

CLINICIAN'S INSTRUCTION MANUAL

Odstock® Dropped Foot Stimulator

Model ODFS® Pace V1.0

Model ODFS® Pace XL V1.0

Software V1.3



SAFETY NOTICE:

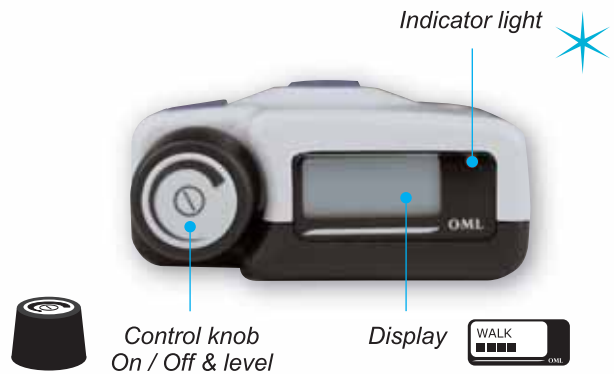
The output of this device has a physiological effect. Read the instructions and precautions before use. The device should only be supplied and set up by a trained clinician.

...a confident choice™

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Key Features



Accessories

ODFS® 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 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 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. 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.

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. 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

Stimulation should not be applied 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 excess of 18 years.

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.

ADVERSE REACTIONS

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

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



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) should be returned to Odstock Medical Limited for recycling.



The CE mark indicates that the ODFS® (XL) Pace 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.



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	ST-OD-PA-01	1
Electrode Lead 1m*	EL-SH-1M-00	1
PALS Neurostimulation Platinum Blue Electrode 50 x 50mm**	ET-90-12-20	1 Pack
PP3 Battery	BA-9V-PR-00	1
Pair of shoe Insoles*	IS-GE-00-10	1
Footswitch Lead 1.2m*	FL-00-1M-20	1
Footswitches***	FS-WD-00-01	2
Elasticated Tubular Bandage Size F*	TU-SF-25-00	1
ODFS® Pace pouch***	AC-PC-PA-00	1
Footswitch Lead Coupler	AC-FC-00-00	1
Linen Drawstring Bag	AC-PB-00-00	1
Clinician Manual		1
User Manual		1
User Quick Start Guide		1
Clinician Quick Start Guide		1
User Infocard		1

* Other sizes available on request

** Other electrode types and sizes available on request

*** Other accessories available

Please visit our web page www.odstockmedical.com

ODFS® Pace XL Kit Contents

Description	Product code	Qty
ODFS® Pace XL Stimulator	ST-XL-PA-01	1
Wireless Footswitch	FS-WL-00-00	1
Insole Pair For Wireless Footswitch (Medium)*	IS-WL-00-MD	1
PP3 Rechargeable Battery LiPo	BA-9V-LP-00	2
Battery Charger 4 Bay LiPo	BA-9V-LP-CH	1
Battery Cover Labels	IS-WL-LB-01	3
Coin Cell Battery CR2430	BA-3V-LI-01	2
Network Joining Tool	AC-NT-00-01	1
Wired 1.5m “all-in-one” Footswitch	FS-WJ-1M-50	1
Electrode Lead 1m*	EL-SH-1M-00	1
PALS Neurostimulation Platinum Blue Electrode 50 x 50mm**	ET-90-12-20	1 Pack
Pair of shoe Insoles*	IS-XL-EV-00	1
ODFS® Pace pouch***	AC-PC-PA-00	1
Elasticated Tubular Bandage Size F*	TU-SF-25-00	1
Linen Drawstring Bag	AC-PB-00-00	1
Clinician Manual		1
User Manual		1
User Quick Start guide		1
Clinician Quick Start Guide		1
User Infocard		1

* Other sizes available on request

** Other electrode types and sizes available on request

***Other accessories available.

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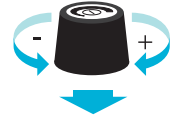
Controls, Connectors and Battery

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 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.



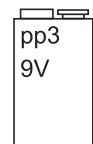
Footswitch lead socket

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, NiCad or Li Po battery can be used. If the device is not to be used for an extended time, remove the battery for storage.



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.



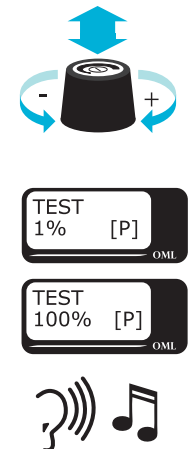
Adjusting the Output Level (Pulse Width)

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. The control lock is not used in Exercise.

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 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 searches for a wireless footswitch. Press the Pause button to end the search early.



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 switch 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 battery level become 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.



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.



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.

Rotate the Control knob anti-clockwise until the output on the display reads 0% and the I/O appears. A beep is heard when 0% is reached.

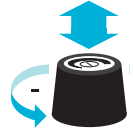
Then press and hold down the Control knob to turn the device off.

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

The ODFS® Pace (XL) can also be turned off from the User Accessible Menu.

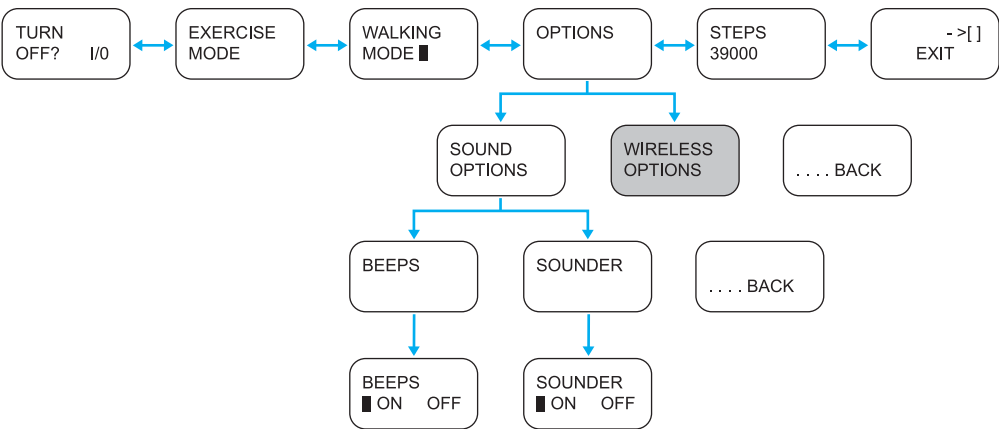
When the ODFS® Pace (XL) is turned off, the pulse width setting is reduced to 1%. The user must reset the level to begin use of the device again. The purpose of this feature is to ensure that ODFS® Pace (XL) users who turn the device up throughout the day as their muscles become tired do not receive an unexpectedly high level of stimulation when they turn the device on the next day. The ODFS® Pace (XL) should therefore not be turned off using the Control knob throughout the day, just paused.

This feature can be overridden. Please see section on Starting Percentage page 25.



User Accessible Menu

To enter the User Menu while paused, press and hold down the control knob for more than 2 seconds. 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. NB. 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 64). 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.

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 agreed activity goals.

Exit

Clicking on EXIT returns you to the current user mode.

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

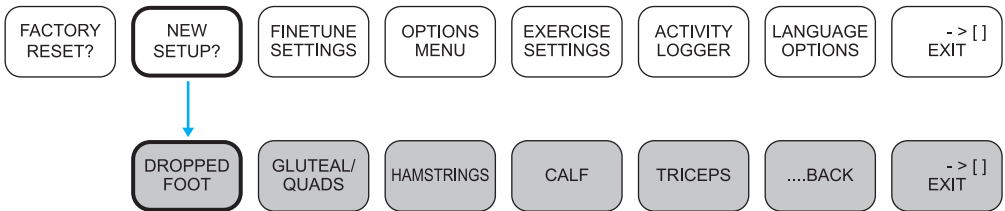
The Control knob is used to navigate around the menu. Twisting the Control knob will bring up each of the menu screens in turn. Options are chosen by clicking down on the Control Knob

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.



New Set-up



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

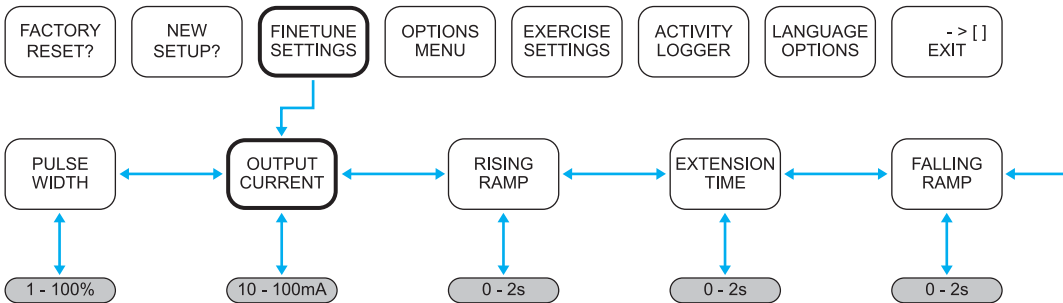
This option allows you to choose from a range of applications and automatically sets the stimulation parameters to appropriate values. The menu structure then guides you through each parameter, allowing you to tune the parameters to each individuals needs.

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



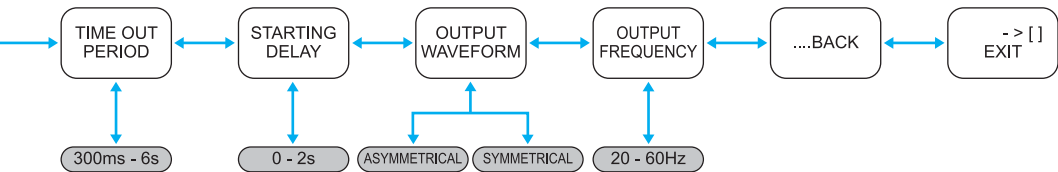
Using Finetune Settings

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 31)

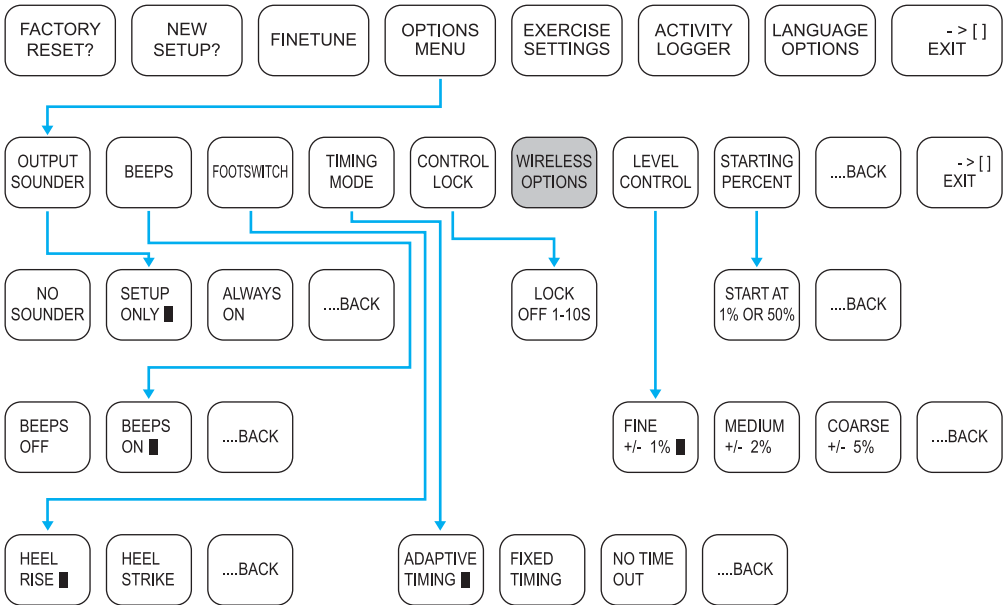
The Finetune menu allows adjustment of all the parameters that make up the applications used in the New Set-up menu.

Adjustments made can be tested 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 34-37)



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 EXERCISE).

The Default is 'SETUP ONLY'.

Beeeps

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 38.



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 39.

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 64.

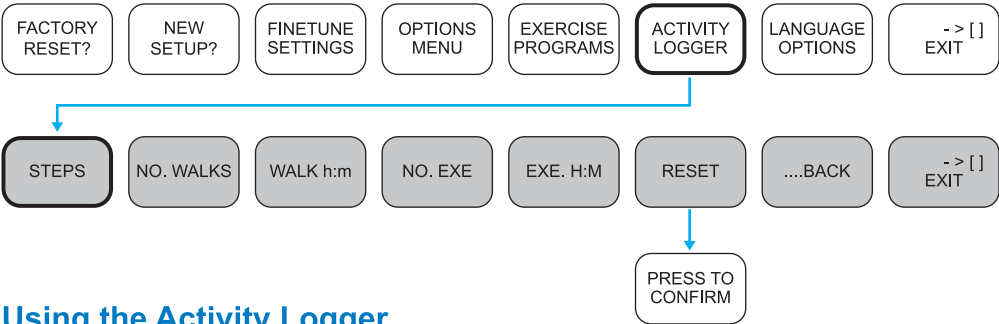
Level Control

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

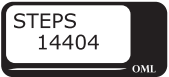


Using the Activity Logger

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 28.

‘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 spent 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?’

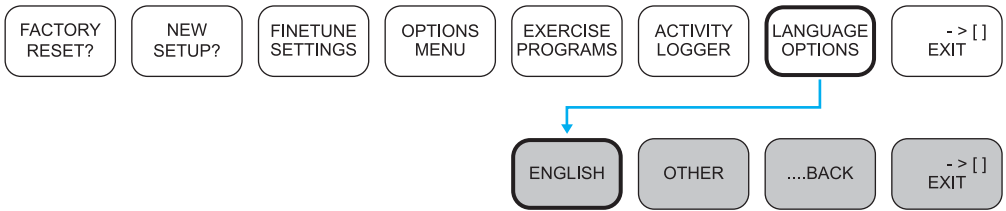
Clears the logger and resets all values to zero. Confirmation is required before this can happen.



Note: If you access the ‘PRESS TO CONFIRM’ screen unintentionally PRESS TO CONFIRM will time out without resetting after 3 seconds.



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.

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. See Clinical Settings Form at the end of this manual. 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 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.

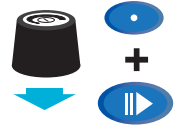
Put the device into Set-up mode by again pressing and holding down the Control knob and then pressing the Test and Pause buttons together, then letting all three buttons go.

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.

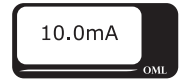


Dropped foot - Setting the current

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

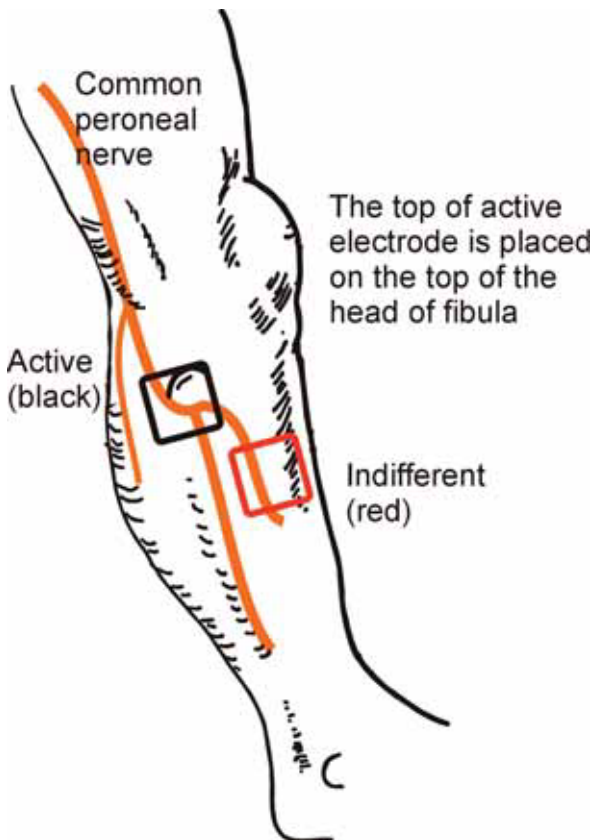


The display shows the output current already set. The minimum current setting is 10mA (milliamps).



The current is set with a pulse width of 180 μ s (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.



Dropped foot - Setting the current

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 40-43)

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 34.



Exiting Set-up and Pulse Width adjustment

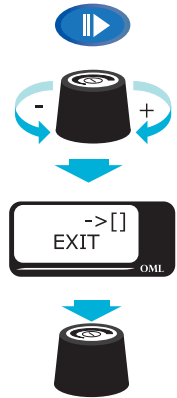
Exiting Set-up mode

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.



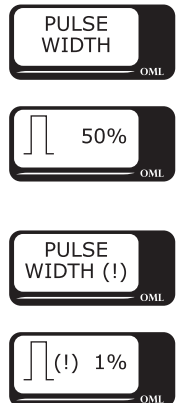
Changing the Pulse Width setting in Finetune

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.

NB. 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.

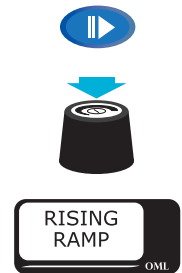
Press the Pause button to exit Active mode and press the Control knob to leave the current setting screen.

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.

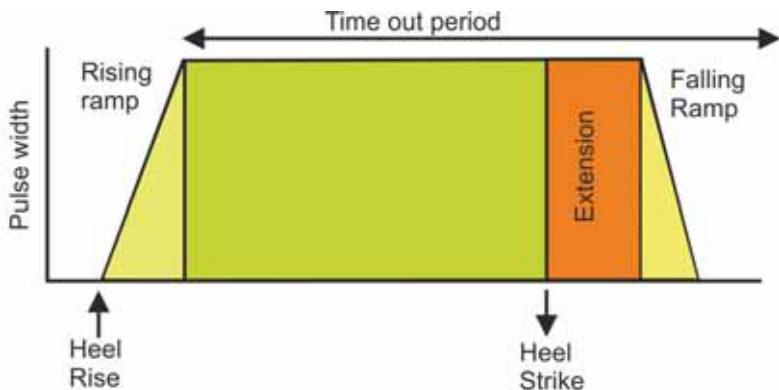


Falling Ramp

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 switch 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 switch 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 41 and 42)

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.



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 a 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 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.

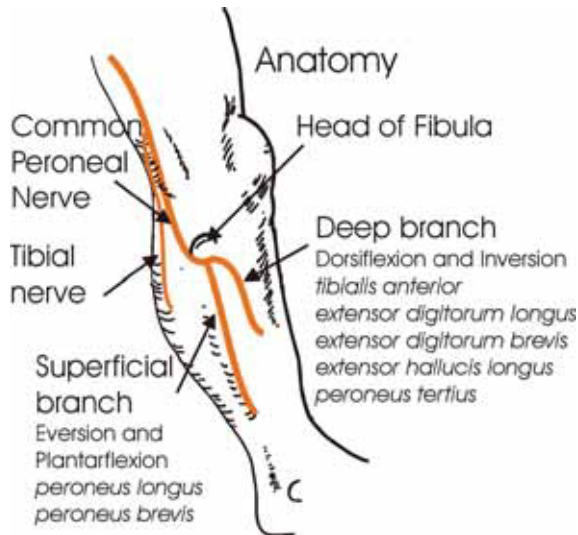
Fixed Time: In this mode stimulation starts on a footswitch change (e.g. heel rise or heel strike) but is ended after a fixed time set by the Time-Out Period. This mode is used when foot contact is inconsistent and gives unreliable triggering. It can be useful if the ODFS® Pace (XL) user is hesitant 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 PALS® electrodes ET-90-12-20. 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, the top back quarter is behind the head and the bottom back quarter is below and behind the head. The Indifferent electrode 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.

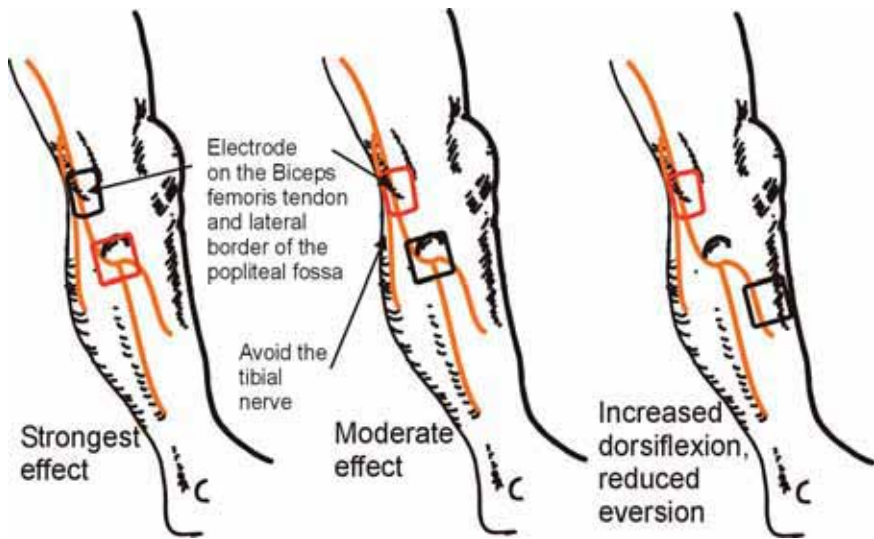
This is the most commonly used position and is usually the easiest for the patient to use independently.

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 Positions - Dropped foot

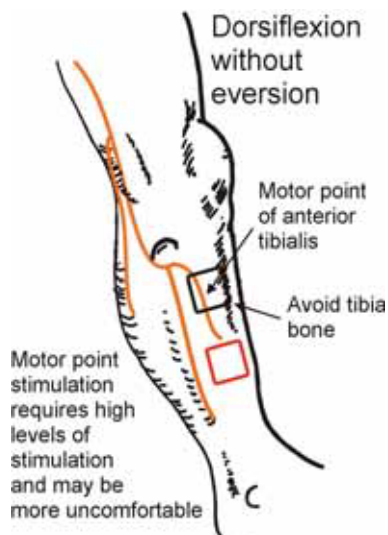


Electrode position 3 (Popliteal fossa)

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.

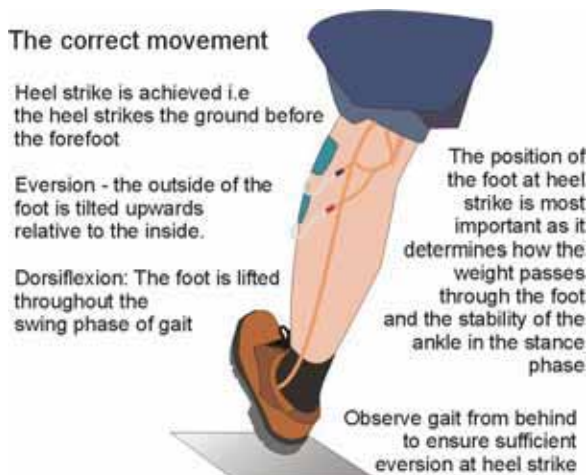


Electrode position 4 (motor point stimulation)

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



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 PALS® Platinum Blue 50mm x 50mm ET-90-12-20 self adhesive electrodes 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.

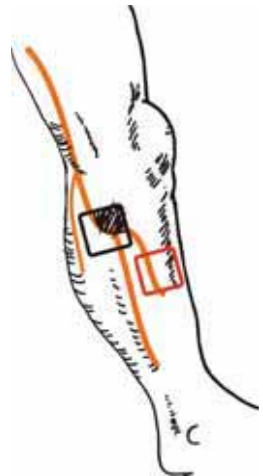
Whichever type of electrodes are used, it is very important that both the skin and electrodes are kept clean. This will help prevent a skin reaction developing. If skin is very dry, or if moisturiser has been used, wash the skin with warm water and dry it before placing the electrodes on the skin. If 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 will cause many tiny abrasions. If long hairs prevent reliable skin adhesion, trim the hairs with 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

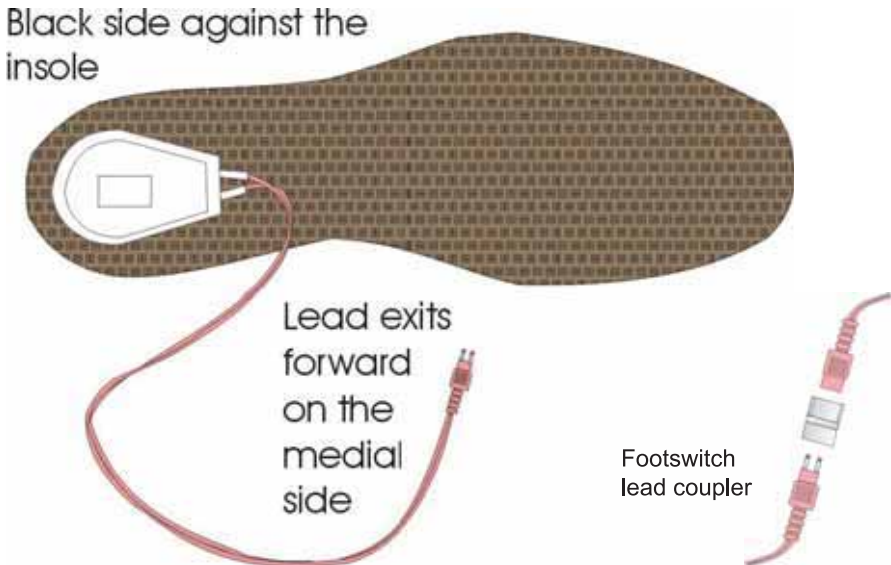
1. Connect the electrodes to the leads by sliding the pin into the connector on the electrodes leads. Ensure that the pin is inserted fully and that no metal is visible.
2. Peel the electrode away from the plastic backing by lifting at the electrodes edge. Do not pull the electrodes lead.
3. Place the 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. 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



The footswitch is fixed on the underside of a cork insole. Remove the wax-paper backing from the adhesive tape on the black side of 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 footswitch further forward on the insole. Avoid placing the switch 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 switch to that side of the insole to improve reliability.

Placing the footswitch on an insole enables the switch to be easily moved from shoe to shoe.

It is also possible to stick the switch to the sole of the foot, running the cable under socks, stockings or tights.

A foot switch coupler can be used to tighten the connection between the footswitch and the footswitch extension leads.

Exercise Stimulation

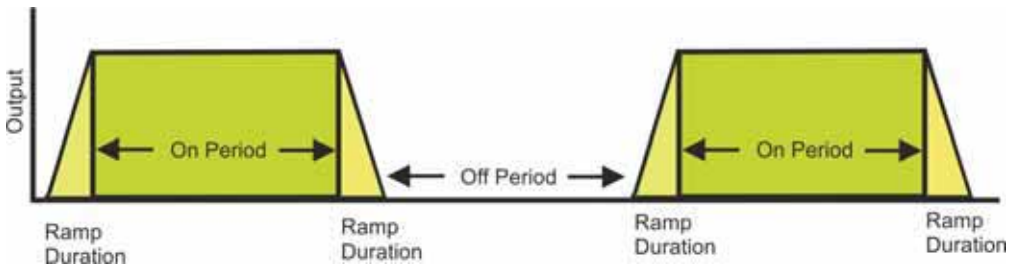
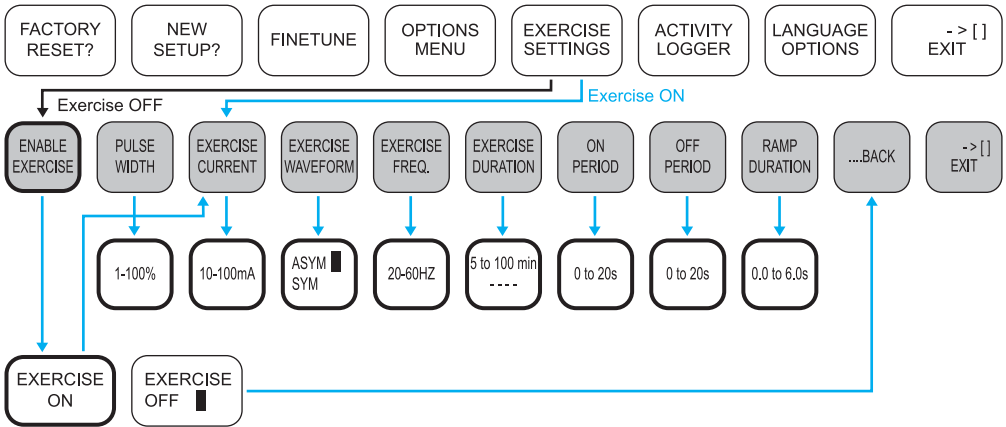
At the initial assessment the ODFS® Pace (XL) is tried and in most cases an improvement in gait is immediately apparent. In some cases a period of electrical stimulation training is useful before using the ODFS® Pace (XL) for walking. This is done using the ODFS® Pace (XL) Exercise mode. This may be 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 55. In all applications, start with short periods of 10 to 15 minutes and build up over time as fatigue resistance increases.

Exercise Stimulation



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.

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 33, 36-37.

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 switch again or the pause switch. 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

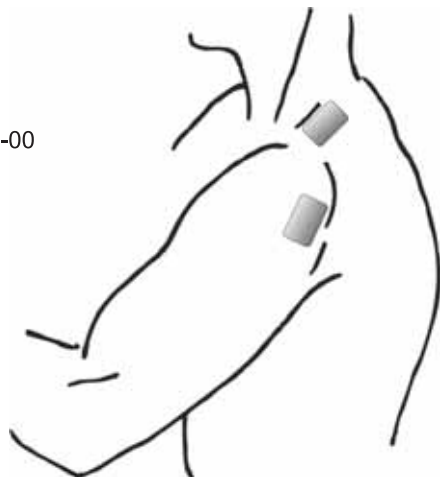
Shoulder subluxation is a common problem following hemiplegia and is often associated with shoulder pain. It occurs when weakened shoulder muscles are unable to support the weight of the arm resulting in stretching of the glenohumeral capsule. Often it can be associated with tightness of the pectoral 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 Pals Plus ET-89-12-00

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.



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 Pals Plus ET-89-12-00

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 plantigrade 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.

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) using the clinic form at the back of this manual. The stimulator settings are also recorded on this form from the Parameter View mode.

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 switch.

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.

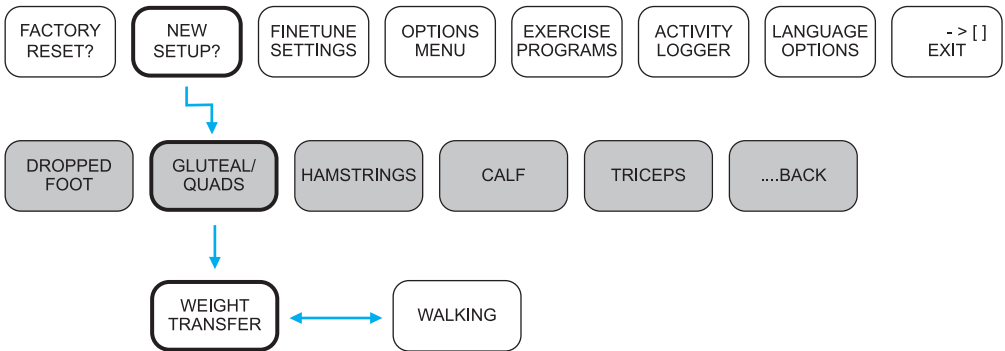
Other muscles can also be stimulated in gait training, using the footswitch to facilitate muscle contractions at the correct time in the gait cycle. The following pages have some suggested applications.

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 ODFS® Pace XL footswitch is restricted to a footswitch 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:

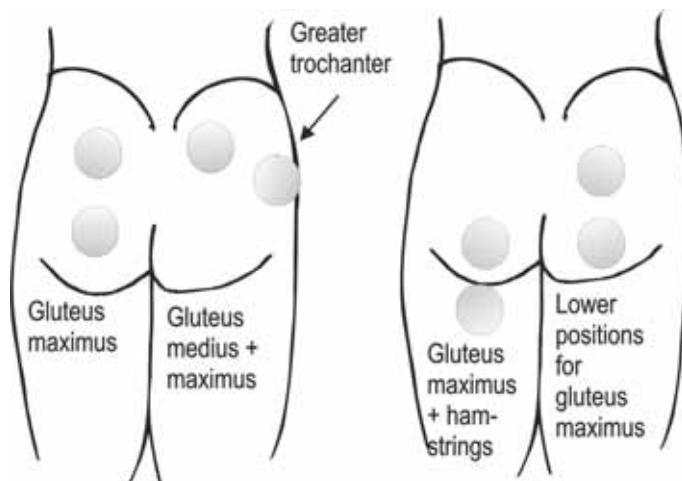
- **Weight Transfer.** This mode is used for practising taking weight on the affected side in hemiplegia. With the patient standing, the therapist instructs the patient to bring weight onto the hemiplegic side. Stimulation is used for either quadriceps or gluteal muscles to facilitate weight bearing. 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

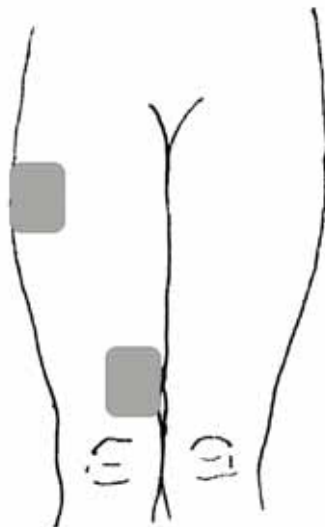


There are several options for electrode placement for the gluteal muscles. Most commonly used is a position combining gluteus maximus for hip extension with gluteus medius for lateral stability. With an Asymmetrical waveform the Active electrode is placed over the muscle the therapist wants to have the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

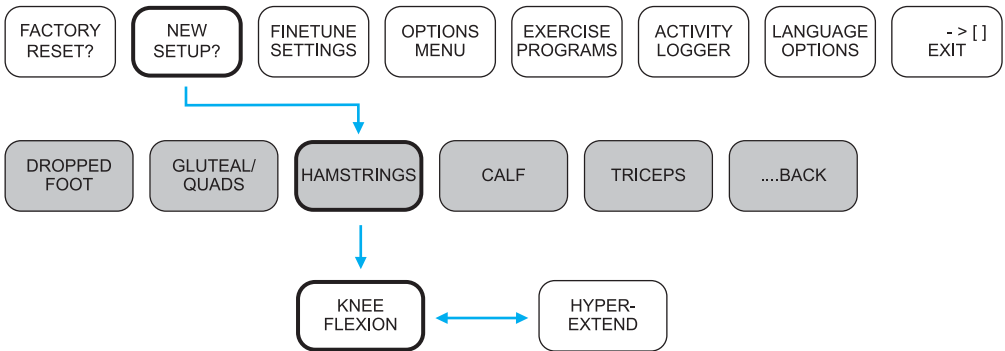
For quadriceps stimulation, place one electrode over the vastus lateralis and one over the vastus medialis. Generally the Active electrode is on the lateralis to give strongest knee extension but can be placed on medialis if this is the weaker muscle. Avoid rectus femoris if hip flexion is to be minimised.

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 ET-87-93-00 or larger electrodes.



New Set-up - Hamstrings

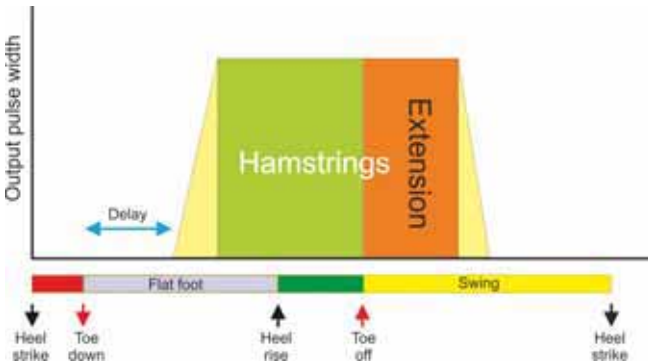


This application is used to control knee flexion by stimulation of the hamstrings. Two options are available:

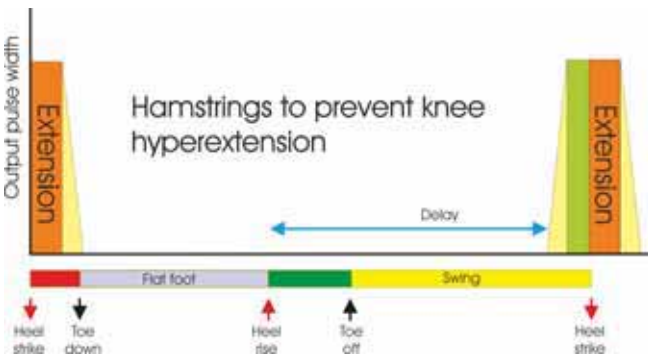
- **Knee flexion.** This option is used to improve knee flexion in the swing phase. The footswitch is placed under the metatarsal heads on the affected side. The delay function is used to start stimulation after flat foot so that hamstrings begin to contract just past mid stance. The aim is to cause 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.

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 PALS Plus ET-87-93-00 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.

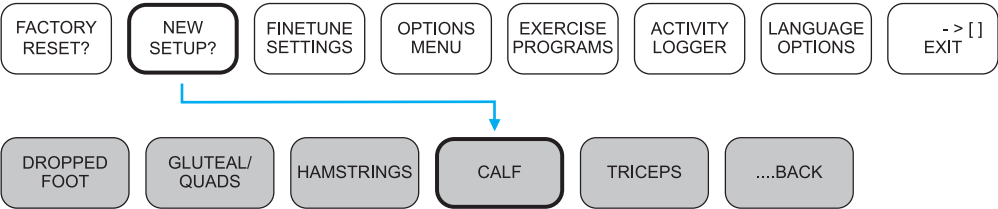


Stimulation envelope for hamstrings used to increase knee flexion at terminal stance and early swing



Stimulation envelope for hamstrings used to inhibit knee hyperextension

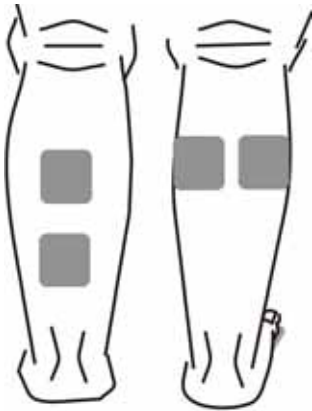
New Set-up - Calf



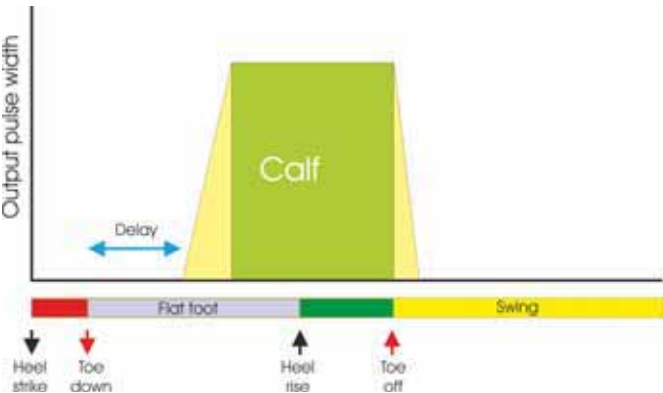
This application is used to train calf activity for push-off in terminal stance. Gastrocnemius can also be used to encourage knee flexion at terminal stance.

A footswitch is placed under the metatarsal heads. Stimulation starts after a small delay after heel strike 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.

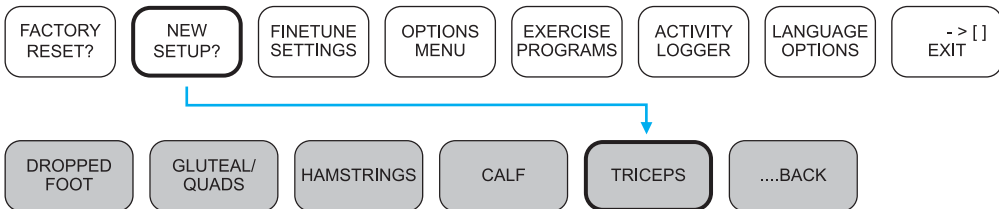


Foot switch under first metatarsal head



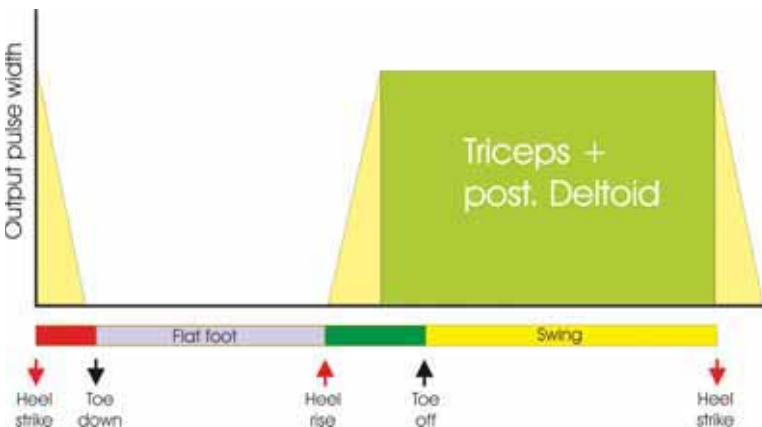
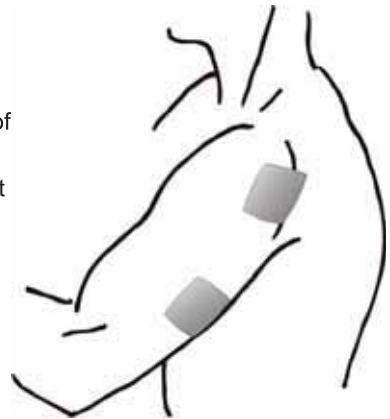
Stimulation envelope for gastrocnemius or soleus to train push off at terminal stance

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

ODFS® Pace XL

The ODFS® Pace XL uses a wireless footswitch to control the stimulation. The Wireless footswitch fits within a shoe insole and is designed to be easily moved from shoe to shoe. Insoles are available in 3 sizes, large, medium and small (see table in Specifications page 71). Insoles may be trimmed using a pair of scissors if required using the printed cutting guide. Please see the table on page 71 for shoe size information. The Wireless footswitch is supplied with a left and a right insole, with one insert.

Fitting the wireless footswitch

Choose the left or right insole that corresponds to the side that will be used to trigger the stimulator and slide the wireless footswitch module into the cavity on the underside of the insole. Place the blank insert into the other insole. Using both insoles prevents a leg length discrepancy, which may affect pelvis alignment and cause lower back pain. Both the wireless insert and the blank insert are held in place using the self-adhesive cover supplied. Remove the waxed paper backing to reveal the sticky tape. The insole is placed in the shoe printed side down.

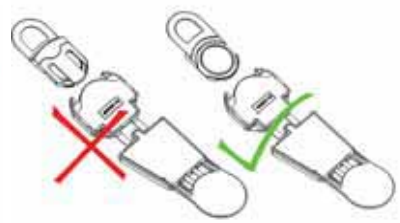


Changing the battery

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:

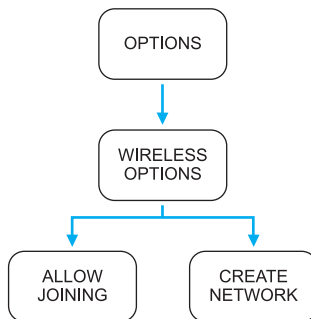
1. Turn the ODFS® Pace XL OFF.
2. Remove the self-adhesive cover from the underside insole by pulling on the tag.
3. Remove the battery from the wireless footswitch by pulling the “D” tab. There is no need to remove the whole unit from the insole.
4. Turn ON the ODFS® Pace XL.
5. Place the new CR2430 battery into the carrier with flat side with the “+” symbol facing down and slide the carrier back into the wireless footswitch.

6. Press the ODFS® Pace XL pause switch and press the foot switch a few times to check that it triggers stimulation correctly. If the stimulator does not trigger, remove and then replace the battery in the footswitch and repeat the procedure.
7. Replace the self-adhesive cover.



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. This process ensures that the ODFS® Pace XL only responds to that Wireless footswitch and that the Wireless foot switch 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.

Go to OPTIONS and select WIRELESS OPTIONS.

If you are in 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 hourglass is displayed, insert a new wireless footswitch battery and then lay the wireless footswitch on a flat surface.

Use the OML Network Joining Tool 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 reset 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.





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).



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 2 or 3 seconds.

ODFS® Pace XL

Create Network

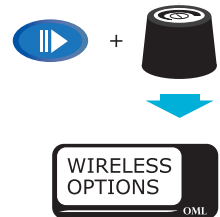
This wireless option sets up a new network. This is sometimes necessary if there is strong radio interference in your area and will be indicated by intermittent operation in one location while operation is trouble free away from that location. CREATE NETWORK will search the radio spectrum for a quiet 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. If access was given to the clinical set up mode it is possible device settings may be accidentally changed. To avoid this, a separate menu is available.

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 OPTIONS. Clicking on this gives access to CREATE NETWORK and ALLOW JOINING options.



ODFS® Pace XL Battery

The power consumption of the ODFS® Pace XL 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.

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.

Water ingress

If water gets into the wireless footswitch remove the footswitch unit from the 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 4 minutes or more. The device is woken up by any small motion of the wireless footswitch. If no movement occurs before pressing the Pause switch 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.

Maintenance and servicing

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

The electrode and footswitch leads should be periodically checked. If they become stiff or the insulation cracks, they must be replaced.

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.

Fault Finding

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

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

The stimulator may be paused	Press pause
Faulty footswitch	Replace footswitch
Faulty footswitch lead	Replace footswitch lead

2. No stimulation but LED flickers

Faulty lead	Replace lead
Faulty electrodes	Replace electrodes
Faulty stimulator	Return to supplier

3. Incorrect movement produced by the stimulation

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 the amplitude control is required at a higher level

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

ODFS® Pace XL Fault Finding

Fault

- NO FOOT SWITCH! is displayed when the Pause is pressed.
- Triggering from the Wireless footswitch is inconsistent.

Possible solution

- Check the battery condition and insertion.
- Move the foot slightly to ensure the footswitch has not entered sleep mode, then try unpausing again.
- Ensure that the wireless footswitch is joined to the network by following the ALLOW JOINING procedure.
- Radio interference may be blocking reception. Reset the network using the CREATE NETWORK procedure.
- Check that the insole is correctly positioned in the shoe.
- Check that weight is placed properly on the heel sensor in gait. If weight bearing is inconsistent, a wired footswitch placed in an area of the shoe that receives consistent weight bearing or placed under the contralateral heel may be more appropriate.
- Check the condition of the coin cell battery.
- Intermittent radio interference may be blocking reception. Reset the network using the CREATE NETWORK procedure.
- The footswitch sensor may need replacing. Return to the supplier for servicing.

Specifications - ODFS® Pace

Output amplitude:	10 to 100mA +/- 10% or 5mA into a 1k ohm load. Approximate increments of 4%
Frequency:	20 to 60 Hz. +/- 10% in 5 Hz steps
Pulse width:	0 - 360 μ s +/- 10%. In 3.6 μ s steps
Output times:	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:	112gm including battery
Operating temperature:	5-27°C
Operating relative humidity:	35-50%
Storage temperature:	0-40°C
Storage relative humidity:	35-50%

Wireless Footswitch Module Specification

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.
Battery	Lithium Coin Cell CR2430, 3V
Battery Life	>3 weeks
Dimensions	136 x 38 x 5.6mm
Weight	18g
Operating Temperature	-10 to 45°C
Storage and Transport Temperature	-20 to 50°C
Operating Relative Humidity	30 to 95%
Storage Relative Humidity	30 to 95%

Wireless footswitch insole size guide

Size	Guide	UK	European	US (Men)	US (Women)
Large	A	12	47.5	13	-
Large	B	11	46	12	-
Large	C	10	45	11	12
Large/Medium	D	9	43	10	11
Medium	E	8	42	9	10
Medium	F	7	41	8	9
Medium/Small	G	6	39.5	7	8
Small	H	5	38	6	7
Small	I	4	37	5	6
Small	J	3	36	4	5

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
Foot switch	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
Foot switch	Heel Stike	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
Foot switch	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
Foot switch	Heel Stike	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
Foot switch	Heel Stike	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
Foot switch	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
Foot switch	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
Foot switch	Heel Rise	Heel
Timing	Adaptive	

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Patents: GB2369019, US6,507,757B1, GB2474239

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

Clinic forms

Example assessment forms are supplied at the end of this instruction manual. The first form is used to record the way the ODFS® Pace (XL) has been setup and any changes to the treatment plan. Use the Parameter table to record all the device parameters. This table lists the parameters in the same order they will appear on the screen.

The second form is used to record progress with the ODFS® Pace (XL). Walking speed is measured over 10m. Allow 1m at either end of the course to allow for acceleration and deceleration. Four measurements are made, 3 without the ODFS® Pace (XL) and one with it. The second and third measurements are used to show the difference made by the device and the 4th is used to see if there is any immediate training benefit. Walking speed is calculated by dividing the distance (10m) by the time taken to walk that distance. As walking speed is a good indicator of the quality of gait, this is used as the main indicator of progress with the ODFS® Pace (XL).

The same form can be used for recording Physiological cost index (PCI). PCI is an indicator of the amount of effort exerted while walking and is calculated by recording heart rate using a Polar Heart rate monitor (Bodycare Products Ltd, 57 Fieldgate Lane, Kenilworth, Warwickshire, CV8 1BT.)

$$PCI = \frac{HR - RHR}{Speed \times 60}$$

Where HR is the heart rate after walking, RHR is the resting heart rate while sitting at rest for at least 3 minutes and speed is in metres per second. PCI can be recorded at the same time as recording walking speed. For more information on recording PCI and walking speed please see reference 3.

Other outcome measures can also be used. For example, The Borg Perceived Effort Scale, The Goal Attainment Scale and Visual Analogue Scales. Please visit www.odstockmedical.com/forms-and-downloads for more example assessment and clinical pathway forms. All forms can be printed or photocopied as required.

ODFS® Pace (XL) v1.3 set-up

Patient Name	Date
DOB/PID	Clinician Sign
Phone Number	Print name
	Designation

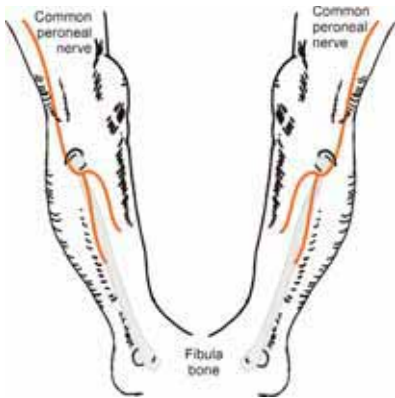
Parameter	Setting
Walking Set up	
Current	mA
R.Ramp	ms
Extn.	ms
F.Ramp	ms
Time out	ms
Delay	ms
Waveform	ASYM / SYM
Freq.	Hz
Sounder	SETUP / OFF / ALWAYS
Beeeps	ON / OFF
Timing	ADAPTIVE / FIXED / NTO
LOCK	OFF /s
LEVEL +/-	1 / 2 / 5 %
On %	1% / 50%
Exe Dur	 min / NO LIMIT
Exe CURR	mA
Exe Wave	ASYM / SYM
Exe Freq	Hz
Exe.on	s
Exe.off	s
Exe.ramp	s
Steps	
No.Walks	
WalkTime	h m
No.Exe	
Exe.Time	h m
Log reset?	Yes /No
Software	
Wireless	
FtSwitch	

Serial Number	
Pulse width	%
Comments	

ODFS® Pace (XL) v1.3 setup

Patient Name	Date
DOB/PID	Clinician Sign
(attach label if available)	Print name
	Designation

	Resting Heart Rate				
	Time for 10m	Heart rate	Increase in heart rate	Walking Speed	PCI
No FES 1					
No FES 2					
With FES					
No FES 3					
% Change NS-S					
% Change NS-S					



Exercise

Comments



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