TOUCH BIONICS ELECTRODE KIT
For both Lamination and Thermoplastic sockets
Product Number:
PL091050A/ PL091060A (50Hz / 60Hz)
091091B
Please read this manual carefully. Pay special attention to the Safety Information.

**Touch Bionics Electrode Kit (Fig. 1) Contents:**

1. Touch Bionics Electrode (50Hz or 60Hz) and Thermoplastic Electrode Mounts
2. Exterior frame dummy and inserts
3. Inner socket dummy, inner socket dummy inserts and thermoplastic electrode dummy mounts
4. Top plate
5. Cable routing plate
6. Gain adjuster
7. Lamination washer
8. Knurled nut
9. Low profile screw

**Safety Information**

Touch Bionics Electrodes should only be positioned in contact with unbroken skin, all three metal pads must make good contact with the patient’s skin.

The patient should take regular breaks during the electrode
adjustment process, as muscle fatigue can lead to irregular signals, and may result in the amplitude being set too high.

If electrical appliances cause strong interference, check the positioning of the electrode and reposition, if necessary.

Do not bend the electrode cable. If damaged, immediately exchange the electrode cable for a new one.

Do not turn the gain adjustment dial beyond its noticeable stopping point.

Do not use the electrode in a prosthesis intended for underwater use, or for bathing.

Carbon fibers can transmit interferences, which can affect the performance of the electrode, and should only be used in the required areas of the prosthesis. Care should be taken to ensure that there is no connection between the patient’s skin and any metal components other than the three metal pads of the electrode surface.

Do not allow the electrode to come into contact with solvents such as acetone.

Educate the prosthesis wearer in the correct use of the Touch Bionics Electrode, as outlined in the User Information section on Page 6.
User Information

If the Touch Bionics Electrode or electrode cable is damaged, the user should turn the terminal device off, remove it from their prosthesis and contact their prosthetist.

Regularly clean the contact surface of the electrode with mild soap and a damp cloth.

Avoid dirt or fluids coming in contact with the Touch Bionics Electrode.

Do not expose the Touch Bionics Electrode to intensive smoke, dust, mechanic vibrations, shocks or extensive heat.
Description

The PL091050A (50Hz) and PL091060A (60Hz) Touch Bionics electrode kits are intended only for the control of upper limb myoelectric prostheses. The high frequency shielding and filtering minimises the effects of electromagnetic interference from the surrounding environment.

This product is compatible with all Touch Bionics’ upper limb myoelectric devices (i-limb ultra, i-limb digits and other i-limb products) and most upper limb myoelectric prostheses from other manufacturers. If you have any questions regarding compatibility of the Touch Bionics Electrode with other manufacturers’ devices, please contact Touch Bionics.
Electrode Positioning and Adjustment

For an optimum fitting, consider the following factors:

**Selected Muscle Groups**
To ensure the function of the prosthesis is more intuitive for the user, choose the muscles used to activate the electrode based on their original function (i.e. muscles used for closing/opening). For successful operation of the Touch Bionics Electrode, the user should be able to activate individual muscle groups.

**Electrode Location**
To find the best location for positioning the electrode, we recommend using one of the myo-testing tools that are widely available on the market. This equipment provides a graphical representation of a patient’s myoelectric signal, ensuring that the area with the strongest signal can be identified.

**Stable Contact with Skin**
For the best response, ensure that the pressure of the electrode’s contact surfaces on the wearer’s skin is evenly dispersed and that the electrode is placed on skin areas with similar characteristics.
**Gain Adjustment**

If the sensitivity of the electrode has to be adjusted to the muscle signal, adjust with the included Gain Adjuster tool (Fig. 9). If the gain is set too high, the wearer will find it easier to activate, and therefore cause accidental operation of the prosthesis. It can also reduce the potential for training the residual limb to improve its muscle response. As a rule, the electrode gain should be set as low as possible, and allow the prosthesis wearer to hold the upper signal for around two seconds. The presence of sweat on the skin will reduce resistance of the skin interface, which may require readjustment of the electrode.

Note: For Touch Bionics’ products, the maximum advisable gain setting is 5.5

Touch Bionics’ biosim-pro software can be used to create custom electrode adjustments for i-limb ultra and i-limb-digits solutions.
Fabrication

The Touch Bionics Electrode kit contains components for the assembly of both Laminated and Thermoplastic inner sockets.

Laminated Inner Socket

1. Flatten the areas where the electrodes will be attached, making sure the Inner Socket Dummy (Fig. 1, Item 3) is flush with the surface of the model.

2. Dry the plaster mold.

3. Prepare and pull a PVA bag over the model. Secure a seal to the vacuum pipe then turn on the vacuum.

4. Attach the Inner Socket Dummy to the flattened areas.

5. Add small pieces of Dacron™ felt under the pins of the Inner Socket Dummy.

6. To connect inner to outer socket use Lamination Washer (Fig. 1, Item 7).

7. Laminate inner socket.

8. Carefully grind the lamination material covering the Inner Socket Dummy until the green surface of the pattern becomes visible (Fig, 2).

9. Proceed to fabrication of outer socket.
10. Make sure to remove the thermoplastic tabs from the inner socket dummy before proceeding with fabrication of outer socket.

**Fabrication of Outer Socket (Lamination)**

1. Remove the Inner Socket Dummy and insert the Exterior Frame Dummy *(Fig. 1 Item 2)*, with the raised area on the outside *(Fig. 3)*. Be sure the small bump is towards the proximal side of the socket.

2. Pull a PVA bag over the inner model and foam to the desired shape.

3. Trim the shaped foam.

4. Configure the socket lamination to the patient’s activities.

5. After curing, remove suction pipe and plaster filling.

6. Remove the inner socket from the outer frame.

7. Burn through the holes of the steel washers; drill and use a tap to create threads (if required) for the Low Profile Screw *(Fig. 1, Item 9)*.

8. Assemble the prosthesis using the Low Profile Screw to attach the inner socket to the outer frame.

**Thermoplastic Inner Socket**

1. Slide the thermoplastic inserts onto the Inner socket
dummy (Fig. 1, Item 3).

2. Use a thin wire to drill air channels from electrode dummy sites to proximal edge of cast outside of trim lines.

3. Secure the Inner Socket Dummy onto the cast and then apply Top Plate (Fig 1, Item 4) onto the dummy.

4. Place Knurled Nuts (Fig. 1, Item 8) onto cast to allow attachment of outer shell.

5. Form the thermoplastic over the cast.

6. Sand the socket to expose the electrode dummy sites (Fig. 4).

7. Proceed to fabrication of outer socket.

8. Once fabrication is complete, discard the green thermoplastic electrode dummy mounts and replace them with the skin-toned thermoplastic electrode mounts.

Fabrication of Outer Socket (Thermoplastic)

1. Remove the Top Plate and replace with Cable Routing Plate (Fig 1. Item 5), with the tab facing distal (Fig. 5).

2. Pull a PVA bag over the inner model and foam to the desired shape.
3. Trim the shaped foam.
4. Configure the socket lamination to the patient’s activities.
5. After curing, remove suction pipe and plaster filling.
6. Drill holes in outer shell at location of knurled nuts on inner socket.
7. Continue assembling the prosthesis using the Low Profile Screw (Fig. 1, Item 9) to attach the inner socket to outer frame.

**Connecting and Inserting the Electrode**

The Touch Bionics’ Electrode Kits are delivered without electrode cable, unless ordered as part of the complete Socket Components Kit. Otherwise, cable must be ordered separately and can be individually shortened.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>PL091029A</td>
<td>3-way electrode cable (300mm)</td>
</tr>
<tr>
<td>PL091030A</td>
<td>3-way electrode cable (600mm)</td>
</tr>
<tr>
<td>PL091031A</td>
<td>3-way electrode cable (1000mm)</td>
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</table>
When cutting the electrode wire, make sure the cut is 90 degrees from the ribbon edge. Any slant in the cut will not allow proper connection and result in electrode malfunction.

1. Insert Electrode Cable with the grey side facing up into the pre-greased Electrode Plug Connector until it is fully inserted (Fig. 6). **Warning**, if the cable is inserted incorrectly the electrode will not function and may be damaged.

2. Press the Electrode Plug Connector with inserted Electrode Cable into the Touch Bionics Electrode with a flat tool (Fig. 7) until a “stop” is felt to establish the connection – the top of the Connector should be level with the case of the Electrode.

3. Disconnect the Electrode Cable by pulling it in a right angle to the electrode (Fig. 8). For cable re-use you must a) trim 5mm from the cable, ensuring new trim line is still perpendicular to cable edge. b) Apply Silicone grease to the Electrode Plug connector location on the Electrode - this is essential to create a protective barrier to moisture.

4. The Touch Bionics Electrode is inserted into the inner socket from the outside or slipping the
electrode into the mounting channels, slightly press the suspension arms together. Light pressure will be sufficient for completing the installation. The electrode compensates vertical travel of up to 2.5mm to allow for volume changes.

**Technical Information**

Power Supply: All batteries compatible with Touch Bionics’ and other manufacturers’ upper limb myoelectric systems
Temperature Range: -15ºC to 60ºC
Frequency Bandwidth: 90 Hz - 450 Hz
Sensitivity Range: 2000 – 100,000 fold

**Warranty**

A 12 months manufacturer’s warranty only applies when the product is used according to the specified conditions and for intended purposes. The Touch Bionics warranty applies only to tested component combinations.

**Declaration of Conformity**

The Touch Bionics Electrode satisfies the requirements of the medical directive *(93/42/EEC)* and has been CE marked accordingly.
PL091050A / PL091060A (50/60 Hertz Electrode Kit)

091071A Electrode Mount

091085A Gain Adjuster

091077A Top Plate

091076A Cable Routing Plate

091081A Mounting Bracket

091082A Bracket

091080A Base Plate
SA91045A - Electrode Inner Socket Dummy Assembly

- 091075A Inner Socket Dummy Insert
- 091073A Inner Socket Dummy
- 091074A Double Sided Adhesive Pad

SA91047A - Outer Shell Dummy Assembly

- 091079A Outer Shell Dummy
- 091078A Outer Shell Dummy Insert

50A (50 Hertz) / OR SA91060A (60 Hertz)

14x8 LP Screw

Knurled Nut **

Lamination Washer

SA91045A - Electrode Inner Socket Assembly for Packaging

2a Dummy Electrode Mount