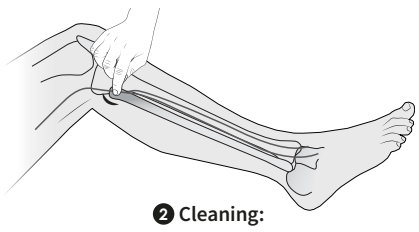
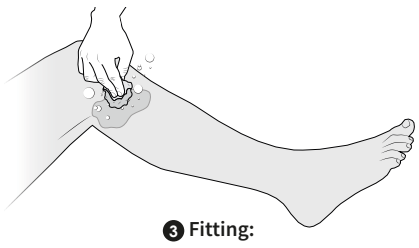
geko™
gekodevices.com

T

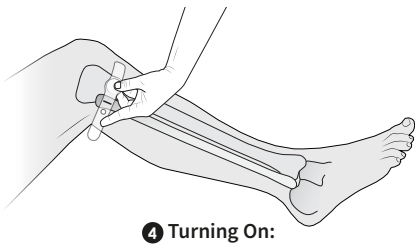
❶ Location:



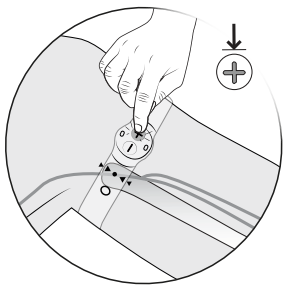
❷ Cleaning:



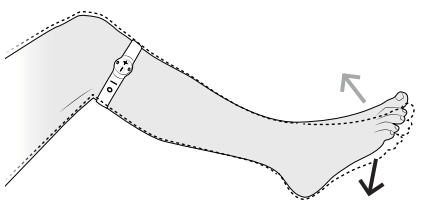
❸ Fitting:



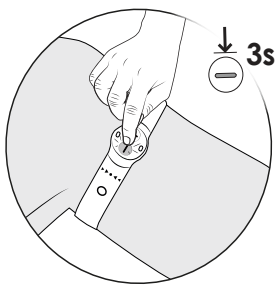
❹ Turning On:



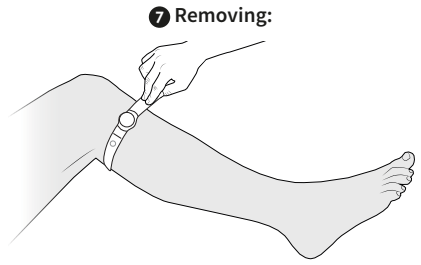
❺ Settings:



❻ Switching Off:



❼ Removing:



℞ **Prescription use only.**

⚠ **Attention: Be sure to read and understand these Instructions for use before applying the geko T-3 device.**

firstkind *living science* OnPulse™ T-3

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**Firstkind Ltd is a wholly owned subsidiary of Sky Medical Technology Limited.*

INSTSKY36A/R2 - March 2020

►Instructions for use / user manual

The geko™ T-3 device is a small disposable, internally powered, neuromuscular stimulation device intended for increasing local blood circulation, the stimulation of the calf muscles to prevent venous thrombosis, and edema reduction, by stimulating the common peroneal nerve at a frequency of 1 Hz (cycles per second). It is intended to be used in hospital, clinic and home environments. It is an integrated device and there are no additional cables or electrodes required for its operation. Familiarize yourself with the components and the skin preparation method before you use the device.

The geko T-3 Neuromuscular Stimulator is intended for:

- Increasing local blood circulation
- Immediate post-surgical stimulation of the calf muscles to prevent venous thrombosis,
- Stimulation of calf muscles to prevent venous thrombosis in non-surgical patients at risk of venous embolism
- Edema reduction

►Fitting instructions

❶ The marker line ▸▸●◂◂ on the geko device should line up with the fibula head, a round lump below the knee on the outside of the lower leg. Ask your healthcare provider if you need help (e.g. nurse or doctor).

❷ It should be applied to clean, dry skin. If there is too much hair in the area it should be removed using trimmers or clippers. Do not shave as this may cause irritation. Wash the skin in the area where the device will be fitted with mild soapy water, rinse, and dry thoroughly; do not apply any moisturiser.

❸ Remove the film from the geko device and place the marker line ▸▸●◂◂ over the fibula head (round lump). Attach the short end round the front of the leg and the longer end towards the back of the leg. The geko device should not be loose, peel off one end and tighten if needed. When correctly fitted, the ⊕ button will always be at the front of the leg.

❹ To turn on, use a short press of the ⊕ button.

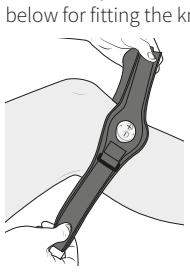
❺ There are 11 settings, shown by the number of times the light flashes before a pause. Use the ⊕ button to increase the setting and ⊖ button to decrease. When working properly the geko device will cause a visible movement of the muscles in the lower leg, moving the foot out and up, which should continue throughout the whole treatment.

❻ To turn it off, hold ⊖ button down for 3 seconds. When the button is held, the light will flash quickly and when turned off the flashing will stop.

❼ Remove carefully in one piece, to avoid damaging the skin.

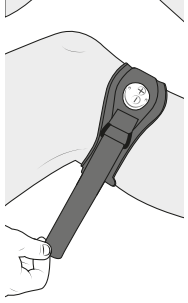
If stimulation is not achieved the geko device can also be fitted in alternative positions, see the website for further details.

If additional adhesion is required, Firstkind recommends the use of a geko knee strap (purchased separately) to ensure that the device remains in place on the leg. See the instructions below for fitting the knee strap.



a) Place the strap over the device with the strap buckle positioned at the side of the leg and the geko T-3 device buttons showing through the strap hole.

b) Wrap the neoprene straps around the back of the leg and secure using the Velcro fastening material.



c) Wrap the long, thin strap round the leg and thread the end of the long strap through the buckle then return the long end to secure with the Velcro fastening tab.

d) Be sure that the strap is comfortable and not tight.

►Contraindications

- Powered muscle stimulators should not be used on patients with cardiac demand pacemakers.
- Powered muscle stimulators should not be used on patients with recently diagnosed DVT.

►Adverse reactions

Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. Switch off the device and remove. The irritation can usually be reduced by using an alternate electrode placement; try lowering the device so the upper edge is positioned very slightly below the crease of the knee.

The geko knee strap is made from a synthetic rubber known as Neoprene (polychloroprene) with a Nylon (polyamide) cover, which are both commonly used in other sports devices such as wetsuits and knee braces. Neoprene and Nylon both have the potential to cause skin irritation or allergic type skin reactions. Do not use the geko knee strap if you have previously experienced a skin reaction to Neoprene or Nylon. If you experience an itching skin rash or irritation when wearing the strap, remove the strap immediately, consult with your medical practitioner, and report the incident to Firstkind Limited.

►Warnings

- The geko T-3 device should only be used if it can be properly applied and set to a stimulation level that will result in visible contractions of the calf and foot muscles. Situations in which the geko T-3 device may not be appropriate include, e.g., excessive edema preventing adequate muscle contraction or knee surgery preventing proper electrode placement.
- The safety and effectiveness of the geko T-3 device have not been evaluated on patients who have undergone a total hip replacement due to fracture.
- Use of this equipment adjacent to other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- The long-term effects of chronic electrical stimulation are unknown.
- Stimulation should not be applied over:
  - the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
  - the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
  - transcerebrally or transthoracically (in that the introduction of electrical current into the heart may cause cardiac arrhythmias).
  - swollen, infected, or inflamed areas or skin eruptions, e.g. phlebitis, thrombophlebitis, varicose veins etc., or in proximity to, cancerous lesions.
- geko T-3 devices should not be used for more than 28 days continuously without specific instructions from the consulting physician.
- The geko T-3 device has no replaceable or serviceable parts and requires no maintenance or calibrations. The unit must not be disassembled. No modification of this device is allowed. Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.
- The geko T-3 device should not be used in combination with MRI scanners (the device is magnetic and should be removed) or in combination with leg positioned ECG leads (the geko device should be switched off during the recording and switched on afterwards.)
- The geko T-3 device should not be switched on unless correctly attached to the patient.
- The geko T-3 device must be kept dry. The patient must not bath or shower while wearing a geko T-3 device.
- Damaged geko T-3 devices or devices with damaged packaging must not be used.

►Precautions

- Safety of powered muscle stimulators for use during pregnancy has not been established.
- Caution should be used for:
  - patients with suspected or diagnosed heart problems.
  - patients with suspected or diagnosed epilepsy.
- Caution should be used in the presence of the following:
  - when there is a tendency to haemorrhage following acute trauma or fracture;
  - following recent surgical procedures when muscle contraction may disrupt the healing process;
  - over the menstruating or pregnant uterus;
  - over areas of the skin which lack normal sensation.
- Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
- Powered muscle stimulators should be kept out of the reach of children.
- Portable powered muscle stimulators should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.

►Reporting of any side effects or adverse reactions

Any side effects or adverse reactions due to use of the geko T-3 device should be reported to Firstkind Limited. Discontinue use of the geko T-3 device until further investigations have been carried out.

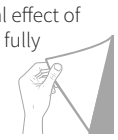
►About the geko T-3 device and muscle stimulation

The physiology:

The body's circulatory system serves to transport and distribute essential substances to the tissues of the body and to remove by-products of metabolism. It also plays a role in the regulation of body temperature, humoral communication throughout the body and adjustments of oxygen and nutrient supply in differing physiological states. The cardiovascular system is made up of a pump (the heart), a series of distributing and collecting tubes and an extensive system of thin vessels that allow rapid exchange with tissues. An average adult has a blood volume of about 5-6 litres. The venous system has a large capacity and may contain some 70% of the blood volume at any time with a large percentage of this in the lower legs. Cardiac output is the volume of blood pumped by the heart per minute and venous return is the volume returning to the heart in the same unit of time. These are interdependent and multiple feedback control loops operate to regulate the cardiovascular system.
Ancillary factors can affect venous return including muscular activity. Contraction of the muscles causes intermittent venous compression and, because of the orientation of the venous valves, blood is forced from the veins toward the heart. Therefore, muscular contraction in the lower limb lowers the mean venous pressure and serves as an auxiliary pump to assist venous return. Muscle contraction lowers capillary hydrostatic pressure and increases local blood circulation.

How geko T-3 device works:

The geko T-3 device is a small disposable, internally powered, neuromuscular stimulation device that is applied externally to the leg. It is self-adhesive and is applied to the outer/posterior aspect of the knee. This positioning enables integral electrodes to apply a stimulus to the common peroneal nerve. This nerve controls the contraction of the calf muscles. The stimulation of this nerve by the geko T-3 device causes the muscles to contract isometrically and will not affect normal movement of the limb nor mobility of the patient. Contraction of the calf muscles will boost blood flow from the lower limbs back to the heart, thus increasing venous return, local blood circulation help prevent venous thrombosis and reduce edema. The geko T-3 device has eleven stimulation levels to balance maximal effect of stimulation with patient comfort. It is fully insulated by the protective moulding and there is no risk of shock.



The patient experience:

The application of the geko T-3 device is very simple and the patient will only experience a cooling effect as the area of skin, to which the device will be applied, is cleaned. Thereafter, the patient will feel as if a small adhesive patch has been applied to the skin.

Upon switching on the geko T-3 device and selecting the appropriate stimulation level, the patient will be aware of the muscle contraction, awareness of which will recede slightly after a few minutes (accommodation).

Over the next hour and the 24 hour treatment period, the patient's awareness of muscle contraction will lessen and the patient can carry out their normal routine including sleep.

Be sure that the geko T-3 device is removed if the patient needs to shower or bath.

The geko T-3 Clinical Studies:

For details of the clinical data for the geko device go to www.gekodevices.com

►Operating information for healthcare professionals

Carefully read all instructions before applying and using the device. If the geko T-3 device has been stored at low temperatures (below 5°C), allow to reach room temperature before use.

Check with the patient at two-hourly intervals that they are still comfortable and being stimulated; if not, adjust the stimulation level accordingly.

Check also that the indicator lights are still flashing as expected for the stimulation level set; if not, try switching the geko T-3 device on again and setting the level. If the geko T-3 device does not work, remove the device and unpack a new geko T-3 device and re-apply.

The geko T-3 device should be replaced after 24 hours. Turn off the device as instructed and remove it carefully from the patient by easing the long end away from the knee and peeling the device gently away from the skin.

The device will stop operating 30 hours after first being turned on.

Before re-applying a geko device, examine the skin for any changes, such as rashes or lesions. Observe the warnings given in **Warnings** and precautions given in **Precautions** regarding the condition of the skin. If the skin shows no signs of irritation, another geko T-3 device can be fitted straight away if required.

The consulting physician will determine for how many days devices are to be used.

►Help

If you require any help with the use of the geko T-3 device, contact Firstkind Limited by dialling 011 44 1494 572040 or log-on at http://www.gekodevices.com/contact-us

►Classification

The device is internally powered by a non-replaceable CR2032 lithium ion coin cell battery. The battery is intended for continuous operation.

Type BF applied part – for direct electrical contact to patient but not direct cardiac application. The whole device is the applied part.

►Disposal of the geko T-3 device

The geko T-3 device is not reusable after its 24 hour operating period. The used device should be disposed of safely. (See below for instructions for battery removal.)

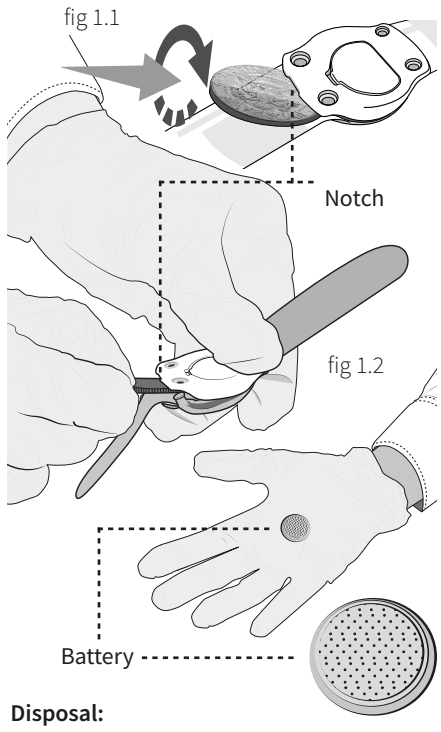
The packaging:

The devices are packed in plastic sleeves. The packing should be disposed of appropriately and can be recycled.

The battery:

The geko device is powered by a battery located inside the protective moulding. The battery must be disposed of safely and in accordance with local procedures in place at your hospital/clinic.

To remove the battery insert a coin or blunt lever between housing mouldings at the end with a small notch (fig. 1.1). Hold the housing firmly, push and twist the coin or lever until the housing breaks apart. (fig. 1.2) giving you access to the components. We recommend that you wear gloves and do not use anything sharp for your own protection.



Disposal:

The protective backing film can be disposed of in normal waste. Once the battery has been removed, the device should be disposed of as other electrodes and dressings in accordance with local procedures in place at your hospital/clinic. DO NOT INCINERATE the battery.

►Specifications

Product name	geko™
Model reference	T-3
Product type	Powered muscle stimulator
Class	BF (whole device is the applied part)
Dimensions	186mm x 31mm x 11mm
Weight	10g (geko™ device only)
Power source internally powered equipment	Battery not replaceable
Battery	Primary lithium coin cell
Operation	Continuous operation– equipment not suitable for use in presence of flammable anaesthetic mixture with air or with oxygen or nitrous oxide
Stimulation modes	11 (selectable pulse widths)
Pulse current	27, 38 or 54mA (±15%) constant current, compliance to 80v
Load impedance	200Ω to 3kΩ for 54mA output pulse voltage set by current and load
Pulses width(200Ω to 10k Ω)	35, 50, 70, 100, 140, 200, 280 µs @27mA, 280 & 400µs @38mA, 400, 560 µs @54mA (±5% +20µs) (open circuit ±5% +50µs)
Repetition rate	1Hz (±5%)
Maximum charge	40µC per pulse maximum
Net charge output	Zero per cycle
Output coupling	Ceramic capacitor
Fault indication	The stimulator device will automatically switch off for over current, under current, low battery voltage or end of 30 hours elapsed time from start
Standards	IEC60601-1 (2005), IEC60601-2-10 (2012), IEC60601-1-2 (2014), ISO 10993

Operating conditions:	
Temperature range	5°C to 40°C
Humidity range	10% to 80% non-condensing
Storage conditions in original packaging:	
Temperature range	-25°C to 40°C
Humidity range	Up to 93% RH non-condensing
Atmospheric pressures	70 kPa to 106kPa
Shelf-life	See expiry date on the pouch label
Transport conditions:	
Temperature range	-25°C to 70°C
Humidity range	10% to 80% non-condensing
Atmospheric pressures	70 kPa to 106kPa
Materials	**Electrode:** Hydrogel **Battery Casing:** Polypropylene **Strap:** PET (Mylar) polyethylene terephthalate
Warranty	Check expiry date on pouch before use and 24 hours stimulation

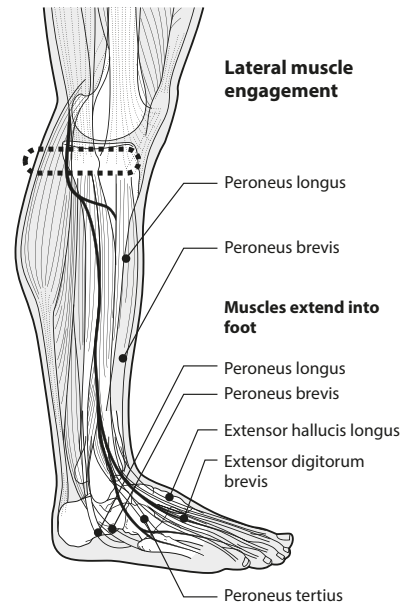
Output voltages and currents:

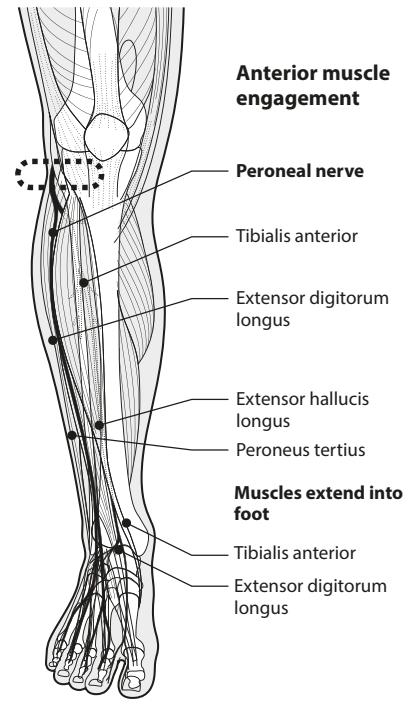
Measured at internal outputs of the pulse generator (±15%)

Pulse widths	**half power setting 400µs**		**full power setting 560µs**	
load	**current**	**voltage**	**current**	**voltage**
0,2 KΩ	38mA	7.6V	54mA	10.8V
0,5 KΩ	38mA	19V	54mA	27V
1 KΩ	38mA	38V	54mA	54V
2 KΩ	38mA	76V	54mA	108V
3 KΩ	38mA	114V	54mA	162V
10 KΩ	38mA	255V	54mA	200V

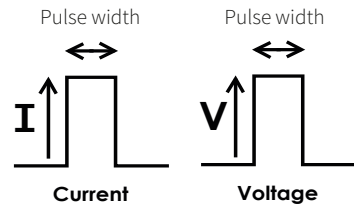
Explanation of the meaning of symbols

	Type BF applied part
	Product not manufactured with Latex
	Single use only – use only on one patient for a single course of treatment
	Storage and transportation atmospheric pressure range whilst within packaging
LOT	Lot number
REF	**Catalogue number**
	Expiry date – do not use after this date
	Storage temperature range whilst within packaging
IP22	Ingress protection rating 22
	Storage and transportation humidity range whilst within packaging
DI	Device identifier
	Manufactured by
	See Instructions for Use
	Do not use if package is damaged
CE 1639	CE Mark of Conformity





Output waveform



Repetition rate: 1Hz