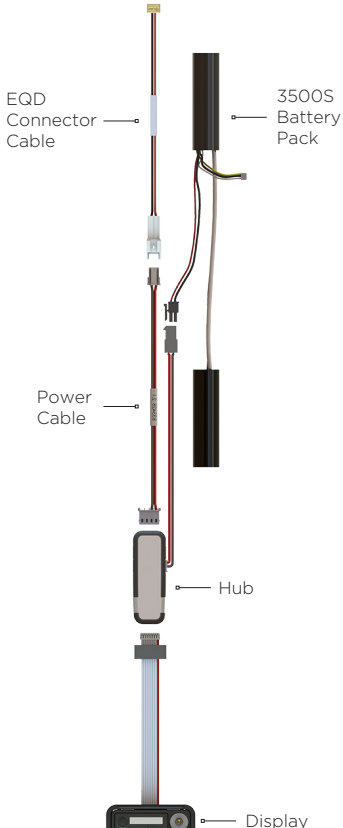
S-Charge System

Battery System with Display and Magnetic Charger

Technical Manual

steeper by eqwal.

steeper USA by eqwal.



Contents

S-Charge System

The S-Charge System is a user-friendly battery system with an OLED Display and a magnetic charger, that is fitted into a prosthesis to allow the user to easily activate, deactivate and charge their prosthesis. The Display informs the user of the remaining power and if there is a charging fault.

In the Box

S-Charge Kit (SC3500)	Quantity
3500S Battery Pack	1
Hub	1
Display	1
Mounting frame	3
Wall charger plus mains adapters (UK, US, EU, AUS)	1
EQD connector cable	1
Power connector cable	1
Battery lamination dummies	1 pair
Hub & Display lamination dummies	1 each
Foam gaskets	3
Alignment sticker	2
Technical manual	1
User guide	1
Extension ribbon cable	1
Silicone sealant and dispenser tip	1

For a 2-way to 4-way connection, or a connection to a short wrist rather than EQD, a Short Wrist connector cable is required (separate order: CBBHA72). See page 8 for setup.

Features and Benefits

- High-capacity 3500mAh batteries.
- The 3500S battery pack fits easily within the prosthesis.
- Fully charges the prosthesis within 6.5 hours.
- Visual Display of the power status.
- Visual Display to inform the user of any charging faults.
- Allows the user to activate and deactivate their prosthesis at the touch of a button.
- Simple to use with one button that switches to and from standby.
- Raised mounting frame to prevent accidental activation.
- Magnetic charger allows for easy connection to the power supply.
- Quick-release magnet protects against damage.
- Automatic Sleep mode activation to save power.

System Compatibility

The S-Charge System is compatible with all powered upper limb systems with equivalent power rating (8.4V at full battery charge, 7.0V at low battery cut off, 2.5A peak current).

Please contact your local service centre for guidance.

Please note: the S-Charge System is only compatible with the Steeper 3500S battery pack.

Principal Dimensions and Specifications

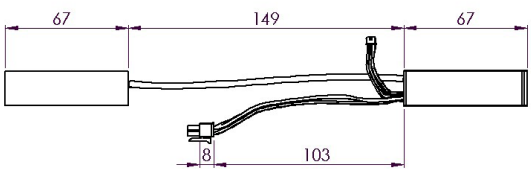
(All dimensions are in mm)

3500S Battery Pack

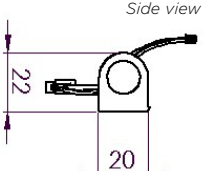
The S-Charge System has been developed to employ the latest advances in battery technology. The system is only compatible with the Steeper 7.2V Lithium-ion 3500S Battery Pack provided.

Please note: The battery cells **must not** be separated. The protection circuitry requires them to be connected.

Top view



Side view

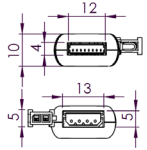


Dimensions per cell (not inc. cables)	67 x 20 x 22mm
Cable length	149mm
Weight	106g
Capacity	3500mAh
Voltage	Nominal 7.2V
Current	2.5A

Hub

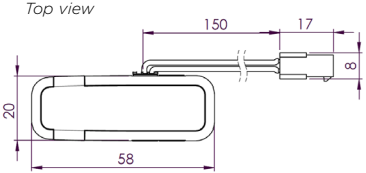
Length	58mm
Width	20mm
Thickness	10mm

Connect to Display end view



Power Cable end view

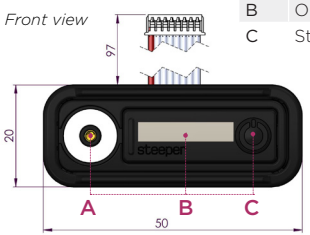
Top view



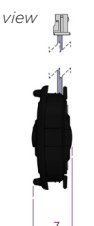
Display & Mounting Frame

Size	50mm x 20mm x 7mm
A	Magnetic charging point
B	OLED Display
C	Standby button

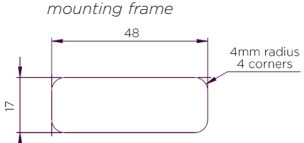
Front view



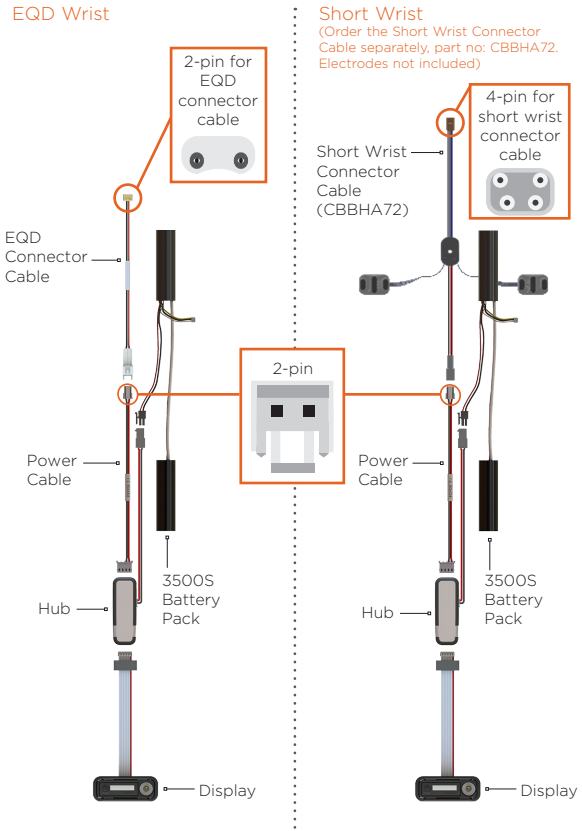
Side view



Hole dimensions for mounting frame



Connecting the S-Charge System

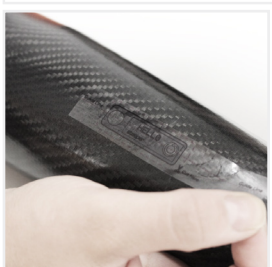


Installation Instructions

The mounting frame for the Display will accommodate a forearm wall thickness of 2 - 2.5mm.

The S-Charge System is designed to be retrofitted to a pre-made forearm. However, if the residual limb is too long to allow all components of the system to fit within the space in the forearm, lamination dummies may be required for a new forearm unit to be created. These are supplied in the box with the S-Charge System.

1. The lamination dummies for the Hub and the Display (shown opposite) can be separated by snapping the adjoining tabs. These, along with the 3500S battery pack dummy, can then be laminated into the forearm using the standard process.



2. After lamination, a hole must be cut for the S-Charge Display. Use the fitting guide label supplied in the box.

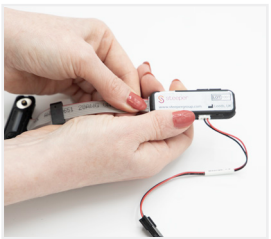
3. Place the alignment sticker onto the desired location of the prosthesis.

4. Using a suitable tool, cut out the template, keeping within the marked lines, and push out the excess material.

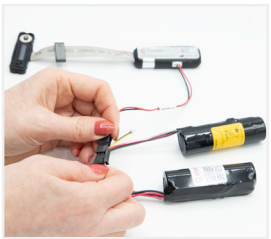
5. File the internal edges of the hole to fit the shape of the mounting frame, and remove any sharp edges.

6. Please note, to connect all the components together, it is recommended in the following order:

a) Firstly, connect the Display with the ribbon cable to the Hub.



b) Next, connect the 3500S Battery Pack to the Hub. The Hub is able to accommodate one Battery Pack.

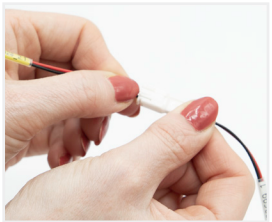


c) Connect the charger to the Display to show charging bar in progress. If fewer than 2 segments are displayed, charge for 30 minutes to achieve an initial charge; ensure a charge of at least 4 hours takes place prior to patient usage.

d) Disconnect the charger and turn off the Hub by pressing the standby button for 1.5 seconds.

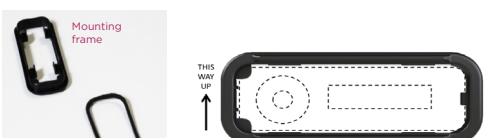
e) Connect the power cable connector to the Hub.

f) Connect the EQD cable to the power cable (if required)



7. Place the foam gasket around the mounting frame, beneath the inner lip.

8. Apply the silicone sealant to the lip and fit the mounting frame to the hole, ensuring the correct orientation as shown below.



9. Ensure the plastic clips of the mounting frame are facing into the hole as shown.

10. Feed the full system through the forearm, and pull the Display through so it exits the forearm through the mounting frame hole. If a bend is required to allow the ribbon cable to run along the forearm, carefully fold it at a minimum distance of 5mm from the Display. Use the extension cable, if required, to ensure that the cable is not strained (with extra care required at the joint with the Display).

11. Secure the system inside the forearm using hook and loop fasteners or similar to prevent movement of the components and damage to the cables.

12. Sit the Display flat on top of the mounting frame and push the corners of the Display until it clicks into place. The front of the Display should sit flush with the mounting frame and the whole unit should feel secure in the forearm.

13. Turn on the power at the Display. Test the terminal device and ensure the unit is fully charged with the magnetic charger supplied, prior to providing to the user.

Important Notes for Fitting

- Press the four corners of the S-Charge Display to gently push it into position - do not exert any pressure onto the Display screen.
- Fitting and maintenance should be conducted in a clean, dry environment and care should be taken to not subject the system to Electrostatic Discharge (ESD).
- Ensure that the fitting process is conducted by a qualified technician.
- Ensure that all components are plugged in securely and that cables are not over-strained.
- Ensure that the unit is fully charged prior to providing to the user and supply the accompanying user guide.
- We recommend the system is charged each night so that a regular charging pattern is established and the user starts each day with a fully charged battery.
- During charging, the surface of the Hub will exhibit an increase in temperature. This is a normal operation and does not signify a fault. The Hub must be positioned to avoid any direct contact with the residual limb. The prosthesis should not be worn during charging, and has a fail-safe fitted to disable the hand and prevent it from operating when the battery is being charged.
- If the battery is in storage it should be charged at least once every six months.
- The Hub can only accommodate one 3500S battery pack.
- Lamination dummies are provided to aid manufacture of the prosthesis.

Important Notes for Fitting Cont.

- Please see page 7 for the Display key when following the initial start-up instructions. (A) Magnetic charging point, (B) OLED Display, (C) Standby button.

Please Note: The standby button must not be pressed with excessive force.

- The S-Charge System must only be fitted by a qualified prosthetic technician, and prescribed by a qualified prosthetist.

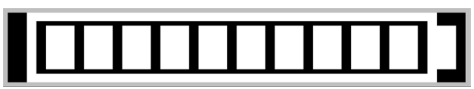
Warning: Do not modify this equipment.

Initial Start-Up

(When connecting the batteries)

The S-Charge System may require a short amount of charging time before initial start-up. Upon completion of set-up, please ensure the device is placed on charge for 4 hours before providing to the user.

1. Connect the Display to the Hub.
2. Connect the 3500S Battery Pack to the Hub.
3. The Display will show the battery status bar.



4. After 10 seconds the system will automatically enter Sleep Mode and the Display screen will become blank. The myoelectric hand is still operational whilst the S-Charge is in Sleep Mode.

Checking the Battery Level

1. Once the system is in Sleep Mode, it can be woken up by a short press of the Standby button.
2. Once woken up, the Display will show the current charge of the battery for 10 seconds, before returning to Sleep Mode.

Deactivating the Prosthesis

1. The prosthesis can be deactivated by holding down the Standby button for 1.5 seconds. The system will then be in Standby Mode.
2. The system will automatically deactivate the prosthesis and the Display screen will become blank.
3. A short press of the standby button will Display the standby symbol when the system is deactivated.

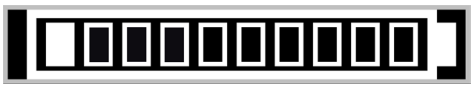
Activating the Prosthesis

1. To activate the system, press and hold the standby button for 1 second.
2. This screen is Displayed after the system has been activated:

3. The system will automatically enter Sleep Mode after 10 seconds where the Display screen will become blank. The prosthesis is still operational whilst the system is in Sleep Mode.

Low Battery Level

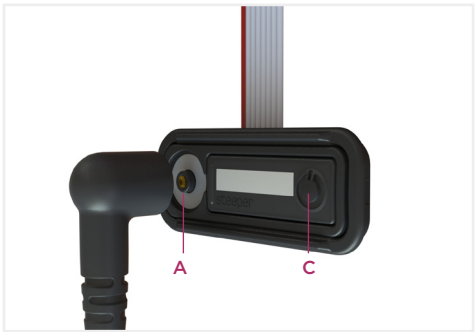
1. When the battery level reaches 10%, the Display will flash the below screen, on the press of the button, if the system is active:



Note: If the battery level then falls below 10%, the system may turn itself off as a safety precaution. It is important that the system is placed on charge as soon as possible once it reaches 10%.

Charging the Prosthesis

1. Connect the magnetic plug (**A**) to the magnetic charging port of the Display.

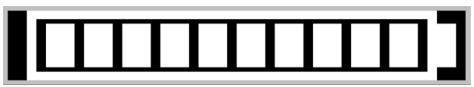


When the magnetic charger is removed, the system will remain OFF. To activate, gently press and hold button (**C**).

2. Once the power supply is turned on, the charging Display will be shown.

3. The solid segments of the battery show the current charge. The cycling segments of the battery highlight the proportion of the battery total capacity that has yet to be charged.

4. When the battery is fully charged, all segments will be solid.



Important Information

- Do not connect or disconnect the batteries from the S-Charge whilst charging.
- The hand will not be operational during charging.
- Do not leave unattended for in excess of 12 hours when charging.
- Do not use the wall charger if it is damaged, and contact your supplier.

Charging Faults

1. If there is a fault detected during charging, the Display will be as follows:

2. If this occurs, disconnect then reconnect the charger.
3. Possible faults indicated by the charging fault image include:
    - Overheating
    - Faulty power supply
    - Faulty battery
    - Faulty circuit
4. If the issue has not been corrected by disconnecting and reconnecting the charger, disconnect for 30 minutes and try again. If the problem persists:
    - The batteries will degrade over time, therefore may require a replacement
    - Charger may be faulty - try a different unit
5. If the problem persists it is important that the system is not used until that fault is rectified. Please contact your provider for further assistance or to order replacement parts.

Troubleshooting

If you do encounter any problems during the set up of the S-Charge System, please note the following troubleshooting advice. For any further information, please contact your supplier. Suitable advice is also provided to the user in the User Guide.

Please note: Before following any of these steps, first ensure that the batteries are charged, the wall charger is plugged in and switched on, and ensure terminal devices are turned on.

Display not working

Carry out in the following order until working:

1. Check that the wall charger is not faulty by using a known functioning charger.
2. Check that the batteries are not faulty by using previously charged batteries.
3. Remove the Display from the forearm by inserting a flat-head screwdriver under the mounting frame (note: the mounting frame will break, replacements are provided within the kit, and are available from Steeper). Check all cables for sign of damage - if damaged, replacement parts are required.
4. If cables show no sign of damage, connect the Display to a functioning Hub. If this works, the Hub will need to be replaced.
5. Connect the Hub to a functioning Display. If this works, the Display will need to be replaced.
6. If the Display still does not work, both the Hub and Display will need to be replaced.

Distorted Display

Carry out in the following order until working:

1. Disconnect all parts and ensure that the areas between the connections are clear of debris.
2. Connect the Hub to the Display and ensure that the connection is pushed in securely.
3. Connect the Battery Pack, and if the screen is still distorted, change the Display with a known working Display. If this works, the Display will need to be replaced.
4. Connect the working Display to a working Hub. If this works, the Hub needs to be replaced.
5. If these steps do not work, the Hub and Display need to be replaced.

A broken battery symbol appears and does not charge

Disconnect the wall charger if connected, then carry out the following:

1. Disassemble the prosthesis as necessary to access the S-Charge Hub (as per the previous guide).
2. Disconnect all parts and ensure that the areas between the connections are clear of debris.
3. Reconnect everything, and if the broken battery symbol is not visible, the system has reset and is functioning correctly.
4. If this does not work, the Hub will need to be replaced.

Prosthesis non-operational despite full charge and power on

Carry out in the following order until working:

1. Check that the terminal device is turned on.
2. Disassemble the prosthesis as necessary to access the Hub. Disconnect the Battery Pack for 10 seconds and then reconnect.
3. If the problem persists, replace the Hub with a unit that is known to be functioning correctly. If this rectifies the issue, the Hub will need to be replaced.
4. Replace the Display with a known working device, if this rectifies the issue the Display needs replacing. If this does not rectify the issue the Hub and Display need to be replaced.

Prosthesis operational despite the S-Charge power off

Carry out the following:

1. Disassemble prosthesis as necessary to access the S-Charge Hub.
2. Disconnect the Battery Pack, then reconnect.
3. If the problem persists, replace the existing Hub with a new Hub.

Care, Cleaning and Safety

The S-Charge System has been designed to minimise the requirement for any maintenance. There are no user/customer-serviceable parts in the S-Charge System. Do not adjust, dismantle, attempt to maintain or modify any component within the system. If any aspect of the device is not functioning as you believe it should, please contact your supplier for guidance.

It is important to encourage the user to inspect their system to ensure early detection of any potential problems, noting the following:

- Ensure that the charging point is always clear of debris.
- Moisture must not enter the S-Charge System. If liquid does enter the system, it must not be operated.
- Overexposure to heat can lead to damage to the Display. Do not leave the system for an extended period of time in the sun.
- Do not expose the S-Charge System to a naked flame or any other excessive heat.
- Avoid impact and do not subject the S-Charge System to excessive loads.
- If the battery gives off an odour, generates extreme heat, becomes discoloured or deformed, or in any way appears abnormal during use, recharging or storage, immediately remove it from the prosthesis.

The Display can be wiped clean using a soft cloth only. Solvents or abrasives **must not** be used as they may damage the screen, thus affecting the visibility of the text and compromising the effectiveness of the ingress protection.

3500S Battery Pack: Important Information

- Handle batteries with care.
- When recharging, only use the specified battery charger.
- For transportation, ensure the batteries are stored in the packaging in which they were provided.
- Store batteries out of reach of children.
- Do not immerse the battery in any liquid.
- Do not use or leave the battery near a heat source such as fire or heater.
- Do not discard the battery in fire or expose it to a flame.
- Do not use or leave the batteries at high temperatures (e.g. in direct sunlight or a vehicle in hot weather). This can cause overheating, burning and performance may degenerate therefore the service life will be reduced.
- If the battery leaks, and the electrolytes get into the eyes, do not rub eyes as this could cause injury to the eyes or loss of sight. Instead, rinse them with clean running water, and immediately seek medical attention.
- Do not strike, throw, drop or damage the battery.
- Do not pierce, disassemble or modify the battery.
- The 3500S battery pack will degrade after a number of cycles. To order a replacement, please contact Customer Services - this is not included in the warranty.
- If batteries are in storage, recharge every six months otherwise the battery function could be affected.

Warning: Do not remove the plastic battery wrapping.

S-Charge: Important Information

- This S-Charge System is an accessory for Class I Medical Devices which meets the general safety and performance requirements in MDR 2017/745 Annex I.
- The S-Charge must only be prescribed and fitted by a qualified prosthetist in a suitable clinical environment.
- 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.
- The Steeper S-Charge System and its associated components are not waterproof and should not be exposed to moisture. Ingress of moisture may cause corrosion and potentially severe damage.
- This product is not designed to be opened and has no user accessible or replaceable internal components.
- In the event of failure or suspected malfunction, please contact Steeper or your supplier. The batteries must only be charged with the appropriate charger and its power supply unit as detailed on page 4. Do not charge the battery whilst the limb is being worn by the user.
- The battery is fitted with a safety circuit to prevent the effects of unintended damage and eliminate the potential hazard. Should the battery or charger fail to operate, please note the circumstances for diagnostic purposes.
- To avoid potential damage to the Wall Charger, do not affix magnetic contact to any metallic surface other than the S-Charge System.

S-Charge: Important Information Cont.

- The S-Charge is designed for use in home healthcare environments (home, restaurants, etc) not hospitals or industrial areas. If the device is used in such environments, the user may need to relocate to operate the device appropriately to be away from potential HF radio devices.
- Portable RF communication equipment, including peripherals (such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the S-Charge, including cables specified by the manufacturer. This could result in degradation of the performance of the Steeper product.
- Use of accessories, transducers and cables other than those specified/provided by the manufacturer of the Steeper product could result in increased electromagnetic emissions or decreased electromagnetic immunity in the equipment, and result in improper operation.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Do not modify this equipment.

Warranty Terms

Item	Warranty Period	Warranty Terms
Hub and Display*	12 months	Design and Manufacture *Mounting frames exempt
Cables	12 months	Design and Manufacture
Charger	12 months	Design and Manufacture
3500S Battery Pack	12 months	Design and Manufacture, correct charging

Where a claim is made under warranty, this claim must be supported by appropriate documentation. Photographs of any failed batteries must be provided in lieu of the product itself. Please do not send faulty batteries back to Steeper. You must state if you wish us to supply a replacement.

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

The designed service life of the S-Charge System is two years. We would recommend replacing the 3500S batteries every 24 months to maintain optimum performance. Other than the guidance outlined in 'Care and Cleaning', no other maintenance is required for this system.

Returns

Prior to Return of any device, the Customer must contact Customer Services for an RA (Returns Authorisation Number) and complete a 8.2.1 FRM 028 Product Concern Report in full and submit with the product return.

Environment and Operational Conditions

Storage Temperature	-20°C (-4°F) to +25°C (+77°F)
Transport Temperature	-20°C (-4°F) to +50°C (+122°F)
Operational	-5°C (+23°F) to +40°C (+104°F)
Charging	0°C (+32°F) to +45°C (+113°F)
Pressure range	700-1060 hPA

65 ± 20% humidity.

Do not expose to ESD above 8kV contact, 15kV air

If the S-Charge System has been in storage, please leave in an ambient temperature (20°C) for a minimum of 2 hours before use.

Disposal

The S-Charge System 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 designated collection points.

Alternatively, in some countries, you may be able to return your products to your local retailer upon the purchase of an equivalent new product.

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 of your nearest designated collection point.

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

Test Certification

The S-Charge System and its associated components listed within this document have been tested and certified to the following standards and requirements:

- Medical Safety Testing:
  - IEC 60601-1: 2005/AMD1:2012.
  - IEC 60601-1-11: 2015; Includes meeting requirements: ISO 14971:2019.
- IP22 to BS EN 60529: 1992+ A2: 2013, when the S-Charge Display is sealed using the silicone sealant as outlined in the fitting instructions.
- IEC62133-2:2017
- UN38.3

IEC60601-1-2: 2014. Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standards: Electromagnetic compatibility - Requirements and tests

Emissions
Radiated RF Emission Group 1 Class B
CISPR 11: 2009+A1: 2010

Immunity
Electrostatic discharge EN61000-4-2: 2008
± 2, 4, 8, 15kV Air Discharge
± 2, 4, 6 kV, Contact discharge

Radiated RF EM Fields
10 V/m, 80 MHz - 2.7 GHz.
AM 80%, 1kHz

EN61000-4-3: 2006 +A1:2007 +A2:2010
- 385 MHz, 18 Hz, 27 V/m
- 450 MHz, 18 Hz, 28 V/m
- 710 – 780 MHz, 217 Hz, 9 V/m
- 810 - 930 MHz, 18 Hz, 28 V/m
- 1720 - 2450 MHz, 217 Hz, 28V/m
- 5240 - 5785 MHz 217Hz, 9 V/m

Quality Assurance

Steeper/SteeperUSA operate a quality management system that fully complies with the requirements of BS EN ISO 13485:2016. This certifies that Steeper/SteeperUSA meet the appropriate international quality standards for 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°: STP-RP616

Continued compliance with the standard is monitored by a program of internal and external audits. Applied Standards:
MDSAP
ISO 14971:2019
Directive RoHS 2015/863/EU.
This S-Charge is an accessory for Class I Medical Devices which meets the general safety and performance requirements in MDR 2017/745 Annex I.

This device is CE marked which indicates that the device meets EU safety, health and environmental requirements. It also indicates the device's compliance with EU legislation and free movement within the European market.

This device is UKCA marked which indicates that the device meets safety, health and environmental requirements. It also indicates the device's compliance with the legislation of Great Britain (England, Wales, Scotland) and free movement within the market of Great Britain.

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 manual, please visit: **www.steepergroup.com**.

Symbols Used on Product & 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 7000 - 3724 Reference no. 3724
	Indicates the authorized representative in the European Community/European Union.	ISO 15223-1:2016 Reference no 5.1.2
	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)
	Indicates the item is a medical device.	ISO/DIS 15223-1:2020
	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
	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)

	Single Patient - Multiple use Symbol	ISO/DIS 15223-1:2020(E) DRAFT Reference no. 5.4.12. (ISO 7000-3706)
	Indicates a medical device that has not been subjected to a sterilization 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 of or recycling instructions for this product. Residents outside the European Union must dispose or recycle this product in accordance with local laws or regulations that apply.	IS EN 50419:2006 Reference no. Fig. 1
	To indicate 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. IS0 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

Notes

Steeper Group
Unit 3, Stourton Link
Intermezzo Drive
Leeds
LS10 1DF
UK

Tel: + 44 (0) 870 240 4133
Email: customerservices@steepergroup.com

www.steepergroup.com

Steeper USA
8666 Huebner Road
Suite 112
San Antonio
TX 78240
USA

Tel: (+1) 210 481 4126
Email: sales@steeperusa.com

www.steeperusa.com

Australian Sponsor
ORTHOPAEDIC APPLIANCES PTY LTD (OAPL), 26-32 Clayton Road, Clayton, VIC, 3168, Australia.

KSA Authorised Representative
AL EWAN MEDICAL COMPANY
Office 14, 1st Floor, Elite Trading Centre Building 7934 King Abdul Aziz Road, Al Rabi, 13315 Riyadh,
Saudi Arabia

EC REP
EMERGO EUROPE
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

STPPR042 Issue 15 September 2024