MTR-C1

High frequency surgical unit with Sterile Bi-polar and Non-sterile Mono-polar Electrodes

User Manual

CE 0120

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Please check the related local regulations before using the equipment. The use of the apparatus may not be permitted if it is not in conformity with the related local law.

- Since the system includes industrial waste materials in the composition, an inappropriate disposal of materials can cause environmental pollution. Therefore, do not dispose of the waste along with common industrial or household waste.
- When disposing of the system in whole or in parts, comply with the related regulations of the standing legislation. For waste disposal related matters, consult with IloodaCo.,Ltd. or authorized agent in each region.

How to Use This User Manual

- Purpose of This User Manual

  The purpose of this manual is to make users be fully aware of the structure, installation, manipulation, operation, and maintenance of Secret System.

- Keeping of This User Manual

  This manual must be kept together with the equipment or near the equipment so as that you can refer to it if necessary.

- Expressions Used in This User Manual

The expressions Caution, Note, and Warning as below are used in this manual.

Symbol	Description
	Warning, Consult Accompany Documents
	General mandatory action manual
	General prohibition indication
	Provision of additional information for assisting users.
	User Manual Reference
	Pushing prohibited
CE 0120	Conformite Europeenne Mark

Please check the related local regulations before using the equipment. The use of the apparatus may not be permitted if it is not in conformity with the related local law.

This equipment is a system applicable to the BI POLAR and MONO modes, which a system corresponding to an option may not be specified in this manual, and its performance and screen menu may be different depending on a handpiece option.

Qualification for Using MTR-C1

It is strictly required that this equipment be used only by the doctor qualified for safety handling and use of HF electrosurgical device.
Thus any persons concerned (nurses etc.) except for a doctor holding a license or a certificate on laser device must not use this equipment.

It is recommended that all the relevant people (nurse etc.) including medical staffs complete the training on installation procedure, operating method and potential hazards of Electrical surgical apparatus, Electrical physics, and interactions of tissues and take the respective safety education program according to each country's regulation in addition to Electrical surgical apparatus safety education.

It is also recommended that the doctor wanting to use the Electrical surgical apparatus obtain anapproval required for using it from the relevant authorizing organization in the country.

Intended User profile.

Depending on IEC60601-1-6 standard for proper use of our equipment was described criteria who can use the device. Refer to following.

User	Doctors	Service engineer
Education	- User training - Basic Maintenance training	- User training - Basic Maintenance Training - Professional Maintenance Training
Knowledge	- Experience with Laser treatment and High frequency surgical treatment. - Requirement medical knowledge.	- Expertise for HF technology. - An information message comprehension required.

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Appendix 1. **LABEL and Symbols**

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Chapter 1. Introduction to MTR-C1

1. Apparatus-verification data

1.1 Main Unit

- Product Name: High frequency surgical unit with Sterile Bi-polar and Non-sterile Mono-polar Electrodes
- Model Name: MTR-C1
- Trade name: Secret
- Classification : Class IIb(MDD 93/42/EEC as amended according to the Directive 2007/47/EC)
- Intended use

  High frequency electrosurgical unit with bipolar and sterile electrode(Needle tip) are a device intended to using for thermal coagulation to the tissue by using high frequency.

1.2 Accessories

- Product Name: Sterile Electrosurgical electrode (Needle Tip)
- Model Name: MTR-AC-16, MTR-AC-25, MTR-AC-10, MTR-AC-C-10

2. Supplied ITEMS

The followings are components (accessories) comprised of this equipment

- Main unit: High-frequency surgical unit with electrodes
- Components
  - BI POLAR Hand-piece (H/P 1.0)
  - BI POLAR Hand-piece (H/P 2.0)
  - MONO POLAR Hand-piece
  - MONO POLAR Hand-piece (Pencil type)
  - Return(Neutral) electrode(Optional)
  - Neutral pad(Optional)
  - Active electrode(Optional)
- Accessories
  - Return electrode
  - Power cable
  - Foot switch & cable

- Power key
- Cable holder
- BI POLAR holder
- MONO polar Hand-piece, MONO Polar Holder
- User manual

- Please use the component and accessory with a higher voltage than maximum output voltage of the device.
- Don't use other spare parts except for the spare parts provided by manufacturer.

3. System introduction

The SECRET systems includes the main unit, a Hand-piece equipped with disposable micro-needle electrodes, disposable needle electrodes, footswitch and LCD touch panel.

The RF energy is delivered using disposable needle type electrode. The RF energy is delivered to the target tissue using Bipolar Hand-piece or Monopolar Hand-piece and needle type electrodes, the electrodes being placed in light contact with the epidermis, and target tissue.

Bipolar hand piece, a major function of high frequency operator, creates a path for new drug delivery by directly passing 16 / 25 thin and precise needles with thickness of 25mm through the skin layer and dermis. Operation is done by supplying RF energy to the penetrated needle.

4. General information about MTR-C1

- Type of protection against electric shock**:** Class I Equipment
- Degree of protection against electric shock : Type BF Applied part
- Degree of protection against the ingress of water
  - Main unit : IPX0
  - Foot switch : IP68
- Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- HF electrosurgical electrode(Micro-needle types)
  : E.O gas sterilization, Disposable(Expiration date : 3years)
- Frequently used functions : Auto mode(Using Bipolar Hand-piece with 25pin)
- Operation Condition
  - Operation Temperature : Recommended within 0℃ ~ 40℃
  - Relative Humidity : 10% ~ 75%
  - Atmospheric Pressure : 700 ~ 1060 hPa
  - Maximum Relative Humidity : 10% ~ 80%
- Storage and Transportation

- Temperature Condition : 0℃ ~ 60℃
- Relative Humidity : 10% ~ 90%
- Atmospheric Pressure : 700 ~ 1060 hPa
- Maximum Relative Humidity : 10% ~ 90%

- Explanation of symbols

SN **Serial Number**	LOT Lot number	 Date of Manufacture
 Caution, consult accompanying documents	 Manufacturer	EC REP Authorized Representative in the European Community
 Neutral electrode referenced to ground.	 Type BF applied part	 Power ON/OFF (Push button)
REF Reference No.	 Foot Switch(IPX68)	F HF isolated patient circuit

5. Essentials for Using Equipment

The laser system is a medical treatment device that may only be used for its intended dermatological treatment purposes.

This manual describes the operation, maintenance and service of the unit.


NOTE

FRAXIS DUO should be protected against unauthorized use

The use of mobile telephones or similar devices is not permitted in the same room during operation of the High frequency.

Due to a possible risk of interference through electromagnetic radiation duringHigh frequency operation, individuals with pace makers should not be present in the sameroom. Pregnant women should also leave the room.

Like any highly-effective medical device, a High Frequency demands special expertise and care in its handling and use. The High Frequency may only be

operated by physicians who have been trained to use the device properly in accordance with the user manual and who are familiar with its therapeutic effects and possible dangers.

CAUTION

- No modification of this equipment is allowed.

The following instructions are the essential guidelines to be surely considered before using the equipment. In case that you don't observe them, the critical damage like the performance degradation of the equipment can be brought about.

- Don't operate the equipment differently from user manual on the purpose of practitioner and never use the equipment from different other purpose than original purpose.
- Never operate the equipment by non-authorized person without supervision from experienced expert
- Patient and operator (doctor) should not carry the metallic materials such as rings, watches, necklaces etc.
- Make sure to turn off equipment and pullout the key not to be operated by others when it is not used or even an operator(doctor) leaves for a moment.
- Never disassemble the equipment. The disassembly of the equipment can be carried out only by an authorized repair person of the manufacturer. It is impossible for the equipment to conduct the laser treatment in a situation when it is disassembled.

5.1 Installation of Equipment

NOTE

Please refer to "Chapter 3. Installation equipment" for installation instructions.

- The equipment must be installed and used only in a safe treatment room of hospital.
- The use of the equipment in other places (i.e. skin care shop, other treatment place etc.) except hospitals is strictly prohibited.
- Only authorized person can operate, manage and repair the equipment.
- The equipment should be moved and installed only in a state of turning-off and placed in a safety flat space.

This equipment has been tested and found to comply with the limits for medical devices in IEC/EN 60601-1-2. These limits are designed to provide reasonable

protection against harmful interference in a typical medical installation.
This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation.
If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

WARNING

To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth.

Not to position Equipment to make it difficult to operate the disconnection device. Install the equipment at least a 100mm distance from the wall.

5.2 Prohibition &Cautions for patients

Regardless of the age, weight and gender, it can treat every patient who needs the treatment for the microvascular disease and lesion. But it is recommended that pay attention to the patients with cardiac pacemaker or dental implant

5.2.1 Prohibition

Prohibition with regard to using this system for treatment of skin disease has yet to be known. But the patient who previously experienced adverse effect with treatment shall be classified as potential treatment patient through preliminary examination.

Careful attention or limitation shall be given during treatment of those described below.

1) Common prohibition

- The pregnant women
- Breast feeding person
- For patients with cardiac pacemaker or other active implants.
- Within 2~3 months after BOTOX or filler treatment.
- Patient with unknown skin disease
- Sensitive patient with hot sensation

2) High frequency treatment prohibition

- Implanted patients to the face with gold thread lifting.
- Metal allergy.

WARNING

Use surgery with caution in the presence of internal or external devices such as pacemakers or pulse generators. Interference produced by the use of device can cause devices such as pacemakers to enter an asynchronous mode or can block the pacemaker effect entirely. Consult the device manufacturer or hospital Cardiology Department for further information when use of electrosurgical appliances is planned for patients with cardiac pacemakers or other implantable devices.

5.2.2 Caution

Make sure to give the treatment only to the patient in accordance with the purpose of this equipment after the doctor's prior diagnosis. The treatment to the patient with other lesion, not with the originally targeted one without the doctor's prior diagnosis is strictly prohibited.Before treatment, make sure to check the patient's skin state and sterilize the region to be treated so as that there are no foreign substances.

Before treatment, remind a patient of the cautions before, during, and after treatment and notify the possibility of occurrence of unintended abnormal symptoms to him or her.

NOTE

Please explain the contents of the following patients after treatment.

- Please avoid being exposed to water or sunlight for extended time till treatment part has been completely restored and notify how to care treated part.
- Hyper-pigmentation (excessive deposit of pigment on treated part) or Hypo-pigmentation (insufficient deport of pigment on treated part) may occur which is temporary symptom requiring no particular treatment.
- Notify to see doctor when experiencing flushing, pricking or any abnormality on or around treated part.

5.3Setting for Output

Set output considering a patient's condition and parameter values before setting it

Place handpieces at a safe place when setting its output. (Handpiece holder)

When adjusting a setting value, start with a small value, and increase the usage and strength gradually until the desired result is produced

- Abide by all the safety related-cautions stated in this manual
- Place the hand-piece in designated position(hand piece holder).
- Check the value of screen first when you set the output value (intensity,

RF, depth etc) according to the operational parameter.

- Use the equipment only onto the skin surface in which there are no infection and other damage.

  Information stating that apparent low output or failure of the hF surgical equipment to function correctly at the normal operating settings may indicate faulty application of the neutral electrode or poor contact in its connections Application of neutral electrode and its connections to be checked before selecting a higher output power
- Apparent low output or failure of the SECRET to function correctly at normal operating settings may indicate. This could be due to a faulty power cord, loose connections inside the unit, the use of a two wire extension cord, or the use of a three-to two prong adapter.
- These faults can result in a burn if the patient plate is used and is not in good contact with the patient. If the neutral electrode (patient plate) is being used, the low power may be due to faulty application or poor contact in its connections.

  In this case, the application of the neutral electrode and it's connections should be checked before selecting a higher power.

- HF surgical equipment could result in an unintended increase of output power.
- When the switch of the device set as "on" state, if the user connects the power cable, the RF energy may radiate in the moment.

  When set-up the device, please check that every switch is 'zero start' state and then operate the device according to set-up order in order not to exceed the voltage of the accessory.

5.4 Additional information of each functions

1) Sterilization HF electrosurgical electrodes(Needle tips)

- Be sure to check the sterilized condition of needle electrodes to be used with the handpiece.
- Do not use needle electrodes that the sterilized packaging is damaged (torn, contaminated etc.), or there is no sterilized packaging.
- After looking a label printed on the sterilized wrapping paper carefully and checking its sterilized date, expiration date etc. surely, use only the needle electrodes decided that there is nothing wrong by checking whether the sterilized condition remains intact.
- Needle electrodes are disposable, which can be used only for a

patient once a day, and a needle electrode opened once must not be reused. Do not treat several people with a needle electrode, and do not use it for several terms or times.

Chapter 2. Safety Cautions

1. Instruction for Environmental safety

1.1 Electrical Hazard

All the users of the equipment should read and observe the following cautions for electrical safety, or electric shocks may take place.

One should not touch any part of equipment other than the system operation part. When doing routines such as connecting or disconnecting the HF Connector, please make sure to unplug or power-off the system.

When system is capable of causing physical injuries to either patients or users then the system operation can be stopped by pressing the emergency stop button. Emergency stop button is located on the front side of the handle and the pressing motion will stop the system operation.

- Make sure to use the system only in a place where there is electric installation, obeying the standards and regulations of each region.
- Do not use water or other liquid solvents when cleaning electrical parts. Prevent water or other liquid from spilling it on the system.
- Install with care not to fall down on electric wires and pipes or to entwine electric wires.
- Make sure to install and use the proper parts and accessories and do not use the different products from the accessories provided along with the equipment.
- Check the damage to the external appearance and electric wires of the equipment on a regular basis.
- Please contact manufacturer In case of replacing the parts.
- To avoid electric shock, the equipment must have ground connection.
- Do not place the device in the corner where it is hard to move the power plug.

- Don't contact the patient and equipment connector at the same time.

1.2 Fire Hazard

All the users of the equipment should read and observe the following cautions for fire hazard, or fire may take place.

Long time use of equipment may cause overheat of equipment.
Also, please make solvent of adhesive and flammable solution used for cleaning and sterilizing fully vaporized before using.
In case equipment is overheated up to a certain degree, it is not operated with error message on the display. If error message is displayed, please turn off and pause the equipment for a while until the temperature falls.

- Do not put the flammable or combustible materials or substances around the treatment room.
- If you use alcohol to handpiece tip, wait up to the time when it is completely evaporated and dried before operating the system.
- Do not radiate the Energy to any part except for the part to be treated.
- Cut off the power immediately in case of fire.
- Do not fail to check the influx of gases inside the treatment room at all times.
- Attention is also drawn to the danger of ignition of endogenous gases

1.3 Electromagnetic compatibility_ Guidance and manufacturer's declaration

Guidance and manufacturer's declaration - electromagnetic emissions		
The MTR-C1 is intended for use in the electromagnetic environment specified below. The customer or the user of the MTR-C1 should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment -guidance
RF Emissions CISPR 11	Group 1	The MTR-C1 uses RF energy only for its internalfunction. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF Emissions CISPR 11	Class A	The MTR-C1 is suitable for use in ail establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The MTR-C1 is intended for use in the electromagnetic environment specified below. The customer or the user of the MTR-C1 should assure that it is used in such an environment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment -guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV Contact ±8kV air	±6kV ±8kV	Floors should be wood, concrete or ceramic tile. If floors arecovered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ± 1kV for input/output lines	±2kV ±1kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differentialmode ±2kV common mode	±1kV ±2kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (<95% dip in U_T)for 5 s	No degradation of function	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MTR-C1 image intensifier requirescontinued operation during power mains interruptions, it isrecommended that the MTR-C1 image intensifier be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration - electromagnetic immunity			
The MTR-C1 is intended for use in the electromagnetic environment specified below. The customer or the user of the MTR-C1 should assure that it is used in such an environment.			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the MTR-C1, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3.5}{V_1}]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5GHz	3 V/m	$d = [\frac{3.5}{E1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E1}]\sqrt{P}$ 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 meters (m). 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 80MHz and 800MHz, the higher frequency range applies.
NOTE 2) These guidelines may not apply in all situations. Electromagnetic propagation 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 MTR-C1 is used exceeds the applicable RF compliance level above, the MTR-C1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MTR-C1.

[b] Over the frequency range 150kHz to 80MHz, field strengths should be less than [V_1] V/m.

Recommended separation distances between portable and mobile RF communications equipmentand the MTR-C1			
The MTR-C1is intended for use in an electromagnetic environment in which radiated RFdisturbances are controlled. The customer or the user of the MTR-C1 can help preventelectromagnetic interference by maintaining a minimum distance between portable and mobile RF communicationsequipment (transmitters) and the MTR-C1as recommended below, according to the maximumoutput power of the communications equipment.			
Rated maximum output power of Transmitter(W)	Separation distance according to frequency of transmitter(m)		
	150 kHz to 80 MHz d = 1.2√P	80 MHz to 800 MHz d = 1.2√P	800 MHz to 2,5 GHz d = 2.3√P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitter rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800MHz, the separation distance for the higher frequency range applies NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Use of accessories, transducers, and cables other than those specified may result in degraded electromagneticcompatibility performance of this device!

2. Caution for safe Use of Equipment

2.1 Caution for product safety

The owner and user of the MTR-C1 are obliged to obey all of the equipment-related safety cautions. The following cautions related with the equipment must be observed.

- The equipment should be used only for defined purposed.
- Operate the equipment only when it is normal condition (No error messages).
- Manage the user manual and all relevant document in good condition and place those where the equipment is installed to be available at any time.
- Be sure to designate system safety personnel in writing. Duties of safety personnel include the following.
  - Supervision of operation of equipment
  -Implementation of safe operation and taking all necessary

measures by supporting owner/operator

- Providing information on the main issues to the labor safety expert in respect of safety and protection for securing safety from the risk of HF emission and cooperation for the expert's job duty

- Only authorized person can operate, manage and repair the equipment.
- Keep clean the equipment, hand piece and holder to be neat without dirt on it.
- Place the handpiece in a stable location and keep the direction of the handpiece away from other people than patient.
- Make sure to turn off the equipment and pull out the key not to be operated by others when it is not used or even an operator (doctor) leaves for a moment.
- Never disassemble the equipment. The disassembly of the equipment can be carried out only by an authorized repair person of the manufacturer.
- It is impossible for the equipment to conduct the treatment in a situation when it is disassembled.
- Never remove the safety instruction and warning label on the equipment.
- Don't impact the equipment
- Don't push the equipment

2.1.1Smoke hazard

HF device is in operation, hazardous gas is mostly generated while tissue is vaporized and such smoke pillar contains virus particle having respiratory organ sized about 0.1μm. So smoke pillar shall be removed from treatment environment

Wearing mask as part of the way to filter the smoke is not recommended

Local discharge ventilation system which is tightly contacted to HF source is recommended which includes portable smoke extractor using charcoal or HEPA filter (0.1μm at least)) with 99% or more extraction efficiency.

Smoke pillar generated during HF treatment may contain growing granular component of tissue and so the smoke shall be ventilated
HF fume and/or plume may contain viable tissue particulates

2.2 Cautions to use HF

- Entire area of neutral electrode(optional) should be reliably attached to a suitably prepared and appropriate area of the patient's body as defined by the manufacturer.
- Patient should not come into contact with earthed metal parts or parts with appreciable capacitance to earth (e.g., operating table supports, etc.)
- Instructions stating, avoid skin-to-skin contact by insertion of dry gauze
- When high frequency surgical equipment and physiological monitoring equipment are used simultaneously on the same patient, place any monitoring electrodes as far as possible from the surgical electrodes.

- Use of bipolar techniques may be desirable in order to avoid unwanted tissue damage for surgical procedures where HF current could flow through relatively small cross-sectional area of body.

Do not use needles as monitoring electrodes during electrosurgical procedures. Inadvertent electrosurgical burns may result.

- The cables to surgical electrodes should be positioned in such a way that contact with the patient or other leads is avoided. Temporarily unused active electrodes should be stored so that they are isolated from the patient.
- Use the lowest output setting necessary to achieve the desired surgical effect.
- Pediatric applications and/or procedures performed on small anatomic structures may require reduced power settings. The higher the current flow, and the longer the current is applied, the greater the possibility of unintended thermal damage to tissue, especially during use on small structures.
- The use of flammable anesthetics or oxidizing gases such as nitrous oxide (N2O) 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.
- Provide as much distance as possible between the electrosurgical generator and other electronic equipment (such as monitors). An activated electrosurgical generator may cause interference with them.
- To avoid incompatibility and unsafe operation, use suitable cables, accessories an active electrodes, including values for the highest allowed H.F. peak voltage.
- Avoid HF output settings where maximum output voltage may exceed rated accessory voltage.

- When using Bipolar mode, associated equipment and active accessories should be selected that have a voltage rating of 400V p-p or greater.

- Failure of the high frequency electrosurgical equipment could result in an unintended increase of output power
- Minor neuromuscular stimulation is possible when arcs between the ACTIVE ELECTRODE and tissue occur. The generator has been designed to minimize the possibility of neuromuscular stimulation.

2.3 Cautions on system use

2.3.1Cautions before Use

- Make sure to read the instructions and use the equipment before using it.
- Make sure to use the equipment on a doctor's prescription.
- Do not connect the power on with a wet hand.
- Be careful not to spill water into the main body. It can cause the damage to the equipment and the fire and electric shock.
- Do not install the equipment in a watery, humid place. It can cause the damage to the equipment and the fire and electric shock.
- Install the equipment at least a 100mm distance from the wall.
- Be careful not to make the power cord pressed by heavy weights or touched by sharp materials. The use of a damaged cord can cause fire or electric shock.
- Never use the equipment near flammables. It can cause the deformation of the main body, the failure in the system, and the fire.
- Make this machine used only a professionally trained person.
- Conduct a prior check on the manipulation of the system.
- Check the switches etc. and then confirm the correct operation.
- Connect all the cords accurately not to break away easily.
- When you use the equipment after a long interval, confirm if it operates normally and safely or not.
- Never disassemble or change the equipment by anybody except by an installation and repair technician. It can cause fire or electric shock.
- Only use the provided accessories. Don't use other accessories not from us.
- Do not use a product with damaged packaging.


NOTE

Operating condition

- Operating condition : within 10℃ ~ 40℃
- Relative humidity : 30% ~ 75%
- Atmospheric pressure : 500 ~ 1060 hPa
- Max relative humidity : 10% ~ 90%

2.3.2 Cautions during Use

- Remove all the interruptions around the equipment when it is used. Do not put papers or other materials on the top of the machine and block the vent.
- When the failure in the system takes place, stop using it, and turn off the power and then contact our customer service center.
- In case of a power outage, turn off the power immediately and put the controlling knob and switches back to the original position.
- Do not use the equipment near a patient monitor.
- Always check if there are some abnormalities on the patient and the equipment during use. If some abnormalities occur on the patient or the equipment, check the patient's safety and stop the equipment. When you confirm that the patient and the equipment have no problems after check-up, continue to use it again.
- Be careful not to install the power cord of another machine at the same time. It can cause the performance degradation of the equipment.
- Do not operate the machine in a place where chemicals are stored or gas is generated.
- Do not pull the cord of the main body by force. It can cause the performance degradation of and the trouble with the machine.
- When using this equipment, electromagnetic emitting devices, portable and mobile RF telecommunications device can cause electromagnetic interference. Please avoid using these devices during treatment.
- In case of electrosurgical unit, please note the following.

- Do not perform an electric surgical procedure if there is a combustible anesthetic.
- Recommendation to position patient leads in such a way that contact with the patient or other leads is avoided
- Because spark and heat associated with an electric surgical procedure may be the cause of a fire, gauze and sponge should be kept as a wet condition, and electrodes for electrical operations should be kept away from ignitable substance and oxygen.
- A fire danger would be increased if an electrical operation is performed in the environment with rich oxygen. Thus, it should be done to lower oxygen levels at the surgery area.
- Avoid operations at the places with rich oxygen and nitric oxides. These two types of gas may cause a fire and burns to patients.
- If possible, cut off the oxygen supply before and during an electric surgical procedure.
- Be careful of combustible gas generated naturally in the intestines.
- Tissues on the end of an activated electrode may be embers of a fire in the environment with rich oxygen in particular.
- Check the proper output energy amounts before and during an electric surgical procedure.
- Blood or saline solution contacted directly with electrodes or other accessories for electric surgical equipments may carry electricity to cause an untended burn. This

may happen by connecting directly with activated electrodes or by an electric capacity between activated electrodes and external electrode's electric heaters. Therefore, conductive liquid should be kept away to prevent a burn. Keep away the outer surface of activated electrodes from the neighboring tissues during a surgical procedure. Keep clean so that conductive liquid is not remained on the electrode before an electric surgical procedure.

- Electrodes should be mounted on the body (electrode support) completely and safely. Otherwise, it may cause a burn to patients.Instructions stating, fluids pooled in the body depressions and cavities should be mopped up before hf surgical equipment is used
- Instructions stating, entire area of neutral electrode should be reliably attached to a suitably prepared and appropriate area of the patient's body as defined by the manufacturer
- Instructions stating, avoid skin-to-skin contact by insertion of dry gauze (For example, connection of patient's both arms and the body)
- Recommendation to, temporarily, store unused active electrodes in a location isolated from patient
- Do not re-operate, reuse, and re-sterilize it.
- For patients who a pacemaker is transplanted, avoid using a single-pole electrode.
- Do not apply to patients with implants.A statement indicating, for patients with cardiac pacemakers or other active implants, a possiblehazard exists due to interference with the action of pacemaker or pacemaker may be damaged, and when in doubt, approved qualified advice should be obtained.
- For pregnant women, be sure to decide whether or not to apply it after consulting with a doctor.
- Set power as low when applying or performing to a small-sized young child.
- If high or lengthy power is applied, it may increase possibility to cause unintended damage to tissues.
- This equipment must be used by doctors.
- Do not use a product with damaged packaging.
- Do not modify or repair arbitrarily.
- When discard the needles, must follow the rule of medical disposal in the country to prevent bio-contamination.

2.3.3 Cautions after Use

- After use, put the control knob and switches back to the original position and turn off the power.
- Be careful not to give an excessive force to the connecting part of cords when you pull out the cords.
- Make sure to turn off the power and take out the key so that other people cannot operate the equipment.
- Do not pull the cord of the main body by force. It can cause the performance degradation of and the trouble with the machine.

3. Labeling

Refer to "Appendix 1. LABEL & Symbols " for shape and adhesion position of the labels attached to this equipment.

4. Maintenance, cleaning and disposal.

4.1 Maintenance

Perform regularly scheduled equipment inspections for safety of patients and users.

Refer to " Appendix 2. Regular Safety inspection"

- Incase of the trouble with machine, make sure to stop using it and contact the store you purchased from or the customer service center.
- Never open the machine and the controller.
- Do not give an impact to the main body. If there had been some impact on it, make sure to use the equipment after check-ups.

4.2 Storage

- Do not keep the equipment in a place where there is some slope, shaking, or possible impact. It can cause the performance degradation of the machine or the fire and electric shock.
- Do not keep the equipment in a place where chemicals are stored or some gas is generated.
- Do not keep the equipment in a place where temperature, air pressure, humidity, ventilation, sunlight, and air containing dust, salt and sulfur have a harmful influence on it.

Keep the equipment in a place far from water.

Storage and transfer condition
- Temperature : Within 10℃ ~ 60℃
- Relative humidity : 10% ~ 90%
- Atmospheric pressure : 500 ~ 1060 hPa
- Max relative humidity : 10% ~ 90%

4.3 Cleaning

1) Main body, HF electrosurgical handpieces

- Clean the main body and connector of hand piece by air to remove dirt.
- For the main body except connector area(Front, Back, LCD), scrub it by softCotton with alcohol on the caution not to be permeated liquid to the connector.

- 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 if HF surgery. There is a risk of pooling flammable solutions under the patient or in body depressions such as the umbilicus, and in body cavities such as the vagina. Any fluids 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 the HF surgical equipment.
- Clean and disinfect only instructed detergents and do not use other detergents.
- Use soft texture material(cotton, cotton swab) and do not use sharp material.
- Don't reuse disinfected materials(cotton, cotton swab).
- Don't scrub hard the machine.
- Have a caution not to be permeate disinfectant to the connector.
- Never apply the disinfectant to the equipment directly.
- Use the soft cotton when disinfect the electro of hand piece. If there is scratch on it, it might cause a problem with output of HF.
- Must turn off the equipment during cleaning, don't clean during operation.
- Use the equipment after disinfectant is completely dry.

4.4 Disposal

- Since the system includes industrial waste materials in the composition, an inappropriate disposal of materials can cause environmental pollution. Therefore, do not dispose of the waste along with common industrial or household waste.
- When disposing of the system in whole or in parts, comply with the related regulationsof the standing legislation. For waste disposal related matters, consult with ILOODA Co.,Ltd. or authorized agent in each region.
- When discard the electrode(Needle tip), must follow the rule of medical disposal in the country to prevent bio-contamination.

The HF electrosurgical electrode(Needle tip) is single use.

Do not re-use.

Please dispose of immediately after use.

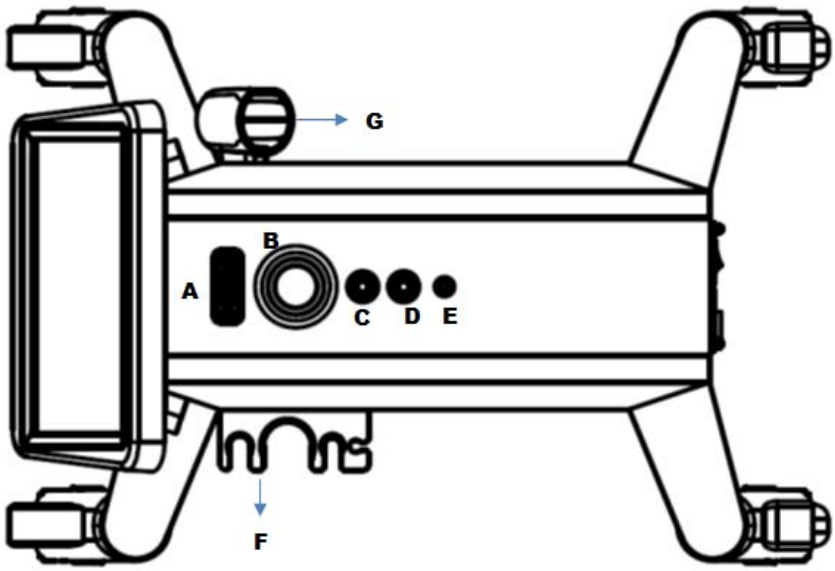
Do not use if package is damaged.

Chapter 3. Installation of Equipment

1. Description of the Equipment

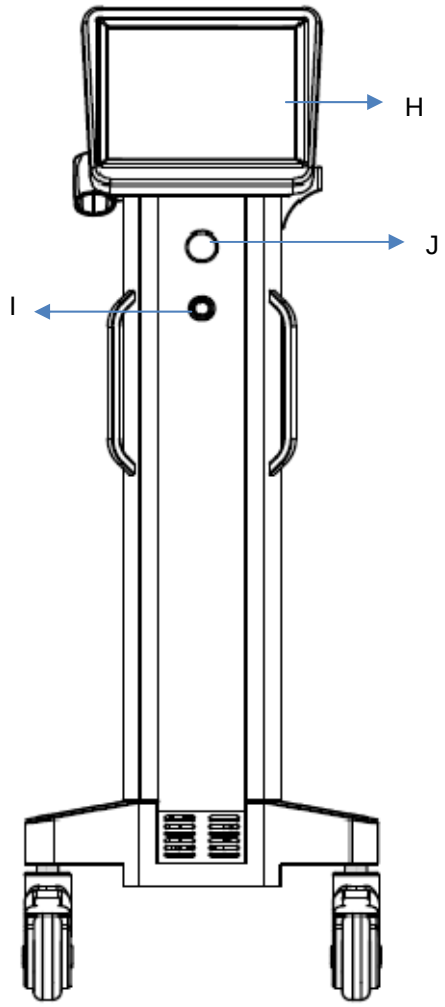
1.1 Description of the Equipment's external structure

1.1.1 Description of the Console



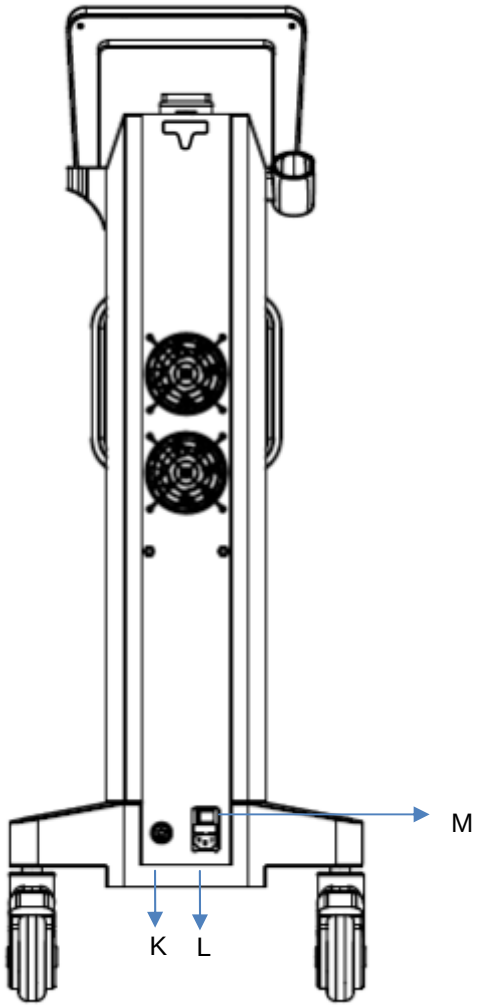
[Upper Side View]

No	Name	Function
A	BI POLAR Connector	Connector that the BI POLAR Hand-piece is connected
B	Cable Holder Connecting Part	Connecting part that the cable holder is connected
C	MONO POLAR CONNECTOR	Connector that the MONO Hand-piece is connected
D	Return Electrode Connector	Connector that the return electrode is connected
E	MONO POLAR Hand-piece CONNECTOR	Connector that the pencil type MONO Hand-piece (with vein needle, sub_cission electrode) is connected
F	MONO POLAR, HOLDER	Holder that places the MONO Hand-piece and the return electrode pole
G	MONO POLAR Hand-piece CONNECTOR	Connector that the pencil type MONO Hand-piece (with vein needle, sub_cission electrode) is connected



[Front View]

No	Name	Function
H	LCD Monitor (TOUCH)	Touch screen that sets and indicates each function
I	ON/OFF Switch	Power on/off
J	Volume Switch	Volume that adjusts the intensity of MODE 2



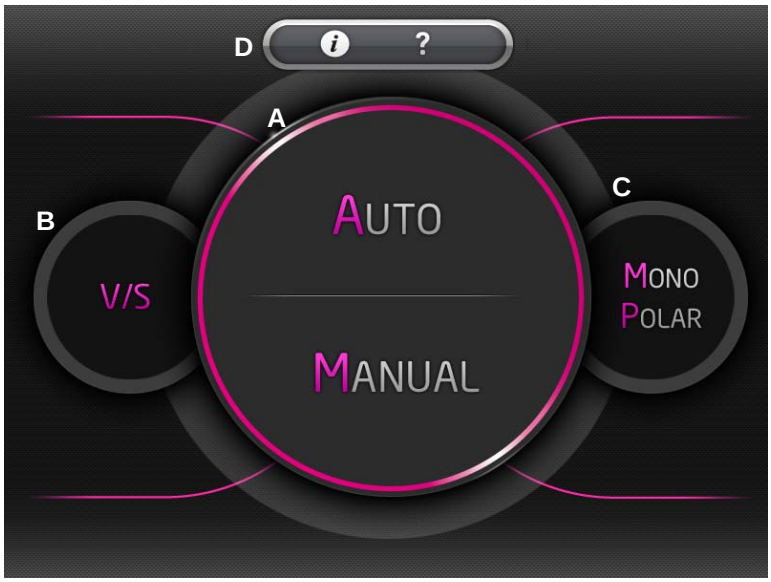
[Back Side View]

No	Name	Function
K	Foot Switch Connector	Connector that connects with a foot switch
L	Power Cord Connector	Connector that connects with the power cord
M	Power switch	Main Power on/off

1.1.2 Description of DISPLAY

: Refer to "Chapter 4. Use of Equipment"

1) MAIN Screen



No	Name	Function
A	Bi-Polar mode (Micro Needle)	Bi-polar mode is composed of "AUTO" and "MANUAL"
B	Bi-Polar mode (Pencil Type)	Bi-polar mode is composed of "VC" and "SC"
C	Mono Polar mode	Mono Polar on menu
D	Information	Provides information about menu

2) AUTO Menu

No	Name	Function
A	Main menu	Icon to return to main menu
B	Volume control	Volume control icon
C	Electrode status	Icon to check electrode status – to clean the electrode, click to show the following pop-up. 
D	Standby / ready	High frequency output standby / ready selection icon
E	Mode conversion	Click the icon to go to each mode.
F	Operation part setting	Operation part setting - Forehead - Eyes - Nose - Cheeks - Lips - Chin - Neck
G	Setting output display	High frequency output value is automatically configured upon selection of operation part
H	Auto mode	Composed of 3 types of auto
I	Shot Count	Represents the number of shots

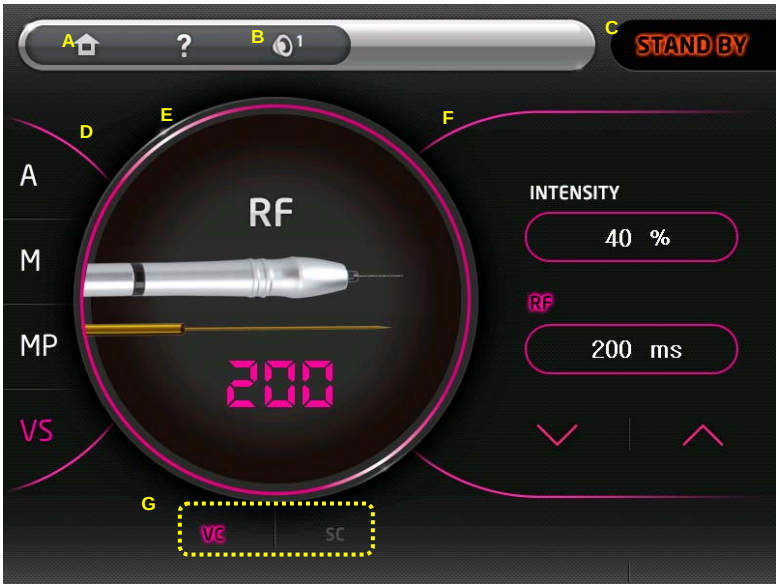
3) MANUAL Menu

No	Name	Function
A	Main menu	Icon to return to main menu
B	Volume control	Volume control icon
C	Electrode status	Icon to check electrode status – to clean the electrode, click to show the following pop-up. 
D	Standby / ready	High frequency output standby / ready selection icon
E	Mode conversion	Click the icon to go to each mode.
F	Output setting display	High frequency output values displayed
G	output setting	High frequency output setting icon - Tip Type: needle electrode type setting - Intensity: high frequency output intensity - RF: high frequency output time - Depth: needle penetration depth - Mode: needle output time interval - Delay Time: needle output time
H	Storage	Icon to save frequently used values and current output setting. It can store up to 5 setting values.

4) Monopolar menu

No	Name	Function
A	Main menu	Icon to return to main menu
B	Volume control	Volume control icon
C	Standby / ready	High frequency output standby / ready selection icon
D	Mode conversion	Click the icon to go to each mode.
E	Output setting display	High frequency output values displayed
F	Output Time	Regulates the output time

5) VS mode_VC



No	Name	Function
A	Main menu	Icon to return to main menu
B	Volume control	Volume control icon
C	Standby / ready	High frequency output standby / ready selection icon
D	Mode conversion	Click the icon to go to each mode.
E	Output setting display	High frequency output values displayed
F	output setting	High frequency output setting icon - Intensity: high frequency output intensity - RF: high frequency output time
G	Mode conversion	Click the icon to go to each mode.

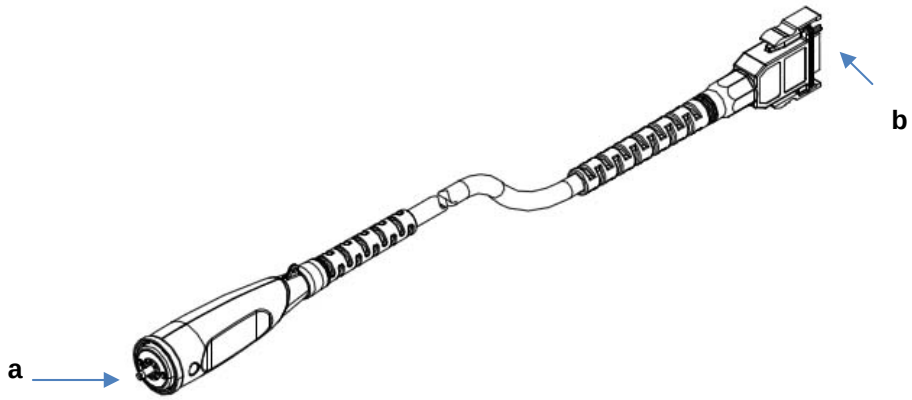
6) VS mode_SC

No	Name	Function
A	Main menu	Icon to return to main menu
B	Volume control	Volume control icon
C	Standby / ready	High frequency output standby / ready selection icon
D	Mode conversion	Click the icon to go to each mode.
E	Output setting display	High frequency output values displayed
F	output setting	High frequency output setting icon - Intensity: high frequency output intensity - RF: high frequency output time
G	Mode conversion	Click the icon to go to each mode.

1.1.3 Description of the Hand-piece

1) BI POLAR Hand-piece(H/P 1.0)

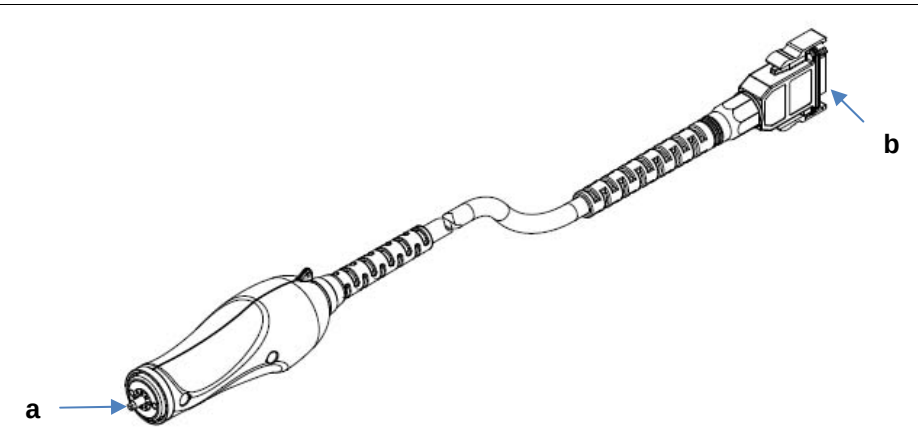
: Connect 25pin electrode or 10pin electrode depending on the application.



No	Name	Function
a	TIP CONNECTOR	Part that connects needle electrodes
b	BI POLAR Socket	Connector that connects to the console

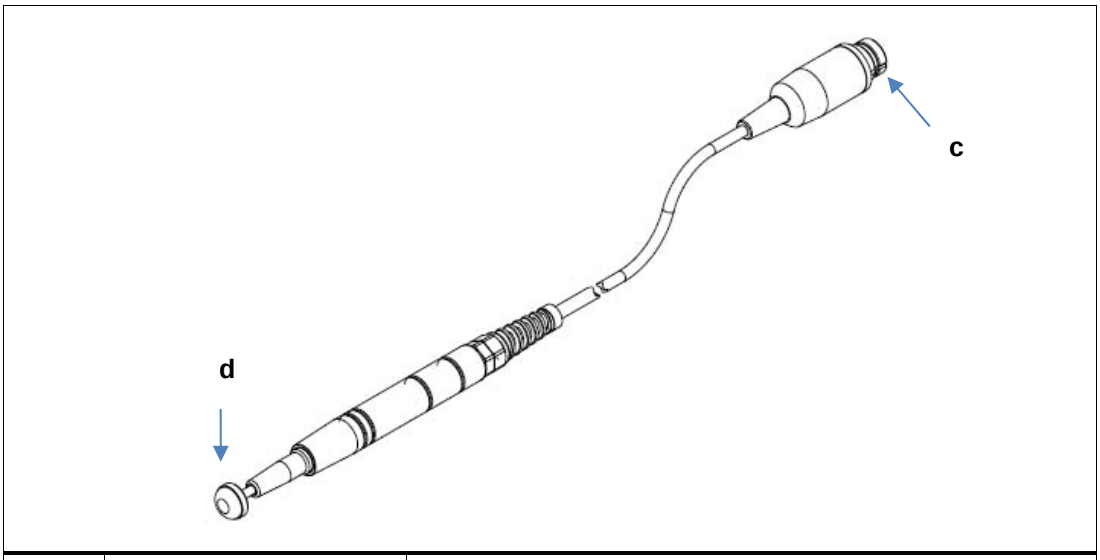
2) BI POLAR Hand-piece(H/P 2.0_Bigger type)

: Connect 64pin electrode, 25pin electrode and 10pin electrode depending on the application.



No	Name	Function
a	TIP CONNECTOR	Part that connects needle electrodes
b	BI POLAR Socket	Connector that connects to the console

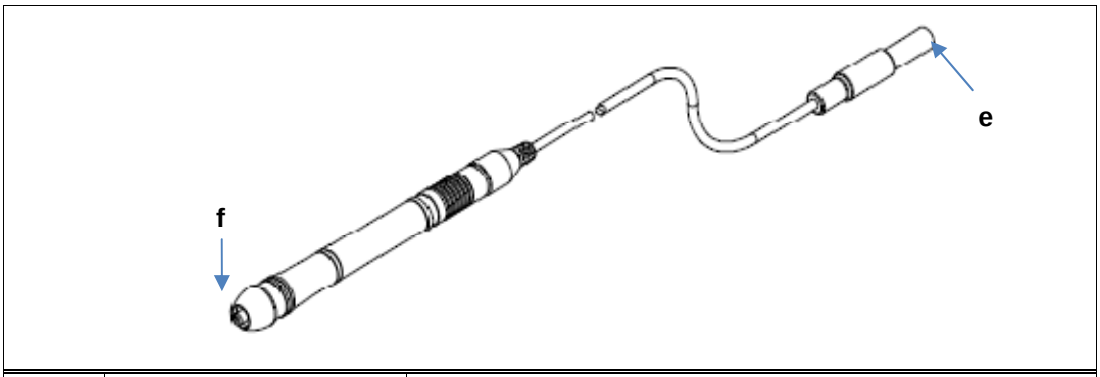
3) Mono-polar Hand-piece (Using with Neutral hand piece)



No	Name	Function
c	MONO POLAR SOCKET	Connector that connects to the console
d	MONO POLAR ELECTRODE (Patient contact)	Transfer the High-frequency current into body.

4) Pencil Type Hand-piece (Used with Needle electrode or Sub_cision electrode)

: Insert Needle electrode to the hand piece.



No	Name	Function
e	Pencil Type H/P SOCKET	Connector that connects to the console
f	Electrode Connector (Patient contact)	Part that connects needle(or sub_cision) electrodes

1.1.4 Active electrodes (Patient contact)

1) Micro- Needle Tip(Optional)

: Used in the case of Micro coagulation. To be used in connection with a Bipolar Hand-piece.

Figure	Name	Function	Hand piece Version(1.0/2.0)
	MTR-AC-25	Pin unit : 25ea Needle ø0.25	Bipolar hand piece(H/P 1.0) Bipolar hand piece(H/P 2.0)
	MTR-AC-10	Pin unit : 10ea Needle ø0.25	Bipolar hand piece(H/P 1.0) Bipolar hand piece(H/P 2.0)
	MTR-AC-C-10	Pin unit : 10ea Needle ø0.25 Tip insulated	Bipolar hand piece(H/P 1.0) Bipolar hand piece(H/P 2.0)
	MTR-AC-64	Pin unit : 64ea Needle ø0.25	Bipolar hand piece(H/P 2.0)

2) Needle electrode (Optional) (Patient contact)

: Insert Needle electrode to the Mono-polar hand-piece(Pencil Type). Single use from Ballet Co.

Model No.	Function.
K3"I"	ø0.003" x 0.80mm (1package : 10ea)
K6"I"	ø0.006" x 0.80mm (1pakage : 10ea)

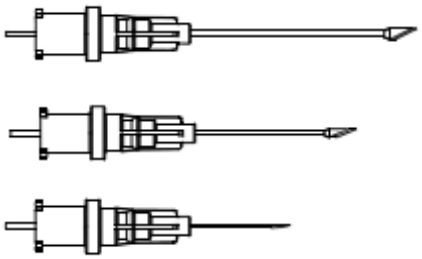
NOTE

Does not provide directly ILOODA CO.,LTD.

Please use approved products such as CE with the above specification.

3) Sub_cision electrode(Optional) (Patient contact)

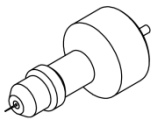
: Insert Sub_cision electrode into Mono polar hand-piece(Pencil type).



Function.
19G x 35mm, knife type
22G x 25mm, knife type
27G x 15.5mm, knife type

4) Needle electrode (Optional) (Patient contact)

: Insert Needle electrode to the Mono polar handpiece (Pencil type).

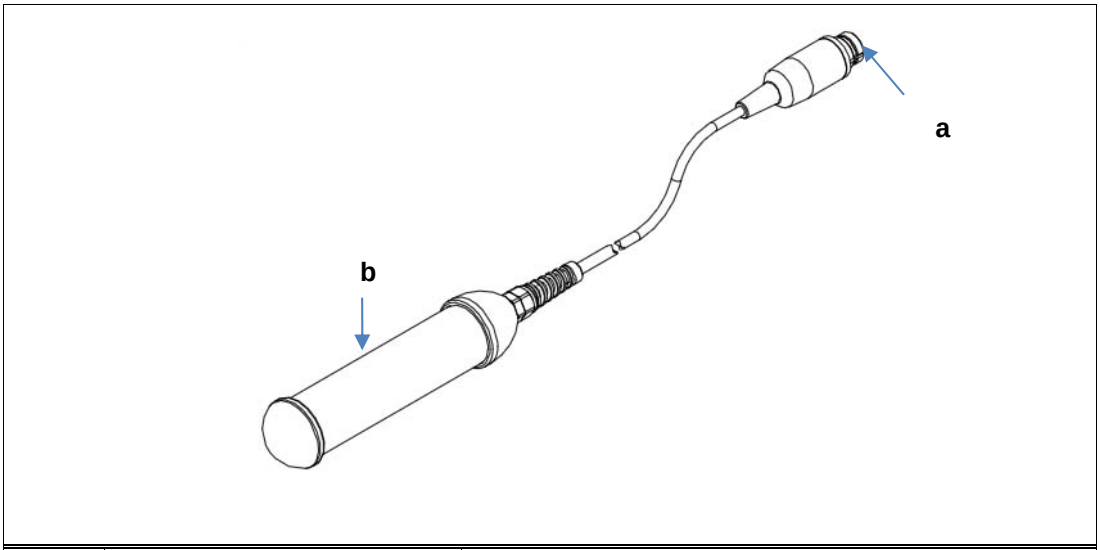


Function.
ø 0.25 mm x 1.5 mm

1.1.5 Neutral Hand-piece(Integral electrode)

: Contact with the body makes the High- frequency current towards the electrode.

It works only Monopolar Mode.



No	Name	Function
a	Neutral Hand-piece Socket	Connector that connects to the console
b	Neutral Hand-piece Electrode (Patient contact)	Part that holds with a hand for making a closed circuit on the human body

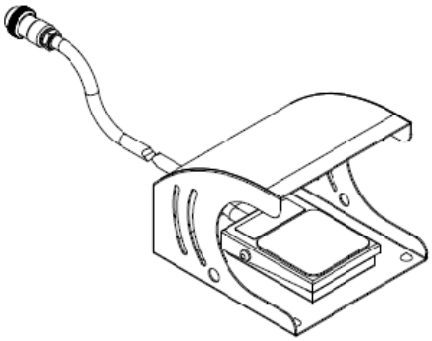
1.1.6 Neutral Pad(Optional) (Patient contact)

: Contact with the body makes the High- frequency current towards the electrode.

Only use Patient plate with Subcision of VSmode. Single use.(Valid date : 2 Years) (CE approval)

1.1.7 Footswitch

: When manipulated by the operator, enables HF output to be produced and, when released disables HF output.



1.1.8The followings are components (accessories) comprised of this equipment.

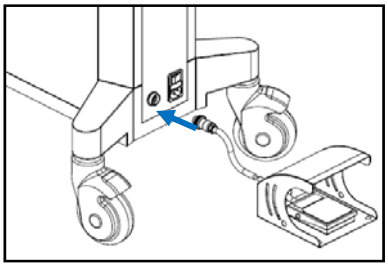
Power Cable	Patient plate cable
	
User Manual	Cable Holder
	

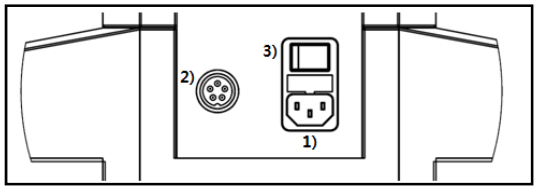
1.2 Installation of the Equipment

1.2.1 Installation of the Console – Accessories

(Refer to images and numbering of the upper and back side views in the '1.1.1 Description of the Console' of Chap 4.)

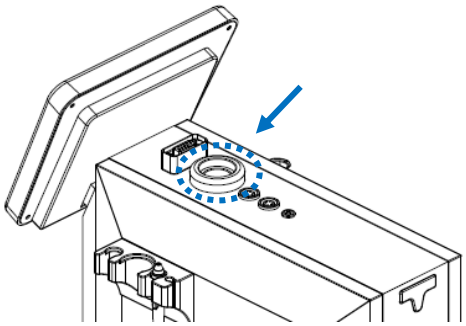
1) Connect the power cable to the power cord connector on the back side of console.
2) Connect the foot switch to the foot switch connector on the back side of console.
3) It is Main power ON/OFF switch.





- Connect the foot switch with the console by positioning at the console's arrow direction when connecting it
- If it is connected incorrectly, an error message is indicated and it may not be worked
- warning: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth

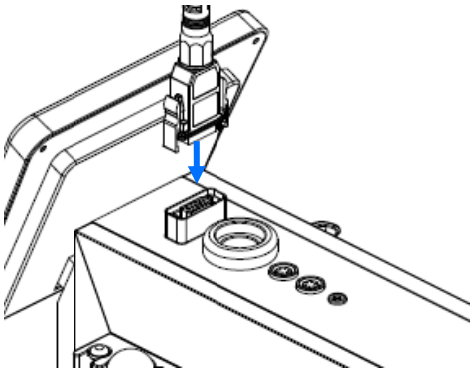
4) Insert the cable holder into the cable holder connector (**B**) on the top of the console vertically, and then turn it clockwise to connect tightly.

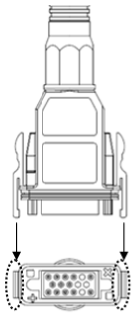


- The cable holder should be tightly connected with the cable holder connector (B) on the console
- If it is not connected correctly, it may disrupt a surgical procedure

1.2.2 Installation of the Handpiece – BI POLAR Handpiece

1) For connecting BI POLAR hand pieceto the main body, connect BI POLAR connector (A) to the key hole of BI POLAR socket properly

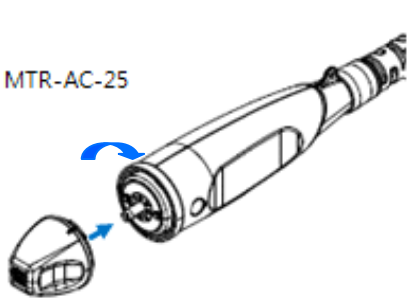


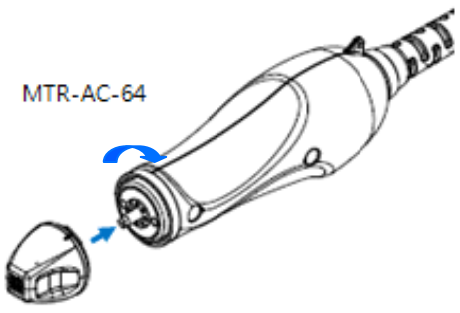


- When connecting bipolar hand piece, attach to the key hole between bipolar connector and bipolar socket.
- Vertically insert until clicking sound is created by the fixing holders on both sides of bipolar socket.
- An error message appears and the product does not function when connection is not done firmly.

2) Connecting Micro-needle type electrode

During connection of the Micro-needle type electrode, attach to the fixing hole between needle electrode and hand piece connector and turn clockwise for connection.(Connecting method of Hand-piece 1.0 and Hand-piece 2.0(Bigger H/P) are the same)





Not connected/bad

- Needle electrode connection status is displayed as below.
  * Not connected or bad connection: red lamp turned on
  * Normal connection: blue lamp on
- An error message appears and the product does not function when connection is not done firmly.

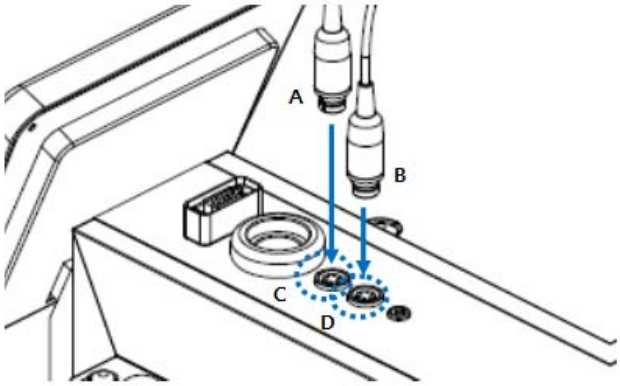
Normal connection

- The lamp is blinking while the needle comes out and goes in, so keep holding the hand piece until the lamp turns off.

* When 64 pin needle is connected with H/P 1.0 version, it is not normally working

1.2.3 Installation of the Hand-piece – MONO Hand-piece(Using with Neutral Electrode Pole)

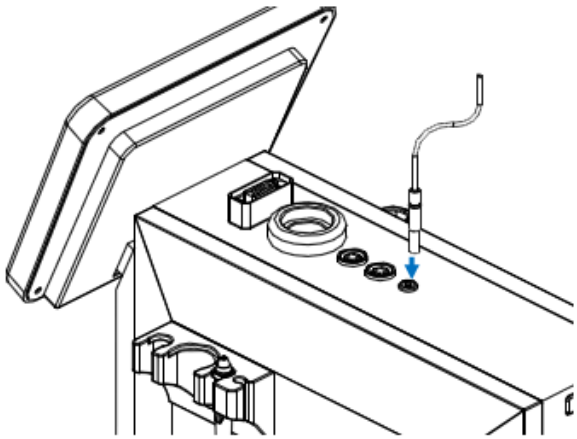
1) Mounting the MONO socket (C) on the MONO connector(A) of the console vertically.
2) Mounting the return electrode socket(D) on the return electrode connector(B) of the console vertically.



- Insert the mono-polar Hand-piece into the connecting hole for mono-polar on the top of the main body until you hear the clicking sound.
- Insert the earth pole Hand-piece into the connecting hole for earth pole on the top of the main body until you hear the clicking sound.
- The Hand-piece must be replaced on the main screen. If the Hand-piece is replaced after entering each mode of the system, an error may be occurred

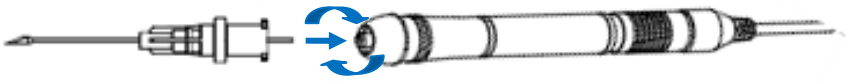
1.2.4 Installation of the Hand-piece –Pencil type Hand-piece, Return Electrode Pole

1) Mounting the Pencil Type H/P SOCKET on the Pencil Type H/P connector of the console vertically.
2) Mounting the return electrode socket on the return electrode connector of the console vertically.



- Insert the mono-polar Hand-piece into the connecting hole for mono-polar on the top of the main body until you hear the clicking sound.
- Insert the earth pole Hand-piece into the connecting hole for earth pole on the top of the main body until you hear the clicking sound
- The Hand-piece must be replaced on the main screen. If the Hand-piece is replaced after entering each mode of the system, an error may be occurred

3) Connecting Needle electrode or Sub_cision electrode



- Connect the electrode connector to needle electrode or sub_cision electrode.
- Connect tightly spinning the electrode because the connector hole is narrow.

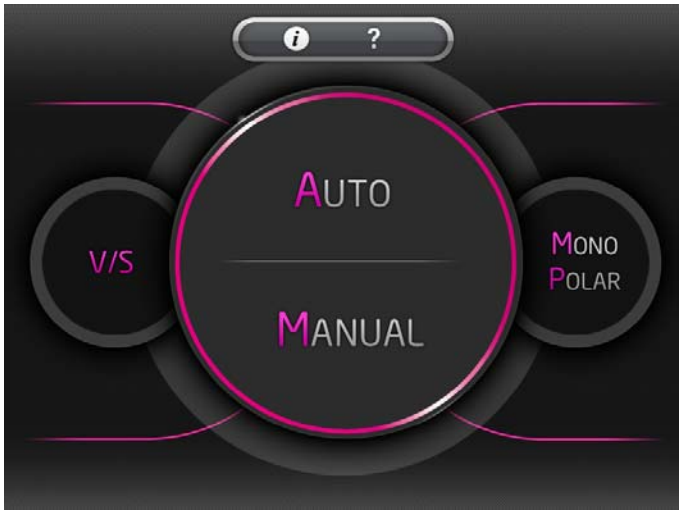
Chapter 4. Use of Equipment

During operation, treat the patient without the accessory (metal bracelet, watch, etc) that may work on the contrary to RF energy.

The user(doctor) should be next to the bed lying the patient, and the device should be placed to use it easily

Install the equipment as per "1.2 Equipment Installation" of 'Installation of equipment in Chapter 4. All operational module and functions are displayed on the LCD monitor and manipulated by touching LCD screen

Put the power key in and turn on, following main screen is appearing. The screen is changed to next screen when the menu is selected.



- **AUTO** : Providing the setting parameter automatically according to the treatment area. (Using two types BI POLAR hand piece)
- **MANUAL** : Able to adjust the setting value manually (Using two types BI POLAR hand piece)
- **V/S :** To use VS mode (Using Monopolar hand piece of Pencil type)
- **MONO POLAR** : To use MONO POLAR hand piece
- **!** : Information menu

NOTE

In VS mode, SC mode and VC mode can be selected.

1. How to use BI POLARMode

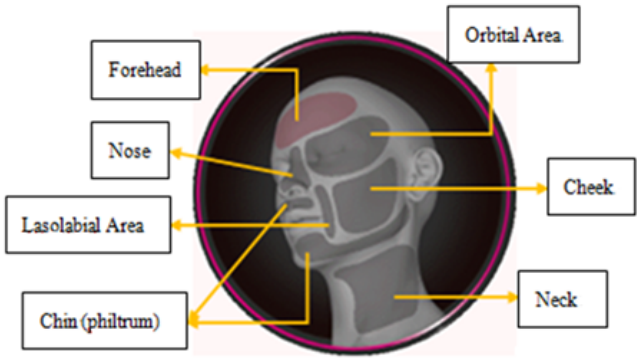
1.1 AUTO

: Automatically setting mode when Bipolar hand-piece(H/P 1.0version) is connected.

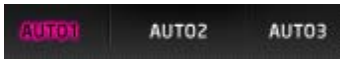
1) Select AUTO menu at the main screen and then following menu is coming.

2) The gray area on the face means main treatment area. The color of treatment area is changed gray to red after choosing the treatment place.

3) Select the treatment area first and then choose below auto1~3 depending on application.

Name of the parts


- **Application**



AUTO 1 : LIFTING

AUTO 2 : ACNE SCAR

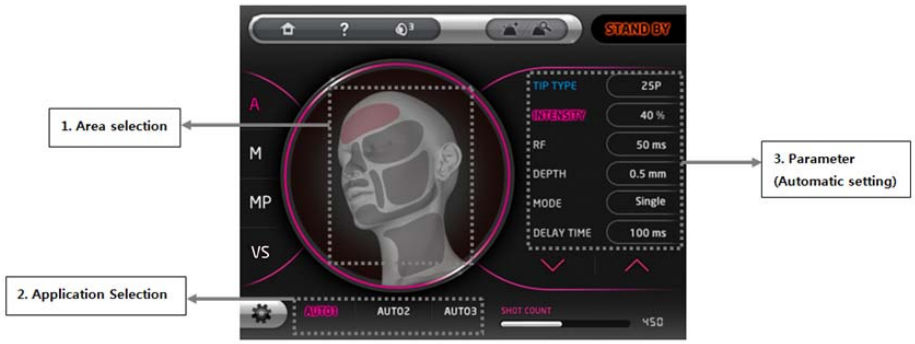
AUTO 3 : ACNE

- Automatic mode setting value

Area parts	AUTO 1			AUTO 2			AUTO 3		
	Intensity	RF time	Depth	Intensity	RF time	Depth	Intensity	RF time	Depth
① Forehead	40~50	50~70	0.5~0.8	40~50	50~70	0.5~0.8	40~50	50~70	0.5~0.8
② Orbital Area	40~50	50~70	1.0~1.2	40~50	50~70	1.0~1.2	40~50	50~70	1.0~1.2
③ Cheek	50~60	50~70	1.2~1.5	20~30	150~200	1.5~2.0	10~30	200~250	1.5~2.0
④ Nasolabial Fold	50~60	50~70	1.5~2.0	20~30	150~200	1.5~2.5	10~30	200~250	1.5~2.5
⑤ Chin	40~50	50~70	1.2~1.5	20~30	150~200	1.2~1.5	10~30	150~200	1.2~1.5
⑥ Nose	50~60	50~70	1.2~1.5	20~30	150~200	1.2~1.5	10~30	150~200	1.2~1.5
⑦ Neck	40~60	50~70	1.5						

4) Select the treatment area and choose below auto 1~3, and then standard parameter is automatically set. (Refer to the parameter Chapter 6, Auto menu setting)

- **Operating Procedure**



- **Terminology(Parameter)**

- INTENSITY : RF Energy

- RF : RF output time

- DEPTH : Needle penetration depth

- MODE : Interval time between Needle coming out (Repeat Time)

- DELAY TIME : Needle out time

5) After setting the value, if you touch the right above **STANDBY**, the color is changed to green and **READY** . If you push the foot switch, the RF Needle is coming out.

6) After the treatment begins, the OPERATION pop up sign is coming in the middle of screen(RF energy emitting). It means RF energy is coming.

OPERATION : Showing energy emitting

7) After finishing the treatment, you touch the right above READY and change to STANDBY, and place the hand piece in the hand piece holder of main body.

8) After finishing the equipment, turn off the Power Button.

1.2 Use of MANUAL menu

1) Select MANUAL menu at the main screen and then following menu is coming

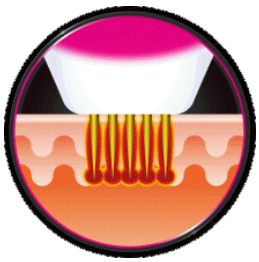
2) Set the individual output value at the right setting menu.

3) Select the parameter and adjust output value with **UP/DOWN ICONS**.

- **Intensity** : RF Energy
  - Setting Range : 0 ~ 100 Level (10 step)
- **RF** : RF output time
  - Setting Range : 50 ~ 950 ms
- **Depth** : Needle Penetration Depth
  - Setting Range : 0.5 ~ 3.5 mm (0.1mm step)
- **Mode** : Interval time between Needle coming out (Repeat Time)
  - Setting Range : Single, 0.2s, 0.5s, 1s, 2s
- **Delay Time** : Needle out time
  - Setting Range : 100ms ~ 1000ms (10ms step)

4) After setting the value, if you touch the right above **STANDBY**, the color is changed to green and **READY** . If you push the foot switch, the RF Needle is coming out.

5) If you start the treatment, the image in the middle of screen is changed into below image(Energy coming), it shows the energy is coming.



OPERATION : The energy is emitted

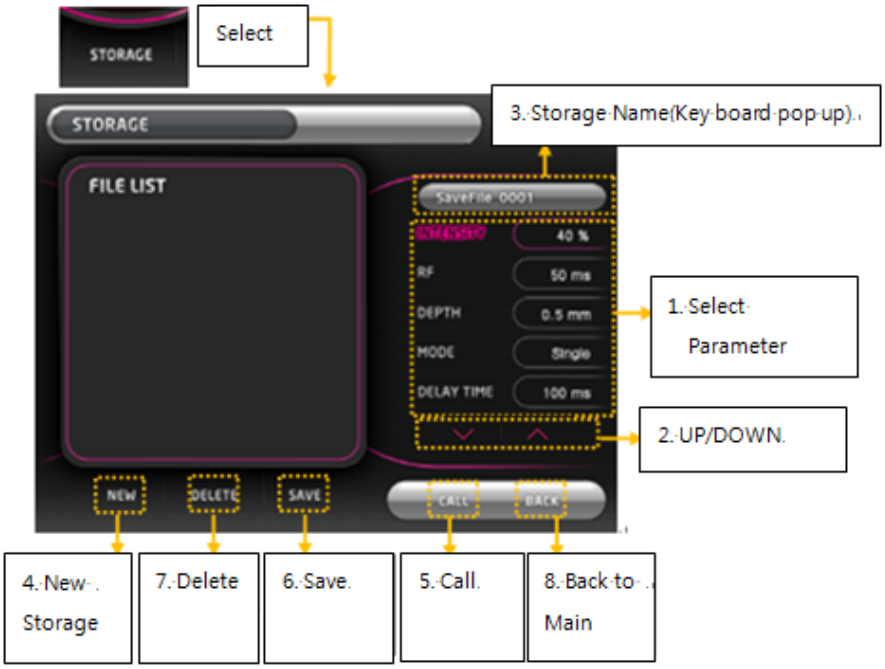
6) After finishing the treatment, you touch the right above READY and change to STANDBY, and place the hand piece in the hand piece holder of main body.

7) After finishing the equipment, turn off the Power Button.

** Optional Menu*

When you story the AUTO menu, press the STORAGE button at the bottom of Menu.

If you choose STORAGE, below screen is coming.



- Storage

① Select the parameter set the value with UP/DOWN button.

② If you choose the name to save, below pop up screen is coming.

③ After putting the name to save , press OK button, pop screen is disappearing the name is changed as you set.

④ After checking the name and parameter and choose NEW button, setting value is saved on the right FILE LIST.

- Call

  Choose a name among FILE LIST select CALL and then the screen is changed to MANUAL menu, and the saved parameter comes.

- Edit

  When you edit the already saved parameter, choose the name you want to edit among the FILE LIST Adjust the value with UP/DOWN button, press the SAVE button, and the amended parameter is saved with same name.

- Delete

  Choose the name you want to delete among FILE LIST, press the DELETE button, the list is deleted. After setting is completed, press the BACK Button, go to back to the MANUAL menu.

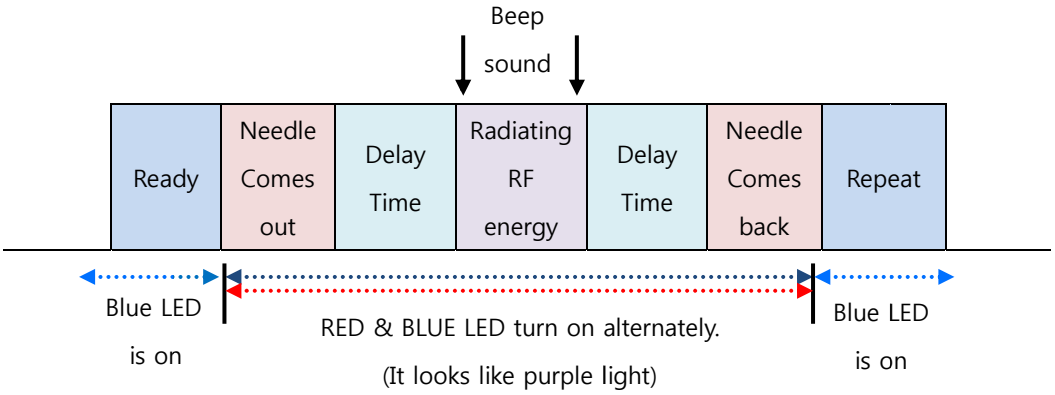
- Must check the Needle Tip before use and do not use the Needle tip which is not good sterilized condition.
- Never reuse Needle Tip again after use.
- Place the Needle pin exactly for the treatment area and press foot switch, not to place the pin

  on the sensitive area(Eyes etc)

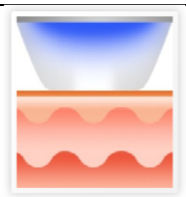
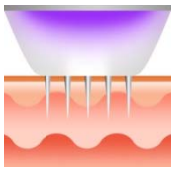
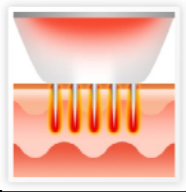
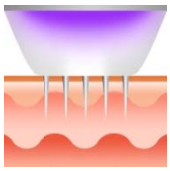
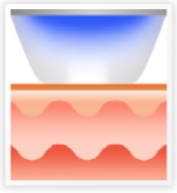
1.3Description of the micro-needle electrode movement

: This is the operation order when push the foot switch and needle comes out

1) Needle output cycle



2) Needle output Flowchart

NO	Action	Image	description
1	Foot Switch OFF		Before push the footswitch, Standby or Ready state in the device In normal state, the blue light is on in the micro-needle electrode.
2	Delay time after Footswitch turns on and Needle forward		As soon as push the footswitch, the needle comes out during the half of setting delay time At this time, the red and blue LED turn on quickly and alternately so it looks like purple light.
3	Emit RF energy		After passing the half of setting delay time, emit the RF energy as much as the setting value. At this time, beep sounds and the red and blue LED turns on quickly and alternately.
4	Delay time After emitting the RF energy,		After emitting the RF energy, during the half of setting delay time, the red and blue LED turn on alternately such as the previous stage and it looks like purple light.
5	After delay time and needle comes back		After finishing final delay time, the needle comes back and enters the electrode. If the needle enters the electrode completely, the red and blue light, which look like purple light, turn off and the blue light turns on.

2. Use of MONO (Hand-piece) Mode

: Uses High frequency current to generate diathermy in body tissues for relieving their pains.

1.1 Use of MONO POLAR

1) Select MONO POLAR menu at the main screen and then following menu is coming

2) Adjust right above **TIME** with **UP/DOWN** button. Only available to control **TIME** , for the **INTENSITY** turn clock wise with volume switch(**I**) on the body of machine while checking patient condition.

- **INTENSITY** : RF Energy
  - Setting Range : 0 ~ 100 Level (1 step)
- **TIME** : RF output time
  - Setting Range : 1 ~ 60 min (1 min step)

3) After setting the TIME, turn the volume switch to clock wise and with 'Tic' sound **STANDBY** is changed to **RUN** and RF is emitting. If you turn the volume switch to clock wise , the **INTENSITY** is increasing generally.

4) **INTENSITY** generally goes up from low level while checking the patient.

5) After the treatment begins, the OPERATION pop up sign is coming in the middle Of screen(RF energy emitting). It means RF energy is coming.

OPERATION : Showing energy emitting

6) When you stop the equipment during operation, touch RUN and then it turns to PAUSE and stop the power.

If you touch again, it turns to RUN and energy is emitting.

7) When you finish the treatment, turn the volume switch to anti clockwise completely and to be STANDBY. Hold the hand piece into hand piece holder.

9) After finishing the equipment, turn off the Power Button.

When you finish the treatment, turn the volume switch to 0 or convert to STANDBY which the patient is holding the ground hand piece.

If you take off the hand piece while not to change to STANDBY(Intensity – 0)/(Energy is coming out), it might cause electric shot and get the burn.

3. VS Mode

: Vein wave Mode for vein treatment

Insert several needle electrodes to thehandpiece(Pencil type) depending on the application.

3.1 VC mode

1) Select VS mode menu at the main screen, select the "VC" mode and then following menu iscoming.

2) Set the individual output value at the right setting menu.

3) Select the parameter and adjust output value with **UP/DOWN ICONS**.

- **INTENSITY** : RF Energy

  - Setting Range : 2~ 100 Level (2 step)

- **TIME** : RF output time

  - Setting Range : 1 ~ 900 ms (10ms step)

The technique is simple but requires absolute rigour.

It is strongly recommended to follow rules ;

a. Insert the needle electrode perpendicular to the skin

b. The zone to be treated must be horizontal.

c. Use the appropriate diameter needle electrodes.

3.2 SC mode(Optional)

1) Select VS mode menu at the main screen, select the "SC"mode and then following menu iscoming.

2)Set the individual output value at the right setting menu.

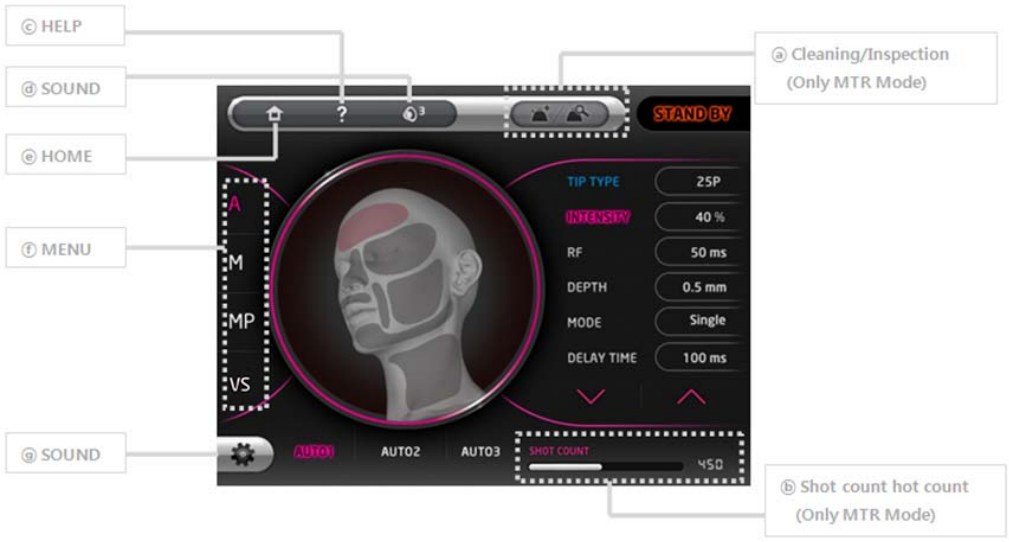
3)Select the parameter and adjust output value with **UP/DOWN ICONS**.

- **INTENSITY** : RF Energy

  - Setting Range : 10~100% (2 step)

4. BI POLAR Mode / General Option

There are general common options on each menu, you can go to optional menu with these optional menus.



4.1 BI POLAR Mode Option

4.1.1 CLEANING / INSPECTION Function

Choose right above "ⓐ" icon and check the needle (dirt and twist of needle) during treatment. Below pop up window coming if you select the icon.

- INSPECTION : Checking Needle condition.
  After touching the icon, the needle comes out and stay for 5 seconds, and check alien material and twist of needle. The needle will be automatically placed at the origin after 5 seconds.
- CLEANING : Cleaning Needle.
  RF is not coming and needle is staying outside. You can clean the needles with cotton or etc. The needles come backward after touching CANCEAL icon.

Function is only for checking dirt(skin particle and blood) and the twist of needle and purposed to better efficacy with less pain.

The CLEANING is not sterilization. Never reuse the needle after cleaning and must

be single use only for one patient.

4.1.2 SHOT COUNT Function

Right below "ⓑSHOT COUNT" shows the number of Needle shot and uncontrollable by intentionally. It is available until 1,500 shots. If the shots are over 1,500 shots, Graphic bar and Number is blinking in red.

4.2 General Option.

1) SOUND Function

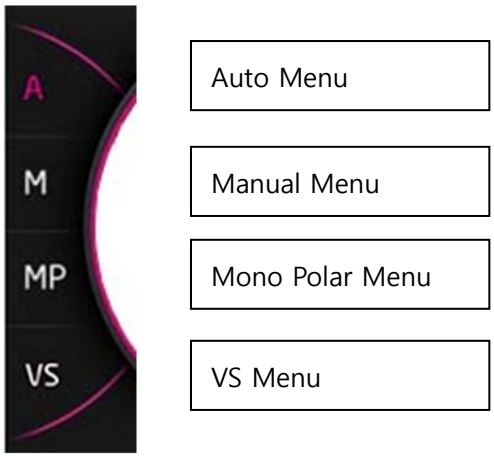
If you touch Above **"ⓓ"** icon, you can control the sound volume.

Whenever touch the icon, it goes 1 level up and goes to mute after maximum level. It goes to level 1 after touching mute.

Setting Range: 1 ~ 5, Mute (rotation)

2) MENU Function.

If you touch left "ⓕ" icon, you can go to treatment setting menu.



3) MAIN Menu(HOME)

If you touch left above "ⓔ" icon, go back to **MAIN** starting menu.

- Should turn on the power after finishing the installation. While the installation is not completed, if you try to turn on the power and go to the treatment mode, the error is coming and not operating.
- Unable to use two hand pieces at the same time. Go to the other treatment mode after finishing the current mode.
- Must set the value at the STANDBY position and after setting the value, go to READY.
- Check the setting parameter for the treatment before changing to READY.
- If you press footswitch (BI POLAR Mode) or turn the volume switch (MONO Mode) when it is READY, the energy is coming. Must place the hand piece on the treatment area and change to READY and press the foot switch for the treatment.
- Only authorized person(doctor) can control the footswitch and volume switch.

Chapter 5. Technical Specification

1. Specification Sheet

Rated input		100-240VAC, 50/60Hz, 400VA	
Accessory Voltage		178.8V more then	
Operation Menu		Auto(A), Manual(M), Mono-polar(MP), VS(VC/SC)	
Spec.	BI POLAR	Operation mode	Auto(A)mode . Manual(M) mode
		Output power (at 500Ω load)	Max 112Vrms ±10% (25W) (with H/P 1.0) Max 188Vrms ±10% (70W) (with H/P 2.0)
		Frequency	2MHz± 10%
		RF Output Time	50ms ~ 950ms
		Depth	0.5mm ~ 3.5mm (0.1 step)
		Repetition	Single, 0.2s, 0.5s, 0.8s, 1s, 2s (Repeat time)
		Intensity	0 ~ 100(Level) (2/5/10 step)
		Active electrodes	Micro Needle electrodes (10pin, 25pin, 64pin)
	MONO	Operation Mode	MP mode
		Output power (at 500Ω load)	Max 460Vp-p ±10% (52W)
		Frequency	2MHz ± 10% / Continuous Wave
		Intensity	0 ~ 100(Level) (1 step)
		Output Time	1 ~ 60min (1min step)
		Active electrodes	Φ15 (Integral electrode)
	VC mode of VS mode	Operation mode	VS mode
		Output power (at 100Ω load)	Max. 600Vp-p ±10%
		Intensity	10~ 100(Level) (10 step)
		Frequency	4MHz ±10%
		Output Time	10~900ms

		Active electrodes	Needle type electrode
	SC mode of VS mode (Optional)	Operation mode	VS mode
		Output power (at 500Ω load)	Max 68Vrms ±10%
		Intensity	2~ 100(Level) (2 step)
		Frequency	2MHz / Continuous Wave
		Output time	Continuous
		Active electrodes	Sub_cision type electrode

※ The specifications mentioned above are subjected to change for the improvement of capability without notice.

2. Output setting energy value per mode

1) A(Auto)/M(Munual) Mode (MTRhandpiecemode)

- Frequency: 2MHz ± 10%
- Intensity: 0 ~ 100 (10 step)
- Output value per Intensity (at 500Ω load)

	Volt (rms)	W
Intensity 10	9.17	0.16
Intensity 20	19.6	0.76
Intensity 30	30.7	1.88
Intensity 40	42	3.52
Intensity 50	53.7	5.76
Intensity 60	65.5	8.58
Intensity 70	77.1	11.88
Intensity 80	88.7	15.73
Intensity 90	101	20.40
Intensity 100	112	25.08

2)VC Mode (MONO pencil-type handpiece mode)

: Choose the Vein wave mode or Subcision mode in VC Mode.

① Vein wave Mode

- Frequency: 2MHz ± 10%
- Intensity: 10% ~ 100% (10 step)
- Output value per Intensity (at 500Ω load)

Intensity	Voltage(RMS)	W
10	4	0.0
20	9	0.2
30	14	0.4
40	21	0.9
50	26	1.4
60	32	2.0
70	38	2.9
80	44	3.8
90	50	5.0
100	55	6.1

② Sub_cision Mode

- Frequency: 2MHz ± 10%
- Intensity: 2% ~ 100% (2 step)
- Output value per Intensity (at 500Ω load)

Intensity	Voltage(RMS)	W
10	4	0.0
20	10	0.2
30	18	0.6
40	24	1.2
50	31	1.9
60	37	2.8
70	44	3.9
80	52	5.3
90	58	6.8
100	66	8.7

3. Frequency of use (treatment interval)

3 ~ 4 weeks interval, total 3~5 treatment are recommended.

Chapter 6. Output power characteristics

Use only accessories that have been approved for use with the SECRET.
Do not use accessories that fail to meet the minimum peak voltage requirements, Peak Voltage vs. control settings.
It is recommended to use only accessories rated at the maximum peak voltage, for a given mode.

Power readouts agree with actual power into rated load to within 20%, whichever is greater.

MODE	Intensity	Output Power	Output frequency	Vp-p max	Crest Factor
Manual (Bipolar Mode (H/P 1.0))	100	25W@500Ω	2MHz	334V	330V/112V = 2.94
Manual (Bipolar Mode (H/P 2.0))	100	70W@500Ω	2MHz	550V	550V/188V = 2.92
VC Mode	100	3@100Ω	4MHz	600V	
SC Mode	100	9W@500Ω	2MHz		

1. A(Auto)/M(Manual) Mode

1.1 Output setting energy value per mode

- Output value per Intensity (at 500Ω load)

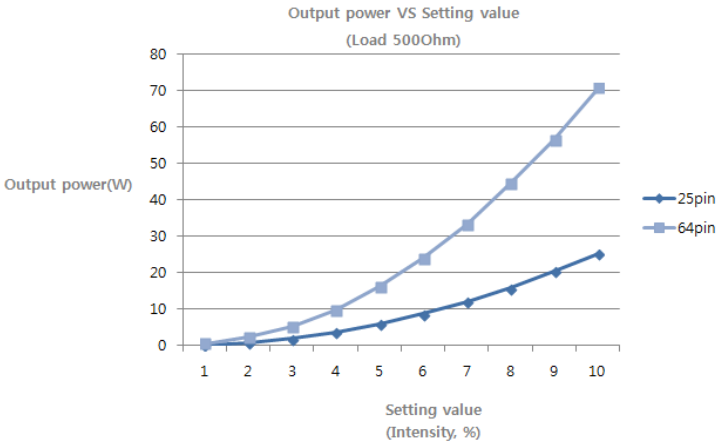
Intensity	Voltage(RMS)	W
10	9.17	0.1
20	19.6	0.7
30	30.7	1.8
40	42	3.5
50	53.7	5.7
60	65.5	8.5
70	77.1	11.8
80	88.7	15.7
90	101	20.4
100	112	25.0

[Connected 25pin electrode]

Intensity	Voltage(RMS)	W
10	15.7	0.5
20	32.8	2.1
30	50.8	5.1
40	69.8	9.7
50	90	16.2
60	109	23.7
70	129	33.2
80	149	44.4
90	168	56.4
100	188	70.6

[Connected 64pin electrode]

- Output diagram

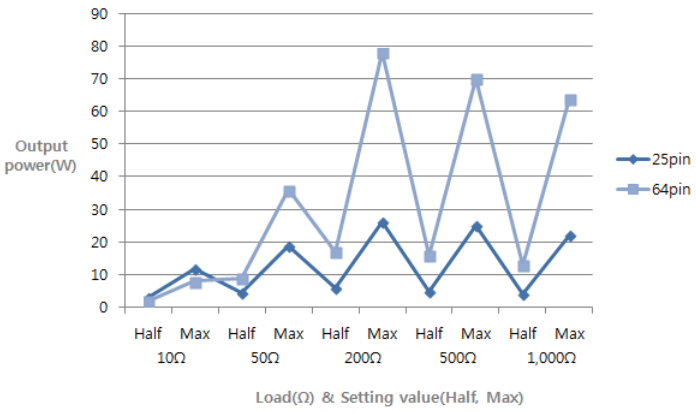


1.2 Load resistance diagram

- Output data

Intensity(%)	Load(Ω	W(Connected 25pin)	W(Connected 64pin)
50(Half)	10Ω	3	2
100(Max)		12	8
50(Half)	50Ω	4.5	9
100(Max)		19	36
50(Half)	200Ω	6	17
100(Max)		26	78
50(Half)	500Ω	5	16
100(Max)		25	70
50(Half)	1000Ω	4	13
100(Max)		22	64

- Output diagram



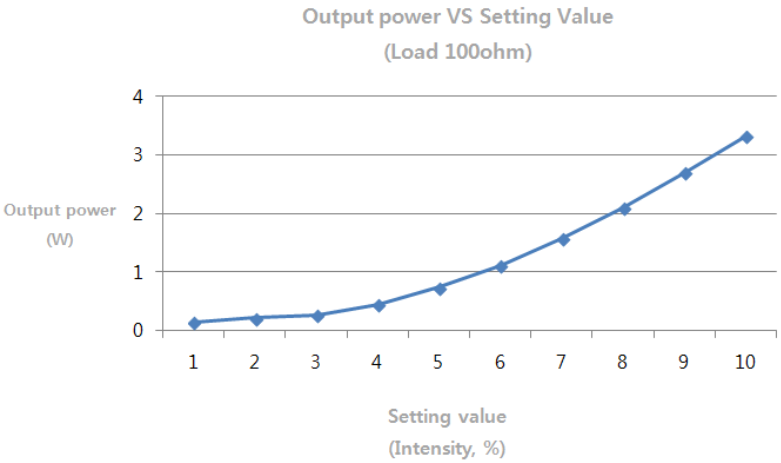
2. VC Mode (MONO pencil-type Hand-piece mode)

: Choose the Vein wave mode or Subcision mode in VC Mode.

2.1 Output setting energy value per mode

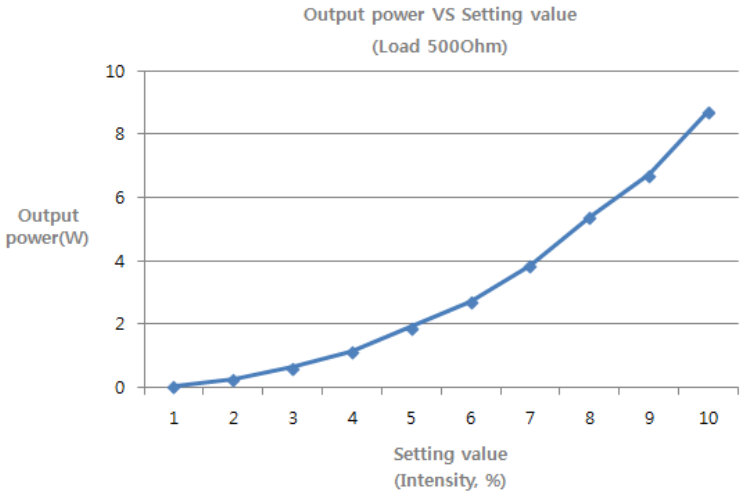
1) Vein wave Mode(VC mode)

Intensity (%)	W
10	0.14
20	0.21
30	0.26
40	0.45
50	0.74
60	1.11
70	1.57
80	2.1
90	2.7
100	3.32



2) Subcision Mode(SC mode)

Intensity (%)	W
10	0.1
20	0.2
30	0.6
40	1.2
50	1.9
60	2.8
70	3.9
80	5.3
90	6.8
100	8.7



Chapter 7. Explanation on Pop-up Messages

These are popup messages for errors or warnings appeared during use or manipulation. If the following message is indicated, stop the surgical procedure immediately, and readjust the equipment after checking the message

1. Error Messages

Screen indicating an error message.

An error message is pop-upped on the screen as follows, and a message is differently appeared in the box depending on the error. Refer to the table below

ERROR	CONTENT	SOLUTION
FOOT SWITCH ERROR	FOOT SWITCH ERROR Please check the foot switch ERROR CODE : E0501	Error message occurred when the foot switch on the back side of the console is disconnected. Check whether or not the foot switch is connected, and connect it again.
SERIAL STATUS ERROR	Serial Status ERROR Please check the Serial Status ERROR CODE : E1301	Message appeared when communication is achieved between systems. Ask the agency.

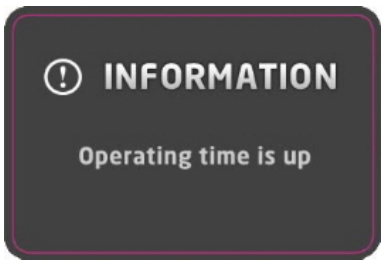
2. Warning Message

Screen indicating a warning message.

A warning message is pop-upped on the screen as follows, and a message is differently appeared in the box depending on the warning. Refer to the table below.

WARNING	CONTENTS	SOLUTION
Warning! Turn off the volume switch	**Zero Start**	In case the volume switch is not 0, the warning sound comes. Set the volume switch to 0 before start.
Warning! Please Check the TIP	**Checking Needle tip connection**	When the needle tip is not connected or not connected properly, the warning sign comes. Must connect the Needle tip to Hand piece completely.
Change the TIP TEXT	**Over count of Needle Tip**	If you use Needle tip over counted, the sign comes. Change the tip to new one.
Warning! EEPROM connection Check	**Checking Error for Shot storage system**	In case of the problem with the storage of Needle shot counting, please contact the agent.
Warning! It might cause damage to the skin	**Over output warning**	In case of increasing RF over 400, the warn comes. Check the patient and adjust the intensity.
Warning! This tip is over used and please change the tip	-	TIP SHOT COUNT comes to MAXIMUM limited number
WARNING Need to update the Hand-piece for this 64 pins tip	**Checking Needle tip connection**	It happens when 64PIN tip is connect to H/P 1.0 at the AUTO / MANUAL

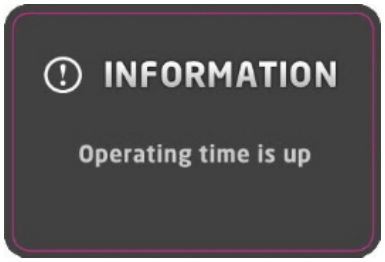
3. Time Message



The screen of warning message.
The Warning window pops up, the description in the box
is different from depending on the sort of warning.
Refer to following chart.

WARNING	CONTENTS	SOLUTION
Operating time is up	**Overtime of treatment**	The operation time is over, stop the treatment time after checking the time or reset the time.

4. Information Message



The screen of warning message.
The Warning window pops up, the description in the box
is different from depending on the sort of warning.
Refer to following chart.

WARNING	SOLUTION
INFORMATION! **Operating time is up**	The operation time is over, stop the treatment time after checking the time or reset the time.
INFORMATION! **Back to the presetting parameter?**	It happens when it is pressed BACK button for AUTO mode at the USER PREESET Mode.
INFORMATION **Save the customized parameter?**	When delete the all USER PREESET parameter, this warning comes
INFORMATION **Do you want Program update?**	When touch UPDATE button at the INFORMATIN mode, this warning comes
INFORMATION **Insert a subcision-needle into the needle holder pen**	When touch SUBCISION button at the Veincure mode
INFORMATION **Insert a veincure-needle into the needle holder pen**	When touch VEINCURE button at the Veincure mode

Appedix1. Label and Symbols

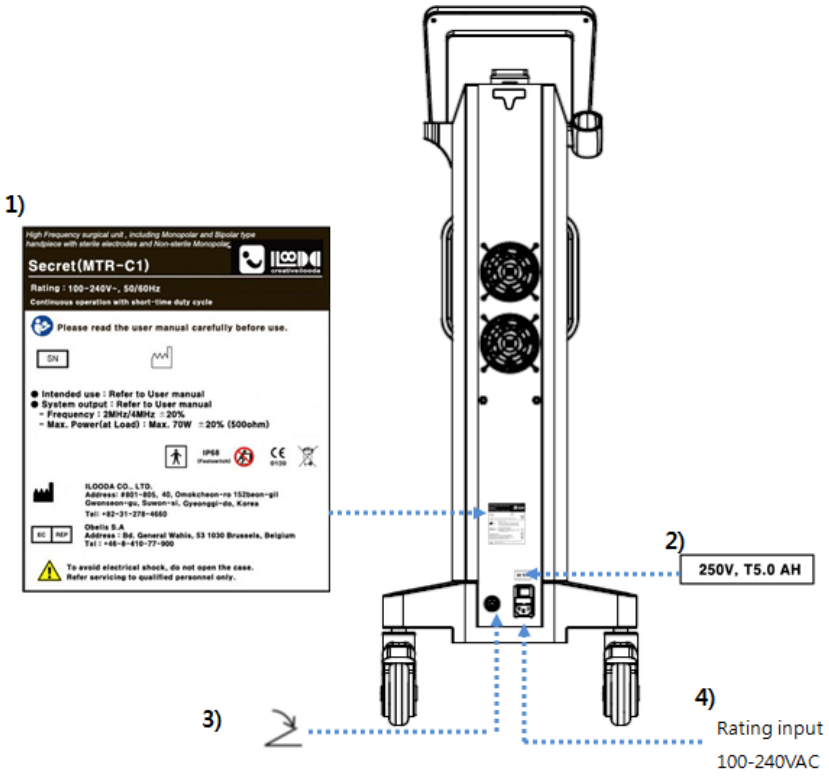
NOTE

The position of the label can be changed arbitrarily manufacturer.

1.1 Labels

1) Main unit

- Back

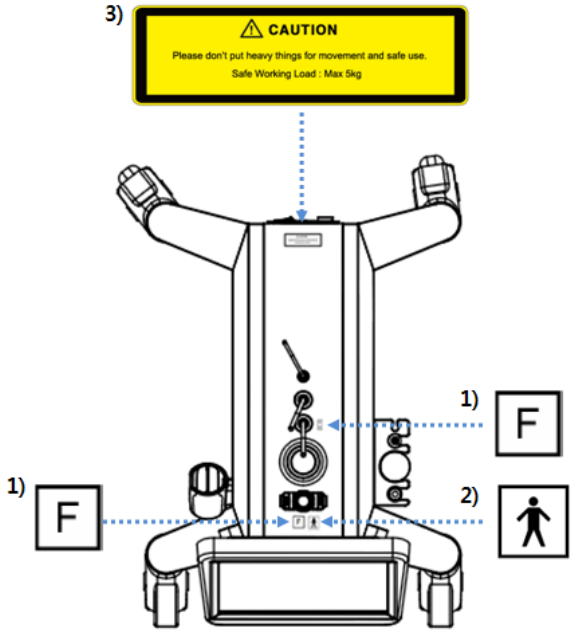


No	PART	Type	Description
1)	Product	LABEL	Attachment 1
2)	Fuse	LABEL	
3)	Footswitch	Text printing(Symbol)	Footswitch connector
4)	Rating input	Text printing(Symbol)	Input power

*Attachment 1

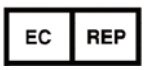
No	Label	Symbol	Content
1)	*High frequency electrosurgical unit, including Bipolar and Monopolar handpiece with sterile electrodes and Non-sterile electrode.* **MTR-C1** **Rating: 100-240Vac, 50/60Hz, 400VA** **Continuous operating with short-time duty cycle** **Please read the user manual carefully before use.** SN ● Intemded use : Refer to User Manual ● System Output : Refer to User Manual - Type of protection : Class1, BF type equipment - Reted power (at Load) : Max. 70W ±20% (at 500Ω load) - Operating frequency : 2㎒ ±20%, Sine wave 4㎒ ±20%, Sine wave (VC mode) IP68 (Footswitch) CE 0120 **ILOODA Co., Ltd.** 801~805 Venture Valley, #958, Gosaek-dong, Gwonseon-gu, Suwon-si, Gyeonggi-do, Korea TEL: +82-31-278-4660/ FAX: +82-31-278-4661 EC REP **Obelis s.a** Address: Bd. General Wahis 53 1030 Brussels, BELGIUM TEL : +32-2-732-59-54 To avoid electrical shock, do notopen the cabinet. Refer servicing to qualified personnel only	SN	Serial No
			Manufacture Date
			User Manual Reference
			Manufacturer
		EC REP	Authorized EC Representative
			Class BF device
			Waste Electrical and Electronic Equipment
			Pushing Prohibited

-Upper



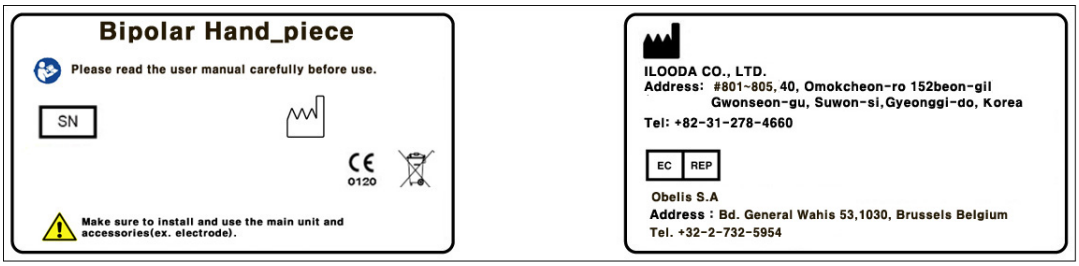
No	PART	Type	Description
1)	Isolated patient	LABEL	High frequency isolated patient circuit.
2)	Applied part	LABEL	BF applied part
3)		LABEL	During movement warning.

Needle Tip Lable

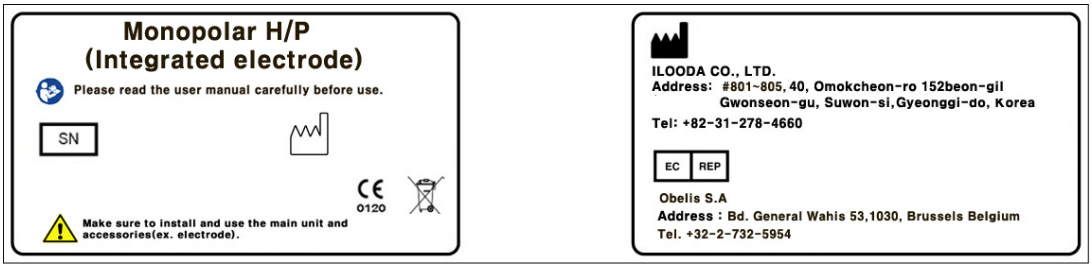
No		Symbol	Label
1-b			Manufacturing date
			Lot number
			Use by date (Expiration date)
			Sterile using EO gas
			Consult User manual
			Single use
			Don't use when packing damaged
			Keep away from sunlight
			Storage temperature limitation
			Manufacturer
			Authorized EC representative

- Hand-pieces

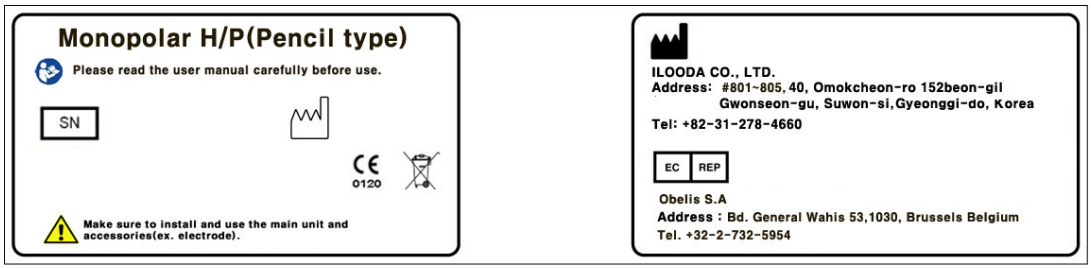
Bipolar Hand-pieces



Monopolar(Integrated electrode) Hand-pieces



Monopolar(Pensil type) Hand-pieces



Appendix 2. Regular Safety Inspection

MTR-C1 is provided with various safety label and safety devices. For the safety use, do not destroy these devices and keep it safe. According to local regulation, safety checking is practiced annually and have to check all safety functions working properly.

- Equipment safety checking

  Refer to the equipment checking list and contact the agent in case of the problem on it, Refer to "Table. daily equipment inspection log"

Object of Inspection	Matters to be Inspected	Result of Inspection YES / NO	Inspector	Remarks
Earthing resistance	Carry out earthing resistance test in accordance with IEC601.			
Short circuit	Carry out short circuit test in accordance with IEC601.			
Insulation	Carry out insulation test in accordance with IEC601.			
Foot switch	1. Check if there is any damage on the machine or cable. 2. Operate foot switch in a standby mode and select treatment mode. It is normal only if READY icon cannot be selected in the treatment mode.			

- RF Block Out System

- Warning of RF radiation

Visual warning on display and audial warning is installed together.

This Warning sign is expressed on LCD and "beep" sound at the same time.

(Inspect annually at least in accordance with regular safety inspection regulation)

- Foot Switch

RF is emitted when the foot switch is pressed.

The error sign is coming and the equipment is not operating when the foot switch is not connected. (Inspect annually at least in accordance with regular safety inspection regulation)

- Cable

Always check the damage of power cable.

Must check the cable before and after use.

Regularly inspect accessories for damage. In particular, electrode cables and endoscopically used accessories should be checked for possible damage to the insulation.

Appendix 3. The revision of User manual

REV	Revisions	Date
IFU-MTR(REV.0)	First Edition of Secret User Manual	1th.FEB.2012
IFU-MTR(REV.1)	Update UI	04th.JUL.2012
IFU-MTR(REV.2)	Contents is changed	10th.SEP.2012
IFU-MTR(REV.3)	Contents is changed	15th.JUL.2013
IFU-MTR(REV.4)	Update Features	27th.FEB.2014
IFU-MTR(REV.5)	Change UI	23th.APR.2014
IFU-MTR(REV.6)	Changed AR	08th.JAN.2015