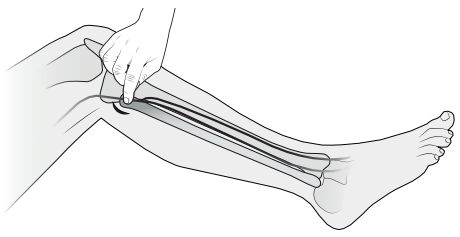
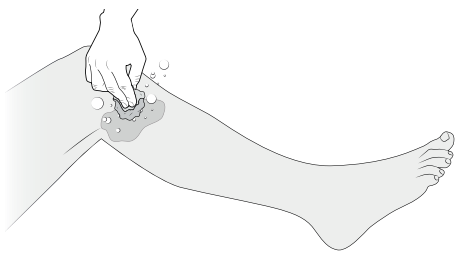
firefly™ T-2

fireflyrecovery.com

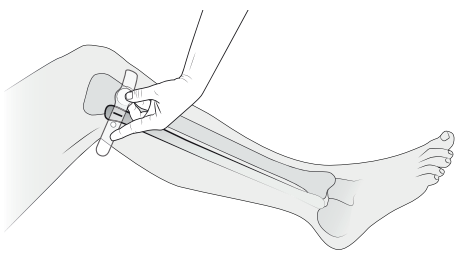
❶ **Location:**



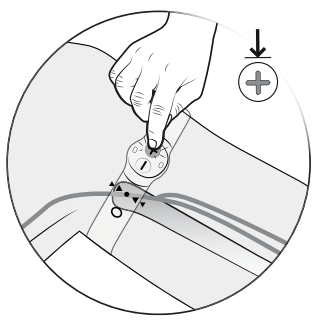
❷ **Cleaning:**



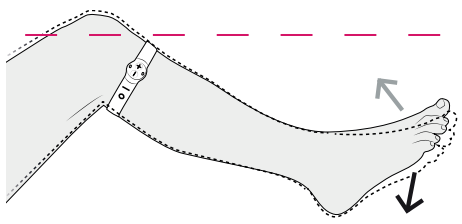
❸ **Fitting:**



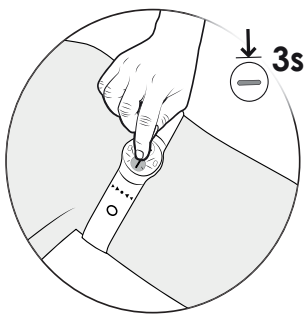
❹ **Turning On:**



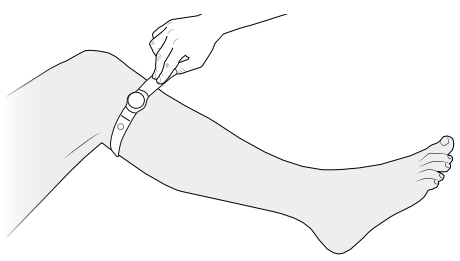
❺ **Settings:**



❻ **Switching Off:**



❼ **Removing:**



⚠ **Attention: Be sure to read and understand these Instructions for Use before applying the firefly™ T-2 device**

firstkind living science OnPulse™ TECHNOLOGY T-2

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INSTSKY10C/R1 - June 2020

▸ Instructions for use / user manual

The firefly™ T-2 device is a small disposable, internally powered, neuromuscular stimulation device for muscle conditioning. It is an integrated device and there are no additional cables or electrodes required for its operation. Familiarize yourself with the components before you use the device.

▸ Indications for use

The firefly™ T-2 device is intended for the stimulation of healthy muscles in order to improve or facilitate muscle performance. The firefly™ T-2 device is not intended to be used in conjunction with therapy or treatment of diseases or medical conditions of any kind.

▸ Fitting instructions

❶ The marker line ▸▸●◂◂ on the firefly™ device should line up with the fibula head, a round lump below the knee on the outside of the lower leg. If you are unsure how to locate the fibula head or the common peroneal nerve, see www.fireflyrecovery.com for further advice.

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 firefly™ 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 firefly™ 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 7 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 firefly™ 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.

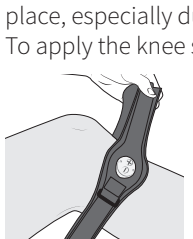
❻ To turn it off, hold ⊖ button down for 3 seconds. When the button is held, the light will flash quickly and when turned off the flashing will stop.

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

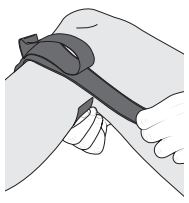
If stimulation is not achieved the firefly™ device can also be fitted in alternative positions, see the website for further details. If additional adhesion is required, Firstkind recommends the use of a firely knee strap (purchased separately) to ensure that the device remains in place on the leg. See the instructions below for fitting the knee strap.

The firefly™ device will run for 30 hours total, but the use time can be allocated over multiple uses rather than continuous use, if desired.

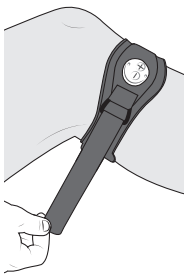
The use of the firefly™ T-2 knee strap is optional, but will help the device to stay in place, especially during physical activity. To apply the knee strap:



a) Place the strap over the device with the strap buckle positioned at the side of the leg and the firefly T-2 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.

The firefly™ T-2 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 firefly™ T-2 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.

▸ Contraindications

Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.

▸ 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.
- 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.
- 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 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.

▸ Adverse reactions

Some users may experience skin irritation or hypersensitivity due to the adhesion material, electrical stimulation or electrical conductive medium. If this happens, you can try reducing the irritation by using an alternate electrode placement, see fireflyrecovery.com for further details. If the skin irritation is significant, switch off the device, remove, and discontinue use. If the skin irritation persists you should consult with your doctor.

▸ Reporting of any side effects or adverse reactions

Any side effects or adverse reactions due to use of the firefly™ T-2 device should be reported to Firstkind Limited by dialling 011 44 1494 572040 or log-on at http://www.fireflyrecovery.com/contact-us. Discontinue use of the firefly™ T-2 device until further investigations have been carried out.

▸ About the firefly™ T-2 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, both of which are important for recovery after intensive exercise. 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. The muscle contractions can be the result of physical activities, but can also be elicited by external electrical stimulation.

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 firefly™ T-2 device works:

The firefly™ T-2 device is a small disposable, internally powered, neuromuscular stimulation device for muscle conditioning. Specifically, the firefly™ T-2 device is intended to be used following intense exercise to facilitate muscle recovery. It is self-adhesive and is applied to the outside of the knee, wrapping around towards the back of the knee. This positioning enables the firefly™ T-2 device electrodes to apply a stimulus to the common peroneal nerve, which runs down the back of the knee and down the side of the lower leg, causing mild contraction of the calf and foot muscles without affecting mobility or other normal movements of the lower leg. Contraction of the calf muscles will boost blood flow from the lower limbs back to the heart, thus increasing venous return and local blood circulation. The increased blood flow resulting from use of the firefly™ T-2 device has been shown to improve recovery from muscle soreness in the lower legs following intense exercise. The firefly™ T-2 device has seven stimulation levels. It is fully insulated by the protective moulding and there is no risk of electric shock.

The user experience

The application of the firefly™ T-2 device is very simple and you will only experience a cooling effect as the area of skin, to which the device will be applied, is cleaned. Thereafter, you will feel as if a small adhesive patch has been applied to the skin.

Upon switching on the firefly™ T-2 device and selecting the appropriate stimulation level (see fitting and operating instructions above), you will be aware of the muscle contraction, but this awareness usually recedes slightly after a few minutes as you become used to the feeling. This is called “accommodation”.

For optimal results, you should apply the firefly™ T-2 device within 1 hour after exercise, and wear the firefly™ T-2 device for as long as possible, but not more than 24 hours continuously. You should be able to carry out your normal routine while wearing the firefly™ T-2 device, including sleep. Be sure to remove the firefly™ T-2 device if you need to shower or bathe.

▸ Help

If you require any help with the use of the firefly™ T-2 device, contact Firstkind Limited by dialling 011 44 1494 572040 or log-on at http://www.fireflyrecovery.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.

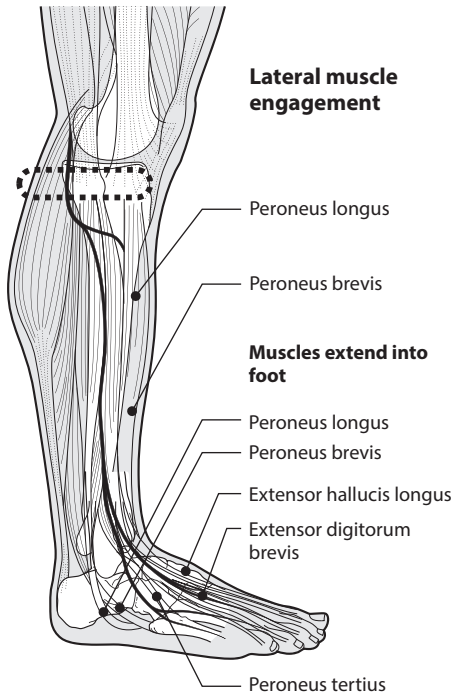
Type BF applied part – for direct electrical contact to patient but not direct cardiac application. The whole device is the applied part.

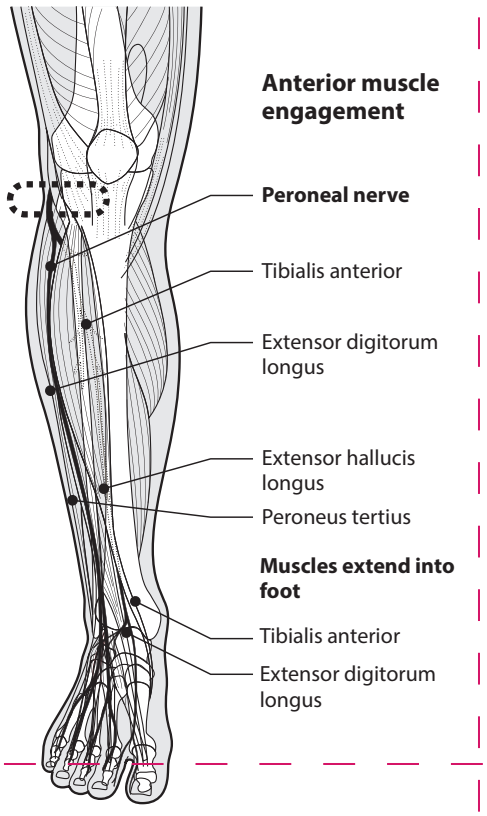
▸ Disposal of the firefly™ T-2 device

The firefly™ T-2 device is not reusable after its 24 hour operating period. The used device should be disposed of safely. The firefly™ T-2 device is powered by a lithium coin battery located inside the protective moulding. Do not remove the battery from the firefly™ T-2 device. Dispose of the entire device after use in the normal, municipal waste or follow local or State procedures for battery disposal, if applicable.
DO NOT INCINERATE.

▸Specifications

Product name	firefly™ T-2
Model reference	T-2
Product type	Powered muscle stimulator
Class	BF
Dimensions	186mm x 31mm x 11mm
Weight	10g (firefly™ T-2 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	7 (selectable pulse widths)
Pulse current	27mA (±15%), constant current, compliance to 80v
Load impedance	200Ω to 3kΩ for 27mA output pulse voltage set by current and load
Pulses width(200Ω to 10k Ω)	50, 70, 100, 140, 200, 280 & 400µs (±5% +20µs) (open circuit ±5% +70µs)
Repetition rate	1Hz (±5%)
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 (2007), ISO 10993
Operating conditions:	
Temperature range	10°C to 40°C
Humidity range	up to 93% non-condensing
Pressure range	70kPa to 106kPa
Storage conditions in original packaging:	
Temperature range	-25°C to 40°C (up to 70°C for short durations only)
Humidity range	Up to 93% non-condensing
Shelf-life	See expiry date on the pouch label
Transport conditions:	
Temperature range	-25°C to 40°C (up to 70°C for short durations only)
Humidity range	up to 93% non-condensing
Materials	**Electrode:** Hydrogel **Battery Casing:** Polypropylene **Strap:** PET (Mylar) polyethylene terephthalate
Use-life	Up to 30 hours of operational life





Output voltages and currents:

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

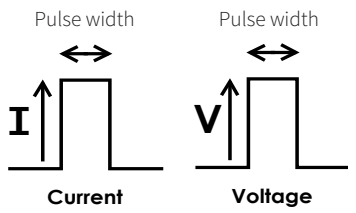
Pulse widths	half power setting 200µs		full power setting 400µs	
load	**current**	**voltage**	**current**	**voltage**
0,2 KΩ	27mA	5.4V	27mA	5.4V
0,5 KΩ	27mA	13.5V	27mA	13.5V
1 KΩ	27mA	27V	27mA	27V
2 KΩ	27mA	54V	27mA	54V
3 KΩ	27mA	81V	27mA	81V
O.P*	0mA	80V to 160V	0mA	80V to 160V

O.P*: Open circuit.

Current rms (500 Ω) 1mA rms maximum.

Voltage rms (500 Ω) 0.5V rms maximum.

Output waveform



Repetition rate: 1Hz

Explanation of the meaning of symbols

Type BF applied part , suitable for direct electrical contact to user but not for direct cardiac application

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 - the adjacent number is the lot number used for traceability

REF **Catalogue number**

Expiry date – do not use after this date

Transportation and storage temperature range - the device must be stored or transported at a temperature between the indicated range

IP22 IP: Ingress Protection IEC 529 -
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°

Storage and transportation humidity range

DI Device identifier

Manufactured by - the firefly™ T-2 device is manufactured by Firstkind Ltd, a wholly owned subsidary of Sky Medical Technology Ltd

Follow the Instructions for Use

Do not use if package is damaged

CE 1639 CE Mark of Conformity