CATHAY MANUFACTURING CORP.

Version No.: B/6
File No.: CE-DNE-0201
Released on: Nov 19th, 2025

Instruction for Use

Disposable Neutral Electrodes

Content

1. Product introduction

1.1. Product name

Disposable Neutral Electrodes

1.2. Brief introduction

This Disposable Neutral Electrode for adult, paediatric and infant patients with conductive adhesive hydrogen-gel is used as neutral reference during electrosurgical procedures, and provide a return path for the high frequency current with such a low current density in the body tissue that physical effects such as unwanted burns are avoided.

1.3. Intended use

Disposable Neutral Electrode adheres to the patient over its entire surface and connected to electrosurgical units. Its purpose is to complete the electrosurgical circuit between the generator, the active electrode, and the patient in monopolar electrosurgery.

1.3.1. Intended users

Medical professionals that have been trained in electrosurgery.

1.3.2. Target patients

The product is applied to the patient who need electrosurgical procedures. Specific product types are applied to different weight of patient population.

1) For the pediatric type: use only on pediatric of 5~15 Kg weight.
2) For the Infant type: use only on infant of less than 5Kg weight.
3) For adult and transverse adult types: use only on adult patients more than 15kg weight.

1.3.3. Indications

Patient undergoing Monopolar electrosurgery

1.3.4. Contraindications

1) The applied products are contraindicated where patients with pacemakers as the use of the ESU may interfere with the pacemaker's circuitry.
2) The applied products are contraindicated where patients with automatic implantable cardioverter / defibrillator (ACID).

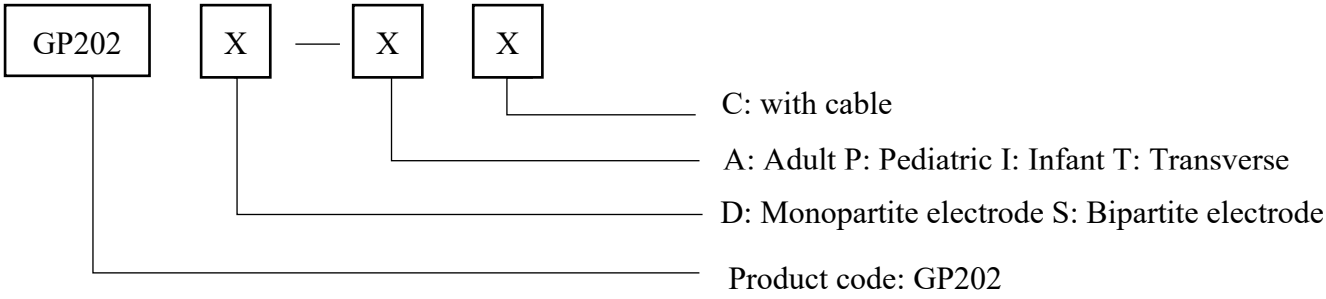
1.3.5. Clinical benefits

Form a current circuit in monopolar electrosurgery to assist in completing

electrosurgery.

1.4. Product model

1.4.1. Model code



Note： D means Monopartite electrode; S means Bipartite electrode. The bipartite electrode has an alarm function when the impedance of CQM system is over 120Ohm while the Monopartite electrode does not.

1.4.2. Illustration

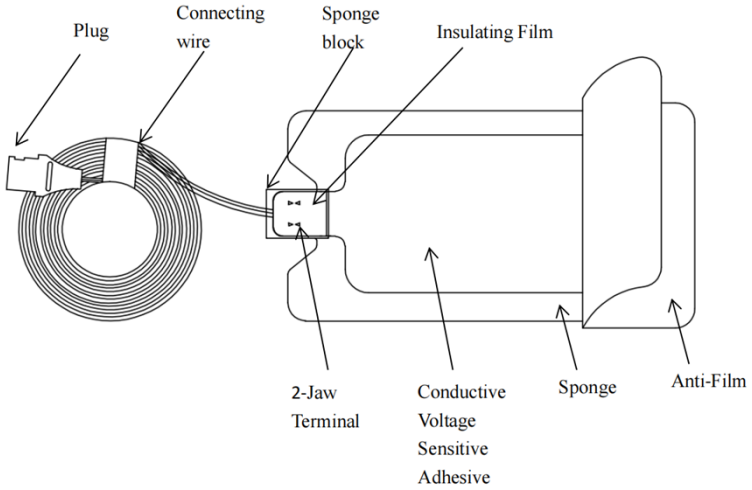


Figure 1 Neutral electrode with cable (Monopartite)

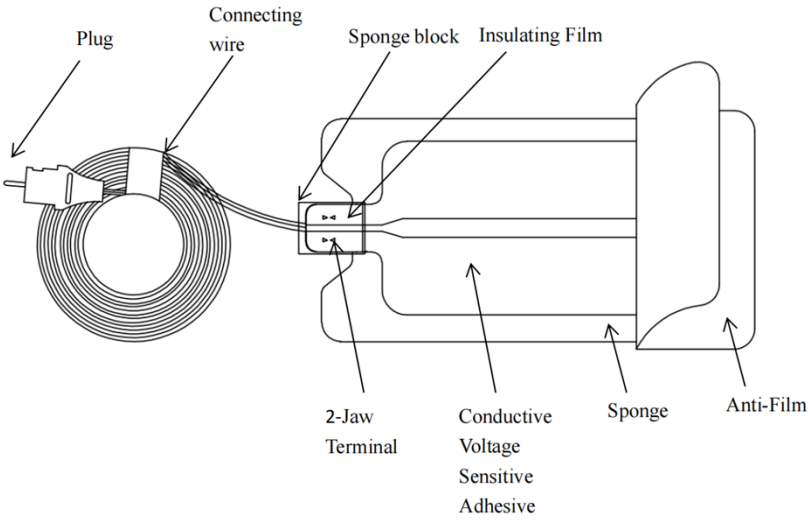


Figure 2 Neutral electrode with cable (Bipartite)

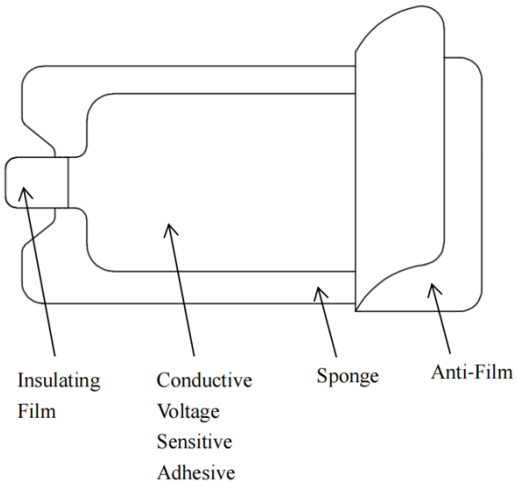


Figure 3 Neutral electrode without cable (Monopartite)

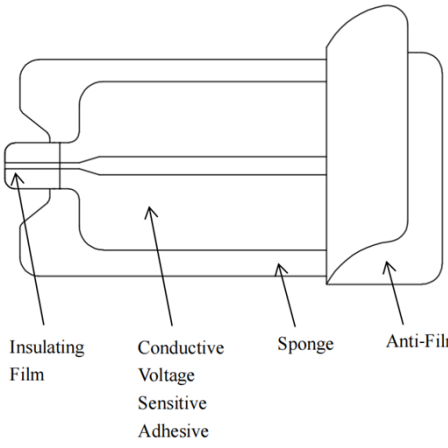


Figure 4 Neutral electrode without cable (Bipartite)

Figure 5 Plug difference between Bipartite and Monopartite

REM-plug: The Rem plug of the neutral electrode cable enables the high-frequency electrosurgery host recognize that the neutral electrode is Bipartite.	Non Rem-plug: The Non Rem-plug of the neutral electrode cable enables the high-frequency electrosurgery host recognize that the neutral electrode is Monopartite.
	

1.4.3. Specification

Table 1: Models without cable

No.	Type	Model	Main structure
1	Adult type	GP202S-A	insulating film, conductive voltage sensitive adhesive, sponge, anti-film
2		GP202D-A	
3	Pediatric type	GP202S-P	
4		GP202D-P	
5	Infant type	GP202S-I	
6		GP202D-I	
7	Transverse adult type	GP202S-T	
8		GP202D-T	

Table 2: product with cable

No.	Type	Model	Main structure
1	Adult type	GP202S-AC	insulating film, conductive voltage sensitive adhesive, sponge, anti-film, cable (sponge block, connecting wire, plug)
2		GP202D-AC	insulating film, conductive voltage sensitive adhesive, sponge, anti-film, cable (sponge block, connecting wire)
3	Pediatric type	GP202S-PC	insulating film, conductive voltage sensitive adhesive, sponge, anti-film, cable (sponge block, connecting wire, plug)
4		GP202D-PC	insulating film, conductive voltage sensitive adhesive, sponge, anti-film, cable (sponge block, connecting wire)
5	Infant type	GP202S-IC	insulating film, conductive voltage sensitive adhesive, sponge, anti-film, cable (sponge block, connecting wire, plug)
6		GP202D-IC	insulating film, conductive voltage sensitive adhesive, sponge, anti-film, cable (sponge block, connecting wire)
7	Transverse adult type	GP202S-TC	insulating film, conductive voltage sensitive adhesive, sponge, anti-film, cable (sponge block, connecting wire, plug)
8		GP202D-TC	insulating film, conductive voltage sensitive adhesive, sponge, anti-film, cable (sponge block, connecting wire)

1.4.4. Accessories

None.

1.5. Combination with HF Electrosurgical Unit

The Disposable Neutral Electrodes are compatible with electrosurgical generators which meet the requirements as follows:

- CE marked
- Comply with EN60601-2-2
- Maximum cut output: 300 Watt at 500 Ohm
- Maximum Coag output: up to 200 Watt
- Electrosurgical generator with contact quality monitoring system (CQM) (such as VIO 300S by ERBE Elektromedizin GmbH)
- Frequency: 350 kHz
- CQM(MAX): 120Ohm

Contact with the manufacturer if you have any needs.
Always connect Disposable Neutral Electrodes 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.

1.6. Warning

- No modification of this equipment is allowed.
- Not intended for use in conjunction with flammable agents.
- Not intended for use in oxygen rich environment.
- For PATIENTS with electrically conductive implants, hazards may exist due to concentration or re-direction of HF currents.
- Before attempting any surgical operation, the Medical professionals 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.
- Please read all information carefully prior to using the device. Failure to follow all applicable instructions may result in serious surgical consequences.
- For connections and correct functioning, follow the instructions for use supplied by the manufacturer of the ESU unit and pencil being used.
- This is a disposable product, do not re-use. Re-use of the product may lead to cross-infection or fall off of electrodes.
- Do not re-position or cut the plate, do not add gel.
- Do not use the product in case:

  - The packaging is not complete
  - There are evident damages on the plate or on the connection cable
  - Gel is not homogeneous or is dry
- During procedure, always select the lowest energy level which is possible. If the coagulation ability of the electrode is lower than usual don't increase the high frequency output before making following controls:
  - Correct positioning of the grounding plate (perfect adherence on the entire surface)
  - The correct connection of the cables and their connectors.
  - The correct activation of the starting keys (hand-switch of foot control)
  - That there is no damage to the insulation of the cables.
  - That the electrode is not dirty.
- If the patient is 're-positioned' check the contact of the plate with the patient's skin and the cable connections.
- The entire area of the Disposable Neutral Electrodes should be reliably attached to a suitably prepared and appropriate area of the patients' body.
- The patient should not come into contact with metal parts which are earthed or which have an appreciable capacitance to earth.
- The application of the Disposable Neutral Electrodes and its connections should be checked before selecting a higher output power.
- 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.
- 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 Disposable Neutral Electrode, including cables specified by the MANUFACTURER. Otherwise, degradation of the performance of this equipment could result.
- 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.
- If any serious incident occurs, it should be reported to the manufacturer and competent authority of the Member State where the user and/or patient is located.
- The VIO 300S HF Electrosurgical Unit will alarm if the impedance of CQM system is over 120Ohm(MAX) or a differential impedance limit not to 40% when using Bipartite Electrode.
- Improper use Disposable Neutral Electrode may lead to electrosurgical burns.

- Do not use electrosurgical units that are not listed as suitable in the declaration of conformity of the Disposable Neutral Electrode.
- Disposable Neutral Electrode is capable of standing a duty cycle of 25% for any mode, defined as 10 seconds active and 30 seconds inactive. Do not activate for long periods. The temperature under the neutral electrode increases when activated for long periods or when activated for several long periods in quick session. The patient is at risk of accidental tissue damage. In this case, make sure that there are sufficient cooling periods without activation. For more information, also refer to the User Manual of the electrosurgical generator.
- If the electrosurgical unit is equipped with a contact quality monitor (CQM, e.g. "NESSY", "EASY", "REM"), always use bipartite electrode. Using bipartite electrodes with a CQM system automatically monitors contact to the patient's skin (this is not possible when using a monopartite electrode).
- The Disposable neutral electrode can only be used in high current mode with a maximum current of 1100mA. Higher current may cause patient burn.

1.7. Cautions

a) Current should flow in parallel to the body surface and never pass through the thorax. The patient must be placed on a dry and perfectly isolated surface. The patient must be kept isolated from conductive parts and the operating table must be earthed. Use dry gauzes to avoid that different areas of the body come into contact with each other.

b) Do not place the electrode on wound and scars, near bone projections, very adipose tissues, close to metallic prosthesis or to ECG electrodes or on areas, where liquids can flow.

c) Do not place the electrode on areas, where it can be subjected to pressure or under patient’s weight.

d) Shave the selected area, clean carefully and skim in order to remove eventual remaining of cream or cosmetics. Dry the selected area.

e) Do not use inflammables during the patient’s preparation. Do not use alcoholic substances or benzoine tincture. Eventual shave remaining or hair can cause burns.

f) If any serious incident occurs, it should be reported to the manufacturer and competent authority of the Member State where the user and/or patient is located.

2. Operation

2.1. Operation environment

The product operates in the following environment:

- Temperature: +10℃ to+40℃
- Relative Humidity: 30-75％

- Atmospheric Pressure: 700 to 1060 hPa

2.2. Application site

Apply the neutral electrode to an appropriate vascularized area of muscle mass site (thigh, buttocks and upper arm is recommended, see figure 6). In any case the application site must be on an intact skin surface.

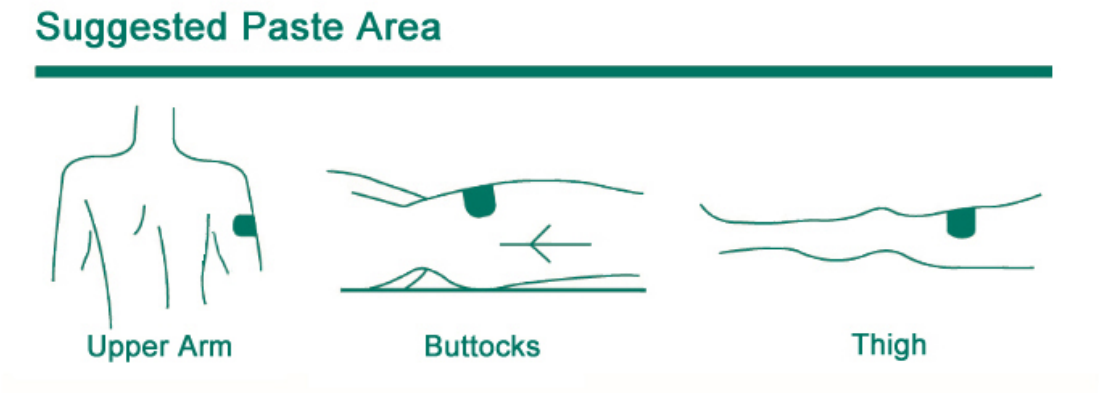


Figure 6 Recommended paste area

For the pediatric type: recommended to be applied on thigh, upper arm, and buttocks.
For the infant type: recommended to be applied on thigh, upper arm, and buttocks.
For the adult type: recommended to be applied on thigh, upper arm, and buttocks.
For the Transverse adult type: recommended to be applied on buttocks.

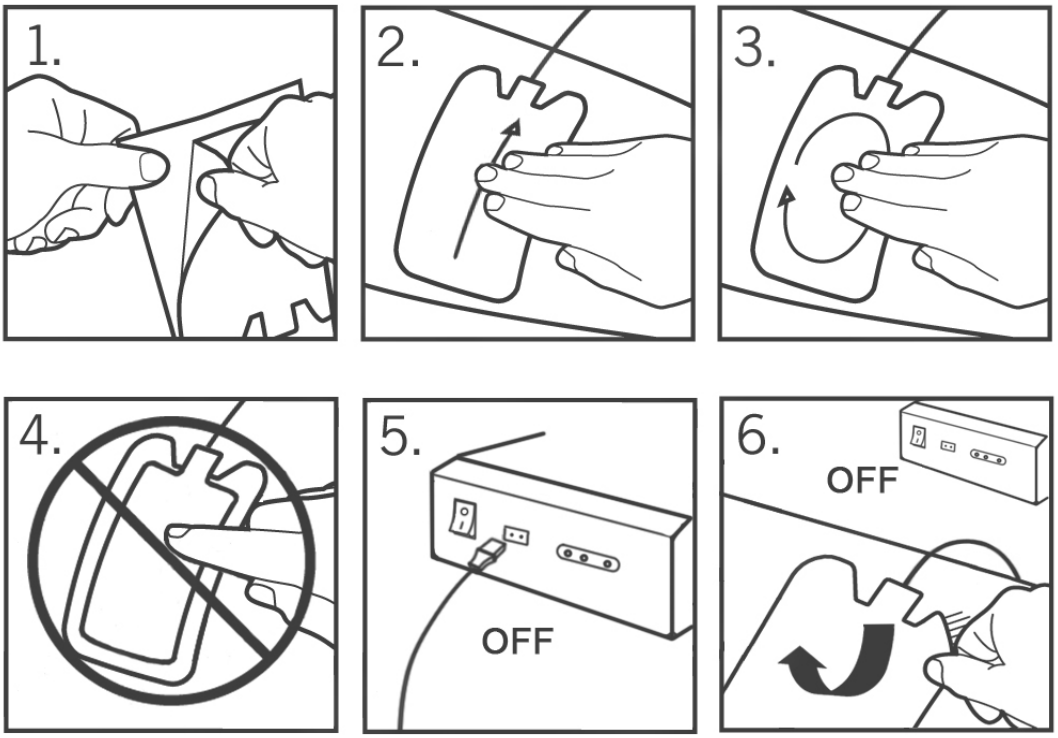
2.3. Preparation

I. Select an appropriate site in close proximity to the surgical site. Avoid placement on bony prominence, skin lesions or folds, tattoos, scars, metal prosthesis or near ECG electrodes and cables. Do not apply where fluid may pool.
II. Always use largest size electrode per the patient weight guidelines which can be properly applied to the site: see section 1.3.2.
III. Prepare the skin at the application site according to facility protocol. If no protocol exists, clip excess hair at application site, clean and disinfect area to remove oils, lotions, etc., and allow to dry thoroughly.
IV. Do not open package until ready to apply pad to skin. Inspect the pad and cable. Do not use if product is expired or apparently damaged. Check expiration date on package.

2.4. Use method

1. Peel off the protection film and place the plate on the prepared area.
2. Apply one end of Disposable Neutral Electrode and smoothly press to the other end.

3. Smooth down the Disposable Neutral Electrode edges after application to ensure that entire surface of the electrode is in contact with the patient's skin.
4. Avoid excessive contact between fingers and glue part. Do not touch the glue.
5. Connect the cable to the high-frequency generator which is in OFF state.
6. At the end of the procedure, disconnect the connections after turning off the generator; take hold of a corner of the Disposable Neutral Electrode and pull gently to slowly remove the product.



2.5. Disposal of waste

The used Disposable Neutral Electrode should be disposed following local government regulation or clinical institutions requirement.

3. Shelf life

2 years

4. Transport and storage

Do not store in direct sunlight, at extreme temperature, or in high humidity.
The stored product shall be placed in a dry and clean place and also follow additional requirements of the warehouse.
Temperature requirement during transport and storage: -5 ~ 40 °C.

Relative Humidity during transport and storage: 20~80 %RH.

5. 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.

5.1. Electromagnetic emissions

The Disposable Neutral Electrode is suitable for use in the specified electromagnetic environment (s) and it has meets the following standard's emission requirements.

NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Phenomenon	Profession healthcare facility environment
Conducted and radiated RF emissions	CISPR 11, Group 1, Class A

5.2. Electromagnetic immunity (for all EQUIPMENT and SYSTEMS)

The Disposable Neutral Electrode is suitable for use in the specified electromagnetic environment (s) and it has meets the following immunity test levels. Higher immunity levels may cause the Disposable Neutral Electrode's essential performance lost or degraded.

Phenomenon	Basic EMC standard or test method	Professional healthcare facility environment
Electrostatic discharge	IEC 61000-4-2	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air
Radiated RF EM fields	IEC 61000-4-3	3V/m 80MHz-2.7GHz 80%AM at 1kHz
Proximity fields from RF wireless communications	IEC 61000-4-3	See the RF wireless communication equipment table in "Recommended minimum separation distances".

equipment		
Conducted disturbances induced by RF fields	IEC 61000-4-6	PATIENT coupling PORT: 3 V in 0.15 MHz - 80 MHz 6 V in ISM radio bands between 0.15 MHz and 80 MHz, 80 % AM at 1kHz

5.3. Electromagnetic immunity (for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING)

The Neutral Electrode is intended for use in the electromagnetic environment specified below. The customer or the user of the Neutral Electrode should assure that it is used in such an environment.

Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF EN 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Radiated RF EN 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

			$d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.5 GHz where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures,
objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur
radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic
environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the
location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

5.4. Recommended separation distances

Nowadays, many RF wireless equipments have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. The Disposable

Neutral Electrode has been tested with the immunity test level in the below table and meet the related requirements of EN 60601-1-2:2015+A1:2021. The customer and/or user should help keep a minimum distance between RF wireless communications equipment and the Disposable Neutral Electrode as recommended below.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3,	Pulse modulation 217Hz	2	0.3	28
1845						
1970						

		4, 25; UMTS				
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

6. Definitions of Signs

	Product Trade marking
MD	Medical device
CE 0197	Comply with Regulation (EU) 2017/745
	Caution
NON STERILE	Non-sterile
	Do not re-use
	Refer to instruction manual/booklet

	Do not use if package is damaged
	Temperature Limits
	The product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.
	Manufacturer
	Authorized Representative in the E.U.
	Model number
	Batch code
	Date of manufacture
	Use-by date
	Unique device identifier
	Importer

Manufacturer: Cathay Manufacturing Corp.
Address: No.328, Xishe Road, Maogang Town, Songjiang Area, Shanghai 201607, P. R. China
Website: http://www.cathaymed.com
electric IFU: http://www.cathaymed.com/products008.htm

E.U. Representative: Llins Service & Consulting GmbH
Address: Heinigstrasse 26, 67059 Ludwigshafen, Germany