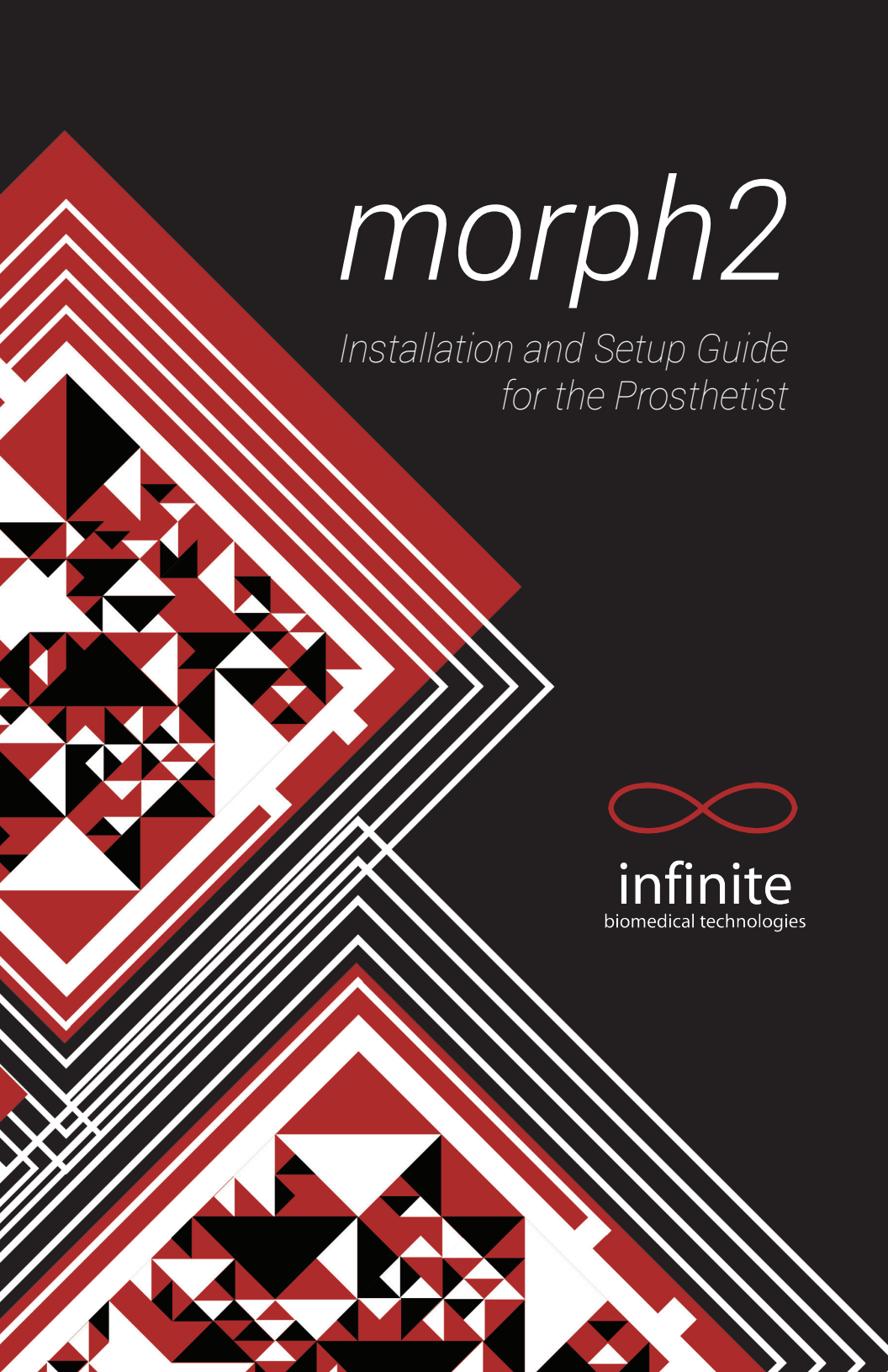




morph2

*Installation and Setup Guide
for the Prosthetist*



infinite
biomedical technologies

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This document provides information for the prosthetist who will be installing morph2.

FCC ID: 07Q-MORPH2

IC: 21990-MORPH2

Contains FCC ID: XDULE40-D2

Contains IC: 8456A-LE4D2



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morph2

INSTALLATION AND SETUP GUIDE FOR THE PROSTHETIST

Thank you for choosing morph2 to help your prosthesis user gain more control of his or her prosthesis! Whether you're retrofitting morph2 into an existing prosthesis or you're building a new prosthesis from the ground up, this guide will familiarize you with morph2 functionality and installation.

The installation of morph2 should be performed exclusively by a licensed prosthetist or technician. morph2 is intended to be operated by a prosthesis user following installation and setup. Any unauthorized handling or installation of morph2 could void its warranty.

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

(443) 451-7175

support@i-biomed.com

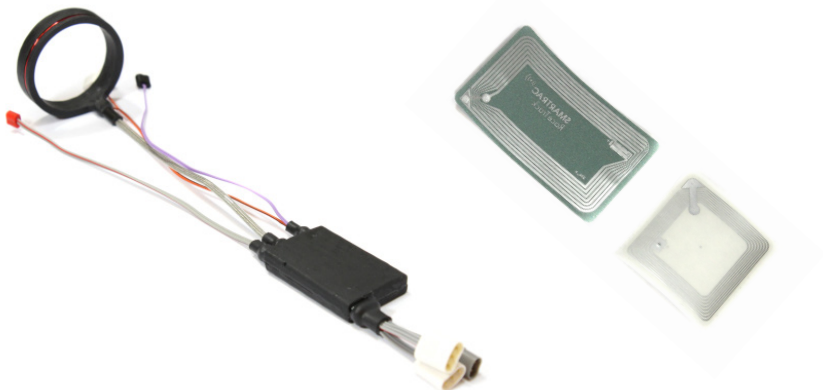


This symbol is used throughout the guide to indicate important cautionary information. Text following this symbol should be read carefully.

table of contents

1. Meet morph2	5
2. Component Description	6
3. Specifications	7
4. Installing morph2.....	8
Before you Begin.....	8
Batteries and Electrodes.....	9
Installation without a Wrist	10
Installation with a ProWrist.....	13
5. Test morph2.....	15
6. Using Tags	16
7. Troubleshooting.....	21
8. Maintaining morph2	23
Preventative Inspection.....	23
Maintenance.....	23
Disposal	23
Repairs, Returns and Warranty	23
9. Safety and Warnings	24

1 meet morph2



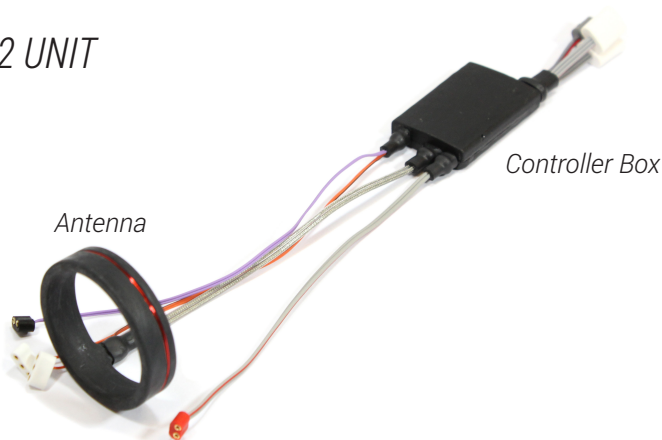
morph2 is an accessory for upper limb prosthetic devices that controls prosthesis mode switching. It works with RFID tags. Each tag is programmed with a command, such as a grip. When morph2 detects a tag near the prosthesis, morph2 wirelessly reads the tag and sends the corresponding command to the connected prosthetic components. This command can switch grips (i.e. from tripod to power grip) or functions (i.e. hand to wrist).

morph2 does not remove any functionality from the prosthetic hand. Users can continue to use traditional operation to switch functions as needed without the use of tags.

morph2 is compatible with the bebionic small (Steeper), bebionic3 (Steeper) and the 6-band ProWrist (Motion Control). If you have a question about compatibility please contact us.

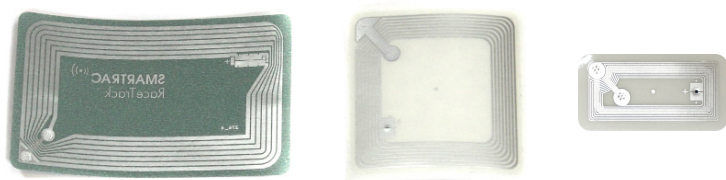
2 component description

MORPH2 UNIT



morph2 includes a controller box and an antenna. The controller box contains input cables for battery and electrodes and output cables that connect to the hand or wrist. The output cables are specific to the hand or wrist that morph2 will connect to. The antenna is a ring that comes in different sizes. Your antenna size depends on the lamination collar of the prosthesis. The antenna is permanently attached to the controller box; do not try to disconnect the antenna from the controller box.

TAGS



Tags are small objects that store information (i.e. hand grips). When morph2 comes close to a tag, morph2 wirelessly reads the tag and sends a command to the hand. For more details on the tags and how to incorporate them into the user's environment, see Section 6.

3 specifications

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 (storage/transport)	15% - 93%
Atmospheric pressure range	860 hPa - 1060 hPa
Input voltage	7.4V
Maximum Output Current	3A
Compatible battery	FlexCell
Recommended battery capacity	At least 2000 mAh
Expected service life	3 years
Compatible electrode	Standard analog electrodes with three-port kidney-style connectors
Tag range	1-8cm (0.4"-3.1")

4 installing morph2

BEFORE YOU BEGIN

Included in the package:

- (a) morph2
- (b) Tags
- (c) FlexCell batteries (if ordered with morph2)

What you'll need:

- (a) FlexCell batteries
- (b) Two EMG electrodes with three-port kidney-style connectors
- (c) Steeper bebionic3 or bebionic small hand
- (d) 6-band coaxial plug
- (e) Lamination collar parts

If using Motion Control 6-band ProWrist (P/N 5010056, 3010832)

- (a) 6-band ProWrist (instead of 6-band Coaxial Plug)
- (b) Motion Control Battery Adapter Cable (P/N: 3010461)



WARNING: Do not place morph2 in a carbon fiber prosthesis. morph2 cannot detect tags through carbon fiber.

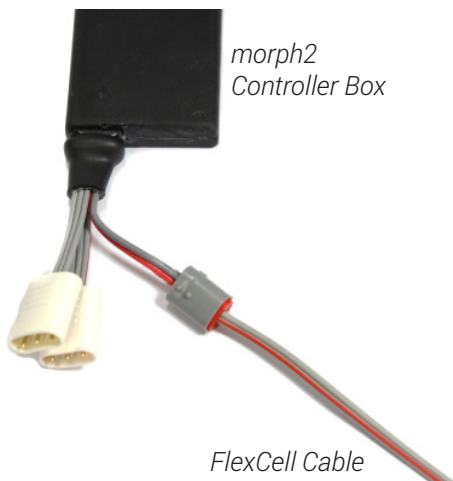


BATTERIES AND ELECTRODES

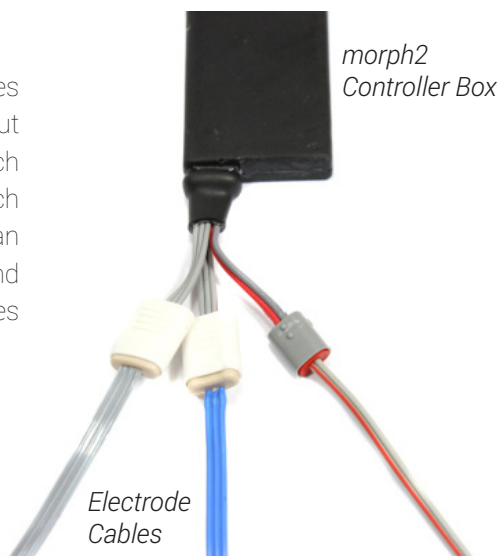


WARNING: Turn the battery OFF before plugging in any cables. Do not attempt to connect the battery or electrodes in a way that is not specified. This could cause permanent damage to morph2, the battery or electrodes.

Plug the FlexCell cable into the morph2 battery input cable. As shown in the picture, the red cables should be on the same side.



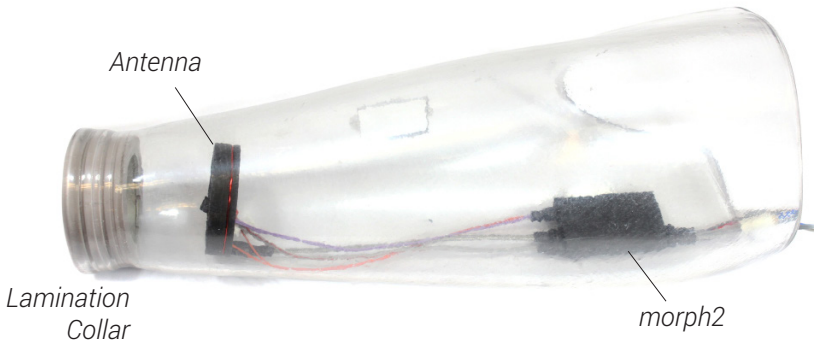
Plug each of the electrode cables into the morph2 electrode input cables. It does not matter which electrode is plugged into which input cable. The signals can be later switched in the hand software. Make sure the cables are plugged in all the way.



Now that your electrodes and battery are connected, insert morph2 through the proximal end of the prosthesis (i.e. end opposite of the lamination collar).



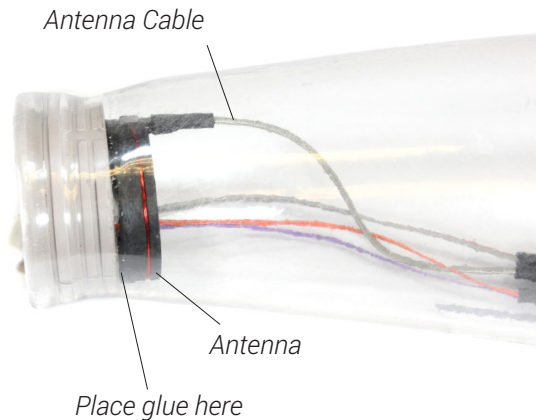
WARNING: Do not place morph2 in a carbon fiber prosthesis. morph2 cannot detect tags through carbon fiber.



INSTALLATION WITHOUT A WRIST

Ensure that the flat side of the antenna is flush against the proximal side of the lamination collar. Antenna cable should extend into the prosthesis.

Use a small amount of adhesive (i.e. glue) to secure the antenna to the lamination collar.



Pull the morph2 output wires through the hole in the lamination collar.

morph2 Output Wires

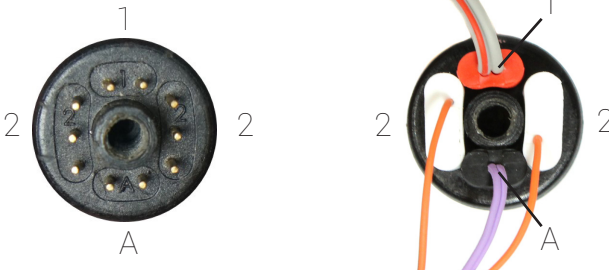


WARNING: Ensure the battery is OFF before plugging in any cables. Do not attempt to connect the morph2 output cables in a way that is not specified. This could cause permanent damage to the hand and morph2.

On the coaxial plug:

- Plug the morph2 red power cable to the pins labeled "1"
- Plug the morph2 purple cable to the pins labeled "A"
- Plug the morph2 orange cables to the pins labeled "2"

Make sure the cables are plugged in all the way.



WARNING: Make sure that the morph2 red connector is plugged into the coaxial plug power pins labeled "1". Incorrectly connecting the red connector could cause permanent damage to the hand and morph2.

Insert the coaxial plug into the lamination collar coupling piece and seal it in place using the small o-ring.



Insert the coupling piece into the lamination collar and secure it with the large o-ring.



INSTALLATION WITH A PROWRIST

NOTE: morph2 is only compatible with the Motion Control 6-band ProWrist (P/N 5010056, 3010832).

First, remove the wrist from the prosthesis. Use adhesive to install the antenna behind the lamination collar. Ensure that the antenna cable is on the edge opposite of the lamination collar.

Pull the morph2 output wires through the hole in the lamination collar.



morph2 Output Wires



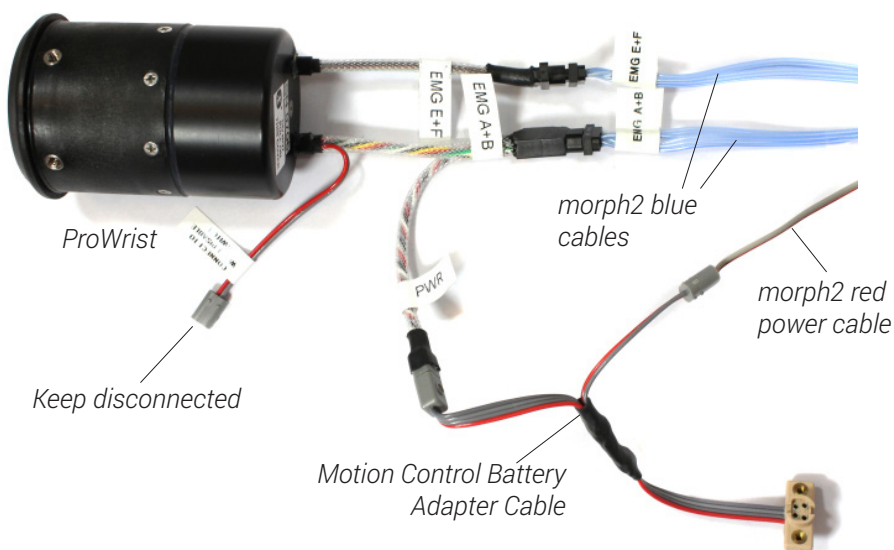
WARNING: Ensure the battery is OFF before plugging in any cables. Do not attempt to connect the morph2 output cables in a way that is not specified. This could cause permanent damage to the hand and morph2.

Plug the morph2 blue cable labeled "EMG A+B" into the ProWrist cable labeled "EMG A+B".

Plug the morph2 blue cable labeled "EMG E+F" into the ProWrist cable labeled "EMG E+F".

Plug the morph2 red power cable into the ProWrist cable labeled "PWR."

NOTE: for the power cable, use the Motion Control Battery Adapter Cable (P/N: 3010461).



Slide the Motion Control 6-band ProWrist through the lamination collar.

NOTE: the wrist should slide through the morph2 antenna.



Secure the ProWrist to the lamination collar with the screws.

5 test morph2

Before fitting the user with the prosthesis, test the prosthesis first.

Once all the components are connected and inside the prosthesis, connect the bebionic hand and turn the FlexCell battery system on. Wait 5 seconds. morph2 will vibrate within 5 seconds to signal that it has received power and is ready to use.

Tap the electrodes with your finger tip and confirm that the hand opens and closes appropriately. If the signals are reversed (i.e. close electrode opens the hand), connect to the hand's software and switch the EMG signals.

Approach a tag to the wrist area of the prosthesis where the morph2 antenna resides. morph2 will vibrate to indicate that it has detected the tag. Tap the electrodes to confirm that the hand switched to the mode labeled on the tag. Familiarize yourself with morph2's detection range by approaching tags to other areas around the wrist.

6 using tags

Tags are small objects that store information (i.e. hand grips). When morph2 comes close to a tag, morph2 wirelessly reads the tag and sends a command to the hand. As soon as morph2 detects the tag, it will vibrate to tell you that it has detected the tag. The tags do not use batteries and therefore do not require periodic maintenance or replacement.

Several tags are included with your morph2 shipment. The tags are already programmed, labeled and ready to use. The following section is intended to help you and your user understand normal use with tags.

GRIP TAGS

Many of your tags will be labeled with a grip name (i.e. power). When morph2 detects a grip tag, it will switch the hand to the grip labeled on the tag. For example, if morph2 detects a tag labeled "power," it will immediately switch the hand to a power grip. The tag does not close or open the hand. The user creates EMG signals to close and open the hand in the new grip.

Once the user approaches a grip tag, the hand no longer responds to EMG triggers (i.e. co-contraction) to switch grips. The hand will only switch grips if the user approaches a different tag or switches the thumb position. However, if the user wishes to use the default or internal switching strategy of the bebionic (i.e. EMG triggers or button on the hand), he/she can do one of the following:

- Approach a tag labeled "regular" or...
- Press the button on the back of the hand or...
- Turn the battery off, then back on.

The bebionic hand has two thumb positions (opposed and non-opposed). If morph2 detects a grip tag for the opposite thumb position, it will create a long vibration to notify the user to switch the thumb position. The table on the next page lists the opposed and non-opposed grips for the bebionic hands.

Opposed Position	Non-opposed Position
Tripod	Key
Power	Finger Point
Precision Open	Mouse
Active Index	Column
Precision Closed	Relaxed

REGULAR TAGS

When morph2 detects a “regular” tag, the hand returns to regular mode, where the user can use EMG triggers and the button to switch grips.

HAND/WRIST TAGS

If the user has a wrist, the user can approach a “hand/wrist” tag to switch between hand and wrist. The wrist must be programmed to switch with a co-contraction to use the “hand/wrist” tag.

LOCK TAGS

If the user approaches a “lock” tag, the prosthesis becomes frozen in its current position. In other words, the hand ignores any EMG signals from the user. If the user wishes to unlock the prosthesis, the user can approach any RFID tag (including “Lock” tag) and the hand will again respond to EMG.

The user may find this tag useful when holding objects (i.e. beverages) to maintain a secure grip. With the lock tag, the user does not have to worry about accidentally opening or closing the hand.

TAG SIZES

You will notice that your tags come in different sizes. Larger tags have a longer range (1-3”) than smaller tags (<1”).

TAG VIBRATION PATTERNS

Everytime it detects a tag, morph2 vibrates to notify the user that it has read the tag and sent a command to the prosthesis. morph2 creates different vibration patterns depending on the tag it detects. This feedback can be very helpful for the user to know the status of the prosthesis. The different vibration patterns are summarized in the table below:

Condition	Vibration Pattern
Grip tag in correct thumb positon	one short vibration
Grip tag in opposite thumb position	one long vibration
Regular tag	one short vibration
Lock tag to lock the prosthesis	two quick vibrations
Lock tag (or other tag) to unlock the prosthesis	one short vibration

Note: morph2 will also vibrate when it is powered on. Allow the device 5 seconds after power on before attempting to control the prosthesis.

TAG PLACEMENT

Tags can be placed virtually anywhere. The user can place them in an environment (i.e. kitchen, office) or carry them (i.e. in the wallet, pants pocket). We explore some strategic tag locations in this section.

Kitchen:

- Key grip tag on the cabinet door to grab a plate from the cabinet.
- Power grip tag near the refrigerator to open the refrigerator door.
- Power grip above the sink to grab a glass.
- Finger point tag near the coffee maker to press buttons on the maker.
- Finger point tag on the stove to press the temperature buttons.
- Lock tag on the wall near the exit to securely carry a dish out to the dining room.
- Regular tag near the front door to return the hand to regular mode before leaving the house.

Closet:

- Column grip tag on the closet wall to slide the prosthetic arm through a coat sleeve.
- Tripod grip tag on the shelf to put on trousers and other items of clothing.

Bathroom:

- Active index tag below the bathroom sink to operate a mirror cleaning spray bottle

Office:

- Finger point tag on the desk to operate the computer keyboard with two hands.
- Key grip tag near the printer to grab a sheet of paper
- Power grip tag at the edge of the desk to pick up a briefcase on the way out.



Carry along:

- Key grip tag in the wallet to hold the wallet open while pulling a card out
- Tripod grip on back of cell phone case to hold phone during texting
- Relaxed grip in front pocket for a quick handshake
- Lock tag on bracelet or watch to quickly freeze prosthesis at any time



TAG LIMITATIONS

The tags have a few limitations. Listed below are several tips to ensure success with morph2:

- Avoid attaching tags to metal surfaces: Metal can decrease the tag range. Feel free to experiment with your user. If the tag cannot be detected on the metal surface, move it to another surface, or add separation between the metal and the tag.
- Place the tags at least 6" apart: If a user approaches two tags that are close together, morph2 may read the unintended tag. Advise your user to add separation between tags or use smaller tags to reduce the risk of overlap.
- Only use tags sold by IBT: There are several variations of tags on the market. morph2 only works with a specific type of tag provided by IBT. Contact IBT if you need additional tags.
- Sticker tags: Some of your tags may be stickers. Advise your user not to wet these tags. Also, advise your user to avoid sticking and unsticking the tags multiple times, as this may wear off the adhesive. You can place these tags on slightly curved surfaces, but this may affect the range. If you believe your tag is damaged, contact IBT for additional tags.

7 troubleshooting

In case of a problem, this section is intended to help you troubleshoot. As a first step, when the unit is not operating as expected, turn the battery off then back on. In case this does not solve the problem, we have included a few possible issues with solutions below. If your issue is not addressed, call us or email us for support (443-451-7175, support@i-biomed.com).

MORPH2 DOES NOT VIBRATE WHEN I POWER ON THE BATTERY

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, tap the electrodes to see if the hand moves. If it does, morph2 and the hand are receiving power. It is possible that morph2 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 finger in the inner socket to feel the vibration there.

If the hand does not move, morph2 and the hand are not receiving power. It is possible that the power cable got disconnected during installation. Please check the cabling inside the prosthesis.

MORPH2 DOES NOT VIBRATE WHEN I APPROACH A TAG

First, check that the battery is on and 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 powered off, turn the battery on, and approach the tag again.

If the battery is charged, try approaching a tag, and tap the electrodes to determine if the hand switches to the mode indicated on the tag. It is possible that morph2 is installed in a way that dampens the vibration. If it does switch, morph2 detected the tag, but the vibration may be too subtle. Please note that the vibration may be easier to detect while wearing the prosthesis. Try placing your finger in the inner socket to feel the vibration there.

If the hand does not switch when you approach a tag, the antenna may be installed in a way that diminishes its range. Consider shifting components away from the morph2 antenna. The antenna's range may degrade if there are too many components touching it.

THE HAND DOES NOT MOVE WHEN I TAP AN ELECTRODE

First, check that the battery is on and 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 powered off, turn the battery on, and approach the tag again.

If the battery is charged, attempt tapping the other electrode to determine if this creates a response. If it does, the electrode that is not working may require a higher gain. Connect to the hand software to visualize the EMG signals and adjust the thresholds. If the gain is not the issue, the electrode may have been disconnected from the morph2 Electrode Input Cable. Or the morph2 output cable may have been disconnected from the terminal device. Check the cabling and ensure that everything is connected correctly.

8 maintaining morph2

PREVENTATIVE INSPECTION

All morph2 systems undergo extensive quality assurance inspections prior to shipping. No additional inspection is required or advised.

MAINTENANCE

No regular maintenance is required for morph2. If you need to replace the battery or electrodes, simply unplug the battery or electrodes from the morph2 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



morph2 should not be thrown away with common household waste. Dispose of morph2 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 regarding repairs and returns. morph2 comes with a 1 year design and manufacturer's defect warranty. Details of the warranty are enclosed separately.

9 safety and warnings



Liquid damage warning: morph2 is not waterproof. Please advise the user to avoid submerging or spilling liquid on or into their prosthesis. This may cause morph2 to be permanently damaged. If the user will be wearing their prosthesis in wet environments, ensure that morph2 is sufficiently protected from the external environment.



Battery use warning: morph2 must be powered by a FlexCell battery system from IBT. We have conducted safety testing to confirm compatibility between morph2 and FlexCell batteries.



Modification warning: Any unauthorized modification to morph2 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 morph2 during safety critical tasks.

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

The testing was performed for typical levels of radiation, but there is a chance that the device is exposed to a concentrated level. If the product is in a high electromagnetic field, such as near an MRI, the device may need to be moved out of this area to function properly.

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

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

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.

notes

notes



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Z0000059rev1 Oct'2016