

L300 Accessories

L300 Hydrogel Electrodes

The L300 hydrogel electrodes are used with the L300 FS Cuff. See Figure 9. Two hydrogel electrodes are used to deliver stimulation from the L300 RF Stim Unit to the muscles in the lower leg. Each hydrogel electrode attaches to a hydrogel electrode base. The side of the electrode with the grid faces the electrode base.

Do not use the L300 FS Cuff without electrodes. Always replace the plastic covers on the hydrogel electrodes between uses.

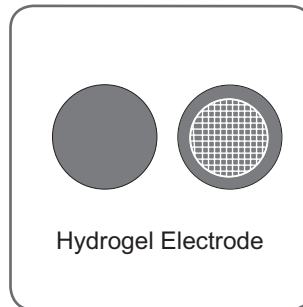


Figure 9: Hydrogel electrode, front (left) and back (right).



Caution: Only use electrodes provided by Bioness Inc.



Caution: Change the electrodes every two weeks.

L300 Hydrogel Electrode Bases

The hydrogel electrode bases are for use with the L300 FS Cuff. See Figure 10. Your clinician will determine the best placement for the hydrogel electrode bases.

The hydrogel electrodes attach to the hydrogel electrode bases. Always attach the grid side of the hydrogel electrodes to the hydrogel electrode bases.

Do not move the electrode bases once your clinician has fit them, other than to replace them. The hydrogel electrode bases need to be replaced approximately once every two years..

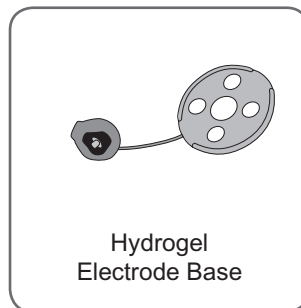


Figure 10: Hydrogel electrode base.

L300 Cloth Electrodes

The L300 cloth electrodes are used to deliver stimulation from the L300 RF Stim Unit to the lower leg muscles. See Figure 11. They are designed to be skin friendly and provide an alternative for people who do not prefer the L300 hydrogel electrodes. They are also for people who have sensitivities to the L300 hydrogel electrodes or other known sensitivities (for example, allergy or skin sensitivity to tape/adhesive).

The L300 FS Cuff uses two cloth electrodes. Each one snaps to a cloth electrode base.

The L300 cloth electrodes must be wet before use and after every three to four hours of use. If the L300 FS Cuff is removed for more than one hour, the cloth electrodes need to be rewet. Allow the cloth electrodes to dry between uses. Do not use the L300 FS Cuff without electrodes.

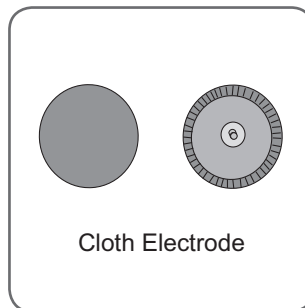


Figure 11: L300 cloth electrode, front (left) and back (right).



Caution: Only use electrodes provided by Bioness Inc.



Caution: Change the electrodes every two weeks.

L300 Cloth Electrode Bases

The L300 cloth electrode bases are for use with the L300 FS Cuff. See Figure 12. Your clinician will determine the best placement for the cloth electrode bases.

The L300 cloth electrodes snap to the L300 cloth electrode bases.

Do not move the electrode bases once your clinician has fit them, other than to replace them. Cloth electrode bases need to be replaced approximately once every two years.

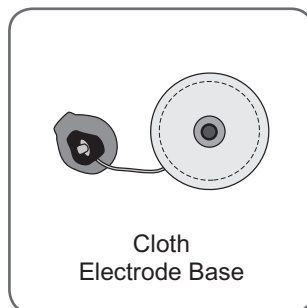


Figure 12: L300 cloth electrode base.

Wrist Strap, Neck Strap, and Belt Pouch

The wrist strap, neck strap, and belt pouch are used to carry the L300 Plus Control Unit. The wrist and neck straps loop through the top of the Control Unit. See Figure 13.



Figure 13: L300 Plus Control Unit carrying options.

Replacement Battery, Gait Sensor

The L300 Plus System Kit includes a replacement coin battery for the Gait Sensor. The battery will need to be replaced approximately every six months. See Figure 14.

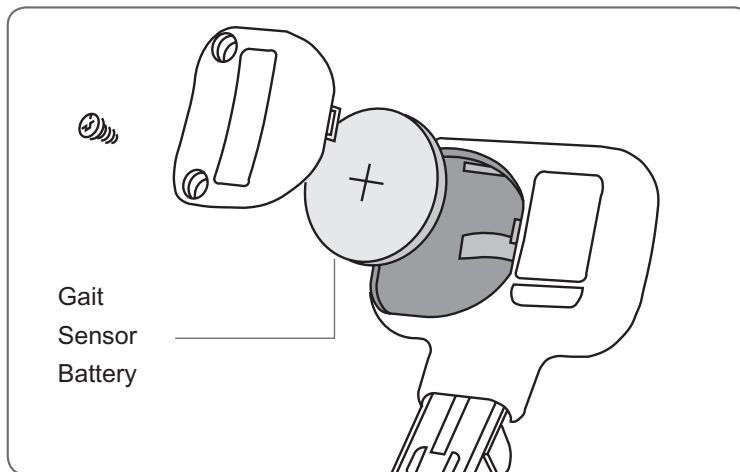


Figure 14: Gait Sensor battery.

Gait Sensor Pads

The Gait Sensor pads are used to stabilize the Gait Sensor pressure sensor in the shoe. See Figure 15.

One Gait Sensor pad is placed under the insole of the shoe of the affected leg. The Gait Sensor pressure sensor is then placed on top of the Gait Sensor pad. Finally, the insole of the shoe is lowered to cover both the pressure sensor and the Gait Sensor pad.

Place the adhesive side of the Gait Sensor pad down.

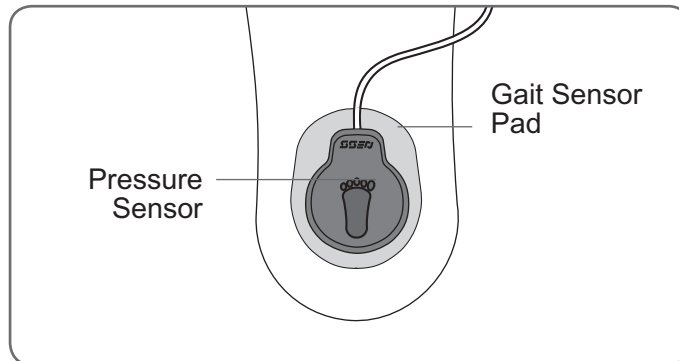


Figure 15: Placement of the Gait Sensor pad and pressure sensor.

Shoe Spacers

The shoe spacers are used to protect the rim of the shoe from the clamp of the gait sensor transmitter. See Figure 16. One shoe spacer is placed over the inner clamp of the Gait Sensor.

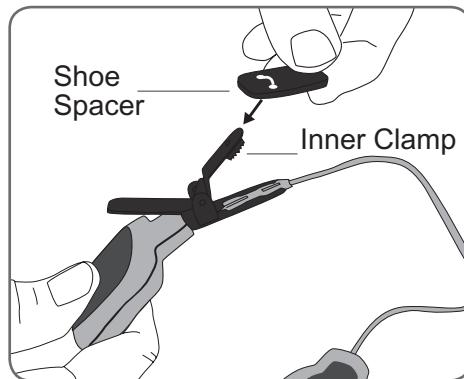


Figure 16: Attaching the shoe spacer.

Phillips Screwdriver

The Phillips screwdriver is used to replace the Control Unit and Gait Sensor batteries.

L300 Plus Accessories

L300 Plus System Charger Set

The L300 Plus system charger set is used to simultaneously charge the L300 RF Stim Unit, the Thigh RF Stim Unit, and the L300 Plus Control Unit.

The system charger set includes a "W" cable and a charger, and a set of interchangeable blades for international outlets. The "W" cable and the charger must be assembled for use. See Figure 17.



Figure 17: L300 Plus System charger set

Thigh FS Cuff Distal Panel Subassembly, Large

The Thigh FS Cuff has two panels: a proximal panel and a distal panel. The distal panel includes the cradle for the Thigh RF Stim Unit. The distal panel is available in two sizes: small and large.

The Thigh FS Cuff in your L300 Plus System Kit features the small distal panel. A large distal panel subassembly is also provided, if needed. See Figure 18.

Your clinician will measure your thigh circumference during your L300 Plus fitting session and determine the appropriate sized distal panel for your Thigh FS Cuff. If the large distal panel subassembly is needed, your clinician will reconfigure your Thigh FS Cuff.



Figure 18: Thigh FS Cuff distal panel subassembly, large.

Thigh FS Cuff Elongation Bar Lock Set

During your L300 Plus fitting session, your clinician will adjust the elongation bar on the Thigh FS Cuff. The elongation bar is used to adjust the distance between the Thigh FS Cuff distal and proximal panels. Once the elongation bar is adjusted, your clinician will lock the position using the lock set. See Figure 19. Do not attempt to adjust the elongation bar.

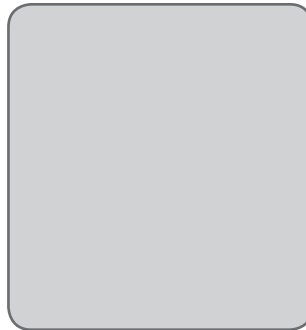


Figure 19: Thigh FS Cuff elongation bar lock set.

Thigh FS Cuff Electrode Marking Ring Set

The electrode marking rings are used to ensure accurate, repeatable positioning of the Thigh FS Cuff cloth electrodes on the Thigh FS Cuff.

During your L300 Plus fitting session, your clinician will determine the best position for the Thigh FS Cuff cloth electrodes. Your clinician will then use the electrode marking ring set to mark the electrode position on the Thigh FS Cuff. See Figure 20.

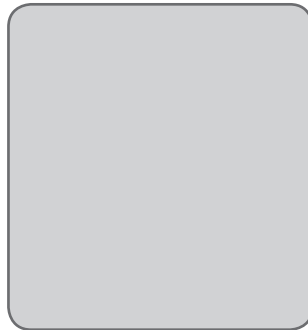


Figure 20: Thigh FS Cuff electrode marking ring set.

Thigh FS Cuff Cloth Electrodes

The Thigh FS Cuff uses two cloth electrodes to deliver stimulation from the Thigh RF Stim Unit to the muscles in your thigh. See Figure 21. The larger cloth electrode is placed on the proximal panel. The smaller cloth electrode is placed on the distal panel.

The Thigh FS Cuff cloth electrodes are larger than the L300 FS Cuff electrodes, and they do not require electrode bases.

The Thigh FS Cuff cloth electrodes must be wet before use and after every four hours of use. If the Thigh FS Cuff is removed for more than one hour, the cloth electrodes need to be rewet. Allow the electrodes to dry between uses.

Do not wear the Thigh FS Cuff without electrodes.



Figure 21: Thigh FS Cuff cloth electrodes.



Caution: Change the electrodes every two weeks.



Caution: Only use electrodes provided by Bioness Inc.

Putting On and Taking Off the FS Cuffs

Preparing the Skin

Before you put on the FS Cuffs, you must prepare the skin where the electrodes will adhere.

To prepare the skin:

1. Clean the skin where the electrodes will touch with a wet washcloth. If any lotions are on the skin, clean the skin with soap and water. Rinse well.
2. If necessary, trim excess body hair from the area using scissors. Do not use a razor. A razor can irritate the skin.
3. Check the skin for signs of irritation. If any irritation is present, stop using the NESS L300 Plus System. Contact your clinician, and wait for complete healing before re-using the system.

Checking and Wetting the Electrodes

Before you put on the FS Cuffs, make sure the cloth electrodes are wet and the covers have been removed from the hydrogel electrodes.

To prepare the electrodes:

1. Check the electrodes for signs of wear. Make certain the electrodes are not worn out, damaged, or old.
2. Wet the cloth electrodes.
3. If using hydrogel electrodes with the L300 FS Cuff, make certain the plastic covers have been removed.

Positioning the L300 FS Cuff

To position the L300 FS Cuff:

1. While seated, slightly straighten your leg as shown in Figure 22. The outline of your kneecap should be clearly defined. (Place your foot on a footrest, if necessary.)

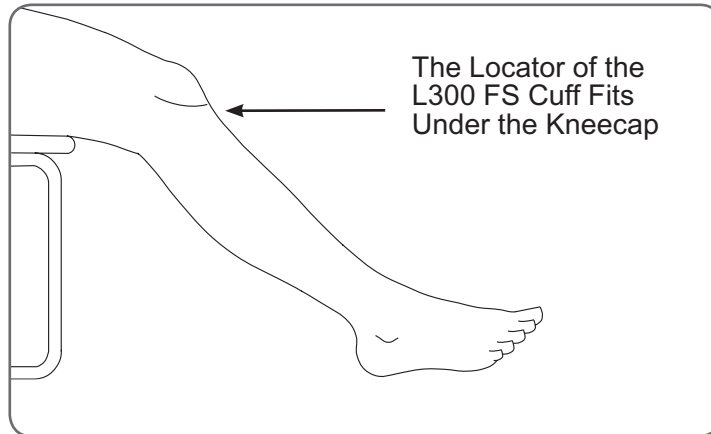


Figure 22: Recommended knee angle for positioning the L300 FS Cuff.

2. Make sure the electrodes are attached to the electrode bases. Then, grasp the front of the FS Cuff by the cradle and tilt the bottom of the FS Cuff up. Slide the locator up your leg until it rests snugly and comfortably below your kneecap. See Figure 23.

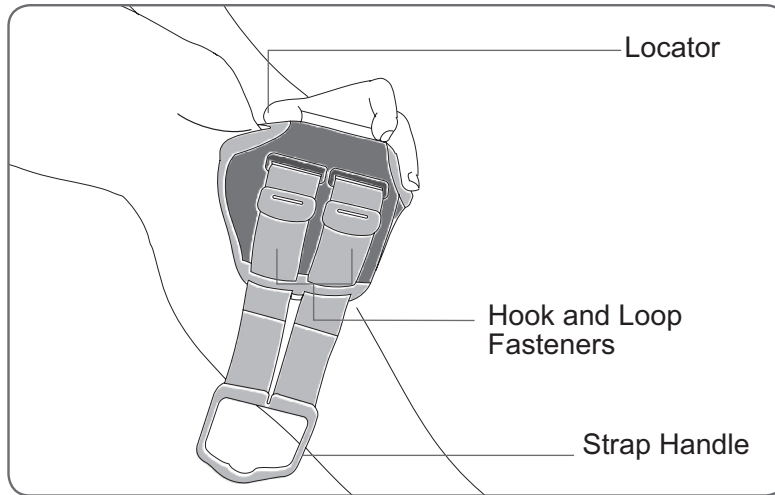


Figure 23: Tilting the L300 FS Cuff for placement on your leg.

3. Hold the locator in place and lower the L300 FS Cuff until it rests flush against your leg. The L300 FS Cuff should gently grip your leg.
4. Grasp the handle of the L300 FS Cuff strap. See Figure 24. With your thumb on the L300 RF Stim Unit cradle, fasten the strap handle around the cradle.

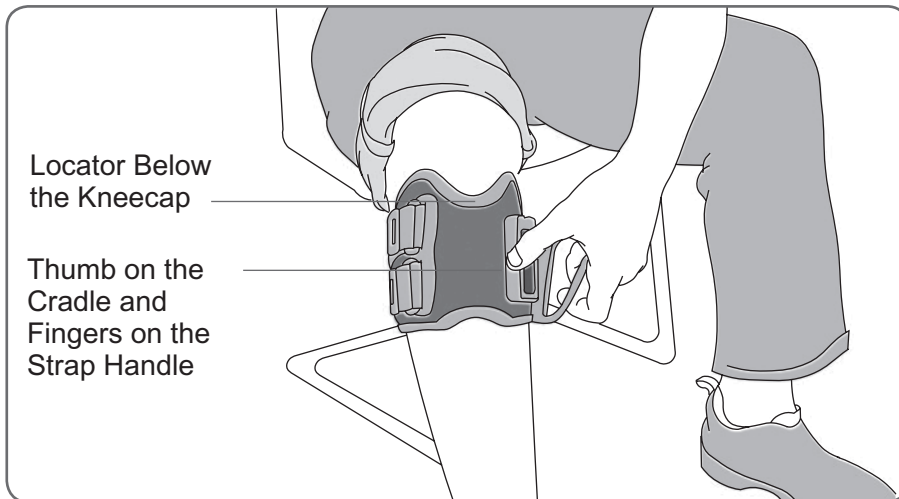


Figure 24: Fastening the L300 FS Cuff strap.

5. Make sure the L300 FS Cuff is correctly positioned. See Figure 25. If it is not, take off the L300 FS Cuff and reposition it. Adjust the hook and loop fasteners (see Figure 5) to ensure a snug fit.

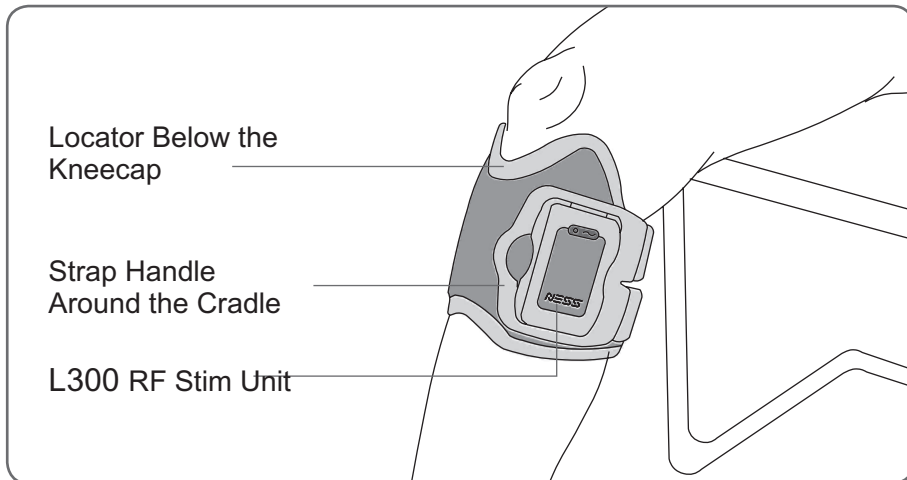


Figure 25: L300 FS Cuff fastened on the right leg.

Removing the L300 FS Cuff

To remove the L300 FS Cuff:

1. Turn off the Control Unit.
2. Unhook the L300 FS Cuff strap handle from the cradle.
3. Slowly lift the L300 FS Cuff away from your skin.
4. Gently peel the electrodes from your skin.
5. If using hydrogel electrodes, reapply the electrode covers to the electrodes.
6. If using cloth electrodes, allow the electrodes to dry.
7. Fully charge the Control Unit, Thigh RF Stim Unit, and L300 RF Stim Unit batteries.



Caution: The L300 FS Cuff should be removed from the skin every three to four hours for 15 minutes to allow the skin to breathe.



Caution: Change the electrodes every two weeks.



Caution: Wash the L300 FS Cuff as necessary to prevent bacterial/fungus buildup.

Positioning the Thigh FS Cuff on the Quadriceps

To position the Thigh FS Cuff on the quadriceps:

1. Sit in a stable position on the edge of a chair. See Figure 26.



Figure 26: Recommended seated position for putting the Thigh FS Cuff on.

2. Loosen the Thigh FS Cuff straps.

3. Place the Thigh FS Cuff on the front of your thigh (quadriceps muscle), with the locator arrow facing up and pointing toward the center of your knee. See Figure 27.

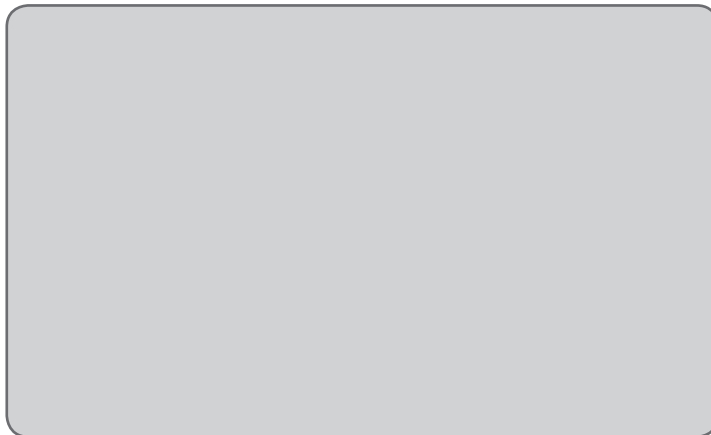


Figure 27: Using the locator to position the Thigh FS Cuff on the quadriceps.

4. Position the edge of the distal panel approximately 2 inches (5 cm) above your knee. See Figure 28.



Figure 28: Positioning the distal panel above the knee.

5. Fasten the FS Cuff distal straps, and tighten the straps to fit. See Figure 29.

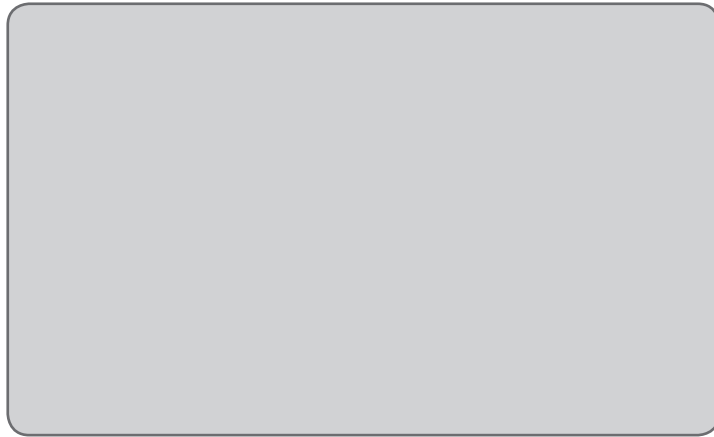


Figure 29: The distal straps fastened.

6. Fasten the FS Cuff proximal straps, and tighten the straps to fit. See Figure 30.



Figure 30: The proximal straps fastened.

Positioning the Thigh FS Cuff on the Hamstrings

To position the Thigh FS Cuff on the hamstrings:

1. Sit in a stable position on the edge of a chair. See Figure 31.

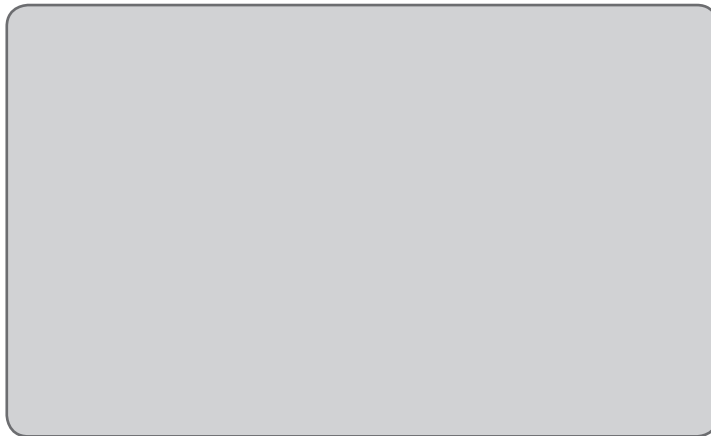


Figure 31: Recommended seated position for putting the Thigh FS Cuff on.

2. Loosen the Thigh FS Cuff straps.

3. Place the Thigh FS Cuff on the front of your thigh, with the locator arrow facing up and pointing toward the center of your knee. See Figure 32. The edge of the distal panel should be two to three inches above the knee.



Figure 32: Using the locator to position the Thigh FS Cuff on the quadriceps before rotating the FS Cuff to the hamstrings.

4. While holding the elongation bar, slowly rotate the FS Cuff to the back of your thigh. Rotate the FS Cuff until the elongation bar is centered on the back of the thigh (the hamstrings). See Figure 33.

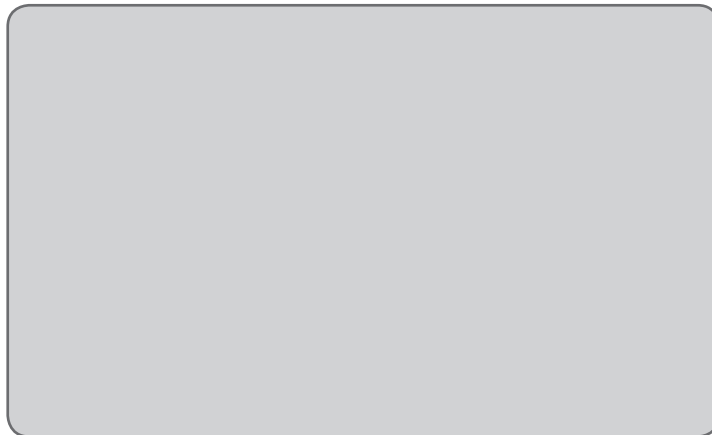


Figure 33: Positioning the Thigh FS Cuff on the hamstrings.

5. Fasten the Thigh FS Cuff distal straps and tighten them to fit. See Figure 34.

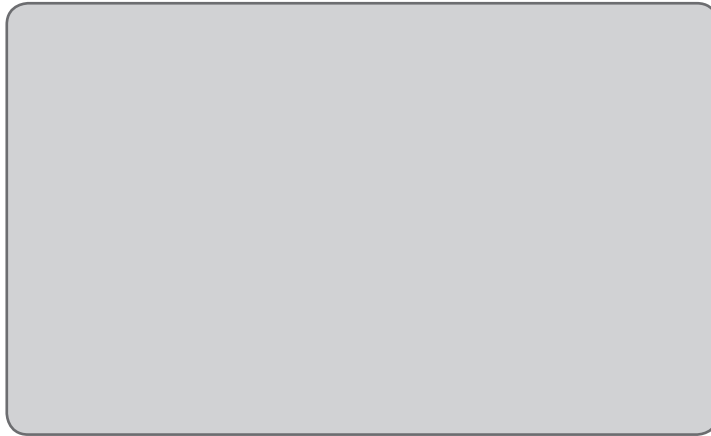


Figure 34: The distal straps fastened.

6. Fasten the FS Cuff proximal straps, and tighten them to fit. See Figure 35.



Figure 35: The proximal straps fastened.

Note: The fasteners should be centered along the top of the thigh.

Removing the Thigh FS Cuff

To remove the Thigh FS Cuff:

1. Turn off the L300 Plus Control Unit.
2. Loosen the Thigh FS Cuff straps.
3. Unfasten the Thigh FS Cuff straps.
4. Slowly lift the Thigh FS Cuff away from your skin.
5. Allow the electrodes to dry.
6. Fully charge the Control Unit, Thigh RF Stim Unit, and L300 RF Stim Unit batteries.



Caution: The Thigh FS Cuff should be removed from the skin every 3 to 4 hours for 15 minutes to allow the skin to breathe.



Caution: Change the electrodes every two weeks.



Caution: Wash the Thigh FS Cuff as necessary to prevent bacteria/fungus buildup.

Placing the Gait Sensor in the Shoe

The Gait Sensor pressure sensor is placed under the insole of your shoe. If your shoe does not have a detachable insole, place the sensor on top of the insole. Then, place a generic soft, thin (one layer versus two) insole over it. Generic insoles can be purchased from drugstores, shoe stores, or Bioness.



Caution: Do not use the Gait Sensor with a rigid insole, such as a custom rigid orthosis or an ankle foot orthosis.

To position the Gait Sensor:

1. Lift the shoe insole.
2. Attach a Gait Sensor pad under the insole, at the heel of the shoe. See Figure 36.

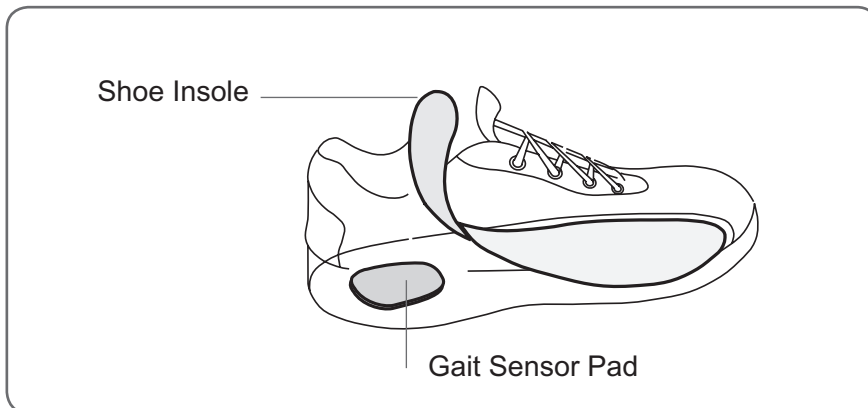


Figure 36: Placement of the Gait Sensor pad.

3. Point the wire of the pressure sensor toward the toe of the shoe. Then, attach the pressure sensor to the Gait Sensor pad. See Figure 37. Refer to the foot image on the pressure sensor for positioning.

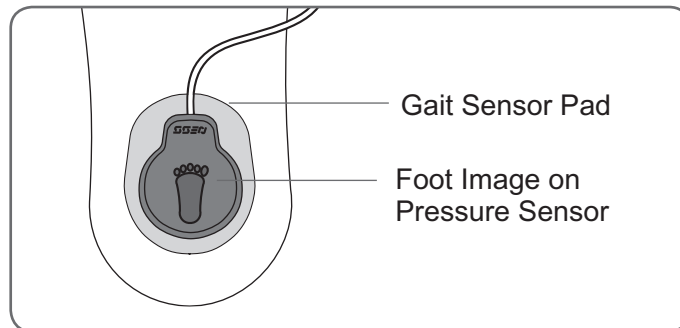


Figure 37: Positioning the pressure sensor in the shoe

4. Cover the inner clamp on the transmitter with the shoe spacer, if desired. See Figure 38. The teeth of the clamp may scuff the shoe, if not covered.

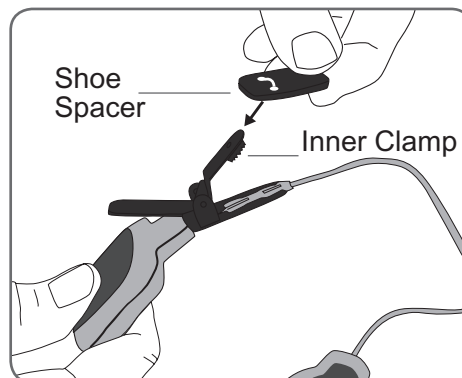


Figure 38: Covering the clamp with the shoe spacer.

5. Clamp the Gait Sensor transmitter on to the inner rim of the shoe. Face the NESS logo on the transmitter away from the ankle. See Figure 39.

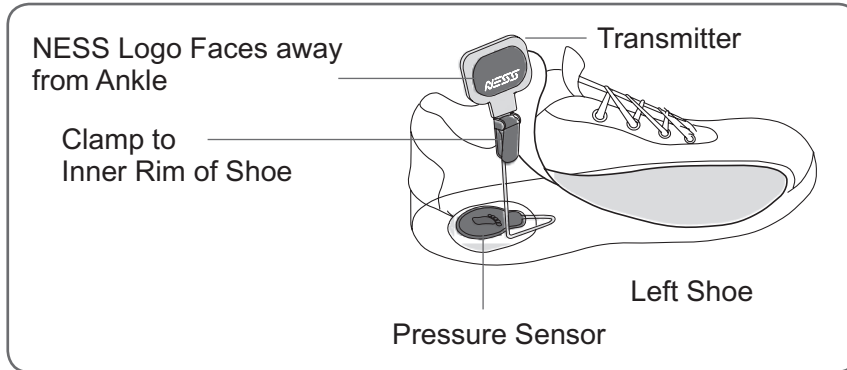


Figure 39: Clamping the transmitter to the inner rim of the shoe.

6. Cover the pressure sensor with the insole. Tuck any excess wire under the insole. See Figure 40.

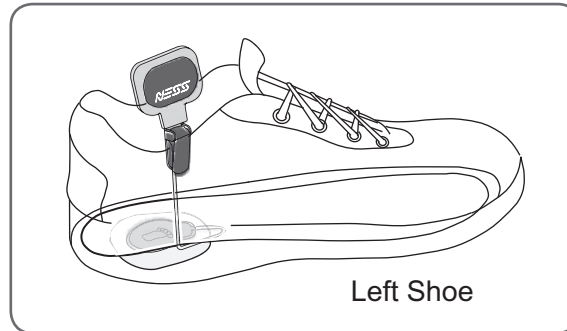


Figure 40: Insole covering the pressure sensor and wire.

Switching Shoes/Gait Sensors

When switching the Gait Sensor to a different shoe, make sure to place a Gait Sensor pad in the other shoe first.

If multiple Gait Sensors are placed in multiple shoes and you want to switch shoes:

1. Turn off the system.
2. Switch shoes.
3. Turn the system back on.

Operating the L300 Plus Control Unit

RF Communication Safety Features

The L300 Plus Control Unit, L300 RF Stim Unit, Thigh RF Stim Unit, and Gait Sensor must be within RF communication range of each other and their batteries charged for the L300 Plus System to operate. If the components become separated, or if a battery is discharged, RF communication will be lost.

If a communication failure occurs that involves the L300 RF Stim Unit:

- The RF Communication Indicator on the Control Unit will flash RED.
- The L300 RF Stim Unit indicator on the Control Unit will be solid RED.
- The status light on the L300 RF Stim Unit will flash RED.
- The Control Unit and L300 RF Stim Unit will emit an audio alert.
- The NESS L300 RF Stim Unit will deliver a warning **default stimulation** to lift the foot for six seconds before the L300 Plus System shuts down.

If a communication failure occurs that involves the Thigh RF Stim Unit:

- The RF Communication Indicator on the Control Unit will flash RED.
- The Thigh RF Stim Unit indicator on the Control Unit will be solid RED.
- The status light on the Thigh RF Stim Unit will flash RED.
- The Control Unit and Thigh RF Stim Unit will emit an audio alert.
- The remaining NESS L300 Plus System components will continue to operate.




Single Component Mode

If communication with the Thigh RF Stim Unit fails and cannot be restored, you can turn off the RF communication failure indicators for the Thigh RF Stim Unit and use the L300 FS Cuff in single component mode. In single component mode, the Thigh RF Stim Unit visual and audio indicators are disabled.

To turn off communication with the Thigh RF Stim Unit, press the  mute button for three seconds.




When the Control Unit is turned off, the default settings will be restored.

Turning On/Off the Control Unit





To turn on the L300 Plus Control Unit, press the  on/off button once. The system will start in standby mode. All display indicators will light up for a few seconds while the system performs a self-test. The  on/off button will flash GREEN to indicate the system is on. To turn off the Control Unit, press the  on/off button once.

Selecting an Operating Mode



Selecting Gait Mode

To select gait mode, turn on the Control Unit, and press the  mode button *briefly*. The Control Unit will beep and the  mode button will start flashing YELLOW SLOWLY (indicating that stimulation is off). When stimulation is on, the  mode button will flash YELLOW RAPIDLY.

Selecting Training Mode

To select training mode, turn on the Control Unit. Press and *hold* the  mode button until the Control Unit beeps, the  mode button starts flashing YELLOW SLOWLY (indicating that stimulation is off), and  (“t” for training) alternates with the intensity level in the digital display. When stimulation is on, the  mode button will flash YELLOW RAPIDLY.

Returning to Standby Mode

To return to standby mode from gait or training mode, press the  flashing mode button briefly. The Control Unit will beep, and the  mode button will stop flashing.


Adjusting Stimulation Intensity

When the Control Unit is first turned on, the stimulation intensity level will be “5”. This level is set by your clinician. Normally, you will not need to adjust stimulation intensity other than when walking on different surfaces or in different shoes.

The L300 Plus Control Unit allows you to adjust stimulation intensity individually for each RF Stim Unit using the RF Stim Unit selection buttons and the plus and minus buttons.

Adjusting the L300 RF Stim Unit

To adjust stimulation intensity for the L300 RF Stim Unit:

1. Press the  "down" button to select the L300 RF Stim Unit. The L300 RF Stim Unit indicator and the arrow next to the L300 RF Stim Unit indicator will light GREEN to confirm the selection. See Figure 41.

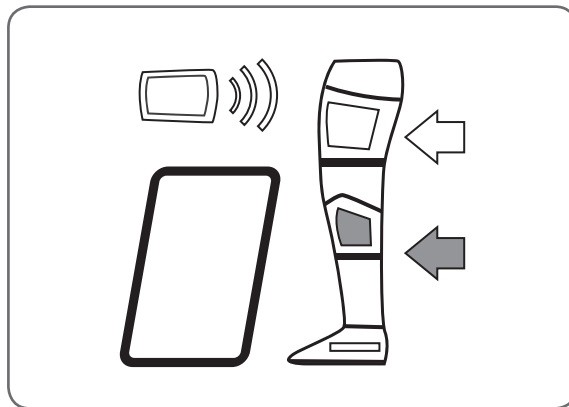




Figure 41: L300 RF Stim Unit selected.

2. Press the  plus or  minus intensity adjustment button on the Control Unit to change the intensity level. The Control Unit will beep with each change in level. The new level will show in the digital display.

Note: An intensity level of “0” equals no stimulation.


Adjustment Guidelines

If your foot slightly drags or catches on the floor while walking, increase stimulation intensity in the L300 RF Stim Unit to lift the foot higher.

If your foot rises too high while walking or if stimulation is unpleasant, decrease stimulation intensity in the L300 RF Stim Unit. Be sure your foot does not drag or catch on the floor after decreasing the intensity level.

Adjusting the Thigh RF Stim Unit

To adjust stimulation intensity for the Thigh RF Stim Unit:

1. Press the  "up" button to select the Thigh RF Stim Unit. The Thigh RF Stim Unit indicator and the arrow next to the Thigh RF Stim Unit indicator will light GREEN to confirm the selection. See Figure 42.

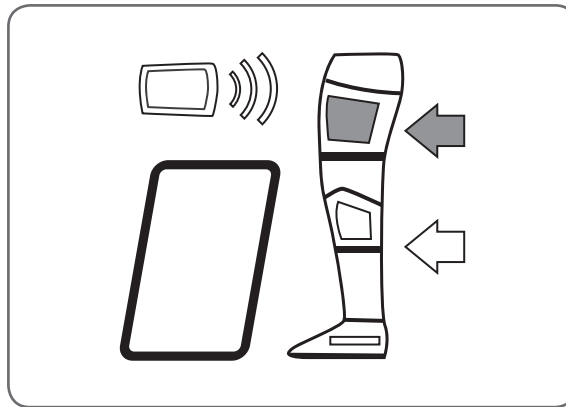




Figure 42: Thigh RF Stim Unit selected.

2. Press the  plus or  minus intensity adjustment button on the Control Unit to change the intensity level. The Control Unit will beep with each change in level. The new level will show in the digital display.

Note: An intensity level of “0” equals no stimulation.

Adjustment Guidelines

If your knee is hyper-extended or not straight enough while stepping, then increase the stimulation intensity level in the Thigh FS Cuff.




If your knee is under-extended or too bent while stepping, then decrease the stimulation intensity level.

Testing Stimulation

The stimulation test button is used to manually check the position of the FS Cuff on the leg. Each FS Cuff can be tested individually.




Testing the L300 FS Cuff

To test the position of the L300 FS Cuff:

1. Place the Control Unit in standby mode.
2. Press the  "down" button to select the L300 RF Stim Unit. The L300 RF Stim Unit indicator and the arrow next to the L300 RF Stim Unit indicator will light GREEN to confirm the selection.
3. Press and hold the  stimulation test button. The L300 RF Stim Unit will stimulate until the  stimulation test button is released.

Testing the Thigh FS Cuff

To test the position of the Thigh FS Cuff:



1. Press the  "up" button to select the Thigh RF Stim Unit. The Thigh RF Stim Unit indicator and the arrow next to the Thigh RF Stim Unit indicator will light GREEN to confirm the selection.
2. Press and hold the  stimulation test button. The Thigh RF Stim Unit will stimulate until the  stimulation test button is released.



Turning on Audio Feedback During Stimulation

The NESS L300 Plus System can be configured to provide audio feedback during stimulation. You can turn on the audio feedback feature for each RF Stim Unit individually using the RF selection buttons and the mute button.

Turning on Audio Feedback for the L300 FS Cuff



To turn on audio feedback during stimulation for the L300 FS Cuff:



1. Place the Control Unit in standby mode.
2. Press and hold the  "down" button (to select the L300 RF Stim Unit) and the  mute button for three seconds. Both the Control Unit and the L300 RF Stim Unit will emit an audio alert when stimulation turns on.

To turn off the audio feedback, press the  mute button or the  on/off button.


Turning on Audio Feedback for the Thigh FS Cuff

To turn on audio feedback during stimulation for the Thigh FS Cuff:

1. Place the Control Unit in standby mode.
2. Press and hold the  "up" button (to select the Thigh RF Stim Unit) and the  mute button for three seconds. Both the Control Unit and the Thigh RF Stim Unit will emit an audio alert when stimulation turns on.


To turn off the audio feedback, press the  mute button or the  on/off button.

Muting the Audio Alerts

Use the  mute button to mute the audio alerts. Only noncritical audio alerts will be muted.

When the system is turned off, the default volume setting is automatically restored.

Muting the Thigh RF Stim Unit Alerts

Your L300 Plus System is designed to operate with or without the Thigh FS Cuff on or operating. However, the L300 Plus Control Unit will recognize that the Thigh FS Cuff is not on or operating and will emit visual and audio alerts. To mute the visual and audio alerts for the Thigh FS Cuff and RF Stim Unit, press and hold the  mute button for three seconds. The Control Unit will cease communication with the Thigh RF Stim Unit.

When the system is turned off, the default settings are automatically restored.