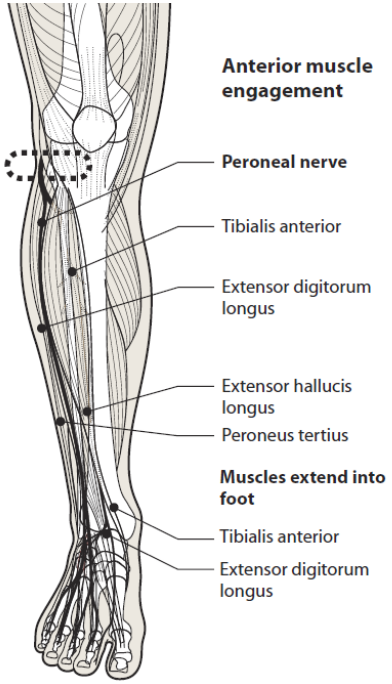
Device Description

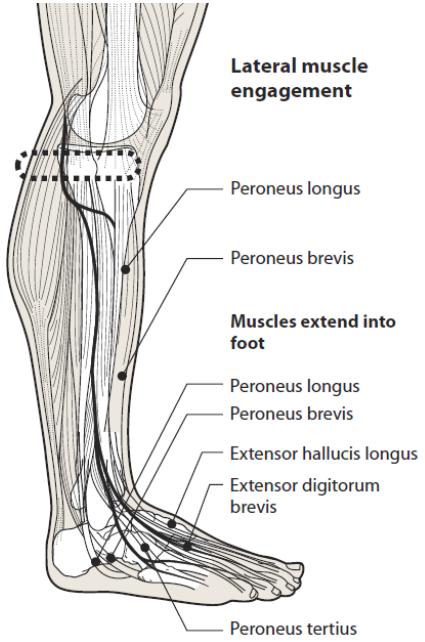
The physiology

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 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/lateral 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 user. 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 several stimulation levels (see table below) to balance maximal effect of stimulation with user comfort. It is fully insulated by the protective moulding and there is no risk of shock



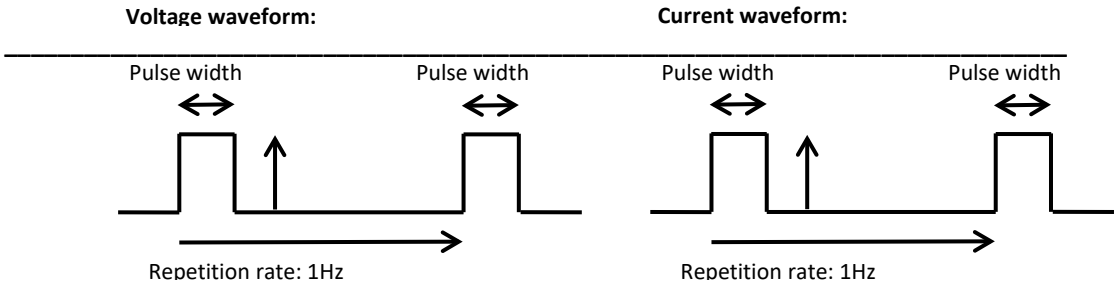


The application of the device is very simple, and the user will only experience a cooling effect as the area of skin, to which the device will be applied, is cleaned. Thereafter, the user will feel as if a small adhesive patch has been applied to the skin. Upon switching on the device and selecting the appropriate stimulation level, the user 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 user's awareness of muscle contraction will lessen, and the user can carry out their normal routine including sleep.

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

Device output specifications

Product name	**firefly**®
Model reference	**T-2**
Model Identifier	T-2
Product type	**Powered muscle stimulator**
Class	**BF** (The entire device is considered to be a user applied part)
Dimensions	186mm x 31mm x 9.35mm
Weight	10g (device only)
Power source	Internally powered equipment, **battery not replaceable**
Battery	**Primary lithium coin cell** - removable for disposal
Operation	**continuous operation** – equipment not suitable for use in presence of flammable anaesthetic mixture with air or with oxygen or nitrous oxide
Stimulation modes	**7** (selected pulse widths)
Pulse current	**27mA**
Load impedance	200Ω to 3k Ω for 27mA output
Pulse voltage	Set by current and load
Pulse width ±10%	**50, 70, 100, 140, 200, 280, 400µs**
Repetition rate	**1 Hz**
Maximum charge	**20µC** per pulse
Net charge output	**Less than 0.1 µC per cycle.** Charge balance is provided by return pulses of low amplitude and same the same total charge as the stimulation pulse
Output coupling	**Ceramic capacitor**
Operating time	**24 hour duration** (maximum 30 hours)
Mode of Operation	The devices are suitable for continuous operation
Indicator display	**Green LED**, flashing to indicate operation and the setting level (pulse width): the number of flashes in the sequence
fault indication	The stimulator device will automatically switch off for over current, under current, low battery voltage or end of operating time



Output voltages and currents: measured at internal outputs of the pulse generator (±15%)

firefly® T-2

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

firefly®

Indicator display **green LED**, flashing
fault indication: the stimulator device will **automatically switch** 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/A1:2013, EN 60601-2-10:2015/AMD1:2016, EN 60601-1-11:2015, EN 60601-1-2:2015, ISO 10993-1:2018

Operating conditions:

Temperature range	10°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.

Storage & transport conditions in original packaging:

Store the device in its protective foil pouch. The storage and temperature range is -25°C to 40°C, though the device will still operate after exposure to 70°C for short durations (up to 2 weeks in total). As it is difficult to monitor storage and transportation temperature, we recommend to store the device at room temperature (up to 30°C), if at all possible.

Temperature range	-25°C to 40°C (up 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-2	Up to 30 hours of operational life in continuous use

Materials:

firefly® T-2 Polyethylene terephthalate (Mylar), polypropylene, polyether ester, hydrogel

Packaging:

Item	**Description**	**Mass of packaging material per device**
		firefly T-2
Primary Packaging 110 x 250mm	Foil laminate pouch - Polyester - Aluminium - Polyethylene	 0.47g 0.67g 1.33g
Secondary Packaging	Cardboard or Wallet	5.4g 11.4g (pack of 5) 18.9g (pack of 3)

Adverse reactions

Skin Inflammation or Irritation

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

Warnings

If you are in the care of a physician, consult with your physician before using this device.

- Do not apply stimulation over your neck because this could cause severe muscle spasms resulting in closure of your airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
- Do not apply stimulation across your chest because the introduction of electrical current into the chest may cause rhythm disturbances to your heart, which could be lethal.
- Do not apply stimulation over painful areas. If you have painful areas, you should consult with your physician before using this device.
- Do not apply stimulation over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins).
- Do not apply stimulation over, or in proximity to, cancerous lesions.
- The firefly® T-2 device is not compatible for use with an MRI scanner. Remove the device if you need to undergo an MRI.
- Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use.
- The firefly® T-2 device must be kept dry. Do not use the firefly® T-2 device in a humid atmosphere (e.g., sauna, hydrotherapy) or while in the bath or shower.
- Do not apply stimulation while driving, operating machinery, or during any activity in which electrical stimulation can put you at risk of injury.
- Do not use the device on children, it has not been evaluated for pediatric use.
- Apply stimulation only to normal, intact, clean, healthy skin.

Precautions

The long-term effects of electrical stimulation are unknown.

- Since the effects of stimulation of the brain are unknown, stimulation should not be applied across your head, and electrodes should not be placed on your head.
- The safety of electrical stimulation during pregnancy has not been established.
- You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).
- Consult your physician before using the firefly® T-2 device if any of the following apply to you:
    - You are pregnant
    - You have a suspected or diagnosed heart disease
    - You have suspected or diagnosed epilepsy
    - You have a tendency to haemorrhage (bleed internally) after an injury or fracture
    - You have had a recent surgical procedure as muscle contractions may disrupt the healing process
- Follow any other precautions recommended by your physician.
- Use caution if stimulation is applied over areas of skin that lack normal sensation.
- Keep this device out of the reach of children.
- Use this device only with the leads, electrodes, and accessories recommended by the manufacturer.
- Use of this device adjacent to other electrical equipment should be avoided because it could result in improper operation. If such use is necessary, this device and the other electrical equipment should be observed to verify that they are operating normally
- The firefly® T-2 device has no replaceable or serviceable parts and requires no user maintenance. The unit must not be disassembled.
- Do not share the firefly® T-2 device with others. Everyone should have their own device to avoid any possibility of contamination that could result in skin reactions.

- Do not use the firefly® T-2 device if the device or its packaging show visible signs of damage. Visit www.fireflyrecovery.com for further advice and usage on the firefly® devices.

Identification

The 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

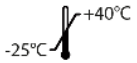
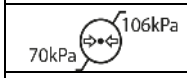
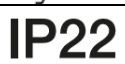
The device has an Ingress Protection (IP) rating of IP22. See the symbols section below for further explanation.

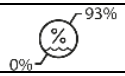
Electro-Magnetic Compatibility (EMC)

The devices have been tested to current safety standards for emission of, and immunity from electro-magnetic radiation, and found to comply. See EMC Declaration below, for full details.

The devices have been tested to current safety standards for immunity from Electrostatic Discharge (ESD). In some circumstances a device may turn off when subject to ESD: however, the device will be undamaged and will operate normally once switched back on.

Symbols

	Type BF applied part
	Product not manufactured with Latex
	Single use only – use only on one user for a single course of treatment
	Storage and transportation atmospheric pressure range whilst within packaging
	Lot number
	Catalogue number
	Expiry date – do not use after this date
	Storage and transportation pressure range whilst within packaging
	Ingress protection rating 22

	EU Authorised Representative
	CH Authorised Representative
	Storage and transportation humidity range whilst within packaging
	Manufactured by
	See Instructions for Use
	UKCA Mark of Conformity
	CE Mark of Conformity
	Do not use if package is damaged
	Importer
	Medical Device
	GTIN number
	MR unsafe
	Visit the website for further information

Declaration of Conformity – Electromagnetic Compatibility

Guidance and manufacturer's declaration – electromagnetic emissions		
The geko and firefly devices are intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment		
Emissions test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	The devuces 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 devices are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes. The devices are internally powered by a lithium coin cell CR2032
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The geko and firefly are intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment			
Immunity test	**IEC60601-1-2 test level**	**Compliance level**	**Electromagnetic environment-guidance**
Electrostatic discharge IEC 61000-4-2	±8 kV contact ±2, 4, 8, 15 kV air	Not applicable ±2, 4, 8, 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. The device may turn-off following Electrostatic discharge, however the device will be undamaged and will operate normally after re-starting
Electrical fast transient/burst IEC 61000-4-2	±2 kV for power supply lines ±1 kV for input / output lines	Not applicable	Not applicable as internally powered device
Surge IEC61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable	Not applicable as internally powered device
Voltage dips, short interruptions and voltage variations on power supply lines IEC6100-4-11	<5% U_T (>95%dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	Not applicable	Not applicable as internally powered device
Conducted immunity		Not applicable	No mains cable or external connections
Power frequency (50/60Hz) Magnetic field IEC61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

Note U_T is the a.c. mains voltage prior to the application of the test level

Guidance and manufacturer's declaration – electromagnetic immunity			
The geko and firefly are intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment			
Immunity test	**IEC60601-1-2 test level**	**Compliance level**	**Electromagnetic environment-guidance**
			Portable and mobile RF communications equipment should be no closer to any part of the devices, Including cables, than the recommended distances calculated from the equation applicable to the frequency of the transmitter Recommended separation distance
Conductive RF IEC61000-4-6	3 V rms: 150kHz to 80MHz	3 V rms	$d=1.2\sqrt{P}$
Radiated RF IEC61000-4-3	10 V/m: 80MHz to 2,5GHz	10 V/m	$d=1.2\sqrt{P}$ 80MHz to 800MHz $d=2.3\sqrt{P}$ 800MHz to 2.5GHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres(m). Field strengths from fixed RF transmitters, as determined by an electromagnetic survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1 At 80MHz and 800MHz 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 strengths from fixed transmitted, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment in the location 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 devices should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the devices. [b] Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.			

Recommended separation distances between portable and mobile communication equipment and the geko and firefly devices

The geko and firefly are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the devices as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter (m)		
	150kHz to 80MHz $d=1.2\sqrt{P}$	80MHz to 800MHz $d=1.2\sqrt{P}$	800MHz to 2.5GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1.0	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitter 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 of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1. At 80MHz and 800MHz 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.

Test specification for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment						
Test frequency (MHz)	**Band** [a] (MHz)	**Service** [a]	**Modulation** [b]	**Maximum power** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)
385	380 - 390	TETRA 400	Pulse modulation [b] 18Hz	1,8	0,3	27
450	430 - 470	SMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
870						
930						
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1 845						
1 970						
2 450	1 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5 500						
5 785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.