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User manual QF019/ODFS Pace V1.2



Odstock Medical Ltd

USER INSTRUCTION MANUAL

Odstock® Dropped Foot Stimulator

Model ODFS® Pace V1.0

Software V1.2



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 User Instruction Manual V1.2
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The Odstock Dropped Foot Stimulator ODFS® Pace 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 must be under the supervision of clinical staff trained in its use by Odstock Medical Limited or their agents.

The ODFS® Pace 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. Patients may also contact Odstock Medical directly if they need additional assistance.

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CONTRAINDICATIONS

The ODFS® Pace 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 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 should not be used by people who have poorly controlled epilepsy.

Autonomic Dysreflexia

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

Latex Allergies

Caution: The Tubigrip® elastic stocking contains natural rubber latex which may cause allergic reactions. This item is provided as an accessory to the ODFS® Pace 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 14 years.



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 complies with European Union Medical Device Directive.



Protected against solid foreign objects of diameter 2.5mm and greater.

Description	Part No.	Qty
ODFS® Pace stimulator	ODFS® IV	1
Electrode lead 1m*	EL-shroud 100	1
PALS neurostimulation Platinum Blue electrodes 5cm x 5cm**	901 220	1
PP3 Battery	MN1604	1
Pair shoe insoles*	IS G10	1
Footswitch lead 1.2m*	FSL 120	1
Footswitches	FSR	2
Carry case		1
Tubigrip sleeve size G*		1
Clinicians manual		1
User manual		1
Clinicians quick start guide		1
User quick start guide		1
Kit bag		1

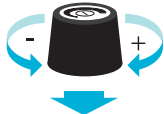
* Other sizes available on request

** Other electrode types and sizes available on request

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 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.

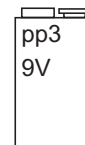


Battery.

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 or NiCad battery can be used.

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



Operating Guide

Turning the stimulator on

Press the control knob and hold it down until the display comes on and the indicator light flashes.

If the stimulator has been set to use beeps, 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 BATTERY

If the battery condition is OK or POOR the ODFS® Pace can still be used but you may need to increase the output level.

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

Operating Modes

The operating mode will then be displayed at the top of the screen and the output level setting at the lower part.

The 3 operating modes are:-

TEST

The stimulator will go to this mode when the footswitch is unplugged and the built in exercise function has been disabled.

EXERCISE

The stimulator will go to this mode when the footswitch is unplugged and has been exercise enabled by the clinician.

WALK

The stimulator will go to this mode whenever the footswitch is plugged in.

Whichever mode is chosen, when the stimulator is turned on it will start up with the output paused. This is shown on the display by [P] once the output is set more than 1%.



Adjusting the output level

The output of the ODFS® Pace is adjusted by first clicking (press and release) and then turning the Control knob. This sets the stimulation pulse width. If the control lock has been deselected by your clinician, the output can be adjusted without first clicking the control knob. The control lock is not used in the Exercise mode.

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

If the stimulator has been set to use beeps, a click will accompany each adjustment increment. The pitch of the click will go up and down as the output is turned up and down. If your clinician has set the BEEPS ON+ option there will be a high pitched 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 1% indicating that clicking the Control knob will turn the device off.

Using the Test button

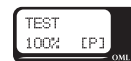
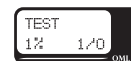
While the stimulator is paused the output can be tested by pressing the Test button.

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.

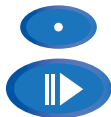
The light flashes in sequence with the stimulation.



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 footswitch is plugged in the screen will display Walk and ODFS® Pace will respond to the footswitch.



If the footswitch is not plugged in and the exercise function has previously been enabled by the clinician, the screen will display EXERCISE and stimulation will immediately begin.



If the foot switch is plugged in while the Exercise sequence is running the ODFS® Pace stimulator will enter Walk mode and will be paused.



If the Exercise function has not been turned on and there is no footswitch plugged in, pressing the Pause button will cause a long beep followed by two short and lower pitch beeps. The display will flash 'NO FOOT SWITCH!'



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 1% and the 1/0 symbol appears. If the BEEPS ON+ option has been set 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.



Sleep Mode

If the stimulator is left paused for longer than 10 minutes it will automatically go into a power saving sleep state. The screen will be blank and the indicator light will flash once every 5 seconds.

The ODFS® Pace can be woken from sleep by pressing the Pause button to start walking or by pressing the Control knob to use the test or exercise mode. The stimulation level will be the same as when the ODFS® Pace went to sleep.

If the ODFS® Pace is left in Sleep Mode for more than 4 hours, it will turn off completely and the output level reset to 1%. The Output level must be adjusted to the required level when the ODFS® Pace turned on again.



Odstock Medical recommend the use of PALS Platinum Blue 50mm x 50mm #901220 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 users with smaller legs including children will 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 elastic cuff (Tubigrip®) 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 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 minutes to dry. This rehydrates the electrode and also removes any debris from the surface. If this is not successful, replace the electrodes. A pair of electrodes should last about four weeks. Replacing electrodes regularly, helps to prevent skin irritation.

Electrode Placement

Electrode Placement

Some care is needed to find the best position for the electrodes. Your clinician will show you how to apply the electrodes and give you a diagram showing the positions.

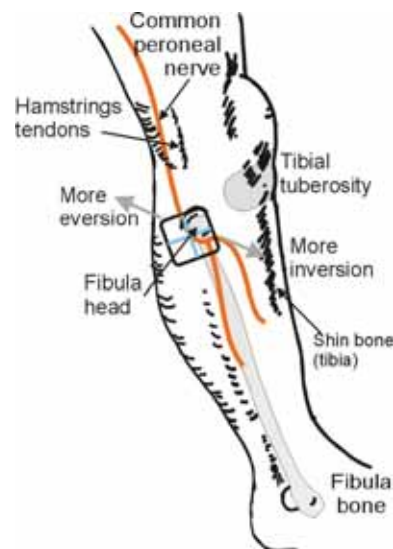
N.B. You should only use the electrode positions that your clinician has asked you to use.

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.

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.



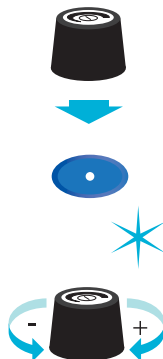
Setting the stimulation level

Getting started

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

Turn on the ODFS® Pace 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.

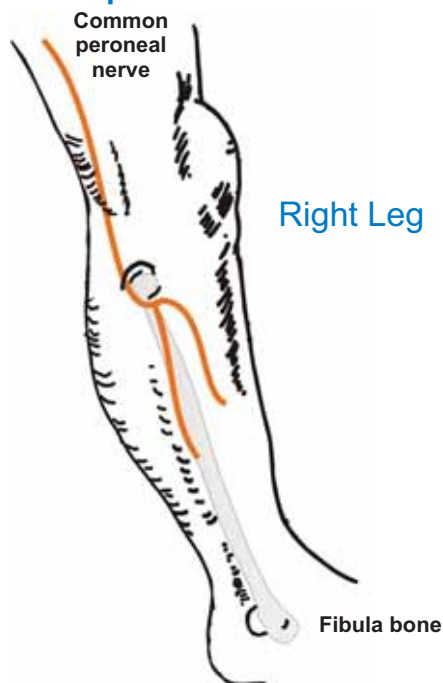


Finding the electrode positions again

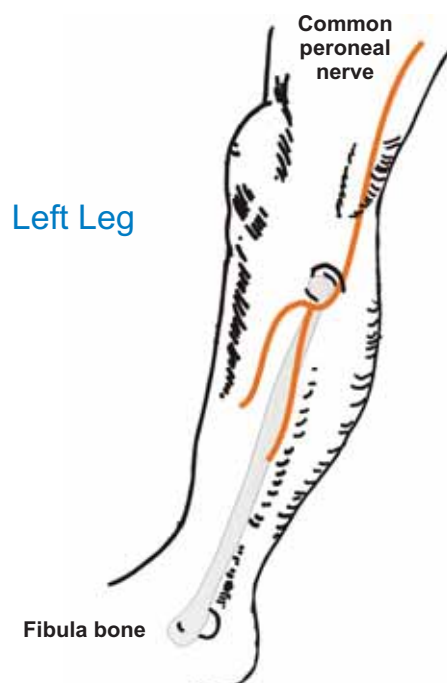
Once the correct electrode positions are found, it is sometimes useful to mark them with an indelible marker pen so they can be easily found again. However it is better to learn to find the electrode placement by understanding the anatomy of your leg and how to move the electrodes to create the correct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

When first starting to use the ODFS® Pace, 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.

Electrode placement



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



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 stimulator	Return to clinic
Faulty electrodes	Replace electrodes

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

Caring for your ODFS® Pace

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 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

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