



RP100

Intermittent Pneumatic Compression Device

Distributor Sell Sheet

RP100 Intermittent Pneumatic Compression Device



Indication for Use:

- Aids the prevention of DVT onset
- Enhances blood circulation in lower extremities
- Diminishes post-operative pain and swelling
- Reducing wound healing time
- Aiding in the treatment of:
stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in lower limbs

Alleva Medical's RP100 is a single-patient portable intermittent pneumatic compression (IPC) device designed to prevent the onset of deep vein thrombosis by stimulating blood flow and increasing venous flow velocity. Its portable and lightweight characteristics are especially ideal for home and community settings. Each RP100 unit is capable of delivering to the calf area 50mmHg of IPC pressure, a level that is clinically proven to improve hemodynamics in deep vein*. It is intended for individuals 21 years or older with high risks of venous thromboembolism (VTE) - individuals who are temporarily or permanent immobilized, undergoing long-distance travel, are post-surgery, older, cancer or obese.

Features:



Meaningful Compression:

Providing IPC up to 50mmHg



No Tubing:

No tubing to pump unit means patient can be ambulatory if s/he desires



Alert System:

Status Indicator light visible to user during use



Extended Battery Life:

16 hours without charging



Ease of Use:

Position line and Left/Right text indicating area of pressure and ensures device is used properly



Patient Compliance Tracker**:

Device can track usage up to 300 sessions



Conversion to a Multi-User Unit:

Removable pump body also allows limited reuse of the unit, lowering cost



Technical Specification:

Pump dimension	13.5 x 7.2 x 3.4cm
Sleeve length	61 x 27cm
Battery type	Bespoke 3.7V Lithium battery
Operating time	16 hours
Charging time	~5 hours to full charge
Pre-set pressure level	50±5 mmHg
Inflation time	≤20 seconds
Rest period	50 seconds
IP class	IP22
US FDA	510k cleared (K191107)
Europe	CE Pending



Accessories:



- Single-Patient Sleeve
RP100-SLV

- Extension Sleeve
RP100-EXT



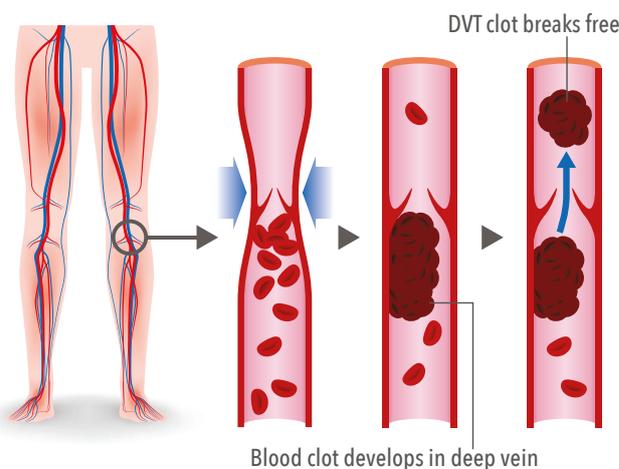
- Adapter
RP100-CHGR

Shipping / Packaging information:

Order code	Product description	Packaging
MI329	RP100 DVT Prevention Unit	10 pairs per shipper
RP100-SLV	Single-Patient Replacement Sleeve	20 pairs per shipper
RP100-EXT	Extension Sleeve for large calf	40 pieces per shipper
RP100-CHGR	dual-port Charger for RP100 unit	20 pieces per shipper

Background on Deep Vein Thrombosis (DVT)

Venous thromboembolism (VTE) refers to a blood clot that starts in a vein, and is associated with increased morbidity and mortality. According to American Heart Association, VTE is the third leading vascular diagnosis after heart attack and stroke, affecting between 300,000 to 600,000 Americans each year. When blood clot develops in the deep vein in the lower leg, DVT occurs. Low blood velocity and lack of blood flow due to immobility are the major causes of clot formation. When DVT clot breaks free from a vein wall, it could travel to the lungs and then blocks some or all of the blood supply, causing a condition called Pulmonary Embolism (PE) and potentially endangering the life of the patient.



* Selected Clinical References

Nose Y, Murata K, Wada Y, Tanaka T, Fukagawa Y, Yoshino H, Susa T, Kihara C, Matsuzaki, M. Journal of Cardiology (2010) 55, 384-390. The impact of intermittent pneumatic compression devices on deep venous flow velocity in patients with congestive heart failure

Malone MD, Cisek PL, Comerota AJ Jr, Holland B, Eid IG, Comerota Aj. Journal of Vascular Surgery (1999) 29(4), 593-9. High-pressure, rapid inflation pneumatic compression improves venous hemodynamics in healthy volunteers and patients who are post-thrombotic

**only available to Durable Medical Equipment providers.

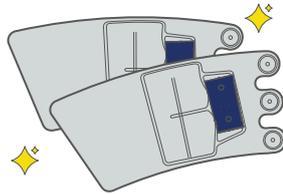
Accentuating Features:

 Reusable



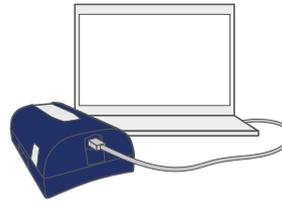
Removable pump body for multi-use

 Hygienic & easy cleaning



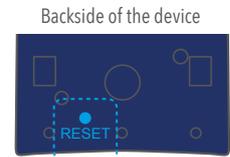
Each patient can have their own set of sleeves

 USB data transfer



Read pump data from computer via USB

 Reset Data

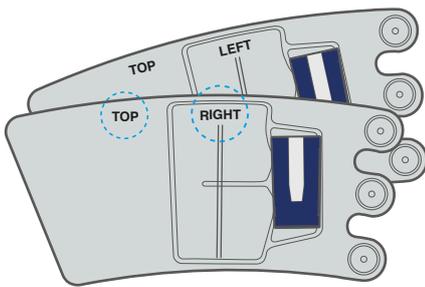


Reset pump data for new user

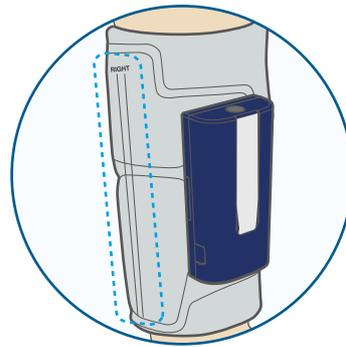
Patient Start Up Guide:

 [Watch demo video](#)

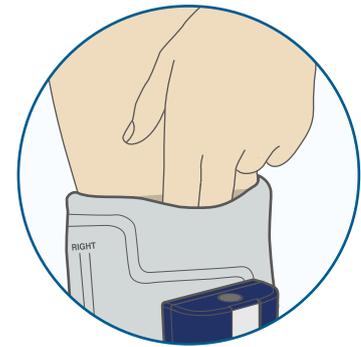
Applying the devices:



The word "TOP" should orient upward. Sleeves are marked with "LEFT" and "RIGHT" for easy identification.



Wrap the sleeve around your calf and align the black lines on sleeve with the center back of the calf.



Secure the sleeve firmly on the calf. You should be able to fit two fingers between the sleeve and your leg.

Operating the devices:



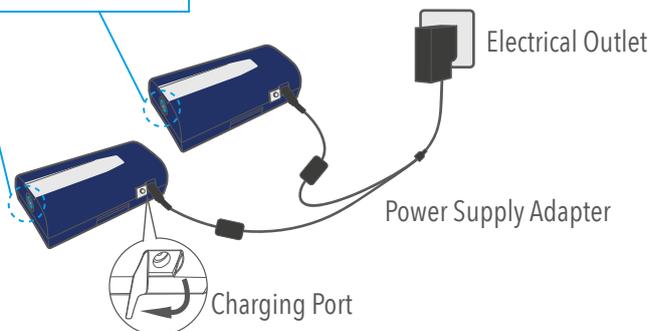
ON: beep sound and blue LED

OFF: beep sound and LED turns off

Charging the devices:

Charging: Blinking blue LED

Complete: Constant blue LED



DO NOT use any other power supply adapter than the one provided

DO NOT charge with the USB port that is located at the bottom of the device

Warning / Error Alarms:

"Alarm Signal"	Cause	Troubleshooting
Yellow LED light blinking every few seconds with alarm sounding. The device then automatically shuts off after 10 seconds.	Device is unable to inflate properly (taking more than 20 seconds to inflate to the pre-set pressure level)	<ul style="list-style-type: none">• Make sure the sleeves are properly placed around the calves and secured with the Velcro tabs.• Make sure the pumps are securely attached to the sleeves with no separation between them.• Contact Customer Service if problem persists.
Yellow LED light blinking every few seconds with alarm sounding. The device then automatically shuts off after 30 seconds.	Device is unable to charge properly	<ul style="list-style-type: none">• Unplug and reconnect the device to the Power Adapter.• Check the input connections.• Contact Customer Service if problem persists.
Yellow LED light blinking every 2 seconds with intermittent with an alarm.	Low Battery	<ul style="list-style-type: none">• Recharge unit with the provided AC adapter

Common Servicing Questions (FAQ)

Q: What is the recommended cleaning instructions for the reusable pump unit?

A: First, switch off the device and make sure any power supply is disconnected. Use a soft damp cloth to wipe the plastic case. Alcohol wipe is also permitted but do not use bleach or other detergents. The sleeves are for single patient use and we do not recommend putting them into laundry or cleaning methods.

Q: What is the warranty period?

A: Alleva Medical Ltd warrants the RP100 DVT Device ("Device") to be free from defects in workmanship and materials for a period of one (1) year from the date the Device is delivered to the original purchaser ("Warranty Period").

Q: What is the current return policy?

A: Return policy varies from regions to regions, and depends on the type of issues the device experienced.

Q: What type of servicing do I need to do?

A: The most common servicing is to remove the pump unit from the sleeve after each patient's use. A separate manual will be provided to you by Alleva. Other tasks would include: cleaning the unit (see above), extracting the usage data through the USB channel, and resetting the usage data.

Q: Can we repair any components inside?

A: We do NOT recommend opening the pump unit to repair any components, as the internal components are laid out delicately and any attempt to repair might affect the safety and performance of the device. Contact Alleva should you have any questions.



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All products are manufactured under US FDA, ISO 13485, and Japan PMDA registered facility of Alleva Medical Ltd.
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