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Example - Early Feasibility Investigational Device Exemption

IDE Section: Device Description

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2. Device Description

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2.1. High-Level Technical Description of Components

The implantable components of the Networked Neuroprosthetic (NNP) System are shown in Figure 2-1 below, and include **remote sensing modules** that sense EMG signals via **recording electrodes**, the signals from which can be used as inputs for control. **Remote actuator modules** provide stimulation to peripheral nerves via **stimulating electrodes**, and are linked to other networked components by **network cables**. A **power module** provides power to all the networked components, as well as wireless communication to the external programming system. Synonyms and abbreviations are listed in Table 2-1.

The external components include the **control tower**, which serves as both a clinical programmer (when used in its clinical configuration) and as the patient's charger (when used in its stand-alone configuration). For clinical programming, communication from the control tower to the power module is achieved with a MedRadio communication link (402–405 MHz). Recharging of the implantable power module is achieved with an external **recharge coil** and an inductive recharge field (3.5kHz). The implanted system can be put into a safe, deactivated mode with an external **reset magnet**.

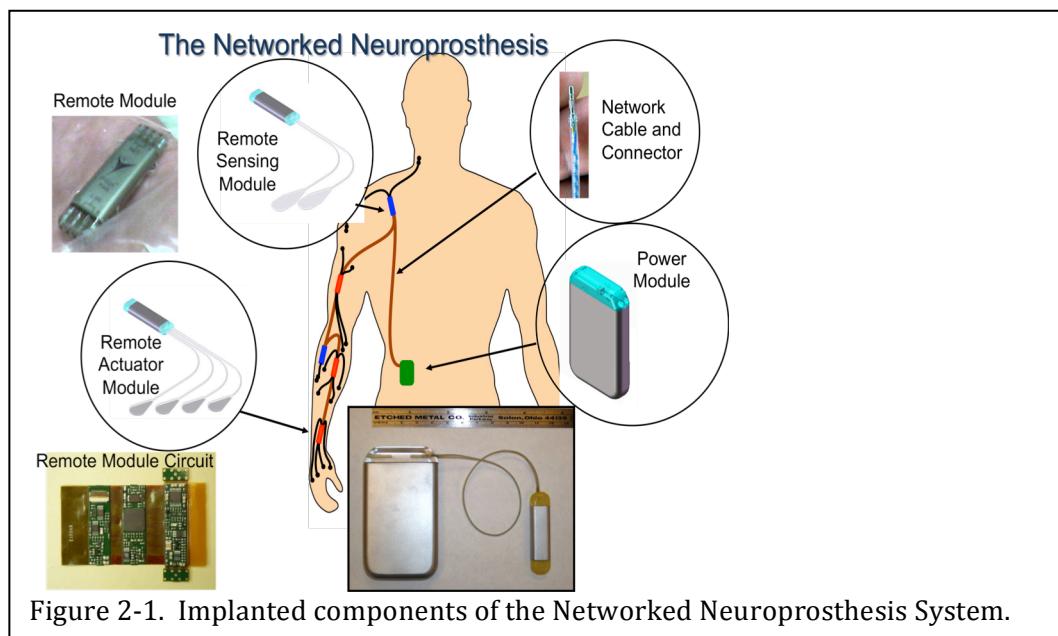


TABLE 2-1. COMPONENT NAMES, SYNONYMS AND ABBREVIATIONS

ABBREV.	NAME	SYNONYM
BP2	2-channel biopotential recording Module	Remote sensing module
CT1	Control Tower	
HCN	Host Computer Notebook	Programming computer station
NC, NC2	Network Cable – 2 conductor	
PG4	4-channel pulse generator module	Remote actuator module, remote stimulating module
PM, PM1	Power Module with 1 network bus	
RM	Remote Module: refers to either PG4 or BP2	

2.2. High-Level Functional Description

2.2.1. Functional Use by the Subject

The NNP System is intended to provide grasp, reach and trunk stability functions to subjects with tetraplegia in order to improve their independence in activities of daily living. After being implanted with the NNP Power Module, Remote Modules, Electrodes, and Connectors, the subject will be able to make use of voluntary muscle contraction to control the coordinated activation of paralyzed muscles into the functional motions of hand grasp and trunk extension. Prior experience has shown that these functions will allow the subject to perform tasks they could not otherwise perform without the stimulation.

The subject, during typical daily use, will experience the following system features:

- Ability to turn the system on or off;
- Logic switching to allow a choice of multiple grasp patterns;
- Graded control that allows proportional opening and closing of the hand, or different degrees of strength of contraction for trunk extension;
- A locking function that allows a grasp pattern to be maintained in a fixed position without the need for continued control input;
- Independent activation of multiple functions, such as elbow extension, forearm pronation, and shoulder stabilization; and
- Sleep mode, to reduce system power consumption during periods of inactivity.

The subject can also perform the following activities with the addition of external components:

- Recharging the implant, using the Recharging Coil and Control Tower;
- Assessing battery status, using the Control Tower;
- Moving into different control states, such as exercise mode or sleep mode, using the Control Tower; and
- Putting the system into a safe, deactivated mode with an external reset magnet.

2.2.1. Functional Use by the Programming Technician

A trained technical specialist performs system programming of the implanted components using the Control Tower, the Programming Computer and Clinical Interface software. The goal is to optimize the subject's performance using the implant as naturally as possible based on their unique presentation considering: voluntary muscle strength, passive and active range of motion, stimulated muscle response, and most importantly, different functional goals and home/community environments. Details of the programming methods are provided in *Appendix B – Functional Description and Programming*. Briefly, there are two major aspects of neuroprostheses programming:

- **Pattern set-up for grasp and/or trunk stability.** This consists of electrode profiling to characterize thresholds for activation and maximum current for selective activation, followed by creation of a grasp template or trunk extension template which establishes the relative activation of each muscle from 0% to 100%.
- **Control signal setup.** The clinician establishes the logic and proportional control methods used by the subject to perform various tasks, including methods to choose

the selection of grasp patterns, open and close the hand proportionally, “lock” and “unlock” the hand, proportionally extend and relax the trunk, and place the system into “sleep” mode or turn off completely.

There are multiple steps to each of these aspects, and there can be interaction between the two, but in general it is possible to concentrate on each aspect individually. The grasp patterns are developed first, which then allows the patient to utilize these grasp patterns for practical testing during the control signal setup phase. More details for programming can be found in *Appendix B – Functional Description and Programming*.

2.3. High-Level Software Description

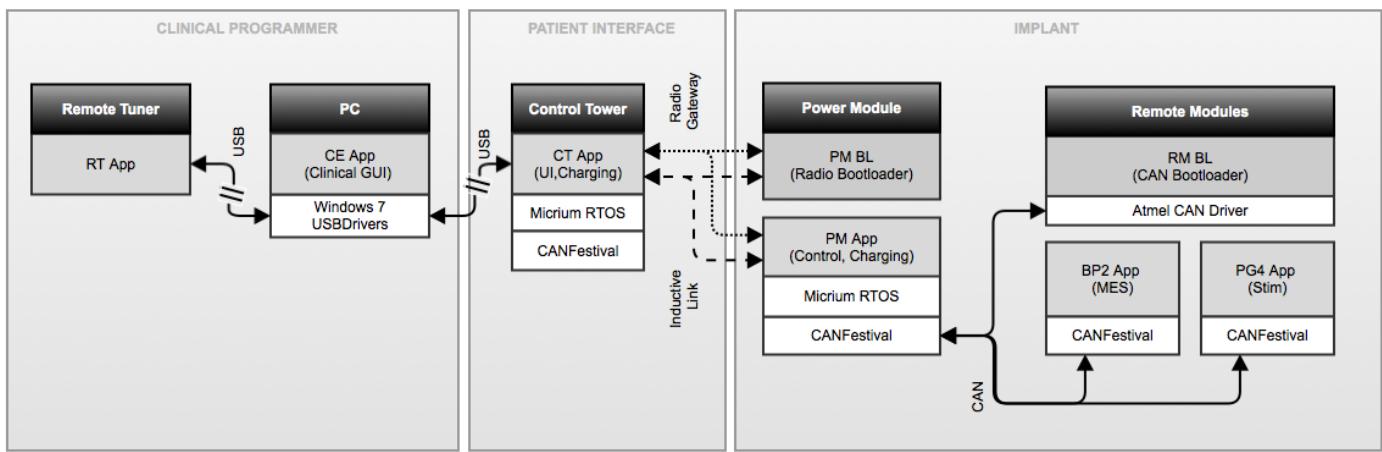


FIGURE 2-2. HIGH-LEVEL SOFTWARE BLOCK DIAGRAM

The solid gray regions represent the eight software components within in the system:

- Control Editor Application (CE App)
- Remote Tuner Application (RT App)
- Control Tower Application (CT App)
- Power Module Radio Bootloader (PM BL)
- Power Module Application (PM App)
- Remote Module CAN Bootloader (RM BL)
- Biopotential Module Application (BP2 App)
- Pulse Generator Application (PG4 App)

Broken lines in the schematic indicate that these connections are temporary for programming and user setup to be performed by a clinician or engineer. Solid lines require a wired connection. Dotted lines indicate a wireless connection. The implanted components can be used without interaction to the external components, however the Control Tower is required for charging, querying system states, and starting the system after complete power down (batteries discharged, emergency shutoff). The PC is required for system programming and configuration.

Please see *Appendix H – Software Description, Verification and Validation* for further details.

2.4. High-Level Design Principles

2.4.1. Principles Of Hardware Design

The functional and technical specifications of the NNP System are based on our analysis of the anticipated clinical applications and our clinical experience in the deployment of multiple neuroprosthetic systems providing motor control. The general design principles upon which the NNP System was based are listed briefly below:

2.4.1.1. Design Principles to Maximize User Functionality

- Maximize user's ability to independently use the system
 - Eliminate the need for external components during functional use so that users do not require assistance
- Permit expandability of the system over time to allow people with SCI to have access to multiple restored functions (as they become available).
- Allow flexibility in the configuration of stimulus (output) and sensor (input) channels to customize user's performance
- Allow modifications to the implanted system through reprogramming.
- Scalable to efficiently meet the needs from simple to advanced system requirements

2.4.1.2. Design Principles to Minimize Risks to Users

As discussed in our Risk Analysis (Appendix C), the **highest severity risks** tended to be **lowest likelihood** and are fully mitigated through skilled surgical technique (for surgical risks) and engineering design (for risks associated with the technology). The highest severity risks include:

- Death, due to:
 - Surgical complications,
 - Infection,
 - Autonomic dysreflexia,
 - Cardiac arrhythmia, or
 - Catastrophic battery overheating.
- Permanent injury, due to:
 - Failed components,
 - Erosion,
 - Migration,
 - Surgical complications,
 - Infections or
 - Burns.

Based on these considerations, the following design principles have been used in the development of the NNP System:

TABLE 2-2: DESIGN CONSIDERATIONS TO MITIGATE RISKS

RISK MITIGATION GOAL	DESIGN CONSIDERATIONS
Minimize exposure to surgical risks	<ul style="list-style-type: none">• Modularity: Ability to modify or upgrade system without complete implant removal• Modularity: Device is designed for ease of implantation; shorter procedure time• Permit surgical installation with limited incisions.• Ability to easily replace components if they do fail.• Battery lifetime of at least 2 years; simple

	replacement procedure
Minimize infection	<ul style="list-style-type: none"> Devices are designed for ease of sterilization, and are provided sterile
Minimize electrical hazards with external components	<ul style="list-style-type: none"> Designed with appropriate attention minimizing leakage currents. Although not claimed as conforming to the standard, the system has been designed and tested with reference to IEC 60601-1-2 and -2
Minimize mechanical failure of electrodes, leads and cables	<ul style="list-style-type: none"> Designed to withstand 1.2E6 stretching cycles, 1.2E5 crushing cycles, 1.2E6 bending cycles, 6.0E5 twisting cycles.
Minimize heating during recharging / run-away heating conditions	<ul style="list-style-type: none"> Recharge limited to safe transcutaneous heating standards. Battery cells have self-extinguishing feature.
Minimize failure of implanted electronics	<ul style="list-style-type: none"> Hermetic enclosure used on all modules.
Minimize adverse physiological reaction to implant	<ul style="list-style-type: none"> Stimulation Levels: Only well-understood, safe stimulation parameters are used. Stimulation output levels are hardware limited to safe levels, taking into account component tolerances. Programmable: Stimulation levels can be modified Physical Design: form factor chosen to prevent erosion Physical Design: Presence of anchoring barbs or suture skirts to prevent migration Physical Design: Small form factor to allow placement in average adult forearm. Materials: Chosen for known biocompatibility
Assure reliable functioning in the presence of EM sources	<ul style="list-style-type: none"> Communication methods and protocols chosen to permit coexistence with other emitters in the same band; wireless communication not used for safety-related or time-critical functions.
Assure safe and reliable functioning of system software	<ul style="list-style-type: none"> Critical and safety-related functions are not controlled by software

Several key principles are described in more detail below:

No external components during functional use. The design of the NNP System allows the neuroprosthesis user to eliminate all external components during functional activities, resulting in a system that is easy for the users to operate, is robust, is cosmetically acceptable, and is applicable to a broad range of neurological indications. The use of implanted power storage, fully implanted sensors, and high performance internal processors frees the user from all external devices during normal operation while also allowing the development of much more sophisticated and functional control algorithms.

Modularity, Flexibility and Configurability of System Components. The NNP System utilizes a number of small implanted modules distributed throughout the body and connected together as a single network of devices. A purpose-built network cable is used to physically connect the modules one to the other, and is used to distribute operating power

and provide the communication link to and from each module, thus simplifying clinical implementation by **simplifying lead routing through the body**. Network communication utilizes the industrial standard “controller area network” (CAN) protocol. Each remote module contains local processing capabilities in order to minimize the communication rate between modules, and can be programmed through a transcutaneous link. The NNP System receives power from implanted lithium ion batteries that are rechargeable through a single inductive transcutaneous link. This novel architecture facilitates system expansion, technical upgrades and functional enhancements.

Ability to modify or upgrade system without complete implant removal. Surgical risks pose some of the greatest severity risks, even though they have low probability. Nevertheless, reducing the impact of surgery-related risks is a key consideration in the design of the NNP. Future iterations on the NNP design can be accomplished by making changes to 1) just the software (requiring no hardware replacements), or 2) to circuitry within the modules (allowing all electrodes to remain in place). The module shell is designed to allow increases or decreases in length (to accommodate added circuitry when necessary) without changing the feedthrough and header configurations or manufacturing procedures.

Surgical installation with limited incisions. The implantation procedure is greatly simplified by allowing multiple network connections to be made into or out of a single module, taking advantage of the common outer shell design used for both stimulating and sensing modules. Remote modules are small enough to be placed in most areas of the body, including the forearms.

System architecture optimized for patient safety and maximum functionality.

Selecting the appropriate architecture was the single most critical step in the neuroprosthetic design process. The system architecture must meet all of the functional requirements, yet be technically feasible to implement. It was essential that the system architecture be flexible so that it could be adapted to a wide range of clinical needs, and to minimize repeat surgeries by the patient. We briefly contrast the NNP System architecture with the other two popular implant architectures (“centralized” and “distributed-wireless micromodules”) in order to illustrate the design considerations that underlie the NNP System concept.

- The centralized architecture, in which everything passes through one central large implanted component, has been the de-facto standard for the design of virtually every commercially available neuroprosthetic for many years [Troyk and Donaldson, 2001]. However, as systems need more channels and expand to include both activation and sensing, this design becomes untenable. Too many leads have to travel in and out of the device, and too much circuitry and power has to be housed in a single capsule. Most importantly, this architecture is very difficult to upgrade without completely re-designing nearly all aspects of the system. Fundamentally, it is not practical to continue to utilize this design concept.
- Another more recent architectural design is the “distributed-wireless micromodule” [Cameron et al., 1997]. The key issue in this architecture is that it is necessary to have *distributed power sources*, which are usually Li-ion rechargeable batteries. Unfortunately, this means that each module must be recharged separately and each module must be replaced each time the battery loses its capacity. This means that the entire system must be replaced every few years due to the limited lifetime of the Li-ion batteries. We feel that distributed power is a

poor choice for practical systems at the present time. By designing a system around the unavoidable depletion of the power source, it becomes apparent that a centralized power source is extremely desirable. This allows replacement, and more importantly recharging, to take place at a single location in the body.

For these reasons, the NNP System was designed to have a single *centralized power source* that could be located in the torso, but *distributed processing and functioning* that is based in the remote modules.

2.4.2. Principles Of Software Design

As detailed in *Appendix H – Software Description, Verification and Validation*, software development proceeded through a standard design, verification and validation process, and key principles were adopted based on our prior experience with earlier systems. A number of key decisions made at the outset of our software development procedure are highlighted below, along with our rationale. Typically, these high-level decisions were focused on using standards whenever possible, encouraging open development for future modifications, and assuring overall safe performance of the system.

1. **Quality of the tools.** Software development tools were chosen for their track record in commercial use, reliability of compilation, debug support, and product support. Compilation poses a tradeoff between size of code and execution speed, a tradeoff that a compiler must make in a way that is also reliable. Debug support is also very important – most of the time spent with the software tools is in debugging. Product support is also important. For these reasons, we chose the Microsoft Visual Studio system for PC development and IAR System tools for embedded development. Both choices represent mainstream tools that are consistently used for commercial products.
2. **Operating systems.** The PC choice was mostly made by considering our clients. The critical operating system choice was for the main CPUs in the system: the Power Module and the Control Tower. Micrium was chosen because it has a track record in safety-critical systems and provides source code. A primary benefit of Micrium is its pre-emptive capability, meaning it has a deterministic response to changing process conditions.
3. **Application Programming Interface (API).** A key principle was to follow standards where applicable and available. The most notable choice of the API was its requirement that all messaging be confirmed. Any safety-critical data always has a confirming message saying that the transaction has been completed. In the event of a non-completed message, the system also features failure mechanisms that monitor messaging traffic. The API (as defined by CANOpen and a standard in itself) comes with an implementation – CAN Festival.
4. **No use of dynamic memory in the controllers.** Because all memory is pre-allocated by the compiler, there is no possibility of memory leaks.
5. **No optimization.** We have chosen to not use any compiler optimization. This reduces the object code complexity and minimizes the possibility of undetected race conditions and reduces some of the troubleshooting issues.

6. **Use of a coding standard.** Michael Barr's Netrino standard was designed to improve readability and reliability of the code being developed. For example, no magic number and the use of "sizeof(array)" for array iterators greatly improves the chance of success for later code changes. Other coding standard recommendations include: minimizing the use of global variables to pass data; minimizing the use of pointer arithmetic (keeping indirection to one level); and organizing the module structure around functional units. An important follow-on to this is the interlinear documentation of the source code. We have chosen to implement a documentation package called Doxygen to be able to assemble the comments and compile them into standalone documents.
7. **Use of scripts.** An important design goal of the NNP system is to be able to reconfigure it for different research investigators with a minimum of effort by the core design team. An earlier system developed by this team was very dependent on different releases of the purchased software and it was limited to a very few number of developers who understood the system. With the NNP, we have opted to provide an inherent language that buffers the internal complexities of the system (by making use of the API), protects the system against crashes by providing a layer of code-checking that prevents memory corruption, and is easily learned by the application developer. It bears a strong resemblance to some of the early BASIC implementations.
8. **High-level functional decomposition and model based design.** Early steps in the design process included a top-level functional decomposition, where major elements were identified and a communication topology was laid out. As the shape of the system became clear, specific elements were interfaced to simulated components of the system under control (i.e. the peripheral nerves and muscles of the subject). Substantial effort was put into building component models or reusing pieces from other projects to provide a feedback mechanism for the control system being designed. This activity, combined with the application knowledge of the NNP team, provided a fairly secure way of demonstrating application characteristics of the NNP system before it was fully built.

2.4.3. Principles of Wireless Communication Design

The NNP System utilizes two wireless links:

TABLE 2-3: WIRELESS LINKS USED IN THE NNP SYSTEM

TYPE	FREQUENCY	COMMUNICATION BETWEEN	USED FOR
Inductive recharge field	3.5 kHz	Recharge Coil and Power Module	Recharging the battery
MedRadio Communication Link	402-405 MHz	Power Module and Control Tower	Programming of implanted components

The following high-level design principles were used during the design of the wireless communication methods for the NNP:

1. **Minimize wireless communication for user functions.** The wireless communication link is used primarily for programming the implanted components in the clinical laboratory, and has only restricted use outside of the lab. For operation of the NNP System outside of the laboratory, it is possible to perform all functional tasks without the Medradio link being active. However, users may use the link in order to obtain the battery charge status, choose an operating mode, or receive operating status feedback.
2. **Minimize use of wireless communication for safety-related functions or time-critical functions.** The NNP does not use wireless communication for any safety-related functions or time-critical functions. In the clinical setting, it is used for programming the implants. The data transmitted over this link can be re-sent if errors are detected. In the presence of significant interference, this process may take a relatively long period of time. If necessary, the programming session could be moved to a different environment offering EMI protection.
3. **Choose communication methods and protocols that permit coexistence with other emitters in the same band.**
 - a. **NNP uses the FDA/FCC regulated MedRadio frequency band and communication protocol.** The MedRadio frequency band is *only* authorized for implantable medical devices. Medical devices that use the MedRadio band must follow the FCC protocols for this band. These protocols use a “Listen-Before-Talk (LBT)” criteria. If a nearby medical device is already using a frequency in the MedRadio band, the NNP wireless link will automatically attempt transmission on other MedRadio frequencies (10 channels available). If no open frequency is detected, then it will either be necessary to wait until one or more nearby device stops transmitting or relocate to an area away from the other transmission sources. This feature prevents the NNP System from generating RF that will interfere with other medical devices.
 - b. **NNP uses low power transmission from the implanted device (also specified by MedRadio).** The NNP System also implements a session key protocol, which requires the external Control Tower to generate an access code that is unique for each communication session. This eliminates any possibility of confusion if multiple devices are attempting to communicate at the same time, since the access code is part of the preamble of each subsequent message. At the end of a communication session, both the Control Tower and Power Module discard the access code.

2.4.4. Principles of Failsafe Function

Two design principles underlie the failsafe function of the NNP.

1. Users need to be able to quickly shut down stimulation if for some reason the system is not responding to commands to stop stimulation. This is accomplished by deactivating the NNP with an easily grasped, **standard pacemaker magnet** placed over the power module’s reed switch, placing it into a **failsafe shut-down (reset) mode**.

2. If the NNP system has been put into failsafe re-set mode, its re-activation must be done with an intention to avoid returning to the undesired previous state. This is accomplished by putting the system through a **startup forcing function**, a single, well-defined, intentional activation process that must be performed with the clinical version of the control tower.

A subsequent known risk introduced by this approach is that the user's power module may come in accidental contact with a strong magnet, activating the fail-safe shutdown inadvertently. This risk is considered low in both severity and likelihood, and is mitigated through precautions in the labeling and user training.

It should be noted that under normal operating conditions, stimulation through the pulse generator is under constant control from the software, and the "Stop Stim" command is the highest priority command of the system, interrupting all other commands. In a typical scenario, the subject would activate the "Stop Stim" command to turn off power to the implanted system. However, it is necessary to provide a rapid shutdown of the implanted NNP System components in the situation where the commands from the control unit fail to communicate, or when the modules stop responding to external commands. **It is important to note that such a hypothetical situation would not be considered an "emergency," because of multiple other safety features that prevent harm to subjects.**

The primary purpose of the NNP failsafe function is to stop stimulation in the event that the stimulator modules are continuing to stimulate and are not responding to commands to stop stimulation. The power module contains a magnetically activated switch for emergency shut-down of the entire NNP System. This switch implements a failsafe shutdown function that will de-energize all of the power module circuitry in the presence of a strong, static magnetic field. The failsafe function disconnects the batteries from the remainder of the implanted system, including the power module and NNP network, immediately shutting down all system operations. Recovery from this shut-down mode is only through a start-up forcing function which requires the inductive recharging link to be placed over the power module. This will re-energize the power module circuitry and initiate a normal power up sequence. It should be noted that the failsafe function and inductive recovery reset is all performed in hardware. After restart, the power module restores power connection and returns to normal operation in the start-up mode.

Patients and clinicians are all provided a **standard pacemaker magnet** to be used to initiate the failsafe reset. Because users may have limited hand function, a U-shaped cuff is attached to the back of the magnet, allowing them to pick it up independently.

2.5. Detailed Descriptions of Implantable Components

2.5.1. Power Module



Figure 2-3. Photograph of power module, showing markings on the superficial side of the module (no markings on back).

The Power Module is an implanted module that has two key functions. First, it houses the rechargeable Li-ion batteries that supply power to the entire NNP implanted system, along with the required recharging link and circuitry. Second, it contains the wireless MedRadio link for transcutaneous communication and system programming. The power module connects to the network through the network cable, placing power onto it for distribution to all remote modules.

The power module is designed for easy surgical replacement, and replacement is an anticipated and expected event based on the eventual depletion of the Li-ion batteries. Power module replacement is accomplished through a single small incision, disconnection of the network segment connection, and replacement with a new power module. This procedure is expected to be an outpatient procedure requiring less than 30 minutes.

The power module is designed to be implanted in the torso, typically either chest or abdomen, because these portions of the body can accommodate the power module package size. This location also allows convenient access for recharging through an inductive link, and easy surgical exposure for replacement.

The power module contains a magnetically activated switch for emergency shut-down of the entire NNP system. This switch implements a failsafe shutdown function that will de-energize all of the power module circuitry in the presence of a strong, static magnetic field.

The power module utilizes a 32 bit ARM-7 microprocessor, the NXP Semiconductor LPC2129 processor. The processor runs a real time operating system (RTOS).

During functional operation, the power module primarily functions as the power source for the entire implanted NNP system. However, due to its significant processing power, it is

capable of performing signal processing and data storage in support of the remote module functions when required. The power module is always active (except under the emergency shut-down condition), but can be placed into and taken out of a low-power ‘sleep’ mode by the user.

The power module has a titanium case with feedthroughs for the network connections and antenna wire. An epoxy header holds the connections and antenna. A polymer nest inside the case holds the batteries and circuitry in place. The coil for inductive battery recharging surrounds the circuitry inside the case. Three identical Li-ion rechargeable cells are connected in parallel to provide the NNP system power.

SPECIFICATIONS

Functional Specifications

- Lifetime of at least 2 years before battery recharge capacity or shelf-life is exhausted
- Full recharge in less than 16 hours
- Enclosure sized to be subcutaneously implanted in the abdomen or chest in a full-size adult
- Biocompatible enclosure
- Single cable network connection to remote modules
- Replacement achieved via a single disconnection and single incision

Technical Specifications

- Provides a bidirectional transcutaneous data-link to the external Control Tower – MedRadio compliant wireless;
- ARM7 core, 32 Bit Microcontroller (can be used in 16 bit mode for greater code density) with ‘on-the-fly’ adjustable clock frequency (computation vs power consumption)
- Expansive non-volatile memory
- RTOS (Micrium)
- Real Time Clock (date and time)
- Inductively-Coupled Recharging and Real-time Powering Link;
- Magnetic (safety) failsafe reset
- On board temperature sensing (multiple sensors) and 3-axis accelerometer
- Lithium Ion rechargeable cells (3), with safety supervision and fuel gauging (600mAh capacity)
- Recharge limited to safe transcutaneous and implant heating standards
- Inductive coupling distance of ~3cm
- Hermetic enclosure

Patient-contacting materials (please refer to Appendix D - Biocompatibility for details)

- Titanium case
- Tecothane header
- Silicone used for header adhesion and backfill
- Polyester reinforced silicone sheeting for suture skirt
- Silicone adhesive and silicone primer for adhesion of suture skirt to capsule

2.5.2. Pulse Generator Module



Figure 2-4. Photograph of the PG4 module.

The four-channel **pulse generator module (PG4)** is a remote module utilized for electrical stimulation of nerve and muscle tissue. The PG4 can deliver stimulation to four independent monopolar electrodes, using the metal case of the PG4 as the common return electrode. The PG4 is small enough to be located in the extremities, including the upper arm and forearm, thus minimizing electrode lead length and simplifying surgical lead routing.

The cathodic stimulation output of the PG4 matches the cathodic stimulation output of the existing implantable neuroprosthetic devices that have been utilized in humans since the 1970's at the Cleveland FES Center, under the following IDE numbers: G890084, G900108, G950116, G040214 and under PMA P950035.

The PG4 is connected to the NNP network through a single network cable. The PG4 gains power from the network, receives data from the network that is utilized to determine the stimulation parameters that should be delivered, and places data on the network regarding its status. The PG4 has four total network connections, allowing a single PG4 to branch from a single network input to three network outputs.

The PG4 has internal processing based on the AVR-core processor (Atmel AT90CAN128). Computational processing is used to identify relevant network data (typically control signal levels from the sensor module) and convert that data into the appropriate stimulus levels to each electrode based on pre-programmed patterns. These patterns are customized to provide the desired coordinated functional responses from each muscle and nerve.

The PG4 combines three levels of failsafe mechanisms to assure that potentially damaging stimulation is not delivered: 1) hardware limits on total charge per pulse, 2) software limits on stimulation parameters, and 3) failsafe magnetic switches in both the PG4 and the power module.

SPECIFICATIONS

Functional Specifications

- Small form factor with sizing appropriate for placement in an average adult forearm.
- 4 independent stimulation channels for each module, with multiple modules possible.

- Produces charge-balanced stimulation parameters, for muscle-based electrodes.
- Connects to existing electrode designs.
- Component lasts at least 10 years.
- Surgical installation and placement must be possible without permanently altering existing electrodes or other components of the system.

Technical Specifications

- (See Tables, below, for stimulation specifications)
- Monopolar – common return electrode (the enclosure)
- Size: maximum dimensions 60mm x 20mm x 10mm
- Multiplexed four-output stimulator
- Four NNP network connections per module
- Receives power and exchanges data along NNP network
- Conversion of AC bus to isolated DC voltage supply
- Magnetic (safety) reset
- AVR-core, 8-bit microcontroller with ‘on-the-fly” adjustable clock frequency

Patient-contacting materials (please refer to Appendix D - Biocompatibility for details)

- Titanium case
- Tecothane header
- UV-cured acrylate adhesive for header adhesion and backfill
- Polyester reinforced silicone sheeting for suture skirt
- Silicone adhesive and silicone primer for adhesion of suture skirt to capsule

TABLE 2-4: STIMULATION OUTPUT SPECIFICATIONS

PARAMETER	SPECIFICATIONS
Number of Output Channels (May be staggered or synchronous (within 1 ms) on different modules.)	4 channels / module. Staggered (resolution = 1 ms, minimum = 1 ms) on single module.
Method of isolation	Galvanic isolation of each module
Waveform	Charge-balanced biphasic
Pulse shape	Rectangular cathodic phase followed by passive recovery anodic phase
Current or Voltage Regulated?	Current
Maximum output voltage	34 V
Maximum output current	20 mA
Frequency	1-50 Hz
Pulse Duration	1-255 us +/- 1 us
For Multiphasic Waveforms	
Symmetrical Phases?	No
Phase Duration *	Cathodic: 0-255 us, 0-20 mA Anodic: ~ 20 ms (at 50 Hz), ~999ms (at 1 Hz); passive recovery; stim. frequency dependent
Method of Charge Balancing	Capacitor
Are charge balancing cycles always completed?	Yes
Net charge (mC/pulse) @500 Ohms	5.1 uc/pulse
Leakage current (nA) @500 Ohms	7 nA

Net DC current (mA) at max pulse rate @500 Ohms	7 nA
Max. phase charge (mC/phase) @500 Ohms	See Table
Max. charge dens. (mC/cm ² /phase) @500 Ohms	
Max. phase power (W/phase) @500 Ohms	
Max. phase power dens (W/cm ² /phase) @500 Ohm	
Pulse delivery mode	Pulse by pulse
Burst delivery	N/A
ON time (seconds)	Variable, indefinite
OFF time (seconds)	Variable, indefinite

* With passive recovery, the Anodic Phase Duration will be the time that the in-line capacitor is connected and able to discharge through the tissue. Essentially the anodic phase is any time the electrode is not cathodic and not open circuit. This duration will change with stimulation frequency, so this anodic time could be expressed as:
 $T(\text{anodic}) = [1/\text{StimFreq} - \text{CathodicDuration} - \text{InterphaseDelay}]$

TABLE 2-5: STIMULATION OUTPUT SPECIFICATIONS BY PHASE

PARAMETER	VALUE	UNITS
Pulse Width	2.55E-04	s
Pulse Amplitude	2.00E-02	A
Electrode Surface Area	~0.08	cm ²
• Intramuscular	7.91	mm ²
• Epimysial	8.55	mm ²
Max Output Stage Voltage	34	V
Expected Tissue Load	500	Ohm
Max Phase Charge	5.10E-03	mC/phase
Max Phase Charge Dens	6.38E-02	mC/cm ² /phase
CALCULATED MAXIMUMS		
	VOS*PA	(R*PA)*PA
Max Phase Power	6.80E-01	2.00E-01
Max Phase Power Density	8.50E+00	2.50E+00

The “PG4 Stim Output Design Verification Test (DVT)” is our internal test used to confirm that stimulation outputs of the Pulse Generator module are equivalent to those previously approved in earlier IDEs. The PG4 design has been demonstrated to pass this DVT.

2.5.3. Biopotential Recording Module



Figure 2-5. Photograph of the BP2 module.

Myoelectric signals (MES) from muscles under voluntary control are recorded by the **biopotential recording module (BP2)**. The BP2 is designed to record myoelectric signals and process those signals for the purposes of neuroprosthetic control. The BP2 can record MES from two different muscles and process the signals independently for different control needs.

The BP2 connects to the same myoelectric recording electrodes that have been utilized since 2003 at the Cleveland FES Center. The recording electrodes can be either an epimysial or intramuscular design and consist of two metal contacts separated by 1cm for differential recording.

The fundamental principles of the myoelectric signal processing in the BP2 is similar to the processing in our current generation of implanted devices, the IST-12, which have demonstrated excellent functional utility [Kilgore et al., 2008]. The purpose of the signal processing is to generate a usable control signal (or signals) from the biopotential signal obtained from the muscle. The processed signal can either be used as a direct proportional control signal, such as the signal used to control grasp opening or closing, or it can be used as a logic signal, such as the signal used to switch between grasp patterns. Without appropriate processing, MES tends to fluctuate too rapidly for practical use as a neuroprosthetic control. Thus, the primary goal of the signal processing is to produce a smoothly varying and stable signal without significant delay between the generation of the MES and the resultant change in the processed signal.

An important aspect of MES acquisition in neuroprosthetics is the need to account for the stimulus artifact. Electrical stimulation of nearby muscles produces large artifacts on the MES recording that can completely distort the signal during and immediately after the stimulus is delivered. The BP2 can use multiple signal processing methods to maximize the signal quality during electrical stimulation, including lowering the signal gain during stimulation and blanking the stimulus artifact.

The module is sized small enough so that it can be located in the extremities, near the muscles to be recorded from. This has the advantage of reducing the lead length, improving

the signal quality and minimizing the range of electrode lead lengths that need to be brought into surgery.

The BP2 is connected to the NNP network through a single network cable. The BP2 gains power from the network, receives data from the network that to determine signal processing parameters and other administrative functions, and places two channels of processed myoelectric data on the network for use by any other module connected to the network. The BP2 has four total network connections, allowing a single BP2 to branch from a single network input to network output to three additional remote modules.

The BP2 has internal processing based on the AVR-core processor (Atmel AT90CAN128). The processing, network interface and powering is identical to the PG4 module. Computational processing in the BP2 is used to identify relevant network data and perform the signal processing on the recorded myoelectric signal.

SPECIFICATIONS

Functional Specifications

- Small form factor with sizing appropriate for placement in an average adult forearm.
- Two myoelectric signal recording channels for each module, with multiple BP2 modules possible in a single NNP system.
- Records and processes myoelectric signals in the presence of nearby stimulation.
- Connection to existing electrode designs.
- Component lasts at least 10 years.
- Surgical installation and placement must be possible without permanently altering existing electrodes or other components of the system.

Technical Specifications

- Dual-channel differential-input signal amplifier
- Software based signal processing (except for anti-aliasing filter)
- High degree of stimulus rejection (blanking option)
- Gain Range : 300 to 7,500 (32 Steps, Logarithmic)
- AC Coupling (High-Pass Filter) 1.6 Hz
- Overload Recovery Time (Anti-aliasing) < 1mS
- Multi-mode operation, processed and raw signal
- Size: maximum dimensions 60mm x 20mm x 10mm
- Four NNP network connections per module
- Receives power and exchanges data along NNP network
- Conversion of AC bus to isolated DC voltage supply
- Magnetic (safety) reset
- AVR-core, 8-bit microcontroller with ‘on-the-fly” adjustable clock frequency

Expected Input Signal Characteristics

- Myoelectric signals (MES)
 - Amplitude – minimum: 10 μ Vp-P, maximum: 20mVp-P
 - Frequency – minimum: 10Hz, maximum 1kHz

Patient-contacting materials (please refer to Appendix D - Biocompatibility for details)

- Titanium case
- Tecothane header

- UV-cured acrylate adhesive for header adhesion and backfill
- Polyester reinforced silicone sheeting for suture skirt
- Silicone adhesive and silicone primer for adhesion of suture skirt to capsule

2.5.4. Network Cable

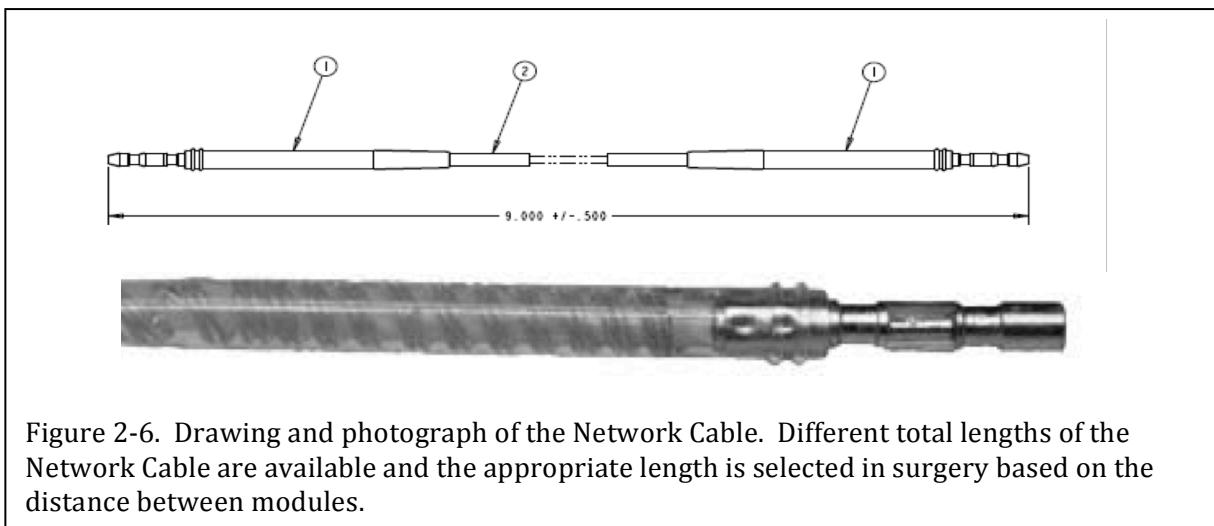


Figure 2-6. Drawing and photograph of the Network Cable. Different total lengths of the Network Cable are available and the appropriate length is selected in surgery based on the distance between modules.

The **Network Cable (NC2)** is utilized to conduct power and communication between implanted modules in the NNP System. Power on the network cable is provided by connection to the power module. Network communication can be generated on the network cable by any module. The network cable is a critical component of the NNP because all remote modules depend on its proper functioning for power and communication. Every remote module must be connected to the NNP network through a network cable.

The network cable is a four-filar (7-strands DFT), two-conductor cable. It is designed to combine features of low electrical resistance with strength and durability. The network cable must conduct the power and communication signal without significant losses and must have excellent fatigue resistance for placement in the extremities where the cable may cross multiple joints.

The network cable is terminated at each end with an identical male connector for connection to any module in the NNP system. The network cable is designed to be easy to connect and disconnect in surgery, yet maintain physical and electrical conduction at the connector within the body for the lifetime of the individual. It is possible to replace each component of the NNP system, including individual modules or network cables, without disrupting the remaining implanted components.

The total length of the cable varies depending on the location in the body, but is typically 10-30cm. Strain relief is provided at each end of the cable for durability and to provide stiffness for insertion into each module.

SPECIFICATIONS

Functional Specifications

- Provide reversible connectivity between modules.
- Flexible, pliable, and extensible enough to user muscle, tissue, or joint motions from transmitting excessive torque through the cables to the implanted components.
- Durable for human use, at least 10 year expected lifetime.
- The network cable must remain functional during and after exposure to the mechanical motions of the limbs.
- Easy surgical replacement
- Biocompatible
- Carry power safely using an alternating current signal

Technical Specifications

- Two isolated electrical conductors
- Must allow a network transmission rate >100Kbits/sec
- Approximate lead resistance < 0.1 ohms/cm
- Identical two-conductor plug-in connector on each end of cable
- Low electrical leakage interconnection < 1 μ A
- Disconnection of connector must be possible without the destruction of the cable or the module to which it is connected
- Interconnection must not require the use of sutures
- Lead flexibility and durability required as follows:
 - Cables shall be functional during and after 1.2×10^6 cycles of stretching to 120% of the initial installed length or separation.
 - Cables shall be functional during and after 1.2×10^5 cycles of crushing by a force of 1.2 Newtons delivered over a 1cm x 2mm bar without sharp edges.
 - Cables crossing joints or regions of great tissue motion shall be functional during and after 1.2×10^6 cycles of bending (wrapping) over a rod of 3mm radius. The angle of bend (wrap) shall be at least 140°. This is a requirement for flexing life; it is not a requirement for wear or abrasion of the cable against the rod.
 - Cables secured to different body tissues shall be functional during and after 6×10^5 cycles of twisting at a rate of 36° of rotation per linear cm of separation about the axis of separation.

Patient-contacting materials (please refer to Appendix D - Biocompatibility for details)

- Silicone elastomer insulation
- Liquid silicone rubber and pigment strain relief with dual O-ring
- Silicone adhesive and low-consistency silicone elastomer for adhesive

DESIGN DETAILS

The network cable is a four-filar, two-conductor cable. Each filar is composed of seven strands of drawn-filled tube (DFT) wire. The DFT wire is a tube of MP35N with a core of Ag (41% Ag) with an outer diameter of 0.0015". Seven DFT wires are insulated in perfluoroalkoxy (PFA) to form a single conductor (or filar) for the network cable. The outer diameter of each PFA-coated filar is 0.0105".

Each network cable is composed of four filar conductors that are helically wound around each other. The four conductors compose the network cable and two conductors are

electrically connected to each of the contact surfaces on the connector. Thus the network cable functions as a two-conductor electrical cable, with redundancy on each conductor. The entire helically wound assembly is housed inside of a silicone tube. The nominal outside diameter of the entire network cable is 0.05". The connector on each end of the network cable is a two-conductor connector similar in design to the standard pacemaker connector (IS-1), but significantly smaller.

2.5.5. Electrode Cables

The electrode cable is fabricated using wires of 316LVM stainless steel (0.034 mm diameter each), organized into a single seven-filament strand and coated with a perfluoroalkoxy polymer (PFA) to form an insulated, conducting filar. The cable is fabricated by winding two filars in tandem, forming a double helix of two conductors electrically insulated along their length. The coiled filars are placed inside medical-grade silicone tubing to form the cable. The cable outer diameter is approximately 1.3 mm. Since both electrode types used are monopolar - one tissue contact - the two filars are shorted to each other at the electrode and connector end, creating a single conductor with half the electrical resistance.

Patient-contacting materials (please refer to Appendix D - Biocompatibility for details)

- Silicone elastomer insulation
- Liquid silicone rubber and pigment strain relief with dual O-ring
- Silicone adhesive and low-consistency silicone elastomer for adhesive

2.5.6. Intramuscular Stimulating Electrodes

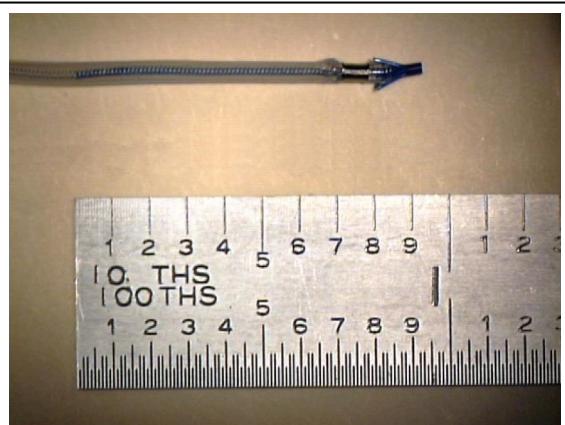


Figure 2-7. Intramuscular stimulation electrode showing metal contact and polypropylene anchoring barb.

The intramuscular recording electrodes used in this study are identical to those used in our other IDE's, G890084, G900108, G950116, and G040214. Electrical stimulation is delivered through metal electrodes placed near or in direct contact with neural tissue. Each electrode consists of the contact itself, a conducting lead, and a dual-contact connector to mate to the PG4 module. The intramuscular stimulating electrode is designed to be inserted into the belly of the target muscle. Despite the location of the electrode inside the muscle, electrical pulses delivered through the electrode cause activation of the nerves branching into the muscle, rather than direct activation of the muscle tissue itself.

The intramuscular stimulating electrode consists of 316LVM stainless steel wire coiled around the outside of the lead tubing [Membreg et al., 1994]. The stimulating surface is 2mm long with an approximate surface area of 8 mm². A 2-mm long polypropylene barbed anchor on the tip of the electrode maintains the position of the electrode in soft tissue. The electrode is inserted into the muscle using a probe and cannula system. The electrode is deployed into the muscle with a hemi-section of 15-gauge 304SS tubing inserted through a sheath of 13XTW-gauge 304SS tubing.

The lead cable is identical to the cable utilized for the epimysial stimulating electrode, described below. A dual-contact connector is used for all connections in the NNP System, as previously described.

Patient-contacting materials (please refer to Appendix D - Biocompatibility for details)

- 316LVM stainless steel electrical contact
- Monofilament polypropylene anchoring barb
- Silicone adhesive over-molding

2.5.7. Epimysial Stimulating Electrodes



Figure 2-8. Epimysial stimulating electrode and connector. The skirt is sewn onto the muscle with the conducting disk near the motor point.

The epimysial electrodes used in this study are identical to those used in our other IDE's, G890084, G900108, G950116, and G040214. Electrical stimulation is delivered through metal electrodes placed near or in direct contact with neural tissue. Each electrode consists of the contact itself, a conducting lead, and a connection to the PG4 module. The epimysial stimulating electrode is designed to be sewn onto the surface of the target muscle. Despite the location of the electrode on the muscle, electrical pulses delivered through the electrode cause activation of the nerves branching into the muscle, rather than direct activation of the muscle tissue itself. Epimysial stimulation electrodes have been utilized for nearly 25 years and have an excellent durability and safety record.

The epimysial stimulating electrode is a platinum-iridium disk with a brim supported by polyester mesh reinforced silicone rubber. The exposed metal contact is a disc 3.3 mm in diameter with a surface area of 8.55 mm². The brim is sandwiched between two layers of

silicone elastomer, leaving the conducting surface exposed through a hole in the top layer. The platinum apron serves to hold the disc in place. The lead wire is welded to the back of the disk using a resistance welder in an inert gas environment. The silicone backing is reinforced with polyester mesh. The electrode is sewn onto the muscle epimysium using sutures through the polyester mesh backing. Five sutures are placed around the perimeter of the electrode backing, each tied with four knots, using 4-0 polyester suture.

The lead cable consists of seven Type-316LVM stainless steel wires (0.034 mm diameter each), organized into a single seven-filament strand and insulated with PFA. The lead is fabricated by winding two lengths of cable in tandem, forming a double helix of two conductors electrically insulated along their length but shorted to each other at the electrode and connector end. The coiled lead is placed inside medical-grade Silicone tubing. The lead outer diameter is approximately 1.3 mm.

The dual-contact connector is used for all connections in the NNP System and is described in more detail in the section on Network Cables (above).

Patient-contacting materials (please refer to Appendix D - Biocompatibility for details)

- Platinum 10% Iridium electrode surface
- Polyester-reinforced silicone sheeting electrode backing and suture skirt
- Low-consistency silicone elastomer over-molding

2.5.8. Port Plugs

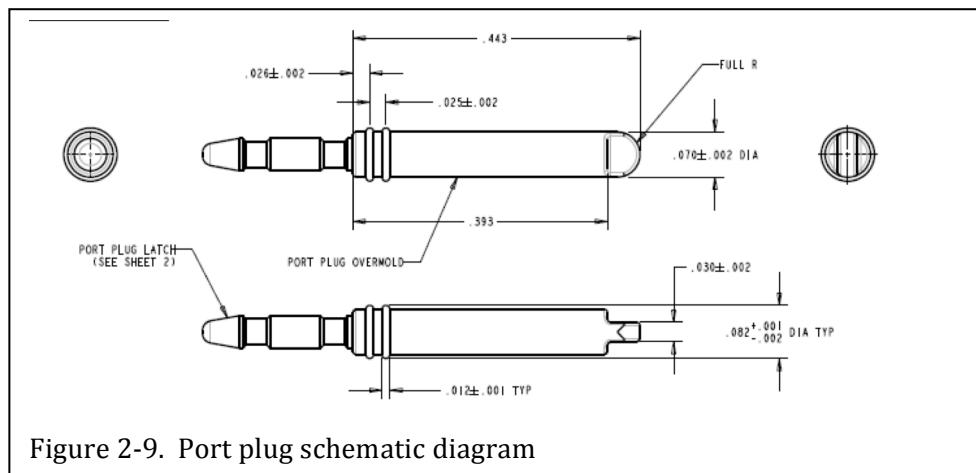


Figure 2-9. Port plug schematic diagram

The Power Module and Remote Module headers have allowance for up to four and eight network connections, respectively. These header connections are closed with a port plug that is placed in the connection during manufacture. Port plugs are removed at the time of surgery to accommodate connection to the Power Module or Remote Module headers.

Patient-contacting materials (please refer to Appendix D - Biocompatibility for details)

- Silicone elastomer insulation tubing
- Liquid silicone rubber strain relief with dual O-ring
- Pigment used in dual O-ring and plug body

2.5.9. NNP-to-Pin Adapter

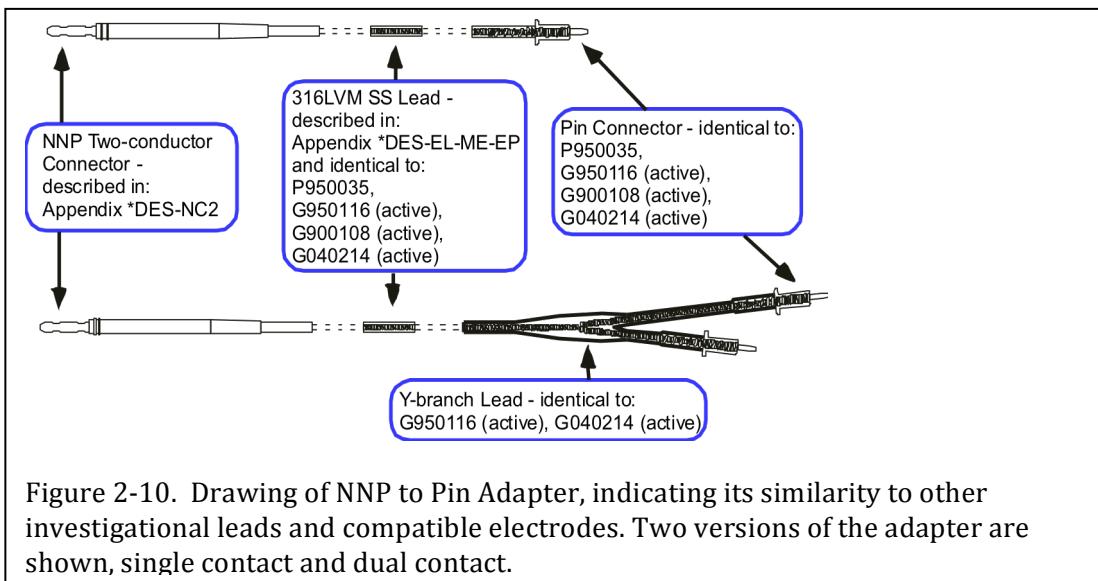


Figure 2-10. Drawing of NNP to Pin Adapter, indicating its similarity to other investigational leads and compatible electrodes. Two versions of the adapter are shown, single contact and dual contact.

The NNP-to-Pin Adapter will be utilized in situations where we need to connect our previous electrodes to the NNP stimulating module. This adapter provides two important advantages:

1. Subjects with previous systems can upgrade their implant without the need to replace all of their electrodes. The electrodes are the critical component of the stimulating and recording system, and replacement would require significant surgery and removal of otherwise fully functioning components.
2. Existing stock of electrodes could be utilized with the adapter for use with the NNP system.

The NNP System utilizes a two-conductor male pin that can be connected to any NNP module. The **NNP-to-Pin Adapter** is a cable consisting of the older pin-style connection on one end and the NNP two-conductor connector on the opposite end. The lead is the identical coiled 316LVM stainless steel wire utilized for the stimulating electrodes in the past and current (NNP) systems. The pin connects to a pin from the implanted device via an interconnecting spring, identical to those described in IDE #G950116. A silicone sleeve is placed around the pins and interconnecting spring to provide electrical insulation.

There are two versions of NNP-to-Pin Adapter. One is used to connect muscle-based stimulating electrodes (epimysial and intramuscular) to the NNP System. Both conductors in the two-conductor lead are connected to the single-pin connector. The other is used to connect muscle-based recording electrodes (epimysial and intramuscular) to the NNP System. The recording electrodes have two separate contacts, each connected to one conductor of the two-conductor lead. Each conductor will be connected to one contact on the two-contact NNP connector.

Patient-contacting materials (please refer to *Appendix D - Biocompatibility* for details)

- 316LVM stainless steel electrical contacts
- Silicone elastomer insulation

2.6. Detailed Description of External Components

External components of the NNP system include the Control Tower, the Host Computer Notebook (also called the clinician interface device, or programming computer), the Recharging Coil, and the External Magnet. These are described in more detail in the sections, below. Figure 2-10, below, shows the software and communications architecture that relates the programming computer, Control Tower and implanted components.

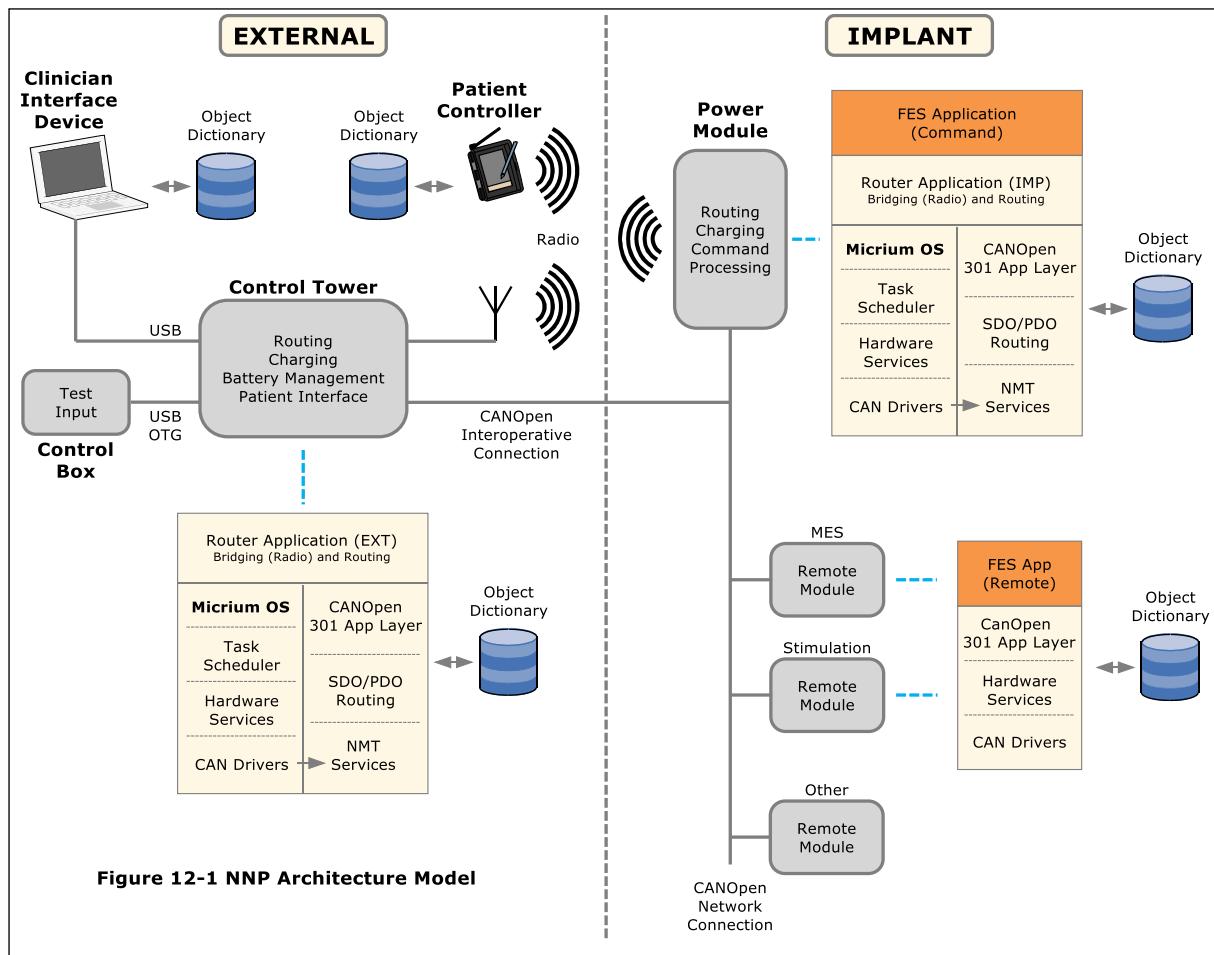


Figure 2-11. NNP Hardware and Software Architecture Model

2.6.1. Control Tower



Figure 2-12. Front and back of the Control Tower.

The Control Tower (CT1) is an external component that provides two key functions: 1) it allows bidirectional wireless communications between the implanted NNP components and external systems (via MedRadio); and 2) it provides inductive link powering and battery charging of the implanted Power Module. The Control Tower is used during surgery, in the clinical setting, and is also issued to each subject as a take-home component. To understand the differences in these use cases, Table 2-6 provides a summary of the Control Tower's operational features in each of these user settings.

TABLE 2-6: CONTROL TOWER USE CASES

USER	SURGEON	CLINICAL PROGRAMMER	STUDY SUBJECT
Use Location	Surgical Suite	In-Clinic	At Home
Host Computer Notebook / Connection	Yes/USB	Yes/USB	No/None
Stand-Alone Mode	Yes	Yes	Yes
Inductive Link Powering	Yes	Yes	Yes
Battery Charging / Connection	Yes/Coil	Yes/Coil	Yes/Coil
Programming of NNP	Yes	Yes	No
Retrieval of Logged Data	Yes	Yes	No
Access Battery Fuel Gauge	Yes	Yes	Yes
Control High-Level NNP States: Standby, Recharge, System Status, Exercise, Active Control	Yes	Yes	Yes
As a programming system, the Control Tower only functions as a router. Stand-alone, the Control Tower functions as a charger, as a system monitor (battery charge level, etc.), and as a secondary means to turn the system on and off. Standalone, the Control Tower cannot be used to program the system.			

The Control Tower can operate stand-alone or be connected to a PC for enhanced control. In a clinical setting the Control Tower and Host Computer Notebook (HCN) are used to communicate with and control the NNP in order to acquire and setup operating parameters. The Control Tower provides a USB interface to the HCN running the Clinical Interface Software, which is used to program and control the NNP. Once parameters are determined,

they are programmed into the implanted NNP components using the Control Tower. The Control Tower communicates with the power module through a low power bidirectional wireless RF link. This wireless communications utilizes the MedRadio 402-405 MHz band. The Control Tower communicates with the HCN through a USB connection.

The patient utilizes the Control Tower in a standalone mode for power module battery charging and to control NNP operating states. The battery charging/powering portion of the Control Tower uses an inductively coupled power transfer link. The user connects an inductive coil to the Control Tower and places the coil on the skin over the power module. Inductive coupling is optimized for power transfer efficiency across the skin and into the power module, and is designed to maintain safe transcutaneous power transfer based on the recharge rate established through recharge testing. The Control Tower provides status of battery charge and related information for the user.

The patient controls major NNP operating states, such as standby, recharge, system status, exercise, and active control (though initiation of function is based on implanted sensing), with the Control Tower using the front panel push-buttons and display. Communication with the NNP is via the MedRadio interface.

FUNCTIONAL SPECIFICATIONS

- Allows clinical programmers, technicians and NNP users access to information regarding the status of the implanted NNP components, including battery charge levels, network communications and overall system status.
- Provides clinical programmers and technicians with an interface between the clinical programming software and the implanted components.
- Provides charging of the implanted power module, for use both in the clinical setting and in the home setting.
- Provides a display and alarms regarding NNP power level.
- Small enough to be carried underneath or behind a standard power wheelchair.
- Provides a wireless interface to the implanted system for clinicians, technicians, and the user
 - Programming of implanted components - requires host computer
 - Application(s)
 - Operating Parameters
 - Control of implanted components
 - Operating mode
 - Clinical setup and testing - requires host computer
 - Retrieval of logged data - requires host computer
 - Status of implanted components
 - System state
 - Alarms
 - Can temperature
 - Transmit coil temperature
 - Low battery
 - Battery fuel gauge
 - Provides charging of Power Module

TECHNICAL SPECIFICATIONS

- Provides interface to the implantable system from the host computer

- Communication hub/gateway structure – multiple connectivity types (USB, TCP/IP, CAN, and MedRadio)
- Stand alone operation with front panel display and pushbuttons
- External control surface inputs via USB
- Size not larger than 12x10x3 inch.
- Provides user control inputs to affect system operation.
- Provides battery status information to be accessed by user during functional use.
- Provides access to system for temporary interfacing of external transducers.
- Radio range of at least one meter.
- MedRadio Frequency range - 402-405 MHz
- Inductive link Frequency range – 3.5 KHz
- Inductive link output power limited to <= 200 mW
- Powered by an internal rechargeable battery
- Control Tower internal battery recharged using a 120V AC power adapter
- USB Host and a USB Device interface
- Antenna for the MedRadio link connected to the enclosure

Microcontroller (uC) - The heart of the Control Tower is the microcontroller. The microcontroller monitors and controls multiple functions as described below. The Control Tower Front Panel provides a graphical display, five pushbuttons, and the power control pushbutton. Several connectors on the rear panel include access to two Controller Area Network (CAN) connectors, two Universal Serial Bus (USB) connectors, (Host, Device), and a network connector (not accessible by the user in a home environment).

System Power - The Control Tower has two sources of power available; an external cUL/UL 60601-1, EN 60601-1 approved AC Adapter, and an internal rechargeable Li Ion Battery. The AC adapter is used to power the system while charging the battery through the Battery Charger block. The Battery Charger implements a constant current followed by constant voltage charge profile appropriate for the Li Ion battery. Battery Charger enable state and operational status are controlled and monitored by the microcontroller. Both the battery voltage and the AC adapter voltage are monitored by the microcontroller through the Power Monitor block.

Radio - The Control Tower Radio provides a bidirectional wireless communications link to/from the NNP Power Module. The MedRadio frequency band of 402 - 405 MHz is utilized for the low power (25 μ W EIRP) radio frequency (RF) link.

Coil Drive System - Power transfer for Power Module battery charging and/or powering of the implanted system is accomplished with a transcutaneous inductive link. This inductive link is formed between the External Coil and the coil contained within the Power Module. The External Coil is driven with a nominal 3.5KHz sinusoidal voltage generated by the Coil Drive block. The sinusoidal Coil voltage amplitude and frequency, hence inductive link power, is controlled by the Coil Drive Power block, which is set in hardware. The microcontroller monitors the Coil Drive current amplitude and Coil waveform frequency.

Sensors - The temperature of the External Coil is measured with a **thermistor** attached to the Coil, and the output of the thermistor is monitored by the microcontroller. A three-axis **accelerometer** is mounted to the Control Tower printed circuit board, and is controlled and monitored by the microcontroller.

2.6.2. Host Computer Notebook and Clinical Interface Software

The Host Computer Notebook (HCN) programming station is used by the clinician to perform the steps necessary to establish functional grasp and control patterns for the NNP system. The process of establishing these parameters is described in *Appendix B – Functional Description and Programming*. The HCN is also used by clinicians and technicians to evaluate the status of NNP system and to troubleshoot any error conditions.

The HCN is a commercially available notebook computer running Windows 7 operating system. The computer is connected to the Control Tower via a USB cable for communication with the implanted NNP components. The HCN is only utilized by trained personnel, including the clinical staff and technical staff. It is portable and can be used in a treatment room, patient room or at an offsite location.

CLINICAL INTERFACE SOFTWARE DESCRIPTION

The Clinical Interface software is utilized for programming and customizing the control and stimulation patterns for each user. The software is utilized by a clinician or technician trained in its use. The general function and operation of the software is very similar to existing versions of the clinical interface software utilized for our previous implanted neuroprosthetic systems and described in previous IDEs (G890084, G950116), PMA P950035, and in multiple scientific publications [Kilgore et al., 1989; Keith et al., 1989; Kilgore et al., 1990; Kilgore and Peckham, 1993; Kilgore et al., 1997; Hart et al., 1998; Kilgore, 2000; Peckham et al., 2001; Kilgore et al., 2008].

The Clinical Interface software performs multiple functions that are required to establish and maintain a working NNP system for each user. These are: 1) control signal evaluation and programming, 2) electrode profiling (evaluate muscle response to stimulation), 3) grasp pattern evaluation and programming, 4) exercise timing programming, 5) download and upload of system parameters to the NNP system, 6) interrogation of system status, and 7) system-related recordkeeping. Each of these functions is generally performed on a separate screen within the Clinical Interface and is described below.

The Clinical Interface software is resident on the Host Computer (described below) and interfaces directly with the Control Tower via a USB connection. The Control Tower then communicates with the implanted NNP components through a wireless MedRadio link. An overview of the software functions is provided in *Appendix H – Software Description and V&V*.

The primary function of the Clinical Interface software is to allow the customization of the control and stimulation parameters for each user so that functional movements are produced and controlled as naturally as possible. The muscle signals generated voluntarily, the response to stimulation, the voluntary strength, and the functional goals, all vary among users in a generally predictable manner. Thus, in order to maximize function for each user, it is necessary to customize the parameters for the neuroprosthesis through an iterative process. The Clinical Interface software provides the clinician with the tools and feedback necessary to perform this iterative customization process. The Clinical Interface software is used directly with the patient, allowing immediate visualization of the parameter changes to the implanted system response. Refer to *Appendix B – Functional Description and Programming*, for additional details on programming for hand function.

Control signal evaluation and programming is performed to establish the parameters that describe the control algorithms, optimize the specific parameters for myoelectric signal processing, and establish the specific threshold and range values for customized control. The Clinical Interface software is used to assist the clinician in customizing the control for each patient.

The methods for developing and customizing grasp patterns for each patient have been well-established in previous studies [Kilgore et al., 1989; Peckham et al., 2001] and consist of a two step process. In the first stage, referred to as the “electrode profiling”, the properties of the individual electrode-muscle units are characterized to describe the threshold level for activation and the maximum current level over which selective activation of the principal muscle is achieved. Having determined these parameters for each electrode, they are entered into a standard “grasp template” which establishes the activation of each of the muscles relative to the others as a function of the command input. This is the grasp programming process. Typically, only a single proportional command governs the activation of all muscles in the grasp pattern. These grasp patterns can also be used in an exercise mode, in which the system automatically ramps the patterns open and closed for a prescribed period of time in order to strengthen the muscles and build endurance, as described in Keith et al., 1989. The process of setting the timing parameters, such as the rate of hand opening and closing and the total time of exercise, is referred to as the exercise timing programming.

Once the different parameters for control, grasp and exercise have been determined, it is necessary to store these parameters in the implanted NNP system so that it can function as programmed during regular, untethered use. Therefore, the Clinical Interface software performs downloading and uploading of system parameters to the implanted NNP system. At the end of each programming session, a final check of the function of the entire system is performed to ensure that the system is performing as expected.

The Clinical Interface software also serves as the primary high-level troubleshooting tool and provides an interface for interrogation of system status. Through the Clinical Interface, it is possible to examine the software and parameters resident on each implanted module, to monitor NNP network traffic, evaluate battery charge state, evaluate the powering levels across the network, and evaluate proper functioning of each electrode. This also provides an interface to set data logging parameters and to download and analyze data logging information.

The Clinical Interface is the primary means of maintaining system-related recordkeeping, such as medical information regarding each patient, dates and types of service, and other relevant information that may be required during a programming session or troubleshooting session with a patient.

SOFTWARE REQUIREMENT SPECIFICATIONS

- Provides the necessary interface to perform control signal evaluation and programming
- Provides the necessary interface to perform electrode profiling
- Provides the necessary interface to perform grasp pattern evaluation and programming
- Provides the necessary interface to set and test exercise pattern timing

- Provides an interface to download and upload parameters to the Control Tower, Power Module and all remote modules in the NNP system
- Provides an interface for interrogation of the implanted components of the system
- Provides a means for system-related recordkeeping
- USB Protocol and Implementation for communication between Clinician Controller and Control Tower
- The Clinical Interface source code will be written in C#
- The PC-based operating system will be Windows 7
- All communication protocols are developed, implemented, tested, and demonstrated using fully functional evaluation test boards before implementation on original hardware.
- Object Dictionaries for each hardware component
- Embedded source code will be developed according to coding guidelines
- All documentation required for compliance with IEC 60601-1-4 and the FDA's guidance for software validation, including but not limited to software requirement specifications, architectural specifications, detailed design specifications, unit/integration/verification/validation test protocols and reports, and risk management documentation.

PARAMETER RANGES, LIMITS AND PROTECTIONS

The Clinical Interface software sets limits on the stimulation output parameters. These limits are the top level of protection against unwanted stimulation delivery. As described in *Appendix H – Software Description and V&V*, stimulation levels are limited to safe ranges in both software and hardware resident in the stimulator module itself. Note that the NNP System is designed so that all critical risk mitigation is performed in hardware.

2.6.1. External Recharge Coil

The External Recharge Coil safely provides the appropriate time varying magnet field required to recharge the Power Module. The recharge coil is externally applied over the site of the implanted Power Module. A thermistor is used to measure the temperature of the coil/skin interface. The Recharge Coil has an asymmetric shape so that it can only be applied with the appropriate surface against the skin. The 3.5 KHz drive level to the Recharge Coil is set in hardware such that the coil temperature at the coil/skin interface cannot exceed 41° C.



Figure 2-13. Photographs of the External Recharge Coil.

The final design of the External Charging Coil has not been established. As noted in *Section 6.4 Anticipated Changes to the IDE*, we anticipate a number of improvements to the power management system of the NNP based on the experience gained in this Early Feasibility IDE, including likely changes to the configuration of the External Recharge Coil. As we learn about real-world patterns of use of the NNP by our study subjects, we can further refine our expectations around run-time, which in turn will drive expectations around recharge frequency and duration. In addition, as we refine our test methods for characterizing heating, we will be able to develop a temperature-based closed-loop recharging feature that minimizes recharge time based on safe heating levels.