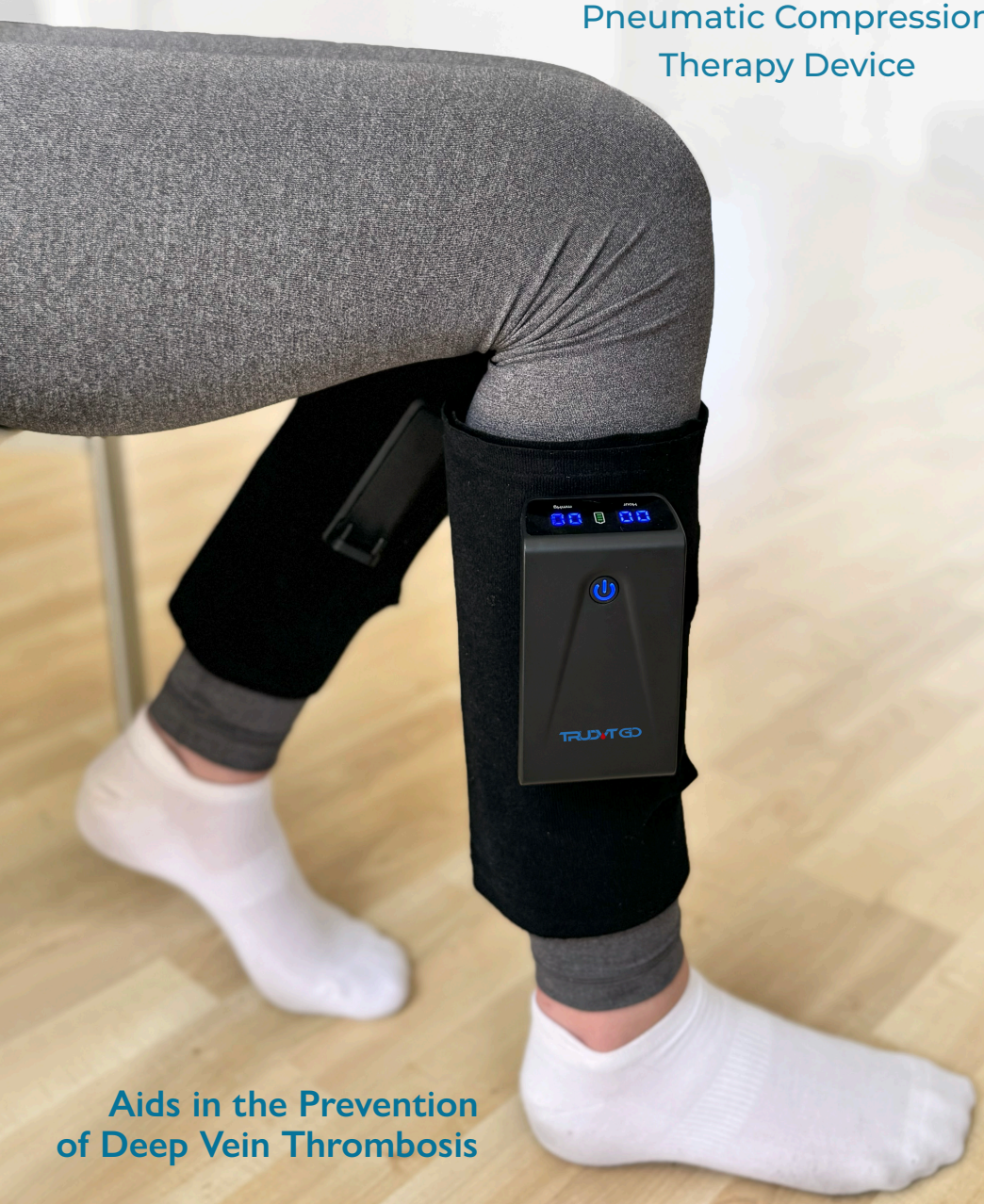
TRUVTGO

Pneumatic Compression Therapy Device



Aids in the Prevention of Deep Vein Thrombosis

OPERATING MANUAL

Please read fully before operating

TRUMED

TABLE OF CONTENTS

PRODUCT SPECIFICATIONS

Items included:

(1) TruDVT Go Controller (Tru-XC111) *2 pcs

(2) TruDVT Go Manual (Rev A Tru-XM111) *1pc

(3) TruDVT Go Charger (Tru-XC111) *1 pc

INTRODUCTION

The TruDVT Go is a user-friendly portable system prescribed by physicians for home or clinical use to prevent Deep Vein Thrombosis (DVT) by stimulating blood flow in the extremities, stimulating muscle contractions.

The device works by using an electronically controlled pump that delivers a preset amount of air to wrap cuffs, which compress the calves to enhance blood flow from the lower extremities, aiding in DVT prevention.

INDICATIONS FOR USE

CAUTION: Federal law restricts this device to sale by, or on the order of, a licensed practitioner.

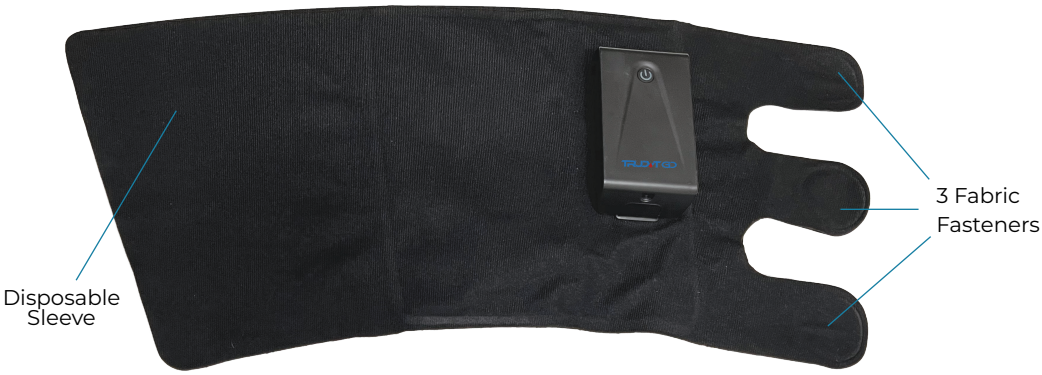
The device uses an inflatable sleeve to simulate kneading and stroking of tissues. It is designed as a user-friendly portable system for home or clinical use to prevent Deep Vein Thrombosis (DVT) by stimulating blood flow in the extremities, mimicking muscle contractions. This device can:

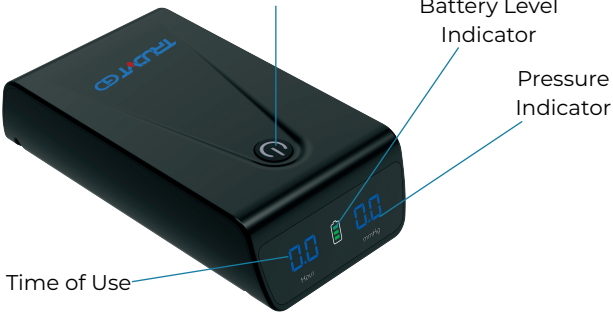
- Enhance blood circulation
- Aid in the prevention of DVT
- Reduce wound healing time
- Diminish post-operative pain and swelling
- Assist in the treatment and healing of stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency, and lower limb edema

It is also useful as a preventive measure for DVT in individuals who will be stationary for extended periods.

COMPONENTS

The product consists of the main device and a detachable wrap sleeve, which can be charged using the supplied power charger/adapter.

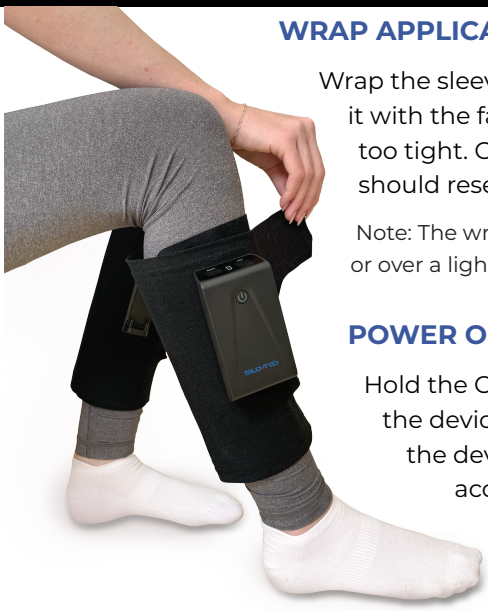




OPERATING INSTRUCTIONS

Installation And Dismantling

The disposable sleeve features a pedestal with a slot for installing the controller. Slide the controller into the slot until you hear a click, indicating it is securely in place. After use, remove the controller by sliding it out along the slot.



WRAP APPLICATION

Wrap the sleeve with the controller around your calf and secure it with the fabric fasteners. Ensure the wrap is snug but not too tight. Once both wraps are secured on your legs, they should resemble the picture on the right.

Note: The wrap can be placed directly against the skin or over a light dressing.

POWER ON

Hold the On/Off button for about 1.5 seconds to turn on the device. You will hear a buzzer sound once when the device powers on. The display will show the accumulated working time and the air pressure will display 00. The indicator under the On/Off button will light up, and the bars inside the battery icon will light up according to the battery level.

POWER OFF

Hold the On/Off button for about 1.5 seconds to turn off the device. You will hear the buzzer sound twice when the device shuts down. The time and air pressure display areas will turn off, the indicator under the On/Off button will go off, and the battery icon bars will disappear.

WORKING MODE

After turning on, the device displays the accumulated working time for 2 seconds. Then, it begins inflating, showing real-time inflation pressure sequentially from 00 to 55 mmHg. Once it reaches 55 mmHg, it maintains this pressure for 4 seconds before starting to deflate. During deflation, the pressure display decreases from 50 to 00, flashing until the next cycle begins. The blue power indicator under the On/Off button will flash slowly throughout this process. (Note: A complete cycle of inflation, deflation, and rest takes approximately 60 seconds).

CHARGE/DISCHARGE

The three green bars inside the battery icon will flash dynamically while the device is charging and become solid when fully charged.

Note:

1. The three green bars represent the battery level: three bars indicate a full charge, two bars mean sufficient power, and one bar indicates low battery.
2. The device can operate normally while charging. Use only the 5V, 2A charger provided by the manufacturer. Using an incorrect charger can damage the device and pose a risk to the patient.

ALARM

Low Battery Voltage: When the battery voltage is critically low, the device will stop working. The first bar in the battery icon will flash quickly, the time display will show “E2,” the air pressure display will show “LB,” and the buzzer will beep for 10 seconds before the device turns off automatically. Charge the device before the next use.

Low Pressure and Air Leakage:

If inflation exceeds approximately 30 seconds without reaching 55 mmHg, the device will stop working. All bars in the battery icon will flash quickly, the time display will show “E1,” the pressure display will show “LP,” and the buzzer will beep for 10 seconds before the device shuts down. Ensure the wrap is snugly tied around the calf to avoid a low pressure alarm.

If the wrap is properly secured, but the battery lights continue to flash, the display shows “LP,” and the device repeatedly shuts down, the device may be damaged. Contact the seller for assistance.

SYMBOL INTERPRETATION

Information essential for proper use will be indicated by corresponding symbols. The following symbols may appear on the device and its labeling.

Symbol	Title
	ON/OFF button
	Refer to instructions for use
IP22	IP code of the device
	Unrecyclable
	This way up
	Date of manufacture
	Batch code
	Manufacturer
	Type BF applied part
	Fragile, handle with care
	Keep the product in the dry place, away from water and rain.
	Product packaging is recyclable
	Symbol for Class II Equipment
	Expiration Date
	Caution: Federal law restricts this device to sale by or on the order of a licensed practitioner.

SAFETY WARNING

Contraindications

This device MUST NOT be used for:

Persons with suspected, active, or untreated deep vein thrombosis, ischemic vascular disease, severe arteriosclerosis, pulmonary edema, severe congestive heart failure, thrombophlebitis, or an active infection.

Legs where cuffs would interfere with vein ligation, gangrene, dermatitis, open wounds, recent skin grafts, massive edema, or extreme deformity.

- Arrhythmia
- Erysipelas
- Any neuropathy
- Unstable hypertension
- Acute inflammatory skin diseases
- Extremities that are insensitive to pain
- Situations where increased venous or lymphatic return is undesirable

WARNINGS AND PRECAUTIONS

- The device wraps are for single-patient use only.
- The device can be operated by the patient.
- The device is intended only for use by the prescribed patient and for its intended purpose.
- Follow the instructions provided by your doctor or the user manual.
- Prevent extremity compartment syndrome by monitoring patients in the supine lithotomy position for extended periods, with or without wraps.
- Diabetic or vascular disease patients require frequent skin assessments; consult a physician.
- The device, alone or with a warming device, may cause skin irritation. Regularly check for discomfort, compliance, and irritation.
- Stop using the device if swelling occurs; consult a physician.
- If pulsations or throbbing occur, loosen the wrap sleeve immediately.
- Only use original accessories, especially the power charger/adapter, to avoid damage to the device or patient.
- Do not open or remove covers; no user-serviceable parts inside. Contact the manufacturer or seller for issues.
- No service should be attempted while the device is in use.
- Do not alter or modify the device.
- Ensure the device is turned off and unplugged before cleaning or disinfecting.
- Do not attempt to walk while using the device.
- When charging, position the device for easy power disconnection.
- Do not use the device in the presence of flammable anesthetic mixtures.
- Do not operate the device in a wet environment or immerse it in any liquid.
- Do not place the device in an autoclave or expose it to direct sunlight, lint, or dust.
- Use and store the device within the manufacturer's specified temperature and humidity range.
- Allow wraps to warm to room temperature if exposed to temperatures below 5°C (41°F).
- Avoid extreme shocks, such as dropping the device.
- Keep the device away from infants, children, and pets. Inspect the device before each use.
- Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC). Portable and mobile RF communications equipment can be affected by

other medical electrical devices.
- Do not use the device in environments with strong electromagnetic interference (e.g., microwave, high-frequency equipment).
- This device is not tested for use in a magnetic resonance (MR) environment and should be kept outside MRI scanner rooms.

ELECTROMAGNETIC COMPATIBILITY

Warning:

Avoid using near active HF surgical equipment and MRI RF shielded rooms due to high EM disturbances.
Do not place this equipment adjacent to or stacked with other equipment to prevent improper operation. If necessary, monitor both for normal function.
Using non-specified accessories, transducers, and cables can increase emissions or reduce immunity, causing improper operation.
Keep portable RF communications equipment, including peripherals, at least 12 inches (30 cm) away to prevent performance degradation.

FCC Statement:

This device complies with part 18 of the FCC Rules.

Technical description:

All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE concerning electromagnetic disturbances throughout the device's expected service life are provided. This includes guidance and the manufacturer's declaration on electromagnetic emissions and immunity.

Guidance and manufacturer's declaration – electromagnetic emission

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

Emission test	Compliance
RF emissions CISPR 11	Group 1, Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies

Guidance and manufacturer's declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or user should ensure it is used in this environment.

Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2kV for power supply lines
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	±1 kV differential mode
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	

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 strength 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Guidance and manufacturer's declaration – electromagnetic immunity		
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T for 0.5 cycle (>95% dip in U_T) 40% U_T for 5 cycles (60% dip in U_T) 70% U_T for 25 cycles (30% dip in U_T) <5% U_T for 5 sec (>95% dip in U_T)	<5% U_T for 0.5 cycle (>95% dip in U_T) 40% U_T for 5 cycles (60% dip in U_T) 70% U_T for 25 cycles (30% dip in U_T) <5% U_T for 5 sec (>95% dip in U_T)
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m

NOTE UT is the ac. mains voltage prior to application of the test level.

Recommended separation distances between portable & mobile RF communications equipment and the device.

The device is intended for use in an environment where radiated RF disturbances are controlled. To prevent electromagnetic interference, the customer or user should maintain a minimum distance between the device and portable or mobile RF communications equipment (transmitters) based on the maximum output power of the communications equipment, as recommended below.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 KHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
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.

Product Program

Program name	Air Pressure (mmHg)
1 auto mode	0-55

TECHNICAL INFORMATION

Model/type: TruDVT Go	Weight 366±10g
Power supply: Powered by an internal 3.7V rechargeable lithium battery	Degree of protection against electric shock Type BF applied part
Pressure: 0-55mmHg (Error: ±5mmHg)	Type of protection against electric shock Class II and built-in battery
Warranty: 1 year	Grade of waterproof: IP22
Recommend Treatment time Prescribed by a physician	Software version: A0
Number of chambers: overlapped air bladders	Treatment position: Calf
Modes: 1 auto mode	Mode of operation: Continuous operation
The time required for the equipment to **warm** from the minimum storage temperature between uses until it is ready for intended use: 30 minutes	The time required for the equipment to **cool** from the maximum storage temperature between uses until it is ready for intended use: 15 minutes
Wrap sleeve size (±10mm) L: 640mm; W: 274mm	Controller size (±1mm): 134x71x34mm
Typical service life of Battery: 300 times of recharging	Adapter for charging Input: AC100-240V, Output: DC5.0V--2A
Typical charging time: Approx. 5 hours	Typical operation time after fully charged: Approx. 24 hours

Note: Not intended to be sterilized.

Not for use in an OXYGEN RICH ENVIRONMENT

Condition of Working, Storage and Transportation

- Atmospheric pressure: 70~106kPa
- Normal working ambient humidity: 15%~90%
- Store and transport ambient humidity: 0~90%
- Normal working ambient temperature: 5~40°C
- Store and transport ambient temperature: -25~70°C

CLEANING AND DISINFECTING

NOTE: Inspect the device and follow cleaning and disinfecting procedures before each use. Cleaning and disinfecting are recommended as needed.

WARNING: Turn off and disconnect the device from the wall outlet before and during cleaning or disinfecting.

DO NOT IMMERSE THE DEVICE IN ANY LIQUID.

Clean the outer surface with a soft cloth moistened with soapy water, then let air dry. Avoid using abrasive or volatile cleaners.

To ensure the device is completely dry before use, leave it turned off and disconnected from the wall outlet for at least 30 minutes after cleaning or disinfecting.

DO NOT place the device or wrap in an autoclave, dryer, or microwave. Avoid using a hair dryer or placing the device near radiators to accelerate drying.

TROUBLESHOOTING

There are no user-serviceable parts. If the device is not operating properly, refer to the common problems and suggested solutions below. If these actions do not resolve the issue, please contact the seller.

Problem	Possible Cause	Solution
The skin turns red or the skin feels irritated	The use time may be too long	Reduce the use time
No display shown on the device	The battery capacity is depleted	Charge the battery
Power cuts off during use	The battery runs out	Charge the battery

MAINTENANCE AND DISPOSAL

The device contains no serviceable parts. Inspect it and all components for damage (e.g., frayed cords, cracked housings, torn wraps) before each use. Refer to the manual for component descriptions.

Do not connect the wall supply if any damage is noticed. Avoid dropping the device or using sharp objects on the wrap with air bladders. If an air bladder is punctured or leaks, do not attempt repairs. Replacement devices are available through customer service.

Avoid folding or creasing the air bladder during use or transportation. The battery is not replaceable; contact customer service for replacement instructions for any damaged items.

If not in use for an extended period, charge the battery every three months to extend its life. Dispose of the device and battery according to local laws; do not discard in landfills or regular waste.

WARRANTY

This device comes with a one-year limited warranty from the date of delivery.
The warranty covers the device only and does not include accessories.

During the warranty period, defective items will be repaired or replaced at no charge.
Misuse, abuse, alterations, or external damage may void the warranty.

For more information, please contact the manufacturer or seller.

CONTACT INFORMATION

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