

sense

Installation and Setup Guide  
for the Prosthetist



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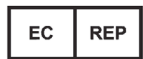
This document provides information for the prosthetist who will be installing Sense.

Contains FCC ID: XDULE40-D2

Contains IC: 8456A-LE4D2



Infinite Biomedical Technologies, LLC.  
8 Market Place, Suite 500  
Baltimore, MD 21202  
(443) 451-7175  
www.i-biomed.com



Mdi Europa GmbH  
Langenhagener Str. 71  
30855 Langenhagen  
Germany

# sense

## INSTALLATION AND SETUP GUIDE FOR THE PROSTHETIST

Thank you for choosing Sense to provide control of the prosthesis. This guide will familiarize you with Sense and help you install the hardware and software.

**Indications for Use:** Sense System with IBT Electrodes is to be used exclusively for external prosthetic fittings of upper limbs.

The system is suitable for pattern recognition control of myoelectric prostheses. It is intended for use on one patient only. Use of the product by another person is not approved by the manufacturer. Installation of the system should be performed exclusively by a licensed prosthetist or technician. Any unauthorized handling or installation of Sense could void its warranty.

Have any questions? We're happy to help. Call us or send us an email.

(443) 451-7175  
support@i-biomed.com



This symbol is used throughout the guide to indicate important cautionary information. Text following this symbol should be read carefully.



Caution: Federal law restricts this device to sale by or on the order of a prosthetist.



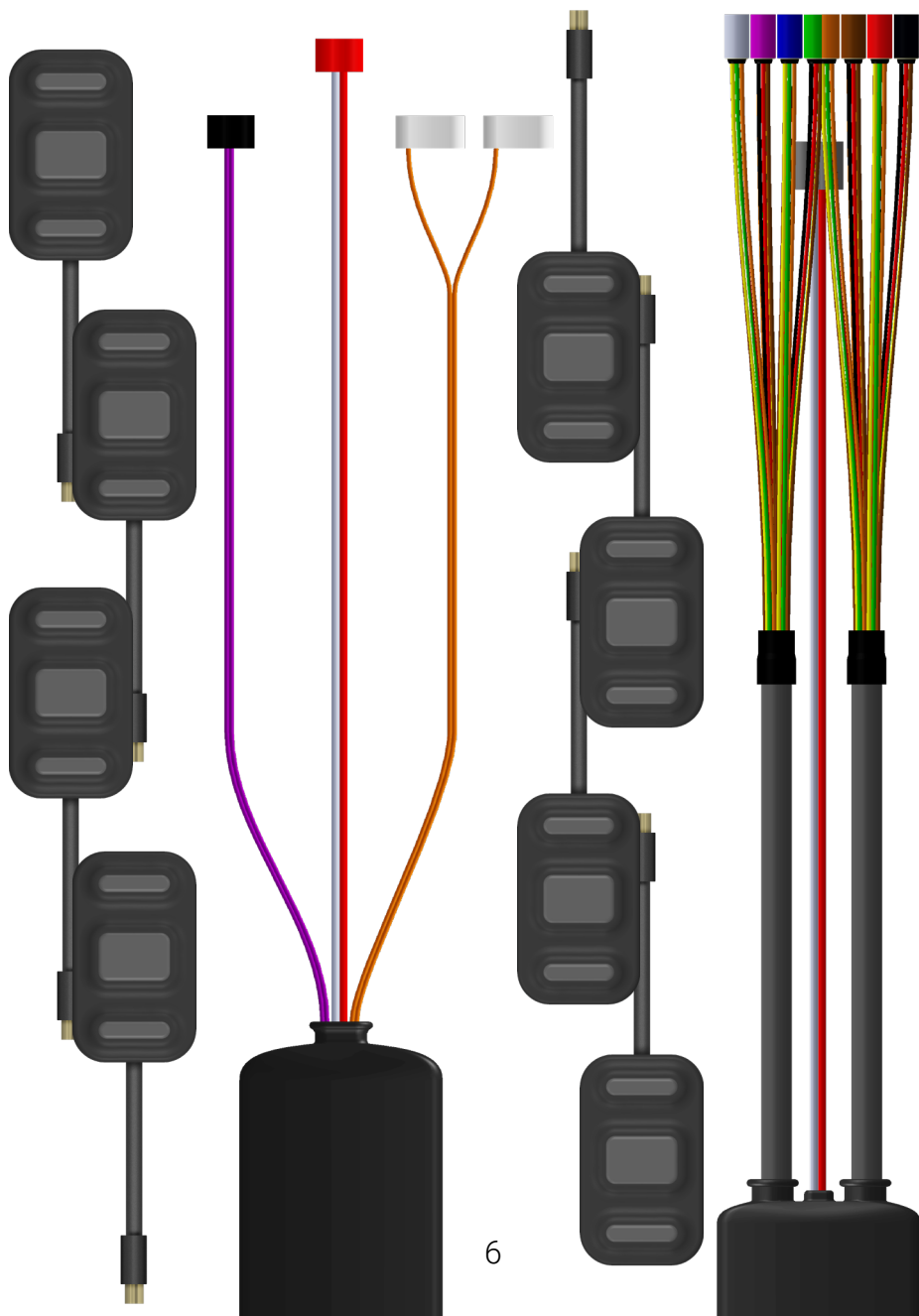
This device includes an RF transmitter or applies radio frequency electromagnetic energy.

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# 1 meet sense



The Sense system has three components:

- 8 IBT Electrodes
- Sense Controller
- Sense Graphic User Interface (GUI)

Sense should only be powered by FlexCell Batteries, unless specified. Sense outputs movement commands as a result of pattern recognition of signals from the IBT Electrodes placed on the user's skin. The Sense System is an alternative to standard direct control, with the advantages of intuitive control, more degrees of freedom, and self-adjustment. Sense does not replace or modify any functionality of connected prosthetic components.

Sense is compatible with most hands and elbows that accept standard analog EMG electrode inputs and motor-driven wrists and elbows. The Sense system is sold with output connections based on the prosthesis configuration. If you have a question about compatibility with other devices, please contact us.



The Sense system was developed for everyday use and must not be used for unusual activities. These unusual activities include, for example, sports with excessive strain and/or shocks to the wrist unit (pushups, downhill mountain biking) or extreme sports (free climbing, paragliding, etc.). Furthermore the Sense system should not be used for the operation of motor vehicles, heavy equipment (e.g. construction machines), industrial machines or motor-driven equipment.

## 2 component description

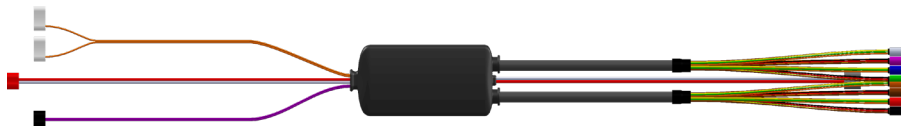
### IBT ELECTRODES

The electrodes detect and amplify raw surface electromyography (EMG) signals from the user's skin and digitize them. The electrodes plug into the Sense Controller for further processing.



### SENSE CONTROLLER

The Sense Controller collects, filters, and classifies the electrode EMG signals, and outputs movement signals to the prosthesis. The Sense Controller contains a Bluetooth module, which allows Sense to wirelessly communicate with the Sense GUI.



### SENSE GUI

The software interface allows the user to visualize their EMG signals, perform calibration of the Sense system, and train with a virtual prosthetic arm.



## 3 specifications

Dimensions (Sense Controller, box only, LxWxH)	59 mm x 27.8 mm x 9.8 mm
Dimensions (IBT Electrode LxWxH)	28.8mm x 16.8mm x 6.7mm
Weight (Sense Controller, 8 IBT Electrodes)	58g
Temperature range (use)	-10°C to +50°C (14°F to 122°F)
Temperature range (transport/storage)	-20°C to +65°C (-4°F to 149°F)
Humidity range (use)	45% - 75%
Humidity range (transport/storage)	15% - 93%
Atmospheric pressure range	860 hPa - 1060 hPa
Input voltage	5 to 10V
Maximum Output Current	3A
Compatible battery	FlexCell, Elbow Battery
Recommended battery capacity	Depends on terminal device. Contact us for recommendations.
Expected service life	3 years
Compatible electrode	IBT Electrodes
Bluetooth	FCC, IC, CE, RoHS, and Bluetooth® 4.0 Certified ISM 2.4GHz module

For FlexCell

Voltage Output	7.4V DC
Capacity Range *	550 mAh - 2200 mAh
Current Output	Up to 7A
Temperature range (use)	0°C to +49°C (32°F to 120°F)
Temperature range (transport and storage)	0°C to +49°C (32°F to 120°F)

\* Capacity range is dependent on how many FlexCell batteries are installed.

# 4 installation

## BEFORE YOU BEGIN

### Included in the Package

- Sense Controller
- IBT Electrodes
- Molding dummies for IBT Electrodes
- Molding dummy for Sense Controller
- FlexCell batteries (if ordered with Sense)
- Microsoft Surface with Keyboard and Charger

### What You'll Need

- FlexCell batteries (if not ordered with Sense)
- Devices specified during ordering

### Terminal Devices That Have Been Tested For Compatibility With Sense

Hands		Wrists	Elbows
SensorHand Speed *	bebionic small	Motion Control Standard Wrist (5010045, 54, 55) <sup>1</sup>	ErgoArm Hybrid Plus (12K44) *
MyoHand VariPlus Speed *	i-limb access *		Boston Digital Elbow <sup>2</sup>
ProHand *	i-limb ultra *		Utah Arm U3+ <sup>3</sup>
ProETD	i-limb ultra revolution *	Ottobock Standard Wrist (10S17)	Motion E2 Elbow <sup>4</sup>
Steeper MyoHand *	i-limb quantum		Espire Elbow Pro/Hybrid
bebionic3 *	Taska Hand	AxonRotation	AxonArm Ergo
	Michelangelo Hand		

<sup>1</sup>If using bebionic or TASKA Hand with direct grip control, wrist requires adaptation - Motion Control P/N 3010869

<sup>2</sup>BE300TMR & BE304-A

<sup>3</sup>5010039, 40, 41 with 3010677 upgrade

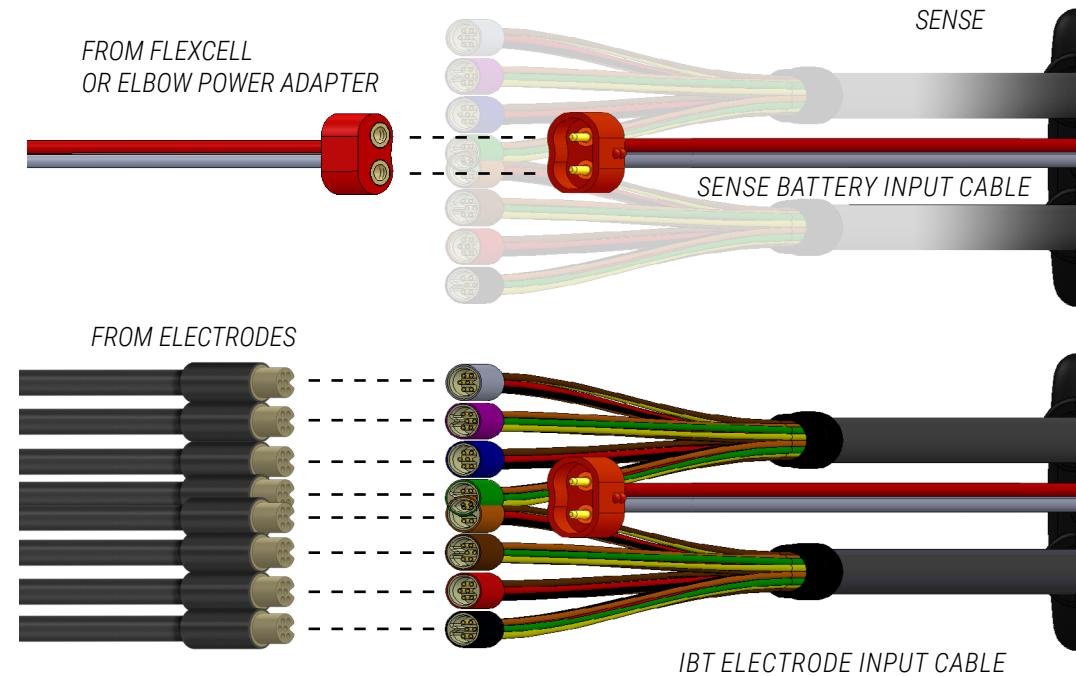
<sup>4</sup>5010094 through 5010101

\* These devices have not been tested with Sense and are likely to be compatible based on similar input requirements.

## CONNECTING IBT ELECTRODES AND BATTERIES



WARNING: Turn the battery OFF before plugging in any cables. Do not attempt to connect the battery or electrodes in a way that is not specified. This could cause permanent damage to Sense, the battery or electrodes.

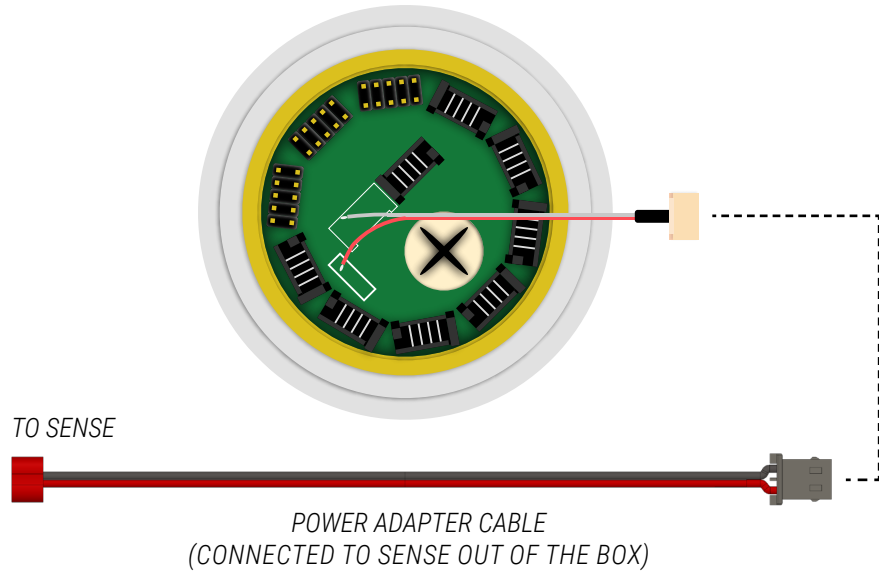


Plug the FlexCell power output cable into the Sense battery input cable. Match the connector orientation in the image above. The power connector is keyed for easy insertion in the correct orientation. Check connector orientation if it is difficult to plug in the power connector.

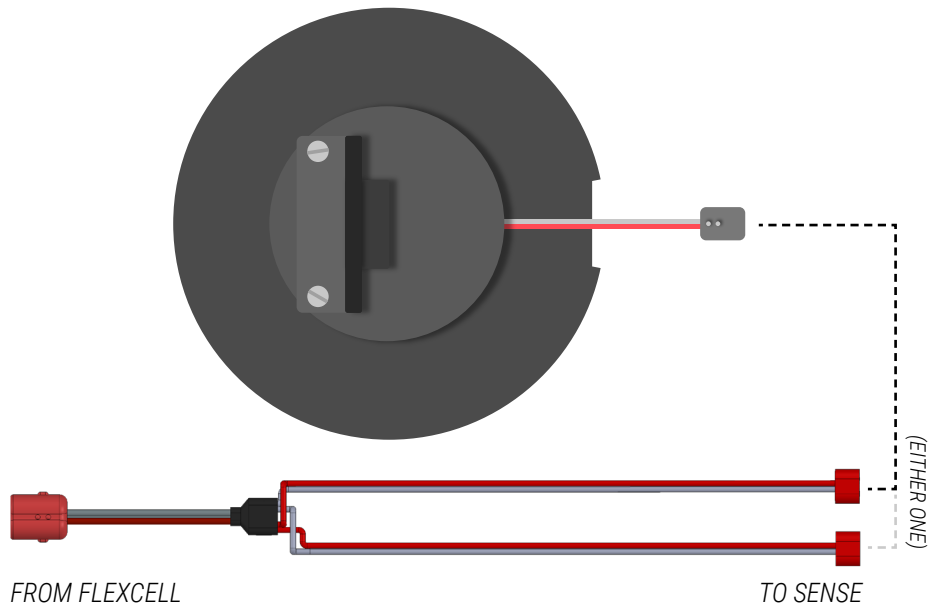
\*Note: Power connections vary for the Boston and U3+ elbows. Please see the next page for more details

Securely plug each of the IBT Electrodes into the electrode input cables on the Sense controller. You can place heat shrink over this connection if needed; however care should be taken to ensure that some part of the colored heat shrink already present on the Sense input cables should be visible. It does not matter which electrode is plugged into which input cable.

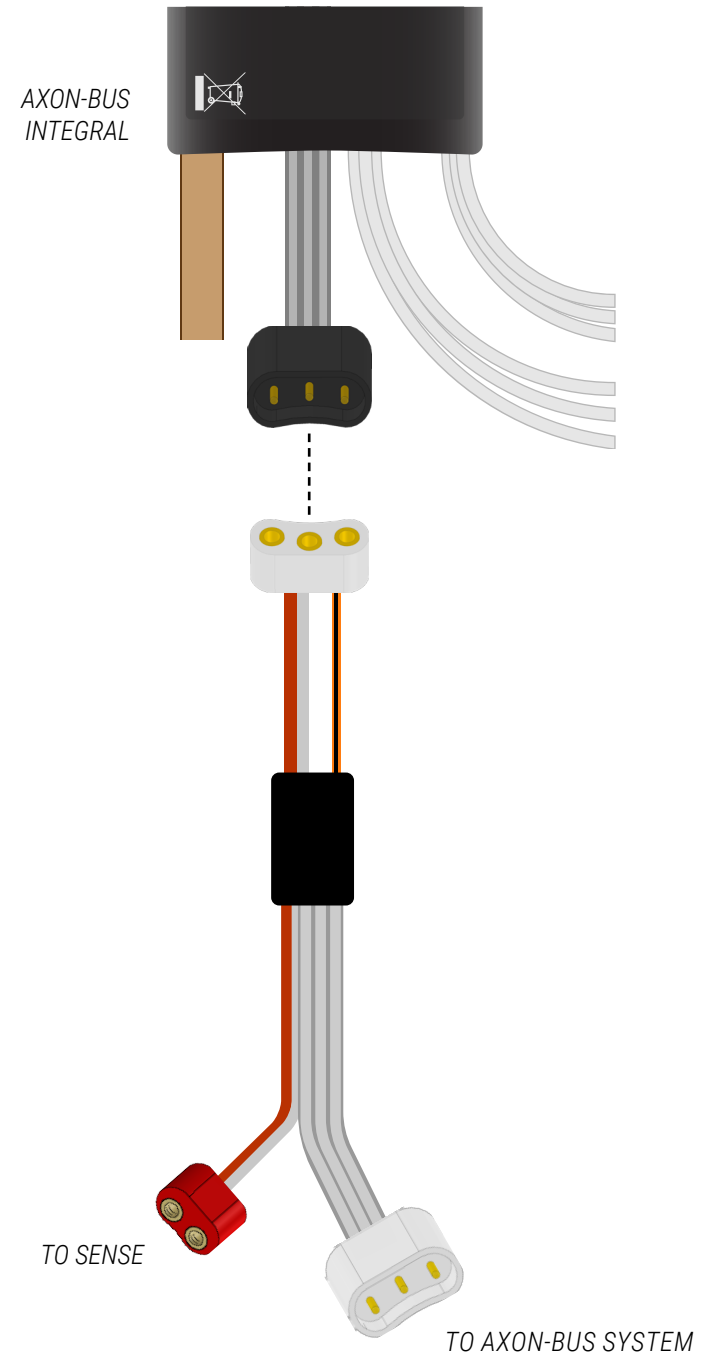
### Boston TMR Elbow



### Motion Control U3+ Elbow



### Axon-Bus System



## POWERING SENSE WITH FLEXCELL

This section is intended to familiarize you with FlexCell operation. If you have used FlexCell before, you may skip to the next section.

### Turning FlexCell On and Off

To turn on FlexCell, press and hold the charging port button for 3 seconds. The seven LEDs will illuminate around the button in a clockwise direction and flash twice. To turn off FlexCell, press and hold the charging port button for 3 seconds. The seven LEDs will illuminate around the button in a counter-clockwise direction.

### Checking Battery Capacity

Briefly press the charging port button to check the battery charge level. The number of LEDs that turn on out of seven provide an indication of capacity. The LEDs will blink when the system is turned off and hold on when the system is turned on.

**Note:** After plugging in the batteries or removing the charger, wait a few seconds before checking the remaining capacity.

**Note 2:** If Sense is connected to a U3+ elbow, press the lock button on the elbow joint after powering on Sense and elbow.

**Note 3:** If Sense is connected to an Espire Pro / Hybrid elbow, make sure to power on the elbow **before** powering on Sense.



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## INCORPORATING IBT ELECTRODES INTO SOCKET

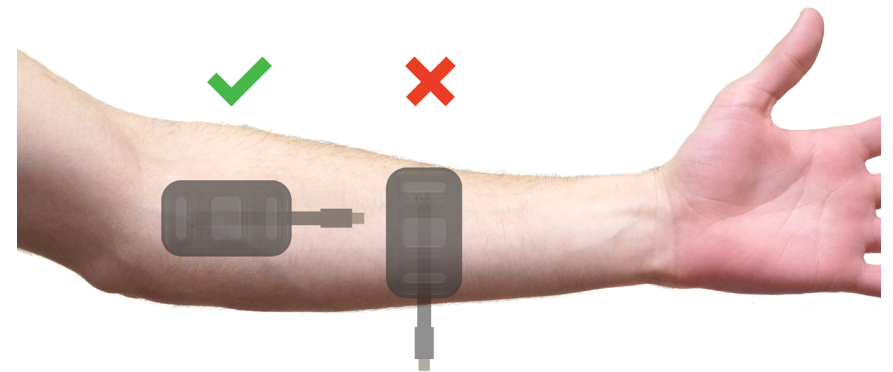
### Selecting Ideal Electrode Sites

Site selection for pattern recognition is different than that for direct control. Cross-talk between electrodes is acceptable, and even encouraged.

Before selecting sites, connect to the Sense Graphic User Interface. See "Sense GUI" section for more information.

Tips for IBT Electrode placement:

- To decrease electrode settling time, prepare skin by moistening with rubbing alcohol (IPA, Isopropyl Alcohol) or water before placing the electrode.
- Set electrode gains to 4 while finding sites. Increase as necessary.
- During site selection, IBT Electrodes can be secured to the limb using a sweatband, medical tape, or other elastic bands. Make sure to orient the electrode so the contacts are perpendicular to the muscle fibers, as pictured.



NOT TO SCALE

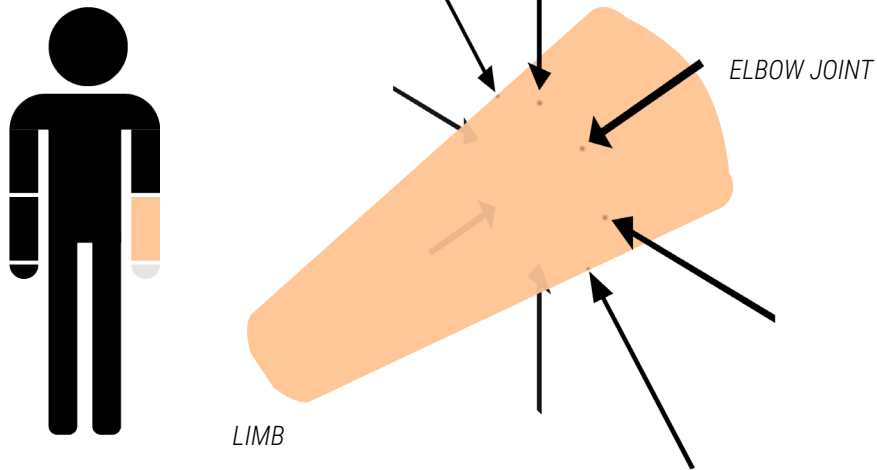
### Transradial Prostheses

Place electrodes circumferentially around the limb with equal distance between them near the proximal end of the residual limb (see figure). Avoid bony areas. Have patients attempt movements with their phantom limb, including "open", "close", "pronate", and "supinate". Increase gain on each electrode as needed.

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**ELECTRODE ARRANGEMENT:  
TRANSRADIAL**



Each electrode should have signal for at least one movement. If this strategy does not yield signal on an electrode for any movement, first try rotating the placements slightly, making sure no electrodes fall over bony parts, or try moving the electrodes along the axis of the residual limb. If the issue persists, follow the guidance laid out for transhumeral prostheses.

**Transhumeral Prostheses**

Transhumeral residual limbs generally require more specific site location. Ask the user if they feel any phantom limb movements in particular locations on their residual limb. Palpate the limb while asking the user to attempt movements with their phantom limb, including "open", "close", "pronate", "supinate", "elbow flexion" and "elbow extension". Look for the following properties of signals when determining sites for Sense:

- Ideal locations exhibit high signal strength for 1-2 different movements and lower signal strength for any number of other movements.
- Each electrode should activate to some degree for at least one movement.
- No electrode should activate at medium-high strength for all movements.

**ELECTRODE ARRANGEMENT:  
TRANSHUMERAL**



*ELECTRODE ARRANGEMENT EXAMPLE*

Once ideal muscle sites have been found, mark them temporarily on the residual limb and make note of them on a check socket, a plaster cast or other limb model before proceeding to the remaining fabrication steps. The table below provides key points for identifying good electrode sites:

Good Sites	Poor Sites
<ul style="list-style-type: none"> <li>• Medium activation for 1-2 movements and lower amplitude for others</li> <li>• Are not identical to other electrode sites in their activation pattern</li> <li>• Do not have the same strength for all movements</li> </ul>	<ul style="list-style-type: none"> <li>• On bony prominences</li> <li>• On skin with thin tissue (will cause sores)</li> <li>• In areas where the tissue will pull away from the socket</li> <li>• In areas where there may be gapping between the skin and the socket in different arm orientations</li> </ul>



WARNING: Ensure IBT Electrodes are placed only on intact skin.

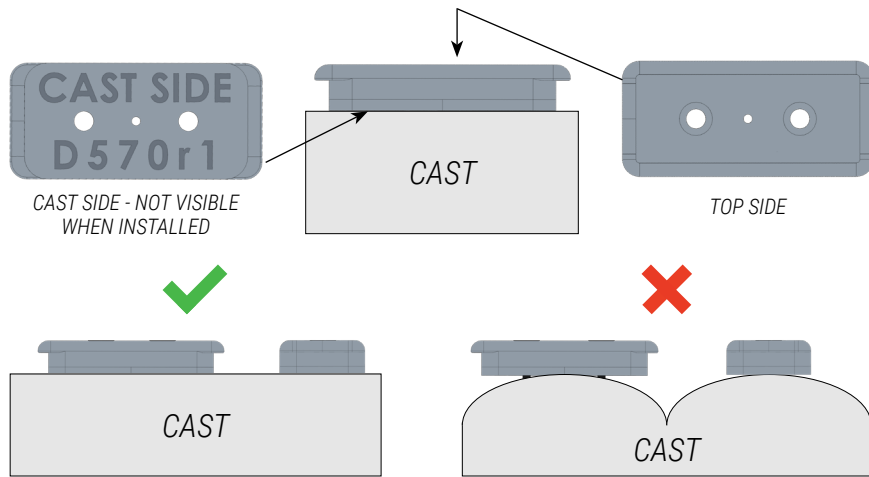


WARNING: After removing the prosthesis, always check for skin irritation and pressure sores under the electrode sites. If irritation is present, discontinue the use of the prosthesis until the skin is healed and check if socket adjustments are necessary to alleviate pressure.

## Fabricating Electrodes into the Inner Socket

Once electrode sites have been marked on the plaster cast, place the electrode dummies on the cast and check to make sure they lay flat against the plaster surface. Make sure the surface of the electrode dummy marked "CAST SIDE" is placed against the plaster cast (see image).

The figure shows the dummy with the cast side in the correct orientation, and the dummy lying flat on the cast surface



If the electrode dummy does not lay flat on the plaster surface, mark an outline of the electrode, remove the dummy and sand down the surface inside and near the outlined mark. Clear the area of debris and place the electrode dummy again.

Note 1: The electrode is designed to properly seal only on flat surfaces. If the area is not flat, the electrode will not seal completely.

Note 2: Make sure that the side of the dummy without the extended edges is in contact with the cast, as shown.

Secure 2 of the nails provided (14ga or 15ga standard nails, roughly 1/2" long) through the two holes in the electrode dummy to the cast. Alternatively, you may use thin double stick tape to secure the dummy to the surface of the cast.

We strongly recommend using one of the techniques below to ensure the plastic is drawn around the dummy uniformly:

- When creating the cast, use a parachute string or straw that runs from the location of the dummy to the proximal end of the plaster. This creates an air channel from the proximal end to the dummy.
- After forming the cast, drill a hole into the plaster under each dummy to the center rod of the cast.
- Use a balloon on the cast and poke pin holes in the balloon around the dummy to allow airflow.

## Inner Socket Fabrication

IBT Electrodes are designed to fit in a self-retaining pocket that is formed into the inner socket using the provided electrode molding dummies. The same dummies can be used for vacuum-forming thermoplastic inner sockets and rolled silicone inner sockets. The following instructions go over standard methods for both material types.



**Socket fit is imperative to successful pattern recognition control.**

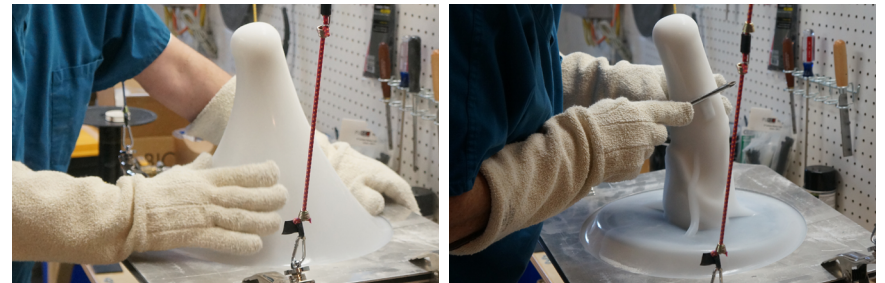


**WARNING:** Do not use the actual Sense Controller and IBT Electrodes during the socket fabrication and lamination process, as it will damage these components. Please use the provided dummies instead.

## Inner Socket Fabrication - Thermoplastic

Place the cast with the installed dummies in the vacuum setup. Tie the base down.

Place hot material over the positive plaster while applying vacuum. Press around the edges of the electrode dummies to ensure the material has formed around all the overhanging edges of the electrode dummy.

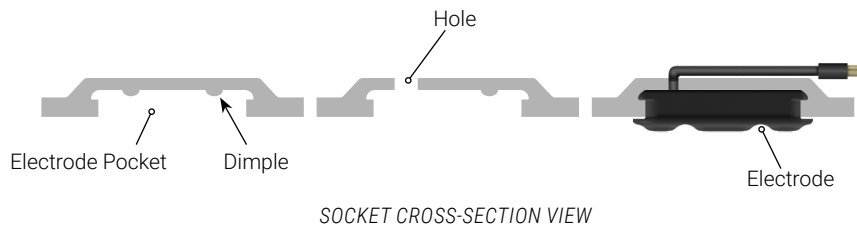




Cut away excess plastic around the socket.

Remove the socket from the plaster cast. When the cast and electrode dummies are removed, the nail holes will leave two dimples in the electrode pocket. These dimples will not interfere with the seating of the electrode. Use one dimple as a guide for a wire exit hole - use a 7/32" or 5.6mm drill bit to create a hole for the electrode cable.

Smooth and/or bevel the hole to prevent cable damage.



We highly recommend **5mm (minimum)- 8mm** soft plastics such as:

- Silicone ProFlex
- Northvane
- OP-TEK Flex

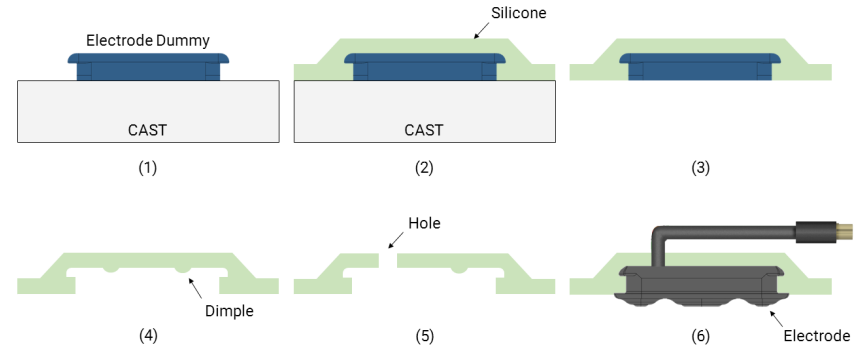
If you plan to use a thicker plastic, we recommend applying heat around the dummy after setting the plastic to ensure the plastic molds tightly around the dummy.

**Important:** Do not heat material for too long or at too high of a temperature. The material will become thin during vacuum forming and will need to be redone.

## Inner Socket Fabrication - Silicone

While building up the silicone over the cast, apply a higher durometer around the electrode dummies, making sure to press the material fully underneath the extended edges of the dummy. We recommend between 50 and 80 Shore A durometer around the electrodes.

If you are creating a suction socket, ensure there is a silicone layer about 2mm thick over the entire back of the electrode dummy. Taper the material on all sides of the dummy down to the cast.

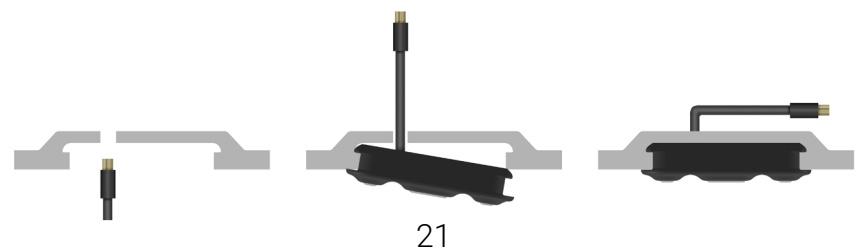


Finish the socket by blending the rest of the material around the edges of the harder material and allow it to cure normally.

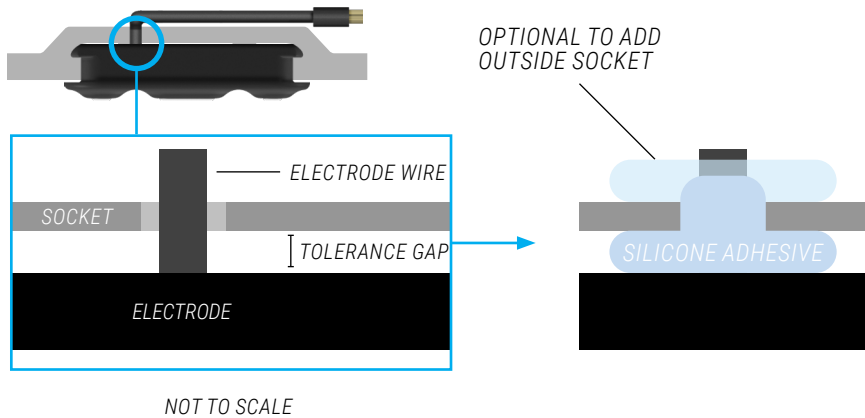
When the material is fully cured, remove the cast. There will be two dimples left from the nail holes. Either of these can be used to align the holes for the cable exit, as the electrode is symmetrical. Use a 7/32" (5.6mm) punch or drill bit to make the hole for the cable exit or cut a slit into the back of the pocket at the location of one of the nail hole dimples.

## Installing the Electrode Into the Inner Socket

Insert the cable into the hole in the inner socket and pull fully through. Align the electrode with the pocket and push on the contact surface to snap it in.



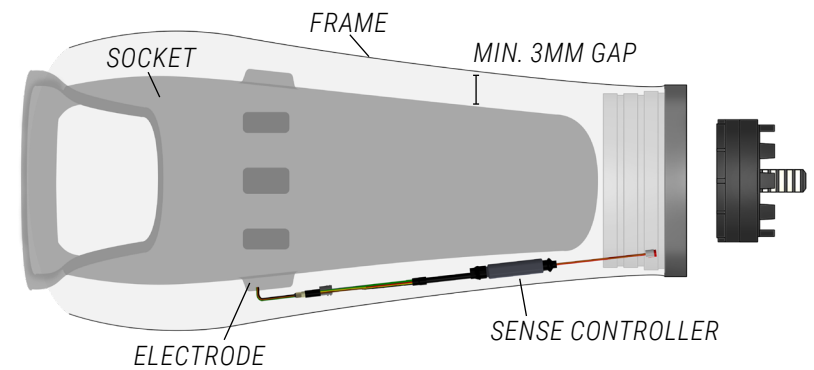
Note: If a suction socket is being created, completely sealing the electrode cable exit helps maintain consistent suction. The cable exit can be sealed with the provided silicone adhesive. To seal the cable exit with silicone adhesive, apply a dime-sized amount of it to the back of the electrode and about 5mm up the cable protruding from the electrode. Do this before snapping the electrode into the pocket. Wait 15-20 minutes for this to dry before testing suction.



## Outer Frame

Do not mold the outer frame directly around the inner socket. **Leave 3mm (around the thickness of a 3-ply sock) between the inner socket and frame to ease assembly and avoid cable damage.** Use the dummy for the Sense controller provided with the system to make sure there is sufficient space in the prosthesis. Otherwise, create the outer frame using standard fabrication techniques.

Note: Place the Sense box near the distal end of the prosthesis for best Bluetooth performance.



*The socket harness or suction mechanism must be well constructed to prevent electrode slip and the need for constant recalibration.*

# INSTALLING SENSE INTO THE PROSTHESIS

Sense has the following electrical output characteristics:

- EMG Signal (5V Envelope)
- Sense is a pass-through for the battery, therefore output voltage matches input battery voltage (5-10V)
- Motor Driver Output (matches input battery voltage)

All terminal devices that accept the aforementioned electrical outputs should be compatible with Sense. For a list of terminal devices that have been tested with the Sense system please refer to page 10 of the user manual and contact IBT for an up-to-date list of all compatible devices that have been tested.

Now that the electrodes and battery are connected, insert Sense through the proximal end of the prosthesis.



**WARNING:** For all setups below, ensure the battery is OFF before plugging in any cables. Do not attempt to connect the Sense output cables in a way that is not specified. This could cause permanent damage to the prosthesis and Sense.

## Connecting to the terminal device, wrist, and elbow

The following are the connections to some of the commonly used prosthetic devices. For connections to all other devices, contact IBT.

\* Data cable availability is device-dependent

Sales P/N	Refer to Sections	Connectors							
		Analog Data Cable (Orange)	Digital Data Cable (Purple)	Wrist Motor Driver	Elbow Motor Driver	Boston Elbow Cable Assembly	U3+ Cable Assembly		
70101-1-1	2	✓	✓						
70101-1-2	2	✓	✓						
70101-1-3	1	✓							
70101-2	1	✓							
70101-3-1	4	✓	✓	✓					
70101-3-2	4	✓	✓	✓					
70101-3-3	3 or 4	✓		✓					
70101-4	3 or 4	✓		✓					
70101-5	4	✓	✓*	✓					
70101-6	2	✓	✓*						
70101-7	3 or 4	✓		✓					
70101-8	1	✓							
70101-9-1	4 and 5	✓	✓	✓	✓				
70101-9-2	4 and 5	✓	✓	✓	✓				
70101-9-3	3 or 4, and 5	✓		✓					
70101-10-1	2 and 5	✓	✓		✓				
70101-10-2	2 and 5	✓	✓		✓				

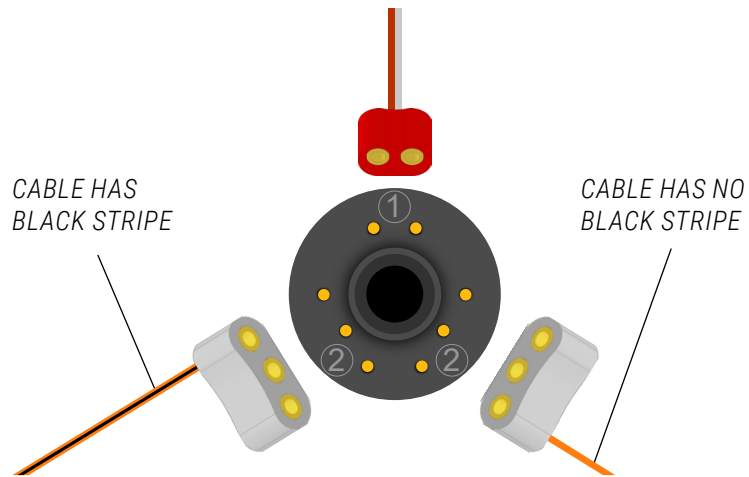
\* Data cable availability is device-dependent

Sales P/N	Refer to Sections	Connectors						
		Analog Data Cable (Orange)	Digital Data Cable (Purple)	Wrist Motor Driver	Elbow Motor Driver	Boston Elbow Cable Assembly	U3+ Cable Assembly	Espire Elbow Assembly (Pro/Hybrid) **
70101-10-3	1 and 5	✓			✓			
70101-11	3 or 4, and 5	✓		✓	✓			
70101-12	1 and 5	✓						
70101-13	Power Input, and 7					✓		
70101-14	Power Input, and 6						✓	
70101-17-1	8							✓
70101-17-2	8							✓
70101-18-1	8							✓
70101-18-2	8							✓
70101-19	8							✓
70101-20	8							✓
70101-21	Power Input, and 9	✓						
70101-22	Power Input, and 9	✓						
70101-23	Power Input, and 9	✓						

Sales P/N	Refer to Sections	Connectors						
		Analog Data Cable (Orange)	Digital Data Cable (Purple)	Wrist Motor Driver	Elbow Motor Driver	Boston Elbow Cable Assembly	U3+ Cable Assembly	Espire Elbow Assembly (Pro/Hybrid) **
70101-24	Power Input, and 9	✓						

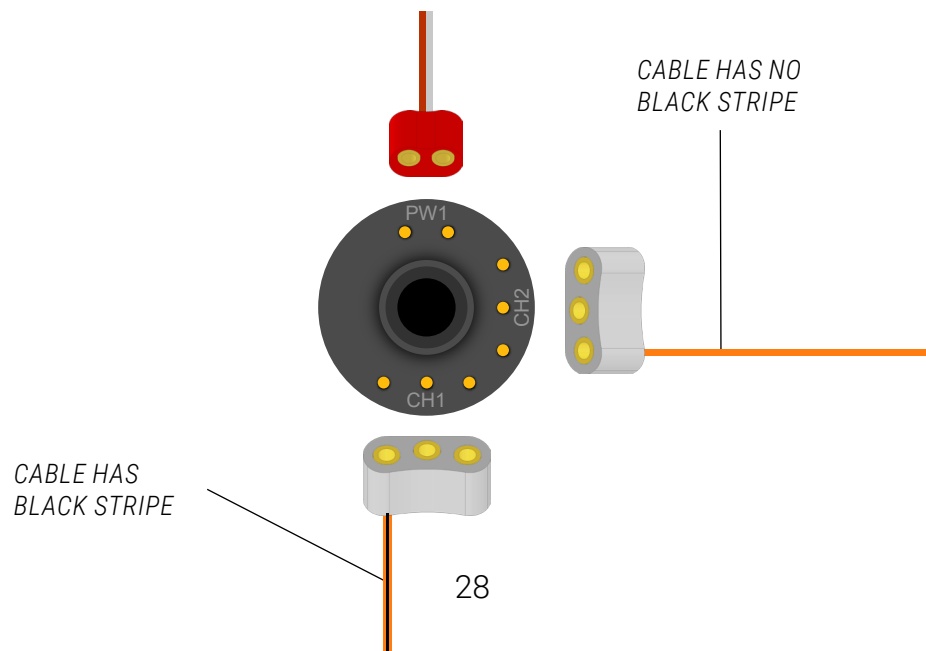
## 1 - Four-Band Coaxial Plug Only (Steeper/OB)

1. Plug the red power output cable into the pins labeled '1'
2. Plug the orange output cables into the pins labeled '2' as shown



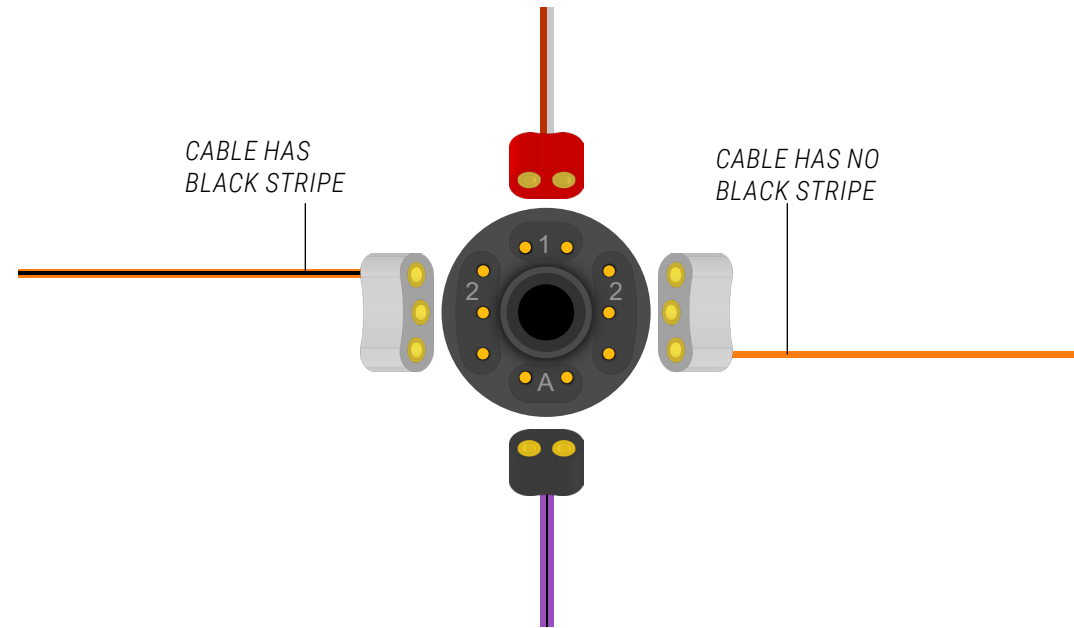
## Four-Band Coaxial Plug Only (Össur)

1. Plug the red power output cable into the pins labeled 'PW1'
2. Plug the orange output cable **with** the black stripe into the pins labeled 'CH1', and the orange output cable *without* the black stripe into the pins labeled 'CH2'.



## 2 - Six-Band Coaxial Plug Only (Steeper/OB)

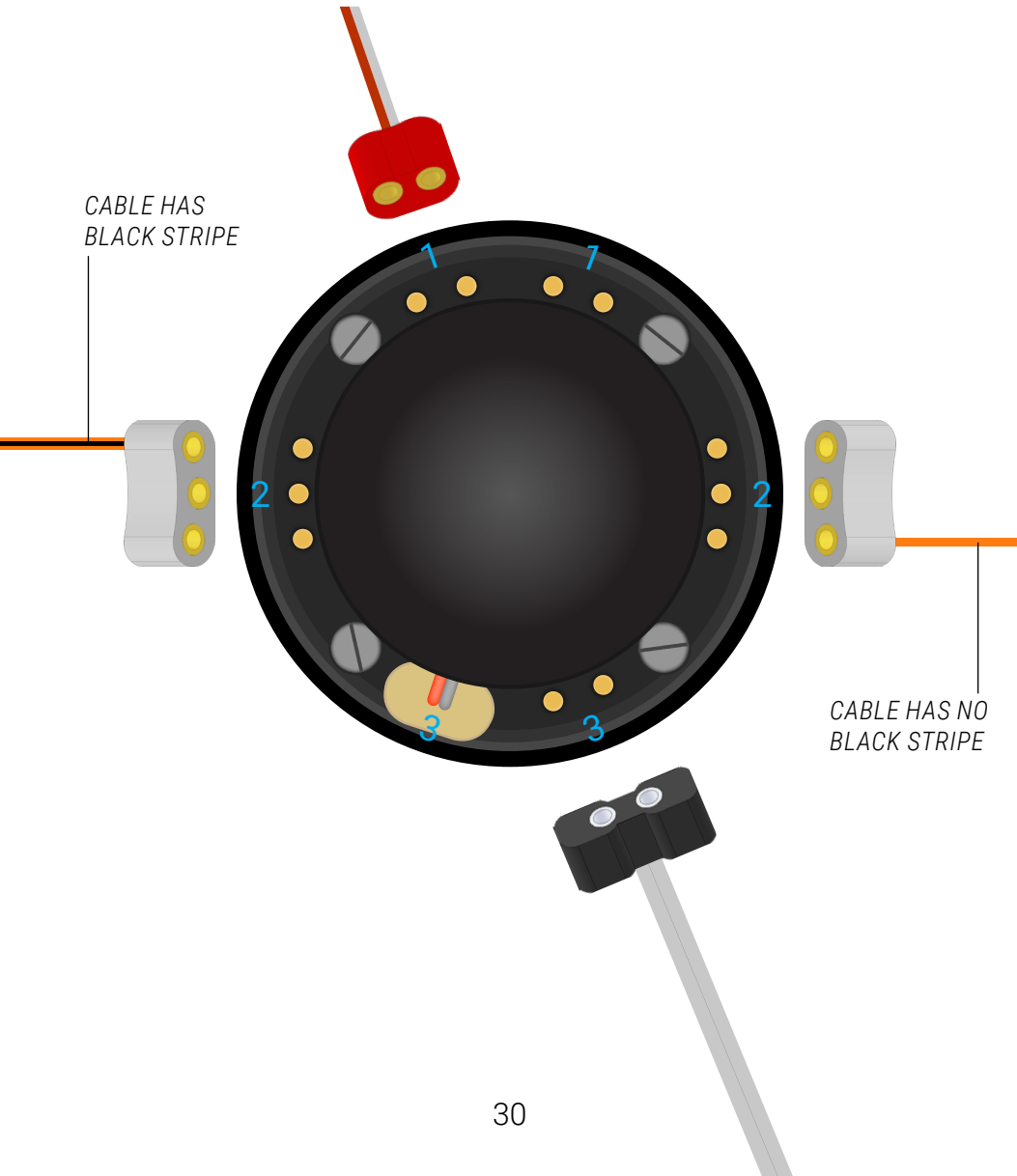
1. Plug the red power output cable into the pins labeled '1'
2. Plug the orange output cables into the pins labeled '2' as shown
3. Plug the purple output cable into the pins labeled 'A' as shown



WARNING: Do NOT reverse red power and purple output cable. This will damage the hand and Sense.

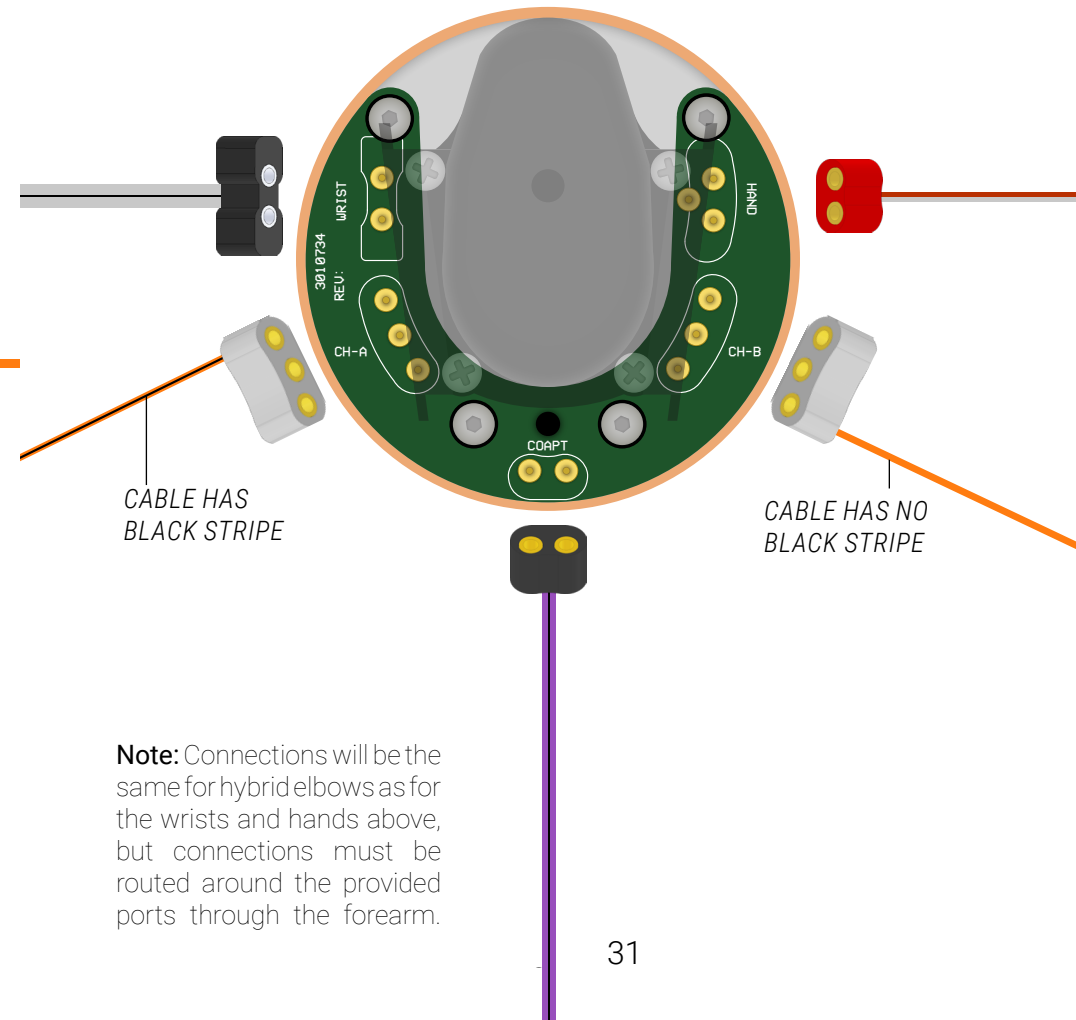
### 3 - Ottobock 10S17 Wrist

1. Plug the orange output cables into the pins labeled '2'
2. If needed, plug the factory provided motor connection into the left pins labeled '3' as shown.
3. Plug the gray figure-8 connector into the right pins labeled '3' as shown. This connection is reversible.
4. Plug the red power output cable into the left pins labeled '1'



### 4 - Motion Control Standard Wrist

1. Plug the orange output cable with the black stripe into the pins labeled 'CH-A'
2. Plug the orange output cable with no stripe into the pins labeled 'CH-B'
3. Plug the gray figure-8 connector into the pins labeled 'Wrist'. This connection is reversible.
4. Plug the red power output cable into the pins labeled 'Hand'
5. Optional: If using communication with bebionic or TASKA Hand, plug the purple output adapter cable into the pins labeled 'CoApt' (for wrist upgrade MC3010869)

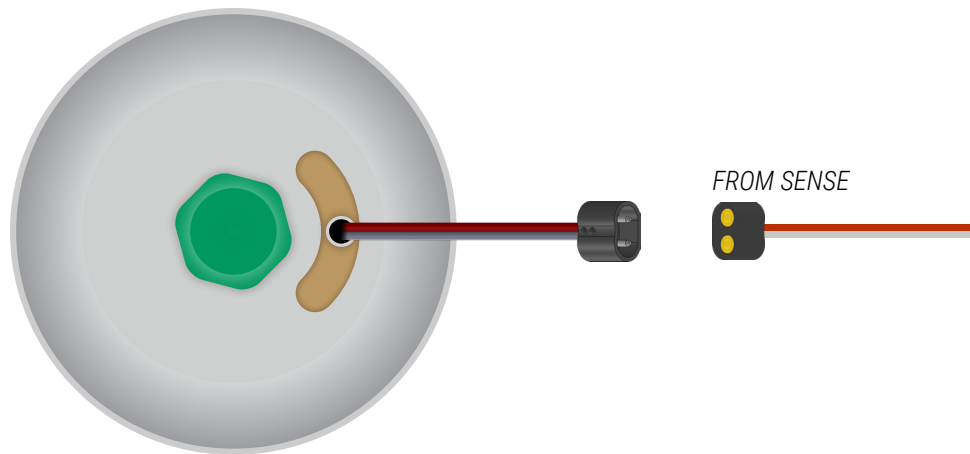


**Note:** Connections will be the same for hybrid elbows as for the wrists and hands above, but connections must be routed around the provided ports through the forearm.



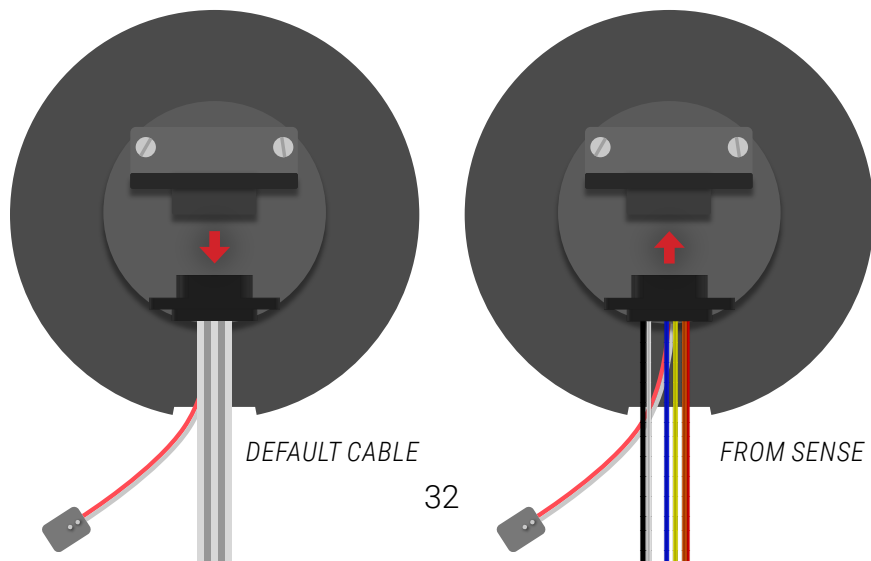
## 5 - E2 Elbow

1. Route cables for hand input, hand power and wrist input through the forearm.
2. Use connections as shown in the previous sections depending on wrist and terminal device components.
3. Connect Sense to E2 elbow as shown below



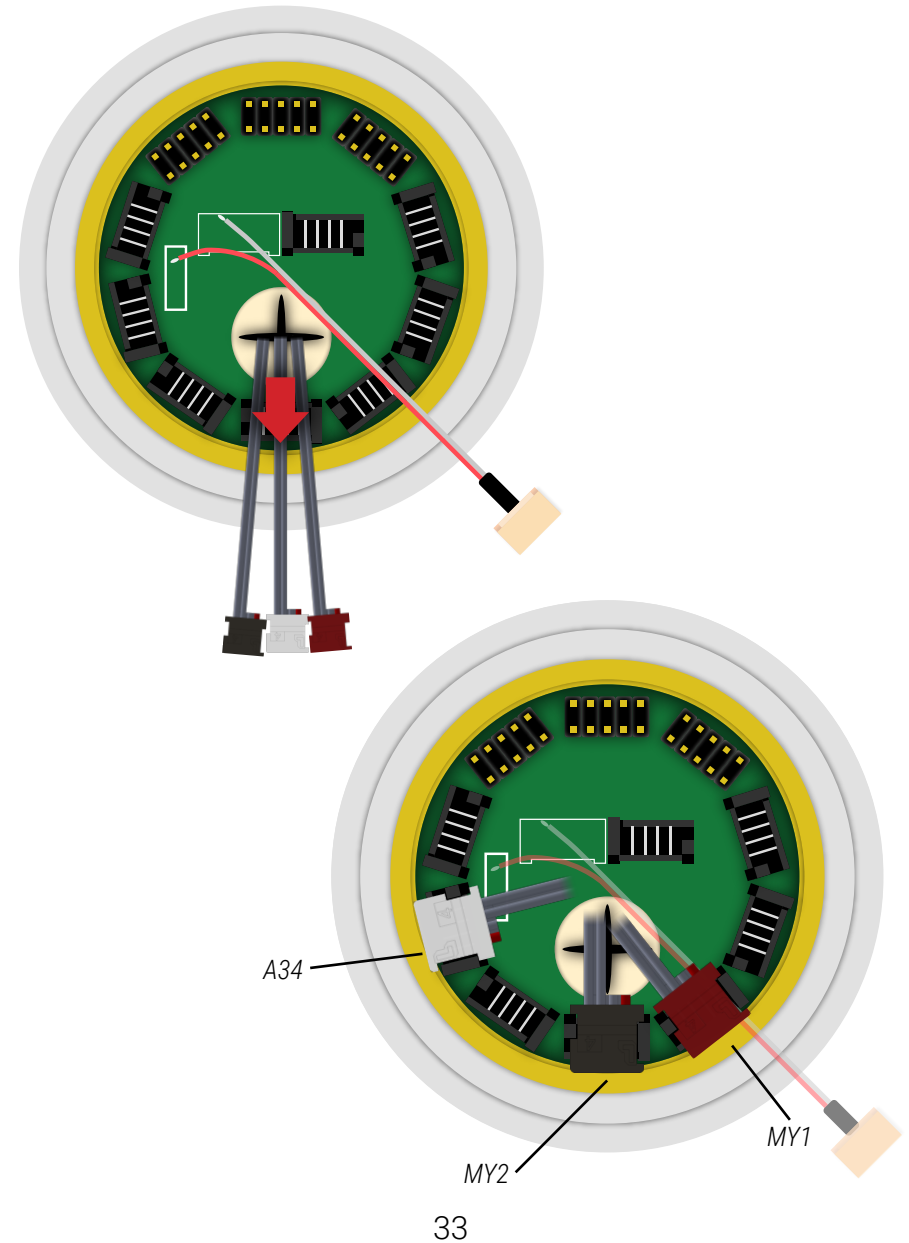
## 6 - U3+ Elbow

1. Unplug the provided 21-pin block connector from the elbow.
2. Plug the 21-pin block connector attached to Sense into the elbow



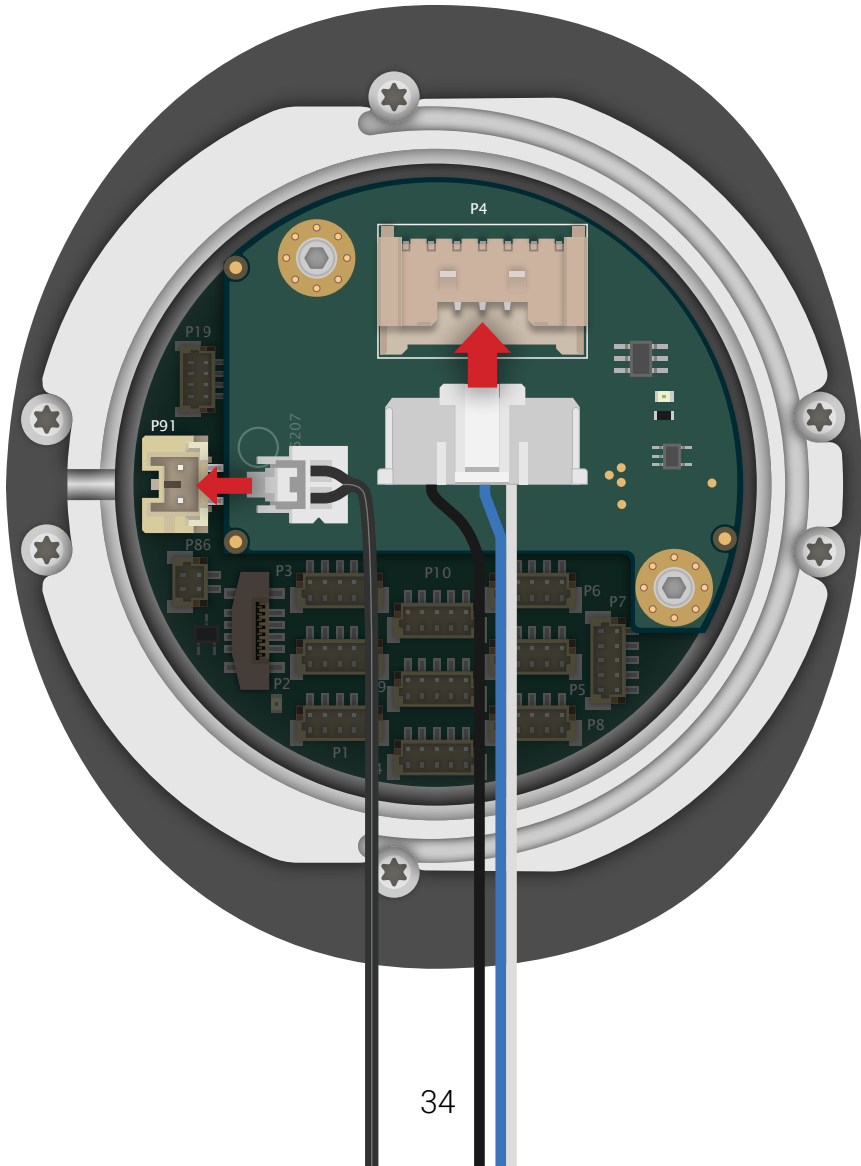
## 7 - Boston TMR Elbow

1. Push the 3 square connectors through the diaphragm of the electrode input board
2. Plug the 3 connectors as shown into their respective connectors – red stripe to MY1, black stripe to MY2, silver stripe to A34



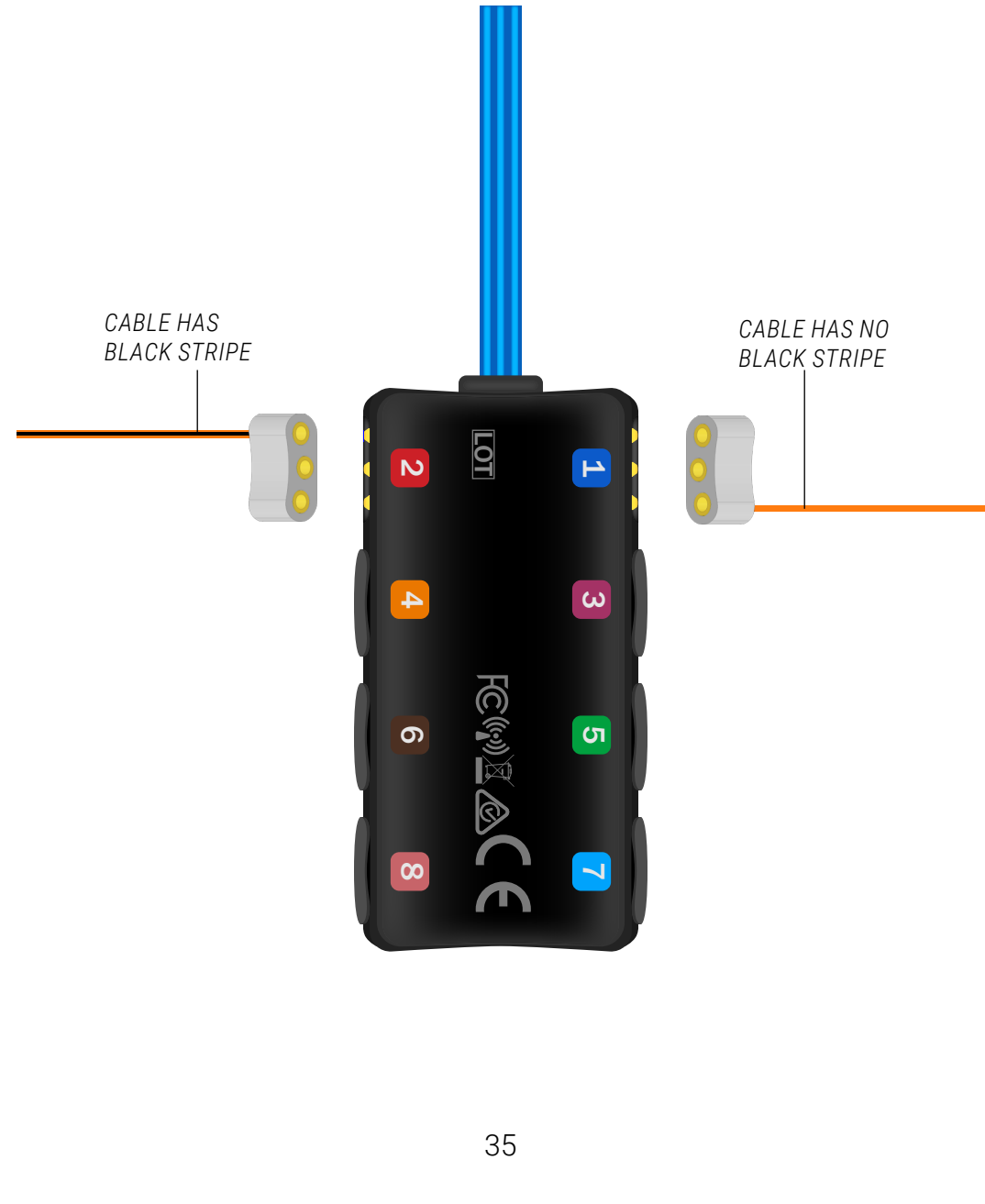
## 8 - Espire Elbow Pro / Hybrid

1. Push the white rectangular connector into the beige port on the upper data board.
2. Optional: If using a Hand with direct grip control, plug the black output adapter cable into the two-pin beige connector P91 on the lower board.



## 9 - Michelangelo, Axon System

1. Plug the orange output cable with the black stripe and combined red/gray cable to Channel 2 of the Axon bus as shown
2. Plug the orange output cable without the black stripe to Channel 1 of the Axon bus as shown



## 5 testing sense

Please test the Sense system before fitting the patient with the prosthesis. Connect all electrodes, prosthesis components, and FlexCells. Power on Sense. It will vibrate twice and then once more after initialization. Connect to the Sense software and view the signals by tapping each electrode contact with your fingertip. You should observe peaks generated every time you tap an electrode contact.

Navigate to the Calibration Setup page and click on the Test button (see software descriptions below). When pressing buttons associated with certain movement, observe if the terminal device, wrist and elbow respond as expected (i.e. wrist supinates after button is pressed). Reverse output cables if the movements are backwards.

If the Sense does not vibrate, peaks are not seen, or the components are not reacting, confirm that all cables are securely connected to the Sense controller and all the other prosthetic components.



**Note:** The patient must first use the device in the presence of a trained practitioner.

## 6 sense GUI

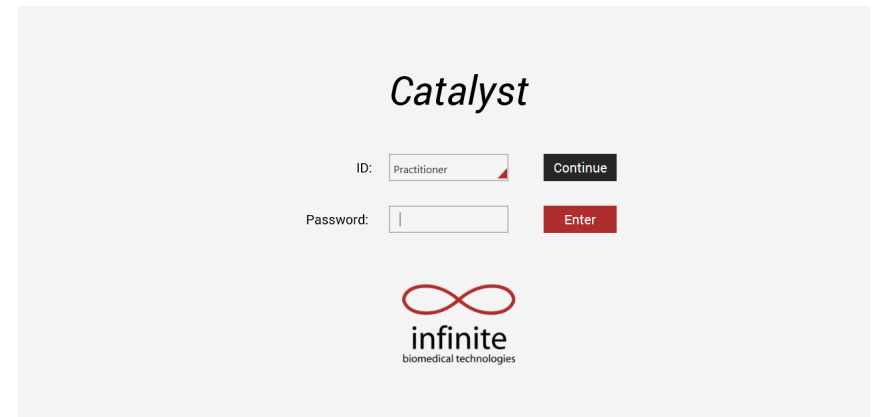
### CONNECTING SENSE TO SOFTWARE

#### Connecting the Sense System to the Sense GUI

The Sense system should already be paired to the Microsoft Surface. Open the Sense GUI.

A Login screen will appear. Select the "Practitioner" ID and type "Sense2017" (no quotations) as the password. Press Enter.

Note: Practitioner's accounts will have several options available that will not be present for Client accounts. Further on these options will be marked with "Practitioner Only".

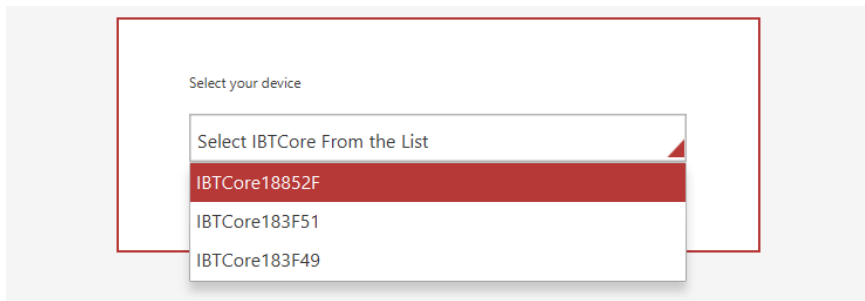


#### Bluetooth Connection

The User Interface will automatically begin searching for Bluetooth devices.

A window will appear listing all available devices. Select the name of the Sense system provided with your order from the list (IBTCoreXXXXXX) and click OK.

**Note:** Sense cannot connect to Catalyst or the IBT App while an attached TASKA Hand is connected to TASKA's HandCal Clinician software. Please close HandCal Clinician before connecting to Sense.



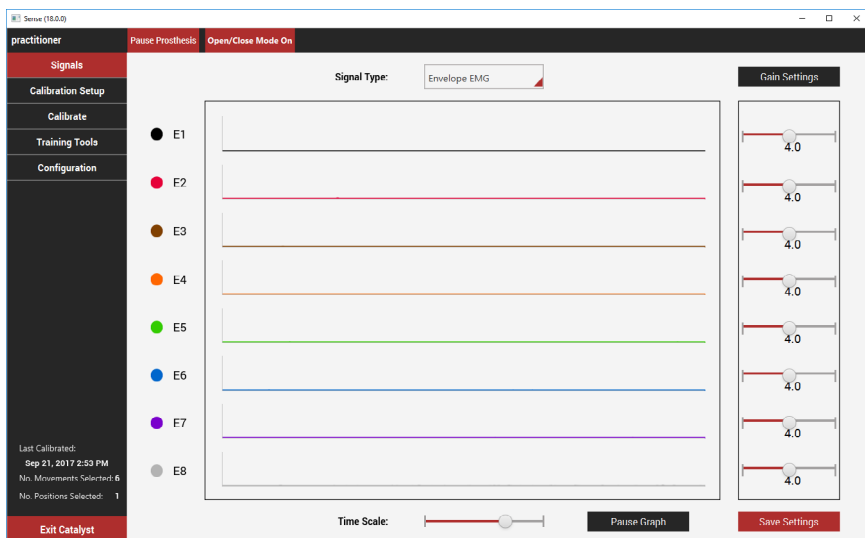
Note: For subsequent uses with the **same** Sense device, you will not need to repeat this step. You will only need to repeat this step if (1) if you're using a different Sense system (i.e. for a different patient); (2) you switch to another computer; or (3) you try to connect to your device while it is off.

**Note:** Please ensure that only one Sense is powered on at a time when connecting it to the software.

## Signals Screen

After successful connection, the default page you see will show you the signals from IBT electrodes. The color coding in the signal viewer corresponds to the colors of the electrode input cable connectors. Here, you can:

- Make sure all electrodes are functioning correctly,
- Check for signal noise
- Verify that the patterns across the electrodes are different



The signals screen has numerous buttons for adjusting the signals and the viewing options. A detailed description of each button's function is given below.

## Pause Graph

The Pause Graph button freezes the plot traces on the signals screen in Sense GUI. Press it again ("Play Graph") to restart.



## Time Scale

Moving the slider tool to the left decreases the time window that signals are displayed for. Moving the slider to the right increases the time window.

## Signal Type (Practitioner Only)

The dropdown menu at the top of the page allows you to switch between viewing raw and envelope signals. The pattern recognition algorithm uses raw signals as the input data for the algorithm. Envelope signals allow for easier visualization of electrode activation especially for electrode site location.



### Adjusting Gains (Practitioner Only)

On the right side of the Signals screen there are sliding selection tools for each electrode. The gains of all active electrodes can be set to a value in the range of 1 to 7. To change the gains, drag the slider button left or right to adjust the gain for each electrode.



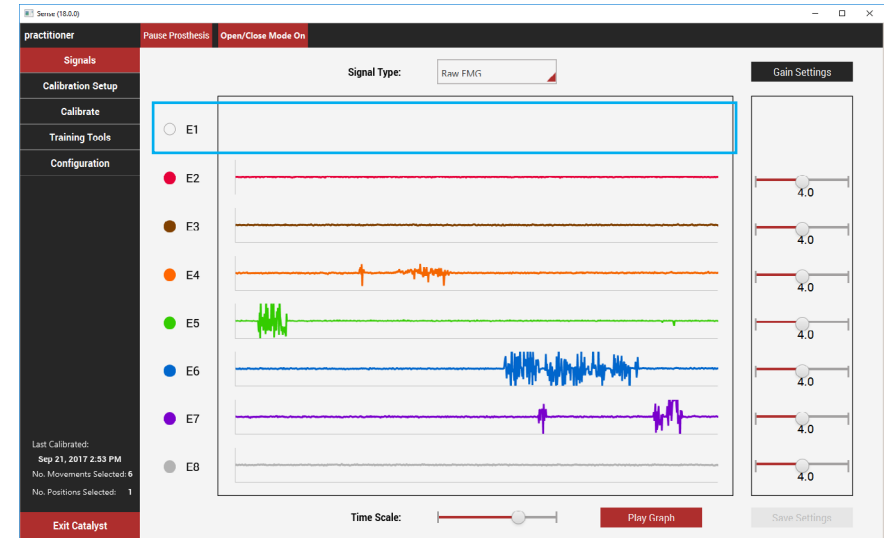
Not all electrodes will be activated during every movement. However, the gain must be high enough that you will see at least a small signal on each electrode during one of the movement patterns. If this is not the case, then the gain has to be increased or the position of the electrode needs to be changed.

If the gain is modified, the new gain is sent automatically to the Sense Controller and the changes are immediately reflected in the signal viewer. However, to save these gains permanently, you must press the "Save Settings" button, which becomes red after any gain is adjusted.

Recalibration is required after changing the gains and before use of the prosthesis.

### Electrode Status (Practitioner Only)

Pattern recognition works best with 8 electrodes, but the system will still work with less. A minimum of 3 must be connected. If an electrode is producing erroneous signals (or not producing signals at all), you can turn it off by clicking on the colored button next to it. To turn it back on, click on the button again. A description of the button status is provided below.



Bright Color

If the button is brightly colored, this indicates that the electrode is on and reading data from the skin.

White

If the button is white, this indicates that the electrode is not turned on or used in the algorithm.


Faded Color

If the button is faded, this indicates that the electrode has not initialized properly. You cannot press the button to turn on the electrode when it is faded. This indicates that the electrode has unplugged or malfunctioned.

Note: while modifying this setting is a practitioner function, the client user will be able to see the circular buttons as indicators instead of active buttons.

### Saving Changes (Practitioner Only)

If changes are made to an Electrode Status or a Gain, there are two methods by which you can save or undo these changes: by clicking the "Save Settings" button or by trying to leave the Signals page via exiting or changing to another tab. In either situation, a window will appear with the following options:



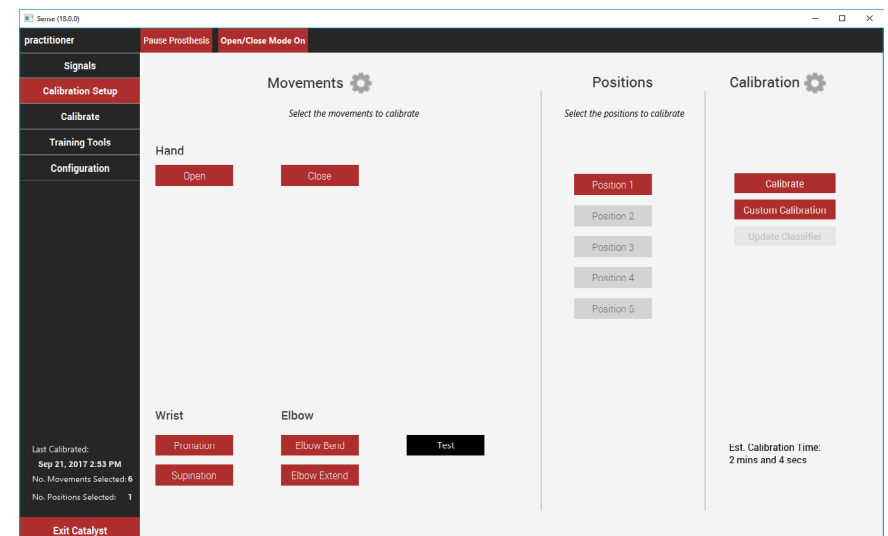
**Changes require recalibration for proper arm control.**  
**Calibrate:** Calibrate with changed settings then save.  
**Save Settings:** Save without recalibration.  
**Discard:** Revert to last saved settings.  
**Cancel:** Go back to Signals page.

Calibrate Save Settings Discard Cancel

1. Calibrate: Because the electrode settings have been modified, the algorithm will need to be recalibrated before it begins classifying correctly again. By clicking Calibrate, the user will be prompted to go through the calibration process and the new electrode settings will be saved after the new calibration session (see below). The movements and positions calibrated will match those from the last saved calibration session.
2. Save Settings: The electrode settings will be saved permanently without updating the classifier. However, the algorithm will eventually need to be recalibrated. This option is useful if you would like to modify options on the Calibration Setup screen.
3. Discard: When electrode status or gain are modified, the information is saved temporarily on the arm. By discarding, you clear these temporary updates and return to the last saved state.
4. Cancel: This button will close the pop-up window and return to the signals page without making any modifications.

### Calibration Setup Screen

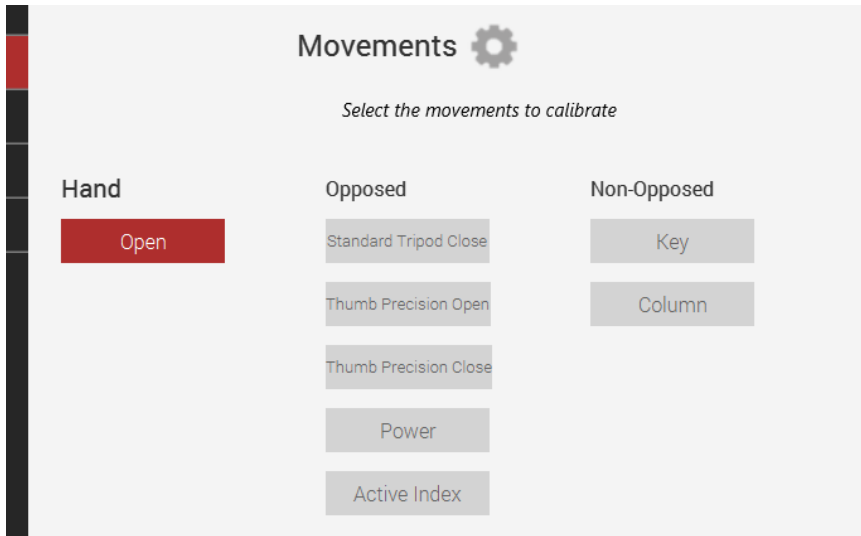
The Calibration Setup screen is where the user can configure the calibration options and where practitioners can test movements and set advanced calibration and movement settings.



## Movements

The movement options listed here are related to the configuration of the device.

The options that are selected here will be part of the pattern recognition algorithm after calibrating. At least one movement must be selected at any given time. There are different indicators for movement selection and they are described below:



Gray only

If a movement button is completely gray, then the movement is not selected to be part of the next calibration process. This movement will not be part of the Sense controller classifier.

Black outline

If a movement button is outlined in black, this means it is selected to be calibrated in the next calibration process. However, these movements have not yet been calibrated.

Red outline

If a movement button is outlined in red, this means that it is selected to be calibrated in the next calibration process. These movements have not been calibrated in all positions. See the section below on Positions.

Red fill

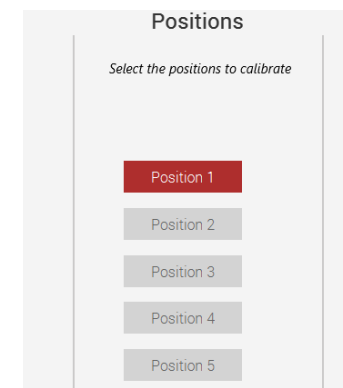
If a movement button is filled in red, this means that it is selected to be calibrated in the next calibration process and the calibration is up to date. No changes need to be made if you do not wish to recalibrate.

Note 1: If the positions selected change, the color indicators on the movement buttons may change as well.

Note 2: If you switch the Microsoft Surface that the software is used on, the color indicators may change. The calibration data is not saved on the Sense Controller, only on the Microsoft Surface.

## Positions

Multi-positional calibration improves the consistency of pattern recognition in a wider range of the arm workspace. For example, muscle signals will appear differently whether the arm is in front of the body, or raised above it. The patient will calibrate all the movements selected in each arm position sequentially, and the data will be aggregated afterwards into a single control. Up to 5 different positions may be selected at once. At least one position must be selected at any given time.

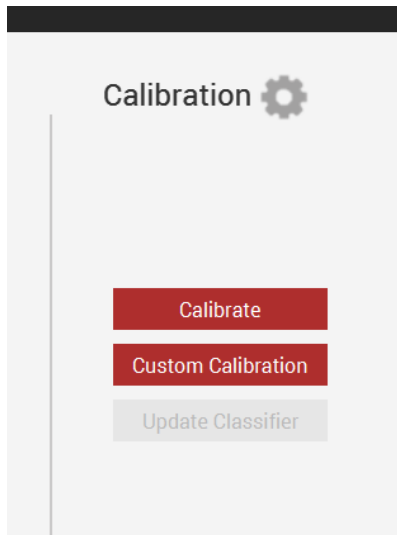


The color indicators for selecting movements, described above, match that for selecting positions.

Note: If the movements selected change, the color indicators on the position buttons may change as well.

### Calibration Options

Under the column labeled "Calibration" there are three options for modifying the classifier:



#### Calibrate

When this option is selected, you will proceed directly to the calibrate screen. All of the movements and positions selected will be recalibrated. The local data will be replaced with new data for all movements.

#### Custom Calibration

When this option is selected, another small window will appear listing all movement and positions that are selected on the Setup page. Select only the movements and/or positions that you would like to recalibrate. All movements and positions listed on this pop up will be a part of the final classifier. However, only the ones that are selected will be recalibrated to have new data replace the old data.

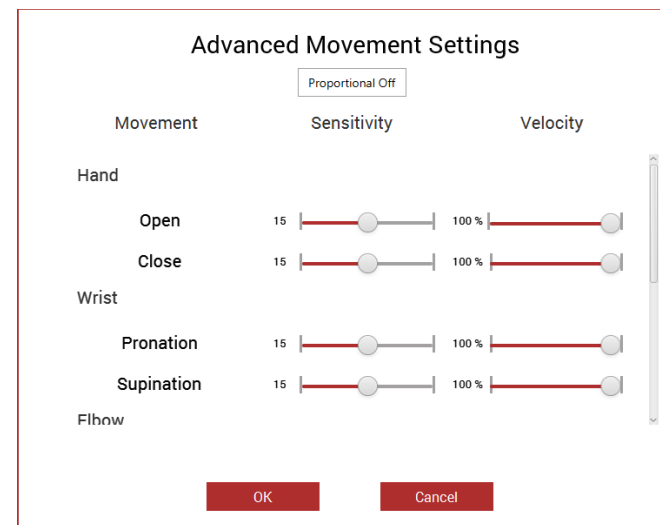
Note: If a movement or positions is outlined in black or red on the Setup page, you are not able to deselect it.

#### Update Classifier

If a movement or position is deselected OR if a movement or position is selected that is filled in red, select Update Classifier to change the movements/positions selected without recalibrating.

### Advanced Movement Settings (Practitioner Only)

The options in this window allow you to fine tune the Sense control. Each movement calibrated has its own specific settings for Sensitivity and Velocity. You can also turn proportional control on or off from this page.



#### Sensitivity

Sensitivity improves the smoothness of control over a movement. Increasing the sensitivity will make the movement more responsive, but has the potential to cause more accidental activation. Decreasing the sensitivity makes the movement more stable, but may cause a small delay before a response by the prosthesis.



## Velocity

Velocity changes the signal voltage output to the prosthesis to increase or decrease the speed of the hand, wrist, or elbow. This option has no effect on the virtual arm.

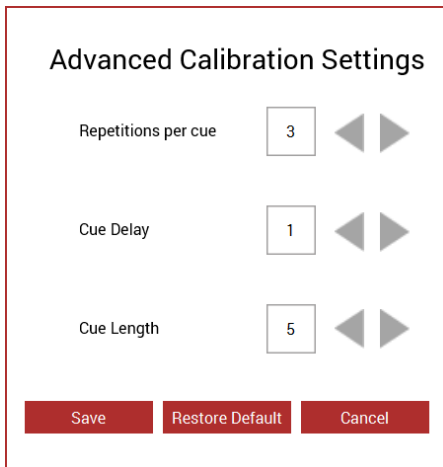
## Proportional

The Proportional button turns proportional control on or off. Proportional control allows the user to change the velocity of any given movement while he/she controls it, by changing the force of the muscle contractions. This means, that if for example the patient mimics closing his/her phantom hand more forcefully, the prosthetic hand will close faster and vice versa. The proportional control functionality is off by default. It is white when off and red when on.

Note: The Advanced Movement Settings window will not open if any options are left uncalibrated on the Setup page.

## Advanced Calibration Settings (Practitioner Only)

The available settings modify the calibration process itself.



**Advanced Calibration Settings**

Repetitions per cue: 3

Cue Delay: 1

Cue Length: 5

Save Restore Default Cancel

## Cue Length

Changing cue length will change the amount of time that each movement cue is displayed for during calibration. Decrease this value to prevent fatigue.

## Cue Delay

Increasing cue delay will add more time between each movement cue. Increase this value if you wish to have more time before each cue is presented to rest and prepare for the next movement.

## Repetitions per Cue

Changing the number of cue repetitions will increase or decrease the number of times you see each movement cue during calibration.

## Restore Defaults

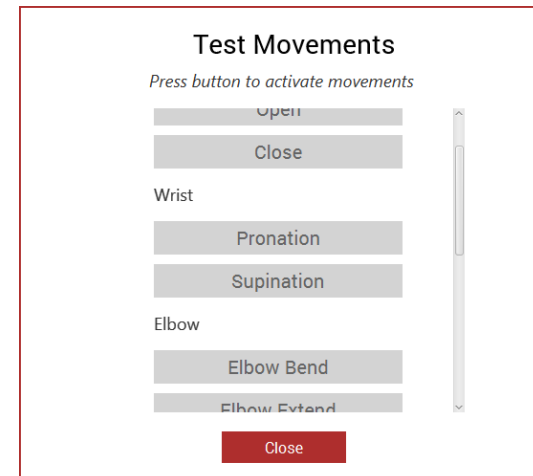
By default, the Cue Length is set to 5 seconds, the Cue Delay is set to 1 second, and the Repetitions per Cue is set to 3 reps.

## Test (Practitioner Only)

The Test window provides a way to test each available movement in the prosthesis, without the need for calibration. By clicking the button associated with a movement, it will activate the selected movement for 4 seconds while preventing other buttons from being pressed.



WARNING: Avoid contact with the prosthesis components while in Test mode.



**Test Movements**

Press button to activate movements

Open

Close

Wrist

Pronation

Supination

Elbow

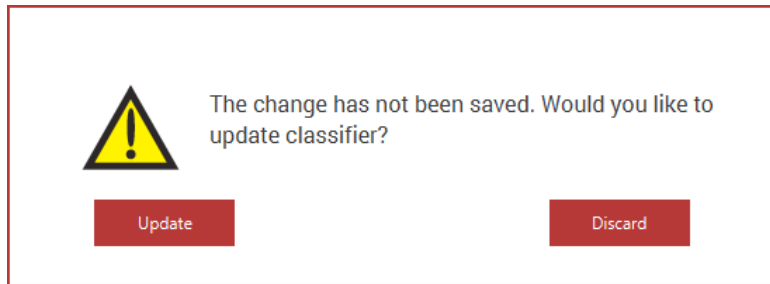
Elbow Bend

Elbow Extend

Close

## Saving Changes

If the movements or positions are modified on the Calibration Setup tab, you must recalibrate or update the classifier to permanently save them. You will be prompted when you leave the Calibration Setup page by the following options



Movement and position options are saved and reloaded each time you log in.

# CALIBRATION

## Introduction to Calibration

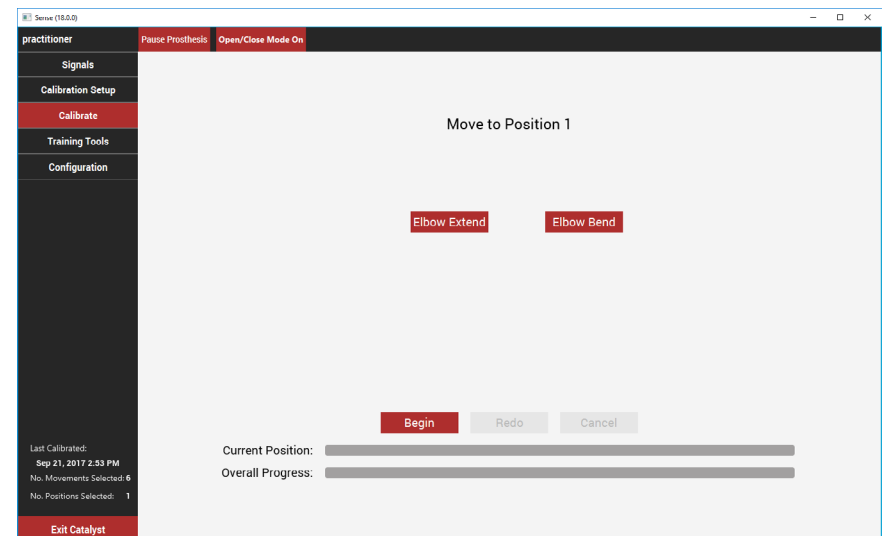
The pattern recognition algorithm must be calibrated for each specific user and electrode locations. It may need to be recalibrated depending on daily or long-term limb fluctuation, or prosthesis slip.

The patient will calibrate by viewing the image on their screen and copying the movement with their phantom limb for the duration of the cue. They do not need to copy the image exactly, only as a guide for which movement to complete.

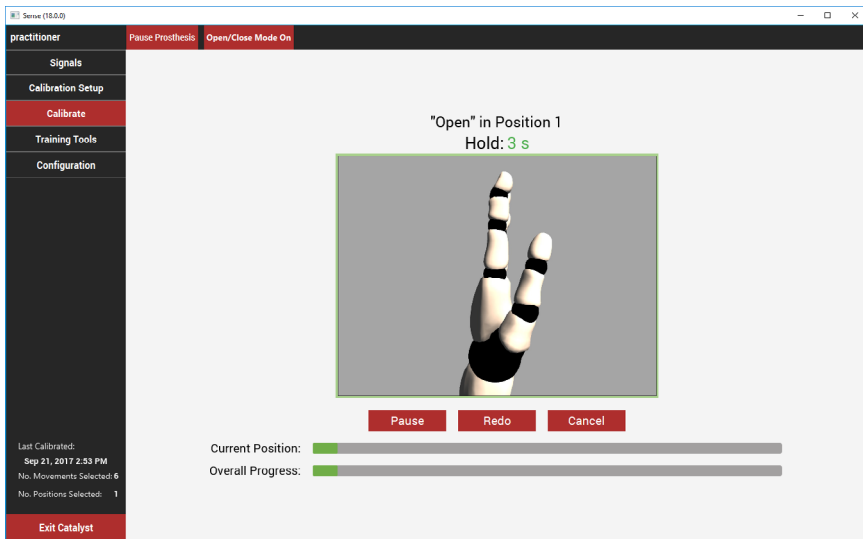
Repetition between the same motion and differentiation between separate movements are extremely important. Remind your patient to complete a **medium** contraction strength during calibration.

## Calibration Window

When you open the Calibration window, you will be reminded which position you are using to calibrate. Transhumeral prosthesis users will see the image below. Use the button to move the elbow to the correct arm position, if the elbow is externally powered.

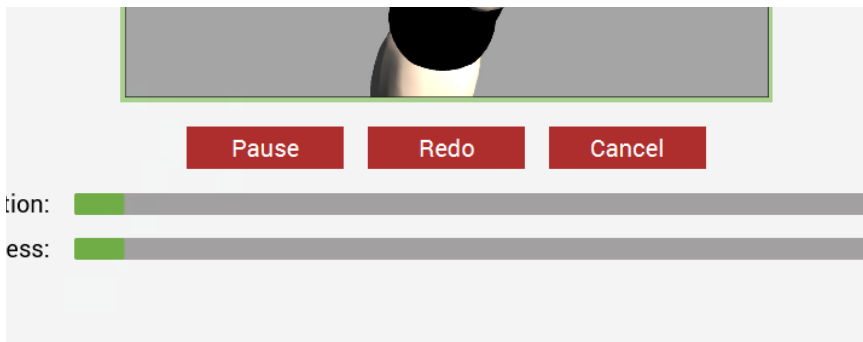


Click Begin to start the calibration process. Outputs to the arm will be paused for the duration of the calibration, therefore the patient will not be able to control it. The Cue Delay time is indicated by the red border around the cue. No data is collected during this time. Data is collected when the cue image is surrounded by a green border. Each cue will be presented the number of times determined by the *Repetitions per Cue*, for a duration determined by the *Cue Length* (see *Advanced Calibration Settings* section).



After each position is calibrated, the patient will have time to rest and move into the next position before continuing the calibration. Continue to the next position by clicking Resume.

A few options exist during calibration that are explained below:



Pause

Calibration is paused until Resume is pressed to continue. No data is collected.

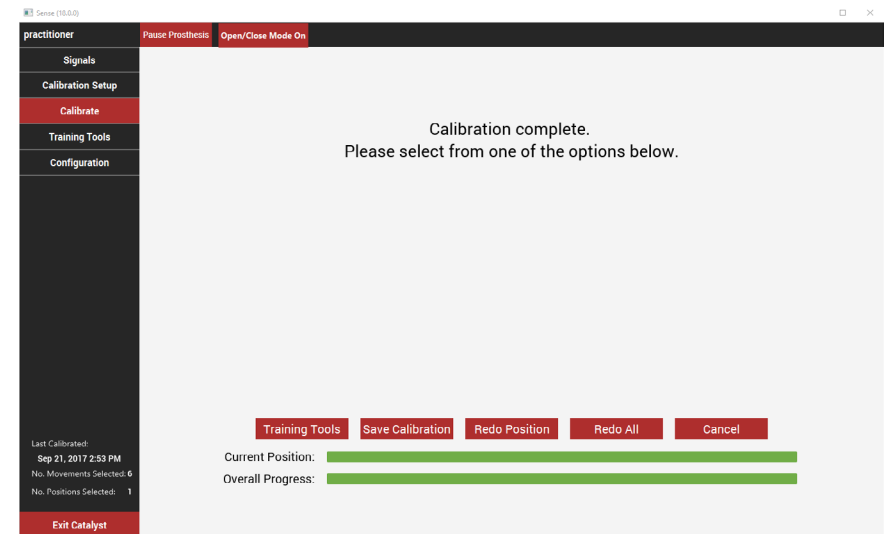
Redo

Data from the current movement (single cue) is removed and the timer is restarted.

Cancel

Cancel the current calibration process and removes the temporary data for cues that were already calibrated

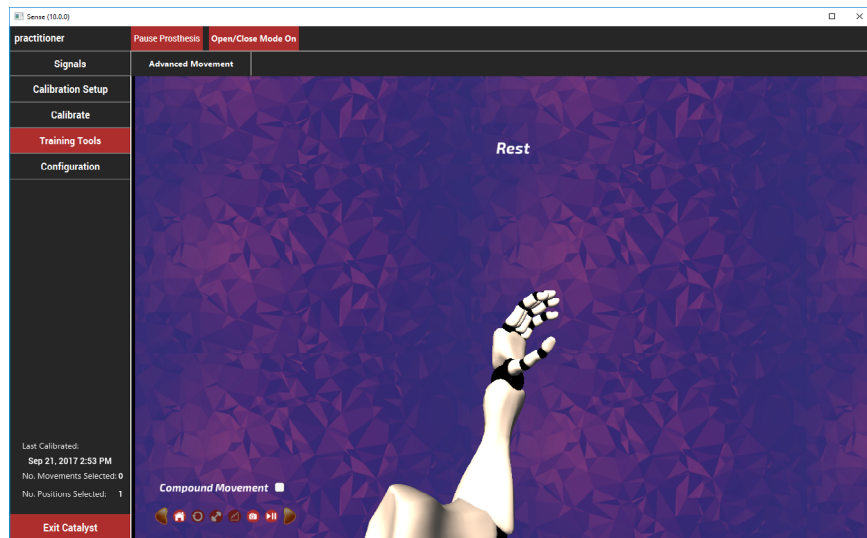
After calibrating all positions, click Save Calibration if you do not wish to redo the calibration. Outputs to the arm will resume. Click Training Tools to use the training games in the virtual environment.



## Training Tools

By clicking on Training Tools after calibration or in the left menu, you will enter the virtual training environment.

By clicking on the Practice button, the patient can use the virtual arm to practice their control. The default is non-compound movements; if you go back to 'Rest', the hand will return to a neutral position. Click the check box for compound movements if you wish to use the virtual arm in the same manner that it will be used in the actual prosthesis; when you return to 'Rest', the hand will remain in the last position achieved.



On the home page, there are 6 game options explained in the table below. Mimic the flash cards as they are presented; the patient has 1 minute to complete each task. Read the description before the level to understand the tasks to complete.

# DOF	Full Movement	Intermediate Movement
1	Level 1: Achieve and hold movement Goal: Movement stability	Level 2: Match movement to indicated final position Goal: Stop movement at desired point
2	Level 3: Achieve wrist, then hand full movement Goal: preposition proximal DOF, avoid accidental activation	Level 4 – Match wrist, then hand to indicated final positions Goal: stop 2 DOF at desired point, avoid accidental activation
3	Level 5 : Achieve elbow, wrist, and hand full movement Goal: preposition proximal DOF, avoid accidental activation	Level 6: Match elbow, wrist, then hand to indicated final positions Goal: stop 3 DOF at desired point, avoid accidental activation

After each level, if you proceed to the score page, you will see the completion percentage. You may also track this in the history page.

## Other Options

On the home screen, various other options also exist to change the difficulty of the game.

### Repetitions

This value indicates the number of times you will see each movement flash card (or combination of flash cards for multi degree of freedom levels).

### Speed

This value indicates how quickly the virtual arm will move. Decrease this value to slow down the arm and make the level easier.



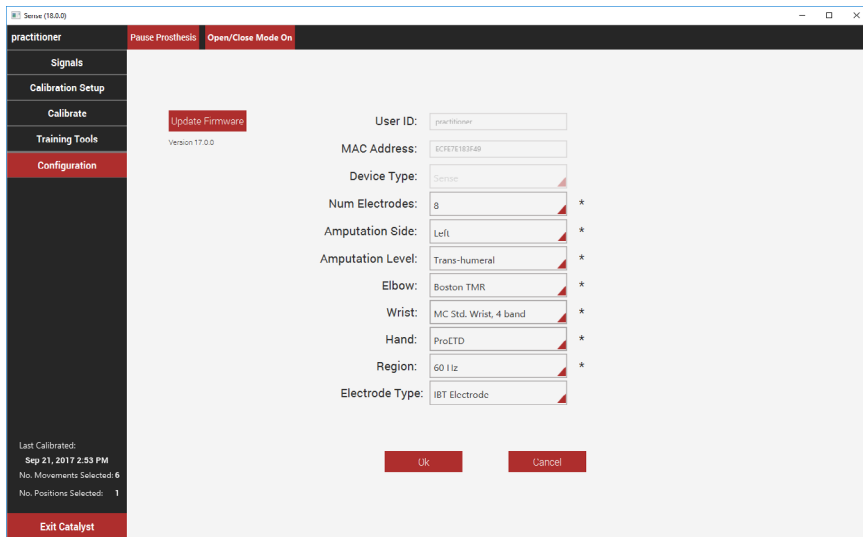
**Note:** Always check the calibration with the virtual arm before using it to control a prosthetic device.



**Note:** Following calibration with the GUI, the prosthetist should test the ability of the user to adequately perform movements and manipulate each degree of freedom in the terminal device

## Configuring the device

Your device will be pre-configured based on the order. If your patient travels to other countries, you may need to change the region to avoid noise introduced by powerlines. (US - 60Hz, EU - 50Hz). Click the gear button at the top left corner of the page. The configuration page lists the settings on the device, these settings should reflect the properties of the terminal device being controlled by the Sense system.



## Pause outputs to the prosthesis

In the top left corner of the GUI, there is a pause button. When selected once, this option pauses outputs to the prosthesis. When selected again, the prosthesis outputs resume. This button is activated automatically when calibrating or using the virtual arm.

## Open/Close Mode

The Open/Close Mode is located to the right of the Pause Prosthesis button - click "Open/Close Mode On" to turn on the mode. When this mode is active, all calibrated grip movements except Open will close the hand in the grip last used before the "Open/Close Mode On" button was pressed. The only exception is the Open movement, which will open the hand in that grip. In order to change grips, you can use the buttons on the back of the hand or an App that comes with the hand. Press "Open/Close Mode Off" to exit the mode.

# 7 sense app

## CONNECTING SENSE TO THE APP

### Introduction to Calibration

Search for "Sense IBT" in the Play Store or Apple Store, and install the version that is compatible with the software on the controller. That information will be printed on the Sense Controller box.

Ensure Bluetooth is enabled on your smart device.

**To perform once:** Power on the Sense controller (see Powering Sense with FlexCell). Wait ten seconds, and within your smart device's Bluetooth pairing menu, search for the Sense controller's device ID that is printed on the Sense controller box (follows the format IBTCoreXXXXXX). Pair the device.

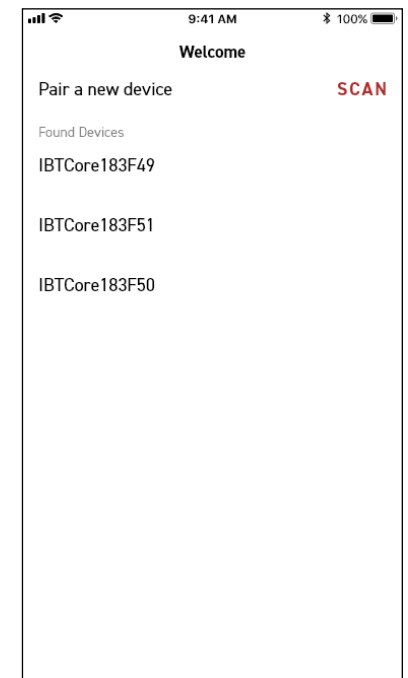
Launch "Sense" on your smart device

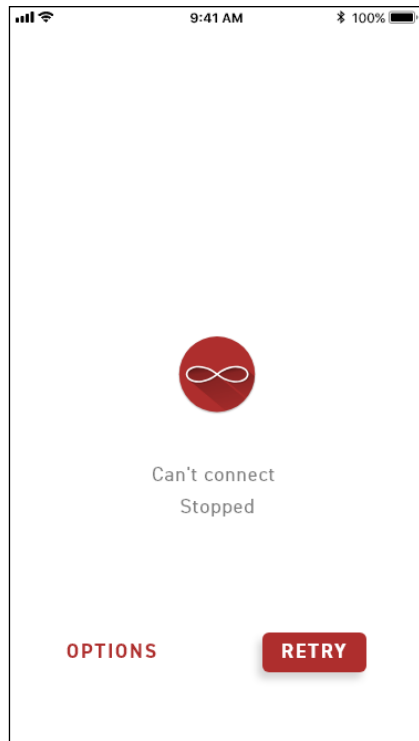
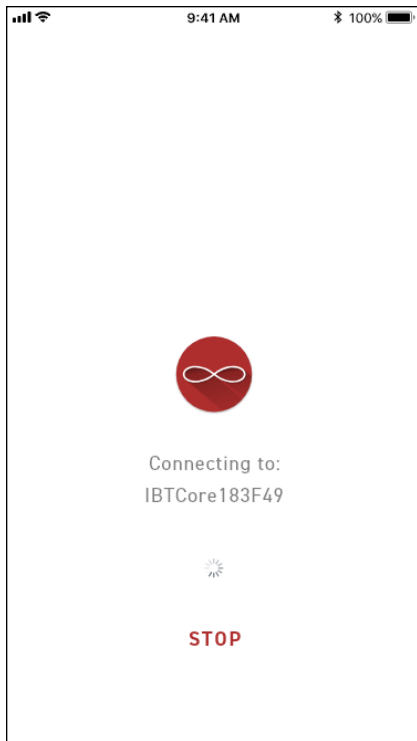


If your smart device is pairing with a Sense controller for the first time, you will be taken to the Welcome menu showing Sense controllers you can connect to. Select the Sense device ID you paired with in the previous step.

Tap on "Scan" if you cannot find the device ID.

**Note:** For subsequent uses with the same Sense device, you will not need to repeat this step. You will only need to repeat this step if (1) if you're using a different Sense system (i.e. for a different patient); (2) you switch to another smart device.





**Note 2:** For subsequent uses with the same Sense device, you will be shown a splash page indicating that the App is attempting to connect to the last connected Sense controller. You can interrupt this process (by tapping “Stop”) if you wish to connect to another controller. From this page, you can either resume the connection by tapping “Options” or be transferred to the Bluetooth page (see “Bluetooth” section on Page 62)..

**Note 3:** Sense cannot connect to Catalyst or the IBT App while an attached TASKA Hand is connected to TASKA’s HandCal Clinician software. Please close HandCal Clinician before connecting to Sense.

## SIGNALS SCREEN

After successful connection, the first page will show you the electrode signals. The color coding in the signal viewer corresponds to the colors of the electrode input cable connectors. Here, you can:

- Make sure all electrodes are functioning correctly,
- Check for signal noise
- Verify that the patterns across the electrodes are different
- View the current output from the classifier

The signals screen has numerous buttons for adjusting the signals and the viewing options. A detailed description of each button’s function is given in the next few sections.

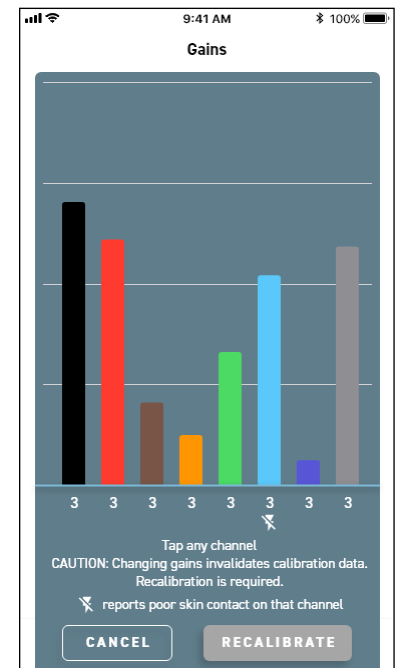
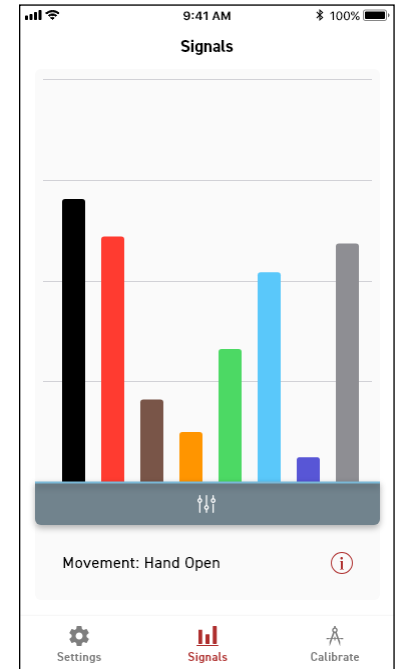
### Signal Settings

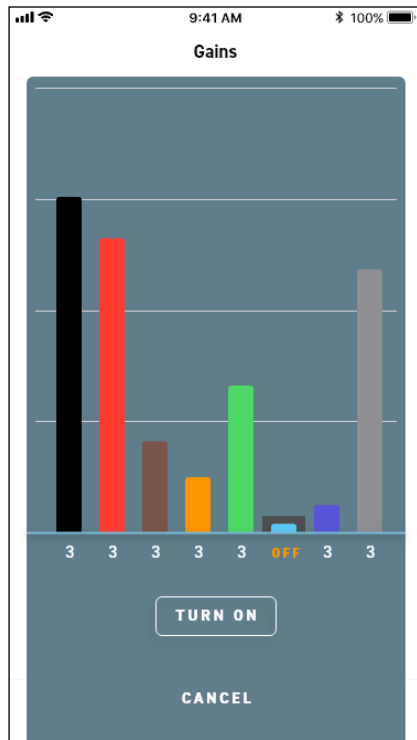
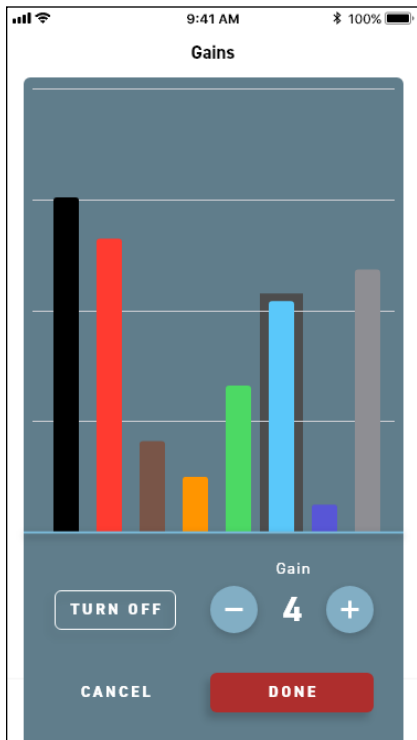
The button below the signal baseline opens options to change signal settings.



**Note:** You must unlock this feature from “Advanced Settings” to adjust gains. Refer to the “Enable Advanced Settings” section on Page 65.

**Note 2:** If you have saved Calibration data, you must recalibrate after changing any electrode settings in this screen, otherwise the prosthesis may respond incorrectly.






The gain will be listed under each bar. Tap on a colored bar to adjust the settings. Tap the + or – button to increase or decrease the gain of that electrode.


You may also choose to turn off the electrode. After tapping the colored bar, click the “Turn Off” button if the electrode is on. If the electrode is already off, you may turn it on after tapping that electrode’s location in the bar graph; gains cannot be adjusted unless the electrode is on. If an electrode is turned off, it will be noted under its respective bar.

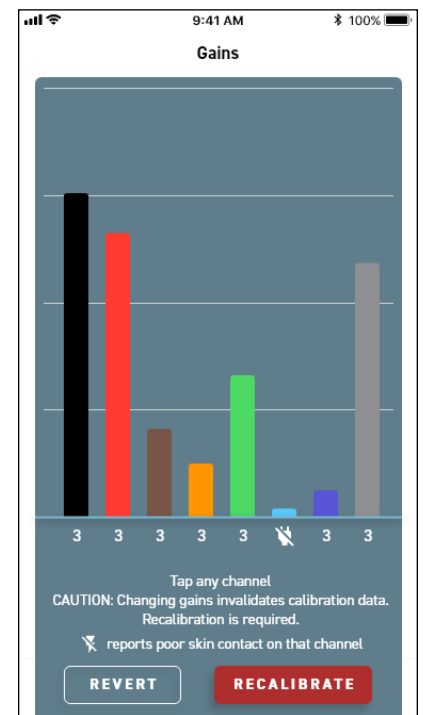
If settings are modified, the new setting is sent automatically to the Sense Controller, and the changes are immediately reflected in the signal viewer. However, to save these changes permanently, you must press the “Recalibrate” button, which becomes red after any gain is adjusted.

Tap “Recalibrate” to be taken to the Calibration Setup page, or tap Revert to revert back to the previous settings.


## Impedance and Disconnection Warnings

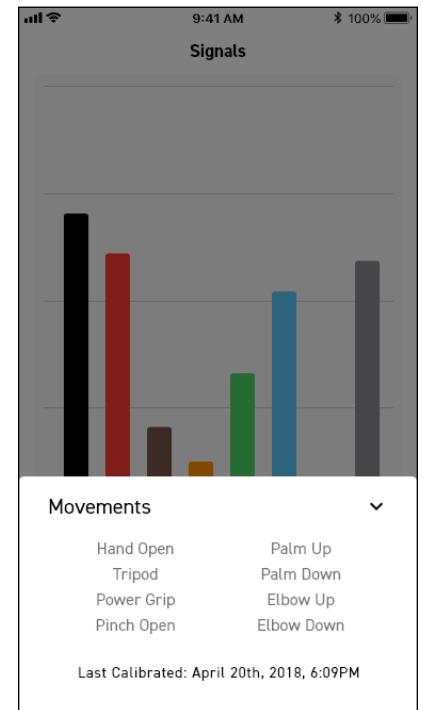
The low impedance icon  under a channel indicates that the corresponding electrode is having difficulty acquiring a consistent EMG signal on that area of skin. Ensure that each individual bar on that electrode is maintaining contact with the skin during the full range of motion of the residual limb.

The disconnect icon  under a channel indicates that the Sense controller has lost communication with that electrode. Ensure that the connector for the electrode is seated all the way and that there is no damage to the cabling.



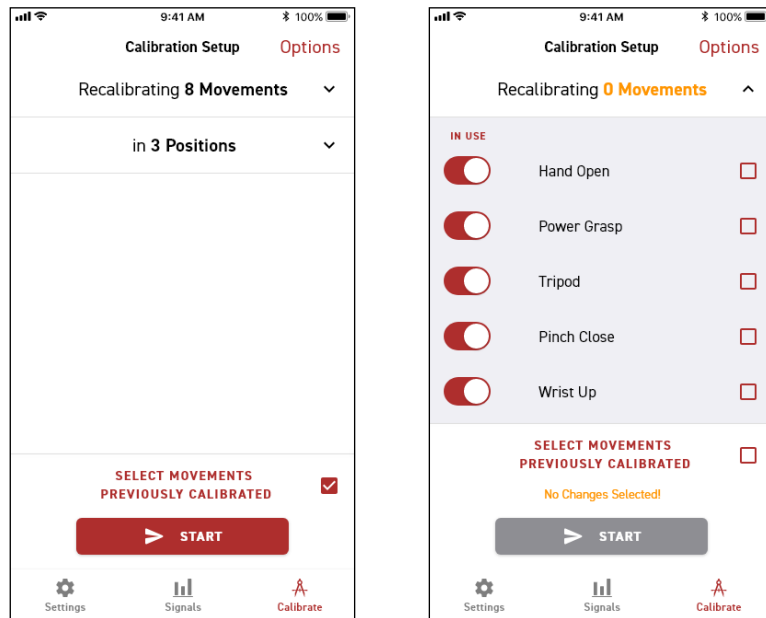
## Movements Popup

On the signals page, tapping the information icon  pops up a window showing the movements you have calibrated, along with the time of last calibration.



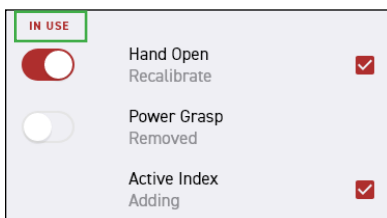
## CALIBRATION SETUP TAB

Tap "Calibrate" on the bottom right to enter Calibration Setup. The Calibration Setup screen is where the user can configure the calibration options.



### Movements

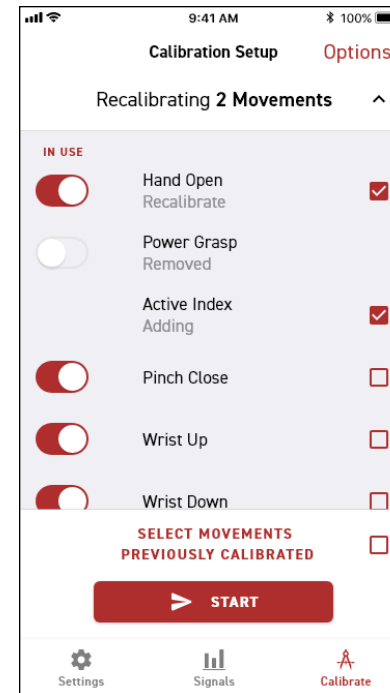
The options that are selected in the "Recalibrating X Movements" dropdown will be part of the pattern recognition algorithm after calibrating. At least one movement must be selected at any given time.



Each row of the movements dropdown shows the name of the movement, a toggle to enable or disable its use ("in use"), a checkbox to mark it for recalibration, and a description of final status of the movement.

The "In Use" toggle on the left indicates that the movement has calibration data and is currently learned by the prosthesis.

- Toggling the switch to "off" (gray) removes the movement from the Sense classifier after updating.
- If the toggle is turned on, and information exists for that movement, that information will be used unless the movement is recalibrated.

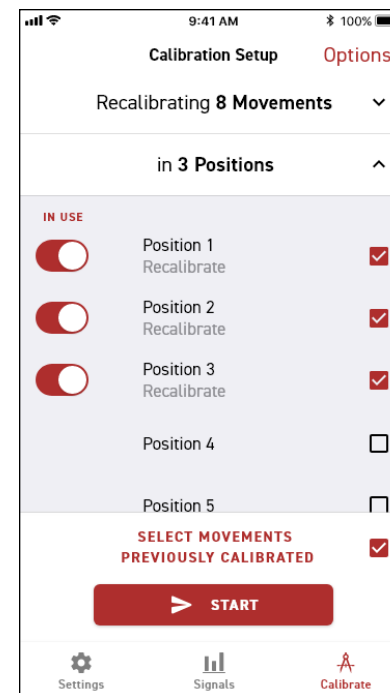


The checkbox on the right marks the movements selected for calibration.

- By checking the box, you are choosing to replace the movement information during a new calibration.
- If you tap a checkbox for a movement that is not "In Use", the toggle on the left will turn on automatically.

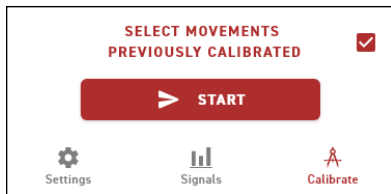
### Positions

Multi-positional calibration improves the consistency of pattern recognition in a wider range of the arm workspace. For example, muscle signals will appear differently whether the arm is in front of the body, or raised above it. You will calibrate all the movements in each selected arm position before moving to the next position, and the data will be aggregated afterwards into a single control. Up to 5 different positions may be selected at once. At least one position must be selected at any given time.



The "In Use" toggle and recalibrate checkbox work the same way as for movements. Positions can be added individually to increase the amount of information.





In order to recalibrate all previously selected options, tap the "Select Movements Previously Calibrated".

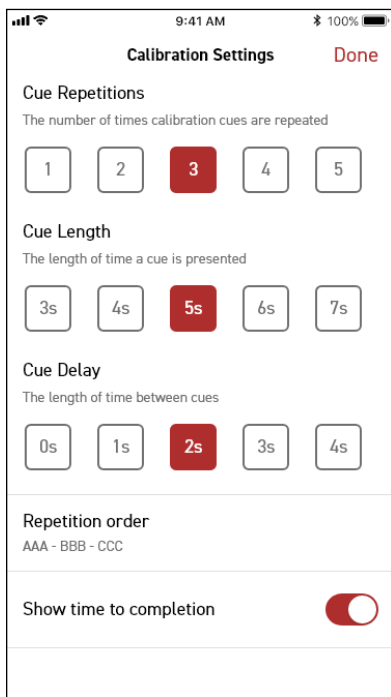
Tap "Start" to begin calibration.

### Calibration Options

Tap "Options" on the top right corner of the Calibration Setup page to modify parameters for the calibration process.

#### Cue Length

Changing cue length will change the amount of time that each movement cue is displayed for during calibration. Increasing or decreasing the cue length will increase or decrease the amount of calibration data collected. Decrease this value to prevent fatigue or with experienced users.



#### Cue Delay

Increasing cue delay will add more time between each movement cue. Increase this value if you wish to have more time before each cue is presented to rest and prepare for the next movement.

#### Repetitions per Cue

Changing the number of cue repetitions will increase or decrease the number of times you see each movement cue and gather data for it during calibration. It is recommended to keep the repetition at a default of 3 and decrease as needed for experienced users.

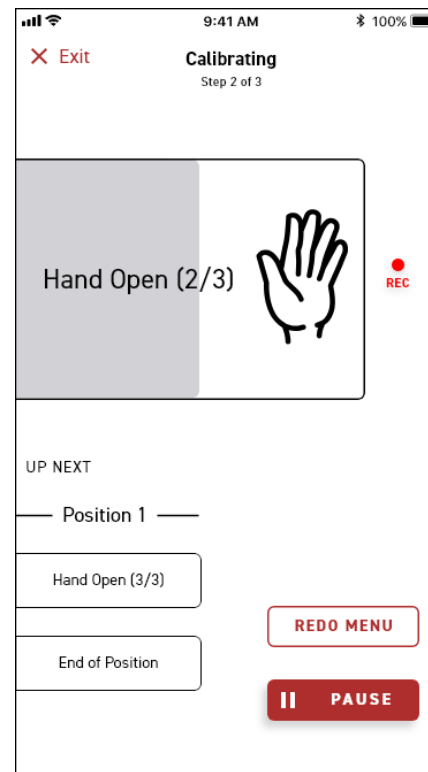
#### Repetition Order

For calibrations with more than one repetition per movement, you can choose between doing all repetitions of the same movement in a row (AAA-BBB-CCC) or doing completing one of each movement and repeating the sequence. (ABC-ABC-ABC).

#### Show time to completion

Shows or hides the estimated total time for a calibration session above the Start button in the Calibration Setup page.

## CALIBRATION

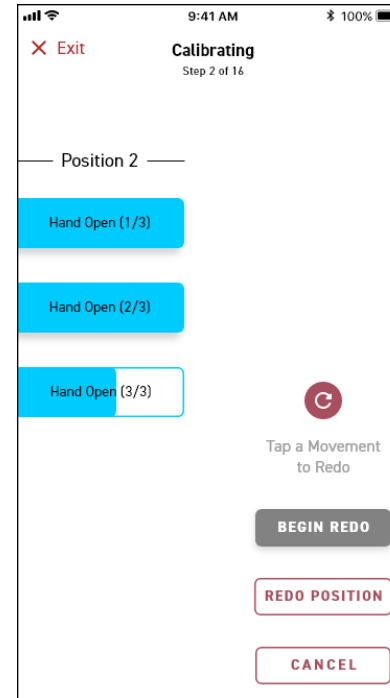
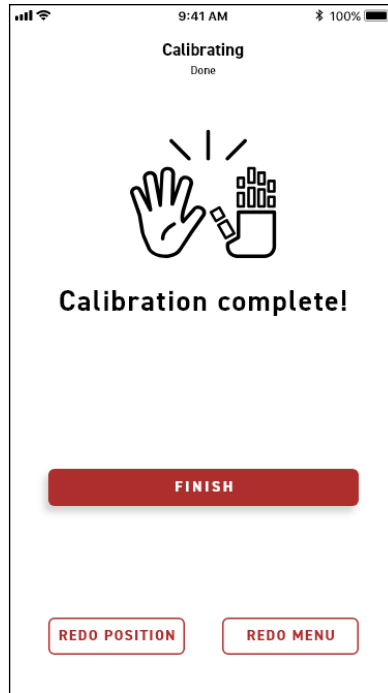
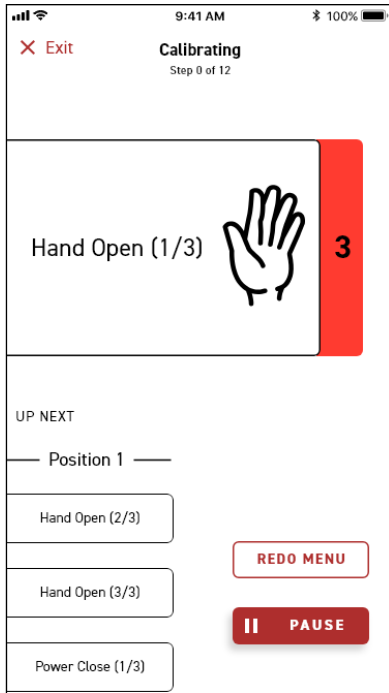


### Introduction to Calibration

The pattern recognition algorithm must be calibrated for each specific user and electrode setting. It may need to be recalibrated depending on daily or long-term limb fluctuation, or prosthesis slip.

The patient will calibrate by viewing the image on their screen and copying the movement with their phantom limb for the duration of the cue. They do not need to copy the image exactly, only as a guide for which movement to complete.

Repetition between the same motion and differentiation between separate movements are extremely important. Remind your patient to complete a medium contraction strength during calibration.



### Redo Menu

Pauses the current Calibration routine and presents the previous movements calibrated. Select the movement you wish to Redo, followed by the movement you would like to Resume afterwards. Select Start to begin the sequence.

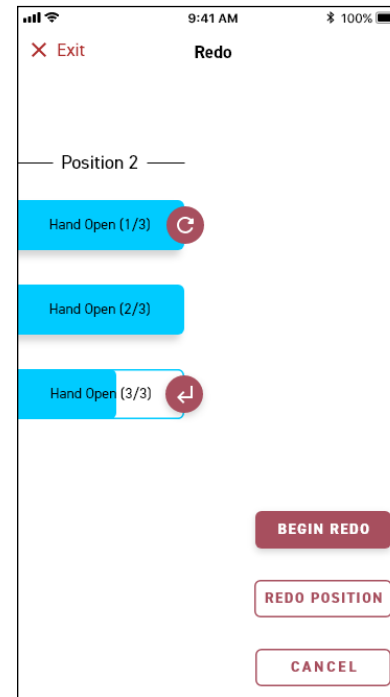
**Note:** You can only recalibrate movements in the current position.

### Redo Position

Allows the user to redo all movement repetitions in the last calibrated position. All previously collected information will be replaced.

After calibrating all positions, select Finish if you do not wish to redo any or all of the position. Outputs to the arm will resume.

**Note:** You may see a "Calibration unsuccessful" page at the end of the calibration sequence. This is because the calibration algorithm could not find distinct patterns from the movements. Consult the training guide, for tips on improving calibration. Make sure movement patterns are distinct from each other.



## Calibration Process

The Calibration process will start automatically. Outputs to the arm will be paused for the duration of the calibration, therefore you will not be able to control it. The Cue Delay time is indicated by the "Starting in..." timer in red.

No data is collected during this time. Data is collected when the cue image is revealed after the timer reaches the end. Each cue will be presented the number of times determined by the Repetitions per Cue, for a duration determined by the Cue Length (see Calibration Options section).

After each position is calibrated, you will have time to rest and move into the next position before continuing the calibration. Continue to the next position by selecting Continue.

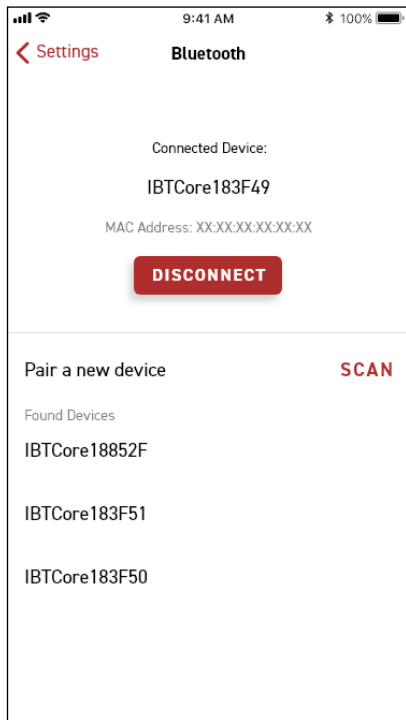
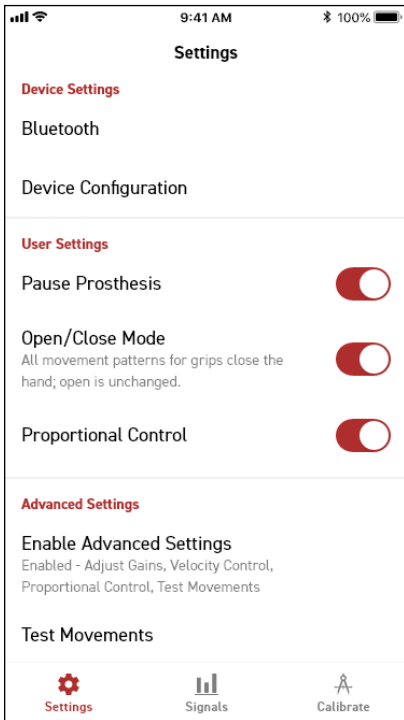
A few options exist during calibration that are explained below:

### Pause

Calibration is paused until Resume is pressed to continue. It will resume in the same location in which it was paused. No data is collected while paused.

# SETTINGS TAB

The settings tab provides maintenance and connection tools for the prosthesis. Certain functions are password-protected to prevent inadvertent adjustments.



## Bluetooth

By selecting Bluetooth in the Settings menu, you can disconnect from the current Sense controller (if you wish to use your smart device to configure multiple Sense controllers) as well as pair to a new one. You can also view the Bluetooth ID of the currently connected Sense controller.

**Note:** If you exit the Bluetooth menu after disconnecting from the current Sense controller, you will be taken to the splash screen. You can still reconnect or return to the Bluetooth menu.

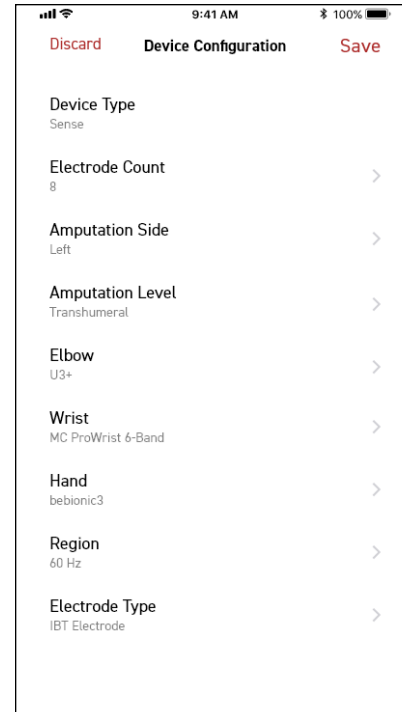
## Pause Prosthesis

Tap the "Pause prosthesis" button to suspend movement of the prosthesis. This does not power off the prosthesis components; it only blocks signal outputs that cause movement in the arm. Tap "Resume prosthesis" to resume function. The prosthesis will resume automatically upon exiting the app.

## Device Configuration

Your device will be pre-configured based on the order. The configuration page lists the settings on the device, these settings should reflect the properties of the prosthesis being controlled by the Sense system.

Tap "Modify" in the top right to begin changing the device configuration. You will be prompted with a password, which is IBT1997 to unlock permanently, or Sense2017 to unlock just for this use. Once cleared, each editable row will have arrows providing options in the next menu, and "Modify" becomes "Save". To exit with saving, tap "Discard" on the top left.

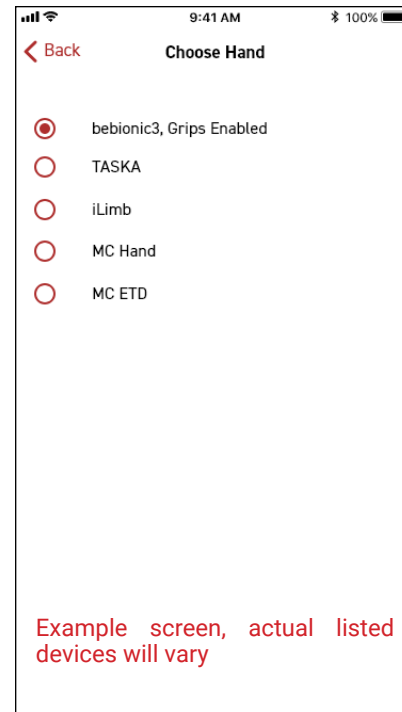


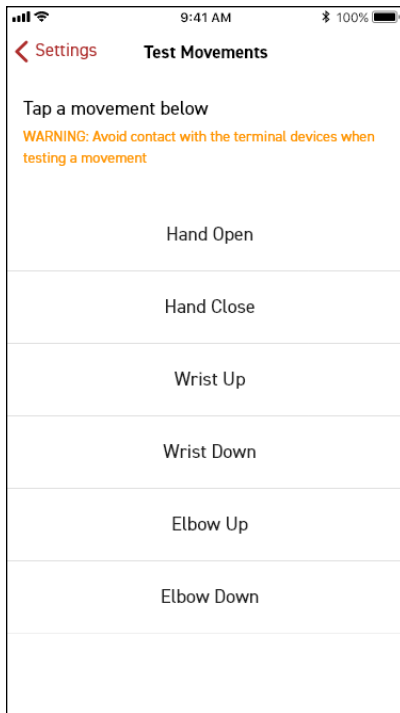
**NOTE:** Changing the device configuration to a setup that does not match the prosthesis may result in undesirable performance and in extreme cases, damage to the prosthesis components.

Tap each row if you wish to change the device configuration.

If your patient travels to other countries, you may need to change the region to avoid noise introduced by power lines. (US - 60Hz, EU - 50Hz).

Once you are satisfied with the changes, tap "Save" on the top right. Wait for the Sense controller to update. Previous calibration data will be lost if new configuration is saved.





## Test Movements (Advanced)

The Test Movements window provides a way to test each available movement in the prosthesis, without the need for calibration. By clicking the button associated with a movement, it will activate the selected movement for 4 seconds while preventing other buttons from being pressed.

**WARNING:** Avoid contact with the prosthesis components while in Test Movements.

## Velocity Settings (Advanced)

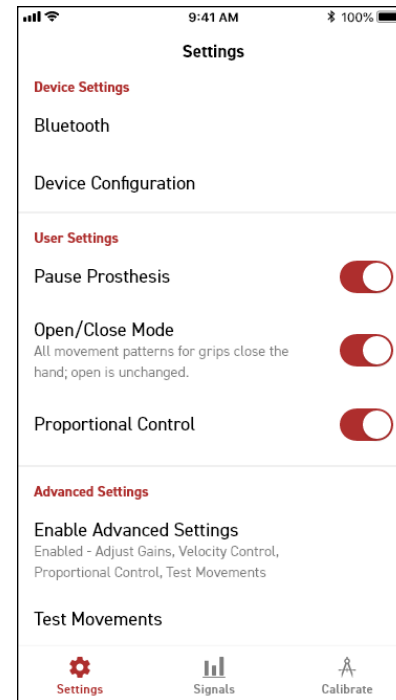
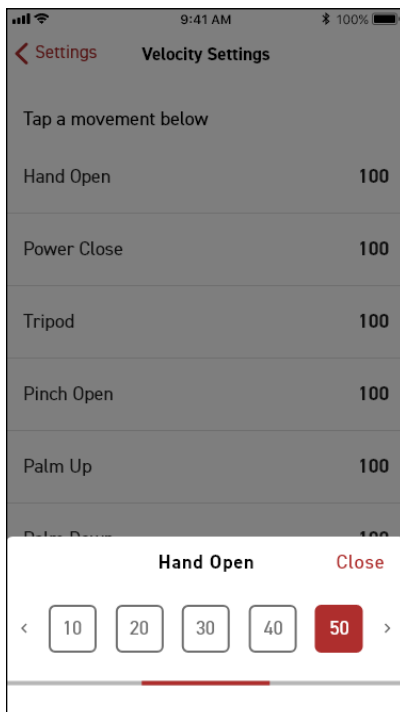
Velocity changes the signal voltage output to the prosthesis to increase or decrease the speed of the hand, wrist, or elbow.

Select a movement and choose a value between 10 and 100 in the popup menu.

## Open/Close Mode

(Located in Settings tab)

When this mode is active, all calibrated grip movements except Open will close the hand in the grip last used before the "Open/Close Mode On" toggle was pressed. The only exception is the Open movement, which will open the hand in that grip. In order to change grips, you can use the buttons on the back of the hand or an App that comes with the hand.

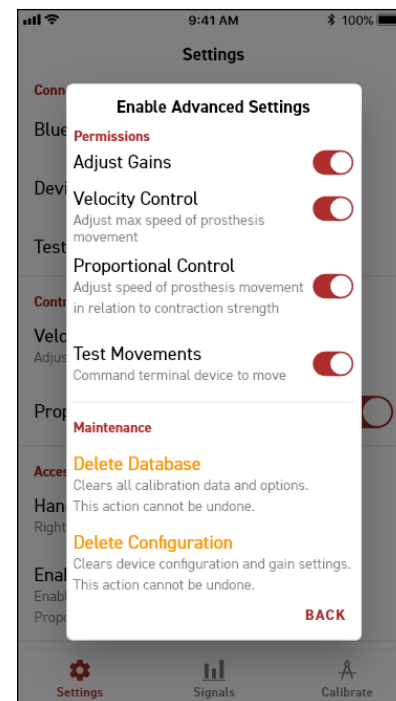


## Proportional Control (Advanced)

The Proportional control switch turns proportional control on or off. Proportional control allows the patient to change the velocity of any given movement while the patient controls it, by changing the force of his/her muscle contractions. This means, that if for example the patient mimics closing his/her phantom hand more forcefully, the prosthetic hand will close faster and vice versa. The proportional control functionality is off by default. It is white when off and red when on.

## Enable Advanced Settings

You can hide certain settings within the Settings tab if you do not wish for a patient to adjust them. Upon selecting "Enable Advanced Settings", you will be prompted with a password. After you enter the password (the same password in the previous section "Device Configuration" on Page 63) it will allow you show or hide electrode settings, velocity control, proportional control, and Test Movements.



In the event that the Sense controller is not functioning correctly, you can delete the Database and Device Configuration. Please contact IBT before proceeding with either of these actions as it can erase all data from the prosthesis.

# 8 troubleshooting

When there are unexpected outputs from Sense or difficulties using the software, always power cycle the Sense device using the FlexCell power button as a first step.

The points below offer some common trouble shooting tips if difficulties continue:

## *SENSE DOES NOT VIBRATE WHEN TURNED ON*

First, check that the battery is charged. Press the button on FlexCell to ensure that there is charge remaining on the battery. If discharged, connect the charger and test again after charging.

If the battery is charged, try connecting the Sense to the PC software or phone app and use the Test button to activate the prosthesis movements. If the prosthesis moves, Sense and the hand are receiving power. It is possible that Sense is installed in a way that dampens the vibration. Please note that the vibration may be easier to detect while wearing the prosthesis. Try placing your hand into the socket to feel the vibration there.

If the hand does not move, Sense and the hand are not receiving power. It is possible that the power cable was disconnected during installation. Please check the cabling inside the prosthesis.

## *SENSE SYSTEM DOES NOT CONNECT TO THE SENSE PC SOFTWARE OR PHONE APP*



- Make sure Bluetooth is enabled on the Microsoft Surface or phone
- Ensure that Sense is paired to the Microsoft Surface.
  - For Phone: Go to Settings > Bluetooth (iOS) or > Connected Devices (Android)
  - For PC: Go to Control Panel > Devices and Printers
- Remove and re-pair the device within the above menu; click device and Remove/Forget. Re-pair the device.

- Check that the prosthesis is on and charged
- Restart Sense and the PC/phone

## *DEVICE CONFIGURATION IS ERASED*

- Fill in all items according to the prosthesis configuration on the device configuration page.

## *NO EMG OUTPUT FROM ELECTRODE*

- Open the Sense software and connect to the Sense system.
- Check that when you tap the electrode, you see a signal change on the signal viewer.
- Try increasing the gain and contract.
- Electrode lift-off:
  - PC Software: If the signal is flat-lined or at maximum, try decreasing the gain to 3 and check for electrode lift-off.
  - Phone App: Check for the  symbol indicating no electrode contact underneath each bar channel.
- Electrode unplugged:
  - PC Software: If one of the circles on the left side of the signal viewer is faded out, this indicates that the electrode is not connected
  - Phone App: If the  icon appears, this indicates a channel is not connected. Check that the electrodes are plugged in and that no cables are damaged.
- If an electrode cable is disconnected, close the software, turn off the device using the FlexCell button, then reconnect the electrode cable to the Sense controller. Turn the device back on, open the Sense GUI and reconnect the device.

## *NOISY SIGNALS ON THE SIGNALS PAGE IN SENSE GUI*

- Make sure that you are not stepping on charging or power cords, or that the arm is not lying next to power cords. Power lines can create some signal interference especially when the electrodes are in air and not contacting skin.

- Make sure you are not near RF equipment and transmitters. Move to a different area and check the signals.
- If you have not waited for signals to settle, wait a few minutes to see if issue persists.
- If the issue persists try re-donning the prosthesis as it most likely means you do not have good contact with an electrode.
- Make sure to use alcohol before donning.
- If the issue persists, turn off this electrode in the software and recalibrate.
- Check for cable damage on this electrode and return the electrode to IBT
- Avoid calibrating near power sources. In addition, check that the Surface or smart device does not have its charger plugged in.

## *TROUBLE CONTROLLING ONE SPECIFIC MOVEMENT WITH THE PROSTHESIS*

- Try recalibrating only that movement.
- Alternatively, you may try adding another position to increase the amount of data available for all movements.
- Make sure to check patient signals (see issue above)

## *PREVIOUSLY WORKING MOVEMENT IS DIFFICULT TO ACHIEVE WITH PROSTHESIS*

- Relax for a few seconds and try again with a gentler contraction.
- Do not try to use more force.
- If these methods do not work, use custom calibration to replace data for that movement.

## *NO OUTPUT TO TERMINAL DEVICE*

- Connect to Sense software:
  - PC Software: On Calibration Setup page, use the Test buttons to check if movement occurs.
  - Phone App: Go to settings tab and activate Test Movements menu.
- If no output, check for cable damage or disconnections.

## *BLUETOOTH ERRORS WHEN CONNECTED TO THE SOFTWARE*

- Check that prosthesis is on and charged
- Close software, power cycle the prosthesis and try re-connecting
  - For Phone: Go to Settings > Bluetooth (iOS) or > Connected Devices (Android)
  - For PC: Go to Control Panel > Devices and Printers
- If the device is not paired, click Add a Device and select your device

## *ERROR: BLUETOOTH IS NOT ACTIVE*

- Go to Devices and Printers or Device Manager and ensure that Bluetooth is enabled on the Microsoft Surface

## *THE PROSTHESIS IS MALFUNCTIONING OR UNRESPONSIVE*

- Power down the system and contact IBT for support.

## *SOFTWARE NEEDS TO BE REINSTALLED*

- Call IBT for support

# 9 maintaining sense

## PREVENTATIVE INSPECTION

All Sense systems undergo extensive quality assurance inspections prior to shipping. No additional inspection is required or advised.

## MAINTENANCE

### Cleaning Electrodes

For best signal responses from the EMG electrodes, we recommend cleaning the electrodes regularly to remove sweat residue and maintain hygiene. Clean the surface of each electrode and the inner socket with a mild soap solution as needed, at least a couple of times a week. Please follow the following steps:

1. Create a solution with water and mild soap
2. Use a soft rag to clean the electrodes with the soap solution
3. Rinse rag or use another damp rag to wipe away soap residue
4. Wait until electrodes are completely dry before donning prosthesis

Note: Isopropyl Alcohol (IPA, also known as rubbing alcohol) may be used instead of soap. Make sure to wipe off alcohol and let dry before donning.



WARNING: DO NOT SUBMERGE whole electrode or arm in a bath of water. This could permanently damage the electrodes, Sense, and the prosthesis.



WARNING: DO NOT USE harsh chemicals, such as acetone, bleach, kitchen cleaners, etc. This could permanently damage the electrodes and the skin.

## IBT Electrode and FlexCell Battery Replacements

IBT Electrodes and FlexCell batteries can be easily replaced if they are damaged or stop working. If you need to replace the battery or electrodes, simply unplug the battery or electrodes from the Sense input connectors. Follow the instructions in Section 4 to plug in the new electrode or battery. For any abnormal issues, discontinue use and contact IBT for support.

## DISPOSAL



The Sense system components should not be thrown away with common household waste. Dispose of Sense components by either returning the unit to IBT or taking the unit to an official electronics disposal site.

## REPAIRS, RETURNS, AND WARRANTY

Please contact IBT at [service@i-biomed.com](mailto:service@i-biomed.com) regarding repairs and returns. The Sense controller and IBT Electrodes come with a 1-year manufacturer's defect warranty. Details of the warranty are enclosed separately.

# 10 safety and warnings



Liquid damage warning: Sense is not waterproof. Please advise the user to avoid submerging or spilling liquid on or into their prosthesis. This may cause Sense to be permanently damaged. If the user will be wearing their prosthesis in wet environments, ensure that Sense is sufficiently protected from the external environment.



Battery use warning: Sense must be powered by a FlexCell battery system from IBT. We have conducted safety testing to confirm compatibility between Sense and FlexCell batteries.



Modification WARNING: Any unauthorized modification to Sense can pose a safety risk to the user and will void the warranty. Changes or modifications not expressly approved by Infinite Biomedical Technologies, LLC could void the user's authority to operate the equipment.



WARNING: DO NOT USE harsh chemicals (such as bleach, kitchen cleaners, etc.) to clean electrodes. This could permanently damage the electrode. If you are not sure if a specific chemical is considered harsh, please call us prior to cleaning the electrode.



WARNING: Do not use Sense during safety critical tasks.



WARNING: Do not drop Sense or the IBT Electrodes. This could cause damage to the Sense electronics.



WARNING: IBT Electrodes are only to be used with the Sense signal processing box or other compatible IBT systems.



Sense needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this document.



Please note that portable and mobile RF communications equipment can affect Sense.



WARNING: Use of accessories and prosthetic parts other than those specified in the product order may result in malfunction of the Sense system and can cause increased emissions and decreased immunity of the Sense system.

# 11 regulatory info

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, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

This product has been tested and verified to ensure that there are no issues or concerns regarding reciprocal interference. This includes EMI, EMC and RF.

This product has been certified and tested by 3rd party testing facilities to the following standards:


- IEC 60601-1, 3rd Edition
- IEC 60601-1-2, 3rd and 4th Edition
- IEC 60601-1-11, 1st Edition
- IEC 61000: See next page

Also compliant as per CISPR 11:2015



Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The Sense System is intended for use in the electromagnetic environment specified below. The customer or the user of the Sense System should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The Sense System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Sense System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Sense System is intended for use in the electromagnetic environment specified below. The customer or the user of the Sense System should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable	Not applicable
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % $U_T$ (>95 % dip in $U_T$ ) for 0,5 cycle  40 % $U_T$ (60 % dip in $U_T$ ) for 5 cycles  70 % $U_T$ (30 % dip in $U_T$ ) for 25 cycles  <5 % $U_T$ (>95 % dip in $U_T$ ) for 5 s	Not applicable	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: $U_T$ is the A.C. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The Sense System is intended for use in the electromagnetic environment specified below. The customer or the user of the Sense System should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the Sense System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance</b>  Not applicable
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 Ghz	10 V/m	$d=0.35 \sqrt{P}$ 80 MHz to 800 MHz $d=0.7 \sqrt{P}$ 800 MHz to 2,5 GHz where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
<sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Sense System is used exceeds the applicable RF compliance level above, the Sense System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Sense System.			

Recommended separation distances between portable and mobile RF communications equipment and the Sense System			
The Sense System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Sense System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Sense System as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter  W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz  $d=[\frac{3,5}{V_i}] \sqrt{P}$	80 MHz to 800 MHz  $d=[\frac{3,5}{E_i}] \sqrt{P}$	800 MHz to 2,5 GHz  $d=[\frac{7}{E_i}] \sqrt{P}$
0,01	Not applicable	0.035	0.07
0,1	Not applicable	0.1106	0.221
1	Not applicable	0.35	0.7
10	Not applicable	1.106	2.21
100	Not applicable	3.5	7
For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			



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