



Odstock Medical Limited

The National Clinical FES Centre
Salisbury District Hospital,
Salisbury, Wiltshire SP2 8BJ
United Kingdom

Tel: +44 (0) 1722 439540

www.odstockmedical.com

enquiries@odstockmedical.com

Registered Company No. 5532620

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User manual QF019/ODFS Pace(XL)

Product code for manual: 11-003-0016



Odstock Medical Limited

USER INSTRUCTION MANUAL

Odstock® Dropped Foot Stimulator

Model ODFS® Pace V1.0

Model ODFS® Pace XL V1.0

Manual Revision 1.1

From Software V1.3.07



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™



Leading Rehabilitation
Through Technology

Salisbury
NHS Foundation Trust



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ODFS® Pace and ODFS® Pace XL User Instruction Manual

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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 (XL) is carried in a pocket.

Use a ball point pen or other similar tool to press the release button through the hole in the centre of the clip to allow the clip to slide from the pouch.



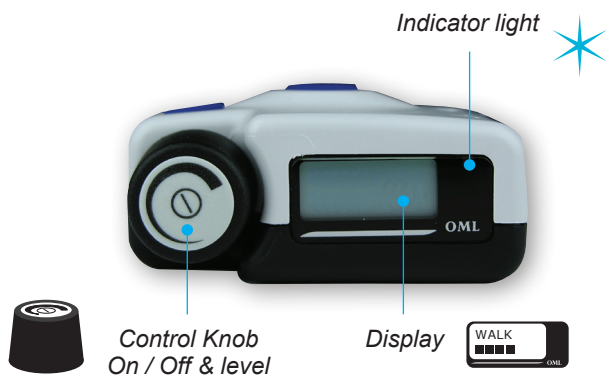
ODFS® Pace (XL) leg strap

An optional accessory. The leg strap connects to the ODFS® Pace (XL) pouch using the easy to use connector plate. Press the button on the top of the connection plate to release the ODFS®

Pace (XL). Use with a 25cm electrode lead and 60cm "all in one" Footswitch or 30cm Footswitch lead with a standard Footswitch. It can also be used with the ODFS® Pace XL Wireless Footswitch. The strap can also be used on the arm for upper limb applications.



Key Features



Introduction

The Odstock Dropped Foot Stimulator ODFS® Pace and its Wireless Footswitch version ODFS® Pace XL is a Functional Electrical Stimulation (FES) device designed to improve walking for people who have a dropped foot or other gait problems. It is controlled with a Footswitch placed in the shoe, which is used to turn on and off the stimulation at the right time while walking. It can also be used for exercising muscles while resting using the exercise function.

The device is suitable for people whose walking is affected due to nerve damage in the spine or brain. This includes stroke, multiple sclerosis, spinal cord injury, hereditary spastic paraparesis, cerebral palsy, head injury and some people with Parkinson's disease.

Use of the ODFS® Pace (XL) must be under the supervision of clinical staff trained in its use by Odstock Medical Limited or their agents.

The ODFS® Pace (XL) should be used as part of an integrated treatment plan. Patients should receive gait re-education training by a suitable clinician while learning to use the device. In general, patients should be in reasonably good health and be able to understand how to use the system.

Patients and / or their family members should contact the clinician who set up the device if they experience any problems using the ODFS® Pace (XL). Patients may also contact Odstock Medical directly if they need additional assistance.

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Salisbury District Hospital,
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United Kingdom

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Fax: +44 (0) 1722 425263
www.odstockmedical.com
enquiries@odstockmedical.com

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 bandage 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 20 years.

Wireless Footswitch Insole

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

Air Travel

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

Batteries

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

ADVERSE REACTIONS

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

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

RESIDUAL RISK

Even though Odstock Medical Limited have taken all foreseeable steps, through design and testing, to ensure

this device is safe and reliable, there remains a small risk of stimulation not being delivered when required. This could lead to a stumble or trip and consequent injury or harm.

Symbols and Definitions



Attention: Device has physiological effect.



Internally powered device with applied parts of insulation type BF.



Read instructions before use.



This product should not be disposed of with other household waste. Please recycle responsibly to promote the sustained reuse of material resources. Contact your local council office or Odstock Medical for advice on recycling.



The CE mark indicates that the ODFS® Pace and ODFS® Pace XL comply with European Union Medical Device Directive.



Protected against solid foreign objects of diameter 12.5mm and greater and dripping water.



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



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



Manufactured by Odstock Medical Limited.



European authorised representative.



Importer.

ODFS® Pace Kit Contents

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

* Other sizes available on request

** Other types and sizes available on request

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

Please visit our web page www.odstockmedical.com

ODFS® Pace XL Kit Contents

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

* Other sizes available on request

** Other electrode types and sizes available on request

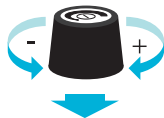
*** Other accessories available - www.odstockmedical.com

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 functional use or exercise. 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 Paused mode are swapped by repeated presses of the button. A long beep is given for entering Active mode and a shorter, higher pitch 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 & Battery

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.



Foot switch lead socket

Located on the side of the case below the electrode lead socket and identified with this footprint symbol. This is where the foot switch lead is plugged into.



Battery

The Battery is accessed by sliding the lid from the rear of the box. Ensure that the battery is correctly inserted.

A single PP3 9V, Standard, alkaline or rechargeable NiMH or LiPo battery can be used.

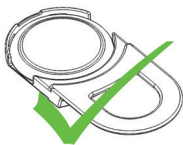
If the device is not to be used for an extended time, remove the battery for storage.



Wireless Footswitch battery

The Wireless Footswitch uses a CR2430 Lithium coin cell 3V battery. Remove the battery for transportation or if the device is not to be used for an extended period.

Remove the battery if instructed not to use wireless devices. Please refer to page 22 for correct insertion of the coin cell battery.



Operating Guide

Turning the stimulator on

Press the Control Knob and hold it down until the display comes on and the indicator light flashes.

If the stimulator has been set to use beeps, quick repeated 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 (XL) can still be used but you may need to increase the output level.

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

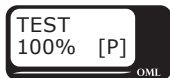


Adjusting the output level

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 by your clinician, the output can be adjusted without first clicking the Control Knob. The control lock is not used in the Exercise Mode.

As the knob is twisted the output level is displayed as a number from 1 to 100, with 100 being the highest setting.

If the stimulator has been set to use beeps, a click will accompany each adjustment increment. The pitch of the click will go up and down as the output is turned up and down. There will be an extra high pitch beep when 50% is reached. This lets you know the output is at the normal operating level. There is also a double low pitched beep at 0% indicating that holding down the Control Knob will turn the device off.



Operating Guide

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 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.

Adjust the level of stimulation while the indicator lamp is flashing. In this way you can feel the change in stimulation while you are adjusting the level. There is no need to click the Control Knob before making an adjustment when the Test button is used.

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

Using the Pause button

When the stimulator is set for Walk or Exercise the Pause button can be used to start and stop the operation of the 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 change to show 'solid' blocks.



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



If in Exercise mode, pressing the Pause button will cause the screen to change to the exercise count-down timer and level indicator blocks. An ascending pattern of beeps is heard. This is different from the beep heard when un-pausing in WALKING mode so that the user does not try to walk using the 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 be displayed while the device searches for a Wireless Footswitch. NOTE - this delay can be up to 30s. Press the Pause button to end the search early. If the search is ended early "WALK ABORTED" is displayed and an audio warning is given.



To stop operation press the Pause button a second time. A shorter higher pitch beep is heard in Walk mode or a descending pattern of beeps in Exercise mode. The battery state is briefly displayed on the screen. Holding the Pause button down will keep the battery level displayed for as long as the button is held down. 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.



Operating Guide

Low battery warning

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

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



Lost Wireless Footswitch connection

If communication is lost between the ODFS® Pace XL and the Wireless Footswitch, upon pausing the screen will display No W.FS! instead of the wireless battery level. If this occurs please refer to the fault finding section on page 35.



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 that the [P] symbol is present.

Click and then rotate the Control Knob anti-clockwise until the output on the display reads 0% and the I/O symbol appears. A low pitch double beep will be heard.

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.



User Accessible Menu

Auto turn off

If the ODFS® Pace (XL) is left turned on in Pause mode, but is not used for more than 4 hours, it will automatically turn off and the output level reset to 1%. The output level must be adjusted to the required level when the ODFS® Pace (XL) turned on again.



User Accessible Menu

This menu allows you to change between Walking and Exercise modes, turn on and off the sounds the ODFS® Pace (XL) makes, check on how many footsteps you have taken, join a new Wireless Footswitch and turn off the ODFS® Pace (XL).

To enter User Accessible Menu; whilst paused, first unlock by clicking (quick press and release) the Control Knob then press and hold down the Control Knob for more than 2 seconds, then release. If Control Lock has been disabled, clicking to unlock will not be necessary.



Choosing WALKING or EXERCISE modes (in User Accessible Menu)

If your clinician has set an EXERCISE mode for you, rotating the Control Knob anti-clockwise one position from WALKING MODE will take you to EXERCISE MODE. A medium pitch double beep is given to indicate this change. Click the Control Knob to enter EXERCISE MODE. A black box will appear to confirm your selection and the screen will change to EXERCISE 1% [P]. NOTE- that whenever the mode is changed the output is reduced to 1%. This is to prevent sudden unexpected increases in muscle contraction. Press the Test button and increase the level while stimulating, until the correct movement is produced.



User Accessible Menu

OPTIONS (in User Accessible Menu)

This menu item gives two further choices. SOUND OPTIONS and if you are using an ODFS® Pace XL, WIRELESS OPTIONS (see section ODFS® Pace XL page 24).

Clicking on SOUND OPTIONS brings two more choices.

BEEPS allows the user to turn on and off the audio beep feedback.

NOTE: Low battery warnings cannot be turned off.

SOUNDER allows a stimulation audio feedback to be turned on and off.

Click on the chosen option and rotate the knob to move the black box between ON or OFF. Click on your chosen option. Use BACK to return to the main menu or EXIT to go to back to the current user mode.



STEPS (in User Accessible Menu)

This screen gives the total number of steps you have taken with the ODFS® Pace (XL) since the log was last reset. You can use this to monitor how much walking you are doing.



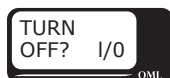
EXIT (in User Accessible Menu)

Clicking on EXIT returns you to the current user mode.



TURN OFF? (in User Accessible Menu)

The ODFS® Pace (XL) can be turned off from the User Accessible Menu. Rotate anticlockwise to the end of the menu until TURN OFF? I/O is reached. A double low pitch beep is given. Click to turn off.

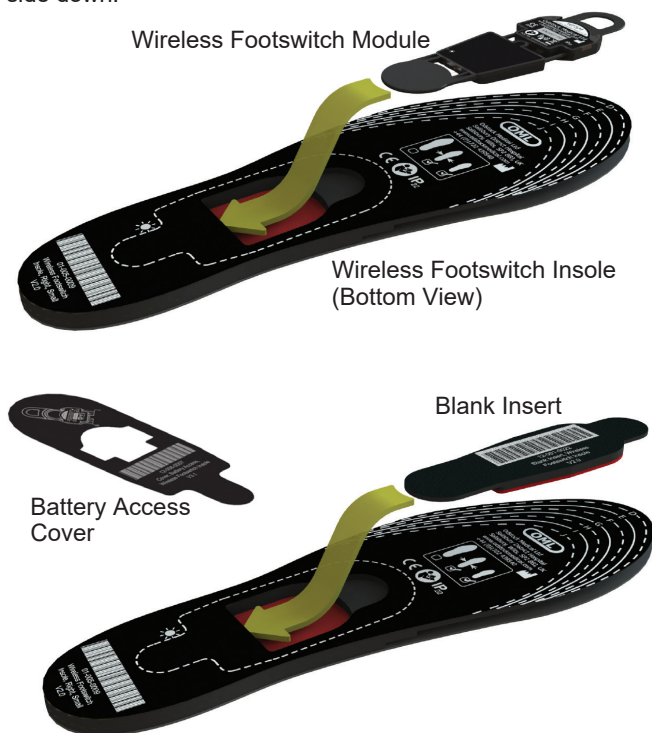


ODFS® Pace XL and the Wireless Footswitch

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. Insoles may be trimmed using a pair of scissors if required. The Wireless Footswitch is supplied with a left and a right insole and one blank 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 in 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 Battery Access Cover supplied. Remove the waxed paper backing to reveal the sticky tape. The insole is placed in the shoe printed side down.

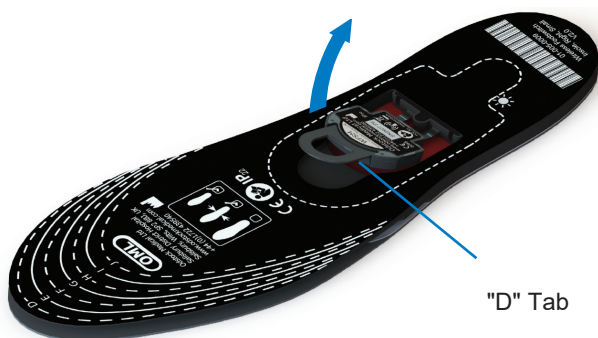


ODFS® Pace XL and the Wireless Footswitch

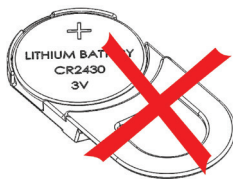
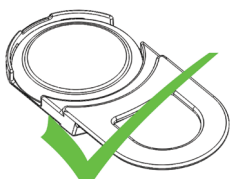
Changing the battery

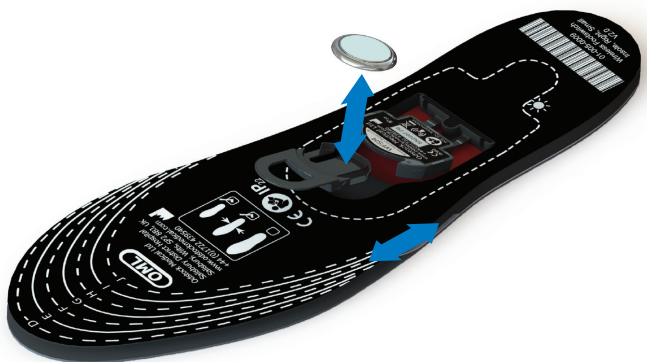
In order to maintain the Wireless Footswitch network connection and prevent a lengthy delay on pressing the Pause button it is important that the battery is changed using the following procedure:

1. Turn the ODFS® Pace XL OFF.
2. Remove the self-adhesive Battery Access Cover from the 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 a new CR2430 coin cell battery into the Battery Tray with the flat side (with the "+" symbol) facing down into the Battery Tray. Slide the Battery Tray back into the Wireless Footswitch Module making sure it is correctly orientated. As the battery is inserted the blue light should blink once, indicating correct orientation of the Wireless Footswitch Module and battery.





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

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

ODFS® Pace XL and the Wireless Footswitch

Joining a new Wireless Footswitch to the ODFS® Pace XL

NOTE - When both the ODFS® Pace XL and Wireless Footswitch are supplied together, they will be pre-joined. However, if supplied separately; 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 Footswitch does not trigger any other ODFS® Pace XL.

To join a new Footswitch first remove the Wireless Footswitch module from the insole and remove its coin cell battery if fitted.

Go to OPTIONS (see User Accessible Menu on page 19) and click the Control Knob.



Rotate the Control Knob until WIRELESS OPTIONS appears. Click the Control Knob.



This will bring up ALLOW JOINING. Click the Control Knob again.

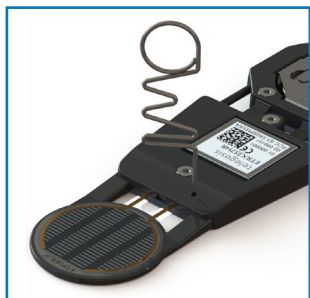


An hourglass will appear indicating that you have 1 minute to complete the joining process. While the hourglass is displayed, insert the Wireless Footswitch battery and then lay the Wireless Footswitch Module on a flat surface.



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





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

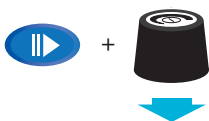


If joining does not occur, JOINING FAILED will be displayed after 1 minute. If this occurs repeat the process, checking the battery insertion or replacing the battery if necessary. If still unsuccessful, this may be due (but unlikely) to radio interference. Try creating a new wireless network (see next section).

Create Network

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

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



ODFS® Pace XL and the Wireless Footswitch

Clicking on CREATE NETWORK will cause the ODFS® Pace XL search the radio spectrum for a free channel and then join a Wireless Footswitch in the same way as ALLOW JOINING. Use the Network Joining Tool to press the Joining Button as described above.



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.

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 Lithium-Polymer rechargeable battery. We recommend to recharge the battery daily.

Activity / inactivity detection

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

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.

Using a wired Footswitch

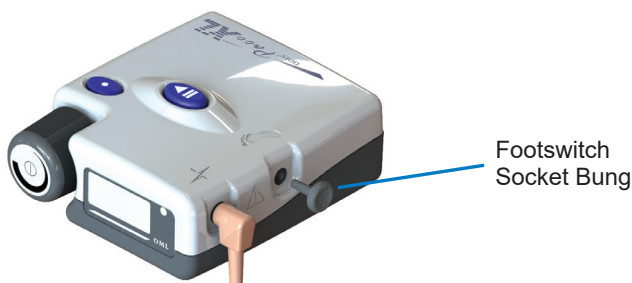
The ODFS® Pace XL can use a wired Footswitch. Simply plug in the Footswitch when the ODFS® Pace XL is paused. The ODFS® Pace XL will disable the transceiver and respond to the wired Footswitch instead of the Wireless Footswitch. To go back to wireless operation disconnect the wired Footswitch.

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.

Wireless Footswitch Bung

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



Electrode Care

Odstock Medical recommend the use of 50mm x 50mm self adhesive electrodes or equivalent for dropped foot correction. 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 including children 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 before placing the electrodes. If moisturisers are required, 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 scissors. All electrodes are for single patient use. An elasticated tubular bandage can be used to hold the electrodes in place.

1. Connect the electrodes to the leads by sliding the pin into the connector on the electrode leads. Ensure that the pin is inserted fully and that no metal is visible.
2. Peel the electrode away from their plastic backing by peeling away 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 either turned off or paused before removing the electrodes. Peel the electrode away from the skin by lifting it at the edge. Do not pull the electrode's 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 in the electrode packaging or in an air tight box.

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.

Electrode Placement

Electrode Placement

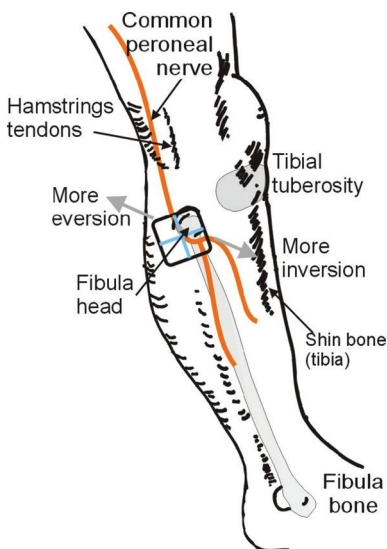
Some care is needed to find the best position for the electrodes. Your clinician will show you how to apply the electrodes and give you a diagram and / or a photo showing the positions. **NOTE-** You should only use the electrode positions that your clinician has asked you to use.

There are four standard sets of electrode positions:

1. The active electrode (black electrode plug) is placed with its top edge on the head of fibula. This is the first bone you will feel if you run your fingers up the side of your leg from the ankle bone. 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 (red electrode plug) is placed about 2cm below and forward of the active electrode. Avoid placing the indifferent electrode over the tibia bone as this will cause the stimulation to sting.

The ideal movement is that the foot is lifted with the outside of the foot lifting slightly higher than the inside. If the right movement is not produced, first try increasing the stimulation level a little. If this is unsuccessful, the position of the active (black plug) electrode is adjusted first. Excessive twisting to the outside (eversion) can be reduced by bringing the active electrode slightly further forward. Twisting inwards (inversion) may be reduced by bringing the electrode further back. The position of the indifferent (red plug) electrode can also be adjusted to balance the lift of the foot in the same way. Again, bringing the electrode towards the shin bone may reduce eversion. Do not pull the electrode over the shin bone as this can be uncomfortable. If toe-curling occurs while walking, place the indifferent (red plug) electrode a few centimetres further down the leg.

2. In some cases twisting out to the side can be decreased while still lifting the foot by reversing the active (red plug) and indifferent (black plug) electrodes. The movement can be adjusted in the same way as in 1.
3. Greater knee bending can be produced by placing the indifferent electrode (red plug) behind the knee. The outer edge of the electrode is placed along the hamstring tendons on the outer side. The active electrode (black plug) is placed at the side of the leg, just below the head of the fibula (see 1.) Sometimes a better movement can be obtained by swapping the red and black electrode lead plugs.
4. If stimulation of the common peroneal nerve is unsuccessful, the muscles that lift the foot can be stimulated directly. The active electrode (black plug) is placed over the widest part of the muscle at the front of the leg, approximately three finger breadths below the tibial tuberosity (the knobby bump at the front of the leg, just below the knee) and one fingers breadth to the outside of the shin bone. The indifferent electrode (red plug) is placed approximately 5cm below the active.



Setting the Stimulation Level

Getting started

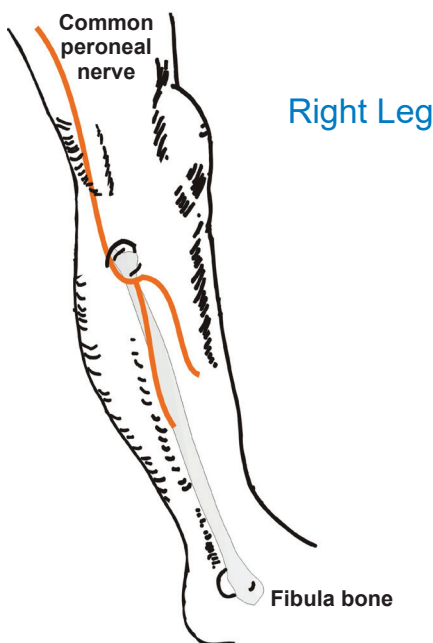
Before walking with the stimulator the output level must be set. Connect the electrodes as described in the previous section. Place your leg in a relaxed slightly bent position.

Turn on the ODFS® Pace (XL) by pressing and holding down the Control Knob.

Press the Test button. Observe that the indicator light flashes. You may feel the sensation of stimulation. While the indicator light is flashing, increase the output level by turning the Control Knob clockwise. Increase the output until the correct movement is achieved. If the movement is incorrect, check the electrode positions.



Electrode placement

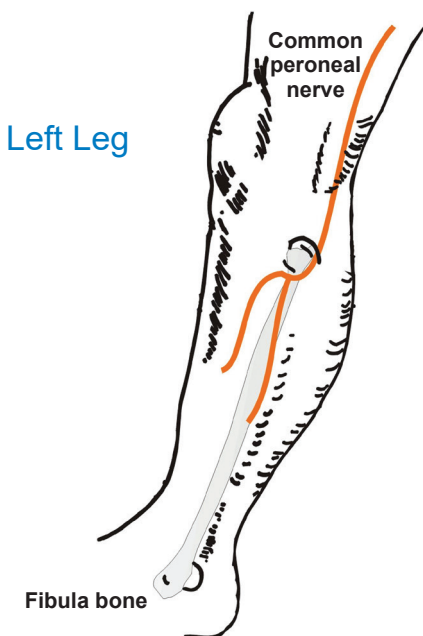


NOTE- Clinician Please mark the position of the electrodes on the diagram(s)

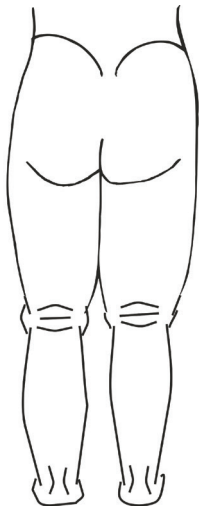
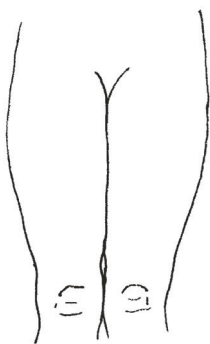
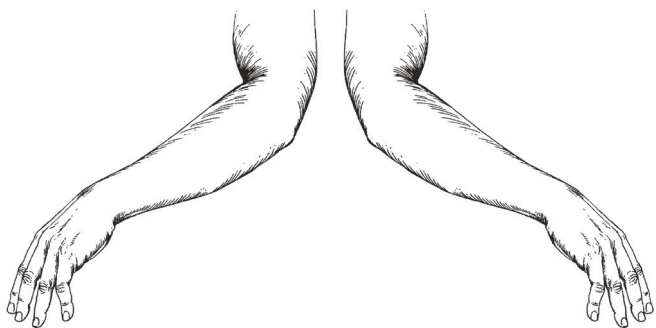
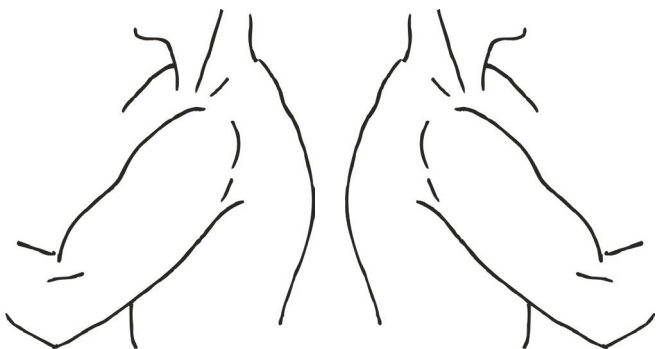
Finding the electrode positions again

Once the correct electrode positions are found, it is sometimes useful to mark them with an indelible marker pen so they can be easily found again. However it is better to learn to find the electrode placement by understanding the anatomy of your leg and how to move the electrodes to create the correct movement.

When first starting to use the ODFS® Pace (XL) , build up its use gradually over a period of two to three weeks. This will allow muscles that may not have been active for a while to build up strength and fatigue resistance.



NOTE- Clinician Please mark the position of the electrodes on the diagram(s)



Fault Finding

Problems

If you have a problem with your stimulator, contact the clinician who provided the device to you.

Fault Finding

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

1. No response to foot switch but response to Test button

The stimulator may be paused	Press Pause button
Faulty Footswitch	Replace the Footswitch
Faulty Footswitch lead	Replace lead
Lead not fully inserted into socket	Check connection

2. No stimulation but LED flickers

Faulty lead	Replace lead
Faulty electrodes	Replace electrodes
Faulty stimulator	Return to clinic
Lead not fully inserted into socket	Check connection

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 or replace electrodes
Muscle fatigue	Rest

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

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

Fault Finding

ODFS® Pace XL Fault Finding

- NO FOOT SWITCH! is displayed when the Pause button is pressed.
- Try unpausing the ODFS® Pace XL again.
- Check the battery condition and insertion.
- Move the foot slightly to ensure the Footswitch has not entered sleep mode.
- 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.
- Triggering from the Footswitch is inconsistent.
- Check that the insole is correctly positioned in the shoe.
- Check the condition of the coin cell battery.
- The Footswitch sensor may need replacing. Return to the supplier for servicing.
- Intermittent radio interference may be blocking reception. Reset the network using the CREATE NETWORK procedure.

Further information and useful video demonstrations can be found on the Odstock Medical Limited website - www.odstockmedical.com

Caring for your ODFS® Pace (XL)

If the device needs cleaning, wipe with a damp cloth. Do not immerse in water or use strong solvents.

If the electrode or Footswitch leads become stiff or damaged in any way, replace them.

FES User Support Group

This is a web based discussion group for users of Odstock Medical FES devices. Visit www.odstockmedical.com for information on how to join the group.

Clinician Contact Details

Please enter the name and contact details of the FES trained clinician who set up the ODFS® Pace (XL) and is responsible for continuing follow up.

Clinician Name:

Clinician Phone number:

E-mail:

Clinic Address:

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Replacement electrodes, footswitches, leads and other accessories are available from:

Odstock Medical Limited

The National Clinical FES Centre
Salisbury District Hospital,
Salisbury, Wiltshire SP2 8BJ
United Kingdom

Tel: +44 (0) 1722 439540
Fax: +44 (0) 1722 425263
www.odstockmedical.com
enquiries@odstockmedical.com

Warranty Information

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

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

The warranty for the Wireless Footswitch is 1 year from the date of purchase.

Should the unlikely event of any failure of the device occur during the warranty period, the device should be returned to the address shown below:

Odstock Medical Limited
Salisbury District Hospital
Salisbury
Wiltshire
SP2 8BJ

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

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

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

Travel Advice

In these days of increased security, FES devices may attract some interest from immigration and security staff at airports and ports. For this reason it is advisable to take the following precautions to ease your journey;

- Unless the device is essential while travelling, pack it in your luggage.
- Always take this instruction manual with the device so you can demonstrate what it is.
- Take a copy of a clinic letter with you so that you can show additional evidence that you received the device as part of a treatment program.
- Like other electronic equipment, the stimulator may effect navigation systems on aeroplanes. Make sure it is turned off whilst sitting down on an aeroplane.
- The stimulator is perfectly safe to be put through both x-ray machines and metal detectors.

ODFS® Pace XL and Wireless Footswitch users

Like all radio telemetry devices the ODFS® Pace XL and 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.

Statement for airport / port staff:

This person is using an Odstock Dropped Foot Stimulator, ODFS® Pace (XL). The purpose of this electronic device is to assist walking for people who have a neurological deficit such as stroke, multiple sclerosis, spinal cord injury, cerebral palsy or similar conditions. The device stimulates nerves in the leg using self-adhesive skin surface electrodes and is controlled using a pressure switch in the shoe. The device is CE marked and complies with all EU directives for medical devices. The device is manufactured by Odstock Medical Limited, UK.