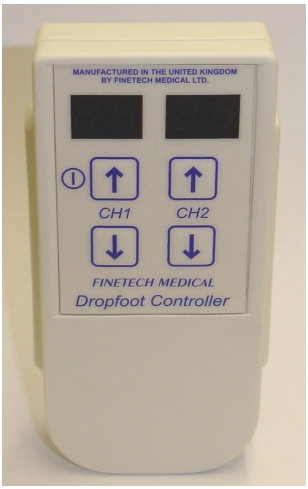
FINETECH MEDICAL LTD
ACTIVE SURGICAL IMPLANTS

The Finetech Medical STIMuSTEP® Implanted FES Dropfoot Controller

Guide for Clinicians



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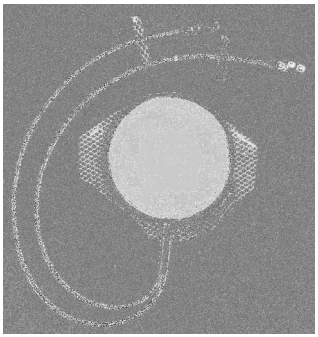
1 Description of the Device

The Finetech Medical STIMuSTEP® implanted dropped foot stimulator is a device for the correction of Dropfoot due to chronic upper motor neurone neurological deficit, typically experienced following stroke. The device stimulates the two branches of the common peroneal nerve using sub-epineural electrodes. This allows independent control of dorsiflexion and eversion. Power and control signals for the implant are passed through the skin using a radio frequency inductively coupled link and the stimulation is timed to the gait cycle using a footswitch placed in the user's shoe. The device is designed to permit simple clinical implementation and also to be convenient and comfortable for the user.

The system comprises of two main parts; the two channel implanted stimulator and an external control box.

1.1 The Implanted Stimulator



The Implanted Stimulator is a solely passive device composed of a receiver body, connecting cables and two electrode array sets.

1.1.1 The Receiver Body

The receiver block is approximately 33mm diameter and 6mm thick. It contains two independent and galvanically separate electrical circuits built upon a ceramic substrate 29mm in diameter. The two circuits are tuned to operate at different frequencies, namely 1 and 2 MHz allowing them to be

individually controlled by the Controller. This octave of difference limits crosstalk between the channels.

The electronic circuits of the receiver block are encapsulated in silicone rubber elastomer to enable them to operate in the implanted environment.

At two opposite quadrants of the diameter of the implant the re-enforced silicone rubber sheet that forms the backing for the implant is enlarged to form suture tags (approximately 5mm x 10mm). These allow fixation of the device.

Metal alphanumeric characters are embedded into the Implanted Stimulator. These show the serial number of the device, and a simple X-ray scan can be conducted to show this information in a patient previously implanted.

Implanted Stimulator Identification Table	
Designator	Description
F	Finetech Medical Ltd.
D	DropFoot Stimulator
nnnn	Serial Number

1.1.2 Connecting Cables

The receiver block is directly connected to the electrode arrays by two separate 1mm diameter Cooper Cables approximately 150mm long. These cables are very flexible and resilient to damage by repeated bending. They are less resilient to damage by crushing, so special care should be taken when handling.

The cable is composed of two helically wound platinum wire conductors with an enamel insulation. The intertwined helixes are encased in silicone rubber elastomer.

1.1.3 Electrode Array Sets

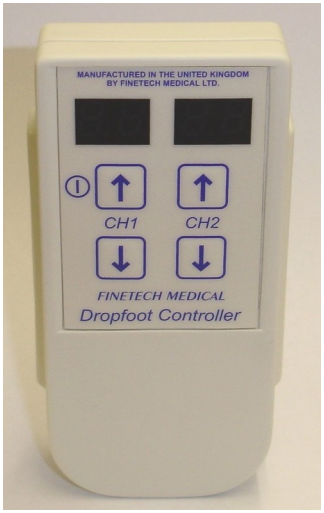
At the end of each cable the conductors are connected to the electrode array sets. Each array is bi-polar, with two stimulating electrodes mounted 5mm apart in a silicone rubber body that measures 9mm long by 2.75mm wide. The array is 0.8mm thick, with the exposed face of the stimulating electrodes protruding by 0.1mm.

The electrode arrays are placed under the epineurium of the nerve, providing good mechanical stability and, due to the proximity to the nerve fascicles, low stimulation currents can be used. The relatively low conductivity of the epineurium restricts unwanted stimulation spread to other nerves. The stimulation pulses have an asymmetric bi-phasic charge balanced waveform. This combined with the use of low currents ensures that the risk of electrode corrosion due to electro-chemical action is minimised.

The stimulating electrodes are made from pure platinum foil 0.076mm thick, well known as an implantable material. Each electrode measures 2.28mm by 1.6mm, with a central circular raised part 0.4mm high and 1mm diameter. The top surface of this raised part forms the exposed part through which stimulation current is applied. The exposed part is finished with a high polish, whilst all other faces are roughened by fine grit blasting to improve adhesion of the subsequent encapsulation.

1.2 The Control Box

The Control Box 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 control box has four control switches to allow adjustment and a four-digit information display.



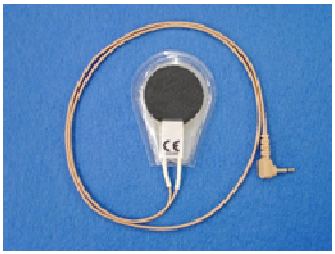
In order for the implant to receive correct stimulation the control box must be fixed in place directly over the implant. The implant is, typically, placed on the lateral aspect of the affected leg posterior and distal to the fibula head. To aid this placement the rear of the control box has a curved interface with a circular indent that is in-line with the internal transmitting circuit element.

To achieve correct alignment, locate the implant by palpation and place the circular indent over the implant. The Controller is held in place with the leg strap.

1.2.1 Leg Strap

The leg strap has two parts, lightweight fabric “hook and loop” type strap. It has a buckle at one end so that fixation is achieved by threading the strap behind the interface

1.2.2 Footswitch



For successful alleviation of dropped foot by electrical stimulation, the stimulation must be timed to be applied during the swing phase of walking only.

The required timing information is obtained by placing a switch under the heel of the patient's foot, inside the shoe. The switch is then connected to the control box by inserting its 2.5mm jack plug connector into the socket on the side of the control box.

For the maintenance of electro-magnetic compatibility use only the type of footswitch originally supplied by the manufacturer (refer to the illustration and Section 13).

1.3 Battery Charger

The internal battery is re-charged by connecting the battery charger to the socket at the bottom end of the controller. The charger is a "plug top" unit for connection to the electricity mains. The battery charger to suit U.K. and Euro type outlets can be found in section 13.

2 Copy of the Declaration of Conformity

Finetech Medical Limited

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Hertfordshire
AL7 1AU
UK

Declaration of Conformity

We, Finetech Medical Ltd,

declare that the **Finetech Dropped Foot Stimulator** is an active implantable medical device and conforms with the requirements of:

European Council Directive 90/385/EEC concerning active implantable medical devices.

Furthermore, we declare that the **Finetech Dropped Foot Stimulator** conforms with the requirements of the following international standards:

EN 45502-1: 1998 – Active implantable medical devices - Safety, Marking and Information provided

EN 60601-1: 1988 (+ amendments A1, A2 and A13) – Medical electrical equipment - Safety

EN 60601-1-1: 1992 (+ amendment A1) – Medical electrical systems - Safety

EN 60601-1-2: 1993 – Medical electrical equipment – Electromagnetic compatibility

The **Finetech Dropped Foot Stimulator** is CE marked by following the conformity assessment routes defined by Annex III and Annex V of directive 90/385/EEC as attested by: BSI (Notified Body Number 0086), Medical Devices Certification, BSI Product Services, Maylands Avenue, Hemel Hempstead, HP2 4SQ, UK

Signed: David Keeling Date: 23-04-05
David Keeling, Managing Director

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Issue 002

3 Purpose of the Device

The device is intended for the correction of dropped foot in those with a chronic upper motor neurone deficit, typically that following stroke. When used for the treatment of appropriate patients, in accordance with the manufacturer's guidelines the stimulator will:

- Improve a patient's gait by correcting the abnormal movement of the affected foot during the swing phase of gait.
- Provide stimulation that is relatively insensitive to minor movements in the Controller and hence, relatively insensitive to repeated donning and doffing.
- Provide selective stimulation of muscles supplied by the two branches of the common peroneal nerve
- Be relatively simple and quick to don and doff.

By provision of dorsiflexion and eversion, the foot clears the ground in the swing phase more easily. This reduces the effort of gait, reducing compensatory activities such as hip hitching and circumlocution. Reduction in effort will lead to a reduction of associated reactions and result in a general lowering of tone. Contraction of the tibialis anterior muscle and the hamstrings via the withdraw reflex may, by reciprocal inhibition; reduce antagonist activity leading to a more normal modulation of tone in gait. Repeated use of the stimulator may then lead to a pattern of "normal" walking being relearned centrally and long term potentiation of the required pattern of synapses may lead to a reinforcement of this pattern of walking. However, a more immediate benefit from the orthotic use of the device is that walking is easier and safer and therefore confidence will improve leading to an extension of mobility range and an overall improvement in quality of life.

As with any implantable medical device it is intended that its use will be recommended or prescribed by the patient's

medical or clinical specialist. The implantation procedure is to be carried out by suitably qualified and supervised surgical teams with aftercare, setting up and patient instruction carried out by qualified physiotherapists or other appropriate medical staff. Once implanted and in use the clinician will have the facility to carry out adjustments to the system settings to optimise performance to suit the particular needs of each patient.

4 Informative Statements

4.1 The Year of Authority to Affix the CE Mark

Authorisation to affix the CE mark to the Finetech Medical STIMuSTEP® dropfoot controller was granted in 2004.

4.2 Sterility Information

The Implant receiver is supplied sterile, packaged in double peel-pouches.

The packaged product is sterilised by high pressure steam in a steam steriliser for wrapped goods and porous loads, conforming to BS3970 part 3, and operated in accordance with Health Service Technical Memorandum No. 10. The sterilisation cycle has been validated by both thermometric and biological indicator determinations. The operating cycle includes a pulsed air-removal stage before the sterilisation hold period. The sterilisation is carried out at 134°C, (+3°C, -0°C), with a maximum allowable overshoot of 5°C. The hold time is not less than 3 minutes and not more than 4 minutes. Colour change indicators on the packaging show that the implant has been subject to the sterilisation process.

The sterilisation expiry date is shown on the implant packaging and the outer packaging. The implant should not be used after the quoted date.

There is no procedure for re-sterilising the implant.

4.3 Pre-Operative Check Requirements

Prior to using the implant it should be confirmed that:

- Both the outside carton and the inner peel-pouches of the implant packaging are un-damaged and free from oil/grease stains or water stains.
- The sterility expiration date is not exceeded.

- The colour change indicators on the peel-pouches show that the implant has been sterilised.

The external parts may be used provided there is no obvious damage to the equipment or the packaging.

4.4 Information for Re-use or if the Packaging is Damaged

The implanted receiver is supplied as a single-use item and should not be re-used. The external control box may be re-used by another patient after appropriate adjustment and cleaning.

If, on unpacking the equipment, it appears that the sterile package has suffered any damage, the package and it's contents should be returned to the manufacturer, or its agent, immediately.

There is no procedure for re-sterilising the implant.

4.5 Storage and Transport Conditions

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

Temperature:	-10°C to + 55°C
Humidity:	0 to 90%
Pressure:	70 kPa to 150 kPa

4.6 Medicinal Products Incorporated in the Device

There are no medicinal products incorporated within the device, nor does the device deliver any medicinal products.

5 Patient Selection

5.1 Selection Criteria

- A dropped foot resulting from an upper motor neurone lesion
- Dorsiflexion and eversion produced by electrical stimulation of the common peroneal nerve, using skin surface electrodes.
- Able to obtain standing from sitting and able to walk at least 50m with appropriate walking aid
- Candidates must not have significant mental impairment, they must understand the purpose of the procedure and be able to give signed informed consent.

5.2 Contra-Indications

- Diabetes, poorly controlled epilepsy and cardiac demand pacemakers are contraindications.
- Peripheral neuropathy of the sciatic nerve, common peroneal nerve or its branches. Spinal cord lesions below T12.
- Any medical condition that would exclude the use of a surgical procedure or anaesthetic.
- Fixed contractures of the Achilles tendon which prevents passive dorsiflexion of the foot
- The effect of use of the device on the unborn child in pregnancy is unknown.

5.3 Selection Procedure

It is recommended that candidates for the implant be first assessed using a skin surface FES device such as the Odstock Dropped Foot Stimulator. This is to ensure that:

- Gait is assisted by electrical stimulation
- Subjects are not affected by autonomic dysreflexia (SCI above T6) or any other effect from electrical stimulation.

- Subjects that receive a significant training effect from using surface stimulation do not receive an unnecessary surgical procedure.
- The subject receives a realistic picture of the benefits that can be expected from receiving the implant and thereby informing their decision to proceed to implantation.

5.4 Patients with High Calf Tone

If high calf tone that restricts the passive range of movement of the ankle and prevents effective use of the skin surface stimulation dropped foot stimulator is present, it is beneficial to use an exercise stimulator prior to walking with FES. The standard electrode positions used for common peroneal stimulation should be used to produce dorsiflexion with eversion. Use a stimulator that has an output envelope that has a long leading edge ramp (more than 2 seconds). This produces a gradual contraction of the dorsiflexion muscle group, below the velocity threshold to produce a stretch reflex in the calf muscles. Long ramps are also more comfortable.

Suggested stimulator parameters (MS2V2 mode 0): Pulse width 300μs, frequency 40Hz, Current 0-100mA, on time 7s, off time 18s, ramp time 6s.

Exercises should begin with periods of 15 minutes increasing over 2 weeks to 30 minutes and should be performed daily. Typically 4 weeks of exercise is sufficient to reduce the calf tone. The exercises are performed in the patient's own home. In extreme cases of calf spasticity, pharmacological intervention such as botulinum toxin can be used. Once calf tone is reduced the skin surface stimulation dropped foot stimulator can be used. Regular use of stimulation for walking (skin surface or implanted) will in most cases maintain the reduction of calf tone.

6 Surgical Procedure

The surgical procedure for implanting the stimulator is described below. Prior to starting this procedure, a nerve integrity check should be performed using a surface peroneal stimulator.

The operation is usually completed in less than one hour. As well as a standard neurological instrument set a surgical nerve stimulator, such as the Finetech Medical Surgical Stimulator BSD260, should be used to locate and identify the relevant nerves by electrical stimulation.

Consideration should be given to having in-place a spare implant and a spare Control Box to minimise the possibility that equipment breakages could terminate a procedure.

6.1 Anaesthesia

A general or spinal anaesthetic should be administered. Long-acting curare like agents is contra-indicated due to their effects on muscle activity. Pre-medication with atropine should be avoided, and if the patient has been taking an antimuscarinic drug this should have been stopped at least seven days before the operation. Neuromuscular block should be absent at the stage of testing the nerves by stimulation. A single bolus of broad spectrum antibiotic, such as Augmentin (amoxicillin and clavulanate potassium), should be given at induction.

6.2 Skin Incision and Identification of Nerves

The patient's knee should be flexed to relax the common peroneal nerve (CPN). Locate the common peroneal nerve by palpation. Make an incision of approximately 50mm along the course of the CPN, on the lateral aspect of the affected leg, beginning just below the head of the fibulae. The CPN and its two main branches, the Deep Peroneal Nerve (DPN) and the Superficial Peroneal Nerve (SPN) should be visually identified.

6.3 Nerve Integrity Check

Nerve identity and integrity should be checked using the surgical nerve stimulator and hooked electrodes. With the stimulator set at a stimulation frequency sufficient to produce tetanic response stimulate first the CPN and subsequently its two main branches (DPN and SPN), individually and then in parallel. Note the response of the foot (see table).

Stimulation site(s)	Expected response
CPN [i_1]	**Ankle dorsiflexion and unpredictable degree of eversion**
DPN [i_2]	Ankle dorsiflexion and inversion
SPN [i_3]	Ankle plantarflexion and eversion

The minimum values of stimulation current or voltage required to produce the expected gross movement of the foot should be recorded.

Providing the expected response is noted in each of the three cases, the surgery can proceed. In the case of no response, the stimulator and electrodes should be rechecked and, if functioning correctly, then the operation should be terminated.

The nerve branches are made up of multiple fascicles that supply different muscles. Consequently the effect of stimulation will vary depending on the exact location of stimulus. The response to stimulation of each nerve must be checked at several stimulation sites, along and around the nerve. It is advantageous to choose a position on the deep branch that produces the least amount of inversion while at the same time producing good dorsiflexion. Similarly a position on the superficial branch that produces the best eversion without excessive plantaflexion should be found.

6.4 Epineural Incisions

Make a small incision through the epineurium at each of two sites – on the DPN and on the SPN. The incisions on the DPN

and SPN should be made at the site where optimal responses were achieved during test stimulation.

At each of the two sites insert an electrode set through the incision ensuring that the exposed metal of the stimulating electrodes is placed in contact with the underlying nerve bundles. The electrode set of Channel 1, indicated by the white marker, must be inserted on the DPN; Channel 2 must be inserted on the SPN. Each set should be inserted at least the length of the electrode set (approximately 10mm) so that the lead alone protrudes from the incision.

Special care should be taken when handling the cables as they are relatively easily damaged by crushing. For this reason handle with fingers or wide, blunt forceps.

6.5 Sub-Epineural Stimulation Settings

At this stage a Control Box should be introduced. This should be placed in a sterile sleeve to allow test stimulation to be applied via the sub-epineural electrodes.

Prior to surgery the battery of the Control Box (and any spare) must be full charged and the unit set to low power (Po 1). See Control Box instructions in section 7 for details.

The control box is switched on using the “Level Mode” by pressing simultaneously the “Up” and “Down” buttons for channel 1. Initially set the level to 10 by pressing the up and down buttons. The control box is then brought over the receiver, lining up the circular indent on the back of the controller with the receiver body and held a distance of approximately 15mm away. Observe the response of the foot as the Controller is brought to the receiver. If no response is detected increase the stimulation level until a detectable dorsiflexion and inversion of the foot occurs. If the response is still insufficient then the power setting can be adjusted to the

higher power setting (Po 2). Record the stimulation level required to achieve the motion.

Switch off Channel 1 by pressing the up and down buttons simultaneously and repeat the process for channel 2 until a corresponding plantarflexion and eversion of the foot occurs. Record the stimulation level required to achieve the motion.

If the responses are poor, the electrode should be repositioned. Also check that the electrode has been inserted with the exposed, un-insulated side facing the inside of the nerve.

Switch on both channels in “Level Mode” by first pressing the up and down buttons simultaneously for channel, 1 followed by the up and down buttons for channel 2. Start at low settings and adjust each setting until a balanced dorsiflexion with eversion movement is achieved. Record the stimulation level required to achieve the motion.

If no detectable motion is observed, the equipment and the electrode placement should be re-checked. If the equipment is shown to be functioning correctly and the electrodes correctly placed then it may be assumed that the Controller cannot produce sufficient energy to produce stimulation. If this is the case, consideration should be given to removing the electrodes, closing the epineural incisions and access wound.

6.6 Securing the Electrodes in Place

The two incisions in the epineurium should be closed by suture thus trapping the electrode set in place. The securing tag, positioned approximately 15mm from the end of the electrode set, should be used to minimise the transfer of strain to the electrode set. The tag can be sutured as a loose band around the nerve or to the surrounding tissue. In some cases the epineurium may be considered the best tissue for fixation

6.7 Securing the Implant

A suitable position for the implant body should be identified and the implant sutured in place using sutures through the re-enforced tabs. The sutures will attach the tabs either to the fascia of the underlying muscle (Peroneus Longus) or to the inside of the skin. The leads should be arranged in such a way as to reduce as far as possible the possibility of mechanical loading on the electrode sites resulting from muscle activity.

6.8 Final Check and Wound Closure

Place the Control Box in the sterile sleeve over the site of the receiver and stimulate at the levels previously required to produce a balanced dorsiflexion movement. If a satisfactory response is found the wound can be closed and appropriately dressed. If no movement is detected increase the stimulation level until a response is found. If response cannot be found then it must be assumed that either the nerve, or the implant, or both have been damaged. If this is the case, consideration should be given to removing the implant and closing the wound.

Standard surgical dressings should be used to cover the wound.

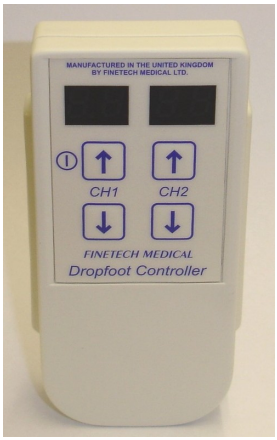
6.9 Recovery

A period of 10 days recovery should be allowed before any further stimulation is applied. The healing of the wound should be monitored using standard postoperative procedures. The patient may return to ambulating as soon as they are fit after the surgery. If an ankle foot orthosis is used it must be ensured that excess pressure is not placed on the wound area. It is important that every effort is made to ensure that the implant is not disturbed in this period. Care should be taken to avoid gross movement and mechanical shocks.

An X-ray photograph of the implanted device, taken soon after implantation, can be used, in case of a complication, to help ascertain if the implant or the electrodes have been moved from their original position.

Post-operatively, the patient should be advised to regularly check the condition of his or her skin over the Implanted Receiver and leads for signs of redness, swelling, or breakdown. If skin breakdown becomes apparent, patients should contact their clinician immediately. The clinician should treat the infection aggressively, taking into consideration the extra risk presented by the presence of the implanted materials.

7 Control Box Instructions



The Control Box is worn directly over the implant and transmits power and signals to the implant by radio frequency inductive coupling.

It has four switches and two two-digit displays on the front, a connector on the side for the footswitch and a connector at the bottom for re-charging the battery.

The button switches are used to set the adjustable parameters of the control box. The switch marked *CH1* ↑ is also used as the On/Off switch.

7.1 Controller Outputs

The controller produces bursts of pulses at 1 and 2MHz, which are received and rectified by the implant. The 1MHz output is Channel 1 both in the Controller and the implant. The burst stimulation frequency is fixed at 30Hz for each channel. The pulse width is adjustable between 00 and 85, corresponding to 0µs and 255µs (independently for each channel) and may be set in Level Mode.

The amplitude of the stimulation (i.e. magnitude of the current pulse delivered to the nerve) is determined by the voltage applied to the Controller coil. This voltage is common to both output channels and may be set in Parameter mode (using the Power parameter). There are 2 available Power settings, with the higher level (Level 2) being approximately 40% greater than the lower.

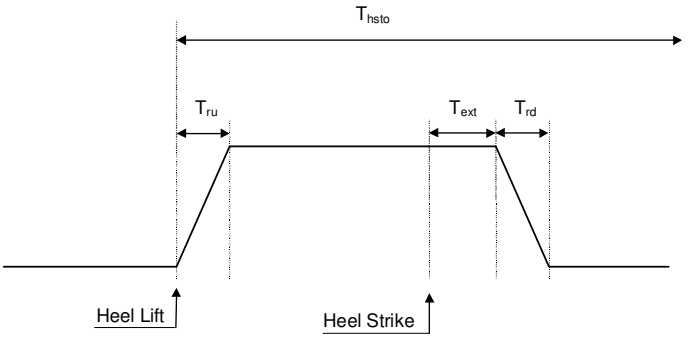
The actual strength of stimulation is a function of both the amplitude and pulse width as it is the total charge delivered to the nerves that determines the excitation of the nerve.

7.2 Envelope Generator

The outputs from the controller are triggered and the timing controlled by the footswitch. When the heel is lifted (as detected by the footswitch) the stimulation pulse width level ramps up from zero to its preset level (as set in Level mode). It then remains at this level until either;

- a heel-strike occurs or
- a time-out interval from the heel-lift is exceeded.

The dynamics are controlled by an envelope generator with a number of adjustable parameters as indicated on the diagram below:



T_{ru} - Ramp Up Time – the time the stimulation takes to ramp up to its set level.

T_{ext} - Extension time – time after heel strike before stimulation starts to ramp down.

T_{rd} - Ramp Down Time – the time the stimulation takes to ramp down to zero.

The above parameters may be adjusted independently for the two output channels.

T_{hsto} - Heel Strike Time Out – the time after which stimulation stops in the event of no heel strike.

These parameters may all be varied (between pre-defined limits) in Parameter mode.

7.3 Operating Modes

The controller has three modes of operation: Normal mode, Level mode and Parameter mode.

7.3.1 Normal Mode

This is the main operational mode of the controller. Stimulation will start after a heel-lift and stop after a heel-strike or timeout. The stimulation envelope is determined by the parameters set in Parameter mode.

Normal mode is entered by pressing and releasing the ***on/off*** switch.

During the time that the switch is held the battery state will be displayed (either '**good**' or '**lo**'). Continuing to hold the switch for 2 seconds will cause the controller to display the firmware version. Holding the switch for a further 2 seconds will cause the controller to enter Parameter Mode.

When the controller is in Normal mode the display shows a single decimal point in the left hand display window. When stimulation is triggered the single decimal point moves to the right hand display window. When the stimulation period ends the display dot returns to the left hand window again.

Normal mode is turned off by pressing and releasing the **on/off** switch or automatically after the time-out period which may be set in Parameter mode.

7.3.2 Level Mode

This mode is used to set the stimulation levels of the two output channels by independently adjusting the stimulation pulse width for each channel. This mode is accessible only when the controller is switched off. Stimulation output is active and continuous in this mode.

Pressing the two left hand switches together (marked '↓' and '↑') will turn on channel 1 and its level will be shown on the corresponding displays as a number between 00 and 85. The switch marked '↓' may now be used to decrease the level and the switch marked '↑' to increase it. Changing the level by 1 changes the pulse width by 3 microseconds. Any changes in level are immediately reflected in the output.

Pressing the '↓' and '↑' switches together again will turn channel 1 off.

Pressing the two right hand switches together (marked '↓' and '↑') will turn on channel 2 and its level will be shown on the corresponding displays as a number between 00 and 85. The switch marked '↓' may now be used to decrease the level and the switch marked '↑' to increase it. Any changes in level are immediately reflected in the output.

Pressing the '↓' and '↑' switches together again will turn channel 2 off.

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.

Display	00-85	00-85	00-85	00-85
Switch	Increase Level Ch1		Increase Level Ch2	
	Decrease Level Ch1		Decrease Level Ch2	
Switches Together	Channel 1 On/Off		Channel 2 On/Off	

Display and Switch Functions – Level Mode

The channel levels set in this mode are stored in non-volatile memory and used during Normal Mode.

7.3.3 Parameter Mode

This mode is used to set the parameters of the envelope generator. These are the parameters that will be used during stimulation but there is no stimulation output in this mode. The parameters are stored in non-volatile memory and any changes are automatically saved on exit from this mode.

This mode may be entered only when the controller is off and is selected as follows: Press and continue to hold the ***on/off*** switch. The display will show the battery state then, after 2 seconds, the firmware version, and then, after another 2 seconds it will enter Parameter mode.

In Parameter mode the left hand '↓' and '↑' switches are used to move up and down through the list of available parameters whose codes and values will be indicated on the display. The value of the selected parameter may be decremented by pressing the right hand '↓' switch and incremented by pressing the right hand '↑' switch.

Display	Selected Parameter (Po etc.)	Parameter Value (0-n)
Switch	Up Parameter List	Increase Setting
	Down Parameter List	Decrease Setting
Switches Together	Switch Off and Exit	-

Display and Switch Functions – Parameter Mode

To exit Parameter Mode, store the programmed values and switch off press the two left hand switches together.

7.3.3.1 Adjustable Parameters

Parameter	Display	Range	Units	Description	Default
Output Power Level	Po	1-2	arbitrary	Selects supply voltage to Controller *(see note below)	1
Heel-strike time-out (T_{hsto})	Ht	0.1-5.0	0.1s	Time before ramp down in the event of no heel-strike	3
Ramp up time 1 (T_{ru1})	u1	0.0-5.0	0.1s	Time for stimulation to ramp up to preset level on channel 1	0.5
Ramp up time 2 (T_{ru2})	u2	0.0-5.0	0.1s	Time for stimulation to ramp up to preset level on channel 2	0.5
Ramp down time 1 (T_{rd1})	d1	0.0-5.0	0.1s	Time for stimulation to ramp down to zero on channel 1	0.2
Ramp down time 2 (T_{rd2})	d2	0.0-5.0	0.1s	Time for stimulation to ramp down to zero on channel 2	0.2
Extension time 1 (T_{ext1})	E1	0.0-5.0	0.1s	Time delay between heel-strike and start of ramp down for channel 1	0.3
Extension time 2 (T_{ext2})	E2	0.0-5.0	0.1s	Time delay between heel-strike and start of ramp down for channel 2	0.3
Idle time-out (Normal mode)	tO	01-60	minutes	Auto power-off period for Normal Mode	60
Idle time-out (Setup modes)	tS	01-10	minutes	Auto power-off period for Level Mode and Parameter Mode	10

Envelope Generator Adjustable Parameters

* If the Power parameter is increased then the output levels on both channels will be set back to their minimum values for safety. Level mode may then be used to set the levels appropriately.

7.3.3.2 System Parameters

System information is displayed at switch on and whilst the ***on/off*** switch is held down. These parameters are not adjustable being for information only.

Parameter	Comment
Battery State	2 states only – 'good' and 'Lo'
Firmware version	vv.rr (where vv = version, rr = revision e.g. 01.02)

7.4 Battery Charging and Indication

The Control Box is powered by an internal 3.7V, 550mAh re-chargeable Li-Polymer battery. The state of charge is shown, at switch on, by the display showing "**good**" or "**Lo**".

Whilst charging is taking place the display will show a horizontally scrolling bar-graph. The Battery Charger also has an orange light indicates charging and change to green when fully charged or trickle charging.

Either the UK charger (FD039) or the Euro charger (FD040) may be used to re-charge the battery. No other charging units should be used as they may cause damage or risk overheating the unit. Only the specified battery chargers or footswitches should be plugged into the control box.

Remove the Control Box from the leg and plug the charger into the socket on the bottom side of the control box and the Battery Charger into a mains outlet. Fully charge will take approximately 2 hours but may take place at any time.

During use the battery is monitored, if it becomes low it will display 'lo' on the screen. At the first opportunity in which rest of more than one minute is detected, the controller will close down. If walking is continued for more than twenty minutes after detecting low battery the controller will close down following the last stimulation period. This is done to prevent damage to the battery from deep discharging.

7.5 Patient's Guide

A separate User's Guide (FTM1031) is supplied with the equipment and this, along with the Implantation Certificate (FTM1032) should be given to the patient. The Implantation Certificate has space for relevant information (Implant serial number, date of implantation, clinicians details etc.) to be recorded.

8 Setting up and using the Stimulator

The implant can be used once the operation site wounds have healed. This will be 10 to 15 days post implantation.

8.1 Pre-Stimulation Checks

Check the wound site and ensure the wound is closed and there are no signs of infection (elevated temperature, redness, swelling etc.)

Passively move the ankle through it ranges and ensure there is no pain experienced by the patient. If there is pain, standard physiotherapy techniques can be used relieve it and mobilise the limb. Therapeutic ultrasound should not be used.

8.2 Trying the Implant for the First Time

The patient should be seated in a comfortable chair. Their leg should be partially extended and supported. The ankle should be free to move.

8.3 Configuring the Controller

Before using the Controller and before attaching it to the patient's leg, the operating parameters must be chosen. A full description and instructions can be found in Section 7.

Enter the parameter mode by pressing and holding down the "On" button for 5 seconds. The display will first show the battery condition, then the firmware version and finally the first parameter. This is the power setting Po. You can scan through the parameters using the channel 1 '↓' and '↑' buttons on the left hand side of the control box. To change the value of the parameters use the channel 2 '↓' and '↑' buttons on the right hand side of the box.

Set the Controller to the following initial settings:

Parameter	Display	Suggested Initial Parameters
Output Power Level	Po	1
Heel-strike time-out (T_{hsto})	Ht	3.0
Ramp up time 1 (T_{ru1})	u1	0.3
Ramp up time 2 (T_{ru2})	u2	0.3
Ramp down time 1 (T_{rd1})	d1	0.2
Ramp down time 2 (T_{rd2})	d2	0.2
Extension time 1 (T_{ext1})	E1	0.3
Extension time 2 (T_{ext2})	E2	0.3
Idle time-out (Normal mode)	tO	60
Idle time-out (Set-up modes)	tS	10

To leave the parameter mode, simultaneously press the channel 2 '↓' and '↑' buttons on the right hand side of the box.

8.4 Controller Adjustments Procedure for Each Patient

Now enter the Level mode. With the Controller turned off, simultaneously press channel 1 '↓' and '↑' buttons on the left hand side of the box. The display on the left hand side will show the number relating to the stimulation output (pulse width). Using the channel 1 '↓' and '↑' buttons on the left hand side of the box, adjust the level till it reads 10.

With the Controller still in the Level mode, hold the box about 10cm away from the implant and then slowly bring it towards the patient's leg. The circular indent on the back of the controller should be lined up with the implant, located by palpating the skin. It may be convenient to temporally mark this position with a skin marker. Observe any movement produced by the dorsiflexion muscle group. A good response is dorsiflexion with varying amounts of inversion or eversion. If a strong contraction is observed before the Controller reaches the skin, do not move the box any closer. Reduce the level of stimulation and repeat the test. If a movement is not observed or is weak, increase the level. Do not hold the Controller against the skin for more than about 5 seconds at a time when there is a strong contraction. This is because a prolonged strong contraction can be uncomfortable.

If after increasing the level to 85 the muscle response is still weak or absent, return to Parameter mode and change the power level to 2 (Po 2). Repeat the above test procedure until a satisfactory response is observed. If no response is observed, refer to the Fault Finding procedure in Section 9.2.

NB. If a satisfactory contraction is produced on power setting 1 but at high level (pulse width) setting, for example over 75, it is usually an advantages to change the Power setting to 2 and readjust the Level to produce the same movement at a lower level setting. This is because this will allow the user 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.

When a satisfactory response is obtained from channel 1, turn it off by simultaneously press the channel 1 '↓' and '↑' buttons

on the left hand side of the box. Now enter the Level mode for channel 2 by simultaneously press the channel 2 '↓' and '↑' buttons on the right hand side of the box. Repeat the test procedure now for channel 2. A level should be found that produces eversion without excessive plantarflexion.

Once levels have been found for both channels, the combined effect can be tested. Put both channels into Level mode by first simultaneously press the channel 1 '↓' and '↑' buttons on the left hand side of the box and then repeating for channel 2. Move the box towards the receiver as before, observing the response. An ideal response is dorsiflexion with approximately 5 degrees of eversion. Adjust the levels until the best response is obtained.

8.5 The Footswitch

The footswitch should be mounted on the underside of a shoe inner sole. This allows the switch to be moved from shoe to shoe and minimises footswitch wear. Peel the waxed paper backing off the double-sided tape on the back of the switch to expose the adhesive. The switch should be placed under the middle of the heel with the lead passing forward towards the toes and then out to the side. If the patient consistently weight bears on one side of the foot (when using the stimulator), the switch can be placed to favour that side. If little weight is taken through the heel, the switch may be more reliable further forward in the shoe. Note that this will change the timing of the stimulation, delaying the start and end of the contraction. Adjustments may be required to the rising edge ramp and extension time to compensate for this. When using the switch for the first time, the switch can be taped in to the shoe to allow it to be easily moved around until the best position is found. Once it is attached to the inner sole it is difficult to remove without damaging the innersole.

Occasionally some people prefer to stick the footswitch directly to the heel of their foot and run cable up under their sock. The

foot switch can be held in place with medical adhesive tape or the double-sided adhesive stickers used for TcPo2 sensors. This may lead to more rapid footswitch ware.

Footswitch lifetime will vary depending on use and the user. Foot switches are a consumable device and will require replacing periodically.

8.6 Leg Strap

The Controller is held in place on the leg by application of the Leg Strap. Place the Controller over the implant and 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 no so tight that blood circulation is effected. The leg should be monitored for marking or swelling. (See User guide FTM1031 for fitting instruction)

8.7 Starting Use

With the Controller and foot switch in place and connected the device can be tried whilst walking. Turn the Controller on by pressing the Channel 1 '↑' button. The patient should be closely supervised the first time the device is used and must use appropriate walking aids such and a walking stick, frame or bars for safety.

As previously mentioned, the movement response may change when the patient is standing compared with sitting. It is sometimes necessary to adjust the levels to compensate for this. Adjusting the levels is best done while the patient is sitting because the constant contraction produced in Level mode can make the user unsteady while standing. Remember not to enter Level mode for an extended time, as a prolonged strong contraction can be uncomfortable.

8.8 Fine tuning

The Controller must now be adjusted to suit the patient's gait.

8.8.1 Rising Edge Ramp u1 and u2

The most important parameter to consider is the rising edge ramp. A rapid contraction of the dorsiflexion muscle group will rapidly stretch the calf muscle. This can induce a stretch reflex, opposing the desired movement. By slowing down the stretch, the reflex can be reduced and the range of ankle movement increased. Ramping also makes the stimulation and muscle contraction more comfortable. Another effect is that it delays the start of the movement till slightly later in the gait cycle. This gives the user time to produce an active push off with the calf muscles at the terminal stance phase of the gait cycle. However, if the rising edge ramp is too long, the stimulation can come on too late to pick up the foot in time for the swing phase.

The correct amount of rising edge ramp will vary from person to person and is dependent on walking speed and the amount of calf tone. A fast walker will require a short ramp while someone with high calf tone (usually they will also walk more slowly) will require a longer ramp.

The process of choosing the ramp is one of trial and error together with clinical observation and feedback from the patient. At first adjust both the rising edge ramps for channels 1 and 2 to be the same. Generally the best ramp setting will be the longest ramp that can be used while still picking up the foot quickly enough at the beginning of the swing phase. The ramp settings can be adjusted separately to fine tune the exact movement but this is generally not required.

8.8.2 Extension time E1 and E2

The next important parameter to set is the extension time E1 and E2. In normal gait, the anterior tibialis is contacting at is most powerful at heel strike and continues till the foot is flat on the ground. This is because it provides an eccentric contraction, lowering the forefoot to the ground. This effect is duplicated by the stimulator by adding a short continuation (or

extension) to the stimulation after heel strike has occurred. The amount of extension required will vary depending on walking speed and calf tone. Too little and the foot will slap against the floor. Too much and the user receives more stimulation than necessary which may result in excessive muscle fatigue. Again, adjustment is a mater of clinical observation and trial and error. Adjust E1 and E2 to the same value unless fine adjustments of movement are required.

8.9 Less Critical Adjustments

8.9.1 Ramp down Time d1 and d2

Ramp down time is adjusted mainly for comfort. Normally only short times are required between 0.0 and 0.3. Adjust both d1 and d2 to the same value

8.9.2 Heel-strike Time-out H1

This parameter sets the maximum time stimulation can continue if the heel is not returned to the ground. This might be the case, for example, when going from standing to sitting. It should be set to be just a little longer than the normal swing time of gait.

8.9.3 Idle Time-out t0

This parameter sets the maximum time that the Controller remains turned on following the last step taken. The setting of t0 depends on the preference of the patient. If they will remember to turn the device on every time they stand up to start walking, then setting t0 to a low value will preserve battery power. If they are forgetful and may be at risk of falling if the stimulator is not switched on set the t0 to its maximum value.

8.9.4 Remaining Parameters

The remaining parameter tS should be left at the default setting.

8.10 Recording the Settings

Once the settings have been finalised, make a record of the parameter settings (including the Level settings) on the record form provided in Section 11. This information can be used to monitor changes and also to duplicate the settings if it is necessary to replace the Controller.

8.11 In-Use

The device is best set up at two clinic appointments on consecutive days. On the first day the device can be set-up and the patient taught to use it. Where appropriate the patient's carer should also be taught to operate the device. The User's Guide must also be given to the user. On the second day the performance is checked and any assessments made.

Initially the device should be used for short periods only and its use built up over a period of 3 weeks when it can be used as desired. Depending on the patient, use should first be restricted to short distances within the patient's home, starting with several periods of around 10 minutes. As muscle strength and fatigue resistance increases walking time and distance can be increased and short distances in the community attempted. Experience suggests that it can take 6 to 18 weeks for a new gait pattern to fully develop.

8.12 Follow Up

Follow up should be given at 6 weeks after initial use. This is repeated 3 months later, a further 6 months after that and then yearly for as long as the device is used. Additional follow up may be required if problems are experienced and the device user should be encouraged to report any problems experienced so they can be corrected as soon as possible.

8.13 Physiotherapy

The device should not be considered as treatment in itself but as part of the patient's overall rehabilitation programme. Many

patients may benefit from additional physiotherapy gait re-education to maximise the benefit they receive from the device.

⚠ WARNING	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.

9 Information / Precautions Required by the Patient

9.1 Battery Limitations

The batteries, within the Control Box, should give several years use; the lifetime actually obtained will depend on the exact charging routine. The approaching end of battery life is signalled by the need to charge more frequently than previously. When this happens the control box should be returned to the supplier for new batteries to be fitted.

9.2 Precautions Should the Device Performance Change

When there is any doubt about the functioning of an implant, the first step is to verify that the external equipment is operating correctly. The most likely problems are due to the footswitch or battery. Ensure that the footswitch is correctly plugged into the connector on the side of the controller. Ensure that the battery is charged (the display will show "**good**" at switch on). A replacement footswitch should be tried.

The following fault finding guide should be followed.

9.2.1 Fault Finding

First check that the Controller is in the correct position 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 take the Controller off the leg and check the parameters of the device in parameter mode. These should match the records for the individual patient. If the parameters are not correct due to accidental adjustment, enter the correct parameters and repeat the above test.

If there is still no response, with the Controller off the leg, set both channel into level mode. Move the Controller over the skin where you believe the receiver to be. If necessary increase the level of stimulation and adjust the power setting.
If no response is found it is probably due to a fault in the equipment. A spare Controller should now be tried. Return the Controller to the supplier for checking and repair.

The integrity of the common peroneal nerve can be tested using skin surface stimulation. If no response is found using skin surface stimulation, it is likely that damage has been caused to the common peroneal nerve. If the nerve responds to skin surface stimulation and the Controller is believed to work correctly, it is possible that the electrodes may have moved. An x-ray should be taken to compare the one taken post surgery. If the electrodes have not moved (it may be hard to tell) the implant may be faulty. This can only be confirmed following surgical investigation.

The external equipment should be returned to the manufacturer for testing before any assumption is made that the implant is faulty. Complete failure of a Dropped Foot Stimulator that formerly worked well is almost sure to be due to failure of the external equipment.

An X-ray picture can be used, in comparison to that taken at time of implantation, to ascertain if the implant has moved or if the electrodes have been dislodged.

The stimulation levels required to achieve balanced dorsiflexion may be expected to slowly increase for as much as a year after implantation. This is due to growth of fibrous tissue around the electrode sites. A significant change in the level of subcutaneous fat over the implant site will also affect the required stimulation levels.

9.3 Precautions over Exposure to External Influences

The patient should be made aware that external influences may affect their equipment and that they may have to obtain advice prior to using the equipment in certain areas or situations. Particular care should be taken in any area that is notified as being possibly hazardous to “Pacemaker Patients”.

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.

9.3.1 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 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 are safe to use.

The Control Box should not be worn or used in the near vicinity of the scanner.

9.3.2 X-Ray Equipment

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

9.3.3 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.

9.3.4 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.

9.3.5 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.

9.3.6 Therapeutic Ionizing Radiation

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

9.3.7 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.

9.3.8 E.C.G. / E.E.G. / E.M.G. Equipment

Perturbation of ECG / EEG / EMG tracings is to be expected if the Dropfoot Control Box external equipment 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

9.4 Limitations on the Use of the Device

9.4.1 Design Limitations

The Finetech Medical STIMuSTEP® dropped foot stimulator should not be used whilst driving, operating dangerous machinery or at any other time that inadvertent triggering could cause un-wanted movement. Switch the Control Box off at these times.

The control box is not sealed against the ingress of water and is classified as type IPX0.

9.4.2 Life of the Implant

The life of an implant, not subject to mechanical damage or component failure, is believed to be set by degradation of the silicone rubber. It is expected to happen (though it has not yet been observed) after 20-25 years. The integrity of the implant in degraded silicone rubber cannot be guaranteed; removal or replacement of the implant should therefore be considered after 20 years.

9.4.3 Use Onboard Passenger Aircraft

As with all electronic equipment the Control Box should not be used whilst the “Fasten Seatbelt” signs are illuminated. To avoid inadvertent triggering the Control Box should be turned off at these times.

9.5 Guidelines on Electromagnetic Compatibility

9.5.1 Application and Use

Medical Electrical Equipment needs special precautions regarding EMC. The STIMuSTEP® system must be setup in accordance with the Clinicians Guide FTM1033 and put into service in accordance with the provided EMC information.

9.5.2 Effects on the System

WARNING: Portable and Mobile RF Telecommunication Equipment can affect Medical Electronic Equipment.

9.5.3 System Compatibility

WARNING: The use of parts other than those specified in Section 13 may affect the system compatibility.

10 List of Symbols Applied

TITLE	Description of the packaged device.
	Sterile by steam or dry heat.
	CE Mark and registration number of the Notified Body for Finetech Medical Ltd.
 FDxxx	The catalogue number of the assembly.
 FDxxxx	Serial number of the assembly.
 xxxx	Manufacturing batch code of the assembly.
	Do not use if package damaged.
	Do not reuse.
	Protect from heat.
	Protect from moisture.
	Attention; consult accompanying documents.
	Storage conditions.
	Manufactured by Finetech Medical Ltd.
 YYYY-MM	Date of manufacture; year and month.
 YYYY-MM	Date of sterility expiry; year and month. The use by date; 2 years duration is standard.
	Degree of protection against electric shock – Type BF Electrically Isolated (Floating) Applied Part.
	Class II equipment.
	The System includes an RF Controller that intentionally applies RF electromagnetic energy for treatment.
	Not for disposal by municipal waste collection systems. Waste to be sorted and returned to manufacturer for recycling.

11 Patient Record Sheet

Finetech Medical STIMuSTEP® Implanted Dropped Foot Stimulator
Controller Parameter Settings

Name _____

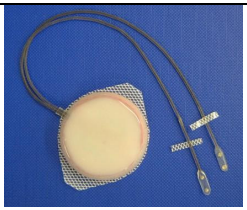
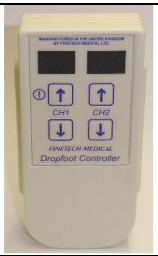
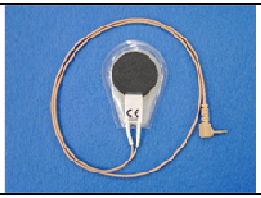
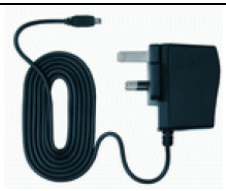
Hospital ID _____Date _____

Parameter	**Display**	**Parameter Setting**	**Level Settings**	
Output Power Level	Po		CH 1	CH 2
Heel-strike time-out (T_{hsto})	Ht		Comments	
Ramp up time 1 (T_{ru1})	u1			
Ramp up time 2 (T_{ru2})	u2			
Ramp down time 1 (T_{rd1})	d1			
Ramp down time 2 (T_{rd2})	d2			
Extension time 1 (T_{ext1})	E1			
Extension time 2 (T_{ext2})	E2			
Idle time-out (Normal mode)	tO			
Idle time-out (Setup modes)	tS			
Shoe inner sole size	R / L			
Controller serial number				
Foot switch serial number				

12 10 Meter Walking Speed and PCI

Name				Date	
Assessment Number			Resting Heart rate (RHR)		
	Time	Heart Rate	Speed (WS) 10/time	Change in Heart Rate HR - RHR	PCI HR-RHR/60 WS
No FES					
Mean					
FES					
Mean					
% Change ((With FES/No FES)-1)x100					
% Change Carry-over ((No FES now/No FES start)-1)x100					
% Change Orthotic ((FES now/No FES start)-1)x100					
Other walking aids used					
Notes					

13 Table of Parts and Abbreviated Specifications

Item	Pt	Picture	Description
Implanted Stimulator	FD006		2 Channel Implant 33mm diameter, only 16grams Lead length 150mm 2 Bi-polar electrodes 2.75 x 9mm Supplied sterile in double peel-pouches
Control Box	FD038		2 Channel Controller 105mm x 55mm x 25mm; 82grams Type BF Applied Part Internal 550mAh Li-Polymer battery Integral leg mounting
Leg Strap	FD037		Fabric “hook and eye” Strap 450mm long Buckle and Fold-Back design for one handed application
Footswitch	FD041		Robust Force Sensitive Resistor technology - no moving parts. Less than 3mm thick 650mm Lead Length
Battery Charger UK: EURO:	FD039 (UK) FD040 (Euro)		Dedicated charger for the FineTech Dropped Foot Stimulator Compact plug-top design Input: 230Vac, 50-60Hz, 0.2A (max) Output: 4.2V, 550mA (max)