

## Device Description

### The physiology

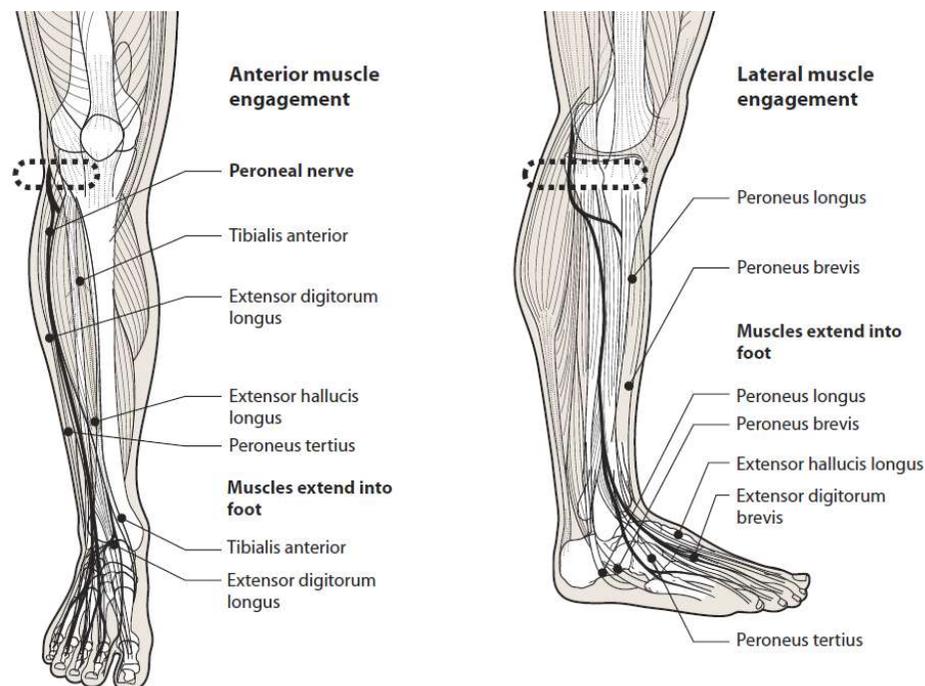
The body's circulatory system serves to transport and distribute essential substances to the tissues of the body and to remove by-products of metabolism. It also plays a role in the regulation of body temperature, humoral communication throughout the body and adjustments of oxygen and nutrient supply 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 OnPulse works

The geko and firefly devices are a small disposable, internally powered, neuromuscular stimulation device that is applied externally to the leg. They are self-adhesive and 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 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 and help prevent venous thrombosis. The device has seven 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 application of the 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 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 treatment period the patient's awareness of muscle contraction will lessen and the patient can carry out their normal routine including sleep.

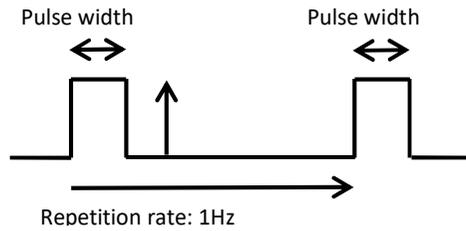
Be sure that the device is removed if the patient needs to shower or bathe.



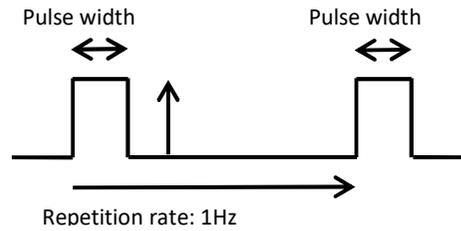
## Device output specifications

Product name	geko™					geko™ plus	firefly™	
Model reference	T-1	T-2	W-2	XW-2	T-3	R-2	T-1	T-2
Model Identifier								
Product type	<b>Powered muscle stimulator</b>							
Class	<b>BF</b> (The entire device is considered to be a patient applied part)							
Dimensions	149mm x 42mm x 11mm	186mm x 31mm x 11mm	186mm x 31mm x 11mm	186mm x 31mm x 11mm	186mm x 31mm x 11mm	186mm x 31mm x 11mm	149mm x 42mm x 11mm	186mm x 31mm x 11mm
Weight	16g (device only)	10g (device only)	10g (device only)	10g (device only)	10g (device only)	10g (device only)	16g (device only)	10g (device only)
Power source	Internally powered equipment, <b>battery not replaceable</b>							
Battery	<b>Primary lithium coin cell</b> - removable for disposal							
Operation	<b>continuous operation</b> – equipment not suitable for use in presence of flammable anaesthetic mixture with air or with oxygen or nitrous oxide							
Stimulation modes	<b>7</b> (selected pulse widths)	<b>7</b> (selected pulse widths)	<b>10</b> (selected pulse widths)	<b>10</b> (selected pulse widths)	<b>11</b> (selected pulse)	<b>8</b> (selected pulse widths)	<b>7</b> (selected pulse widths)	<b>7</b> (selected pulse widths)
Pulse current	<b>27mA</b>	<b>27mA</b>	<b>54mA</b>	<b>54mA</b>	<b>27, 38 or 54mA</b>	<b>54mA</b>	<b>27mA</b>	<b>27mA</b>
Load impedance	200Ω to 3kΩ for 27mA output	200Ω to 3k Ω for 27mA output	200Ω to 3k Ω for 54mA output	200Ω to 3k Ω for 54mA output	200Ω to 3k Ω for 54mA output	200Ω to 3kΩ for 54mA output	200Ω to 3kΩ for 27mA output	200Ω to 3k Ω for 27mA output
Pulse voltage	Set by current and load							
Pulse width ±10%	<b>70, 100, 140, 200, 280, 400 and 560µs</b>	<b>50, 70, 100, 140, 200, 280, 400µs</b>	<b>25, 35, 50, 70, 100, 140, 200, 280, 400 and 560µs</b>	<b>25, 35, 50, 70, 100, 140, 200, 280, 400 and 560µs</b>	<b>35, 50, 70, 100, 140, 200, 280 µs @27mA, 280 &amp; 400µs @38mA, 400, 560 µs @54mA,</b>	<b>50, 70, 100, 140, 200, 280, 400 and 560µs</b>	<b>70, 100, 140, 200, 280, 400 and 560µs</b>	<b>50, 70, 100, 140, 200, 280, 400µs</b>
Repetition rate	<b>1HZ</b> (±5%)							
Maximum charge	<b>20µC</b> per pulse	<b>20µC</b> per pulse	<b>40µC</b> per pulse	<b>40µC</b> per pulse	<b>40µC</b> per pulse	<b>40µC</b> per pulse	<b>20µC</b> per pulse	<b>20µC</b> per pulse
Net charge output	<b>Less than 0.1 µC per cycle.</b> Charge balance is provided by return pulses of low amplitude and same the same total charge as the stimulation pulse							
Output coupling	<b>Ceramic capacitor</b>							
Operating time	<b>24 hour duration</b> (maximum 30 hours)	<b>24 hour duration</b> (maximum 30 hours)	<b>Two, 6 hour sessions</b>	<b>Two, 12 hour sessions</b>	<b>30 hours maximum elapsed time from start</b>	<b>24 hour duration</b> (maximum 30 hours)		
Mode of Operation	The devices are suitable for continuous operation							
Indicator display	<b>green LED</b> , flashing to indicate operation and the setting level (pulse width): the number of flashes in the sequence							
fault indication	the stimulator device will <b>automatically switch</b> off for over current, under current, low battery voltage or end of operating time							

**Voltage waveform:**



**Current waveform:**



**Output voltages and currents: measured at internal outputs of the pulse generator ( $\pm 15\%$ )**

**geko™ T-1 and firefly™ T-1**

pulse width	half-power setting 280 $\mu$ s		full-power setting 560 $\mu$ s	
load	current	voltage	current	voltage
200 $\Omega$	27mA	5.4V	27mA	5.4V
500 $\Omega$	27mA	13.5V	27mA	13.5V
1000 $\Omega$	27mA	27V	27mA	27V
2000 $\Omega$	27mA	54V	27mA	54V
3000 $\Omega$	27mA	81V	27mA	81V
current rms (500 $\Omega$ )	1mA rms maximum			
voltage rms (500 $\Omega$ )	0.5V rms maximum			

**geko™ T-2 and firefly™ T-2**

pulse width	half-power setting 200 $\mu$ s		full-power setting 400 $\mu$ s	
load	current	voltage	current	voltage
200 $\Omega$	27mA	5.4V	27mA	5.4V
500 $\Omega$	27mA	13.5V	27mA	13.5V
1000 $\Omega$	27mA	27V	27mA	27V
2000 $\Omega$	27mA	54V	27mA	54V
3000 $\Omega$	27mA	81V	27mA	81V
current rms (500 $\Omega$ )	1mA rms maximum			
voltage rms (500 $\Omega$ )	0.5V rms maximum			

### geko™ plus R-2, geko™ W-2, geko™ XW-2

pulse width	half-power setting 280µs		full-power setting 560µs	
load	current	voltage	current	voltage
200Ω	54mA	10.8 V	54mA	10.8 V
500Ω	54mA	27 V	54mA	27 V
1000Ω	54mA	54 V	54mA	54 V
2000Ω	54mA	108 V	54mA	108 V
3000Ω	54mA	162 V	54mA	162 V
current rms (500Ω)	<b>1.3mA</b> rms maximum			
voltage rms (500Ω)	<b>0.7V</b> rms maximum			

### geko™ T-3

pulse width	half-power setting 400µs @38mA (level 9)		full-power setting 560µs @54mA (level 11)	
load	current	voltage	current	voltage
200Ω	38mA	7.6 V	54mA	10.8 V
500Ω	38mA	19 V	54mA	27 V
1000Ω	38mA	38 V	54mA	54 V
2000Ω	38mA	76 V	54mA	108 V
3000Ω	38mA	114 V	54mA	162 V
current rms (500Ω)	<b>1.3mA</b> rms maximum			
voltage rms (500Ω)	<b>0.7V</b> rms maximum			

### geko™, geko™ plus and firefly™

Indicator display	<b>green LED</b> , flashing fault indication: the stimulator device will <b>automatically switch</b> off for over current, under current, low battery voltage or end of its run time (see the Instructions for Use provided with the device for details of the run (treatment) time.
Standards	EN60601-1:2006, EN 60601-2-10:2012, EN60601-1-11:2010, EN 60601-1-2: 2015, ISO 10993-1:2009

#### Operating conditions:

Temperature range	5°C to 40°C,
Humidity range	up to 93% RH non-condensing
Atmospheric pressures	70 kPa to 106 kPa

The device should be used at between 5 and 40°C. If the storage conditions were outside of this range allow time for the device to reach room temperature before use: 30 minutes should be sufficient.

The geko™ is compatible with HF surgical equipment, and will continue to operate in its presence. The device must be outside of the sterile area and it is recommended that electrodes are not be used within 50mm from the device in order to prevent inadvertent damage to the geko™ device.

### Storage & transport conditions in original packaging:

Store the device in its protective foil pouch. The storage and temperature range is -25°C to 70°C for short durations (up to 2 weeks in total). As it is difficult to monitor storage and transportation temperatures we recommend to store the device at room temperature (up to 30°C), if at all possible.

Temperature range	-25°C to 70°C for short durations only
Humidity range	up to 93% RH non-condensing
Atmospheric pressures	70 kPa to 106 kPa
Shelf-life	see expiry date on the pouch label

### Storage conditions outside of original packaging:

The device will deteriorate if removed from its original package, and must be left in its original package until just prior to use. The device may be removed temporarily and reapplied if necessary, for example to prevent the device getting wet during bathing or showering. If it must be removed keep it at clean, dry and at room temperature between uses, and reapply as soon as possible.

### Use-life

firefly™ T-1	Up to 30 hours of operational life
geko™ T-1	Up to 30 hours of operational life in continuous use
geko™ T-2, geko™ plus R-2	Up to 30 hours of operational life in continuous use
geko™ W-2	Up to 12 hours of operational life, in two, 6 hour treatment sessions
geko™ XW-2	Up to 24 hours of operational life, in two, 12 hour treatment sessions
geko™ T-3	30 hours of operational life from the time it is first turned on. After 30 hours has elapsed, the device will be permanently disabled

### Materials:

**geko™ T-1, firefly™ T-1** Polyethylene terephthalate (Mylar), ethylene-vinyl acetate, polypropylene, hydrogel

**geko™ T-2, W-2, XW-2, T-3 geko™ plus R-2, firefly™ T-2** Polyethylene terephthalate (Mylar), polypropylene, polyether ester, hydrogel

### Warnings

Implanted electronic devices (for example a cardiac pacemaker): - specialist medical opinion should be obtained before the patient is subjected to stimulation.

Recently diagnosed or suspected DVT: specialist medical opinion should be obtained before the patient is subjected to stimulation.

Read the instructions carefully before use. Only apply the device in accordance with instructions. Improper use of this device can be dangerous.

The geko™ device may be operated either by the patient or a third party. Patients should be trained in the positioning and operation of the device, as well as warnings and precautions to be observed to ensure safe use of the device.

Keep out of the reach of children and pets.

No modification of this equipment is allowed.

Do not use whilst driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user or others at undue risk of injury.

Stimulation should not be applied across or through the head, directly on the eyes, covering the mouth, on the front of the neck, (especially the carotid sinus), or from electrodes placed on the chest and the upper back or crossing over the heart.

Application of electrodes near the thorax may increase the risk of cardiac fibrillation.

Do not apply over sore, infected or inflamed areas, broken skin or skin eruptions, e.g. phlebitis, thrombophlebitis, varicose veins etc.

Do not apply over or, in proximity to, cancerous lesions.

Do not use in proximity (i.e. within 1m) of short wave/microwave equipment, as this may affect the device.

Portable and mobile RF communications equipment can affect medical electrical equipment.

Do not use if packaging is open or appears damaged.

Do not use a device that appears to be damaged.

Do not use the device in close proximity to heat sources, such as fires or radiant heaters, as excess heat may affect the performance of the device.

In some cases skin inflammation or irritation can develop in the contact area: either remove the device or re-attach in the alternative fitting location. If the condition persists or recurs obtain specialist medical advice before resuming use.

Medical advice should be sought when the patient is pregnant, has diagnosed heart conditions or epilepsy, or following surgery where muscle contractions may disrupt the healing process.

The device should be removed before the patient undergoes MRI as it contains ferromagnetic components.

The device should be switched off during ECG monitoring using leg electrodes as it may interfere with ECG leg electrode signals.

The device is not intended for use in an oxygen rich environment.

Do not place the device in the mouth. The device is a choke and potential allergic hazard. If the device or any component is swallowed seek IMMEDIATE medical assistance. Serious harm could be caused if the battery is swallowed.

### **Precautions**

Check the device is functioning correctly every 2 hours.

Use the device only as instructed.

Visit [www.gekodevices.com](http://www.gekodevices.com) for further advice and usage tips. Keep out of the reach of children.

Do not switch on unless correctly attached to the patient.

The device must be kept clean and dry. Do not bath or shower whilst wearing the device.

Do not apply a device that has been worn by another individual as this will carry a risk of infection.

Specialist medical opinion should be obtained before devices are used for more than 28 consecutive days.

Remove the device carefully, lifting the tail-end first and applying a constant gentle force.

Excessive force may damage the device.

### **Identification**

Each device has a model identification logo which can be seen on the device itself, on the labels and the Instructions for Use provided with the device. See above for details. The label bears the manufacturing Lot number and expiry date of the device.

### **Instructions for Use**

Please read the Instructions for Use BEFORE using the device. Both this document and the Instructions for Use provided with the device include important fitting instructions and safety information essential for safe and effective use of the device.

### **IP Classification**

The device has an Ingress Protection (IP) rating of IP22. See the symbols section below for further explanation.

## Symbols

	<b>Follow the instructions for use</b>		<b>Lot number</b>
	<b>On/Increase stimulation</b> button		<b>Manufactured by</b>
	<b>Off/Decrease stimulation</b> button		<b>Expiry date</b> – do not use after this date
	<b>Type BF applied part</b> - for direct electrical contact to patient but not direct cardiac application		<b>CE Mark of Conformity</b> (with Notified Body number)
	<b>Single use only</b> – use only on one patient for a single course of treatment		<b>Do not use if package is damaged</b>
	<b>Product not manufactured with Latex</b>		<b>See Instructions for Use</b>
	<b>On/Off/stimulation setting</b> (T-1 only)		<b>CE Mark of Conformity</b>
	<b>Storage, transportation and operational temperature ranges</b>		<b>IP: Ingress Protection IEC 529</b> 2x: Protection against fingers or other object not greater than 80mm in length and 12 mm in diameter x2: Protection from vertically dripping water when tilted to 15°
	<b>Storage and transportation humidity range</b>		<b>Storage and transportation atmospheric pressure range</b>



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