S-Charge System

Battery System with Display and Magnetic Charger

User Manual

steeper by eqwal.

steeper USA by eqwal.

Contents

Your S-Charge System

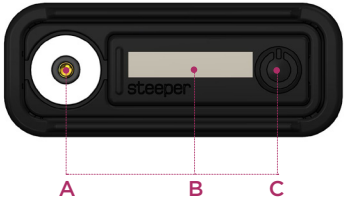
The S-Charge System is an easy to control charging system that is fitted into your prosthesis to allow you to easily activate, deactivate, charge and monitor the power status on your prosthesis.

Your S-Charge System is operated using a standby button, a visual display and a magnetic wall charger.

The Display screen which is mounted into your prosthesis, notifies you of the remaining power within the system and informs you if there is a charging fault.

For more information, the image opposite shows the operational buttons for the display.

The S-Charge Display



A	Magnetic charging point
B	OLED display
C	Standby button

Features and Benefits

- Fully charges the prosthesis within six hours and thirty minutes.
- Visual display of the power status.
- Visual display informing you of any charging faults.
- Allows you to activate and deactivate your prosthesis at the touch of a button.
- Simple to use 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.

Compatibility

Please only use your S-Charge System with the prosthesis provided by your prosthetist.

The S-Charge System is only compatible with the Steeper 3500S Battery Pack.

Appropriate Usage

Your S-charge System is designed to be used around the home and community (restaurants, supermarkets etc.) Where advanced technology may be in use, please see 'Important User Information'.

Starting the S-Charge System

1. To activate the S-Charge System, hold down the standby button (**C**) for 1 second.

2. The Display will show the battery status bar.

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

Note: The S-Charge System may require a short amount of charging time before initial start-up. See page 11 for instructions on how to do this.

Waking up the S-Charge System

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.

Warning: Do not press the Display screen, as this may damage the S-Charge System.

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 to the magnetic charging port (**A**) of the S-Charge System

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

2. Once the power supply is turned on, the charging display will be shown: (in this example charging indicator is showing battery at 40%)

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 on the charging display will be solid.

Important Information

- The terminal device will not be operational during charging.
- Do not use the wall charger if it is damaged, and contact your supplier.

Putting the Prosthesis into Standby

1. The prosthesis can be deactivated by holding down the Standby button (**C**) 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.

Charging Fault

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

2. If this occurs, disconnect and reconnect the charger.
3. If the problem persists, disconnect for 30 minutes and try again.
4. If the issue has not been resolved, contact your prosthetic provider.

Warning: To ensure that the S-Charge System does not become damaged, do not directly press the display whilst switching the S-Charge System in/out of Standby Mode.

Care and Cleaning

- It is important to inspect your S-Charge System regularly to ensure early detection of any potential problems.
- The S-Charge System has been designed to require minimal maintenance, therefore if the device is not functioning as you believe it should, please contact your prosthetic provider for guidance.
- The Display can be gently wiped clean using a soft cloth only. The use of solvents or abrasives may damage the screen, thus affecting the visibility of the text.
- If used with a glove, please ensure that water does not run down the inside of the glove at any time.

Important User Information

- Do not adjust, dismantle, attempt to maintain or modify the S-Charge System. Tampering with the device will invalidate the warranty.
- The S-Charge System is not moisture or waterproof. If liquid does enter the system, it must not be operated and should be returned to your clinician immediately.
- Do not expose the system to a naked flame or excessive heat.
- Avoid impact and do not subject the system to excessive loads.
- The prosthesis will not be operational during charging.
- Do not modify - these products are not designed to be opened and have no user accessible or replaceable internal components.
- Do not attempt to charge the system whilst the prosthetic limb is being worn.
- Do not directly press the display at any time as this may cause damage to the S-Charge System.

Important User Information Cont.

- Do not leave unattended for more than 12 hours when charging.
- When recharging, only use the specified battery charger provided with the S-Charge System.
- If the battery is in storage, recharge every six months otherwise the battery function could be affected.
- If the system gives off an odour, immediately remove the prosthesis and contact your clinician.
- To avoid potential damage to the Wall Charger, do not affix magnetic contact to any metallic surface other than the S-Charge System.
- 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 clinic and/or user is established.

Important User Information Cont.

- If the device is used in hospitals or industrial environments, the user may need to relocate from potential High Frequency (HF) radio devices to operate the device appropriately.
- Portable Radio Frequency (RF) communication equipment, including peripherals (such as antenna cables and external antennas) should be used at a minimum distance of 30cm (12 inches) away from any part of the S-Charge, including cables specified by the manufacturer. Failure to do 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

Important User Information Cont.

equipment, and result in improper operation.

- Do not stack the prosthesis on top of or under any other equipment as this could result in improper usage, cause damage to a part within the limb and invalidate the warranty.

Troubleshooting

If you do encounter any problems with any of the components in your S-Charge System, disconnect and reconnect the charger. If this has not rectified the fault, disconnect the device for 30 minutes and try again. If the problem persists, please contact your prosthetist for further assistance.

Please do not attempt to open or modify any components within the S-Charge System. This could cause injury and will invalidate the warranty.

Please note: Before following the troubleshooting guidance, ensure that the batteries are charged, the wall charger is plugged in and switched on, and the prosthesis has not been deactivated by any other means.

Display not working when power button pressed

Please contact your prosthetist for further assistance.

Distorted display

1. If the prosthesis is operational, run until the batteries are flat, then charge for 15 minutes.
2. If the prosthesis is not operational but the distorted display is still visible, connect the wall charger for 15 minutes.
3. If the problem persists, return the S-Charge System and the wall charger to your clinician for further assessment.

Fault with charging system

1. If there is no response on-screen when the wall charger is connected for 30 minutes, return the S-Charge System and the wall charger to your clinician for assessment.
2. If the broken battery symbol has appeared, disconnect and leave for 30 minutes. If the problem persists, return the S-Charge System and the wall charger to your clinician for assessment.

Prosthesis non-operational despite S-Charge being fully charged and powered on

Put the system into standby and leave for two hours, then retry. If the problem persists, return the S-Charge System and the wall charger to your clinician for further assessment.

Prosthesis operational despite S-Charge powered off

Run the batteries until they are flat then recharge, the system should now function correctly. If the problem persists, return the S-Charge System and the wall charger to your clinician for further assessment.

Disposal

The S-Charge System is an electrical device and should not be mixed with general household waste.

For safe disposal of this Device please contact the Clinic/Hospital where this device was fitted or supplied who will advise you on the best method of disposal.

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

Warranty

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 warranty period for the S-Charge is 12 months.

The designed service life of the S-Charge System is 2 years. Other than the guidance outlined in 'Care and Cleaning', no other maintenance is required for this system.

Environmental 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° (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.	

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 during fitting.

- 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.

Quality Assurance cont.

Applied Standards:
ISO 13485:2016
ISO 14971:2019
MDSAP
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 user guide, 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)
EC REP	Indicates the authorised representative in the European Community/ European Union.	ISO 15223-1:2016 Reference no 5.1.2
UDI	Indicates a carrier that contains Unique Device Identifier information.	MDR 2017/745 23.2(h) ISO 15223-1:2016
LOT	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)
UK CA	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
CE	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)

MD	Indicates the item is a medical device	ISO/DIS15223-1:2020
NON STERILE	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)
	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. ISO 7000 -1135)
FSC	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

	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 distributor.	ISO 7000 - 3724 Reference no. 3724

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Australian Sponsor

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NON STERILE

FSC

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