ODFS

DROPPED FOOT STIMULATOR

USER MANUAL

Caution: Federal Law restricts this device to sale by or on the order of a practitioner licensed by the law of the state in which he/she practices to use or order the use of the device.

CONTACT INFORMATION

Please contact your Clinician or Therapist if you are experiencing any difficulties.

Clinicians Name: _____

Phone: _____

Therapists Name: _____

Phone: _____

NDI Medical

One Chagrin Highlands
2000 Auburn Drive, Suite 320
Cleveland, OH 44122
216.378.9106
www.odfs.com

001-MAN-000-1

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1.0 INTRODUCTION

This manual is intended to provide information for the safe use of the ODFS Dropped Foot Stimulator for you and your caregiver.

Your therapist will train you to use the information in this manual. Call your therapist if you need help in understanding how to use your ODFS.

2.0 INDICATIONS FOR USE

The ODFS is a device that uses low levels of electrical stimulation to help those having a dropped foot lift their foot and improve their walking.

Additional benefits may include

- muscle re-education (retraining your muscles to act as they did before your injury)
- prevention/retardation of disuse atrophy (decrease bulk of muscle tissue when your muscles are not used)
- maintained or increased joint range of motion
- increased local blood flow

The ODFS is a medical device and should only be used under medical supervision for adjunctive therapy for the treatment of dropped foot following an upper motor neuron injury.

3.0 CONTRAINDICATIONS

The ODFS should not be used on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electrical shock, burns, electrical interference, or death.

4.0 WARNINGS

Neck Stimulation - Stimulation should not be applied over the patient's 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 the patient's heart rhythm or blood pressure.

Chest Stimulation - Stimulation should not be applied across the patient's chest because the introduction of electrical current into the chest may cause rhythm disturbances to the patient's heart, which could be lethal.

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.

Cancer - Stimulation should not be applied over, or in proximity to, cancerous lesions.

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.

Bathing/Showering - Stimulation should not be applied when the patient is in the bath or shower.

Sleeping- Stimulation should not be applied when the patient is sleeping.

Machinery Operation- Stimulation should not be applied when the patient is driving, operating machinery, or during any activity in which electrical stimulation can put the patient at risk of injury.

Consult with the patient's physician before using this device, because the device may cause lethal rhythm disturbances to the heart in susceptible individuals.

Stimulation should only be applied to normal, intact, clean skin.

5.0 PRECAUTIONS

Long-term Effects - The long-term effects of electrical stimulation are unknown.

Transcerebral Stimulation - The effects of stimulation of the brain are unknown. Therefore, stimulation should not be applied across the patient's head and electrodes should not be placed on opposite sides of the head.

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

Skin Irritation - Some patients may experience skin irritation or hypersensitivity due to electrical stimulation or electrical conductive medium (gel). The irritation can usually be reduced by using an alternate electrode placement. A slight reddening of the skin under the electrode is normal. If stimulation causes long-term marking of the skin, discontinue use and consult your physical therapist.

Cardiac - Patients with suspected or diagnosed heart disease should follow precautions recommended by their physicians.

Epilepsy - Patients with suspected or diagnosed epilepsy should follow precautions recommended by their physicians.

Hemorrhage - Caution should be used if the patient has a tendency to bleed internally, such as following an injury or fracture.

Recent Surgery - Caution should be used following recent surgical procedures when stimulation may disrupt the healing process.

Gynecology - Caution should be used over the menstruating or pregnant uterus.

Sensory Loss - Caution should be used over areas of skin that lack normal sensation.

Keep Out of Reach of Children - Keep this device out of the reach of children.

Electrodes/Leads - Use this device only with the leads, electrodes, and accessories recommended by the manufacturer.

Spasticity - If stimulation causes increased spasticity (involuntary, exaggerated muscle stiffness and spasm), discontinue use and consult your physical therapist.

Supervision of a Licensed Practitioner - Use this device only under the continued supervision of a licensed practitioner.

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 device. If you are sensitive to products that contain latex, your clinician will discuss possible alternatives (to using this elastic stocking) with you.

6.0 ADVERSE REACTIONS

Skin Irritation - Skin irritation and burns beneath the electrodes have been reported with the use of electrical stimulators applied to the skin.

Headache/Painful Sensations - Headache and other painful sensations have been reported during or following the application of electrical stimulation near the eyes and to the head and face.

Report any undesirable outcomes, malfunctioning of the device, mistakes in using the device, or injury from the use of this device to your clinician. Your clinician is responsible for reporting all of these events to the designated US distributor of the ODFS, NDI Medical, in writing:

- via email odfsinfo@ndimedical.com
- or fax 216-378-9116
- or mail to NDI Medical, 2000 Auburn Drive Suite 320, Cleveland, OH 44122

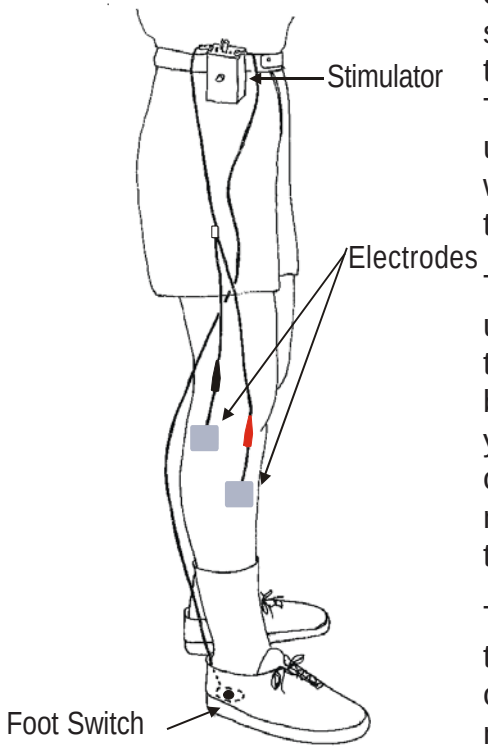
7.0 CONTENTS OF STANDARD PACKAGE

The ODFS System contains the following components:

- ODFSIII V6.2 Stimulator
- (1) set of electrode leads (1m)
- (2) packages of PALS neurostimulation 5cm x 5cm square Platinum Blue electrodes
- (1) elastic stocking (Tubigrip size F) **Caution:** This product contains natural Rubber Latex which may cause allergic reactions.
- (1) alkaline battery (9V)
- (1) pair of cork insoles (Size 10.5)
- (1) foot switch lead (1.2m)
- (2) foot switches
- (1) carrying case
- (1) User Manual
- (1) User Quick Reference Guide

8.0 DESCRIPTION OF SYSTEM COMPONENTS

8.1 DEVICE DESCRIPTION



Stimulating a nerve in the side of your leg will activate the muscles that lift the foot. The stimulation is timed by using a "foot switch" that is worn inside your shoe under the heel of your foot.

The ODFS System is made up of several parts connected together and worn on your body. The stimulator allows you to turn the system on and off and to make some adjustments as instructed by your therapist.

The stimulator is an electronic device about the size of a pack of playing cards. It may be worn on a belt clip or in your pocket. The electrode leads are cables worn under your clothing that connect the stimulator to self sticking skin surface electrodes on the side of your leg. A small foot switch is placed in your shoe under the heel. The foot switch is connected to the stimulator by a separate lead. The foot switch turns the stimulation on and off in time with your walking pattern. The cork insole keeps the foot switch in the correct position in your shoe. The elastic tubing helps keep the electrodes and cables in the proper position.

8.2 PATIENT SYSTEM COMPONENTS

8.2.1 Stimulator

The stimulator generates the electrical stimulation. It is lightweight, wearable and battery operated. The stimulator is programmed by your therapist specifically for you. **Figure 1** displays the front panel of the stimulator.

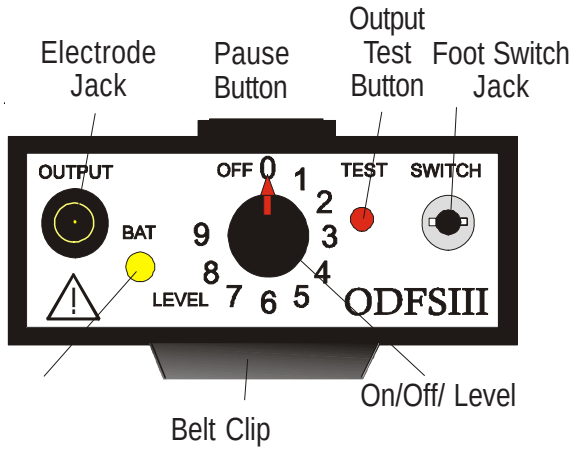


Figure 1. Stimulator Front Panel

Electrode Jack - jack for the electrode lead
Pause Button - temporarily turns stimulator off
Test Button - checks the electrode position and output level
Foot Switch Jack - jack for foot switch
On/Off Level - turns stimulator on/off and increases stimulus
Belt Clip - clip for attaching to belt/clothing
Battery Indicator - flickers yellow showing output, flickers red showing low battery

8.2.2 Electrode Leads

The Electrode Lead is a cable that connects your stimulator to your electrodes (see **Figure 2**).

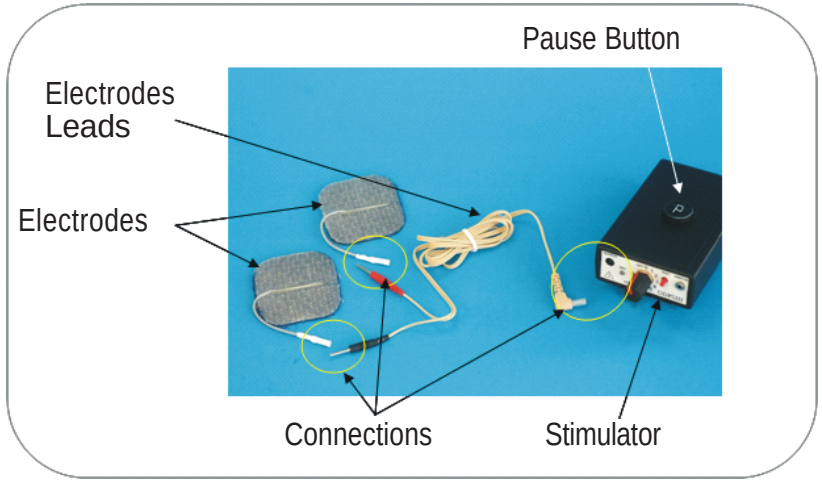


Figure 2. Electrode Leads and Electrodes

8.2.3 Electrodes

Electrodes are reusable and self sticking to the skin (see **Figure 2**). Electrodes conduct the stimulation through the skin into the nerve and muscle of your lower leg. The usual electrode size is 5 cm x 5 cm. At times, your therapist may choose to use a different size based on your size and comfort. Your electrodes should be reused for a period of time. It is important to replace your electrodes when they become worn or loose their stick. A pair of electrodes usually last about one month of daily use.

8.2.4 Elastic Tubing

Elastic tubing (Tubigrip - Size F) aids in securing your electrodes and leads around your leg. **Caution:** This product contains natural Rubber Latex which may cause allergic reactions.

8.2.5 Battery

Your stimulator is powered by one standard 9V alkaline battery.

8.2.6 Cork Insole

The foot switch is adhered to the underside of a cork insole to maintain the correct position of your foot switch within your shoe. The insole transfers easily between your shoes.

8.2.7 Foot Switch Lead

The foot switch lead is a cable that connects your stimulator to your foot switch (see **Figure 3**).

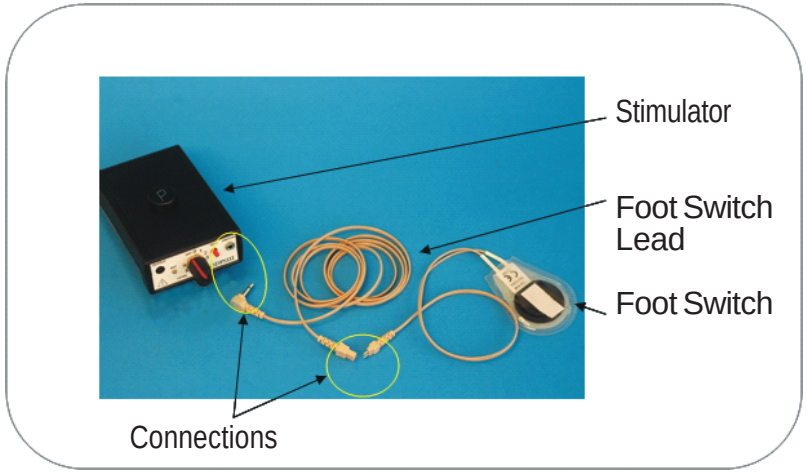


Figure 3. Foot Switch Lead and Foot Switch

8.2.8 Foot Switch

A small foot switch is placed in the shoe under your heel (see **Figure 3**). The foot switch turns the stimulation on and off in time with your walking.

8.2.9 Carrying Case

A carrying case is included to help protect and keep the system clean. Store your stimulator and lead wires in the case when they are not in use.

8.3 ADDITIONAL ACCESSORIES

Additional accessories, such as alternate lead lengths are available from your therapist. Your therapist will determine if you require any of these accessories.

9.0 OPERATING THE ODFS SYSTEM

9.1 PREPARING THE SKIN

Properly caring for your skin where the electrodes will be placed is important and may have the following benefits:

- Allows for more stimulation to reach the desired area
- Prolongs the life of the electrodes
- Reduces the risk of skin irritation
- Could improve your comfort

Prepare your skin under the electrodes as follows:

1. Wash your electrode sites with mild soap and water. Rinse and dry thoroughly.
2. Trim excess body hair from the electrode sites with scissors. DO NOT shave the site. Shaving may cause increased sensitivity.

NOTES:

- Do not place your electrode on cut, broken, or irritated skin.
- Do not use skin creams near the electrode sites.
- If skin irritation develops, remove your electrodes and discontinue using the stimulator. Consult your therapist or clinician.

9.2 ELECTRODE PLACEMENT

Position yourself comfortably in a straight backed chair. When finding the electrode position and testing the device it is best to have your leg straight.

1. Be sure the stimulator is turned off.
2. Connect the electrodes to the leads by inserting the pin on into the connector on the end of the electrode. Push the pin all the way in so no bare metal is seen. Repeat this step for your second electrode.
3. Remove any oil or lotion from your skin before applying electrodes. See section on Preparing the Skin.
4. Check your skin for cuts, abrasions or reddened areas. Do not apply electrodes over these areas. Contact your therapist for instructions.
5. Peel the electrode away from the plastic sheet by lifting at the electrode edge. Do not pull the electrode by the connection.
6. Place the electrode connected to the **black plug** on your leg as instructed by your therapist.
7. Place the electrode connected to the **red plug** on your leg as instructed by your therapist. The lead color is important.
8. Typical electrode placement is described below and pictured in **Figure 4**.

NOTE: Your therapist may give you different electrode placement instructions to get the best result for you. Follow your therapist's home going instructions including the electrode position worksheet on page 25 of this manual.

- The electrode connected to the **black plug** is placed over the common peroneal nerve, just below the head (top) of the fibula bone.
- To find your fibula locate the ankle bone on the outside of the ankle. Run your fingers up this bone on the outside of your leg. The top of the fibula bone will be the bony bump you feel before you get to your knee.
- The electrode connected to the **red plug** is placed approximately 2 inches below and slightly forward of the black plug electrode.

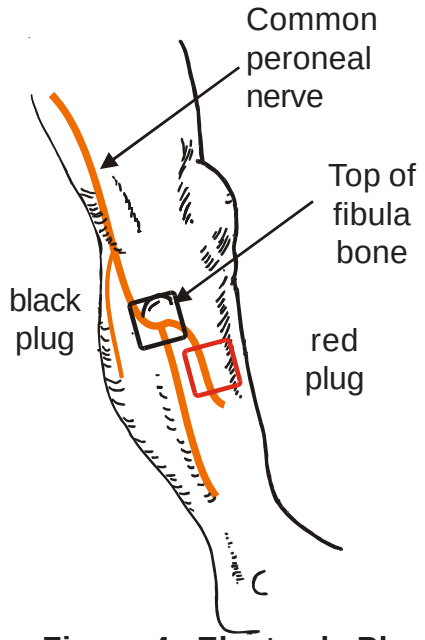


Figure 4. Electrode Placement

9.3 STIMULATOR SET UP

1. Connect the electrode lead to the socket labelled as **OUTPUT** on your stimulator.
2. Turn the stimulator on until you hear a beep then press the **TEST** button.
3. Adjust the level of stimulation by turning clockwise the black dial labelled **ON/OFF/ LEVEL** to the level recommended by your therapist.
4. Watch your foot move. The ideal movement is the foot lifted (dorsiflexion) with a small amount of turning to the outside (eversion). Your therapist will advise you if your foot movement is correct.

NOTE: The test button will provide stimulation for a short period of time and then stop. You will need to press the test button again.

a. If the correct movement is not produced:
   1. Increase the stimulation level a little
   2. Press the test button again
b. If the correct movement is not produced adjust the position of the electrodes.
   1. If your foot is turning outward too little, bring the active (**black plug**) electrode further back to increase turning outward.
   2. If your foot is turning outward too much, bring the active (**black plug**) electrode slightly further forward to decrease turning outward.
   3. The position of the passive (**red plug**) electrode can also be adjusted to balance the lift of the foot in the same way. Bring the electrode towards the shin bone to decrease excessive outward turning of the foot. Avoid stimulation directly over the shin bone. It can be uncomfortable.

Contact your therapist if you have problems getting the correct response you want from the stimulator.

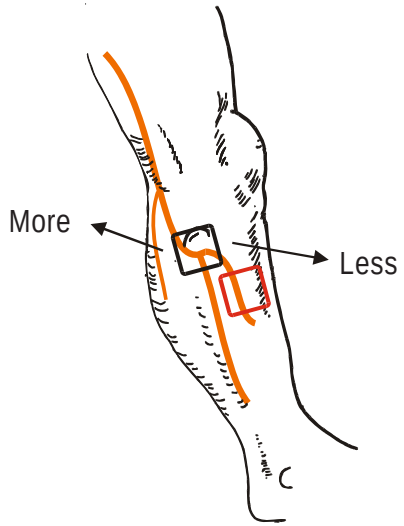


Figure 5 Adjustment for Turning the Foot to the Outside

9.4 CONNECTING THE FOOT SWITCH

Once your electrodes are positioned correctly;

1. Place your stimulator in the Pause mode by pressing the Pause button once.
2. Connect your foot switch to the foot switch lead.
3. Attach the sticky side of the foot switch to the heel of your cork insole (see **Figure 6**). If the therapist has already done this, place the cork insole into your shoe.

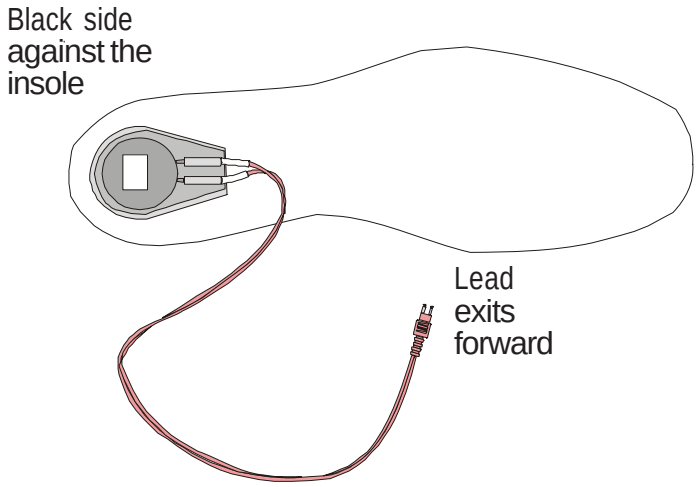


Figure 6. Foot Switch

4. Place your cork insole with foot switch attached into your shoe.

5. Connect your foot switch lead to the socket on the stimulator labelled SWITCH.

9.5 Using Stimulation

1. With the foot switch connected and the stimulator turned on, the stimulation will start when you lift the heel of your foot off the floor and will stop when your heel is on the floor.

2. To stop the stimulation for a short time, press the **PAUSE** button. To restart the stimulation, press the **PAUSE** button again.

NOTES:

- When the stimulator is turned on or taken out of Pause mode, a beep is heard. When the ODFS is put into its pause mode a shorter and higher beep is hear.
- The tubigrip sleeve can be placed over the electrodes and leads to help maintain their position.

CAUTION: It is important to use the ODFS gradually over a period of two to three weeks. This will allow your muscles to build strength. Initially, only wear the electrodes for the period the stimulator is used. Gradually increase the time the electrodes are worn as your skin becomes use to the electrodes.

9.6 REMOVING THE ODFS SYSTEM

1. After use, turn your stimulator off by turning the **ON/OFF/ LEVEL** dial counter-clockwise, until it ''clicks'' and the pointer is pointing upwards to the number zero "0".

2. Peel your electrode away from your skin by lifting it at the edge. Do not pull the electrode by the connector.

3. Return the electrodes to the plastic sheet and remove the electrode lead by pulling the plug from the connector. Do not pull on the electrode lead.

4. After removing the electrodes inspect your underlying skin for any irritations. Wash and dry the area to remove any remaining gel.

5. Remove the foot switch/cork insole from your shoe.

6. Store all parts in the bag provided.

9.7 CLEANING AND MAINTENANCE

Stimulator and Leads:

- Do not immerse in water.
- Clean using a damp cloth.
- Do not use alcohol-based cleaners.

Electrode:

After repeated use, your electrodes will lose their stickiness. Dampen the surface of the electrodes with water and leave for a few minutes to dry. If this is not successful, replace the electrodes. Electrodes should last four to six weeks. See **Table 2** for re-ordering information.

Leads and Foot Switch:

The condition of the leads and foot switch should be inspected from time to time. If the leads become worn or if the plastic covering becomes stiff or brittle, replace the item.

10.0 TROUBLESHOOTING

TABLE 1. BASIC TROUBLESHOOTING TIPS

Problem	Possible Cause	Solution
Stimulation weak	Old or dried out electrodes	Moisten electrode with water or replace electrodes
	Dry Skin	Moisten skin with water
	Battery Low	Replace battery
Stimulation weak with new battery	Incorrect battery insertion	Check battery placement
	Poor electrode contact	Reapply electrodes, secure firmly, moisten skin and/or electrodes with water
	Damaged or worn lead wire or electrode	Replace lead wire or electrodes
Stimulation ineffective	Improper placement of electrodes	Reposition electrodes
No stimulation or Low Battery Indicator Flickers in response to either test button or foot switch	Stimulation in sleep mode	Press Pause button
	Incorrect position of battery	Check battery placement
	Battery low	Replace battery
	Faulty Stimulator	Contact your therapist for instructions

TABLE 1. BASIC TROUBLESHOOTING TIPS (CONT.)

Problem	Possible Cause	Solution
Low Battery Indicator flicker changes from yellow to red	Battery low	Replace battery
No response to foot switch but response to test button	Faulty foot switch	Replace
	Faulty foot switch lead	Replace
Intermittent stimulation while walking	Foot switch position moved	Relocate the foot switch
	Faulty foot switch	Replace
	Faulty electrode or foot switch lead	Replace
Incorrect movement produced by stimulation	Incorrect electrode placement	Reposition electrodes
	Poor electrode contact	Moisten electrodes and skin with water

NOTE: Contact your therapist if you still have problems after following the troubleshooting tips.

11.0 TRAVEL OR INTERNATIONAL USE

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

- Check with your carrier to confirm that this device can be carried on the airplane.
- Unless use of the device is essential when traveling, pack the device in your luggage.

- Always take the instruction manual with the device so that you can demonstrate what the device is
- The stimulator is safe to be put through both X-Ray and metal detector machines.
- Like other electronic equipment, the stimulator may affect navigation equipment on airplanes. Make sure it is turned off while sitting down in the plane.
- Foreign power sources do not affect this battery powered device.

12.0 GLOSSARY

Dorsiflexion - Lifting the foot or toes upward.

Dropped foot - The inability to lift the foot or toes up while walking, which results in the foot being dragged forward or swung out to the side, frequently causing tripping.

Electrode - The electrode is a self adhesive gel based pad that is used to pass the stimulation current into the body. Electrodes come in various shapes and sizes.

Eversion - Turning of the foot to the outside.

Gait - Pattern of walking

Inversion - Turning of the foot to the inside.

Peroneal nerve - The nerve that controls dorsiflexion or lifting of the foot.

Spastic tone - (Spasticity) - Involuntary, exaggerated muscle stiffness and spasm

Swing phase - Time during walking when the foot and leg are moving forward; from the time the toe is off the ground until the heel strikes the ground.

Therapeutic Diathermy - High-frequency electromagnetic radiation, electric currents orultrasonic waves used to heat body tissues for therapeutic purposes, including, but are not limited to, bursitis, synovitis, muscle spasms, and joint stiffness.

Warning, the stimulation output has a physiological effect. Read instructions before use.

Equipment type BF

13.0 SPECIFICATIONS

Output: asymmetrical or symmetrical bi-phasic voltage driven waveform

Output amplitude: 20 (+/- 4) to 100 (+/- 10) mA into a 1k ohm in parallel with a 100nF load with an asymmetrical bi-phasic output, 20 (+/- 4) mA to 80 (+/- 8) mA in symmetrical bi-phasic mode

Frequency: 40 (+/- 4) Hz

Pulse width: 7 (+/- 4) to 365 (+/- 20) microseconds

Output time: 0.2 (+/- 0.02) to 6 (+/- 0.6) seconds

Extension time: 0 to 1.2 (+/-0.02) seconds

Rising edge ramp times: 0 to 2 (+/- 0.5) seconds

Falling edge ramp times: 0 to 2 (+/- 0.5) seconds

Low battery indication: 7.0 (+/- 0.2) V

Quiescent current consumption: 1.5 - 4mA depending on controls settings

Max current consumption: 43 (+/- 4) mA max current and pulse width settings output into a 1K Ohm, 100nF load.

Battery: Standard 9V alkaline

Battery life: 2 to 3 weeks of average use for an alkaline battery (depending on usage)

Operating temperature range: 5 - 27 C (41.0 - 80.6 F)

Operating relative humidity range: 35 - 50 %

Storage temperature range: 0 - 40 C (32 - 104 F

Storage relative humidity range: 35 - 50%

Recommended electrodes:

The ODFS has been tested and approved for use with the following electrodes. No other electrodes are recommended.

- PALS Platinum Blue 50 x 50 mm self-adhesive electrodes, Axelgaard Model #901220
- PALS Platinum Neurostimulation Electrodes, 1.5" x 2.5" oval (4 x 6.4cm), Axelgaard Model #896230

14.0 ODFS COMPONENTS AND ACCESSORIES

Table 2 lists the components of this ODFS system and their part numbers. These components may be ordered by faxing order form to 216.379.9116 or visiting the NDI Medical web site at www.odfs.com.

TABLE 2 System Components

Patient Components	Catalog Number
ODFSIII V6.2 Stimulator	**9025**
1 set of electrode leads (1m)	**9035**
2 packages of 4 PALS neurostimulation 5cm x 5cm square platinum blue electrodes	**9026**
1 elastic stocking (tubigrip size F)	**9027**
1 alkaline battery (9V)	**9028**
1 pair of cork insoles	**9029**
Foot switch extension lead (1.2m)	**9040**
Foot switch (2)	**9030**
Carrying case	**9031**
User Manual	**9032**
User Quick Reference Guide	**9049**
Optional accessories	
Electrode leads (0.5m)	**9034**
Electrode leads (1.5m)	**9036**
Foot switch extension leads (60cm)	**9037**
Foot switch extension leads (75cm)	**9038**
Foot switch extension leads (100cm)	**9039**
PALS Neurostimulation 4cm x 6.4cm oval platinum blue electrodes	**9043**

NOTE: Do not use any other accessories, electrodes or leads other than the ones provided with your system or purchased from the manufacture.

15.0 WARRANTY

The ODFS stimulator is warranted against material defects in material and workmanship for a period of one year from date of delivery. The exclusive remedy for breach of the foregoing warranty is, at purchaser's option, either (i) the repair or replacement of the defective stimulator or (ii) a refund of the purchase price paid for the defective stimulator.

Carrying cases, lead wires, electrodes and other accessories are warranted to be free from defects in workmanship and materials at the time of delivery.

The foregoing warranty shall be void with respect to any component which, following delivery has been subject to accident, abuse, misapplication, improper repair or installation or alteration.

THE FOREGOING WARRANTY IS THE SOLE AND EXCLUSIVE WARRANTY AND NDI MEDICAL DISCLAIMS ANY AND ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

IN NO EVENT IS NDI MEDICAL RESPONSIBLE FOR ANY SPECIAL, INDIRECT, PUNITIVE, INCIDENTAL OR CONSEQUENTIAL DAMAGES RELATED TO THE ODFS SYSTEM COMPONENTS, WHETHER OR NOT THE SAME WERE FORESEEABLE OR NDI MEDICAL WAS ADVISED AS TO THE POSSIBILITY OF SUCH DAMAGES.

NOTE: Warranty period begins from the date of shipment.

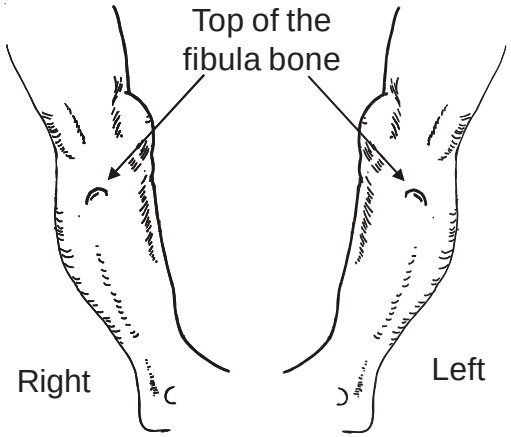
16.0 ODFS DROPPED FOOT STIMULATOR - ELECTRODE POSITION WORKSHEET

Patient Name: _____

Therapist Name: _____

Therapist Contact Info: _____

Electrode Position



Clinician/therapist: Please mark on this diagram the location and polarity of the electrodes.

ODFS Sn	Shoe Size	F/S lead length
Electrode lead length	**Electrode Type and Size**	**Output level**

Signed _____

Date _____