



Agilik 1.1 KAFO Fabrication Instructions

(Qualified personnel only)

Document Number: D0602-02

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1 Foreword



These instructions relate to the custom fabrication of a knee-ankle-foot-orthosis (KAFO) to be suitable for use with the Agilik 1.1 actuators.

- Agilik 1.1 Model Ref BP07369

Bionic Power Inc. reserves the right to make updates to these instructions at any time. Please ensure you have the latest version of this document by contacting your local Bionic power representative.

- ▶ Please read this document carefully before proceeding with KAFO fabrication and observe the Safety Notices.
- ▶ Please refer to D0476_Agilik 1.1 Instructions for Use for information on using the product.
- ▶ Report each serious incident in connection with the product, in particular a worsening of the state of health, to the manufacturer and to the relevant authority in your country. Please keep this document for your reference.

1.1 Explanation of Safety Information

 WARNING	Hazardous situation that, if not avoided, might result in serious injury.
 CAUTION	Hazardous situations that, if not avoided, might cause a minor to moderate injury.
NOTICE	Information related to safety.

2 Instructions for KAFO Fabrication

2.1 Overview

The Agilik is based around the lateral femoral epicondyle. The final placement should have the pivot point adjacent to the Lateral Femoral Epicondyle (LFE) as seen below.

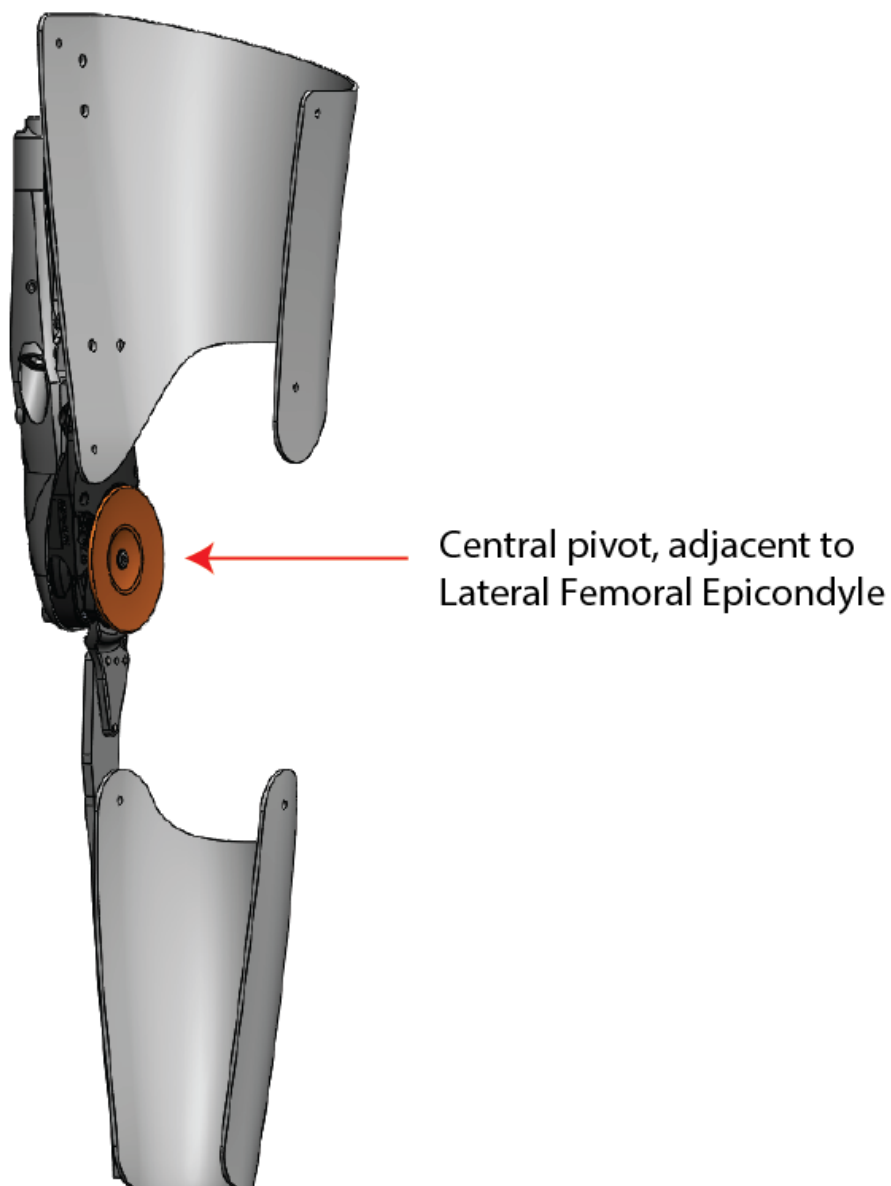


Figure 1 LFE location

2.2 KAFO construction

2.2.1 Shell Construction

KAFO Shells to be constructed per usual orthotic methods with certain requirements listed below. See also Figure 2 KAFO Requirements to see relevant location for each letter.

- a. Thigh Shell to have high lateral and posterior sides. Optimal shell height on the posterior is at gluteal furrow, but trim for patient's comfort.
- b. Shells must be trimmed so that the leading anterior edge is at least 1" posterior of the front of the leg, so that the straps curve around the thigh and shin (as opposed to going straight from one side of the Shell to the other) and pull the KAFO snugly around the leg and towards the posterior. We recommend attaching the straps to the interior of the KAFO Shells but the exterior is OK as well. See Figure 3 Strap Locations From Above.
- c. Cut-outs in Shells must leave a minimum of 3" (76mm) vertical of posterior material, for structural strength.
- d. Bottom, posterior edge of thigh Shell to be as low as possible without creating a pinch hazard.
- e. Bolts at either end of the Aluminum Upright must be a minimum of 4" (101mm) apart. For the smallest KAFO's, it may be necessary to bend the aluminum upright over the ankle joint's upright and fasten them both through the shell. Figure 2 KAFO Requirements shows a sample KAFO with bolts that are too close together.
- f. Trim the KAFO thigh shells so they are 1" (25mm) above the Condyle Cover.
- g. The medial knee hinge of the KAFO should be assembled per regular practice but be offset from the leg no more than .25" (6mm). See Notice below for additional requirements. The physiotherapist and orthotist shall collaborate to define the maximum knee extension allowable by the KAFO for each patient.
- h. Keep the extra length and width of the foot orthosis to a minimum. The added dimensions affect the patient's gait negatively.
- i. Patient's strength should be considered when choosing the thickness and/or ribbing of the shell material, using as thin a material as possible that will still maintain enough rigidity. Extra weight due to excess thickness is undesirable. We do not recommend lining the KAFO with foam for the same reason.

NOTICE**Medial Hinge Inclusion**

1. If a user exhibits hyperextension in their normal gait, a stop locking medial hinge customized for the specific patient must be included in the KAFO fabrication to prevent hyper extension. It shall be determined by the certified orthotist if a medial hinge is required.
2. If the patient is 70kg or over, a medial hinge must be included.

CAUTION

Please ensure any trimming of the KAFO does not result in sharp/rough edges.

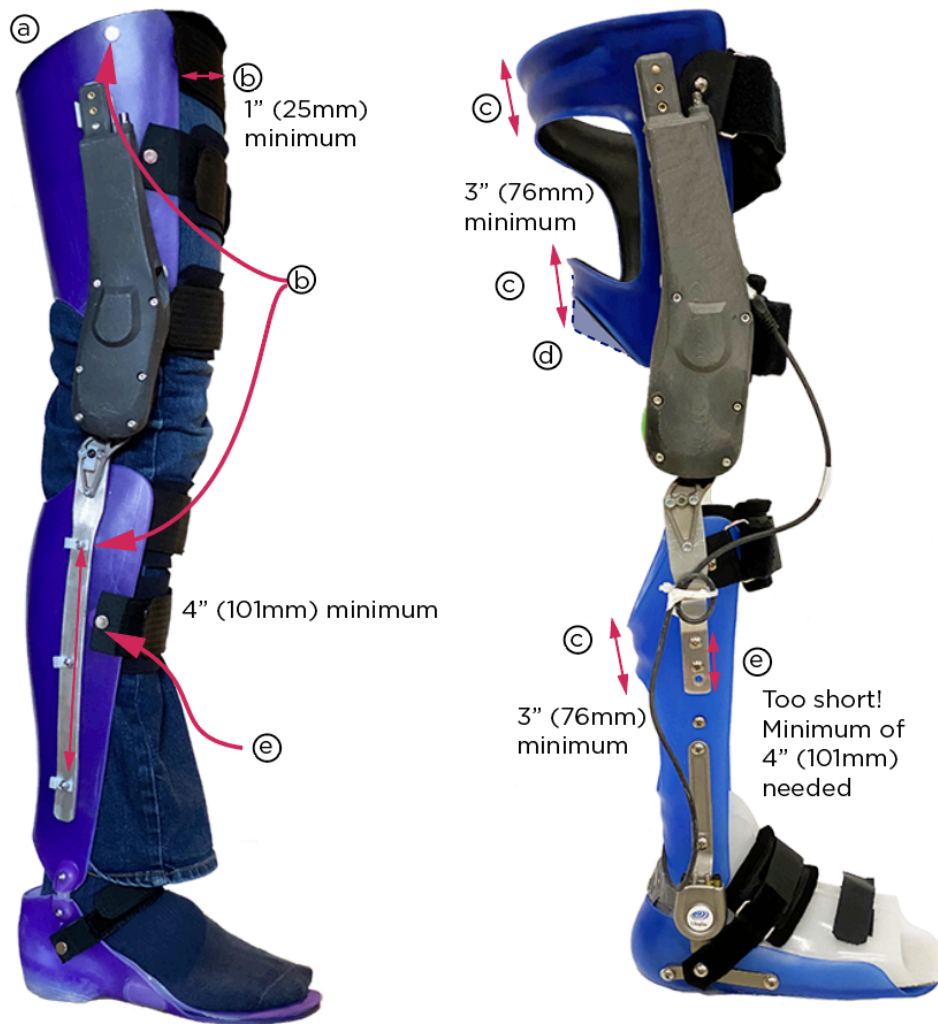


Figure 2 KAFO Requirements

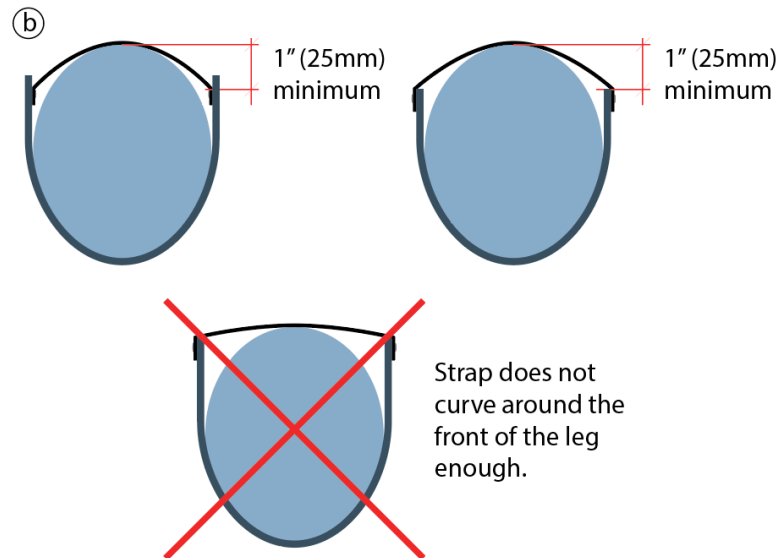


Figure 3 Strap Locations From Above

2.2.2 Footbed Construction

- Create footbed insert out of NickelPlast X-Firm or very similar material, Shore A 65-70. If a softer material is required for comfort, the HDPE Footprints (BP07856) must be placed above the FSR and under the footbed.
- The bottom side of the footbed insert and inside of the AFO footplate should be as flat as possible to ensure the best results from the Foot Sensor. The AFO footplate and footbed insert width needs to be as wide as possible under the medial arch to create a good contact surface for the foot sensor. See Figure 4 Footbed Width.
- Mold footbed on plaster cast, adding as many laminations as needed for heel height. The plantar surface should be ground/milled totally flat, see Figure 4 Footbed Width. Place footbed on plaster leg and mold polypropylene or other shell material over combined cast and footbed. The Foot Sensor will go between the footbed and the KAFO foot plate.
- For users that exhibit equinus, the Foot Sensor may be attached underneath the bottom of the AFO footplate instead of between the footbed and the footplate. The goal is to have the Foot Sensor have flat surfaces above and below it. This means the bottom of the foot must be made flat with sufficient width underneath the medial arch to adhere the sensor.



As wide as possible
underneath the
medial arch

Figure 4 Footbed Width

2.3 Using the Actuator Jig

The Actuator Jig is used in combination with a common metal jig that is typically used during KAFO construction. The Actuator Jig and sliding metal jig are needed for determining the correct spacer width.

- Screw the Upper Spacer and Lower Spacer into the Jig with two P0572 fasteners as seen below.

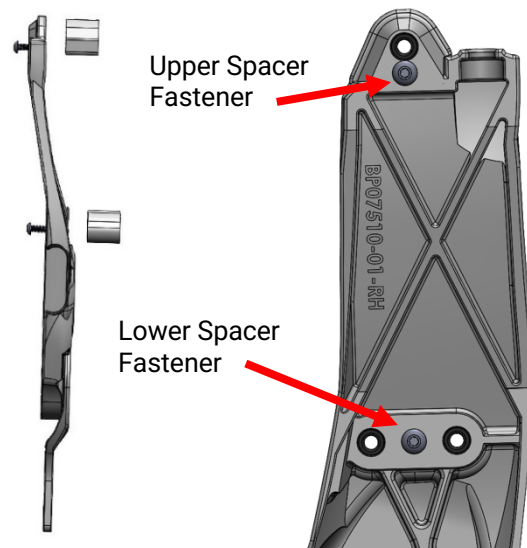


Figure 5 Upper and lower spacer location

- The metal jig allows the Actuator Jig to slide in and out laterally so the spacers can be checked against the KAFO as they are ground to match surfaces with the KAFO Thigh Shell. Fix the KAFO shells to the molded leg and setup the Jigs as shown below (KAFO not pictured).
- Add the Actuator Jig to the metal placement jig and position Spacers against the Upper Shell. The central pivot on the Jig should be lateral to the lateral femoral epicondyle.



Figure 6 Metal jig to be used with KAFO Assembly Jig

- The Actuator Jig should be positioned so that when the KAFO is upright, the Actuator will be vertical. The red lines in the figure above indicate features that should be used to determine the angle of the Actuator Jig.



Figure 7 Vertical upright and actuator

- After the actuator jig is oriented correctly on the sliding metal jig, grind the spacers as shown below in Figure 8. The Actuator will be mounted so that it is as close to the upper KAFO shell as possible to minimize access and minimize axial (transverse plane) twisting torque, so the spacers should be ground so that the Actuator Jig is as close as possible to the KAFO shell.

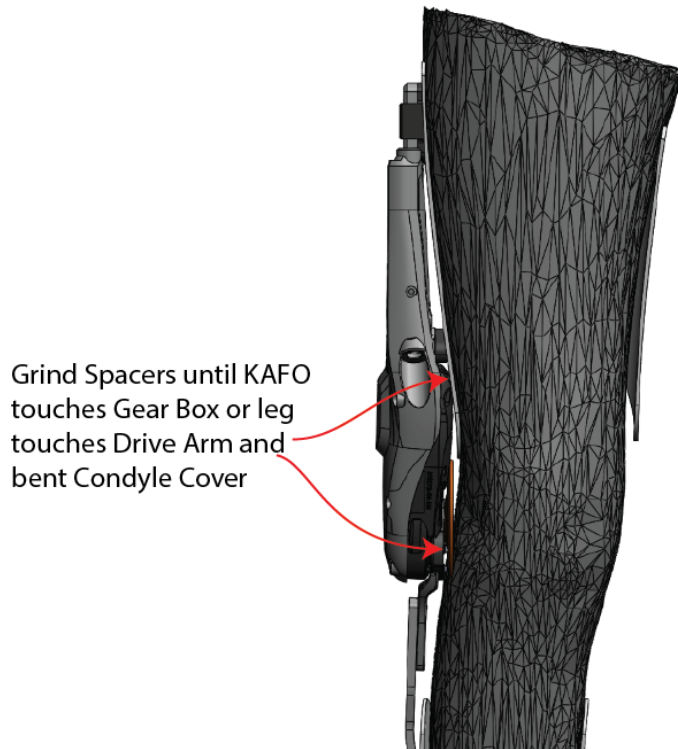


Figure 8 Grinding Spacers

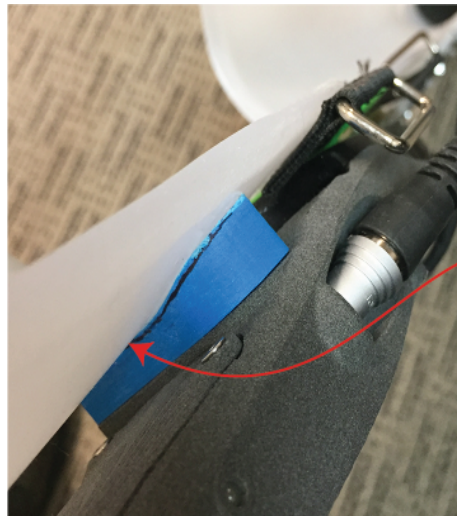


Figure 9 Ground Spacer

- After the Spacers are ground to match, use the jig and Spacers as a drill guide to drill three 4.2mm diameter holes in the KAFO Upper Shell shown in Figure 10.

Drill three 4.2mm holes in the KAFO thigh shell using the jig and ground spacers as a guide in the locations shown here.

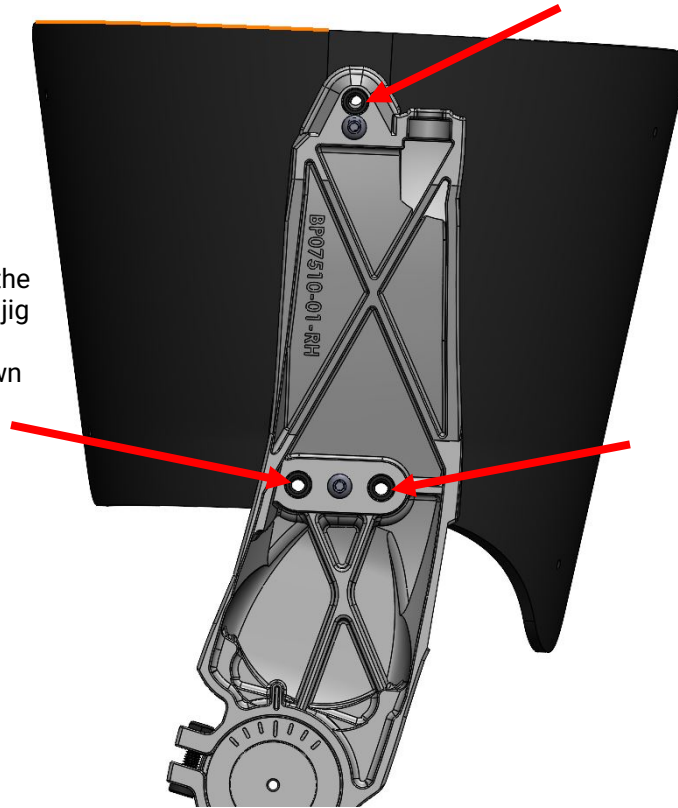


Figure 10 Hole locations

2. Remove the jig and Spacers from the sliding metal jig and attach the Spacers to the Actuator and KAFO Upper Shell with 4mm screws provided as in Figure 11.
 - a. The Actuator has threaded inserts and multiple screw lengths are provided in the box. Choose a length depending on the final dimensions of the spacers after being ground. Screws should extend past Spacer into the threaded inserts 4-6mm.
 - i. P0480 12 mm
 - ii. P0481 16 mm
 - iii. P0482 20 mm
 - iv. P0513 25 mm
 - v. P0514 30 mm

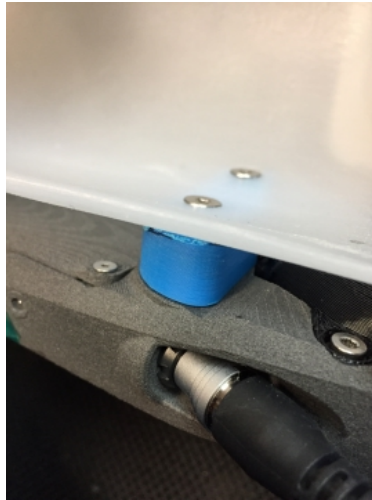


Figure 11 Spacer and Actuator

2.4 Aluminum Uprights

The Aluminum Upright attaches to the Drive Arm with four P0449 bolts. Please tighten to 2.7Nm. The Aluminum Upright should be vertical when leg is fully straight and standing up. See Figure 7.

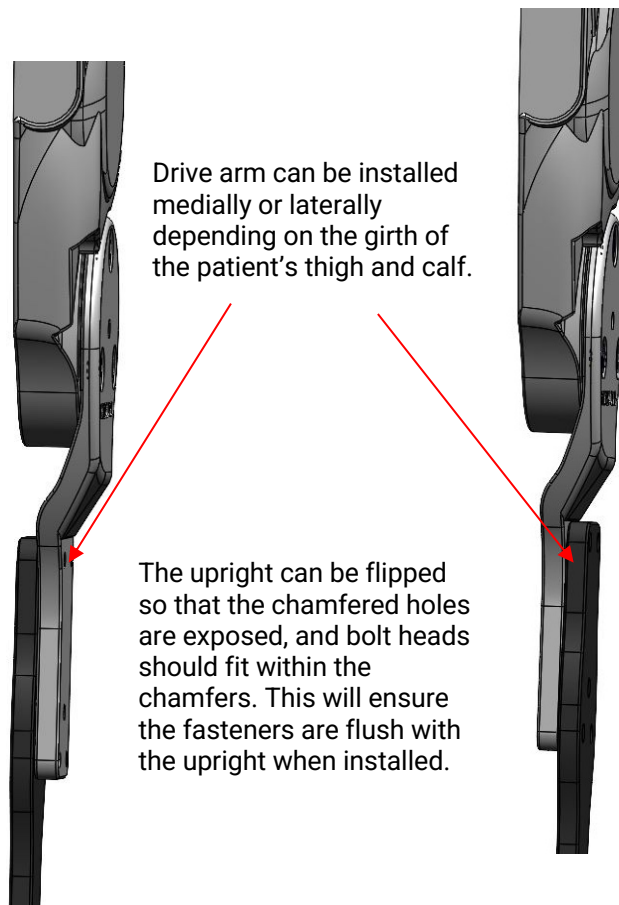


Figure 12 Ways to attach the Drive Arm

If more space is needed in either direction, the M1298 spacers can be used to add distance between the aluminum upright and the drive arm. If the M1298 spacer is used, use longer P0602 (M4x14) screws provided to fasten the upright to the drive arm with the spacer in between as shown below.



Figure 13 Spacer between Upright and Drive Arm

The upright may need to be bent to match the Lower Shell while attached to the Drive Arm on the Actuator as shown below.



Figure 14 Bending Aluminum Upright

The Aluminum Upright is now part of the individual's KAFO. If a new KAFO is fabricated, a new Aluminum Upright will be needed. Contact the manufacturer to receive new uprights.

Drill 2 or 3 (depending on the length of the shell) 4.2mm diameter holes through both Aluminum Upright and Lower Shell as seen in Figure 15. Attach the Aluminum Upright to KAFO Lower Shell using P0481 M4 screws, P0224 washers and P0350 nuts provided. Include the P0478 Plastic Cable Clips and clip the FSR cable in.



Figure 15 Upright screws

CAUTION

Please ensure all fasteners are flush with the internal surface of the Shell of the KAFO to prevent abrasion of the patient. Chamfering fastener holes may be necessary.

2.5 Shell Straps

The ends of the straps on the inside of the KAFO shall be trimmed or covered with foam as the burnt edges will be rough.

See 2.2.1 Shell Construction and Figure 3 Strap Locations From Above for strap location recommendations.

2.6 FSR Assembly

Remove the liner on the tape on the back of the FSR and adhere it to the footplate of the AFO with the white force concentrators oriented upwards as shown below. Place the footbed insert on top of the FSR.



Figure 16 Orientation of FSR on AFO

2.6.1 Trimming the FSR

In the case where the patient's foot is much smaller than the FSR, trim the FSR in the following order until the FSR is small enough to fit between the footbed and AFO without sticking out.

1. Trim the clear plastic at the heel.
2. Trim the clear plastic at the toe.
3. If trimming the plastic at the ends is not enough, and you need to trim the silver sensors themselves, start at the toe end and trim off the furthest toe sensors. Trim the whole sensor off - do not trim in the middle of the silver sensors or your FSR may not function correctly. Do not trim laterally across the FSR in any location other than the red lines in Figure 17 Trimming Order.

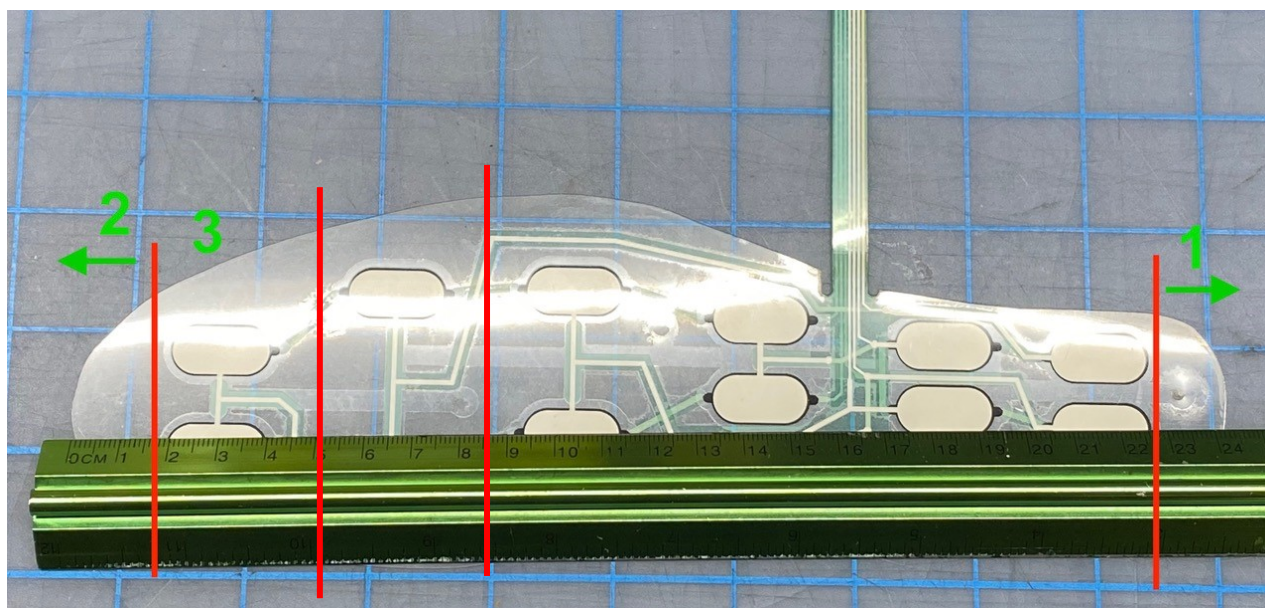


Figure 17 Trimming Order

3 Contacting the Manufacturer

If you have questions or need to complete an incident report, please contact your local representative as a first point of contact. In the case you cannot reach your local representative, you may contact us by e-mail at support@bionic-power.com or by mail using the address provided below:

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