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Example - Early Feasibility Investigational Device Exemption

IDE Section:

Appendix B – Functional Description and Programming

B. Appendix B – Functional Description and Programming

This section contains:

B.1. Introduction

A more detailed description of the functional operation and programming strategy for the NNP-UE system is provided here as an example of the methods used to provide one single function, hand grasp. A goal of the Early Feasibility IDE is to identify the optimal method for programming *two* functions, hand grasp and trunk stability, in one system that can be used easily by subjects.

B.2. Descriptive Operation Of The NNP-UE System

The NNP-UE System is intended to provide grasp and reach functions through coordinated electrical activation of the paralyzed musculature. Coordinated stimulation of selected hand and forearm muscles is controlled via myoelectric activity from muscles that are still under voluntary control by the patient (i.e. they are not paralyzed). Thus, the patient makes maximal use of their remaining voluntary musculature to control multiple paralyzed muscles in a manner that allows the patient to perform activities that they could not perform without the stimulation.

When possible, the NNP-UE System is implemented with MES recordings from four muscles, typically a wrist extensor, a shoulder elevator and bilateral neck muscles (platysma being the most common). The wrist muscle provides a direct proportional control, which the user can vary from 0% to 100% by maintaining varying degrees of contraction of the muscle. The remaining three muscles are generally utilized as "logic" signals, which means they generate a brief "on" command that can be used to trigger a variety of functional tasks. The advantage of using some muscles as logic commands is that the user does not have to maintain contraction of these muscles for prolonged periods, nor does the user have to learn to produce a graded contraction from these muscles. The functions controlled via MES include the grasp pattern selection, opening and closing of the hand in a proportional manner, turning the system on and off, turning elbow extension on and off, and the ability to lock and unlock the hand so that a grasp can be maintained in a fixed position without the need for continued control input.

During active functional use, the user will normally be in the hand open position, and their proportional control muscle, usually the wrist muscle, will be relaxed. If the user wants to acquire an object, the user will reach out using their voluntary musculature and position their open hand around the object. Once the hand is properly positioned around the object, they will then contract their proportional control muscle. This will increase the proportional control signal, which will cause the grasp to close around the object. The user can adjust the force of the grasp by adjusting the level of contraction of their proportional control muscle. Once the user has acquired the object, they can maintain their grip on the object by maintaining a consistent intensity of muscle contraction in their proportional control muscle. If the user intends to hold an object for a prolonged period of time, it is desirable to initiate a "lock" command, which maintains a constant level of stimulation irrespective of the proportional command signal. The lock command is routinely desirable for most tasks. Therefore, if the user maintains the command at 100% for a brief period (typically two seconds), the lock command is automatically issued. Alternatively the lock command can be executed by performing a quick jerk of one of the user's "logic" control muscles, typically a neck muscle. Once the hand is locked, the user can fully or partially relax their proportional control muscle and the grasp will still remain closed around the object. The lock command reduces fatigue in the user's voluntary muscles, which are often weakened due to their SCI. Once the user has completed the activity and they wish to open their hand and place the object back on the table or shelf, they can generate an "unlock" command. The unlock command can consist of two quick bursts of activity from the forearm (referred to as a "double-click") or a quick burst of activity from one of the logic muscles. Typically the "double-click" is performed using a predetermined time pattern so that the second burst of activity must occur within one to two seconds after the first burst. When the unlock command is initiated, the grasp transitions back into the state where grasp opening and closing is controlled directly by the contraction level of the proportional control muscle. During the initial period immediately after unlocking, the proportional control slowly transitions to direct proportional control with a slow time constant. This prevents the grasp from suddenly opening when the subject unlocks and the proportional control happens to be at a low level. Once the user regains proportional control, relaxation of their proportional control muscle will decrease the proportional control signal, causing the grasp to open and releasing the object.

If the user is anticipating performing multiple tasks, they will typically leave the stimulation 'on' with the grasp open, and ready to perform the next task. If the user desires to use a different grasp pattern, they can switch grasp patterns by activating one of the logic muscles with a rapid twitch or series of twitches. The timing and magnitude of these twitches is established through evaluation to be a movement pattern that is very unlikely to occur unintentionally during normal activities. Each successive activation of the grasp mode logic command will toggle the grasp pattern among multiple types of grasp patterns. Once the user identifies that their hand is in their desired pattern, the grasp is open and the user immediately gains proportional control of their grasp. Grasp control proceeds as it does with any grasp; a strong contraction results in grasp closing and relaxation results in grasp opening.

The user can also independently activate other functions, such as elbow extension, forearm pronation or shoulder stabilization, by producing a specific pattern of myoelectric activity in the logic control muscles. The system can be tailored to the needs and physiology of each user, within the configuration of utilizing myoelectric activity from one or more voluntary muscles to control the electrical stimulation of one or more paralyzed muscles to produce functional movements. In general, reaching functions enhanced with electrical stimulation are either "on" or "off" and the user contracts their voluntary antagonists against the stimulated musculature to modulate position if necessary [Lemay and Crago, 1996; Grill and Peckham, 1998; Bryden et al., 2000]

If the user is anticipating a period of inactivity, they can turn the NNP system "off" by pushing a button on the Control Tower or by using a specific pattern of myoelectric activity. This action places the system into a "sleep" (or standby) mode, which reduces the system power consumption and prolongs internal battery life. "Wake up" from the sleep mode can be accomplished by holding down a button on the Control Tower for at least two seconds.

B.3. Procedure For Neuroprosthesis Programming

Maximum benefit from the neuroprosthesis requires tuning of the parameters involved in command algorithm processing and in the patterned electrical activation of the paralyzed muscles. The process of tuning is necessary because each patient presents with a unique array of voluntary muscle strength, passive and active range of motion, stimulated muscle response to stimulation and, most importantly, different functional goals and home/community environments. The primary goal of the neuroprosthesis programming procedure is to tailor the multiple system parameters to produce functional movements that are controlled as naturally as possible. Neuroprosthesis programming is an iterative process that actively involves the clinician/therapist and the patient in order to achieve the optimum results. Typically neuroprosthesis programming is performed over a period of a few sessions, each lasting a few hours, with patients spending ample time attempting a variety of activities to identify grasp and control features that need further tuning.

There are two major aspects of neuroprosthesis programming: control signal setup and grasp pattern setup. 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.

B.3.1. Grasp Pattern Setup

The methods for developing and customizing grasp patterns for each subject have been well-established in previous studies over the past 30 years [Kilgore et al., 1989; Kilgore and Peckham, 1993; Kilgore, 2000; Peckham et al., 2001] and consist of a two step process. In the first step, referred to as "electrode profiling", the properties of the individual electrode-muscle units are characterized to describe the threshold level for activation and the maximum current level at which selective activation of the principal muscle is achieved. Unusual characteristics of the electrode-muscle response are also noted during this step, such as a highly non-linear recruitment or significant muscle length-dependent activation. These factors generally can be avoided by proper placement of the electrode during surgery. The electrode profile provides the grasp programmer with a complete picture of the individual stimulated movements that are available for coordination into useful functional patterns.

Once the electrode profile is completed, the threshold and maximum stimulation parameters for each electrode 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. The function that relates the proportional command input (0% (open) to 100% (closed)) to the stimulation level for each electrode is referred to as the "stimulus map" [Kilgore et al., 1989]. An example of a typical stimulus map is shown in Figure B-1. Only a single command governs the activation of all muscles in each grasp pattern. Multiple grasp patterns are generated, each providing a unique grasp function, such as a lateral pinch, palmar grasp, power grasp, etc.. Refinement of the grasp is accomplished by increasing or decreasing the stimulus parameters of individual muscles in order to achieve the desired coordination and smooth hand movement. This procedure has now become a standard procedure that is practiced by therapists in deploying clinical neuroprostheses [Peckham et al., 2001].

Grasp parameters are also used in an exercise mode in which the muscle is conditioned post-operatively in order to increase muscle strength and endurance. The muscle conditioning paradigm that we have utilized consists of ten cycles of each grasp pattern in which each cycle consists of one second of hand opening followed by a two second transition from open to close, followed by a one second hand closing, followed by a transition back to opening. This is conducted for both lateral and palmar prehension for a period of 50 minutes per hour. Generally, the subject is instructed to increase this exercise from one hour per day, up to as many hours per day as is convenient over approximately a two month rehabilitation period. Most subjects, once they are actively using their neuroprosthesis functionally during the day, find that continued exercise is not necessary and that their stimulated muscles maintain good endurance with regular daily use only.

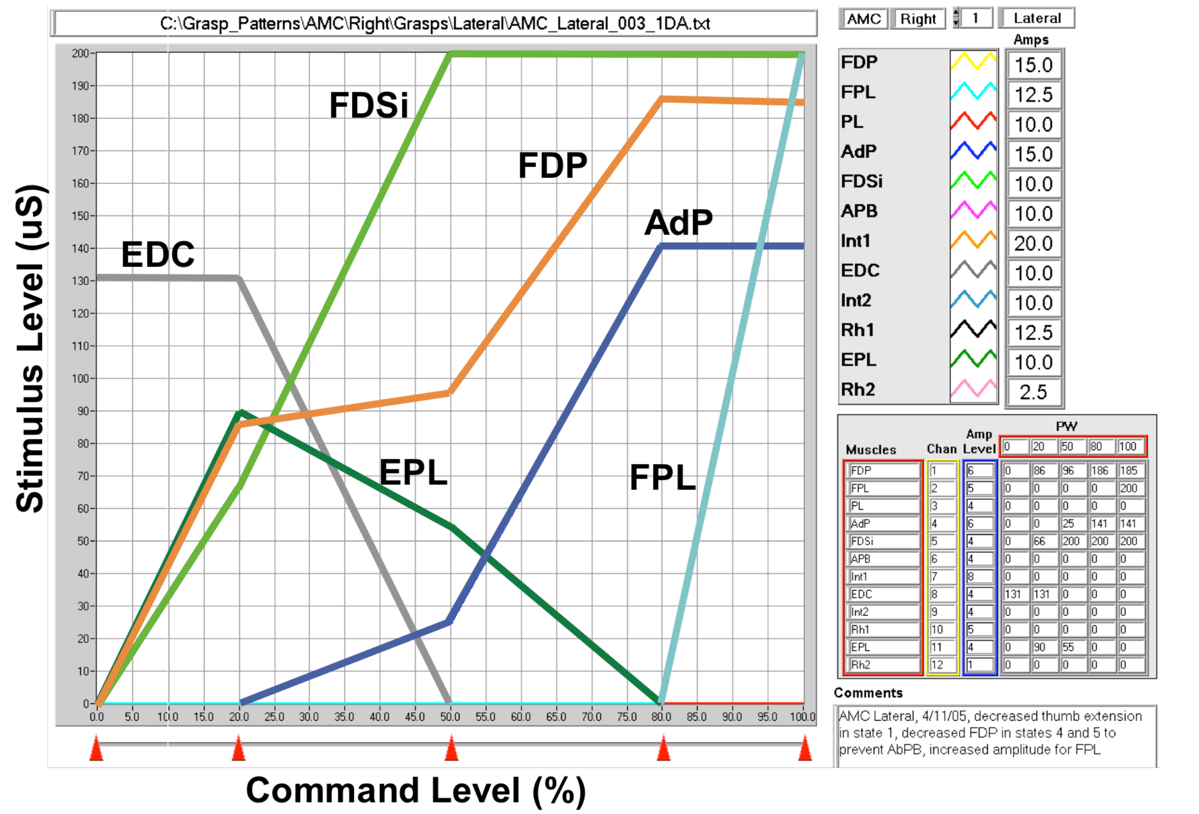

Figure B-1. Typical grasp stimulation map, relating the proportional command input to the stimulation level to each electrode. The specific pattern shown is the lateral grasp in which the fingers and thumb are extended at 0%, then the fingers close and then the thumb pinches against the lateral aspect of the index finger (maximum pinch at 100%).

B.3.2. Control Signal Setup

Control signal evaluation and programming is performed to establish the parameters that describe the control algorithms, adjust the specific parameters for myoelectric signal processing, and establish the specific threshold and range values for customized control [Hart et al., 1998; Kilgore et al., 2008]. The NNP functions that must be under the control of the user include: the selection of the grasp pattern (typically two to four grasp patterns are provided), the opening and closing of the hand in a proportional manner, and the ability to “lock” and “unlock” the hand so that a grasp can be maintained in a fixed position without the need for continued control input. In addition, it is desirable to enable the users to turn the stimulation on and off when needed. Finally, if patients are provided with elbow extension through triceps stimulation, forearm pronation, or shoulder/trunk stabilization, a control signal is needed to turn the stimulation on and off. If the user has sufficient control over the muscles providing MES, they may also gain some proportional control over these latter functions, such as the ability to control the level of triceps stimulation. These commands can be accomplished through the use of the myoelectric signal inputs, or by depressing a button on the Control Tower (if desired). One MES channel is used to control grasp opening and closing, and is generally placed on the most distal upper extremity muscle under voluntary control, typically the extensor carpi radialis longus (ECRL) or brachioradialis (Br). Additional MES channels are used to provide state or logic commands, such as system on/off and selection of the grasp pattern. These signals are typically derived from myoelectric signals from proximal muscles, such as trapezius or platysma, and can also be derived from an external switch input located on the Control Tower.

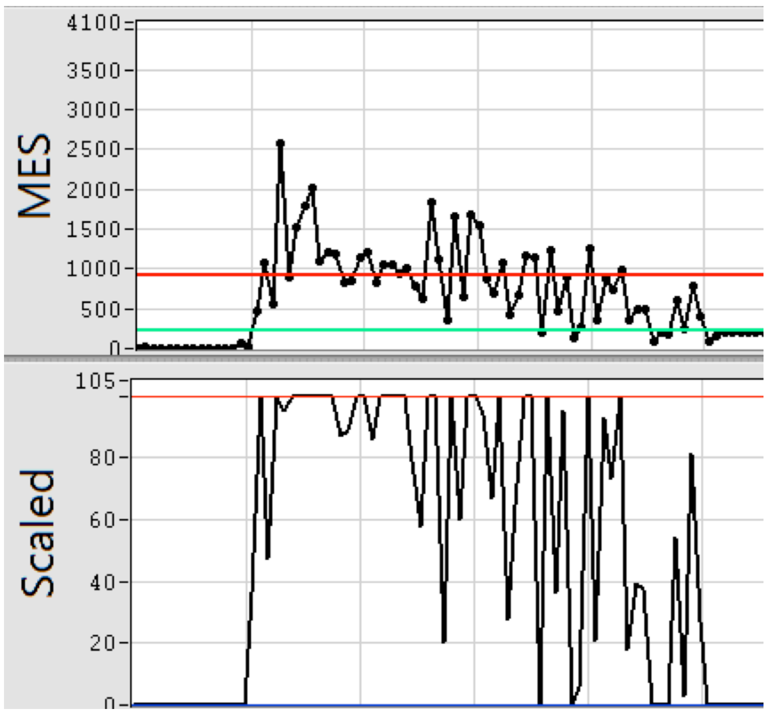

Figure B-2. MES scaling parameter. The original (unscaled) signal is shown on top, with the scaled signal shown in the lower graph. The scaled signal is truncated so that it cannot go below 0% or above 100%. Scaling allows the user to control the MES without having to exert a high level of effort to achieve a 100% command signal.

The myoelectric control algorithm must be customized for each patient in order to maximize functional benefits of the neuroprosthesis. First, patients are asked to alternate between maximal voluntary contractions of the control muscles and periods of relaxation while the computer records the signals from each myoelectric recording electrode. This allows the software to identify the magnitude of signal obtained from each recording electrode. The first parameter to be set is the MES scaling parameter, as shown in Figure B-2. The scaling establishes the threshold MES value that corresponds to 0% command range and the maximum MES value that corresponds to 100% command. MES values below the threshold all correspond to 0% command and MES values above the maximum established by the scaling saturate the command at 100%. It is not possible for the command value to be outside of the range 0 to 100. Note that if the range is set very narrow, with the maximum value nearing the threshold value, the command effectively becomes an “on/off” switch, where the command is either 0% or 100%.

If the control muscle is to be used as a proportional signal for control of grasp opening and closing (or similar functions), then the next step in the control setup is to establish the adaptive stepsize filter characteristics. The adaptive stepsize filter is well-suited for neuroprosthetic control applications because it combines a smooth, steady signal with a minimal response delay during rapid movements, as shown in Figure B-3. The stepsize filter allows increasingly larger step increases in the command level as long as the incoming signal continues to change in the same direction. When the incoming signal changes direction, the allowed stepsize is reset to the smallest value. Using these two principles, large rapid fluctuations in the command are smoothed to an insignificant ripple, whereas large movements in a single direction are reproduced with very little delay due to the filter.

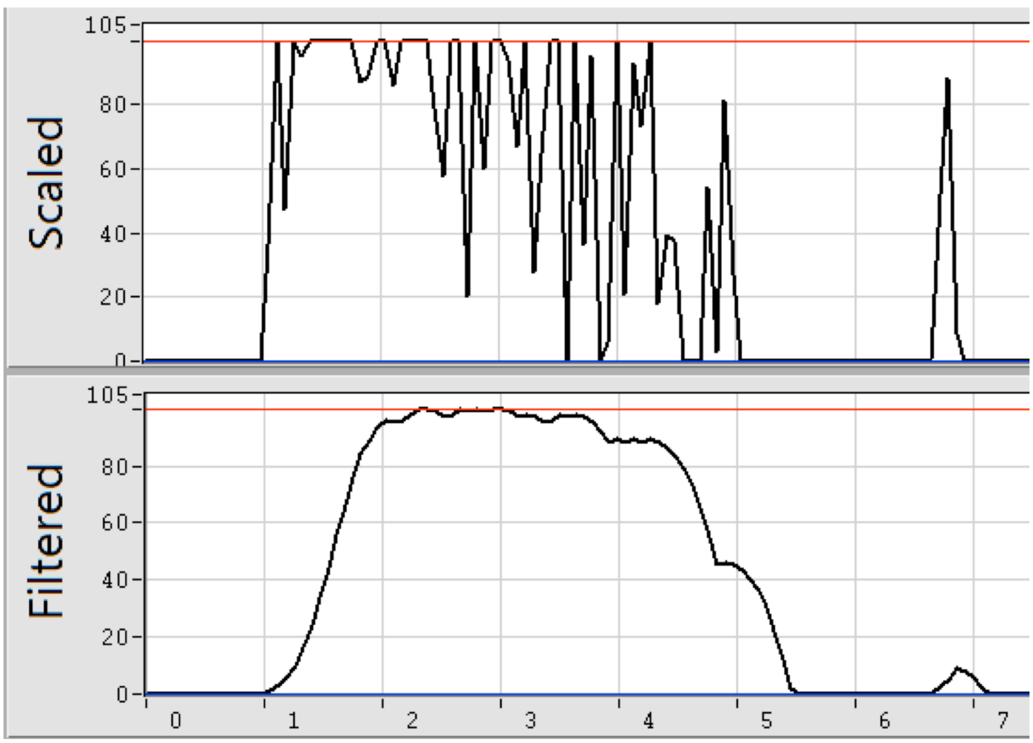

Figure B-3. Adaptive stepsize filter applied to the incoming signal to produce a smooth, rapidly responding command signal output. This signal is used to proportionally control the grasp output. Note that large rapidly fluctuating noise is smoothed to almost a flat line. From a practical standpoint, the control can be reduced to an on/off ramp if the range used to generate the scaled signal is very narrow.

If a control muscle is to be used to produce a logic command, the incoming myoelectric signal is processed differently. For use as a logic command, it is important that the subject can generate the signal easily, but the signal must be unique enough that the subject does not inadvertently generate the signal during unrelated tasks. This can be accomplished very successfully by requiring the logic signal to meet three characteristics, as shown in Figure B-4. First, a "quiet period" is required in which the incoming signal must stay below a threshold. This prevents logic signals from being detected incorrectly in the midst of ongoing functional tasks. The duration of the quiet period can be set as needed, but is typically less than one second. Second, the change in the incoming signal (i.e. velocity) must exceed a "rising threshold". Once the rising threshold is exceeded, the third criterion is that the change in the incoming signal must drop below a "falling threshold" within a fixed period of time. All of these parameters can be tuned to the individual user so that they can easily generate this signal reliably. Once subjects gain experience generating this signal, they are able to reliably generate the signal when desired, but rarely generate the signal unintentionally.

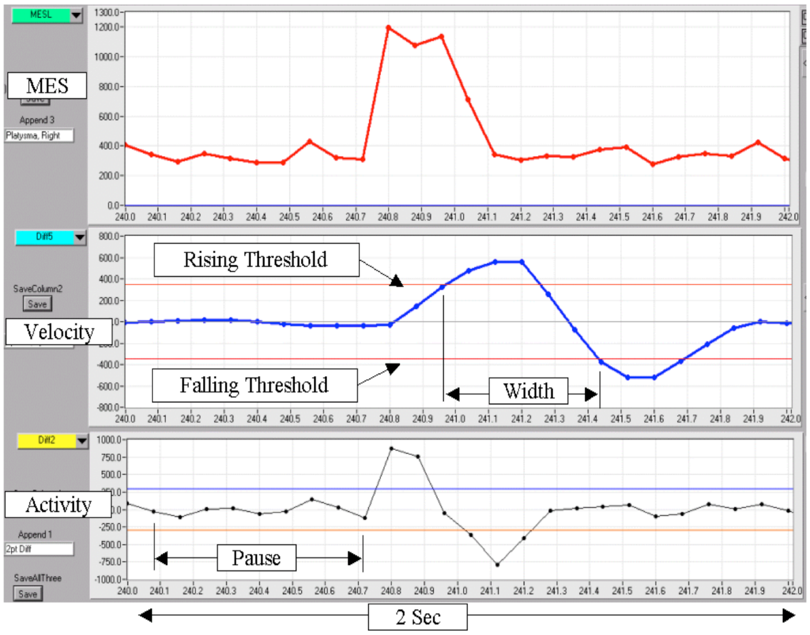

Figure B-4. Twitch detection parameters for using the myoelectric signal as a logic command input.

Once the basic signal processing parameters are established, patients are then instructed in how to make the desired control movements, and the ensuing signal is recorded. Biofeedback, supplied on screen is used to assist in training patients regarding their success or failure in generating the desired signals. The goal of this setup phase is to determine the range of useful signal amplitudes for each myoelectric channel. Patients will also be asked to perform functional movements that could potentially interfere with the control signal (such as arm movements if the electrode is located on the trapezius, or facial expressions if the electrode is located on the platysma), resulting in further refinement of the control signals. An initial control algorithm is developed based on the empirical observations by the programmer. Patients are then given the opportunity to evaluate the performance of their neuroprosthesis by performing simple tasks. During the operation of the neuroprosthesis, the patient's control signals are continuously monitored. Information regarding the patient's success or failure in generating the appropriate control is also monitored by the clinician. The clinician continues to make adjustments to the parameters and repeat testing in an empirical manner until the patient has good control of their grasp functions. An example of a successful control parameter setup procedure is shown in Figure B-5, showing the user generating a proportional command signal with one muscle (ECRL) and a logic command signal with a second muscle (platysma).

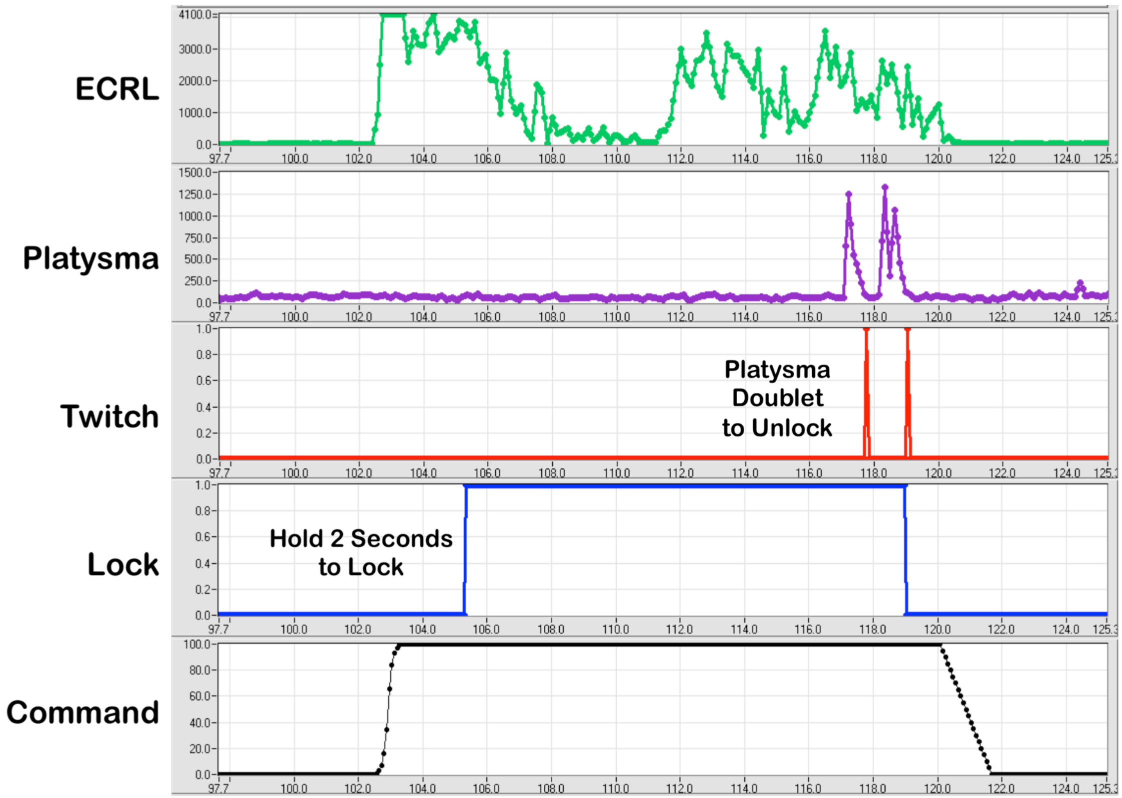

Figure B-5. Complete set of control parameters after successful setup. The top two traces show the filtered, rectified, integrated and sampled myoelectric signal from the extensor carpi radialis longus (ECRL) and platysma muscles. The bottom trace (command) shows the 0 to 100% command level that is a combination of the processed proportional signal from the ECRL and the lock/unlock signal from the Platysma. Lock occurs automatically when the command is held at 100% for more than two seconds. The middle trace shows the doublet unlock command generated by the Platysma, resulting in a slow ramp down in the proportional signal.