https://cosmiic.org

Example - Early Feasibility Investigational Device Exemption

IDE Section:

Draft Labeling

13. Draft Labeling

This section contains:

13.1. Package Labeling / Product Markings

13.1.1. Control Tower

Labels affixed to the Control Tower read as follows:

NNP Team at Case Western Reserve University
[redacted] CAUTION – INVESTIGATIONAL DEVICE LIMITED BY UNITED STATES LAW TO INVESTIGATIONAL USE

13.1.2. Implanted Components

All components of the NNP System are purchased and stored at the NNP Facility on the campus of Case Western Reserve University. All devices are couriered to the clinical facilities by research staff. Therefore, no devices are shipped. Once implanted devices are received from the manufacturer and inspected at the NNP Facility, they are under the continuous control of the NNP Team until the time they are implanted in a human subject. Packaging on hardware to be sterilized is labeled with the item name (e.x. "PG4" or "IM Electrode"), date of manufacture, and lot/serial number if applicable. The date of the sterilization procedure is also added to the packaging after the process is complete. The package label will also indicate that the device is MR unsafe, and will include appropriate universal markings to indicate MR unsafe.

13.2. Physician Manual

For this single-center Early Feasibility study, our surgeons, [redacted], have been instrumental in defining the stages of the surgical procedure(s) for the NNP-UE and NNP-T configurations. The Physician Manual will be developed prior to expanding our study to a multi-center pivotal clinical trial, along with a training program for implanting surgeons and rehab specialists (e.g., occupational and physical therapists).

In lieu of a Physician Manual, implanting surgeons, [redacted], will be presented with the indications, contraindications, warnings, and precautions from the Patient Manual, for this Early Feasibility study.

13.3. Patient Manual

User's Manual
Cleveland FES Center
Upper Extremity
Networked Neuroprosthetic (NNP)
System

For Investigational Use Only

Rev 2.0
September 10, 2014

Contact Information

Physician:

Clinician:

Technical Support:

Precautions for Patients with FES Implants

Contraindications

A. **Do Not Undergo MRI.** Exposure to the magnetic field of an MRI unit may causing heating, movement of the implant, or damage to the electronic circuitry.

B. **Do Not Apply Surface Stimulation Once the Stimulator is in Place.** This includes, for example, EMG testing (**electrodiagnostics**), use of a **NMES** unit for muscle strengthening or use of a **TENS** unit. Contact the Cleveland FES Center to discuss specific applications of surface stimulation.

Warnings

A. **WARNING: Use Caution When Having Ultrasound.** Ultrasound should not be performed over the area where the electrodes and stimulator are located as it may cause damage to the implanted electronics.

B. **WARNING: Use Caution When Having Lithotripsy.** Lithotripsy may cause damage to electronic circuitry. Consult FES Center.

C. **WARNING: Use Caution When Having Diathermy.** Diathermy may cause damage to the implanted electronics. Consult FES Center.

D. **WARNING: Contact the Cleveland FES Center prior to any surgery, if possible.** In **emergency surgery situations**, the implant stimulator should be treated as a pacemaker.

E. **WARNING: Do Not Hesitate to Use External Defibrillators**. The use of **external defibrillators** may make the implant non-operational, but does not alter the effectiveness of defibrillators. Do not hesitate to use them if necessary.

F. **WARNING: Do Not Hesitate to Use CPR.** CPR will not harm the implant.

G. **WARNING: Do Not Use a Pacemaker Magnet Near the Implant**. Magnets used for pacemakers will turn off the implanted device.

Precautions and Notes

H. **CAUTION: X-rays** and/or **mammograms** will not harm the implant, but the implant image may obscure the view of other structures

A. **NOTE: CAT** scans can be safely used with the NNP system.

B. **NOTE:** Cell phones, cordless phones and wifi can be safely used with the NNP system.

C. **CAUTION:** Prior to undergoing other types of imaging, including **PET** scans, please consult with the Cleveland FES Center.

D. **CAUTION:** Prior to undergoing invasive procedures (**surgeries**) in the implant area or near the electrodes or leads, please consult with the Cleveland FES Center.

E. **CAUTION:** Placement of **catheters** and **needles** should not be done in the arm with the implant stimulator, as it increases the risk of puncturing an electrode lead.

F. **CAUTION**: The Cleveland FES Center should be notified prior to the surgical installation of orthopaedic implants such as **artificial hips**, or any cardiovascular implants such as **artificial heart valves**.

G. **CAUTION:** The Cleveland FES Center should be notified prior to any **dental surgery**.

H. **CAUTION:** Sources of interference with the implant should be avoided, if possible. These may include: portable radio transmitters, metal detectors, anti-theft systems such as those used in retail stores, welding equipment, high-voltage industrial equipment, and RFID systems. Proximity to these sources may cause unexpected behavior of the system.

When To Call Us

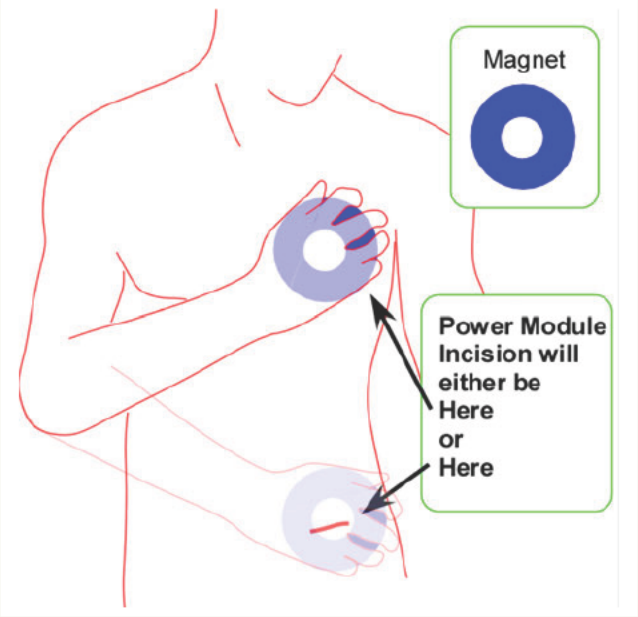
A. Any sudden change in grasp patterns or grasp strength, or if the stimulation suddenly feels different.
B. Warm sensation around the power module or excessive heating underneath the recharging coil.
C. Areas of pain, redness or swelling in the implanted arm or over the power module, especially if they occur over an electrode or a module.
D. If any module appears to have shifted to a different place.
E. If you are diagnosed with pneumonia, a uninary tract infection, pressure sores or any other systemic infection, please contact us to let us know. Any time a doctor prescribes antibiotics, please let us know.
F. If you will be undergoing any kind of surgical procedure, including dental work, contact us prior to the surgery if possible.
G. If you experience an episode of autonomic dysreflexia.
H. If you experience asymmetrical swelling in your legs.
I. If you are admitted to the hospital, please contact us, or have someone in the hospital staff contact us.
J. If you experience any unusual performance of the system that may be caused by proximity to electromagnetic sources. Any unusual performance of the system should be reported so that we can trouble-shoot possible causes.

Emergency Shut-off of the NNP System

If you need to shut-off the NNP System immediately and it is not shutting off when you depress and hold the red button on the Control Tower, take the following steps.

Find the large round magnet supplied with the NNP System.

Find the approximate location of the power module (see diagram). It will either be under an incision in your chest or abdomen. This is the same place that you place the charging coil.



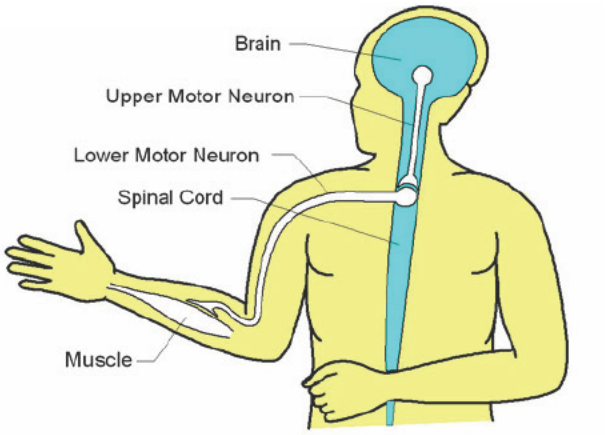
Place the magnet on the skin over the power module. You can lay the magnet on the skin. If the NNP System doesn't immediately shut off, continue to move the magnet on the skin around the area of the incision. Also, move the magnet in and out from your body quickly. The NNP System should shut off immediately.

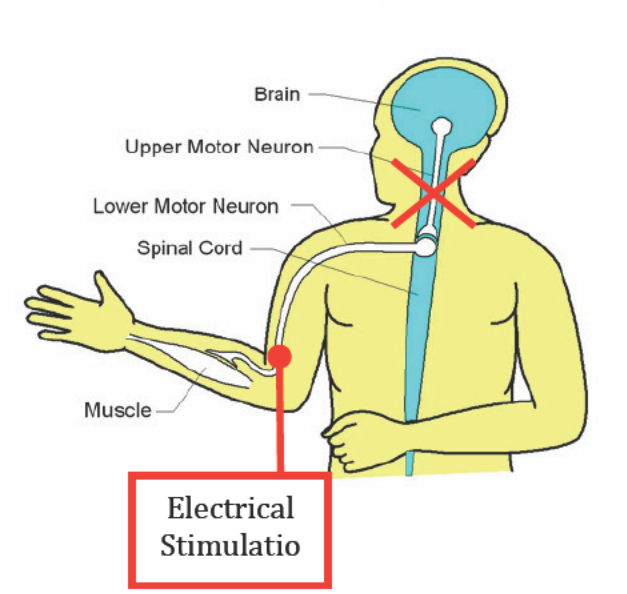
Once the NNP System has been shut off, you must call the Cleveland FES Center. You will need to return to the Center to have the NNP System evaluated and restarted.

Remember to keep the magnet away from credit cards – it can erase them.

Theory

Prior to spinal cord injury, your muscles are controlled by signals from the brain as shown to the right. Signals from the brain travel down to upper motor neurons and connect (synapse) in the spinal cord with lower motor neurons. The signals (action potentials) conduct down the lower motor neurons to the muscles, causing them to contract.



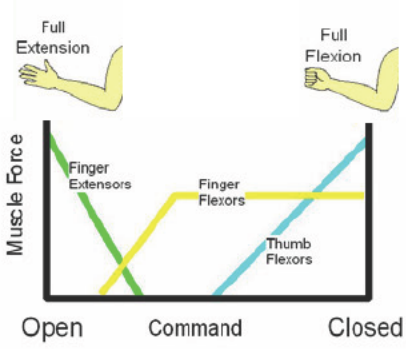


When a spinal injury occurs, the upper motor neurons can be damaged, preventing the signals from the brain from reaching their connection with the lower motor neurons.

As long as the lower motor neurons are not harmed, they may be activated with electrical stimulation, causing the muscle to contract.

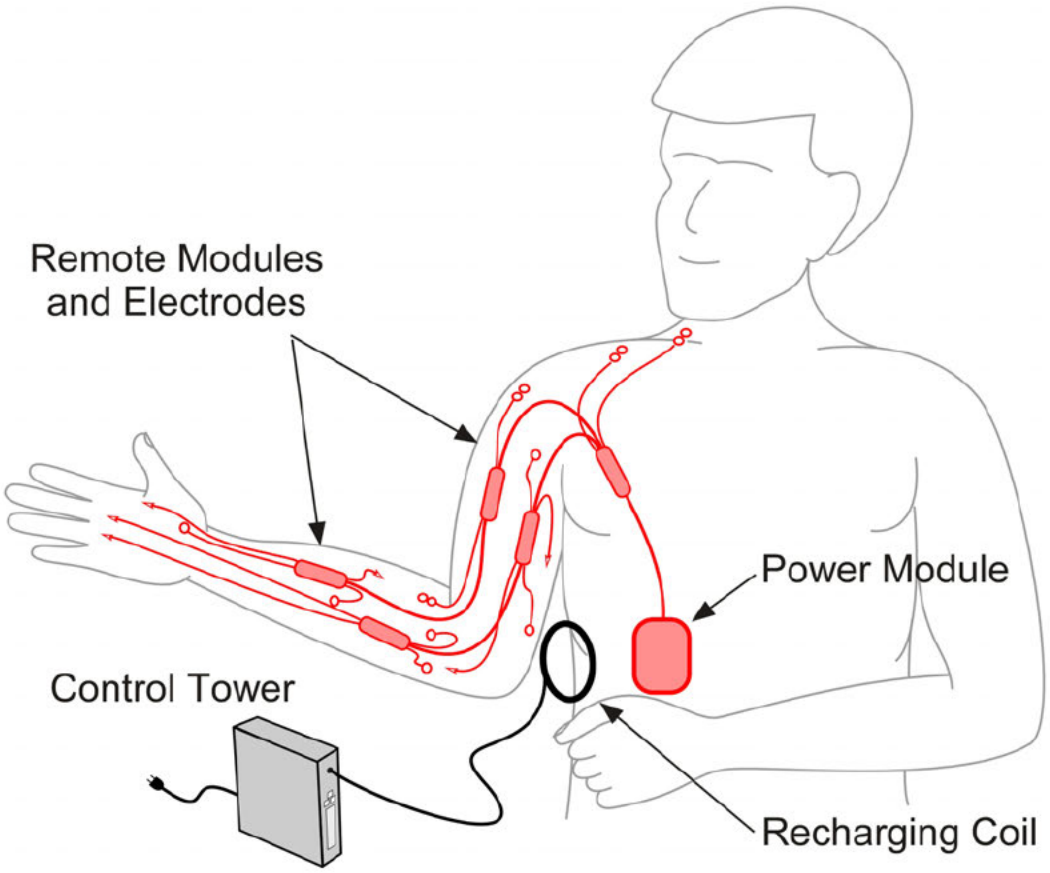
Muscles for which the lower motor neuron is damaged, are called "denervated" and cannot be activated by electrical stimulation.

The Functional Electrical Stimulation (FES) hand grasp system consists of a device which stimulates the undamaged lower motor neurons by placing electrodes on the innervated muscles. The muscles which are stimulated are coordinated into a functional pattern of activation, providing basic hand and/or arm function, which is controlled in some way by the user.



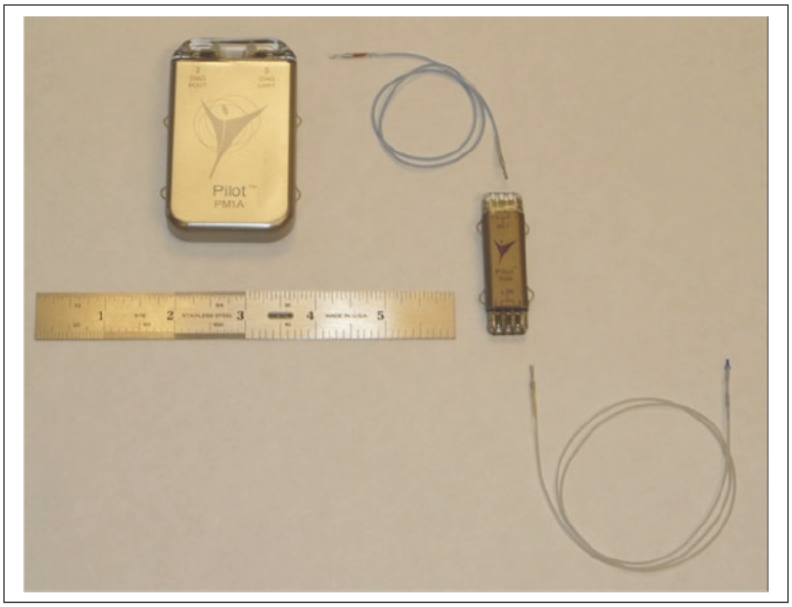
The NNP devices record a signal from nerves with intact upper motor neurons, which are under the control of the user, and use those signals as a command source for the coordinated stimulation patterns.

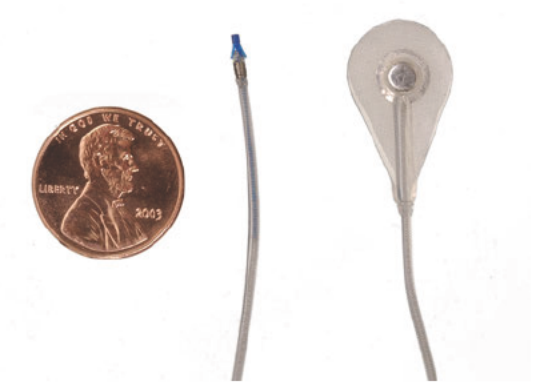
Internal Components



The NNP system, which has been implanted, is similar to the one illustrated above. The precise module and electrode placements will vary from patient to patient, depending upon the specific needs and availability to stimulate and/or record electrical activity. The Power Module is located in either the abdomen or chest and provides power for the system. It is also where you will place the recharge coil. The remote modules located in your chest and arm can be either stimulators or sensors. The stimulators are connected to electrodes that can activate your paralyzed muscles. The sensors are connected to electrodes that record the myoelectric signals (MES), also known as electromyography (EMG) recordings, from muscles that you can voluntarily activate. You control the stimulation to your hand and arm through the movements that you make with the control muscles, as explained later in this book.

The implanted components of the NNP System are shown in the photo to the right. It is able to record MES from two to four locations, and stimulate up to twenty individual muscles. Power is delivered by the power module (top left). A network cable connects each one of the remote modules to the power module inside your body.





Shown on the left are the stimulating electrodes, which are either inserted into the paralyzed muscles, or sutured to the surface of the muscles.

During surgery, the best location for each electrode is determined, as well as which type will be used to provide the optimum response from the muscle during stimulation.

Shown to the right is the MES recording electrode, which is sutured to the muscle that is still under voluntary control. This electrode has two recording surfaces. This allows it to record the very small electrical signals from the muscles when they contract, and still be able to reject unwanted signals in the environment (such as lights, radios or cell phones).

External Components

The Control Tower and Recharge Coil, used with the UE NNP System, are shown above. They are described in more detail under the device use section.

Control Tower: This box provides you with information about the status of your implanted NNP System. It contains the connection to plug in your recharge coil for recharging. The Control Tower has a display that shows you the charge state of the internal NNP System battery (the one inside your body). The Control Tower also stores information that can be used for reprogramming or evaluating your system if necessary. The Control Tower has a rechargeable battery inside that can be recharged by plugging the Control Tower into the wall outlet.

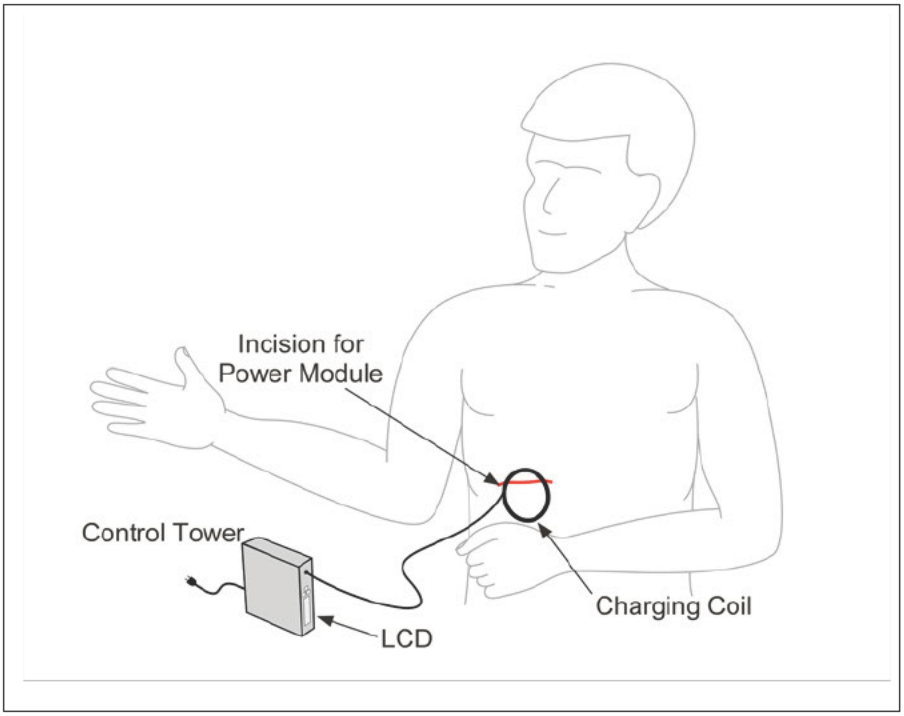
Recharge Coil: The recharge coil is used to recharge the implantable battery inside your body. The coil is placed on the skin over the Power Module, as shown on the next page.

Charging the NNP System

1. Turn off the power to the Control Tower by pushing the round grey button (the power indicator will go out).

2. Connect the Charging Coil to the Control Tower.

3. Turn on the Control Tower by pushing the round grey button again.



4. Place the Charging Coil on the skin over the Power Module in your chest or abdomen, as shown in the diagram. Your clinician will help you locate the incision that will be over the top of the Power Module. When you are in the right spot, the Control Tower will indicate "Charging" on the LCD display. Once the coil is in the right spot, tape it in place.

5. Continue charging all night if possible. If you have completely discharged the batteries, it may take as long as 14-16 hours to completely recharge the batteries. The Control Tower will automatically stop recharging when the implanted battery is fully charged.

6. You can check the charge state of your implanted battery by pushing the green button on the Control Tower and reading the LCD display on the Control Tower.

7. If the Control Tower LCD display reads "FAULT", that indicates that the Control Tower is unable to charge the implanted battery. Call the Cleveland FES Center for service.

Exercise Mode

1. Set up the Control Tower somewhere nearby (within a few feet). Push the orange button on the front panel of the Control Tower. This will initiate the exercise mode. Your hand will automatically open and close in the pre-programmed exercise mode. The exercise will automatically shut off when it is completed. Typically the exercise mode lasts six to eight hours.

2. If you wish to stop the exercise mode, push the red square button on the Control Tower. This will stop the exercise mode. If you restart the exercise mode after this, it will start over and run from the beginning.

Your Grasp Exercise Routine

Total Time:_____

Duty Cycle: _____ Min On / _____ Min Off.

Patterns Used:

_____
_____
_____
_____
_____
_____
_____

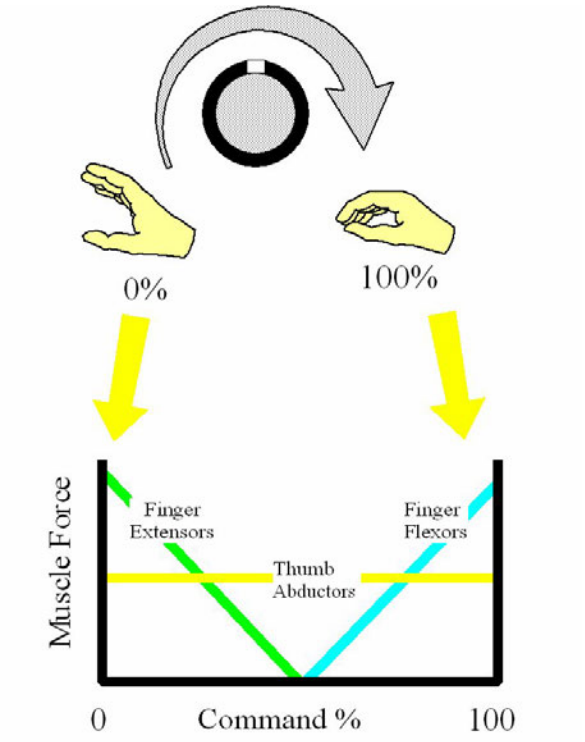
Special Instructions:

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Functional Use

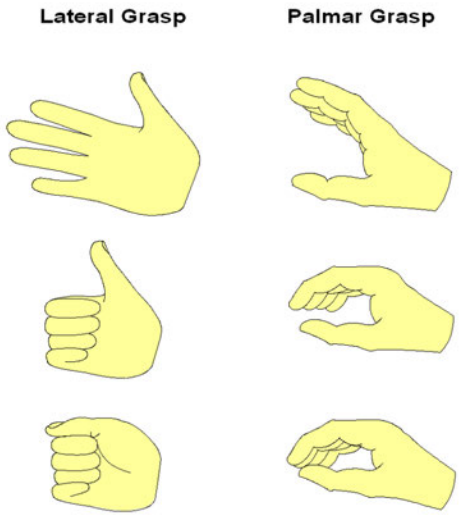
1. To start active use of the system, you will need to wake it up from sleep mode. You can do this by strongly activating you wrist extensor for about five seconds. When the system becomes active, it will automatically place you into your lateral grasp with the stimulation set to open your hand. When you hand opens, you will know that the system is in active mode and ready for use.

2. Your system will contain a number of hand grasp patterns that are custom designed to meet your needs and abilities. An example of that pattern is shown diagrammatically below.



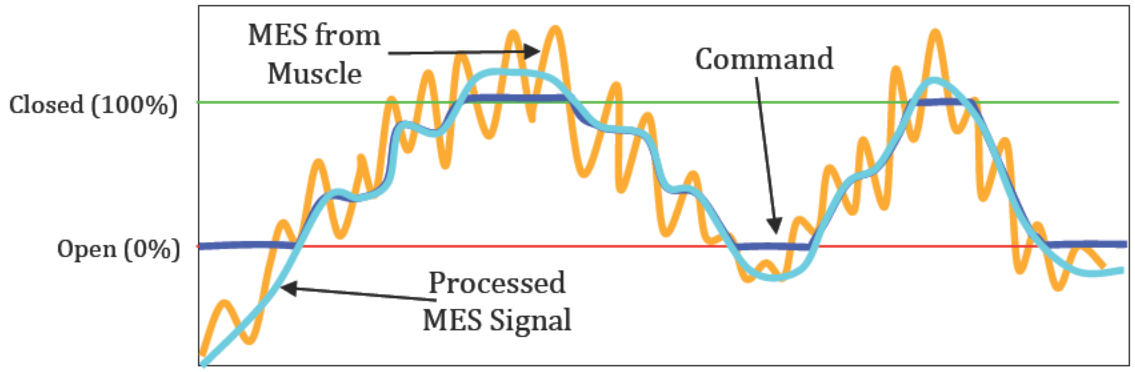
As the command is "turned up", the finger extensors relax (less force) and the finger flexors tighten (more force). By combining the muscles/electrodes in different ways, we can produce a variety of grasping patterns, each of which may be opened and closed with a command movement (such as raising the wrist).

Two of the most common grasp patterns are shown to the right. The lateral grasp is used for such activities as holding a pen or fork, while the palmar grasp is used for larger objects, such as a glass or can.



3. To change which stimulation pattern is being used, make a rapid contraction of your _____ muscle. The system will jump to the next grasp each time you strongly contract your _____. If you are on your last grasp, it will cycle back around to the first.

4. To open and close your hand, contract your _____ muscle strongly. The NNP System processes the signal from your muscle to make it control your hand closing smoothly but slightly delayed. This is because the MES recorded from your muscles needs to be filtered to provide smooth control. If the processed (smoothed) command signal exceeds 100% command, the command stays at 100%.



5. If you want to maintain a command level, without maintaining the contraction of the command muscle, you may do so by giving a "lock" command. This command tells the System to lock the command until told to "unlock". The command may be locked as follows:

   Hold the command above 80% for _____ seconds.

6. To unlock the command and regain control of the command level, you may issue an "unlock" command. Do the following:

   Produce a "double-click" signal (similar to doing a double-click with a mouse button). This method will be adjusted to your comfort level and may require some practice.

7. To turn the NNP System off (back into "sleep" mode), contract both your _____ muscle and _____ muscle for three seconds or pushing and holding the red button on the Control Tower for three seconds. Putting the NNP System in sleep mode when you are not actively using it will prolong the charge on the internal batteries. Push the green button to wake your system up.

Trunk Stability Instructions

Functional Use

1. To start active use of the system, you will need to generate a specific movement of your muscles. Different movements will initiate different stimulation patterns to produce the movement desired. These movements and patterns have been customized for you, and are as follows:

	Movement you must make	
Stimulation Pattern	**To turn stim on**	**To turn stim off**
Trunk posture during seating	_____	_____
	_____	_____
Erect seating	_____	_____
	_____	_____
Left side lean	_____	_____
	_____	_____
Right side lean	_____	_____
	_____	_____
_____	_____	_____
	_____	_____

2. If you anticipate not using the trunk stimulation for a period of time, you can turn the NNP system off by (back into "sleep" mode) contracting both your _____ muscle and _____ muscle for three seconds or by pushing and holding the red button on the Control Tower for three seconds. Putting the NNP System in sleep mode when you are not actively using it will prolong the charge on the internal batteries. Push the green button on the Control Tower to wake your system up.

Your Trunk Exercise Routine

Total Time:_____

Duty Cycle: _____ Min On / _____ Min Off.

Patterns Used:

_____
_____
_____
_____
_____
_____
_____

Special Instructions:

_____
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