



Deep Venous Thrombosis Therapy

USER MANUAL - MAX

About DVT Solutions (Australia) Pty Ltd

DVT Solutions Pty. Ltd. (Australia) is dedicated to developing new technologies with innovations in fighting the venous disease since 2006

Our Vision: To provide solutions to the growing epidemic of Venous Thrombosis.

We are a proudly Australian-owned and operated company based in Sydney, Australia

Vekroosan® DVT is designed and manufactured in Australia by our design and engineering teams at state-of-the-art facility in Sydney.

Although Vekroosan® may not quickly provide what it is, it is an innovative device used for controlling fluid stasis created as a result of chronic venous insufficiency of the lower limbs.

Vekroosan® is the product brand name for is a mobile calf compression device that wraps around the calf using Velcro straps. The Device includes a series of pumps that provide gentle massage to the leg, simulating the natural mechanism of muscular contraction, promoting healthy venous blood flow.

Vekroosan® has been proven to reduce lower limb swelling and pain, when used for the patients suffering from chronic venous insufficiency with proven benefits at increasing venous velocity.

Vekroosan® can also be used in combination with anticoagulation therapy to help reduce the incidence of DVT for in the patients post orthopaedic surgeries.

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Consultant Haematologist

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Before you begin to use the Vekroosan® Sequential Calf Compression Device, read carefully all the instructions contained in this manual and observe all Safety and Precautions Warnings. If you have any questions regarding the use of this product consult your Physician or Clinician prior to use.

Safety Warning

Vekroosan® system should not be used in the following conditions:

- ✔ It is the responsibility of the provider to ensure that the user can use this product safely.
- ✔ The Device must not be used for patients that have a known blood clot. Use of the device may dislodge the blood clot and create undesirable complications.

Consult your Carer for advice if Vekroosan® is suitable for your treatment.

- ✔ Make sure that the device is fitted correctly. Refer fitting instructions on page 9.
- ✔ Electrical equipment may be hazardous if misused. There are no user-serviceable parts in the pump. The pump's case must only be opened by authorised technical personnel.
- ✔ No modification to this equipment is allowed.
- ✔ Ensure that the device is turned off prior to cleaning and inspection.
- ✔ Keep the device away from sources of liquids and DO NOT immerse in water.
- ✔ Do not use the Device in the presence of uncontained flammable liquids or gasses.
- ✔ Only the pump and garment combination should be used. The correct function of the device cannot be guaranteed if incorrect pump/garment combination is used.

Precautions

For your own safety and the safety of the equipment, always adhere to the following precautions:

- ✔ Do not expose the system to naked flames, such as cigarettes, etc.
- ✔ Do not store the system in direct sunlight.
- ✔ Do not use Phenol based products to clean the system.
- ✔ Do not drop the system.
- ✔ Make sure the system is clean and dry prior to usage and storage



Electromagnetic Compatibility (EMC)

This product complies with the requirements of applicable EMC Standards. Medical electrical equipment requires special precautions regarding EMC and needs to be operated in accordance with the following instructions:

- ✔ The use of accessories not specified in this manual may result in increased emissions by, or decreased immunity of, the equipment, affecting its performance.
- ✔ Portable and mobile radio frequency (RF) communications equipment (e.g. mobile/cell phones) can affect medical equipment.
- ✔ If this equipment needs to be used adjacent to other electrical equipment, normal operation must be verified before use.
- ✔ For detailed EMC information contact DVT Solutions Pty Ltd.

Expected Service Life

Vekroosan® has an expected service life of three years. To maintain the condition of the device have the device serviced regularly according to the schedule recommended by DVT Solutions.

To maintain the condition of the device in good working order do not use unapproved accessories or attempt to modify, disassemble or otherwise misuse the Vekroosan® system. Failure to observe this caution could result in the device not being covered by warranty.



Environmental Protection

Incorrect disposal of this equipment and its component parts, particularly batteries or other electrical components, may produce substances that are hazardous to the environment. To minimise these hazards, contact DVT Solutions for information on correct disposal.

Design Policy and Copyright

® and ™ are trademarks belonging to DVT Solutions Pty Ltd. As our policy is of continuous improvement, we reserve the right to modify designs without prior notice. The content of this publication may not be copied either whole or part without the consent of DVT Solutions Pty Ltd.

Introduction

About this Manual

This manual is your introduction to the Vekroosan® Sequential Calf Compression Device. You must read and fully understand this manual before using the device.

Keep this manual as a reference for day-day routines and as a guide to maintenance and contact details for additional information.

If you have any difficulty understanding this manual and you are not sure on how to operate do not use this product. Contact your clinician or carer for clarification.

Intended Use

The intended use of this product is to prevent Deep Vein Thrombosis (DVT). The Garment, although intended for single use, may be reused only if appropriately cleaned between therapies.

Vekroosan® should only be used as part of a prescribed plan of care and should not be used where an existing blood clot may be present in the calf being treated.

This device emits visual and audio signals. Users with sight and hearing problems should use this device under the supervision of an able family member or carer. All users and carers should read and understand this manual, including the operation instructions, warnings and cautions.

About Vekroosan

Vekroosan® operates on a 45-second automatically timed cycle consisting of approx. 15 seconds of inflation per Cuff followed by 10 seconds of maintaining inflation and 10 seconds of deflation with each cycle repeating every 60 seconds for approx.. 30-minutes followed by a 3-minute rest. After the rest period the cycle will repeat for another 30-minutes of therapy before the device turns off. Additional therapy sessions can be initiated by turning the device ON again.

Vekroosan® can be used in the home environment. Consult your health carer for appropriate Therapies best suitable for your needs.

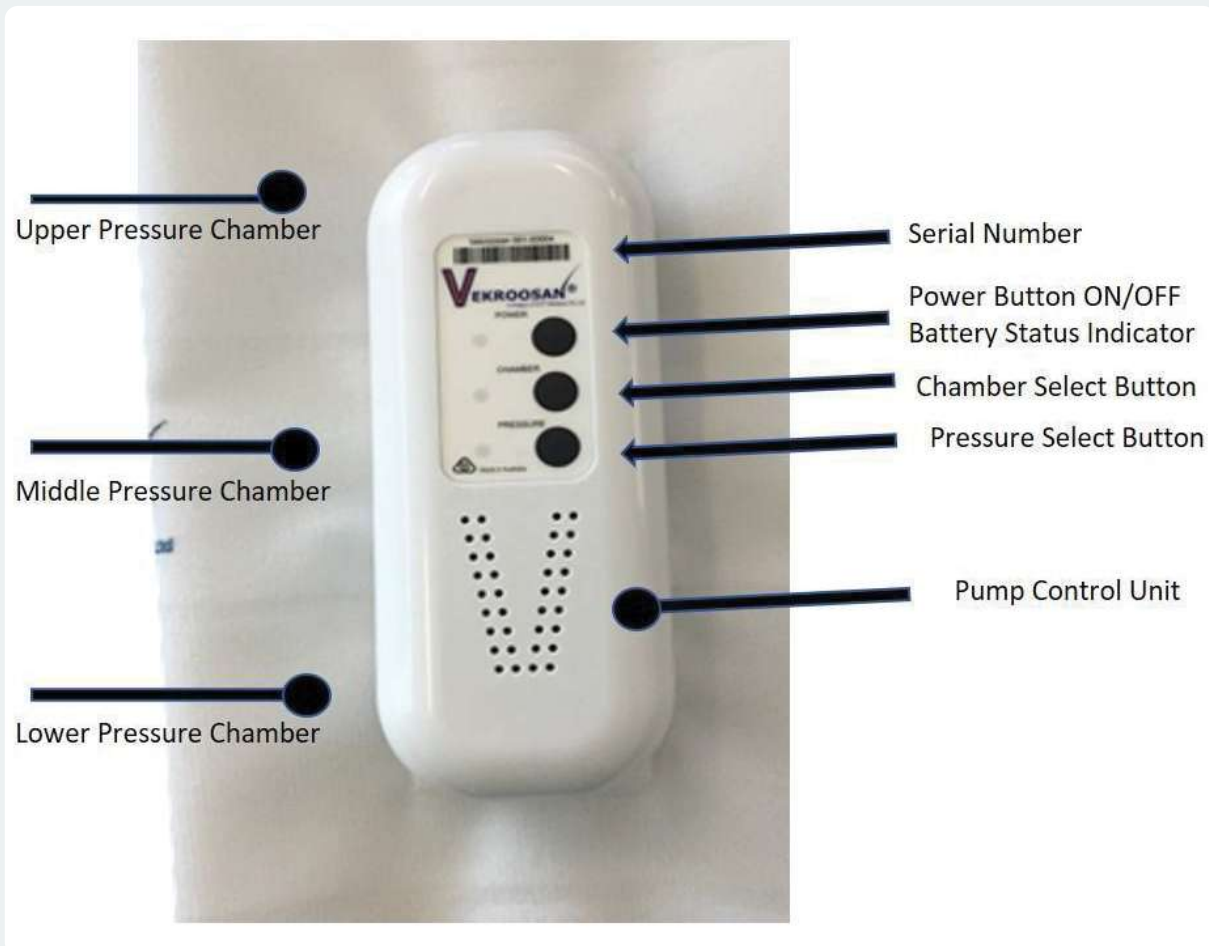


Figure 1 - Vekroosan®

Indications

The Vekroosan® sequential calf compression device (SCCD) is designed to apply modulated external sequential pneumatic pressure to lower limbs of patients with chronic venous disorders, sufferers of Deep Venous Thrombosis (DVT) and related complications when combined with an individual monitoring programme.

This system represents one aspect of a DVT strategy; if the patient's condition changes the overall therapy regime should be reviewed by the prescribing clinician.

The above are guidelines only and should not replace the clinician's judgement.

Contraindications

Vekroosan® system should not be used in the following conditions:

- ✔ Severe arteriosclerosis or other ischaemic vascular diseases
- ✔ Known or suspected acute Deep Vein Thrombosis (DVT) or phlebitis.
- ✔ Severe congestive cardiac failure or any condition where an increase of fluid to the heart by be detrimental.
- ✔ Pulmonary embolism.
- ✔ Any additional condition where the device would interfere, including gangrene, recent shin graft, dermatitis or untreated infected leg wounds.

If you are unsure of any contraindications refer to your clinician before using the device.

Cautions

Proper garment fitting of the device is essential:

- 1 As the device can be fitted to either the left or right calf the pump must face to the outside of the calf to allow easy access to operational settings.
- 2 The garment should be positioned in such a way that it does not create any potential for constant pressure points on the patient's limb. Additional care should be taken when placing garment on any deformed area or areas with significant oedema.
- 3 The device should be removed immediately if the patient experiences tingling, numbness or pain, and the clinician should be notified immediately.
- 4 Vekroosan should be used with CAUTION on patients with:
 - ✓ Insensitive extremities.
 - ✓ Diabetes.
 - ✓ Impaired circulation.
 - ✓ Fragile or impaired skin.

These are guidelines only and should not replace clinical judgement and experience.



Guidelines and Recommendations

General Recommendations

- 1 While using the device the patient's limbs should be checked periodically and more frequently if the patient has known circulatory or skin problems, or is a diabetic.
- 2 Clinical judgement should be used to determine if the patient's skin condition requires additional measures, or if the treatment should be discontinued and alternate modalities be used.
- 3 Patients should be instructed in the appropriate use of the device, the purpose of the therapy and that any complications should be reported to the clinician or nursing staff immediately.

DVT Prophylaxis

- ✓ Vekroosan® should be applied to the patient pre-operatively, prior to the indication of anaesthesia.
- ✓ The system should be used continuously for no less than 72 hours post-operatively or until the patient becomes fully ambulatory.
- ✓ If the garment cannot be applied to the operative limb during surgery, it may be applied to the limb once the patient reaches the recovery unit.

In the non-surgical patient, the device should be initiated immediately the risk of DVT formation is identified.



Fitting the device

Garment Application

- 1 It is recommended that you seek advice from your medical practitioner to show you how to fit the Vekroosan® SCCD to your calf for the first time.

Garments are for single patient use only. Do not use the garments on a different patient after treatment.

- 2 Wrap the Cuff around the calf so that the cuff is positioned approx. mid-way between the knee and the ankle.
- 3 Ensure that the pump is facing outward prior to securing the device to the calf.
- 4 Once positioned correctly on the calf secure the device to the calf using the three Velcro tabs.
- 5 The device should fit snugly on the leg. Do not overtighten and at the same time the device should not slip up and down the leg. Adjust as necessary with the Velcro tabs.
- 6 The Vekroosan® logo should be pointing towards the knee.

Garment Removal

- 1 Pull on the Velcro tabs to unwind the chambers and remove the device.

Pre-Use Check

Before powering the Vekroosan® system, ensure that:

- ✔ Garments have been applied to the patient's leg correctly, close fitting and without creases or folds
- ✔ The Vekroosan® Logo is pointing towards the knee and the power switch can be easily reached by the patient.

Start Up

Turn ON the Vekroosan® SCCD by pressing the power button. The power indicator will initially turn WHITE and a BEEPING sound will be heard when the device turns ON. Shortly after the power indicator will turn Green indicating that the batteries are fully charged.

If at turn on the power indicator turns BLUE instead of Green then the batteries are not sufficiently charged to run a therapy session and the device will turn OFF. Please charge the batteries as described in Charging the Battery on page 11.

The Garments will inflate to the set pressure starting from the lower cuff, centre cuff and followed by the upper cuff.

The three chambers will inflate and deflate in a sequence repeating approx. every 20 to 30 seconds. Once all three chambers are inflated to the set pressure the chambers will deflate to the minimum pressure set and the cycle will repeat for the duration of the therapy. On completion of the therapy the device will turn off.

After approx. 5 therapy sessions the battery will become partially depleted. When the battery depletes to a level which still has approx. 1 hour of usage remaining a Beep will be heard and the Power Indicator will flash yellow. The power indicator will continue to lash yellow every 10seconds indicating that the batteries should be re-charged.

Changing Pressure Setting

Cuff Pressure

Cuff pressure can be changed to suite the individual needs of patients. Vekroosan® is factory set for all three cuffs to 60 mmHg. You should consult your clinician to determine what appropriate pressure should be used to treat your condition.

- 1 Turn on the Vekroosan® SCCD and check the Power Led is indicating Green.

You should seek advice from your clinician before changing chamber pressures to ensure that the pressure selection is appropriate for you therapy.

- 2 While the Vekroosan® SCCD is pumping, press and hold the chamber select button for around 2 seconds, the chamber indicator should light up. Keeping the Chamber Select Button depressed will result in the indicator scrolling through the colours listed below. Release the Button when the appropriate chamber is selected.
- 3 The chamber indicator's colour shows which chamber will be affected. Repeat Step 2 until the colour desired is lit.

- A **Red:** bottom chamber
- B **Green:** middle chamber
- C **Blue:** top chamber
- D **White:** all chambers

- 4 Once you have selected the desired chamber:
- 5 Press and hold the pressure select button for around 2 seconds, the pressure indicator should light up.
- 6 The pressure indicator's colour indicates the pressure setting. Repeat Step 4 until the desired pressure corresponds with the indicator colour.

Pressure indicator colours are:

- A **Red:** bottom chamber
- B **Green:** middle chamber
- C **Blue:** top chamber

It will take approx. 5 seconds for the new setting become effective.



Charging Battery

- 1 Plug the smaller end of the USB cable into the Vekroosan® SCCD.
- 2 Plug the other end of the USB cable into the USB charger supplied.
- 3 Plug the charger into a 240V General Purpose Outlet and switch on the power point.
- 4 If using a USB Charger not provided with this product (Not Recommended) ensure that the Power Point is turned on as some USB chargers do not have an indicator that the power is being supplied.
- 5 Charging time may vary depending on the charge of the battery. Approx. time for a complete re-charge is 2-3 hours.
- 6 To check if the battery is charged turn on the device and check to see if the power indicator turns green. If it indicates green then the battery is fully charged and the device is available for use.
- 7 Disconnect the charging cable from Vekroosan®. Remove the USB charger from the General Purpose Outlet and store in a safe place for future use.

Decontamination

The following processes are recommended, but should be adopted to comply with the local or national guidelines (Decontamination of Medical Devices) which may apply within the Healthcare Facility. If you are uncertain, you should seek advice from your local Infection Control Specialist.

Caution

Do not use Phenol-based solutions or abrasive compounds or pads during the decontamination process as these will damage the surface coatings. Avoid immersing in water during the cleaning process. Do not spray cleaning solutions directly onto the pump controller.

Cleaning

Before you start:

- 1 The Vekroosan® SCCD must be turned off and disconnected from the USB charger before cleaning.
- 2 Do not submerge the pump into any liquid.
- 3 Do not use harsh cleaners.
- 4 Do not remove the pump unit from the cuff.

Cleaning Procedure:

- 1 Using a soft cloth moist with 70% isopropyl alcohol, clean the outer surface of the pump unit.
- 2 For stains on the cuff, use a disinfectant spray and clean in a gentle manner.
- 3 Wipe all excess liquid off using a dry cloth and allow the unit to dry out for a minimum of 1 hour.

Changing Pressure Setting

Maintenance

The equipment has been designed to be maintenance free.

Servicing

All servicing is to be performed by the manufacturer or authorized service provider. DVT Pty Ltd (Australia) will make available service manuals, component parts lists and other information necessary for trained personnel to service or repair the equipment.

Service Period

DVT Pty Ltd recommends that Vekroosan is serviced every 12 months by DVT Pty Ltd (Australia) authorized agent.

General Care

Check the device for general wear and tear including the USB charger and cable. In the event the device has been subjected to abnormal treatment, eg. immersed in water or dropped the unit must be returned to an authorised service center for evaluation.

Product label & serial number

The serial number label is located on the top front of the unit just above the barcode. Quote this serial number when requesting service.



Contents of the Box

- ✓ 1 Vekroosan® DVT pump and cuff assembly
- ✓ 1 USB Charging Cable
- ✓ 1 5V Charger
- ✓ 1 Instructions for Use
- ✓ 1 Warranty Card

Technical Data

Dimension	Pump Unit: 185mm x 75mm Cuff: 310mm x 630mm approx.
Weight	611g approx.
Source of Power	3.7 Volt Li-ion rechargeable battery
Power Supply	5V 1A USB
Battery Charge Time	4 hours approx.
Operation Temperature	+5°C to +40°C
Default Setting	80mmHg
Settings Available	40/60/80 mmHg
Pressure Tolerance	±5%
Treatment Cycle Length	1 hours approx..



Manufacturer's Declaration

Guidance and manufacturer's declaration – electromagnetic emissions

Vekroosan is intended for use in the electromagnetic environment specified below. The customer or the user of this device should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1	The device 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 device is suitable for use in all establishments including domestic establishments and those directly connected to public power supply network that supplies buildings used for domestic purposes

Warranty

The Vekroosan® SCCD is warranted for a period of 12 months from date of purchase.

Authorised Service & Repair Centre

DVT Solutions (Australia) Pty Ltd

- ✓ **Email:** vekroosan@vekroosan.com.au
- ✓ **Location:** Unit 5/1-5 Derby Street
Kogarah NSW, 2217 Australia.
- ✓ **Phone:** +61 418224400
- ✓ **Office:** Suit 7/287 Military Rd. Cremorne NSW, 2090, Australia.

Contact Information

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