Myo Kinisi
Myoelectric Hand
User Guide

steeper
Creating life's turning points, together

Contents

Your Myo Kinisi

The Myo Kinisi is a myo-electrically controlled terminal device engineered to provide optimal control, responding intuitively to the strength and speed of your muscle contractions. This prosthetic hand is designed to be tailored to individual needs, with wrist and hand mode options for your comfort and usability.

This device aims to assist Activities of Daily Living (ADLs), by providing easy to control, high speed grasp, alongside a strong grip force.

Your device is supplied with a durable hand shell to protect the internal mechanism of the hand. Your prosthetist will fit a cosmetic outer glove - Steeper recommend the Elegance Plus range of reinforced silicone gloves. The Elegance Plus range has been designed specifically for the Myo Kinisi offering an enhanced cosmetic appearance and available in 19 TrueFinish™ colour shades.

Features of the Myo Kinisi

- Enhanced grip force.
- Intuitive myoelectric muscle contraction response.
- Independently controlled opening and closing speeds.
- Opening and closing speed that can be customised by your prosthetist for optimal usage.
- Variety of control modes selected, by your prosthetist, allows users across a range of abilities to benefit from myoelectric control of their prosthesis.
- Integrated function button to turn the hand on/off.
- Auto-grip feature allows the user to have confidence when gripping unstable objects.
- Durable PVC inner hand shell.
- Improved cosmesis and longevity with a range of durable, reinforced cosmetic outer gloves.
- Independently controlled mechanical safety feature.

Important User Information

- The Myo Kinisi 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 Myo Kinisi or its associated components.
- This Device is a Class I Medical Device which meets the general safety and performance requirements in MDR 2017/745 Annex I.
- If a serious incident occurs, in relation to the device, it should be reported to the Manufacturer and the competent authority of the Member State in which the user and/or patient is established.
- Before detaching the Myo Kinisi from the power source, you must ensure that the Myo Kinisi is switched off, press and hold the function button; as described in 'The Function Button' (p.9) and then check the hand functionality to ensure it is switched off.
- If your Myo Kinisi 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 Myo Kinisi 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.

Important User Information Cont.

- It is the responsibility of each user to ensure they comply with local regulations before operating any motorised vehicle.
- It is important to inspect your myoelectric hand regularly to ensure early detection of any potential problems. If the device is not functioning as you believe it should, contact your prosthetist for guidance.
- The cosmetic outer glove must be worn at all times to protect the hand shell. To clean the cosmetic outer glove, use a damp cloth to gently remove any marks. **Do not** use solvents.
- The Myo Kinisi 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 to your clinician for safety checks and/or repair.
- 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 and avoid exposing the hand to long periods of direct sunlight.
- The prosthesis must not be worn whilst the batteries are charging. **Note:** the myoelectric hand will not function while charging.
- Do not touch any live electrical equipment with the Myo Kinisi.

- Do not subject the hand to impact, mechanical vibrations, or excessive load.
- The maximum carry load for the Myo Kinisi is 12.5kg (27.55lb)
- Do not store the device in a fully closed position, always store with the fingers and thumb slightly open.
- 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.
- The safety release mechanism must only be used when the grip cannot be released; such as a loss of power.

Please visit **www.steepergroup.com** for the latest version of this user guide.

Warning: Do not modify this equipment.

Specific Activity Use

The Myo Kinisi should be turned off during an activity where it will remain in the same position for long periods of time, or when you want to prevent accidental operation of the device - particularly if you are using the residual limb during the activity, as this may cause your muscles to send signals which operate the hand.

If your Myo Kinisi 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.

Whilst using the hand, if you intend to drive you **MUST** ensure the device is turned **off** (see the function button section on how to do this), and in a position which allows you to easily remove the hand from the vehicle. Driving with the power on may result in accidental/unintentional operation of the hand, potentially causing loss of vehicle control and injury as a result.

Steeper highly recommends assessment from an authorised/specialist test centre to determine your ability to control a vehicle whilst using a prosthesis, and if you require any adaptations to the vehicle itself. It is the responsibility of the user to ensure compliance with local regulations before operating a motor vehicle.

Taking care when using this device will maximise its functionality and ensure your safety.

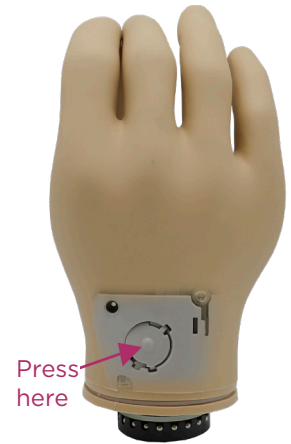
The Function Button

The Myo Kinisi has a low profile function button, located on the back of the hand (as shown in the diagram).

- The Myo Kinisi is on by default after connecting to a power source; initial start up of the device will take between 2-4 seconds after which you can operate the device.
- To switch off the device press and hold the button for 3 seconds, a feedback vibration will indicate that the device is switching off.
- To switch the Myo Kinisi back on, press the function button for for 1 second - a vibration feedback will indicate the device is on.
- When the device is on; the auto-grip function can be activated by pressing and releasing the function button (see p.10).

Note: The force required to press this button has been designed to avoid accidental operation.

Note: If the Myo Kinisi is not functioning this will likely be because the system is off - press the button firmly to turn it on.



Location of the function button
(Illustration to show button beneath the hand shell).

Activating the Auto-Grip Feature

The auto-grip feature is designed to give the user greater confidence when grasping objects. When gripping an object, this feature will offer a grip strength that automatically adjusts to accommodate for any slip of the gripped object. Your prosthetist will advise whether or not this feature is enabled on your Myo Kinisi (only available in Mode 1).

Auto-grip utilises the function button; please see page 9 for a diagram of the button location.

To operate:

- The hand must be in an open position and powered on.
- Briefly press the function button; a single short burst vibration will indicate auto-grip is active.
- Close the hand onto the object until the grip force increases to elicit 1 pulse. Auto-grip is now engaged; ensuring the grip strength applied to the object is maintained.
- Once auto-grip is active, the hand must be engaged in gripping an object within 1 minute; otherwise the auto-grip function will automatically deactivate.
- If the object is removed, the hand will close.
- Once engaged, auto-grip is cancelled by a strong open signal, or after 2 minutes if the gripped object does not slip.
- Auto-grip can also be cancelled by pressing the function button a second time before gripping the object (producing a double burst vibration).

Mechanical Safety Release

In the event that the grip cannot be released; such as a of loss of power to the Myo Kinisi, the safety release button can be used to disengage the thumb.

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

Re-engaging the thumb

To re-engage the safety release, press the release button and push the thumb back to its approximate original position. Release the button and move the thumb until it clicks back into its original position. There is no need to return the Myo Kinisi to your prosthetist unless a fault is suspected.

For reassurance that the thumb has been repositioned correctly, grip an object before commencing with other activities.

Mechanical Safety Release Button
(Illustration to show button beneath the hand shell).

Additional Safety Feature

When the battery runs low the hand will slow; this is intentional to signal that the battery should be recharged or changed.

If the battery fully discharges during use, as a final action, the Myo Kinisi will open and remain in an open position until the battery is recharged or changed.

Grip Strength Pattern

The Myo Kinisi is designed to offer a grip strength pattern to users:

- A **first grasp** action will achieve an average grip designed to be used for softer or more delicate objects.
- A **second grasp** action offers a firmer grip.
- A **third grasp** action will achieve the maximum grip strength.

This pattern is common across all modes.

Your prosthetist will set the maximum pulses count (Max Pulse) from 1-3.

Control Mode Overview

The Myo Kinisi can be configured to your needs by your prosthetist. There are five modes which offer different control options; each of these have parameters which can be adjusted by your prosthetist.

The Myo Kinisi is supplied in Mode 1 as a default mode and this also includes the auto-grip feature.

Your prosthetist will work with you to select the control mode which best suits your needs.

Mode 0: 'AUTO CLOSE'
Single Site: Auto Close
A simple mode where a signal rising above a pre-determined threshold will open the hand and removal of the signal will close the hand.

Mode 1: 'DUAL ELEC'
Dual Site: Open/Close Signal - Default Mode
The only mode to use two inputs to control opening and closing the hand independently. This is the default mode on the Myo Kinisi and offers the auto-grip function to tighten the grip on slipping objects. **This is the most commonly used control mode.**

Mode 2: 'QUICK OPEN'
Single Site: 2 Channel Signal
In this mode a fast rising signal will open the hand and a slow rising signal will close the hand.

Mode 3: ‘ALTERNATE’

Single Site: Successive Signals

In this mode, the first signal will open the hand, a second signal occurring after a set period of time will close the hand. Signals given in quick succession will continue to move the hand in the same direction.

Mode 4: ‘PULSE’

Single Site: Successive Signals

This mode uses a short ‘burst’ signal to open the hand and a longer sustained signal to close the hand.

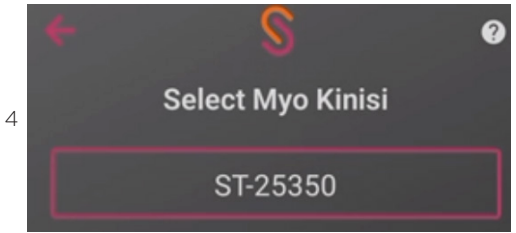
Note: For a more detailed explanation of the mode in which your Myo Kinisi has been programmed, please speak to your prosthetist.

The Steeper Myo Kinisi App Introduction

Accessing the Steeper Myo Kinisi App

1. Ensure **Bluetooth** and **WiFi** are enabled on your device to be able to pair a Myo Kinisi hand.
2. Search ‘Steeper Myo Kinisi’ in the Apple App Store or Google Play Store and download the Steeper Myo Kinisi App. The app can be used across mobile devices including phones and tablets.
3. Turn on the Myo Kinisi hand you wish to connect, this activates the Bluetooth connectivity.
4. Select “Scan for Hand” available Myo Kinisi hands will become visible.

4



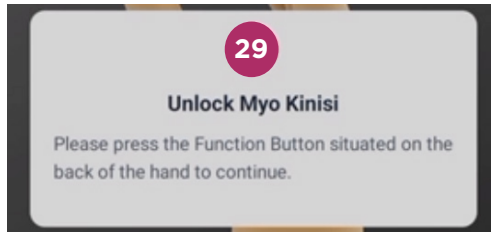
Note: Bluetooth connection initiates for the first 2 minutes of the Myo Kinisi being powered on. After this the Bluetooth will disable. To reactivate, switch the device OFF and ON again.

The Steeper Myo Kinisi App Introduction Continued

5. When a connection is established with the hand, a notice to 'Unlock Myo Kinisi' will appear; to unlock press the Function Button (See p.9 for location) within the 30 second time frame.

Note: Bilateral users; only switch on the hand you wish to update, ensure other Myo Kinisi device is switched off to ensure connectivity of the hand you wish to update.

5



Firmware Update

Steeper may release firmware updates to improve hand function, both clinician and user can perform this function.

1. Select 'Firmware Update' from the home screen, select the serial number and unlock by pressing the Function Button within 30 seconds.
2. If the firmware is up to date a notice is displayed with a green tick, if this is displayed no further action is required. If the Myo Kinisi hand requires an update the app will advise you of the firmware version available.
3. Select the new firmware version available and allow up to 90 seconds for this to be applied to the hand.
4. A notice will be displayed that the firmware update is completed.

Troubleshooting

Error Message	Corrective Action
Myo Kinisi Device not Found	Ensure Bluetooth is enabled on your device. Switch the Myo Kinisi OFF and then ON to reactivate Bluetooth.
Failed to Unlock	Press the Function Button within the 30 second time frame.
Myo Kinisi has been disconnected	Ensure Bluetooth is enabled on your device. Switch the Myo Kinisi OFF and then ON to reactivate Bluetooth.
Device Timeout	Turn the Myo Kinisi OFF and then ON again.

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 an 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	

Warranty Terms

The warranty for the Myo Kinisi is two years. Warranty covers design and manufacturing issues only.

Where a claim is made under warranty by your provider on your behalf, this claim must be supported by appropriate documentation. You may be asked by your provider to take photographs of any failed products 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 or accidental 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 Myo Kinisi is five years. Outside of this, your prosthetist should contact their local Steeper representative for possibilities regarding service and repair.

Returns

If items are to be returned for any reason, please contact your prosthetist.

Quality Assurance

Steeper/SteeperUSA operate a UKAS approved quality management system and fully complies with the requirements of BS EN ISO 13485:2016. This certifies that Steeper/SteeperUSA meet the appropriate international quality standards for the design, manufacture and supply of prosthetic products.

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 prosthetic and orthotic products.

MHRA Registration N°: 0000006617
FDA Registration N°: 9612243
Model N°: RP628

This Device complies with the requirements of the Medical Device Regulations MDR 2017/745.

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.

This device is CE marked to confirm the device is compliant with EU Legislation and meets the EU safety, health or environmental requirements. The CE mark may be applied on packaging, accompanying literature or an enclosure, rather than the product itself.

This device is UKCA marked to confirm the device is compliant with the legislation of Great Britain and meets the health, safety or environmental requirements. The UKCA mark may be applied on packaging, accompanying literature or an enclosure, rather than the product itself.

Test Certification

The device and its associated components listed within this document have been tested and certified to the following standard and requirements:

IEC 60601-1:2005, AMD:2012
IEC 60601-1-11:2015
IEC 60601-1-2:2014
RTCA DO – 160G

Includes meeting requirements of ISO 14971:2019.

Disposal

The Myo Kinisi is an electrical device and should not be mixed with general household waste. For proper treatment, recovery and recycling, please take this product(s) to the clinic where it was prescribed or fitted for appropriate local advice.

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 further details regarding your nearest designated collection point. Penalties may be applicable for incorrect disposal of this waste, in accordance with your national legislation.

Certifications

The Device and its associated components listed within this document have been tested and certified to the following standard and requirements:

IEC 60601-1:2005, AMD:2012
IEC 60601-1-11:2015
IEC 60601-1-2:2014
RTCA DO – 160G
Includes meeting requirements of ISO 14971:2019.

This section details the regulatory certification status of BGM220S Modules in various regions which is contained in the Myo Kinisi BT (Bluetooth). The module used is also known by its model name BGM220S12A.
The address for the module manufacturer and certification applicant is:

SILICON LABORATIES FINLAND OY
Alberga Business Park, Bertal Jungin aukio 3,
02600 Espoo, Finland

EU and UK – CE and UKCA
The Myo Kinisi BT has met the radio EMC tests according to ETSI 301 489-x Relevant Standards and does not contain any deviations in the PSD, EIRP and spurious emissions measurements , as defined in the ETSI 300 328 Standard.

The BGM220S modules have been tested against the relevant harmonized/designated standards and are in conformity with the essential
requirements and other relevant requirements of the Radio Equipment Directive (RED) (2014/53/EU) and of the Radio Equipment
Regulations (RER) (S.I. 2017/1206).

The modules are entitled to carry the CE and UKCA Marks, and a formal Declaration of Conformity (DoC) is available at the product
web page which is reachable starting from https://www.silabs.com/.

USA FCC
The Myo Kinisi BT complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions.
1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesirable operation.

Changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter except in accordance with FCC multi-transmitter product procedures.

This transmitter meets the Mobile requirements at a distance of 20 cm and above from the human body, in accordance to the limit(s) exposed in the RF Exposure Analysis.

This transmitter also meets the Portable requirements at distances equal or above those listed for convenience in Minimum Separation Distances for SAR Evaluation Exemption (BGM220S12A)

The end product has a label stating ' contains FCC ID: QOQ-BGM220S'.

Certifications Continued

ISED Canada
The module has been certified for integration into the Kinisi Bluetooth as:

• The antenna is installed such that a minimum separation distance as stated above is maintained between the radiator (antenna)
and all persons at all times.
• The transmitter module is not co-located or operating in conjunction with any other antenna or transmitter.

This device complies with ISED's license-exempt RSS standards.

End Product Labelling

The BGM220P module is labelled with its own IC ID. If the IC ID is not visible when the module is installed inside another device, then
the outside of the device into which the module is installed must also display a label referring to the enclosed module. In that case, the final end product must be labelled in a visible area with the following:

"Contains Transmitter Module IC: 5123A-GM220P "

or

"Contains IC: 5123A-GM220P"
CAN ICES-003 (B)
This Class B digital apparatus complies with Canadian ICES-003.

ISEDC (Français)
Le module a été approuvé pour l'intégration dans des produits finaux exclusivement réalisés par des OEM sous les conditions suivantes:

• L'antenne doit être installée de sorte qu'une distance de séparation minimale indiquée ci-dessus soit maintenue entre le radiateur
(antenne) et toutes les personnes avoisinante, ce à tout moment.
• Le module émetteur ne doit pas être localisé ou fonctionner avec une autre antenne ou un autre transmetteur que celle indiquée
plus haut.

Tant que les deux conditions ci-dessus sont respectées, il n'est pas nécessaire de tester ce transmetteur de façon plus poussée. Cependant,
il incombe à l'intégrateur OEM de s'assurer de la bonne conformité du produit fini avec les autres normes auxquelles il pourrait
être soumis de fait de l'utilisation de ce module (par exemple, les émissions des périphériques numériques, les exigences de périphériques PC, etc.)

Étiquetage des produits finis
Les modules BGM220P sont étiquetés avec leur propre ID IC. Si l'ID IC n'est pas visible lorsque le module est intégré au sein d'un
autre produit, cet autre produit dans lequel le module est installé devra porter une étiquette faisant apparaitre les référence du module
intégré. Dans un tel cas, sur le produit final doit se trouver une étiquette aisément lisible sur laquelle figurent les informations suivantes:

"Contient le module transmetteur: 5123A-GM220P "
or
"Contient le circuit: 5123A-GM220P"
L'intégrateur OEM doit être conscient qu'il ne doit pas fournir, dans le manuel d'utilisation, d'informations relatives à la façon d'installer
ou de d'enlever ce module RF ainsi que sur la procédure à suivre pour modifier les paramètres liés à la radio.
CAN ICES-003 (B)Cet appareil numérique de classe B est conforme à la norme canadienne ICES-003.

Symbols Used on Product and Packaging

Symbol	Definition	Source
	Indicates the medical device manufacturer.	ISO 15223- 1:2016 Reference no. 5.1.1. (ISO 7000-3082)
	Indicates the medical device distributor.	ISO Ref 3724 (ISO 7000 - 3724)
	Indicates the authorised representative in the European Community / European Union	ISO 15223-1:2016 Reference no 5.1.2
	The requirements for accreditation and market surveillance relating to the marketing of products; Medical Device Regulations.	765/2008/EC, 768/2008/EC MDR 2017/745 (Articles 2, 13, 14, 20, 21, 22, 74 and Annex V)
	Certification mark that indicates conformity with the applicable requirements for products sold within Great Britain (England, Wales, Scotland)	https://www.gov.uk/guidance/using-the-ukca-marking
	Indicates a carrier that contains Unique Device Identifier information.	MDR 2017/745 23.2(h) ISO 15223-1:2016
	Indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223- 1:2016 Reference no. 5.1.5. (ISO 7000-2492)
	Bluetooth device fitted - Bluetooth Symbol.	Trademarks of Bluetooth Special Interest Group (SIG)

	Meets FCC requirements per 21 CFR Part 15.	Federal Communications Commission.
	Indicates the item is a medical device.	ISO/DIS 15223-1: 2020 Reference no 5.7.7.
	Indicates a medical device that has not been subjected to a sterilisation process.	ISO 15223- 1:2016 Reference no. 5.2.7. (ISO 7000-2609)
	This product contains electrical and electronic components that may contain materials which, if disposed of with general waste, could be damaging to the environment. Residents of the European Union must follow specific disposal or recycling instructions for this product. Residents outside the European Union must dispose of or recycle this product in accordance with local laws or regulations that apply.	IS EN 50419:2006 Reference no. Fig. 1
	Indicates the medical device may be used multiple times (multiple procedures) on a single patient.	ISO/DIS 15223- 1:2020(E) DRAFT Reference no. 5.4.12. (ISO 7000-3706)
	Mobius logo indicates that the marked item or its material is part of a recovery or recycling process.	ISO 704, ISO/IEC 13251, ISO 10987-1, ISO 9687 (Reference no. ISO 7000 -1135)
	Packaging is covered by the Forest Stewardship Council assurance that it is made with, or contains, forest-based materials from FSC-certified forests or reclaimed sources.	FSC Certification

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