



Cirvo Compression System Instructions for Use REST Trial Protocol CL00383

Company Information

Headquarters:

Radial Medical, Inc.

2500 Grant Road

Mountain View, CA 94040

United States

Phone: (650) 530-0154

Fax: (650) 962-4555

Email: customerservice@radialmedical.com

Table of Contents

Company Information	1
Section 1 Contents.....	3
Section 2 - General Information	4
The Cirvo Compression System	4
What is Compression Therapy?.....	4
Physician Reference	4
How does the Cirvo Compression System work?.....	5
What data is collected by the Cirvo Device?.....	5
Section 3 - Indications for Use	5
Section 4 - Contraindications	6
Section 5 - Cautions and Warnings	6
Section 6 - Wireless Security.....	8
Section 7 - Use	9
Section 8 - Specifications and Performance	16
Section 9 - Storage and Handling.....	17
Section 10 - Maintenance.....	17
Section 11 - Disposal.....	17
Section 12 - Troubleshooting	18
Section 13 - Customer Service.....	18
Section 14 - Symbols.....	19
Section 15 – Electromagnetic Interference	21
Section 16 – Electromagnetic Emissions.....	26



Figure 1: Packaging

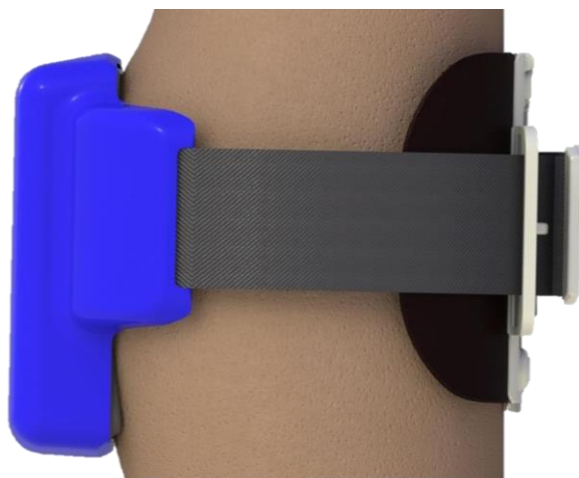


Figure 2: Cirvo on leg (side view)



Figure 3: Shin pad magnetic clasp



Figure 4: Charger (plugged in)

Section 1 - Contents

FA-00430 Cirvo Compression Device and AC Charger – Qty: 2 ea.
IFU-00522 Clinical Instruction For Use (IFU) – Qty 1 ea.

Section 2 - General Information

The Cirvo Compression System

The Cirvo Compression System consists of a compression device packaging (**Figure 1**), the Cirvo Compression Device (**Figures 2 & 3**) and 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 group³.

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 JJ, 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 therapy⁴.

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 (pending FDA clearance) 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

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 (pending FDA clearance) 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 submerge 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.

- Do not turn on the Cirvo Device if it has not been attached to the calf/leg. The attachment assembly might fly around and cause injury.
 - 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 - Wireless Security

1. It is recommended that the iOS Mobile device be password protected to prevent unauthorized access.
2. All data sent by Cirvo is AES-128 encrypted across the Bluetooth wireless transport to avoid interception.
3. It is recommended that the iOS device operates with the latest version of the Radial App upon notification from Radial.
4. Firewall/Virus protection is provided via the iOS.
5. Turn off Bluetooth on iOS device when the Bluetooth is not in use to prevent unauthorized access.

Section 7 - Use

Opening Package and Charging Cirvo Compression Device

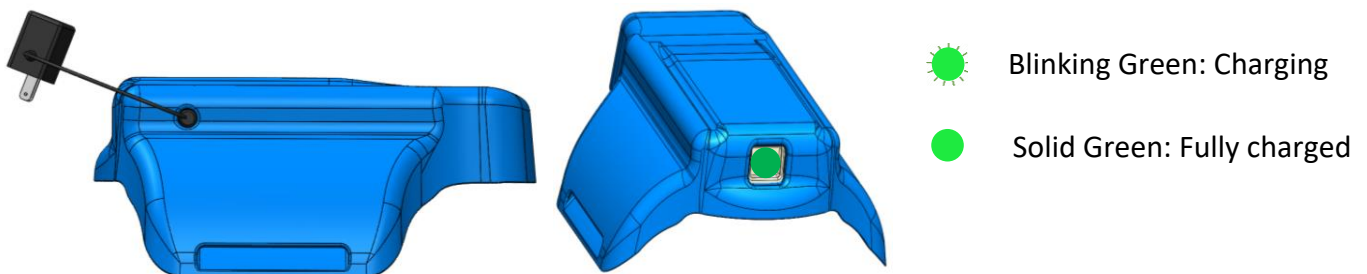


Figure 5: Charging. Connect AC Charger to Cirvo Compression Device (Left) and plug into AC outlet; light on top of controller (Right) will show charging status.

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 Devices (**Figure 5**) and plug AC Chargers into 110V AC outlet.



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.

3. At complete charge (solid green), the Cirvo Device will be ready for use.

Launching App



1. Tap on the Cirvo App icon to launch the application.

Privacy Policy

1. App will launch with Radial Medical Privacy Policy and option to allow "I agree" or decline "I do not agree" collection of personal information. **This information will enable sending of text and email alerts to patient to reinforce compliance with therapy.** Declining collection of personal information will not affect ability to proceed to therapy. If patient declines collection of personal information, advance to "Initiating Therapy" section.

<p>Radial Medical Privacy Policy</p> <p>Radial Medical ("Radial Medical," "we," "our," and/or "us") values the privacy of individuals who use our application and related services (collectively, our "Services"). This privacy policy (the "Privacy Policy") explains how we collect, use, and share information from users of our Services ("Users"). By using our Services, you agree to the collection, use, disclosure, and procedures this Privacy Policy describes.</p> <p>Information We Collect</p> <p>We may collect a variety of information from or about you or your devices from various sources, as described below.</p> <p>A. Information You Provide to Us.</p> <p>Profile Information. When you use our Services, you have the option of giving us your name, email address, and phone number.</p> <p>Communications. If you contact us directly, we may receive additional information about you. For example, when you contact our Customer Support Team, we will receive your name, email address, phone number, the contents of a message or attachments that you may send to us, and other information you choose to provide.</p> <p>B. Information We Collect When You Use Our Services</p>	<p>You can update your account and profile information or close your account through your profile settings. If you have questions about your privacy on the Services or this privacy policy, please contact us at privacy@radialmedical.com.</p> <p>Changes to this Privacy Policy</p> <p>We will post any adjustments to the Privacy Policy on this page, and the revised version will be effective when it is posted. If we materially change the ways in which we use or share personal information previously collected from you through the Services, we will notify you through the Services, by email, or other communication.</p> <p>Contact Information</p> <p>If you have any questions, comments, or concerns about our processing activities, please email us at privacy@radialmedical.com or write to us at 2500 Grant Rd. G01, Mountain View, CA 94040.</p> <p>Last Updated: 2/12/19</p> <p>I Agree I Do Not Agree</p>
---	--

Figure 6: Privacy Policy

User Information

Your Contact Info	Welcome to Radial!	Your Home Address
<p>Email Address</p> <p>Mobile Phone Number</p> <p>I consent to receive SMS messages</p> <p>NEXT</p>	<p>Tell us a little about yourself</p> <p>First Name</p> <p>Last Name</p> <p>Date of Birth (MM/DD/YYYY)</p> <p>Gender (Optional)</p> <p>NEXT</p>	<p>We need this in case we need to send you a different device</p> <p>Address</p> <p>Apt, Suite, Etc (Optional)</p> <p>Zip Code</p> <p>City</p> <p>State</p> <p>DONE</p>

Figure 7: Personal Information (optional)

1. Enter patient (optional) information as prompted.

Initiating Therapy

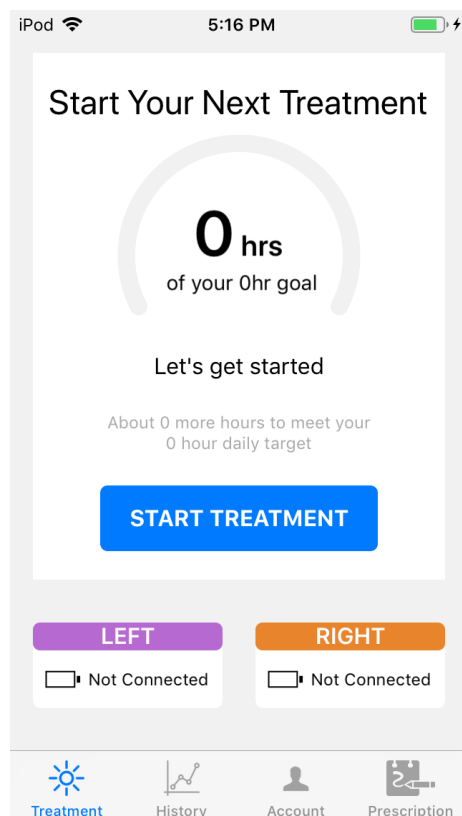


Figure 8: Start treatment

1. Cirvo app will automatically detect and connect to Cirvo devices. Text next to battery icon will show “Charging” when device plugged in and charging, “Not connected” upon initiation and then battery status once connected. Bluetooth connection is not required once therapy has initiated. Touch icon labeled “Start Treatment” **Figure 8** to initiate fitting process.



Do not attempt to run device while device is plugged in and charging.

Fitting and Starting Therapy

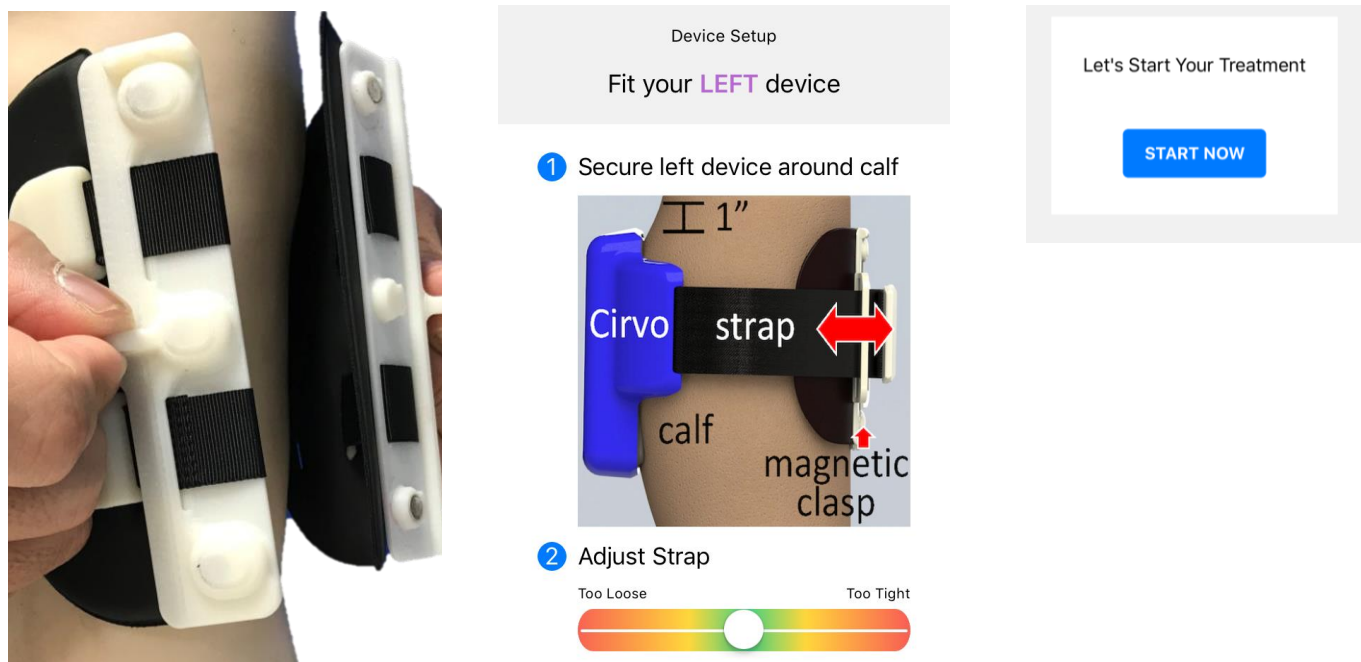


Figure 9: Placing and fitting Cirvo

1. Physician will instruct the patient in proper fitting the first time.
2. Loosen all 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 **Figure 9 (left)**,

Note: It is highly recommended that fitting process be performed while patient is seated in chair with feet planted on the ground for consistent fitting.

3. Center the controller unit onto your calf area as illustrated in **Figure 9 (center)**, 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 (left)**. Ensure that the flaps are properly positioned so the magnets attract each other and secure.
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 center**) until appropriate tension is achieved and the circle on the slider bar is in the green zone continuously for 1 sec.
6. Tap "Start Now" to initiate therapy **Figure 9 (right)**.

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



Do not immerse Cirvo Device or AC Charger in water.

Stopping Therapy

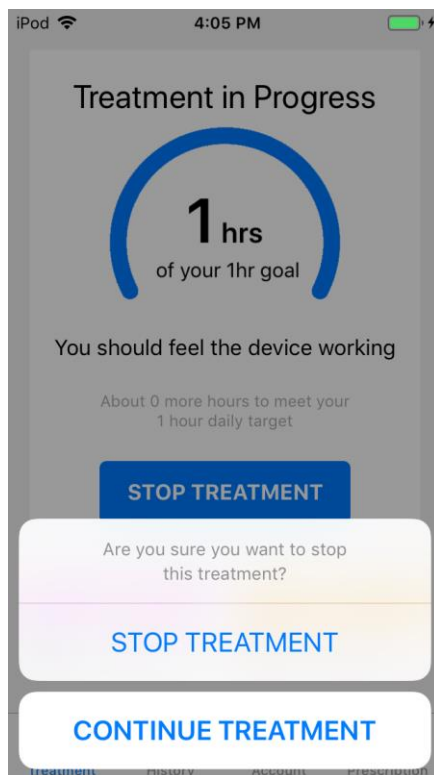


Figure 10: Stopping Therapy

1. When inner circle is completely filled (light blue instead of white), the minimum therapy session is complete.
2. Touch “Stop Treatment” in center discontinue therapy **Figure 10**.
3. App will confirm you would like to stop treatment. If so, tap Stop treatment pop up.
4. Cirvo can be also be stopped by touching and holding the green light on top of device for 6 seconds.
5. Loosen hook and loop straps, grasp both handles on the magnetic clasp, and disengage magnets to remove the Cirvo Compression Device from leg.

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	8 th 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:

- Nylon – Controller cover and chassis
- Polyurethane impregnated Polyester EVA Foam – Shin guard
- Ultracloud, Thermomoldable EVA Foam – Compression Plate Pad
- 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 Cirvo Compression Device 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.

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	Retry device pairing
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 - 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
---	--	----------------------------------	------------------------------	---

Section 15 – 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

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The <i>Cirvo Compression System</i> is intended for use in the electromagnetic environment specified below. The customer or user of the <i>Cirvo Compression System</i> should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	The <i>Cirvo Compression System</i> 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. The <i>Cirvo Compression System</i> 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.
RF Emissions CISPR 11	Class B	
Harmonics EN 61000-3-2	Class A	
Voltage Fluctuations / Flicker	Complies	

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)

(Valid for test levels: HOME HEALTHCARE ENVIRONMENT)

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
<p>The <i>Cirvo Compression System</i> is intended for use in the electromagnetic environment specified below.</p> <p>The customer or user of the <i>Cirvo Compression System</i> should ensure that it is used in such an environment.</p>			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic Discharge (ESD) 61000-4-2	±8kV Contact ±15kV Air	±8kV Contact ±15kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
Electrical Fast Transient / Burst (EFT) IEC 61000-4-4	±2kV for power supply lines ±1kV for input / output line (I/Os)	±2kV for power supply lines ±1kV for input / output line (I/Os)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential mode ±2kV Common mode	±1kV Differential mode ±2kV 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 <i>Cirvo Compression System</i> requires continued operation during power mains interruptions, it is recommended that the <i>Cirvo Compression System</i> be powered from an uninterruptible power supply or 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	30A/m	30A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

(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 <i>Cirvo Compression System</i> is intended for use in the electromagnetic environment specified below. The customer or the user of the <i>Cirvo Compression System</i> 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 (6 Vrms in ISM and amateur radio Bands within 150kHz – 80MHz)	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the <i>Cirvo Compression System</i> , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$
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 <i>Cirvo Compression System</i> 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 <i>Cirvo Compression System</i> .			
^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 <i>Cirvo Compression System</i> is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the <i>Cirvo Compression System</i> can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the <i>Cirvo Compression System</i> 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 16 – Electromagnetic Emissions

(Valid for test levels: HOME HEALTHCARE ENVIRONMENT)

Guidance and manufacturer's declaration – Electromagnetic Emissions		
The <i>Cirvo Compression System</i> is intended for use in the electromagnetic environment specified below. The customer or the user of the <i>Cirvo Compression System</i> should assure that it is used in such an environment.		
Emissions Test	Compliance	
RF emissions CISPR 11	Group 1	The <i>Cirvo Compression System</i> 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 <i>Cirvo Compression System</i> 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	Complies	

(Valid for test levels: HOME HEALTHCARE ENVIRONMENT)

Guidance and Manufacturer's declaration – Electromagnetic Immunity			
The <i>Cirvo Compression System</i> is intended for use in the electromagnetic environment specified below. The customer or the user of the <i>Cirvo Compression System</i> 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 <i>Cirvo Compression System</i> requires continued operation during power mains interruptions, it is recommended that the <i>Cirvo Compression System</i> 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.						