DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service P950035

Memorandum

Date . AUG 15 1997

From Director, Office of Device Evaluation (HFZ-400)
Center for Devices and Radiological Health (CDRH)

Subject Premarket Approval of NeuroControl Corporation Freehand System® - ACTION

To The Director, CDRH
ORA _____

ISSUE. Publication of a notice announcing approval of the subject PMA.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

(1) a premarket approval order for the above referenced medical device (Tab B); and

(2) the availability of a summary of safety and effectiveness data for the device (Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.

Susan Alpert, Ph.D. M.D.

Attachments
Tab A - Notice
Tab B - Order
Tab C - S & E Summary

DECISION

Approved _____ Disapproved _____ Date _____

Prepared by Levering Keely, CDRH, HFZ-450, 11/19/96, 443-8517

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DRAFT

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

[DOCKET NO. _____]

NeuroControl, Corp.; Premarket Approval of Freehand System®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application submitted by NeuroControl, Corp., Cleveland, OH, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Freehand System®. After reviewing the recommendation of the Neurological Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of August 15, 1997, of the approval of the application.

DATES: Petitions for administrative review by (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Levering Keely,

Center for Devices and Radiological Health (HFZ-450),

Food and Drug Administration,

9200 Corporate Blvd.,

Rockville, MD 20850,

301-443-8517.

SUPPLEMENTARY INFORMATION: On June 17, 1996, NeuroControl Corp., Cleveland, OH 44106, submitted to CDRH an application for premarket approval of the Freehand System®. The system includes: implantable receiver-stimulator Model 202-1, implantable epimysial electrode set Model 203-1, surgical electrode positioning kit Model 207-1, patient external system Model 204-1, programming system Model 209-1. The system is an upper extremity neuroprosthesis and is intended to improve a patient's ability to grasp, hold, and release objects. The system is indicated for use in patients who: are tetraplegic due to C5 or C6 spinal cord injury (ASIA Classification); have adequate functional range of motion of the upper extremity; have intact lower motor neuron innervation of the forearm and hand musculature; and are skeletally mature.

On September 25, 1996, the Neurological Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application.

On August 15, 1997, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act), (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the

FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h), (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: _____.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 1997

Ms. Julie Grill
Manager, Clinical Studies and Regulatory Affairs
NeuroControl Corporation
Chester Conference Centers, Suite WI-310
1945 East 97th
Cleveland, Ohio 44106-4720

P950035
Freehand System®
Filed: June 17, 1996
Amended: August 14 and 28, December 18, 1996; January 6, May 12 and 19, July 29 and 30, and August 12, 1997

Dear Ms. Grill:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Freehand System®. The system includes: implantable receiver-stimulator Model 202-1, implantable epimysial electrode set Model 203-1, surgical electrode positioning kit Model 207-1, patient external system Model 204-1, programming system Model 209-1. The system is an upper extremity neuroprosthesis and is intended to improve a patient's ability to grasp, hold, and release objects. The system is indicated for use in patients who: are tetraplegic due to C5 or C6 spinal cord injury (ASIA Classification); have adequate functional range of motion of the upper extremity; have intact lower motor neuron innervation of the forearm and hand musculature; and are skeletally mature. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that to ensure the safe and effective use of the device that the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

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CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the act.

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

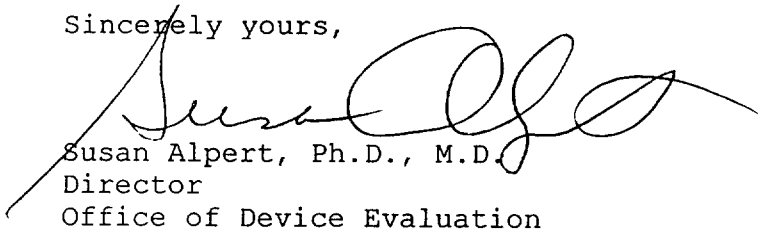
You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have questions concerning this approval order, please contact Levering Keely at (301) 443-8517.

Sincerely yours,



Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the **addition** of, but **not the replacement** of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. **This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.**

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant**(s)** involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and
(b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies

of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1) A mixup of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984, and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices

(1) may have caused or contributed to a death or serious injury or

(2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for this PMA, you shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Division of Surveillance Systems (HFZ-531)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive, 340
Rockville, Maryland 20850
Telephone (301) 594-2735

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the address below or by telephoning 1-800-638-2041.

Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

I. General Information

Device Generic Name(s):	Implantable Functional Neuromuscular Stimulator for Restoration of Hand Grasp, Hold, and Release Motor Control Neuroprosthesis
Device Trade Name:	NeuroControl *Freehand System*®
Applicant Name and Address:	NeuroControl Corporation Chester Conference Centers 1945 E 97th Street Suite W1-315 Cleveland, OH 44106
Premarket Approval Application Number:	P950035
Date of Panel Recommendation:	September 25, 1996
Date of Notice of Approval to the Applicant:	AUG 1 5 1997

II. Indications for Use

The NeuroControl *Freehand System*® is intended to improve a patient's ability to grasp, hold, and release objects. It is indicated for use in patients who:

- are tetraplegic due to C5 or C6 level spinal cord injury (ASIA Classification);
- have adequate functional range of motion of the upper extremity;
- have intact lower motor neuron innervation of the forearm and hand musculature; and
- are skeletally mature.

III. Device Description

The NeuroControl *Freehand System*® is an RF powered motor control

neuroprosthesis which consists of both implanted and external components. It utilizes low levels of electrical current to stimulate the peripheral nerves that innervate muscles in the forearm and hand providing functional hand grasp patterns. The NeuroControl *Freehand System®* consists of the following subsystems:

- the **Implanted Components** include the Implantable Receiver-Stimulator, Epimysial Electrodes, and Connectors (Sleeves and Springs).

- the **External Components** include the External Controller, Transmit Coil, Shoulder Position Sensor, Battery Charger, and Remote On/Off Switch.

- the **Programming System** consists of the Pre-configured Personal Computer loaded with the Programming Interface Software, the Interface Module, and a Serial Cable.

- the **Electrode Positioning Kit** includes the Surgical Stimulator, Epimysial Probe, Anode Plate, and Clip Lead.

The Implanted Receiver-Stimulator is a passive device (it does not include a battery) that is completely powered by external radio frequency signals generated by an External Controller. The External Controller is a microprocessor based, battery operated portable device which is typically attached to the patient's wheelchair. Stimulating pulses generated by the External Controller are coupled through the skin to the Implantable Receiver-Stimulator via a small antenna which is taped over the implant site. The stimulating pulses are delivered by the Implantable Receiver-Stimulator to eight Epimysial Electrodes, seven of which are placed on the epimysium of selected muscles in the patient's forearm and hand, and one which can be placed in a sensate location near the implant site to provide sensory feedback to the patient. The electrical stimulating pulses applied to the Epimysial Electrodes cause the selected muscles to contract in a coordinated manner in order to synthesize two major grasping patterns - palmar and lateral prehension.

The stimulus patterns used to provide these movements are programmed into the memory of the External Controller using a pre-configured Personal Computer loaded with the *Freehand System®* Programming Software. The stimulus is regulated proportional to the movement of the patient's shoulder via the Shoulder Position Sensor. The control parameters associated with the sensor are also programmed into the External Controller. Thus, movement of the shoulder provides opening and closing of the hand. A push button switch

mounted on the chest which is part of the Shoulder Position Sensor assembly enables the patient to select the desired grasp configuration. The patient is also able to lock in and maintain a grasp force or hand position by rapid elevation of the shoulder when they attain the desired force or position. The control scheme is entirely proportional (a linear relationship between the processed command signal from the shoulder to the table of stimulus parameters associated with each muscle), enabling the patient to freely grade movement and force produced by the hand as they move their shoulder. There are no electrical or parameter adjustments external to the External Controller which are accessible to the patient.

The Implantable Receiver-Stimulator produces an asymmetric, balanced-charge biphasic, regulated-current stimulus waveform. The pulse width, pulse amplitude, and frequency of its eight channels can be independently controlled. In the *Freehand System®*, muscle force is modulated by varying the primary pulse's width, which can be varied from 0 to a maximum of 325 msec. Pulse amplitude can be set at 2, 8, 14, or 20 mA per channel. The capacitor coupled stimulator assures that there is no net charge delivered to body tissue. The pulse stimulus frequency can range from 0 to 500 Hz. The *Freehand System®* Programming Software limits the System to a choice of 12 or 16 Hz and limits the pulse width to a maximum of 200 msec per channel.

Materials in direct tissue contact have demonstrated biocompatibility and a long history of use in implantable devices. Biocompatible tissue contact materials used for the implanted components (Implantable Receiver-Stimulator, Epimysial Electrodes, and In-line Connectors) include titanium, silicone elastomer, platinum (90 percent) iridium (10 percent), and non-absorbable sutures.

IV. Contraindications, Warnings, and Precautions

Contraindications

The NeuroControl *Freehand System®* is contraindicated in patients with the following characteristics:

- uncontrolled spasticity (upper extremity)
- active or recurrent sepsis
- implanted cardiac pacemaker

Warnings

The *Freehand System*® may only be prescribed, implanted, or adjusted by clinicians who have been trained and certified in its implementation and use.

- **Magnetic Resonance Imaging (MRI)**: Do not expose patients to MRI. There are potential effects of induced currents and radio frequency heating of the device when exposed to magnetic fields and radio frequency fields associated with MRI systems which may result in patient injury.

Precautions

- **Surface Stimulation**: Electrical surface stimulation (muscle stimulator, EMG, or TENS) should be used with caution on or near the instrumented upper extremity as it may damage the system. Contact NeuroControl prior to applying surface stimulation.
- **X-rays, mammography, ultrasound**: X-ray imaging (e.g., CT or mammography), and ultrasound have not been reported to affect the function of the Implantable Receiver-Stimulator or Epimysial Electrodes. However, the implantable components may obscure the view of other anatomic structures.
- **Antibiotic prophylaxis:** Standard antibiotic prophylaxis for patients with an implant should be used to protect the patient when invasive procedures (e.g., oral surgery) are performed.
- **Ultrasound**: Therapeutic ultrasound should not be performed over the area of the Implantable Receiver-Stimulator or Epimysial Electrodes as it may damage the system.
- **Diathermy**: Therapeutic diathermy should not be used in patients with the *Freehand System*® as it may damage the system.
- **Invasive Procedures**: To avoid unintentional damage to implanted components, invasive procedures such as drawing blood or administering an intravenous infusion should be avoided on the implanted arm or in the area of the Implantable Receiver-Stimulator or near sites of the Epimysial Electrodes.
- **Serum CPK levels**: Exercise and muscle activity are known to cause changes in certain blood enzymes measured by standard laboratory and clinical tests, such as serum CPK. Exercise, whether volitional or induced by electrical stimulation, may produce elevated serum CPK levels. If a

Freehand System patient has elevated CPK, fractionation is indicated to differentiate between CK-MM from skeletal muscle and CK-MB from cardiac muscle that could be the result of cardiac injury.

- **Drug Interactions**: Muscle inhibitors and muscle relaxants may affect the strength of muscle contraction achieved using the Freehand System. It is recommended that these medications be stabilized prior to implementing the Freehand System so that muscle response to electrical stimulation can be accurately evaluated.
- **Safety and effectiveness** of the *Freehand System®* have not been established in patients with the following conditions:
  - ◊ children who are skeletally immature (usually males < 16 years, females < 15 years)
  - ◊ prior history of a major chronic systemic infection or other illness that would increase the risk of surgery
  - ◊ poorly controlled autonomic dysreflexia
  - ◊ seizures and balance disorders
  - ◊ pregnancy

- **Safety critical tasks:** Patients should be advised to avoid performing tasks which may be critical to their safety, e.g., holding an automobile (throttle or brake), handling an object that could injure the patient (scald or burn), etc.
- The patient should be advised to avoid the use of a compression cuff for measuring **blood pressures** on the arm in which the *Freehand System®* is implanted.
- **Post-operatively**, the patient should be advised to regularly check the condition of his or her skin across the hand, across the volar and dorsal aspects of the forearm, and across the chest where the *Freehand System®* Receiver-Stimulator, leads and Electrodes are located for signs of redness, swelling, or breakdown. If skin breakdown becomes apparent, patients should contact their clinician immediately. The clinician should treat the infection, taking into consideration the extra risk presented by the presence of the implanted materials.
- **Keep it dry**: The user should avoid getting the external components, cables, and attachments of the *Freehand System®* wet.

- The patient and caregiver should be advised to **inspect the cables and connectors** regularly for fraying or damage and replace components when necessary.

V. Alternative Practices and Procedures

There are currently two therapeutic approaches used to restore some degree of hand function: surgical reconstruction and external orthotics.

VI. Marketing History

The NeuroControl *Freehand System®* has not been marketed in the U.S. or any other country. All components of the NeuroControl *Freehand System®* which have been used to date have been the subject of clinical trials under an Investigational Device Exemption in the US and under the respective government authorities in other countries.

VII. Adverse Events

The Freehand System clinical trial involved 62 devices implanted in 61 patients and 128 cumulative implant years (median implant duration = 1.6 years, range < 1 month to 11 years). Adverse events (AEs) reported from this clinical trial included 15 AEs requiring surgery and 79 AEs not requiring surgery. One patient died during the course of this trial. This death was due to cardiac arrest and judged to be unrelated to the device.

Observed Adverse Events

The tables below reports these events and the percent of patients involved for the events requiring surgery and the AEs not requiring surgery.

Table 1. Tabulation of Adverse events

All patients implanted, N=61, 128 implant years

AEs requiring surgery	Number Events	Number Patients	% of Patients
Receiver reposition or replaced	3	3	5%
Skin opening repaired	4	4	7%
Electrode breakage	3	3	5%
Infection requiring electrode removal	3	3	5%
Infection requiring system explant	1	1	2%
Tendon adhesion	1	1	2%
Total	15	12	20%

AEs - Nonsurgical	Number Events	Number Patients	% of Patients
Swelling/discomfort over implantables	23	13	21%
Skin irritation from externally applied products	15	14	23%
Irritation from incisions or sutures	13	10	16%
Skin irritation from splints/casts	11	6	10%
Inadvertent excitation of elbow flexors	9	5	8%
Sensation over implant anode during stimulation	5	5	8%
Thumb k-wire snagged	1	1	2%
Splint caught in eye	1	1	2%
Sensation under coil	1	1	2%
Sensation on tongue through metal	1	1	2%
Cigarette burn in hand	1	1	2%
Total	79	31	51%

Adverse Events Requiring Surgery

Infections: Four subjects experienced infections at the electrode sites during the clinical study. Three of the four were local infections which required only electrode removal. In one case, the entire implant had to be removed.

Receiver-Stimulator Repositioned: The Receiver-Stimulator had to be repositioned in three different subjects. In two cases the device rotated along its axis, and in one case it was repositioned because the electrodes were too tight across the axilla and restricted the shoulder abduction. The procedure for implantation has been modified to include suturing of the silicone skirt to anchor the device.

Electrode Breakage: Two electrodes used for sensory feedback broke during the study in two patients, one due to implant rotation and one due to caretaker squeezing over the electrode. One electrode used for motor function failed in another patient.

Follow-up surgery was necessary in some of the above events and included surgery to remove electrodes, scar revision, stimulator repositioning, and various tenolysis and joint releases or fusion procedures.

Non-Surgical Adverse Events

Inadvertent Excitation of Elbow Flexors: Inadvertent biceps contraction as a result of the return current pathway caused elbow flexion in nine cases. This was corrected by adjustment of the stimulus parameters below the threshold of excitation.

Other Minor Events: A variety of other adverse events were reported in the clinical study including the following: blisters/sores from exercise splints/casts, swelling/irritation from sutures, swelling/discomfort over implantable components, skin irritation from tape products, unable to turn unit off, warm sensation under coil causing skin irritation, sensation on tongue through metal utensil, cigarette burn while holding cigarette in insensate hand (1 event).

External Controller Malfunctions - There have been over 100 reports since 1993 of external controller malfunctions. However, modifications to the external controller have substantially reduced the occurrence of these malfunctions. These malfunctions included:

- Corruption of memory due to low battery power or electrostatic discharge.
- Mechanical problems including pinched wiring harnesses, loosened internal hardware, dead battery cells, excessive battery consumption.

Potential Adverse Events

Possible adverse events, including those which have been observed in the clinical trial, include:

- device malfunction
- fibrosis and scarring
- infection
- rejection (immunologic)
- skin irritation
- surgical revision
- tissue breakdown

VIII. Summary of Studies

A. Nonclinical Studies

1. Biocompatibility

All of the tissue contact materials used in the implantable components have been used in similar clinical applications such as cardiac pacemakers and have well known biocompatibility characteristics. NeuroControl Corporation submitted material purity certifications and referenced supplier master files and NDA/PMA and 510(k) files as evidence of the biocompatibility of these materials. In addition, biocompatibility screening was done on final production devices to confirm biocompatibility after material processing.

2. Electrode and Lead Assembly Mechanical Testing

Eight Implantable Receiver-Stimulator proximal lead-connector-electrode assemblies were subjected to a series of stretching, crushing, bending and twisting tests to validate the mechanical durability of these devices. Prior to testing, the samples were subjected to three cycles of sterilization. The assemblies were subjected to 1,222,000 cycles of stretching, 123,361 cycles of crushing, 1,200,556 cycles of flexing, and 600,000 cycles of twisting. These *in vitro* tests simulate greater than 10 years of severe use. Resistance and leakage current measurements were made before and after each series of tests. Following the tests, all of the assemblies were still within specification, indicating that these assemblies are sufficiently durable for their intended application and duration.

3. Long-Term Testing of Electrode-Lead In-line Connector

Long-term testing of eleven of the In-Line Connectors was performed in normal unbuffered saline at 37°C to simulate implant conditions. Eight of the connectors were tested as an integral part of one implantable system and three were tested as individual leads. Two of the implantable system channels were passive and the other six were stimulated with a current pulse of 20 mA and pulse widths of 100, 150, or 200 msec. The electric fields produced in the saline were measured throughout the testing. After 38 months of testing, there was no detectable change in

pulse output from any channel and no leakage current from the connectors. One connector spring in a passive channel and one strain relief spring in an active channel showed minor corrosion after 480 hours and 1464 hours, respectively. All others showed no degradation.

4. Qualification Stress Testing of the Hybrid Circuit

   Seven hybrid circuits for the Implantable Receiver-Stimulator were subjected to a battery of qualification tests according to MIL-STD-833D. These consisted of stabilization bake, temperature cycling, burn-in, constant acceleration, and visual inspection. All seven of the hybrids tested passed this test. In addition, destructive tests consisting of bond strength/ die shear strength tests were conducted on two hybrid circuits and a total of eleven bonds and wires. All bonds and die attachments passed the minimal strength requirement. Five circuits completed and passed long-term steady-state life testing.

5. Implantable Receiver-Stimulator Capsule and Feedthrough Testing

   Three capsules were tested for gross and fine leakage per MIL-STD-833D, and a finished Implantable Receiver-Stimulator device was tested to evaluate the integrity of the electrical connections to the hybrid circuit and its securement to the capsule. Testing was conducted at room temperature before and after stressing the circuits. Stress conditions included vibration, mechanical shock, and temperature cycling. The capsules met specifications for hermeticity following the external stresses which are greater than those expected under normal shipping, storage, and use conditions. Cathodic phase currents for each channel of the Implantable Receiver-Stimulator were tested for each of four current settings. In addition, the Implantable Receiver-Stimulator was tested using the Programming Configuration to verify the ability to vary the pulse parameters. The Implantable Receiver-Stimulator continued to function according to specification after stress.

6. Qualification Testing of the *Freehand System*® External Components

   The *Freehand System*® with External Controller, the Interface Module, the Shoulder Position Sensor, the Transmit Coil, and the Surgical Stimulator were tested to verify correct operation under varying

conditions, including different power sources, variations in battery or line voltage, and variations in operating temperature and tested within design specifications.

7. Electromagnetic Compatibility Immunity Testing

   The *Freehand System®* was tested to demonstrate its immunity to disruptions by the electromagnetic environment. The Implantable Receiver-Stimulator was tested for immunity to radiated fields of in excess of 20 v/m and near its operating frequency of 6.78 MHZ (worst case conditions). The *Freehand System®* External Components, including the External Controller, Shoulder Position Sensor, and the Transmit Coil, were also tested for immunity to radiated fields of 20 v/m over the frequency range of 26 to 1000 MHz. The *Freehand System®* components that are used during programming of the System (External Controller mated with the Interface Module and with Shoulder Position Sensor and Transmit Coil connected) were tested for susceptibility to radiated fields of 3 v/m over frequencies of 26 to 1000 MHZ. The Personal Computer was placed outside the maximum field area during the latter test. The 3 v/m field strength was chosen for these components since they are used under more controlled conditions. Results of this testing demonstrate that the *Freehand System®* and its components are not significantly affected by these interfering fields.

8. Electromagnetic Compatibility Emissions Testing

   Electromagnetic emissions from the *Freehand System®* were measured with general guidance of CISPR 11 (Class B, residential use) (BS-EN 55011) and it was found to be in compliance with the standard.

9. Electrostatic Discharge Testing

   Electrostatic Discharge Testing was conducted on the external components using IEC 801-2 for general guidance. These components passed for discharges up to 12 kV.

B. Animal Studies

NeuroControl Corporation submitted results from three studies involving thirteen dogs to support the safety of the *Freehand System®*. These studies were conducted to evaluate components of the device, implantation protocols, long-term operation, and biological response.

In the first study, the effect of chronic electrical stimulation such as used by the *Freehand System®* was evaluated in five dogs for 51, 39, 15, 17, and 35 months (a total of 157 animal months of exposure). The study found that the application of chronic electrical stimulation to Epimysial Electrodes did not result in significant changes in tissue.

In another study, the In-line Connectors used in the *Freehand System®* were evaluated in dogs. Twenty-four connectors were implanted in three dogs for 40, 21, and 14 months. Five additional connectors were implanted in one dog with passive leads and intramuscular electrodes. No leakage current or cuff displacement was detected throughout the study period. At explant the connectors were encapsulated in connective tissue.

In a third study, (the *Freehand System®* Implantable Receiver-Stimulator, Epimysial Electrodes, and In-Line Connectors were implanted in five dogs to simulate clinical use. Implant periods ranged from 111 to 1055 days. The performance of the System was monitored during the implant period. The study results indicate that the Receiver-Stimulators functioned according to specifications throughout the implant period. Tissue response to the Epimysial Electrodes was consistent with expected mild foreign body response. In the first three dogs, 18 of 24 electrodes failed as a result of a five with no failures.

C. Clinical Studies

1. Multi-Center Study of the Implanted System

a. Introduction

A multi-center clinical investigation was conducted at fifteen investigational sites to evaluate the safety and effectiveness of the NeuroControl *Freehand System®*. A total of 61 patients were enrolled in the study and implanted with the NeuroControl *Freehand System®*. Table 2 provides a summary of the clinical sites and the patients enrolled at each site. An additional five patients were implanted (1 in Japan, 2 in New Zealand, and 2 in Sydney, Australia) but were not participants in this clinical study protocol.

Table 2. Summary of Participating Clinical Investigational Sites

Investigator	Site	Number of Patients
P. Hunter Peckham, Ph.D. Michael W. Keith, MD Kevin Kilgore, Ph.D.	Cleveland, Ohio MetroHealth Medical Center University Hospitals of Cleveland Cleveland VA Medical Center	19
Randal R. Betz, MD	Philadelphia, Pennsylvania Shriners Hospitals, Philadelphia Unit	8
Peter H. Gorman, MD Andy Eglseder, MD	Baltimore, Maryland Baltimore VA Medical Center	6
Douglas Brown, MD	Melbourne, Australia University of Melbourne Austin Hospital	6
Vincent R. Hentz, MD Amy Ladd, MD	Palo Alto, California Palo Alto VA Medical Center	2
Allen W. Wiegner, Ph.D. Mark J. Koris, MD	West Roxbury, Massachusetts West Roxbury VA Medical Center	2
Dan Greenwald, MD Audrey Nelson, RN Araceli Denoga, MD	Tampa, Florida James A. Haley VA Medical Center Tampa General Hospital	2
Mike Bednar, MD Terry Light, MD Larry Vogel, MD	Chicago, Illinois Shriners Hospitals, Chicago Unit	2
David Applebaum, MD Marc Levinson, MD Kevin Scanlon, OT	Delray, Florida Delray Community Hospital Pinecrest Rehabilitation Hospital	1
Michelle James, MD	Sacramento, California Shriners Hospitals, Sacramento Unit (formerly San Francisco Unit)	1
John Hobby, MD	Salisbury, United Kingdom Salisbury District Hospital	7
Yves Allieu, MD Emmanuel Rabischong, Ph.D. Michel Benichou, MD	Centre Propara Parc Eumomedicine Montpellier, France	1
Arand Nene, MD Sebrand Schepel, MD	Roessingh Research and Development Het Roessingh The Netherlands	2
P. Sett, MD	Southport, United Kingdom Southport District Hospital	1
Jacques Tessier, MD	LeMans, France Centre de l'Arche	1

The study was a prospective, multi-center clinical trial that used the implemented hand of each patient as its own control. This design is essential since spinal cord injuries are highly variable across patients,

do not represent consistent deficits, and require that different rehabilitative treatments be used from patient to patient, thus prohibiting the use of matched controls. Furthermore, spinal cord injuries are rarely symmetric within an individual (i.e., affecting both sides equally), thus prohibiting the use of the contralateral limb in the same patient as a control.

b. Patient Selection

Patients enrolled in the study and implanted with the NeuroControl *Freehand System®* were required to meet the following selection criteria:

Inclusion Criteria:

- skeletally mature individuals who are tetraplegic (International Classification group 0, 1, or 2 (O or Cu)) due to traumatic spinal cord injury leaving a C5 or C6 ASIA functional motor level (ASIA classification).
- good health
- at least one year post-injury
- either sex, approximately 16 years of age or older
- intact vision
- functional in a wheelchair with adequate trunk support
- have a positive attitude, high motivation, a strong desire for increased function, good adjustment to their injury, good attendant support, and a willingness to return to the clinic for periodic evaluation and testing.
- integrity of the lower motor neurons (peripheral nerves) to the muscles to be activated, and those muscles must exhibit adequate stimulated strength (grade 4-5 for finger and thumb flexors, grade 3-5 for finger and thumb extensors) following a surface stimulation conditioning program.
- adequate strength in the proximal muscles of shoulder abduction and external rotation and elbow flexion to perform functional tasks with the hand to be implanted with the device (e.g., they can raise their hand to their mouth for eating and drinking activities).

Exclusion Criteria:

- functional limitations in the range of motion of joints of the upper extremity
- hypersensitivity that inhibits the ability to sustain pressure over

their digits

- extensive denervation of the forearm or hand musculature
- extensive irreversible contractures in the joints of the upper extremities
- prior history of a major chronic systemic infection or other illness that would increase the risk of surgery or inclusion in the study
- diabetes
- immunologic diseases
- heart disease
- cardiac arrhythmias
- undiagnosed or high risk breast masses
- dermatologic conditions
- uncontrolled spasticity
- any major physiological system failure

c. Methodology

Prior to surgery patients underwent a period of surface muscle stimulation to build muscle strength and fatigue resistance. Patients who were unable to attain sufficient muscle strength in key muscles, synergists, or appropriate substitutes after sixteen weeks of training were ineligible for the implant.

The Implantable Receiver-Stimulator was implanted in the chest wall and the Epimysial Electrodes were implanted on selected muscles of the forearm and hand. Augmentative surgical procedures and tendon transfers were performed in conjunction with implantation of the *Freehand System*® as deemed necessary by the hand surgeon.

Following the surgery and healing of the arm, the patients underwent a period of exercise using electrical stimulation from the implanted system to build up muscle strength and endurance. After the patients were fully healed and had attained adequate muscle strength, they began rehabilitation, during which they received training in device operation, and the External Controller was programmed with functional grasp patterns and control parameters. Patients were evaluated for performance at rehabilitation, and at six and twelve months after rehabilitation.

The results of the evaluations at rehabilitation were used as the

primary efficacy endpoint. Three primary measures of effectiveness were used to evaluate patients' performance with and without the *Freehand System*® by 1) measuring the stimulated range of motion (SROM) of each finger; 2) measuring the amount of pinch force which could be generated in each grasp pattern; and 3) evaluating the patient's ability to grasp, move, and release six standard objects in the Grasp Release Test (GRT). Pinch force, stimulated range of motion, and the GRT provide objective, quantified measures of changes in patient performance with the neuroprosthesis. The GRT was specifically designed to assess the patient's ability to grasp and release six standardized objects -- three with lateral grasp (peg, weight, and fork) and three with palmar grasp (block, can, and tape). The objects vary in size, weight, and texture and were chosen to be functionally analogous to objects utilized in activities of daily living. The tasks included in the GRT require minimal use of the trunk and proximal upper extremity, focusing instead on opening and closing of the hand itself. The GRT consists of a pretest and a main test. In the pretest the patient attempts to grasp and release each object. If the patient is unable to manipulate an object, with or without the neuroprosthesis, the object is not included in the main test. In the main test, the patient attempts to grasp, move, and release each object as many times as possible during 30 second trials. The proportion of patients who pass or fail the pretest and the number of "completions" for each object with versus without the neuroprosthesis are used as measures of efficacy for the GRT test.

In order to be considered a success, patients were required to improve in all three primary efficacy measures:

1) Increase the range of motion actively achieved (SROM),
2) Increase the pinch force produced in palmar, lateral, and five finger pinch, and
3) Increase the number of tasks that patients can successfully complete in the Grasp-Release Test.

In addition, the number of patients who were able to manipulate at least one more of the GRT objects with the neuroprosthesis, and the number who can either manipulate at least three more objects or all six objects with the neuroprosthesis, compared to performance without the neuroprosthesis, was determined.

As supplemental data, performance of Activities of Daily Living (ADL) was assessed to measure the extent to which the *Freehand System®* improved patients' ability to perform daily tasks, and a User Satisfaction Survey was conducted to determine patients' opinions and feelings about the *Freehand System®*. These assessments were conducted to demonstrate how patients integrate hand grasp function and retained function to perform meaningful activities of daily living with less assistance and more confidence.

d. Patient Population

A total of sixty-one patients were enrolled in the study and implanted with the neuroprosthesis. The patients ranged in age from 15 to 57 years, with a median age of 30 years. Seventy-nine percent were male and 21 percent female. Forty-two of the patients (69 percent) had C5 level injuries and sixteen had C6 level injuries (25 percent) (Data were not yet available on the remaining three patients).

Time between injury and implant ranged between 1.1 and 32.2 years with a median of 4.5 years. Thirty-nine patients (64 percent) had the *Freehand System®* implemented on their right side, and twenty-two (36 percent) had it on their left side. All of the patients had one or more augmentative surgical procedure or tendon transfer to augment hand function and optimize the ability of the patient to achieve maximum function with the *Freehand System®*.

e. Gender Bias Analysis

Patient enrollment and inclusion and exclusion criteria in the clinical trial were chosen to avoid gender bias.

Of all patients enrolled, 13 (21%) were females. The preponderance of male patients reflected the gender ratio in the overall spinal cord injury population (18% female, 82% male).[1]

Since there were no apparent gender-related differences in the safety or effectiveness outcomes, the results for men and women are combined in the presentations which follow.

1 National Spinal Cord Injury Statistics Center, University of Alabama, Birminghan, 1997

f. Efficacy Results

The primary efficacy evaluations were performed at rehabilitation. A total of 32 patients had completed rehabilitation at the time of submission. Time between implant of the *Freehand System®* and completion of rehabilitation averaged 7 months and ranged from 3 months to greater than 26 months. Since that submission, 46 patients have completed rehabilitation. Efficacy results on the original 32 patients are summarized below, with primary endpoint data updated to include the 46 patients.

Stimulated Range of Motion

Any increase in stimulated range of motion was considered an improvement due to the device. Data at rehabilitation for stimulated range of motion were available for the lateral grasp pattern (n=41) and the palmar grasp pattern (n=39) and are summarized in Table 3. The magnitude of the SROM varied widely between patients due to the variation in the types of augmentative surgical procedures applied and hand postures presented in each patient. However, all patients with SROM measurements exhibited an increase with the neuroprosthesis. Thus, 100 percent of the patients satisfied the SROM criteria for success.

Table 3. Results of Stimulated Range of Motion Study: Total Active Motion

Lateral Grasp Pattern (n=41)

FINGER	INDEX	LONG	RING	SMALL	THUMB
Mean (degrees)	93.2	92.6	93.1	70.4	76.3
STD (degrees)	57.1	48.8	48.6	63.2	37.8
Median (degrees)	86.0	85.0	85.0	65.0	78.0
Range (degrees)	10 - 260	-13 - 200	3 - 185	-108 - 235	-15 - 175

Palmar Grasp Pattern (n = 39)

FINGER	INDEX	LONG	RING	SMALL	THUMB
Mean (degrees)	73.9	85.2	88.1	68.6	23.1
STD (degrees)	61.0	48.5	48.5	52.5	30.9
	58.0	90.0	80.0	57.0	15.5

Median (degrees)					
Range (degrees)	1 - 260	0 - 195	0 – 195	-15 - 210	-46 - 95

Pinch Force

Lateral, palmar, and five finger pinch forces were measured at Entry and each evaluation point after surgery with and without the neuroprosthesis. At the time of database closure, data were available on 29 patients at study Entry, 32 patients at rehabilitation, and 23 patients at Post-rehabilitation follow-up of six months or greater. Data at rehabilitation have been updated to include a total of 46 patients achieved since submission. Results are shown in Table 4 below.

Table 4. Summary of Pinch Force Measurements (Newtons) With and Without the Neuroprosthesis

Grasp	Entry (Baseline) n = 29	Rehabilitation (n = 46)		Follow-up (n = 23)	
		Without NP	With NP	Without NP	With NP
Lateral					
Mean	1.4	2.7	12.8	2.7	14.6
Std. Dev.	1.9	3.1	4.4	2.7	6.8
Median	0.8	1.6	12.0	2.0	13.0
Range	0-8.2	0-12.7	5.4-26.6	0-10.1	5.9-32.9
Palmar*					
Mean	0.7	1.0	7.0	1.1	7.3
Std. Dev.	0.9	1.5	4.6	1.1	4.9
Median	0.2	0.7	6.4	0.8	5.9
Range	0-3.1	0-7.8	1.7-25.1	0-4.1	2-17.7
Five Finger*					
Mean	1.0	1.3	7.8	1.7	8.9
Std. Dev.	1.2	1.6	4.3	1.8	4.9
Median	0.4	0.8	6.7	1.4	7.6
Range	0-4.9	0-5.9	0.8-20.7	0-8.2	3.3-20.7

* n=28 at Entry

Pinch forces measured in all three grasp configurations with the neuroprosthesis on are significantly greater than measured without the neuroprosthesis. Most importantly, all patients realized some improvement in pinch force measurements in at least one grasp pattern with the neuroprosthesis compared to without the neuroprosthesis. Pinch force measurements at six months or greater

Follow-up after rehabilitation were not significantly different from measurements at rehabilitation.

Grasp Release Test (GRT)

GRT Pretest: The GRT Pretest results at rehabilitation are summarized in Table 5. As shown in the table, more patients could grasp and release each of the six objects using the neuroprosthesis than could without it. All but one (98 percent) of the patients increased the number of objects they could manipulate by at least one with the neuroprosthesis compared to without the neuroprosthesis, and seventy-two percent increased the number of objects they could manipulate by three or more objects.

As anticipated, the GRT Pretest results at follow-up were consistent with results at rehabilitation.

Table 5. Summary of GRT Pretest Results

		Rehabilitation (n = 46)		≥ Follow-up 6 Mo (n = 24)	
Grasp	Object	Without NP	With NP	Without NP	With NP
Lateral	Peg	40 (87%)	46 (100%)	22 (92%)	24 (100%)
	Weight	0 (0%)	42 (91%)	0 (0%)	20 (83%)
	Fork	0 (0%)	40 (87%)	0 (0%)	20 (83%)
Palmar	Block	34 (74%)	45 (98%)	20 (83%)	24 (100%)
	Can	13 (28%)	36 (78%)	6 (25%)	20 (83%)
	Tape	9 (20%)	32 (70%)	7 (29%)	18 (75%)

Main GRT: Table 6 summarizes the number of "completions" achieved by the patients at rehabilitation and at follow-up, with and without the neuroprosthesis. At rehabilitation, there was a statistically significant increase in the number of completions for the weight, fork, can and tape when the neuroprosthesis was used. The neuroprosthesis did not improve patients' ability to manipulate pegs and blocks (the two lightweight objects which are easiest to

manipulate). At rehabilitation, the difference in the number of completions was not statistically significant for the block. For the peg, patients were able to perform more completions without the neuroprosthesis. Overall, all patients were able to improve their ability to grasp and release test objects in the GRT, and the number of completions at follow-up was consistent with those at rehabilitation.

Table 6. Summary of GRT Completions in 30 Second Trials

Object		Rehabilitation (n = 32)		Follow-up (n= 24)	
		Without NP	With NP	Without NP	With NP
Peg	Mean	12.4	9.0	10.4	9.0
	Std. Dev.	8.6	4.4	8.5	4.4
	Median	12	8	8.5	8.5
	Range	0-28	0-20	0 - 28	0 -17
Weight	Mean	0	3.5	0	3.1
	Std. Dev.	0	2.7	0	3.1
	Median	0	4	0	2.0
	Range	0	0-9	0	0 - 11
Fork	Mean	0	4.2	0	4.2
	Std. Dev.	0	3.4	0	3.8
	Median	0	4	0	3.5
	Range	0	0-11	0	0 - 14
Block	Mean	10.7	9.8	9.8	9.0
	Std. Dev.	9.7	5.5	9.5	5.2
	Median	11	8	9.0	8.0
	Range	0-27	3-24	0 - 34	2 - 19
Can	Mean	1.2	5.5	1.1	3.4
	Std. Dev.	2.8	4.7	3.0	3.7
	Median	0	5	0	2.5
	Range	0-11	0-18	0 - 12	0 - 10
Tape	Mean	1.0	2.8	1.0	2.6
	Std. Dev.	2.8	2.9	1.9	2.9
	Median	0	2	0.0	1.5
	Range	0-13	0-10	0 - 7	0 - 9

Activities of Daily Living (ADL) Evaluations:

The assessment of the impact of the *Freehand System®* on activities of daily living was accomplished using three ADL evaluation tools:

the ADL Abilities Test, the ADL Assessment, and the ADL Assessment Follow-up. Both the ADL Abilities and ADL Assessment evaluations were performed at rehabilitation. The ADL Assessment Follow-up was conducted at six months or greater following completion of rehabilitation.

In the ADL Abilities Test, subjects were trained and tested to their highest level of ability in selected tasks with and without the neuroprosthesis. Each patient was evaluated to determine whether the neuroprosthesis decreased the amount of assistance required to perform each activity. In addition, patients were asked to express, for each task, whether they preferred to perform the task with the neuroprosthesis, without the neuroprosthesis, or had no preference. Twenty-eight patients were evaluated using this Test. Across all patients and tasks, 50 percent showed an improvement in independence score. If only the tasks in which external assistance is required from an attendant or from adaptive aids were analyzed, 75 percent were able to improve with the neuroprosthesis. Across all patients and tasks evaluated, 78 percent preferred to use the neuroprosthesis to perform the activities.

In the ADL Assessment, patients and clinicians identify goal activities prior to implantation for which they would like to use the *Freehand System®*. Prior to surgery, these activities were demonstrated according to the methods typically used. At rehabilitation, patients were trained in these goal activities and then assessed according to whether they met their goals, whether the neuroprosthesis decreased the amount of assistance required to complete a task, and whether they preferred to perform the task with the neuroprosthesis, without the neuroprosthesis, or had no preference. Eleven patients were evaluated using this Test. Across all patients and tasks tested, 81 percent showed improvement in performance using the neuroprosthesis compared to their typical method prior to implantation. Patients scored their goals as being met for 89 percent of tasks tested, and therapist scored the goals as being met for 84 percent of tasks. For 85 percent of tasks, patients expressed preference for using the neuroprosthesis.

The objectives of the ADL Assessment Follow-up were to determine whether patients used the *Freehand System®* in activities of daily living and, if not, whether they were able to use the System. At follow-up, subjects were re-evaluated in the tasks tested at rehabilitation. In addition, their satisfaction with their abilities was scored and their preference for performing activities (with the neuroprosthesis, without the neuroprosthesis, or no preference) was expressed. Twenty-two patients were evaluated with this instrument. Patients "typically" used the System to perform 53 percent of the activities tested. For 66 percent of the activities, patients reported using the System sometimes, and 91 percent of patients reported using the system for at least one of the activities tested. In those activities for which the System is not typically used, patients demonstrated their ability to perform 82 percent of the activities using the neuroprosthesis. Whether or not patients typically used the *Freehand System®* for activities, for 88 percent of tasks, subjects were satisfied with their performance, and therapists were satisfied with performance of 92 percent of activities. Finally, patients reported that they preferred to use the neuroprosthesis in 59 percent of the tasks tested.

User Satisfaction Survey

A User Satisfaction Survey was mailed to patients who had been using the neuroprosthesis for six months or greater after rehabilitation. Responses were received from twenty-nine patients. The survey consisted of 38 questions that asked about general satisfaction with the *Freehand System®*, its impact on daily activities, occupation, and the need for external assistance. Patients utilizing the *Freehand System®* reported overall satisfaction with the performance of the System, and indicated that it had a positive impact on their lives and activities, and enabled them to be less dependent on adaptive equipment and assistance from others when using the device.

2. Multi-Center Study of the Percutaneous System

A multi-center study of the percutaneous neuroprosthesis system was conducted prior to the implant system study to assess the effectiveness of

the system. Nine patients at five research centers were subjected to Pinch Force Tests, Standard Object Tests (predecessor to the GRT), and Common Object Tests (predecessor to the ADL Abilities Test). Results were available on a subset of nine patients from this study.

The median pinch forces measured on these nine patients are shown in Table 7, and are similar to those found in the implant study. Measurements without the neuroprosthesis were not made.

Table 7. Summary of Pinch Force Measurements with the Neuroprosthesis in the Percutaneous System Study
(n=9 patients)

Grasp Pattern	Median Pinch Force (Newtons)
Lateral	21.1
Palmar	7.8
Five Finger	3.9

Standard Object Tests (SOT) results were comparable to GRT results from the implant study. All patients were able to grasp and release more objects with the neuroprosthesis than without it, and had improved performance with the neuroprosthesis for the weight, fork, and tape objects. For the other three objects (peg, block, and can) the patients performed approximately equally with or without the neuroprosthesis.

For the Common Object Test (COT), with results scored as in the implant study, for all tasks and patients, 54 percent showed an improvement in independence score, and 72 percent preferred the neuroprosthesis. These results were similar to those obtained in the ADL Abilities Test in the implant study.

The few adverse effects reported in the study were predominantly related to the percutaneous electrodes. One patient suffered electrical burns on hands and forearms, and another patient experienced a mild electrical shock. These events led to modifications of the External Controller, and the connectors for the Shoulder Position Sensor and the Transmit Coil. With the implanted system there is no longer any direct electrical

connection to the patient, because the percutaneous electrodes have been eliminated.

Since the percutaneous system and the implanted system share the same grasp patterns, control algorithm, and stimulus waveform, the data from the percutaneous study support the effectiveness of functional neuromuscular stimulation using the NeuroControl *Freehand System®*.

IX. Risk-Benefit Analysis

Laboratory and clinical data provide reasonable assurance that the *Freehand System®* is safe and effective when used according to the approved labeling.

X. Conclusions Drawn from Studies

The laboratory and clinical data provide reasonable assurance that the NeuroControl *Freehand System®* is safe and effective in providing tetraplegic patients with increased hand grasp function when used in accordance with the directions for use. Using the *Freehand System®*, all patients in the two studies were able to increase the stimulated range of motion of their hand, increase the pinch forces generated by the hand, and improve their ability to grasp and release objects. The improvements were shown to be stable in patients who were followed for six months or longer after rehabilitation.

XI. Panel Recommendations

At an advisory meeting held on September 25, 1996, the Neurological Devices Panel recommended that the NeuroControl Corporation PMA for the Freehand® System should be approved on the condition that additional engineering and biocompatibility data be submitted to FDA, and that labeling be revised.

XII. CDRH Decision

CDRH concurred with the Neurological Devices Panel's recommendation and NeuroControl submitted amendments to the FDA which satisfactorily addressed the outstanding concerns. FDA issued an approval order on AUG 15 1997. The applicant's manufacturing facility was inspected and was found to be in compliance with the device Good Manufacturing Practice regulations (21 CFR Part 820).

NeuroControl Corporation

FREEHAND System®

Implantable Functional Neurostimulator (FNS)

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NeuroControl Corporation
FREEHAND System®
Implantable Functional Neurostimulator (FNS)

PACKAGE INSERT

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

1. DEVICE DESCRIPTION

The NeuroControl *Freehand System®* is an RF powered motor control neuroprosthesis which consists of both implanted and external components. It utilizes low levels of electrical current to stimulate the peripheral nerves that innervate muscles in the forearm and hand providing functional hand grasp patterns. The NeuroControl Freehand System consists of the following subsystems:

- the **Implanted Components** include the Implantable Receiver-Stimulator, Epimysial Electrodes, and Connectors (Sleeves and Springs).
- the **External Components** include the External Controller, Transmit Coil, Shoulder Position Sensor, Battery Charger, and Remote On/Off Switch.
- the **Programming System** consists of the Pre-configured Personal Computer loaded with the Programming Interface Software, the Interface Module, and a Serial Cable.
- the **Electrode Positioning Kit** includes the Surgical Stimulator, Epimysial Probe, Anode Plate, and Clip Lead.

2. INTENDED USE / INDICATIONS

The NeuroControl *Freehand System®* is intended to improve a patient's ability to grasp, hold, and release objects. It is indicated for use in patients who:

- are tetraplegic due to C5 or C6 level spinal cord injury (ASIA Classification)
- have adequate functional range of motion of the upper extremity
- have intact lower motor neuron innervation of the forearm and hand musculature and
- are skeletally mature

3. CONTRAINDICATIONS

The NeuroControl *Freehand System*® is contraindicated in patients with the following characteristics:

- uncontrolled spasticity (upper extremity)
- active or recurrent sepsis
- implanted cardiac pacemaker

4. WARNINGS

The *Freehand System*® may only be prescribed, implanted, or adjusted by clinicians who have been trained and certified in its implementation and use.

- **Magnetic Resonance Imaging (MRI)**: Do not expose patients to MRI. There are potential effects of induced currents and radio frequency heating of the device when exposed to magnetic fields and radio frequency fields associated with MRI systems which may result in patient injury.

5. PRECAUTIONS

- **Surface Stimulation**: Electrical surface stimulation (muscle stimulator, EMG, or TENS) should be used with caution on or near the instrumented upper extremity as it may damage the system. Contact NeuroControl prior to applying surface stimulation.
- **X-rays, mammography, ultrasound**: X-ray imaging (e.g., CT or mammography), and ultrasound have not been reported to affect the function of the Implantable Receiver-Stimulator or Epimysial Electrodes. However, the implantable components may obscure the view of other anatomic structures.
- **Antibiotic prophylaxis:** Standard antibiotic prophylaxis for patients with an implant should be utilized to protect the patient when invasive procedures (e.g., oral surgery) are performed.
- **Ultrasound**: Therapeutic ultrasound should not be performed over the area of the Implantable Receiver-Stimulator or Epimysial Electrodes as it may damage the system.

- **Diathermy**: Therapeutic diathermy should not be used in patients with the *Freehand System*® as it may damage the system.
- **Invasive Procedures**: To avoid unintentional damage to implanted components, invasive procedures such as drawing blood or administering an intravenous infusion should be avoided on the implanted arm or in the area of the Implantable Receiver-Stimulator or near sites of the Epimysial Electrodes.
- **Serum CPK levels**: Exercise and muscle activity are known to cause changes in certain blood enzymes measured by standard laboratory and clinical tests, such as serum CPK. Exercise, whether volitional or induced by electrical stimulation, may produce elevated serum CPK levels. If a Freehand System patient has elevated CPK, fractionation is indicated to differentiate between CK-MM from skeletal muscle and CK-MB from cardiac muscle that could be the result of cardiac injury.
- **Drug Interactions**: Muscle inhibitors and muscle relaxants may affect the strength of muscle contraction achieved using the Freehand System. It is recommended that these medications be stabilized prior to implementing the Freehand System so that muscle response to electrical stimulation can be accurately evaluated.
- **Studies have not been conducted** on the use of the *Freehand System*® in patients with the following conditions:
    - children who are skeletally immature (usually males < 16 years, females < 15 years)
    - prior history of a major chronic systemic infection or other illness that would increase the risk of surgery
    - poorly controlled autonomic dysreflexia
    - seizures and balance disorders
    - pregnancy

  Risks and benefits in patients with any of these conditions should be carefully evaluated before using the *Freehand System*®
- **Safety critical tasks:** Patients should be advised to avoid performing tasks which may be critical to their safety, e.g., controlling an automobile (throttle or brake), handling an object that could injure the patient (scald or burn), etc.
- The patient should be advised to avoid the use of a compression cuff for measuring **blood pressures** on the arm in which the *Freehand System*® is implanted.
- **Post-operatively**, the patient should be advised to regularly check the condition of his or her skin across the hand, across the volar and dorsal aspects of the forearm,

and across the chest where the *Freehand System*® Receiver-Stimulator, leads and Electrodes are located for signs of redness, swelling, or breakdown. If skin breakdown becomes apparent, patients should contact their clinician immediately. The clinician should treat the infection, taking into consideration the extra risk presented by the presence of the implanted materials.

- **Keep it dry**: The user should avoid getting the external components, cables, and attachments of the *Freehand System*® wet.
- The patient and caregiver should be advised to **inspect the cables and connectors** regularly for fraying or damage and replace components when necessary.

6. ADVERSE EVENTS

The Freehand System clinical trial involved 62 devices implanted in 61 patients and 128 cumulative implant years (median implant duration = 1.6 years, range <1 month to 11 years). Adverse events (AEs) reported from this clinical trial included 15 AEs requiring surgery and 79 AEs not requiring surgery.

One patient died during the course of this trial. This death was due to cardiac arrest and judged to be unrelated to the device.

6.1 Observed Adverse Events

The tables below reports these events and the percent of patients involved for the events requiring surgery and the AEs not requiring surgery.

Table 1. Tabulation of Adverse events

All patients implanted, N=61, 128 implant years

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Skin opening repaired	4	4	7%
Electrode breakage	3	3	5%
Infection requiring electrode removal	3	3	5%
Infection requiring system explant	1	1	2%
Tendon adhesion	1	1	2%
Total	15	12	20%

AEs – Nonsurgical	# Events	# Patients	% of Patients
Swelling/discomfort over implantables	23	13	21%
Skin irritation from externally applied products	15	14	23%
Irritation from incisions or sutures	13	10	16%
Skin irritation from splints/casts	11	6	10%
Inadvertent excitation of elbow flexors	9	5	8%
Sensation over implant anode during stimulation	5	5	8%
Thumb k-wire snagged	1	1	2%
Splint caught in eye	1	1	2%
Sensation under coil	1	1	2%
Sensation on tongue through metal	1	1	2%
Cigarette burn in hand	1	1	2%
Total	79	31	51%

Adverse Events Requiring Surgery

Infections: Four subjects experienced infections at the electrode sites during the clinical study. Three of the four were local infections which required only electrode removal. In one case, the entire implant had to be removed.

Receiver-Stimulator Repositioned: The Receiver-Stimulator had to be repositioned in three different subjects. In two cases the device rotated along its axis, and in one case it was repositioned because the electrodes were too tight across the axilla and restricted the shoulder abduction. The procedure for implantation has been modified to include suturing of the silicone skirt to anchor the device.

Electrode Breakage: Two electrodes used for sensory feedback broke during the study in two subjects, one due to implant rotation and one due to a caretaker squeezing a pustule over the electrode. One electrode used for motor function failed in another patient.

Follow-up surgery was necessary in some of the above events and included surgery to remove electrodes, scar revision, stimulator repositioning, and various tenolysis and joint releases or fusion procedures.

Non-Surgical Adverse Events

Inadvertent Excitation of Elbow Flexors: Inadvertent biceps contraction as a result of the return current pathway caused elbow flexion in nine cases. This was corrected by adjustment of the stimulus parameters below the threshold of excitation.

Other Minor Events: A variety of other adverse events were reported in the clinical study including the following: blisters/sores from exercise splints/casts, swelling/irritation from sutures, swelling/discomfort over implantable components, skin irritation from tape products, unable to turn unit off, warm sensation under coil causing skin irritation, sensation on tongue through metal utensil, cigarette burn while holding cigarette in insensate hand (1 event).

External Controller Malfunctions - There have been over 100 reports since 1993 of external controller malfunctions. However, modifications to the external controller have substantially reduced the occurrence of these malfunctions. These malfunctions included:

- Corruption of memory due to low battery power or electrostatic discharge.

- Mechanical problems including pinched wiring harnesses, loosened internal hardware, dead battery cells, excessive battery consumption.

6.2 Potential Adverse Events

Possible adverse events, including those which have been observed in the clinical trial, include:

- Device malfunction
- Fibrosis and scarring
- Infection
- Rejection (immunologic)
- Skin irritation
- Surgical revision
- Tissue breakdown

7. CLINICAL STUDIES

The purpose of the trial was to prospectively demonstrate that the Freehand System improves the ability to grasp, hold, and release objects for C5 or C6 level tetraplegic patients.

Design and Patients: A multi-center trial was conducted at 15 sites (9 in the U.S., 1 in Australia, 2 in England, 2 in France, and 1 in the Netherlands) using a common protocol. Each subject served as his/her own control, thus paired comparisons were made between function in the instrumented hand with the Freehand System turned on versus with the Freehand System turned off. Of the 61 patients implanted with the Freehand System, 48 (79%) were male, median overall age 30 years (range 15-57). All patients had clinically complete spinal cord injuries with 72% classified as C5 and 28% classified as C6. Median duration of implant was 1.4 years (range <1 mo to 11 yr) Total experience was 129 implant years.

Methods: Functional evaluations were conducted at baseline pre-operatively (56 patients), post-operatively at Rehabilitation (46 patients), at ≥ 6-months post-Rehabilitation (24 patients) and at ≥ 12-months post-Rehabilitation (13 patients). Key measures at Rehabilitation and subsequent follow-up testing assessed device usage and

changes in function over time including: assessment of "active" finger range of motion, grasp force, and ability to manipulate 6 standard objects in the Grasp-Release Test (GRT). In 28 patients, ability to perform activities of daily living and patient satisfaction with and continued use of the device over time was also evaluated.

Results: The Freehand System enabled patients with C5/C6 level tetraplegia to grasp, hold, and release objects. All patients tested demonstrated increased active finger motion and increased grasp force. All but one patient demonstrated the ability to manipulate objects in the GRT using the Freehand System which could not be manipulated without. Patients with higher cervical injuries (C5) exhibited greater improvement in GRT scores than those with lower cervical injuries (C6).

Table 2. Representative Effectiveness Measurements

All patients with follow-up at Rehabilitation, N=46

Measurement		N	OFF (m±SD)	ON (m±SD)	Difference [95% CI][a]
Pinch force (Newton's)					
	Lateral	46	3.0 ±3.1[b]	13.0 ±4.5	10.0 [9.1,10.9]
	Palmar	46	1.2 ±1.6	6.7 ±4.9	5.5 [3.7, 7.2]
Stimulated ROM[c] (deg)					
	Lateral	41	0 ±0[c]	87 ±54	87 [71,103]
	Palmar	39	0 ±0	79 ±53	76 [64, 94]
Primary Outcome Measure		N	# (%)	Target	[95% CI][d]
Manipulate ≥ 1 more objects		46	45 (98%)	75%	[ ]
Manipulate ≥ 3 more objects		46	33 (72%)	50%	[ ]

[a] CI = Difference ± 1.96• SEM , SEM = SD / sqrt (N)

[b] Pinch force was non-zero due to tenodesis

[c] SROM was zero due since measurements were done with the wrist fixed

[d] CI for the ratio calculated according to Cohen, 1986.

All patients evaluated (28 of 28) demonstrated improved ability to perform at least one tested activity of daily living using the Freehand System. Most (26 of 28) patients reported continued functional use of the device beyond 6 months.

Surgical revision (one or more) occurred in 18 of the first 38 (47%) patients including electrode placement or revision in 16 (42%) and 10 for refinement of hand function (e.g., tendon transfers). One patient died (judged unrelated), and 4 developed infections, one of which was associated with the only device explant. (See Table 1 for listing of adverse events).

8. INDIVIDUALIZATION OF TREATMENT

For optimal outcome, the following elements should be considered when selecting candidates for the Freehand System:

- Prior to implant, key muscles or their substitutes should achieve a muscle grade of 3 or greater for extensors and 4 or greater for flexors with electrical stimulation for best results.
- Patient goals should be assessed pre-operatively to determine if their expectations of the *Freehand System*® are reasonable. Patients should be motivated for improved independence and have good family or caregiver support.
- Candidates for the *Freehand System*® should be in good health and be able to understand the operation of the *Freehand System*®.
- Proximal muscle strength and range of motion should be adequate to position the hand for functional activities.
- Patients with higher cervical injuries (C5) have shown greater improvement in clinical evaluation scores than those with lower cervical injuries (C6). However, many stronger (C6) patients have also shown improvement in clinical evaluations and have demonstrated the ability to perform many activities with the Freehand System.

9. DIRECTIONS FOR USE

Specific Directions For Use can be found in the Clinician and Patient Manuals.

10. PATIENT COUNSELING INFORMATION

It is important that patients who are candidates for the Freehand System be counseled regarding their use of and expectations for the device. The following should be considered in this counseling:

- Patients and caregivers should be counseled regarding the post-operative recovery and rehabilitation process and the additional burdens placed upon them during this phase.
- Patients should be counseled on the importance of reporting to their physician problems which may compromise their health or the implant (e.g. skin breakdown, infections, changes in performance of the System (function or sensation), etc.).
- Patients should be counseled that the implementation of the Freehand System and refinement of hand function may be a process requiring more than one surgery to complete.
- Patients should be counseled to have realistic expectations regarding their abilities with the Freehand System.
- The patient should be trained in the proper maintenance of the *Freehand System*®. A clinician should explain the operation and maintenance of the System as described in the Clinician Manual and the Patient Manual.
- Post-operatively, the patient should be advised to report any unusual sensations, muscle contractions, or changes in hand function to the clinician immediately.

11. HOW SUPPLIED

The Implantable Receiver-Stimulator and the Epimysial Electrodes ard supplied in STERILE dual tray packages. The Surgical Electrode Positioning Kit is supplied in STERILE single tray packages. The opened Surgical Electrode Positioning Kit should be presented to enable the scrub nurse to retrieve the Surgical Stimulator. Do not drop the Surgical Stimulator into the sterile field as it could tear sterile drapes. External Component Kits are provided for patients and replacement components can be obtained from NeuroControl Corporation. Programming Systems are provided to trained clinical centers.

NeuroControl Corporation

The Freehand System

Clinician Manual

CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician.

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NeuroControl Freehand System
Clinician Manual

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1.0 INTRODUCTION

This manual is intended to be used as a reference by clinicians who have successfully completed NeuroControl CorporationÁs Freehand System training program. It provides guidance in the implementation and operation of the Freehand System.

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1.1 Device Description

The NeuroControl *Freehand System*® is an RF powered motor control neuroprosthesis which consists of both implanted and external components. It utilizes low levels of electrical current to stimulate the peripheral nerves that innervate muscles in the forearm and hand providing functional hand grasp patterns. The NeuroControl Freehand System consists of the following subsystems:

- the **Implanted Components** include the Implantable Receiver-Stimulator, Epimysial Electrodes, and Connectors (Sleeves and Springs).
- the **External Components** include the External Controller, Transmit Coil, Shoulder Position Sensor, Battery Charger, and Remote On/Off Switch.
- the **Programming System** consists of the Pre-configured Personal Computer loaded with the Programming Interface Software, the Interface Module, and a Serial Cable.
- the **Electrode Positioning Kit** includes the Surgical Stimulator, Epimysial Probe, Anode Plate, and Clip Lead.

1.2 Intended Use / Indications

The NeuroControl *Freehand System*® is intended to improve a patient's ability to grasp, hold, and release objects. It is indicated for use in patients who:

- are tetraplegic due to C5 or C6 level spinal cord injury (ASIA Classification)
- have adequate functional range of motion of the upper extremity
- have intact lower motor neuron innervation of the forearm and hand musculature and
- are skeletally mature

1.3 Contraindications

The NeuroControl *Freehand System*® is contraindicated in patients with the following characteristics:

- uncontrolled spasticity (upper extremity)
- active or recurrent sepsis
- implanted cardiac pacemaker

1.4 Warnings

The *Freehand System*® may only be prescribed, implanted, or adjusted by clinicians who have been trained and certified in its implementation and use.

- **Magnetic Resonance Imaging (MRI)**: Do not expose patients to MRI. There are potential effects of induced currents and radio frequency heating of the device when exposed to magnetic fields and radio frequency fields associated with MRI systems which may result in patient injury.

1.5 Precautions

- **Surface Stimulation**: Electrical surface stimulation (muscle stimulator, EMG, or TENS) should be used with caution on or near the instrumented upper extremity as it may damage the system. Contact NeuroControl prior to applying surface stimulation.
- **X-rays, mammography, ultrasound**: X-ray imaging (e.g., CT or mammography), and ultrasound have not been reported to affect the function of the Implantable Receiver-Stimulator or Epimysial Electrodes. However, the implantable components may obscure the view of other anatomic structures.
- **Antibiotic prophylaxis:** Standard antibiotic prophylaxis for patients with an implant should be utilized to protect the patient when invasive procedures (e.g., oral surgery) are performed.

- **Ultrasound**: Therapeutic ultrasound should not be performed over the area of the Implantable Receiver-Stimulator or Epimysial Electrodes as it may damage the system.
- **Diathermy**: Therapeutic diathermy should not be used in patients with the *Freehand System*® as it may damage the system.
- **Invasive Procedures**: To avoid unintentional damage to implanted components, invasive procedures such as drawing blood or administering an intravenous infusion should be avoided on the implanted arm or in the area of the Implantable Receiver-Stimulator or near sites of the Epimysial Electrodes.
- **Serum CPK levels**: Exercise and muscle activity are known to cause changes in certain blood enzymes measured by standard laboratory and clinical tests, such as serum CPK. Exercise, whether volitional or induced by electrical stimulation, may produce elevated serum CPK levels. If a Freehand System patient has elevated CPK, fractionation is indicated to differentiate between CK-MM from skeletal muscle and CK-MB from cardiac muscle that could be the result of cardiac injury.
- **Drug Interactions**: Muscle inhibitors and muscle relaxants may affect the strength of muscle contraction achieved using the Freehand System. It is recommended that these medications be stabilized prior to implementing the Freehand System so that muscle response to electrical stimulation can be accurately evaluated.
- **Studies have not been conducted** on the use of the *Freehand System*® in patients with the following conditions:
  - children who are skeletally immature (usually males < 16 years, females < 15 years)
  - prior history of a major chronic systemic infection or other illness that would increase the risk of surgery
  - poorly controlled autonomic dysreflexia
  - seizures and balance disorders
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  Risks and benefits in patients with any of these conditions should be carefully evaluated before using the *Freehand System*®

- **Safety critical tasks:** Patients should be advised to avoid performing tasks which may be critical to their safety, e.g., controlling an automobile (throttle or brake), handling an object that could injure the patient (scald or burn), etc.
- The patient should be advised to avoid the use of a compression cuff for measuring **blood pressures** on the arm in which the *Freehand System®* is implanted.
- **Post-operatively**, the patient should be advised to regularly check the condition of his or her skin across the hand, across the volar and dorsal aspects of the forearm, and across the chest where the *Freehand System®* Receiver-Stimulator, leads and Electrodes are located for signs of redness, swelling, or breakdown. If skin breakdown becomes apparent, patients should contact their clinician immediately. The clinician should treat the infection, taking into consideration the extra risk presented by the presence of the implanted materials.
- **Keep it dry**: The user should avoid getting the external components, cables, and attachments of the *Freehand System®* wet.
- The patient and caregiver should be advised to **inspect the cables and connectors** regularly for fraying or damage and replace components when necessary.

1.6 Adverse Events

The Freehand System clinical trial involved 62 devices implanted in 61 patients and 128 cumulative implant years (median implant duration = 1.6 years, range <1 month to 11 years). Adverse events (AEs) reported from this clinical trial included 15 AEs requiring surgery and 79 AEs not requiring surgery.
One patient died during the course of this trial. This death was due to cardiac arrest and judged to be unrelated to the device.

1.6.1 Observed Adverse Events

The tables below reports these events and the percent of patients involved for the events requiring surgery and the AEs not requiring surgery.

Table 1. Tabulation of Adverse events

All patients implanted, N=61, 128 implant years

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Tendon adhesion	1	1	2%
Total	15	12	20%

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Cigarette burn in hand	1	1	2%
Total	79	31	51%

Adverse Events Requiring Surgery

Infections: Four subjects experienced infections at the electrode sites during the clinical study. Three of the four were local infections which required only electrode removal. In one case, the entire implant had to be removed.

Receiver-Stimulator Repositioned: The Receiver-Stimulator had to be repositioned in three different subjects. In two cases the device rotated along its axis, and in one case it was repositioned because the electrodes were too tight across the axilla and restricted the shoulder abduction. The procedure for implantation has been modified to include suturing of the silicone skirt to anchor the device.

Electrode Breakage: Two electrodes used for sensory feedback broke during the study in two subjects, one due to implant rotation and one due to a caretaker squeezing a pustule over the electrode. One electrode used for motor function failed in another patient.

Follow-up surgery was necessary in some of the above events and included surgery to remove electrodes, scar revision, stimulator repositioning, and various tenolysis and joint releases or fusion procedures.

Non-Surgical Adverse Events

Inadvertent Excitation of Elbow Flexors: Inadvertent biceps contraction as a result of the return current pathway caused elbow flexion in nine cases. This was corrected by adjustment of the stimulus parameters below the threshold of excitation.

Other Minor Events: A variety of other adverse events were reported in the clinical study including the following: blisters/sores from exercise splints/casts, swelling/irritation from sutures, swelling/discomfort over implantable components, skin irritation from tape products, unable to turn unit off, warm sensation under coil causing skin irritation, sensation on tongue through metal utensil, cigarette burn while holding cigarette in insensate hand (1 event).

External Controller Malfunctions - There have been over 100 reports since 1993 of external controller malfunctions. However, modifications to the external controller have substantially reduced the occurrence of these malfunctions. These malfunctions included:

- Corruption of memory due to low battery power or electrostatic discharge.
- Mechanical problems including pinched wiring harnesses, loosened internal hardware, dead battery cells, excessive battery consumption.

1.6.2 Potential Adverse Events

Possible adverse events, including those that have been observed in the clinical trial, include:

- Device malfunction
- Fibrosis and scarring
- Infection
- Rejection (immunologic)
- Skin irritation
- Surgical revision
- Tissue breakdown

2.0 FREEHAND SYSTEM COMPONENTS

The NeuroControl Freehand System is a radio frequency motor control neuroprosthesis which consists of both implanted and external components. It utilizes low levels of electrical current to stimulate the peripheral nerves that innervate muscles in the forearm and hand in a selective, repeatable, and controlled manner providing functional hand grasp patterns. The System is comprised of four subsystems: the Patient Implantable System, the Patient External System, the Electrode Positioning Kit, and the Clinical Programming System.

2.1 Patient Implantable System

The patient implantable system is comprised of the components which are surgically implanted. These include the Implantable Receiver-Stimulator, the Epimysial Electrodes, and the Connectors.

2.2 Patient External System

The patient external system is used by the patient to operate the implantable system. This is comprised of the External Controller, the Shoulder Position Sensor, the Transmit Coil, the Battery Charger, and the Remote ON/OFF Switch.

2.3 Electrode Positioning Kit

The electrode positioning kit is used intraoperatively to determine the optimal position the Epimysial Electrodes on the appropriate muscles. It is comprised of the Surgical Stimulator, the Epimysial Probe, the Anode Plate, and the Clip Lead.

2.4 Clinical Programming System

The clinical programming system is used to program the Patient External System with the control parameters for the Patient Implantable System. It is comprised of Pre-configured PC loaded with the Programming Interface Software, the Interface Module, and a Serial Cable.

3.0 PRE-OP ASSESSMENT / SURGICAL PLANNING

3.1 Comprehensive Physical Examination

The comprehensive physical examination of the candidate for the Freehand System should include the following standard clinical laboratory studies:

- Complete blood count and sedimentation rate
- Clotting profile (prothrombin time, partial thromboplastin time, platelet count)
- SMA 6 and SMA 12 or equivalent
- HIV and Hepatitis B screening
- Urinalysis and urine culture and sensitivity
- Nasal swab for culture and sensitivity
- Chest X-ray, mammograms for females
- Recent ultrasound of the renal/urinary tract for stones
- Recent dental exam

3.2 Pre-surgical Planning, Mapping, and Measurement

3.2.1 Determine the Location of Implantable Receiver Stimulator

The Implantable Receiver Stimulator is generally positioned on the chest wall in a location similar to that of a pacemaker. Unlike patients with a pacemaker, however, these patients may require lateral supports or straps when sitting in the wheelchair and/or assistance in transferring between chair and bed, etc. To prevent damage to the implanted components caused by transfer activities or skin breakdown due to pressure from supports, observe the patient in their wheelchair to assess the proposed location of the Implantable Receiver Stimulator and determine if there are any pressure areas in the upper torso from lateral supports or straps.

The implant is oriented so that the leads come out cranially with the antenna (receiver coil) below. The length of the leads should be selected so that they are not looped or kinked.

In female patients, the Implantable Receiver Stimulator should not be implanted under breast tissue.

3.2.2 Determine the Location of Motor Electrodes

Motor electrodes are placed on the innervated muscles of the arm, forearm, and/or hand: EPL, AdP, AbPB, FDP, FDS, EDC, FPL are Akey@ muscles. Muscles selected for electrode placement should have at least a grade 4 response to stimulation for flexors and grade 3 for extensors.

NOTE: If any of the above muscles are denervated, the electrode should be placed on the synergist or transferred muscle. Refer to the discussion of "Substitution Procedures" below.

3.2.3 Determine the Location of the Sensory Electrode

If sufficient motor function can be obtained using only 7 motor electrodes, one electrode can be used to provide the patient with sensory feedback. This electrode is placed in an area of normal sensation, usually the upper

shoulder deltoid area. Before implementing the System, this area should be mapped using surface stimulation to be sure that there are no painful or hypersensitive areas at this location.

4.0 IMPLANT SURGERY

4.1 NeuroControl Supplies

In addition to the usual supplies required for surgical procedures, such as sterile goods (gowns, drapes, prep supplies, radiopaque sponges, electrosurgical units and accessories, and dressing materials), there are two additional categories of supplies and equipment necessary for the surgical implantation of the Freehand System. The first category is dedicated to the implantation and assessment of System function and is obtained from NeuroControl Corporation. The second category consists of materials used for the augmentative and reconstructive surgical procedures (fusions, tenodesis, tendon transfers, etc.) which are performed during the same surgery.

Supplies which are ordered from NeuroControl Corporation consist of the Surgical Set, the Surgical Programming/Test Station, and the Patient External System. Elements of each group are listed below.

Freehand Implantable / Surgical Set

(qty = 2, *Return unused items to NeuroControl)*

- Implantable Receiver Stimulator (qty = 1)
- Surgical Electrode Positioning Kit (qty = 1)
- Implantable Electrode Set (sizes 4, 8 - 70 cm; *Return unused sizes to NeuroControl*)
- Implantable Connector Kit *(Return unused connectors)*
- Scanlan Tunneler (qty = 1)
- Coil Sheath (qty = 1)
- Coil Sheath Usage Instructions (qty = 1)
- Neuroprosthesis Implant Record (qty = 1)

Surgical Programming/Test Station

(Return to NeuroControl)

- Preprogrammed Computer with Charger (qty = 1)
- Implant Stimulator (qty = 1)
- Interface Module (qty = 1)
- Serial Cable (qty = 1)
- Charger (qty = 1)
- Power Strip --U.S. Only-- (qty = 1)
- Extension Cord --U.S. Only-- (qty = 1)
- Carrying Case (qty = 1)

Patient External System

- External Controller (qty = 1)
- Charger (qty = 1)
- Transmit Coil (qty = 2)
- Shoulder Position Sensor with shoulder mounts & rods
- Shoulder Position Sensor Tape (qty = 1 pkg., 33 sheets / pkg.)
- Transmit Coil Tape (qty = 1 pkg., 50 sheets / pkg.)
- Storage Case

4.2 General Surgical Supplies and Equipment

Implantation of the Freehand System requires both general purpose and the specialized supplies required for hand surgery. Typical equipment, instruments, and supplies used for these procedures are provided below.

Equipment

- hand table
- pneumatic tourniquet
- prep pad with cuff
- Esmarch bandage
- sitting stools
- cast cart
- heating pad (K-pad) for arm table
- power sources (pneumatic or electric, as appropriate)
- electrosurgical unit and dispersive electrodes
- suction containers

Sterile supplies

- gowns and gloves
- towels and drapes
- steri drape
- radiopaque sponges (raytec sponges, lap pads/tapes)
- dressing materials (xeroform gauze, kerlix, fluffs, elastic bandage, ace bandages)
- antibiotic irrigation (polymyxin/bacitracin or equivalent
- prep set (betadine or equivalent for patients allergic to betadine or iodine)
- half strength peroxide in saline for cleaning skin after surgery

Sterile Instruments

- Drills, drivers, and drill bits of various sizes
- K-wires of various sizes
- Hand instruments
- Tendon instruments
- Bipolar ESU cord and forceps
- Measuring tape
- Rubber bands
- Hand (lead hand)
- Blades

Sutures

- Ethibond 2-0SH X-833-H
- Ethibond 4-0RB-1 X-871-H
- Ethibond 0 SH D/A B524-H
- Vicryl 0 CT-1 27" J340H
- Vicryl 2-0CP-2 UNDY J869H
- Vicryl 4-0PS-2 UNDY J496H
- Nylon 4-0PC-3 1964G
- Mersilene 5 CTX RIB RS22

4.3 Augmentative, Reconstructive, and Substitution Procedures

Implantation of the Freehand System is generally accompanied by augmentative/reconstructive and substitution procedures (tendon transfer of paralyzed muscles) which are performed during the same surgical procedure and are accomplished before the placement of the Freehand implants.

4.3.1 Augmentative and Reconstructive Surgery

The goals of augmentative and reconstructive procedures of the hand for implementation of the Freehand System are as follows: (1).To provide the patient with as functional a grasp as possible; (2). To compensate for

function lost due to weak or denervated key muscles; (3). To position the hand and forearm optimally for functional tasks; (4). To reduce potential grasp problems due to joint contracture or laxity; and (5). To simplify control of grasp by minimizing the degrees of freedom.

Any combination of procedures may be performed with a single patient. Typical procedures are listed in Table x below.

Table x. Typical Augmentative/Reconstructive Procedures

Procedure	Indication
Thumb IP Arthrodesis or FPL/EPL split	Hypermobile thumb IP joint that prevents transmission of pinch force to the thumb tip
	Use of FPL as primary thumb flexor (AdP denervated)
FDS Synchronization (allows single electrode to move all four fingers; balance fingers w/ digit 5 loose)	Non-synchronous finger flexion
	Partial denervation of FDS
FDP Synchronization	Non-synchronous finger flexion
	Partial denervation of FDP
FDS Zancolli-Lasso	MP hyperextension; lack of IP extension(Claw hand or intrinsic minus hand posture)
Radial Osteotomy	Inability to pronate forearm in supinated position
EDC Synchronization (allows single electrode to move all four fingers)	Non-synchronous finger extension

4.3.2 Substitution Procedures: Tendon transfer of paralyzed muscles

The need for substitution procedures is indicated by weakness or denervation in one of the key muscles (EPL, AdP, AbPB, FDP, FDS, EDC, FPL) with no other available synergist muscle. FES transfer of a paralyzed muscle is recommended to provide the function of a key muscle. The muscle being transferred must be paralyzed with an upper motor neuron lesion and should have a muscle grade of 4 or better with maximum stimulation.

The guidelines provided in Table x below provide some of the available options for substitution of lost or deficient function in the key muscle groups. The optimum function is given as a reference point.

Table x. Guidelines for Substitution/Transfer Procedures

Muscle Group	Optimum Function	Options to Augment Weak Function
Extensor Pollicis Longus (EPL)	Produces full extension of thumb CMC, MP and IP joints to their PROM limit.	1. Fuse thumb IP joint; use EPB. 2. Transfer EIP to EPL. 3. Transfer to EPL one or more of the following: EPB, AbPL, ECU, ECRL (if paralyzed), ECRB, BR (if paralyzed).
Adductor Pollicis (AdP)	Produces at least 10 Newtons of thumb pinch (1 kg, 2.2 lbs).	1. Fuse thumb IP joint; use FPL. 2. Use FPB as thumb flexor. 3. Transfer EIP to AdP.
Abductor Pollicis Brevis (AbPB)	Produces full abduction of the thumb CMC joint to its PROM limit.	1. Use AbPL and FPB. 2. Transfer to AbPB (or OP): PL, PT, FPL, FCR, FCU.
Flexor Digitorum Profundus (FDP)	Produces full flexion of all three finger joints for all four fingers to their PROM limit and produces approximately 10 Newtons of grip force.	1. Partial denervation: Tie tendons together if remaining tendons produce a grade "4" contraction or better. 2. If FDS produces a grade "4" or better contraction with good closing of the hand, FDS can be used as the only finger flexor. 3. Transfer FCU, FCR, PT, PL, or BR (if paralyzed) to FDP.
Flexor Digitorum Superficialis (FDS)	Produces approximately 10 Newtons of grip force in palmar grasp (all four fingers together).	1. Partial denervation: Tie tendons together if remaining tendons produce a grade "4" contraction or better. 2. Transfer FCU, FCR, PT, PL, or BR (if paralyzed) to FDS.
Extensor Digitorum Communis (EDC)	Produces full extension of all three finger joints for all four fingers to their PROM limit.	1. Often the Zancolli-Lasso procedure on the FDS will provide improved finger extension as long as the EDC shows strong extension of the MP joints. 2. Transfer to EDC one or more of the following: ECU, EIP, EPB, ECRL (if paralyzed), BR (if paralyzed), ECRB.

4.4 Implanting the Freehand System

In addition to the implantation of Freehand System components, the surgery includes augmentative, reconstructive, and substitution procedures. The sequence of events in a typical System implantation procedure, with a description of those events is below.

Note: ANESTHESIOLOGIST/ANESTHETIST SHOULD BE INSTRUCTED NOT TO USE NEUROMUSCULAR BLOCKING AGENTS DURING SURGERY!

1. Thumb IP stabilization, if indicated, is typically performed first.

2. The pocket for the Implantable Receiver Stimulator is created. The Anode Plate is placed into the pocket with the metal side facing towards the skin.

3. Any voluntary muscle transfers are performed. Both sides of the transfer are marked with 9-0 metal suture wire.

4. Note: Paralyzed muscle transfers and synchronizations should be performed before the placement of Epimysial Electrodes on the muscle. The tension should be set with the elbow flexed at 90 degrees and with the wrist neutral. Tetanic contraction of the muscle should be utilized.

5. The next steps are the placement of the Epimysial Electrodes, the FDS Zancolli-Lasso procedure (if indicated), and synchronization of flexor tendons (AdP, AbPB, FPL, FDS, FDP, EPL, and EDC Electrodes).

   Electrode Mapping To determine the optimal placement of the Epimysial Electrodes, the Surgical Stimulator, with the Epimysial Probe inserted into the connector for channel one (red), is used. The Anode Plate is connected into the anode connector (black) and the Anode Plate is placed into the implant pocket.

Stimulation amplitude is generally set at 20 mA and the stimulus frequency at 12 Hz. The pulse duration is varied from 0 to 200 msec to observe the electrode recruitment properties. Stimulus twitches can be used to detect muscle thresholds.

The Epimysial Probe is moved over the surface of the muscle while the stimulation is delivered. The muscle response is observed to determine the optimum electrode placement. The most important electrode input/output characteristics are the following (in order of importance):

1. ***Maximal force w/ minimal spillover:*** The best electrode placement is one that recruits the entire muscle prior to spillover to another functional muscle group, and generates strong grasp force or, in the case of extensors, moves the joint through maximum range of motion. If no other muscle groups are recruited at the maximum stimulation level, the electrode placement is good. If this is not possible, try to find the electrode placement which gives the maximal muscle force output prior to spillover. Note: Spillover from EPL to EPB usually occurs and is desirable. Spillover between FDS and FDP usually occurs and is not a problem.

2. ***Length Dependency:*** Length dependency describes the dependence of the muscle force output on joint angle changes. To test this property, temporarily suture the electrode in the optimum location for maximum force and stimulate the muscle at a constant level. While the stimulation is on, move the distal joints though their range of motion (including the wrist and forearm for extrinsic muscles). If large changes in the muscle force output are detected, the electrode location is poor. Test other locations to determine if length dependence can be reduced without sacrificing force. Large changes in muscle force output occur when the contraction of the muscle draws the electrode closer to the motor point (or away from the motor point), resulting in a positive feedback situation. The most likely solution to this problem is to move the electrode farther away from the motor point, although this is not a guaranteed solution.

3. ***Gain:*** Gain describes the rate at which muscle forces increases as the stimulus is increased. Very high gain can be detrimental to the grasp, although it is less important than maximum force and length dependency. High gain results from the electrode being too close to a nerve branch. Sometimes the effective gain can be lowered by using a lower stimulus amplitude. The Surgical Stimulator allows the option of testing the electrode at lower amplitude levels. The Implantable Receiver Stimulator can also operate individual channels at the same lower amplitude levels.

If there is no response to stimulation, check to assure that the probe and anode are plugged into the Surgical Stimulator and that the Stimulator is ON. Attempt to stimulate a muscle with known contraction (from pre-surgical work with the patient). Check to make sure that the muscles have received adequate blood supply and that no neuromuscular blocking agents were used. Try using the backup Epimysial Probe and Anode Plate if necessary.

If the response to stimulation suddenly stops, check to make sure that the Epimysial Probe and Anode Plate are still plugged into the stimulator. Check to make sure that the Anode Plate is still located in the implant pocket. If all the connections appear intact, try using the backup epimysial probe and anode.

If the response to stimulation seems to diminish, check for adequate blood supply to the muscle. If the blood supply is good, the muscle may be fatigued.

If the SurgeonÁs Stimulator does not appear to be working, try using the backup Surgeon's Stimulator.

Placing and Suturing Electrodes Use 4-0 braided non-absorbable suture, with a round (not cutting) needle. Place five sutures around the periphery of the Epimysial Electrode, using four knots with each suture. The exposed metal stimulating area must be placed toward the muscle surface for motor electrodes and toward the skin surface for the sensory electrode. Always test the electrode placement after

suturing by attaching the Clip Lead to the electrode connector. Make sure that the tissue covers the electrode as if the wound was closed. Record the serial numbers from each electrode used on the Neuroprosthesis Implant Record.

6. The leads of the Epimysial Electrodes are passed to a common connection site, typically in the upper arm. The incision is made. The Scanlan tunneler is inserted and passed subcutaneously between the incision and the distal Electrodes. The leads are then passed proximally to the connection site.

7. The Anode Plate is removed from the pocket and replaced with the Implantable Receiver Stimulator. The exposed titanium surface (the anode) must be placed so that it faces the skin surface. The Stimulator is secured to the pectoralis fascia with four stitches in the skirt using 2-0 braided non-absorbable suture. A minimum of four knots should be used per suture. The serial number should be recorded on the Neuroprosthesis Implant Record.

8. The Sensory Electrode is placed, if indicated.

9. The Scanlan Tunneler is inserted into the implant pocket and subcutaneously directed to the common connector site.

10. The Electrode leads are connected to the Implantable Receiver Stimulator in the following manner. First insert the Electrode lead pin into the connector sleeve until the collar on the Electrode lead meets the end of the sleeve. The spring must then be gently twisted a half turn in the clockwise direction to insert the pin into it. Once the pin is in the spring, gently tug the Implantable Receiver-Stimulator lead and the Electrode lead to make sure the pins are firmly held by the spring. Gently smooth any wrinkles in the sleeve and tie the sutures at each end.

11. Each motor channel of the Implantable Receiver Stimulator should be tested verify function before the wound is closed.

12. After testing, the wound is closed and the splint/cast is applied with the elbow flexed 90 degrees, wrist neutral, and fingers free.

Note: The casting position may change if voluntary tendon transfers were performed in conjunction with FES.

4.5 Implant Testing

4.5.1 Final Implant Testing

The implanted System should be tested after all of the Epimysial Electrodes have been placed, tunneled, and connected to the Implantable Receiver Stimulator, and before anchoring the Implantable Receiver Stimulator and closing the wounds.

4.5.2 Equipment Set-up

The equipment should be assembled and connected as described in the Software User's Manual.

The surgery Transmit Coil should be placed into the Coil Sheath in order to be passed into the sterile field. The connector end should be connected to the External Controller outside the sterile field. The Transmit Coil is then placed over the receiving coil of the Implantable Receiver Stimulator.

4.5.3 Test Procedure

The Surgical Programming / Test Station is used to test each of the motor channels and verify a muscle response. The stimulation is increased beginning with 0 msec. The Software User's Manual should be consulted for additional details.

4.5.4 Troubleshooting

Condition	Recommended Actions
No response from first channel	Test all the other channels in sequence. If all but one channel fires, verify the connection of the Epimysial Electrode at the common connector site. To determine if the problem is with the implant channel or with the electrode lead, switch the connection between two of Epimysial Electrodes. Check the distal end of the Epimysial Electrode to be sure that it is still sutured in place. Check the lead for any nicks or cuts. Replace the Epimysial Electrode if necessary.
No response from any channel	-Verify that the Transmit Coil is sending out a signal by using the Implant Simulator. If the Transmit Coil is sending out a signal, push down on the coil over the implant or move it slightly away (within the coronal plane and within an inch or so) from the center of the receiving coil. Make sure that the anode of the Implantable Receiver Stimulator touches the skin in the pocket. Step through all eight channels again at maximum stimulus level. Disconnect one of the Epimysial Electrodes and use the Surgical Stimulator and Clip Lead to stimulate the Electrode directly. If there is no response from the Epimysial Electrode, check the tourniquet and verify that no muscle relaxants have been used. Restore the blood supply and continue to attempt stimulation. When the response has returned, replace the Implantable Receiver Stimulator and reconnect the Epimysial Electrode that was previously disconnected. If the Implantable Receiver Stimulator still does not stimulate, replace it with the backup unit.
Transmit Coil is not sending a signal	Restart the External Controller and the Interface Module and try again. Check all of the cable connections. If the software appears to be working (i.e., no error messages), try using the backup Transmit Coil. Restart the External Controller and the Interface Module and test for a signal again. If there is still no signal coming from the coil, try using the backup External Controller. Exit the program and plug in the backup External Controller. Restart the External Controller and the Interface Module and try again. If the backup External Controller also does not send out a signal, or if the computer or the Interface Module appear to have failed, disconnect the External Controller from the computer and contact NeuroControl Corporation at 800-378-6955 for technical support.

4.6 X-ray

An x-ray of the chest and extremity, shoulder to finger tips, is recommended at the end of the implant procedure after the cast has been applied and before the patient leaves the operating room.

4.7 Immobilization and Post Operative Follow Up

4.7.1 Goals

The goals for immobilization and postoperative follow up are to allow time for tendon transfer healing and stabilization/encapsulation of the Implantable Receiver Stimulator and Epimysial Electrodes.

4.7.2 Guidelines

Stimulation too early could create unstable electrodes while stimulation too late in the recovery process could lead to longer recovery of muscle. Stimulation too fast could result in inflammation while stimulation too slow could result in the formation of adhesions and limited ROM.

4.7.3 Methods

To promote electrode stabilization and wound healing, the arm is casted, restricting elbow, forearm, and wrist movement. The arm should be immobilized for three weeks after surgery.

To allow tendon transfer healing, it is appropriate to begin slow, low level stimulation at three weeks post surgery. This should be increased to higher levels of stimulation with increasing levels of resistance over four to six weeks. The patient should be ranged passively according to standard tendon transfer protocols.

To build muscle strength after surgery, allow approximately one month of electrical stimulation exercise at maximum functional levels after the tendon transfer healing is complete. *See the next section on EXERCISE guidelines.* These guidelines are for the stable, healed arm.

DO NOT use those guidelines during the three week electrode stabilization period or during any tendon transfer healing time.

The patient is ready to initiate grasp and control set-up at the end of one month of maximal exercise.

4.8 Electrode Removal

If it is necessary to remove or replace an electrode, do not reuse the connector spring and sleeve. Cut the sutures tied at either end of the sleeve. Gently remove the spring from the implantable receiver-stimulator lead by grasping the strain relief portion of the lead, twisting the spring in the clockwise direction, and pulling the lead. Slide the sleeve off of the proximal lead. Use a new spring and sleeve to connect the new electrode.

5.0 EXERCISE

5.1 Goals

The goals of the exercise program are to build and maintain muscle strength for functional use and to prevent the formation of adhesions subsequent to tendon transfers and other surgical alterations.

5.2 Regimen

The generally recommended exercise regimen consists of daily exercise (8 hours/day while sleeping, 7 days/week). The patient should exercise for at least 4 weeks at maximum functional levels before beginning the rehabilitation phase of Freehand System implementation.
Initially, some patients may have trouble sleeping through the exercise, but almost all patients eventually become accustomed to the process and can sleep through it.

5.3 System Set Up

The exercise program is initiated by performing the following set up steps:

1. Plug the charger into the external control unit, then plug the charger into a wall outlet.

2. Plug the transmitting coil into the external control unit.

3. Push the start button on the front of the external control unit.

4. Place the transmitting coil over the implant and tape it in place with adhesive or a tight-fitting garment.

5. After the exercise session, unplug the transmitting coil.

6. Patients can exercise without charging, but the batteries may not last through a subsequent day of functional use.

5.4 Use of Functional Grasp During the Exercise Phase

Patients may be provided with a preliminary grasp and control setup during the exercise stage, once they can exercise at full force with no precautions. They must be made aware that factors such as muscle fatigue, lack of training, unfamiliarity with the device, *et cetera* may result in their not having a very good grasp at this point in time, but that the preliminary grasp is being provided so that they can practice and familiarize themselves with the device on their own if they wish. It is very important that patients understand that they should not become frustrated if they have trouble using the device during this period, and that formal grasp and control setup, as well as formal training, will be provided once they have completed the exercise regimen.

If a preliminary grasp is provided to a patient, the clinician should consider disabling the lock feature, based on their best judgement after working with the patient. Some patients have difficulty mastering the lock function and may experience frustration if it is introduced early in the training phase.

If the physician does provide a patient with a preliminary grasp, and subsequently determines during the formal programming/training stage that certain key parameters should be changed (e.g., directions of shoulder movement to use for proportional control and for lock), it is important that they remember and that the patient is reminded that it may be necessary to "unlearn" some things they became accustomed to during the exercise stage.

5.5 Programming Exercise Parameters

5.5.1 Detailed Instructions

The Software User's Manual contains detailed instructions for programming the External Controller.

5.5.2 Exercise Grasp Patterns

The functional grasp patterns should be used as the exercise patterns unless there are special circumstances; e.g., immediate post-op follow-up, interference with exercise splint, etc.

5.5.3 Special Exercise Patterns

The development of special exercise patterns involves determining the maximum stimulation levels. The typical exercise pattern involves ramping up on the extensor muscles, holding for a few seconds, ramping down the extensors and ramping up the flexors, holding for a few seconds, and then ramping down the flexors. The neuroprosthesis can alternate between as many as four different exercise patterns. In addition, an extra switch can be used to change between two patterns where, for example, one pattern requires the use of a splint and the other pattern does not. These capabilities are described in the Software User's Manual.

5.6 Long Term Exercise

Once patients begin using their Systems for daily functional use, their exercise needs will change. There are no specific rules that apply to all patients. The following are offered as guidelines:

1. Many patients exercise every other night or every third night.

2. Some patients prefer exercising for shorter time periods (4 hours) to reduce hand fatigue in the morning when they want to use it.

3. Instruct patients to increase their exercise time if their grasp seems weak or fatigues quickly.

6.0 PATIENT TRAINING

6.1 Teaching the Patient about the Freehand System

6.1.1 Goals

The goals of training are to assure that the patient understands how the System works, how to use it functionally, and how to don and doff it. For safe and optimal performance, patients must understand not only when to call their medical practitioner, but also how to maintain the System. Patients must also understand the medical and practical limitations of having an implant.

6.1.2 Resources

The Freehand System User's Manual provides detailed operating information and should be used to explain the function of the Freehand System, use of each of the Freehand System components (External Controller, Charger, Shoulder Position Sensor, Transmit Coil, and Remote ON/OFF Switch), maintenance, and troubleshooting.

6.2 System Assembly

The patient should be taught to use the System for both exercise and functional use.

6.3 Basic Operation

The following are elements of basic System operation which must be understood by all patients:

1. Turning the System on
2. Selecting the grasp pattern
3. Setting the zero point
4. Proportional control
5. How to lock the grasp
6. How to unlock and regain control
7. Turning the System off
8. Exercise use
9. Use of the remote on/off switch

6.4 System Tones and Sensory Levels

The Freehand System uses audible tones and sensory stimulation (in some patients) to inform the patient about System status. The following states result in a tone or sensate stimulus:

1. System on
2. Exercise mode
3. Grasp pattern selection
4. Zero detection
5. System off
6. Lock/Unlock
7. Realign
8. Low battery
9. Proportional sensory signal
10. Lock/Unlock sensory signal

6.5 Don/Doffing the System

The use of the System will require patients and caregivers to integrate new equipment and change care patterns. These patients may need help from caregivers for placement of the Transmit Coil and Shoulder Position Sensor.

6.6 System Maintenance

Like any other piece of equipment, the Freehand System requires maintenance to assure proper operation.

6.6.1 Charging

The System has been designed to run for approximately 2 days of normal use with a full charge. Patients should be instructed to charge the System for 8 hours every night.

6.6.2 Cleaning and Storage

Detailed information related to cleaning and storage of Freehand System components is provided in the User's Manual and should be reviewed with the patient.

6.6.3 Warnings\Precautions

The warnings, precautions, and patient counseling information that are described in the Patient Manual and Package Insert should be reviewed with the patient.

7.0 SYSTEM SET-UP

The Patient System is generally configured to provide lateral and palmar grasp patterns, an exercise regimen, and to adjust control parameters. The Software UserÁs Manual should be consulted to assist in developing and programming the Patient External System with these parameters.

8.0 INDIVIDUALIZATION OF TREATMENT

Physicians are reminded that the Freehand System may not provide the same results in all patients for whom it may be indicated. Key elements for optimal patient outcome are provided in Section 8 of the Package Insert in the Appendix.

9.0 PATIENT COUNSELING

Candidates for the Freehand System should be counseled regarding their use of and expectations for the System. Elements of counseling are provided in Section 10 of the Package Insert in the Appendix.

10. REFERENCES

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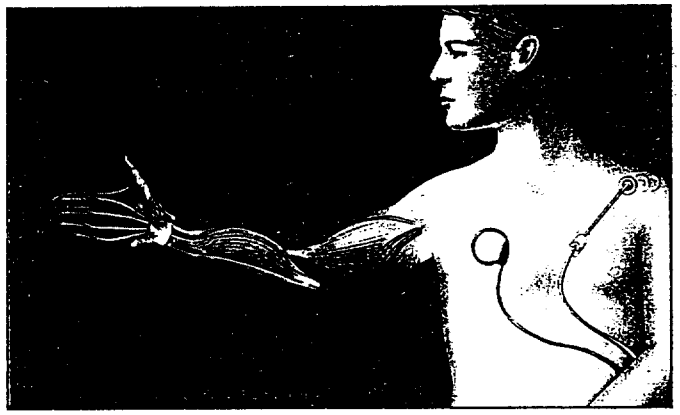
User (Patient) Manual

NeuroControl Freehand System User's Guide



NEUROCONTROL
CORPORATION

NeuroControl Corporation
Freehand System

User's Manual

NeuroControl Corporation
Cleveland, Ohio
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IMPORTANT INFORMATION

Introduction

This purpose of this manual is to provide instructions on how to operate *The Freehand System®* and to provide important information for users of *The Freehand System®*. This manual will help you and your caregivers identify the parts of your system, and will instruct you on how to put them on and take them off, how to operate the System, and how to care for it. If you need further help understanding how to use your System, please contact your doctor or NeuroControl Corporation.

The Freehand System® is an implanted neuromuscular stimulator intended for use in skeletally mature individuals who are quadriplegic due to traumatic spinal cord injury at the C5/C6 level. *The Freehand System®* is intended to improve these individuals' ability to grasp, hold, and release objects.

The Freehand System® is a prescription device and is safe only under the supervision and prescription of physician. This manual therefore is intended for reference by you and your doctor, and is to be used in combination with proper training and counseling by your doctor or therapist in the safe use of *The Freehand System®*.

Warnings

- Testing has not been completed on the effects of MRI on the Freehand System and its users. Exposure to MRI could cause injury to you or damage to the implant. MRI should not be performed on patients with the Freehand System at this time.

Precautions

- Electrical surface stimulation (muscle stimulator, EMG, or TENS) should be used with caution on or near the instrumented upper

extremity as it may damage the system. Contact NeuroControl prior to applying surface stimulation.

- X-rays, mammograms, or other imaging techniques are safe once *The Freehand System®* is implanted, but the implantable components may block the image of tissues under them.

- Before having dental, ENT, or other "high risk" medical procedures, you may need to take antibiotics to prevent infection. You should discuss this with your doctor before you have the procedure.

- Therapeutic ultrasound should not be performed over the area of the implantable receiver-stimulator as it may damage the device.

- Therapeutic diathermy should not be used as it may damage the device.

- Procedures that break the skin, such as drawing blood or administering an intravenous infusion with a hypodermic needle, should be avoided on the arm in which *The Freehand System®* is implanted.

- You should not use *The Freehand System®* to perform tasks that may be critical to your safety. An example may be the dependence of your hand to hold the throttle or brake mechanism of an automobile, or to hold a very hot object.

- Blood pressure readings with a compression cuff should be avoided on the arm in which *The Freehand System®* is implanted.

- You should check the condition of the skin across your hand, across both the front and back aspects of your forearm, and across your chest where *The Freehand System®* stimulator, leads and electrodes are located for signs of redness, swelling, or sores. If there are any of these signs, please contact your doctor immediately.

- Avoid getting the external components of *The Freehand System®* wet as it may cause damage to the device. In the event that the components become submerged in water, do not use them and

contact your clinician or NeuroControl Corporation for further instruction.

- Proper maintenance of your *Freehand System®* is essential. Your doctor will review these procedures with you. You should frequently inspect *The Freehand System®* cables and connections for any visible fraying or damage. Report any damage to your clinician.

- You should report any unusual sensations or muscle contractions to your clinician immediately.

- *The Freehand System®* lets you automatically exercise your hand and forearm muscles for preset periods of time. Your clinician will program your *Freehand System®* for the proper amount of exercise time. Unless directed by your clinician, you should avoid exercising for longer times.

- It is important to stay healthy and to notify your clinician immediately if you have any illness, infections, or unusual conditions.

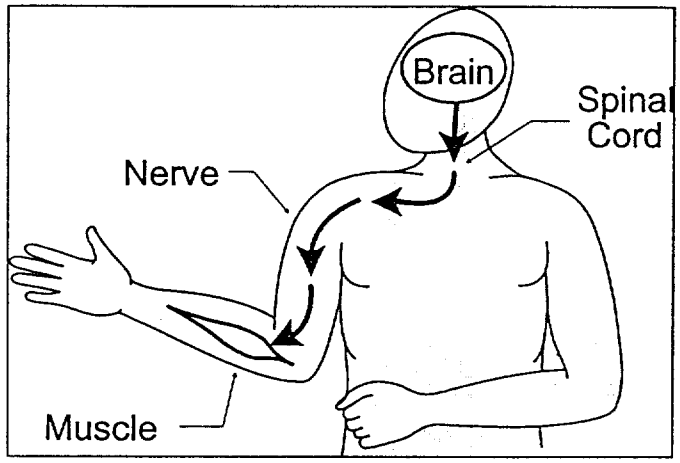
- Drugs that relax or otherwise affect your muscles may affect how your Freehand System works. It is important that you tell any doctor who gives you medicine about your Freehand System.

- Certain blood tests (such as one called CPK) may be affected by your Freehand System. It is important that you tell any doctor who treats you that you have the Freehand System to be sure that changes in your blood are not due to a more serious problem (such as a heart attack).

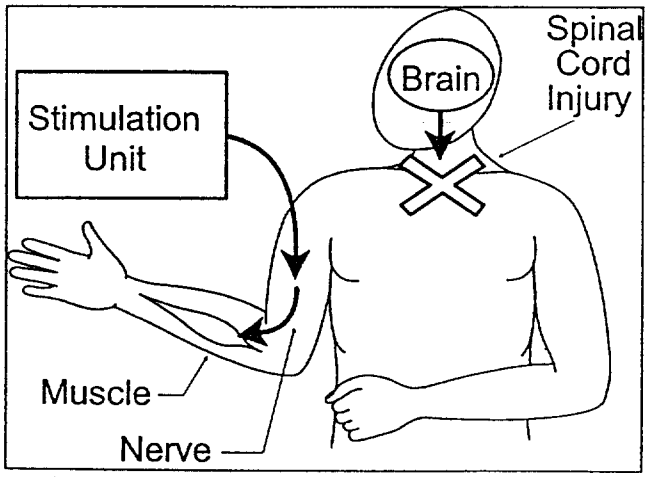
How Does The Freehand System Work?

Functional Electrical Stimulation (FES), also called *Functional Neuromuscular Stimulation,* is a method used to provide function to otherwise paralyzed muscles. *The Freehand System®* uses FES to provide hand grasp function to individuals who have been paralyzed as a result of spinal cord injury.

To achieve **normal muscle function** electrical signals from the brain travel down the **spinal cord** to lower (*peripheral*) nerves in the shoulder and arm. These nerves carry the signals down to the muscles causing them to contract.



Normal Muscle Function



Spinal Cord Injury

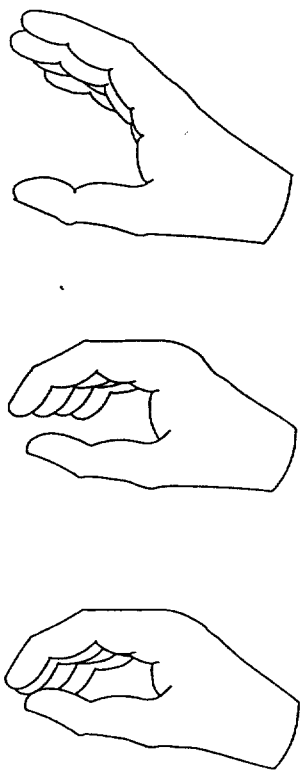
In the case of **spinal cord injury**, the path from the spinal cord to the peripheral nerves is broken. The brain still sends signals, but they cannot reach the peripheral nerves.

Using FES, low levels of electrical current are sent to the peripheral nerve through the use of a stimulation unit. If the peripheral nerve is still intact, the electrical current causes a signal to be sent along the nerve to the muscle, causing muscle contraction.

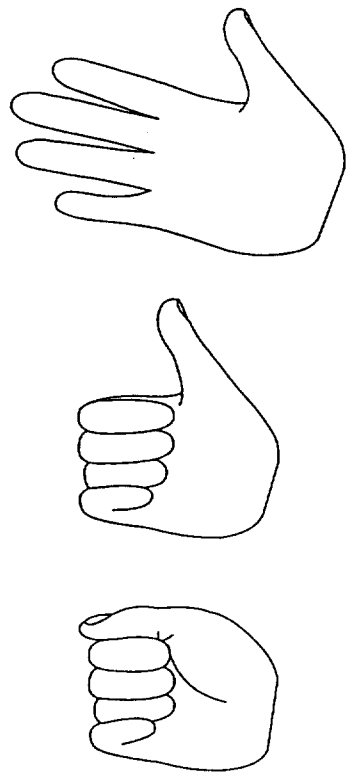
By stimulating a number of such nerves to the appropriate muscles in a controlled manner, FES can produce **functional hand grasp** patterns.

Your Freehand System has been setup by your clinician to provide two grasp patterns (palmar and lateral grasps) and an exercise regimen. The palmar grasp (also known as tip pinch) will close the tips of your fingers against the tip of your thumb. The palmar grasp can be used to grasp larger objects such as a cup or book. The lateral grasp pattern (also known as key pinch) will close your thumb against the side of your flexed index finger. This grasp can be used for grasping small or narrow objects such as a pen or fork.

During exercise the Freehand System will automatically open and close your hand for the length of time determined by your clinician. Your clinician will have programmed your system to exercise the muscles in patterns, usually lateral and palmar, that will help strengthen your grasp and help reduce muscle fatigue.



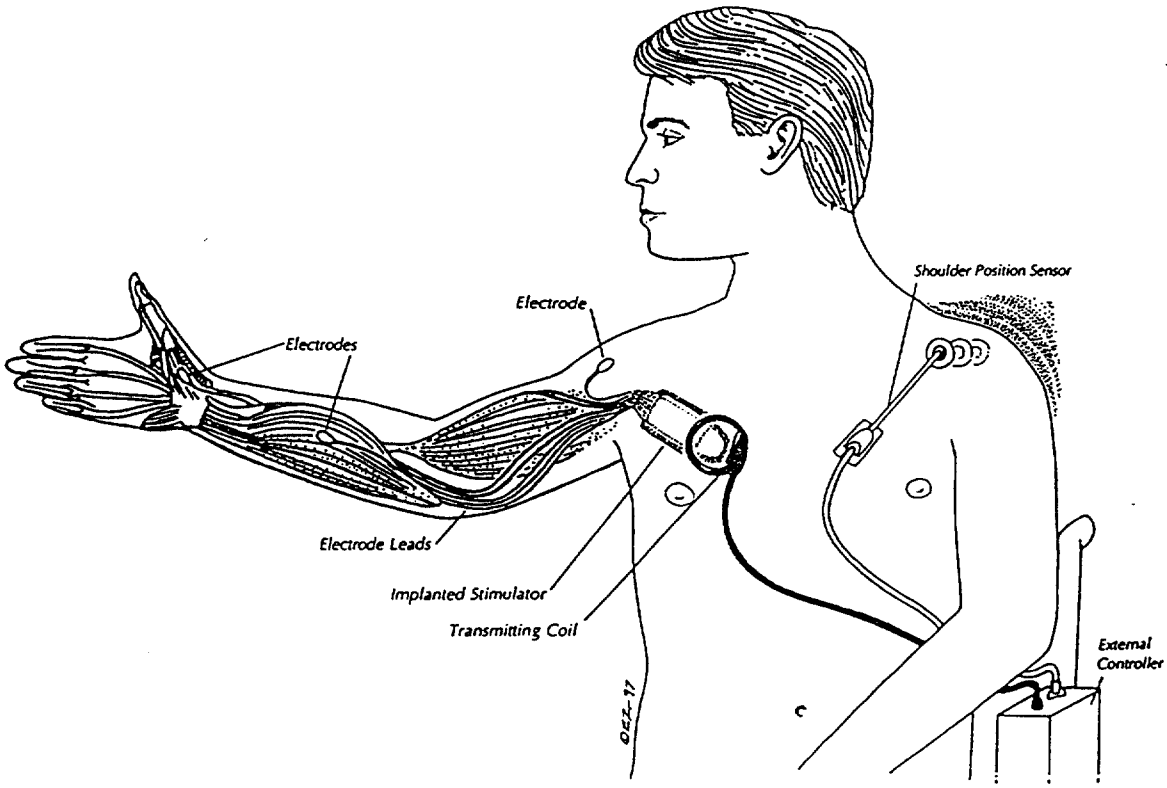
Palmar Grasp



Lateral Grasp

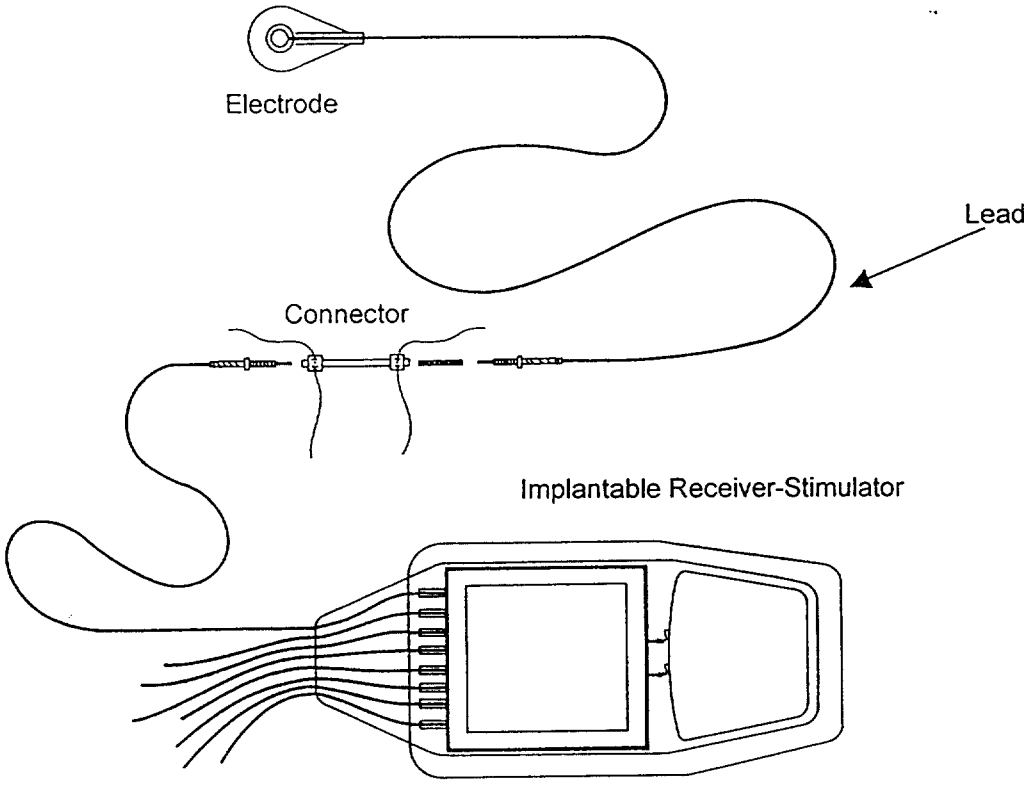
The Freehand System

Your Freehand System is made up of **implanted** and **external components**.



Implanted Components

The implanted components are placed inside your forearm, hand, and chest by your surgeon.



1) Implantable Receiver-Stimulator
   The implantable receiver-stimulator is placed under the skin on your chest by your surgeon. It receives commands from the external controller and sends signals to the electrodes and leads which are attached to your muscles. There is no battery in the implantable receiver-stimulator. It is powered by radio frequency signals sent from the external controller.

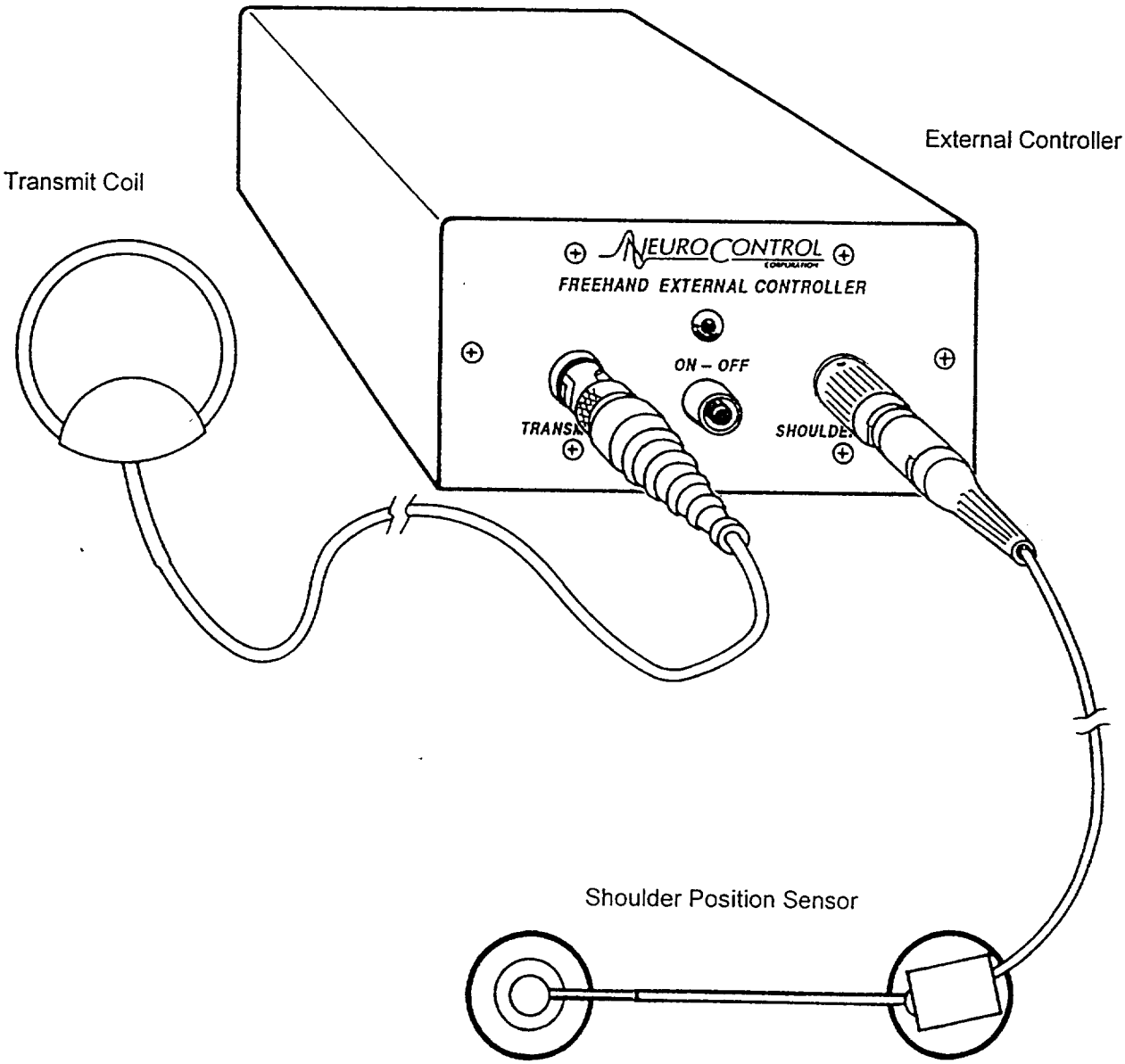
2) Electrodes and Leads
   The leads are the wires that are implanted in your arm which carry signals from the implantable receiver-stimulator to the muscles in your forearm and hand. The electrodes are the discs that are placed on your muscles which deliver the electrical stimulation to your nerves and make your muscles contract.

3) Connectors
   The connectors mate the leads from the implantable receiver-stimulator to the leads from the electrodes.

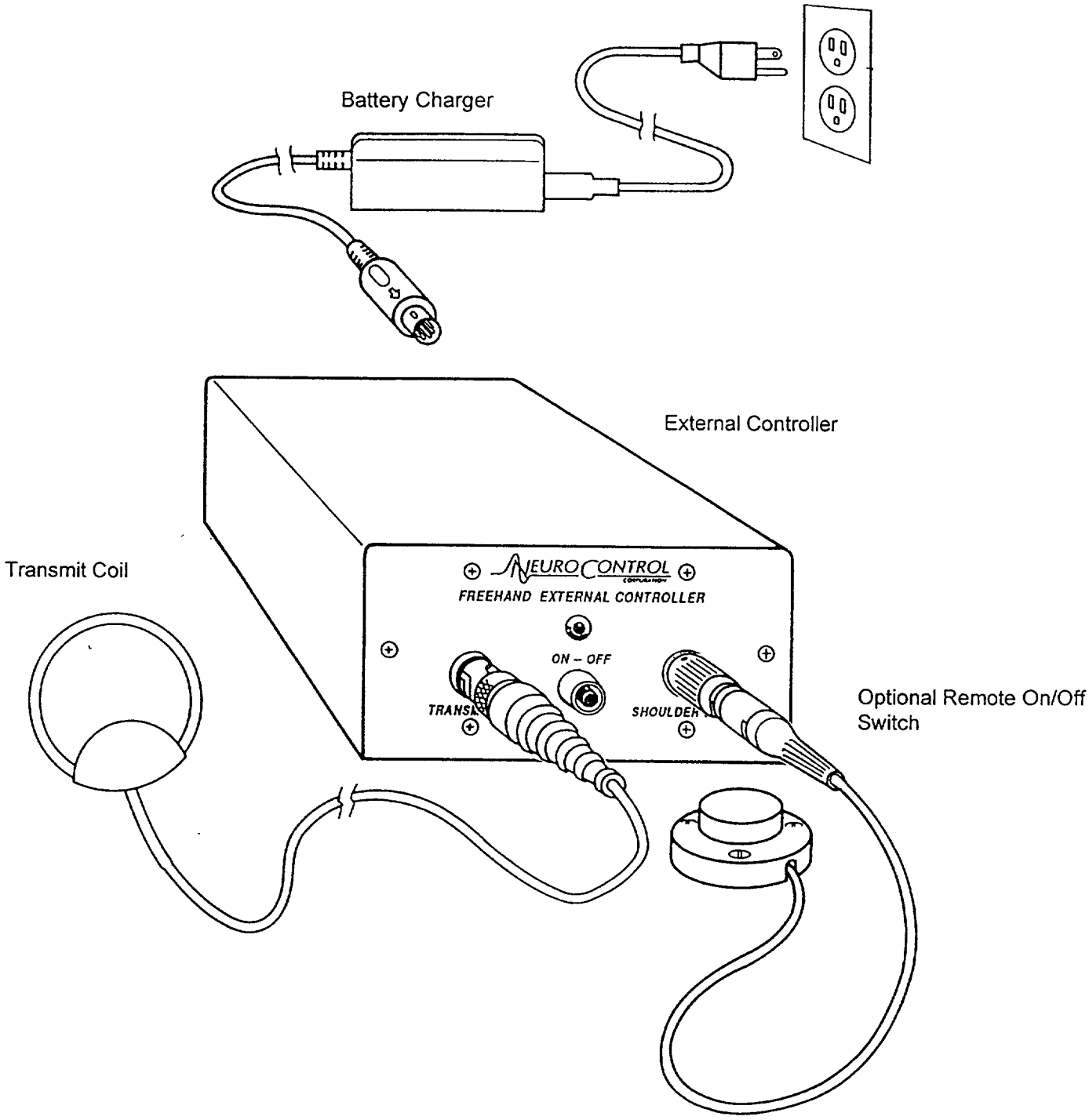
External Components

The external components let you select and operate the lateral grasp, palmar grasp, and exercise modes.

Functional Configuration



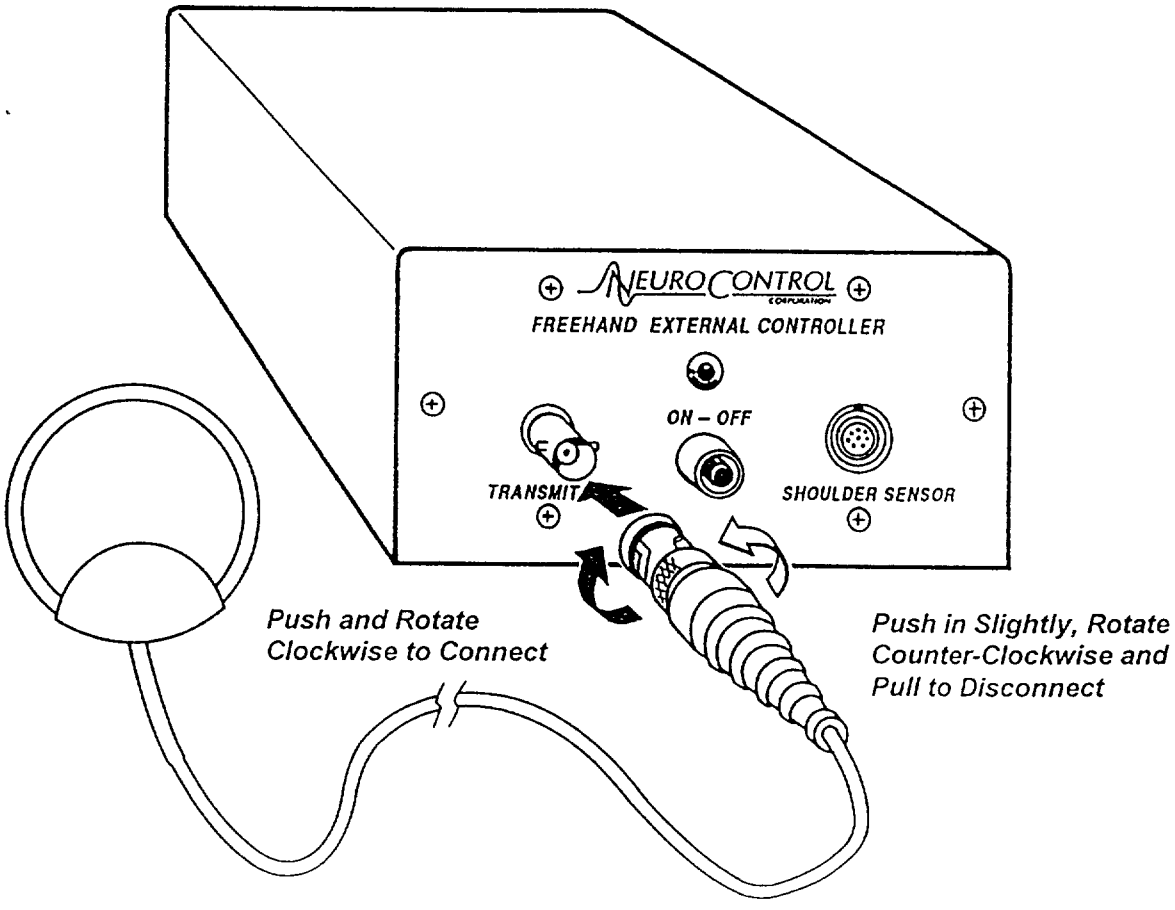
Exercise Configuration



1. External Controller
   The external controller provides the control of the implantable receiver-stimulator. It is customized by your clinician specifically for your muscles and stores the information for operating in lateral grasp, palmar grasp, and exercise. The external controller uses rechargeable batteries that provide the power for your implanted stimulator as well as the operation of the external components.

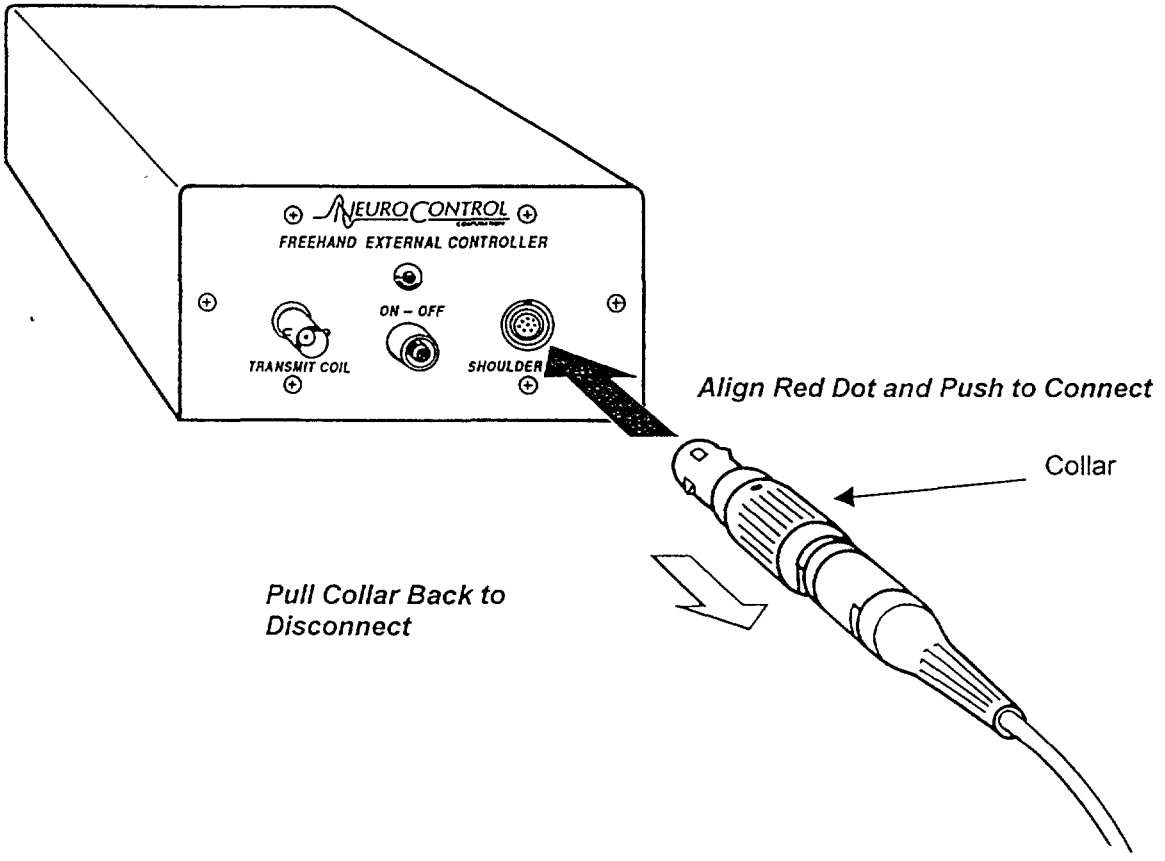
2. Transmit Coil
   The transmit coil sends radio frequency signals from the external controller through your skin to the implantable receiver-stimulator. The transmit coil is connected to the front of the external controller whenever you want to use the Freehand System for lateral grasp, palmar grasp, or exercise. The "coil" end of the transmit coil is secured over your implanted stimulator as described below and as instructed by your clinician.

   To connect the transmit coil cable to the external controller, align the connectors and push while turning clockwise. The connector will lock in place.



3. Shoulder Position Sensor
The shoulder position sensor detects movement in your shoulder that the Freehand System uses to control the opening and closing of your hand. It also houses a switch that is used to turn the System on and off and to select lateral or palmar grasp patterns. The shoulder sensor is connected to the front of the external controller whenever you want to use the Freehand System for lateral or palmar grasp. The plastic shoulder mount with rod is inserted into the rod extending from the main body. The assembly is secured to your chest and shoulder as directed by your clinician.

To connect the shoulder sensor cable to the external controller, align the cable with the dot on the connector positioned up. Push the connector in until it clicks and locks in place.



4. Remote On/Off Switch
   The remote on/off switch is used to turn the external controller on or off during exercise when the shoulder position sensor switch is not attached. The remote on/off switch may be connected instead of the shoulder sensor when the Freehand System is used for exercise. This is not necessary for operation but is provided as a convenience if you wish to manually turn the system on or off during the automatic exercise timing. *(Figure 1)*

5. Battery Charger
   The battery charger is used to keep the batteries in the external controller charged for remote use. The charger is connected to the rear of the external controller and to a wall outlet and will charge the batteries whenever it is connected. *(Figure 2)*

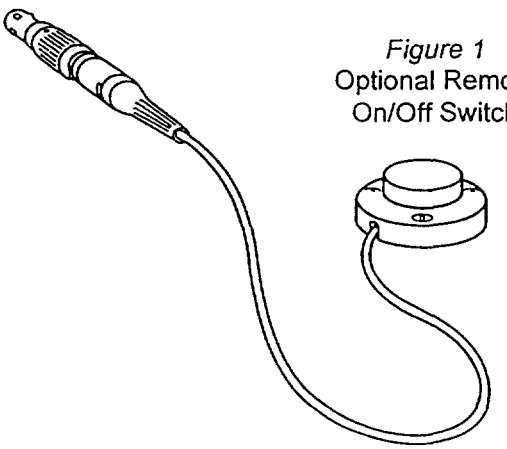


Figure 1
Optional Remote
On/Off Switch

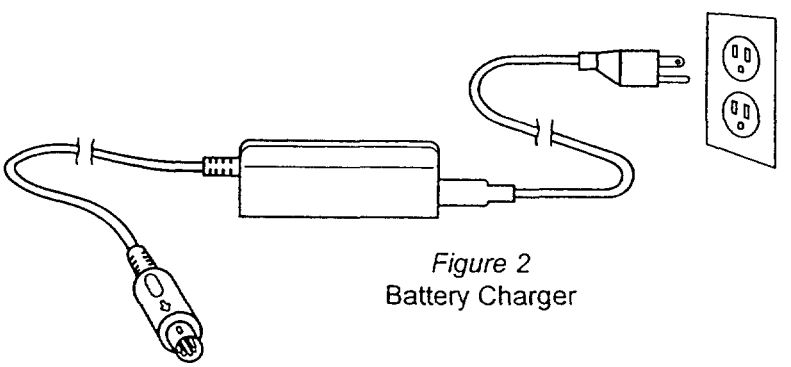


Figure 2
Battery Charger

6. Mounting System
   To attach the shoulder sensor and transmit coil to your chest, your clinician will provide you with either adhesive tape or a garment which will hold these components in their appropriate location. Your clinician will instruct you and your caregiver in how to place and attach these external components.

Operating the Freehand System

The Freehand System operates in two basic modes, **functional** and **exercise**. The functional mode lets you choose the lateral and palmar grasps when the shoulder sensor is connected. The exercise mode operates when the shoulder sensor is not connected. For either mode of operation the transmit coil must be connected.

Placing the Transmit Coil

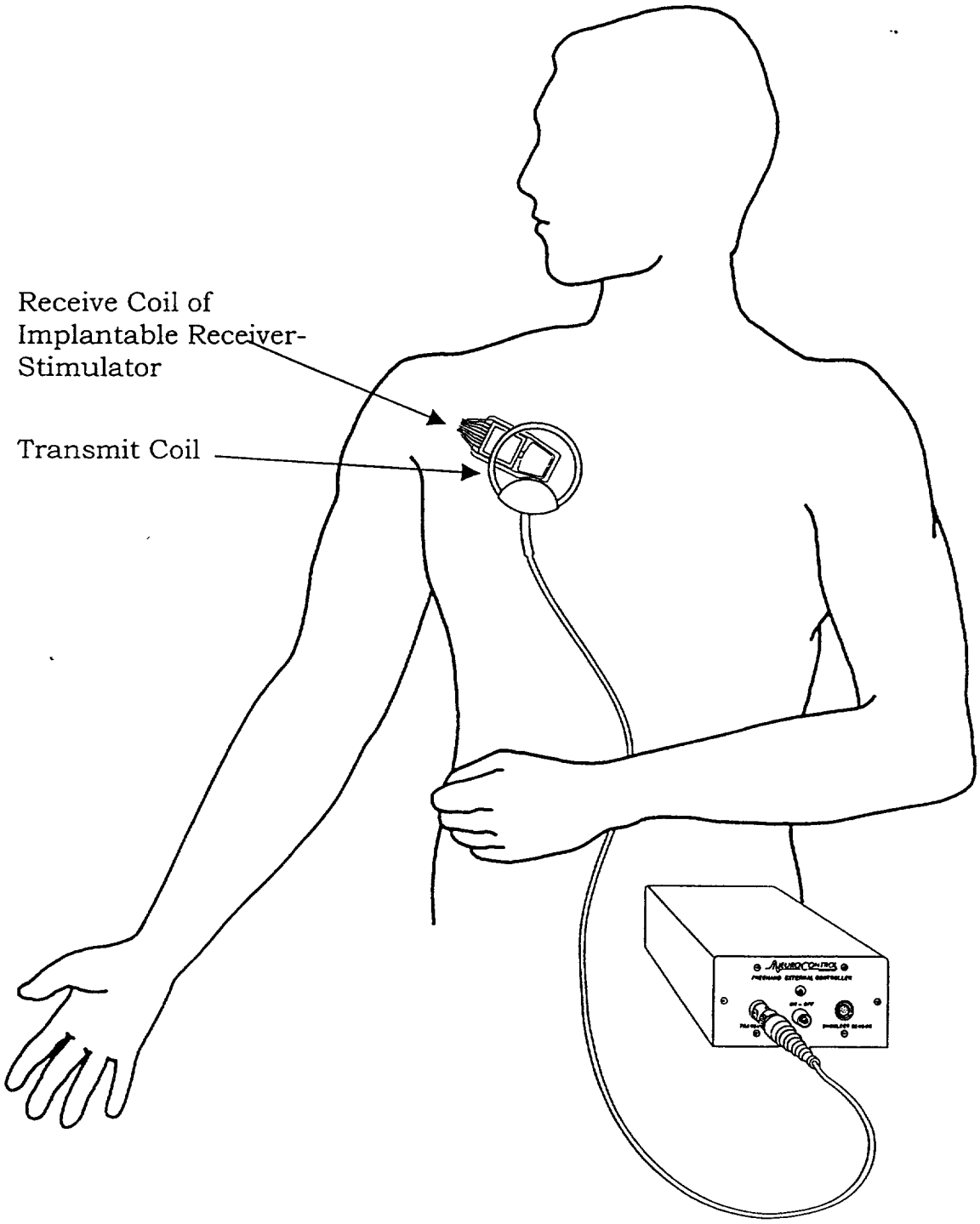
The transmit coil is placed on the skin directly over the implantable receiver-stimulator to provide power and stimulus information to the implant. It must be positioned over the lower end as instructed by your clinician. The transmit coil may be taped to your chest or secured to a tight fitting garment that will hold it in a constant position. Your clinician will help you identify the best location for your transmit coil. The following guidelines may be helpful.

If your implant stimulator has been placed so that the outline of the implant can be seen under your skin, position the transmit coil so that it overlaps the receive coil by about ½" to 1" (1½ to 2½ cm).

If your implant stimulator has been placed deeper, so that you can't see the outline of the implant, locate the receive coil by feel and center the transmit coil over the center of the receive coil.

If your grasp does not start with the placement as identified by your clinician or above, see the troubleshooting section for additional help.

Transmit Coil Placement

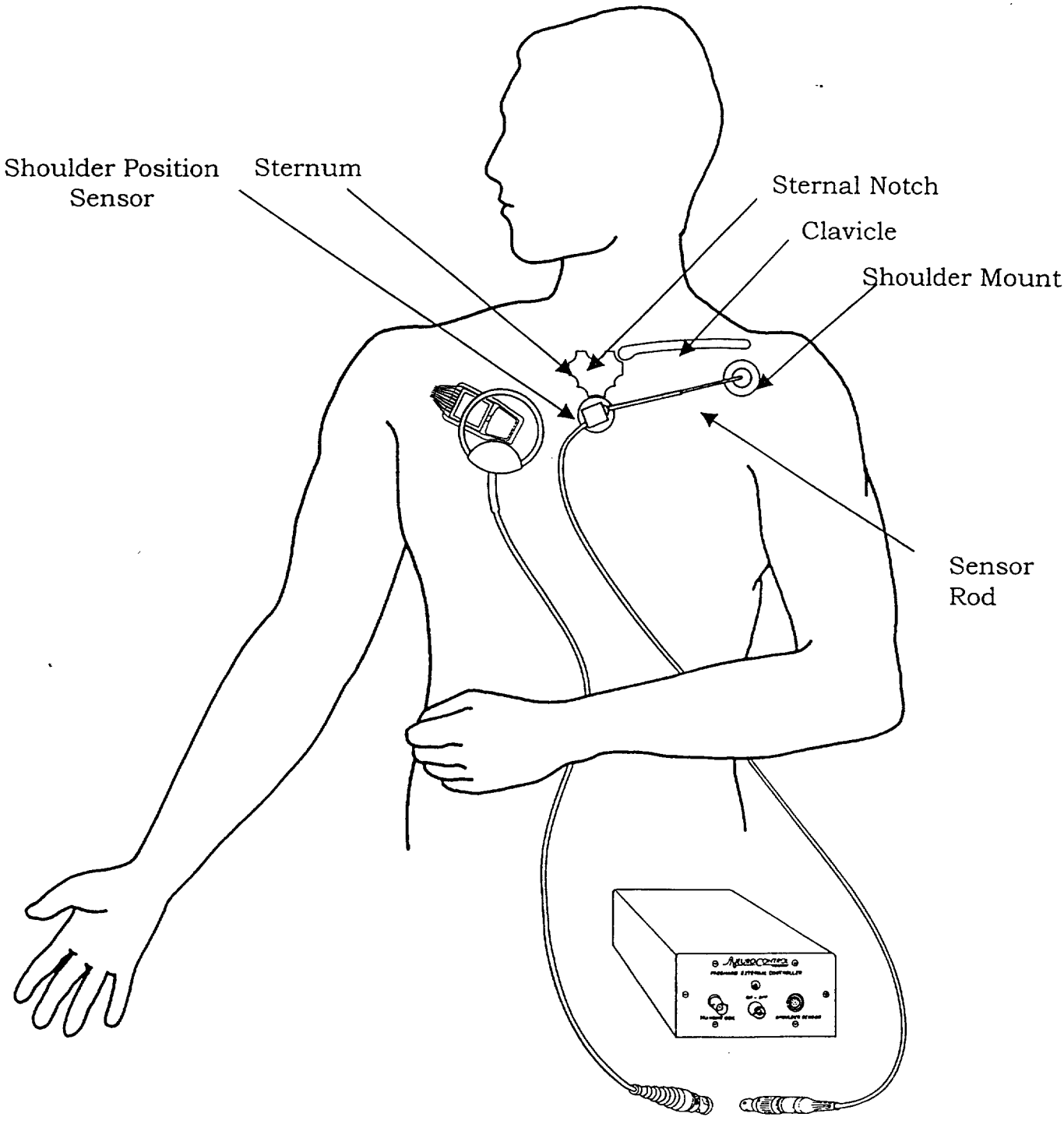


Placing the Shoulder Position Sensor

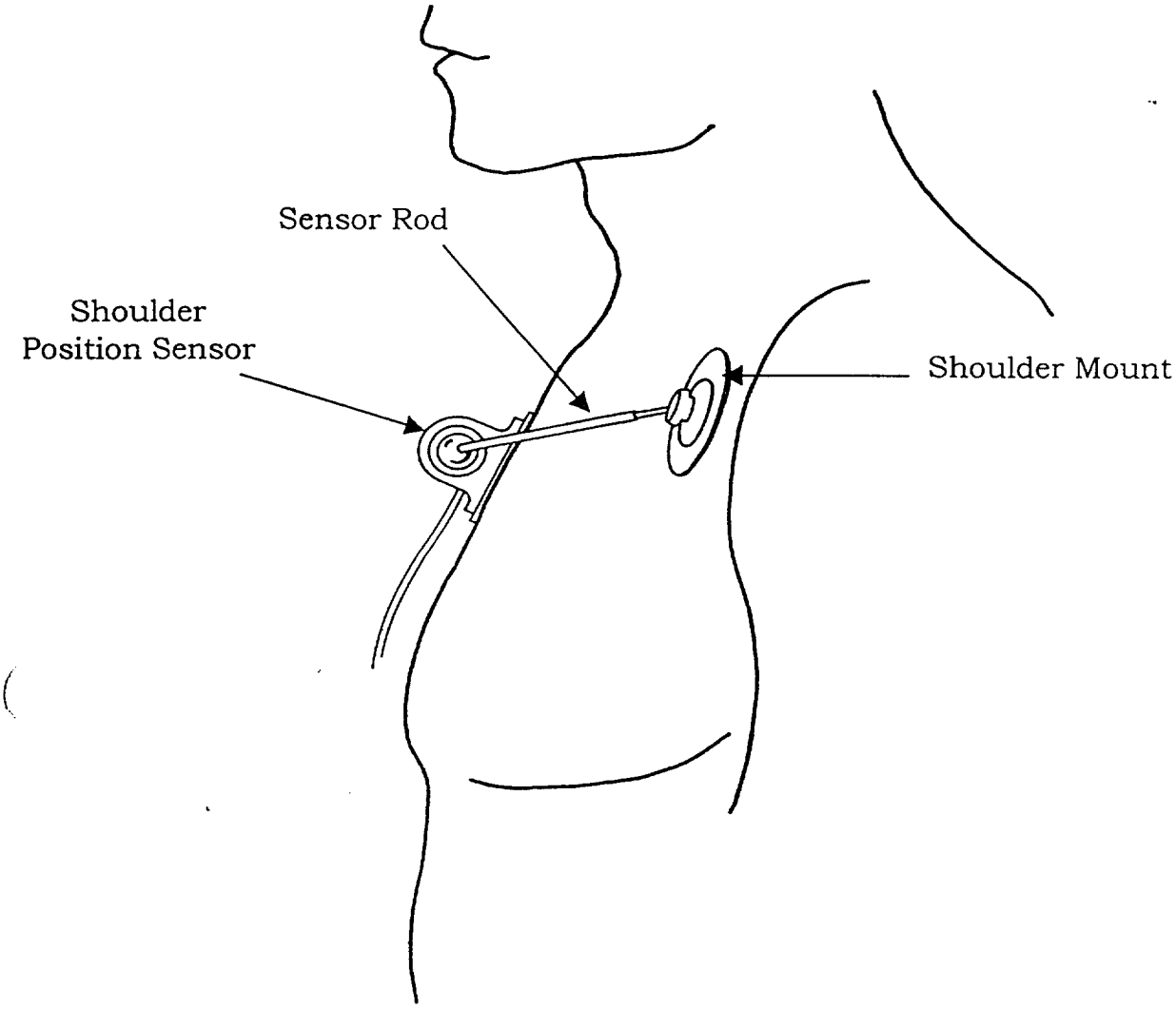
The shoulder position sensor is a two-part assembly that senses the position of your shoulder relative to your chest. This information is then used in functional mode to open, close, and lock your grasp. The two parts of the shoulder sensor are the body (the part with the cable coming out of it) and the shoulder mount (the rod with the plastic cup on the end). Both the body and the shoulder mount may be secured to your skin with a double-sided tape or attached to a tight fitting garment. Your clinician will identify the best location for your shoulder sensor during the initial programming and setup of your Freehand System. If you decide to use a garment to secure your shoulder sensor you must have your system programmed with the garment. While small day-to-day changes in placement of the shoulder sensor are acceptable, a drastic change in location may require reprogramming if it affects your ability to open, close, and lock your grasp.

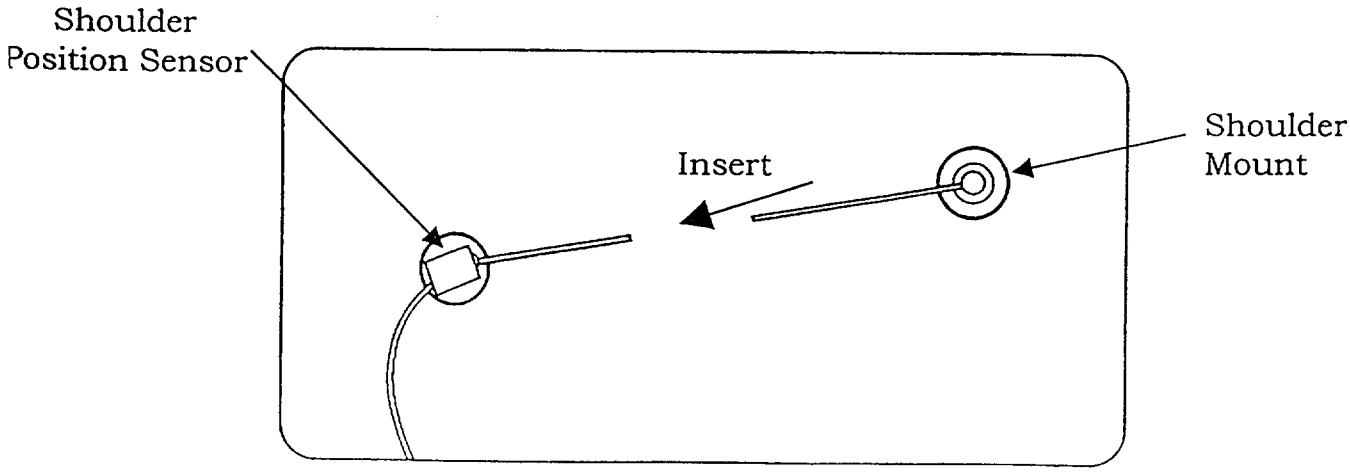
To secure the shoulder sensor on your chest first insert the shoulder mount rod into the rod extending from the body then position the assembly as instructed by your clinician. Be sure after the shoulder sensor is positioned that the rod is not limited by hitting the edge of the sensor body.

Placing the Shoulder Position Sensor



Placing the Shoulder Position Sensor





Functional Grasps

To operate the Freehand System in the functional mode (lateral or palmar grasp) you must have both the transmit coil and shoulder sensor connected. Your clinician will have programmed your system so that either back and forth shoulder movements or up and down shoulder movements will open and close your grasp. The following sequence will allow you to operate your system:

- Move your shoulder to the position corresponding to "grasp open" and turn the system **on** by pressing the switch mounted in the shoulder sensor. You will hear a short beep and / or feel your sensory electrode turn on. You will also see the front panel on/off light come on.
- The system will start stimulating in lateral grasp and you can move your shoulder to close or open your hand.
- A small quick motion with your shoulder will lock your grasp. You will hear a short high-pitched beep and / or your sensory electrode will turn off.
- Another small quick motion with your shoulder will unlock your grasp. You will hear a short low-pitched beep and / or a short sensory stimulation. Your hand will not open or close until you move your shoulder to the position at which you locked. You will hear another beep and your sensory electrode will turn back on. You can then move your shoulder to open or close your grasp again.
- Pressing the switch in the shoulder sensor will switch between lateral and palmar grasps. Each time you press the switch you will hear a short beep and / or feel a cue from the sensory electrode. Each time you switch grasps you will also need to move your shoulder to the "grasp open" position.
- By holding the switch down for 3 seconds you will turn the system off. You will hear a double high to low-pitched beep when the system turns off and the front panel on/off light will turn off.

Exercise Operation

To use the Freehand System for exercise you only need to plug the transmit coil into the external controller, however it is recommended that you also plug the charger in. The remote on/off switch may also be used. Your clinician will have programmed your system for the exercise time and stimulation levels. The following sequence will start your system in exercise:

- Press either the front panel or remote on/off switch. You will hear ten short beeps.
- The System will start in the first exercise grasp and turn off automatically at the end of the exercise.

Component Removal and Storage

To take the Freehand System off, first make sure it is turned off by seeing that the light on the front of the external controller is off. If it is not off, you may turn it off from the shoulder sensor switch, the front panel switch, or the remote on / off switch. Next disconnect the transmit coil then the shoulder position sensor or remote on / off switch. You may then remove the transmit coil and / or shoulder sensor from your body. Be sure that your skin is in good condition and is not irritated from any tape used to secure them.

You should store the components of the Freehand System in the storage case provided when not in use. This case protects the components and is a convenient way to hold all the parts.

Care and Maintenance

Your Freehand System is intended to be used in a dry environment. It should be protected from exposure to rain, spills, high humidity, and other moisture as necessary. The battery charger is intended for indoor use only.

Charging

Your Freehand System will operate continuously for eight hours on a full charge. When the batteries are fully discharged it will take sixteen hours to fully recharge. When the system is in the functional mode a low battery warning may be given if the charge on the batteries drops too low. The warning is a short beep followed every five seconds by another short beep for a total of thirty seconds. The system will then shut down.

To charge your external controller, plug the Freehand battery charger into the power supply plug on the back of the unit and into a wall outlet. The external controller will charge even while you are exercising. You may leave the Freehand battery charger plugged into the wall even when it is not charging the external controller.

Cleaning

The external controller may be cleaned with a damp cloth over its exterior surface. Do not wash or submerse the external controller for cleaning. For heavier dirt or stains a mild detergent, such as dish soap, may be used for cleaning followed by a damp cloth. Tape residue may be cleaned off the transmit coil and shoulder sensor with rubbing alcohol. The cables should be wiped clean with mild detergent. Allow all items to air-dry completely before using.

If your external controller is accidentally submersed do not use it until you call NeuroControl Corporation for further instruction.

Inspecting Cables

You should periodically inspect the cables on the transmit coil, shoulder sensor, remote on/off switch, and charger for cracking or breaks in the insulation, especially at either end. If the insulation on one of your cables is cracked or broken do not use it and replace it with a new cable.

Troubleshooting

If you have any questions or concerns with the Freehand System and need assistance, call NeuroControl Corporation at 800-378-6955.

If your stimulator does not seem to be working, try the following steps:

1. **With nothing connected to the External Controller**
   a) Hold the *on/off switch* on the front of your External Controller in for three seconds.
   b) *Release* the switch for at least ten seconds.
   c) Push the on/off switch in *briefly* and release.
   d) The system should respond with three *beeps* (one beep, then six seconds later a double-beep). If it does not, plug the charger into the External Controller and try again.
   e) If there is still no response, *call your clinician or NeuroControl Corporation.*

If the system beeps after test #1:

2. **Connect the Transmit Coil and Charger (no shoulder sensor)**
   a) Hold the *on/off switch* on the front of your External Controller in for three seconds.
   b) *Release* the switch for at least ten seconds.
   c) Push the on/off switch in *briefly* and release.
   d) The system should respond immediately with ten *beeps*
   f) If you only hear the double-beep after six seconds the External Controller has turned off and you need to *call your clinician or NeuroControl Corporation.*
   e) If you hear the ten beeps try placing the transmit coil to start the exercise stimulation. Note that you will have to wait for any "onset" delay time that your therapist may have programmed into the exercise timing prior to the stimulation starting.
   f) If this does not work, try using a replacement coil
   g) If there is still no response, *call your clinician or NeuroControl Corporation.*

If you are able to exercise using test #2:

3. **Connect the Transmit Coil and Shoulder Sensor (no charger)**
   a) Turn the exercise *off* using the on/off switch on the front of the external controller (you will hear the double-beep).
   b) Plug in the shoulder sensor and use the switch mounted in the shoulder sensor to turn the system back on.
   c) If the system beeps but there is no stimulation, try *switching* grasp patterns.
   d) If there is still no stimulation, *call your physician or therapist.*

e) If there is no beep when you push the shoulder controller switch, try pushing the *on/off* switch on the front of the external controller.

h) If there is still no response, *call your clinician or NeuroControl Corporation.*

i) If you are able to start the system in functional mode, but it doesn't respond properly when you move your shoulder, *call your clinician or NeuroControl Corporation.*

If you call your clinician or NeuroControl Corporation, be ready to answer the following questions:

1. Does the system:
   a. beep normally?
   b. make unusual beeps?
   c. make no sound at all?
2. Does the system:
   a. work for exercise?
   b. work for functional?
   c. not work in either mode?
3. When was the last time that the unit was charged, and for how long was it charged?

Other reasons to call your *clinician*:

1. If the stimulation *looks* or *feels* suddenly different.
2. If your *grasp patterns* look different than what you are used to.
3. If there is any *redness* or *swelling* over the area of the implant or over the electrodes.
4. You should inform your clinician if you have any *illness* requiring the use of medications or if you need *surgery* for any reason.

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Patient ID Card

From

Freehand System ID Card

Note: The owner of this card has an implanted neuroprosthesis called the Freehand® System located in the chest, arm and hand. This device may activate a metal detector and is visible on x-ray.

Name:
Location of Implant:
Surgeon:
Surgeon's Phone #

Implant Serial #:
Hospital:
Date of Implant:

NeuroControl Corporation
Cleveland, OH

Customer Service
TOLL FREE 800.378.6955

Back

CONTACT: The treating Surgeon or NeuroControl Corporation Customer Service at 800-378-6955 before using any of the following modalities or treatments unless you are certified for care of the Freehand System. In general observe precautions used for cardiac pacemakers and orthopaedic implants. Patients are at risk for infection or device damage.
IMAGING: Strong magnetic fields (MRI) can permanently damage the device or injure the patient.
ELECTRICAL STIMULATION: Do not apply any type of therapeutic electrical stimulation.
ULTRASOUND AND DIATHERMY: Do not use therapeutic ultrasound or diathermy over implant, leads, or electrodes.
INVASIVE PROCEDURES: Wires, electrodes and the implant in the hand, arm, and chest are visible on x-ray. Avoid any elective invasive procedures that could damage the system.
SERUM CPK: CPK may be elevated. Fractionation is indicated to rule out cardiac injury.
ORAL SURGERY: Protect the implant with antibiotics prior to and after dental surgery.
INFECTION: Infection of any body part or organ can endanger the implanted system. Notify the responsible Surgeon or NeuroControl Corporation immediately. Special antibiotic protocols are needed.