NESS L300

User Guide

User Guide Copyright

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Environmental Policy

Service personnel are advised that when changing any part of the NESS L300, care should be taken to dispose of those parts in the correct manner; where applicable, parts should be recycled.

When the lifecycle of the NESS L300 TM has been completed, the product should be discarded according to the laws and regulations of the local authority.

For more detailed information regarding these recommended procedures, please contact your local or regional NESS L300 distributor.

NESS is committed to continuously seeking and implementing the best possible manufacturing procedures and servicing routines.

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.

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1. Introduction to your NESS L300

Clinical Aspects

The NESS L300 system is intended for improving gait in people suffering from drop foot as a result of a central nervous system injury or disease. Drop foot is the inability or partial ability to raise the foot and toes toward the body (dorsiflexion). This condition is a common result of impairment or injuries to the central nervous system such as stroke, traumatic brain injury, multiple sclerosis, or cerebral palsy. Patients with drop foot tend to drag their foot during the swing phase of walking and usually try to compensate for the dragging by hiking their hip or swinging it in a circular motion (circumduction). These patients tend to be less stable, suffer the risk of frequent falls, and expend more energy when walking.

The NESS L300 is intended to provide ankle dorsiflexion in individuals with drop foot. During the swing phase of gait, the NESS L300 electrically stimulates muscles in the weak leg to provide flexion of the foot; thus, it may improve the individual's gait. The NESS L300 also may facilitate muscle re-education, reduce muscle spasm, prevent/retard disused atrophy, maintain or increase joint range of motion and increase local blood flow.

Advanced Technology in Rehabilitation

The NESS L300 system is comprised of an electronic orthosis, a foot sensor, and a control unit, which are ergonomically designed and aesthetically pleasing. The advanced ergonomic design of the orthosis ensures constant and snug contact of each electrode during limb motion and muscle contraction.

The NESS L300 system stimulates the common peroneal nerve in the lower leg causing the muscles that lift the foot and toes to contract. During walking the foot sensor detects when the foot is off the ground and sends a radio signal which initiates the stimulation causing the foot to move in a natural motion according to your walking pattern.

For Your Health and Safety

Contraindications

- Patients with a demand-type cardiac pacemaker should not use the NESS L300.
- Stimulation should not be applied over, or in proximity to, cancerous lesions.
- The NESS L300 should not be used over areas of regional disorders, such as a fracture or dislocation, which would be adversely affected by motion from the stimulation.

Warnings

- The long-term effects of chronic electrical stimulation are unknown.
- The orthosis should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
- Simultaneous connection of the L300 to the patient and to high-frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the electronic module of the orthosis.
- Do not use the NESS L300 in close proximity (less than 3 feet) to short wave or microwave therapy equipment as it may produce instability in the orthosis electronic module output.
- System configuration should only be performed by an authorized clinician.

Precautions

- Patients with an implanted electronic device (for example a cardiac pacemaker) should not be subjected to stimulation unless specialist medical opinion has first been obtained.
- Inflammation in the region of the NESS L300 may be aggravated by motion, muscle activity or pressure from the orthosis. Use of the device should be temporarily halted until the inflammation clears.
- Caution should be used for patients with suspected or diagnosed heart problems.
- Caution should be used in the presence of the following:
    - When there is a tendency to hemorrhage following acute trauma or fracture.
    - Following recent surgical procedures when muscle contraction may disrupt the healing process.
    - Over areas of the skin which lack normal sensation.
- Caution should be used for patients with suspected or diagnosed epilepsy.
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium or alternate electrode placement.
- Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
- The NESS L300 should be used only with electrodes supplied by NESS Ltd.
- Specific physician clearance should be obtained prior to use in patients with alteration of normal arterial or venous flow due to local insufficiency, occlusion, arterio-venous fistula for the purpose of hemodialysis, or primary disorder of the vasculature.

- Specific physician clearance should be obtained when there is a structural deformity or placement of metal implant in the area to be stimulated.
- The safety of the NESS L300's use during pregnancy has not been established.
- Skin problems in areas of contact with the orthosis may be aggravated by use of the NESS L300.
- The NESS L300 should be turned off before removing or replacing the electrodes.
- The NESS L300 should be kept out of the reach of children.
- The NESS L300 Control Unit is splash proof. However, it should be protected it from any contact with water such as dampness from sinks, bathtubs and shower stalls, from weather such as rain or snow or any other source of water.
- Do not leave the NESS L300 stored in a car in hot weather where the temperature may exceed the recommended storage temperature and could cause damage to the device.
- Should any technical problem occur, that is not covered in the troubleshooting section of this manual; contact your clinician or NESS L300 distributor. Do not attempt to repair your NESS L300.
- The orthosis is meant to be worn only on the leg of the user for whom it is fitted. It should not be applied to anyone else or any other part of the body.
- Put on the orthosis only when the NESS L300 is turned off. Do not activate it until it is fastened in place.
- The system should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.

Adverse Reactions

In the unlikely event of any of the following occurrences, stop using your NESS L300 immediately and consult your personal physician.

- Signs of significant skin irritation or pressure sores on the limb in areas of contact with the orthosis.
- A significant increase in muscle spasticity.
- A feeling of heart-related stress during stimulation.
- Swelling of the leg, knee, ankle, or foot.
- Any other unanticipated reaction.

Radio Communication Information

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions

(1) This device may not cause harmful interference.
(2) This device must accept any interference received, including interference that may cause undesired operation.

Parts of the NESS L300 communicate via radio communication and have been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
  Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications to this equipment not expressly approved by the NESS Ltd. could void the user's authority to operate the equipment.

The antenna for each transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

2. General Overview of your NESS L300

Components of the NESS L300

The NESS L300 is supplied with the following components:

- Control Unit
- Orthosis
- Orthosis Electronic Module
- Foot sensor
- Electrodes
- Carrying case
- User Manual
- Charger (supplied separately)

Figure 1: L300 System Components in carrying case

The Orthosis

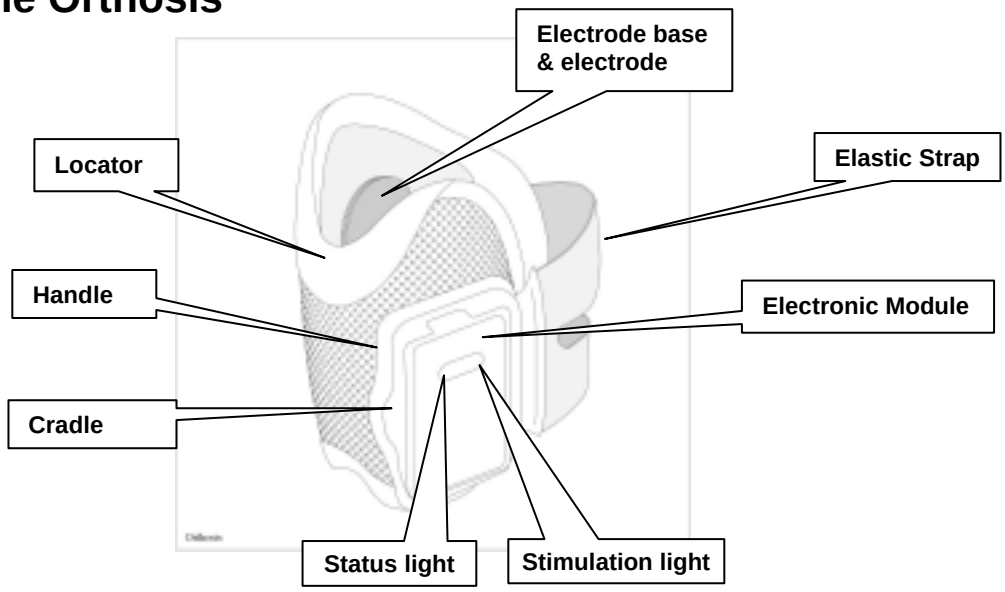


Figure 2: The Orthosis

- The orthosis is light weight and has a low profile allowing it to be easily positioned under trousers.
- It is anatomically designed to allow accurate placement on the leg.
- An electronic module containing the stimulator, battery and communication circuit, is integrated into the orthosis cradle. It may be snapped in or out of the orthosis for maintenance or cleaning.
- The entire device is held in place by an adjustable elastic strap which may be fastened easily using one hand.
- Two electrodes are attached to their bases on the inner lining of the orthosis. Their position in the orthosis has been

carefully determined by the clinician during fitting. The electrodes may be easily replaced by the user without changing their positions

Indicator lights on the orthosis electronic module

Indicator lights on the electronic module display the status of the unit and when stimulation occurs.

Status Light	System on	Flashes green
	Low battery	Flashes yellow
	Charging	Alternating between yellow and green
	Battery fully charged	Constant Green
	Malfunction	Constant or flashing red light
Stimulation Light	Stimulation applied	Flashes rapid yellow
	Stimulation inactive	Flashes slow yellow

The Foot Sensor

The foot sensor (Figure 3) detects whether the foot is on the ground or in the air and transmits radio signals to the electronic module in the orthosis, according to which the stimulation is activated.

The foot sensor consists of a pressure sensor worn underneath the inner sole of the shoe, along with a small transmitter attached to the upper edge of the shoe by a special clip.

There is no need to detach the foot sensor between uses.

The foot sensor transmitter is powered by a small non-rechargeable battery which needs replacing approximately every six months of use.

The foot sensor by default should be placed under the paretic (weak) foot. In some cases the foot sensor may be placed under the non-paretic foot according to a clinician's judgment.

Note	The foot sensor should be placed only under the foot designated by the clinician.

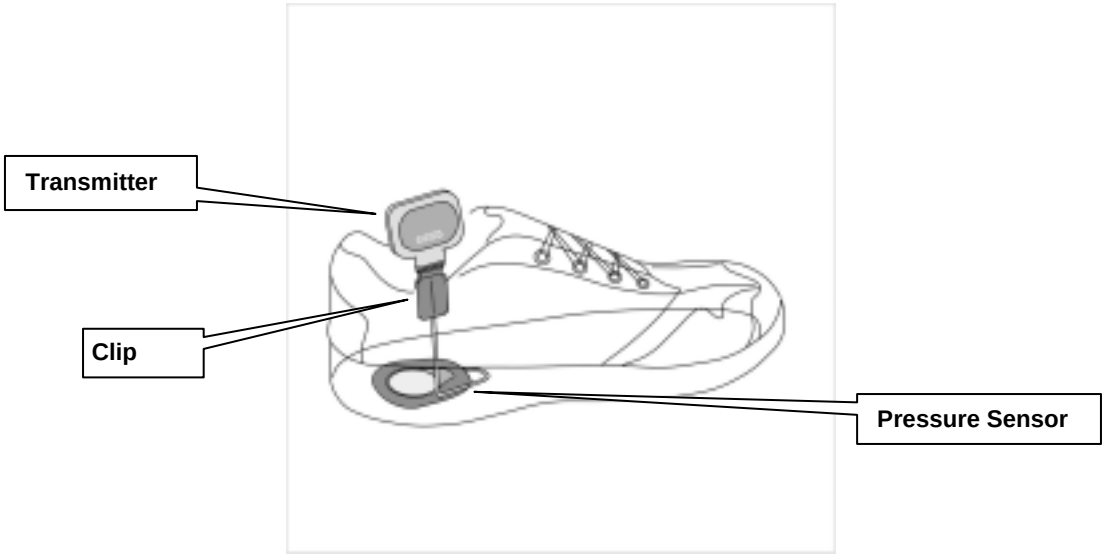


Figure 3: Foot Sensor

The Control Unit

The control unit (see figure 4) enables the user to activate/deactivate the system, select the operation mode, fine-tune the stimulation intensity and receive information regarding the system by visual and audio indicators.

It can be carried around the neck using the neck strap supplied, in a pocket or belt pouch.

It is powered by a single rechargeable AAA battery.

During operation, the control unit maintains two-way communication with the electronic module in the orthosis. If communication is lost the system will cease working.

Operating Button	Description
ON/OFF	Turns the control unit ON and OFF
Trigger mode	Selects Gait, Training or Standby Mode
Volume Adjustment	Adjusts the volume of the audio indications
Intensity Adjustment	Adjusts the intensity of stimulation

Control Unit Buttons and Display

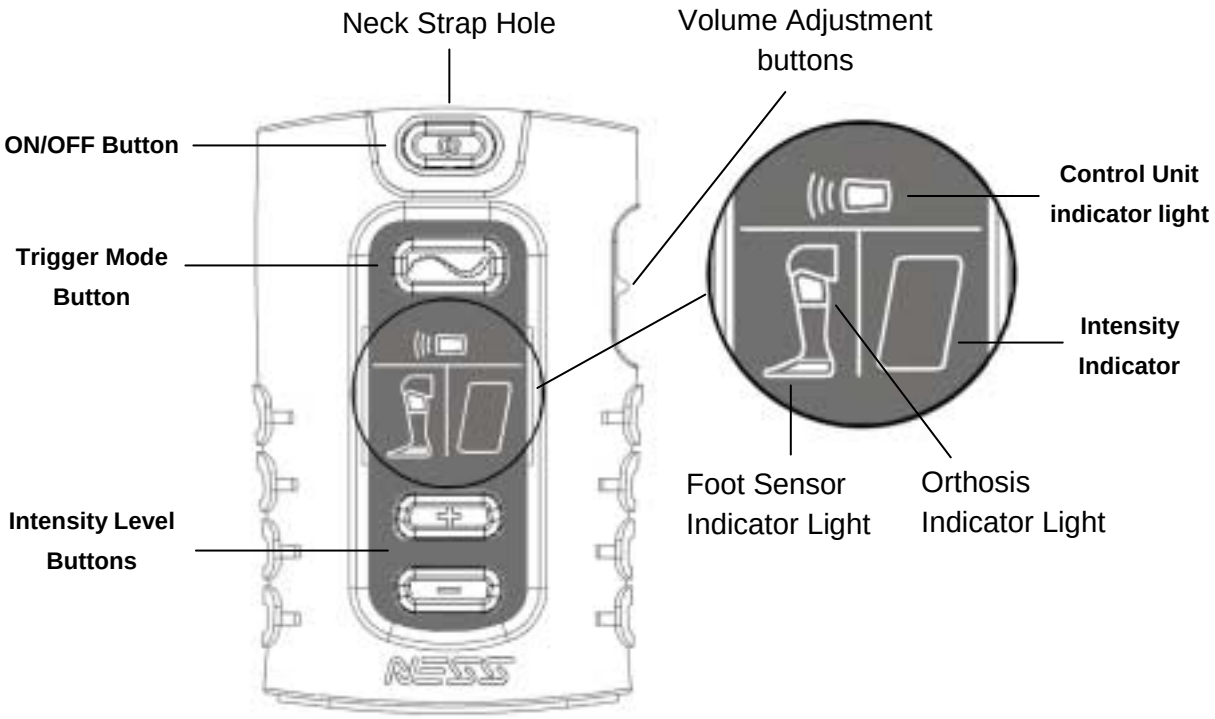


Figure 4: Control unit buttons and display

Operating the Control Unit

Turning on the system

Press the On/Off button once. The system will automatically start in **Standby Mode**. All display indicators will light up for a few seconds while the system performs a self-test, then the On/Off button flashes green to indicate that the system is activated.

Selecting the Mode

To select the Gait Mode: after the unit is turned on, press the trigger mode button once briefly. You should hear a beep and the trigger mode button will begin to blink slowly. During stimulation the button blinks rapidly.

To select the Training Mode: after the unit is turned on, press the trigger button and hold it for 3 seconds (long press), until a beep is heard. The trigger mode button will begin to blink slowly. In addition, the intensity indicator displays a “t” alternating with the intensity.

To go back to the Standby Mode: from the Gait or Training mode, press the trigger button again briefly, you should hear a beep, and the trigger mode button will stop blinking.

Adjusting the stimulation intensity level

During the fitting process your clinician set the stimulation type and intensity according to your exact needs, normally there is no need to adjust the stimulation intensity however it may be necessary while walking on different surfaces or with various footwear.

To lift the foot higher:

If the foot slightly drags or catches on the floor while walking the stimulation level should be increased by pressing the "+" button.

To decrease foot lift:

If you feel that your foot rises too high while walking or that the stimulation is unpleasant, the intensity level can be reduced by pressing the "-" button. After reducing the intensity take care that your foot doesn't drag or catch on the floor.

- When the intensity level is altered the intensity level appears on the display of the control unit and a corresponding beep is emitted
- When the system is turned on the intensity is automatically set to "5" which is the intensity set by the clinician if the intensity is reduced to "0" there will be no stimulation.

 **Note**	*Do not increase the stimulation intensity level set for you by your clinician by more than two levels without first consulting him or her.*

Adjusting the volume of the audio indication

Use the volume and △ buttons ▽ to adjust the volume.

- Each press of the button will increase or decrease the volume, and you will hear a beep at the volume you have selected.
- Reducing the volume to the minimal setting will mute the control unit.
- When you turn the system off, the volume level will be saved unless the volume was set to "mute," in which case the volume level will be automatically adjusted to the default level.

Control Unit Display and Audio Indications

Visual Display

	Color	Flash	Meaning
On/Off Button	Green	Slow	System is activated
Trigger mode button	Yellow	Slow	System in gait or training mode but not stimulating
		Rapid	System in gait or training mode and stimulating
All display lights	Red, yellow and green	Alternating colors one after the other for 1.5 seconds	Self-test at startup
Intensity indicator		0-9	Intensity level setting
		The letter “t” and intensity digit alternate	Training Mode
		Segments of the digit rotate in a circular pattern	Charging

Audio indications

The audio alert beeps when:

- The system is first turned on.
- The battery is weak.
- There is an indication, such as a malfunction, which will be indicated visually on the control unit.
- When the control unit is separated from the system, for example when the system is worn, and the controller is left on a table.

3. Operating Modes

Standby mode

The system is ON, and waiting for commands. Stimulation is not applied in the Standby mode.

 **Note**	*While using the system, the various components of your NESS L300 must not be separated. If the system components are separated for any reason, radio contact will be lost and the system will cease all activity until communication is reestablished.*

Gait mode

Select this mode for walking. In the Gate mode the stimulation is synchronized by the foot sensor, in order to achieve foot lifting during the swing phase of walking and foot rest during the stance phase.

Training mode

Select this mode for muscle training while you are sitting or lying down. The purpose of the training mode is to facilitate muscle re-education, prevent or retard disuse atrophy of the calf muscles, maintain or improve range of motion of the ankle joint, reduce spasticity and improve local blood circulation.

In the training mode the stimulation is applied in pre-determined cycles adjusted by your clinician and works independently of the foot sensor

 **Note**	*The training mode can also be used to check if the orthosis was placed accurately on the leg. If the foot does not respond to the stimulation as it should, the user should reposition the orthosis*

4. Daily Use of your NESS L300

Activating and Using the System

Make sure the foot sensor is installed, if not, then install it according to the section “Placing the Foot Sensor in your Shoe.”

1. Remove the protective covers from the electrodes

Put on the orthosis.

Turn on the control unit.

Select either the gait or training mode.

Begin walking or let the training mode exercise your leg in place.

Putting on the orthosis

In order to ensure proper foot movement make sure the orthosis is positioned accurately.

 **Note**	*Before putting on the orthosis make sure to remove the protective covers from the electrodes.*

Positioning the orthosis on the leg

While seated, slightly extend the lower leg as in Figure 5. This causes the outline of the kneecap to be clearly defined. It may be helpful to place the foot on a small stool or footrest.

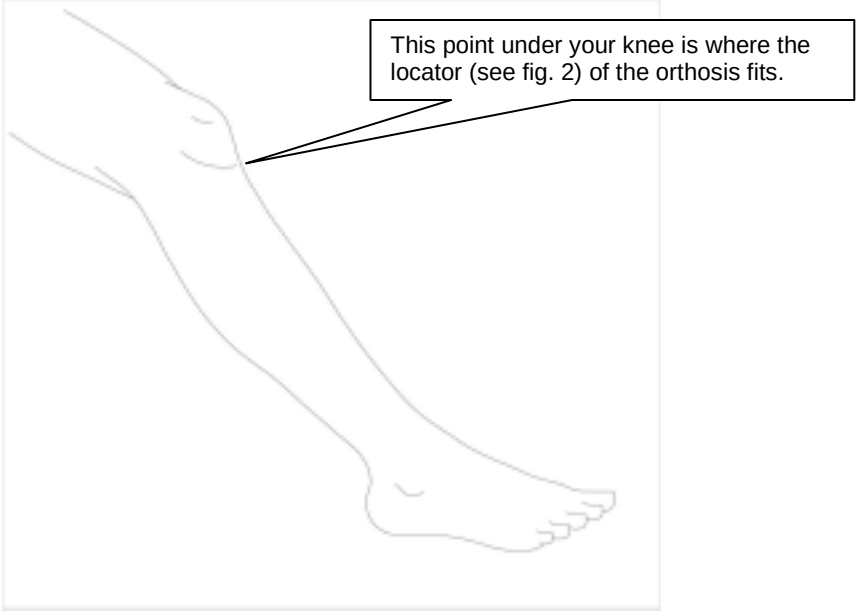


Figure 5: Positioning the Leg

1. Place the orthosis onto the leg, with the "U" of the upper edge, called the Locator, snugly, but comfortably against the lower part of the kneecap, as in Figure 6.

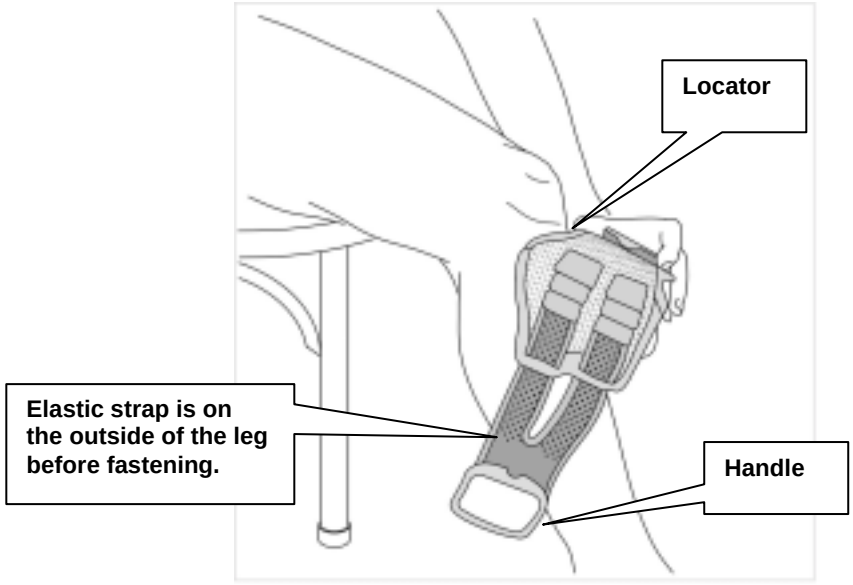


Figure 6: Placing the Orthosis on the Leg

2. After the locator is in position, slide the orthosis against the leg so that it fits snugly under the kneecap. The orthosis will gently grip the leg. Make sure it remains in place until you fasten the strap according to one of the methods described below.

Fastening the strap

The fastening of the strap is meant to be performed with one hand although if the other hand is functional, it is easier to use both hands.

1. With the orthosis in place as in Figure 7, carefully grasp the handle of the elastic belt with the fingers of the *opposite* hand. In Figure the orthosis is on the right leg, so the handle is grasped by the left hand.

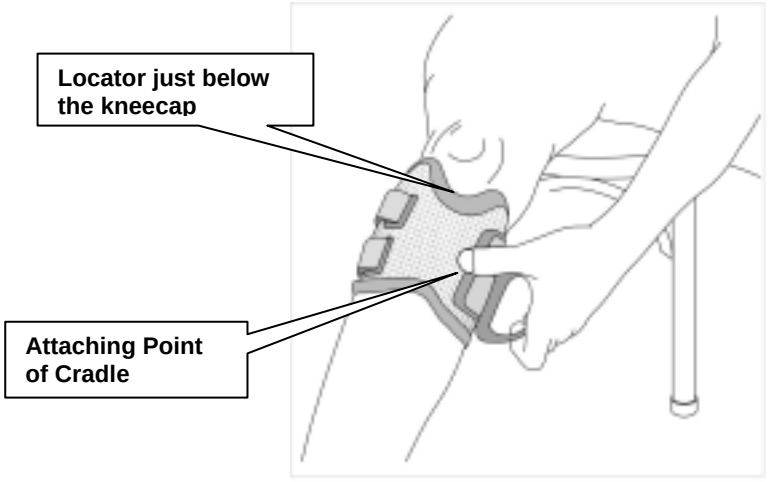


Figure 7: Fastening the Strap (First Method)

2. Placing your thumb on the cradle, hold the orthosis in place while you pull the handle toward the cradle and position it around the cradle.

Figure 8 shows the orthosis when it is placed correctly on the right leg.

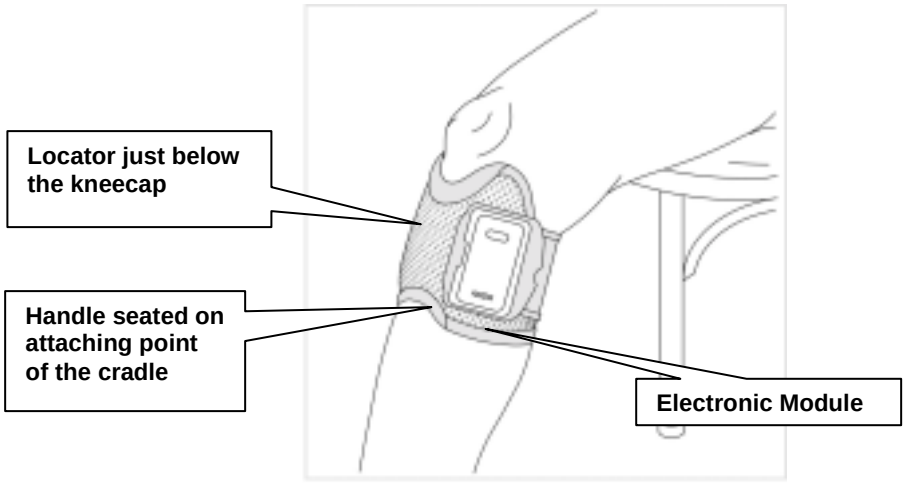


Figure 8: Orthosis Fastened in Place

Note	*"Bad electrode contact" indication* *If for any reason there is no contact between the electrodes and the skin, all the indication lights will start flashing red and no stimulation will be applied, to resolve this see the troubleshooting section.*

Taking off the Orthosis

1. Press the On/Off button once to shut the system OFF.
2. Unhook the strap handle of the orthosis, and remove the orthosis.
3. Moisten the electrodes and place protective covers over them.
4. Charge the battery fully at the end of your daily use.

5. Care and Maintenance

Batteries

Note

The batteries must be charged before the first use, after every day's use, and after extended storage.

Low Battery Warning

When one of the component batteries is low, its indicator light on the control unit flashes yellow; for more information see the following table:

Low Battery in the Orthosis	Starts to flash slowly accompanied by an audio indication.	Orthosis battery is low- Approx. 4 hours use left.
	Medium speed flash, audio indication every 10 minutes	Orthosis battery is low- Approx. 1 hours use left.
	Rapid Flashing and an audio indication every 1 minute	Orthosis battery is low- Approx. 10 minutes use left.

Low Battery in the Control unit	Starts to flash slowly accompanied by an audio indication.	Control unit battery is low- Approx. 4 hours use left.
	Medium speed flash, audio indication every 10 minutes	Control unit battery is low- Approx. 1 hours use left.
	Rapid Flashing and an audio indication every 1 minute	Control unit battery is low- Approx. 10 minutes use left.

Low Battery in the Foot sensor	Starts to flash slowly accompanied by an audio indication.	Foot sensor battery is low- Approx. 14 days of use left.
	Medium speed flash, audio indication every 2 hours.	Foot sensor battery is low- Approx. 7 days of use left.
	Rapid Flashing and an audio indication every hour	Foot sensor battery is low- Approx. 2 days of use left.
	Rapid Flashing and an audio indication every 30 seconds	Foot sensor battery is low- Approx. 15 minutes of use left

Charging the Batteries

Control Unit and Orthosis

Note	*Only the Control and Orthosis units' batteries are rechargeable.*

1. Open the cover of the charger socket at the bottom of the control unit as in Figure 9.

Figure 9: Control Unit Charger Socket

2. Connect the charger cable to the control unit and the orthosis electronic module as in Figure and plug into the wall socket. You should see a circular charging icon on the control units' digital display and the status light on the module should start flashing alternating between yellow and green.

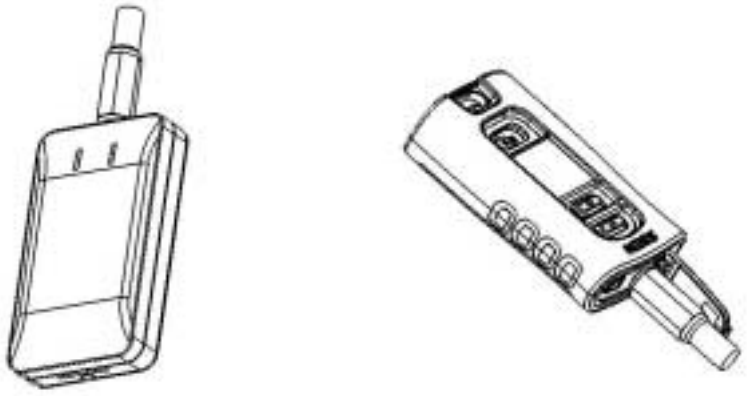


Figure 10: Charging the Batteries

Leave the charger connected until the letter "F" appears on the control units' digital display and the orthosis electronic modules' status light turns a constant green, indicating a full charge. The charging process should last approximately 3 hours.

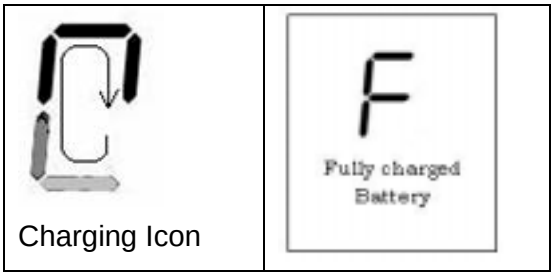


Figure 11: Charging Indicators

Replacing the Batteries

Orthosis Electronic Module

The electronic module's battery needs replacing approximately every 2 years by a NESS certified technician.

Foot Sensor

The battery in the foot sensor is not rechargeable, and needs replacing approximately every 6 months. To install a new battery (Lithium coin cell, CR2430):

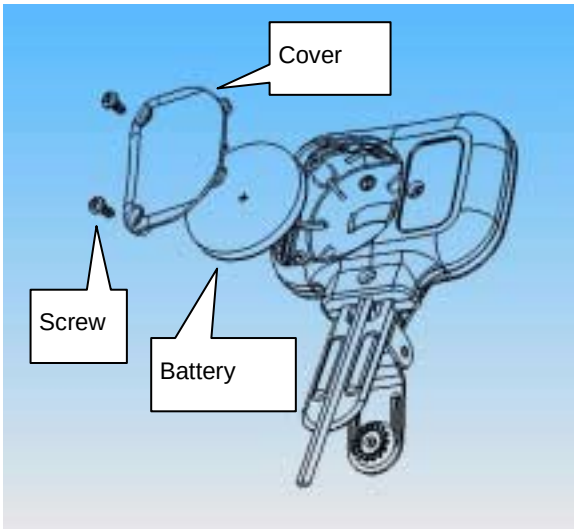
3. Unscrew the screws from the battery cover.

Slide the cover out.

Remove the old battery.

Insert the new battery (The "+" should face up).

Slide the cover back into place and reinstall the screws.



Tip: If you are unable to replace the battery yourself, your clinician or local watchmaker should be able to assist you

Figure 12: Replacing the Foot Sensor's Battery

Control Unit

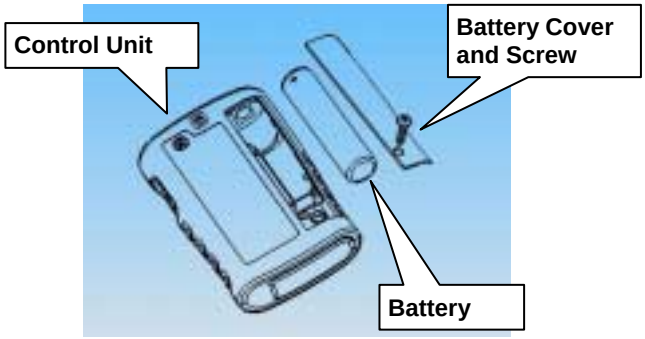
The control unit's battery is a rechargeable AAA battery and needs replacing approximately every 2 years.

Note	*The batteries must be charged before the first use, after every day's use, and after extended storage.*

1. Remove the screw from the battery cover on the back of the control unit.
2. Remove the battery cover.

Remove the old battery.

3. Insert a new battery (rechargeable AAA), according the "+" and "-" marks in the battery socket.
4. Slide the cover back into place and tighten the screw.



Tip: If you are unable to replace the battery yourself, your clinician or local watchmaker should be able to assist you

Figure 13: Control Unit and Battery

Replacing Electrodes

The electrodes should be replaced every 2-3 weeks. It is recommended to replace the electrodes regularly in order to maintain optimum efficiency.

 **Attention**	*The NESS L300 should be used only with electrodes supplied by NESS Ltd.*

1. Make sure the system is off
2. Pull the electrode gently out of its base. Take care not to detach the electrode base, which is attached to the inside of the orthosis.
3. Snap in a new electrode, and make sure it's firmly attached to the electrode base.
4. Remove the protective cover from the electrode before using the system. The cover should be put aside and saved, for later use.

Cleaning your NESS L300

All parts may be cleaned by wiping with a damp cloth.

Electrical components are not waterproof, so **do not immerse them in water.**

When the orthosis needs a thorough cleaning:

1. Remove the electronic module.
2. Immerse in lukewarm water with a small amount of mild detergent.
3. Rinse thoroughly and let dry in the shade (do not hang).
4. Reattach the electronic module after the orthosis is completely dry.

	Do not use a washing machine or drier.

6. Replacing and Installing System Components

Replacing and registering components

When one or more of the NESS L300 electronic components are replaced, a procedure must be performed to *register* the new component as part of the system. This ensures that there is radio communication between the components of the system. These components are:

- Stimulation unit
- Foot sensor
- Electronic control unit

1. Make sure the control unit is turned OFF.
2. Press the “Trigger mode button” and “-” button at the same time and hold them for 3 seconds.

The segments of the stimulation intensity display will light up in 2 alternating circular patterns until the registration is complete (See Figure).

The letter “C” (short for connected) will appear if registration was successful and a green light will appear on the control unit indicating a successfully registered component

 **Note**	*If the component registered was the orthosis' electronic module its status light will also turn green.*

The letter “E” (short for Error) will appear if the registration was unsuccessful. If the letter “E” appears, repeat steps 1-3, if the problem persists see the section "troubleshooting."

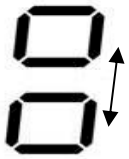
		
In the process of registering	Registration Complete	Registration Unsuccessful

Figure 14: Digital Display while Registering

Removing and Installing the Orthosis Electronic Module

The following figure shows how to detach the electronic module from the orthosis, this should be done only for cleaning the orthosis, or for maintenance purposes.

1. Pull the upper edge of the electronic module out of the cradle.
2. Pull the electronic module out of the cradle.
3. To reinstall the module, insert the bottom part into the cradle and push the module gently into the cradle to reinstall.

Figure 15: Removing the electronic module from the orthosis

Note	*No more than one control and stimulation unit can be registered in your system at any time, registering a new unit will automatically remove your old unit from the system.*

Placing a Foot Sensor in your Shoe

The foot sensor should be placed under the shoes' insole.

1. Remove the inner sole of the shoe.
2. Place the pressure sensor in the shoe, directly below where the center of your heel fits, with the adhesive side downward.

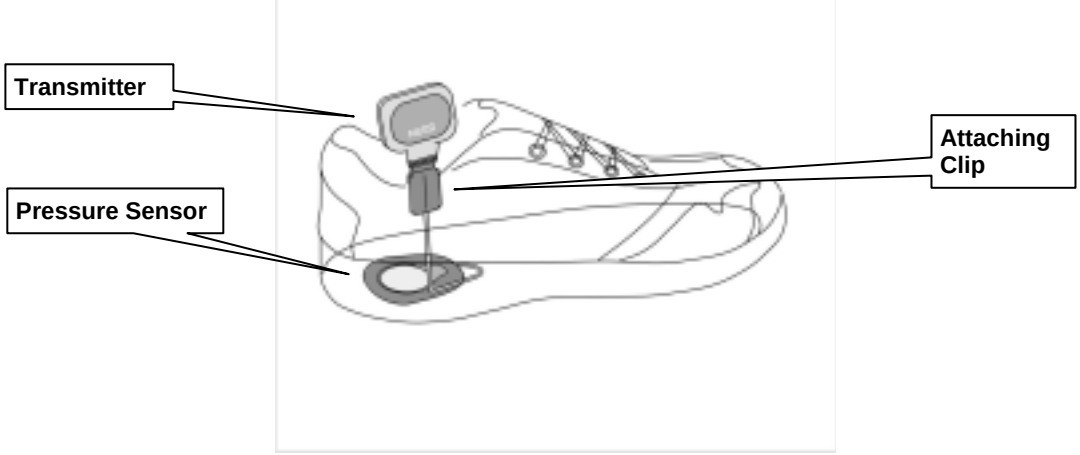


Figure 16: Foot Sensor in Place (Left Shoe Shown)

3. Press the sensor to fasten it to the shoe.
4. Insert the inner sole of the shoe; making sure any excess wire is tucked out of the way under the inner sole.
5. Attach the transmitter of the foot sensor to the upper edge of the inner side of the shoe The NESS logo on the transmitter should face away from the foot.

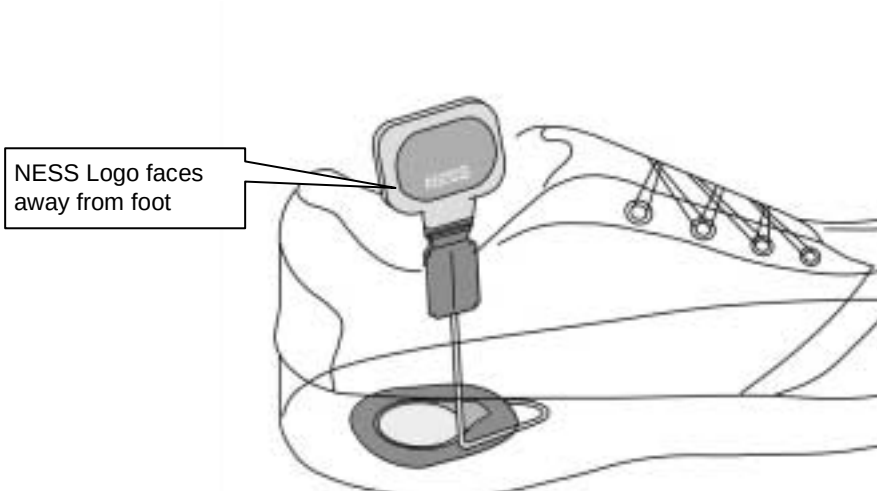


Figure 17: Transmitter in Place on a Left Shoe

Note	*Up to four different foot sensors can be used with one L300 system, allowing you to use several pairs of shoes without the need to transfer your foot sensor from shoe to shoe.*

7. Accessories

The NESS L300 comes with a variety of accessories that are designed to help you avoid the inconvenience and distraction of holding your control unit.

1. Neck strap:

The neck strap allows you to hang the control unit around your neck. If you find it more convenient you may insert it into your shirt pocket.

2. Wrist strap:

The wrist strap allows you to hang the control unit from your hand, or to pull it out of a pocket or pouch easily.

3. Belt pouch:

This small pouch fits on your belt for quick and easy storage of the control unit.

8. Troubleshooting

To locate your local NESS L300 distributor, call 972-9-7485738 or visit our website: www.nessltd.com

Error light indications

Indicators	Color	Flash	Meaning
All three Component lights on the control unit	Red	Cycles between Control unit, Orthosis, and Foot Sensor, also “E” appears on digital display	Radio communication lost
	Red	All the component lights flash simultaneously. “E” flashes on the digital display.	Bad electrode contact with the calf.

Indicator	Color	Flash	Meaning
Orthosis, Foot sensor or Control unit indication light	Red	Flashing	Malfunction-dangerous to the hardware
		Constant	Fault-dangerous to the owner or charge malfunction
	Yellow	Flashing	Low battery

Problems and their solutions

Problem	Solution
Any part of your NESS L300 kit (Orthosis, Stimulation Unit, Control Unit, Foot Sensor etc.) is broken, damaged or becomes detached.	Contact your NESS L300 distributor.
The Control Units' display does not light up when you switch ON the Control Unit.	Make sure the battery is charged (see the section "Charging the batteries" for instructions). If, after charging the battery, the Mode display still does not appear, contact your NESS L300 distributor.
A problem which is not covered in this manual occurs	Contact your NESS L300 distributor.
During charging, **"E"** appears on the screen.	Try to reconnect the charger cable, if this doesn't help contact your NESS L300 distributor.
Electrodes are frayed, peeling, damaged, or falling off the Orthosis.	Replace with new electrodes according to the section "Replacing Electrodes"
After charging your batteries, they are still low.	Your batteries need replacing.

Problem	Solution
No error indications appear, but there is no movement of the ankle.	1. Turn OFF the system. 2. Take the Orthosis off your calf. 3. Put the Orthosis on your calf while making sure that the Orthosis is properly positioned on your calf, as described in "Putting on the orthosis" 4. Turn ON the Control Unit again, and press the Trigger Button. If there is still no ankle movement contact your NESS L300 distributor.
I feel stimulation from the orthosis, but my foot does not respond in a satisfactory way.	1. Make sure that the Orthosis is snug against your calf and that the electrodes are in close contact with the skin. 2. Make sure you are in the desired mode. If the ankle movement is still unsatisfactory, turn OFF the system. 3. Remove the Orthosis, then replace it on your calf, making certain that the Orthosis is positioned correctly, as described in "Putting on the orthosis" If the configuration is still unsatisfactory, contact your NESS L300 distributor.
System malfunction indication appears.	Cease use of system and contact your NESS L300 distributor.

Problem	Solution
The "bad electrode contact" indication appears.	1. Turn OFF the system. 2. Remove the orthosis from your leg. 3. Make sure the electrode protective covers were removed and there is no disturbance to contact between the electrodes and the skin. 4. Make sure that the electrodes are installed properly according to section "Replacing Electrodes"), and that a snapping sound was heard when the electrode was inserted into its base. 5. The electrodes may be missing or damaged if this is the case then install new electrodes according to section "Replacing Electrodes" 6. Put the Orthosis on your calf, turn the Control Unit ON again, and press the Trigger button. If the problem persists then: 7. Check that the orthosis electronic module is in place and locked it (see the section Removing and Installing the Orthosis Electronic Module), if not reattach it to the orthosis. If the problem persists then contact your NESS L300 distributor.

Problem	Solution
"Radio communication lost" indication appears.	Make sure that all the components are in radio range of each other, the system will not work if all components aren't present.

9. Specifications

Control Unit Specifications	
Classification	Internally powered, continuous operation
Operation Modes	Gait, Training
Operating voltage	1.2 V
Operation current	30 mA
Battery type	Rechargeable AAA NiMH 1.2V, 750 mAh
Charging time	4.5 Hours (typical) using provided power supply
Charging cycles	At least 300 charging cycles
Operation period	At least 2 days between charges
Shelf life	At least 2 weeks between charges
Controls	On/Off illuminated button Trigger mode button for changing system modes Intensity +/- buttons to enable the user fine tune intensity Volume +/- buttons controls buzzer volume
Indications	3 Status LED: Control Unit, Orthosis Electronic Module – Indicate battery & component status Numerical display designates relative stimulation intensity Illuminated buttons designates system operation mode. Buzzer for audible indications
Carrying	Wrist strap, Neck strap, Pouch
Dimensions	Height: 71mm Width: 46mm Depth: 17.5mm
Weight	45 grams

Water protection	IPX1
Environmental	Transport & Storage: 0 – 35 Cº Operating: 0-45 Cº Charging: 10-45 Cº (50-113 F º) 10% to 85% relative humidity 900hPa to 1060hPa atmospheric pressure

Orthosis Electronic Module Specifications	
Classification	Internally powered, continuous operation with type BF applied parts
Operating voltage	3.7 V
Operation current	70 mA
Battery type	Rechargeable Prismatic LiIon (Lithium Ion) 3.7V, 700 mAh
Charging time	3 Hours (typical) using provided power supply
Charging cycles	At least 350 charging cycles
Operation period	At least 2 days between charges
Battery discharge time when stored	At least 1 week between charges
Indications	Status (fault, battery, charging) & Stimulation LEDs Buzzer for audible indications

Pulse Parameters		
Drive method:	Constant current	
Intensity	0-80 mA, 1 mA resolution (measured at positive phase)	
Shape:	**Symmetric**	**Asymmetric**

Positive phase width	100 µS	200 µS	300 µS	100 µS	200 µS	300 µS
Negative phase width:	100 µS	200 µS	300 µS	400 µS	800 µS	1200 µS
Intra-phase interval	50 µS			0		
Pulse duration	250 µS	450 µS	650 µS	500 µS	1000 µS	1500 µS
Max load	1100 Ω	800 Ω	500 Ω	1300 Ω	1100 Ω	900 Ω
Gait Parameters						
Pulse repetition rate	1, 2, 3, 4, 5, 6, 7, 8, 9, 10,15, 20, 25, 30, 35, 40, 45 PPS					
Ramp up	0-4 Sec, 0.1 Sec resolution					
Ramp down	0-4 Sec, 0.1 Sec resolution					
Delay	0-3 Sec, 0.1 Sec resolution					
Max duration	0-10 Sec, 0.1 Sec resolution					
Training Parameters						
On time	1-8 Sec, 1 Sec resolution					
Off time	2-15 Sec, 1 Sec resolution					
Ramp up	0-4 Sec, 1 Sec resolution					
Ramp down	0-4 Sec, 1 Sec resolution					
Total time	1-60 Min					

Application	Attached to a cradle in the NESS L300 Orthosis

Dimensions	Height: 74mm Width: 43mm Depth: 15mm
Weight	53.7 grams
Water protection	IPX1
Environmental	Transport & Storage: 0 – 35 Cº Operating: 0-45 Cº Charging: 10-45 Cº (x-x F º) 10% to 85% relative humidity 900hPa to 1060hPa atmospheric pressure

Orthosis specifications	
Orthosis	Fabric-Polymer orthosis for electrode relocation and single handed attachment
Limb size	28 – 50 cm limb circumference
Maintenance	Immerse in cold water when needed and let dry in free air. NOTE: First remove stimulator NOTE: DO NOT use drier
Dimensions	Height: 160mm Width: 100mm Depth: 125mm
Weight	Approx 160 grams

Electrode specifications	
Electrodes	Two, 45 mm reinforced hydrogel electrodes. NOTE: Use only electrodes provided by NESS Ltd.
Electrode base	Two relocateable polymer electrode bases for individual fitting

Foot Sensor Specifications	
Classification	Internally powered, continuous operation with type BF applied part
Operating voltage	3.0 V
Operation current	20 µA
Battery type	Lithium coin cell, CR2430, 280 mAh
Operation period	6 months (typical)
Shelf life	2 years
Transducer	Force Sensitive Resistor.
Attachment	To the inner side of shoe lining using clip
Dimensions of the transmitter	Height: 80mm Width: 50mm Depth: 10mm
Weight	35 grams
Water protection	IPX4
Environmental	Transport & Storage: 0 – 35 Cº Operating: 0-45 Cº Charging: 10-45 Cº (x-x F º) 10% to 85% relative humidity 900hPa to 1060hPa atmospheric pressure

Power Supply specifications	
Voltage	5V ± 5%
Current	1300 mA Note: Use only power supply provided/approved by NESS

Wireless link specifications	
Frequency band	2.4 GHz, ISM band
Transmission power	Complies with regulations (FCC 15.247 for US / ETSI EN300-440 for Europe).

List of Symbols

	Attention, See Instructions for Use
	Serial Number
IPX1	Drip - proof
IPX4	Splash -proof
IPX7	Watertight (immersible)
	Class II
	Type BF Applied Part
	Non-Ionizing Radiation