HELICA TC & PROBES

Operating Instructions & Service Information

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HELICA
Medical Instruments

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FOREWORD

The Helica TC r2 device is a major development in tissue coagulation and cutting. The concept was developed in the UK and makes possible a wide range of improved surgical techniques in a variety of specialities.

Please consult this manual carefully before use as it gives detailed operating instructions.

Brief Description of Equipment
The Helica Thermal Coagulator is an apparatus that generates an ionised gas plasma flame for use in medicine, particularly for soft tissue coagulation.

It consists of two parts:

A power generator and control unit with associated Helium gas supply, providing an alternating current at fixed frequency with a power range of 2 to 33 W and a controlled low pressure gas supply.

An application probe to supply Helium gas and power to the application point.

The generating unit produces an ionised gas plasma flame in a low-pressure controlled Helium gas flow at the open end of an application tube (probe). This creates a corona-type flame issuing from the open end of the probe with high electron temperature but low molecular temperature of about 20°C. When the probe end is brought close (within 3mm) to a capacitive surface such as human tissue, the corona type flame changes to an arc discharge flame with a temperature of approx. 800°C. The inert Helium gas flow in which the discharge takes place protects the area of discharge and minimises oxidation.

The power unit is standard for all applications.

The probe consists of a tube carrying the Helium with a supply wire enclosed. The diameter and design of the probe varies, with different lengths of probe, different designs of end and different diameters of tubing for a variety of applications.

Intended Use

The device is a helium gas electrosurgical cutting and coagulator for use in all soft tissue surgery – laparoscopic, endoscopic and open.

Exclusion Criteria

The following are excluded from intended use:

• Patients with advanced endometriosis.

• Patients who are pregnant.

Equipment Application Specification

The device has several medical purposes as a treatment as it is used for helium gas electrosurgical cutting and coagulation for use in all soft tissue surgery – laparoscopic, endoscopic and open.

UNPACKING & INSTALLATION

UNPACKING

The Helica TC is shipped in two parts, the trolley and the instrument, which is supplied in a case. The case should not be discarded as it can be used for returning the unit for routine servicing, maintenance or repair. Dispose of the other packaging carefully. The Helica TC Instrument & Probes should be stored in dry conditions 8º - 40ºC, less than 75% humidity.

The wheeled trolley contains the accessories. In the UK a Size F medical helium cylinder is required for use with the Helica TC and is not supplied. The hospital will supply the helium.

The consumable probes are supplied packaged and sterilised. These items are for one use only and should be disposed of as clinical waste through the hospital system.

INSTALLATION

The installation and initial testing of the instrument will be carried out by a Helica Service Engineer. As part of every loan/purchase agreement there is a period of instruction, which will normally be given by the Helica Service Engineer at the time of installation or as agreed. Helium medical grade size F should be made available at the time of installation.

Note: Grounding/Earthing Continuity can be achieved when the unit is connected to an earth of hospital grade.

Please note that the instructions for use of diathermy & laser equipment should be followed as per their own operating instructions manual and following their normal procedures. The Helica TC should not be considered the same as diathermy or laser.

PRE-USE CHECK

When the device is to be used, connect the mains lead. Check that when the main ON/OFF switch on the rear of the machine is switched on, the Green light is illuminated on the front panel.

Ensure the helium gas hose is connected to the back of the unit and have not been disturbed since the last time of use. Then switch ON the Helium gas cylinder. After switching on the gas, check the contents gauge, which is marked between 0 (empty) and 3000 (full), that there is sufficient gas in the cylinder for the operation of the instrument during the session.

The helium hose pressure, which is controlled by the cylinder regulator, is approximately 20psi – 1.5 bar. In the UK, the Mediline S400 Regulator is used.

To check leakage from the helium bottle, firstly turn on the gas and note the level displayed on the contents gauge. Now shut of the supply from the cylinder and note if there is any fast decline of the needle on the contents gauge. If the needle drops after the bottle supply has been turned off, this indicates that here is a leak.

If the needle holds steady for a reasonable time (20 seconds), there is no leak in the piping system within the instrument. If there is a drop in the pressure the connections should be checked. There will probably be a hissing noise easily identifying the position of the leak.

If any issues with the helium flow system are apparent, please contact your Helica representative.

Helium is an inert gas and is not dangerous unless breathed in large quantities.

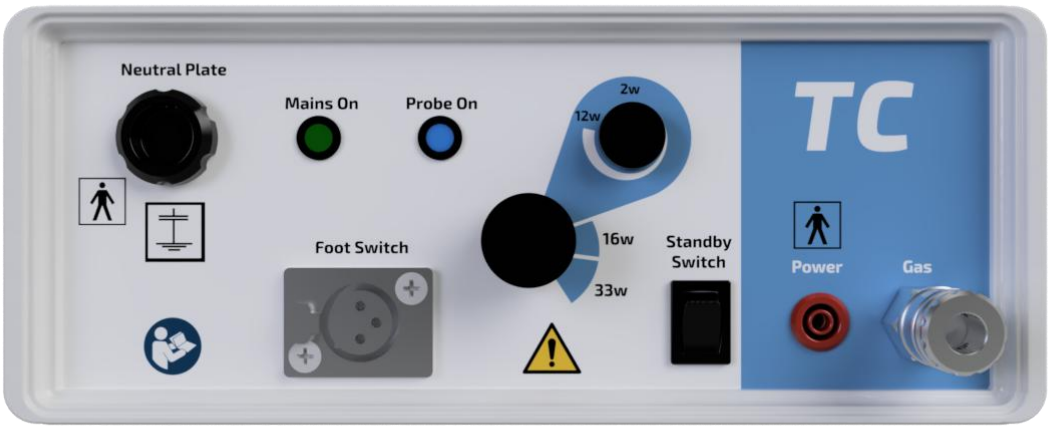
The probe must be directed to an earth or metal object to check the unit is operating. Using the foot switch, the tester holding he probe will charge up and may discharge to metal in a similar way to static charge caused by some carpets or cars.

Test Procedure – Check the plasma beam against a very wet swab. Do not test near the patient. When a plasma beam is clearly observed at the end of the probe, the instrument is ready for use.

[See section – Operating Instructions page 13-14 & Explanation of front panel page 7-8]

After these checks have been carried out the instrument is ready for use, according to the Helica TC operating instructions detailed in the section “OPERATING INSTRUCTIONS – HELICA TC”.

EXPLANATION OF FRONT PANEL MARKINGS



MAINS ON

When the green indicator is on, the unit is powered correctly. It is controlled by the main rear ON/OFF switch above the power inlet socket.

STANDBY SWITCH

The standby switch next to the probe connection of the front panel controls the power to the probe in combination with the footswitch. The standby switch should be in the down - OFF position when the machine is not in use for a significant period of time, for example between operations and when changing probes. The standby switch must be in the up - ON position before the footswitch can operate the probe.

POWER CONTROL

POWER SWITCH

This three-way switch controls the probe power. Always start at the 2W–12W setting and adjust upwards until the required level of power is reached.

For laparoscopic operations the power should be set to the 2W-12W range. The 16W and 33W settings are provided for open surgery use.

LOW POWER TRIM

This adjuster knob allows variable power within the 2W-12W power range. This is the range used in laparoscopic surgery. The knob has no effect when the power control is at the 16W or 33W setting.

NEUTRAL PLATE

The neutral plate attached to the patient is plugged into this socket. The lead or an adaptor is supplied. This applied part is defined as type BF. Please read plate fitting and patient earthing procedures in the Warnings Section.

WARNING: A neutral plate must always be used when operating the Helica T.C. The instrument will not work unless the cable or adaptor is fitted in the front panel socket via the magnetic connector and the buzzer will sound intermittently.

FOOTSWITCH

A socket for the cable of the remote switch, normally a blue foot switch or equivalent which when stood on activates the probe.
The plug is a push fit and retained by a clip. Care should be taken when unplugging.

SOCKET MARKED "GAS He"

Helium gas connection plug (on the probe) is a press fit into this socket. Support the rear of the unit and push the plug into the socket. To release, hold the outer ring of the socket and push towards the unit. The plug will then pop out of the socket.

PROBE ON

The blue indicator shows when power and gas flow are active and flowing to the probe. A buzzer will sound at the same time as the blue indicator is lit. Both are controlled by the combination of the standby switch and the footswitch.

SOCKET MARKED "POWER"

Socket for the electrical connection of the probe. Care should be taken not to stretch the plug. It should be fitted after the gas plug is connected. Make sure the plug is fully inserted before use. This applied part is type BF.

WARNINGS

PLEASE READ CAREFULLY

WARNING: To avoid the risk of electric shock, this equipment must only be connected to supply mains with protective earth.

WARNING: No modification of this equipment is allowed. Invalides insurance etc. We will carry out all required maintenance.

WARNING: Probes are supplied sterilised and are one use only. Care must be taken not to touch other parts of the probe when fitting the probe socket and plug to the unit.

WARNING: When demonstrating the Helica TC instrument, the plasma beam should be activated against a metal object held in the demonstrators non gloved hand or against a large metal object such as a trolley or earth. N.B. Care should be taken as the demonstrator's body will charge a small amount of electricity through capacitance especially if the device is operated and not discharged against any of the above objects. At this time the demonstrator could discharge against any of the above objects similar to static discharge experienced on a car. In a normal theatre operation with a patient, with the surgeon using rubber gloves, patient plates etc. This will not happen. The demonstrator discharging against earth is a highly unlikely occurrence as the body dissipates the electrical charge very quickly, but the combination of events should be noted by any user.

WARNING: Check the plasma beam against a wet swab. Do not test near the patient.

WARNING: Only Helica Instruments Ltd accessories should be used with the Helica TC instrument. All accessories provided by Helica Instruments Ltd are rated for peak voltage. However, standard diathermy patient plates are suitable for use with the Helica TC instrument.

WARNING: The probe cable should be positioned so it has no contact with the patient or other leads or cables.

WARNING: The Instrument is not suitable for use in the presence of flammable anaesthetic gas mixture with air, oxygen or nitrous oxides. Flammable anaesthetics and oxidising gases should be avoided unless these agents are sucked away.

WARNING: Although the necessary EMC standards have been met, use in theatre must be monitored.

WARNING: HF surgical equipment may adversely influence the operation of other electronic equipment.

WARNING: Do not change the power setting (2W-12W,16W & 33W) when the probe beam is running.

WARNING: Please do not open/close the cutting probes whilst depressing the footswitch.

WARNING: Do not use the probe as a manipulator.

WARNING: This device should not be stacked with other medical devices.

WARNING: Cables and accessories not provided by Helica Instruments Ltd may negatively affect EMC performance.

WARNING: Portable RF communications equipment including antennas, can affect medical electrical equipment. This equipment should be used no closer than 30 cm (12 inches) to any part of the device.

WARNING: Do no position the equipment to make it difficult to disconnect the mains lead.

WARNING: Apparently low output or failure of the HF surgical equipment to function correctly at the normal operating settings may indicate faulty application of the neutral plate or poor contact in its connections. In this case, the application of the neutral electrode and its connections should be checked before selecting a higher output power.

WARNING: Unless a compatible monitoring neutral plate is used with a contact quality monitor, loss of safe contact between the neutral plate and the patient will not result in an auditory alarm.

WARNING: Neuromuscular stimulation may occur while using the Helica TC.

FRONT PANEL POWER CONTROLS

The front panel power control consists of power settings of 2W-12W, 16W and 33W. 2W-12W is used for laparoscopic work while 16W or 33W for larger lesions during surgery. A patient neutral plate is required when using any of these settings.

To give greater control in the 2W-12W range there is a separate 2W-12W power trim. This operates only when the main power control setting is on 2W-12W and gives an adjustable power between 2W and 12W. During laparoscopic work the low power trim is normally set mid-range, at 6W. In all 2W-12W settings, the plasma beam remains broadly at the same intensity. Difficulty in seeing the plasma beam will occur when extremely bright lighting is used.

The standby switch is the probe ON/OFF Switch. It is located beside the probe connections. It should be switched to the OFF position when exchanging probes.

The footswitch governs the Probe ON indicator, which is directly above the power setting. A buzzer sounds so that both visual and audio signals indicate the probe is activated.

Do not change the power settings when the plasma beam is running.

EXPLANATION OF REAR PANEL MARKINGS

POWER INLET SOCKET

The power inlet socket on the rear of the machine consists of a 3-part inlet. The inlet is for the cable which is fitted with a UK 13 amp plug and with a socket for the instrument on the other end.
The F1 and F2 fuse holders above the socket are fitted with circuit protection fuses. Fuse information is provided on the lid of the instrument.
Above the fuses is the main ON/OFF switch. It is marked **I** for ON and **O** for OFF. The power indicator on the front panel is marked Mains On and coloured green.
If any extension is taken from the main supply, you must ensure that it is of the correct rating.

FUSES - F1, F2 & F3

The F1 and F2 fuses are the mains inlet fuses. Values are marked on the lid of the Helica TC. (F1 & F2 Fuse T3.15AH 240V)
The F3 fuse protects the amplifier within the unit. (F3 Fuse T3.15AH 240V). It is not user changeable.

OPEN/LAPAROSCOPIC SWITCH

This rear panel switch selects the operation mode of the gas supply cut-off timing. With this switch in the open position, the instrument is used in open surgery where it is convenient to quickly spot cauterise, using the footswitch to control the plasma beam over the area. So that this can be achieved effectively and rapidly, the gas does not switch off until several seconds after the footswitch is released. If the probe is activated within this time the plasma beam will arc instantaneously. This has been found to be a great advantage in open surgery.

In laparoscopic surgery total control of the gas flow is required because controlled pressure and volume within the cavity are required. The gas supply therefore switches ON and OFF

with the beam. This feature is set at the beginning of the procedure and does not usually have to be altered during the procedure.

GAS He (HELIUM INLET)

The gas inlet port is connected, at the time of the installation of the unit, by a hose to the regulator fitted to the Helium cylinder in the Helica trolley. The pressure is set to 1.5 bar (20psi).

The regulator on a Helium cylinder may have 2 gauges. One indicates the volume content of the cylinder and should be checked prior to any operation. The other gives the delivery pressure which should be 1.5 bar.

The Mediline S400 regulator ON is depicted by the helium bottle pressure reading on the gauge. The Helium cylinder should be switched to OFF immediately after use. Helium is a thin gas and leakage occurs over any period of time e.g. overnight.

TRAINING

Training will be carried out by a trained Helica rep during the installation of the device or at and point upon request by relevant staff & consultants. Consultants shall be trained in the safe use of the device prior to use.

OPERATING INSTRUCTIONS – HELICA TC & PROBES

To ensure the safe testing and surgical performance of the Helica TC instrument and Laparoscopic/open surgery probes, the following **pre, inter** and **post**-operative procedures should be observed by machine operators and surgeons:

Pre-operative

1. Unwind the Mains lead from the trolley and plug into an appropriate 3 pin socket and switch the power on at the mains.

2. Switch on the power to the instrument. The switch is located on the back-right hand side of the instrument. Check that the green power indicator on the front panel of the instrument is illuminated.

3. Ensure the regulator on top of the helium bottle is connected to the rear of the device. Open the helium cylinder valve and check cylinder contents via the regulator valve display. If the needle displays a very low amount of Helium, change the bottle prior to use.

4. Footswitch safety cut-out should be pressed to the up – **on** – position – front panel.

5. Check that the procedure switch, located on the back-left hand side of the instrument, is correctly pointing in the direction of the operative procedure required. i.e. open or laparoscopic.

6. Connect a neutral plate to the patient, then to the instrument, using the cable or adaptor as required. The instrument will not work unless this cable or adaptor is fitted.

7. Special attention is required when setting power and trim levels, the surgeon should advise the operator.

8. Position the instrument and footswitch relative to the surgeon and operating site.

9. Open probe pocket and offer to scrubbed assistant.

10. Gas and electrical connectors are passed back for connection to the instrument – front panel.

11. Surgeon is to test the probe prior to use:

    Test Procedure – Check the plasma beam against a **very** wet swab. Do not test near the patient. When a plasma beam is clearly observed at the end of the probe, the instrument is ready for use.

Inter-operative

Whilst in use, to avoid an energy discharge incident:

1. Never touch the end of the probe directly to exposed skin or gloved hand.
2. Never flood the probe during use – avoid excess fluids at all times.
3. Never touch test the probes using the exposed cutting tips
4. Never re-use the probes – always destroy after use.
5. It is not recommended to use the full power settings for laparoscopic operative procedures.
6. Never leave the helium gas supply turned on at the main cylinder valve after use.

Post–operative

At the end of the procedure/list:

1. Standby switch should be switched to the down – **off** – position.
2. Remove the used probe from the front panel by pushing back the ring on the gas connection and the plug will be released for removal, additionally pull out the red power plug on the probe connection lead and dispose of the entire probe assembly in the hospitals 'Sharps bin' following the hospitals own sharps waste management procedures.
3. Switch off the mains switch at the rear of the instrument.
4. Turn off the helium gas supply at the main cylinder valve.
5. Switch off power supply at mains socket and remove the plug.
6. Stow cables on the trolley and remove the trolley to a safe area in the theatre.

GAS CONTROL

Prior to the use of this system, verify that it is Helium gas that is contained in the cylinder.

Helium gas supply must be medical grade.

The recommended Helium gas cylinder is 2200 litres. This provides approximately 7 hours continuous operating time for typical flow rates for open and laparoscopic surgery.

On the back of the Helica TC Instrument there is a surgery mode switch. It is marked Open and Laparoscopic. The function of this switch in the Open position is to switch OFF the gas several seconds AFTER the probe has been deactivated using the foot switch. It has been found that during open surgery there is a necessity for a spotting effect which is a rapid operation of the foot switch and with hand foot co-ordination picking off small areas. As the gas was switching off at the end of the cycle, there was a delay due to the dispersal of the gas before the plasma beam would activate again. This feature has resolved this.

When using the device in the laparoscopic mode, the ingress of excess gas has to be avoided. When the surgery mode switch is in the laparoscopic position the gas is controlled directly by the footswitch. This causes a little delay, but the need for spotting is not so prevalent in the laparoscopic mode.

The surgery mode switch is normally set at the initial set-up before the operation starts. In some cases, where only one procedure is used, the surgery mode switch may never be moved during its time within a specific theatre.

PRESSURE & VOLUME OF HELIUM GAS

When the Helica TC instrument is in use and the footswitch is depressed, an internal solenoid operates to allow Helium gas to flow from the end of the probe. The pressure is pre-set within the instrument and is capable of coping with any probe.

When in laparoscopic use, the helium gas flows into the cavity which has been inflated with CO_2 gas. Care should be taken to ensure the system of pressure control within the cavity is maintained at a safe pressure, especially since the addition of insufflator's filters.

Insufflators which are electronically controlled and have smoke evacuation will be suitable for use with the Helica TC. Using the flow-controlled insufflators, the bleed off and leakage have to be adjusted bearing in mind the addition of gas when the Helica TC instrument is operated. This can be achieved with a bleed off from a cannula if necessary.

Overall pressure within the cavity should be considered and monitored, especially for initial trials and until an operating procedure has been established.

Remove the laparoscopic probe from the body when not in use.

If any clinical signs of gas embolism are observed, terminate the use of the Helica TC instrument immediately.

Electronic insufflators with audible and visual over-pressurisation warning signals should be used during all laparoscopic procedures.

Use patient monitoring for early detection of venous or pulmonary gas embolism during long procedures.

For more information on Helium please read the Helium safety data sheet from BOC Ltd.

TYPES OF PROBES & USES

Type	Code	Description
LT	4001/5256	Laparoscopic coagulating probe
LTS	4001/5257	Stiffer laparoscopic coagulating probe
LTSL	4001/5258	Longer stiff laparoscopic coagulating probe
LTC (Retractable tip)	4001/5301	Laparoscopic coagulating & cutting probe
OCL90	4001/8615	Open surgery probe
OCLB230	4001/8631	Longer bent open surgery probe
LTR	4001/5259	Robotic surgery probe

Please contact the Helica office for other speciality probes

IMPORTANT: For safe use of the LT, LTS, LTSL probes

Familiarise yourself with the coagulating probe prior to use.
Always start using the low power setting (6 watts) and increase power as required.
Care must be taken when probes are introduced through the cannula.

IMPORTANT: For safe use of the LTC probes

Familiarise yourself with the cutting probe prior to use.
Remember to remove the red plastic protective cover from the cutting tip end.
Always start using the low power setting (6 watts) and increase power as required.

Care must be taken when probes are introduced through the cannula. It is recommended to hold the yellow outer sheath so that the cutting tip stays inside the probe. Afterwards, by moving the yellow outer sheath up & down will expose and retract the cutting tip. Care should be taken that this is done under vision. To retract the probe from the cannula, use the blue handle this will keep the cutting tip inside the probe.

Always retract the cutting tip when not in use, especially when inside the peritoneal cavity.

IMPORTANT: For safe use of the OCL, OCLB Probe

Familiarise yourself with the cutting probe prior to use.
Remember to remove the red plastic protective cover from the cutting tip end
Always start using the low power setting (6 watts) and increase power as required.
Use the cauterising beam to create plasma, heating the cutting tip before dissecting.

Remember to vent out the gas from the peritoneal cavity and monitor the gas pressure.

IMPORTANT: For safe use of the LTR Probe

Familiarise yourself with flexible nature of this probe before use.
Always start using the low power setting (6 watts) and increase power as required.
Use the cauterising beam to create plasma.

Remember to vent out the gas from the peritoneal cavity and monitor the gas pressure.

Do not use the probes or cutting tips as manipulating tool. – Ensure its highlighted.
IMPORTANT: The HF probe is a type BF applied part.

PROBE CONTROL

The Helica TC works by producing an electrical discharge that mixes with helium, resulting in a plasma beam that discharges from the tip of the probe. If the tip becomes clogged with saline, blood or any other material this will affect the operation of the instrument. Bending the tip of the probe can result in the plasma beam not being in the centre of the tubing. Therefore, check the tip prior to use. Any matter which is obstructing the end of the probe will have adverse effects and will not allow the smooth operation of the instrument.

Hot blood entering the end of the tube will congeal and solidify after use. This has to be removed for the probe to operate normally. If saline is up the tube the Helium gas will blow this away and the probe will then operate correctly. To check if an operation is correct the plasma beam should be inspected. If this working correctly the instrument will operate when moved closely to the tissue which requires treatment. The probe should be held at 90 degrees to the tissue. This may not always be possible, but the nearer to 90 degrees the better. An angle less than 45 degrees may affect the performance but laparoscopically a more acute angle is sometimes unavoidable. Starting the probe further away and moving closer will help.

After developing a feel for the instrument, the surgeon will be able to adjust his techniques so that difficult areas can be treated. The depth of penetration is controlled by the power on the control panel at the front of the instrument. This is also controlled by the distance of the probe from the tissue and the length of time that the plasma beam is directed to a particular area.

The Helica TC, unlike the argon gas coagulator, operates at a lower power and gas flow, the recommended starting parameter for power for the Helica TC is 6 watts then increase the power until the desired effect is achieved. The starting probe - to - tissue gap is 5mm. The gas flow is automatically determined by the probe diameter. Laparoscopically use the lowest power necessary for the desired effect. Avoid 33w power and long duration applications of the Helica TC to tissue sensitive to depth of penetration such as vessels covered by thin membranes. Unwanted tissue damage may result.

Contraindications

The extensive use of the Helica TC on the digestive tract (for example the stomach and intestines) is contraindicated and may lead to post-operative complications such as tissue rupture. The Helica TC probes are a Class IIa transient device and should be used for less than one hour during surgery.

SERVICE AND REPAIR INFORMATION

The Helica TC Instrument must not be opened, repaired or adjusted by any unauthorised personnel. There are no user serviceable parts within in unit. All repairs must be carried out by qualified Helica engineer, please follow the procedures described below. The Helica TC remains the property of Helica Instruments Ltd unless otherwise stated.

Contact a Helica representative in the UK for service and repair information. When calling, please provide the serial number of the unit.

A brief written description of the problem should be attached to the unit when it is returned for service/repair.

The unit must be packed in its original container or in another Helica approved container that will provide adequate protection during shipment.

Helica Instruments will not be responsible for any unauthorised returns or for units damaged in shipment due to improper packing.

An exchange unit may be provided whilst the unit is being serviced/repaired.

To clean wipe with a damp cloth. Cleaning and disinfecting agents should be non-flammable or allowed to evaporate before HF surgery.

The user must regularly inspect accessories including damage to insulation especially on laparoscopic and endoscopic accessories.

Service & Repair Information can be obtained from the address below:

Helica Instruments Ltd
222 Lanark Road West
Currie
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EH14 5NW

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Fax: +44 (0) 131 443 4755
Email: info@helica.co.uk
Website: http://www.helica.co.uk

WARRANTY

Helica Instruments warrants that, at the date of its delivery to the hospital, the Helica TC equipment is free from defects, inferior materials and unsatisfactory workmanship. Helica Instruments further warrants that the equipment is fit for the purposes described in the labelling attached, when used in accordance with the directions for use. If the equipment is not used in accordance with such directions the warranty is void and of no effect.

In terms of this warranty, but only for a period of one year from the date of original delivery, Helica Instruments will repair, or at its discretion replace, the Helica TC equipment supplied free of charge. This will be carried out by a Helica Service Engineer. This warranty is given only to the original user and is not transferable. It does not cover auxiliary equipment or disposable accessories not supplied by Helica Instruments Ltd.

No other expressed or implied warranty exists, including any warranty of merchantability or fitness for any other purpose than that described in the labelling. Helica Instruments' sole obligation is the original user's sole remedy in terms of this warranty to repair or at Helica Instruments' option replace the equipment supplied.

Helica Instruments is not liable for material, proximate, incidental or consequential damages arising out use of the Helica TC equipment. Any modifications, alterations, re-calibrations or abuse of the equipment, or any servicing or repair by anyone other than a Helica or other authorised representative renders a charge and will also affect Helica's Company Liability Insurance.

TECHNICAL SPECIFICATIONS

The Helica Thermal Coagulator is an apparatus that generates an ionised gas plasma beam for use in surgery particularly for soft tissue coagulation.
It consists of two parts:

1. A power generator and control unit with associated Helium gas supply, providing an alternating current at fixed frequency of 60 kilo Hertz with a power range of 2 to 33 watts and a controlled low pressure gas supply.

2. An application probe to supply Helium gas and power to the application point.

As a requirement of the Medical Device Directive 93/42/EEC Annex IX, and with guidance from MEDDEV 2.4/1 Rev 9 (June 2010) Helica have classified their products as follows:
The Helica Thermal Coagulator is considered a Class IIb Medical device and is assessed against that classification.
The Helica Probes Family are considered a Class IIa Medical device and is assessed against that classification.

The instrument produces an ionised gas plasma beam in a low-pressure controlled Helium gas flow at the open end of an application tube (probe). This creates a corona-type flame (plasma beam) issuing from the open end of the probe with high electron temperature but low molecular temperature of about 20°C. When the probe end is brought close (within 3mm) to a capacitive surface such as human tissue, the corona type flame (plasma beam) changes to an arc discharge flame with a temperature of approx. 800°C.

The inert Helium gas flow in which the discharge takes place protects the area of discharge and minimises oxidation.

The power unit is standard for all applications.

Isolation from the mains supply is achieved by disconnecting the appliance coupler.

The probe consists of a tube carrying the Helium with a supply wire enclosed. The diameter and design of the probe varies, with different lengths of probe, different designs of end and different diameters of tubing for a variety of applications.

The recommended helium gas cylinder is approximately 2200 litres. This provides about 10 hours continuous operating time for typical flow rates for open and laparoscopic surgery.

Input:

Helium gas - Medical Grade at 20psi or 1.5 bar
Electrical supply - 115-230VAC, 50/60Hz, 2A

Output:

2 – 33 watts Peak voltage 1200 volts

Physical dimensions: W= 25cm L=40cm H= 11cm
Weight of TC: ~5kg

OPERATING & STORAGE CONDITIONS

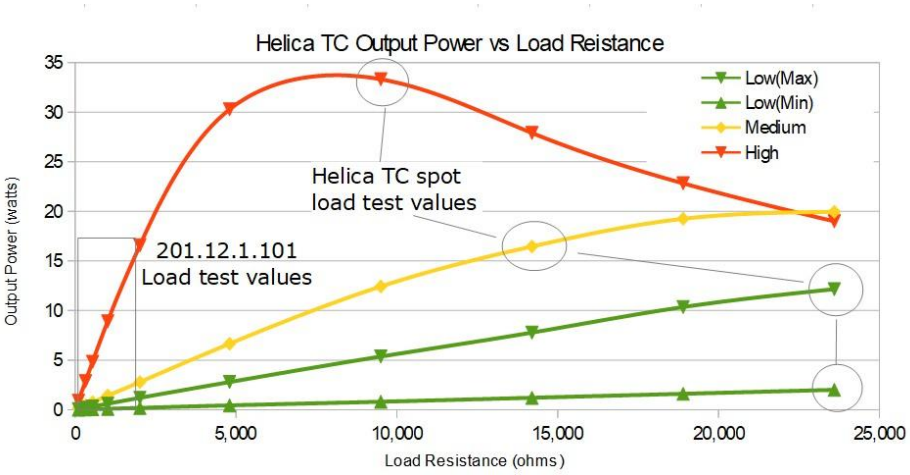
Use Conditions:

Temperature Range:
8-40°C
Humidity Range:
<75%
Pressure Range:
~100kPa

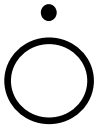
Storage Conditions

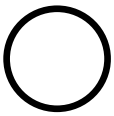
Temperature Range:
8-40°C
Humidity Range:
<75%
Pressure Range:
~100kPa

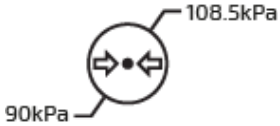
POWER OUTPUT DATA

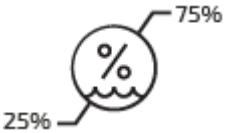


EXPLANATION OF SYMBOLS

	Type BF applied part complying with IEC 60601-1
	Consult instructions for use
	Caution
	Batch code
	Catalogue number
	Do not reuse
	Notified Body
	Sterilised using Ethylene oxide
	Variability in steps
	Variability
	Off (only for part of the equipment)

	Manufacturer
	Date of manufacture
	Use by date
	Do not resterilise
	Do not use if packaging is damaged
	Keep dry
	Serial Number
	Non ionising radiation
	Off (power disconnection from the mains)
	On (power connection to the mains)
	On (only for part of the equipment)

	Neutral Plate Grounding Symbol
	Risk of Overbalance
	Storage Pressure Range
	Packaging Fragile

	Warning
	European Representative
	Storage Temperature Range
	Storage Humidity Range

ELECTROSURGICAL PATIENT PLATE

Preparation

Choose a well vascularised convex site near the surgical area, but not closer than about 20cm.
Avoid scar tissue, bony prominences, excess hair (shave if necessary), the ECG electrodes and places where fluids may pool, as improper site selection may cause electro surgical burn.

Application

Remove backing film and apply the plate to the patient. Make sure that it sticks well over the whole surface to ensure adequate contact with the skin.
Secure cable clamp into the plate tab.
Following surgical procedure, remove plate slowly to avoid skin trauma.

Warnings

1. A patient plate must be fitted, the instrument will not work unless the cable or adaptor is plugged into the socket on front panel via the magnetic connection.

2. Do not use electrode gel.

3. The entire area of the neutral plate should be reliably attached to the patient's body and as close to the operating field as possible.

4. Do not reposition plate after initial application.

5. Do not reuse plate.

6. Do not let the patient come in contact with earthed metal parts or which have an appreciable capacitance to earth (for example operating table supports etc.)

7. Use anti-static sheeting where necessary.

8. Insert dry gauze to prevent skin-to-skin contact.

9. Monitoring electrodes should be placed as far as possible from surgical electrodes when they are used simultaneously on the same patient.

10. Needle monitoring electrodes are not recommended.

11. Monitoring systems incorporating high frequency current limiting devices are recommended.

12. Surgical electrode cables should be positioned so that they are not in contact with the patient or other leads and cables. Temporarily unused active electrodes should be stored so that they are isolated from the patient.
13. The output power selected should be as low as possible for the intended purpose.

14. Neutral Plates and its connections should be checked before selecting a higher output power.

15. Flammable anesthetics or oxidizing gases should be avoided unless these agents are sucked away.

16. Highest HF peak voltage is calculated to be 1200V AC.

17. For surgical procedures where the HF current could flow through parts of the body having a relatively small cross- sectional area, the use of bipolar techniques may be desirable in order to avoid unwanted coagulation.

18. The use of flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen should be avoided if a surgical procedure is carried out in the region of the thorax or the head, unless these agents are sucked away. Non- flammable agents should be used for cleaning and disinfection wherever possible.

    Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application of HF surgery. There is a risk of pooling of flammable solutions under the patient or in body depressions such as the umbilicus, and in body cavities such as the vagina. Any fluid pooled in these areas should be mopped up before HF surgical equipment is used. Attention should be called to the danger of ignition of endogenous gases. Some materials for example cotton, wool and gauze, when saturated with oxygen may be ignited by sparks produced in normal use of HF surgical equipment.

19. For patients with cardiac pacemakers or other active implants, a possible hazard exist because of interference with the action of the pacemaker may occur, or the pacemaker may be damaged. In case of doubt, approved qualified advice should be obtained.

20. Please note that the instructions for use of diathermy & laser equipment should be followed as per their own operating instructions manual and following their normal procedures. The Helica TC should not be considered the same as diathermy or laser.

21. If the sterile packaging for the single use probe is damaged discard single use probe.

HELICA TC ACCESSORIES

Regulator & Hose
Mediline S400
Regulator
Specification sheet on page 30

REM Blue Footswitch
Specification on page 31
Male connector

HERGA footswitch

SKINTACT Dispersive plate/Neutral plate cable
SKINTACT NEK300D

Magnetic Patient Plate Connector Rosenberger RoDI® Rosenberger Diagnostic Interface Cable assembly, Male Magnetic Circular Connector

MEC mains cable

Helica TC stand – please clean with damp cloth and leave to dry naturally

REGULATOR INFORMATION
FOOTSWITCH INFORMATION

MEC
MEDICAL LIMITED

Single Stage Regulators

SPECIFICATION SHEET

MEC Medical Single Stage Regulators in a wide range of configurations and gases with International inlet connections available.

The MEC range of Single Stage Medical Regulators are CE approved and are manufactured under strict BS EN ISO 13485quality design and management systems at our UK production facility. Designed and manufactured to fully comply with BS EN ISO 10524-1 and The Medical Devices Directive 93/42/EEC.

Features

- Bullnose, Pin Index, Nut & Stem and International inlet connections available
- Nickel plated inlet and outlet connections at either bottom or side entry
- Robust brass body construction for prolonged service life
- Serial number and replacement date, clearly marked on rear of regulator.

Specification

Inlet Pressure	200 bar maximum
Delivery Pressure	4 bar pre-set
Maximum Flow Rate	~50 l/min
Available for a range of medical gases	Oxygen
	Air
	Nitrous Oxide
	Entonox

CE

REM – Zethon - Footswitch

The Footswitch conforms to Iso 9001:2000, EN46001 (CE marking), ISO 13485

ELECTRICAL

Switch

Rating : This should be equal to or better than 24 Volts @l/2 Amp. (Machine Spec.).
Life : Minimum 100,000 operations
Contacts : Momentary, Laser cut Stainless circumferential ring contacts
Force : Actuation force should be between 10-50 Newton's (Pedal Pressure)

CABLE SPEC.

Single Unit: 3 Core Artic Grade P.V.C. Ins. 1.5mm^2 30/0.25 Insulated to 8.5mm O/D
Double Unit: 3 Core 3183Y
British Standard BS 6500:1994, Table 16.
Artic Grade cable has been chosen for Blue & Yellow units for colour coding and improved flexibility over standard cable. The outer Insulation should be quite thick to prevent any chance of damage through abrasion & wear/ tear.

CLASSIFICATION OF DEVICE

Refer to Annex 9 93/42/EEC for exact classification.

The product has been reclassified in June 2004 by the MHRA and is therefore deemed class 1.

This supercedes recommended classification change by the Expert Working Group at the European Commission has reclassified all Diathermy & Cautery equipment, see SGS file, Letter Dr Simon Richards 19/1/00.

BRITISH STANDARD REQUIREMENT (Standards maintained on file)

BS EN 60601-1	BS 5724 General Requirements for Safety 2nd Edition 2000-12
BS EN 60601-2-2	BS 5724 Specification for high frequency surgical equipment
BS EN 6500	Mains Voltage cable standards

Footswitch cable has to be durable and able to handle a minimum of 24 Volts @ 0.5 amp.

Environment

44.6aa Ingress of liquids into switching parts of Footswitches & Fingerswitches
Refer to the standard and enclose test results if applicable.

Actuation Force- Footswitches

56.11 The force required to activate the switch must not be less than 10 N or > SON over an area of 625mm^2

Order Code	REM Code	Description	Colour	Material	Generator	Length
101427	REM – 050R	Mono, single	Blue	Rubber	Eschmann 300/400	3m

6226 Foot Switches

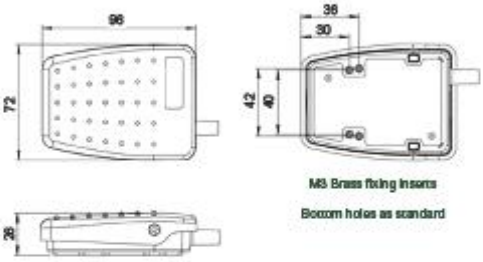
herga Technology Ltd

For IPX7/IPX8 single & double pole switching UL Approved / IEC 60601-1

- Low profile, rear hinged switch designed for improved user comfort
- All plastic construction with raised tread pattern and anti-slip pad
- Versatile and innovative design make it an ideal product for OEM use
- Switches designed to meet medical, industrial/office/commercial standards
- Option for customers to fit own cable

c US

Reference dimensions



General specifications

Standards/approvals	Footswitch: EN 60950, EN 60601-1:2006, UL 60601-1:2005, ANSI/AAMI ES60601-1:2005/(R)2012, CSA-C22.2 No 60601-1:14, UL File № E353500
Degree of protection	EN 60529 IPX7 (IPX8 upon request)
Connection method	Stripped cable cores or connector of your choice
Electrical rating	Max. 3A 24V AC/DC
Contact configuration	SPST N/O, SPST N/C, SPCO, DPST N/O, DPST N/C, DPCO

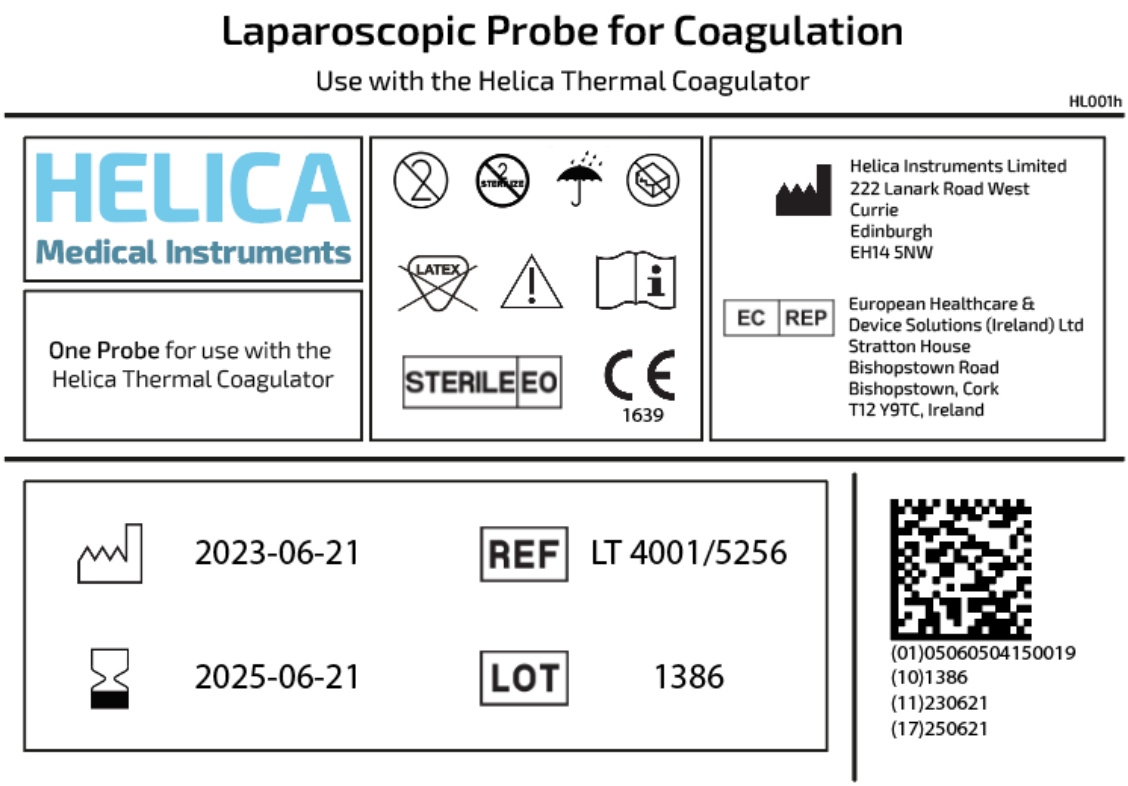
Operating temperature range	-20 to +60°C
Body material	Thermoplastic
Weight	0.14Kg (including cable)
Additional information	Customized versions available (logos, cordsets, colours, guards)

VARIOHM HOLDINGS

6226 Foot Switch 15.07

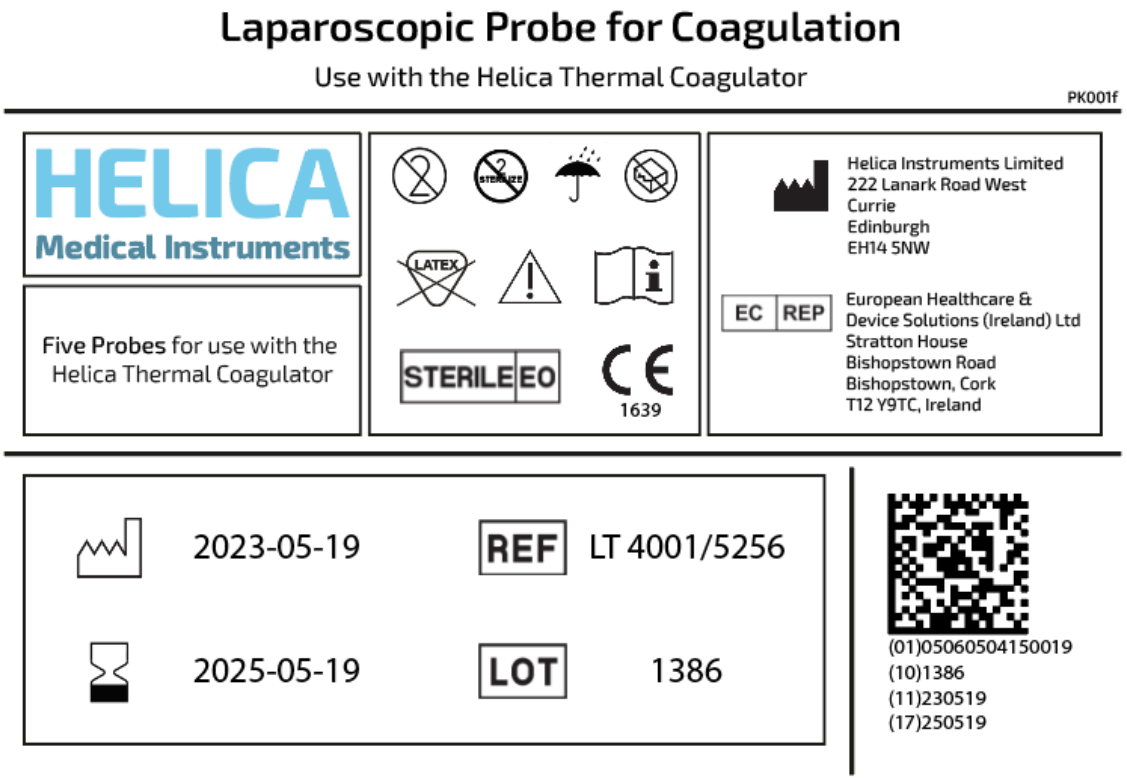
LABELS IN USE WITH PROBES & PACKAGING

Example of front label of probe packaging



PROBE OUTER BOX INFORMATION

Example of the outer probe box



CYLINDER GASES – HELIUM

A Member of The Linde Group

SAFETY DATA SHEET
Helium, compressed
Issue Date:
Last revised date:
16.01.2013
07.09.2016
Version: 1. 3

Available from: www.boconline.co.uk/en/sheq/safety-data-sheets/index.html