USER INSTRUCTION MANUAL
Odstock Dropped Foot Stimulator

Model: ODFS® Pace V1

Model: ODFS® Pace XL V1

Software: V1.4

The output of this device has a physiological effect.

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

This instruction manual is intended for the end user and should be supplied to them by the clinician.

Read the instructions and precautions before use.

USA only: Rx Only

...a confident choice

OML | Leading FES Rehabilitation

NHS Salisbury NHS Foundation Trust

Contents

Introduction

The Odstock Dropped Foot Stimulator ODFS® Pace and it's wireless 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 the stimulation on and off 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 paraparisis, 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. Users should receive gait re-education training from a suitable clinician while learning to use the device. In general, users should be in reasonably good health and be able to understand how to use the system.

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

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

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

Key Features of the Stimulator

ODFS® Pace (XL) Pouch and Belt Clip

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

Intended Use

The ODFS® Pace (XL) is intended to be used for the alleviation of neurological injury or disability due to upper motor neurone disease or injury including stroke, multiple sclerosis incomplete spinal cord injury (T12 and above), head injury, cerebral palsy, Parkinson's disease and hereditary spastic paraparesis. Electrical stimulation is triggered from a switch input or cyclically during an exercise programme. Gait events are detected by a wired or wireless footswitch.

The primary application is as a long term orthotic aid for the correction of dropped foot for both adult and paediatric individuals. Other movement deficits can be addressed by stimulation of additional muscle groups, singularly or in conjunction with the correction of dropped foot, for the purpose of functional movement training and/or gait assistance.

The ODFS® Pace (XL) may also strengthen muscles, reduce spasticity, increase range of movement, reduce oedema and increase local blood flow. Stimulation can also modulate the central nervous system promoting neuroplasticity.

The ODFS® Pace (XL) is designed for use in home healthcare/residential and hospital/ healthcare environments.

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

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

Contraindications

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

Warnings

Neck stimulation

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

Open or infected wounds

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

Cancer

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

Electronic monitoring equipment

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

Transcerebral stimulation

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

Strangulation

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

Chest stimulation

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

Epilepsy

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

Choking

Small parts of the system could be a choking hazard.

Sleeping

Do not use the stimulator whilst sleeping.

Batteries

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

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

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

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

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

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

Please refer to battery specification on page 47 of this instruction manual.

High frequency surgical equipment

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

Oxygen rich environments

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

External orthopaedic metal fixation

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

Latex allergies

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

Flammability

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

Electromagnetic emissions

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

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

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

Precautions

Degradation of stimulator, consumables and accessories

Do not use the device if the stimulator, cables, footswitch or electrodes are damaged in any way. Replace the cables if they become stiff or have cracked insulation.

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. Only apply electrodes as described in this instruction manual.

Exposed electrode pins

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

Skin irritation

Some people may experience skin irritation due to electrical stimulation or from the electrodes. The irritation can usually be reduced by using an alternative type of electrode, different device settings or a new electrode position. A slight reddening of the skin under the electrodes is normal and this should clear within 1 hour of stopping stimulation. If stimulation causes long term marking of the skin, the user should discontinue use and contact their clinician. *Please refer to electrode care on page 35 of this instruction manual.*

Skin care

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

Prevention of pressure sores.

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

Spasticity

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

Machinery operation and driving

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

Bathing/showering/swimming

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

Water ingress

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

Shortwave and microwave therapy

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

Autonomic dysreflexia

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

Cardiac/exercise stress

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

Deep vein thrombosis

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

Injury, fracture or surgery

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

Pregnancy

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

Prescribed user

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

Long-term effects

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

Air travel/wireless restricted area

Like all radio telemetry devices the ODFS® Pace XL should not be used in wireless transmission mode in areas where use of wireless devices is restricted. In areas of restriction the ODFS® Pace XL can be used in airplane mode, with a wired footswitch. Please refer to accessory user instructions for details of use within wireless restricted areas. Please refer to airplane mode on page 27 of this instruction manual

Accessories and consumables

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

Battery change and battery cover

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

Equipment modification

Do not tamper with or modify the equipment.

Shelf life

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

Equipment re-use

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

Storage temperature

Do not store outside of the temperature limits as detailed in the specification on page 47. If the ODFS® Pace (XL) or accessories (excluding electrodes) have been stored at the minimum (-20°C) or maximum (70°C) storage temperatures, allow at least 10 minutes in ambient temperature before use. This time may be required following system removal from cold storage for the screen on the stimulator to reach full clarity.

Use of small electrodes

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

Hot surfaces

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

Adverse reactions

The 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 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 trip or fall and possible injury or harm.

Safe disposal of equipment

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

Symbols and Definitions

Attention: device has a physiological effect

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

Applied parts of insulation type BF.

Read the instructions and precautions before use.

Consult instructions for use.

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

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

Date of manufacture.

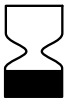
IP22

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

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

Do not get any part of the system wet.

Symbols and Definitions



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

Manufactured by Odstock Medical Limited

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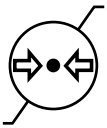
Salisbury, Wiltshire, UK **enquiries@odstockmedical.com**

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

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

Do not store outside of the specified relative humidity limits.



Do not store outside of the specified atmospheric pressure limits.

Rotation and power on/off

Location of footswitch socket.

Location of electrode socket.

Test button.

Symbols and Definitions

Pause/start button.

LOT

Batch number.

SN

Unique serial number of the stimulator.

REF

Odstock Medical Limited stimulator reference number.

EC REP

European authorised representative.

MD

Medical Device

Light flashes on the ODFS® Pace (XL)

Beeps heard from the ODFS® Pace (XL)

Importer

Changing the Battery

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

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

Removing and installing the battery

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

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

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

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

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

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

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

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

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

> Only recharge the lithium polymer battery using the charger supplied.

1.

2.

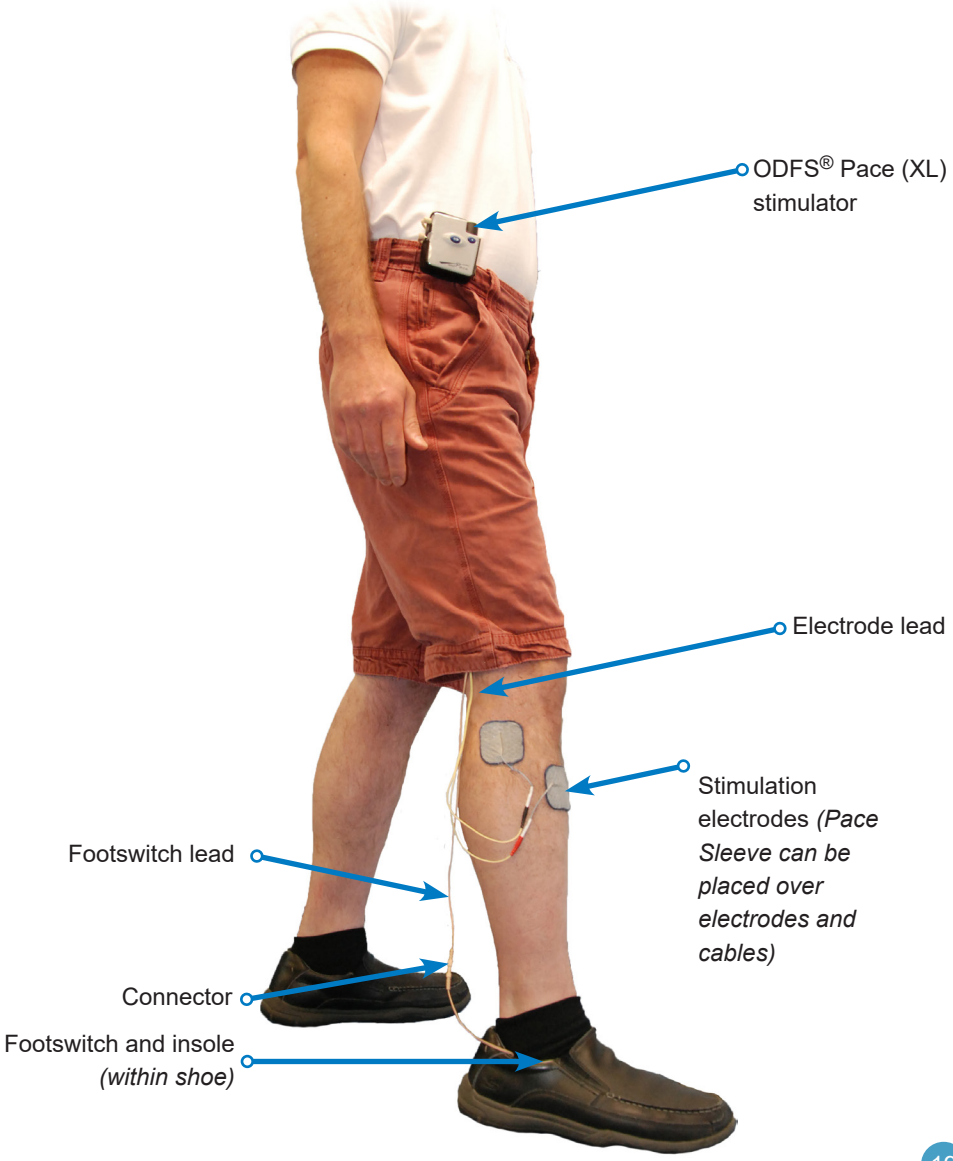
3.

4.

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

System Set-up on a User

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

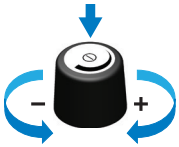


Controls

Control knob

This control has three actions;

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



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

Test button

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

Pause button

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

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

Connectors

Electrode lead socket

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

Footswitch lead socket

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

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

Turning the stimulator on

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

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

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

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

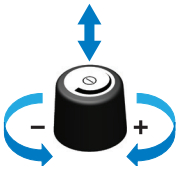
Your clinician will have set the ODFS® Pace (XL) to turn on at either 1%, 50%, or the last used level before turning off.

Stimulation modes

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

> Exercise mode must be enabled by the clinician for it to be available to the user.

Adjusting the output level (pulse width)



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

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

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

Using the test button

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

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

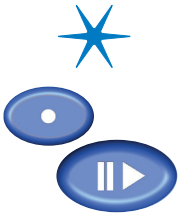
The indicator light will flash and if the stimulator has been set to use beeps, a ‘chirp’ will accompany the light flash in **walk mode** or a ‘beep-chirp-beep’ in **exercise mode**.

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

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

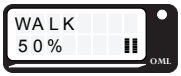
The light flashes in sequence with the stimulation.

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



Using the pause button

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



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

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

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

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

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

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

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

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

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

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

Low battery warning

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

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

Lost wireless footswitch connection

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

If this occurs please refer to the troubleshooting section on page 44.

Turning the stimulator off

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

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

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

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

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

The stimulator can also be turned off from the **user accessible menu**. Please refer to page 26 for further details.

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

Auto-turn off

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

Exercise mode

Exercise mode is used to train and strengthen muscles. In **exercise mode** the stimulation comes on and off automatically to set timings without the need of a **footswitch**.

If your clinician has set an **exercise mode** for you, the method of entering **exercise mode** is different for ODFS® Pace and ODFS® Pace XL.

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

For the ODFS® Pace XL, **exercise mode** is entered via the **user accessible menu** (see page 26).

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

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

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

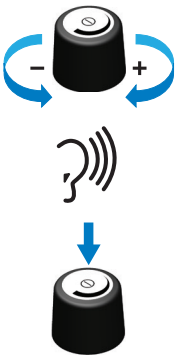
> If a different muscle group is used for exercise to that of walking, make sure that the **electrodes** are in the intended position.

User Accessible Menu

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

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

Changing between walk and exercise modes



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

Options

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

Beeps

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

Sounder

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

Wireless options

This menu is only visible on the ODFS® Pace XL. “WIRELESS OPTIONS” allows for either a **wireless footswitch** or **remote control** accessory to be joined to the ODFS® Pace XL. This is described in more detail on page 37 and the instruction manual that accompanied the wireless accessory.

Airplane mode

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

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

Steps logger

My steps

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

Total

The “TOTAL” screen gives the total number of steps taken with the stimulated leg since last being reset by the clinician.

Exit

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

Menu time out

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

Auto turn off

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

The output level maybe require adjustment when turned on again.

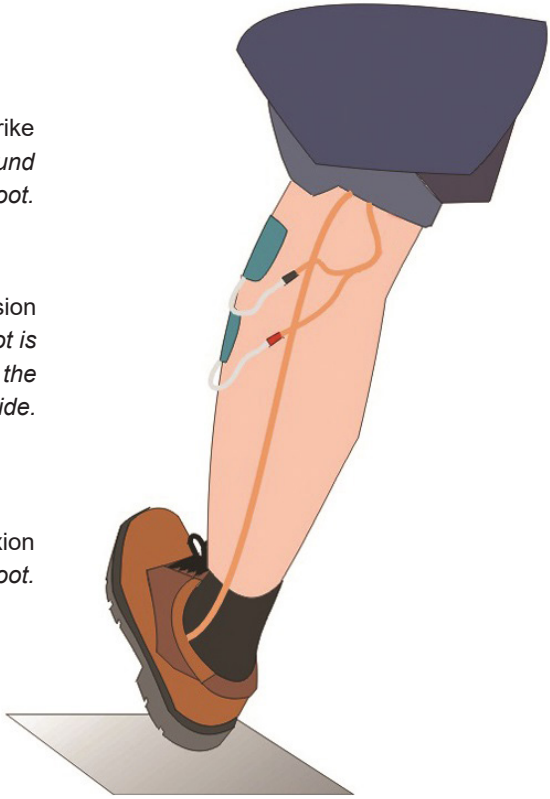
The Correct Movement For Dropped Foot Correction

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

Heel strike
Heel strikes the ground before the forefoot.

Eversion
The outside of the foot is lifted upwards relative to the inside.

Dorsiflexion
Lifting of the forefoot.



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.

Place your leg in a relaxed, slightly bent position when placing the electrodes.

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 pin) 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. Press the 4 corners of the **electrodes**, the tissue under 3 corners will feel soft, the corner over the head of fibula will feel harder. The **indifferent electrode** (red electrode pin) is placed about 2cm below and forward of the **active electrode**. Avoid placing the indifferent electrode over the tibia bone as this may cause discomfort.

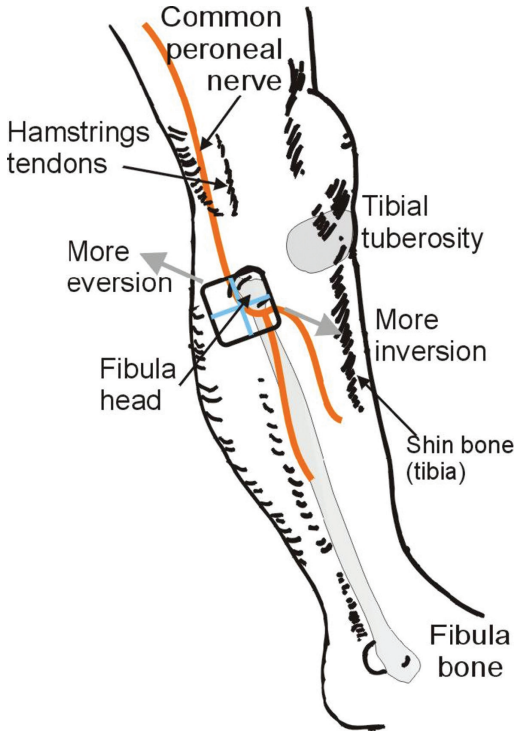
The ideal movement is that the foot is lifted with the outside of the foot lifting slightly higher than the inside. If the correct movement is not produced, first try increasing the stimulation level a little. If this is unsuccessful, the position of the **active electrode** is adjusted first. Excessive twisting to the outside (eversion) can be reduced by bringing the **active electrode** slightly further forward (see image on page 31). Twisting inwards (inversion) may be reduced by bringing the **electrode** further back. The position of the **indifferent 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 put the **electrode** over the shin bone as this can be uncomfortable. If toe-curling occurs while walking, place the **indifferent 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 and indifferent **electrodes**.

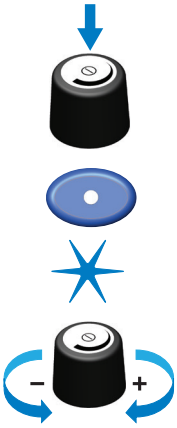
3. Greater knee bending can be produced by placing the **indifferent electrode** behind the knee. The outer edge of the **electrode** is placed along the hamstring tendons on the outer side. The **active electrode** is placed at the side of the leg, just below the head of the fibula. Sometimes a better movement can be obtained by swapping the red and black **electrode lead** pins.

4. If stimulation of the common peroneal nerve is unsuccessful, the muscles that lift the foot can be stimulated directly. The **active electrode** is placed over the widest part of the muscle at the front of the leg, approximately three finger breadths below the tibial tuberosity (the knobbly 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** is placed approximately 5cm below the active.

Changing movement of the foot by adjusting the electrode positions



Getting started



Once the electrodes are placed and before walking with the stimulator the output level must be set.

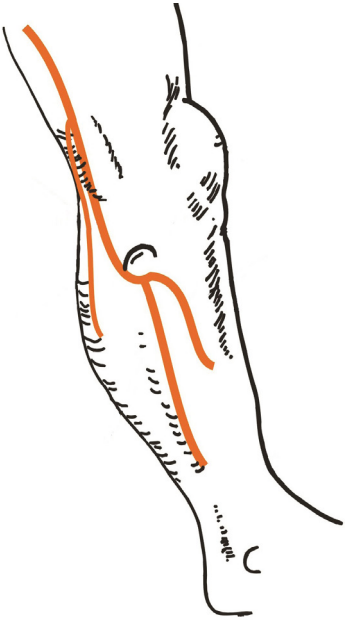
Turn on the ODFS® Pace (XL) by pressing and holding down the **control knob**.

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 level until the correct movement is achieved. If the movement is incorrect, check the electrode positions.

Electrode positions

Clinician: please mark electrode positions on the appropriate diagrams below:

Right Leg



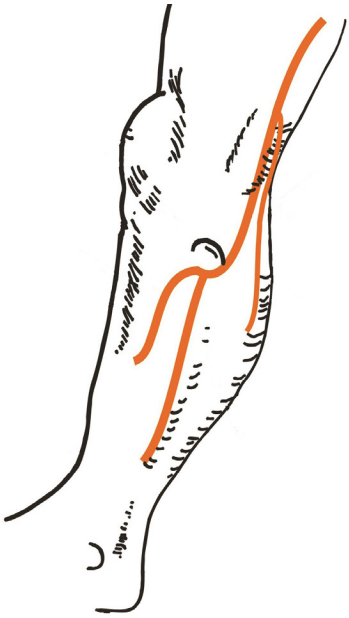
Finding the electrode positions again

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.

Building up use of stimulation

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.

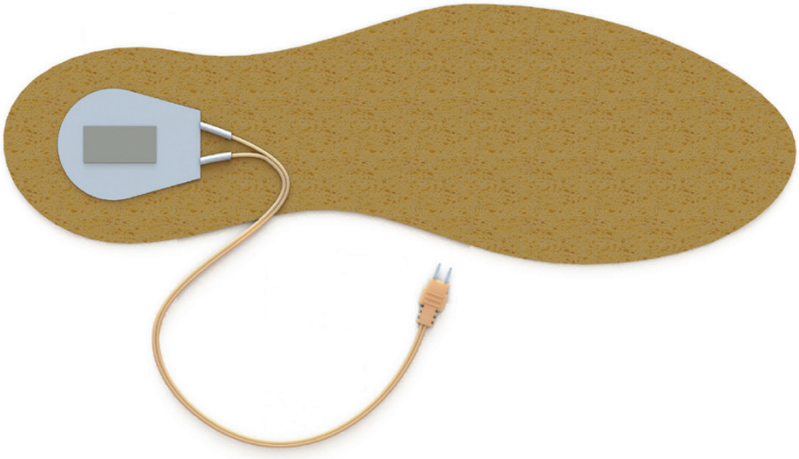
Left Leg



Footswitch Placement

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

Your clinician will set-up the position of the **footswitch** to best suit your walking.



Electrodes and Electrode Care

Odstock Medical Limited recommend the use of 50mm x 50mm self adhesive square electrodes supplied within the ODFS® Pace (XL) boxed kits. These electrodes have proved to be the most reliable in clinical practice, are the easiest to use and the least likely to cause skin irritation. An alternative electrode type is the PALS® Plus range, available in a variety of sizes suitable for other applications as well as dropped foot. ODFS® Pace (XL) users (such as paediatric 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 and in good condition. This will help prevent skin irritation developing.

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

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

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

All electrodes are for single person use.

A Pace Sleeve (supplied in the kit) can be used to hold the electrodes and leads in place.

Follow the instructions provided with the electrodes.

Electrode use and daily care

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

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

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

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

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

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

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

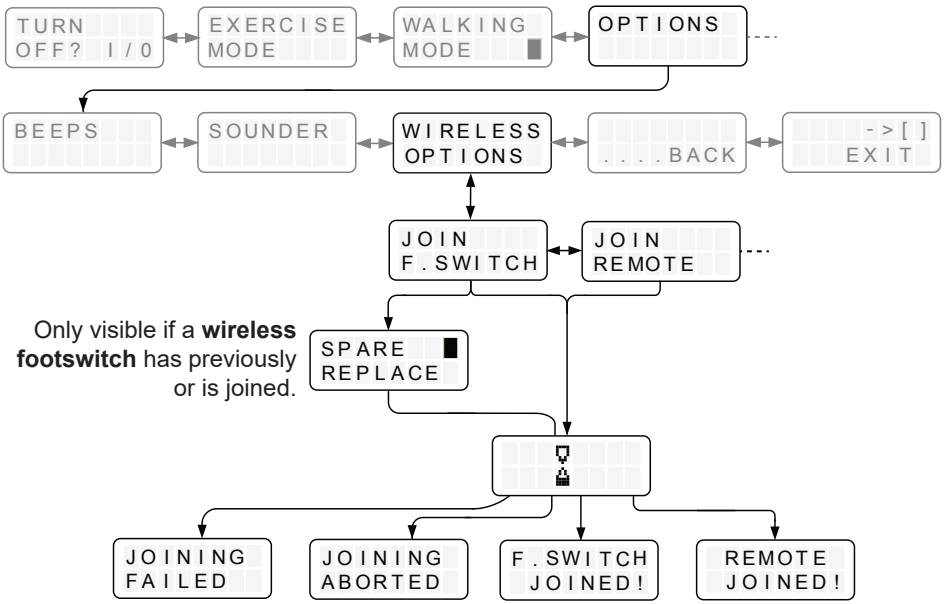
Replacing **electrodes** regularly helps to prevent skin irritation.

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

The clinician and user are able to join accessories to the ODFS® Pace XL. If your clinician has provided your accessories, these should have been joined. Some accessories may require input from a clinician. If you have problems following the joining process please contact your clinician or Odstock Medical Limited.

Wireless joining of accessories in the user accessible menu

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



The wireless joining mode can be accessed from the **user accessible menu** (page 26). To enter this menu, click and then hold down the **control knob** for 2 seconds. This presents the user with the ability to join a **wireless footswitch** or a **remote control**. Once the accessory device starts it's joining mode, select either JOIN F.SWITCH or JOIN REMOTE on the ODFS® Pace XL. An hour glass will be displayed and may remain on the screen for up to 2 minutes during the joining process.

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

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

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

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

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

4

Spare or replace wireless footswitch

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

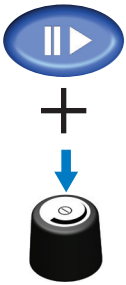
Create network menu

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

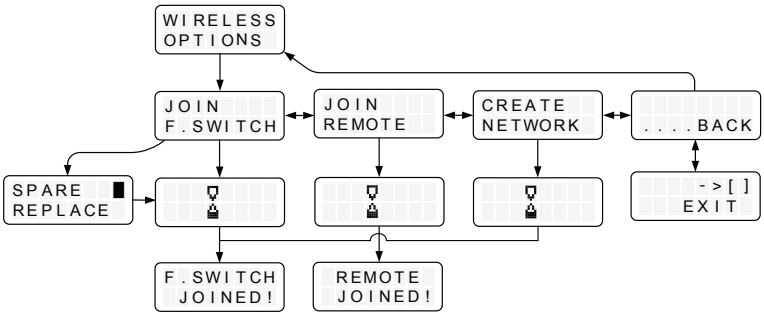
If this option is selected the wireless accessories currently joined will need to be re-joined.

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

Create network



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



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

Cleaning and Care Guidance

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

Remove the **battery** before cleaning the system.

Do not scrub with abrasive material

Make sure all parts are dry before re-use.

Stimulator

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

Do not immerse the stimulator in water

Do not clean with solvents.

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

Electrodes

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

Do not use a cloth to clean the electrode gel.

Do not immerse **electrodes** in water.

Do not use soap

Leads and footswitches

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

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

Servicing

The ODFS® Pace (XL) does not require any regular servicing. If it becomes faulty please refer to troubleshooting on page 44 or return to Odstock Medical Limited.

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

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

Maintenance

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

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

Calibration

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

Expected Service Life and Maintenance

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

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

Travel Advice

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

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

ODFS® Pace XL users

Like all radio telemetry devices the ODFS® Pace XL and wireless accessories should not be used while flying. Set the ODFS® Pace XL to "**airplane" mode** and use a wired footswitch. Please refer to page 27 on how to set "**airplane" mode**.

Statement for airport/port staff

This person is using an Odstock Dropped Foot Stimulator, ODFS® Pace (XL) produced by Odstock Medical Limited, Salisbury, UK. The purpose of this electronic device is to assist the walking of 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 relevant EU directives for medical devices. It is approved by the FDA for use in the United States of America.

Troubleshooting

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

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

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

If there is no stimulation during gait, remove **footswitch** from the shoe and try to trigger between 2 fingers. If this triggers the stimulator, consider moving the position of the **footswitch** in the shoe to a more suitable location. Refer to page 34.

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

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

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

3. Incorrect movement produced by the stimulation

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

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

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

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

5. The stimulator does not turn on

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

6. Interference from other wireless devices

Fault	Action
Intermittent or no wireless connection to wireless accessories.	Move away from potential source of interference Turn the system and wireless accessories off and on. Create a new network or if using a remote control follow instructions supplied with this device. Refer to page 39 for create network.

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

Audio warnings

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

Error messages

If an error message is shown turn off the device by pressing and holding the **control knob**. Turn the device back on and if the error message reappears, contact Odstock Medical Limited.

Error Message	Fault
“ERROR!!! 1”	Hardware fault. Contact Odstock Medical Limited.
“ERROR!!! 2”	Hardware fault. Contact Odstock Medical Limited.

Warranty Information

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

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

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

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

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

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

Technical Specification - ODFS® Pace (XL)

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

Wireless Information - ODFS® Pace XL

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

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

Like all radio telemetry devices the ODFS® Pace XL and wireless accessories should not be used while flying. Set the ODFS® Pace XL to **airplane mode** and use a **wired footswitch**. Please refer to page 27 on how to set **airplane mode**.

Electromagnetic Emissions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Notes

Notes

Regulatory Representatives

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

EC REP

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

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