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Instruction for Use of Electrosurgical Pencils

CE 0123

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Table of Contents

1. WRARNING

1. This product cannot be adequately cleaned and/or sterilized by the user in order to facilitate safe reuse, and is therefore intended for single use. Attempts to clean or sterilize these devices may result in a bioincompatibility, infection, or product failure risks to the patient.
2. Do not modify this device without authorization of the manufacturer.
3. Do not remove the active electrode from the surgical site while energy is activated. Unintended tissue effect or burns may occur.
4. Place active accessories in a holster or in a clean, dry, non-conductive and highly visible area away from the patient or user when not in use. Inadvertent contact with the patient may result in burns. Contact with drapes or linens may cause a fire. Unintended tissue effect or burns may occur.
5. Due to concerns about the carcinogenic byproducts (such as tissue smoke plume and aerosols), protective eyewear,filtration masks, and effective smoke evacuation equipment should be used.
6. Fire/Explosion Hazard The following substances contribute to increased fire and explosion hazards in the operating room:

- Oxygen-enriched environments
- Oxygen agents, such as N20 atmospheres

– Verify all anesthesia circuit connections are leak free before and during use of electrosurgery.
– Verify endotracheal tubes are leak free and that the cuff seals properly to prevent oxygen leaks.
– If an uncuffed tube is in use, pack the throat with wet sponges around the uncuffed tube.
– If possible, stop supplemental oxygen at least one minute before and during use of electrosurgery.
– When using electrosurgery in the same room with gases or flammable substances, prevent pooling of fluids and the accumulation of gases under surgical drapes or near the surgical site.

- Alcohol-based skin prepping agents and tinctures

– Activate the electrosurgical unit only after vapors from skin prep solutions and tinctures have dissipated.

- Naturally occurring flammable gases (such as methane) that may accumulate in body cavities.

7. **Fire Hazard** The sparking and heating associated with electrosurgery can provide an ignition source.
8. Connect adapters and accessories to the electrosurgical unit only when the energy is off. Failure to do so may result in an injury or electrical shock to the patient or operating room personnel.

9. Do not activate the instrument when not in contact with target tissue, as this may cause injuries due to capacitive coupling with other surgical equipment.
10. Activate the electrosurgical unit only when it is ready to deliver electrosurgical current and the active tip is in view. Injury to operating room personnel or the patient may result.
11. Aspirate fluid from the area before activating the instrument. Conductive fluids (for example, blood or saline) in direct contact with or in close proximity to an active electrode may carry electrical current or heat away from target tissues, which may cause unintended burns to the patient.
12. Prior to increasing the intensity, check the adherence of the return electrode and its connections. Apparent low output or failure of the device to function correctly at the normal operating settings may indicate faulty application of the return electrode or poor contact in its connections.
13. Do not use electrosurgery in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N20) and oxygen) or in close proximity to volatile solvents (such as ether or alcohol), as explosion may occur.
14. Both oxygen (O2) and nitrous oxide (N2O) support combustion. Watch for enriched O2 and N2O atmospheres near the surgical site, especially during head and neck surgery. Enriched O2 atmospheres may result in fires and burns to patients or surgical personnel.
15. Do not place instruments near or in contact with flammable materials (such as gauze or surgical drapes). Instruments that are activated or hot from use may cause a fire.
16. The CSY series pencil is not a fluid-removal device.
17. Tissue buildup (eschar) on the tip of an active electrode poses a fire hazard, especially in oxygen-enriched environments, such as in throat or mouth procedures. Eschar plus high oxygen may create embers. Keep the electrode clean and free of all debris.
18. Always use the lowest power setting that achieves the desired surgical effect. Use the active electrode for the minimum time necessary in order to reduce the possibility of unintended burn injury.
19. Loss of safe contact between the neutral electrode and the patient will not result in an alarm unless a compatible monitoring return electrode is used.
20. Before use, examine the electrosurgical unit and accessories for defects. Do not use cablesor accessories with damaged (cracked, burned, or taped) insulation or connectors. This may be done visually under magnification or with a high voltage insulation testing device.
21. Before attempting any surgical operation, the physician should be trained in the principles of relevant surgery including patient selection, surgical techniques, current medical literature, and management of complications and hazards of electrosurgery in that procedure.
22. Please read all information carefully prior to using the device. Failure to follow all applicable instructions may result in serious surgical consequences.

23. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

24. 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.

25. 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 Electrosurgical Pencils, including cables specified by the MANUFACTURER. Otherwise, degradation of the performance of this equipment could result.

2. Intended Use/Intended users

2.1 Intended Use

The Electrosurgical Pencil is used for cutting and coagulation to remove tissue and control bleeding by using high frequency during electrosurgical with a specified Electrosurgery Unit.
CY series and CSY series can remove the smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system.

2.2 Intended users

This product should only be used by, or under the supervision of, Medical professionals that have been trained in electrosurgery

3. Indication / Contraindications:

3.1 Indications:

The applied products are indicated for use in tissue cutting and coagulating as required or encountered in General surgery, thoracic surgery, gynecology surgery where the tip of the product can be accessable easily.

3.2 Contraindications:

a) The applied products are contraindicated where patients with pacemakers as the use of the ESU may interfere with the pacemaker's circuitry.
b) The applied products are contraindicated where patients with automatic implantable cardioverter/ defibrillator (ACID).
c) The use of this device is contraindicated in patients with the following conditions: Acute inflammation, pregnancy, malignancy, unresolved/ unaccessible adnexal pathological.

d) The applied products are contraindicated for use in tubal ligation procedure.

3.3 Intended patient population

The Electrosurgical pencils is intended to be used with any patient requiring the utilization of electrosurgery.

3.4 Clinical benefits

The electrosurgical devices used in combination with compatible generators and accessories, provide monopolar energy for cutting and coagulating soft tissue. The coagulators with smoke evacuation have significantly less incidence of postoperative bleeding compared to alternative technologies, such as sutures, ultrasonic dissectors, monopolar devices without smoke evacuation, and bipolar forceps.

3.5 Intended medical conditions

The device is not intended to treat a specific disease but rather is used as tools in any number of operations. The evolution of such devices has resulted in the expansion in the range of electrosurgery. The device provides a means to cut and coagulate soft tissue during a surgical procedure while smoke evacuation (smoke function is only applicant to CY and CSY series).

4. Product Introduction

The Electrosurgical Pencils are used for the cutting and coagulation of soft tissue and have a conductive cable which is designed for use with high frequency surgical generator (Electrosurgical unit).

The hand pieces are made of plastic with two buttons or a rocker switch toward the distal part of the pencil in the case of the hand-controlled pencils. One button or switch is to control the cutting mode, CUT, of the ESU while the other controls the coagulation mode, COAG.

The applied electrosurgery, monopolar, is the emitance of the high frequency alternating current, HFAC, from the diathermy via an active electrode through the patient's body tissues and then returned back to the diathermy machine via a dispersive electrode (patient return pad).

4.1 Operation Environment

The Electrosurgical pencil is intended for use in the Professional healthcare facility

environment
Ambient temperature: 10-30 ℃
Relative humidity: 20-80%
Atmospheric pressure: 700-1060 hPa

Precaution：This product is prohibited from being used in MRI scan environment.

4.2 Classification:

- Regulation(EU)2017/745:Class IIb, according to Rule 9
- Degree of protection against electric shock:Type BF Applied part
- Electric shock protection grade: The electric shock protection grade of the product depends on the connected high frequency electrosurgery (generator) apparatus.

Please refer to the user manual of the designated high frequency apparatus.

4.3 Inspection before using

- Before using, the Electrosurgical Pencil with which this device will be used must be carefully and thoroughly inspected for cleanliness and proper function to determine that it is appropriate for patient use. Please refer to the manual supplied with the Electrosurgical Pencil.
- Open the Electrosurgical Pencil and confirm that there are no loose and kinked wires.
- With the gloves on, run your fingertips gently over the entire length of the insertion portion to check for any sign of crushed surfaces, excessive bends, broken areas, or other damages.

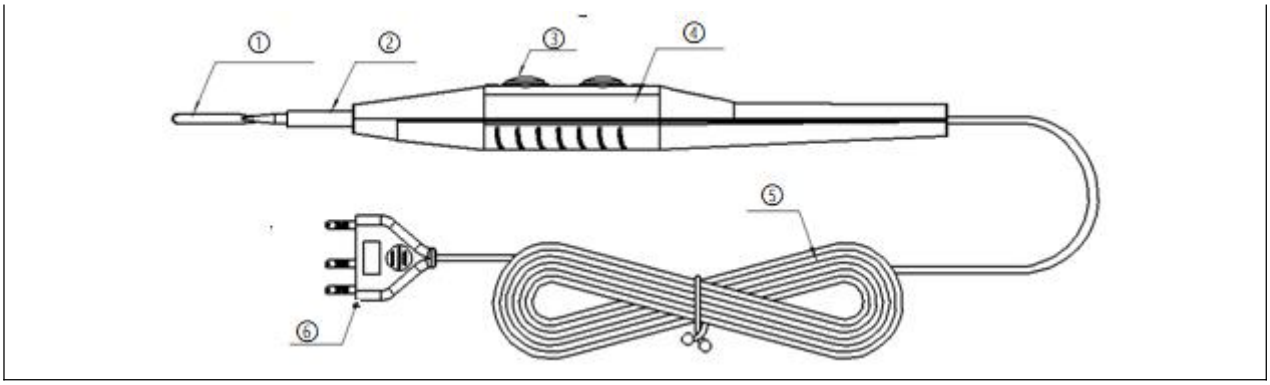
4.4Product description

4.4.1 CS series description

REF	CS1001-1	handle control，telescope blade, cable length:3m
REF	CS1001-2	handle control，telescope blade, cable length:5m

- For use with maximum peak voltage of 2200 volts.
- Model of operation: Continuous Operation. Operation time within 1 min.
- The electrode adopts Stainless materials, Connecting sleeve and Shell adopt PVC
- The cable adopts PVC sheathed flexible wire.
- Shelf-life: Following relevant storage requirements of this IFU, the shelf-life of this disposable electrosurgical pencil can be guaranteed as 3 years after relevant accelerating aging and stability tests verification.

CS serial is mainly composed by: ①Telescope electrode. ②Scalable insulated sleeve③buttons, ④holder⑤cable⑥Plug



4.4.1.1 Compatibility

- The CS series electrosurgical pencil plug includes a standard three-prong plug that fits into VIO 300S HF Electrosurgical Unit manufactured by ERBE Elektromedizin GmbH with the following technical parameters:

- CE marked
- Comply with EN60601-2-2
- Maximum cut output: 300 Watt at 500 Ohm;
  Maximum Coag output: up to 200 Watt;
- NE monitoring system: NESSY or equivalent system
- Frequency: 350 kHz.
- CQM(MAX): 120Ohm.
- Contact with the manufacturer if you have any needs
- To ensure its compatibility with the Electrosurgical Pencilss, the following measures will be taken:
- Monitoring (CFDA EU FDA) obtained from open channels (CFDA EU FDA) conducts a search and confirmation of whether there is any change per quarter on the generators manufactured by ERBE Elektromedizin GmbH, CONMED Corporation, Johnson & Johnson and 3M company.
- Inquiry from the official website of the generator manufacturer, see if the public instructions and product performance data have been updated
- Collect the product's instructions or other information from the customer to confirm whether there is a change;
- If the change occurs, the company will evaluate whether to re-verify whether it needs to be compatible;
- Do compatibility verification on VIO 300S HF Electrosurgical Unit manufactured by ERBE Elektromedizin GmbH within 5 years.

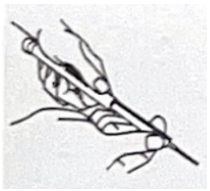
  CAUTION:

  The temperature may reach 60 ˚C during operation.

  Always connect the Electrosurgical Pencils to the designated Electrosurgical Unit. The use of devices that is incompatible with this device may lead to injury of the patient or damage of the device.

4.4.1.2 Operation

1. Peel open the pouch. Be careful not to allow the package or any of its contents to come in contact with the non-sterile portions of the packaging. To aid in transfer of sterile product, the electrosurgical pencils has been packaged in an open transfer bag.
   Precaution
   The transfer bag is not a sterile barrier.
2. Remove and discard the plastic tip protector, and ensure the electrode is fully inserted.
   Notice
   See the images below for proper extension and retraction of the device

	To extend or retract the electrode, hold the insulated sleeve and gently slide the electrode in or out.

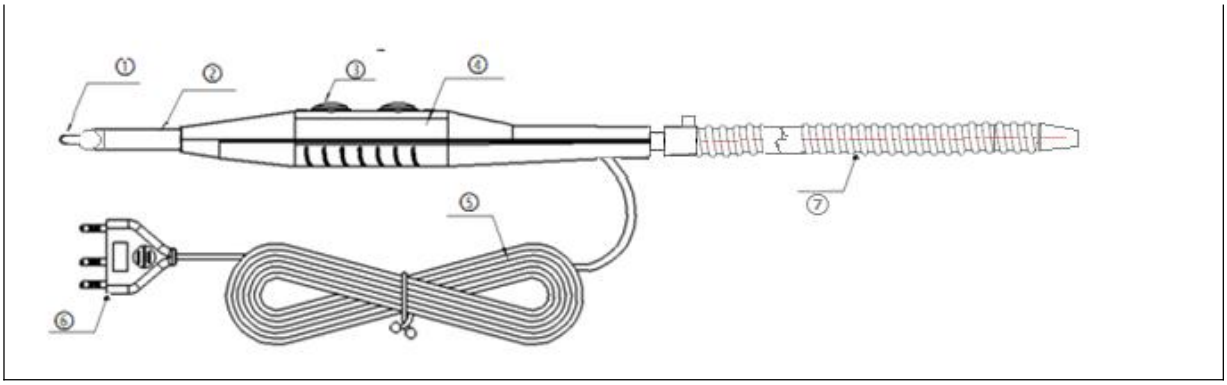
3. Plug the pencil's 3-prong power-cord connector into a compatible electrosurgical generator's monopolar accessory port. Ensure the port's receptacles match the plug's pin configuration.
4. Turn on the generator and the smoke evacuation unit..
5. Test the cut mode by pressing (CUT) switch and the coagulation mode by pressing (COAG) switch. Check that the electrosurgical unit responds correctly.

Electrosurgical Generators

- Check the manufacturer's instructions for proper setup, use, and troubleshooting of the electrosurgical generator. Refer to the manufacturer's precautions before use.

4.4.2 CY series description

REF	CY1001-1	handle control，smoke evacuation,fixed blade, cable length:3m
REF	CY1001-2	handle control，smoke evacuation,fixed blade, cable length:3m
– For use with maximum peak voltage of 2200 volts. – Model of operation: Continuous Operation. Operation time within 1 min. – The electrode adopts Stainless materials, Connecting sleeve and Shell adopt PVC – The cable adopts PVC sheathed flexible wire. – Shelf-life: Following relevant storage requirements of this IFU, the shelf-life of this disposable electrosurgical pencil can be guaranteed as 3 years after relevant accelerating aging and stability tests verification.		
CY serial is mainly composed by: ①electrode with smoke nozzle. ②Insulated sleeve③ buttons, ④holder⑤cable⑥Plug⑦somke tube		



4.4.2.1 Compatibility

- The CY series electrosurgical pencil plug includes a standard three-prong plug that fits into VIO 300S HF Electrosurgical Unit manufactured by ERBE Elektromedizin GmbH .technical parameters refer to 4.4.1.1:
- Compatible with a wide variety of smoke evacuation systems using the included, or optional smoke-hose adapters, smoke evacuation connector size : ϕ 10mm.

4.4.2.2 Operation

1. Peel open the pouch. Be careful not to allow the package or any of its contents to come in contact with the non-sterile portions of the packaging. To aid in transfer of sterile product, the electrosurgical pencils has been packaged in an open transfer bag.

   Precaution

   The transfer bag is not a sterile barrier.
2. Connect the tubing provided with the CY electrosurgical pencil to the smoke evacuation system or other appropriate vacuum source.
3. Remove and discard the plastic tip protector
4. Plug the pencil's 3-prong power-cord connector into a compatible electrosurgical generator's monopolar accessory port. Ensure the port's receptacles match the plug's pin configuration.
5. Increase smoke evacuation by positioning the smoke nozzle close to the point of the tissue interaction.
6. Turn on the generator and the smoke evacuation unit..
7. Test the cut mode by pressing (CUT) switch and the coagulation mode by pressing (COAG) switch. Check that the electrosurgical unit responds correctly.

Electrosurgical Generators

- Check the manufacturer's instructions for proper setup, use, and troubleshooting of the electrosurgical generator. Refer to the manufacturer's precautions before use.

Smoke Evacuator

- Use of an adapter may be required for 10 mm tubing to connect to the smoke

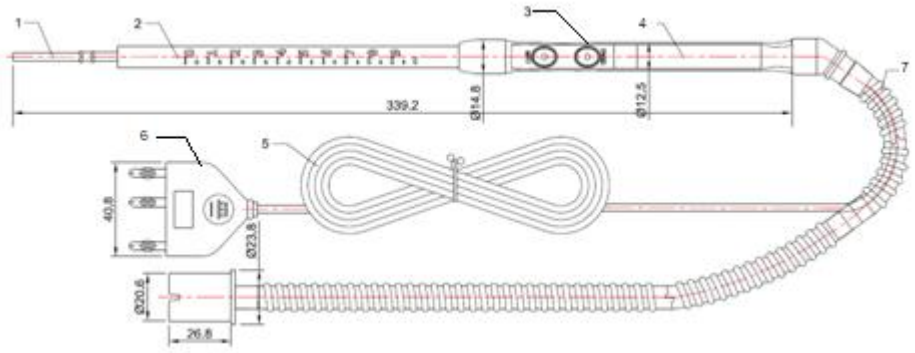
evacuator.

4.4.3 CSY series description

REF	CSY1001-1	handle control,smoke evacuation,telescope blade,cable length:3m
REF	CSY1001-2	handle control,smoke evacuation,telescope blade,cable length:5m

- For use with maximum peak voltage of 2200 volts.
- Model of operation: Continuous Operation. Operation time within 1 min.
- The electrode adopts coated Stainless materials, Connecting sleeve and Shell adopt ABS plastic.
- The cable adopts PVC sheathed flexible wire.
- Shelf-life: Following relevant storage requirements of this IFU, the shelf-life of this disposable electrosurgical pencil can be guaranteed as 3 years after relevant accelerating aging and stability tests verification.

CSY serial is mainly composed by: ① electrode with Tefloncoating. ② Telescope smoking nozzle ③buttons, ④holder⑤cable⑥Plug⑦somke tube



4.4.3.1 Compatibility

- The CY series electrosurgical pencil plug includes a standard three-prong plug that fits into VIO 300S HF Electrosurgical Unit manufactured by ERBE Elektromedizin GmbH .technical parameters refer to4.4.1.1:
- Compatible with a wide variety of smoke evacuation systems using the included, or optional smoke-hose adapters, smoke evacuation connector size : ϕ22.5mm.

4.4.3.3 Operation

1. Peel open the pouch. Be careful not to allow the package or any of its contents to come in contact with the non-sterile portions of the packaging. To aid in transfer of sterile product, the electrosurgical pencils has been packaged in an open transfer bag.

Precaution

The transfer bag is not a sterile barrier.

2. Connect the tubing provided with the CSY electrosurgical pencil to the smoke evacuation system or other appropriate vacuum source.

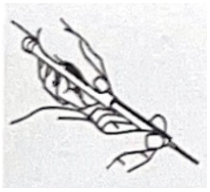
Precaution

Ensure proper placement of return electrode.

3. Remove and discard the plastic tip protector, and ensure the electrode is fully inserted.

Notice

See the images below for proper extension and retraction of the device

	To extend the smoke telescoping smoke nozzle, hold the hand piece and gently slide the telescoping smoke nozzle in or out.

4. Plug the pencil's 3-prong power-cord connector into a compatible electrosurgical generator's monopolar accessory port. Ensure the port's receptacles match the plug's pin configuration.
5. Increase smoke evacuation by positioning the telescoping nozzle close to the point of the tissue interaction.
6. Turn on the generator and the smoke evacuation unit..
7. Test the cut mode by pressing (CUT) switch and the coagulation mode by pressing (COAG) switch. Check that the electrosurgical unit responds correctly.

Electrosurgical Generators

- Check the manufacturer's instructions for proper setup, use, and troubleshooting of the electrosurgical generator. Refer to the manufacturer's precautions before use.

Smoke Evacuator

- Use of an adapter may be required for 10 mm tubing to connect to the smoke evacuator.

4.4.4 Important Notice

- Wipe the electrode often with moist gauze or other material.
- The CSY series electrosurgical pencil has been shipped with apremium electrode that has a coating to reduce sticking of eschar. Cleaning the electrode with a scratch pad or other abrasive object, scraping with a sharp object, or bending beyond 90 degrees may damage the electrode. If the electrode is damaged, discard it.
- Using coated electrodes at high power settings may cause damage to the coating. If the coating is damaged, discard the electrode. The electrode coating may deteriorate when used with tissue response generators at higher power settings.
- Any serious incident that has occurred in relation to the device should be reported

to the manufacturer and the competent authority of the Member State

5. Precaution

1. The Electrosurgical pencil is shipped with a single-use electrode that is not designed to withstand resterilization. Safely discard after use to prevent injury to hospital personnel.
2. For procedures where visualization may beimpaired, be alert to these potential hazards:

- The electrode tip may remain hot enough to cause burns after the current has been deactivated.
- Inadvertent activation or movement of the activated electrode outside of the field of vision may result in injury to the patient.
- Localized burns to the patient or physician may result from electrical currents carried through conductive objects. Current may be generated in conductive objects by direct contact with the active electrode, or by the active accessory being in close proximity to theconductive object.

6. After Surgery

6.1 Dismantling

1. After the procedure, turn off the smoke evacuation unit and electrosurgical generator.
2. Disconnect the pencil assembly from the generator and smoke evacuation unit.

6.2 Disposal

Dispose of the entire pencil assembly (pencil,electrode, tubing and power cord) in accordance with your facility's policy forbiohazards and sharps. Do not resterilize.
Replace and dispose all items in accordance with your institutional protocol.

Warning

This product cannot be adequately cleaned and/or sterilized by the user in order to facilitate safe reuse, and is therefore intended for single use. Attempts to clean or sterilize these devices may result in a bioincompatibility, infection, or product failure risks to the patient.

7. Product maintenance

7.1 Cleanness & Sterile Status

It's a sterilized disposable product produced in 100,000 class clean room to control the cleanness and bio-burden of the final product.
After primary packaging in separate plastic & permeate paper pouch with sealing process in clean room, the final product is sterilized by EO gas to ensure a sterile status.

Before the product releasing, the EO residue is ensured to below 10mg/Kg.

7.2 Transport and Storage

Do not store in direct sunlight, at extreme temperature, or in high humidity, to ensure the sterile primary package status will not be jeopardized.
Make sure the packed equipment will not be pressured by surrounding objects.
The stored product shall be placed in a dry and clean place and also follow additional requirements of the warehouse.

- Temperature requirement in warehouse: -5 ~ 40 °C.
- Humidity requirement in warehouse: 20 ~80 %RH.
- Atmospheric pressure: 700-1060 hPa

8. EMC Declaration

This product should not be used adjacent to or stacked with other unit. If adjacent or stacked use is necessary, this product should be observed to verify normal operation in the configuration in which it will be used.

8.1 Electromagnetic emissions

The Electrosurgical pencil is intended for use in the Professional healthcare facility environment specified below. The customer or the user of Electrosurgical pencil should assure that it is used in such an environment. *NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A)*

Phenomenon	Compliance
Conducted Emission CISPR 11	Group 1 Class A
Radiated RF Emission CISPR 11	Group 1 Class A

8.2 Electromagnetic immunity (for all EQUIPMENT and SYSTEMS)

The CP1001 Electrosurgical pencil is intended for use in in the Professional healthcare facility environment specified below. The customer or the user of the CP1001 Electrosurgical pencil should assure that it is used in such an environment.

Phenomenon	Professional healthcare facility environment
Electrostatic discharge(ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM fields EN 61000-4-3	3V/mrms Test Frequency: 80MHz-2.7GHz Modulation: 80% AM at 1 kHz
Proximity fields from RF	Location: Both horizontal and vertical antenna orientations; Test four

<table>
<tr><td>wireless communications equipment
IEC 61000-4-3</td><td>sides (Front, Back, Left, Right).
See the RF wireless communication equipment table in "Recommended minimum separation distances".
<table>
<tr><td colspan="5">Table 9 from IEC 60601-1-2:2014+AMD1:2020</td></tr>
<tr><td>Test frequency (MHZ)</td><td>Band[a)] (MHZ)</td><td>Service [a)]</td><td>Modulation</td><td>IMMUNITY TEST LEVEL(v/m)</td></tr>
<tr><td>385</td><td>380 to 390</td><td>TETRA 400</td><td>Pulse modulation 18HZ</td><td>27</td></tr>
<tr><td>450</td><td>430 to 470</td><td>GMRS 460,FRS 460</td><td>FM ±5Khz deviation 1Khz sine</td><td>28</td></tr>
<tr><td>710</td><td rowspan="3">704 to 787</td><td rowspan="3">LTE Band 13,17</td><td rowspan="3">Pulse modulation 217HZ</td><td rowspan="3">9</td></tr>
<tr><td>745</td></tr>
<tr><td>780</td></tr>
<tr><td>810</td><td rowspan="3">800 to 960</td><td rowspan="3">GSM 800/900,TETRA 800, iDEN 820, CDMA 850, LTE Band 5</td><td rowspan="3">Pulse modulation 18HZ</td><td rowspan="3">28</td></tr>
<tr><td>870</td></tr>
<tr><td>930</td></tr>
<tr><td>1720</td><td rowspan="3">1700 to 1990</td><td rowspan="3">GSM 1800;CDMA 1900; GSM 1900;DECT; LTE Band 1.3.4.25;UMTS</td><td rowspan="3">Pulse modulation 217HZ</td><td rowspan="3">28</td></tr>
<tr><td>1845</td></tr>
<tr><td>1970</td></tr>
<tr><td>2450</td><td>2400 to 2570</td><td>Bluetooth, WLAN, 802.11 b/g/n, RFID 2450,LTE Band 7</td><td>Pulse modulation 217HZ</td><td>28</td></tr>
<tr><td>5240</td><td rowspan="3">5100 to 6800</td><td rowspan="3">WLAN 802.11 a/n</td><td rowspan="3">Pulse modulation 217HZ</td><td rowspan="3">9</td></tr>
<tr><td>5500</td></tr>
<tr><td>5785</td></tr>
</table></td></tr>
<tr><td>Rated power frequency magnetic fields
IEC 61000-4-8</td><td>30 A/m
Test Frequency: 50Hz or 60Hz</td></tr>
<tr><td>Proximity magnetic fields
IEC 61000-4-39</td><td>8A/m, CW for 30kHz.
65A/m, 2,1kHz Pulse modulation for 134,2kHz.
7,5A/m, 50kHz Pulse modulation for 13,56MHz</td></tr>
<tr><td>Electrical
fast transient/burst
IEC 61000-4-4
(Only applicable for cables of sterile Electrosurgical Pencil)</td><td>± 2 KV (Input AC power port)
± 1 kV (SIP/SOP port)
100 kHz repetition frequency</td></tr>
<tr><td>Conducted disturbances induced by RF fields EN 61000-4-6
(Only applicable for cables of sterile Electrosurgical Pencil)</td><td>3 V rms in Test Frequency: 150 kHz- 80 MHz
6 V rms in ISM bands between 0,15 MHz and 80 MHz, Dwell Time: 3s
Modulation: 80% AM at 1 kHz</td></tr>
</table>

WARNING: The Operator should not use the system and should inform the customer service, if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES

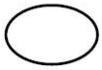
WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally."

WARNING: 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: 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 Electrosurgical pencils, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."

9. Icon table

	Caution
	BATCH CODE
	DO NOT RESTERILIZE
	Do not re-use
	Used by
	Catalogue number
	Date of manufacture
	Authorized Representative in the E.U.
	Manufacturer
	Temperature Limits
	Humidity limitation

	Atmospheric pressure limitation
	Keep away from sunlight
	Consult Instruction for Use
	Do not use if package is damaged
	Medical device
	WEEE information for the disposal or recycling of waste EEE Check with your local Authority or retailer for recycling advice
	Product Trade marking
	STERILIZED USING ETHYLENE OXIDE
	CE Marking
	Unique Device Identifier
	Importer
	Single sterile barrier system