



Radial Medical Compression System User Manual

Company Information

Headquarters:

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

Phone: (650) 962-4560
Fax: (650) 962-4555
Email: radialmedical@customerservice.com

Contents

Company Information	1
Section 1 - Contents	3
Section 2 - General Information	4
The Radial Medical Compression System	4
User Manual	4
Section 3 - Cautions and Warnings	4
Section 4 - Use	6
Charging	6
Connecting	7
Fitting	8
Initiating and Stopping Compression	9
Compliance	10
Section 5 - Storage and Handling	11
Section 6 - Maintenance	11
Section 7 - Disposal	11
Section 8 - Troubleshooting	12
Section 9 - Customer Service	12

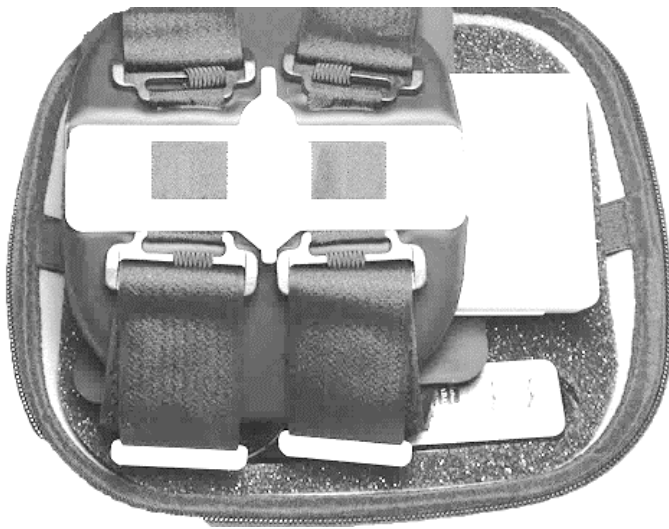


Figure 1: Packaging

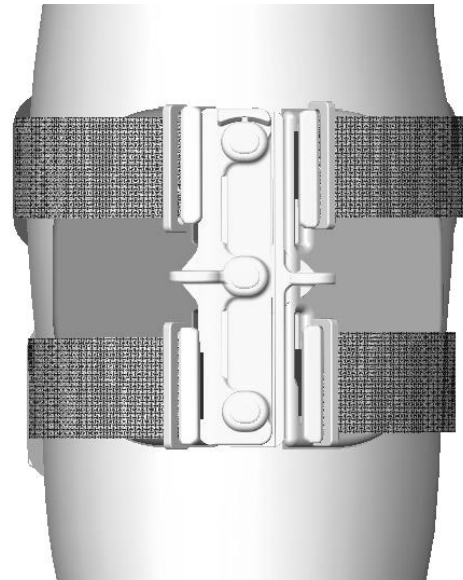


Figure 2: RMCS Front View (shin)

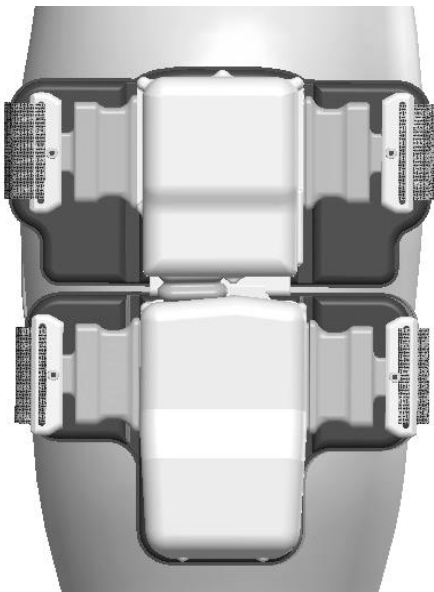


Figure 3: RMCS Back View (calf)

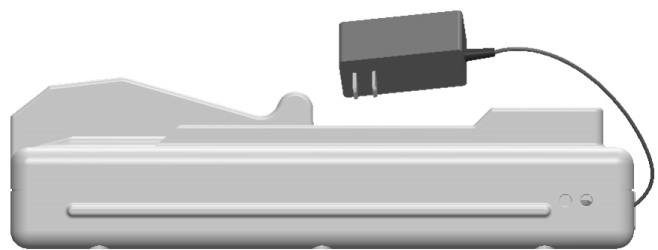


Figure 4: Charging Station

Section 1 - Contents

FA-0053	Radial Medical Compression System (RMCS) with internal battery – Qty: 1ea
FA-0058	Desktop Charger Unit w/Charger AC Adapter – Qty 1ea
IFU-00057	Instructions For Use (IFU) – Qty 1ea
IFU-00229	User Manual – Qty 1ea

Section 2 - General Information

The Radial Medical Compression System

The Radial Medical Compression System is a light weight, portable device that wraps around the calf/lower leg. The device is designed to provide compression to the calf area like the pressure of a massage. The compression is designed to assist blood flow in the venous or arterial system.

User Manual

The document includes instructions on how to use the device once it has been prescribed and set-up by a qualified physician or health provider.



Section 3 - Cautions and Warnings

- This product is supplied non-sterile.
- This product is indicated for single-user use only.
- Do not use without the guidance and direction of a physician and/or health care provider.
- Discontinue use and notify your physician and/or health care provider should the you experience pain, numbness, or other adverse reaction to compression therapy.
- Keep RMCS out of reach of children.
- Do not use any harsh solvents such as ammonia, acetone or bleach to clean the unit.
- Do not attempt to sterilize the RMCS 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 or service the RMCS or 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.

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.

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 help.

Section 4 - Use

Charging

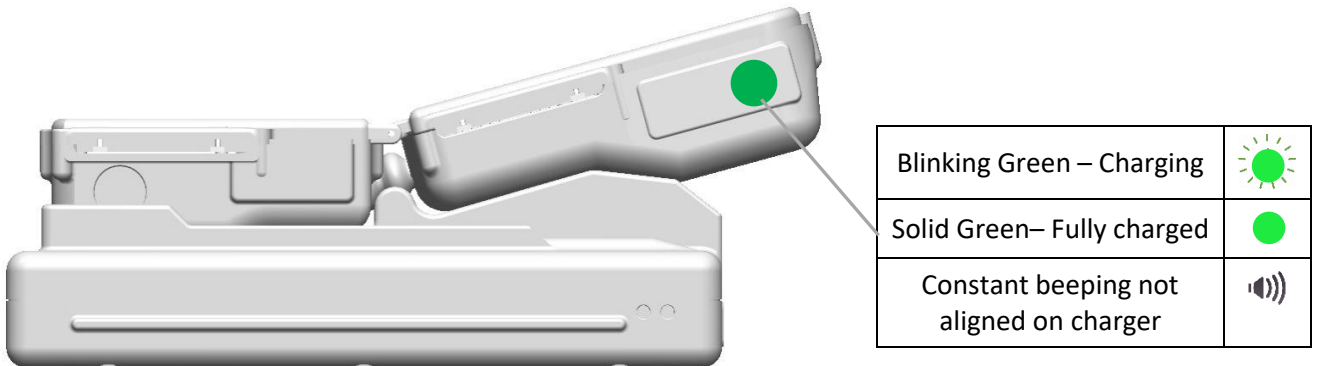


Figure 5: Charging. Plug in. Place RMCS on charge cradle until solid green light.

1. Remove RMCS and 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 RMCS or charger.

2. Plug DC plug into end of charging station. Plug AC adaptor into 110V AC outlet.



Charge with supplied charger only, using a standard outlet. Do not attempt to plug charger into a damaged or non-standard outlet.

3. Place unit on charger as shown in Figure 5. Charger will beep once when charging is initiated. Battery indicator will indicate charging status **Figure 5**.
4. At complete charge (solid green), controller unit will be ready for use.

Connecting

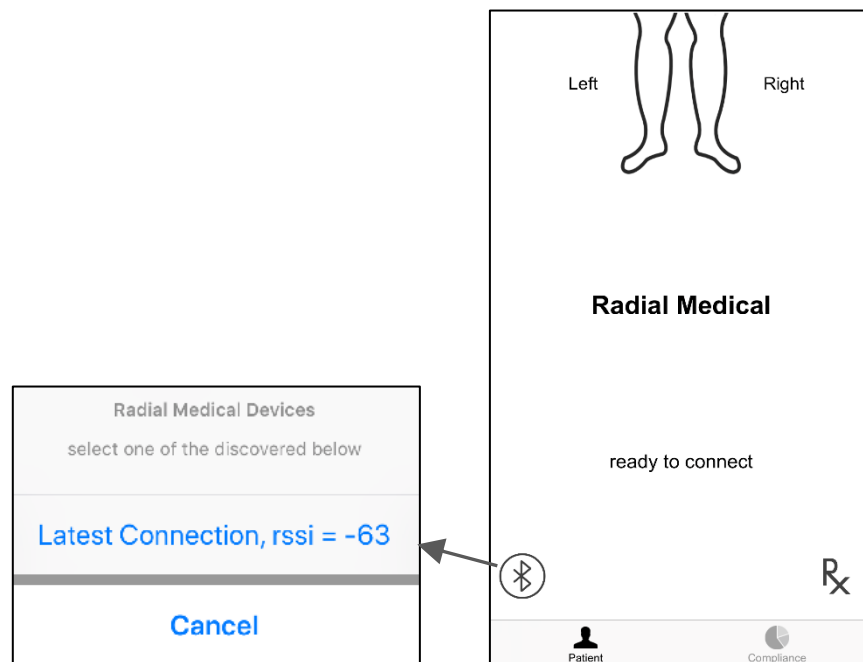


Figure 6. Connecting device. Tap Bluetooth icon, then “Latest Connection”.

5. Your physician and Radial Medical representative will assist you in installing the most current version of the Radial Medical application onto your iPhone and programming your device with your prescription compression therapy.
6. Tap on the Radial Application icon  to launch the application.
7. Connect device to phone by touching Bluetooth icon on lower left (Figure 6 – right).
8. Pair device by touching “Latest Connection” (Figure 6 – left).

Fitting

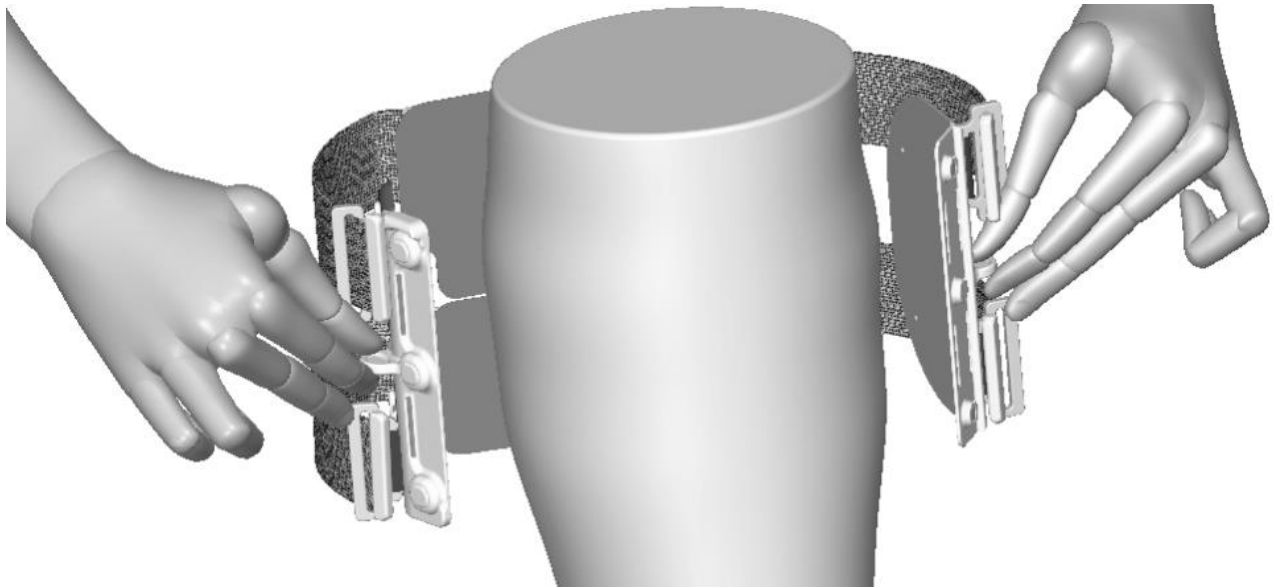


Figure 7. Fitting Device. Loosen hook and loop straps. Grasp handles. Place around leg. Clasp on shin

9. Loosen all four Hook and loop straps completely and pull magnet clasp apart by moving outer (right) shin half away from you and inner (left) shin half toward you.
10. Center the controller unit onto your calf area as illustrated in **Figure 7**, approximately 1" below the back of your knee. For comfort, a stocking may be worn under RMCS.
11. Bring together the two mating halves of the shin guard as illustrated in **Figure 7** while ensuring that the foam/pads are properly positioned to enable the magnets to attract each other and secure the halves.
12. Mate the magnets together and use the Hook and loop straps to secure the controller unit onto the lower leg/calf area.

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

Initiating and Stopping Compression

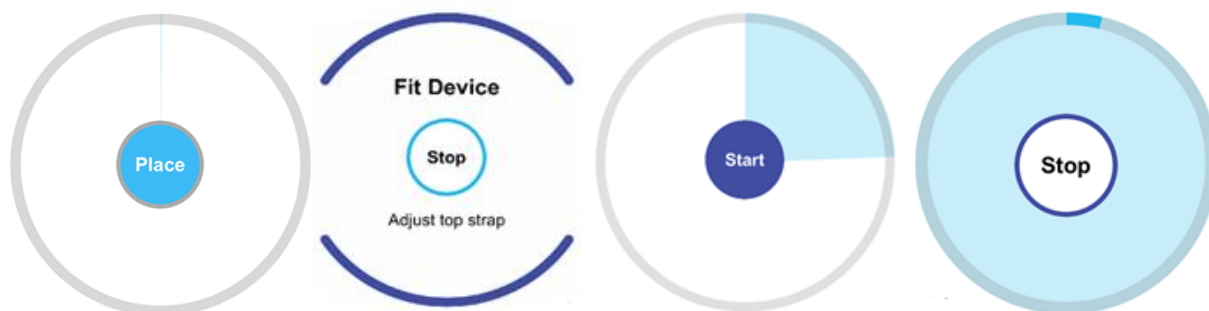


Figure 7: a) Placement , b) Fitting, c) Start therapy, d) Therapy complete and stop

13. Tap the center circle icon labeled “Place” **Figure 7a**.
14. Fit device by adjusting top tension (top arc) and bottom strap tension (bottom arc) until they turn from light blue to dark blue for 2 seconds. Arcs will increase in length with more tension and decrease in length with less tension **Figure 7b**.
15. Touch icon labeled “Start” **Figure 7c**. Compression therapy session will begin.



Do not immerse RMCS or charger in water or attempt to wear while bathing.

16. When inner circle turns completely light blue, your therapy session for the day is complete. Touch “Stop” in center circle once **Figure 7d**.

Note: You can discontinue therapy by either removing device from leg, touching “Stop” or touching the blinking light on the device once **Figure 8**.

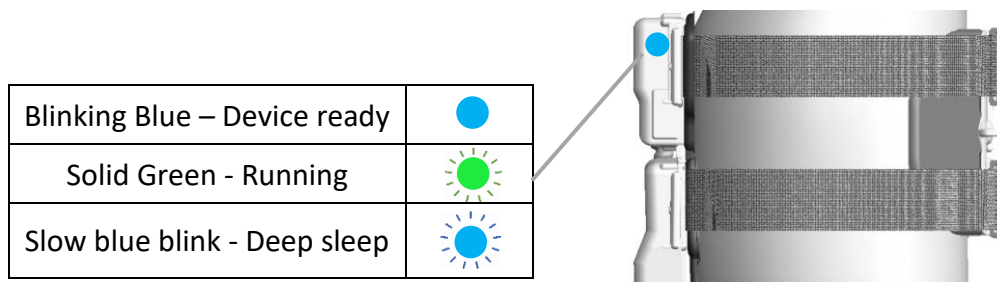


Figure 8. Device touch sensor

17. Loosen hook and loop straps, clasp both shin guard handles, and disengage magnets and remove device from leg.
18. Place RMCS on charging cradle to prepare for next therapy session.

Compliance

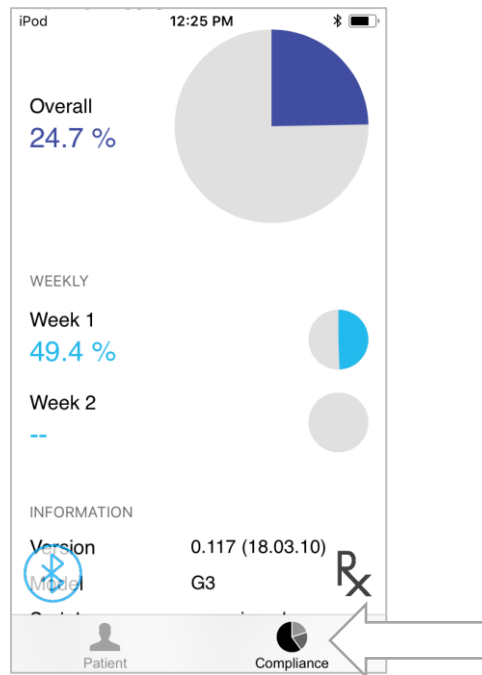


Figure 9. Compliance

19. To check your compliance with your prescribed therapy, touch “Compliance” icon (arrow) at bottom of screen. Your overall progress with the total therapy is shown as “Overall” pie chart and weekly compliance is shown per week below in corresponding pie charts **Figure 9**.

20. To return to patient view, touch “Patient” icon on bottom of screen.

Section 5 - Storage and Handling

- Storage and operation parameters as follows:
 - Temperatures between 10°C – 40°C (50°F – 104°F)
 - Relative Humidity (RH) range of 30 % to 75 %;
 - Atmospheric pressure range of 70kPa to 106kPa;
- Avoid excessive heat and cold.
- Do not store device in direct sunlight.
- Clean and dry device dry prior to storage.
- Reasonable care should be taken when handling and using the RMCS.
- 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 6 - Maintenance

- Do not attempt to perform any service or maintenance on charger or RMCS.
- 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 Radial Medical 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 7 - Disposal

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

Section 8 - Troubleshooting

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

Problem	Possible Cause	Corrective Action
Will not charge	RMCS not aligned on charger	Remove RMCS and re-align in cradle
Difficult to place on leg	Hook and loops straps are too tight	Release tension on the hook and loop straps
	Incorrectly sized device	Contact Radial for replacement calf pads
	Hook and loop straps damaged	Contact Radial for replacement device
Not compressing leg	Battery not charged	Place RMCS on charger
	Device not paired correctly	Follow connecting steps 6-8.
Application does not function	Corrupted application	Contact Radial to re-install application

Section 9 - Customer Service

Return all improperly functioning or damaged components to the manufacturer

Call or email the manufacturer for a return material authorization (RMA) number and further instructions

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

Phone: (650) 962-4560
Fax: (650) 962-4555
Email: radialmedical@customerservice.com