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Clinician Manual QF018/ODFS Pace (XL)

Product code for manual: 11-003-0015



Leading Rehabilitation
Through Technology

Odstock Medical Limited

CLINICIAN'S INSTRUCTION MANUAL

Odstock® Dropped Foot Stimulator

Model ODFS® Pace V1.0

Model ODFS® Pace XL V1.0

Manual Revision 1 (December 2014)

From Software V1.3.04



SAFETY NOTICE:

The output of this device has a physiological effect. Read the instructions and precautions before use. The device should only be supplied and set up by a trained clinician.

...a confident choice™



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Salisbury **NHS**
NHS Foundation Trust

Contents

Key Features	3
Accessories	4
Introduction	5
Important Information	7-10
ODFS® Pace and ODFS® Pace XL Kit Contents	11-12
Controls, Connectors and Battery	13
Operating Guide	14-17
User Accessible Menu	18
Set-Up Menu	20
Finetune Settings	22
Options Menu	24
Activity Logger	26
Language	28
Parameter View Mode	29
Auto Turn Off and Set-Up Time Out	30
Clinical Applications - Dropped Foot	31
Finetune - Dropped Foot	35
Options Menu - Footswitch / Timing Mode	39-40
Electrode Positions - Dropped Foot	41
The Correct Movement - Dropped Foot / Electrode Care	45
Electrode Care	45-46
Wired Footswitch	47
Exercise Stimulation	48
Using Exercise Stimulation	51
Patient Selection - Dropped Foot	53
Clinical Procedure - Dropped Foot	55
ODFS® Pace (XL) in Physiotherapy Gait Training	56
New Set-Up - Gluteal / Quads	57
New Set-Up - Hamstrings	59
New Set-Up - Calf	61
New Set-Up - Triceps	62
Wireless Footswitch Module Key Features	63
Wireless Insole Key Features	64
Wireless Footswitch	65
Changing the Battery of the Wireless Footswitch Module	67
ODFS® Pace XL	69
Maintenance, Servicing and Fault Finding	73
Specifications	76
Wireless Footswitch Insole Size Guide	78
Warranty Information	79
Default Settings	80
References	82
Clinic Forms	83

Key Features



Accessories

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.



ODFS® Pace (XL) leg strap

An optional accessory. The leg strap connects to the ODFS® Pace pouch using the easy to use connector plate. Press the button on the top of the connection plate to release the ODFS® Pace pouch. Use with 25cm electrode leads and 60cm "all in one" Footswitches or ODFS® Pace XL Wireless Footswitch. The strap can also be used on the arm for upper limb applications.



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 stroke, multiple sclerosis, incomplete spinal cord injury (T12 and above), head injury, cerebral palsy, Parkinson's disease and hereditary spastic paraparesis.

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 placed, typically over the common peroneal nerve as it passes over the head of the fibula and over the motor point of tibialis anterior. Stimulation produces dorsiflexion and eversion of the foot and in certain electrode configurations produces a withdrawal reflex, adding knee flexion and hip flexion. Electrical stimulation feels like "pins and needles" and most people 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 device user.

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 hip extension, knee flexion and extension and push-off in terminal stance.

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

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.

Important Information

CONTRAINDICATIONS

The ODFS® Pace (XL) should not be used on patients 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 in breathing. Stimulation over the neck could also 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, e.g. phlebitis, thrombophlebitis, varicose veins. Stimulation should only be applied to normal intact, clean skin.

Cancer

Stimulation should not be applied over, or in proximity to, cancerous tumours.

Electronic Monitoring Equipment

Stimulation should not be applied in the presence of electronic monitoring equipment, such as cardiac monitors and ECG 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.

Sleeping

Stimulation should not be applied when sleeping.

Chest Stimulation

Stimulation should not be applied across the chest because the introduction of electrical current into the chest may cause rhythm disturbances to the patient's heart, which could be fatal.

Important Information

PRECAUTIONS

Handling Electrodes

Do not handle electrodes while the stimulation is on. Always make sure that the ODFS® Pace (XL) is Paused before adjusting the electrodes.

Electrodes/Leads

Use this device only with the leads, electrodes, and accessories recommended by the manufacturer. Replace leads if they become stiff or damaged in any way.

Skin Irritation

Some people may experience skin irritation due to electrical stimulation or 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 electrode is normal and this should clear within 1 hour of stopping stimulation. If stimulation causes long-term marking of the skin, discontinue use and seek medical advice.

Skin Care

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

Spasticity

If stimulation causes increased spasticity (involuntary, exaggerated muscle stiffness and spasm), discontinue use and consult your 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

Do not use the stimulator, or any part of the stimulator system in the bath or shower.

Shortwave Therapy

Do not use the stimulator within three metres of physiotherapy short wave therapy equipment.

Epilepsy

Patients 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.

Autonomic Dysreflexia

ODFS® Pace (XL) 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). If affected, discontinue use and consult your physician.

Cardiac

Patients with suspected or diagnosed heart disease should follow the exercise precautions recommended by their physicians.

Haemorrhage

Electrical stimulation should not be carried out in areas of the body affected by recent injury, fracture or surgery.

Pregnancy

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

Children

The ODFS® Pace (XL) is not a toy! Only use as instructed by the clinician.

Latex Allergies

Caution: The elasticated tubular stocking contains natural rubber latex which may cause allergic reactions. This item is provided as an accessory to the ODFS® Pace (XL) device. Do not use if sensitive to products that contain latex.

Long-term Effects

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

Wireless Footswitch Insole

If the user has poor sensation in the feet we advise regular inspection of the condition of the feet as poor fitting Wireless Footswitch Insole(s) may lead to areas of increased pressure. If this is the case we would advise the user to contact the clinician who set up the system.

Air Travel

Like all radio telemetry devices the ODFS® Pace XL Wireless Footswitch should not be used while flying. We recommend that the ODFS® Pace XL is used with a wired Footswitch for air travel. The Wireless Footswitch should be carried in luggage with its battery removed.

Batteries

We advise to only use batteries recommended by Odstock Medical Limited. All battery technologies carry a very small risk of explosion. Ensure you follow the instructions for installing, using and disposing of the battery. Please read the information supplied with the batteries.

Important Information

ADVERSE REACTIONS

The ODFS® Pace (XL) user should report any undesirable outcomes, malfunctioning of the device, or injury from the use of this device to the Clinician who provided it to them.

The Clinician is responsible for reporting all adverse events to Odstock Medical Limited or their local representative.

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. This could lead to a stumble or trip and consequent injury or harm.

Symbols and Definitions



Attention: Device has physiological effect.



Internally powered device with applied parts of insulation type BF.



Read instructions before use.



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



The CE mark indicates that the ODFS® Pace (XL) complies with European Union Medical Device Directive.



Protected against solid foreign objects of diameter 1.2 mm or greater and dripping water.



Protected against solid foreign objects of diameter 2.5mm and greater. No protection from water.



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



Manufactured by Odstock Medical Limited.

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ODFS® Pace Kit Contents

Description	Product code	Qty
ODFS® Pace Stimulator	01-001-0001	1
Electrode Lead 1m*	03-001-0008	1
Neurostimulation Electrodes 50 x 50mm	See pack for product code	1 Pack of 4 electrodes
PP3 Battery (9V)	05-001-0002	1
Pair of Cork Insoles, Size 10	01-005-0025	1
Footswitch Lead 1.2m*	03-001-0003	1
Footswitch with 30cm lead**	01-005-0023	2
Elasticated Tubular Bandage Size G*	16-005-0018	25cm (approx.)
ODFS® Pace Pouch***	15-005-0003	1
Footswitch Lead Coupler	12-001-0024	1
Linen Drawstring Bag	15-005-0002	1
Clinician Quick Start Guide	11-003-0003	1
Clinician Manual	11-003-0001	1
User Manual	11-003-0002	1
User Infocard	11-003-0006	1
Warranty Card	11-003-0007	1

* Other sizes available on request

** Other types and sizes available on request

*** Other accessories available e.g. leg strap, swivel clip, carabiner.

Please visit our web page www.odstockmedical.com

ODFS® Pace XL Kit Contents

Description	Product code	Qty
ODFS® Pace XL Stimulator	01-001-0002	1
Wireless Footswitch Module	01-001-0003	1
Wireless Footswitch Insole Kit Large/Medium/Small - <i>Wireless Footswitch Insoles (pair) Large/Medium/Small</i> - <i>Odstock Medical Limited Foam Insoles (pair)</i> - <i>Blank Insert</i> - <i>Battery Access Covers (x3)</i>	00-004-0001/2/3 12-008-0007	1
PP3 Rechargeable Battery LiPo	05-001-0003	2
Battery Charger 4 Bay LiPo	05-001-0005	1
Coin Cell Battery CR2430	05-001-0004	2
Network Joining Tool	10-007-0001	1
Wired 1.5m "all-in-one" Footswitch	01-005-0026	1
Electrode Lead 1m*	03-001-0008	1
Footswitch Socket Bung	12-001-0021	1
Neurostimulation Electrodes 50 x 50mm	See pack for product code	1 Pack of 4 electrodes
ODFS® Pace Pouch***	15-005-0003	1
Elasticated Tubular Bandage Size G*	16-005-0018	25cm
Linen Drawstring Bag	15-005-0002	1
Clinician Quick Start Guide	11-003-0003	1
Clinician Manual	11-003-0001	1
User Manual	11-003-0002	1
User Infocard	11-003-0006	1
Warranty Card	11-003-0007	1

* Other sizes available on request

** Other types and sizes available on request

*** Other accessories available e.g. leg strap, swivel clip, carabiner.

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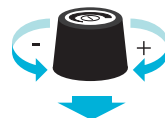
Controls, Connectors and Battery

Controls

Control Knob

This control has three actions;

- Twist clockwise to turn up or 'Increase'
- Twist anticlockwise to turn down or 'Decrease'
- Press down to 'Click' or 'Select'



Test button

This button is used when testing the output level and to assist finding the correct electrode position. The Test button only functions when the stimulator is paused.



Pause button

This button is used to start the stimulation. This is called Active mode. When not in Active mode the ODFS® Pace (XL) is said to be paused or in Pause mode. Active and Pause mode are switched by repeated presses of the button. A long beep is given for entering Active mode and a shorter, higher pitched beep given for exiting Active mode.



When the Pause mode is entered, the display will briefly flash up the battery condition. To keep the battery condition displayed for longer, 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 lead socket and identified with footprint symbol. This is where the Footswitch lead is plugged into.



Battery

The battery is accessed by sliding the lid from the rear of the box. Ensure that the battery is correctly inserted. A single PP3 9V, Standard, alkaline or rechargeable NiMH or LiPo battery can be used. If the device is not going to be used for an extended period of time, remove the battery.



Operating Guide

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.

During the start up process the battery condition will be briefly 'displayed as 'GOOD', 'OK', 'POOR' or 'REPLACE'

If the battery condition is 'OK' or 'POOR', the ODFS® Pace can still be used but it may be necessary to increase the output level.

If 'REPLACE' is displayed, the indicator light flashes and a siren beep heard. The ODFS® Pace (XL) can still be used but the battery should be replaced as soon as possible.

When the ODFS® Pace (XL) is turned on, the output level (pulse width) is set to 1%. This default Starting Percentage can be set to 50%. Please see section on Starting Percentage on page 25.



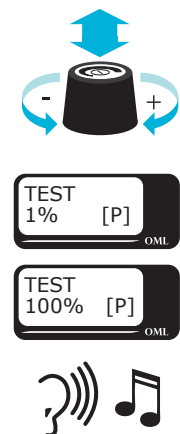
Adjusting the Output Level (Pulse Width)

The output of the ODFS® Pace (XL) is adjusted by first clicking (press and release) and then turning the Control Knob. This sets the stimulation pulse width. If the control lock has been deselected in the options menu (page 25), the output can be adjusted without first clicking the Control Knob. Control lock is disabled in Exercise Mode when active.

As the knob is twisted the output level is displayed as a number from 1 to 100%.

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. Likewise there is a double low pitch beep at 0% to indicate that the ODFS® Pace (XL) can be turned off.

It is good practice to only adjust the output while there is a stimulation output. This enables an instant feedback of the effect of the change.



Using the Test button

While the stimulator is paused, the output can be tested by pressing the Test button. 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.

While there is an output from the device the level indicator (pulse width) appears as a row of blocks on the lower line.

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

Press the Pause button to start operation.

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

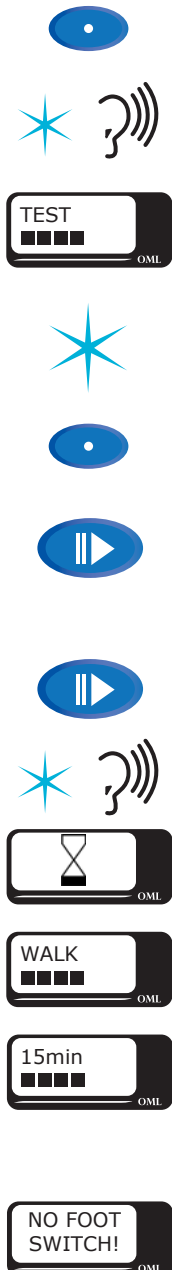
The level indicator will be shown on the display.

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.

If in Walk mode the screen will display 'WALK' and the ODFS® Pace (XL) will respond to the Footswitch.

If in Exercise mode the screen will change to the exercise count-down timer and level indicator blocks. Press the Pause button to start and stop exercise. There is a different beep for starting and stopping exercise stimulation compared with WALKING mode. This is to inform the user which mode they are in and help prevent attempts to walk with the device in EXERCISE mode.

If in Walk mode and there is no Footswitch present the screen will display "NO FOOT SWITCH!" and an audio warning is given. If ODFS® Pace XL is used there will be a delay and an hourglass symbol will displayed while the devices



Operating Guide

searches for a Wireless Footswitch. NOTE - this delay can be up to 30s. 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 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.



If the Pause button is held down 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 on the bottom line for the Wireless Footswitch.



Low battery warning

If either ODFS® Pace (XL) or Wireless Footswitch battery level becomes too low while walking, a regular warning beep will be heard. When the device is paused, a 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 pausing, the screen will display No W.FS! instead of the wireless battery level. If this occurs please refer to the fault finding section on page 73.



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 [P] symbol is displayed, if not pause the stimulator.

Click and then rotate the Control Knob anti-clockwise until the output on the display reads 0% and the I/O 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 18 for details of the User Access Menu.

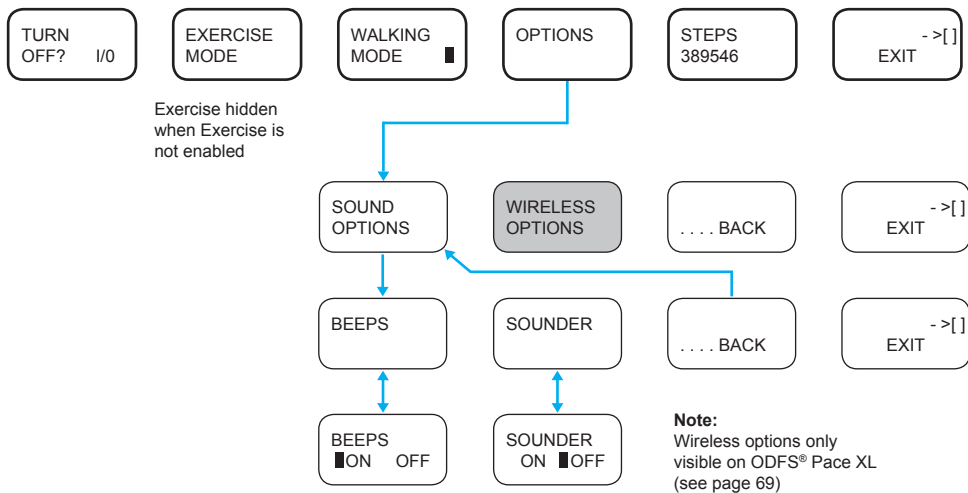
If the stimulator is left turned on in Pause mode, but is not used for more than 4 hours, it will automatically turn off and the output level reset to 1%. The output level must be adjusted to the required level when the stimulator is turned on again. The purpose of this feature is to ensure that stimulator users who turn the device up throughout the day as their muscles become tired do not receive an unexpectedly high level of stimulation when they turn the device on the next day. The stimulator should therefore not be turned off using the Control Knob throughout the day, just paused.

The stimulator can also be set to turn on at 50%. Please see page 25.



User Accessible Menu

To enter the User Accessible Menu; whilst paused, first unlock by clicking the Control Knob then 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 the black box.



Changing between Walk and Exercise modes

Rotate the Control Knob to progress along the menu. When the WALKING MODE, EXERCISE MODE or TURN OFF? I/O 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 option. NOTE - when the mode is changed the output level is reduced to 1%.



Options

This menu item gives two further choices. SOUND OPTIONS and WIRELESS OPTIONS (ODFS® Pace XL only, see page 69). Clicking on SOUND OPTIONS brings two more choices. BEEPS allows the user to turn on and off the audio beep feedback. SOUNDER allows a stimulation audio feedback to be turned on and off. Click on the chosen option and rotate the Knob and then click to choose ON or OFF. The black box indicates the current setting. Use BACK to return to the main menu or EXIT to go to back to the current user mode.

Steps

This screen gives the total number of steps taken with the ODFS® Pace (XL) since the log was last reset. The step count can be used to encourage users to achieve planned activity goals.

Exit

Clicking on EXIT returns you to the current user mode.

Menu timeout

The User Accessible Menu will exit back to the current user mode after 1 minute of inactivity.

Set-up Menu

FACTORY
RESET?

NEW
SETUP?

FINETUNE
SETTINGS

OPTIONS
MENU

EXERCISE
SETTINGS

ACTIVITY
LOGGER

LANGUAGE
OPTIONS

- > []
EXIT

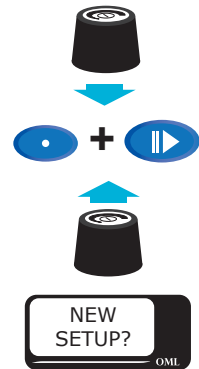
Accessing the Set-up menu - “The 3 button trick”

When the stimulator has been turned on and is paused, the Set-up menu can be accessed.

All of the parameters necessary for setting up the stimulator are contained within the Set-up menu. To prevent these settings from being inadvertently adjusted, the Set-up menu is under normal circumstances not 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 buttons.
4. Release the Control Knob and the first screen of the Set-up menu will be displayed.



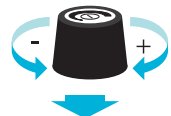
Using the Set-up menu

The Control Knob is used to navigate around the menu. Twisting the Control Knob will bring up each of the menu screens in turn. Options are chosen by clicking down on the Control Knob

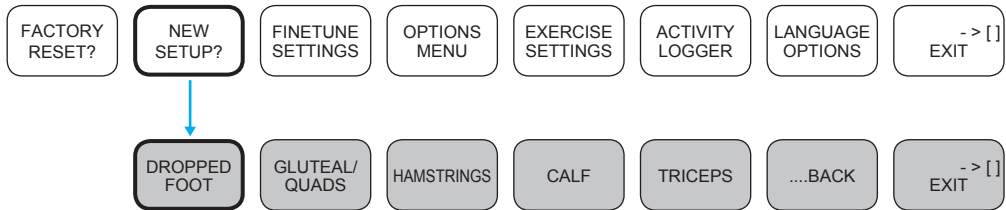
The first time that the Set-up menu is accessed after turning on, you will be asked if you want to perform a ‘NEW SETUP?’. On each subsequent visit, the first option will be either FINETUNE SETTINGS if the setup menu is entered from Walk mode or EXERCISE SETTINGS if the setup menu is entered from Exercise mode. These options allow you to adjust individual parameters without resetting all the parameters to their default values.

Each time that the ‘NEW SETUP?’ screen is displayed a double beep is heard. This is to remind you that using this option will overwrite all of the previous settings.

If the FACTORY RESET screen is reached two double warning beeps are given to warn you that choosing this option will reset all settings and data logs.



New Set-up



New Set-up

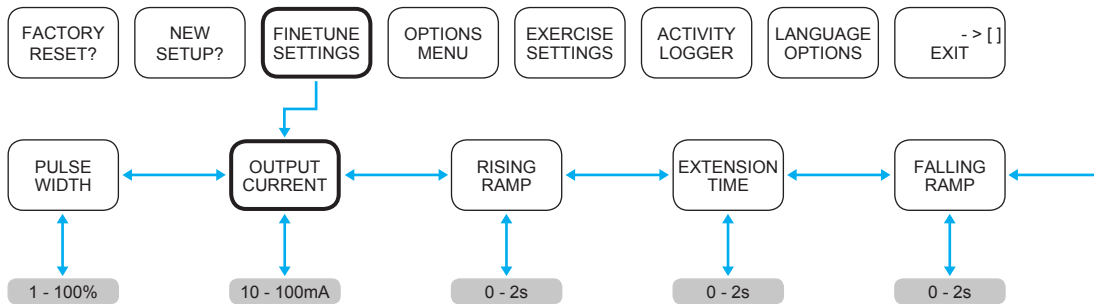
This option allows you to choose from a range of applications and automatically sets the stimulation parameters to appropriate values. The menu structure then guides you through each parameter, allowing you to tune the parameters to each individuals needs.

This menu has the following gait options:

- Dropped Foot using heel rise or heel strike
- Gluteal or Quadriceps muscles in walking and 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 each time the ODFS® Pace (XL) is used with a new user.

Finetune Settings



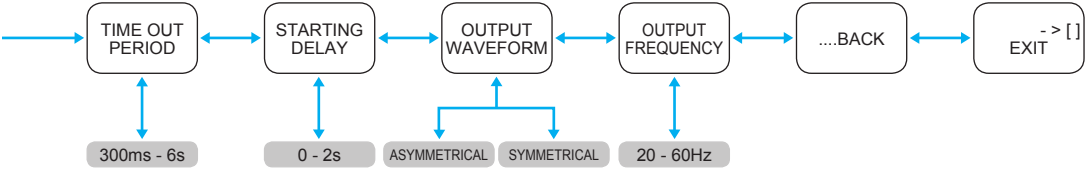
Using Finetune Settings

Once you have chosen the application you need from the 'NEW SETUP?' screen, the next menu item to appear on the screen is 'CURRENT'. Current is the first parameter on the Finetune menu. This parameter sets the contraction strength and it needs to be set for each individual ODFS® Pace (XL) user (see page 32)

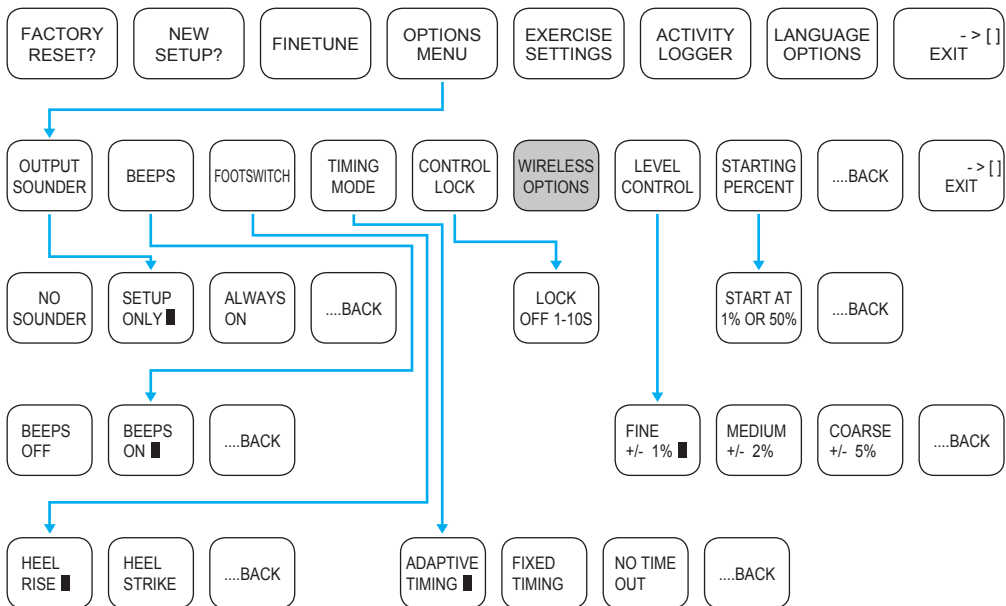
The Finetune menu allows adjustment of all the parameters that make up the applications used in the New Set-up menu.

Adjustments made can be tested during walking while in the Finetune menu by pressing the Pause button. An audio feedback of stimulation is given allowing easier judgment of timing parameters. Stay in Finetune until all adjustments are complete.

Each item of the Finetune menu will be described in the Clinical Application section of this manual (page 35-38)



Options Menu



Options Menu

This menu allows adjustment of less frequently changed settings. The currently set option is indicated by a black square.

Output sounder

This is the audible feedback that accompanies the stimulation. This is used to check the timing of the stimulation while watching the ODFS® Pace (XL) user walk. There are three options:

- 'NO SOUNDER' - the sounder will be turned off in all modes.
- 'SETUP ONLY' - the sounder will work while adjustments are being made in 'FINETUNE'.
- 'ALWAYS ON' - the sounder will work at all times (except when in EXCERCISE).

The Default is 'SETUP ONLY'.

Beeps

This option allows you to turn on or turn off the beeps.

There are two options:

- 'BEEPS OFF'
- 'BEEPS ON'

The Default is 'BEEPS ON'.



Footswitch

This option allows you to choose if stimulation is triggered when weight is placed on (heel strike) or taken off (heel rise) the Footswitch. For a full description and clinical application of this parameter please see page 39.



Timing mode

This option sets the timing action of the Footswitch.



- In 'ADAPTIVE TIMING' stimulation is started and stopped by the Footswitch up to a maximum time set by the 'TIME OUT PERIOD' (Finetune menu).
- In the 'FIXED TIMING' mode stimulation starts with a Footswitch but continues for as long as the time set by the 'TIME OUT PERIOD' (Finetune menu).
- In 'NO TIME OUT' (NTO) stimulation is started and stopped by the Footswitch but there is no maximum time.

For a full description and clinical application of this parameter please see page 40.

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.



Wireless option

ODFS® Pace XL only. Please see page 69.

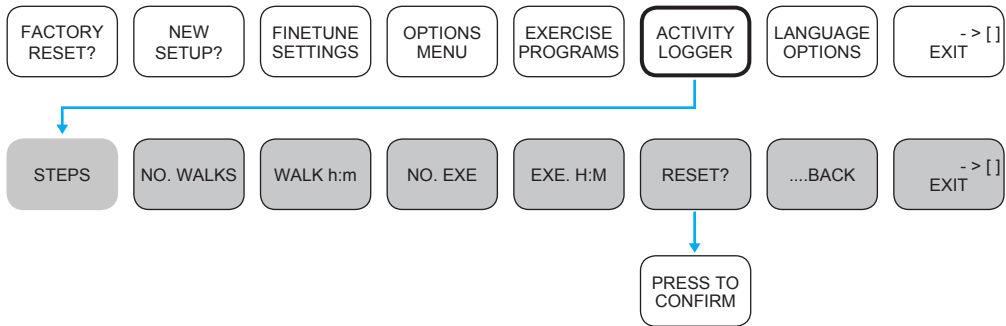
Level control

This option allows you choose the increments used by the Level Control. There is a choice of Fine 1% steps, Medium 2% steps and Coarse 5% steps. The default is Fine 1%. Choose the other settings for more rapid adjustment of output level.

Starting percent

This option allows you to choose whether the output level is set to 1% or 50% at turn on. The default is 1%, which ensures the level is reset to an appropriate level each time the ODFS® Pace (XL) is used. 50% can be chosen for more rapid use of the device if the user gets a consistent response from this level of stimulation.

Activity Logger



Using the activity logger

After opening the Set-up menu navigate to the activity logger screen and click the Control Knob. Use the Control Knob to navigate around the sub menu and read off the stored log data. This data can also be read in Parameter View Mode see page 29.

'STEPS'

Records the total number of footsteps (affected side only) since the logger was last reset.



'No. WALKS'

Records the number of times that stimulation was started for walking since the logger was last reset.



'WALK h:m'

Records the total time in hours and minutes that the stimulator has been active in walk mode since the logger was last reset.



'No. EXE'

Records the number of times that the stimulator has been used for exercise since the logger was last reset.



'EXE. h:m'

Records the total time in hours and minutes that the stimulator has been used for exercise since the logger was last reset.



'RESET?'

Clears the logger and resets all values to zero. Confirmation is required before this can happen.

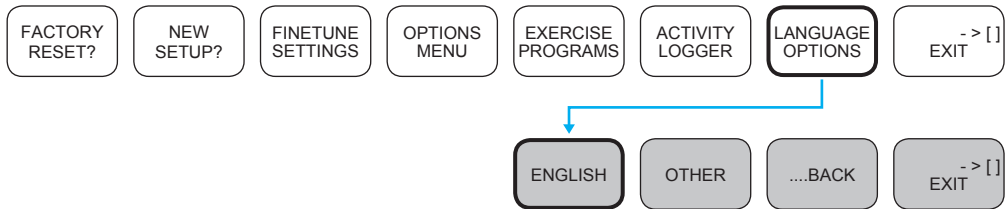


Note: Once 'PRESS TO CONFIRM' is displayed, press the Control Knob again to confirm the reset. If RESET was selected unintentionally, this screen will timeout after 3 seconds without affecting the data.



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



Using language options

After opening the Set-up menu navigate to the Language options screen and click the Control Knob.

Scroll through the language options using the Control Knob and click on your chosen option.

Not all available languages may be available on every device. Contact Odstock Medical Limited for further information.

Parameter View Mode

This facility allows all the parameter and activity logger values to be viewed without going into Set-up mode. Additionally the data logger values can be reset to zero. This is used to copy down the device settings at the end of a clinic session for record keeping. Clinical settings forms and care pathways can be downloaded from www.odstockmedical.com. It is not possible to adjust parameters in this mode.

With the device turned off, press and hold down the Test button and then press and hold down the Control Knob until the 'Setup' screen appears. The display will now show the first screen, which is the basic walking set-up. This uses the codes listed below.

DF - Dropped foot

GQ - Gluteal / Quadriceps

H - Hamstring

C - Calf

T - Triceps

KF - Knee flexion

HE - Hyper extension

HS - Heel strike

HR - Heel rise

NTO - No Time-Out

Navigate by twisting the Control Knob to go backwards or forward. Press Pause button to exit Parameter view mode, or press and hold the Control Knob to turn off.



Auto Turn Off and Set-up Time Out

Auto turn off

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

Note. Unless the STARTING PERCENT has been set to 50% the pulse width is reduced to 1% when the device turns off and will need to be reset by the user before walking.

Set-up time-out

If the ODFS® Pace (XL) is left in the Set-up menu (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 User mode (paused).

If, while in Set-up, the ODFS® Pace (XL) is left in Active mode (i.e. the user is walking with the ODFS® Pace (XL)) for more than 10 minutes, the next time that the Pause button is pressed to stop walking, the ODFS® Pace (XL) will exit Set-up and go to the User mode.

Clinical Applications - Dropped Foot

Turn the device on by pressing the Control Knob down for 1 second.

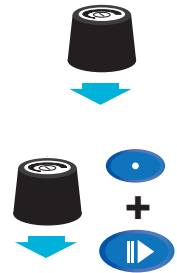
Put the device into Set-up mode by again pressing and holding down the Control Knob and then pressing the Test and Pause buttons together, then letting all three buttons go.

A double beep is heard and the screen display will read 'NEW SETUP?'. If you wish to set the device up for a new user or a new application with the same user, choose this option by pressing the Control Knob. This will reset all the parameters to default values including setting the current to its minimum.

If you wish to make adjustments to an existing set-up, rotate the Control Knob clockwise one step to the Finetune screen. This option allows adjustment of individual parameters without resetting all of them.

Select 'NEW SETUP?'. The next screen allows you to choose a treatment type. Choose 'DROPPED FOOT' by clicking the Control Knob.

The next screen lets you choose how the ODFS® Pace (XL) is controlled by its Footswitch. For dropped foot the most common way 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 from the foot switch. Select this option.

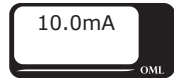


Dropped Foot - Setting the Current

The menu screen will display 'OUTPUT CURRENT'. Click to enter the current setting menu.

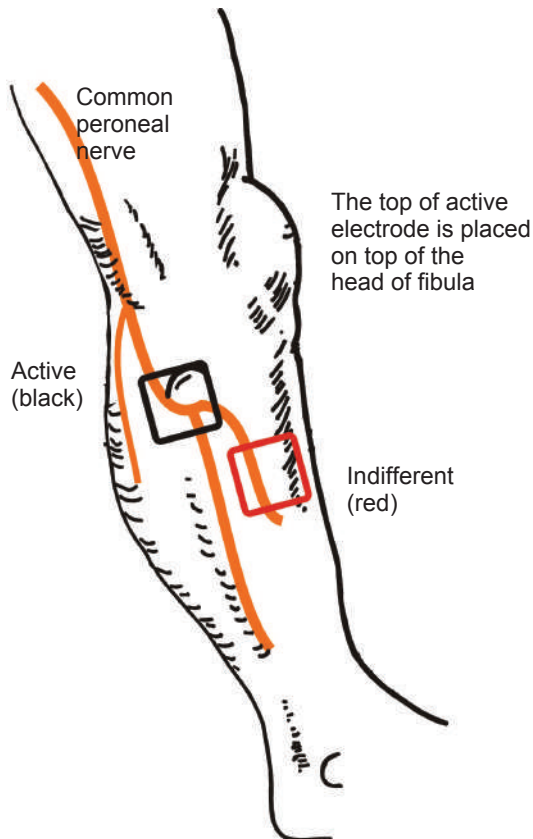


The display shows the output current already set. The minimum current setting is 10mA (milliamps).



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

While the patient is sitting with their leg in a relaxed, near extended position, place the electrodes as shown below.



To test the current output, press and release the Test button. The LED will flicker to indicate an output and an audio signal is given. 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 and falling ramps.

While stimulating, increase the current by rotating the Control Knob clockwise. Observe the effect on the patient. You will need to repeatedly press and release the Test button to find the correct setting. The current can only be increased while stimulating, but can be reduced between test stimulations.

The correct movement is dorsiflexion with a small amount of eversion. If the correct movement is not produced, refer to the section on electrode positions (pages 41-45).

Once a good movement is produced, place the Wired or Wireless Footswitch in the shoe and try walking. Press the Pause button to enter Active mode. A long beep is heard. The patient can then walk with the device.

It is often the case that the level of stimulation needs adjusting when the ODFS® Pace (XL) user is walking. This can be because the level of calf tone is different when upright or you may have wrongly estimated the amount of dorsiflexion required for walking. Unlike when using the Test button, the current can be increased between steps. Click and turn to make adjustments.

If the ODFS® Pace (XL) user is walking well, then you have completed the set-up procedure! The Set-up mode can be exited and the ODFS® Pace (XL) issued.

To make adjustments to the stimulator's settings please see page 35.



Exiting Set-up and Pulse Width Adjustment

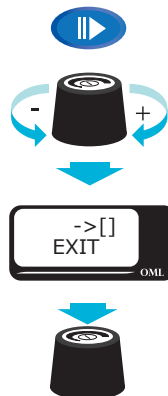
Exiting Set-up mode

Press the Pause button to leave Active mode.

Press the Control Knob to go out of the current setting screen.

Rotate the Control Knob until the Exit screen is reached.

Press the Control Knob again to exit the Set-up mode.



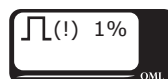
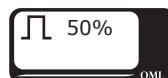
Changing the Pulse Width setting in Finetune

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

If the pulse width is increased, reduce the current before testing.

NOTE - when testing the output while in 'PULSE WIDTH' it is the current that is adjusted while stimulating.



Pulse width out of range warning

If you enter FINETUNE with a pulse width setting outside the normal operating range (45-55%) the PULSE WIDTH (!) warning is given. If the pulse width is at the intended setting, ignore this warning by rotating the Control Knob to access the rest of the FINETUNE menu. If the pulse width is incorrect, click the Control Knob to enter the pulse width setting screen. Set the pulse width to 50% or other intended level.

Finetune - Dropped Foot

Rising Ramp

While the default setting will be suitable for many people, often some adjustments are required to achieve the best result.

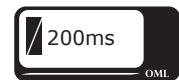
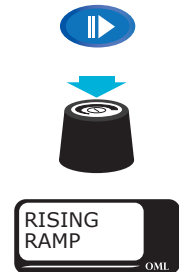
Press the Pause button to exit Active mode and press the Control Knob to leave the current setting screen.

The next screen you come to is 'RISING RAMP'. This parameter allows you to choose how fast the stimulation rises to its maximum pulse width once a stimulation output starts. There are 4 reasons why you might 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.
- In people 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 ramp helps to prevent this happening.
- Some people find a rapid rise of pulse width uncomfortable. A longer ramp may be more acceptable.
- If dorsiflexion occurs too soon, 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.

However, 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.

Click to select. The rising ramp can be adjusted from 0 to 2000ms. Turn the Control Knob clockwise to increase the ramp time. The default for dropped foot is 200ms. This is suitable for most slow walkers.



Finetune - Dropped Foot

Extension

Extension allows you to add a period of stimulation after weight is returned to the heel switch (or taken off it in Heel Rise mode). This enables an eccentric contraction in the anterior tibialis, 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 also be used to provide eversion for ankle stability in initial weight bearing when there is excessive inversion.

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

Use the sounder to set the Extension so that the stimulation ends at the point the foot is flat on the ground. Extension can be adjusted from 0 to 2000ms. The default for dropped foot is 200ms.

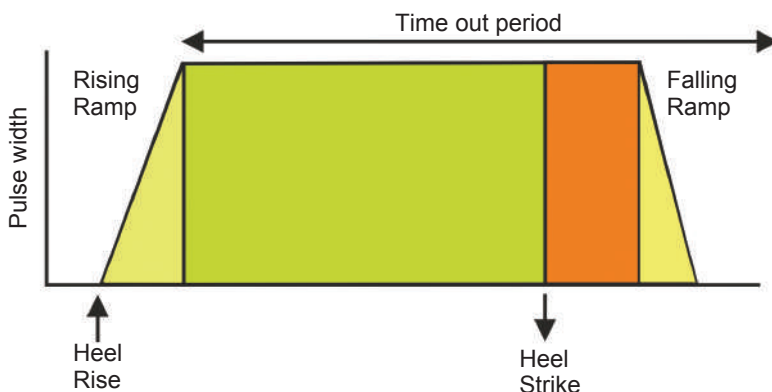


Falling ramp

The 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 0 and 2000ms. The default for dropped foot is 150ms.



Envelope



Finetune - Dropped Foot

Time-Out period

The Time-Out Period is the maximum time that stimulation can last for from a single footswitch or Test button trigger. It should be set just a little bit longer than the longest stride time taken by the user. 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 user will get a long stimulation when they take weight off the footswitch when sitting down. The Time-Out Period can be adjusted between 300ms and 6000ms (6 seconds).



Starting delay

The Starting Delay allows the stimulation to begin a little time after the Footswitch change. 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. The delay can be adjusted between 0 and 2000ms. Leave at 0ms for dropped foot.

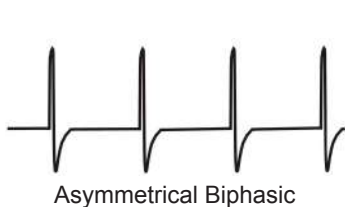


Output waveform

The ODFS® Pace (XL) has a choice of 2 waveforms, Asymmetrical biphasic 'ASYM' and Symmetrical biphasic 'SYM'. The set waveform is marked with a black square.

When the Asymmetrical biphasic waveform is used, the strongest stimulation effect is under the Active electrode (black electrode plug). This can be useful in creating stimulation effects. For example, placing the Active electrode over the common peroneal nerve and Indifferent electrode over the anterior tibialis will generally produce dorsiflexion with eversion. Swapping the electrodes around will give more dorsiflexion and less eversion. (See pages 42 and 43)

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



Asymmetrical Biphasic



Symmetrical Biphasic



Finetune - Dropped Foot

Output waveform - skin irritation

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

If skin irritation occurs after using Asymmetrical biphasic, allow the skin to heal, and then change to Symmetrical biphasic to reduce the likelihood of reoccurrence.



Frequency

Frequency is the number of pulses per second measured in Hertz (Hz). The standard frequency for dropped foot stimulation 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. 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 has been particularly useful for some people who have MS who do not get a good response at 40Hz. However, using higher frequencies can increase muscle fatigue. Frequency is adjustable from 20 to 60Hz in 5Hz steps.



Testing and Walking in FINETUNE

The ODFS® Pace (XL) parameters can be tested and the output current adjusted at any point in the Finetune menu. Only the Current can be adjusted while testing or walking.

If you have a parameter selected, the screen will change to 'WALK or TEST' when either Pause or Test buttons are pressed.



Options Menu - Footswitch

Footswitch

The Footswitch menu allows you to choose if the stimulator is triggered on heel rise (when weight is taken off the switch) or heel strike (when weight is put back on the switch).

For dropped foot correction, heel rise is more commonly used. The switch 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.

However, 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 switch so the heel strike setting is used. Some faster walkers also prefer this mode.

In Heel Strike mode users should take their first step each time with their non-affected leg.

If this mode is chosen from the Option menu, all other parameters will be left unchanged. When the 'HEEL RISE' / 'HEEL STRIKE' option is chosen in the 'NEW SETUP?' menu, all parameters are set to defaults.



Options Menu - Timing Mode

Timing mode

The ODFS® Pace (XL) has three timing modes.

Adaptive Timing: In this mode stimulation is started by a Footswitch change (e.g. heel rise or heel strike) and ended by a Footswitch change (e.g. heel strike or heel rise). If the second Footswitch change 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.

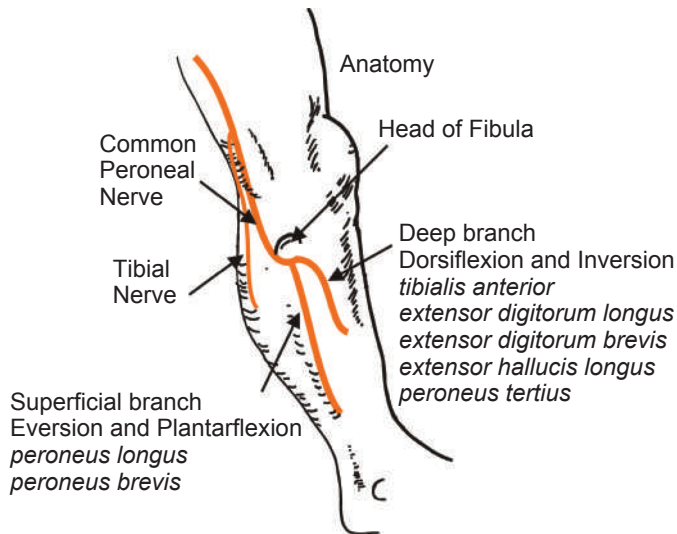
Fixed Time: In this mode stimulation starts on a Footswitch change (e.g. heel rise or heel strike) but is ended after a fixed time set by the Time-Out Period. This mode is used when foot contact is inconsistent and gives unreliable triggering. It can be useful if the ODFS® Pace (XL) user is hesitant in taking steps, taking weight on and off the Footswitch as multiple attempts are made.

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 used for stimulating anti gravity muscles such as Quadriceps or Gluteus Maximus.



Electrode Positions - Dropped foot

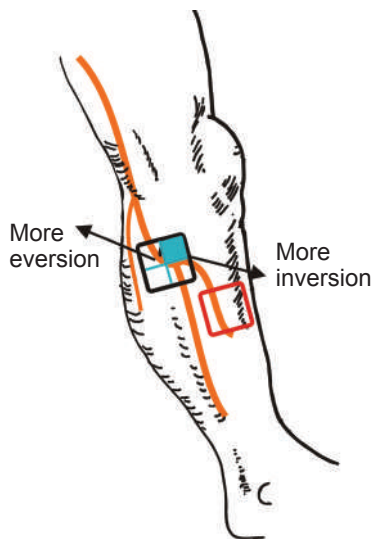


Dorsiflexion is produced by stimulation of the common peroneal nerve and / or its branches. By choosing the position of the electrodes it is possible to tailor the response to suit each individual. Generally, the common peroneal is stimulated where it is most superficial, either where it passes the head 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*.

Electrodes and waveform

The following descriptions of electrode placements assume 50 x 50 mm square electrodes recommended by Odstock Medical Limited. An Asymmetrical waveform is assumed unless otherwise stated.

Electrode Positions - Dropped Foot

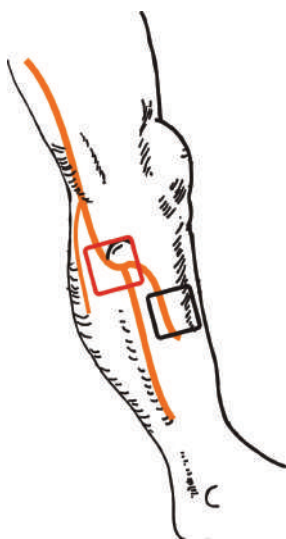


Electrode position 1 (standard)

The Active electrode (black electrode plug) is placed with its top edge on the head of fibula. Imagine the electrode divided into quarters. The top front quarter is on 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 plug) is placed over the Anterior Tibialis. Avoid placing the Indifferent electrode over the Tibia bone as this will cause the stimulation to sting.

If there is too much eversion produced, move the Active electrode forwards. If too much inversion is produced, move the Active electrode backwards and upwards.

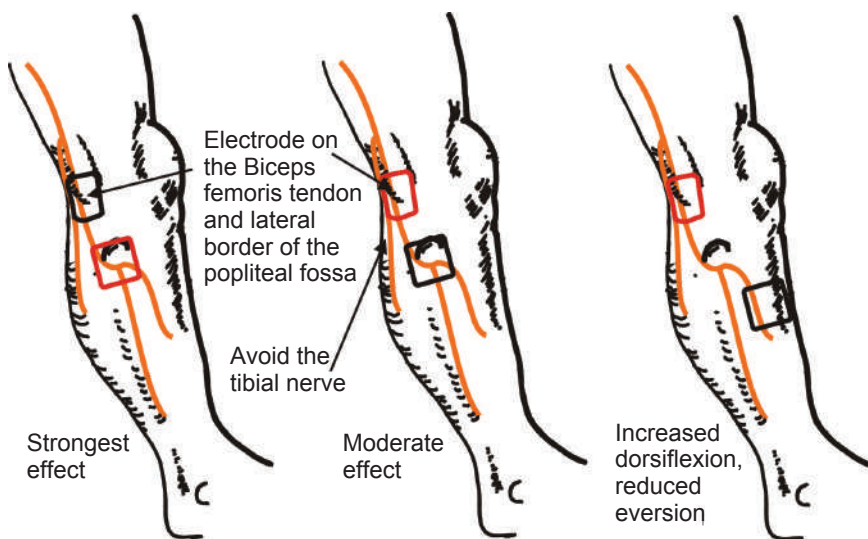
This is the most commonly used position and is usually the easiest for the patient to use independently.



Electrode position 2 (reversed polarity)

If too much eversion is produced by the standard electrode position, reverse the polarity of the electrodes, placing the Active electrode (black electrode plug) on the motor point of Anterior Tibialis and Indifferent electrode (red electrode plug) 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 position 1 to modify the response.

If this position produces too much inversion, change the Output Waveform to Symmetrical biphasic. This will give an equal stimulation effect on both electrodes, producing more eversion than Position 2 and less than the standard position.



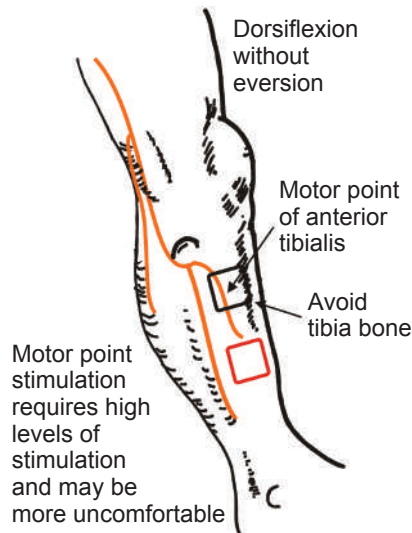
Electrode position 3 (Popliteal fossa)

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. Do not place the electrode too medially as this may recruit the Tibial Nerve, causing calf activity. This position can increase knee flexion by recruiting the 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 on the Popliteal Fossa. Alternatively, a withdrawal reflex with a stronger element of dorsiflexion and less eversion can be achieved by placing one electrode on the motor point of Anterior Tibialis and the other in the Popliteal Fossa.

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

Electrode Positions - Dropped Foot



Electrode position 4 (motor point stimulation)

If the other three positions all produce too much eversion, stimulate the motor point of Anterior Tibialis directly by placing the Active electrode on the motor point and the Indifferent electrode more distally. This position generally requires greater stimulation intensity so can be less comfortable than stimulation of the common peroneal nerve. If too much inversion is produced, move either or both electrodes laterally towards the peroneus longus and brevis.

Occasionally, ODFS® Pace (XL) users may experience toe clawing (flexion) while walking. Greater toe extension may be achieved in positions 1 and 4 by placing the Indifferent electrode more distally, over the toe extensor motor points.

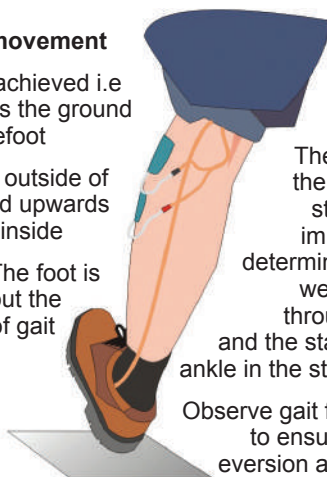
The Correct Movement - Dropped Foot & Electrode Care

The correct movement

Heel strike is achieved i.e the heel strikes the ground before the forefoot

Eversion - the outside of the foot is fitted upwards relative to the inside

Dorsiflexion: The foot is lifted throughout the swing phase of gait



The position of the foot at heel strike is most important as it determines how the weight passes through the foot and the stability of the ankle in the stance phase

Observe gait from behind to ensure sufficient eversion at heel strike

The aim is to produce as natural 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 the ground. 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.

Electrode Care

Odstock Medical recommend the use of 50mm x 50mm self adhesive square electrodes supplied by Odstock Medical Limited or equivalent for dropped foot correction. 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) users with smaller legs may require smaller electrodes.

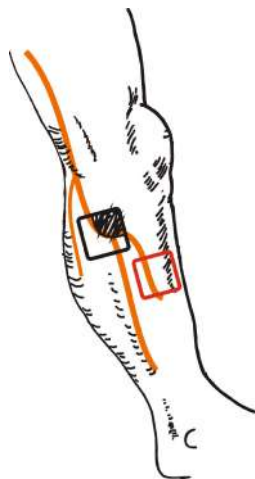
Whichever type of electrodes are used, it is very important that both the skin and electrodes are kept clean. This will help prevent a skin reaction developing. If skin is very dry, or if moisturiser has been used, wash the skin with warm water and dry it before placing the electrodes on the skin. If moisturisers are required, use water based products such as E45 cream 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 patient use. An elasticated tubular bandage can be used to hold the electrodes in place.

Electrode Care

1. Connect the electrodes to the leads by sliding the pin into the connector on the electrodes leads. 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 electrodes edge. Do not pull the electrodes 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 and remove the electrode lead by pulling the plug from the lead connector. Do not pull on the electrode lead. Store the electrodes in the packaging provided. Alternatively leave the leads connected and store the leads with the electrodes.
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 four weeks. Replacing electrodes regularly helps to prevent skin irritation. Electrodes should not be transferred between users.

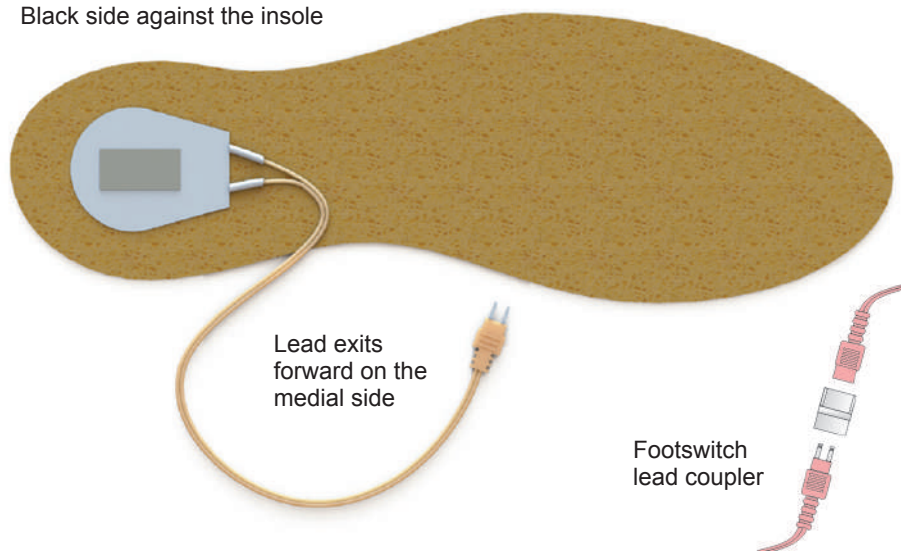
When the electrodes positions have been found, it is very important to teach the ODFS® Pace (XL) user how to find the positions for themselves. The key to this is teaching how to find the head of the fibula bone. One technique is to teach the ODFS® Pace (XL) user to place a finger on the lateral malleolus 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. Providing a photograph of the electrode positions is also beneficial. Also mark in the User Instruction Manual and Quick Start Guide the position of the electrodes. Finally, some ODFS® Pace (XL) users choose to draw around the electrodes with a skin marker. Use colour coding to identify the polarity of the electrodes.



Wired Footswitch

Black side against the insole



The Wired Footswitch should be fixed on the underside of a Cork or Odstock Medical Limited Foam Insole. Remove the wax-paper backing from the adhesive tape on the black side of Wired Footswitch and place on the insole. The lead passes forward in the shoe and exits under the medial arch of the foot. If stimulation is required slightly later in the gait cycle, place the Wired Footswitch further forward on the insole. Avoid placing the Wired Footswitch further forward than the metatarsal heads to maintain reliable triggering.

If the user tends to weight bear on either the lateral or medial side of the foot, move the Wired Footswitch to that side of the insole to improve reliability of triggering.

Placing the Wired Footswitch on an insole enables the Wired Footswitch to be easily moved from shoe to shoe.

It is also possible to stick the Wired Footswitch to the sole of the foot, running the cable under socks, stockings or tights. It is recommended that the black side faces up.

A Wired Footswitch lead Coupler can be used to tighten the connection between the Wired Footswitch and the Footswitch Lead.

Exercise Stimulation

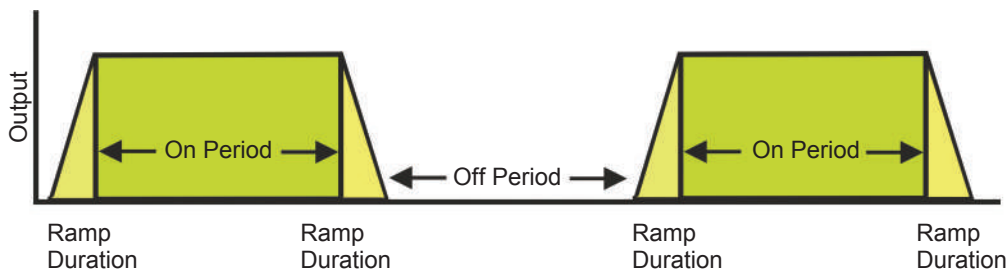
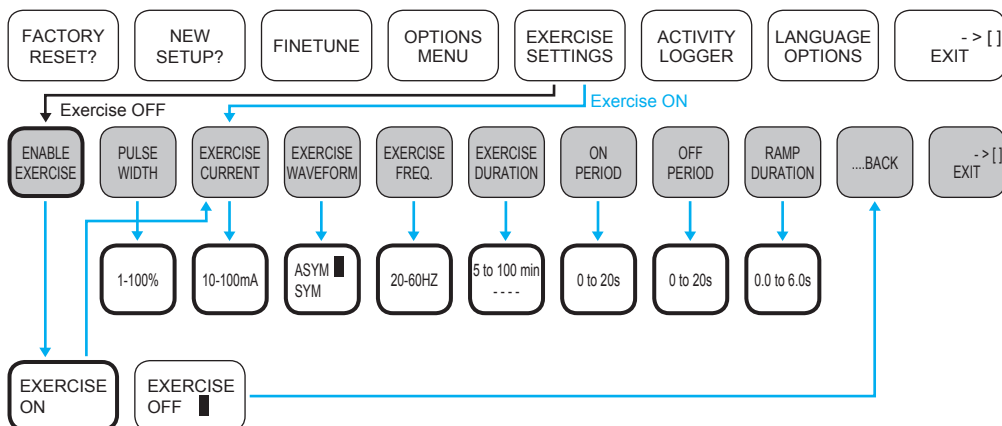
At the initial assessment the ODFS® Pace (XL) is tried and in most cases an improvement in gait is immediately apparent. In some cases a period of electrical stimulation training is useful before using the ODFS® Pace (XL) for walking. This is done using the ODFS® Pace (XL) Exercise mode. This may be 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 the 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 till 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 user 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 Gait Training' on page 56. 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.



Enable Exercise

Use this option to enable the exercise programme. If the Exercise mode is not required by the user, it is good practice to disable the Exercise mode. This will prevent device users from using the Exercise mode to walk. (Disabled is the default option). The menu items after ENABLE EXERCISE are not visible unless EXERCISE ON has been chosen. Please also note that the EXERCISE ENABLE is set to OFF when a new default setting is chosen in NEW SETUP? This also resets all exercise parameters.

Exercise stimulation parameters

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

Exercise Stimulation

However, if different output levels are used for Walk mode and Exercise mode, one set of parameters may give an over strong contraction if used on the incorrect muscle group. For this reason, the pulse width is automatically set back to 1% each time the user changes the mode.

As in FINETUNE, Pulse Width, Current, Waveform and Frequency can be chosen. An explanation of these parameters and their default settings please refer to the Finetune Settings section on page 34, 37-38.

Exercise duration

You can choose the maximum time for exercise in a range 5 to 100 minutes in 5 minute steps. 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 is 15 minutes.

On period

The stimulation can be set to remain on for a period from 0 to 20 seconds between ramping up and ramping down. The default is 5 seconds.

Off period

The stimulation can be set to stay off for a period from 0 to 20 seconds between ramping down and ramping up again. The Off Period allows time for blood circulation to return to the muscle, replenishing oxygen and removing metabolic waste. If the Off Period is too short, muscle fatigue may result. The Off Period is normally not set shorter than the on period. The default is 5 seconds.

Ramp duration

For the exercise mode the rising ramp and the falling ramp share the same timing. The ramp duration can be set from 0 to 6 seconds in 0.1 second steps. If the person has spasticity, choose a ramp of 2.0 seconds or more to avoid eliciting a stretch reflex. If the person experiences clonus in response to stimulation, lengthen the ramp until the clonus is eliminated. People who find stimulation uncomfortable will find longer ramps more comfortable. The default is 2.0 seconds.

Testing in Exercise

The exercise stimulation can be tested at any point in the exercise menu. Press the Test button to get a single output burst consisting of the chosen stimulation output parameters, on period and ramp duration. The stimulation can be stopped at any point by pressing the Test button again or the Pause button. The repeated stimulation sequence including the chosen off period can be tested by pressing the Pause button.



Using Exercise Stimulation

Setting up exercise

First enable exercise by clicking on EXERCISE ON. A black box will appear to confirm the selection and the screen will change to EXERCISE CURRENT. The pulse width automatically sets to 50% so no adjustment is normally required. Press the Test button and adjust the current intensity until the required muscle contraction is produced. Click to accept this setting. The default exercise timings can be tested by pressing the Pause button. The ON and OFF PERIOD and RAMP DURATION can then be adjusted while the ODFS® Pace (XL) is paused.

Shoulder subluxation

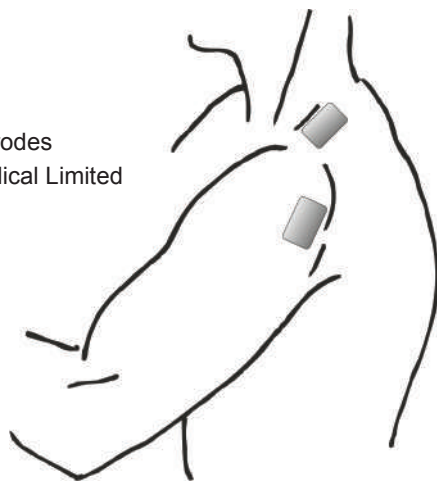
Shoulder subluxation is a common problem following hemiplegia and is often associated with shoulder pain. It occurs when weakened shoulder muscles are unable to support the weight of the arm resulting in stretching of the glenohumeral capsule. Often it can be associated with tightness of the pectoral 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 posterior to the clavicle bone. 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 current level until the humerus is seen to lift into the glenohumeral socket. Do not increase the 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 self adhesive electrodes recommended by Odstock Medical Limited

Start with exercise durations of 15 min twice a day. Increase the exercise duration by 5 min 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.



Using Exercise Stimulation

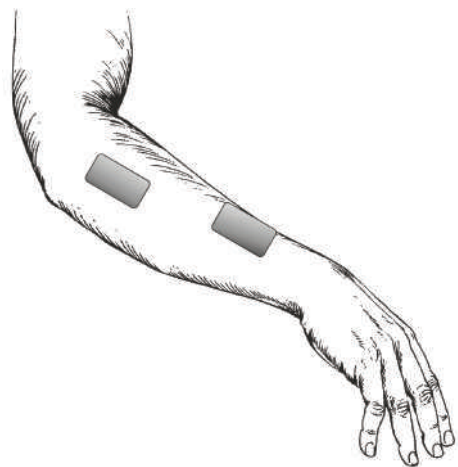
Forearm extensors

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. 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 current intensity until wrist finger and thumb extension is produced. Avoid meta-carpal phalangeal (MCP) hyperextension by limiting current intensity. 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 self adhesive electrodes recommended by Odstock Medical Limited



Start with exercise durations of 15 min twice a day. Increase the exercise duration by 5 min 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 using the leg strap, enabling practice while moving about. Continue daily exercises for 3 to 6 months. Continue longer if withdrawal of the exercise reverses the benefits achieved.

Patient Selection - Dropped Foot

Use of ODFS® Pace (XL) as an orthosis

Cause and 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 occur in conditions such as stroke, multiple sclerosis, incomplete spinal cord injury at T12 or above, cerebral palsy, familial / hereditary spastic paraparesis, head injury and Parkinson's disease.

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 fixed contracture preventing plantargrade is a contraindication.
- Able to obtain standing from sitting unaided. Use of aids such as sticks, frame or crutches is acceptable.
- Able to walk a minimum distance of about 10m. Use of aids such as ankle foot orthosis (AFO), sticks, frame or crutches is acceptable.
- 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 criteria 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 device user is tired or when the deficit is relatively mild.

Factors affecting stimulation

- People with oedema or large amounts of subcutaneous tissue have an increased distance between the electrode and the nerve requiring 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.

Patient Selection - Dropped Foot

Motivation, understanding and independence

- Able to understand the aims of the treatment and be motivated to comply with 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 is 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 is acceptable if more clinical support is available.

Clinical Procedure - Dropped Foot

Patients are first assessed against the selection criteria listed previously and contraindication list at the front of this manual. 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 ODFS® Pace (XL) user is taught how to use the device and shown how to place the electrodes. 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 ODFS® Pace (XL) user is then seen in clinic again the next day and their ability to use the device is checked. Any additional instruction required is given and outcome measures taken. Record outcome measures such as walking speed and Physiological Cost Index (PCI). The stimulator settings are also recorded on the Care Pathway from the Parameter View mode. Care Pathway and other clinic forms are available at <http://www.odstockmedical.com/forms-and-downloads>.

The ODFS® Pace (XL) user 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 ODFS® Pace (XL) users 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.

ODFS® Pace (XL) in Physiotherapy Gait Training

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 therapist 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 as an “extra pair of hands”, controlling the movement of the foot while leaving the therapist free to facilitate other movements. The device can be used in this way for treadmill training.

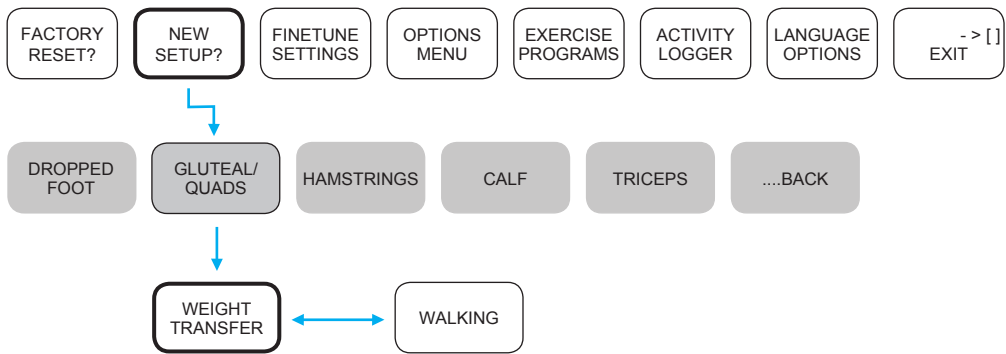
Other muscles can also be stimulated in gait training, using the Footswitch to facilitate muscle contractions at the correct time in the gait cycle. The following pages have some suggested applications.

Remember that the sensory effect of stimulation can be a useful tool to inform the ODFS® Pace (XL) user when to produce a voluntary contraction. Also the sounder function can be used to give audio biofeedback, further enforcing the learning effect.

In many of these applications it may be necessary to use a second ODFS® Pace (XL) to control the dropped foot or some alternative means. Odstock Medical also produce a 2 channel device, the O2CHSII for these applications.

Please note that the Wireless Footswitch is restricted to triggering from under the heel. Some of the following applications use a Footswitch under the metatarsal heads. For these applications use a wired Footswitch or add a starting delay (approximately 150ms) to simulate the timing from a Footswitch under the metatarsal heads.

New Set-up - Gluteal/Quads

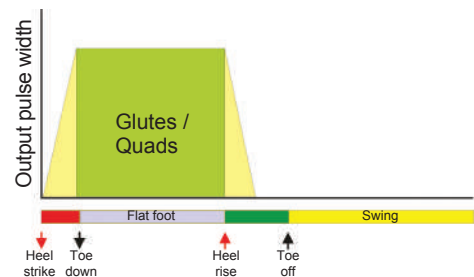


This application is for training of the muscles used in standing. It can also be used to retrain gait following hip and knee surgery. The Footswitch is placed under the heel on the affected side. There are two variations:

- **Weight Transfer.** This mode is used for practising taking weight on the affected side in hemiplegia. With the patient standing, the therapist 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 the 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. Therapists may choose to change the Timing mode to No Time-Out to maintain hip or knee extension in standing when walking stops.

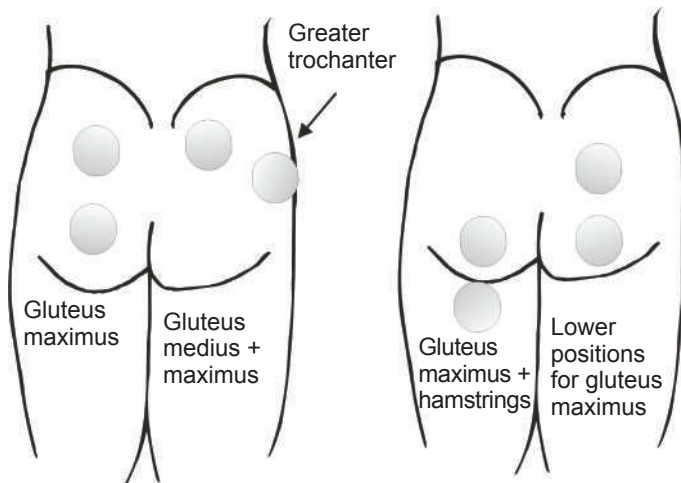


**Stimulation envelope for
Weight transfer application**



**Stimulation envelope for
Glutes or quads in walking**

New Set-up - Gluteal/Quads

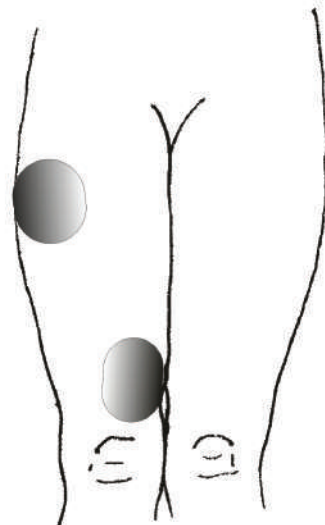


There are several options for electrode placement for the gluteal muscles. Most commonly used is a position combining gluteus maximus for hip extension with gluteus medius for lateral stability. With an Asymmetrical waveform the Active electrode is placed over the muscle the therapist wants to have the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

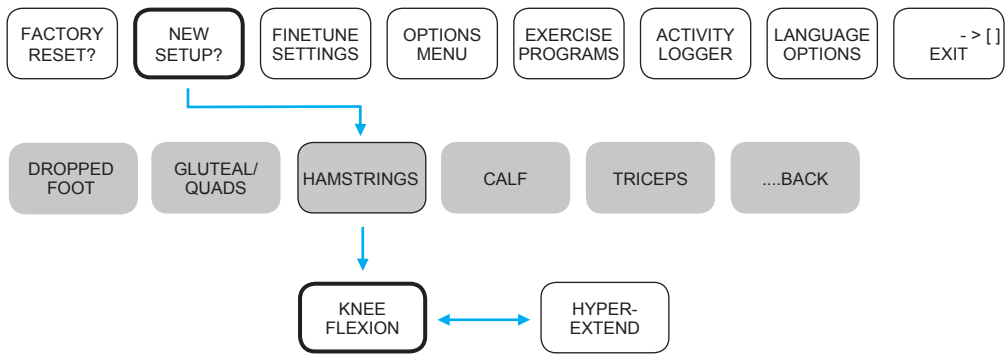
For quadriceps stimulation, place one electrode over the vastus lateralis and one over the vastus medialis. Generally the Active electrode is on the lateralis to give strongest knee extension but can be placed on medialis if this is the weaker muscle. Avoid rectus femoris if hip flexion is to be minimised.

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 self adhesive electrodes recommended by Odstock Medical Limited or larger electrodes.



New Set-up - Hamstrings



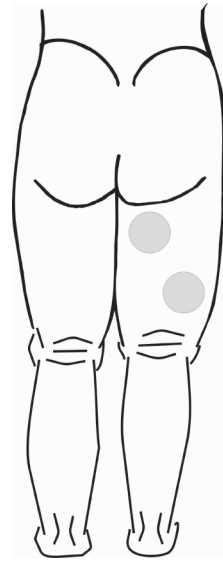
This application is used to control knee flexion by stimulation of the hamstrings. Two options are available:

- **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 relax. Use the sounder to adjust 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.
- **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.

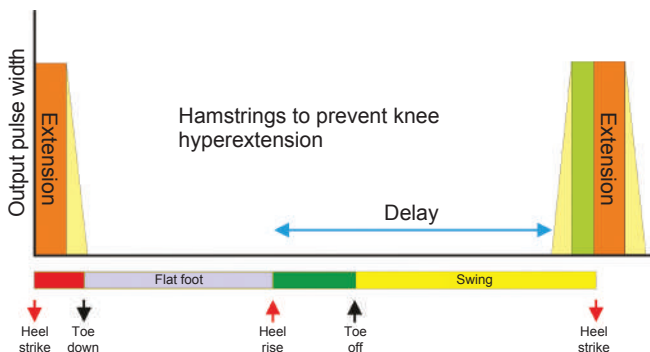
New Set-up - Hamstrings

The Active electrode is placed on the middle of the hamstrings while the Indifferent electrode is placed distally. Do not place the Indifferent electrode too close to the Popliteal Fossa as this may recruit the popliteal nerve. Use 70mm diameter self adhesive electrodes recommended by Odstock Medical Limited or larger electrodes.

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.

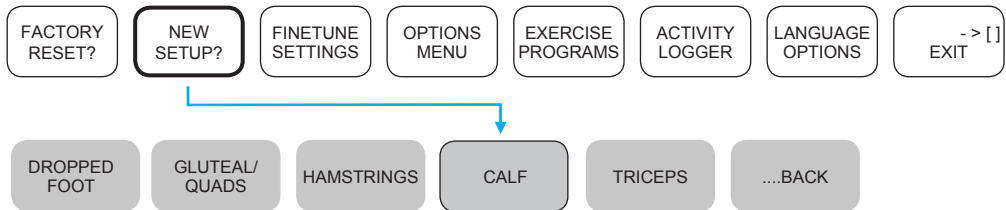


Stimulation envelope for hamstrings used to increase knee flexion at terminal stance and early swing



Stimulation envelope for hamstrings used to inhibit knee hyperextension

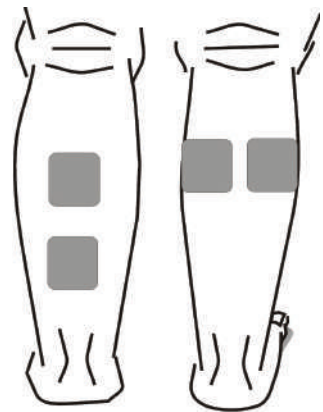
New Set-up - Calf



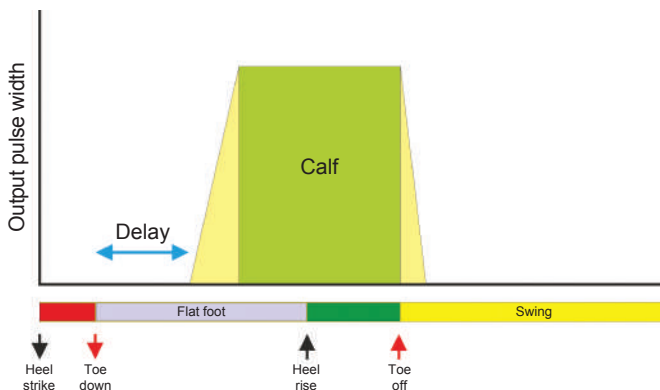
This application is used to train calf activity for push-off in terminal stance. Gastrocnemius can also be used to encourage knee flexion at terminal stance.

A 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.

For soleus, 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 program) to get equal stimulation effect on each head.

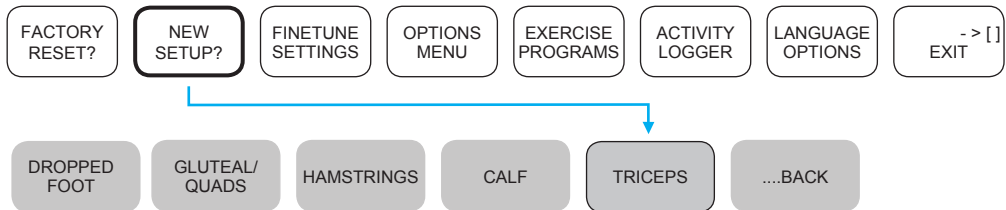


Foot switch under first metatarsal head



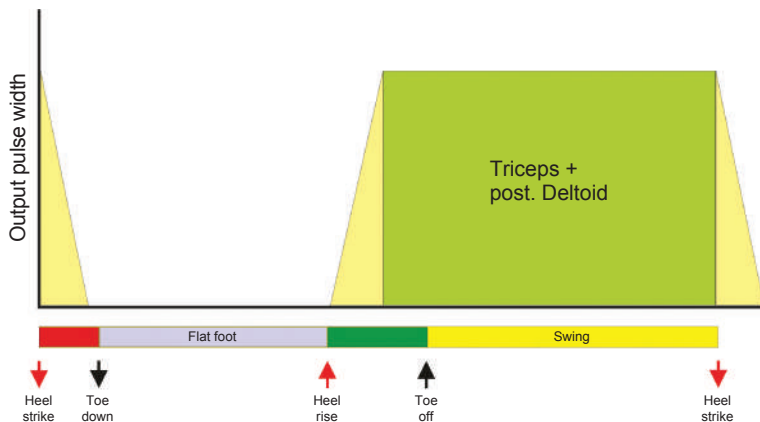
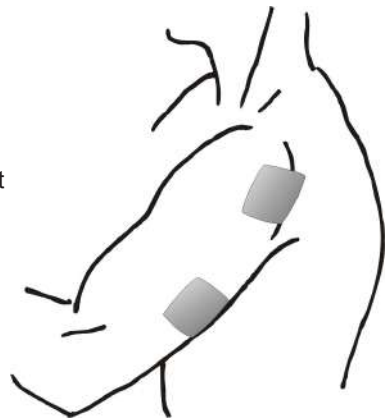
Stimulation envelope for gastrocnemius or soleus to train push off at terminal stance

New Set-up - Triceps



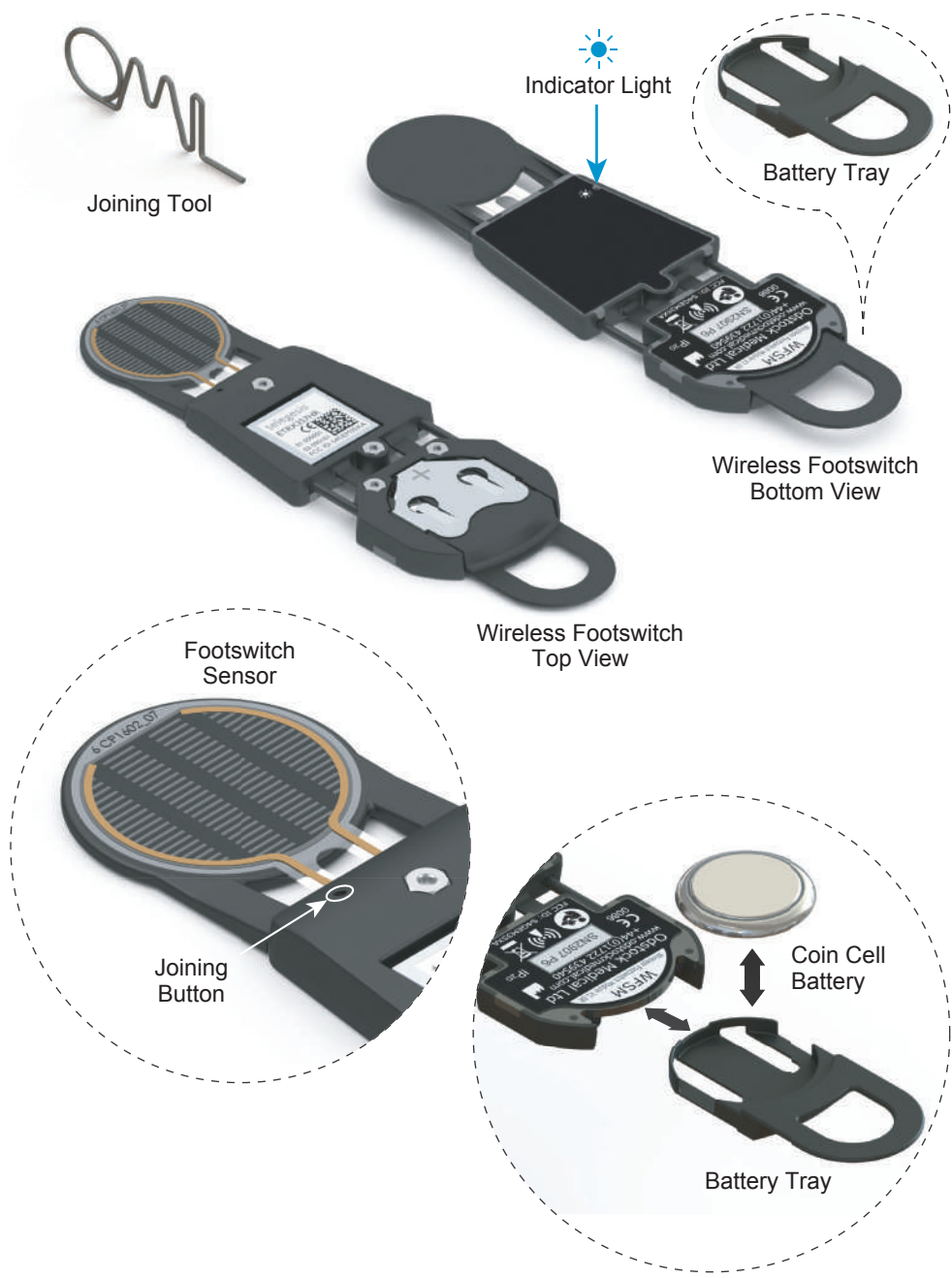
This application is intended to train arm swing in patients who experience a lot of associated reaction in the upper limb while walking. The triceps and posterior deltoid muscles are stimulated to coincide with the swing phase of gait. The Footswitch is placed under the heel on the affected side and stimulation begins at heel rise, ending at heel strike. Stimulation extends the elbow and shoulder.

Place one electrode over mid triceps and the other over the posterior deltoid. In this program a Symmetrical biphasic waveform is set, giving an equal stimulation of both muscles. Alternatively, an Asymmetrical biphasic waveform can be chosen and the Active electrode placed on whichever muscle requires the strongest response.



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

Wireless Footswitch Module Key Features



Wireless Insole Key Features



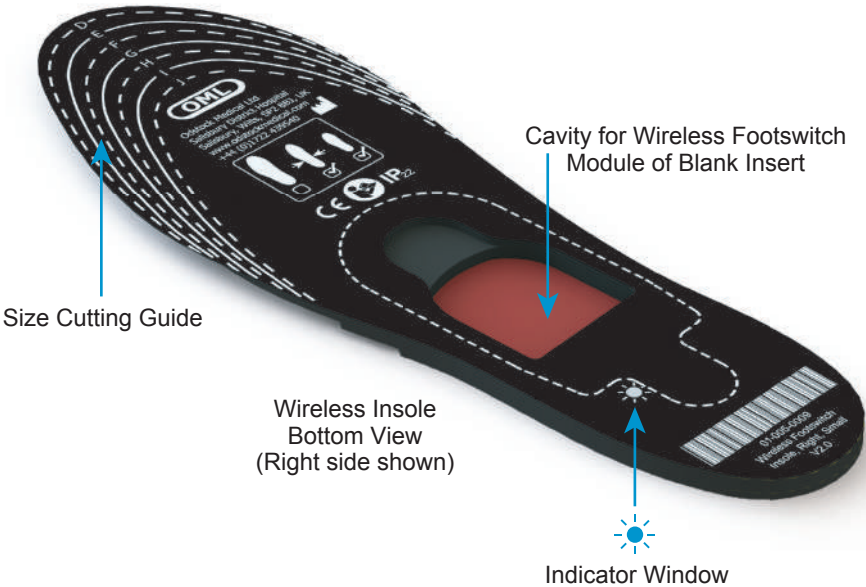
Battery Access Cover



Blank Insert
Top View



Blank Insert
Bottom View



Size Cutting Guide

Cavity for Wireless Footswitch
Module of Blank Insert

Wireless Insole
Bottom View
(Right side shown)

Indicator Window

Wireless Footswitch

ODFS® Pace XL battery

The power consumption of the ODFS® Pace XL with Wireless Footswitch triggering is considerably higher than a non wireless ODFS® Pace. For this reason we recommend that it is only used with the supplied Li-Polymer rechargeable battery. Recharge the battery daily.

Fitting the Wireless Footswitch Insole

The ODFS® Pace XL uses a Wireless Footswitch to control the stimulation. The Wireless Footswitch fits into a shoe and can be easily moved between shoes. Wireless Footswitch Insole pairs are available in 3 sizes; small, medium and large. Please refer to the table on page 78 for sizing information. The Wireless Footswitch Insoles may be trimmed along the cutting guides using a pair of scissors. Care should be taken when trimming the Wireless Footswitch Insoles to ensure correct sizing. The supplied card cutting guide can be used to ensure best fit before trimming the Wireless Footswitch Insoles. Trim the card cutting guide and check it fits inside the shoe, before using it as a template to trim the Wireless Footswitch Insoles. The Wireless Footswitch Insole should not be modified beyond trimming along the cutting guides as this can affect its structural integrity.

Fitting of the Wireless Footswitch Module and Blank Insert

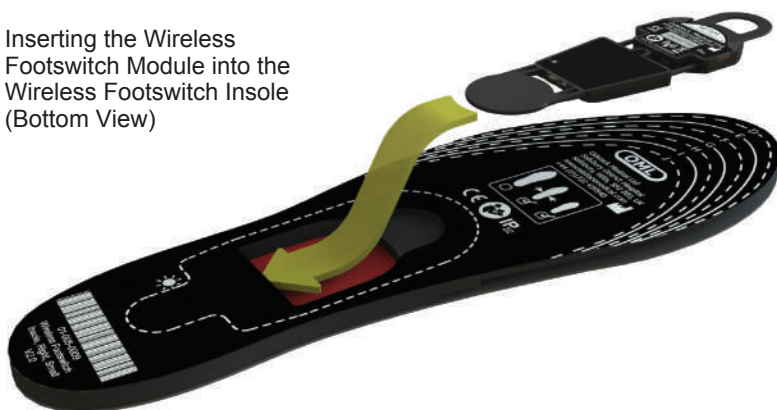
The Wireless Footswitch is supplied with a left and a right insole, with one Blank Insert. Choose the left or right side Wireless Footswitch Insole that corresponds to the side that will be used to trigger the stimulator and slide the Wireless Footswitch Module into the cavity in the underside of the Wireless Footswitch Insole. Place the Blank Insert into the other Wireless Footswitch Insole. Using both Wireless Footswitch Insoles prevents a functional leg length discrepancy, which may affect pelvis alignment and cause lower back pain.

In situations with problems triggering from the stimulated side, the Wireless Footswitch can be used to trigger from the opposite foot.

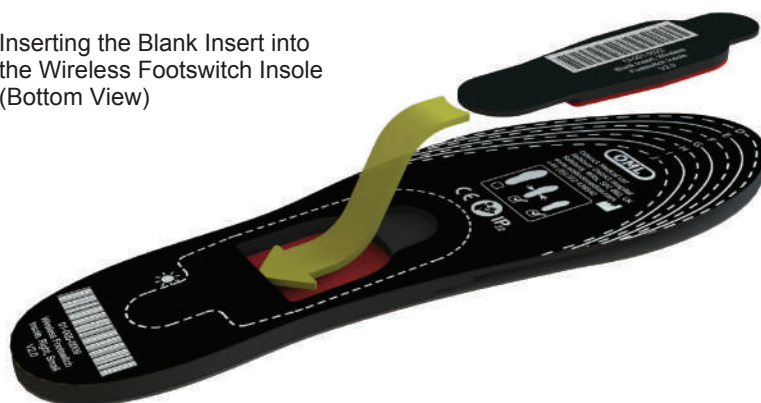
Both the Wireless Footswitch Module and the Blank Insert are protected by placing the self-adhesive Battery Access Cover on the underside of the Wireless Footswitch Insole. **The Wireless Footswitch is placed in the shoe printed side down.**

Wireless Footswitch

Inserting the Wireless Footswitch Module into the Wireless Footswitch Insole (Bottom View)



Inserting the Blank Insert into the Wireless Footswitch Insole (Bottom View)



Footwear

We recommend using footwear with a flat base. Using footwear which results in deforming the Wireless Footswitch may lead to early failure due to increase pressure on the Wireless Footswitch Module. You may consider removing the fitted insole that is present in some shoes. The Wireless Footswitch should not be used with high heel shoes.

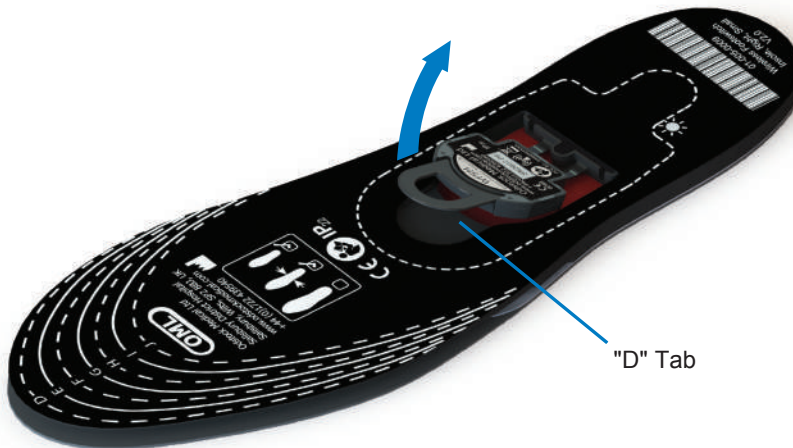
Using the Wireless Footswitch Insole with orthotic inserts

For correct operation the Wireless Footswitch should remain flat in the shoe. Orthotic Insoles should be placed on top off, not below, the Wireless Footswitch. Note: In some cases this set up may not produce a reliable detection of gait events and therefore not trigger the stimulator reliably. In this case triggering from the other shoe, or using fixed time should be considered.

Changing the Battery of the Wireless Footswitch Module

In order to maintain the Wireless Footswitch network connection and prevent a lengthy delay on pressing the Pause button it is important that the battery is changed using the following procedure:

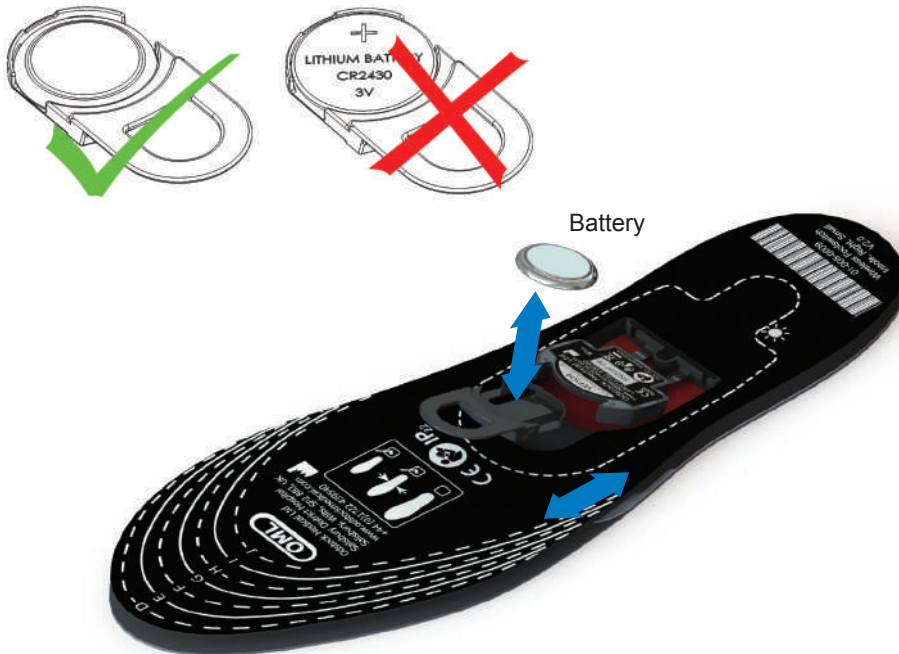
1. Turn the ODFS® Pace XL OFF.
2. Remove the self-adhesive Battery Access Cover from the underside of the Wireless Footswitch Insole by pulling the tab of the cover.
3. Remove the coin cell battery from the Wireless Footswitch Module by first gently lifting up the battery section, then pulling on plastic "D" tab of the Battery Tray. **There is no need to remove the Wireless Footswitch Module from the Wireless Footswitch Insole cavity.**



4. Turn ON the ODFS® Pace XL.

Changing the Battery of the Wireless Footswitch Module

5. Place a new CR2430 coin cell battery into the Battery Tray with the flat side (with the “+” symbol) facing down into the Battery Tray. Slide the Battery Tray back into the Wireless Footswitch Module making note of its correct orientation. As the battery is inserted the blue light should blink once, indicating correct orientation of the Wireless Footswitch Module and battery.



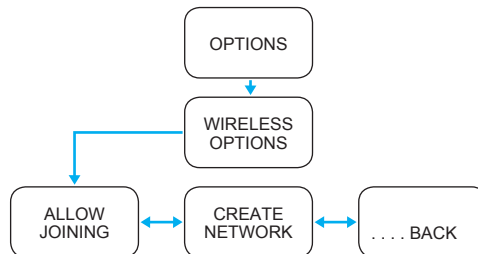
6. To ensure communication between the ODFS® Pace XL and the Wireless Footswitch Module press the ODFS® Pace XL Pause button and press the heel section of the Wireless Footswitch Insole (you may need to press quite hard) a few times to confirm that it triggers the stimulator. If the stimulator does not trigger, repeat the battery change process.
7. Replace the Battery Access Cover onto the base of the Wireless Footswitch Insole aligning it with the hashed outline.

A video showing how to change the battery for the Wireless Footswitch Module can be found at www.odstockmedical.com

ODFS® Pace XL

Joining a new Wireless Footswitch to the ODFS® Pace XL

Before a new Wireless Footswitch can be used it must first be joined to the ODFS® Pace XL. Likewise, a new ODFS® Pace XL will need to be joined to an existing Wireless Footswitch. This process ensures that the ODFS® Pace XL only responds to that Wireless Footswitch and that the Wireless Footswitch does not trigger any other ODFS® Pace XL. When both the ODFS® Pace XL and Wireless Footswitch are supplied together, they will be supplied pre-joined. Joining can be done in either the OPTIONS menu in Clinical Setup mode or using the options menu in the User Accessible Menu.



- To join a new footswitch first remove the Wireless Footswitch Module from the insole and remove its coin cell battery if fitted.
- From either OPTIONS menu select WIRELESS OPTIONS.
- If you are in Clinician Setup mode you will be given 2 options; ALLOW JOINING and CREATE NETWORK. In the User Accessible Menu there is only the option to ALLOW JOINING. Choose ALLOW JOINING.
- While the hour glass is displayed, insert a new coin cell battery into the Wireless Footswitch Module and lay the Wireless Footswitch Module on a flat surface.
- Use the OML Network Joining Tool or other suitable blunt pointed implement such as a paper clip to press the Joining button. The button is in a small recess close to the nut and bolt that holds the casing together. Be careful not to press on the footswitch sensor while using the OML Network Joining Tool to press the Joining button.

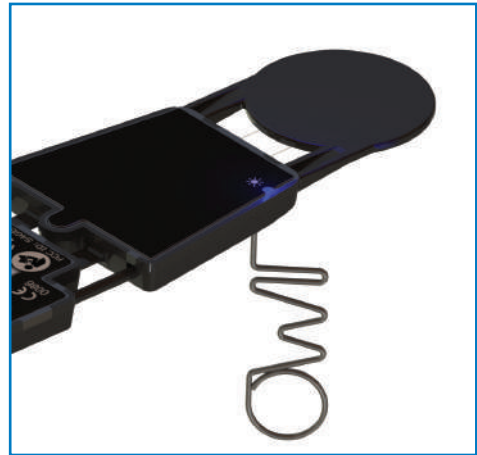
The LED on the underside of the Wireless Footswitch will flash slowly indicating the joining process has begun.

The hourglass will show for up to 1 minute.

Within the 1 minute time interval, the joining process can be aborted by pressing the Pause button. In this case "JOINING ABORTED" will be displayed.



ODFS® Pace XL



After a few seconds the ODFS® Pace XL will give a beep to indicated joining has occurred and the screen will change to F.SWITCH JOINED! and then to EXIT.



If joining does not occur JOINING FAILED will be displayed after 1 minute. If this occurs repeat the process, checking the battery insertion or replacing the battery if necessary. Also check that close proximity joining has not been entered by accident (rapid LED flashing, see below). If still unsuccessful, this may be due to radio interference. Try creating a new wireless network (see below).



A video showing how to join a Wireless Footswitch Module to an ODFS® Pace XL can be found at www.odstockmedical.com

Close proximity joining

In a busy clinic or FES course it is possible that more than one ODFS® Pace XL will be being joined to a Wireless Footswitch at the same time. To avoid the wrong devices joining, close proximity joining can be used, where the Wireless Footswitch is held in contact with the back of the ODFS® Pace XL case.

To enter Close proximity joining mode follow the same procedure as above except press and hold down the footswitch sensor before and while pressing the Joining button with the OML Network Joining tool.

The LED on the underside of the Wireless Footswitch will flash quickly indicating close proximity joining mode has started. While the hourglass is displayed hold the middle section of the Wireless Footswitch against the label on the back of the ODFS® Pace XL. The ODFS® Pace XL will acknowledge joining after a few seconds.

Create Network

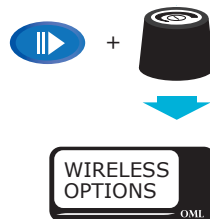
This wireless option sets up a new network. This is sometimes necessary if there is strong radio interference in your area and will be indicated by intermittent operation in one location while operation is trouble free away from that location. CREATE NETWORK will search the radio spectrum for a quiet channel and then join a Wireless Footswitch in the same way as ALLOW JOINING. Please note that if you choose this option without joining a Wireless Footswitch, your existing network settings will be lost and you will need to re-join the Wireless Footswitch.



User access to Create Network

Very occasionally it may be necessary for ODFS® Pace XL users to reset the network if they experience unreliable operation due to radio interference. This will be indicated by intermittent operation in one location while operation is trouble free away from that location.

First make sure the ODFS® Pace XL is turned off. Press and hold down the Pause button. While holding down the Pause button, press the Control knob to turn the ODFS® Pace XL on. Keep holding down the Pause button until the screen changes to WIRELESS OPTION, then release the Control knob. Clicking on this gives access to CREATE NETWORK and ALLOW JOINING options.



Using a wired Footswitch

The ODFS® Pace XL can use a wired footswitch. Simply plug in the footswitch when the ODFS® Pace XL is paused. The ODFS® Pace XL will disable the transceiver and respond to the wired footswitch instead of the Wireless Footswitch. To go back to wireless operation disconnect the wired footswitch.

Turning off the Wireless Footswitch

There is no off switch on the Wireless Footswitch. The device will enter a low power state if it is not being used but if it is not to be used for an extended period (weeks or months), remove the coin cell battery.

ODFS® Pace XL

The effect on Default Settings

When using the Wireless Footswitch please note that default settings used for Calf and Hamstring assume that a wired footswitch is used, positioned under the toe. As the Wireless Footswitch is activated only at the heel, adjustments to stimulation delay and extension parameters may be required.

Water ingress

If water gets into the Wireless Footswitch remove the footswitch unit from the Wireless Footswitch Insole and remove the coin cell battery. Allow to air dry for 24 hours. Once dry, replace the battery and test its operation. If unresponsive, check the battery condition and replace if necessary. If the device is still non responsive contact the supplier.

Activity / inactivity detection

To save battery power the Wireless Footswitch goes into a sleep mode when no activity is detected for 30 minutes or more. The device is woken up by any small motion of the wireless footswitch or pressure on the heel area of the Wireless Footswitch. If no movement occurs before pressing the Pause button to begin walking, the Wireless Footswitch will not be detected by the ODFS® Pace XL. If this occurs a small movement of the foot will wake the device up.

Using the ODFS® Pace XL where wireless devices are not permitted

If you are advised to switch off all electronic devices containing radio or wireless technologies e.g. while flying, use the wired Footswitch and remove the coin cell battery from the Wireless Footswitch Module.

Footswitch Socket Bung

The ODFS® Pace XL is supplied with a rubber bung which is to be inserted into the footswitch socket when being used with the Wireless Footswitch. Remove bung when using the wired footswitch.



Maintenance and Servicing

The ODFS® Pace (XL) does not require any regular servicing or calibration. If it becomes faulty, please return to the supplier or distributor for repair.

The electrode and Footswitch leads should be periodically checked. If they become stiff or the insulation cracks, they must be replaced. Also check the condition of the Wireless Footswitch Insole prior to placing back into the shoe.

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

If cleaning is required use mild soap or antibacterial solution on a cloth. Do not immerse or use strong solvents.

ODFS® Pace (XL) Fault Finding

To help you understand some of the problems that might occur, here is a list of potential faults with some solutions.

1. No response to the Footswitch but response to Test button

Fault	Action
The stimulator may be paused	Press pause
Faulty Footswitch	Replace Footswitch
Faulty Footswitch lead	Replace Footswitch lead
Loose connector - leads not fully inserted into sockets	Check for proper connections

2. No stimulation but LED flickers

Fault	Action
Faulty electrode lead	Replace electrode lead
Faulty electrodes	Replace electrodes
Faulty stimulator	Return to supplier
Loose connector - Leads not fully inserted into sockets	Check for proper connections

3. Incorrect movement produced by the stimulation

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

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

Fault	Action
Failing battery	Replace battery
Poor electrode contact	Dampen the electrode and skin with water
Poor electrode condition	Replace electrodes
Muscle fatigue	Rest

Maintenance and Servicing

ODFS® Pace XL with Wireless Footswitch Fault Finding

Fault

- NO FOOT SWITCH! is displayed when the Pause button is pressed.

Possible solution

- Apply pressure to the heel area of the Wireless Footswitch, to ensure it has not entered sleep mode, then try unpausing again. Standing on the Wireless Footswitch will provide sufficient pressure.
 - Check the Wireless Footswitch coin cell battery is inserted correctly, referring to the diagrams in the battery change procedure, pages 67-68.
 - Remove the coin cell battery and reinsert, following the battery change instructions, pages 67-68.
 - Try a new coin cell battery, following the battery change procedure, pages 67-68.
 - Ensure the Wireless Footswitch is joined to the ODFS® Pace by following the ALLOW JOINING procedure, page 69.
 - The Wireless Footswitch Module may be worn. Replace with a new one, following the ALLOW JOINING procedure if necessary, page 69.
 - The Wireless Footswitch Module may be faulty. Return to the supplier for inspection.
 - Contact the supplier.
-
- ODFS® Pace XL screen displays TEST instead of WALK
 - Triggering from the Wireless Footswitch is inconsistent.
- Turn the ODFS® Pace off and then on again and try unpausing once more.
 - Check that the Wireless Footswitch Insole is correctly positioned in the shoe.
 - Ensure that the user's weight properly contacts the heel area of the Wireless Footswitch Insole. If weight bearing is inconsistent and leads to poor triggering the Wireless Footswitch Module can be placed in the contralateral Wireless Footswitch Insole. Note - this will require the Footswitch parameter to be changed to heel strike. A wired Footswitch can also be tried.
 - Check the condition of the Wireless Footswitch Insole and replace if worn.

- Triggering from the Wireless Footswitch is inconsistent.
- Check the Wireless Footswitch coin cell battery is inserted correctly, referring to the diagrams in the battery change procedure, pages 67-68.
- Remove the coin cell battery and reinsert, following the battery change instructions, pages 67-68.
- Try a new coin cell battery, following the battery change procedure, pages 67-68.
- Radio interference may be blocking reception. Follow the CREATE NETWORK procedure, page 71.
- The Wireless Footswitch Module may be worn. Replace with a new one, following the ALLOW JOINING procedure if necessary, page 69.
- The Wireless Footswitch Module may be faulty. Return to the supplier for inspection.
- Contact the supplier.
- The joining procedure was not successful.
- Turn the ODFS® Pace XL off and wait for 5 seconds. Turn the ODFS® Pace XL on and try to join again.
- Wireless Footswitch software version not displayed in the Parameter View Mode.
- Ensure a good coin cell battery is being used in the Wireless Footswitch Module.
- Apply pressure to the raised section of the heel area of the Wireless Footswitch and enter Parameter View Mode again.

Further information and videos can be found at www.odstockmedical.com

Specifications - ODFS® Pace

Output amplitude:	10 to 100mA +/- 10% or +/- 3mA (which ever is greater) into a 1k ohm load.
Frequency:	20 to 60 Hz. +/- 10% in 5 Hz steps
Pulse width:	0 - 360 μ s +/- 10%. In 3.6 μ s steps
Time out period:	0.3 to 6 seconds. +/- 10%. In 50 ms steps
Delay:	0 to 2 seconds. +/- 10%. In 50 ms steps
Ramping times:	0 to 2 seconds. +/- 10%. In 50 ms steps
Extension times:	0 to 2 seconds +/- 10%. In 50 ms steps
Output waveform:	Symmetrical or Asymmetrical biphasic passive charge balanced.
Exercise duration:	5 to 100 minutes +/- 10% in 5 minute steps or no limit
Exercise on period:	0 to 20 seconds +/- 10% in 1 second steps
Exercise off period:	0 to 20 seconds +/- 10% in 1 second steps
Exercise ramp time:	0 to 6.0 seconds +/- 10% in 0.1 second steps
Battery:	PP3, 9v.
Battery life:	3 to 6 weeks of average use for an alkaline battery. 4 to 8 days for a NiCad or NiMH rechargeable battery. 3 to 6 weeks with Li Po rechargeable battery.
Size:	72 x 62 x 26 mm
Weight:	68g without battery

Specifications - ODFS® Pace XL / Wireless Footswitch

Wireless Footswitch Module and ODFS® Pace XL

Frequency Band	2.4-2.483GHz (2.4GHz ISM Band)
FCC ID	S4GEM35XA
Wireless Compliance	The wireless Module used has been designed to meet all national regulations for world-wide use. The Wireless Module is EC-R&TTE Certified (CE0681) and complies with FCC CFR Part 15 (USA) meeting the requirements for modular transmitter approval as detailed in the FCC public notice DA00.1407.transmitter.

	Wireless Footswitch Module	ODFS® Pace XL
Battery	Lithium Coin Cell CR2430, 3V must conform to IEC 60086	LiPo Rechargeable PP3, 9V
Battery Life	>3 weeks	1-3 days
Dimensions	136 x 38 x 5.6mm	72 x 62 x 26 mm
Weight	18g	75g excluding battery

Wireless Footswitch Insole

Materials:	Polyethylene Terephthalate, Yampi, Ethylene-Vinyl Acetate, Reflex LT Polyester (Battery Cover Labels)
Gross Dimensions:	Thickness at toes: 3mm, thickness at heel: 9mm
Product Weight:	70 grams each (without Wireless Footswitch Module)
Operational Temperature:	-10°C to 45°C
Storage & Transport Temperature:	-20°C to 50°C
Operating Relative Humidity:	30 to 95%
Storage Relative Humidity:	30 to 95%
Usage:	Only to be used in conjunction with an Odstock Medical Limited Wireless Footswitch Module.
Maximum User Weight:	120 kilograms

Wireless Footswitch Insole Size Guide

Wireless Footswitch Insole Size Guide

OML Trimming Guide	Shoe Sizes				Wireless Insole Sizes		
	UK Shoe Size	European Shoe Size	US (Men) Shoe Size	US (Women) Shoe Size	Large (73mm Width)*	Medium (67mm Width)*	Small (62mm Width)*
A	12	47.5	13	-	✓		
B	11	46	12	-	✓		
C	10	45	11	12	✓		
D	9	43	10	11	✓	✓	✓
E	8	42	9	10		✓	✓
F	7	41	8	9		✓	✓
G	6	39.5	7	8		✓	✓
H	5	38	6	7			✓
I	4	37	5	6			✓
J	3	36	4	5			✓

* Width measured at the narrowest part of the insole

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.

The warranty for the Wireless Footswitch is 1 year 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 the address shown below:

Odstock Medical Limited
Salisbury District Hospital
Salisbury
Wiltshire
SP2 8BJ

Should the failure be due to manufacturing or material defect the device will be repaired or a replacement supplied free of charge. This warranty is valid providing that:

1. the failure cannot be attributed to misuse or improper fitting
2. it can be certified by demonstrable evidence that the fitting was done by a registered accredited user

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

Default Settings

Dropped Foot Heel Rise

Parameter	Default Setting	Units/ Position
Current	10	mA
R.Ramp	200	ms
Extn.	200	ms
F.Ramp	150	ms
Time out	2500	ms
Delay	00	ms
Waveform	ASYM	
Freq.	40	Hz
Footswitch	Heel Rise	Heel
Timing	Adaptive	

Dropped Foot Heel Strike

Parameter	Default Setting	Units/ Position
Current	10	mA
R.Ramp	200	ms
Extn.	200	ms
F.Ramp	150	ms
Time out	2500	ms
Delay	00	ms
Waveform	ASYM	
Freq.	40	Hz
Footswitch	Heel Strike	Heel
Timing	Adaptive	

Glutes / Quads Weight Transfer

Parameter	Default Setting	Units/ Position
Current	10	mA
R.Ramp	500	ms
Extn.	00	ms
F.Ramp	500	ms
Time out	NTO	ms
Delay	00	ms
Waveform	ASYM	
Freq.	40	Hz
Footswitch	Heel Strike	Heel/Met Head
Timing	NTO	

Glutes / Quads Walking

Parameter	Default Setting	Units/ Position
Current	10	mA
R.Ramp	200	ms
Extn.	00	ms
F.Ramp	300	ms
Time out	2500	ms
Delay	00	ms
Waveform	ASYM	
Freq.	40	Hz
Footswitch	Heel Strike	Heel
Timing	Adaptive	

Hamstring Knee flex

Parameter	Default Setting	Units/ Position
Current	10	mA
R.Ramp	200	ms
Extn.	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 hyperextensions

Parameter	Default Setting	Units/ Position
Current	10	mA
R.Ramp	200	ms
Extn.	200	ms
F.Ramp	200	ms
Time out	700	ms
Delay	700	ms
Waveform	ASYM	
Freq.	40	Hz
Footswitch	Heel Rise	Heel
Timing	Adaptive	

Calf

Parameter	Default Setting	Units/ Position
Current	10	mA
R.Ramp	200	ms
Extn.	00	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

Parameter	Default Setting	Units/ Position
Current	10	mA
R.Ramp	300	ms
Extn.	00	ms
F.Ramp	200	ms
Time out	2500	ms
Delay	00	ms
Waveform	SYM	
Freq.	40	Hz
Footswitch	Heel Rise	Heel
Timing	Adaptive	

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Patents: GB2369019, US6,507,757B1, GB2474239. Wireless Footswitch Patent Application Numbers. PCT/GB2012/052612 and UK 1118580.8

For up-to-date information on national guidelines and clinical evidence for FES please visit www.odstockmedical.com/clinical-evidence.

Clinic Forms

Example clinical assessment forms are available in the forms and download section of our website - www.odstockmedical.com. You can use these forms to record the settings of the ODFS® Pace (XL) and record treatment plan notes. Use the Parameter View Mode to record the settings (page 29).

NOTES