Instructions for Use
(Single-use electrosurgery electrode)

1. Product Name
: LAPALEX-G

2. Model Name

No.	Model Name	Hook Type	Remark
1	GYG-LC5×350	L-HOOK	Basic type
2	GYG-LC5×450	L-HOOK	
3	GYG-JC5×350	J-HOOK	
4	GYG-JC5×450	J-HOOK	
5	GYG-SC5×350	SPATULA	
6	GYG-SC5×450	SPATULA	
7	GYG-LCB5×350	L-HOOK	Suction/Irrigation Button change type
8	GYG-LCB5×450	L-HOOK	
9	GYG-JCB5×350	J-HOOK	
10	GYG-JCB5×450	J-HOOK	
11	GYG-SCB5×350	SPATULA	
12	GYG-SCB5×450	SPATULA	

3. Intended Purpose
: A single-use electrosurgery electrode has application in minimally invasive procedures to facilitate tissue dissection, coagulation, irrigation, and fluid evacuation through a common trocar sleeve.

3.1. Clinical Benefit
- Improvement of satisfaction as the cosmetic outcome aspect
- Reduction of post-operative pain
- Increase of safety outcome than conventional multi-port laparoscopic surgery

4. Intended User

Job	Doctor
Age	Not relevant
Gender	Not relevant
Education	Professional doctor license
Knowledge	Knowledge of laparoscopic surgery
Language	User is able to read the manual in international language.
Experience	Experience of laparoscopic surgery

5. Intended Patient Population

Age	Adult
Weight	Not relevant
Gender	Not relevant
Nationality	Not relevant
Language	Not relevant
Medical condition	A patient requiring laparoscopic surgery

6. Symbol Description

No.	Symbol	Title of symbol	Description of symbol	Reference
1		Reference number	Indicates the product model.	ISO 15223-1:2021
2		Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2021
3		Medical device	Indicates the item is a medical device	ISO 15223-1:2021
4		Unique device identifier	Indicates a carrier that contains Unique Device Identifier information	ISO 15223-1:2021
5		Date of manufacture	Indicates the date when the medical device was manufactured	ISO 15223-1:2021
6		Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC	ISO 15223-1:2021
7		Follow instructions for use	Indicates the need for the user to consult the instructions for use	ISO 15223-1:2021
8		Caution	To signify a general warning	ISO 15223-1:2021
9		Authorised representative in the European Community	Indicates the authorized representative in the European Community/European Union	ISO 15223-1:2021
10		CE Marking	"CE" which literally means "European Conformity"	ISO 15223-1:2021
11		Temperature Limit	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1:2021
12		Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.	ISO 15223-1:2021

No.	Symbol	Title of symbol	Description of symbol	Reference
13		Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.	ISO 15223-1:2021
14		WEEE Marking	The product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.	Annex IX of 2012/19/EU
15		Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	ISO 15223-1:2021
16		Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.	ISO 15223-1:2021
17		Type BF applied part	Type BF applied part	IEC 60601-1:2005+ AMD1:2012 + AMD2:2020
18		Use-by date	Indicates the date after which the medical device is not to be used.	ISO 15223-1:2021
19		Fragile-handle with care	Indicates a medical device that can be broken or damaged if not handled carefully	ISO 15223-1:2021
20		This way up	Indicates that the packaged product has been moved to the correct vertical position.	ISO 15223-1:2021
21		Keep dry	Indicates medical devices that require protection from moisture.	ISO 15223-1:2021
22		Do not use if package is damaged and consult instructions for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information NOTE 1 This symbol can also mean “Do not use if the product sterile barrier system or its packaging is compromised”. NOTE 2 For products that do not have instructions for use, the recommendation to consult them does not	ISO 15223-1:2021
23	℞ only	Prescription Use	Indicates the prescription use in accordance with 21CFR801.15 (c)(1)(i)(F) and 21CFR801.109(b)(1)	21CFR801.109(b)(1)

7. Precautions and Warnings

- Disposable. Do not reuse.
- Please check the product packaging carefully before use. If the product packaging is damaged, the product can no longer be used.
- Please check the marking on the sterilization packaging box. A “red” mark means that this product has not been sterilized with ethylene oxide and cannot be used directly in hospitals, and a “blue” mark means that it has been sterilized with ethylene oxide.
- Please check the product's expiration date before use. The product's expiration date is 3 years, and products that have passed the expiration date cannot be used.
- Do not press the Suction Button and Irrigation Button at the same time.
- Ensure the suction and irrigation lines are connected to their respective connectors. The connectors are differentiated by shape, and the irrigation line is marked with a blue stripe. Connecting the lines incorrectly may result in unintended fluid flow and patient injury.
- This product is a single-use medical device and cannot be reused or re-sterilized after use.
- Dispose of used products in accordance with relevant requirements for hospital equipment waste.
- A physician with specialized knowledge of suction pumps under the guidance of an experienced professional.
- This product should only be used by a physician with specialized knowledge of inhalers under the guidance of an experienced professional.
- The user and/or patient that 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 in which the user and/or patient is established.
- This device shall be used with an electrosurgical unit (ESU) that has been tested, and conforms with its relevant IEC 60601 series of standards including its collaterals, particulars, national deviations and differences. (e.g. IEC 60601-1, IEC 60601-2-2, etc.)
- Do not exceed the output settings specified by the electrosurgical generator manufacturer. Excessive power settings or prolonged activation may result in excessive thermal damage, patient burns, or unintended tissue injury. Always use the lowest effective power setting and minimize activation time. Refer to the instructions for use (IFU) of the electrosurgical generator for detailed guidance on output settings and activation duration.
- Improper setup or use of the electrosurgical generator or return electrode may result in patient burns or injury. For additional instructions on proper use, refer to the instructions for use (IFU) of the electrosurgical generator and return electrode.
- This device is a monopolar electrosurgical instrument. A return electrode (neutral electrode) must be used during operation to prevent patient burns or injury.
- This device is designed for single-use only. Re-using the device may pose serious risks to both patients and users due to technical factors identified by the manufacturer:
  Failure to achieve complete decontamination can lead to cross-infection between patients, potentially causing severe medical conditions such as bacteremia, pneumonia, diarrhea, abdominal pain, and spontaneous bacterial peritonitis.
- Modification of this device is not permitted.
- Do not modify this device without authorization from the manufacturer.
- If this device is modified, appropriate inspection and testing shall be performed to ensure its

continued safe use.

7.1. Contraindication

- These instruments are not intended for contraceptive coagulation of fallopian tissue but may be used to achieve hemostasis following transection of the fallopian tube.
- These instruments are not intended for use when minimally invasive techniques are contraindicated

7.2 Limitation

1) Compatibility Device

The device can be available in all products with suction/irrigation pump and electrosurgical generator on the market.

The device connector (Electrode cable) is designed to be compatible with standard electrosurgical generators.

The device is compatible with irrigation pumps equipped with flexible tubing connectors designed to connect to Luer-lock connectors or barbed connectors (e.g., approximately 6 mm inner diameter).

The device is also compatible with suction pumps equipped with flexible tubing connectors designed to connect to barbed connectors (e.g., approximately 6 mm inner diameter).

However, the size of the connecting tubes or connectors shall be following;

Category	Diameter	Power
Suction	The inner diameter is Ø6	3PIN
Irrigation	Attach to Lure Lock	
Electrode	Ø4	

Category	Specification	
Suction	Vacuum Flow	Max. -480mmHg
	Flow Range	Max. 1.4l/min.
Irrigation	Pressure Range	Max. 300mmHg
	Flow Range	0.1~1.1l/min.
Electrosurgical mode	Cut	Max. 200W
	Coag	Max. 80W
Trocar	Compatible Trocar Minimum/Maximum Diameter	Ø5.5~Ø6

8. Side Effect

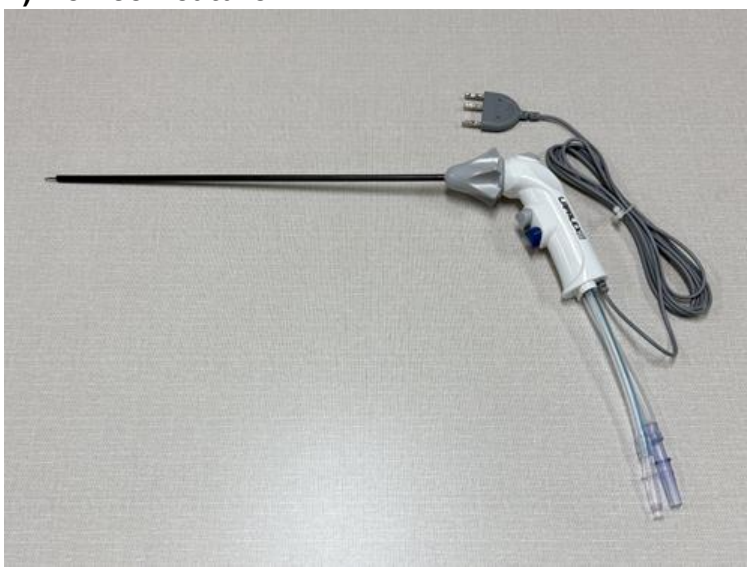
: Complications from thermal injury

9. Device Description

1) General Description

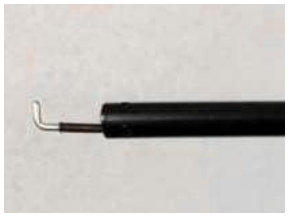
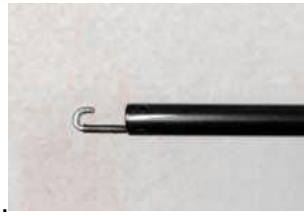
: When high frequency energy from electrosurgery penetrates the electrode through cables and connectors, the high frequency current from the electrode is applied to the human body.
It is used to cauterize tissues using thermally polarized methods that are applied and heat generated by biological resistance.

2) Device Feature

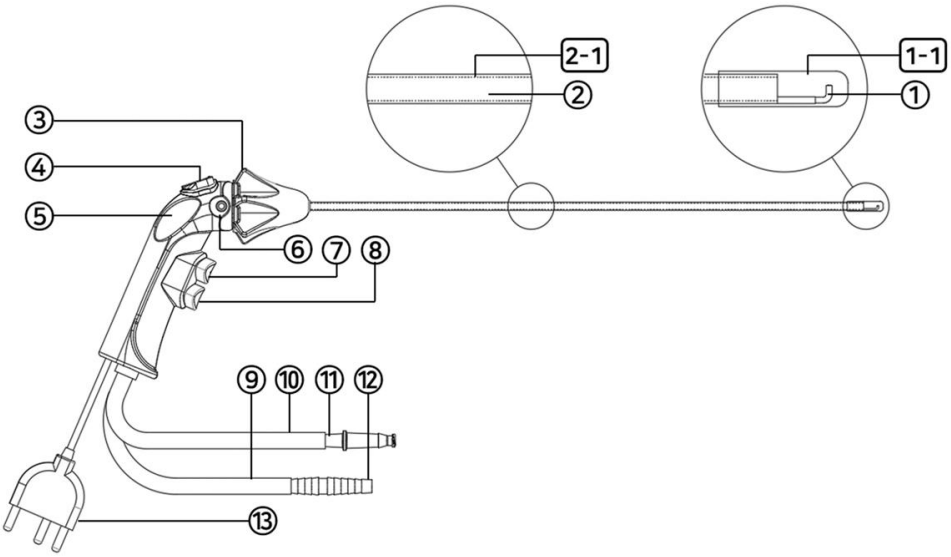


* Suction/Irrigation Button change type
: Only different with buttons location. And others function all same.

* Hook Type

Hook		
		
L-hook	J-Hook	SPATULA

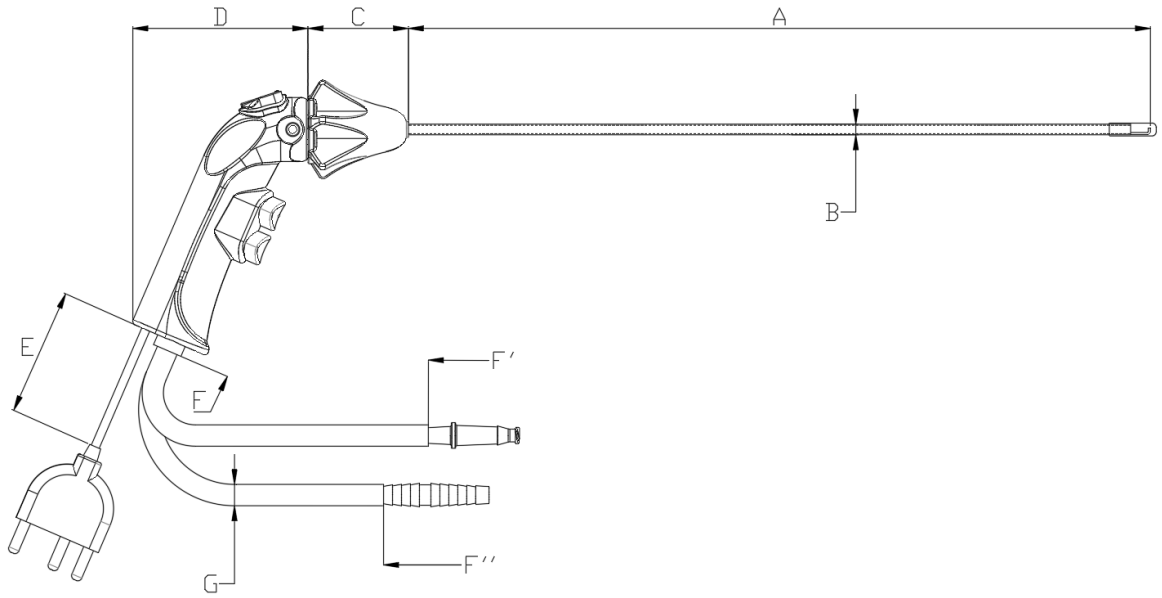
3) Part Description



No.	Name of part	Function	Remark
1	Hook	Tips for Incision and Coagulation of Tissue	L-HOOK J-HOOK SPATULA
1-1	Hook Cover	Caps protecting hooks	
2	Shaft	Pathways for Inhalation and Injection of Liquid	
2-1	Shaft Insulation Cover	Cover to protect shaft current from external exposure	
3	Rotator	Exposure control of hooks and parallel and rotational motion control of shaft	
4	Electrode Button	Buttons for manipulating incision and coagulation	
5	Handle	Handles for Using the Instrument	
6	Assembly Button	When the shaft and handle are detached. Buttons used	
7	Fluid Control Button 1	Button for controlling liquid suction or irrigation. - Basic Type: Suction Button - Suction/Irrigation Button change type: Irrigation Button	
8	Fluid Control Button 2	Button for controlling liquid suction or irrigation. - Basic Type: Irrigation Button - Suction/Irrigation Button change type: Suction Button	
9	Suction Tube	Liquid suction tube	
10	Irrigation Tube	Liquid irrigation tube	
11	Irrigation Connector	Connector to connect to irrigation pump	Connector shape differs from Suction Connector

			(No.12)
12	Suction Connector	Connector to connect to suction pump	Connector shape differs from Irrigation Connector (No.11)
13	Electrode Cable	Cable to Electrosurgery Machine	3 Pin type

4) Dimensions



No	Model Name	Dimensions (mm)							
		A	B	C	D	E	F-F'	F-F"	G
1	GYG-LC5×350	335	ø5	47.3	82	2810	160	120	ø8.5
2	GYG-LC5×450	450	ø5	47.3	82	2810	160	120	ø8.5
3	GYG-JC5×350	335	ø5	47.3	82	2810	160	120	ø8.5
4	GYG-JC5×450	450	ø5	47.3	82	2810	160	120	ø8.5
5	GYG-SC5×350	335	ø5	47.3	82	2810	160	120	ø8.5
6	GYG-SC5×450	450	ø5	47.3	82	2810	160	120	ø8.5
7	GYG-LCB5×350	335	ø5	47.3	82	2810	160	120	ø8.5
8	GYG-LCB5×450	450	ø5	47.3	82	2810	160	120	ø8.5
9	GYG-JCB5×350	335	ø5	47.3	82	2810	160	120	ø8.5
10	GYG-JCB5×450	450	ø5	47.3	82	2810	160	120	ø8.5
11	GYG-SCB5×350	335	ø5	47.3	82	2810	160	120	ø8.5
12	GYG-SCB5×450	450	ø5	47.3	82	2810	160	120	ø8.5

10. How to Use

10.1. Pre-use preparation

1) Read the instructions before use
2) Check the packaging status before use
- Package damage
- Shelf-life period is valid

3) Should be used by doctor or trained specialists to ensure proper use of the instrument.

10.2. Operating method

1) Remove the handle and shaft from the package.
2) Connect the suction line and irrigation line to the liquid line connection part extending from the bottom of the handle.
- The suction and irrigation connectors have different shapes to prevent misconnection.
- The irrigation line is additionally identified by a blue stripe.
- Ensure each line is connected to the correct connector before use.

3) Connect the three-prong connector at the end of the electrosurgical cable to the hand-controlled output part of the electrosurgical device.
4) Use as follows depending on the purpose.
- Electrode Tip Exposure: To adjust the exposure of the electrode tip, slide the shaft rotator handle forward and backward to advance or reverse the shaft cover.

- Electrode Tip Rotation: Turn the shaft rotor handle.

- Liquid suction/irrigation: Press suction button for liquid aspiration (S).
  Press the irrigation button to vent the liquid.(I)
- Using an electrosurgical device: To use the electrode tip, press the electrode button on the handle. Press the Cutting button when cutting tissue, and the Coag button when coagulating tissue.

5) After using the tissue cutting, coagulation, or liquid suction/irrigation function, observe the area to confirm the result.

10.3. How to archive and manage after use

1) Disconnect the product from the electrosurgical device.
2) Since it is a single-use device, dispose it after use.

10.4. Troubleshooting

:

1) Insufficient Irrigation Flow Rate
- Ensure the irrigation line is properly connected to the Irrigation Connector.
- Check for kinking or blockage in the irrigation tubing and correct as necessary.
- Verify that the irrigation pump is operating within the pressure range and flow range recommended by the pump manufacturer.
- If leakage is observed at the connection, disconnect and reconnect the irrigation line securely.
- If the problem persists, discontinue use and replace the device.

2) Insufficient Suction Rate
- Ensure the suction line is properly connected to the Suction Connector.
- Check for kinking or blockage in the suction tubing and correct as necessary.
- If tissue or debris is suspected to be blocking the suction path, activate the irrigation function once to flush the fluid pathway, then resume suction.
- Verify that the suction pump is operating within the pressure range and flow range recommended by the pump manufacturer.
- If leakage is observed at the connection, disconnect and reconnect the suction line securely.
- If the problem persists, discontinue use and replace the device.

3) Insufficient CUT/COAG Performance
- Ensure the electrode cable connector is properly connected to the monopolar output of the electrosurgical generator.
- Ensure the return electrode (patient pad) is properly attached to the patient's skin.

- Check for any visible damage to the electrode cable or connector and discontinue use if damage is found.
- Verify that the electrosurgical generator is operating within the output settings recommended by the generator manufacturer.
- If the problem persists, discontinue use and replace the device.

4) If you have a problem, contact your local dealer.

10.5. Cleaning and disinfection

: The device is single-use device. Do not re-use after cleaning and disinfection.

10.6. Disposal

: Since it is a single-use device, dispose it after use.

The device contains components that are classified as industrial waste, and caution must be exercised when disposing of this product as the disposal of certain components may result in environmental pollution. Do not dispose of this equipment as general industrial or household waste. Ensure that you comply with applicable regulations in your region when disposing of all or part of this product. For more information on waste disposal, contact GAYOUNG Medical Co., Ltd. or an official agency in your region.

11. Specifications

Item	Specification	
Maximum rated accessory voltage	1,000 Vp	
Suction	Vacuum Flow	Max. -480mmHg
	Flow Range	Max. 1.4l/min.
Irrigation	Pressure Range	Max. 300mmHg
	Flow Range	0.1~1.1l/min.
Electrosurgical mode	Cut	Max. 200W
	Coag	Max. 80W
Trocar	Compatible Trocar Minimum/Maximum Diameter	Ø5.5~Ø6
Single use only / Multiple use	Single use device	
Sterilization	Ethylene oxide (EO) GAS Sterilization	
Mode of operation	Continues operation	
Suitability for use in an oxygen rich environment	No suitable	
Applied part	Hook	
Suction		
Environmental Condition	1) Operation Environmental condition ① Ambient temperature: 10℃~40℃ ② Ambient humidity: 30 ~ 75% RH ③ Atmospheric pressure: 70kPa ~ 106kPa 2) Transport Environmental condition ① Ambient Temperature: -25℃ ~ 55℃ ② Ambient Humidity: 10% ~ 90% ③ Atmospheric Pressure: 70kPa ~ 106kPa 3) Storage Environmental condition ① Ambient Temperature: -25℃ ~ 55℃ ② Ambient Humidity: 10% ~ 90% ③ Atmospheric Pressure: 70kPa ~ 106kPa	

12. Electromagnetic Compatibility (EMC)

This device is intended for use in professional healthcare facility environments, such as hospitals and operating rooms.
This device is designed to be in compliance with IEC 60601-1-2, which contains electromagnetic compatibility (EMC) requirements for medical electrical equipment. The limits for emissions and immunity specified in this standard are designed to provide reasonable protection against harmful interference in a typical facility.
The system complies with the applicable essential performance requirements in IEC 60601-1 and 60601-2-2. Results of immunity testing show that the essential performance of the system is not affected under the test conditions described in the following tables.
The essential performance of this device is to deliver HF energy for cutting and coagulation and to maintain suction/irrigation functions when used as intended with compatible electrosurgical equipment.

⚠	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. · 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 device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

- **Electromagnetic Emissions**

This device is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic Environment – Guidance
Conducted Emissions at Mains Power Ports (CISPR 11)	Group 1, Class A	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Conducted Emissions at Telecommunication Ports (CISPR 11)	N/A (Does not apply because no IP is assigned)	The device has no telecommunication ports.
Radiated Electric Field Emissions (CISPR 11)	Group 1, Class A	The device is suitable for use in industrial areas and hospitals. If used in a residential environment, it may not provide adequate protection to radio communication services.
Harmonic Current Emissions (IEC 61000-3-2)	Class A	The device is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network

		that supplies buildings used for domestic purposes.
Voltage Fluctuations and Flicker (IEC 61000-3-3)	Complies	Mains power quality should be that of a typical commercial or hospital environment.

- **Electromagnetic Immunity**

This device is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.

Immunity Tests	IEC 60601 Test Level	Compliance	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact discharge ±2 kV, ±4 kV, ±8 kV, ±15 kV air discharge	Complies	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF EM fields (IEC 61000-4-3)	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	Complies	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance.
Immunity to proximity magnetic fields (9 kHz to 13.56 MHz)	30 A/m @ 9 kHz 8 A/m @ 13.56 MHz (See IEC 60601-1-2 Table 11)	Complies	Power frequency and proximity magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
Proximity fields from RF wireless communications equipment (IEC 61000-4-3)	Test levels specified in IEC 60601-1-2 Table 9: 27 V/m (385 MHz) 28 V/m (450 MHz) 9 V/m (710, 745, 780, 810, 870, 930 MHz) 28 V/m (1720, 1845, 1970 MHz) 28 V/m (2450 MHz) 9 V/m (5240, 5500, 5785 MHz)	Complies	RF wireless communications equipment should be maintained at a minimum separation distance of 30 cm (12 inches) from any part of the device, including cables.
Electrical fast	±2 kV for AC	Complies	

Immunity Tests	IEC 60601 Test Level	Compliance	Electromagnetic Environment – Guidance
transient / burst IEC 61000-4-4	power supply lines ±1 kV for AC signal lines 100 kHz repetition frequency		Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line-to-line ±0.5 kV, ±1 kV, ±2 kV line-to-ground	Complies	Mains power quality should be that of a typical commercial or hospital environment..
Conducted disturbances induced by RF fields IEC 61000-4-6	3 Vrms (0.15 MHz – 80 MHz) 6 Vrms in ISM bands 80% AM at 1 kHz	Complies	Portable RF communications equipment should be used no closer than the recommended separation distance.
Power frequency magnetic field IEC 61000-4-8	30 A/m 50 Hz and 60 Hz	Complies	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
Voltage dips IEC 61000-4-11	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% UT; 1 cycle 70% UT; 25 cycles (50 Hz) / 30 cycles (60 Hz)	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Voltage interruptions IEC 61000-4-11	0% UT; 250 cycles (50 Hz) / 300 cycles (60 Hz)	Complies	If the user requires continued operation during power interruptions, it is recommended that the device be powered from an uninterruptible power supply (UPS) or battery.

※ Note: This device is not life-supporting equipment.

※ Note: U_T is the A.C. mains voltage prior to application of the test level.

※ Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

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13. Website

Instruction of the safety and performance can be found on the following website

http://www.gymed.co.kr/doc_eng/sub2_2.php