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User manual QF019/ODFS Pace V1.3



Odstock Medical Ltd

USER 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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ODFS® Pace and ODFS® Pace XL User Instruction Manual V1.3

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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 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.



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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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 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.



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 2.5mm and greater.



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



Manufactured by Odstock Medical Limited.

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
Tubular Elasticated Bandage	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		N/A
User Manual		1
User Quick Start Guide		1
Clinician Quick Start Guide		N/A
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
Coin Cell Battery CR2430	BA-3V-LI-01	2
Network Joining Tool	AC-NT-00-01	1
Wired 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
Tubular Elasticated Bandage	TU-SF-25-00	1
Linen Drawstring Bag	AC-PB-00-00	1
Clinician Manual		N/A
User Manual		1
User Quick Start guide		1
Clinician Quick Start Guide		N/A
User Infocard		1

* Other sizes available on request

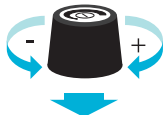
** Other electrode types and sizes available on request

*** Other accessories available. Please visit our web page www.odstockmedical.com

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.



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.

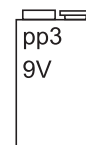


Battery

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, NiCad 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 used 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.



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.

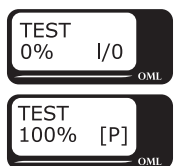
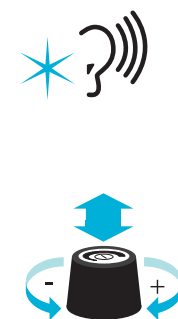
If REPLACE is displayed, the indicator light flashes and a siren beep is heard. The ODFS® Pace (XL) can still be used but the battery should be replaced as soon as possible.

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 0 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.



Using the Test button

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

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 changes to show 'solid' blocks.

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

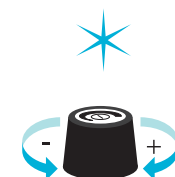
When the stimulator is set for Walk or Exercise the Pause button can be used to allow the stimulation to start.

Press the Pause button.

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 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 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.



If in Exercise mode, pressing the Pause button will cause the screen to change to the exercise count-down timer and level indicator blocks.



To end stimulation press the Pause button a second time. A short high pitch beep is given and the battery state briefly displayed. If the Pause button is held down the battery level will stay on the screen. 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 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.



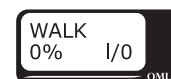
Turning the stimulator off

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 long beeps.



Auto turn off

If the ODFS® Pace (XL) is left turned on but is not used for more than 4 hour, 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 new wireless footswitches and turn off the ODFS® Pace (XL).



When the device is paused (and not on 0%), press and hold down the Control Knob for more than 2 seconds. Screen will then change to current mode, i.e. WALKING or EXERCISE mode.



Choosing WALKING or EXERCISE modes

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].

Please 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 switch and increase the level while stimulating, until the correct movement is produced.

OPTIONS

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 16).

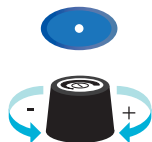
Clicking on SOUND OPTIONS brings two more choices.

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

N.B 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.



STEPS

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

Clicking on EXIT returns you to the current user mode.

TURN OFF?

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 cover supplied. Remove the waxed paper backing to reveal the sticky tape. The insole is placed in the shoe printed side down.

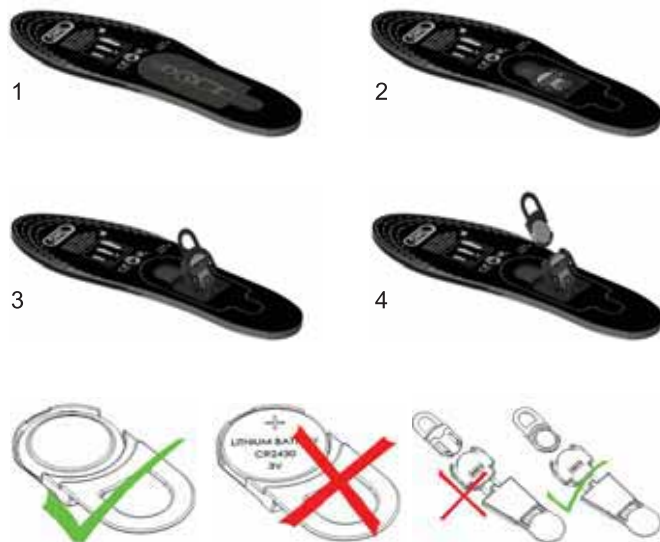


Changing the battery

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 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 button 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 test.
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.

To join a new footswitch first remove the wireless footswitch module from the insole and remove its coin cell battery.

Go to OPTIONS (see User Accessible Menu) and click the control knob.

Rotate the control knob till 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 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 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. 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.

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 Li-Polymer rechargeable battery. Recharge the battery daily.

Activity / inactivity detection

To save battery power the 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 foot switch will not be detected by the ODFS® Pace XL. If this occurs a small movement of the foot 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, 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 then 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.

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. 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

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 showing the positions. **N.B.** You should only use the electrode positions that your clinician has asked you to use.

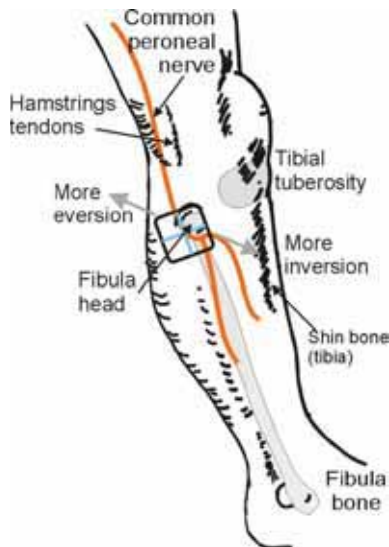
There are four standard sets of electrode positions:

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.

Setting the stimulation level

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 5 cm below the active.

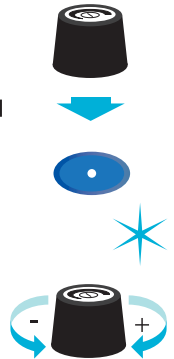


Getting started

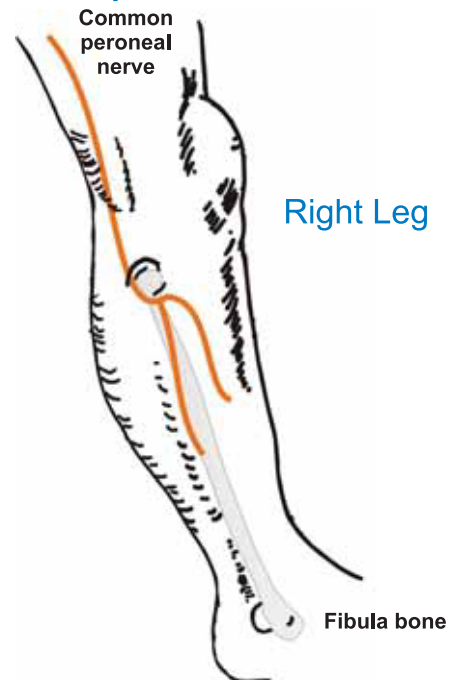
Before walking with the stimulator the output level must be set. Connect the electrodes as described in the previous section. Place your leg in a relaxed slightly bent position.

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

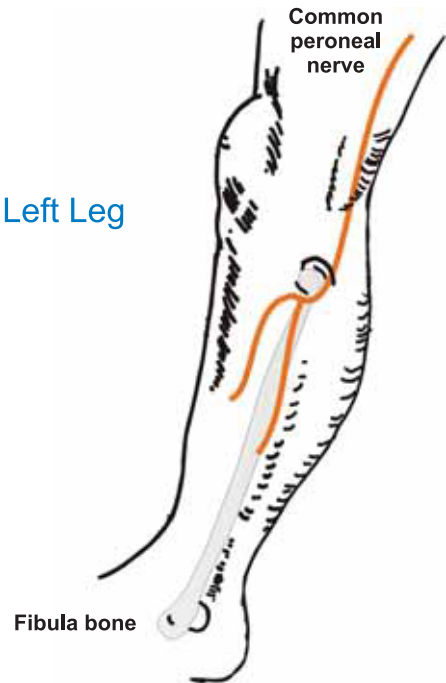


N.B. Clinician Please mark the position of the electrodes on the diagram(s)

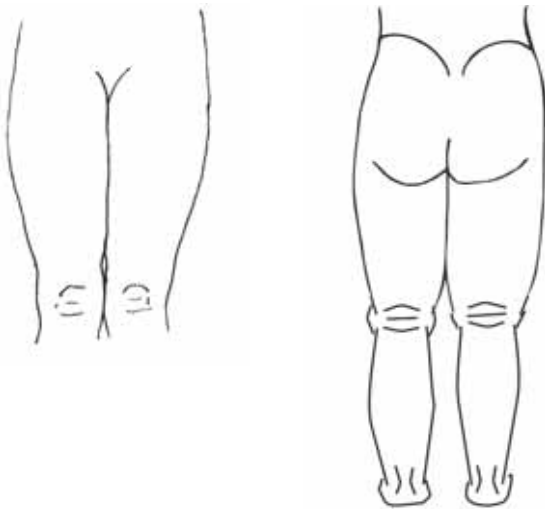
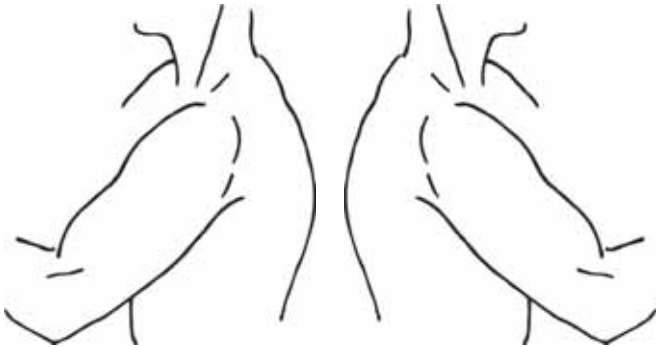
Finding the electrode positions again

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.



N.B. 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

2. No stimulation but LED flickers

Faulty lead	Replace lead
Faulty electrodes	Replace electrodes
Faulty stimulator	Return to clinic

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

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

ODFS® Pace XL Fault Finding

Fault	Possible solution
• NO FOOT SWITCH! is displayed when the Pause button is pressed.	• 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.

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,
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