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Example - Early Feasibility Investigational Device Exemption

IDE Section:

Appendix K – NNP Simulated Use Testing

K. Appendix K – NNP Simulated Use Testing

This section contains:

K.1. Test Purpose

The purpose of the NNP Simulated Use Test is to demonstrate end-to-end function of the entire NNP System. The Simulated Use Test includes the hardware and software. Note that recharging of the Power Module has been performed separately from the Simulated Use Test and is described in *Appendix I – Battery Testing and Heating Characterization*.

K.2. Methods

The test simulates a functional use condition in which the myoelectric signal amplitude is used to proportionally control a multi-electrode grasp pattern. The test is composed of five basic steps: 1) Power-up Operation, 2) Wireless Communication, 3) Proportional Control, 4) Failsafe Shutdown, and 5) Failsafe Restart. The test conditions are shown in Table K-1. NNP hardware is connected as shown in Figure K-1. Software is loaded on the BP2 that allows processing of the myoelectric signal (MES) into a single proportional command input and places that data on the network. Software loaded on the PG4 allows the module to read the MES data and use the data from one of the two channels to convert into a proportionally controlled stimulus output. Software is loaded onto the Power Module to allow powering of the network, to request module ID at 2 Hz and broadcast Power Module battery charge level at 1Hz. Circuit evaluation boards are utilized for this test, allowing access to multiple test points in each circuit if necessary.

Table K-1. Simulated Use Test Conditions.

Simulated Use Test

Test Conditions

Condition	Value
Input Signal Waveform	100 Hz sinusoid
Input Signal Amplitude	0-4 Vpp
Simulated Electrode Load	1000 Ω
Module ID Request Rate (per module)	2 Hz
Charge State Request Rate	1 Hz
Temperature	R.T.
PM-Wireless	Active
PG4-Interphase Interval, all channels	50 µs
PG4-Intrapulse Interval, all channels	50 ms
PG4-Interpulse Interval between channels	1 ms
PG4-Pulse Duration	0 - 250 µs
PG4-Amplitude	20 mA, 2 mA, 0 mA
BP2-Raw/Processed	Processed
BP2-Gain	1, 5
BP2-Software Rectification	On
BP2-Software Integration Window	40 ms
BP2-Sample rate	2000 samples/sec

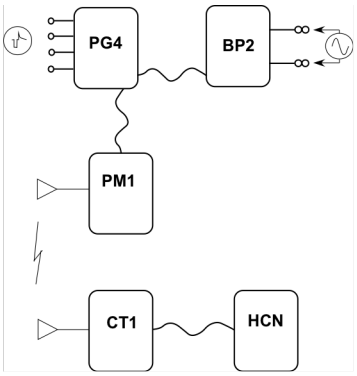

Figure K-1. System hardware setup for the simulated use test.

K.2.1. Power-up Operation

The purpose of this test is to verify that connecting modules onto a powered network does not cause unwanted stimulus pulses or other current delivery through the electrodes. The Power Module is established operational with no module connected to the network. Each electrode output is monitored as the PG4 board is connected to the network (first) and then as the BP2 board is connected.

K.2.2. Wireless Communication

With the Power Module, PG4 and BP2 connected together, wireless MedRadio communication is established between the Clinician Interface Software and Power Module via the Control Tower. Each module is requested to acknowledge presence on the network and to return module ID. Proper module ID is verified. Power Module charge state is requested and verified. For the remainder of the testing, module ID and Power Module charge state are continuously monitored at 1Hz.

K.2.3. Proportional Control

Under normal use, myoelectric control signals are processed and converted to one or more command signals for neuroprosthetic control. The most common and heavily utilized algorithm is to use the magnitude of the processed MES for direct proportional of the grasp pattern function. A typical function relating the processed MES (in A/D units) to the grasp command signal (0% to 100% maximum range) will be loaded into the BP2 module for each of the two MES channels. The MES gain will be set at two distinct levels: a low gain (1) for one channel and a high gain (5) for the other channel.

Grasp patterns are developed that relate the command input to the stimulation level on each channel. Typically only the stimulus pulse duration and stimulus amplitude are varied, while the remaining stimulation parameters remained fixed across all patterns. A typical pulse duration function for a four-channel "grasp" will be downloaded into the PG4 for the Simulated Use Test. Stimulus amplitude is typically constant as a function of command input, but can vary across channels. For the Simulated Use Test, channels 1 and 2 will be set at 20 mA, channel 3 at 2mA, and channel 4 at 0mA. Note that channel 4 is set to maintain a zero pulse duration and zero pulse amplitude throughout the test, and serves to verify that there is no unwanted stimulus or current output during changing command inputs.

A simulated MES, consisting of an amplitude-controlled 100 Hz sinusoid is injected into each of the two BP2 channels. The amplitude of the input signal is varied between 0 V_{pp} and 4 V_{pp} in order to obtain the desired command percentages based on the MES-command function. Note that the actual input signal voltages are not critical, and typical MES signals are likely to be in the 0-20mVpp range.

Stimulation output is monitored at five input signal levels: 0 Vpp (below 0% command level), 10% command, 50% command, 90% command, and 4 Vpp (saturates 100% command). These values provide a representation of the entire command space and test the proper operation when the input signal saturates at either the minimum or maximum command level. Once the stimulation output for these conditions has been recorded, the PG4 is reprogrammed to utilize the second BP2 channel for proportional control. The second BP2 channel has a high gain (5) and therefore is saturated at most signal input levels. Stimulation output will be monitored at three input signal levels: 0 Vpp (below 0% command level), Vpp level equivalent to 50% command at low gain (saturates 100% command at high gain), and 4 Vpp (saturates 100% command at high gain). These levels will demonstrate that the stimulus output properly adjusts due to the gain (based on the 50% signal input levels between the two tests) and properly operates at both the minimum and maximum command levels.

K.2.4. Failsafe Shutdown and Restart

The Failsafe shutdown is initiated, and the system is then restarted using the inductive forcing function. Stimulation output is monitored while the inductive forcing function is performed on the Power Module to reset and restart the Power Module. Proper recovery of the system is verified by repeating the saturated MES test at the low gain condition.

K.3. Test Results

The test results of the Simulated Use Test are shown in Table K-2, next page. All conditions passed.

K.4. Conclusions

The fundamental, critical functionality of the NNP System is confirmed to perform as intended.

Table K-2. Simulated Use Test Results.

NNP Simulated Use Test	Test Results
Power-up Operation Test	
No stimulation output on powered connection	Pass
Wireless Communication Test	
All modules acknowledge presence on network	Pass
Proper module ID on network	Pass
PM charge level received	Pass
No Signal Test - Low Gain Condition	
Calculated command % within tolerance on both channels	Pass
Pulse duration within tolerance on each channel	Pass
Intra-pulse interval within tolerance on all channels	Pass
Interphase interval within tolerance on all channels	Pass
Amplitude within tolerance on each channel	Pass
Interpulse interval within tolerance	Pass
Mid Signal Tests (10%, 50%, 90%) - Low Gain Condition	
Calculated command % within tolerance on both channels	Pass
Pulse duration within tolerance on each channel	Pass
Intra-pulse interval within tolerance on all channels	Pass
Interphase interval within tolerance on all channels	Pass
Amplitude within tolerance on each channel	Pass
Interpulse interval within tolerance	Pass
Saturated Signal Tests (100%) - Low Gain Condition	
Calculated command % within tolerance on both channels	Pass
Pulse duration within tolerance on each channel	Pass
Intra-pulse interval within tolerance on all channels	Pass
Interphase interval within tolerance on all channels	Pass
Amplitude within tolerance on each channel	Pass
Interpulse interval within tolerance	Pass
No Signal Test - High Gain Condition	
Calculated command % within tolerance on both channels	Pass
Pulse duration within tolerance on each channel	Pass
Intra-pulse interval within tolerance on all channels	Pass
Interphase interval within tolerance on all channels	Pass
Amplitude within tolerance on each channel	Pass
Interpulse interval within tolerance	Pass
Saturated Signal Tests (50%,100%) - High Gain Condition	
Calculated command % within tolerance on both channels	Pass
Pulse duration within tolerance on each channel	Pass
Intra-pulse interval within tolerance on all channels	Pass
Interphase interval within tolerance on all channels	Pass
Amplitude within tolerance on each channel	Pass
Interpulse interval within tolerance	Pass
Failsafe Shutdown and Restart Test	
Device ID received from all devices	Pass
No output on all channels, 0% input signal	Pass
Repeat Saturated Signal Tests, Low Gain Condition	Pass