CLINICIAN'S INSTRUCTION MANUAL
Odstock Dropped Foot Stimulator

Model: ODFS® Pace V1

Model: ODFS® Pace XL V1

Software: V1.4

The output of this device has a physiological effect.

The device must be set up by a person who has been trained in the use of FES.

This instruction manual is intended for the clinician only.

The clinician should ensure that the separate user instruction manual is issued to the end user.

Read the instructions and precautions before use.

USA only: Rx Only

...a confident choice

OML Leading FES Rehabilitation

NHS Salisbury

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Intended Use

Intended Use Statement

The Odstock Dropped Foot Stimulator ODFS® Pace and its wireless version ODFS® Pace XL are intended to be used for the alleviation of neurological injury or handicap due to upper motor neurone disease, injury or disfunction, including but not limited to stroke, multiple sclerosis, incomplete spinal cord injury (T12 and above), head injury, cerebral palsy, Parkinson's disease and hereditary spastic paraparesis.

The primary medical indication of ODFS® Pace and ODFS® Pace XL devices is the treatment and correction of dropped foot due to neurological conditions. The devices can be used as an alternative or adjunct to orthotic devices or other walking aids, or to provide a longer-term therapeutic effect.

Other movement deficits can be addressed by stimulation of additional muscle groups, singularly or in conjunction with the correction of dropped foot, for the purpose of functional movement training and / or gait assistance.

ODFS® Pace and ODFS® Pace XL devices are also intended to be used for muscle strengthening, reduction in muscle spasms, increase range of movement, alleviation of oedema, increase in local blood flow and promotion of neuroplasticity by modulating the central nervous system.

Intended Users and Use Environment Statement

ODFS® Pace and ODFS® Pace XL devices are intended to be used both by patients and clinicians and are designed for use in home healthcare / residential and hospital / healthcare environments.

The devices must be fitted and configured to be appropriate for each patient's needs by qualified and trained clinical staff.

Intended Patient Population Statement

ODFS® Pace and ODFS® Pace XL can be used by both adults and paediatric individuals and are primarily intended for patients whose walking is affected due to nerve damage, disease or disfunction in the spine or brain, but have remaining lower motor neurone function. This includes but is not limited to stroke, MS (Multiple Sclerosis), Spinal cord injury, FSP/HSP (Familial or Hereditary Spastic Paraparesis, CP (Cerebral Palsy), head injury and Parkinson's disease.

In addition to drop foot, the devices are also intended for people with deficits in knee flexion or extension, hip extension and abduction and push off at terminal stance. Finally, ODFS® Pace devices can be used by patients to strengthen and / or control other muscles used in gait such as but not limited to, hamstrings, quadriceps, gluteal and calf muscles or for arm swing

Intended Use

Clinical Benefits Statement

Use of the ODFS Pace (XL) may:

- improve the safety of walking, demonstrated by the reduction of the incidence of falls,
- improve the quality of walking demonstrated by increased walking speed when FES is used,
- reduce the effort of walking, demonstrated by reduced oxygen consumption, physiological cost index and Borg rate of perceived effort scale,
- improve health related quality of life, demonstrated by patient reported outcome measures,
- have a training effect, improving walking ability with out the device, after the device has been used for an extended period, demonstrated by increased walking speed.

Introduction

The Odstock Dropped Foot Stimulator Pace (ODFS® Pace) is a single channel, footswitch controlled stimulator designed to correct dropped foot in upper motor neurone conditions. These conditions include but are not limited to, stroke, multiple sclerosis, incomplete spinal cord injury (T12 and above), head injury, cerebral palsy, Parkinson's disease and hereditary spastic paraparesis.

The ODFS® Pace (XL) can be used in two ways. Firstly, it is an assistive device, improving mobility at home and in everyday life. In this instance the device user will be taught how to use the device without the direct supervision of the clinician. Secondly, it can be used as a training device for use in the clinical setting, where greater clinical supervision may be appropriate.

Two versions of the device are available; the ODFS® Pace, which uses a wired footswitch and the ODFS® Pace XL, which operates using either a wireless (radio telemetry) footswitch or a wired footswitch. Both devices allow flexible electrode positioning and can be worn on a leg strap, belt clip or carried in a pocket.

Skin surface electrodes are typically placed over the common peroneal nerve as it passes over the head of the fibula and over the motor point of the tibialis anterior. Stimulation produces dorsiflexion and eversion of the foot and in certain electrode configurations produces a withdrawal reflex, adding knee flexion and hip flexion. Electrical stimulation feels like "pins and needles" and most patients quickly become used to the sensation.

The ODFS® Pace (XL) has a comprehensive set of stimulation parameters that allow it to be applied across a broad set of clinical presentations. While the clinician can choose any combination of parameters, easy to use default settings can be used for most applications, requiring only a little fine tuning for each patient.

The ODFS® Pace (XL) is also designed for more general rehabilitation use. An exercise mode provides cyclic stimulation for muscle conditioning prior to walking or strengthening other muscle groups. Stimulation programmes are also provided for early gait re-training of other muscle actions such as knee flexion/extension and push-off in terminal stance.

The ODFS® Pace (XL) has a facility for data logging, enabling patient progress and adherence to be monitored.

The ODFS® Pace (XL) must only be set up by a person who has been trained in the use of FES. The clinician should also review the use of the device regularly. Odstock Medical Limited recommend that this is done soon after set-up (usually within a week), 6 weeks later, 3 months after that and then in 6 months and at least annually for as long as the device is used.

Further details about training courses for Clinicians are available at https://odstockmedical.com/healthcare-professionals/Training-courses

FES for Dropped Foot

By provision of dorsiflexion and eversion, the foot clears the ground in the swing phase of gait more easily. This increases safety and speed, and also reduces the effort of gait, reducing compensatory mechanisms such as hip hitching and circumduction. Reduction in effort can lead to a reduction of associated reactions and result in a general lowering of spastic tone.

Safety in weight bearing is also improved because initial floor contact is made with the heel and then loading is along the mid-line of the foot, correcting the tendency to weight bear on the lateral border.

Contraction of the tibialis anterior muscle and the hamstrings via the withdrawal reflex may, by reciprocal inhibition, reduce antagonist activity in the calf and quadriceps muscle groups leading to a more normal modulation of tone. Repeated use of the stimulator may, by long term potentiation of the required pattern of synapse activity in the spinal cord and brain, lead to the pattern of more “normal” movement being relearned.

However, a more immediate benefit from the orthotic use of the device is that walking is easier and safer and therefore confidence is increased, leading to an extension of mobility range and an overall improvement in quality of life.

Residual Risk

Even though Odstock Medical Limited have taken all foreseeable steps, through design and testing, to ensure this device is safe and reliable, there remains a small risk of stimulation not being delivered when required.

Adverse Reactions

The patient should report any undesirable outcomes, malfunctioning of the device, mistakes in using the device, or injury from the use of this device to the clinician who provided it to them.

The clinician is responsible for reporting this feedback to Odstock Medical Limited or their local representative.

Serious Incident Reporting

If you experience any serious incident related to the use of the ODFS® Pace (XL), please report it immediately to us, the manufacturer, and also notify the competent authority in the Member State in which you, the user or patient, are established.

Patient Selection for Dropped Foot

Cause of functional deficit:

Neurological deficit due to an upper motor neurone lesion. An upper motor neurone lesion is defined as one that occurs in the brain or spinal cord at or above the level of T12. This is often but not exclusively associated with spasticity.

Upper motor neurone lesions resulting in dropped foot can occur in conditions such as, but not limited to stroke, multiple sclerosis, incomplete spinal cord injury (T12 or above), cerebral palsy, familial/hereditary spastic paraparesis, head injury and Parkinson's disease.

For FES to have an effect, the lower motor neuron must be intact. The common peroneal nerve and the muscles it connects to must have remaining function.

Nature of functional deficit:

Dropped foot is defined as a deficit of dorsiflexion and/or eversion of the ankle. While this will be frequently associated with lack of heel strike, FES can be successfully used to correct inversion at first contact to significantly improve the stability of the ankle in the stance phase, improving the safety of gait.

Functional ability:

- Able to passively achieve a neutral angle of the ankle. A resistance due to spasticity of the calf muscles can be overcome but stimulation will not provide any benefit for those people with a fixed contracture.
- Able to stand from sitting, without assistance from another person. Use of aids such as sticks, frame or crutches is acceptable.
- Able to walk a minimum distance of about 5m unaided or with use of aids such as an ankle foot orthosis (AFO), sticks, frame or crutches.
- A reasonable exercise tolerance is required for treatment sessions. However, FES often reduces the effort of walking therefore poor exercise tolerance is only an exclusion criterion in extreme cases.
- There is no maximum walking distance limit. FES devices have been successfully used in cases where a dropped foot only becomes a significant problem when the patient is tired or when the deficit is relatively mild.

Patient Selection for Dropped Foot

Factors affecting stimulation

- Patients with oedema or large amounts of subcutaneous tissue have an increased distance between the electrode and the nerve, and may require higher stimulation intensity in order to achieve a muscle contraction. This may be uncomfortable.
- Poor skin condition can make stimulation difficult as this may affect electrical conduction and skin tolerance to the electrodes.

Motivation, understanding and independence

- The patient should be able to understand the aims of the treatment and be motivated to adhere to treatment protocols. Where appropriate, carer support can assist in using the equipment.
- Where patients live alone and do not have carer assistance, they must be able to place electrodes and operate the equipment independently. If family or carer support is present, less independence may be required.

Use of ODFS® Pace (XL) in gait training

The ODFS® Pace (XL) can be used in early gait re-education. The selection requirements are as above but a general lower level of mobility and independence may acceptable if more clinical support is available.

Clinical Procedure for Dropped Foot

Patients are first assessed against the selection criteria listed previously and the contraindication list. The device is then tried. If an improvement in gait is achieved then treatment can commence.

Once a good set-up has been achieved, the patient will be taught how to use the device and shown how to place the electrodes by their clinician. It is often useful to also teach family members or care givers so assistance can be offered by them at home. Proper training in the use of the device is key to its successful use. The patient is then seen in clinic again within a week and their ability to use the device is checked. Any additional instruction required is given and outcome measures taken. The stimulator settings are also recorded on the clinical settings form from the parameter view mode on page 42. Clinical settings and other clinic forms are available at http://www.odstockmedical.com.

The patient is followed up at 6 weeks, after a further 3 months, a further 6 months and then yearly or 6 monthly for as long as the device is used.

The patient should be encouraged to contact the clinic if they experience any problems with the device or its use. Prompt response to problems will ensure the best outcome from the treatment.

The clinician shall brief the user on any known contraindications and warnings to the use of this system and any precautions to be taken. The clinician shall issue and guide the user through the User Instruction Manual.

Contraindications

The ODFS® Pace (XL) should not be used on those who have a cardiac pacemaker, implanted defibrillator, or other electronic implanted device unless investigations demonstrate that there is no interaction between the devices.

Warnings

Neck stimulation

Stimulation should not be applied over the neck, because severe spasm of the muscles may occur and the contractions may be strong enough to close the airway or cause difficulty breathing. Stimulation over the neck (especially the carotid sinus) could have adverse effects on heart rhythm or blood pressure.

Open or infected wounds

Stimulation should not be applied over open wounds or over swollen, infected or inflamed areas or skin eruptions. Stimulation should only be applied to normal, intact, clean skin. Dilated capillaries and movement caused by moving muscles may disrupt healing tissue.

Cancer

Stimulation should not be applied over, or in proximity to, cancerous tissues as increased local blood flow may increase tumour growth.

Electronic monitoring equipment

Stimulation should not be applied in the presence of electronic monitoring equipment, such as cardiac monitors and electrocardiogram alarms. Monitoring equipment may not operate properly when the electrical stimulation device is in use.

Transcerebral stimulation

The effects of stimulation of the brain are unknown. Therefore, stimulation should not be applied across the head and electrodes should not be placed on opposite sides of the head, directly on the eyes or covering the mouth.

Strangulation

There is a risk of strangulation with the wires of the system. Do not place leads around the neck. Use an appropriate length of lead.

Chest stimulation

Stimulation should not be applied between the chest and upper back, crossing over the heart, because the introduction of electrical current into the chest may cause rhythm disturbances to the heart, which could be fatal.

Epilepsy

Users with suspected or diagnosed epilepsy should follow precautions recommended by their physicians. The ODFS® Pace (XL) should not be used by people who have poorly controlled epilepsy. Users should be at least 3 months clear of fits.

Choking

Small parts of the system could be a choking hazard.

Sleeping

Do not use the stimulator whilst sleeping.

Batteries

Only use batteries, chargers and power supplies recommended by Odstock Medical Limited. All battery technologies carry a very small risk of explosion if used incorrectly. Do not use or recharge a battery if it is damaged or swollen in any way. Do not charge non-rechargeable batteries.

Ensure you follow the instructions for installing, using, storing and disposing of the battery (please refer to instructions for use accompanying the battery charger).

Do not touch the terminals of the battery or battery charger.

Do not charge (rechargeable batteries only), operate or store batteries outside of their specified temperature ranges.

Do not short circuit the battery. Doing so may lead to excessive heat and possible burns.

When transporting batteries cover the terminals with tape or other non-conductive material to prevent the terminals electrically shorting.

Please refer to battery specification on page 93 of this instruction manual.

High frequency surgical equipment

Simultaneous connection to high frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.

Oxygen rich environments

Do not use stimulation within oxygen rich environments such as a hyperbaric oxygen chamber or in close proximity to an oxygen mask.

External orthopaedic metal fixation

Stimulation should not be applied in the area of exposed orthopaedic metal work.

Latex allergies

The Pace Sleeve contains Lycra which may contain natural rubber latex which may cause allergic reactions. This item is provided as an accessory to the ODFS® Pace (XL) and is not required for use. Do not use if sensitive to products that contain latex.

Flammability

Do not use the stimulator near flammable fuels, fumes or chemicals. Do not use flammable cleaning products to clean the device.

Electromagnetic emissions

Use of accessories, transducers and cables other than those specified or provided by Odstock Medical Limited could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ODFS® Pace (XL) including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

MRI Compatibility

The ODFS® Pace (XL) is not MRI compatible and patient harm and device damage may result if the device is worn during an MRI exam or enters the MRI environment. Remove the device and all accessories prior to entering the MRI environment.

Important Information

Exposed electrode pins

Ensure that the pins of the electrode wire are fully inserted into each electrode before use.

Skin irritation

Some people may experience skin irritation due to electrical stimulation or from the electrodes. The irritation can usually be reduced by using an alternative type of electrode, different device settings or a new electrode position. A slight reddening of the skin under the electrodes is normal and this should clear within 1 hour of stopping stimulation. If stimulation causes long term marking of the skin, the user should discontinue use and contact their clinician. Please refer to electrode care on page 50 of this instruction manual.

Skin care

Do not shave the skin under the electrodes. If long hairs require removal, cut the hairs using scissors. If skin moisturisers are required, use overnight and remove residue using warm water with a mild soap before applying electrodes in the morning.

Prevention of pressure sores.

Users should check the integrity of their skin that is in contact with the electrodes, lead, footswitch or stimulator, each time the device is used. If pressure marking occurs, remove the cause of the pressure and recommence use once the skin marking has cleared.

Spasticity

If stimulation causes increased spasticity (involuntary, exaggerated muscle stiffness and spasms), the user should discontinue use and consult their clinician.

Machinery operation and driving

Stimulation should not be used when driving, operating machinery, or during any activity in which electrical stimulation could distract or put the user at risk of injury.

Bathing/showering/swimming

Do not use stimulation in the bath, shower or when swimming.

Water ingress

Do not get the stimulator or any part of the system or accessories wet. Water ingress may stop the stimulator or accessories working. If submerged, remove battery (if present), dry out thoroughly and return to Odstock Medical Limited for assessment. If liquid is spilt on the stimulator, remove battery and dry out thoroughly prior to re-use.

Shortwave and microwave therapy

Do not use in close proximity (e.g. 1m) to a shortwave or microwave therapy medical equipment as it may produce instability in the stimulator output.

Autonomic dysreflexia

Users who have high level spinal cord injuries (T6 and above), may experience symptoms of autonomic dysreflexia (increased blood pressure or sweating) in response to stimulation. This may also be seen in users with multiple sclerosis. If affected, the user should discontinue use and consult their physician.

Cardiac/exercise stress

Users with suspected or diagnosed heart disease should follow the exercise precautions recommended by their physician.

Deep vein thrombosis

Users with suspected or diagnosed deep vein thrombosis should follow the exercise precautions recommended by their physician.

Injury, fracture or surgery

Electrical stimulation should not be carried out in areas of the body affected by recent injury, fracture or surgery. Movement caused by moving muscles may disrupt healing.

Pregnancy

The safety of using electrical stimulation during pregnancy has not been established.

Prescribed user

The device should only be used by the user that the system has been prescribed for. Keep out of reach of non-intended users. Only use as instructed by the clinician.

Long-term effects

The long-term effects of electrical stimulation are unknown. Odstock devices have been successfully used by individuals for over 20 years.

Air travel/wireless restricted area

Like all radio telemetry devices the ODFS® Pace XL should not be used in wireless transmission mode in areas where use of wireless devices is restricted. In areas of restriction the ODFS® Pace XL can be used in airplane mode, with a wired footswitch. Please refer to accessory user instructions for details of use within wireless restricted areas. Please refer to airplane mode on page 31 of this instruction manual

Accessories and consumables

Only use accessories and consumables recommended by Odstock Medical Limited. Do not connect with equipment other than that intended to be used with this system as defined within this instruction manual or that of the other equipment.

Battery change and battery cover

Do not operate the stimulator with the battery cover removed. Disconnect all the leads prior to opening the battery cover. The clinician/carer should not be in contact with the user when changing the battery.

Equipment modification

Do not tamper with or modify the equipment.

Shelf life

Do not use the consumables if they have passed their expiry date.

Equipment re-use

Electrodes, Pace sleeve and insoles are single patient use only. If re-using other parts of the system ensure a thorough clean using anti-bacterial wipes.

Storage temperature

Do not store outside of the temperature limits as detailed in the specification on page 93. If the ODFS® Pace (XL) or accessories (excluding electrodes) have been stored at the minimum (-20°C) or maximum (70°C) storage temperatures, allow at least 10 minutes in ambient temperature before use. This time may be required following system removal from cold storage for the screen on the stimulator to reach full clarity.

Use of small electrodes

The use of small electrodes (less than 32mm diameter) may result in higher charge density especially when using high output settings (current, pulse width, frequency) and may lead to an increase in the likelihood of skin irritation. When possible, use larger electrodes. Always monitor skin condition closely.

Hot surfaces

The surface of the ODFS® Pace (XL) can reach a maximum temperature of 44°C when using the device at very high output levels and in a maximum ambient temperature of 40°C. Do not wear next to the skin if using very high output levels with an ambient temperature above 36°C, as this may cause burning of the skin.

Safe disposal of equipment

Care should be taken to dispose of parts and accessories of the device in the correct manner. In order to protect the environment, the product and its accessories should not be disposed of in household waste. Please dispose of as per local regulations. Alternatively equipment can be returned to Odstock Medical Limited for disposal.

Symbols and Definitions

Attention: device has a physiological effect

Caution (used throughout the instruction manual to identify caution item).

Applied parts of insulation type BF.

Read the instructions and precautions before use.

Consult instructions for use.

This product should not be disposed of with other household waste. Your ODFS® Pace (XL) and accessories can be returned to Odstock Medical Limited for appropriate disposal.

The CE mark indicates that the ODFS® Pace (XL) comply with applicable European laws.

Date of manufacture.

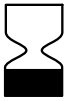
IP22

Protects against the ingress of solid foreign objects of diameter 12.5mm or greater. Vertically falling water drops have no harmful effect.

ODFS® Pace XL only. Contains a radio transmitting device.

Do not get any part of the system wet.

Symbols and Definitions



Expiry date (Year, Month, Day) of product (may relate to specific components, such as **electrodes** and **batteries** inside the packaging).

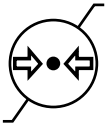
Manufactured by Odstock Medical Limited

Odstock Medical Limited
National Clinical FES Centre
Salisbury District Hospital
Salisbury, Wiltshire, UK

Do not use if the packaging is substantially damaged. Proceed with caution and check components for damage prior to use.

Do not store outside of specified temperature limits. If accompanied by <mo; for storage less than 1 month. If >mo; for storage greater than 1 month.

Do not store outside of the specified relative humidity limits.



Do not store outside of the specified atmospheric pressure limits

Rotation and power on/off (switches device between fully on and fully off states).

Location of footswitch socket.

Location of electrode socket.

Test button.

Symbols and Definitions

Pause/start button.

Batch number

Unique serial number of the stimulator

Odstock Medical Limited stimulator reference number

European authorised representative

unique device identifier

Medical Device

Light flashes on the ODFS® Pace (XL)

Beeps heard from the ODFS® Pace (XL)

Importer

Distributor

Patient information website

Key Features

ODFS® Pace (XL) Pouch and Belt Clip

The pouch has an integral belt loop and fixing for a carabiner. The belt clip is easily removable, reducing the overall size if the ODFS® Pace (XL) is carried in a pocket. Use a ball point pen or other similar tool to press the release button through the hole in the centre of the clip to allow the clip to slide from the pouch.

Changing the Battery

A single PP3 9V, alkaline or rechargeable nickel metal hydride (NiMH) or lithium polymer (LiPo) **battery** can be used.

If the device is not going to be used for an extended period of time, remove the **battery**. Do not use if the **battery cover** is missing.

Removing and installing the battery

1. Remove **electrode** and **footswitch leads** from the stimulator.

1.

2. Remove the **battery cover** by pressing down on the finger grip and sliding the cover backwards.

3. If a **battery** is in place then remove by using the corner of the **battery cover** to lift the battery.

Do not hit the ODFS® Pace (XL) casing in order to remove the battery as this may result in damage to internal components.

2.

4. Insert the **battery**, ensuring that the **battery** is orientated in the correct polarity.

Place the non-terminal end of the **battery** into the ODFS® Pace (XL) and rotate the terminal end into the battery compartment as shown below.

3.

5. Replace the **battery cover** securely by sliding it on to the back of the ODFS® Pace (XL) casing.

Prior to replacement of the **battery cover** check the battery compartment for loose items that may cause a short circuit or **battery** disconnection.

4.

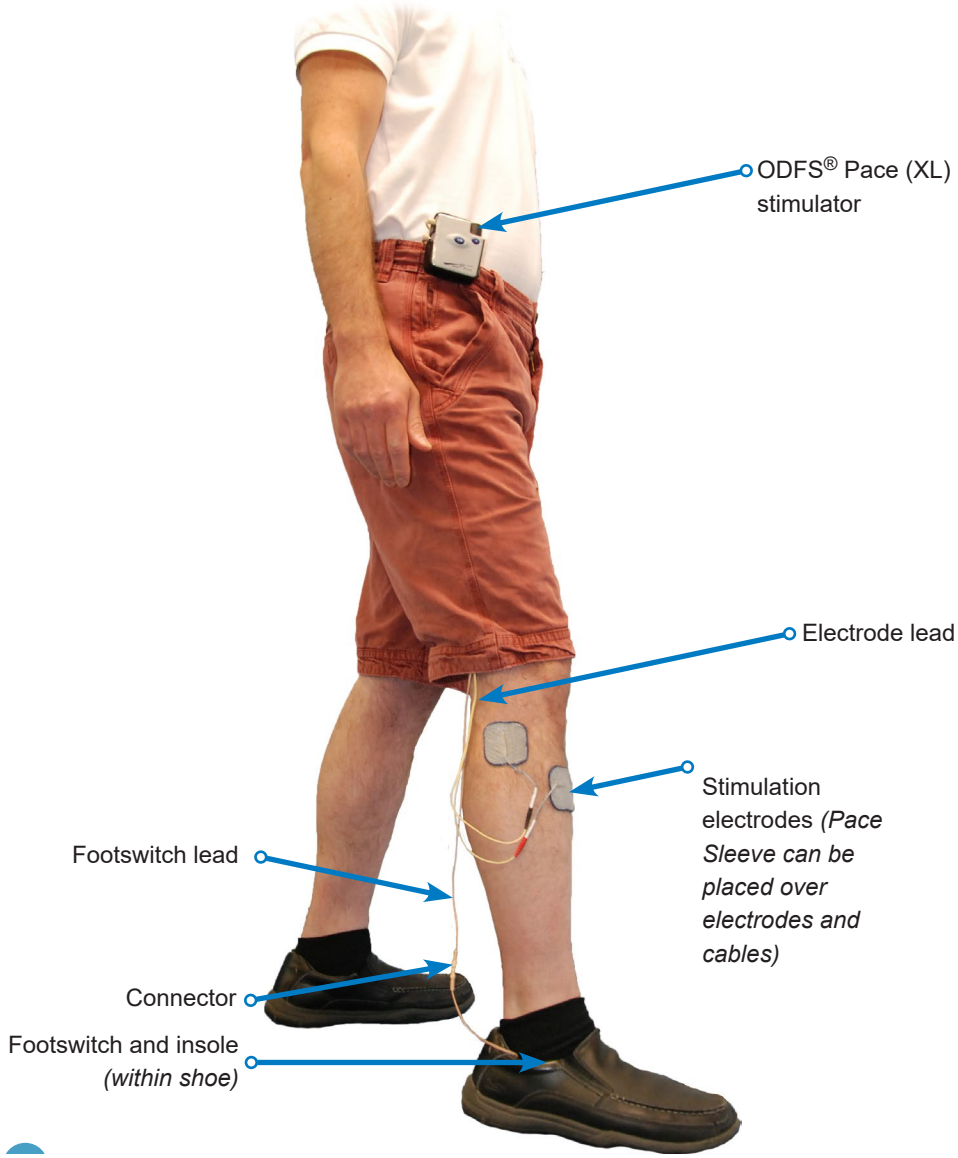
The ODFS® Pace XL is supplied with a lithium polymer rechargeable battery. This will need to be recharged at the end of every, or every other day.

Only recharge the lithium polymer battery using the charger supplied.

Activity data is stored in the memory only when the device is paused. It is therefore important to pause and turn off the stimulator before removing the battery to prevent data loss.

System Set-up on a Patient

A typical system set-up is shown in the photograph. The footswitch is within the shoe, typically placed mid-line of the foot and under the heel. The footswitch is placed on the underside of the supplied insole. For a wireless set-up (ODFS® Pace XL) the footswitch and footswitch lead would be replaced by a wireless accessory.



Controls

Control knob

This control has three actions;

- Twist clockwise to turn up or ‘increase’
- Twist anticlockwise to turn down or ‘decrease’
- Press down and release to unlock, click or select

The **control knob** is also used to navigate the menu and select menu options.

Test button

This button is used to test the output level and to assist in finding the correct **electrode** position. The **test button** only functions when the stimulator is paused. A single envelope or “burst” of stimulation is given for each press of the **test button**.

Pause button

This button starts (**active mode**) and stops (**pause mode**) stimulation. **Active** and **pause modes** are cycled by pressing the **pause button**. In **walk mode**, a long beep is given for entering **active mode** and a shorter, higher pitched beep is given for exiting **active mode**.

When the **pause mode** is entered, the display will briefly show the battery condition. To keep the battery condition displayed for longer, continue to hold down the **pause button**.

Connectors

Electrode lead socket

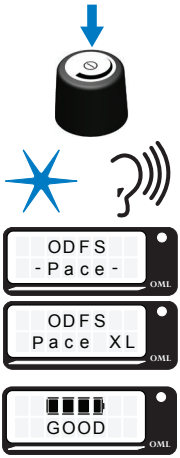
Located on the side of the case near the top and identified with a waveform symbol. This is where the **electrode lead** is plugged into.

Footswitch lead socket

Located on the side of the case below the **electrode socket** and identified with a footprint symbol. This is where the **footswitch lead** is plugged into.

The ODFS® Pace XL can use a wired footswitch. Simply plug in the footswitch when the ODFS® Pace XL is paused. To revert to wireless, disconnect the wired footswitch.

Turning the stimulator on



Press the **control knob** and hold it down until the display comes on and the indicator light flashes. If the stimulator has been set to use beeps, a series of three short beeps will accompany the light flash. The display will either show “ODFS -Pace-” or “ODFS Pace XL” depending upon the device variant.

During the start up process the battery condition will be displayed as “GOOD”, “OK”, “POOR” or “REPLACE” for 4 seconds. This can be escaped from by pressing any button.

If the battery condition is “POOR” the ODFS® Pace (XL) can still be used but it may be necessary to increase the output level.

If “REPLACE” is displayed, the indicator light flashes and a warning beep is heard. The battery should be replaced/ charged as soon as is practical. At the end of useful battery life a beep will sound every 30 seconds.

When the ODFS® Pace (XL) is turned on, the output level (pulse width) is set to 1%. The default starting % can be changed to 50% or the last level used in **active mode** before turning off. See starting percentage page 38.

Stimulation modes

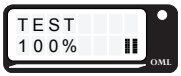
The ODFS® Pace (XL) has 2 modes, **walk mode** and **exercise mode**. **Walk mode** is a functional stimulation mode that uses a **footswitch** to trigger stimulation. In **exercise mode** stimulation is controlled by an internal timer and is not intended to be used for walking. When in **walk mode**, the display will show “WALK” if a **wired footswitch** is detected or a **wireless footswitch** has been joined. Otherwise the display will show “TEST” when the stimulator is paused. If in **exercise mode** the display will show “EXERCISE” when the stimulator is paused.

Exercise mode must be enabled by the clinician for it to be available to the user. See page 30 for how to change modes.

Adjusting the output level (pulse width)

The output level of the ODFS® Pace (XL) is adjusted by first clicking (press and release to disable the control lock) and then turning the **control knob**. This sets the stimulation pulse width which determines the strength of the muscle contraction. When the control lock is on, a lock symbol is shown on the display. If the control lock has been disabled (see control lock page 37), the output can be adjusted without first clicking the **control knob**. By default the control lock is enabled after 4 seconds of inactivity to prevent accidental pulse width adjustment.

As the **control knob** is turned the output level is displayed as a number from 0 to 100%, with 100% being the highest output level. It is good practice to only adjust the output while there is stimulation. This provides an instant feedback of the effect of the change.



If the stimulator has been set to use beeps, an audible click will accompany each adjustment increment. The pitch of the click will go up and down as the output is turned up and down. When 50% is reached an extra high pitch beep is heard. This allows the user to know when they have reached the normal operating level without looking at the screen. There is a double, low pitch beep at 0% to indicate that the ODFS® Pace (XL) can be turned off by holding down the **control knob**.

Using the test button

While the stimulator is paused, the output can be tested by pressing the **test button**. Pressing the **test button** delivers a single burst of stimulation. The display will show “TEST”.

To ensure stimulation output is as expected use the **test button** prior to entering **active mode**. There is no need to click the **control knob** before adjusting when the **test button** is used.

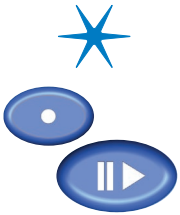
The indicator light will flash and if the stimulator has been set to use beeps, a ‘chirp’ will accompany the light flash in **walk mode** or a ‘beep-chirp-beep’ in **exercise mode**.

While there is an output from the stimulator the level indicator (pulse width) appears as a row of blocks on the lower line. The maximum (i.e. 100% pulse width) is indicated as 6 blocks.

The level displayed follows the output as it ramps up and down.

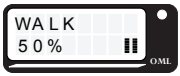
The light flashes in sequence with the stimulation.

The stimulation will time-out and stop or can be stopped at any time by pressing the **test button** again or pressing the **pause button**.



Using the pause button

When the stimulator is set for walk or exercise the **pause button** is used to start and stop the operation of the stimulator. Pausing the stimulator between walks saves power, prolonging battery life.



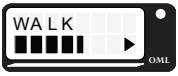
The stimulator indicates that it is in **pause mode** by displaying a pause symbol on the screen.

Press the **pause button** to start operation (**active mode**).

The indicator light will flash and if the stimulator has been set to use beeps, a long beep will accompany the light flash.

If the ODFS® Pace XL is used there will be a short delay while the network connection is checked. The hourglass symbol will be shown.

Once in **active mode**, the pause symbol will change to a play symbol on the screen.



If in **walk mode** the screen will also display “WALK” and the ODFS® Pace (XL) will respond to the **footswitch**.

If in **exercise mode** the screen will change to the exercise countdown timer and level indicator blocks. The stimulator will automatically pause at the end of the countdown timer. There is a different beep for starting and stopping exercise stimulation compared with **walk mode**. This is to inform the user which mode they are in and helps to prevent attempts to walk with the device in **exercise mode**.

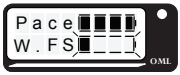
If the **exercise mode** is not enabled on ODFS® Pace and there is no **footswitch** present, when the **pause button** is pressed the screen will display “NO FOOTSWITCH!” and an audio warning beep given. If an ODFS® Pace XL is used there will be a delay and an hourglass symbol will be displayed while the stimulator searches for a wireless device. NOTE - this delay can be up to 10s. Press the **pause button** to end the search early. If the search is ended early “WALK ABORTED!” is displayed and an audio warning is given.

To stop stimulator operation, press the **pause button** again. A shorter higher pitch beep is heard in **walk mode** or a descending pattern of beeps in **exercise mode**.

From **active mode**, the battery level will be displayed. If a **wireless footswitch** is being used, the battery level of the ODFS® Pace XL is shown on the top line and the **wireless footswitch** shown on the bottom line. If the **pause button** is held down the levels will remain on the screen.

Low battery warning

If either the ODFS® Pace (XL) or **wireless footswitch** battery level becomes too low while walking, a regular warning beep will be heard. When the stimulator is paused, a warning siren beep is heard and the battery level screen will be shown. The battery symbol relating to the low battery will flash to indicate which battery needs replacing.



Pausing the device between walks saves power, prolonging battery life.

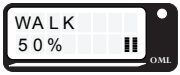
Lost wireless footswitch connection

If communication is lost between the ODFS® Pace XL and the **wireless footswitch**, upon entering **active mode**, the screen will display “No W.FS!”. Upon pausing the stimulator the screen will display “No W.FS!” instead of the **wireless footswitch** battery level. If communication is lost whilst in **active mode**, the ODFS® Pace XL will automatically pause and display “W.FS LOST!!” after approximately 1 minute.

If this occurs please refer to the troubleshooting section on page 86.

Turning the stimulator off

The stimulator can only be turned off when the output has been paused. This is to prevent the device being accidentally turned off while walking.



Check to see if the pause symbol is displayed. If not displayed, pause the stimulator.

Click and then rotate the **control knob** anti-clockwise until the output on the display reads 0% and the I/0 appears. A double beep is heard when 0% is reached.

Then press and hold down the **control knob** to turn the device off.

If the stimulator has been set to use beeps, the light flashes will be accompanied by two beeps.

The stimulator can also be turned off from the **user accessible menu**. Please refer to page 29 for further details.

The stimulator does not need to be turned off throughout the day, just paused. This prevents the need to reset the level each time the ODFS® Pace (XL) is turned back on.

Auto-turn off

If the stimulator is left turned on in **pause mode**, but is not used for more than 4 hours, it will automatically turn off, to save battery power.

Exercise mode

Exercise mode is used to train and strengthen muscles. In **exercise mode** the stimulation comes on and off automatically to set timings without the need of a **footswitch**. Before **exercise mode** can be used it must first be enabled, see exercise set-up page 65.

For the ODFS® Pace, **exercise mode** is accessed simply by removing the **footswitch lead** plug from the stimulator.

For the ODFS® Pace XL **exercise mode** is entered via the **user accessible menu** (see page 30).

When **exercise mode** is reached the screen will display “EXERCISE” and the output level is reduced to 1%.

To start exercise, press the **pause button** and the countdown timer will appear indicating the remaining time of the exercise session. While the light is flashing, increase the output level to produce a suitable muscle contraction.

To stop exercise, press the **pause button** or insert the **footswitch** to return to **walk mode**.

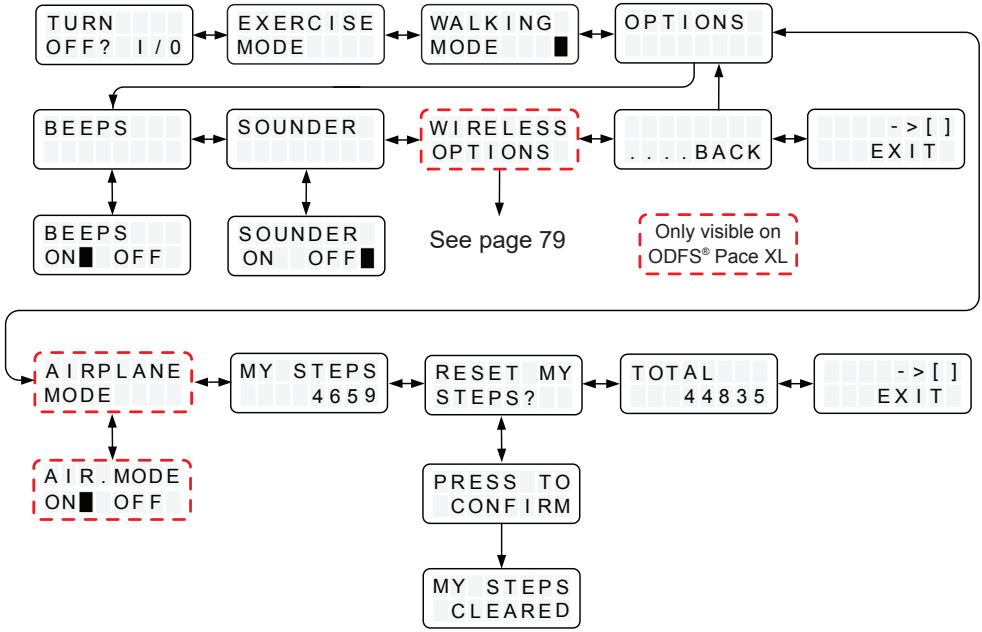
If a different muscle group is used for exercise to that of walking, make sure that the **electrodes** are in the intended position.

User Accessible Menu

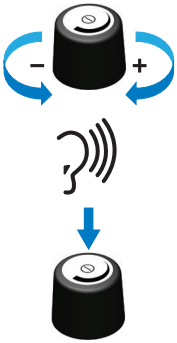
To enter the **user accessible menu** the stimulator should be paused. Unlock by clicking the **control knob**. Press and hold down the **control knob** for more than 2 seconds, then release. If control lock has been disabled, clicking to unlock will not be necessary. If beeps are enabled, a double descending pattern of beeps is heard and the current mode is displayed, indicated by a flashing black box.

If using a **remote control**, the channel number will be displayed while the **control knob** is held down.

The **user accessible menu** structure is shown below.



Changing between walk and exercise modes



Rotate the **control knob** to progress along the menu. When “WALK MODE”, “EXERCISE MODE” or “TURN OFF? I/0” screens are reached a high, medium and low pitch double beep is given enabling changing of modes or turning off without sight of the screen. Click the **control knob** to select the chosen options. Note: when the mode is changed from “WALK MODE” to “EXERCISE MODE” the output level is reduced to 1%. When the mode is changed from “EXERCISE MODE” to “WALK MODE” the output level is reset to the option chosen in "STARTING PERCENTAGE" see page 38. If an ODFS® Pace is being used a screen instructing the patient to either insert or remove the **footswitch lead** will be shown. The mode will not change until this is completed.

Options

This menu item gives three further choices. “BEEPS”, “SOUNDER” and “WIRELESS OPTIONS” (ODFS® Pace XL only). Click the chosen option and rotate the **control knob** and then click to choose “ON” or “OFF”. The black box indicates the current setting. Use “BACK” to return to the **user accessible menu** or “EXIT” to go back to the current **patient mode**.

Beeps

Allows the patient to turn on or off the audio beep feedback. For example the active and paused beeps.

Sounder

Allows the patient to turn “ON” or “OFF” stimulation audio feedback.

Wireless options

This menu is only visible on the ODFS® Pace XL. “WIRELESS OPTIONS” allows for either a **wireless footswitch** or **remote control** accessory to be joined to the ODFS® Pace XL. This is described in more detail on page 79 and the instruction manual that accompanied the wireless accessory.

Airplane mode

This menu item is only visible in the ODFS® Pace XL. It allows the patient to turn on or off **airplane mode**. **Airplane mode** disables all wireless communication of the stimulator. When active, an image of an aircraft is shown on the screen in **pause mode**.

The ODFS® Pace XL can still be used for walking however a **wired footswitch** is required. **Exercise mode** can still be used when in **airplane mode**.

Steps logger

My steps

The “MY STEPS” screen gives the total number of steps taken with the stimulated leg. "MY STEPS" can be reset by the patient using the next screen, "RESET MY STEPS". When the **control knob** is clicked a screen will appear asking for confirmation before resetting the "MY STEPS" count. Patients can monitor how much they walk and set themselves personal goals.

Total

The “TOTAL” screen gives the total number of steps taken with the stimulated leg since last being reset by the clinician. This can be reset in the **parameter view menu** or set-up menu.

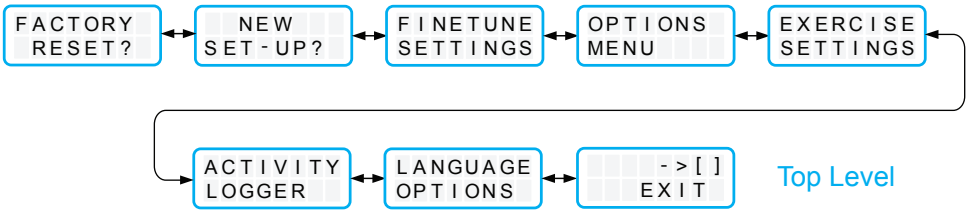
Exit

Clicking on “EXIT” returns you to the current **patient mode**, i.e. **walk mode** or **exercise mode**.

Menu timeout

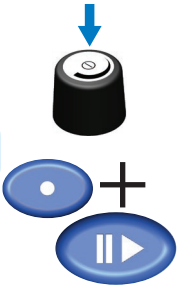
The **user accessible menu** times out after 1 minute of inactivity.

The set-up menu is used by the clinician to configure the ODFS® Pace (XL) to the patient's needs. This menu contains all of the parameters necessary for setting up the stimulator. The top level structure of the set-up menu is shown below.



Top Level

Accessing the set-up menu ("three button trick")



Before accessing the set-up menu, first turn the stimulator on and ensure that it is in **pause mode**.

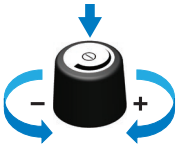
To prevent these settings from being inadvertently adjusted, the set-up menu is not intended to be accessible by the patient.

To access this menu:

1. Click and hold down the **control knob**.
2. While continuing to hold down the **control knob** simultaneously press the **test** and **pause buttons**.
3. Release the **test** and **pause button**.
4. Release the **control knob** and the first screen of the set-up menu will be displayed.

Using the set-up menu

The **control knob** is used to navigate around the menu. Turning the **control knob** will cycle along the menu, displaying each menu screen in turn. A selection can be made by clicking down on the **control knob**.



The first time that the set-up menu is accessed after turning on, you will be asked if you want to perform a "NEW SET-UP?". On each subsequent visit, the first option will be either "FINETUNE SETTINGS" (if the set-up menu is entered from the **walk mode**) or "EXERCISE SETTINGS" (if the set-up menu is entered from the **exercise mode**). These options allow adjustment of individual parameters without resetting all the parameters to their default values.

Each time that the “NEW SET-UP?” screen is displayed a double beep is heard. This is to remind that using this option will overwrite all of the previous settings.

If the “FACTORY RESET” screen is reached, three warning beeps are given to warn that choosing this option will reset all settings and data logs. This includes the wireless network.

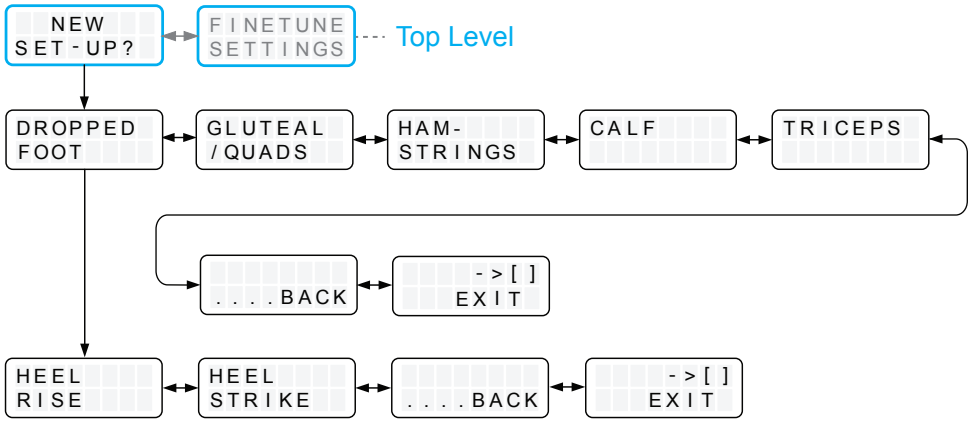
New set-up menu

Entering “NEW SET-UP?” allows the clinician to choose from a range of applications and automatically sets the stimulation parameters (timings and waveform) to appropriate default values. The menu structure then guides the clinician through each parameter, allowing the clinician to tune the parameters to each individual patient.

Gait options:

- Dropped foot using heel rise or heel strike
- Gluteal or quadriceps muscles, for walking or for training weight transfer or sit-to-stand
- Hamstrings for increased knee flexion or reduced knee hyperextension
- Calf muscles for push-off at terminal stance
- Triceps and posterior deltoid for improved arm swing/reduced associated reaction in gait.

Always use this menu branch (“NEW SET-UP?”) each time the ODFS® Pace (XL) is used with a new patient.



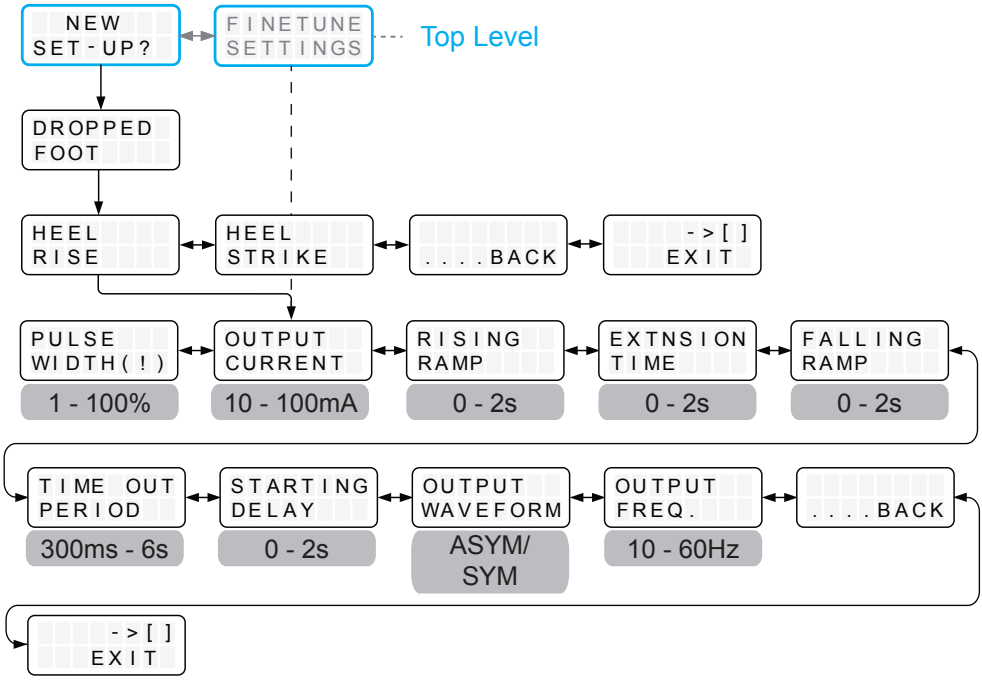
Finetune Settings Menu

Once you have chosen the application you need from the “NEW SET-UP?” screen, the next menu item to appear on the screen is “OUTPUT CURRENT”. This is also the first parameter on the “FINETUNE SETTINGS” menu. This parameter sets the contraction strength and it needs to be set for each individual patient (see page 54).

The “FINETUNE SETTINGS” allows adjustment of all the parameters that make up the applications used in the “NEW SET-UP?” menu. The default parameters are suitable for many patients, however parameters can be adjusted through “FINETUNE SETTINGS” to optimise the effect for each patient.

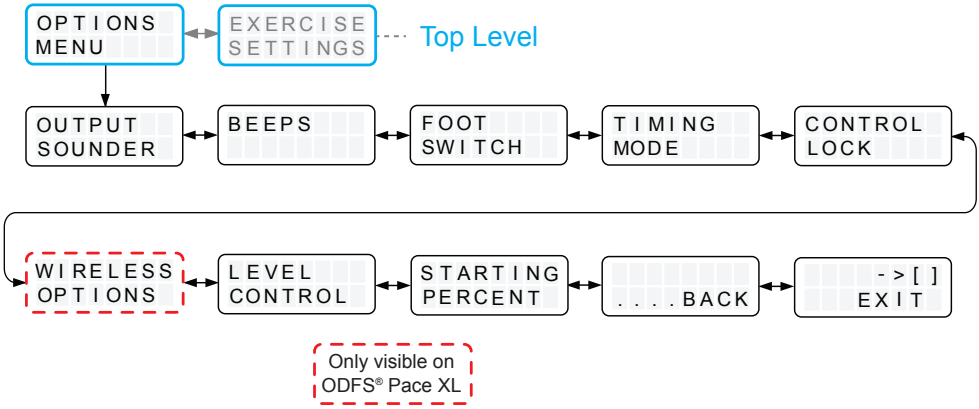
Adjustments made can be tested during walking (**active mode**) while within the “FINETUNE SETTINGS” menu by pressing the **pause button**. Stimulation can also be tested in this menu by pressing the **test button**. An audio feedback of stimulation is given allowing easier judgment of timing parameters. Stay in “FINETUNE SETTINGS” until all adjustments are complete.

Each item within “FINETUNE SETTINGS” is described in the Clinical Application section of this manual (page 56 to 61)



Options Menu

This menu allows adjustment of less frequently changed settings. The currently set option is indicated by a black square. The menu structure within “OPTIONS” is shown below.

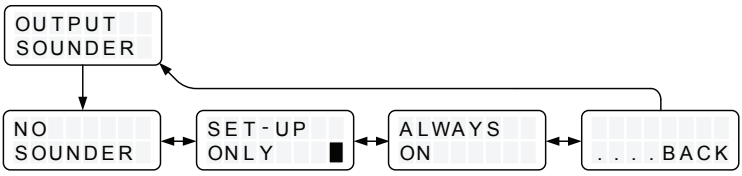


Output sounder

This is an audible feedback that accompanies the stimulation. This is used to check the timing of the stimulation while watching the patient walk. There are three options:

- “NO SOUNDER” - the sounder will be turned off in both **patient mode** and **set-up mode**. Choose this option if the patient finds the sounds distracting whilst the device is being set-up.
- “SET-UP ONLY” - the sounder will work whilst adjustments are made in “FINETUNE SETTINGS”, “NEW SET-UP?” and “EXERCISE” menus.
- “ALWAYS ON” - the sounder will work at all times in both **patient mode** and **set-up mode**. This is useful for the patient, carer or clinician to hear when the stimulation is on. Some people with Parkinson’s disease find the audible cue useful to overcome freezing episodes.

The default is “SET-UP ONLY”.

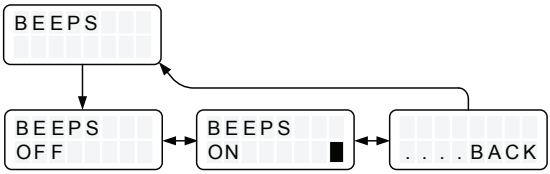


Beeps

This menu allows the clinician to turn on or turn off beeps. Beeps indicate an action has occurred on the ODFS® Pace (XL), such as 50% pulse width being reached. It is not possible to turn off the beeps for low battery warning as this is a safety feature of the device.

- "BEEPS ON" - beeps are enabled.
- "BEEPS OFF" - beeps are disabled.

The default is “BEEPS ON”.

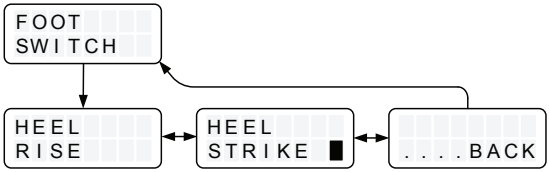


Footswitch

This option allows the clinician to select whether the stimulation is triggered when weight is placed on the footswitch (heel strike) or taken off the footswitch (heel rise). For a full description of these modes and their applications please refer to page 62.

- "HEEL RISE"
- "HEEL STRIKE"

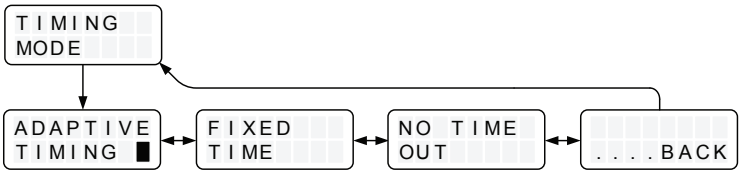
The setting is also defined during the "NEW SET-UP?" phase.



Timing mode

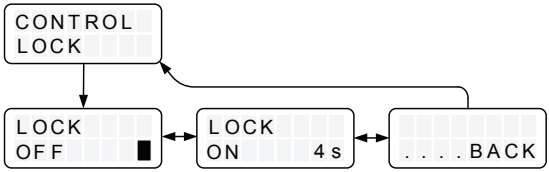
This option sets the timing action of the footswitch. For a full description of these modes and their application please refer to page 63.

- “ADAPTIVE TIMING” - stimulation is started and stopped by the **footswitch** up to a maximum time set in the “TIMEOUT PERIOD” menu (within “NEW SET-UP?” and “FINETUNE SETTINGS”).
- “FIXED TIMING” - stimulation starts with a **footswitch** but continues for the time set in the “TIMEOUT PERIOD” menu (within “NEW SET-UP?” and “FINETUNE SETTINGS”).
- “NO TIME OUT” - stimulation is started and stopped by the **footswitch** but there is no maximum time. The “TIMEOUT PERIOD” is not applied when using this setting.



Control lock

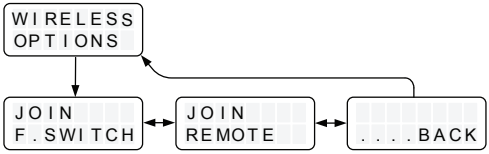
The control lock is intended to stop accidental adjustment of the output level. This option sets the period after the **control knob** is clicked that the output level can be adjusted. The period can be adjusted between 1 and 10 seconds with a default of 4 seconds. The control lock can also be turned off, allowing the level to be adjusted without first clicking the **control knob**.



The **control lock** also functions within **active mode** when in the set-up menus ("NEW SET-UP?" and "FINETUNE") to prevent the patient or clinician inadvertently adjusting output current.

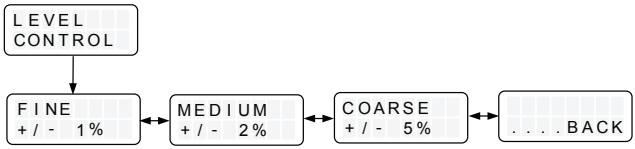
Wireless options

This menu is only visible on the ODFS® Pace XL stimulator. This menu is described in more detail on page 79.



Level control

This option allows the clinician to choose the increments by which the pulse width changes for the patient. There is a choice of "FINE" (1% steps), "MEDIUM" (2% steps) and "COARSE" (5% steps). The default is "FINE" (1% steps). Choose the other settings for more rapid adjustment of the pulse width.

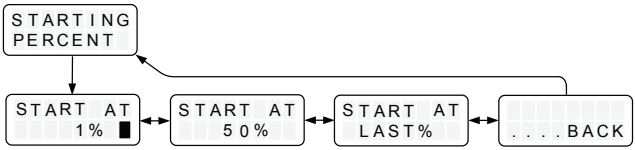


Starting percentage

This option allows the clinician to choose whether the pulse width at turn on is set to 1%, 50% or at the last used value (pulse width previously used in **active mode** with at least one step having been taken) for **walk mode** only.

The default is 1%, which ensures that the level is reset to a minimum each time the ODFS® Pace (XL) is turned on.

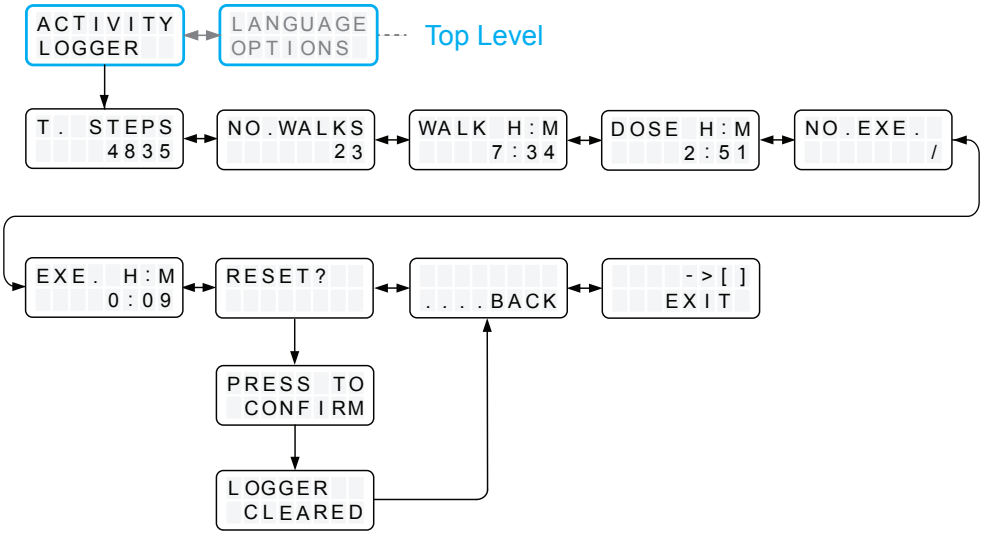
The other options allow for a more rapid use of the stimulator and can be used if the patient gets a consistent response from this level of stimulation. Do not use “START AT LAST %” if the patient regularly turns the level up throughout the day to compensate for fatigue.



If the ODFS® Pace (XL) **exercise mode** is used to exercise a different muscle than the one used for walking and the output current is significantly different to that used for walking, use "START AT 1%" to avoid unintended accidental high intensities when changing mode.

Activity Logger

After entering the set-up menu, navigate to the “ACTIVITY LOGGER” screen and select using the **control knob**. Use the **control knob** to navigate around the menu and read the stored logger data. The logger data can also be read through the **parameter view mode** (please refer to page 42).



The logger can be used to monitor device usage in order to determine treatment adherence either for use in walking or for exercise.

This logger data can only be reset by the clinician, from within the activity logger or **parameter view menu**.

Total steps

The "T. STEPS" (replicated in the **user accessible menu** as “TOTAL”) records the total number of steps taken with the stimulated leg since last reset.

Number of walks

The “NO. WALKS” records the number of times that stimulation is started for walking since the logger was last reset. The data is only recorded if at least one step has been taken by the patient.

Walk time

The “WALK H:M” records the total time in hours and minutes that the stimulation has been in **active mode** since the logger was reset. This time is recorded from the first step to the point at which the ODFS® Pace (XL) is paused.

Dose time

The “DOSE H:M” records the total time in hours and minutes that the stimulation has been delivered in **walk mode** since the logger was reset. This time includes the whole of the stimulation envelope for each step taken.

Number of exercises

The “No. EXE” records the number of times that the **exercise mode** has been activated and at least a single stimulation envelope has been delivered.

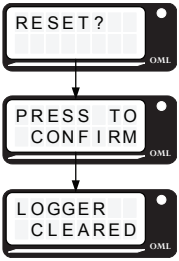
Exercise time

The “EXE H:M” records the total time in hours and minutes that the stimulator has been in **active mode** (the period between unpausing and pausing the stimulator in **exercise mode**).

Reset

Resets all of the above logger values to zero. Confirmation is required prior to the reset occurring.

Once “PRESS TO CONFIRM” is displayed, press the **control knob** to confirm the reset. If “RESET?” was selected unintentionally then this screen will time out after 3 seconds without affecting the logger data.



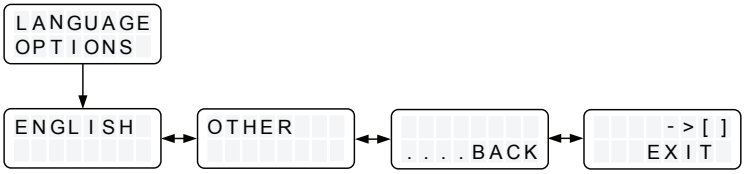
Activity data is stored in the memory only when the device is paused. It is therefore important to pause and turn off the stimulator before removing the battery to prevent data loss.

Language Selection

The ODFS® Pace (XL) is available in a selection of language variants. To change language from the default enter the set-up menu and rotate the **control knob** until the “LANGUAGE OPTIONS” screen is reached. Select this by pressing the **control knob**.

Scroll through the language options by rotating the **control knob**. Click the **control knob** to select your chosen language.

Not all available languages are present on every ODFS® Pace (XL). If a language is not present contact Odstock Medical Limited for assistance.



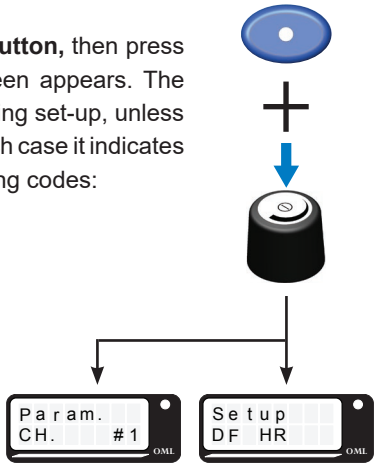
Parameter View Mode

This facility allows all the parameters and activity logger values to be viewed without entering the **set-up mode**. Additionally the data logger values can be reset to zero.

This feature is used to copy down all of the device settings at the end of a clinic session into the clinical settings form. Clinical settings forms can be downloaded from www.odstockmedical.com. It is not possible to adjust any of the parameters in this mode.

Entering parameter view mode

With the stimulator turned off, press and hold the **test button,** then press and hold down the **control knob** until the set-up screen appears. The display will show the first screen which is the basic walking set-up, unless the stimulator is joined to a **remote control** device in which case it indicates the channel number. The set-up screen uses the following codes:



- DF - Dropped Foot
- GQ - Gluteal/Quadriceps
- H - Hamstrings
- C - Calf
- T - Triceps
- KF - Knee flexion
- HE - Hyper-extension

followed by either...

- HS - Heel strike
- HR - Heel rise

An additional acronym used later within the menu:

- NTO - No time out

The **parameter view mode** has an additional data log called "Σ STEPS" (sigma STEPS). This is the total number of steps ever taken with the device and cannot be reset in "ACTIVITY LOG", "FACTORY RESET" or **parameter view mode**. This is recorded for maintenance purposes.

Software versions are displayed at the end of this menu system.

Navigate through the menu by rotating the **control knob**. Press the **pause button** to exit the **parameter view mode.** Hold down the **control knob** to turn off the stimulator.

Auto Turn Off and Set-up Time Out

Auto turn off

If the ODFS® Pace (XL) is paused and not used for more than 4 hours, the device will automatically turn off.

Unless the “STARTING PERCENTAGE” has been set to 50% or “START AT LAST%” the pulse width is reduced to 1% when the device turns off and will need to be reset to an operational level prior to walking or exercising.

Set-up time out

If the ODFS® Pace (XL) is left in the **set-up mode** (but not in **active mode**) for longer than 10 minutes without any adjustments being made, it will automatically exit **set-up mode** and return to the **patient mode** (paused).

If the ODFS® Pace (XL) is left in the set-up menu (and it is also in **active mode** with the patient walking with the device) for longer than 10 minutes, the next time that the **pause button** is pressed to stop walking the ODFS® Pace (XL) will exit the **set-up mode** and enter the **patient mode** (paused).

In both cases the current set of parameters is preserved.

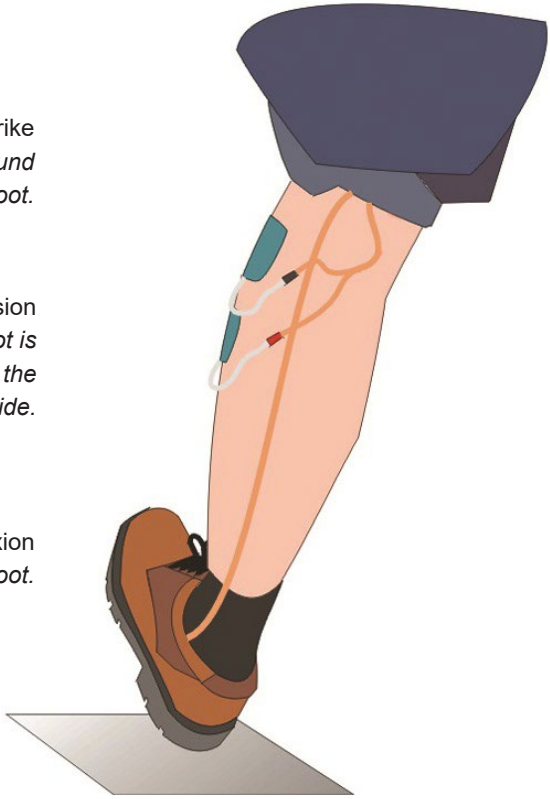
The Correct Movement For Dropped Foot Correction

The aim of stimulation is to produce as natural a movement as possible. Stimulation produces dorsiflexion and eversion as the foot leaves the ground, leaving sufficient time for push off using voluntary calf activity if it is present. The foot clears the ground with sufficient clearance to prevent the toe from catching. Stimulation enables heel strike, and maintains control of the ankle as the foot is lowered to the ground, preventing foot slap. Because heel strike occurs with a degree of eversion, weight is borne through the mid-line of the foot, stabilising the ankle through stance phase. The position of the foot at heel strike is important as it determines how the weight passes through the foot and the stability of the ankle in the stance phase. Observe the gait pattern from behind the patient to ensure sufficient eversion at heel strike.

Heel strike
Heel strikes the ground before the forefoot.

Eversion
The lateral side of the foot is lifted upwards relative to the medial side.

Dorsiflexion
Lifting of the forefoot.



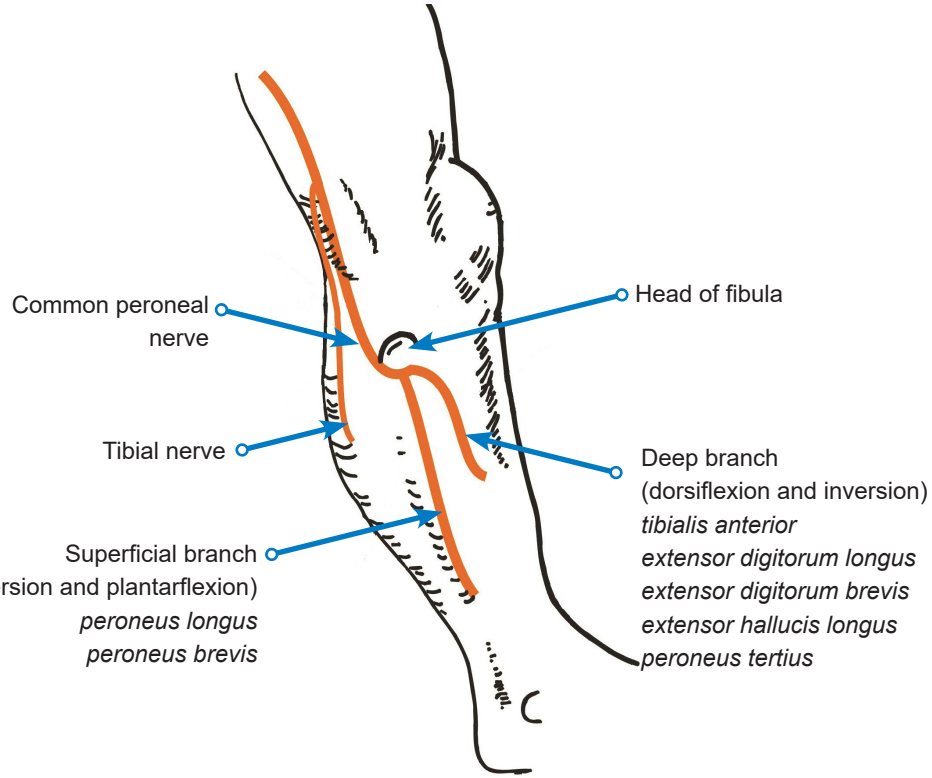
Anatomy of the Lower Leg

Dorsiflexion is produced by stimulation of the common peroneal nerve and/or its branches. By choosing the position of the **electrodes** it is possible to tailor the response to suit each individual patient. Generally, the common peroneal nerve is stimulated where it is most superficial, either where it passes the head of fibula or in the popliteal fossa. **Electrodes** can also be placed over the point where the nerves enter the muscles, typically over the motor point of tibialis anterior.

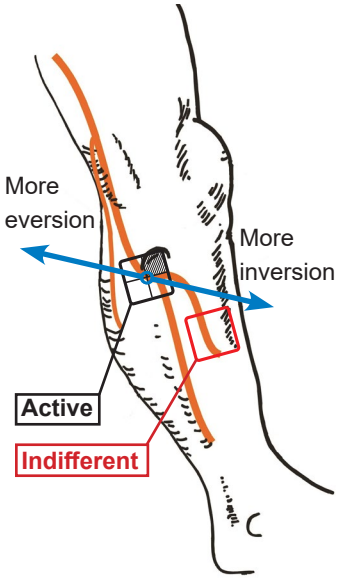
For the following **electrode** placements assume 50mm x 50mm square **electrodes**.

An asymmetric waveform is assumed unless otherwise stated

When changing between **electrode** positions, always turn down the CURRENT OUTPUT before testing the new position.



Electrode Positions for Dropped Foot



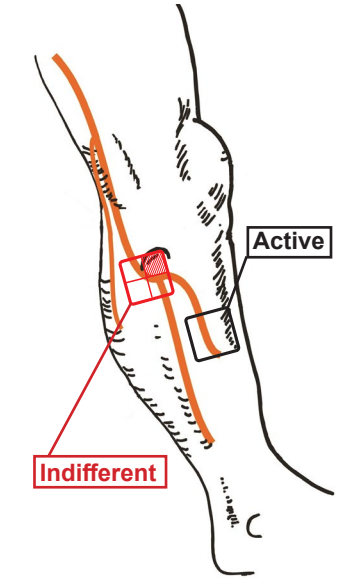
1. Standard electrode position

Imagine the **electrode** divided into quarters. The **active electrode** (black electrode pin), the top front quarter is placed over the head of fibula, the bottom front corner is below the head of fibula, the top back quarter is behind the head of fibula and the bottom back quarter is below and behind the head of fibula. The **indifferent electrode** (red electrode pin) is placed over the tibialis anterior.

> Avoid placing the **indifferent electrode** over the **tibia bone** as this may cause discomfort.

If there is too much eversion produced, move the **active electrode** anteriorly. If too much inversion is produced, move the **active electrode** backwards and upwards.

This is the most commonly used position and is usually the easiest for the patient to use independently.



2. Standard, reverse polarity electrode position

If too much eversion is produced by the standard **electrode** position, reverse the polarity of the **electrodes**, placing the **active electrode** (black electrode pin) on the motor point of tibialis anterior and **indifferent electrode** (red electrode pin) on the head of fibula. It is common with this **electrode** position to require a slightly higher stimulation intensity. The **electrode** on the head of fibula can be adjusted in the same way as the standard position to modify the response.

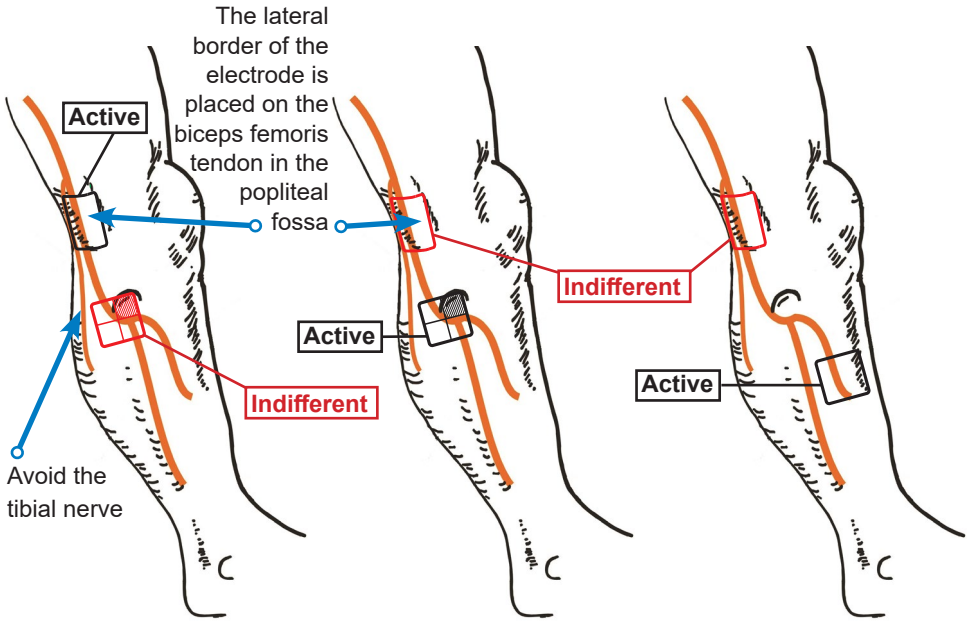
If this position produces too much inversion, change the **output waveform** to **symmetrical biphasic (SYM)**. Refer to page 59. This will give an equal stimulation effect on both **electrodes**, producing more eversion, and less eversion than the standard position.

3. Popliteal fossa electrode position

If a stronger response is required, place one of the **electrodes** on the lateral border of the popliteal fossa. Place the outer edge of the **electrode** along the biceps femoris tendon, with the lower border of the **electrode** along the centre of the knee crease. Do not place the **electrode** too medially as this may recruit the tibial nerve, causing plantarflexion. This position can increase knee flexion by recruiting the flexion withdrawal reflex. This reflex consists of hip, knee and ankle flexion together with ankle eversion and hip external rotation.

The strongest effect is with the **active electrode** in the **popliteal fossa**. If this produces too much eversion, place the **indifferent electrode** in the **popliteal fossa**. Alternatively, a flexion withdrawal reflex with a stronger element of dorsiflexion and less eversion can be achieved by placing one **electrode** on the motor point of tibialis anterior and the other in the **popliteal fossa**.

With all these positions, change the waveform to **symmetrical biphasic** to modify the response further.



Strongest effect

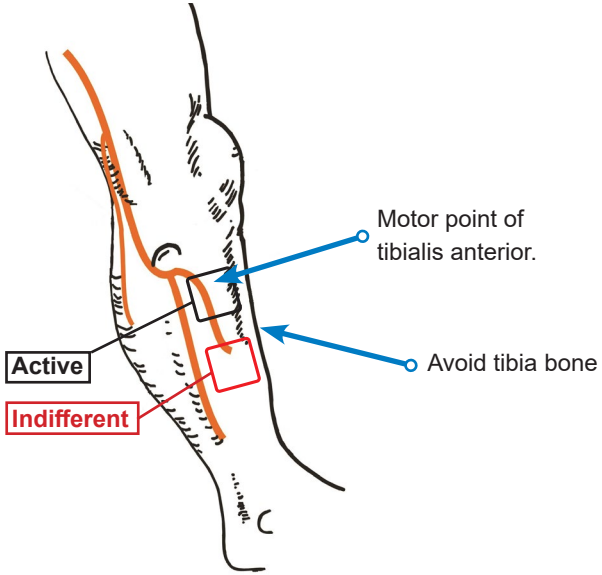
Moderate effect

Increased dorsiflexion, reduced eversion

4. Motor point electrode position

If the other three positions all produce too much eversion, stimulate the motor point of tibialis anterior directly by placing the **active electrode** on the motor point and the **indifferent electrode** more distally. If too much inversion is produced, move either or both **electrodes** laterally towards the peroneus longus and brevis.

This position generally requires greater stimulation intensity so can be less comfortable than stimulation of the common peroneal nerve.



5. Toe clawing

Occasionally, a patient may experience toe clawing (flexion) while walking. Greater toe extension may be achieved in standard and motor point **electrode** positions by placing the **indifferent electrode** more distally, over the toe extensor motor points.

Footswitch Placement

The footswitch is used to detect when the foot is on or off the ground and triggers the stimulation to occur at the correct time in the gait cycle. The **footswitch** is placed on the underside of a cork or solid foam **insole** with the black disc of the **footswitch** stuck to the **insole**. Soft foam **insoles** are not recommended as they may move in the shoe. The **insole** allows the **footswitch** to be moved from shoe to shoe easily and may also reduce wear, prolonging the life of the **footswitch**. Cut the **insole** to size using a pair of scissors or obtain the correct size.

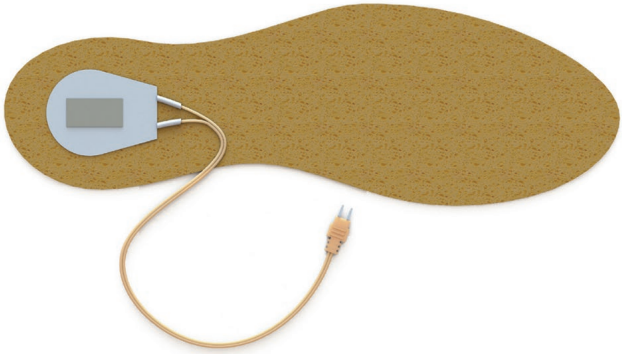
For "DROPPED FOOT" and applications such as "QUADS/GLUTES" in walking and "TRICEPS", the **footswitch** is normally placed under the heel. However, if weight bearing through the heel is unreliable, the **footswitch** may be placed further forward in the shoe. In the same way, if weight bearing is along the lateral or medial side of the foot, the **footswitch** can be placed laterally or medially to compensate for this. Use the sounder when in **set-up mode** to check the reliability of **footswitch** action, checking that stimulation starts and stops at the correct time and is continuous through swing phase ("DROPPED FOOT") or stance phase ("QUADS/GLUTES").

For applications such as "HAMSTRINGS" and "CALF", the **footswitch** is often placed under the 1st and 2nd metatarsal heads, starting the stimulation a little later in the gait cycle. Do not place the **footswitch** further forward under the toes as this usually results in an unreliable trigger.

If the **footswitch** is under the heel it is orientated so that the **lead** passes forward in the shoe exiting either under the medial arch or lateral side of the foot.

It is also possible to stick the **footswitch** directly to the sole of the foot using medical tape, with the cable running up the leg under the sock, stocking or tights.

Footswitches are consumable items and will last typically 6 to 12 months depending on use. Their condition and action should be checked at each clinical follow up session. Always supply a spare footswitch to the patient.



Electrodes and Electrode Care

Odstock Medical Limited recommends the use of 50mm x 50mm self adhesive square **electrodes** supplied within the ODFS® Pace (XL) boxed kits. These **electrodes** have proved to be the most reliable in clinical practice, are the easiest to use and the least likely to cause skin irritation. An alternative **electrode** type is the PALS® Plus range, available in a variety of sizes suitable for other applications as well as dropped foot. ODFS® Pace (XL) patients (such as paediatric patients) with smaller legs may require smaller **electrodes**.

The use of small **electrodes** (less than 32mm diameter) may result in higher current density especially when using high output current settings and may lead to an increased risk of skin irritation.

Whichever type of **electrodes** are used, it is very important that both the skin and **electrodes** are kept clean and in good condition. This will help prevent a skin irritation developing.

If skin is very dry, or if moisturiser has been used, wash the skin with warm water and dry it before placing the **electrodes** on the skin. If moisturisers are required, use water based products and apply at night before going to bed.

Do not place **electrodes** over broken skin or a rash of any kind.

Do not shave the skin as this may cause many tiny abrasions. If long hairs prevent reliable skin adhesion, trim the hairs with scissors or a beard trimmer.

All **electrodes** are for single person use.

An Pace sleeve (supplied in the kit) can be used to hold the **electrodes** and **leads** in place.

Follow the instructions provided with the electrodes.

Electrode use and daily care

1. Connect the **electrodes** to the **wires** by sliding the pin into the connector on the **electrodes**. Ensure that the pin is inserted fully and that no metal is visible.

2. Peel the **electrode** away from the plastic backing by lifting at the **electrode's** edge. Do not pull the **electrode's lead**.

3. Place the **electrodes** on the skin as described in the **electrode** placement section. Care should be taken when putting on clothing over the **electrodes** and **wires**.

4. After use, ensure that the ODFS® Pace (XL) is turned off before removing the **electrodes**. Peel the **electrode** away from the skin by lifting it at the edge. Do not pull the **lead**. Return the **electrodes** to the plastic backing. The **leads** can be left connected. Store the **electrodes** in the packaging provided ensuring that they are sealed to prevent them drying out.

5. After repeated use the **electrodes** lose their stickiness. Dampen the surface of the **electrodes** with water by running two fingers under a tap then wiping across the **electrode** a couple of times and then leave for a few seconds to dry. This rehydrates the **electrode** and also removes any debris from the surface. If this is not successful in restoring the stickiness, replace the **electrodes**.

Electrodes should also be replaced if they become worn, pitted, damaged or contaminated.

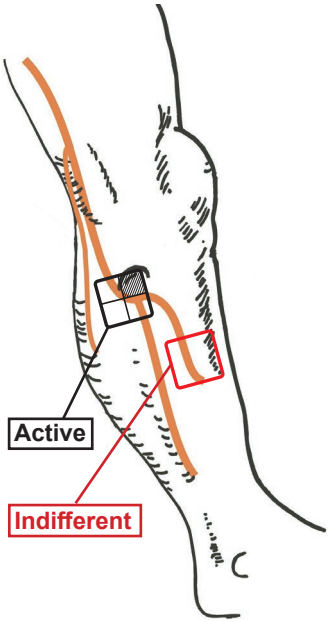
A pair of **electrodes** should last about three to four weeks of daily use.

Replacing **electrodes** regularly helps to prevent skin irritation.

Teaching electrode positioning to the patient

When the **electrode** positions have been found, it is very important to teach the patient how to find the positions for themselves. The key to this is teaching how to find the head of the fibula bone. One technique is to teach the patient to place a finger on the lateral malleolus at the ankle then move the finger up the outside of the leg until the next bony prominence is found, which will be the head of fibula. Make sure there is no confusion with the lateral condyle on the tibia bone.

It is often useful to draw on the back of the **electrode** that is on the head of the fibula, the outline of the head of fibula, as shown on the image. This enables the **electrode** to be easily lined up with the anatomical landmark. Teach the patient to press over the four quadrants of the **electrode**, identifying that 3 corners will feel soft and the corner over the head of fibula feeling harder. Providing a photograph of the **electrode** positions is also beneficial. Also mark in the user instruction manual the position of the **electrodes**. Finally, some patients choose to draw around the **electrodes** with a skin marker (although this is not a substitute for learning the anatomical landmarks). Use colour coding to identify the polarity of the **electrodes**.



Begin by turning the ODFS® Pace (XL) on by pressing and holding down the **control knob** for 1 second. Enter the **set-up mode** by pressing and holding down the **control knob** and then pressing the **test** and **pause buttons** and then releasing all three. This "three button trick" is described on page 32.

New patient

A double beep is heard and the screen will display "NEW SET-UP?". If you wish to set the device up for a new patient, or a new application for a current patient choose this option by clicking the **control knob**. This will reset all parameters to default values.

Current patient

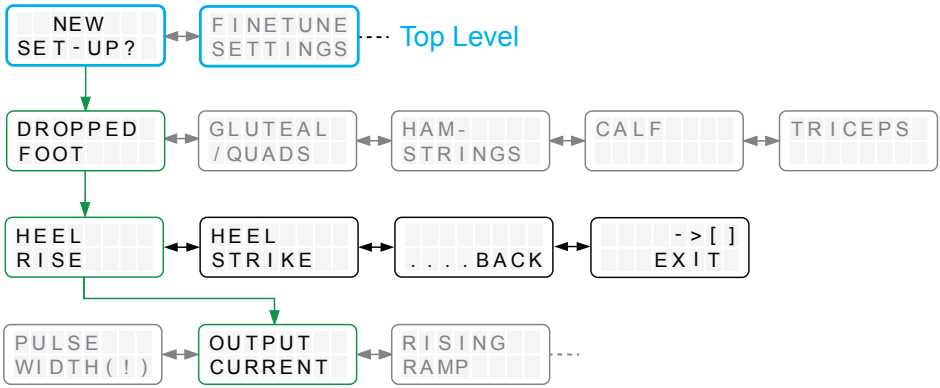
If you wish to make adjustments to an existing set-up, rotate the **control knob** clockwise to "FINETUNE SETTINGS", ignoring "NEW SET-UP?". This option allows adjustment of individual parameters without resetting all to default values.

Dropped Foot using “NEW SET-UP”

Selecting treatment and trigger

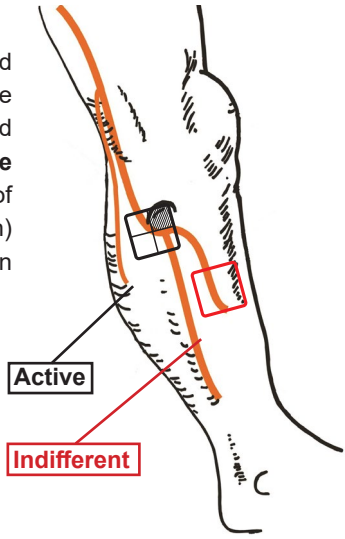
Within “NEW SET-UP?” the following screen allows selection of a treatment type. Select “DROPPED FOOT”. The other treatment options are described later in this manual.

The next screen allows selection of the method of stimulation trigger. For dropped foot the most common is to use “HEEL RISE”. In this mode the **footswitch** is placed under the heel on the affected side. Stimulation will start when weight is taken off of the **footswitch**. Select this option using the **control knob**. The next screen that will appear is the "OUTPUT CURRENT" screen.



Positioning the electrodes

Before the current can be set the **electrodes** must be placed in position. The first position to try is position 1. While the patient is sitting with their leg relaxed, near a full extended position, place the **electrodes** as shown below. The **active electrode** (black electrode pin) is placed over the head of fibula with the **indifferent electrode** (red electrode pin) placed over the tibialis anterior. For further information regarding **electrode** positioning please refer to page 46.

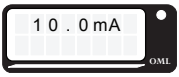


Output current

Current represents the amplitude of the pulse being delivered by the stimulator. Increasing current increases the strength of the muscle contraction.

The menu screen will display “OUTPUT CURRENT”. Click the **control knob** to enter the current setting menu.

The display shows the output current already set. The minimum current setting is 10mA (milliamps).

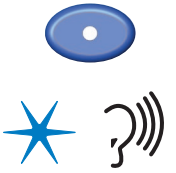


The current is set with a pulse width of 50% (180µs), which is half the pulse width range. This is to allow the patient to increase and decrease the contraction strength by increasing or decreasing the pulse width, compensating for day to day variations in muscle fatigue, **electrode** position and battery condition or changes in muscle tone.

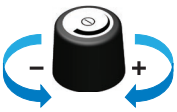
When “NEW SET-UP?” is selected the ODFS® Pace (XL) automatically sets the pulse width to 50%.

When “FINETUNE” is selected the ODFS® Pace (XL) uses the pulse width last used in the **patient mode**. It is best practice to set the pulse width to 50%.

To test the output current, press the **test button**. The indicator light will flicker and the audio signal is given (if sounder has not been disabled) to show that an output is being delivered. A bar graph will appear on the bottom line of the display that indicates the pulse width of the stimulation. The bar graph will change, indicating the rising ramp and falling ramp.



While stimulating, increase the output current by rotating the **control knob** clockwise. Repeated presses of the **test button** will be required to find the correct setting of output current. The output current can only be increased while stimulating but can be reduced at any time. Observe the effect on the patient. Increase the output current until the foot dorsiflexes with a small amount of eversion. If the correct movement is not produced, refer to the **electrode** positioning on page 46.



Dropped Foot using “NEW SET-UP”

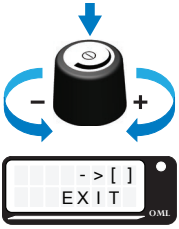
Once a good movement is produced, place the **footswitch** in the shoe (refer to page 49) and try walking. Press the **pause button** to enter **active mode**. A long beep is heard, the patient can now walk with the device.

It is often the case that the level of stimulation needs adjusting when the patient is walking. This can be because the level of calf tone is different when upright or you may have misestimated the amount of dorsiflexion required for walking. Unlike when the **test button** is used, the output current can be increased at any time the device is **active** when in **set-up mode**. Click the **control knob** and turn to make adjustments.

If the patient is walking well, then the set-up procedure has been completed. The **set-up mode** can be exited and the ODFS® Pace (XL) issued to the patient.

However, it is common for the device to require some adjustment to optimise the patients walking. See FINETUNE: Dropped Foot page 56.

Exiting the set-up mode

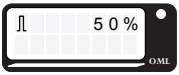


1. Press the **pause button** to leave **active mode**.
2. Press the **control knob** to leave the **output current** setting screen.
3. Rotate the **control knob** clockwise until the "EXIT" screen is reached.
4. Press the **control knob** to select "EXIT" and return to the **patient mode**.

Adjusting parameters and testing in the FINETUNE menu

With the exception of the output current all parameters within "FINETUNE SETTINGS" can only be adjusted while the ODFS® Pace (XL) is paused. The effect of a parameter change can be tested in walking at any point by pressing the **pause button** to enter **active mode**. While in **active mode** only the current can be adjusted. This is also the case when using the **test button**.

Adjusting the pulse width in set-up mode

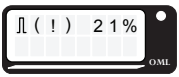


It is normal to leave the pulse width set to its default of 50% (180µs). However sometimes it is useful to set a different pulse width:

- If a strong contraction is produced at 10mA, reduce the pulse width.
- If an insufficient contraction is produced at 100mA, increase the pulse width.
- Sometimes a larger or smaller pulse width may be more comfortable.

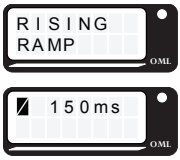
> While testing the output within the “PULSE WIDTH” menu it is the output current that is adjusted if the **control knob** is rotated. This is also the case when the stimulator is **active** whilst in **set-up mode**.
>
> If pulse width is increased, reduce the output current prior to testing.

Pulse width out of range warning



If the “FINETUNE SETTINGS” menu is entered with a pulse width setting outside of the normal operating range (45% to 55%) the “PULSE WIDTH(!)” warning is given. If the pulse width is at the intended setting, ignore this warning by rotating the **control knob** clockwise to access the rest of the menu. If the pulse width is incorrect, click the **control knob** to enter the “PULSE WIDTH(!)” menu and adjust to 50% or other intended level.

Rising ramp

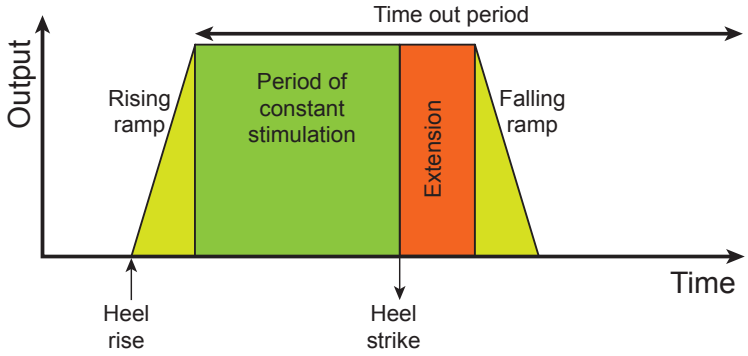


This parameter allows the clinician to choose how fast the stimulation rises to its maximum pulse width. There are 4 reasons why the clinician may want to adjust this parameter:

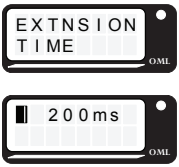
- If the foot does not lift quickly enough at heel rise, the rising ramp can be reduced to speed up the response to stimulation.
- For patients who have spasticity in their calf muscles, a rapid rise in pulse width will cause a rapid stretch of the calf that may result in a stretch reflex. This reflex will oppose dorsiflexion and may appear as a general stiffening of the calf or clonus spasm. A longer rising ramp time helps to prevent this happening.
- Some people find a rapid rise in pulse width uncomfortable. A longer ramp may be more acceptable.
- If stimulation causing dorsiflexion occurs too soon in the gait cycle, it is difficult for the patient to use their calf muscles to push forward at terminal stance. A longer ramp may allow this to happen.

> In all cases it is important that the stimulation ramps fast enough to cause dorsiflexion when the foot is lifted. For this reason, faster walkers will require shorter ramps.

The rising ramp timing can be tested by pressing and releasing the **test button** or in walking by pressing the **pause button** to enter **active mode**. The default setting for rising ramp is 150ms and it can be adjusted between 0ms and 2000ms. Turn the **control knob** clockwise to increase the ramp time. It is unusual to use a ramp time greater than 300ms for walking.



Extension



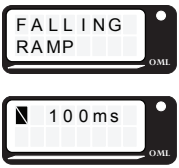
Extension allows the clinician to add a period of stimulation after weight is returned to the **footswitch** (or taken off it in heel strike). This enables an eccentric contraction in the tibialis anterior, lowering the foot to the ground. If the extension is too short, the ankle will lack control at the weight acceptance phase of gait. An audible slap may be heard as the foot strikes the ground.

Extension can be used to provide ankle stability in early stance where excessive ankle tone pulls the foot into inversion. Also a longer extension may help reduce knee hyperextension by increasing tibial progression in early stance.

Do not use an excessively long extension as this reduces the period between muscle contractions increasing muscle fatigue.

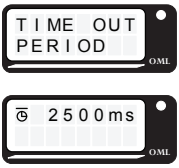
Use the sounder function to set the correct extension so that the stimulation ends when the foot is flat on the ground. The extension can be adjusted from 0ms to 2000ms. Turn the **control knob** clockwise to increase the extension. The default for dropped foot is 200ms. It is unusual to use an extension time greater than 350ms.

Falling ramp



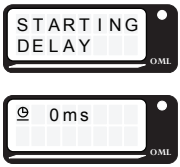
Falling ramp is the length of time the pulse width takes to reach zero after the extension has ended. It can be used with the extension to control the movement of the foot after heel strike and increase comfort. It can be adjusted between 0ms to 2000ms. The default for dropped foot is 100ms. It is unusual to require a falling ramp greater than 300ms.

Time out period



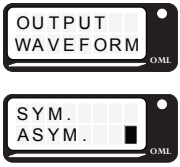
Time out period is the maximum time that stimulation can last for from a single **footswitch** or **test button** trigger. It should be set a little longer than the longest stride time taken by the patient. Ensure this is long enough for activities such as stair climbing. For comfort, do not set the time out period too long as this means the patient will get a long simulation period when they take weight off the **footswitch** when sitting down or when the **test button** is used. The time out period can be adjusted between 300ms to 6000ms. Turn the **control knob** clockwise to increase the time out period. The default for dropped foot is 2500ms.

Starting delay



Starting delay allows the clinician to set a delay to the onset of stimulation following a **footswitch** change (either heel rise or heel strike). This allows a muscle contraction at a time other than when weight is placed on or removed from the **footswitch**. This parameter is not normally used in dropped foot correction. However, it is sometimes used if triggering from a **footswitch** positioned on the unaffected side. When the output sounder is on, an audible click is heard at the beginning of the delay period. Use this to help judge the correct delay setting. The starting delay can be adjusted between 0ms and 2000ms. The default for dropped foot is 0ms.

Output waveform

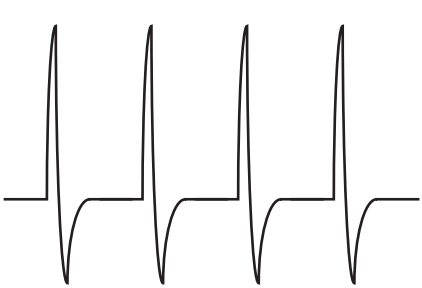


The ODFS® Pace (XL) has two choices of waveform; asymmetric biphasic, (“ASYM”), and symmetric biphasic, (“SYM”). The set waveform is marked with a black square on the screen.

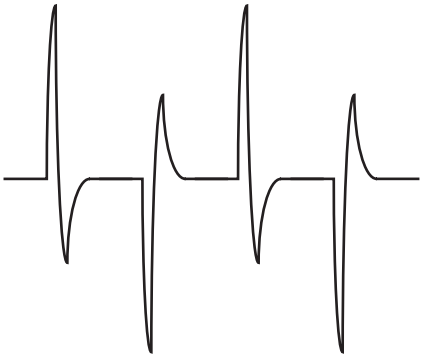
When the asymmetric biphasic waveform is used, the strongest stimulation effect is under the **active electrode** (black electrode pin). This can be useful in creating stimulation effects. For example, placing the **active electrode** over the common peroneal nerve and **indifferent electrode** (red electrode pin) over the tibialis anterior will generally produce dorsiflexion with eversion. Swapping the **electrodes** around will usually provide more dorsiflexion and less eversion.

With symmetric biphasic, the polarity of every other pulse is reversed. This means both **electrodes** have equal stimulation effect. For many people this will produce a better balance of eversion and inversion. Some people find this waveform more comfortable.

The waveform is shown below demonstrating the reversed second pulse resulting in a balancing effect.



Asymmetric biphasic waveform



Symmetrical biphasic waveform

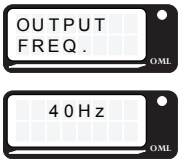
Turn the **control knob** to select either “ASYM” or “SYM”. The default for dropped foot is asymmetric biphasic waveform.

Output waveform - skin irritation

In the case of people who have sensitive skin, symmetric biphasic is less likely to produce skin irritation in reaction to the **electrodes**.

If skin irritation occurs after using asymmetric biphasic, discontinue use and allow the skin to heal and then recommence device use using symmetric biphasic to reduce the likelihood of recurrence. If a new patient has a history of skin irritations or poor skin quality choose a symmetrical biphasic waveform at the beginning of treatment.

Frequency



Frequency is the number of pulses per second measured in Hertz (Hz). The default frequency for dropped foot is 40Hz.

A lower frequency can be used to reduce fatigue in the stimulated muscles and may also sometimes reduce the spastic response in the calf muscles. A lower frequency can sometimes be useful for people who have a “straight leg” gait as it can allow better knee flexion by reducing the spastic response to stimulation.

Increasing the frequency will tend to produce a brisker reaction and may produce a greater withdrawal reflex (a reflex consisting of hip, knee and ankle flexion).

Increasing the frequency can be useful for some people who do not get a strong enough response to stimulation at 40Hz. Frequency is adjustable between 10Hz to 60Hz.

Using higher frequencies can increase muscle fatigue.

Frequencies lower than 20Hz should be used with care for walking as it may not provide a strong enough muscle contraction.

Footswitch trigger options

The "FOOTSWITCH" menu allows the clinician to choose if the stimulator is triggered on heel rise (when weight is taken off the **footswitch**) or heel strike (when weight is put back on the **footswitch**).

For dropped foot correction, heel rise is more commonly used. The **footswitch** is placed under the heel of the affected side. This means all the equipment is on the same side of the body. This is considered more convenient by most people.

If this mode is chosen from the “OPTIONS MENU”, all other parameters will be left unchanged. When the “HEEL RISE”/”HEEL STRIKE” option is chosen in the “NEW SET-UP?” menu, all other parameters are set to default.

Footswitch on the contralateral side

If foot contact is unreliable on the affected side, it can be more effective to place the **footswitch** under the heel on the opposite side. This can give a more reliable trigger but now the stimulation needs to begin when weight is put on to the **footswitch**, therefore the heel strike setting is used. Some faster walkers also prefer this mode.

In this set-up, patients should take their first step with their non-affected leg. Otherwise, stimulation will only occur on the second step of the affected side.

For patients who have a prolonged double support time (both feet are on the ground), it is sometimes necessary to add a delay period to ensure that dorsiflexion does not occur too soon. It can also be necessary to adjust the extension time. Observe the gait while listening to the sounder to judge the optimal settings for these parameters.

Timing mode

The ODFS® Pace (XL) has three timing modes. The default timing mode for dropped foot is adaptive timing.

Adaptive timing

In this mode stimulation is started by a **footswitch** change (e.g. heel rise or heel strike) and ended with a **footswitch** change (e.g. heel strike or heel rise). If the second **footswitch** change (to end stimulation) does not occur before the set time out period, stimulation will end automatically. This timing mode adapts well to walking speed changes and is used in most default settings including dropped foot.

Fixed time

In this mode stimulation is started by a **footswitch** change (e.g. heel rise or heel strike) but is ended after a fixed time set by the time out period. This mode is used when the foot contact is inconsistent and gives unreliable triggering. It can be useful if the patient is hesitant in taking steps, taking weight on and off the **footswitch** as multiple attempts are made. This may, for example, be useful for some people who have Parkinson's disease.

Carefully adjust the time out period by listening to the sounder and watching the response to stimulation. Stimulation should end at the point the foot returns to being flat on the ground after heel strike.

No time out

This mode is similar to adaptive timing except there is no maximum time for stimulation output. The output simply follows the **footswitch**. An extension is still added to the end of the stimulation output. This mode is not normally used in dropped foot correction but is used for stimulating anti-gravity muscles such as quadriceps or gluteus maximus.

Exercise Stimulation

At the initial assessment the ODFS® Pace (XL) is tried and in most cases an improvement in gait is immediately apparent. In some cases a period of electrical stimulation training is useful before using the ODFS® Pace (XL) for walking. This is done using the ODFS® Pace (XL) **exercise mode**. This may be indicated for the following reasons:

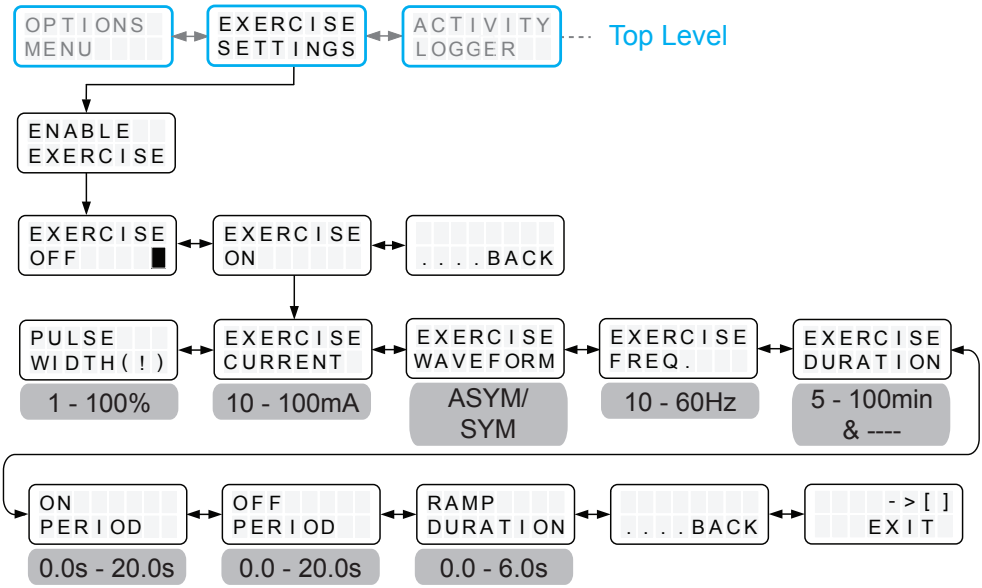
- To strengthen muscles. Regular exercise with electrical stimulation will increase muscle bulk leading to increased strength and fatigue resistance. Electrical stimulation exercises can be used for many of the affected muscles.
- To reduce spasticity and increase ankle range of movement. Regular stretching of the calf muscles using common peroneal stimulation may lengthen the muscle and tendons. It is thought that common peroneal nerve stimulation will also, via reciprocal inhibition, reduce calf over activity and if repeated may lead to extended periods of reduced calf tone.
- To accustom the patient to the sensation of electrical stimulation. If a candidate for the ODFS® Pace (XL) is sensitive to the sensation of the stimulation, tolerance to the sensation can be built up over time by exercising each day, gradually increasing the level of stimulation day by day until a sufficient contraction is produced.
- To reduce oedema. In some cases, excessive oedema may reduce the range of ankle mobility. Daily exercise stimulation may, by the venous pump action of the calf compartment, reduce fluid pooling in the foot and lower leg.
- To allow the patient to become accustomed to placing the **electrodes**.

Commonly, exercise is started with relatively short periods, for example twice a day for 10 minutes and gradually increased over a period of several weeks as strength and fatigue resistance improves to up to two periods of 30 minutes.

Exercise stimulation can also be used to strengthen and reduce spasticity in other muscle groups. In the next section there are two examples of upper limb exercises suitable for use with people who have had a stroke. Lower limb muscles may also be exercised. For **electrode** positions see the section on 'ODFS® Pace (XL) in Physiotherapy' on page 70. In all applications, start with short periods of 10 to 15 minutes and build up over time as fatigue resistance increases.

Please also visit the video section of the Odstock Medical Limited Website.

www.odstockmedical.com



Enable exercise

Use this option to enable the exercise programme. The default setting is “EXERCISE OFF”. This will simplify device operation and prevent patients from attempting to walk whilst in **exercise mode**. The parameters following “ENABLE EXERCISE” are hidden unless “EXERCISE ON” has been selected.

Enable exercise by selecting “EXERCISE ON”. A black box will appear to confirm selection and the screen will progress to “EXERCISE CURRENT”. As with walking set-up the **pulse width** is automatically set to 50%. Adjust the “OUTPUT CURRENT” until a muscle contraction is produced. Click to select the “OUTPUT CURRENT” setting. The default exercise parameters can be tested by pressing the **pause button**. If parameter changes are required these can be adjusted and tested in turn by using the **test button** or **pause button**.

Exercise stimulation parameters

The ODFS® Pace (XL) allows the choice of different output parameters for exercise and walking. This means the patient can use exercise to train a different muscle group to those used for walking. For example, upper limb or other leg muscles can be exercised.

However, if different output levels are used for **walking mode** and **exercise mode**, one set of parameters may give a strong contraction if used on the incorrect muscle group. For this reason, the pulse width is automatically set back to 1% each time the patient changes from **walking mode** to **exercise mode**.

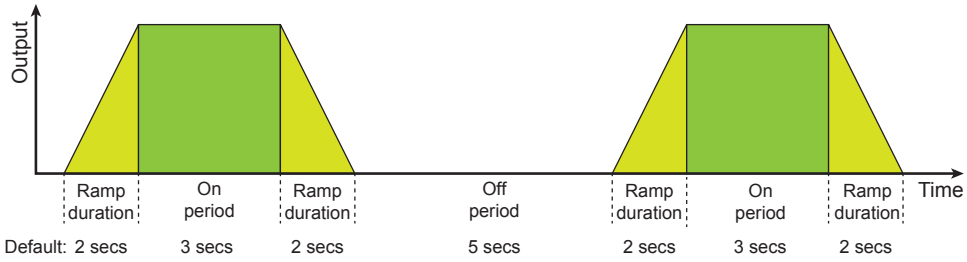
When changing from **exercise mode** to **walking mode**, the pulse width will be set to the selected starting percentage (within the options menu). If **exercise mode** is used for a different muscle group to that used for walking, the patient should ensure that the **electrodes** are in the correct location prior to walking.

As in “FINETUNE SETTINGS”, pulse width, current, waveform and frequency can be chosen. For an explanation of these parameters and their default settings please refer to the “FINETUNE SETTINGS” section of pages 56-61.

Exercise duration

The exercise duration can be selected from 5 to 100 minutes in 5 minute intervals. If the exercise duration is increased past 100 minutes, the screen changes to “----” indicating that there is no limit to the exercise duration. The default exercise duration is 15 minutes.

The graph of the stimulation output is shown below and describes ramp duration, on period and off period.



On period

The stimulation can be set to remain on for a period from 0 to 20 seconds in 0.5 second intervals. The default on period is 3 seconds.

Off period

The stimulation can be set to stay off for a period from 0 to 20 seconds in 0.5 second steps. The off period is measured between the down ramp and up ramp. The off period allows time for blood circulation to return to the muscle, replenishing oxygen supply and removing metabolic waste. The default off period is 5 seconds.

If the off period is too short, muscle fatigue may result. The off period is normally not set shorter than the on period.

Ramp duration

Within **exercise mode** the rising ramp and falling ramp share the same time and are described as ramp duration. The ramp duration can be adjusted between 0 to 6 seconds in 0.1 second intervals. If the person has spasticity it is recommended that a ramp duration of 2.0 seconds or greater be used to avoid eliciting a stretch reflex. If the person experienced clonus in response to stimulation the ramp duration should be increased until clonus is eliminated. People who find stimulation uncomfortable will find long ramps more comfortable. The default ramp duration is 2.0 seconds.

Testing in exercise mode

Exercise stimulation can be tested at any point within the exercise menu. Press the **test button** to get a single burst of stimulation at the chosen parameters (on period and ramp duration). The stimulation can be stopped at any point by pressing the **test button** again or pressing the **pause button**. The repeated stimulation sequence including the chosen off period can be tested by pressing the **pause button**.

Shoulder subluxation

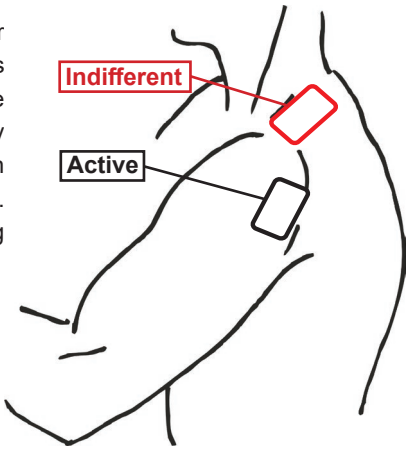
Shoulder subluxation is a common problem following hemiplegia and is often associated with shoulder pain. It occurs when weakened shoulder muscles are unable to support the weight of the arm resulting in stretching of the glenohumeral capsule. Often it can be associated with tightness of the pectoral muscles resulting in internal rotation of the humerus. Electrical stimulation can be used to retrain the shoulder muscles, reducing the subluxation and pain.

Place the **indifferent electrode** over the supraspinatus muscle just superior to the spine of scapula. Place the **active electrode** over the posterior deltoid. If there is no internal rotation place the **active electrode** over the middle fibres of deltoid. Adjust the output current until the humerus is seen to lift into the glenohumeral socket. Do not increase the output current to such an intensity that shoulder extension or abduction is produced. If trapezius activity causes shoulder elevation, move the **indifferent electrode** slightly more laterally or anteriorly.

Suggested settings and protocol

Waveform:	ASYM
Frequency:	40Hz
On period:	8s
Off period:	8s
Ramp duration:	2.0s
Electrodes:	30 x 50mm or 50 x 50mm self adhesive **electrodes** recommended by Odstock Medical Limited.

Start with exercise durations of 15 minutes twice per day. Increase the exercise duration by 5 minutes a week until 30 minutes is reached. Once fatigue resistance is built up the on period can be gradually increased. Reduced subluxation and pain reduction can be achieved in a 4-6 weeks of daily exercise. Continued exercise may be required to maintain long term benefit.



Exercise Stimulation Examples

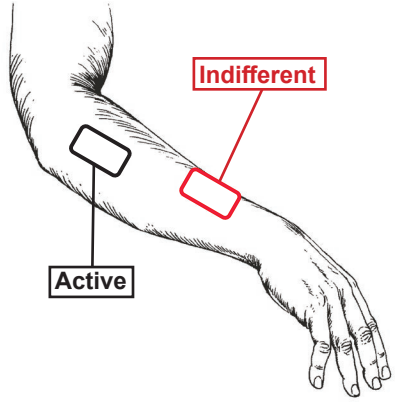
Forearm extensors

Weak finger, thumb and wrist extension in conjunction with flexor spasticity is a common problem following hemiplegia. Electrical stimulation exercises can be used to strengthen the extensor muscles, inhibit flexor spasticity and increase the range of motion of the hand and wrist.

Place the **indifferent electrode** on the dorsal aspect of the forearm three finger breadths proximal to the wrist (ulnar styloid). This is over the motor points of extensor pollicis, abductor pollicis longus and extensor indicis. Place the **active electrode** about three finger breadths proximal to the **indifferent electrode** and offset laterally by half an **electrode** width. This is over the posterior interosseous branch of the radial nerve, which innervates wrist, finger and thumb extensors. Adjust the output current until wrist, finger and thumb extension is produced. Avoid meta-carpal phalangeal (MCP) hyperextension by limiting output current. If radial deviation of the wrist is produced move the **active electrode** towards the ulna side of the forearm. Likewise move the **electrode** the other way if there is ulna deviation. If there is excessive wrist extension and insufficient finger and thumb extension try a symmetric waveform or swap the polarity of the **electrodes**. If extension of the wrist/fingers triggers a stretch reflex or flexor spasticity, increase the ramp duration producing a more gradual stretch of the flexors.

Suggested settings and protocol

Waveform:	ASYM
Frequency:	40Hz
On period:	5s
Off period:	5s
Ramp duration:	2.0s
Electrodes:	30 x 50mm or 50 x 50mm self adhesive **electrodes** recommended by Odstock Medical Limited.



Start with an exercise duration of 15 minutes twice a day. Increase the exercise duration by 5 minutes a week until 30 minutes is reached. Practice reaching and grasping in synchrony with the stimulation but be careful excessive voluntary effort does not result in raised flexor spasticity and reduced hand opening. The ODFS® Pace (XL) may be worn on the arm, enabling practice while moving about. Continue daily exercises for 3 to 6 months. Continue longer if withdrawal of the exercise reverses the benefits achieved.

ODFS® Pace (XL) in Physiotherapy

The ODFS® Pace (XL) can be used in gait re-education using the methods for dropped foot correction described so far. However, there are additional techniques that can be used.

It can be useful to use common peroneal nerve stimulation to practice stepping, prior to progressing to walking. The device can be controlled using the **footswitch** or by the clinician using the **test button**.

The individual components of gait can be broken down and practiced, using the ODFS® Pace (XL) to provide assistance where required.

The ODFS® Pace (XL) can be used to stimulate other muscles while walking. Using the **footswitch** and the correct combination of starting delay and extension, muscle contractions can be timed to occur at any point in the gait cycle.

Remember that the sensory effect of stimulation can be a useful tool to inform the patient when to produce a voluntary contraction. Also, the sounder function can be used to give audio biofeedback, further enforcing the learning effect.

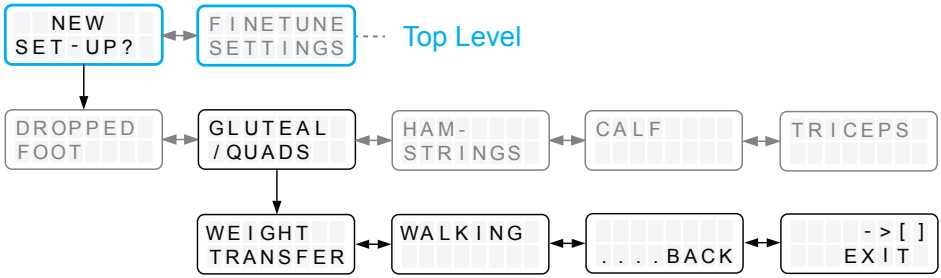
The ODFS® Pace (XL) has a series of gait options, accessed from the "NEW SET-UP?" menu. For each gait option, first set the current intensity so that a comfortable contraction is produced. The stimulation parameters can be adjusted to suit the individuals gait characteristics. Listen to the sounder and adjust each parameter until the muscle contraction occurs at the correct time.

It is often useful to combine these additional muscles with common peroneal nerve stimulation to correct dropped foot. This can be done by using two ODFS® Pace (XL) devices. If two ODFS® Pace XL are used with a **remote control**, both stimulators can be triggered using a single **wireless footswitch**. Please see the **remote control** instructions manual for information on how to achieve this.

Odstock Medical Limited also produce a 2 channel FES walking device. Please visit the Odstock Medical Limited web page for information on all OML devices (www.odstockmedical.com).

Gluteal/Quadriceps

This application is for training of the muscles used in standing. It can also be used to retrain gait following hip and knee surgery. The **footswitch** is placed under the heel on the affected side. The menu structure is shown below. There are two variations to chose from:



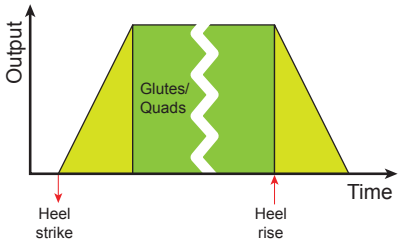
Weight transfer

This mode is used for practising taking weight on the affected side in hemiplegia. With the patient standing, the clinician instructs the patient to bring weight onto the hemiplegic side. Stimulation is used for either quadriceps or gluteal muscles to facilitate weight bearing. A long rising ramp is used to produce a comfortable, smooth start to muscle contraction. Stimulation stays on for as long as weight is maintained on the **footswitch**.

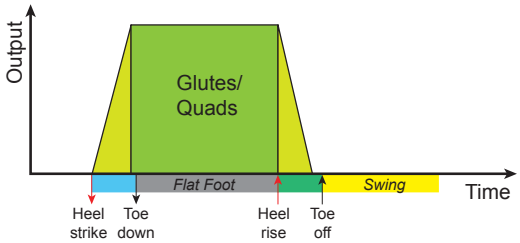
Walking

This application stimulates the same muscles but parameters are set appropriately for walking with the ODFS® Pace (XL). A faster rising ramp is used with adaptive timing so stimulation ends after a time out period. If appropriate, a second ODFS® Pace (XL) can be used for dropped foot correction. Clinicians may choose to change the timing mode to no time out to maintain hip or knee extension in standing when walking stops.

Stimulation envelope for weight transfer

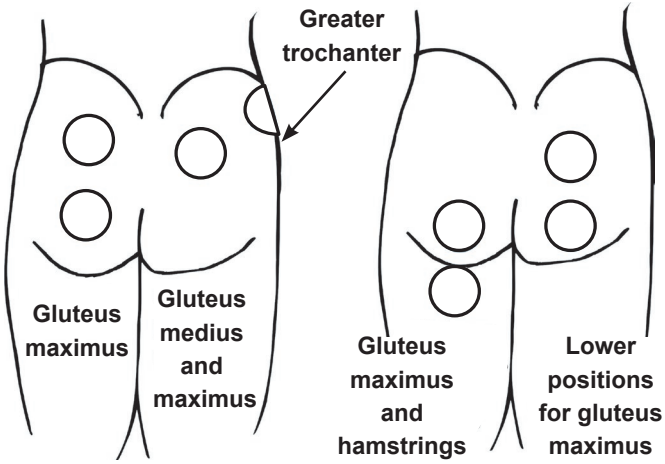


Stimulation envelope for glutes or quadriceps in walking



Gluteal/Quadriceps

There are several options for electrode placement for the gluteal muscles. Most commonly used is a position combining gluteus maximus for hip extension with gluteus medius for lateral stability. With an asymmetrical biphasic waveform the **active electrode** is placed over the muscle the clinician wants to have the greatest effect. A symmetrical biphasic waveform is used for a balanced effect.

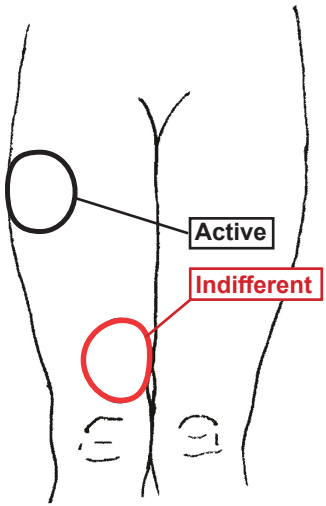


For quadriceps stimulation, place one **electrode** over the vastus lateralis and one over the vastus medialis. Generally the **active electrode** is on the lateralis to give strongest knee extension but can be placed on medialis if this is the weaker muscle. Avoid rectus femoris if hip flexion is to be minimised.

To practice sit-to-stand, place the **footswitch** under the metatarsal heads.

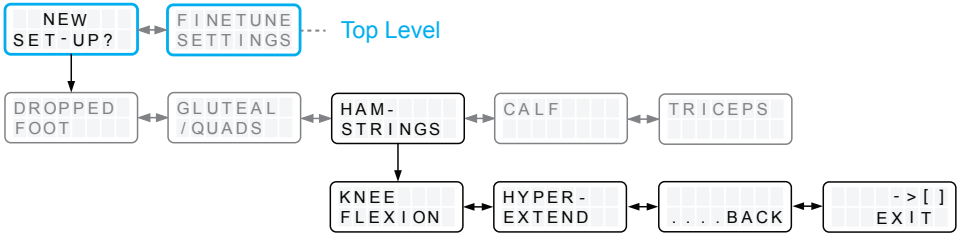
In both muscle groups sometimes low level sensory stimulation can be sufficient to facilitate the movement.

For either muscle group use 70mm or larger self adhesive **electrodes** recommended by Odstock Medical Limited.



Hamstrings

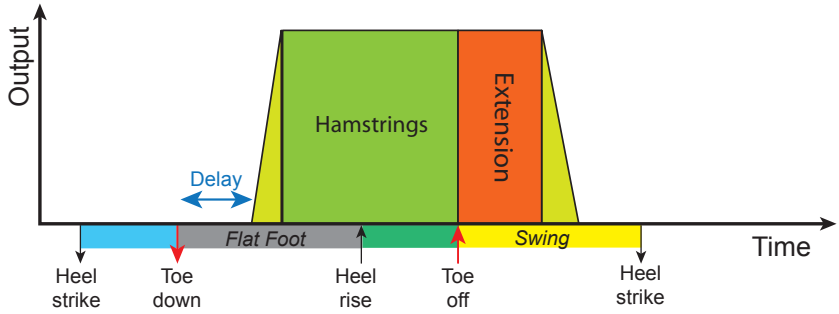
This application is used to control knee flexion by stimulating the hamstrings. The menu structure is shown below. There are two variations to choose from:



Knee flexion

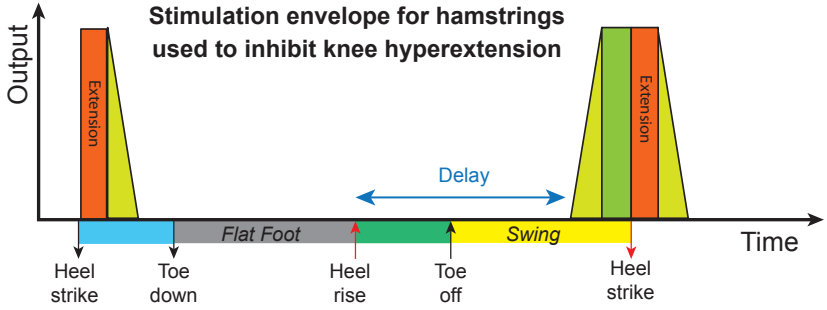
This option is used to improve knee flexion in the swing phase. The **footswitch** is placed under the metatarsal heads on the affected side. The delay function is used to start stimulation after flat foot so that hamstrings begin to contract just past mid-stance. The aim is to cause relaxation of the quadriceps muscles, allowing the knee to bend. Use the sounder when adjusting the delay to the correct amount. Stimulation continues until mid-swing. Adjust the **extension** time so that stimulation ends at the point the affected leg passes the non affected leg.

Stimulation envelope for hamstrings used to increase knee flexion at terminal stance and early swing



Hyperextension

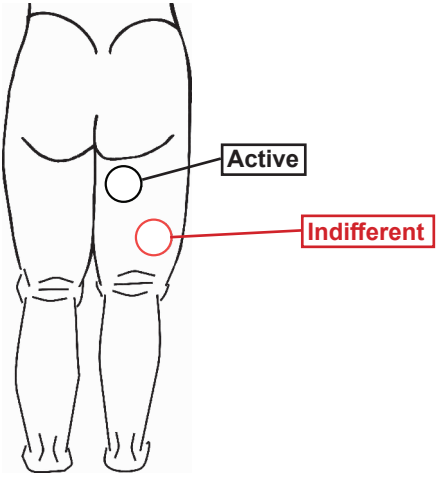
In this application a burst of hamstring activity is given just before heel strike. With the **footswitch** placed under the heel on the affected side, the starting delay is used to delay stimulation triggered by heel rise. Use the sounder to correctly adjust the starting delay. The length of stimulation is adjusted using the time out period.



Electrode set-up

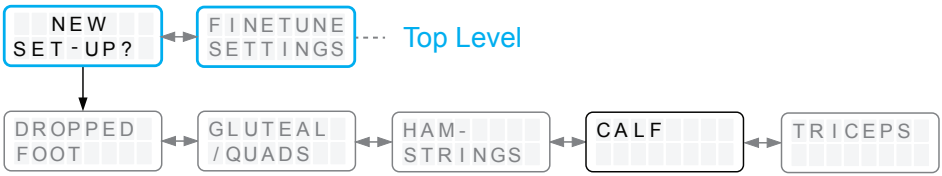
The **active electrode** is placed medially to the mid-line of the hamstrings while the **indifferent electrode** is placed distally and on the lateral side of the mid-line. Do not place the **indifferent electrode** too close to the popliteal fossa as this may recruit the tibial nerve. Use 70mm diameter, or larger self-adhesive **electrodes** recommended by Odstock Medical Limited.

Note: Knee hyperextension is often related to hip retraction in the stance phase. Knee hyperextension may be more effectively addressed by training gluteus maximus activity.

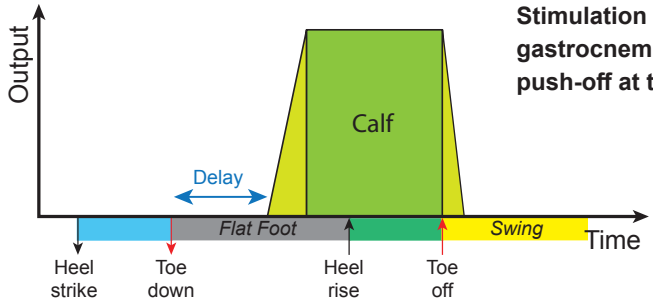


Calf

This application is used to train calf activity for push-off in terminal stance. Gastrocnemius can also be used to encourage knee flexion at terminal stance. The menu structure is shown below. Note that there is no secondary option beneath “CALF”.

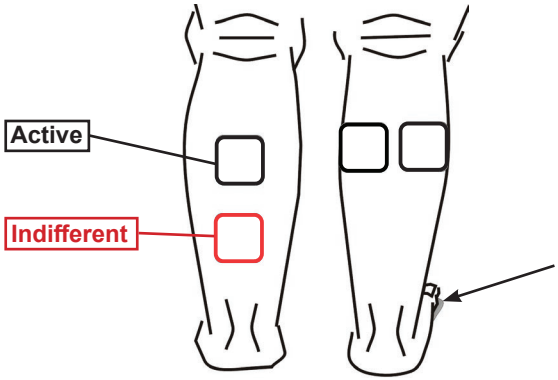


The **footswitch** is placed under the metatarsal heads. Stimulation starts after a small delay after the foot becomes flat on the ground and continues until the metatarsal heads leave the ground. Use the sounder to correctly adjust the starting delay time so that calf stimulation occurs just past mid-stance.



Stimulation envelope for gastrocnemius or soleus to train push-off at terminal stance

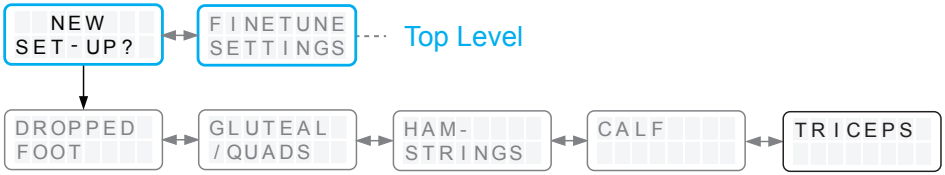
For soleus, use an asymmetrical biphasic waveform, place the **active electrode** in mid-calf region with the **indifferent electrode** placed distally. For gastrocnemius, place an **electrode** on each head of the muscle. Use a symmetrical biphasic waveform (default in this programme) to get equal stimulation effect on each head. Use 50 x 50mm or 70mm diameter **electrodes**.



Footswitch placed under the metatarsal heads

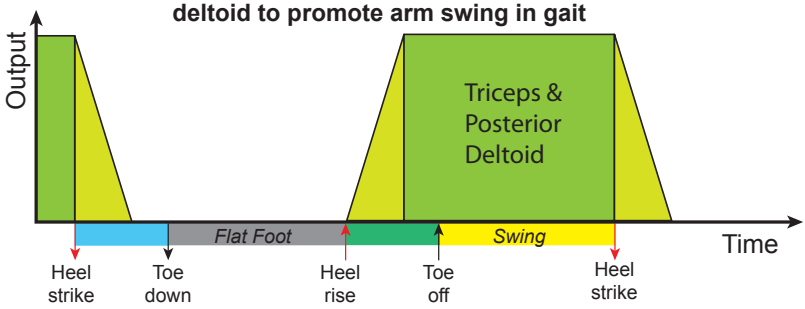
Triceps

The triceps application is intended to train arm-swing in patients who experience a lot of associated reaction in the upper limb while walking. The menu structure is shown below. Note that there is no secondary option below “TRICEPS”.

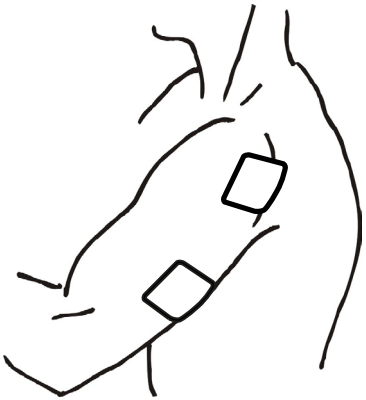


The triceps and posterior deltoid muscles are stimulated to coincide with the swing phase of gait. The **footswitch** is placed under the heel on the affected side and stimulation begins at heel rise, ending at heel strike. Stimulation extends the elbow and shoulder.

Stimulation envelope for triceps and posterior deltoid to promote arm swing in gait



Place one **electrode** over mid-triceps and the other over the posterior deltoid. In this programme a symmetrical biphasic waveform is set, giving an equal amount of stimulation to both muscles. Alternatively, an asymmetric biphasic waveform can be chosen and the **active electrode** placed on whichever muscle requires the strongest response.



Other Muscles - Hip Flexion

The ODFS Pace (XL) can be used to activate other muscles while walking that are not covered by the pre-set default setting. The clinician can choose the timing parameters to produce a contraction at the right point of the gait cycle. Here are two examples.

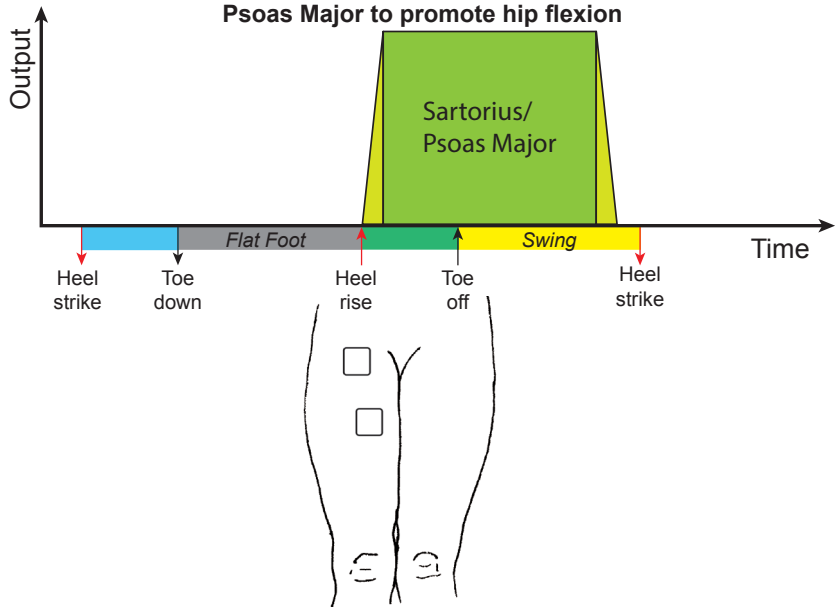
Hip Flexion

The body's main hip flexor muscle, the Psoas Major lies deep within the pelvis and is difficult to stimulate except for its distal end where it is close the skin surface. Hip flexion with external rotation can be achieved using the Sartorius muscle. Place one **electrode** over the Psoas Major at the top of the thigh slightly to the medial side so activation of rectus femoris is minimised. Place the second **electrode** approximately a hand width distally to the first electrode and slightly medially following the line of the Sartorius muscle to the medial side of the knee.

Stimulation timing can be based on the Triceps default settings. Reduce the TIME OUT PERIOD to about 450ms and rising ramp to 150ms. Choose the FIXED TIME timing mode in the OPTIONS menu. Using a **footswitch** under the heel, stimulation will start at heel rise and should end just before heel strike. Adjust the TIME OUT PERIOD while listening to the sounder to achieve the correct timing.

This arrangement can produce weak to moderate hip flexion but is limited because increasing the intensity may recruit the quadriceps muscles and hence knee extension.

Stimulation envelope for Sartorius / Psoas Major to promote hip flexion



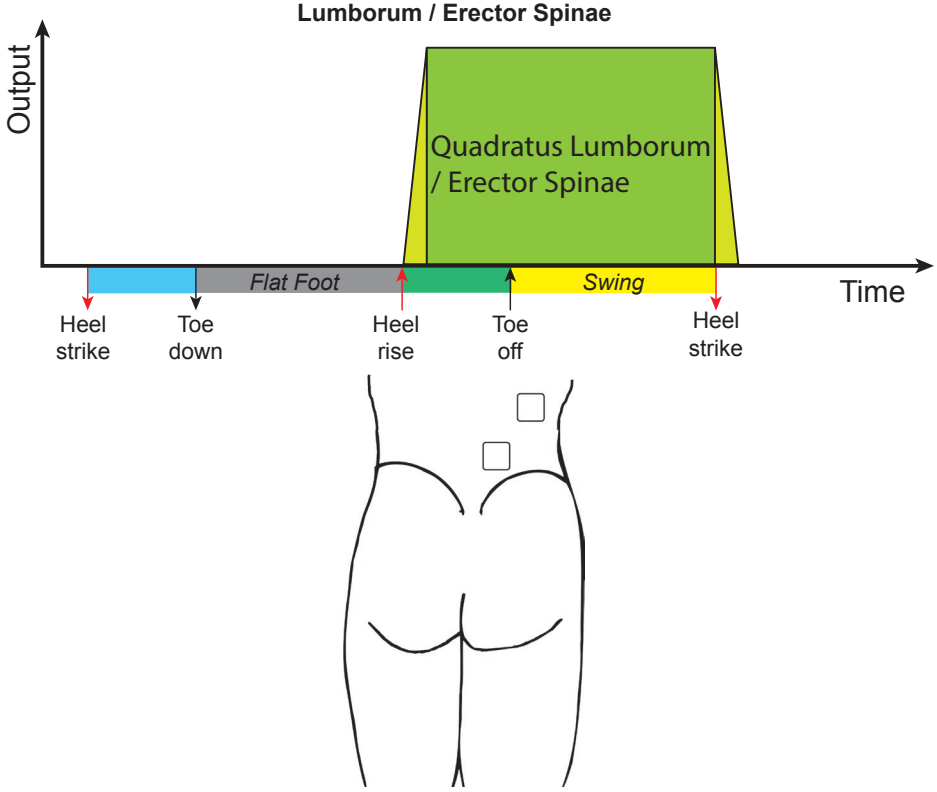
Trunk rotation and pelvis support

Weakness in the muscle around the pelvis can cause the pelvis to drop in the swing phase of gait, reducing ground clearance. Stimulating the Erector Spinae and Quadratus Lumborum muscles can prevent the pelvis from dropping and extend and rotate the trunk, assisting with the forward progression of the body. Place one electrode above the sacrum at about the level of the L5/4 vertebrae. Place the second electrode about 3 fingers width above and laterally to the 1st electrode.

Stimulation can be based on the Triceps default settings. Reduce the rising ramp to about 150ms. With a footswitch placed under the heel on the same side, stimulation will start at heel rise and end at heel strike.

This arrangement can be effective at reducing the effort expended in walking. High levels of stimulation may give an exaggerated lordosis.

Stimulation envelope for Quadratus Lumborum / Erector Spinae

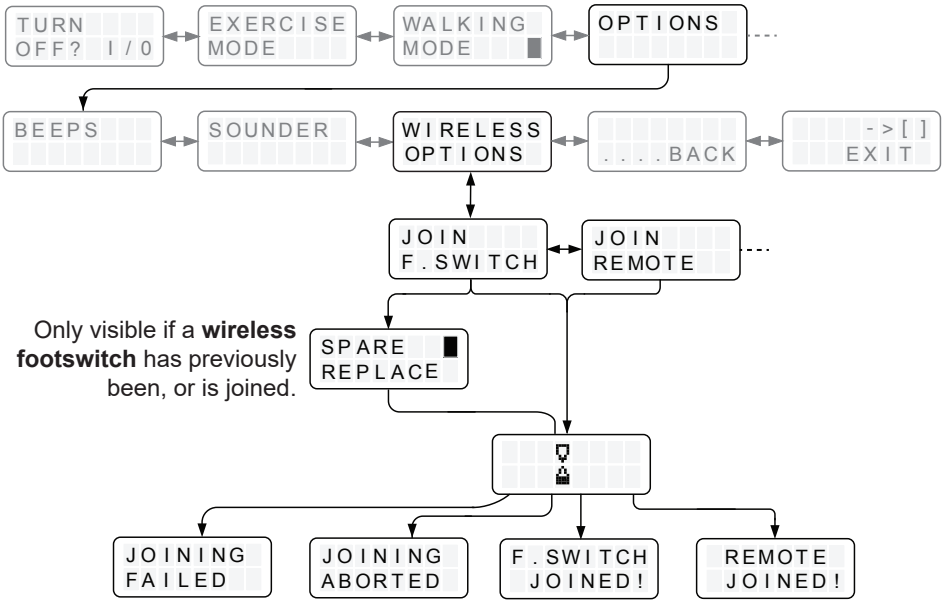


The ODFS® Pace XL is capable of accepting a selection of Odstock Medical Limited wireless accessories. Before a wireless accessory can be used it must first be joined to the ODFS® Pace XL. Each accessory may have a different method of enabling 'joining' (a procedure to connect two devices so that they are able to communicate wirelessly with each other). For each of the accessories please refer to the instructions for use accompanying these devices.

The clinician and user are able to join accessories to the ODFS® Pace XL. Some accessories may require input from a clinician. If you have problems following the joining process please contact Odstock Medical Limited.

Wireless joining of accessories in the user accessible menu

Wireless joining mode can be accessed within the **user accessible menu**. The menu structure is shown below.



To enter this menu, click and then hold down the **control knob** for 2 seconds. This presents the patient with the ability to join a **wireless footswitch** or join to a **remote control**. Once the wireless accessory starts it's joining mode, select either "JOIN F.SWITCH" or "JOIN REMOTE" on the ODFS® Pace XL. An hourglass will be displayed and may remain on the screen for up to 2 minutes during the joining process.

When successful the screen will indicate that either a **wireless footswitch** or **remote control** has successfully joined.

If unsuccessful “JOINING FAILED” will be displayed. The patient can cancel the joining process by pressing the **pause button** whilst the hourglass is on the screen.

If joining a **remote control** and a **wireless footswitch**, the **remote control** must be joined first.

If joining a **remote control** and a **wireless footswitch** is already joined, it will be necessary to rejoin the **wireless footswitch** after the **remote control** has been joined.

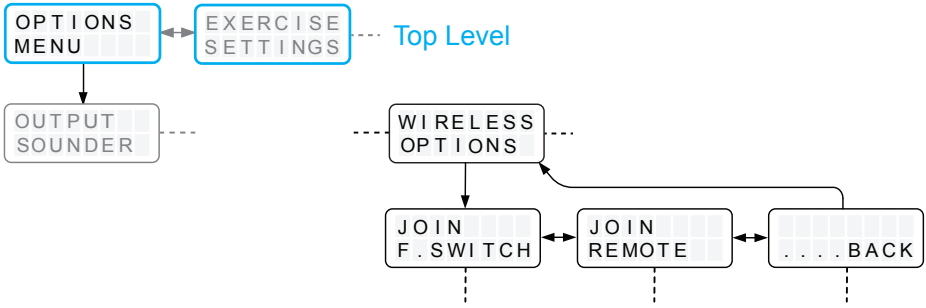
If “JOIN REMOTE” is selected all previous network settings will be erased, irrespective of whether a **remote control** device is joined or not.

Spare or replace wireless footswitch

The ODFS® Pace XL allows the use of one spare **wireless footswitch**. Therefore, if a **wireless footswitch** has previously been successfully joined, the ODFS® Pace XL will ask whether the next **wireless footswitch** being joined is a replacement or a spare. This enables the patient to have a spare **wireless footswitch** or use another **wireless footswitch** in a second pair of shoes. Rotate the **control knob** to select the required function.

Wireless joining of accessories in clinician set-up mode

The **set-up menu** also allows joining of accessories in the same manner as that of the **user accessible menu**. This is accessible as shown below:



Create network menu

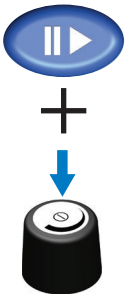
An additional menu is available for clinicians and patients to allow resetting of a network in case of interference. If there is strong interference this may result in intermittent operation in one location while operation is trouble free away from that location. This menu allows access to “CREATE NETWORK” that is able to select a quieter channel and improve wireless communication.

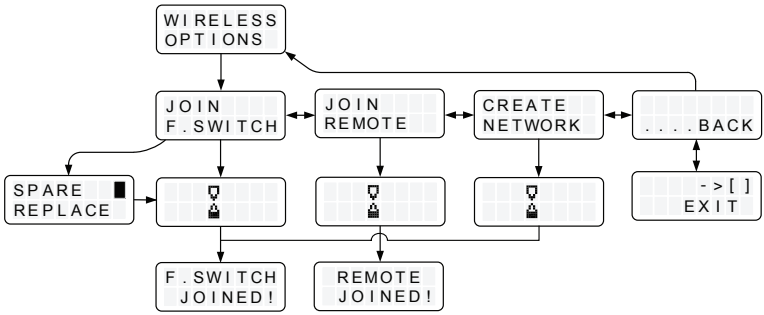
If this option is selected the wireless accessories currently joined will need to be re-joined.

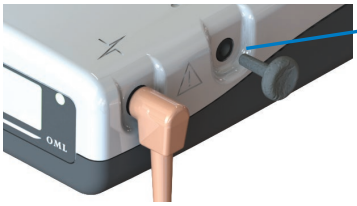
This option must be used if the network needs to be reset for use without a **remote control**, if a **remote control** has been previously used. The **wireless footswitch(es)** will then need to be re-joined.

Create network

“CREATE NETWORK” will delete all **wireless accessories** from the network and starts the process of joining a new **wireless footswitch**. “CREATE NETWORK” is accessed through the **advanced wireless options** menu. With the stimulator turned off, press and hold down the **pause button**. Whilst holding down the **pause button**, press the **control knob** to turn the ODFS® Pace XL on. Keep the **pause button** pressed until “WIRELESS OPTIONS” is displayed on the screen. Release all buttons. Select “WIRELESS OPTIONS” to enter the menu using the **control knob**. Rotate the **control knob** to select “CREATE NETWORK”. The menu structure is shown below.







Footswitch Socket Bung

The ODFS® Pace XL is supplied with footswitch socket ‘bung’ to prevent dust or moisture ingress. This can be removed allowing a wired **footswitch** to be used.

Cleaning and Care Guidance

Many of the components of the system can be cleaned. The system does not require regular cleaning, only as necessary. Please follow the instructions below.

Remove the battery before cleaning the system.

Do not scrub with abrasive material.

Make sure all parts are dry before re-use.

Stimulator

The ODFS® Pace (XL) stimulator can be cleaned by wiping with a damp cloth or anti-bacterial wipes.

Do not immerse the stimulator in water.

Do not clean with solvents.

Remove any debris within the battery compartment by hand. Ensure that debris does not get between the battery contacts and battery terminals.

Electrodes

To clean **electrodes**, dampen the surface of the **electrodes** with water by running two fingers under a tap then wiping across the **electrode** a couple of times.

Do not use a cloth to clean the **electrode** gel.

Do not immerse **electrodes** in water.

Do not use soap.

Leads and footswitches

Use anti-bacterial wipes to clean these components, or they can be cleaned using a damp cloth soaked in water.

If parts are very dirty or cannot be easily cleaned, replace with new.

System use between patient

Electrodes, insoles and **Pace Sleeve** are single patient use.

All other parts of the system shall be cleaned with anti-bacterial wipes and allowed to dry prior to re-use.

Servicing

The ODFS® Pace (XL) does not require any regular servicing. If it becomes faulty please refer to troubleshooting on page 86 or return to Odstock Medical Limited.

The operation of the system should be checked regularly. If the **footswitch lead** or **electrode lead** becomes stiff or cracked they should be replaced.

Remove the battery if the device is not going to be used for an extended period of time.

Maintenance

The ODFS® Pace (XL) does not need maintenance beyond that described in the cleaning and care instructions.

To prolong the life of LiPo rechargeable batteries if they are not used regularly, fully charge every 3 months.

Calibration

The ODFS® Pace (XL) and its consumables and accessories do not need calibrating by either the clinician or end user.

Expected Service Life and Maintenance

This is an indication of the life span of the parts (figures based upon daily use). Life span will depend on usage.

Part	Expected Service Life	Shelf Life
ODFS® Pace (XL) Stimulator	5 years	N/A
• Electrode socket	2 years	N/A
• Footswitch socket	2 years	N/A
Footswitch	6 - 12 months	N/A
Footswitch lead	6 - 12 months	N/A
Electrode lead	6 - 12 months	N/A
Neurostimulation electrodes	3-4 weeks	See expiry date
Pace sleeve	3 months	N/A
ODFS® Pace (XL) pouch	2 years	N/A
Cork insoles	3 months	N/A
Foam insoles	1 year	N/A
PP3 Battery (9V) (non-rechargeable)	3-6 weeks	See expiry date
PP3 rechargeable battery LiPo	100 charge cycles (>65% capacity)	Charge fully every 3 months
Battery charger 4 bay LiPo	5 years	N/A

Travel Advice

The ODFS® Pace (XL) system may attract attention from security staff at airports and shipping ports. For this reason it is advisable to take the following precautions to ease your journey.

- Unless the use of the ODFS® Pace (XL) system is essential while travelling, pack it in your luggage.
- Always take this instruction manual with the device so that you can demonstrate what it is.
- Take a copy of a clinic letter with you so that you can show additional evidence that the device is part of a treatment programme.
- Like other electronic equipment, the ODFS® Pace (XL) and accessories may effect navigation systems on aeroplanes. Make sure it is turned off during take-off and landing.
- The ODFS® Pace (XL) system can be put through both x-ray machines and metal detectors.

ODFS® Pace XL users

Like all radio telemetry devices the ODFS® Pace XL and wireless accessories should not be used while flying. Set the ODFS® Pace XL to “airplane” mode and use a **wired footswitch**. Please refer to page 31 on how to set “airplane” mode.

Troubleshooting

To help you understand some of the problems that might occur, here is a list of potential faults with some solutions. For assistance in setting up, using or maintaining the equipment please contact Odstock Medical Limited or their local representative.

1. No stimulation response to the footswitch but response to the test button

Fault	Action
The stimulator may be paused	Press the pause button
Faulty footswitch	Replace footswitch
Faulty footswitch lead	Replace footswitch lead
Lead not fully inserted/connected	Check for proper connection
Worn or loose footswitch socket	Return to supplier
Faulty stimulator	Return to supplier

If there is no stimulation during gait, remove **footswitch** from the shoe and try to trigger between 2 fingers. If this triggers the stimulator, consider moving the position of the **footswitch** in the shoe to a more suitable location. Refer to page 49.

2. No stimulation but the LED light flickers and the screen indicates stimulation

Fault	Action
Faulty electrode lead	Replace electrode lead
Faulty electrodes	Replace electrodes
Lead not fully inserted/connected	Check for proper connection
Worn or loose electrode socket	Return to supplier
Faulty stimulator	Return to supplier
Impact or water damage	Return to supplier

It is easier to test whether the stimulator is delivering an output by pressing the **test button** rather than relying on the **footswitch**.

3. Incorrect movement produced by the stimulation

Fault	Action
Incorrect electrode placement	Refer to electrode placement instructions
Poor electrode contact	Dampen the electrodes and skin with water
Muscle fatigue	Rest

It could be that the user's medical condition has changed recently and therefore alternative settings may be required.

4. The correct movement produced but a higher output level is required

Fault	Action
Incorrect electrode placement	Refer to electrode placement instructions
Poor electrode condition	Replace electrodes
Poor electrode contact	Dampen the electrodes and skin with water
Muscle fatigue	Rest
Failing battery	Replace (or recharge)* the battery

5. The stimulator does not turn on

Fault	Action
Battery empty	Replace (or recharge)* the battery
Battery not present	Install battery
Battery incorrectly inserted	Change battery orientation
Battery cap not removed	Remove battery cap
Battery contacts damaged	Return to supplier
Stimulator faulty	Return to supplier
Impact or water damage	Return to supplier

6. Interference from other wireless devices

Fault	Action
Intermittent or no wireless connection to wireless accessories.	Move away from potential source of interference Turn the system and wireless accessories off and on. Create a new network or if using a remote control follow instructions supplied with this device. Refer to page 81 for create network.

*Do not try to recharge non-rechargeable batteries. Only charge batteries in a charger suitable for the battery chemistry.

Audio warnings

Warning	Action
Stimulator beeps every 30 seconds	Replace/charge the battery
Siren beep is heard	Replace/charge the battery

Error messages

Error Message	Fault
“ERROR!! 1” “ERROR!! 2” 	Hardware fault. If an error message is shown turn off the device by pressing and holding the **control knob**. Turn the device back on and if the error message reappears, contact Odstock Medical Limited.
"!! CHECK SETTINGS" 	The selected exercise timing combinations of on period, off period and ramp duration cannot be delivered. Choose alternative timings.

Warranty Information

The ODFS® Pace (XL) stimulator has a warranty of 2 years from the date of purchase or date of initial fitting by a registered FES clinician. The warranty will default to the date of purchase if the warranty registration form is not received within 3 months. Warranty’s are not transferable.

The warranty for the Wired Footswitch is 1 month from the date of purchase.

Should the unlikely event of any failure of the device occur during the warranty period, the device should be returned to Odstock Medical Ltd.

Should the failure be due to manufacturing or material defect the device will be repaired or a replacement supplied free of charge.

The warranty is valid providing that the failure cannot be attributed to misuse

This warranty is in addition to any statutory rights available to the purchaser.

Default Functional Settings

Dropped Foot - Heel Rise

Parameter	Default Setting	Units/ Positions
Output Current	10	mA
R.Ramp	150	ms
Exten.	200	ms
F.Ramp	100	ms
Time Out	2500	ms
Delay	0	ms
Waveform	ASYM	
Freq.	40	Hz
Footswitch	Heel Rise	Heel
Timing	Adaptive	

Dropped Foot - Heel Strike

Parameters	Default Setting	Units/ Positions
Output Current	10	mA
R.Ramp	150	ms
Exten.	200	ms
F.Ramp	100	ms
Time Out	2500	ms
Delay	0	ms
Waveform	ASYM	
Freq.	40	Hz
Footswitch	Heel Strike	Heel
Timing	Adaptive	

Glutes/Quads - Weight Transfer

Parameter	Default Setting	Units/ Positions
Output Current	10	mA
R.Ramp	500	ms
Exten.	0	ms
F.Ramp	500	ms
Time Out	NTO	ms
Delay	0	ms
Waveform	ASYM	
Freq.	40	Hz
Footswitch	Heel Strike	Heel/Met Head
Timing	NTO	

Glutes/Quads - Walking

Parameters	Default Setting	Units/ Positions
Output Current	10	mA
R.Ramp	200	ms
Exten.	0	ms
F.Ramp	300	ms
Time Out	2500	ms
Delay	0	ms
Waveform	ASYM	
Freq.	40	Hz
Footswitch	Heel Strike	Heel
Timing	Adaptive	

Note: the output current is set to 10mA (lowest setting) and should be adjusted appropriately for each patient.

Default Functional Settings

Hamstring - Knee Flexion

Parameter	Default Setting	Units/ Positions
Output Current	10	mA
R.Ramp	200	ms
Exten.	300	ms
F.Ramp	150	ms
Time Out	2500	ms
Delay	350	ms
Waveform	ASYM	
Freq.	40	Hz
Footswitch	Heel Strike	Met Head
Timing	Adaptive	

Hamstring - Knee Hyperextension

Parameters	Default Setting	Units/ Positions
Output Current	10	mA
R.Ramp	200	ms
Exten.	200	ms
F.Ramp	200	ms
Time Out	800	ms
Delay	700	ms
Waveform	ASYM	
Freq.	40	Hz
Footswitch	Heel Rise	Heel
Timing	Adaptive	

Calf

Parameter	Default Setting	Units/ Positions
Output Current	10	mA
R.Ramp	200	ms
Exten.	0	ms
F.Ramp	100	ms
Time Out	2500	ms
Delay	200	ms
Waveform	SYM	
Freq.	40	Hz
Footswitch	Heel Strike	Met Head
Timing	Adaptive	

Triceps

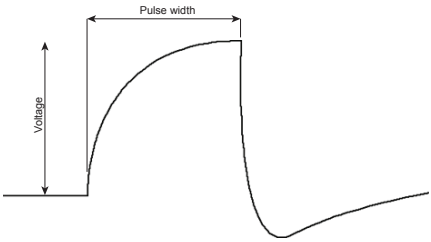
Parameters	Default Setting	Units/ Positions
Output Current	10	mA
R.Ramp	300	ms
Exten.	0	ms
F.Ramp	200	ms
Time Out	2500	ms
Delay	0	ms
Waveform	SYM	
Freq.	40	Hz
Footswitch	Heel Rise	Heel
Timing	Adaptive	

Default Exercise Setting

Exercise

Parameter	Default Setting	Units/ Positions
Output Current	10	mA
Waveform	ASYM	
Freq.	40	Hz
Duration	15	min
On period	3.0	sec
Off period	5.0	sec
Ramp	2.0	sec

Output Specification - ODFS® Pace (XL)

Output current:	10 to 100mA ± 10% or ± 3mA (which ever is greater) into a test load of 1kΩ±1% in parallel with 100nF±10%. Output is stated in mA in respect to this load. Output is not a constant current output. Actual current will increase with lower impedance and decrease with higher impedance. The output current stated is peak. Output: 0.5mA steps 10mA to 20mA. 1mA steps 20mA to 40mA. 2mA steps 40mA to 100mA.
Maximum intensity (rms)	16.2mA (rms)
Frequency:	10 to 60 Hz ± 10% in 5 Hz steps
Pulse width:	0 to 360 µs ± 10% in 3.6 µs steps (presented as %, 0 to 100%). Pulse width is the term used by Odstock Medical Limited to describe the duration of the output pulse from 0 until the 'corner' when the output falls rapidly indicating driven current flow has ended. 
Timeout period:	0.3 to 6 seconds ± 10% in 50ms steps
Delay:	0 to 2 seconds ± 10% in 50ms steps
Ramping times:	0 to 2 seconds ± 10% in 50ms steps
Extension times:	0 to 2 seconds ± 10% in 50ms steps
Output waveform:	Symmetrical and asymmetrical biphasic passive charge balanced
Exercise duration:	5 to 100 minutes ± 10% in 5 minutes steps or no limit
Exercise on period:	0 to 20 seconds ± 10% in 0.5 second steps
Exercise off period:	0 to 20 seconds ± 10% in 0.5 second steps
Exercise ramp time:	0 to 6 seconds ± 10% in 0.1 second steps

Technical Specification - ODFS® Pace (XL)

Medical device classification:	Class IIa, internally powered, continuous operation. Type BF applied part(s) 	
Ingress protection rating	Rating of IP22. Vertically falling drops have no harmful effects when the stimulator is tilted at any angle up to 15° on either side of the vertical. Do not get the device wet! Protected against objects entering the stimulator of 12.5mm and above.	
	Operational	Storage & Transport
Temperature:	Electrodes: 5 to 27°C Alkaline Battery: -20 to 54°C Lithium Battery: -10 to 40°C System (excluding above items): 5 to 40°C	Electrodes: 5 to 27°C >1 month Electrodes: 0 to 40°C <1 month Alkaline Battery: 5 to 30°C Lithium Battery: 0 to 35°C System (excluding above items): -20 to 70°C
Relative humidity:	Electrodes: 35 to 50% System & Batteries: 15 to 90%	Electrodes: 35 to 50% System & Batteries: 15 to 90%
Atmospheric pressure:	700 to 1060hPa	700 to 1060hPa
Stimulator size:	72 x 62 x 26 mm	
Stimulator:	ODFS® Pace	ODFS® Pace XL
Battery:	PP3, 9V	PP3, 9V
Battery life of average use:	Alkaline battery: 3 to 6 weeks NiCad or NiMH rechargeable battery: 4 to 8 days Lithium polymer rechargeable battery: 3 to 6 weeks.	Alkaline battery: 1 to 2 days NiCad or NiMH rechargeable battery: use not recommended Lithium polymer rechargeable battery: 1 to 2 days
Stimulator weight:	68g without battery	75g without battery

Wireless Information - ODFS® Pace XL

Description	The ODFS® Pace XL contains an industry standard ZigBee PRO compliant RF telemetry module, the ETRX3.
Contains RF transmitter (FCC ID)	S4GEM35XA
Industry Canada (IC-ID)	8735A-EM35XA
Frequency band	2.4 to 2.483 GHz (2.4GHz ISM band)
Radiated power	+8dBm
Wireless compliance	The wireless module used has been designed to meet all national regulations for worldwide use. The wireless module complies with the requirements of the Radio Equipment Directive (2014/53/EU) and complies with FCC CFR Part 15(USA) meeting the requirements for modular transmitter approval as detailed in FCC public notice DA00. 107. Transmitter.
Quality of service	The ODFS® Pace XL is designed and tested to have a response rate of less than 100ms latency depending on system configuration after the detection of a heel event.
Co-exsistence and interference	The system has been stringently tested in a range of scenarios showing that it is not susceptible to interference. However, there is no guarantee that other wireless communication devices will not interfere with wireless communications. The module is also certified to European Certification (ETSI) EN 300 328:V2.1.1 (radio) EN301 489-1 V2.1.1 (EMC) EN301 489-17:V3.3.1 (EMC) and IEC 60950-1:2005+AMD2:2013
Wireless Communication indications	On pausing the ODFS® Pace XL, the wireless connection is confirmed by display of a battery level for the footswitch. If the connection Is not found, the message 'No WFS!' is displayed (pg.27 Clinician Manual, pg.24 User manual) To connect an new footswitch or re-establish a failed connection follow the procedure on pg.79-80 of the Clinician Manual, pg.37-38 of the User Manual.
Security requirements	No user security measures required. AES-128 hardware supported encryption implemented. No patient identifiable data is transmitted or retained by the device.

If the performance of the system is compromised by other equipment (such as home routers), the user should turn off the system and move away from the interfering equipment. Please refer to fault finding.

Like all radio telemetry devices the ODFS® Pace XL and wireless accessories should not be used while flying. Set the ODFS® Pace XL to **airplane mode** and use a **wired footswitch**. Please refer to page 31 on how to set **airplane mode**.

Electromagnetic Emissions

The ODFS® Pace was tested with electrodes, footswitch, electrode lead and footswitch lead of the maximum length (electrode lead – 1.5m, footswitch lead – 1.5m and footswitch – 0.6m). The ODFS® Pace XL was tested with 2 OML LINQ™ using one 0.6m footswitch in each and the OML Remote. Details of these accessories can be found in the manual.

Manufacturer's declaration of electromagnetic emissions		
The ODFS® Pace (XL) is intended for use in the electromagnetic environment specified below. The customer or user of the ODFS® Pace (XL) should ensure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment guidance**
RF emissions CISPR 11	Group 1	The ODFS® Pace (XL) uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radiated Spurious Emissions ETSI EN 300 328 V2.1.1	Clause 5.4.9 (30MHz to 12.75GHz)	
Radiated emissions FCC/CFR 47:Part 15.209:2017	Class B (30MHz to 25GHz)	
RF emissions CISPR 11	Class B	The ODFS® Pace (XL) is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	No connection to mains (Battery-operated)	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	No connection to mains (Battery-operated)	

Manufacturer's declaration of electromagnetic immunity			
The ODFS® Pace (XL) is intended for use in the electromagnetic environment specified below. The customer or user of the ODFS® Pace (XL) should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV contact ± 15 kV air	± 8kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC 6100-4-4	No connection to mains (Battery-operated)		ODFS Pace® (XL) does not have a mains power supply
Surge IEC 6100-4-5	No connection to mains (Battery-operated)		
Voltage dips, short interruptions and variations IEC 61000-4-11	No connection to mains (Battery-operated)		
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial, hospital or domestic environment.

Manufacturer's declaration of electromagnetic immunity continued			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Portable and mobile RF communications equipment should be used no closer to any part of the ODFS® Pace (XL), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Conducted RF IEC 61000-4-6	3 Vrms (150 kHz to 80 MHz) 6 Vrms in ISM bands	3 Vrms (150 kHz to 80 MHz) 6 Vrms in ISM bands	Recommended separation distance: $d = 1.2 * \sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 Mhz to 2.5 GHz	10 V/m	Recommended separation distance: $d = 1.2 * \sqrt{P}$ (80 Mhz to 800 MHz) $d = 2.3 * \sqrt{P}$ (800 MHz to 2.5 GHz)

Note 1: Where (P) is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer and (d) is the recommended separation distance in metres (m).

Note 2: Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol.

Note 3: At 80 MHz and 800 MHz, higher frequency range applies.

Note 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in which the ODFS® Pace (XL) is used, exceeds the applicable RF compliance level above, the ODFS® Pace (XL) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the ODFS® Pace (XL).

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Electromagnetic Compliance

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2 * \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 * \sqrt{P}$	800MHz to 2.5GHz $d = 2.3 * \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.20	1.20	2.30
10	3.79	3.79	7.27
100	12.0	12.0	23.0

For transmitters rated at a maximum output power not listed above, the recommended separation distance in metres (m) can be estimated using the equation applicable to the frequency of the transmitter where is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Regulatory Representatives

Odstock Medical Limited is based in the United Kingdom. Odstock Medical Limited uses external bodies as representatives where required by local regulations.
Any adverse incidences or regulatory problems should be reported via local representative. If in doubt please contact Odstock Medical Limited for advice.

EC REP

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The Netherlands

Enquiries should be initially directed to your local distributor. If in doubt please contact Odstock Medical Limited.

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Local contact information may be placed here.

Notes

Notes

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OML | Leading FES Rehabilitation

CE 2797

NHS Salisbury

PACE-IFU-11-003-0078 (DOC-626) Ver. 8

Approved By:

(CO-112) Various updated to the Technical Documentation for Pace (XL) incl. BEP/BER, RA, DoC

Description

Upload BEP/BER for Pace (XL) and Accessories, Revised RA to cover cybersecurity risks, updated DoC to refer to other regulations, updates to the TD summary

Justification

Initial release and controls in GG

Assigned To:	Initiated By:	Priority:	Impact:
Steven Crook	Steven Crook	Medium	Minor

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