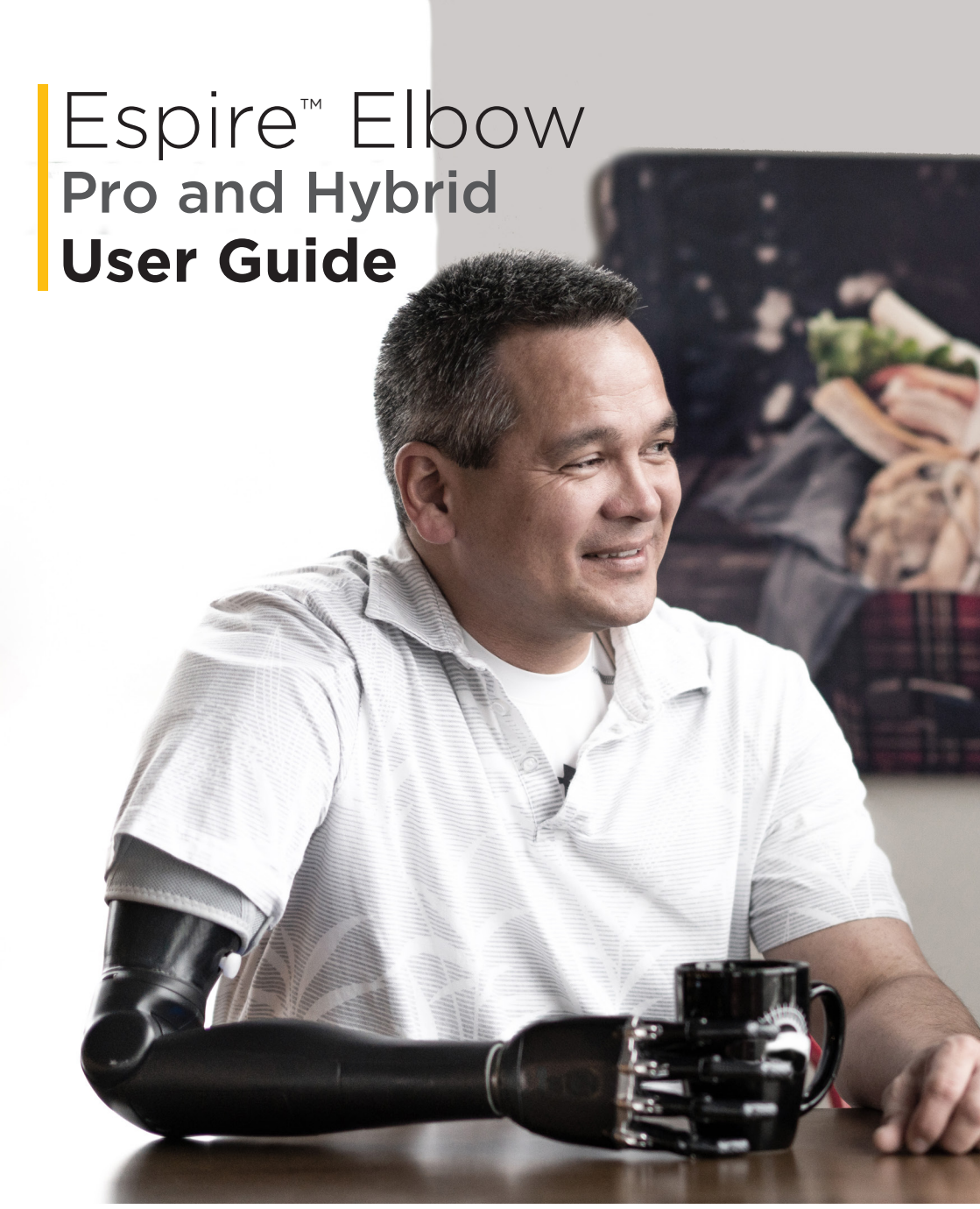
Espire™ Elbow
Pro and Hybrid
User Guide



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WELCOME

Intended Use

The Espire Elbow system is only to be purchased, configured and fitted by a qualified prosthetist. These Devices are Class I Medical Devices (In the EU) which meet the general safety and performance requirements in MDR 2017/745 Annex I

The operations contained in this document are intended for the end user.

Intended Use Statement

The Espire Elbow is to be used exclusively for external prosthetic fittings of the upper limbs. The Espire Elbow Pro and Hybrid models process the user's input signals to activate and control powered elbow movement.

What's Included with Your Device

Espire Elbow System

(2) 10.8 V Smart Lithium Ion Batteries

Espire Elbow Battery Charger

Technical Specifications

Specifications	
Weight Limit	11.3kg/25lb
Maximum Lifting Force	4.5kg/10lb
Flexion Angle (preset control)	-5^0 - 135^0
Speed (preset control)	135^0/sec
Mode of operation	Continuous

Device Operation – internally powered	
Battery (removable)	Smart Li-Ion 10.8 V, 3,000 mAh
Time to full charge	3.5 hours
Charger	100-250 VAC, 24 V, 2.5A DC

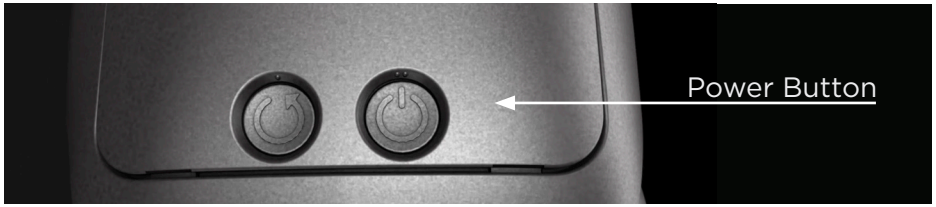
Environmental Use Conditions	
Charging (temperature)	0°C to +45°C (32°F to 113°F)
Operating (temperature)	5°C to 40°C (41°F to 104°F)
Storage & Transport (temperature)	-20°C to +60°C (-4°F to 140°F)*
Operating Relative Humidity	15% to 90%

*Note: If storing device above or below operating temperature, allow the device to return to within operating temperature range and leave the device to sit for 15 minutes before using.

IP Rating

IP22	Protected from touch by fingers and objects greater than 12mm. Protected from water spray less than 15° from vertical.

Powering on the Espire Elbow



The power button is located on the underside of the Espire Elbow. To turn the device on or off, press and hold the power button for 4 seconds. When the device is powered on or off, a multi-coloured light on the LED indicator will flash for 1 second.

The system may also be configured with an external switch for turning the Espire Elbow on and off. Pressing the switch will also turn the system on or off.

Feature	Description
Power Button	Press and hold for 4 seconds to turn Espire ON or OFF

Elbow LED Indication - Power

Colour	Indicator	Status
Multi-Colour Blink		Power ON or OFF

LED Indicator

The Espire Elbow features a single, multi-coloured LED Indicator located on the centre of the forearm near the elbow joint. This LED is used to display information such as battery life, calibration start and stop times, and system errors. The chart below outlines each LED pattern.

Press the power button for 1-second to activate the LED indicator light on the forearm. This indicator tells the user how much life is left in their current battery. The Espire must be powered on to use this feature.

Feature	Description
Power Button	Press and hold for 1 second to indicate the battery status

Espire Elbow All LED Indications

Colour	Indicator	Status
4 Green Blinks		Battery 100% Charged
3 Green Blinks		Battery Less Than 75%
2 Green Blinks		Battery Less Than 50%
1 Green Blink		Battery Less Than 25%
Yellow Solid		Critically Low - Charge Battery
Red Blinking		Minor System Error (Battery Overpowered, Object Too Heavy)
Red Solid		Critical Error (Contact your Prosthetic Provider/Clinician who will contact Steeper Group)
Blue Solid		Bluetooth Connection

BATTERIES AND CHARGING

The Battery

The Espire Elbow system is supplied with two removable lithium-ion batteries. It is advised to rotate use of these batteries, keeping one as a spare for backup power. For most users, one battery will last an entire day*, depending on the prosthetic components, condition of the battery and the frequency of use.

**Based on average use during an 8-hour period*

⚠ Caution: Use only the Steeper Group manufactured Espire Elbow battery pack and the provided battery charger with the Espire Pro and Hybrid systems. Always follow the manufacturer's instructions for proper removal of and replacement of battery pack.

Note: If storing the Espire Elbow for an extended period without using, remove battery pack from the elbow before storage.

Battery Installation and Removal

Batteries can be removed and replaced as necessary. To remove the battery, simply push the battery cover clip and gently lift it off the elbow. Use the pull tab to remove the battery.

Installing a battery is the reverse process. Ensure that the battery connections are facing the distal opening of the forearm and that the Steeper Group logo on the top of the battery is visible. Insert the battery into the elbow, ensuring that the pull tab is accessible for future removal. Then, angle battery cover to insert closest to elbow first and apply. The battery cover clip will "click" into place when seated.

Battery Charger

Espire Elbow systems are supplied with a Smart Charger for the lithium-ion battery. The charger is recommended for daily use and will assure that the battery will receive a full charge and provide maximum running time. There are two charger types (single-bay or dual-bay) and three power adapter options (US, UK, or European) to match the needs of different regions. There is also a car charger available.

⚠ Caution: Using a different A/C adapter than the one provided with your battery charger may cause damage to the Espire battery or battery charger.

Charging the Battery

Charging the Espire Elbow Battery

1. Place the charger on a flat, level surface away from sources of heat and moisture. Plug the A/C connector from the power supply into the back of the charger and connect the power supply to the main A/C supply using the cable supplied.
2. If the battery you wish to charge is inside of the Espire Elbow, it must first be removed from the battery bay. Remove the battery cover using the clip and remove the battery by using the pull tab.
3. Place the battery into the battery bay ensuring that the 5-way connector is fully seated. The LEDs in the status window will provide status information and the charger will automatically begin charging.
   Recharge time from empty is approximately 3.5 hours.

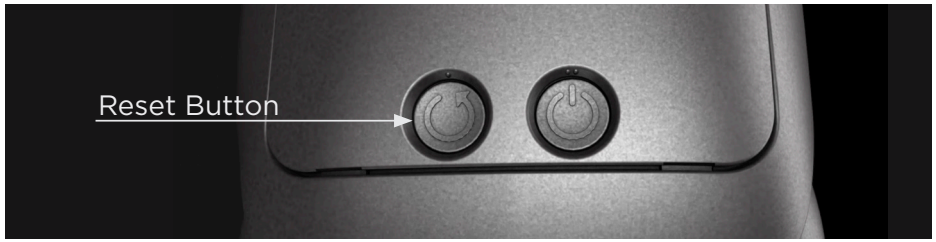
Battery Charger LED Indications

Colour	Indicator	Battery Status
Green Blinking	▬ ▬ ▬ ▬	Charging
Green Solid	▬▬▬▬	Fully Charged
Red Solid	▬▬▬▬	Error

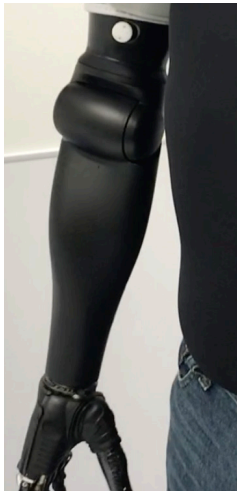
RECALIBRATION USING THE RESET BUTTON

Recalibration Overview – For Users with A/C Myoelectrodes Only

Changes in volume of your residual limb may lead to decreased contact with the myoelectrodes in your prosthetic socket. This decreased contact may cause your Espire Elbow system to respond more slowly or erratically. If this occurs, it may help to recalibrate the system.



How to Recalibrate



During At Rest Calibration:

Feature	Description
Reset Button	Press and hold for 1 second to begin “At Rest” calibration

1. Press and hold the reset button for 1 second to begin “At Rest” calibration.
2. A tone will play to signify the start of calibration.
3. While sitting or standing upright, relax your muscles and hold the Espire Elbow straight down in an extended position. If successful, a success tone (ascending tone) will play to signify the end of the “At Rest” calibration. If unsuccessful, a failure tone (descending tone) will play, and you should repeat “At Rest” calibration.

During At Rest Calibration:

- You may sit or stand upright
- Allow the device to remain motionless at your side
- Avoid swaying or allowing the device to swing
- Do not flex any muscles at this time

During Strong Signal Calibration:

Feature	Description
Reset Button	Press and hold for 4 seconds to begin “Strong Signal” calibration

1. Press and hold the reset button for 4 seconds to begin “Strong Signal” calibration.
2. A tone will play to signify the start of calibration.
3. While standing upright, activate all myo signals used for device control (both flexion and extension) at a comfortable but deliberate level. If successful, a success tone, (ascending tone) will play to signify the end of the “Strong Signal” calibration. If unsuccessful, a failure tone, (descending tone) will play, and you should repeat the “Strong Signal” calibration.

During Strong Signal Calibration:

- You may sit or stand upright
- Activate all myo signals used for device control throughout the duration of the calibration

The Espire Elbow system has now been recalibrated.

Note: Contracting your muscles too hard will set the device calibration at an unrealistic level. Use an intensity that you will be comfortable using throughout the day.

COUNTERBALANCE ADJUSTMENT (HYBRID ELBOW ONLY)

Counterbalance Overview

The Counterbalance assists in flexion and extension of the Espire Elbow. Different amounts of tension are necessary based on the elbow's overall length and the weight of the terminal device.

Counterbalance Adjustment

Direction	Adjustment	Result
	Turn the dial posteriorly (backwards) to increase the counterbalance weight. Note: Elbow cannot be over-adjusted. In this direction, it will simply reach maximum flexion.	Supports more load on the elbow
	Turn the dial anteriorly (forwards) to decrease the counterbalance weight Note: Elbow will spring back into flexion according to how much spring lift assist is put into the system if it exceeds the minimum adjustment.	Supports less load on the elbow

MAINTENANCE AND TROUBLESHOOTING

Troubleshooting

> ⚠ Caution: The Espire Elbow should never be serviced while connected to the end-user. Ensure that the device is disconnected and powered off before any service or maintenance is performed. This device should never be serviced while in use. Never let children handle this device unsupervised. Take caution when using this device around pets that may cause damage to the device.

If the Espire Elbow system becomes unresponsive or control becomes erratic, try the following:

- Turn the system off, wait several seconds and power back on.
- Perspiration can diminish the performance of myoelectrodes. Remove the prosthesis and wipe down the inside of the socket with a clean, dry cloth including the electrodes.
- Ensure that all visible wire connections are secure, and no wires have become entangled or frayed.
- Make sure the battery has sufficient charge. If the battery is too low, swap it with an extra, fully charged battery. Ensure that the battery is fully inserted into the Espire Elbow.
- Recalibrate the system (for prostheses with A/C myoelectrodes only).

INTENDED USE AND SAFETY

Intended Use Statement

The Espire Elbow is to be used exclusively for external prosthetic fittings of the upper limbs. The Espire Elbow processes the user's input signals to activate and control powered elbow movement.

Intended Users

The Espire Elbow is intended for use only by the individual being fitted with the device. The manufacturer does not approve use by any other person/s. This device is intended to be fitted, fabricated and set up only by a qualified prosthetist.

Indications and Contraindications

Indications for use of the Espire Pro or Hybrid elbow system include the following:

- Adequate limb length to allow for appropriate socket fit at a level above the elbow. This would include elbow disarticulation, trans-humeral, shoulder disarticulation and fore quarter
- Adequate muscle activity for myoelectric control (if utilised)
- Adequate cognitive ability to master technology and input requirements of device
- The patient is able and willing to participate in training for use of the myoelectric control of the prosthesis (if utilised)
- Access to a qualified prosthetist for fitting and servicing of the elbow system
- Able and willing to charge power source on a daily basis

Contraindications for use of the Espire Pro or Hybrid elbow system include the following:

- Any condition that prevents socket fitting, such as a complicated wound or intractable pain which precludes socket wear
- Inability to tolerate the weight of the prosthesis
- Inability to produce muscle or body movement necessary for operation of the terminal device(s)
- Specific environmental factors—such as excessive moisture or dust, or inability to charge the prosthesis
- Extremely rural conditions where maintenance ability is limited

Safety

Legend of Symbols

	Note: Possible technical damage.
	Info: Basic information regarding this product.
⚠	Caution: Possible risk of accident or injury.
⚠	Warning: Possible risk of severe accident or injury.

Caution: Failure to follow the safety instructions below can lead to damage or malfunction of the product. Follow the safety instructions and stated precautions in this document.

Safety Instructions

Please ensure you are fully aware of all the safety instructions before leaving the clinic.

Info: Use on aircraft

Airlines may not permit the use of this device on their aircraft. Check with your airline before traveling to ensure this device is allowed for use on the plane.

Info: Disposal

These products may not be disposed of with household waste in some jurisdictions. Disposal that is not in accordance with the regulations of your country may have a detrimental impact on health and the environment. Please observe the information provided by the responsible authorities in your country regarding return and collection processes.

Caution: Battery damage

Damage can occur to the battery when dropping, knocking, crushing, vibrating or puncturing. Avoid damaging lithium batteries and devices. Always inspect for signs of damage, such as hissing, leaking, cracking/bulging and smoking before use. Immediately remove a device or battery from service, and place away from flammable materials if any of these signs are present. In the event of battery damage, immediately and carefully remove battery and please contact your qualified Prosthetist regarding safe disposal and replacement. In the event of contact with the skin rinse immediately and contact medical care immediately.

Caution: Manipulation of system components

Independent changes and/or modifications to system components may lead to faulty control or malfunction of the Espire Elbow, resulting in a risk of injury. No modifications on your Espire Elbow except those described in this information document are authorised. The Espire Elbow and damaged components may only be opened or repaired by certified Steeper Group technicians.

Caution: Penetration of dirt and humidity

The penetration of dirt and humidity may lead to faulty control or malfunction of the Espire Elbow and result in a risk of injury. Ensure that neither solid particles nor liquids can penetrate the Espire Elbow.

Caution: Mechanical overloading

External mechanical influences or loads, such as impacts and vibration, can lead to faulty control or malfunction of the Espire Elbow and result in a risk of injury. The Espire Elbow should not be subjected to mechanical vibrations or impacts.

Caution: Thermal overloading

Extreme temperature conditions can lead to faulty control or malfunction of the Espire Elbow and result in a risk of injury. Avoid areas outside the specified operating temperature range. The operating temperature range must be between 5 °C and 40 °C (41.0 °F and 104.0 °F).

Caution: Magnetic interference

The Espire Elbow and connected components can malfunction when near high-tension power lines, transmitters, transformers, or other sources of strong electromagnetic radiation (such as security systems for goods in department stores). This can result in a risk of injury. The electrodes should be set to as low a sensitivity as possible. If corresponding malfunctions occur repeatedly, please have the electrode settings checked by your prosthetist.

Caution: Improper use

Any type of excessive strain, overload or improper use may lead to faulty control or malfunction of the Espire Elbow, resulting in a risk of injury. The Espire Elbow was developed for everyday use and must not be used for unusual activities. These unusual activities include, for example, sports with excessive strain and/or shocks to the wrist joint (pushups, downhill mountain biking, etc.) or extreme sports (free climbing, paragliding, etc.). Do not use when swimming or in wet environments. Careful handling of the prosthesis and its components not only increases their service life but, above all, ensures your personal safety. Should the prosthesis be subjected to unusual stresses (such as a fall), immediately contact a qualified prosthetist and have the prosthesis inspected for any damage.

Caution: Lifting objects

Do not exceed the active lift limit of 4.5kg/10lbs

Caution: Consequences of product deterioration

Wear and tear on system components can lead to malfunction of the Espire Elbow, resulting in a risk of injury. Follow the specified service intervals. The service life of this device is 5 years for device, parts, and accessories. For warranty detail please see document STPPR180 Limited Warranty/Elbows.

Battery packs should be rotated in use of device, allowing a battery pack to not be used for more than 3 months can degrade the service life.

Caution: Water and humidity

The electrical and mechanical systems of your Espire Elbow are not water-resistant. Water must be prevented from entering the Espire Elbow. Be careful not to let water run over the top of the prosthetic glove and enter the Espire Elbow as well as the terminal device. If water enters the inside of the prosthesis for any reason, immediately switch off all components and stop using or charging them. A qualified prosthetist must be contacted immediately to assess the device and avoid further damage.

Caution: Risk of accident while operating a vehicle

An upper extremity amputee's ability to drive a vehicle is determined on a case-by-case basis. Factors include the type of fitting (amputation level, unilateral or bilateral, residual limb conditions, design of the prosthesis) and the amputee's abilities. All persons are required to observe their country's national and state driving laws when operating vehicles. For insurance purposes, drivers should have their driving ability examined and approved by an authorised test centre. For maximum safety and convenience, Steeper Group recommends that, at the very least, a specialist evaluate the need for any adaptations to the vehicle. It is indispensable to ensure that the driver can operate the vehicle without any risk with the Espire Elbow turned off. Driving with the Espire Elbow turned ON may present a risk if the Espire Elbow inadvertently moves due to unintentional muscle contraction or other causes. A doctor or prosthetist should be consulted before operating a motor vehicle with this device; otherwise the Espire Elbow is not approved for use while driving.

Caution: Too close to HF communication devices (e.g. mobile phones, Bluetooth devices, WIFI devices)

If too close to HF communication devices, interference with internal data communications can result in malfunctions of the product. This can lead to a risk of injury. Therefore, keeping the following minimum distances from these HF communication devices is recommended.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Espire Elbow, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Caution: EM Disturbances

Do not use the Espire Elbow near active HF SURGICAL EQUIPMENT and the RF shielded room of an EM SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high. High levels of Electro Magnetic disturbances may cause system to stop functioning properly, either not responding to input signal(s) or no movement of the joints.

Caution: Overheating of drive unit

Continuous use of the Espire Elbow over a longer period (e.g. frequent lifting and lowering) can lead to overheating of the drive unit. Touching overheated components can result in painful situations. Caution should be exercised during use by patients having skin with decreased heat sensitivity. In case of overheating, the performance of the Espire Elbow is impaired and the full lifting force can no longer be utilised. The activities must be discontinued until the drive unit has cooled. After cooling, the full functionality is restored.

Caution: Risk of pinching where the elbow joint bends

Ensure that fingers and other body parts are not in this area when bending the elbow joint.

Caution: Operating the product near active implanted systems

When operating the product, there is a risk of temporary influences of active implantable systems (e.g. pacemakers, defibrillators etc.) because of electromagnetic interference of the product.

When operating the product in the immediate vicinity of active implantable systems, ensure that the minimum distances stipulated by the manufacturer of the implant are observed.

Make sure to observe any operating conditions and safety instructions stipulated by the manufacturer of the implant.

Caution: Unsupervised use

It is not recommended for children to operate this device without the supervision of an adult. Use extreme caution around small children and household pets.

Warning: Using with other equipment

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, any equipment needs to be agreed appropriate with their Prosthetist and/or Steeper.

Warning: Use only specified equipment

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment, and result in improper operation.

Warning: Operation of equipment in hospitals

The Espire Elbow was designed for use in residential environments (home, restaurants, etc.) not hospitals or industrial areas. If device is used in environments such as hospitals or industrial areas, the user might have to relocate to operate the device appropriately so that it is away from other HF radio devices.

Warning: Adverse Incident.

If a serious incident occurs relating to the device, full details must be reported to the Manufacturer and the competent authority of the Member State in which the user and/or patient is established.

EMC Compliance – Specific Mitigations

The Espire Elbow was tested to the listed standards at the appropriate levels for Home Health Care Equipment below to ensure safety of the product regarding immunity and emissions. All devices maintained their performance during and after the tests were completed.

This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, (2) this device must accept any interference received, including interference that may cause undesired operation.

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes: (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le onctionnement.

QUALITY ASSURANCE

Quality Statement

Steeper/SteeperUSA operate a quality management system that fully complies with the requirements of 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°: RP652

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.

Definitions of symbols used in this device and its packaging

Symbol	Definition	Source
	Consult instructions for use.	BS EN ISO 15223-1: 2012 Reference no. 5.4.3
	Keep dry.	BS EN ISO 15223-1: 2012 Reference no. 5.3.4
	This product contains electrical and electronic components that may contain materials which, if disposed 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 or recycle this product in accordance with local laws or regulations that apply.	IS EN 50419:2006 Reference no. Fig. 1
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.	USA Code of Federal Regulations 21 CFR Part 801 § 801.109(b)(1)
	Refer to instruction manual/booklet.	IEC TR 60878 Ed. 3.0 b:2015

	The requirements for accreditation and market surveillance relating to the marketing of products; Medical Device Directive.	765/2008/EC 768/2008/EC MDD 93/42/EEC Articles 4,11,12,17, Annex II)
	Type BF applied part.	765/2008/EC 768/2008/EC MDD 93/42/EEC Articles 4,11,12,17, Annex II) IEC 60601-1, IEC 60878, ISO 9687:2015 Reference no. 5334
	Temperature limit.	ISO 15223-1 Reference no. 5.3.7
	Storage humidity range.	ISO 15223-1 Reference no. 5.3.8
IP22	Protection against solid foreign objects of 12.5 mm diameter and greater, and protection against vertically falling water drops when tilted up to 15 degrees.	IEC 60601-1, Table D.3, Symbol 2
	Bluetooth® wireless or enabled technology.	Trademarks of Bluetooth Special Interest Group (SIG)
	Complies with Australian Radio communications requirements.	AS/NZS 4417.1:2012
	Medical device manufacturer.	ISO 15223-1, Clause 5.1.1
	21 CFR Part 15 Meets FCC requirements per 21 CFR Part 15.	Federal Communications Commission
	Battery is recyclable - follow local recycling & reclaiming procedures.	ISO 7000 Reference no. 1135
	China RoHS Mark I logo. Product does not contain toxic and hazardous substances or elements above the clip level in any material or application including those exempt from the requirements of the EU RoHS Directive.	SJ/T11364-2006
	Subject to recycling under the Waste Disposal Act.	Environmental Protection Administration, R.O.C.(Taiwan)
	Note: Possible technical damage.	
	Info: Basic information regarding this product.	
	Caution: Possible risk of accident or injury.	
	Warning: Possible risk of severe accident or injury.	
MD	Indicates that this item is a medical device.	

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MADE IN THE UK

STPPR148 Issue 2 June 2021