the following cases:

- Acute thrombophlebitis
- In medical situations where increased venous and lymphatic return is undesirable
- Severe atherosclerosis or other ischemic vascular diseases
- Suspected or known acute deep vein thrombosis
- Severe congestive cardiac failure
- Existing pulmonary edema
- Existing pulmonary embolism
- Extreme deformity of the limbs
- Any local skin or tissue condition which the device would interfere such as gangrene untreated or infected wounds, recent skin graft, and dermatitis
- Known presence of malignancy in the legs
- Limb infections, including cellulitis, that have not received antibiotic coverage
- Presence of Lymphangiosarcoma

Section 5 - Cautions and Warnings

- This product is intended for hospital use, physician office use and home use.
- The use of the Cirvo Compression System in aircraft has not been evaluated.
- This product is supplied non-sterile.
- This product is indicated for single-user use only.
- Keep Cirvo Device out of reach of children. Swallowing small parts might cause choking and injury.
- Do not use any harsh solvents such as ammonia, acetone or bleach to clean the unit.
- Do not attempt to sterilize the Cirvo Device or charger.
- Not suitable for use in the presence of flammable mixtures.
- Return all improperly working or damaged components to the manufacturer.
- Do not attempt to open, service or modify the Cirvo Device or its AC Charger.
- Avoid exposure to significant moisture (e.g. rain) and do not submerse the product in liquid.
- Rechargeable battery pack is not serviceable or replaceable. Do not throw the battery into the fire. Recycle and dispose the battery properly.
- Use only the provided AC Charger to charge the Cirvo Device.
- Cirvo Device might become excessively hot during operation or charging. Do not use the device when it is hot.
- Do not put finger(s) underneath the strap/fitting. Device might pinch finger(s) during operation.
- Do not use the Cirvo Device if it creates skin-allergic reaction.
- Electromagnetic interference may occur in the vicinity of other household appliances and/or electronic equipment. Move the device away from other appliances and /or electronic devices if interference occurs.
- Electromagnetic interference/disturbance may also occur if Cirvo Device is in the vicinity of the following sources of electromagnetic disturbances: Diathermy, Lithotripsy, Electromagnetic anti-theft systems and metal detectors. If necessary, move the device away from these (and other appliances and /or electronic devices) if interference occurs.
- Keep power cord out of reach of children and animals to avoid strangulation.
- Use of accessories such as AC Charger other than what comes with the Cirvo Device or is provided by the Radial Medical may result in compromised user safety and/or device performance.

Section 6 - Symbols

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	ISO 15223-1, Clause 5.1.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1, Clause 5.1.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Date of manufacture	Indicates the date when the medical device was manufactured.
	ISO 15223-1, Clause 5.1.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Catalogue or model number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1, Clause 5.1.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	ISO 15223-1, Clause 5.1.5	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1, Clause 5.1.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Use by	Indicates the date after which the medical device is not to be used.
	IEC 60601-1, Table D.2, Symbol 10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Follow instructions for use	Refer to instruction manual/booklet.
	ISO 15223-1, Clause 5.4.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Attention: Read all warnings and precautions in instructions for use	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of

				reasons, be presented on the medical device itself.
	ISO 15223-1, Clause 5.3.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Keep dry	Indicates a medical device that needs to be protected from moisture.
	ISO 15223-1, Clause 5.3.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Store temperature range	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 15223-1, Clause 5.4.2	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure
	IEC 60601-1, Table D.1, Symbol 20	Medical electrical equipment —	Type BF applied part	To identify a type BF applied part complying with IEC 60601-1.
	ISO 15223-1, Clause 5.2.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	ISO 15223-1, Clause 5.2.8	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened
	EN 50419	Marking of Electrical and Electronic Equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE).	Recycle: Electronic Equipment	DO NOT THROW IN TRASH.
Caution: Federal law restricts this device to sale by or on the order of a physician.	21 CFR 801.15(c)(1)(i)F 21 CFR 801.109	Labeling-Medical devices; prominence of required label statements. Labeling-Prescription devices.	Prescription only	Requires prescription in the United States.

	Bluetooth Special Interest Group (SIG)	Bluetooth wireless technology	Bluetooth-enabled device	Wireless products featuring Bluetooth® technology

Regulatory Compliance Notices:

USA-Federal Communications Commission (FCC)

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This product does not contain any user serviceable components. Any unauthorized product changes or modifications will invalidate warranty and all applicable regulatory certifications and approvals, including authority to operate this device. IFU-00444 Rev 01 Page 10 of 30.

FCC Part 15 Digital Emissions Compliance We, Radial Medical Inc., declare under our sole responsibility that this product complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

WARNING: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates and radiates radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

Reorient or relocate the receiving antenna. Increase the separation between the equipment and receiver. Connect the equipment into an outlet on a circuit different from the one the receiver is connected to.

Consult Radial Medical Inc. for assistance.

Opening Package and Charging Cirvo Compression Device

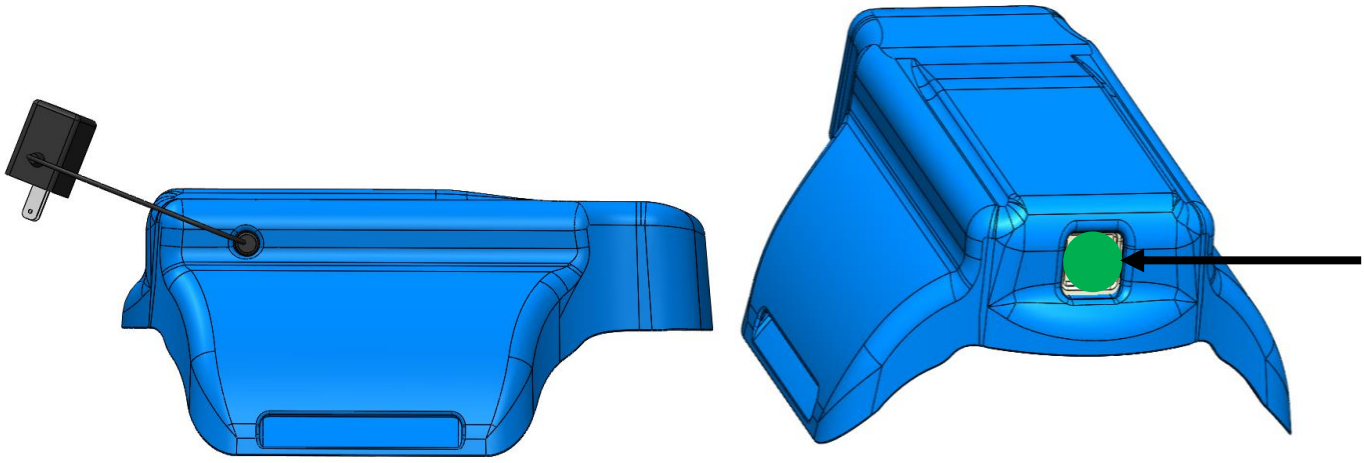


Figure 5: Charging. Connect AC Charger onto Cirvo Compression Device (Left) and plug into AC outlet; light on top of controller (Right) will show charging status.

Blinking Green: Charging	
Solid Green: Fully charged	

1. Remove Cirvo Device and AC Charger from packaging. Inspect for any visible physical damage such as cracked components, sharp edges, loose components, etc.

⚠ **Do not use the device if the packaging shows signs of damage or exposure to water or any signs of damage to the Cirvo Compression Device or AC Charger.**

2. Plug DC plug into Cirvo Device (**Fig. 5**) and plug AC Charger into 110V AC outlet.
3. ⚠ **Charge using only the supplied AC Charger – using a standard outlet. Do not attempt to plug Cirvo Device into a damaged or non-standard outlet**.
4. At complete charge (solid green), the Cirvo Device will be ready for use.
5. Tap on the Cirvo App icon  to launch the application.
6. Follow instructions as prompted – **Figure 6 & 7** (Left Leg) and **Figure 8** (Right Leg)
7. Adjust straps as prompted.

Connecting via Bluetooth and Prescribing Therapy

(If the iOS mobile device is not pre-loaded with the most current version of the Cirvo App, please contact Radial Medical Inc. for further assistance)

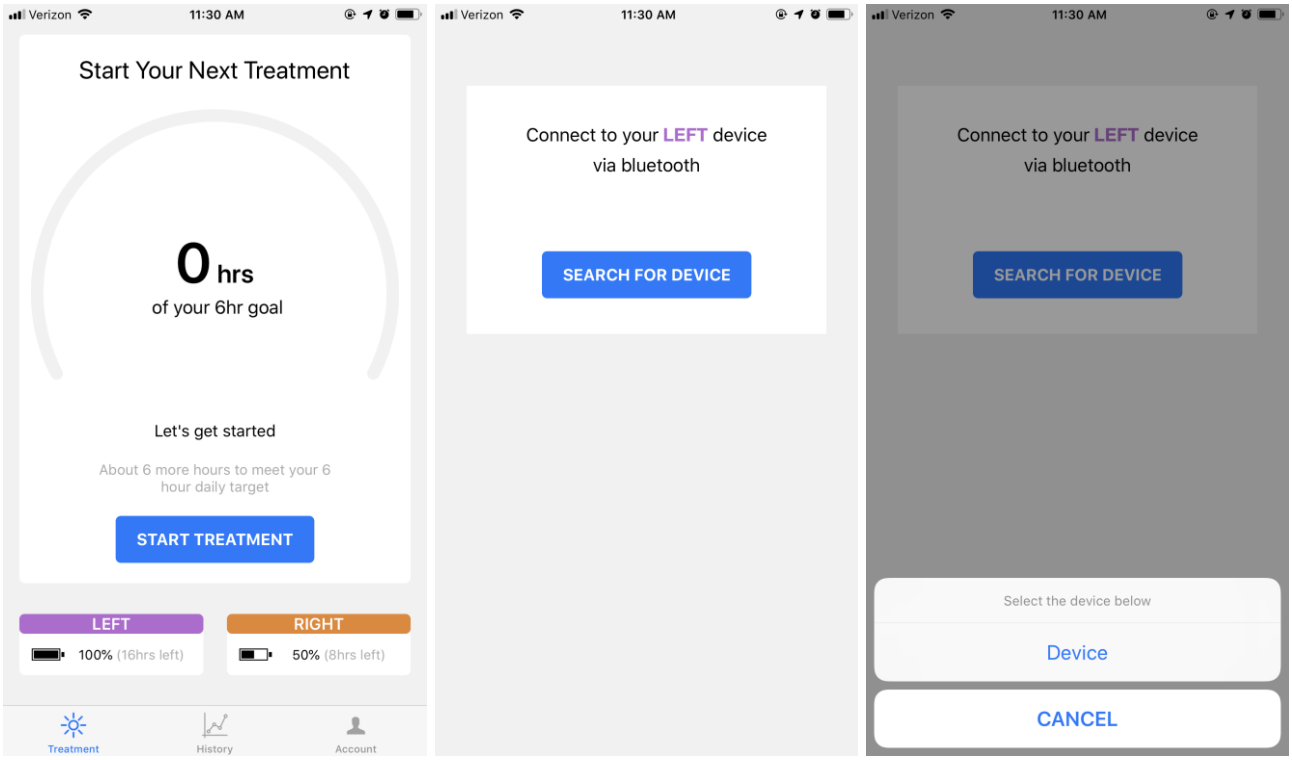


Figure 6: Connecting Cirvo Compression Device to Cirvo Mobile App

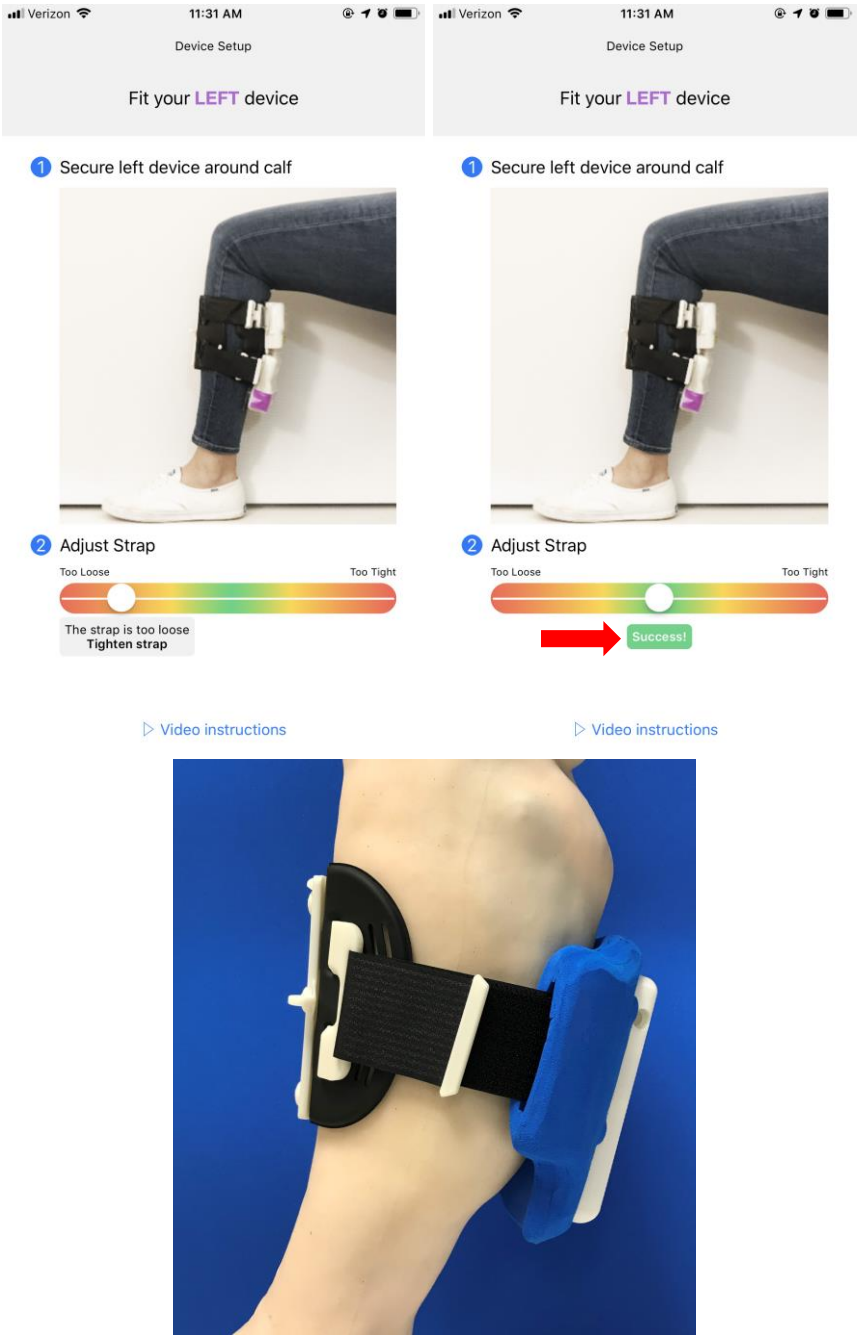
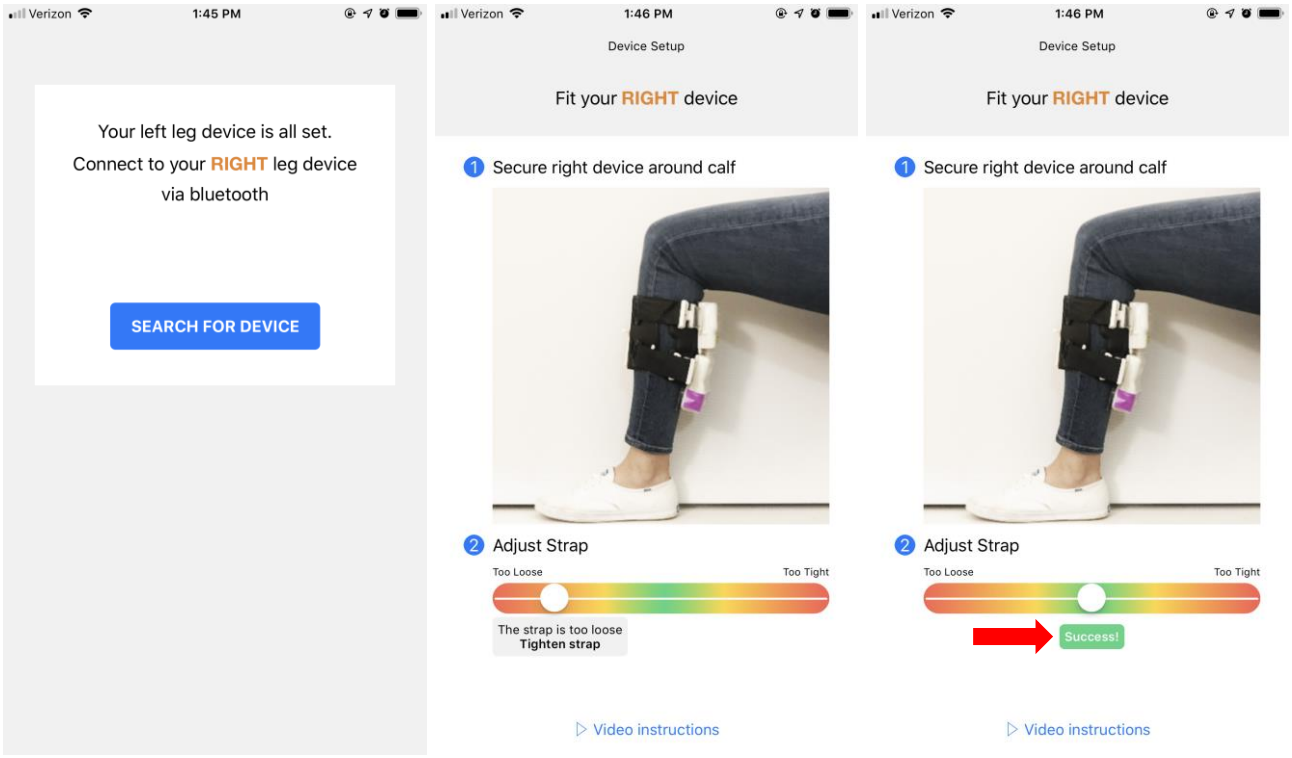


Figure 7: Adjusting Cirvo Device straps to correct tension – Left Leg.



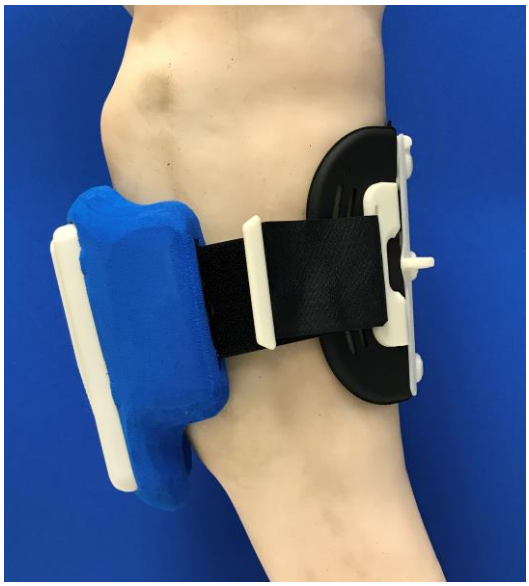


Figure 8: Adjusting Cirvo Device straps to correct tension – Right Leg.

Fitting

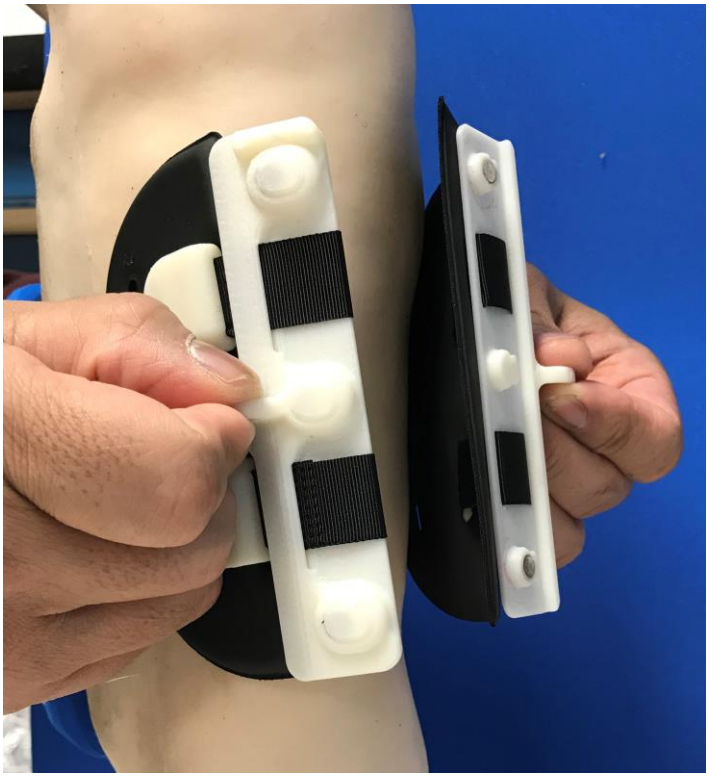


Figure 9. Placement – Loosen Strap; Grasp handles. Place around leg. Snap to fasten

1. Physician will instruct the patient in proper fitting the first time.
2. Loosen the hook and loop straps completely. Pull the magnetic clasp apart by grasping the handles and pulling the two flaps of the clasp away from each other.
3. Center the controller unit onto your calf area as illustrated in **Figure 7** and **Figure 8**, approximately 1" below the back of your knee. For comfort, a stocking may be worn under the Cirvo Device
4. Bring together the two flaps of the magnetic clasp as illustrated in **Figure 9.** Ensure that the flaps are properly positioned so the magnets attract each other and secure the halves
5. Once the magnetic clasp is closed, tighten the hook and loop straps to secure the Cirvo Device in place. You will further adjust the tension of the straps using the Cirvo App (see **Figure 9**).

Note: If the Cirvo Device is difficult to place on leg, check to see that all hook and loop straps are fully loosened.

Initiating and Stopping Therapy

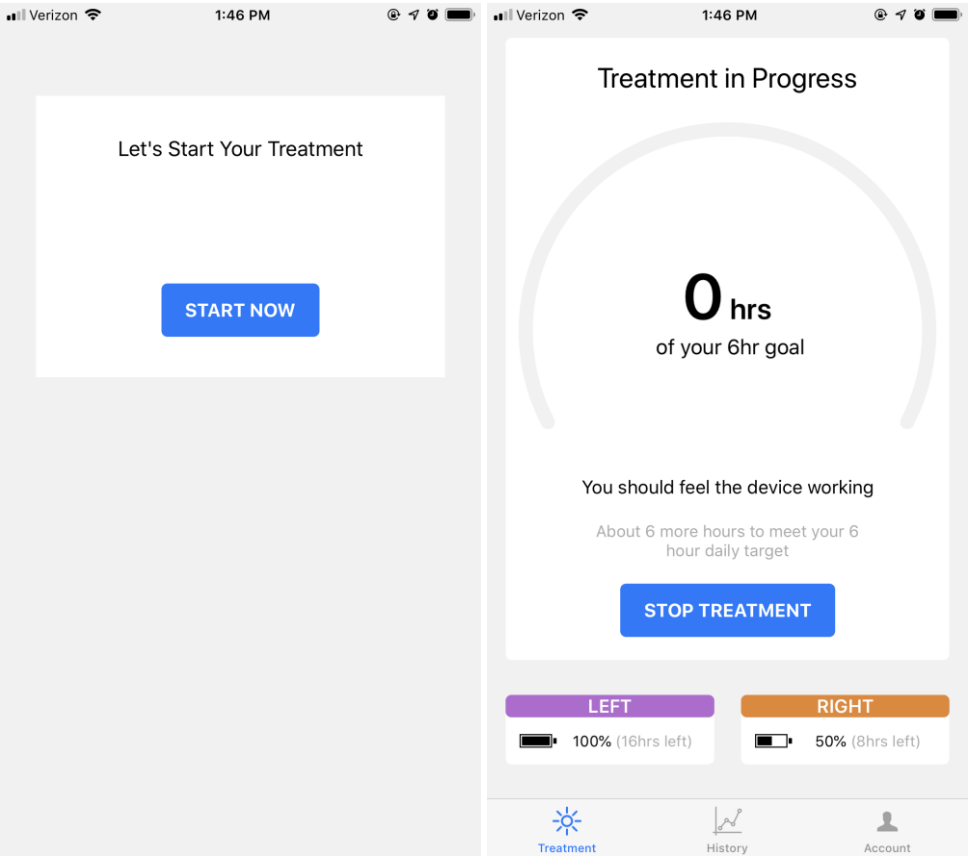


Fig. 10: (a) "START NOW"; **(b)** "Treat in Progress"

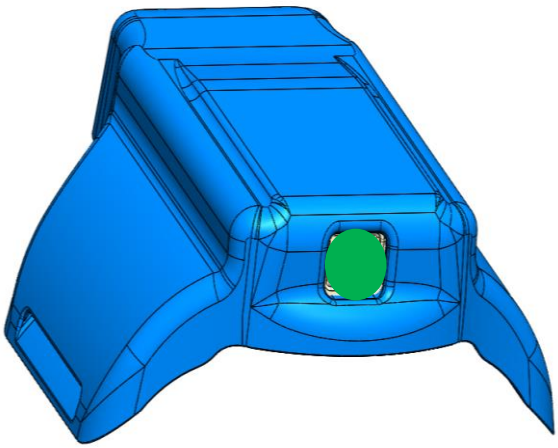
1. Touch icon labeled "START NOW" **Figure 10a**. Compression therapy session will begin.

Do not immerse Cirvo Device or AC Charger in water. When inner circle is completely filled (light blue instead of white), the therapy session is complete.

2. Monitor therapy progress as illustrated on **Figure 12**.
3. Touch "STOP TREATMENT" icon to discontinue therapy **Figure 10b** or **Figure 13.**

Note: You can discontinue therapy either by removing the Cirvo Compression Device from leg and touching "STOP TREATMENT" on the iOS device screen OR by holding down the touch switch (**Figure 5**) for 6 seconds.

4. Loosen hook and loop straps, grasp both handles on the magnetic clasp, and disengage magnets to remove the Cirvo Compression Device from leg.
5. Charge the Cirvo Compression Device using the AC Charger to connect it to an AC outlet (**Figure 5**)



Rapidly Blinking Blue – Device being fitted	
Blinking Green – Device fitting successful	
Solid Green – Device Running	
Slow Blue Blink – Device in Deep Sleep mode	

Figure 11. LED Indicators – Cirvo Device status.

Compliance and Therapy Progress

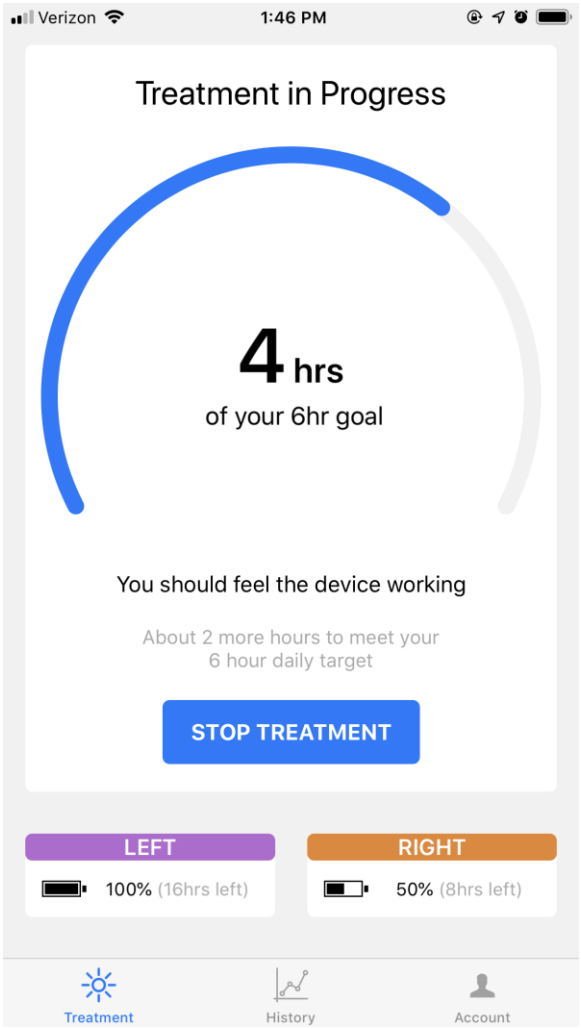


Figure 12. "Treatment-in-Progress" screen

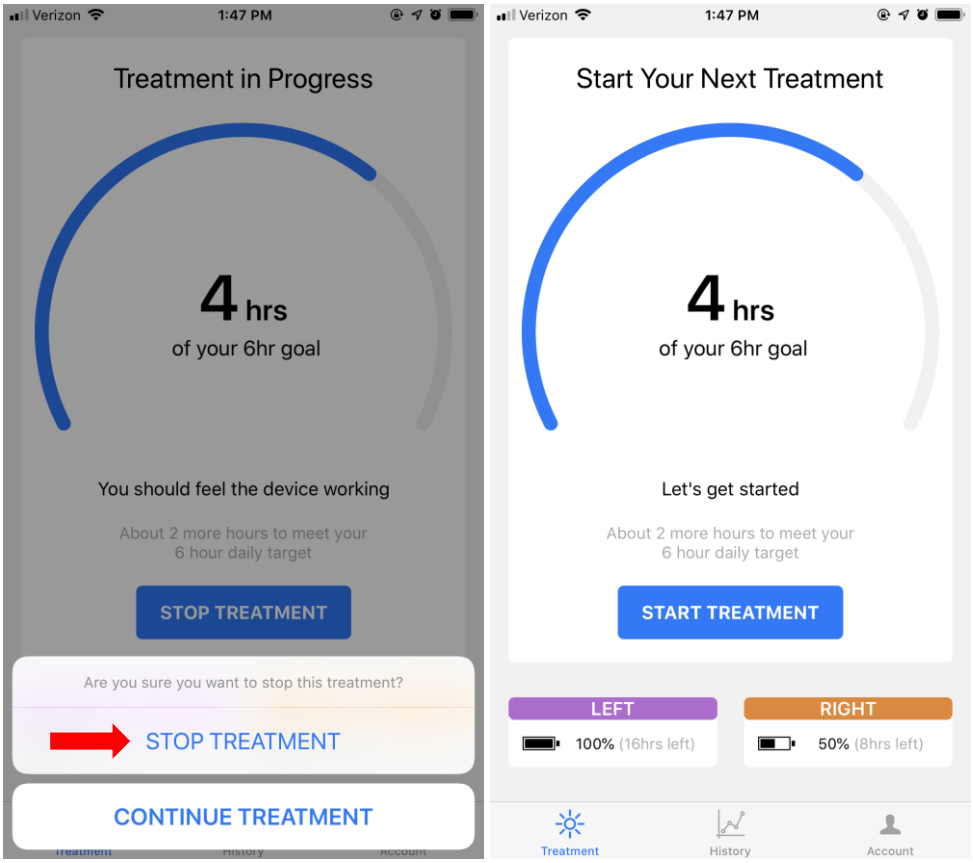


Figure 13. "STOP TREATMENT" and "Start Your Next Treatment" screens

Section 8 - Specifications and Performance

Technical Specifications		
Size	**All Dimensions are Approximations (Inches)** - Controller Unit: 5 ½ x 2 ¾ x 1 ¼ - Compression Plate Pad: 6 ¾ x 7 ½ (Curved) - Velcro Straps: 8 ½	
Weight	~10 oz	
Battery	7.4VDC, 750mAH, Rechargeable Lithium Polymer	
Recharge Time	~2Hrs	
Mains Supply	AC Adapter, 12Vdc x 2A	
Active Mode	Sequential Compression	
Pressure	40-60 mmHg	
Dwell	30 – 120 seconds	
Water Ingress	IPX4	
Dust Ingress	IP5X	
Enclosures	IP54	
Frequency of Transmission	2.4 GHz – 2.485 GHz	
Type / Frequency Characteristics	Frequency Hopping Spread Spectrum	
Radiated Power	5dBm	
Systems Requirements	**Device**	**Model**
	iPad	
	iPod	8th Generation; 32G
	iPhone	SE; X; 8

Materials

The Shin guard and Compression Plate Pad (Calf), both patient-contact materials, are intended to be worn over the prescribed duration. As needed, wipe down the guard and pad with soft towel and 70% IPA. If necessary during the prescription period, contact manufacturer for replacement shin guard and/or compression plate pad. Patient-contact material include the following:

- ABS – Controller covers
- Polyurethane impregnated Polyester EVA Foam – Shin guard
- Ultracloud, Thermomoldable EVA Foam – Compression Plate Pad
- Acetal Polymer – Chassis Handle
- Nylon Ribbon – Hook and Loop Straps
- Nylon Ribbon; Braided Elastic – Chassis Handle Assembly

Section 9 - Storage and Handling

- Storage parameters as follows:
    a. Temperatures between -25°C to +5°C (-13°F – 41°F) and
    b. +5°C to +35°C (41°F – 95°F) at relative humidity up to 90%, non-condensing;
    c. >35°C to 70°C at a water vapor pressure up to 50 hPa
- Operation parameters as follows:
    d. Temperatures between +5°C to +40°C (50°F – 104°F)
    e. Relative Humidity (RH) range of 15 % to 90 % non-condensing;
    f. Atmospheric pressure range of 700 hPa to 1060 hPa;
- Avoid excessive heat and cold.
- Do not store device in direct sunlight and/or in an environment with excessive dust/lint.
- Clean and dry device dry prior to storage.
- Reasonable care should be taken when handling and using the Cirvo Compression Device.
- Heavy impacts, contact with sharp objects and rough handling should be avoided.
- Do not immerse the device in fluid. If the controller unit or charger becomes soaked with fluid or otherwise damaged, do not use the device.

Section 10 - Maintenance

- Do not attempt to perform any service or maintenance on the Cirvo Compression Device.
- Replace the patient-contact surface if they become excessively soiled.
- If needed, contact Radial Medical for replacement patient-contact foam attachments.
- Before each daily use, the Cirvo Compression Device should be fully charged for a minimum of two (2) hours.
- As needed, wipe down the shin guard and calf pad with soft towel and disinfectant.
- If necessary during the prescription period, contact manufacturer for replacement shin guard or calf pad if they become excessively soiled or damaged.
- As needed, wipe the patient-contact surfaces of the device using a soft cloth and a mild disinfectant and/or detergent prior to use.
- Device has been shown to operate reliably for up to two months of operation.

Section 11 - Disposal

For disposal of any components of the Cirvo Compression System, please follow local waste regulations. If necessary, consult your local institutional waste-management service or municipal waste authority for additional instructions.

Section 12 - Troubleshooting

The following table provides a troubleshooting guide for the Cirvo Compression System.

Problem	Possible Cause	Corrective Action
Will not charge	Defective Battery	Contact Radial Medical Customer Service for replacement device
Difficult to place on leg	Velcro Strap too tight	Release tension on the Velcro strap
	Velcro Strap too loose	Adjust the Velcro strap to desired tightness
	Incorrectly sized device	Contact Radial Medical Customer Service for replacement calf pads
	Hook and Velcro Strap damaged	Contact Radial Medical Customer Service for replacement device
Not compressing leg	Battery not charged	Charge Device (using provided AC Charger)
	Cirvo Device not paired correctly	Follow connecting **Figures 6-8**
Application does not function	Corrupted application	Contact Radial Medical to re-install application

Section 13 - Customer Service

Return all improperly functioning or damaged components to the manufacturer

Call or email Radial Medical for a return material authorization (RMA) number and further instructions

Radial Medical, Inc.
2500 Grant Road
Mountain View, CA 94040
United States

Phone: (650) 530-0154
Fax: (650) 962-4555
Email: customerservice@radialmedical.com

Section 14 – Electromagnetic Interference

This device has been tested and found to comply with the limits for medical devices in accordance with EN60601-1-2:2014 . These limits are designed to provide reasonable protection to assure the safety of medical devices from interference from other electrical equipment and devices. This equipment can be affected by radio frequency energy and, if not installed and used in accordance with the instructions, may cause interference to other devices in the vicinity. There is no guarantee that interference will not occur in a particular installation.

(Valid for test levels: HOME HEALTHCARE ENVIRONMENT)

<table>
<tr><td colspan="3">Guidance and Manufacturer's Declaration – Electromagnetic Emissions</td></tr>
<tr><td colspan="3">The Cirvo Compression System is intended for use in the electromagnetic environment specified below. The customer or user of the Cirvo Compression System should ensure that it is used in such an environment.</td></tr>
<tr><th>Emissions Test</th><th>Compliance</th><th>Electromagnetic Environment – Guidance</th></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Group 1</td><td>The Cirvo Compression System 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.</td></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The Cirvo Compression System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonics
EN 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage Fluctuations / Flicker</td><td>Complies</td></tr>
</table>

(Valid for test levels: HOME HEALTHCARE ENVIRONMENT)

<table>
<tr><td colspan="4">Guidance and Manufacturer's Declaration – Electromagnetic Immunity</td></tr>
<tr><td colspan="4">The Cirvo Compression System is intended for use in the electromagnetic environment specified below.
The customer or user of the Cirvo Compression System should ensure that it is used in such an environment.</td></tr>
<tr><th>Immunity Test</th><th>IEC 60601
Test Level</th><th>Compliance Level</th><th>Electromagnetic Environment – Guidance</th></tr>
<tr><td>Electrostatic Discharge (ESD)
61000-4-2</td><td>±8kV Contact
±15kV Air</td><td>±8kV Contact
±15kV Air</td><td>Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%</td></tr>
<tr><td>Electrical Fast Transient / Burst (EFT)
IEC 61000-4-4</td><td>±2kV for power supply lines
±1kV for input / output line (I/Os)</td><td>±2kV for power supply lines
±1kV for input / output line (I/Os)</td><td>Mains power quality should be that of a typical commercial or hospital environment.</td></tr>
<tr><td>Surge
IEC 61000-4-5</td><td>±1kV Differential mode
±2kV Common mode</td><td>±1kV Differential mode
±2kV Common mode</td><td>Mains power quality should be that of a typical commercial or hospital environment.</td></tr>
<tr><td rowspan="4">Voltage dips, short interruptions and voltage variations on power supply input lines
IEC 61000-4-11</td><td>Voltage Dips 30% reduction, 25/30 periods
At 0°</td><td>Voltage Dips 30% reduction, 25/30 periods
At 0°</td><td rowspan="4">Mains power quality should be that of a typical commercial or hospital environment. If the user of the Cirvo Compression System requires continued operation during power mains interruptions, it is recommended that the Cirvo Compression System be powered from an uninterruptible power supply or
battery.</td></tr>
<tr><td>Voltage Dips > 95% reduction, 0.5 period,
At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°</td><td>Voltage Dips > 95% reduction, 0.5 period,
At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°</td></tr>
<tr><td>Voltage Dips > 95% reduction, 1 period At 0°</td><td>Voltage Dips > 95% reduction, 1 period At 0°</td></tr>
<tr><td>Voltage Interruptions > 95% reduction, 250/300 periods</td><td>Voltage Interruptions > 95% reduction, 250/300 periods</td></tr>
<tr><td>(50/60 Hz)
Magnetic Field
IEC 61000-4-8</td><td>30A/m</td><td>30A/m</td><td>Power frequency magnetic fields should be that of a typical commercial or hospital environment.</td></tr>
</table>

(Valid for test levels: 3V for 150kHz to 80MHz; 10V for 80MHz to 2700 MHz)

HOME HEALTHCARE ENVIRONMENT

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The ***Cirvo Compression System*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***Cirvo Compression System*** should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the ***Cirvo Compression System***, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz (6 Vrms in ISM and amateur radio Bands within 150kHz – 80MHz)	3 Vrms	**Recommended separation distance** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz	10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz 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]
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 ***Cirvo Compression System*** is used exceeds the applicable RF compliance level above, the EQUIPMENT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ***Cirvo Compression System***. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

(Valid for test levels: 3V for 150kHz to 80MHz; 10V for 80MHz to 2700 MHz)

HOME HEALTHCARE ENVIRONMENT

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT			
The ***Cirvo Compression System*** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ***Cirvo Compression System*** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ***Cirvo Compression System*** 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 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

(Valid for test levels: In Table 9)

PROFESSIONAL HEALTHCARE FACILITY and HOME HEALTHCARE ENVIRONMENT

Immunity to RF Wireless Communications Equipment						
Test Frequency MHz	**Band [a] MHz**	**Service [a]**	**Modulation [b]**	**Maximum Power W**	**Distance Meters**	**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
710 745 780	704 - 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
810 870 930	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
1720 1845 1970	1700 - 1900	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
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 5500 5785	5100 - 5800	WLAN 802.11a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9

[1] For some services, only the uplink frequencies are included.

[2] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[3] 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.

Section 15 – Electromagnetic Emissions

(Valid for test levels: HOME HEALTHCARE ENVIRONMENT)

<table>
<tr><td colspan="3">Guidance and manufacturer's declaration – Electromagnetic Emissions</td></tr>
<tr><td colspan="3">The Cirvo Compression System is intended for use in the electromagnetic environment specified below.
The customer or the user of the Cirvo Compression System should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions Test</td><td>Compliance</td><td></td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The Cirvo Compression System 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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The Cirvo Compression System 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.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage Fluctuations / Flicker emissions</td><td>Complies</td></tr>
</table>

(Valid for test levels: HOME HEALTHCARE ENVIRONMENT)

Guidance and Manufacturer's declaration – Electromagnetic Immunity			
The ***Cirvo Compression System*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***Cirvo Compression System*** 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	±8 kV contact ±15 kV air	±8 kV contact ±15 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 ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	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	Voltage Dips 30% reduction, 25/30 periods At 0°	Voltage Dips 30% reduction, 25/30 periods At 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ***Cirvo Compression System*** requires continued operation during power mains interruptions, it is recommended that the ***Cirvo Compression System*** be powered from an uninterruptible power supply or a battery.
	Voltage Dips > 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Voltage Dips > 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	
	Voltage Dips > 95% reduction, 1 period At 0°	Voltage Dips > 95% reduction, 1 period At 0°	
	Voltage Interruptions > 95% reduction, 250/300 periods	Voltage Interruptions > 95% reduction, 250/300 periods	
(50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

(Valid for test levels: in Table 9)

PROFESSIONAL HEALTHCARE FACILITY and HOME HEALTHCARE ENVIRONMENT

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	1 700 – 1 990	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	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						

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.