Manufactured by:	Document ref. ERMC 002-01	Distributed by:
ERMC ELECTRO RANGE MFG CO	**General instructions & guidelines for the use, care, handling and reprocessing of *ERMC RE-USABLE ELECTROSURGICAL HAND CONTROL FINGERSWITCHES AND ELECTRODES***	BOLTON SURGICAL of SHEFFIELD

Devices	• These instructions apply to: • All re-usable hand control fingerswitches complete with electrode and cable. • All monopolar electrodes.
Intended use	• A re-usable electrosurgical device comprising a control handle permanently attached to a specialised cable and connector which is fitted with a re-usable monopolar electrode for use in electrosurgery procedures by persons with the required specialist knowledge and training for selectable, targeted delivery of high frequency electric current to effect cutting or coagulation of biological tissues and to control bleeding by connection of the device to an electrosurgical generator unit (ESU).
How supplied	LATEX ERMC re-usable hand control fingerswitches and electrodes are **LATEX FREE**, including their packaging. NON STERILE ERMC re-usable hand control fingerswitches and electrodes are supplied non-sterile and must be cleaned and sterilised prior to each use.
Cautions and Warnings	• These instructions are intended for use only by appropriately qualified persons with the required specialist knowledge and training. • **If this device is/was used on a patient with, or suspected of having Creutzfeld Jakob Disease (CJD), the device cannot be reprocessed and must be destroyed to eliminate the risk of cross-contamination.** • When handling and reprocessing biologically contaminated instruments always handle with care wearing appropriate protective gloves, eyewear and clothing in accordance with local Health & Safety procedures. • Misuse of an instrument for tasks other than those for which it is intended may result in failure of the instrument due to over-stressing causing misalignment, cracks or other irreparable damage as well as unnecessary harm to the patient or user. • Follow the manufacturer's instructions and warnings for any decontaminants, disinfectants and cleaning agents used. • Fire risks are associated with improper use and handling of electrosurgical instruments and accessories. Do not place them in contact with or near to flammable or explosive substances (eg. drapes, gauze, and oxygen sources). • Insert and remove electrodes to or from the hand control fingerswitch before connection to the ESU or only while it is in the "OFF" or "STANDBY" mode. Failure to do so may result in injury or electrical shock to the patient or operating room personnel. • Connect the hand control fingerswitch connector to the ESU only while it is in the "OFF" or "STANDBY" mode. • When temporarily not in use, a sterile, non-conductive holster or quiver should be used to hold electrosurgical instruments and accessories safely, electrically insulated from the patient. • Activate the electrosurgical current supply only if the contact areas are in full view and the electrosurgical instrument has good contact with the tissue that needs to be treated. Use the lowest possible power setting available to achieve the desired surgical effect. • During use, take care to avoid contact between energised electrosurgical instruments and any other metallic instruments or objects. • Modification of electrodes, including bending, is not recommended. This may cause irreparable damage and adversely affect performance. • Observe the use and safety instructions supplied by the manufacturer of the ESU to be used.
Contraindications	• Do not use the instrument if, in the opinion of the surgical practitioner, patient safety risks outweigh the benefits. • Before undertaking electrosurgery procedures on patients with pacemakers or other active implants, a cardiologist or appropriate medical specialist must be consulted as special requirements may apply (e.g. low HF-current, patient monitoring).
Limitations of use and reprocessing	• ERMC re-usable hand control fingerswitches and electrodes, when used in accordance with these instructions have been validated capable of withstanding the number of reprocessing cycles shown below (in accordance with HTM 01-01). - Re-usable hand control fingerswitches – 25 reprocessing cycles following which it is recommended to return them to Bolton Surgical Limited for full inspection or replacement if necessary. - Monopolar electrodes – 25 reprocessing cycles. (See also 'Maintenance and Repair' section below)

Reprocessing instructions

Preparation for use	• ERMC re-usable hand control fingerswitches and electrodes are supplied non-sterile and before first time use must be cleaned, inspected and sterilised as described below. • Ensure the electrode is fully inserted into the hand control fingerswitch such that its insulation sleeve is firmly seated with no unintended exposed metal.
At point of Use	• To operate the monopolar electrosurgical features: - the YELLOW button activates the CUT function - the BLUE button activates the COAG function • Check the active portion of the electrode regularly for soft tissue residues (eschar) which if not removed may impair the functionality of the device and result in increased patient scarring. - Sterile, Disposable Tip Cleaner Pads for this purpose are available from Bolton Surgical Ltd. • Do not allow the fingerswitch cable to lay parallel in close proximity to the cables of other electrosurgical devices.
From point of use	• Immediately after use, remove gross soil using absorbent wipes. Wherever possible, do not allow blood, surgical debris or bodily fluids to dry on the instruments. • For best results and to maximise their service life reprocess instruments immediately after use. If transfer to reprocessing is likely to take time, consider covering the instruments with a damp cloth or use an enzymatic foam spray cleaner to help prevent soil drying. • Do not leave instruments soaking in saline or chlorinated solutions. • Avoid instrument damage during transportation to reprocessing (ie. do not mix heavy or sharp devices with delicate items).
Automated Machine cleaning and disinfection	• Whenever possible automated cleaning methods are preferable to manual methods to provide a more reliable and consistent process and, to reduce staff exposure to contaminated devices and the cleaning agents used. • **Use only either 'CE' marked or validated washer-disinfector machines and low foaming, non-ionising cleaning agents and detergents following the machine manufacturer's instructions for use and any warnings.** • Instruments covered by these instructions can withstand neutral or alkaline cleaning agents up to 12.5 pH. • Instruments covered by these instructions can be thermally disinfected at 90°C to 95°C for 1 minute minimum. • Load instruments carefully and orientated to allow them to drain. • Place heavy instruments with care into the bottom of containers, taking care not to overload wash baskets. • Avoid contact between devices if movement during washing could cause damage or impair the washing action. • Ensure that soft, high purity water which is controlled for bacterial endotoxins is used in the final rinse stage. • On completion, unload the washer disinfector and visually inspect each device for dryness and any remaining soil. If soil remains, repeat the cleaning process or, clean manually (see 'Manual Cleaning and Disinfection' section below) and repeat the automatic cleaning cycle to achieve disinfection. • Remaining wetness may be removed with medical grade compressed air or by using a lint free cloth. ***NOTE:*** *These reprocessing instructions and recommendations have been independently validated for the above Devices using a washer-disinfector operated in accordance with the requirements of HTM01-01.*

Manual cleaning and disinfection	• **Manual cleaning is not advised if an automatic washer-disinfector is available. If this equipment is not available, use the following process:** 1. Use a double sink system (wash/rinse) dedicated for instrument cleaning (not used for hand washing). Ensure that the water temperature does not exceed 35°C. 2. In the first sink, keeping the instrument submerged, use a soft bristle brush or damp cloth to apply a 'CE' marked mild cleaning solution to all surfaces until all soil has been removed. Pay particular attention to crevices and electrode fitment. Always brush away from the body and avoiding splashing. 3. In the second sink, rinse instruments with soft, high purity water which is controlled for bacterial endotoxins, so that water reaches all parts of the instrument and rinses all surfaces without residue, then carefully hand dry or use a drying cabinet. 4. After cleaning, visually inspect all surfaces for complete removal of soil and fluids. If ANY soil or fluid is still visible, return the instrument for repeat decontamination. ***NOTE:*** *Disinfectants must be used according to the instructions of the manufacturer and the specified exposure time observed.*
Inspection Before each use:	• Inspect fingerswitches, full length of cable and connector for damage including, cuts, cracks, broken or distorted plastic parts and insulations, wear, staining and, broken, loose or significantly bent connector pins. • Inspect electrodes for physical damage to tip and connector including nicks, burns, distortion and corrosion. Inspect insulation sleeve for cuts, voids, cracks, abrasions, etc. • Do not use damaged instruments. • Remove for repair or replacement any worn out or damaged instruments.
Sterilisation	• **Use either 'CE' marked or validated vacuum autoclave operating at 134 - 137°C, for a minimum holding time of 3 minutes – always follow the instructions of the machine manufacturer.** • Ensure instruments are fully dry before sterilisation. • Wrap re-usable hand control fingerswitches separately or place in a container so as to prevent contact with other instruments. • Sterilisation cases should be loaded just prior to the sterilisation step. • When sterilising multiple instruments in one autoclave cycle, ensure that the steriliser's maximum load limit is not exceeded.
Storage	• Ensure instruments are dry before storage and stored in dry, clean conditions at ambient room temperature.
General cleaning and sterilising precautions	• Hand control fingerswitches are not suitable for ultrasonic cleaning. • Do not soak instruments in hot water, alcohol, disinfectants or antiseptics to avoid coagulation of mucus, blood or other body fluids. Do not exceed two hours soaking in any solution. • Avoid the use of steel wool, wire brushes or harsh abrasive agents. • The quality of the water used for diluting cleaning agents and for rinsing medical devices should be carefully considered. Mineral residues from hard water can result in staining of the device or prevent effective cleaning and decontamination. De-scaling agents, if used, will not harm the devices. • If practicable, it is good practice to avoid processing instruments of different metallic composition close together to minimise risk of electrolytic damage. • Delicate instruments require special handling to prevent damaging the tips. Use caution during cleaning and sterilisation. A non-fibrous sponge should be used to wipe off all blood and debris. • No part of the process shall exceed 140°C.
Additional information	• Other forms of cleaning and sterilisation** (i.e. Low temperature steam and Formaldehyde, Ethylene Oxide and Gas Plasma) are available. However, always follow the instructions for use as issued by the equipment manufacturer and always consult with them if in any doubt over the suitability of any process used. • Cleaning and sterilising guidelines are available in Health Technical Memorandum - HTM01-01 ***NOTE:*** *It is the responsibility of the reprocessor to ensure that the reprocessing that is actually performed using the equipment, materials and personnel in the reprocessing facility achieves the desired results. This requires validation and routine monitoring of the process. Likewise, any deviation by the reprocessor from the instructions provided above must be properly evaluated for effectiveness and potential adverse consequences.* ** Products covered by this IFU have not been validated for these forms of cleaning and sterilisation.
Maintenance and repair	• Re-usable hand control fingerswitches and electrodes cannot be repaired. If you have any question regarding the fitness for purpose of a used instrument, contact Bolton Surgical Ltd or your medico-technical department. • Instruments returned to Bolton Surgical for inspection or maintenance ***must*** be decontaminated and sterilised and be accompanied with the relevant documented evidence. Failure to supply decontamination/sterilisation certification will result in products being returned untouched for re-processing and delayed service.
Limited Warranty	• ERMC re-usable hand control fingerswitches and electrodes are guaranteed for a period of 5 years from the date of purchase or until completion of 25 reprocessing cycles, whichever occurs soonest (terms & conditions apply) against product failure resulting from defective materials and workmanship, when used by persons with the required specialist knowledge and training, for the purpose for which the device is intended and, properly maintained in accordance with these instructions and guidelines. • Liability is refused for products which have been modified as compared to the originally supplied product, misused, incorrectly handled or, used for a purpose that differs in any way from product's stated Intended Use.
Returned Goods Policy	• Customers wishing to return goods for any reason must do so in accordance with Bolton Surgical's Returns Policy (document ref. POL 009) a copy of which is supplied with each order or, is available online by visiting www.boltons.co.uk. • Determination of a product defect will be made by Bolton Surgical Ltd on behalf of Electro Range Manufacturing Co.
Disposal	• End of service life instruments must be decontaminated and sterilised prior to disposal. • Disposal should be in accordance with local waste management protocols.
Incident reporting	• Report any serious incident that has occurred in relation to the use of a device covered by this IFU to the Distributor and the Authorised Representative for the country in which the incident occurred and in accordance with the reporting rules applicable in that country.

Explanation of symbols used on labels

										
Manufacturer	Manuf. Product Code	Manuf. Batch Code	Supplied Non-Sterile	Supplied Latex Free	Keep dry	Keep away from heat	Caution	Consult Instructions for Use	United Kingdom Responsible Person	European Union Authorised Representative

Electro Range Mfg Co. 250M Daska Road Ghuinke 51040, Sialkot, Pakistan.
T: +92 (0) 321 610 0080 E-mail: info@electrorange.com

CE 1639

Manufactured and Distributed under ISO 13485 registered quality management systems.

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Sign:

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