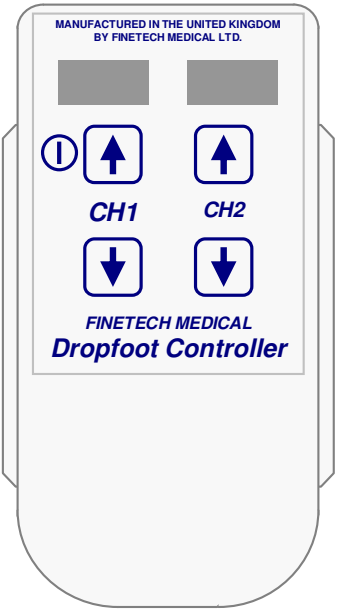
STIMuSTEP®
Implanted Dropfoot Controller

DFC-2 User Guide



August 2009

This guide MUST be read and understood by all relevant persons prior to using the STIMuSTEP® system.

Need help?

If you need advice about any aspect of your STIMuSTEP® system please:

- email us at info@finetech-medical.co.uk
- contact us or your distributor via our website www.finetech-medical.co.uk
- telephone us on +44 (0)1707 330942

Key to Symbols used in this *User Guide*

Contra-indications
These notes describe situations where you should not use your STIMuSTEP®

Warnings and Cautions
Make sure that you understand these notes before using you STIMuSTEP®

Important Note
This symbol appear next to points to remember about your STIMuSTEP®

The STIMuSTEP® system has been manufactured in the United Kingdom since 2004 by:

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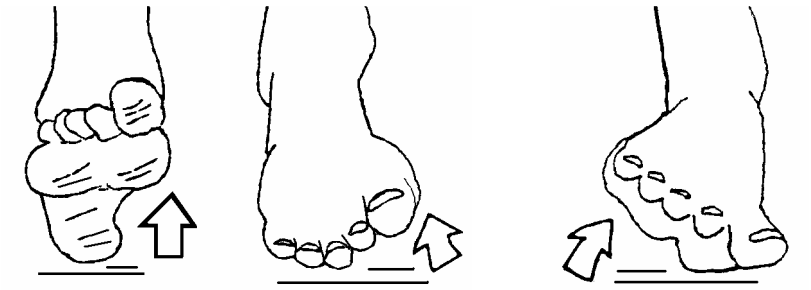
1 Introduction

This *User Guide* provides information for the safe use of your STIMuSTEP®*;* for you, your family, your caregivers and your doctor/surgeon/clinician.

2 How does the STIMuSTEP® Work?

The STIMuSTEP® system is intended for the correction of dropped foot in chronic stroke patients. The implant has two stimulation channels, which are used to stimulate two branches of the common peroneal nerve.

- Channel-1 stimulates the deep branch, which controls muscles that produce dorsiflexion and some inversion.
- While Channel-2 stimulates the superficial branch, which controls muscles that produce eversion of the foot.

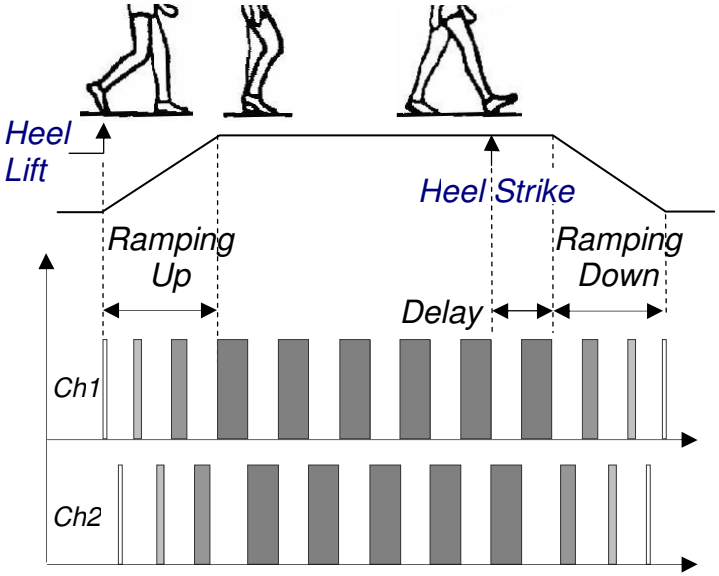


Dorsiflexion Inversion Eversion

Channel-1 **Channel-2**

By controlling the relative proportion of the stimulation to the two nerves, the correct movement of dorsiflexion with about 5 degrees of eversion can be reliably and repeatably produced.

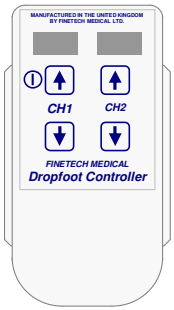
The control signals for stimulation are transmitted through the skin using radio telemetry from a *Controller* worn externally over the implant, held in place by an elastic strap.



The *Controller* is activated from a *Footswitch* placed in the users' shoe. Stimulation begins when the heel is lifted off the ground. Stimulation is ended when the heel strikes the ground.

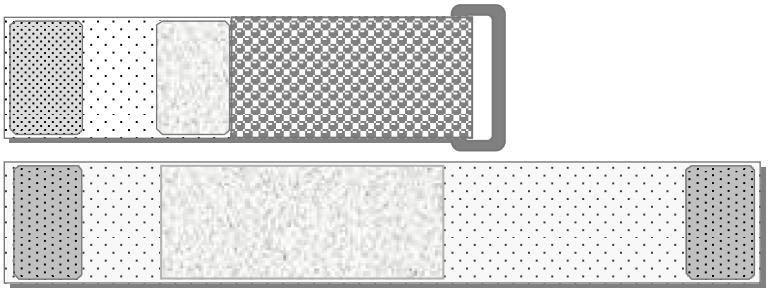
Experience with the device to date indicates that the device is well accepted by the users and that walking speed is increased with a reduction of effort of walking.

3 Components of the System

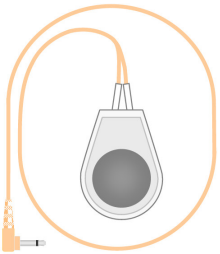


The *Controller* is the source of the power and signals that are transmitted to the *Implanted Receiver* through the skin by radio frequency inductive coupling. It is housed in a small plastic box with an integral rechargeable battery.

The *Leg-Strap* is used to hold the *Controller* in position on the affected leg and is designed for easy fitting and removal. The two parts of the *Leg-Strap* are held together with Velcro.



The *Footswitch* is used to detect heel-strike and heel-lift that triggers stimulation from the *Controller*. See Section 4.1 for fitting instruction.



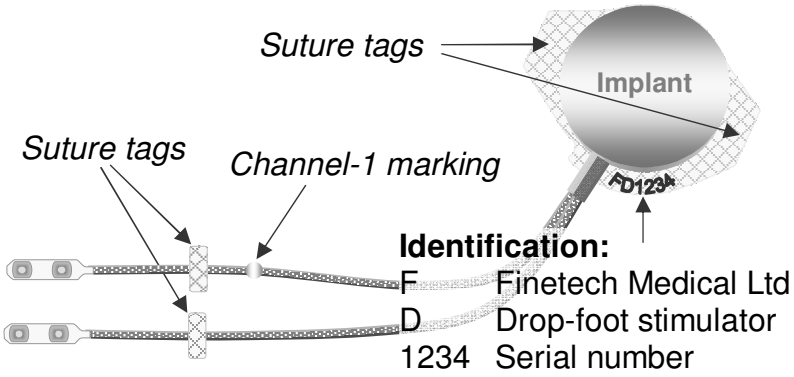
The *Footswitch's* lifetime will vary depending on use and the user. *Footswitches* are a consumable item and will require replacing periodically.

The Battery Charger is used to recharge the *Controller* from the mains outlet (wall socket). The *Controller* cannot be used for stimulating during recharging.

UK charger FD039

Euro charger FD040

The *Implanted Receiver* is typically implanted by your surgeon under the skin on the side of the leg just below the knee. It receives electrical signals from the external *Controller* and sending these to the nerves that lift and straighten the foot.

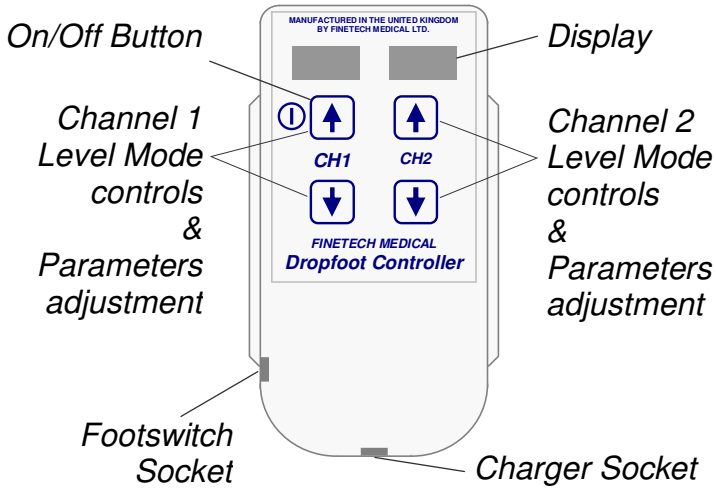


Identification:

F	Finetech Medical Ltd
D	Drop-foot stimulator
1234	Serial number

4 Using the STIMuSTEP®

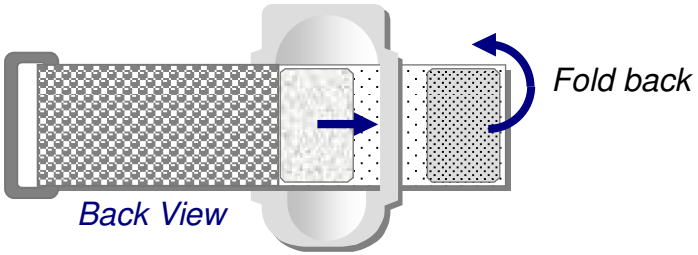
Before using your *Controller*, it must be set up by your clinician.



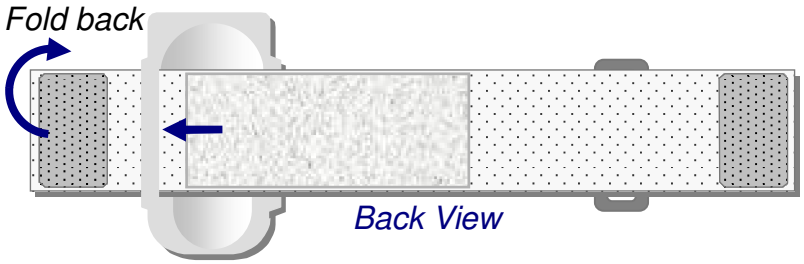
4.1 How to fit the *Leg-Strap*

Please follow the fitting instructions below for the correct fitting procedures to avoid damage to the system.

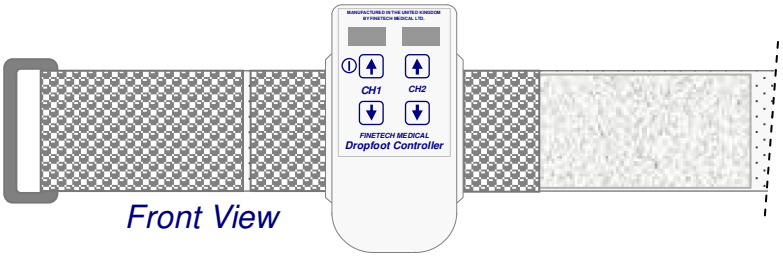
Step 1: Take the short strap with the buckle and feed through the slot on the right hand side for left foot use (or the slot on the left hand side for right foot use) as shown and fold back the strap so that the Velcro locks together.



Step 2: Take the long strap and feed through the slot on the left hand side for left foot use (or the slot on the right hand side for right foot use) as shown and fold back the strap so that the Velcro locks together.



Step 3: The ready to wear *Controller* is shown below.



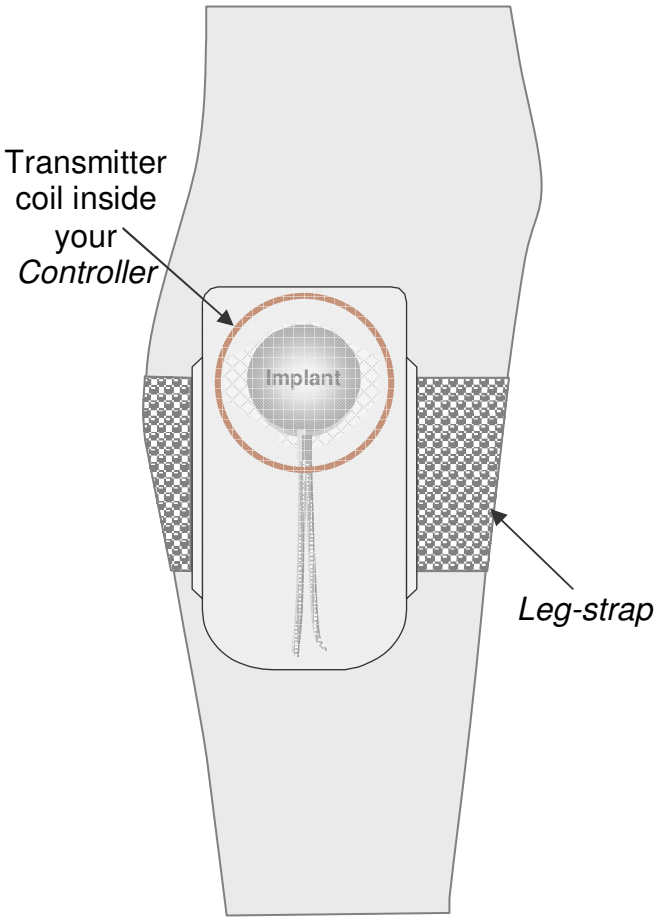
Strapping the *Controller* onto the Leg

In order for the implant to receive correct stimulation, the *Controller* must be strapped in place directly over the implant site. The implant site is, typically, on the side of the affected leg. To aid this placement the rear of the *Controller* has a curved interface with a circular indent that is in-line with the internal transmitting coil. The implant can be located by palpating the skin.

- Place the *Controller* over the implant site and positioning so that the implant is in the centre of the transmitter coil as shown.

- Bring the strap around the leg, feed it through the buckle and bring it back on itself.

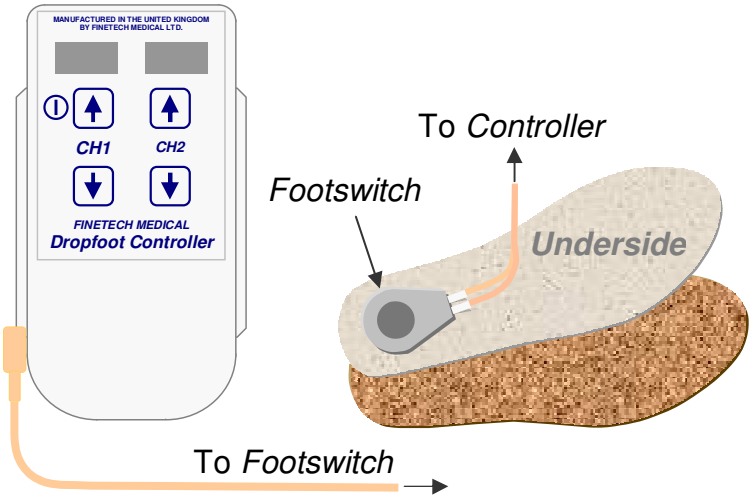
- The strap should be tight enough to hold the box in place but not so tight that blood circulation is effected.



4.2 How to fit the *Footswitch*

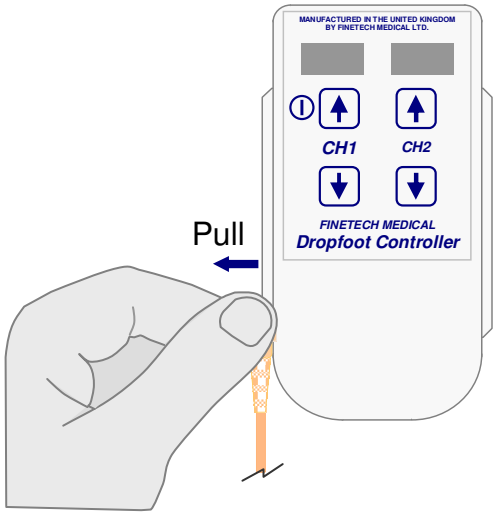
The *Footswitch* should be mounted on the underside of a shoe insole. This allows the *Footswitch* to be moved from shoe to shoe and minimises *Footswitch* wear.

- Peel the waxed paper backing off the double-sided tape on the *Footswitch* to expose the adhesive.
- Place the *Footswitch* on the underside of a shoe insole, in a position so that it is directly in the centre of the heel.
- Place the insole in shoe of the affected leg.
- Hold the *Controller* firmly and gently push the right angle plug into the socket until you here a click.



Disconnect the *Footswitch* from the *Controller*

- Hold the *Controller* and the right angle plug firmly.
- Pull right angle plug side-ways as shown to avoid damage to the socket.



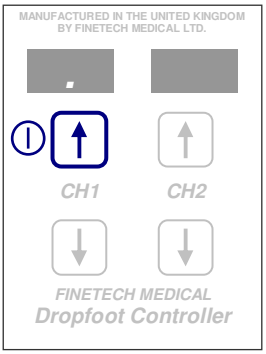
Warning

- *Do not pull on the cable.*
- *Do not hang the Controller on the cable*
- *Do no wrap cable around the Controller*
- *Do not tie knots in the cable*
- *Do not plug any other connector into the Controller other than the Footswitch connector.*

4.3 Walking with the STIMuSTEP®

NORMAL MODE

Your STIMuSTEP® is ready when the *Controller* and the *Footswitch* are correctly fitted and are connected together. All you need to do is *Switch On* the *Controller* and start walking. Stimulation will start after a heel-lift and stop after a heel-strike or default timeout of 3 seconds.



Switch On by pressing and holding the ***On/Off*** button for about **1 second**. The battery state will be displayed briefly as either **'good'** or **'Lo'**, and then the display shows a dot in the left display window. When stimulation starts, the dot moves to the right display window.

When the stimulation period ends, the display dot returns to the left display window again.

Warning
Do not press this button repeatedly as it could cause the microprocessor to lock up.

Switch Off by pressing and releasing the ***On/Off*** button. If the *Controller* is not being used it will automatically switch off; the default switch off time is normally set at 60 minutes.

You could enter *Parameter Mode* by accident if you hold the ***On/Off*** button for 4 seconds. If this happens, exit immediately (see *Parameter Mode* below).

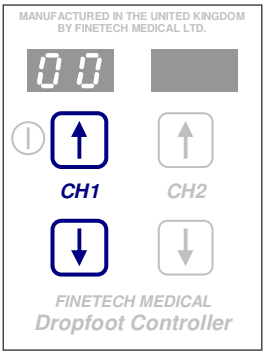
4.4 Advance Settings

LEVEL MODE

This mode is used to set the stimulation *Pulse Width* (pulse duration) of the two output channels, independently. The pulse duration will be determined by your clinician and set up to suit your needs. Some users may wish to access this mode to increase the level if they experience muscle fatigue or increased calf tone when they use the device for walking. Also, it is common for calf tone to increase when standing due to postural support reflexes and stretching of the calf muscles. A greater output may then be required from the stimulator to produce the desired movement.

Level mode is accessible only when the *Controller* is switched off. In this mode, stimulation output is active and continuous. The pulse duration of each channel will be shown on the corresponding displays as a number between ***00*** and ***85***.

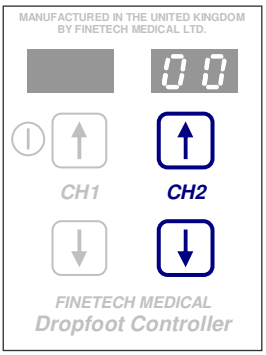
Channel-1: This channel produces *dorsiflexion and inversion* that lifts the foot.



Enter *Level Mode* of *Channel 1* by pressing the two buttons on the left hand side of the *Controller* together simultaneously. The level will be shown on the corresponding displays. Use these ***Up*** and ***Down*** buttons to increase or decrease the value. Any changes in level are immediately reflected in the output.

Switch off Chanel-1 by pressing these two buttons together again and the value is set.

Channel-2: This channel produces *plantarflexion and eversion* that straightens the foot.



Enter *Level Mode* of *Channel 2* by pressing the two buttons on the right hand side of the *Controller* together simultaneously. The level will be shown on the corresponding displays**.** Use these ***Up*** and ***Down*** buttons to increase or decrease the value. Any changes in level are immediately reflected in the output.

Switch off Channel-2 by pressing these two buttons together again and the value is set.

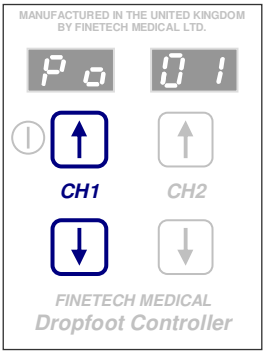
Both channels may be turned on at the same time to assess the combined effect. When both channels are off (blank display) then the *Controller* is off. The settings in this mode are stored in the memory and used during *Normal Mode*.

Note that the setting will not be stored in the memory if the *Controller* switches off automatically by the time-out function.

IMPORTANT: *Ask your clinician for a copy of the settings and understand how to set it back after you have made changes to the stimulation levels.*

PARAMETER MODE

This mode is used to set the parameters for stimulation and should not be adjusted by the user. Any adjustment in this mode should be made by your clinician. The parameters are stored in the memory and any changes are automatically saved on exit from this mode.



The first parameter display is the power level; either 01 or 02.

If this mode is entered by mistake, it should immediately be exited by pressing the left hand ***Up*** and ***Down*** buttons together simultaneously

4.5 Charging the Battery

Knowing the State of Charge

The state of charge is shown at switch on, briefly showing '***good***' or '***Lo***'. If the display shows '***Lo***' then the unit will switch off after 5 seconds; you will not be able to use your stimulator until you have recharged your battery.

During normal use, if your *Controller's* battery becomes low (the display will show '***Lo***'). At the first opportunity in which rest of more than 1 minute is detected, the *Controller* will shut down. If walking is continued more than 20 minutes after detecting low battery, the *Controller* will shut down following the last stimulation period. If this happens you will not be able to use your stimulator until you have recharged your battery.

When to Charge

The battery may be re-charged at any time, however it will not be charged if it is 95% full or higher. A fully charged battery will last up to 40 hours in continuous use at maximum settings. For most users, a fully charged battery will last in excess of one week. Therefore, re-charging the battery everyday is not necessary.

It is recommended that the Controller be recharged after the 2nd or 3rd day of use. Following this charging routine will prolong the life of the battery.

How to Charge

The internal battery should only be used under the following conditions:

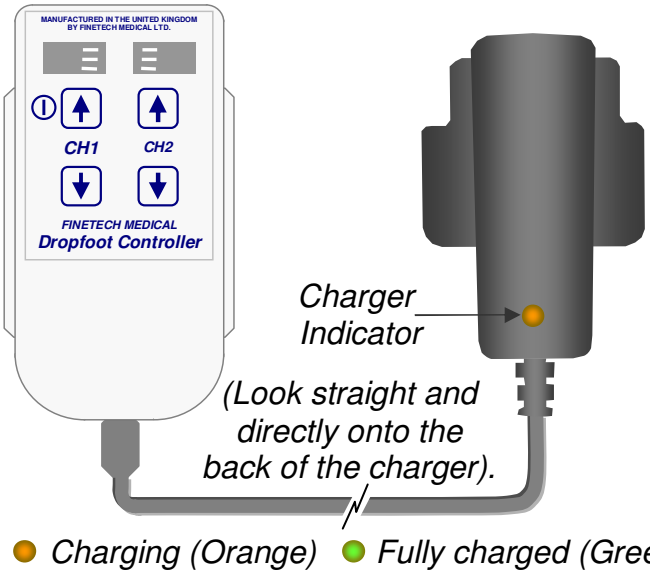
Normal use	**-10°C to +55°C**
Charging	**0°C to +45°C**

- Remove the *Controller* from the leg.
- Unplug the *Footswitch* from the *Controller*.
- Plug the *Battery Charger* into the socket on the bottom side of the *Controller*
- Plug the *Battery Charger* into a mains outlet.

Warning

Never *attempt to use any Battery Charger other than the one supplied with the stimulator. Using the wrong charger could damage the battery, which may cause leakage and subsequent damage to the device.*

Warning
DO NOT attempt to charge the Controller whilst it is attached to your leg.



Charging (Orange) *Fully charged (Green)*

It is normal for the *Battery Charger* indicator to show a bright orange/red colour during charging if looking from high above. This is affected by the viewing angle but not a fault.

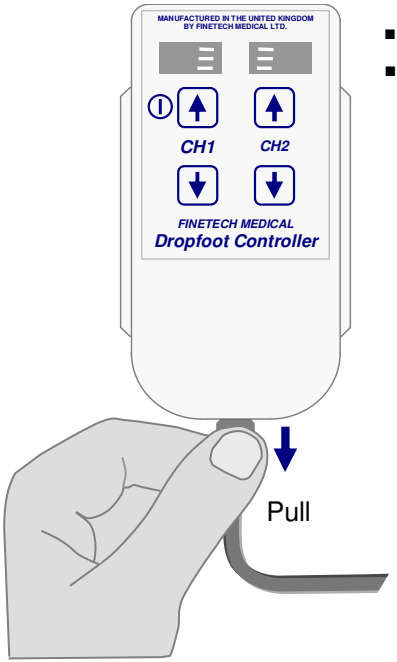
Whilst charging is taking place, the display will show a horizontally scrolling bar-graph. The *Battery Charger* also shows an ***Orange*** light, which indicates the battery is being charged and changes to **G*reen*** when fully charged or trickle charging.

If the *Battery Charger* is plugged into the *Controller* with a fully charged battery, the display briefly shows a

horizontally scrolling bar-graph and a **G*reen*** light on the charger.

A fully discharged battery will take approximately 2 hours to re-charge; a partially discharged battery will take less than 2 hours to re-charge. It is normal for the charger to get warm, to prevent overheating ensure that it is not covered. The battery cannot be overcharged. However, the *Controller* should be disconnected from the charger when fully charged to help prolong the life of the battery.

Disconnect the *Battery Charger*



- Hold the *Controller* firmly.
- Pull the *Battery Charger* connector straight out.

Warning
Do not rock the connector side to side that could cause damaged to the connector.

5 Care and Maintenance

Care of the Leads

The *Footswitch* or *Battery Charger* lead can be damaged internally by rough handling. Never kink it or wrap it tightly around the *Controller*. When unplugging, always pull the connector not the lead.

Repair and Maintenance

Do not open the *Controller*. It contains no user serviceable parts. Inappropriate repair could result in the device failing to function. The device should always be returned to Finetech Medical or distributor for any repair or maintenance work.

Battery Replacement

The battery is a special unit, which must only be changed by authorised personnel. The batteries, within the *Controller*, should give several years of use; the lifetime actually obtained will depend on the exact charging routine (see Section 4.5 for more information). The approaching end of battery life is signalled by the need to charge more frequently than previously. Return the whole *Controller* to Finetech Medical or your local distributor to have a new battery fitted.

Old batteries need to be disposed of in accordance with local regulations (e.g. recycling) and should not be disposed of as household waste.

Caution

The battery used in this device may present a fire or chemical burn hazard if mistreated. Do not disassemble or heat above 100°C (212°F) or incinerate.

Disposal of Equipment

It is recommended that any external equipment that is not required should be returned to Finetech Medical.

Storage and Transportation Instructions

Like any electronic equipment, the Controller should not be exposed to excessive temperatures. Do not leave it on a radiator or in a car in direct sunshine, even in the glove compartment. Although the *Controller* is designed to withstand minor knocks, it can be damaged by being dropped from a height or subjected to severe impact. If in doubt, return it to Finetech Medical or distributor for testing and repair.

The equipment should be transported and stored within the following limits of environmental temperature, humidity and atmospheric pressure.

Temperature	**-10℃ to + 55℃**
Humidity	**0 to 90%**
Pressure	**70 kPa to 150 kPa**

Cleaning

All parts of the *Controller* system can be cleaned by wiping with a soft cloth slightly moistened with clean water and a little mild detergent.

Caution

Do not submerge the device in liquid. Do not use solvents or abrasives. Never allow the Battery Charger to get wet.

Drying

If the *Controller* is accidentally dropped in water it should be carefully dried before using again. Wipe all parts with a dry cloth or tissue then allow to air-dry for at least eight hours. Check that the plugs and sockets are dry before reconnecting the foot switch or the charger. Do not use heat or hot air such as a hair dryer, as this may damage the *Controller*.

6 Troubleshooting

No Stimulation: If the *Controller* fails to work, the most likely causes are that the foot switch is not connected correctly or the *Controller* is not charged. Check that the *Footswitch* is plugged in and the connector is pushed firmly home. Another possibility is that the foot switch is damaged. Try replacing the foot switch with a new one. Check also that the *Controller* has been charged correctly. If the fault persists after you have checked the charging, connections and replaced the foot switch, you will need to return the *Controller* and charger to the manufacturer or agent for repair or replacement.

The following fault finding guide should be followed.

- First check that the transmitter is in the correct position on the leg and is turned on. Check that the battery level is '**good**'.

- Press the foot switch between finger and thumb. Observe any response from the muscles and also check that the green dot moves between the 2 windows of the display.

- If the green dot does not move, try a spare foot switch.

- Sometimes the foot switch may work when pressed between fingers and thumb but not work correctly when in the shoe. This may be because it is incorrectly positioned. Some users may only place a small amount of weight through the switch. If this is the case the position of the switch can be moved to an area under the foot where loading is more reliable. Sometimes, as foot switches age, their sensitivity reduces. It is then necessary to replace the switch.

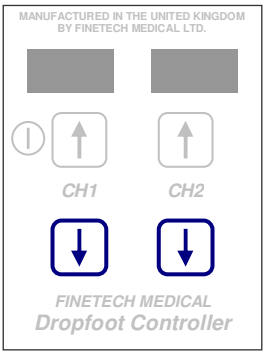
- If the green dot does move but there is no movement of the muscles then the Parameters of the *Controller* may need adjustment. Obtain advice from your treatment centre or clinician before attempting to make any change.

- If you still cannot obtain a response then it is probably due to a fault in the equipment. If you have a spare transmitter then it could now be tried.

- Any equipment requiring repair must be returned to Finetech Medical or distributor.

- The external equipment should be returned to Finetech Medical for testing before any assumption is made that the implant is faulty.

The Controller Will Not Turn On: If the *Controller* does not response to the ***On/Off*** button, the electronics may need to be reset.



Resetting the *Controller*

This is achieved by pressing the two lower buttons together for 3 seconds to reset the *Controller*. Now turn on the *Controller* using the ***On/Off*** button.

If still no response after resetting the *Controller* then it could be that the battery has gone flat. Try to recharge the *Controller* (see Section 4.5). If it fails to charge, see "The Controller Will Not Charge" before returning the equipment to the supplier.

The *Controller* Will Not Charge: No scrolling bar-graph is shown when connected to the charger:-

- If the charger is plugged into the *Controller* with a fully charged battery, the display briefly shows a horizontally scrolling bar-graph and a stable ***Green*** light on the charger indicator. The *Controller* does not require charging. Remove the charger from the *Controller*.

- If the charger unit shows a stable ***Green*** LED, this indicates that the battery is full and the *Controller* is likely being locked-up. Reset the *Controller* by pressing the two lower buttons together for 3 seconds.

- If the charger indicator is flickering between ***Green*** and ***Orange*** when the charger is being connected to the *Controller*, this indicates that the charger could not

sense the battery. It is likely that the internal fuse of the *Controller* has blown or there is a broken lead. Return the *Controller* and *Battery Charger* to Finetech Medical or distributor for checking and repair.

The charger indicator should be looked at perpendicular (straight and direct) to the back of the charger for correct colouring.

7 Warranty Information

Finetech Medical Ltd. warrants the external components of the STIMuSTEP® free from defects in workmanship and materials for two years from the date of implantation.

Finetech Medical Ltd. will repair or replace, at its discretion, any product found to be defective within the warranty period.

This warranty does not apply to any product which has been damaged due to misuse, or that was repaired or altered other than by the manufacturer.

8 Information for Healthcare Professionals

This section contains important information for all healthcare professionals dealing with users who have a STIMuSTEP®. Please read it carefully when considering treatment options.

Implantation Certificate (FTM1032)

An Implantation Certificate is issued to the patient with every STIMuSTEP® and lists information regarding:

- The Patient

- Place of Implantation
- System Details
- Physician Remarks
- Contact Details

A list of precautions is given below. However this list cannot be exhaustive and the patient may need to request advice for un-foreseen situations.

M.R.I. Scanners: Mild stimulation may be caused by scanners which use a low radio frequency; these are generally older machines with weak magnetic flux density of 0.5 Tesla and below. Patients implanted with the STIMuSTEP® should not be scanned in such machines. Larger and more modern MRI machines use much higher frequencies and have flux densities of 1.0 Tesla or 1.5 Tesla (and higher) and are safe to use. The *Controller* should not be worn or used in the near vicinity of the scanner.

X-Ray Equipment: X-ray procedures do not affect the implant but the external components should not be exposed.

Ultrasound Equipment: Diagnostic ultrasound does not affect the implant. Therapeutic ultrasound should not be used as the device may inadvertently concentrate the energy and cause harm.

Therapeutic Ionizing Radiation: Therapeutic ionizing radiation may affect or damage the internal components of the device and this damage may not be immediately detectable.

Diathermy (Therapeutic and Cutting): Therapeutic diathermy (short wave and micro-wave), as used in some physiotherapy treatments, is contra-indicated as the implant may inadvertently concentrate the energy and cause harm. Cutting Diathermy is harmless to the patient and to the implant, provided the instrument does not make direct contact with the exposed metal of the stimulating electrodes.

Treatments that Pass an Electrical Current through the Body: Treatments such as (but not limited to) T.E.N.S. pain relief and evoked potential studies that pass an electrical current through the body may influence the device. Care should be taken to monitor for possible effect especially at the initial stage of treatment. The effect of external defibrillation is unknown.

Metal Detectors and Security Scanners: Finetech Medical has manufactured many implanted stimulators that operate in a similar way to the Dropped Foot Stimulator. There are no records of any influences from metal detectors or security scanners, nor should any be expected. Security staff may require that the external equipment be passed through an X-ray baggage scanner. No damage to the equipment is likely to occur.

E.C.G. / E.E.G. / E.M.G. Equipment: Perturbation of ECG / EEG / EMG tracings is to be expected if the external *Controller* is switched on in the neighbourhood of a patient with ECG / EEG / EMG electrodes in place. The ECG / EEG / EMG will return to normal after the external equipment is switched off.

Technical Specification

Parameters	*Specifications*
External Controller DFC-2	
Battery capacity	550mAh, 4.2V (max) Li-Polymer
Usage time	up 40 hours
Charging time	2 hours
Operating frequency	1MHz and 2MHz
Stimulation pulse width	0 - 255µs adjustable
Stimulation pulse rate	30Hz fixed
Idle Timer	0 – 60 minutes
Size	105 x 55 x 25mm
Weight	80 grams
Protection against water ingress.	IPX0 (not sealed)
Charger Unit FD039/ FD040	
Input	100-240Vac, 50-60Hz, 0.2A max
Output voltage	4.2 Volt DC
Load current	500mA (maximum)
Size	74 x 65 x 65mm
Weight	100 grams
Footswitch	
Overall dimensions	57mm x 43mm x 3mm Lead: 650mm, 2.5mm right angle plug

9 Important Information

This section contains important information regarding the safe use of the STIMuSTEP®. Please read it carefully.

If you need to go to the doctor, physiotherapist, dentist or other healthcare specialist for any kind of therapy or procedure, it is essential that you make him/her aware of your implant and that you refer them to the section; Information for Healthcare Professionals.

⚠ Warnings and Cautions

Healthcare Professionals

You MUST notify all healthcare professionals (including your dentist) that you have a STIMuSTEP® implanted and refer them to this manual BEFORE undergoing any surgical or therapeutic procedures.

Autonomic Dysreflexia

Use of the STIMuSTEP® system may trigger autonomic dysreflexia in users with spinal cord injury above T5/T6. Typical symptoms are sweating, pounding headache, tingling sensation on the face and neck, blotchy skin around the neck and goose bumps. If you experience any of these, stop using the system immediately and consult your doctor.

Epilepsy

Use of the STIMuSTEP® system is not advised for users with poorly controlled epilepsy. Stop use immediately and consult your doctor if you experience any epileptic symptoms.

Pregnancy
The safety of using the STIMuSTEP® during pregnancy or birth has not been established. Please consult your doctor.

Spasticity
Spasticity should be monitored, and if affected, use of the device should be stopped.

Damage from Liquids
Do not allow the external components, cables, and attachments of the STIMuSTEP® to come into contact with water as this may cause damage to the system. Please contact us or your distributor if you get the STIMuSTEP® wet.

Implant Care
Care should be taken not to put undue pressure on the *Implanted Receiver* and *Electrode Assembly*.

Important Note

Design Limitations
The STIMuSTEP® should not be used whilst driving, operating dangerous machinery or at any other time that inadvertent triggering could cause un-wanted movement. Switch the *Controller* off at these times.

Skin Condition
Check your skin daily for any signs of redness, swelling, or sores especially in the areas where the *Implanted*

Receiver is located. Call your doctor immediately if you notice any change in your skin condition.

Change in Health or Stimulation Effectiveness

It is important to stay healthy and to notify your doctor immediately if you become sick, get an infection, experience any unusual sensations or muscle contractions, or notice any change in how your STIMuSTEP® works.

Unintended Stimulation

It is important to notify your clinician if you experience unintended stimulation when your STIMuSTEP® is not in use. While there have been no reports of system activation or malfunction due to electromagnetic interference (such as from retail anti-theft detectors, airport metal detectors, or other electronic devices), even after testing, it is not possible to guarantee that this will not occur. If possible, note when and where the stimulation occurred and report this information to your clinician and Finetech Medical.

Flying with the STIMuSTEP®

As with all electronic equipment the *Controller* should not be used whilst the "Fasten Seatbelt" signs are illuminated. To avoid inadvertent triggering the *Controller* should be turned off at these times.

Electrical Interference

In general, the STIMuSTEP® should not be used in conjunction with other electrically powered devices. If it is suspected that it is causing interference with any other electrical device, then either move the *Controller* away from the device, or alternatively switch the device off for a

period of time if it is practical to do so. Portable and Mobile RF Telecommunication Equipment can affect Medical Electrical Equipment.

System Compatibility

The use of parts other than those specified in Section 3 may affect the system compatibility.

10 Graphic Symbols

Symbol	*Description*
	Attention – Please read the manual before using.
	Contra-indications.
	Important note.
	CE Mark and registration number of the Notified Body for Finetech Medical Ltd.
	Degree of protection against electric shock – Type BF Electrically Isolated (Floating) Applied Part.
	Not for disposal by municipal waste collection systems. Waste to be sorted and returned to manufacturer for recycling.
	The System includes an RF *Controller* that intentionally applies RF electromagnetic energy for treatment.
	The catalogue number of the unit.
	Serial number of the unit. FDnnnn
	Power button (On/Off)
	Parameter increase
	Parameter decrease

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