

Odstock[®] Medical

FES

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Functional Electrical Stimulation (FES)

FES is a technique used to produce contractions in paralysed muscles by the application of small pulses of electrical stimulation to nerves that supply the paralysed muscle. The stimulation is controlled in such a way that the movement produced provides useful function. FES is used as an orthosis to assist walking and also as a means of practising functional movements for therapeutic benefit.

Odstock[®] Medical provides a range of neuromuscular stimulators designed to improve the functional ability of people with a neurological condition. The devices have been developed over many years of collaboration between clinical engineers, clinicians and patients at the National Clinical FES Centre, Salisbury District Hospital. The devices are suitable for use by physiotherapists and other clinicians in routine clinical practice.

Who can use FES?

For FES to be effective both the nerve and the muscle supplied by the nerve must be undamaged. For this reason FES can be used in condition such as:

- Stroke
- Multiple sclerosis (MS)
- Spinal cord injury, T12 and above (SCI)
- Parkinson's disease
- Cerebral palsy (CP)
- Head injury (HI)
- Familial or hereditary spastic paraparesis (FSP)

In these conditions paralysis is due to an upper motor neurone lesion. FES can also be used in orthopaedic conditions where muscle weakness is due to disuse or inhibition.

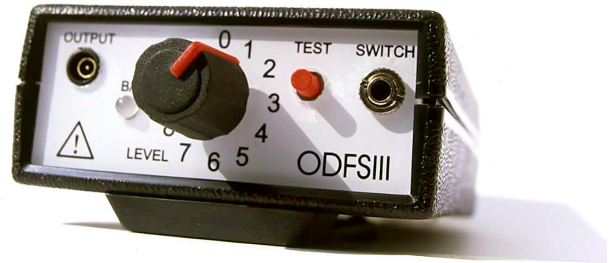
FES is not suitable for lower motor neurone conditions such as:

- Peripheral nerve lesions
- Polio
- Motor neurone disease
- Guillain-Barre Syndrome

Odstock[®] Medical Limited

Odstock[®] Medical was established as a NHS owned spin off company by Salisbury NHS Foundation Trust in April 2006. The company was formed to exploit the success of the FES work carried out by the Department of Medical Physics and Biomedical Engineering at Salisbury District Hospital over the previous 20 years. The company aims to continue the development of FES and provide the highest standards of clinical service to the NHS. The new commercial status will enable expansion and will ensure as many people as possible can benefit from the techniques and technology developed in Salisbury.

ODFS - Odstock® Dropped Foot Stimulator



The Odstock® Dropped Foot Stimulator (ODFS) is a single channel, foot switch controlled stimulator designed to correct dropped foot in upper motor neurone conditions. Skin surface electrodes are placed, typically over the common peroneal nerve as it passes over the head of the fibula and the motor point of tibialis anterior. Stimulation produces dorsiflexion and eversion of the foot and in certain electrode configurations produces a withdrawal reflex, adding knee and hip flexion. The rise and fall of the stimulation can be adjusted to prevent a sudden contraction that might induce a stretch reflex of the calf muscles. There are also facilities to add an extension to the stimulation envelope after heel strike, mimicking the natural activity of the anterior tibialis muscle, which contracts eccentrically to lower the foot to the ground and stabilises the ankle at initial contact.

Dorsiflexion and eversion in swing phase of gait produces:

- Improved ground clearance
 - Reduced tripping and falls
 - Reduced compensatory activity
 - Reduced effort of walking
 - Reduced spasticity
 - Increased walking speed
- Heel strike with eversion
 - improved loading response
 - greater stability in stance
- Greater range of mobility
- Greater safety, confidence and independence while walking
- Long term therapeutic benefit
- Greater social interaction and improved quality of life

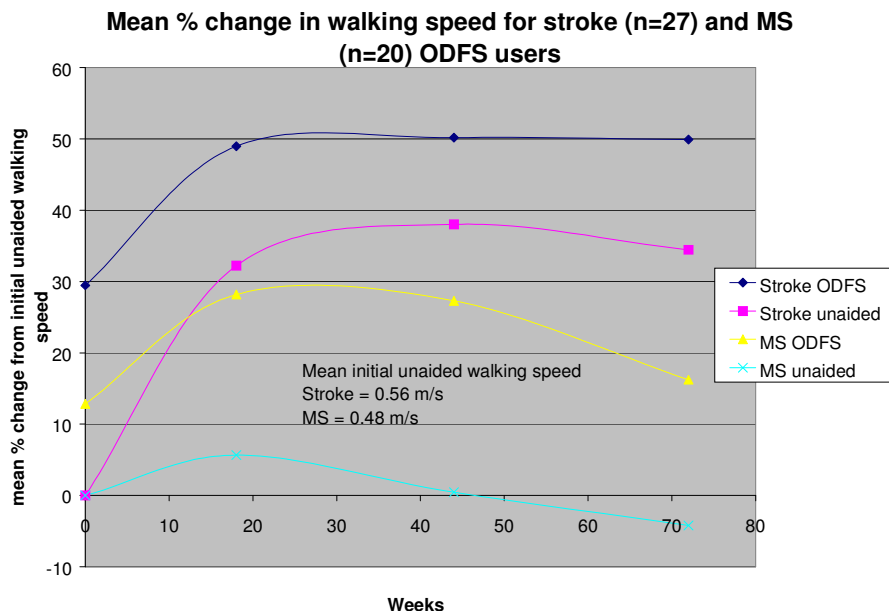
The ODFS's main application is as a long term mobility aid. However the ODFS can also be used in gait re-education following stroke and spinal cord injury. Typical minimum ability to use the ODFS is to be able to stand from sitting unaided and walk 10m or more with appropriate aids or assistance from another person.



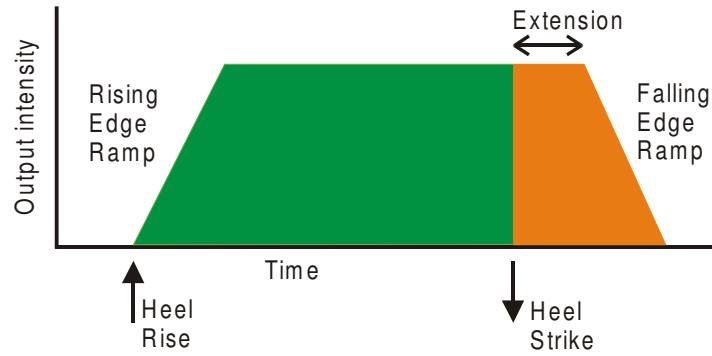
Clinical Evidence

The ODFS was subject of a randomised controlled trial (RCT) that showed that chronic stroke patients walked 16% faster with the device with a reduction of physiological cost index (an estimate of the effort of walking) of 29%¹. The FES group also showed a reduction in quadriceps spasticity and a reduction in anxiety and depression. QALY analysis (Quality Adjusted Life Years) indicated a significant positive cost / benefit from the treatment². The trial results together with case series data from subjects who had MS, were presented to the South and West Regional Health Authority Development and Evaluation Committee³ who recommended the ODFS for use in the UK's National Health Service for patients with upper motor neurone lesions (1996).

A subsequent audit of clinical service over the first 18 weeks of use confirmed the results of the original RCT and also showed a significant training effect i.e. an improvement in walking ability when not using the stimulator, in a group of 111 stroke subjects⁴. Overall, users walked 27% faster when they used the device with a training effect of 14%. In a subgroup of 27 ODFS users walking speed both with and without the device was observed to improve over the first 18 weeks and thereafter remain unchanged. As the ODFS users were an average of 5.4 (sd ± 10.7) years post stroke, this supports the hypothesis that the training effect observed was due to the use of the stimulator rather than natural recovery following the stroke. In a group of 78 MS subjects, users walked 20% faster when using the device⁵. However, no training effect was observed. In a subgroup of 20 MS users, this improved walking speed with the device was shown to also peak at 18 weeks with no significant change from initial values after that time, indicating the ODFS is an effective orthotic device.

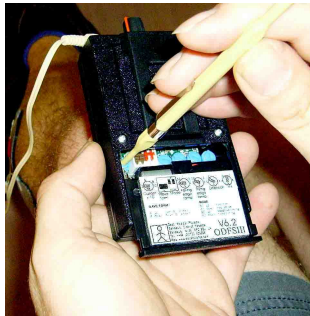
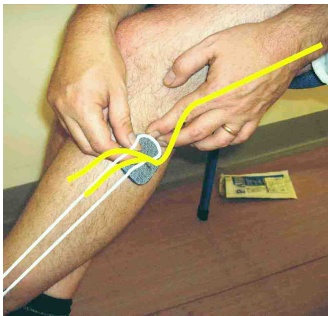


A questionnaire survey indicated that the most common reasons for using the ODFS were that it reduced the effort of walking, reduced tripping and improved confidence while walking⁶. Compliance with treatment was 92% at 18 weeks and 86% at 1 year⁷. In the year 2000 the device was recommended by the Royal College of Physicians in their publication "National Clinical Guidelines on Stroke"⁸.



Features

- Output: Asymmetrical or symmetrical biphasic voltage driven waveform.
- Output amplitude: 20 to 100 mA asymmetrical biphasic output
20 to 80 mA symmetrical biphasic output
- Frequency: 40 Hz.
- Pulse width: 7 to 365µs.
- Output time: 0.2 to 6 s.
- Extension time: 0 to 1.2 s
- Rising edge ramp time: 0 to 2 s.
- Falling edge ramp time: 0 to 2 s.
- Flexible triggering: Heel rise or heel strike (foot switch on contralateral side)
Adaptive or fixed timing
- Intelligent footswitch: The sensitivity adapts to the weight of the user.
- Controls: Easy to use amplitude control, test and pause switches
- Low battery indication
- Battery: PP3, standard 9V alkaline or rechargeable battery
- Weight (with battery): 143gm
- Dimensions: 95 x 61 x 26 mm (excluding controls and belt clip)
- Approvals: CE marked and FDA approved.



ODFS users comments

'The stimulator has become a necessary part of me and makes my life a lot easier. I don't avoid walking now and I feel far more confident. I haven't fallen using the stimulator, so it's taken the fear of doing a lot of damage away. I'm now starting to widen my scope of activity quite dramatically. In fact, I think it is a fabulous improvement and I'm delighted with it.'
K. D. 11th May 2004

'I would say that with the stimulator it's half the effort to walk. I find I enjoy things more and I am far more conscious of where I am because I do not have to think about getting my foot in front of the next one all the time. It gives me more freedom and more independence. I've even gone for a walk by myself. It's certainly nice to be back in the real world again.'
G. M. 14th April 2004

O2CHS - Odstock® Two Channel Stimulator



The O2CHS is a 2 channel foot switch controlled stimulator designed to assist dropped foot and other gait problems following an upper motor neurone lesion. It has the same facilities as the ODFS with additional features to control the interaction of the two channels. The following combinations of muscles can be stimulated:

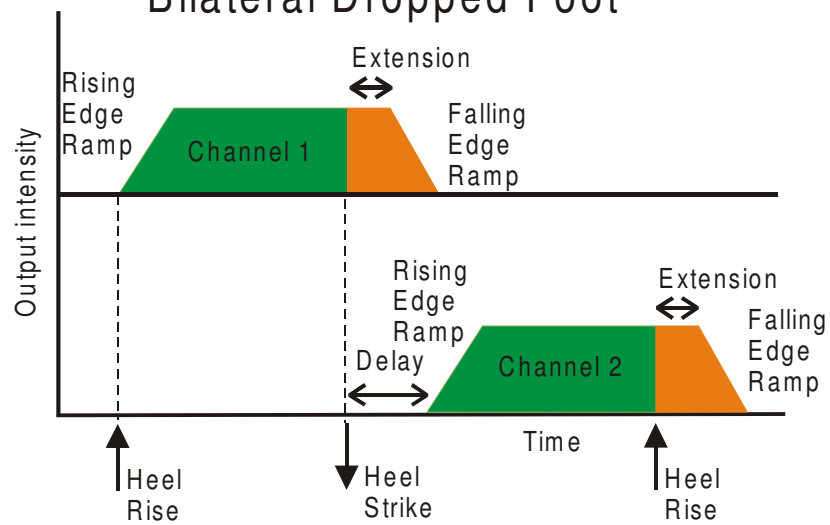
| Stimulated muscles /groups | Conditions | Problem addressed |
|--|--------------------|--|
| Bilateral dorsiflexion | MS, FSP and CP | bilateral dropped foot |
| Dorsiflexion with hamstrings | Stroke and MS | Dropped foot with reduced knee flexion |
| Dorsiflexion with gluteal muscles | Stroke and MS | Dropped foot with hip flexion / adduction in stance |
| Dorsiflexion with quadriceps | Incomplete SCI | Dropped foot with quadriceps weakness |
| Dorsiflexion with calf muscles | Stroke, MS, CP etc | Dropped foot and lack of push off in terminal stance |
| Dorsiflexion with triceps / deltoid | Stroke. | Dropped foot with strong associated reaction in the upper limb |
| Bilateral erectispinie / gluteal muscles | SCI, FSP | Trandelenburg gait |
| Bilateral quadriceps | SCI, FSP | Quadriceps weakness |

The timing of muscle activation can be adjusted so that a contraction can occur as weight is transferred on or off a footswitch or set to occur at other times in the gait cycle by adding a delay following a footswitch transition. The device is used as an orthotic aid, replacing conventional splinting and also as a training device assisting gait re-education.

Clinical Evidence

The most common use for the O2CHS is for correction of bilateral dropped foot. An audit of 18 people with MS showed that walking speed increased by a average of 48% with the device after 18 week use⁷. A second audit of stroke and MS patients using gluteal muscle stimulation with common peroneal stimulation demonstrated further increases in walking speed when the hip extensors were added⁹. Gains in walking speed was also demonstrated when knee flexors or plantaflexors were added to common peroneal stimulation¹⁰.

Bilateral Dropped Foot



Features

| | |
|--------------------------|--|
| Output: | Asymmetrical or symmetrical biphasic voltage driven waveform. |
| Output amplitude: | 20 to 100 mA asymmetrical biphasic output, 20 to 80 mA symmetrical biphasic output. |
| Frequency: | 20 to 60 Hz. |
| Pulse width: | 7 to 365 μ s. |
| Output times: | 0.2 to 6 s. |
| Extension times: | 0 to 1.2 s |
| Delay time (Ch. 2 only) | 0 to 2 s |
| Rising edge ramp times: | 0 to 2 s. |
| Falling edge ramp times: | 0 to 2 s. |
| Flexible triggering: | Heel rise or heel strike Adaptive, fixed timing or no time out |
| 1 or 2 footswitches: | Can be controlled by 1 or 2 foot switches. |
| Intelligent footswitch: | The sensitivity adapts to the weight of the user. |
| Controls: | Easy to use amplitude controls, test and pause switches |
| Low battery indication | |
| Battery: | PP3, standard 9V alkaline or rechargeable battery |
| Weight (with battery): | 200gm |
| Dimensions: | 125 x 70 x 26 mm (excluding controls and belt clip) |
| Approvals: | CE marked |



MS2V2 - Odstock® Microstim 2V2



The Odstock® Microstim 2V2 is a general purpose neuromuscular stimulator designed specifically for use in neurological rehabilitation. The device has 10 modes of operation providing combinations of parameters suitable for a range of treatments. It is designed to be simple to use with the minimum necessary user controls. The output stimulation intensity is ramped at the beginning and end of each cycle by pulse width modulation to produce a comfortable sensation. The device's simplicity makes the MS2V2 ideal for home use for regular exercise. Applications include:

- Strengthening weak or paralysed muscle¹¹
- Re-education of movement following stroke^{12, 15}
- Reduction of shoulder subluxation and associated pain^{8, 13}
- Control of spasticity¹¹
- Increase muscle bulk¹⁴
- Increase local blood circulation¹⁴
- Retraining of muscles following tendon transfers¹¹
- Adjunct to botulinum toxin treatment¹⁶
- Adjunct to splinting treatment
- Preparation for the ODFS / O2CHS⁷

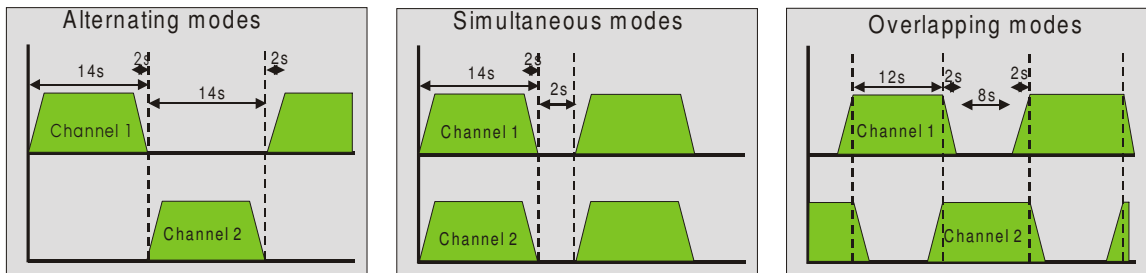
Stimulation modes

| Mode | Frequency (Hz) | Action | Ramp (s) |
|------|----------------|--------------|----------|
| 0 | 40 | Alternate | 6 |
| 1 | 40 | Simultaneous | 6 |
| 2 | 20 | Continuous | - |
| 3 | 20 | Alternate | 2 |
| 4 | 20 | Simultaneous | 2 |
| 5 | 40 | Continuous | - |
| 6 | 40 | Alternate | 2 |
| 7 | 40 | Simultaneous | 2 |
| 8 | 40 | Overlapping | 2 |
| 9 | 20 | Overlapping | 2 |

Other parameters available on request.

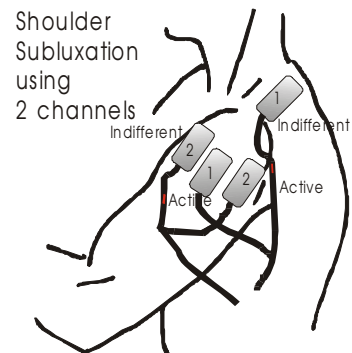
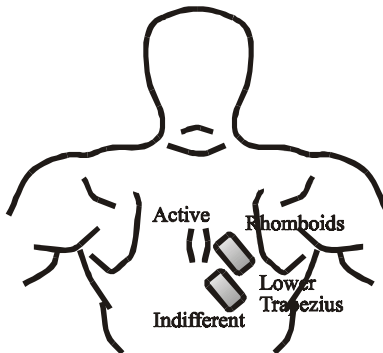
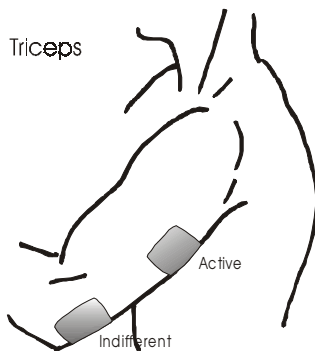
Alternate: Channel 1 ramps up, holds at its maximum and then ramps down. Channel 2 begins to ramp up once channel 1 has ramped down, holds at it's maximum and then ramps down. The sequence then repeats. Intended for exercising complementary pairs of muscle such as flexors and extensors or bilateral muscle groups

- Simultaneous:** Both channels ramp up, hold at the maximum and then ramp down. There is then a gap before the sequence repeats. This is intended to exercise synergistic muscles
- Overlapping:** This is a variation on Alternate designed for subluxed shoulder. Channel 1 ramps and holds as before but channel 2 begins ramping before channel 1 starts to ramp down. Channel 1 begins ramping down once channel 2 reaches its maximum. This is intended for exercising two parts of the deltoid muscle while maintaining the humerus bone in the glenoid humerus socket.
- 20Hz Low frequency for reduced muscle fatigue
- 40Hz Fast frequency for smooth comfortable contraction where fatigue is not an issue or a reflex response is required
- 2s ramp For general exercise
- 6s ramp For very high tone patients it provides a gradual contraction that will reduce velocity dependent stretch reflexes. Also used when the patient is hypersensitive to the sensation of stimulation

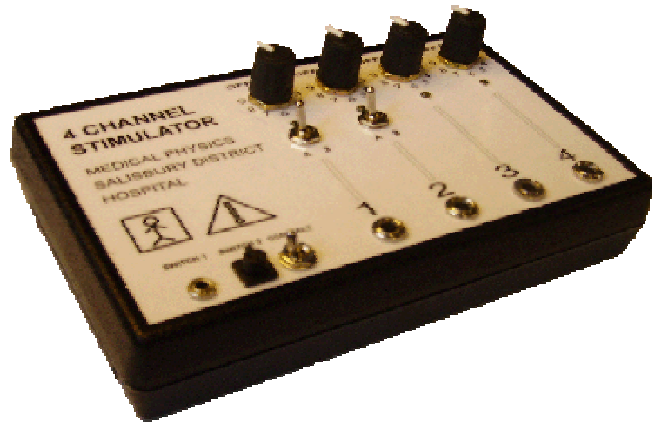


Additional parameters

- Wave form: Asymmetrical biphasic voltage driven
- Output current: 0 - 100mA
- Pulse width: 300µs
- Low battery indication
- Battery: PP3, standard 9V alkaline or rechargeable battery
- Weight (with battery): 165gm
- Dimensions: 125 x 70 x 26 mm (excluding controls)
- Approvals: CE marked



O4CHS – Odstock® 4 Channel Exercise Stimulator



The Odstock® Four Channel Stimulator is a neuromuscular stimulator intended for the exercise of weak or paralysed muscle. It is designed to be simple to use with facilities to vary exercise parameters. The output can be ramped at the beginning and end of each cycle to give a comfortable sensation and prevent stretch induced spasticity. Powered by a standard 9V battery, the unit is intended for home use to allow regular exercise. An optional accessory allows control of the stimulator using a foot pedal or hand switch. Applications include:

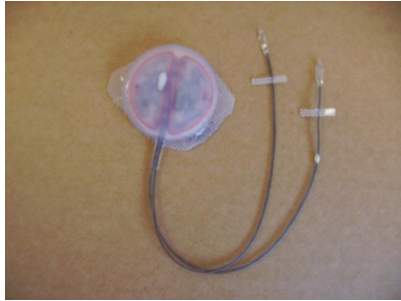
- Strengthening weak or paralysed muscles¹¹
- Re-education of movement following stroke^{12, 15}
- Control of spasticity¹¹
- Increase muscle bulk¹⁴
- Increase local blood circulation¹⁴
- Retraining of muscles following tendon transfers¹¹
- Adjunct to botulinum toxin treatment¹⁶
- Adjunct to splinting treatment
- Preparation for the ODFS / O2CHS⁷
- FES rowing

Features

| | |
|------------------------|---|
| Output: | Asymmetrical voltage driven waveform. |
| Output amplitude: | 20 to 115 mA |
| Frequency: | 12 to 50 Hz |
| Pulse width: | 100 to 450µs |
| Period times: | 12 to 60 s (total cycle time including on time, off time and ramps) |
| On times: | 1 to 12 s |
| Ramp times: | 0 to 9 s |
| Operation Modes | Continuous output 2 channels alternate with 2 channels 3 channels alternate with 1 channel 4 channels alternate with a rest period |
| External control | Remote hand switch to switch pairs of channels Pulse width control using foot pedal |
| Battery: | PP3, standard 9V alkaline or rechargeable battery |
| Weight (with battery): | 230gm |
| Dimensions: | 146 x 92 x 32 mm (excluding controls) |
| Approvals: | CE marked |

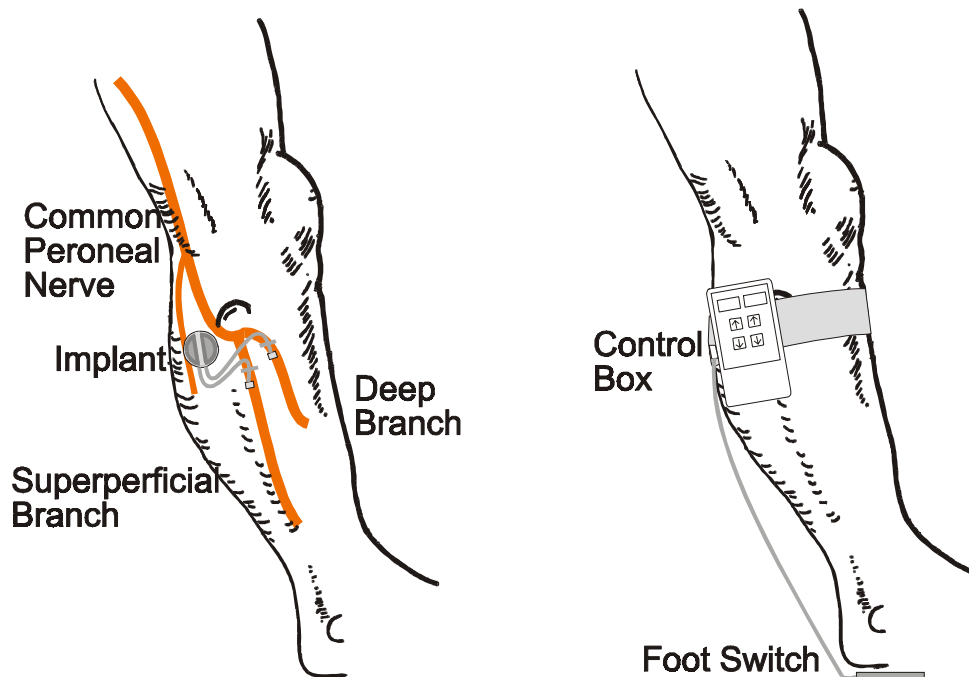
STIMuSTEP Implanted Dropped Foot Stimulator

UK distributor for
Finetech Medical Ltd



The STIMuSTEP is an implanted neuromuscular stimulator intended for the correction of dropped foot following an upper motor-neurone lesion. While providing the same function as the ODFS, the device removes the need to accurately place electrodes each day, reduces the sensation of the stimulation and improves the convenience for the user. The rise and fall of the stimulation can be adjusted to prevent a sudden contraction that might induce a stretch reflex of the calf muscles. There are also facilities to add an extension to the stimulation envelope after heel strike, mimicking the natural activity of the anterior tibialis muscle, which contracts eccentrically to lower the foot to the ground and stabilises the ankle at initial contact.

The device stimulates the two branches of the common peroneal nerve using electrodes inserted into the epineurium of each nerve. The deep branch supplies



the tibialis anterior (TA), extensor hallucis longus (EHL), extensor digitorum longus (EDL) and peroneus tertius (PT) muscles. These muscles produce dorsiflexion with weak inversion. The superficial branch supplies the peroneus longus/brevis (PL, PB) and sometimes extensor digitorum brevis (EDB) These muscles produce eversion and weak plantarflexion. By carefully controlling the stimulation to each nerve, a movement of dorsiflexion with eversion can be achieved^{17, 18, 19}.

The device is powered and controlled using close coupled telemetry from a transmitter box worn directly over the implant. Stimulation begins at heel rise and continues until heel strike, controlled using a heel switch. The STIMuSTEP is implanted under general anaesthetic in day surgery procedure taking approximately 1 hour.

Dorsiflexion and eversion in swing phase of gait produces:

- Improved ground clearance
 - Reduced tripping and falls
 - Reduced compensatory activity
 - Reduced effort of walking
 - Reduced spasticity
 - Increased walking speed
- Heel strike with eversion
 - improved loading response
 - greater stability in stance
- Greater range of mobility
- Greater safety, confidence and independence while walking
- Greater social interaction and improved quality of life

Features

| | |
|-------------------------|---|
| Output: | Capacitively coupled symmetrical waveform |
| Implant: | Passive, inductively coupled at 1MHz and 2 MHz |
| Electrodes: | Epineural 1mm diameter PIIr electrodes 5mm separation |
| Output amplitude: | Two levels approximately 1mA max |
| Frequency: | 30 Hz. |
| Pulse width: | 0 to 300µs in 3 µs steps. |
| Output time: | 0.1 to 9.9 s in 0.1 s steps. |
| Extension time: | 0 to 9.9 s in 0.1 s steps. |
| Rising edge ramp time: | 0 to 9.9 s in 0.1 s steps. |
| Falling edge ramp time: | 0 to 9.9 s in 0.1 s steps. |
| Controls: | Menu driven using navigation buttons |
| Low battery indication | |
| Battery: | Internal rechargeable battery |
| Weight: | 78gm |
| Dimensions: | 85 x 46 x 16 mm |
| Approvals: | CE marked |



Clinical Service

Odstock Medical provides a comprehensive clinical FES service for both NHS and privately funded clients. Services are provided at the National Clinical FES Centre in Salisbury and also at an out reach clinic in Glasgow. Access to the service is by GP or Medical Consultant referral and referrals are received from all over the UK and beyond. Current services include:

Correction of dropped foot using the ODFS

Correction of more complex gait problems using the O2CHS

Correction of dropped foot using the STIMuSTEP

Reduction of shoulder subluxation following stroke using the MS2V2

Retraining of upper limb function using the MS2V2 and the O4CHS

Maintenance of skin and muscle condition for prevention of pressure sores following SCI using the O4CHS

Provision of specialised custom FES interventions for specific problems

If you would like Odstock Medical to provide a clinical service or would like help in establishing your own clinic, please contact us. For other centres providing a clinical service using Odstock® devices and techniques, please contact us or visit www.odstockmedical.com

Research and clinical assessment

Odstock® Medical continues to develop and assess new FES techniques. The team of Engineers and Clinicians work with partners from academia and industry to bring new ideas to clinical realisation and then through the regulatory process to market. The team has considerable experience at planning and executing clinical trials and clinical assessment of assistive technology. We are always keen to develop new collaborations in the field of FES development.



The Accredited User System

To ensure that patients receive the best from Odstock devices, it is mandatory that all clinicians receive training in the use of the ODFS or the O2CHS before they use it with their patients. Odstock® Medical provides training courses for its devices and maintains a list of all clinicians that are trained. Odstock® Medical does not provide either device to a clinician whose name is not on the accredited user list.

FES Training Courses

FES courses are held at the National Clinical FES Centre in Salisbury and also at other centres on request. All courses are followed by a 2 month loan of the equipment used on the course. Please check our web page www.odstockmedical.com for an up to date list of courses and venues. If you would like a course to be held at your own centre, please contact us.

Introduction to FES and the ODFS.

This 2 day course provides the essential neurology and theory for FES and explains the application of the ODFS and MS2V2. The course has a large practical element with participants practising using the devices on themselves and with patient volunteer. This course is mandatory before the ODFS can be purchased. A version of this course is also offered for those with a speciality in paediatrics.

Introduction to the O2CHS

This 1 and 1/2 day course teaches the essentials of the O2CHS. Participants should have experience of the ODFS before attempting this course. Like the ODFS course there is a large practical element with participants practising using the devices on themselves and with patient volunteer. This course is mandatory before the O2CHS can be purchased.

Introduction to electrical stimulation of the upper limb

This 1 day course teaches the application of the MS2V2 for therapeutic exercises of the upper limb following stroke and tetraplegia. The course covers essential neurophysiology and the theory of neuroplasticity. Use of the device is taught and it's application practised on the course participants and patient volunteers.

STIMuSTEP

Training is provided for surgeons and other clinicians in the implementation of the STIMuSTEP system. Training is organised around STIMuSTEP implantations enabling teams to observe all aspects of the procedure. Teams will also receive training in the ODFS as this device is used in the assessment and training of STIMuSTEP users.

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Contact Details:

ODSTOCK[®] MEDICAL LIMITED

The National Clinical FES Centre

Salisbury District Hospital,

Salisbury, Wiltshire,

SP2 8BJ, United Kingdom

Tel +44 (0) 1722 429065

Fax +44 (0) 1722 425263

www.odstockmedical.com

enquiries@odstockmedical.com



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