Select Myoelectric Hands Technical Information

For use with systems in the range of 6-8.4V



Contents

Steeper Select Myoelectric Hand	3	Spare Parts
Important Clinician Information	4	Fitting the Elegance Cosmetic Glove
Important User Information	6	Returns
Technical Information	8	Warranty Terms
Batteries	9	Disposal
Electrodes	9	Quality Assurance
Cables	10	Document Symbols Key
On/Off Switch	10	
Safety Release	11	
Selection of the System's Programs	12	
Summary of the System's Programs	13	
Typical Applications of Programs 0-9	16	
Auto Battery Voltage Selection	19	
Maintenance Instructions	20	

21

21

23

24

25

26

27

Steeper Select Myoelectric Hand

Steeper Select Myoelectric Hands are electrically operated devices designed to meet the needs of most upper limb amputees. Available in four sizes, they combine optimum control function with cosmetic restoration.

Electronics are housed within a moulded PCB casing enclosure mounted within a high-grade aluminium allov chassis. The finger and thumb assemblies are mounted with bronze bushes and attached via a linkage. The finger assembly is driven by an electric DC motor via a set of gears.

Steeper Select Myoelectric Hands are controlled with Select Myo electrodes or switch inputs and the electronics have been equipped with supercapacitor technology (sizes between $6^{3/4} - 8^{1/4}$) to provide efficient control and power conservation.

Features of the Steeper Select Myoelectric Hand

- Compatible with Steeper Friction and Quick Disconnect wrist ranges ٠
- Can be ordered with M12 or 1/2" x 20 TPI studs, compatible with third party wrists ٠
- Compatible with the Steeper and other 6-8.4V power systems
- Simple selection for one of nine system programs ٠
- Soft and durable PVC inner cosmesis
- Integral ON/OFF switch
- Auto battery voltage (ABV) selection ٠

🚹 Important Clinician Information

- The Steeper Select Myoelectric Hand must only be prescribed and fitted by a qualified prosthetist in a suitable clinical environment.
- Do not adjust, dismantle, attempt to maintain or modify the Steeper Select Myoelectric Hand or its associated components.
- It is important to encourage the user to inspect their myoelectric hand regularly to ensure early detection of any problems.
- Ensure that the hand is securely fitted to the wrist plate of choice for the hand to function.
- If the Steeper Select Myoelectric Hand is not functioning as expected, check the electrode connection/connectors are not damaged.
- The Steeper Select Myoelectric Hand is not dirt or waterproof, therefore moisture and/or debris must not enter the hand. If liquid/debris does enter the hand, it must not be operated and should be returned for safety checks and/or repair.
- In the event of device failure, or suspected malfunction, please contact Steeper Customer Services or your local Steeper distributor.
- Unless under clinical supervision, the user must always operate the hand with the inner PVC cosmesis fitted.
- To clean the outer glove or the hand shell, use a damp cloth to gently remove any marks. Do not use solvents.

- Do not expose the Steeper Select Myoelectric Hand to a naked flame or excessive heat. Avoid exposing the hand to long periods of direct sunlight.
- Do not expose the Steeper Select Myoelectric Hand to any live electrical components.
- Do not subject the hand to impact, mechanical vibrations, or excessive load.
- Before attaching or detaching the Steeper Select Myoelectric Hand from the battery pack, the user must ensure that the power has been disconnected by pressing the On/Off button and checking the hand functionality to ensure it is off. This is to avoid a potential current surge to the hand when it is connected/disconnected from the battery pack.
- Do not use a combination of batteries with varying voltages to power the hand.
- Ensure the end user is fully informed of the care and operation of this product.
- This product is intended for use by a single user during daily activities. See warranty for further information.
- If this product does not meet your expectations, please contact Steeper Customer Services or your local Steeper distributor.

See www.steepergroup.com for the latest version of this technical manual.

Warning: Do not modify this equipment.

🛕 Important User Information 🛛

- If your Steeper Select Myoelectric Hand has been fitted with a Quick Disconnect Wrist, the device must be consciously positioned when performing any turning actions to prevent unintentional disconnection of the hand at the wrist.
- When driving, the hand must be turned **off,** and in a position that prevents permanent connection between the device and the vehicle. Driving with the Steeper Select Myoelectric Hand switched on may result in accidental/ unintentional operation of the hand, presenting a significant risk of losing control of the vehicle and injury as a result.
- If exposed to salt water, contact your prosthetist immediately to arrange an inspection, and return to Steeper for repair if required.
- Do not expose the device to a naked flame or excessive heat. Avoid exposing the hand to long periods of direct sunlight.
- The prosthesis must not be worn whilst the batteries are charging.
- Do not touch any live electrical equipment with the hand.
- Avoid impact and do not subject the device to excessive load.
- The Steeper Select Myoelectric Hand must not be used during extreme sports. Steeper does not accept any responsibility for damage or injury due to improper use.
- Do not store the device in a fully closed position, always store with the fingers

and thumb slightly open.

- Whilst the battery pack is being charged, the hand will not function.
- When attaching or detaching the hand to and from your prosthetic limb, it is important to first disconnect the power by pressing the on/off button (see the 'On/Off Button' section in this guide for location and how to power off). This is to avoid a potential current surge to the hand when it connects/ disconnects with the battery pack.
- In the event that the device or prosthesis is exposed to unusual substances or stresses, please stop using the device immediately and contact your prosthetist to arrange an inspection, and return for repair if required.

Warning: Do not modify this equipment.

Technical Information

Environmental and operational conditions:

Storage and Transport

-20°C (-4°F) to +50°C (+122°F)

If the hand has been in storage or has been transported, place the device in ambient temperature (20°C) two hours prior to using

Operational	-5°C (+23°F) to +40°C (+104°F)
Pressure Range	700-1060 hPA

Maximum 80% relative humidity, non-condensing

Do not expose to EM emissions above 8kV contact, 15kV air

Batteries

The Select Myoelectric hand has been developed to employ the latest advances in battery technology. We recommend the use of Steeper 7.4V Lithium Polymer Batteries (BLPA72) as this generation of batteries offers a far better power to weight ratio than traditional Lithium Ion packs. However, Steeper Lithium Ion batteries (B22606) are compatible.

Electrodes

For optimum functionality we recommend that Steeper electrode, part number Elec 50 or 60 is used with Select Myoelectric hands.

Cables

Steeper manufactures and supplies a range of cables for the Select Myoelectric system. These include: Electrode cables in three lengths, (ECA=300, ECA=600 or ECA=1000) made from a flat ribbon cable terminated in a three hole plug at one end. The cable is suitable for insulation displacement connections provided on the Elec 50 or 60. It is important to follow the installation instructions provided.

A Connector Block cable is available for use when a Friction wrist or threaded stem interface is supplied with the prosthesis. This is CBBHA72 and is used with the BLPA72 Lithium Polymer battery system. If a quick disconnect wrist is used, the electrode cables and battery cables plug directly into the back of the co-axial plug.

Safety Release

In the event of loss of power to the Myo Select, the safety release button can be activated.

The safety release spring is located on the outside of the thumb. Press this firmly and push the top of the thumb backwards to activate the safety release.

If the safety release is under load and cannot be depressed, it can be activated by putting pressure on the thumb from the palm outwards whilst depressing the safety release spring.

To reengage the safety release, move the thumb back into its original position it will then click back into the correct position. There is no need to return the Myo Select.

This must only be used in the event of loss of power on the Myo Select.

On/Off Switch

An integral on/off switch is provided. This is operated by pressing downward through the cosmesis on the dorsal surface above the wrist. Pushing down will switch the hand on. Pressing on the palmar surface will switch the hand off for activities such as driving.

Selection of the System's Program

- The system is pre-set at the factory to program 1.
- To alter the program it is necessary to adjust a small rotary switch located on the lateral flank of the chassis.
- To access the rotary switch the inner PVC cosmesis must be removed, taking care not to damage the cosmesis during removal.
- A circular label containing a set of numbers 0-9 is visible on the outer face of one of the chassis members.
- Using the adjustment tool (supplied with the hand), engage the slot inside the casing.
- Carefully rotate the tool to the desired program on the label.
- Once the program has been selected, check the hand operation and replace the inner cosmesis.

It is recommended that KY GeI is used on the hand chassis to aid fitting of the inner glove. The use of talc powder is not recommended.

Do not press hard upon the adjustment tool as this will result in damage to the electronics.

Summary of the System's Programs

The hand can be easily configured for switch, on/off or proportional control with one or two inputs. Nine programs have been provided to optimise control for the individual user.

Notes:

Site: the position on an individual muscle mass giving the most reliable signal.

Threshold: means a signal level that, when reached by sufficient muscle contraction, causes an action. The Electrode Gain Control (EGC) is used to alter the amplification level that needs to be reached to cross the threshold and switch the hand on.

Proportional: means that the speed of the hand can be changed by varying the strength of the muscle contraction. Changing the EGCs alters the balance of the two muscle signals.

Co-contraction: means that both muscles are contracted together. Changing the balance of the EGC will reduce this effect.

0. One site: Muscle contraction opens the hand, relaxing the muscle allows it to close. A sustained signal opens the hand fully. The EGC can be set high to make this easy for the user. This is a threshold program.

1. Two sites: Tightening an individual muscle makes a signal that opens the hand at a speed in proportion to the strength of contraction. Another muscle, operated independently, closes the hand at a speed in proportion to its contraction. Both muscles operating together will always

cause the hand to open (co-contraction). If there are no signals the hand will stop. This is the factory set program.

2. Two sites: The first muscle to contract (open or close site) takes precedence. After a brief period the individual muscles can be used, depending on their balance, to open or close the hand at a speed proportional to contraction. If there are no signals the hand will stop.

3. Two sites: The EGCs are used to set threshold levels on both electrodes, individual muscles contract until the threshold is reached and hand switches on to open or close. Co-contraction always opens the hand.

4. Two sites: EGCs on the two electrodes are used to set threshold switching levels. The first muscle signal to reach its threshold takes precedence and opens or closes the hand. As the individual/thresholds are reached the hand switches on to open or close. In the absence of signals that are high enough the hand remains stationary.

5. One site: A short fast muscle pulse opens the hand fully. A second smooth contraction closes the hand proportionally to contraction. At any time the hand can be fully opened by relaxing and then giving a fast contraction. The hand can be stopped by relaxing the muscle.

6. One site: A large signal opens the hand; if the muscle tension is relaxed the hand stops. A small signal closes the hand at constant speed. Both signals must reach the threshold preset on the electrode (EGC).

7. One site: A quick signal opens the hand fully. A slow signal closes the hand at constant speed. Both signals must reach the threshold preset on the electrode.

8. One site: The hand control measures the rise and fall in signal and drives the hand open and closed accordingly. The speed is selected by the size of the difference in signal level from one of four speeds available.

9. Reset battery voltage to 6.6 volts.

Typical Applications of Programs 0-9

The program options can be used to address many different clinical applications. Whilst the majority of users will be able to operate a proportional two muscle (site) system others may need to experiment to find the best solution for them; It is for these users that we have included a number of one and two site options.

When an inexperienced user first encounters Select Myoelectric systems they may find operation difficult. This may be made worse by their skin condition or an inability to contract particular muscles. A myo site tester is often used to display the signals that are generated and build the user's skill in control. However in many situations it is unnecessary to use an expensive tester when what the user actually needs is confidence that they can open and close the hand at will.

Program 0 is used for this early experience.

To test for useful muscle sites on the residual limb, ask the user to contract different muscles. Palpate these muscles and mark the places where strong muscle contraction is apparent. Only use sites where the electrodes will remain in contact with the skin during movement of the prosthesis. Initially it may be necessary to moisten the skin.

Switch the hand off and remove the inner cover. Set the mode control to 0. Assemble the system on a table in front of the user with a charged battery BLPA72 in its holder and an ECA=1000 cable fitted to a single Elec 50 or 60 electrode. Switch the hand on and demonstrate muscle contraction and its effect on the hand. Search the marked areas for a suitable control site. Mark the optimum site and, using a tennis sweat band or surgical tape to

hold the electrode in position, encourage the user to practice opening until they are proficient. Initially, it may be necessary to set the gain control high, so that the user can sustain the signal and hold the hand open as long as is desired. Have at least two half hour sessions using this technique. If it is possible to identify two antagonist sites alternate between them.

Once confidence has been established, move the switch to location 1 for two muscle control and rebuild the system to use two electrodes with their associated cables. Programs 1 and 2 are rather similar. With 1, if both muscles are contracted at once the hand will always open. The hand can then be opened or closed proportionally by contracting each muscle in turn. The speed of the hand will be controlled by the level of contraction.

With program 2, the first muscle to contract takes command and the hand will open and close accordingly. This is a useful option when trying to balance a strong muscle against a weak muscle or in cases where the user drops objects when first activating the hand. Programs 3 and 4 are switch (threshold) programs. By adjusting the gain control on each electrode the strength of the Select Myoelectric signal at which the hand will operate can be set.

Once triggered, the hand will run open or closed but when the signal drops below the threshold the hand is switched off and will remain stationary. Program 3 will always open if a co-contraction signal is received first; this means that the thresholds are usually set high. With program 4, the first signal received decides the level of initial movement; it is possible therefore to set the close electrode control high to ensure held objects are always retained.

Position 5 is used when only one control signal can be generated reliably. This is a sequential

program. The user tightens the muscle quickly and the hand opens fully. The muscle is relaxed then the next signal closes the hand smoothly and with speed proportionally to signal level. To open the user generates another fast signal. This is a difficult program to master but is useful for people with limited muscle control.

Program 7 is similar but is a threshold type of program. A quick signal opens and a smooth signal closes. Both signals will operate the hand at a constant speed but the signals have to reach a threshold, set on the electrode to trigger action. It is suitable for switch control.

Programs 6 and 7 are possibly the most useful for a user with a well-controlled single muscle. With program 6, a large signal opens the hand. If the muscle is relaxed the hand stops and a second smooth contraction closes the hand proportionally. Program 8 measures the difference in signal level over a set time. If the difference is positive the hand opens, if negative the hand closes.

Depending on the size of the difference the hand will select from one of four speeds. To the user this feels like a proportional control in both directions.

Auto Battery Voltage Selection

The Select hands are preset in the manufacturing facility to run on 7.4 volt batteries. They are therefore fully functional with the Steeper BLPA72 batteries. If these batteries are chosen for the initial system, no change is required.

Most systems will use a 7.4 Volt Select BLPA72 battery as these give a significantly higher capacity. When a Select hand is fitted to this configuration of system the hand detects the higher voltage and resets automatically for optimum performance. When the battery is discharged the hand will run open and stop. The battery must be recharged before it is reused. We recommend that the battery is always recharged overnight.

In rare cases, it may be necessary to change from a 7.4 V system to a 6.6 V system. To do this, before inserting the battery, remove the PVC inner hand cover. Switch to position 9 on the dial switch and insert the battery. This reconfigures the hand to 6.6 Volts. The hand will confirm the reset by automatically opening and closing. It is ready for use once the dial switch has been used to select the system program as desired and the inner cover has been replaced.

Maintenance Instructions

The Steeper Select Myoelectric hand design has been developed to minimise the requirement for any maintenance. However, to maintain performance it is good practice to lubricate the internal mechanism periodically. This procedure should be performed at least once a year by a suitably qualified or experienced technician.

- Carefully remove the cosmetic and inner gloves
- The internal gearing mechanism of the hand will be visible
- Lightly lubricate/grease the gear teeth with a suitable compound (we recommend Molykote DX)
- Operate the hand several times to check for correct function
- If the hand performs satisfactorily then the inner glove should be fitted

It is recommended that KY GeI is used on the hand chassis to aid fitting of the inner glove. The use of talc powder is not recommended.

If in doubt, contact Steeper Customer Services, who will be happy to provide advice and assistance.

Spare Parts

Refer to the Steeper Upper Limb Prosthetic Components Catalogue or the company website found at www.steepergroup.com. A full list of spare parts and illustrations will be available. Alternatively, please contact us to discuss your requirements.

Fitting the Elegance[™] Cosmetic Glove

The Steeper Select Myoelectric hands have been designed to be complemented by the Elegance™ range of cosmetic gloves. These are available in PVC or Silicone.

We recommend the TrueFinish[™] shade option for best appearance. Use of these cosmetic gloves will allow optimal hand performance.

To fit the cosmetic glove:

- Lightly lubricate the outer surface of the PVC inner glove using KY Gel
- Fix the hand in a vertical jig or mount vertically in the prosthesis
- PVC only warm the glove for about three minutes, using a hot air gun or an oven set on minimum (less than 100°C). Take care to avoid localised overheating. DO NOT USE A NAKED FLAME.

- With the hand in the closed position pull the glove over the hand, manipulating it carefully to avoid excessive stretching
- When the tips of the fingers have entered the palm of the glove, the hand should be partially opened. This will allow the glove to be pushed down over the fingers and thumb
- The cosmetic glove should fit closely over all fingers and the thumb. It should cover the hand and when fitted to the prosthesis, extend up the forearm without wrinkles, folds or bridging
- PVC only areas of stretch formed during the fitting process can be removed by careful application of local heating
- The glove can now be trimmed to the desired length

The design and manufacture of Steeper equipment and components are subject to a policy of continuous reappraisal. The company therefore reserves the right to introduce changes and withdraw products without notice.

Returns

If items are to be returned for any reason, please contact Steeper Customer Services or your local Steeper distributor quoting the part number and serial number (where applicable).

All items must be returned to Steeper with a returns authorisation number and a completed returns form, both of which can be obtained from Steeper Customer Services.

Warranty Terms

The warranty for the Steeper Select Myoelectric Hand is two years. Warranty covers design and manufacturing issues only.

Where a claim is made under warranty, this claim must be supported by appropriate documentation. Photographs of any failed products must be provided in lieu of the product itself. If applicable, please do not send faulty batteries back to Steeper.

The warranty will be void on all system components if any components have been subject to abuse, modification, neglect, deliberate damage, loads beyond those for which the product was designed, or repair or maintenance by an uncertified person.

The design and manufacture of Steeper equipment and components are subject to a policy of continuous reappraisal. The company therefore reserves the right to introduce changes and withdraw products without notice.

The service life of the Steeper Select Myoelectric Hand is 2 years.

Disposal

The Steeper Select Myoelectric Hand is an electrical device and should not be mixed with general household waste. For proper treatment, recover and recycling, please take this product(s) to designated collection points.

Disposing of this product correctly will help save valuable resources and prevent any potential negative effects on human health and the environment, which could otherwise arise from inappropriate waste handling.

Please contact your local authority for futher details regarding your nearest designated collection point.

Penalties may be applicable for incorrect disposal of the waste, in accordance with your national legislation.



Quality Assurance

Steeper is registered with both the Medicines and Healthcare Regulatory Authority in the UK, and the Food and Drugs Administration of the United States Government for the manufacture and supply of prosthetics and orthotics products.

MHRA Registration N°: 000006617

FDA Registration N°: 9612243

Model N°: RSL-RP628

Continued compliance with the standard is monitored by a program of internal and external audits.

All individual products are marked indicating that they comply with the requirements of the Medical Device Directive 93/42/EEC. The **C** mark may be applied on packaging, accompanying literature or an enclosure, rather than the product itself. The design and manufacture of Steeper equipment and components are subject to a policy of continuous reappraisal. The company therefore reserves the right to introduce changes and withdraw products without notice.

For the most recent issue of this technical literature, please visit: www.steepergroup.com.



CE marking indicates that the manufacturer has checked that this product meets EU safety, health and environmental requirements. It also indicates product's compliance with EU legislation and free movement within the European market.



WEEE marking indicates that this electronic product should not be disposed of in unsorted household waste.



'Mobius' logo indicates that the product packaging can be recycled.



FSC logo indicates that the packaging is certified under the FSC system.

Indicates that Steeper Group are a medical device manufacturer.

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