Secret DUO

User Manual

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Exemptions

The information provided by ILOODA is correct and reliable.
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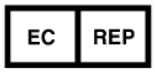

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Please check the related local regulations before using the equipment. The use of the apparatus may not be permitted if it is not in conformity with the related local law.

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 DUO 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
 CAUTION!	The symbol informs the user that particular care is required for safe and efficient operation of the system.
 WARNING!	This symbol advises the user of serious danger (bodily injury or death) for the patient and the user.
	General mandatory action sign
 NOTE	Provision of additional information for assisting users.
	Instruction for use


NOTE

- 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 Operation 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 hand-piece option.
- Read and thoroughly understand this section before operating the System.

Qualification for Using Secret DUO

It is strictly required that this equipment be used only by licensed physician qualified for safety handling and use of laser and high frequency surgical device.
Thus, any person working in the setting of this equipment (e.g., nurse, technician, etc.) except physician holding a license or a certificate on laser device must not use/operate this equipment.

Only physicians are allowed to possess key of this equipment and please separate key from key switch of equipment when not in use to protect equipment from being used by other persons.

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 laser equipment, laser physics, and interactions of tissues and take the respective safety education program according to each country's regulation in addition to laser-related safety education.

It is also recommended that the physician wanting to use the laser equipment obtain an approval 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 - Certified by manufacturer
Knowledge	- Experience with Laser treatment and High frequency surgical treatment. - Requirement of medical knowledge - Requirement of information message comprehension	- Expertise for Laser and HF technology. - An information message comprehension required.

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Chapter 1. Introduction to Secret DUO

1. Apparatus-verification data

- Device Name: 1540nm Laser system and High frequency surgical system sterile micro needle electrodes
- Model Name: Secret DUO
- Classification: Class IIb (MDD 93/42/EEC as amended according to the Directive 2007/47/EC)

2. Supplied ITEMS

The followings are components (accessories) comprised of this equipment

- Main unit: Combination type devices (1540nm Laser system and High frequency surgical system)
- Components
  - Laser handpiece (Laser part)
  - Bigger handpiece (Bipolar type)(HF part)
  - SmartCure handpiece (Monopolar type) (HF part)
  - Neutral handpiece(Integral electrode) (HF part)

- Sterile Electrosurgical electrode (Micro-needle electrodes)
  - Bipolar type: MTR-AC-10, MTR-AC-16, MTR-AC-25, MTR-AC-64, MTR-AC-C-10, MTR-AC-C-16, MTR-AC-C-25, MTR-AC-C-64
  - Monopolar type: MTR-AC-01, MTR-AC-04, MTR-AC-19G, MTR-AC-22G, MTR-AC-27G
- Accessories
  - Power cable, Cable holder
  - Handpiece holder
  - Foot switch
  - Laser handpiece beam guide
  - Key Switch
  - Goggles for User (Goggles for Doctor) (Laser part)
  - Eye Guards for Patient (Laser part)
  - Remote Interlock
  - User manual

Don’t use other parts except for the parts provided by manufacturer.

3. System introduction

Secret DUO is a combination of laser surgical system using 1540nm wavelength and High frequency surgical system using High-frequency. Because Secret DUO is a simple combination of 1540nm laser system and High frequency surgical system, energy transmission part is clearly distinguished.

Laser part of Secret DUO consists of control system, LCD touch screen control panel, laser emission and delivery system, foot switch, safety features (including Interlock, Key switch) and hand-pieces. HF(High Frequency) part of Secret DUO consists of control system, LCD touch screen control panel, Bipolar and Monopolar hand-pieces equipped with single use micro needle electrodes and footswitch.

4. General information about Secret DUO

- Type of protection against electric shock**:** Class I Equipment
  Degree of protection against electric shock : BF Type
- Degree of protection against the ingress of water
  - Main unit: IPX0, - Foot switch: IPX8
- Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Applied parts: Laser hand piece beam guide, Micro needle electrodes, Neutral handpiece
- HF electrosurgical electrode(Micro-needle types)
  : E.O gas sterilization, single use (Expiration date: 3years)
- Operation Condition
  - Operation Temperature: Recommended within 10℃ ~ 40℃
  - Relative Humidity: 10% ~ 75%
  - Atmospheric Pressure: 800 ~ 1060hPa
- Storage and Transportation
  - Temperature Condition: 10℃ ~ 60℃
  - Relative Humidity: 10% ~ 90%
  - Atmospheric Pressure: 500 ~ 1060 hPa
- Storage and Transportation for Sterile micro needle electrodes
  - Temperature Condition: 0℃ ~ 20℃
  - Humidity: Below 65%R.H

- Explanation of symbols

SN Serial Number	LOT Lot number	 Date of Manufacture
 Caution	 Manufacturer	EC REP Authorized Representative in the European Community
 Remote Interlock	 Type BF applied part (HF part)	STOP Emergency Laser Emission Stop Switch
 Power ON/OFF	 Irradiation	F HF isolated patient circuit
 User Manual Reference	 Foot Switch(IPX8)	

5. Essentials for Using Equipment

Secret DUO is a medical treatment device that may only be used for its intended dermatological treatment purpose.

NOTE

Secret DUO should be protected against unauthorized use

CAUTION!

- The use of mobile telephones or similar devices is not permitted in the same room during operation of the Laser and HF.
- Due to a possible risk of interference through electromagnetic radiation during operation, individuals with pace makers should not be present in the same room. Pregnant women should also leave the room.
- Use the electrode needle tip exactly for the treatment area and press foot switch, not to use the electrodes tip on the sensitive area (Eyes etc)
- Do not combine laser treatment with electric surgery treatment.
- The remodeling or modification of this equipment is absolutely prohibited

NOTE

- Like any highly-effective medical device, it demands special expertise and care for its handling and use. Secret DUO 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.

The following provisions are essential guidelines that must be noted before using this equipment. In case the following provisions are not observed, the equipment performance degradation and unexpected severe damages may be incurred.

CAUTION!

- Use of controls or adjustments, or performance of procedures other than those specified herein may be hazardous. Therefore, personnel operating or maintaining this device should read this manual and become thoroughly familiar with all its safety requirements and operating procedures before attempting to use or operate the system.
- Unauthorized persons must not operate the equipment without the supervision of an expert.
- The patient or the operator must not use the equipment while wearing rings, wristwatches, or necklaces.
- Check if the equipment power is on, and separate the key switch to prevent it from being operated by someone else.
- Do not disassemble the equipment. Disassembly of the equipment can only be conducted by the repair agent designated by the manufacturer. It is impossible to perform treatment with the equipment disassembled.

5.1 Installation of Equipment

NOTE

Please refer to "Chapter 4. Installation equipment" for installation instructions.

- The equipment must be installed and used only in a safe treatment room/setting in the hospital or clinic.
- The use of the equipment in places other than hospital or clinics, e.g., skin care shop, cosmetic treatment place, etc., is strictly prohibited.
- Only authorized person may operate, manage and repair the equipment.
- The equipment must be moved and installed only when it is completely turned off and placed in a secure and flat space, respectively.
- This equipment should be placed without causing(e.g., connection plug) any difficulty to operate properly.
- Install the equipment at least a 100mm distance from the wall.

CAUTION!

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

5.2 Setting for Output

Before configuring the equipment parameters, take the state of the patient into account.

The equipment parameter configuration must be performed in standby mode.

When adjusting the equipment parameter configuration, start with a small value and gradually increase the intensity until the desired value is reached.

- The handpiece should be always settled on a stable location (handpiece holder), and the direction of the handpiece must not be towards someone other than the patient.
- The laser irradiation unit should be directed downward.
- When changing the equipment output value, first check the screen indications if the applied parameters are properly configured at all times.
- Use only on the surface of skins without infection or any other damages.

CAUTION!

- 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 ‘off’ state and then operate the device according to set-up order in order not to exceed the voltage of the accessory.

5.3 Additional information of each function

5.3.1 Laser part

1) Eye Protection

All of the persons around the laser equipment in use (doctor, patient, nurse and other supporting staffs) must wear the appropriate eye protection tools. Never take a direct look at the laser beam guide.

CAUTION!

- Avoid eye exposure to direct radiation. (Must use goggle)
- Improper use of equipment may cause a damage on the eyes due to direct or pulverized emission of laser beam. (Must use goggle)

To protect eyes, shall wear the goggles specially manufactured to be compatible with specific wavelength.

Goggles by wavelength shall meet the following safety requirements at least

Goggles for users

Wavelength	1410-1550nm
Optical Density	OD5+@1400-1550nm
Block type	OD5+
Visible light transmittance	VLT : 32%
L-Ratings	DI-LB3, 1400-1550nm

Goggles for patients

YL-800W1

- Color of eyecup / white
- Detachable and adjustable rubber strap
- Nose bridge / M
  (Exchangeable S, M and XL bridges are included)
- Safety Eyeguard comes with softcase.

CE DIR 180-315 D L8 + IR L4
DIR >315-1400 D L5 + IR L7
D >1400-10600 D L3

5.3.2 High Frequency electrosurgical part

1) Sterilization HF electrosurgical electrodes (Micro-needle electrodes)

CAUTION!

- Be sure to check the sterilized condition of micro-needle electrodes to be used with the hand piece.
- Verify the sterilization information, e.g., sterilized date, expiration date, etc., on the label printed on the sterilized wrapping paper; use only the micro-needle electrodes with intact sterilized conditions.
- Micro needle electrodes are single-use; thus, they must not be reused. If a needle electrode package is opened, it must not be reused.
- Do not treat multiple patients with the same micro-needle electrode; do not use it repeated times.

WARNING!

- Do not use micro needle electrodes that the sterilized packaging is damaged (torn, contaminated etc.), or there is no sterilized packaging.
- Micro-needle electrodes are single-use; thus, they must not be reused. If a needle electrode package is opened, it must not be reused.

Chapter 2. Professional clinical information

The purpose of this manual is to review treatments and techniques and to provide general guidelines for the safe and effective use of the Secret DUO.

1. Intended use

- Laser part: It is intended to use in general and plastic surgery and in dermatology.
- High Frequency surgical system with sterile micro needle electrodes part: It is intended to using Thermo-coagulation using a sterile micro needle electrodes

1.1 Specific Indication

- 1540nm laser system: Facial scar treatment
- High frequency system with sterile microneedle electrodes:
  - Bipolar type(RF Mode): Acne scar treatment
  - Monopolar type(SmartCure Mode): Acne treatment

2. Intended patient population

Considerations	Requirement description	
Age	Over 18 years old	
Health	There are no special requirement	
Nationality	Multiple	
Skin type	**RF mode**	**Laser mode**
	N/A	I-III
Gender	N/A	

3. Complication and Adverse Effects

Complication, though rare, can occur with any treatment procedure. All possibilities should be discussed with the patient and understood prior to treatment.

Failure to comply with post care instructions may increase the probability of complications.

3.1 Adverse effects

Following adverse reactions would be occurred during treatment.

1) Laser treatment

- Pigmentation change (Dark skin patient)
- Temporary pain (recommend anesthesia cream)
- Erythema
- Edema

2) High frequency treatment

- Pain
- Erythema
- Edema
- Crusting
- Dryness
- Folliculitis
- Post-inflammatory hyperpigmentation

3.2 References

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4. Contraindications

Contraindications 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.

- The pregnant women or breast feeding person
- For patients with cardiac pacemaker or other active implantable metal device in treatment area.
- Botox®/collagen/fat/filler injections or other methods of augmentation with injected material in the treated area prior to treatment.
- Patient with unknown skin disease.
- Subjects with body piercing (in the treated area).
- Subjects who suffer from autoimmune disorders or diabetes.
- Subjects using blood thinning medications.
- Subjects with clotting disorders.
- Patients undergoing treatment for skin cancer
- Use precaution when treating areas with very thin skin.
- Sensitive patient with hot sensation or subjects who have any form of suspicious lesion in the treatment area.
- Impaired immune system due to immunosuppressive diseases such as AIDS and HTV, or use of immunosuppressive medications.
- Patients with history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area, may be treated only following a prophylactic regime.
- Any active condition in the treatment area, such as sores, psoriasis, eczema, and rash.
- History of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin.
- Face lift or eyelid surgery within a year prior to treatment.
- Facial dermabrasion, facial resurfacing, or deep chemical peeling within the last 3 months, if face is treated.
- Having received treatment with Laser(light), RF or other devices in the treated area within 1 month prior to treatment (according to the doctor’s judgment).
- Use of non-steroidal anti-inflammatory drugs (NSAIDS, e.g., ibuprofen containing agents) one week before and after each treatment session.
- Any surgical treatment in the treatment area within the last 3 months or before complete healing.
- Treating over tattoo or permanent makeup
- Any other medical condition according to the doctor’s judgment.

-
- Excessively tanned skin from sun, tanning beds or tanning creams within the last two weeks.
- Use caution in patients with known sensitivities or allergies to the metals or gold plating that are contained including chromium and nickel.
- Use caution in patients with known sensitivities or allergies to the light.

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. Precautions

Make sure to give the treatment only to the patient in accordance with the purpose of this equipment after physician's prior diagnosis. The treatment to the patient with other lesion(s) not included in the originally indicated one(s) without physician'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, inform a patient about the cautions before, during, and after treatment and notify the possibility of occurrence of unintended abnormal symptoms to him or her.

Please explain the contents of the following to the patient 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 deposit of pigment on treated part) may occur which is temporary symptom requiring no particular treatment.
Notify to see physician when experiencing flushing, pricking or any abnormality on or around treated part.

Precaution for High frequency treatment

- Avoid intensive sun exposure 3 days before the treatment.
- 3 Days before the treatment void the use of products that might affect skin sensitivity such as Glycolic Acid, Salicylic Acid, Retin-A® and other products containing Isotretinoin

Chapter 3. Safety Cautions

1. Instruction for Environmental safety

1.1 Electrical Hazard

All the users of the Secret DUO must be aware of and observe the cautions outlined in this section for electrical safety and to avoid electrical shocks.

In case of an emergency, push the Emergency stop button, located on the front side of the handle, to power-off the system.


NOTE

- The Secret DUO must be used only at locations with electrical equipment complying with related specifications and regulations.
- Do not use water or other liquid solvents when cleaning electrical components. Do not spill water or liquid on the equipment.
- When installing, watch out to avoid tripping over wiring/piping or tangling of wires.
- Components and accessories must be installed and used by checking the specifications, and do not use arbitrary products other than the accessories that were supplied with this equipment.
- Regularly inspect exterior or wire damages.
- When replacing components, send inquiries to the manufacturer.
- In order to avoid electric shock, check if the power is properly connected when using the equipment.


WARNING!

- Do not contact the connector part of the equipment and the patient at the same time.
- The device generates high voltage within the Control Unit. The control Unit contains no user-serviceable components. To avoid personnel injury, ensure that the system covers are properly closed before operation. Do not attempt to open the system covers. Service is to be performed by authorized personnel only.

1.2 Fire and Burn Hazard

All the users of the equipment should be aware of and observe the cautions for fire hazard outlined in this section. As with any medical system, long time use of equipment may cause overheat of equipment. Substances, such as gas, located in the treatment room, may cause fire when during treatment. Pay special attention regarding prevention of influx of gases inside the treatment room.

In case of an emergency, push the Emergency stop button, located on the front side of the equipment, to power-off the system.

- Anesthetics - Anesthetics administered either by inhalation or topically must be approved as nonflammable.
- Instruments - Since laser beams are reflected by most shiny surfaces, all instruments used in laser treatment should have brushed, burnished, or blackened, non-reflective surfaces.
- Laser Fiber Fire Hazard – The Secret DUO Laser System fibers carry significant laser energy. If the fiber were to break during laser pulsing, a sudden flash or flame may be observed at the break point. This flash or flame with each pulse will continue until pulsing is stopped. Individuals in contact with this flash or flame could receive a burn. Ignition of combustible materials (including clothing) in the proximity of the fiber break could also occur.
- If a break or sudden flash or flame is observed in the fiber, discontinue pulsing immediately.
- Because a break could occur suddenly, always position the fiber during each use such that it is in full view. For example, do not drape the fiber over the shoulder or around the back, leaving a portion of the fiber out of view during use.

- Do NOT operate the Secret DUO in rooms and areas where danger of explosion exists.
- The Secret DUO is NOT suitable for use in the presence of flammable mixtures.
- Avoid flammable or combustible materials/substances (e.g. cotton/wool saturated with oxygen) in the treatment room. aller
- Ensure only treatment area receives laser radiation. Avoid firing the energy at hair, clothing, fabrics, and other flammable substances that may ignite.
- Ensure solvent of adhesive and flammable solutions used for cleaning treatment area, is fully vaporized before treatment.
- Attention to the danger of ignition of endogenous gases that may occur during normal use of the Secret DUO is required.
- In case of fire, immediately shut laser system off, by using the Emergency button.
- Ensure system and hand piece is fully dry after cleaning prior to treatment.
- If the system is overheated, an error message is displayed. Once an error message is displayed, stop the operation, turn off the power, and stop the operation until the internal temperature drops.

- Extreme caution must be used whenever oxygen is present during the laser treatment. The presence of oxygen greatly accelerates combustion of any flammable material. Failure to follow adequate precautions could result in a fire and possible injury to the patient or staff.
- Hair, gauze, masks, cannula and airway materials can be ignited by laser energy in an oxygen enriched atmosphere. Even if thoroughly soaked with saline, flammable materials can be ignited by laser energy in the presence of oxygen. The following sequence can lead to a flash fire during laser treatment
- During treatment, the laser pulse strikes combustible material which absorbs the laser energy, resulting in the heating of the material beyond the combustion point. This can be as simple as the singeing of the tip of a single hair at the hairline, eyebrow, or eye lash.
- This momentary, and possibly unnoticeable, ignition sets off a more significant flash fire. The fire then follows a path from the peripheral area of the oxygen enriched atmosphere towards the most oxygen enriched zone. This is generally the oxygen source

2. Caution for safe Use of Equipment

2.1 Caution for product safety

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


NOTE

- Use the Secret DUO for the designated purpose only.
- Use this equipment only when it is in proper operation.
  (There must be no error messages)
- Manage this user manual and all other related resources in a good condition and furnish where the equipment is installed for availability at all times.
- Designate an officer in charge of safety management by written document.
- For PATIENTS with cardiac pacemakers or other active implants, a possible hazard exists because interference with the action of the pacemaker may occur, or the pacemaker may be damaged. In case of doubt, approved qualified advice should be obtained.
- The task of the officer in charge of safety management is as follows.
  - Laser/HF equipment operation supervision
  - Implement safe operation and take all necessary measures

2.2 Cautions to use(treatment) LASER

The laser-related provisions included in the manual aims at protection of both the operator and the patient during laser treatment.

Laser equipment is classified to varying grades according to the potential risk due to the equipment. Secret DUO is classified as 4 Grade in laser risk grades by IEC60825-1.


CAUTION!

- Before turning on the laser switch, make sure all protective covers are in proper places including the front panel.
- Improper use of the equipment may cause the laser light to be released directly or dispersed, inducing eye damage.
- Laser light may cause fire or explosion.
- Control, adjustment or usage that are not specified in this manual may cause dangerous laser exposure.
- Always wear protective glass(laser goggle) with the protection performance sufficient to protect the eye from laser beams of each wavelength.

- Comply with all safety-related precautions specified in this user manual.
- When changing a setting value of the equipment, always check first the screen indications to see if the treatment application parameter is properly set.
- Do not place objects such as mirrors or metal that can reflect the laser inside the treatment room.

Make sure to designate the range of “laser zone” that can exceed the maximum allowable radiation value during the use of the laser, and install laser warning at the entrance to prohibit entry while the laser is in operation.


CAUTION!

- Never press the foot switch before verifying that the position of the handpiece is safe.
- While operating the laser, prevent unnecessary persons from entering the treatment room.

2.2.1 Optical Hazard.

The Secret DUO has a laser wavelength of 1540nm, which can cause damage to the retina of the eye, if safety precautions/cautions have not been followed. The laser beam emanating from the hand piece has the potential to cause damage to the eye, as well as serious burns on skin and other areas. It is important that all personnel receive proper training regarding safety and risks of the laser system

As the AIMING BEAM passes down the same delivery system as the WORKING BEAM, it provides a good means of checking the integrity of the delivery system. If the AIMING BEAM is not present at the distal end of the delivery system, its intensity is reduced or it looks diffused, this is a possible indication of a damaged or malfunctioning delivery system


NOTE

Laser protective glasses(Laser goggle)

In order to protect the eye sufficiently and properly, you must use only the protective glasses manufactured for specific laser wavelengths. Although there are various laser goggles, you must use the appropriate protective glasses suited to each wavelength (color).

Before using Laser goggle, check for damage or scratches, and if there is something wrong, replace Laser goggle with a new Laser goggle with the same model

You must not look directly at the laser-emitting tip, and the same applies even when wearing laser goggles.

- The eye guards for patient must remain opaque and not pass any light. The patient eye guards should not reflect light or conduct heat, in case accidental radiation

occurs.

- The laser beam emitted by the Secret DUO is capable of causing loss of vision. Energy emitted by the 1540nm laser system that enters the eye will be focused directly on the retina. Direct contact of the laser beam on the retina can cause temporary clouded vision, retinal lesions, long-term scotoma(vision absence in an isolated area), long term photophobia (sensitivity to light) and/or loss of vision.
- Use the patient eye guards provided with this equipment.
- Do not take a direct look at the tip from which the laser is radiated, even when you are wearing the laser goggles.
- Only use safety goggles recommended by Ilooda.

2.2.2 Risk of Laser Release

The Secret DUO has a laser wavelength of 1540 nm, which can cause damage to the retina of the eye, if safety precautions/cautions have not been followed. The laser beam emanating from the hand piece has the potential to cause damage to the eye, as well as serious burns on skin and other areas. It is important that all personnel receive proper training regarding safety and risks of the laser system.

To protect against accidental radiation, all personnel (doctor, patient, nurse and other supporting staffs) must wear appropriate laser safety goggles provided with the Secret DUO, when laser equipment is in use. it is important to recognize the risk of the laser beam (if visible or not). Remove safety laser goggles only after the system has been shut-down.

It is essential to safely and properly use the hand piece during treatment. Ensure the hand piece tip is facing downward at all times. Place the hand- piece in the hand piece holder when not in use. When treatment has been paused or stopped, place the system in standby mode or turn system off.

Post a warning sign for laser radiation on the outside of treatment room.

- The patient must wear eye guards provided with the laser system during treatment.
- Do NOT look directly at the tip on the hand piece when attached to the laser, even when wearing the laser safety goggles.

2.2.4 Smoke hazard

When Secret DUO, which is a combination of class 4 laser system and high frequency electro surgical system, 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 laser and HF source is recommended which includes portable smoke extractor using charcoal or HEPA filter (0.1μm at least) with 99% or more extraction efficiency.


NOTE

- It is recommended to use a smoke evacuator/filter medical device (containing charcoal or HEPA filter (0.1μm at least) with 99% or more extraction efficiency) with the Secret DUO during treatment
- Smoke plume generated during laser treatment can be inhaled into the lungs, causing upper respiratory irritation or in-vitro mutagenic potential.
- Wearing a mask during treatment as protection against the smoke plume is NOT recommended.

2.3 Cautions to use High Frequency treatment

- Do not let the patient be in contact with metal parts grounded on the floor. (e.g. operating table support)
- Place dry gauze in between skins to avoid contact (e.g. armpit)
- When using high-frequency operator and physiological monitoring device simultaneously on the patient, place the monitoring electrode as far away from the operating electrode as possible.
- Do not let the electrode cable touch the patient. Separate and store electrodes that are not in use.
- When high frequency surgical system 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 treatment where HF current could flow through relatively small cross sectional area of body.


NOTE

Do not use needles as monitoring electrodes during electro surgical treatment. 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.
- Pediatric applications and/or treatment 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.
- Provide sufficient distance as much as possible between electrical operator or other electrical equipment (e.g. monitor). When activated, the electrical operator may cause electromagnetic interference with other equipment.
- Observe the patient state and start from low energy and gradually increase to output the desired energy value.
- In order to prevent unsafe activity, use the cables and accessories provided alongside this equipment. These accessories satisfy the maximum output voltage of the main unit.

- The output power may be intentionally increased due to the error of electrical operating equipment.
- It is recommended not to use the AC mode and SC mode higher than 15W maximum. (The maximum output power of AC mode and SC mode is 45W.)
- When a gap occurs between the electrode and the tissue, a minor neuromuscular stimulation may occur. This equipment is designed to minimize the possibility of neuro-muscle stimulation.

- Micro-needle electrodes are single-use.
- Use a new tip for each new treatment.
- Throughout the treatment course, make sure that the integrity of the tip isn't being compromised and that no needle is broken or bent.

2.4 Cautions on system use

2.4.1 Cautions before Use

- Before use, make sure to read the user manual thoroughly.
- Make sure to use according to the doctor's prescription.
- Do not connect the power with wet hands.
- Take caution not to spill water or liquid on the main unit. It may cause equipment damage or fire/electric shock.
- Do not install the equipment at a location with a lot of water and humidity. It may cause equipment damage or fire/electric shock.
- Install the equipment at least a 100mm distance from the wall.
- Take caution to avoid pressing down on the power cord with a sharp object and heavy weight. Using a damaged cord may cause fire or electric shock.
- Do not use near flammable substances. It may cause the main unit deformation, system malfunction or fire.
- Only the professionally trained persons should use the equipment.
- Execute pre-inspection before the system operation.
- Inspect the switches and such to verify accurate operation..
- Connect all cords and such accurately to avoid breaking away.
- When using an equipment that has not been in use for a certain period of time, check for the normal or safe operation of the machinery beside the above provisions.
- Never disassemble or modify the equipment unless by the install/repair technician. It may cause fire/electric shock.
- Before using for electrical treatment, check for proper output energy amount.
- Use the provided accessories only. Do not use the accessories that are not supplied by the manufacturer.
- Do not use products with damaged packaging.\


NOTE

Operation Condition

- Temperature : Recommended within 10℃ ~ 40℃
- Relative humidity : 10% ~ 75%
- Atmospheric pressure : 500 ~ 1060 hPa

2.4.2 Cautions during Use

- During use for laser treatment , make sure to wear the user goggle and the patient eye Protective glass(eye guard).
- Clear the area of obstacles during the equipment operation.
- Do not place paper and other objects on top of the equipment or block the ventilation ducts.
- In case of the equipment malfunction, make sure to stop the use and turn off the power, and then contact our customer support.
- In case of power outage, turn off the power immediately, and return the control handle, switches and such back to the original position.
- Do not use this equipment near the patient monitoring device.
- Always check for anomalies with the equipment or the patient during use.
  In case of an anomaly with the equipment or the patient during use, check for the patient's safety and then stop the use, and inspect the state of the equipment and the patient, and resume the use in case there are no issues.
- Do not look into the laser light reflected off a medium or directly applied to the eye.
- 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 high frequency treatment, please note the following.
  - Do not perform an electric surgical treatment 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 treatment 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.
  - Check the proper output energy amounts before and during an electric surgical treatment.

- Blood or saline solution contacted directly with electrodes or other accessories for electric surgical equipment 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 treatment. Keep clean so that conductive liquid is not remained on the electrode before an electric surgical treatment.
- Electrodes should be mounted on the body (electrode support) completely and safely. Otherwise, it may cause a burn to patients.
- 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 possible hazard 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.
- Do not use a product with damaged packaging.
- When discard the needles, must follow the rule of medical disposal in the country to prevent bio-contamination.
- Fit the electrode tip perfectly to the skin during the treatment. If you do not, unexpected burns may occur to the patient.

2.4.3 Cautions after Use

- After use, return the components such as handpiece and key switch to the original position according to the set procedure, and then turn off the power.
- When unplugging cords, do not apply excessive force at the cord connector part like pulling on the cord. It may cause performance deterioration and system issues.
- After use, make sure to turn off the power and remove the key switch so that others cannot operate the equipment.

3. Labeling

The Secret DUO is provided with various safety labels and safety devices. For the safety use, do not through-out or damage these safety devices and keep labelling good condition.

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

ILOODA CO.,LTD recommends performing regularly scheduled equipment inspections for safety of patients and uses. The Secret DUO must be regularly serviced by an ILOODA CO.,LTD authorized service technician.

Refer to "Appendix 2. Regular Safety inspection"

- Check for external damage to the system (touchscreen, hand piece, cords, foot switch etc.) on a regular basis.
- Stop use of the system and contact the authorized representative if experiencing problems or system failure.
- Do NOT drop or strongly bump (impact) the system.
- If the system has been dropped or strongly bumped, notify the authorized service technician prior to using the Secret DUO.
- The main body unit contains no user-serviceable components.
- To avoid personnel injury, do not attempt to open the system covers. Service is to be performed by authorized personnel only.

4.2 Storage

- Do NOT store the system in an uneven place, possibility of shaking, or chance of impact as it may cause performance degradation of the system, fire and/or electrical shock.
- Do NOT store the system in an area where chemicals are stored, or gas is generated.
- Do NOT keep the system stored in an environment where temperature, air pressure, humidity, ventilation, sunlight, and air containing dust, salt and sulfur have a harmful influence on the device.
- Avoid dripping, standing, or splashing water near the device.

NOTE

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

4.3 Cleaning

CAUTION!

Turn off the equipment prior to cleaning
Never clean the equipment when the system is operating

4.3.1 Main body, handpieces

- Clean the main unit and hand-piece connector by blowing air and such to avoid dust accumulation.
- Clean the main unit except for the connector part (Front, Back, LCD) using a smooth cloth with alcohol and rubbing softly to avoid alcohol from entering the connector part.

4.3.2 Laser beam guide

- Wipe the laser guide with a clean soft cloth soaked in 70% - 90% isopropyl alcohol. Ensure the cloth is not dripping with the liquid.

CAUTION!

- Do not immerse the handpiece in water
- Recommend the use of non-flammable cleaning agents.
- Assure that the Hand-piece is dried from any inflammable alcohol.
- Activity of alcohol is limited in the presence of organic matter.
- Always perform the cleaning procedure prior to disinfection.
- Ensure solvent of adhesive and flammable solutions used for cleaning treatment area, is fully vaporized before treatment.
- Ensure system and hand piece is fully dry after cleaning prior to treatment.
- Non-flammable agents should be used for cleaning and disinfection wherever possible.
- Clean and disinfect only with recommended cleaning agents.
- Use soft texture material (cotton, cotton swab)
- Do NOT use sharp materials when cleaning
- Do NOT reuse cleaning/disinfection materials (cotton, cotton swab)

- Do NOT allow cleaning/disinfection solution to spill /leak onto any of the connectors
- Do NOT directly apply cleaning/disinfection solution directly to the equipment

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 system with common industrial or household waste.
- When disposing of the system in whole or in parts, comply with the related regulations of the region.
- For waste disposal related matters, consult with ILOODA Co., Ltd. or authorized agent in the region.

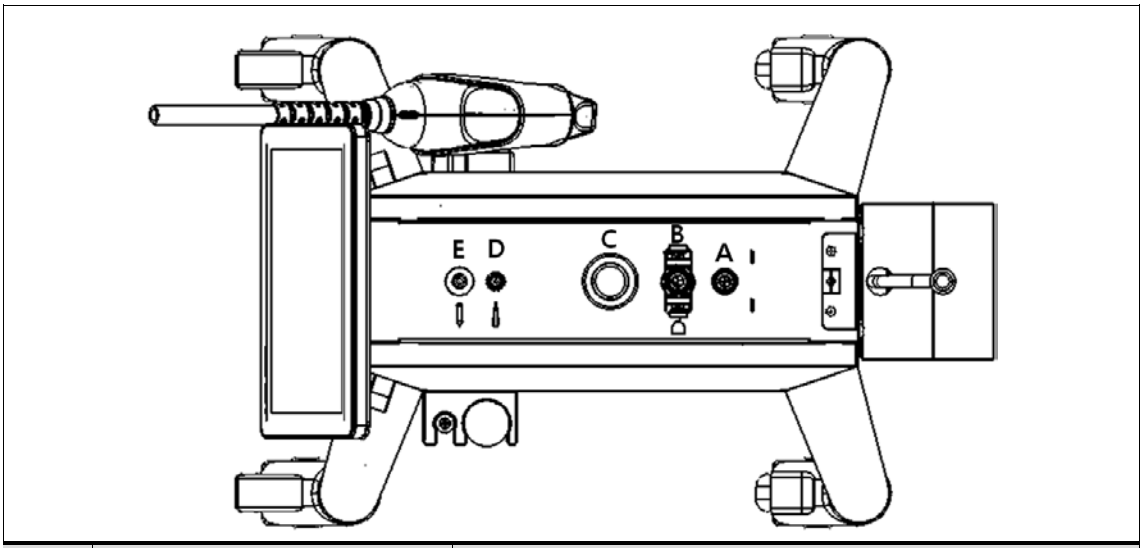
- The HF electro surgical electrode (Needle tip) is single use.
- The HF electro surgical electrode (Needle tip) is intended for a single patient. Please use a new tip for every patient
- Please dispose the HF electrode immediately after use.
- Please don't use HF electrodes that expiration date has expired(3years).
- Must check the HF electrode (sterile micro needle electrodes) before use and do not use HF electrode (sterile micro needle electrodes) which is not good sterilized condition.

Chapter 4. Installation of Equipment

1. Description of the Equipment

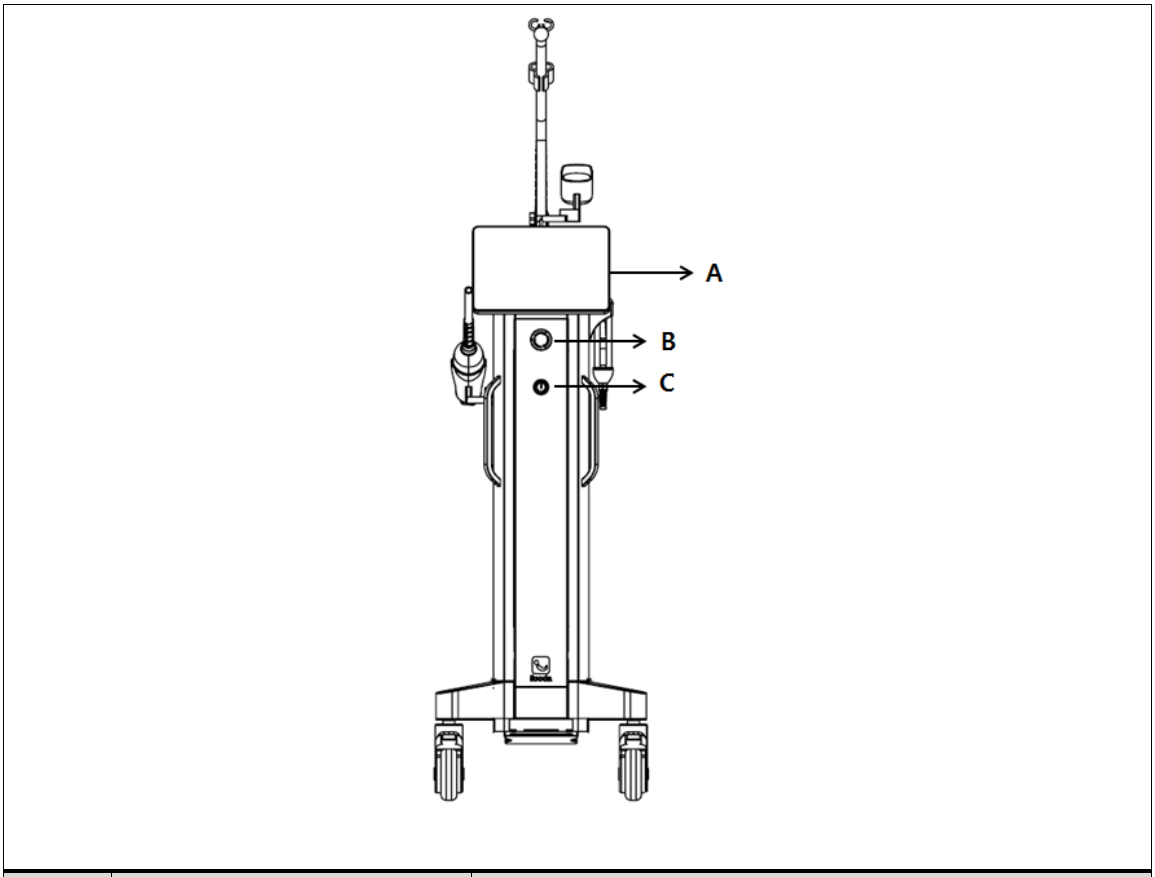
1.1 Description of the Equipment's external structure

1) Upper



No	Name	Function
A	Laser hand-piece Connector	Connector that the laser hand-piece is connected
B	Bigger hand-piece Connector	Connector that the Bigger hand-piece is connected
C	Cable holder Connector	Connector that places the cable holder connector
D	SmartCure hand-piece Connector	Connector that SmartCure hand-piece is connected
E	Neutral hand-piece Connector	Connector that the neutral hand-piece is connected

2) Front



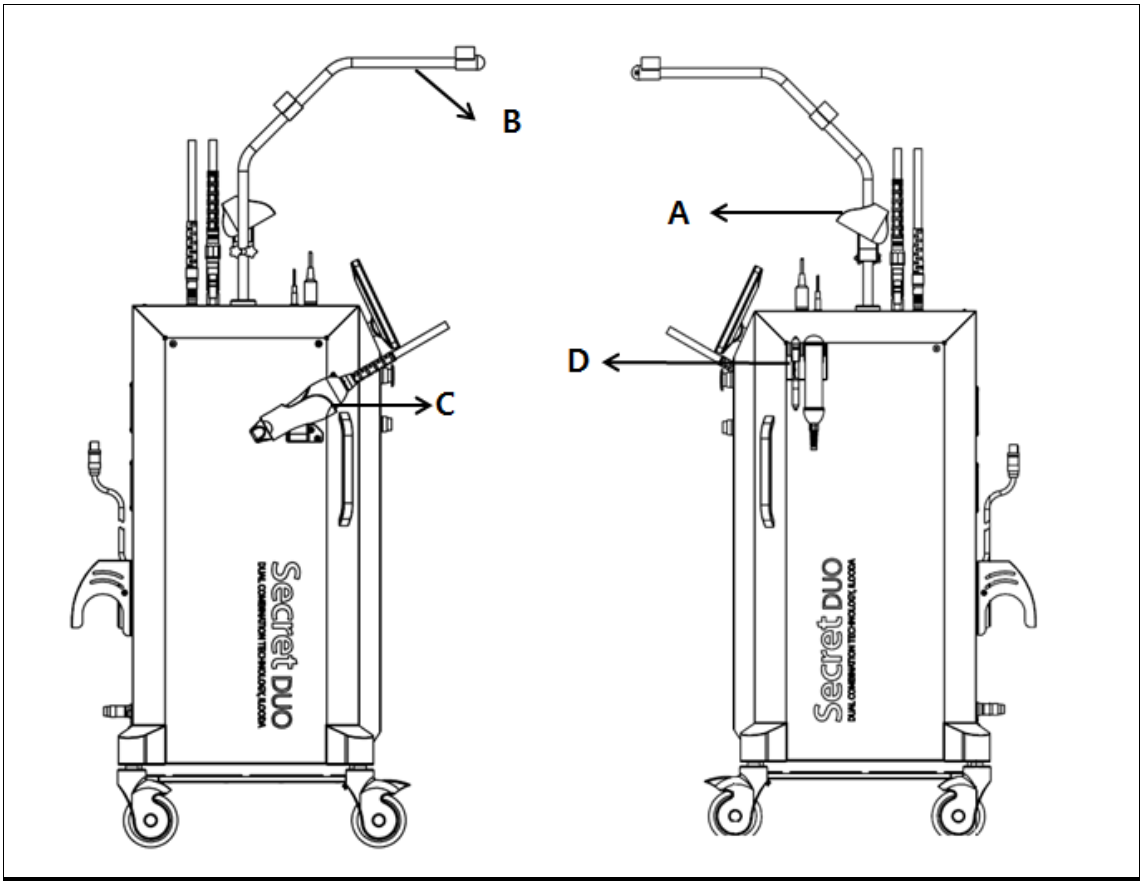
No	Name	Function
A	LCD monitor(Touch)	Touch screen to set and display various functions
B	Emergency stop switch	Stop the laser irradiation immediately in case of emergency
C	Key switch	Key switch to turn the device power ON or OFF

CAUTION!

Pressing the emergency stop switch stops the laser output immediately.

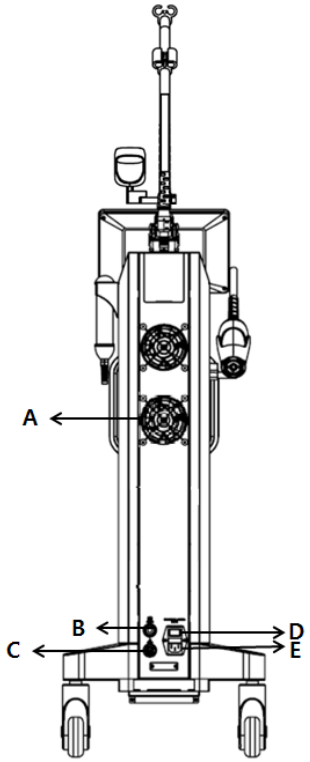
* In case the emergency stop switch is pressed, turn the red button in the direction of the arrow (clockwise) to return to the original position before the system start.

3) Side



No	Name	Function
A	Laser hand-piece holder	A device to fix the Laser hand-piece when not in use
B	Cable Holder	Holder for fixing cables
C	Bigger hand-piece holder	A device to fix the bigger hand-piece when not in use
D	SmartCure hand-piece holder	A device to fix the SmartCure and Neutral hand-piece when not in use

4) Back



No	Name	Function
A	FAN	Part that draws internal heat out
B	Remote interlock connector	Connector that the Remote interlock is connected
C	Foot switch connector	Connector that the Foot switch is connected
D	Power switch	Main Power on/off
E	Power cable connector	Connector that the Power cable is connected

1.2 Description of DISPLAY

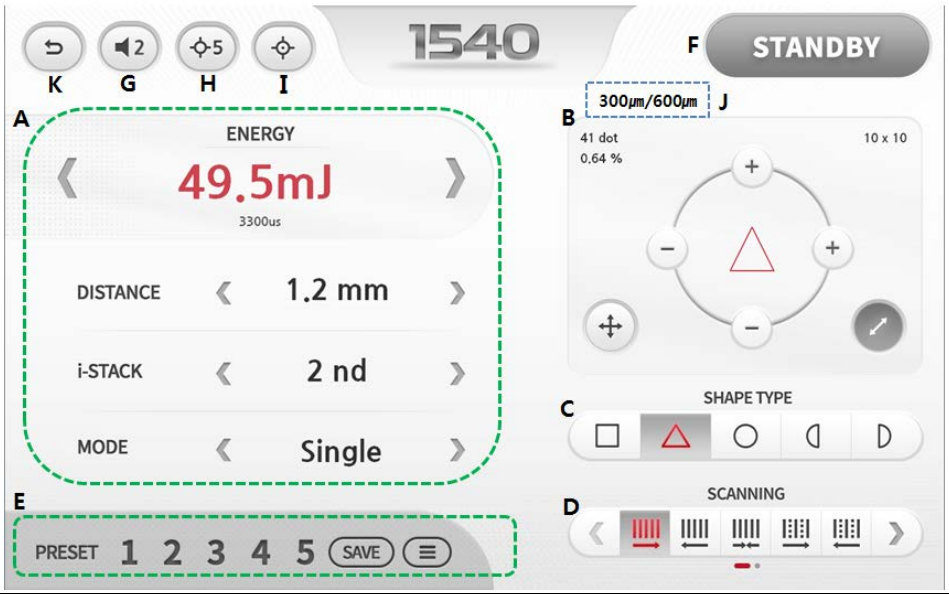
: Refer to "Chapter 5. Use of Equipment"

1) MAIN Screen

No	Name	Function
A	1540 Mode	The Laser Mode with 1540nm wavelength The operator sets desired parameters using the menu.
B	RF Mode	The RF Mode using the Bigger handpiece. It consists of an AUTO mode in which the corresponding parameters are automatically provided for each treatment area and a MANUAL mode in which the operator can set desired parameters.
C	SmartCure Mode	The SmartCure Mode using the SmartCure handpiece. The operator sets desired parameters using the menu
D	Information	Provides information about mode

2) 1540 Mode

- The Laser Mode with 1540nm wavelength
- The operator sets desired parameters using the menu



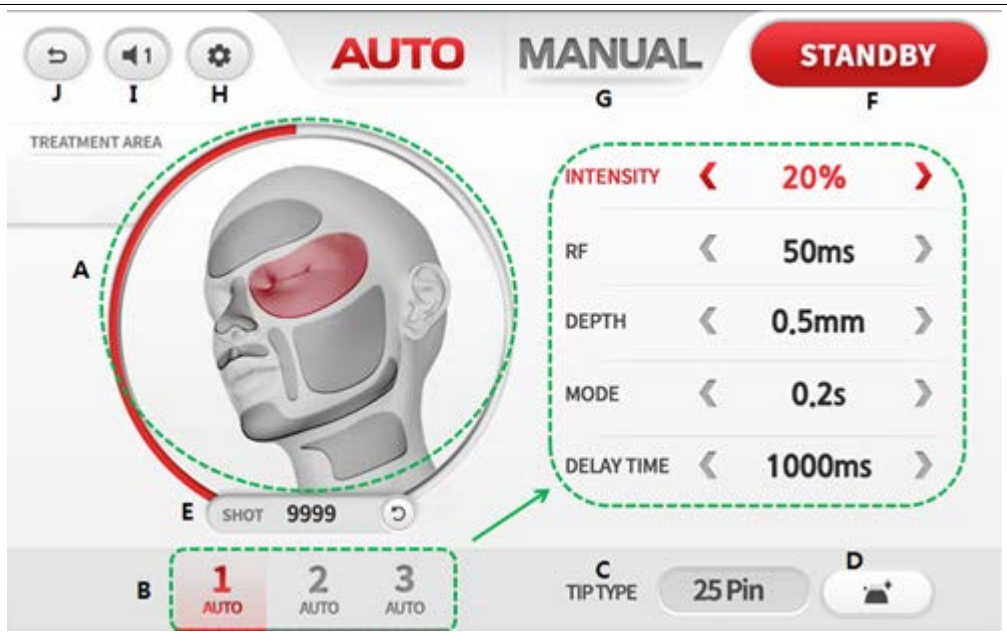
No	Name	Function
A	Laser output setting	Output energy setting menu - Energy: output energy setting - Distance: dot distance setting - i-stack: output repetition setting - MODE: output repetition time setting
B	Irradiation area setting	Laser irradiation area setting icons : Size control for each direction, : Overall size control , : Size control
C	Shape Type	Irradiation shape setting
D	Scanning	Irradiation pattern setting
E	Preset	Storage: Icon to save set value of the patient. Save: Icon to save frequently used values and current output setting. It can store up to 5 setting values.
F	Standby/Ready	Laser Standby / Ready selection icon
G	Sound	Select SOUND Volume
H	Aiming Beam	Aiming beam brightness control
I	Beam Guide	Adjust the position of the beam
J	Beam Guide type	Automatically display according to the connected beam guide type (300 ㎛/600 ㎛).
K	Back	Icon to return to Main screen

3) RF Mode

- It is used by connecting a Bigger hand-piece with micro-needle electrodes.

3-1) AUTO Mode

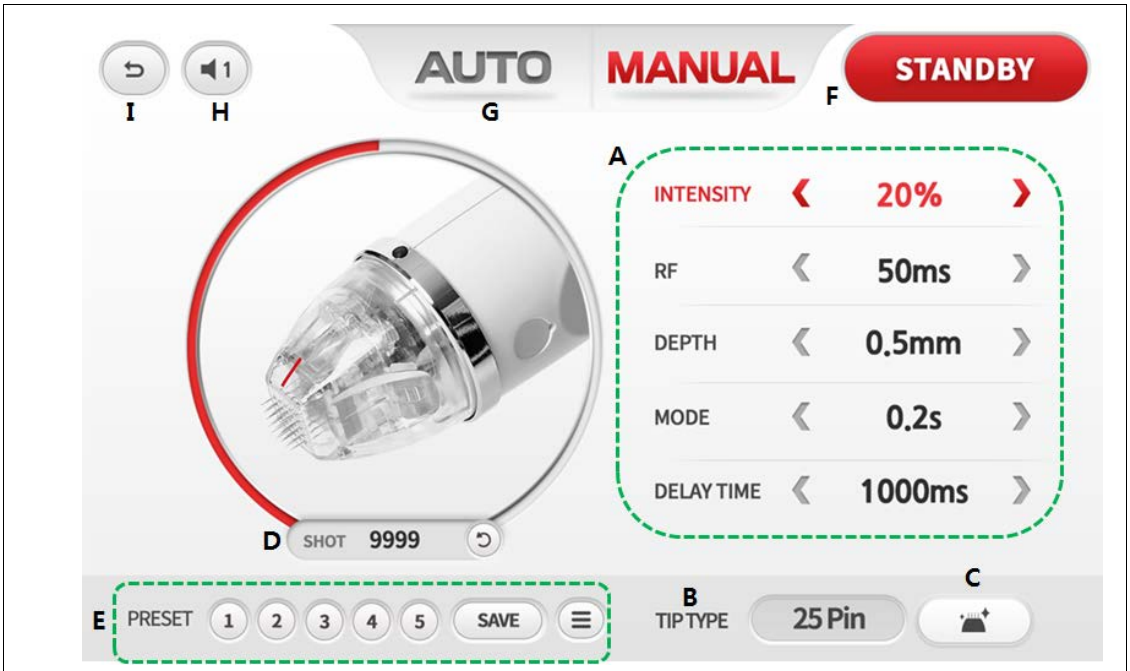
Auto Mode is recommended parameters provided by the manufacturer and frequently used parameters can be saved.



No	Name	Function
A	Treatment Area Setting	Operation part setting (Treatment area)
B	Auto mode	Composed of 3 types of auto RF value is automatically configured upon selection of operation part
C	Tip Type	Needle electrode type
D	Electrode status	Icon to check electrode status or to clean the electrode, click to show the following pop-up. CLEANING INSPECTION
E	Shot Count/Reset	Record the number of SHOT used during the treatment
F	Standby / ready	RF Standby / Ready selection icon
G	Mode conversion	Click the icon to go to Manual Mode.
H	Setting	Icon to save frequently used values and current output setting. It can store up to 3 setting values.
I	Sound	Select SOUND Volume
J	Back	Icon to return to Main screen

3-2) MANUAL Mode

The operator sets desired parameters using the menu

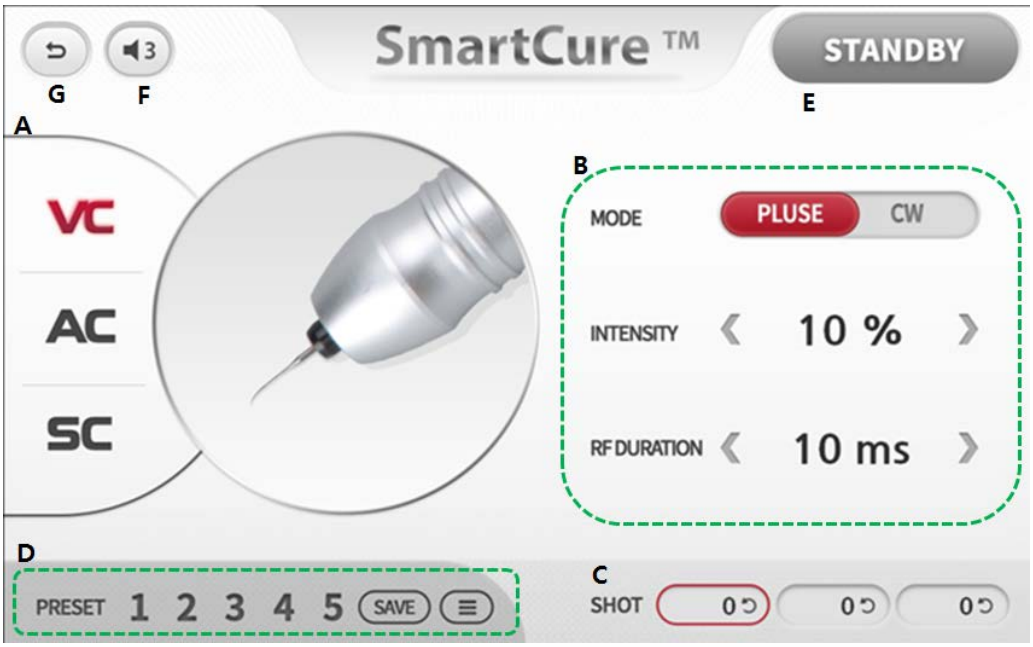


No	Name	Function
A	Output setting	RF output setting icon - Intensity: RF output intensity - RF: RF output time - Depth: Needle penetration depth - Mode: needle Output time interval - Delay Time: Needle output time
B	Tip Type	Needle electrode type
C	Electrode status	Icon to check electrode status or to clean the electrode, click to show the following pop-up. 
D	Shot Count/Reset	Record the number of SHOT used during the treatment
E	Preset	Storage: Icon to save set value of the patient. Save: Icon to save frequently used values and current output setting. It can store up to 5 setting values.
F	Standby / ready	RF Standby / Ready selection icon
G	Mode conversion	Click the icon to go to Auto Mode.
H	Sound	Select SOUND Volume
I	Back	Icon to return to Main screen

4) SmartCure Mode

- It is used by connecting a SmartCure hand-piece with micro needle electrodes.
- The operator sets desired parameters using the menu

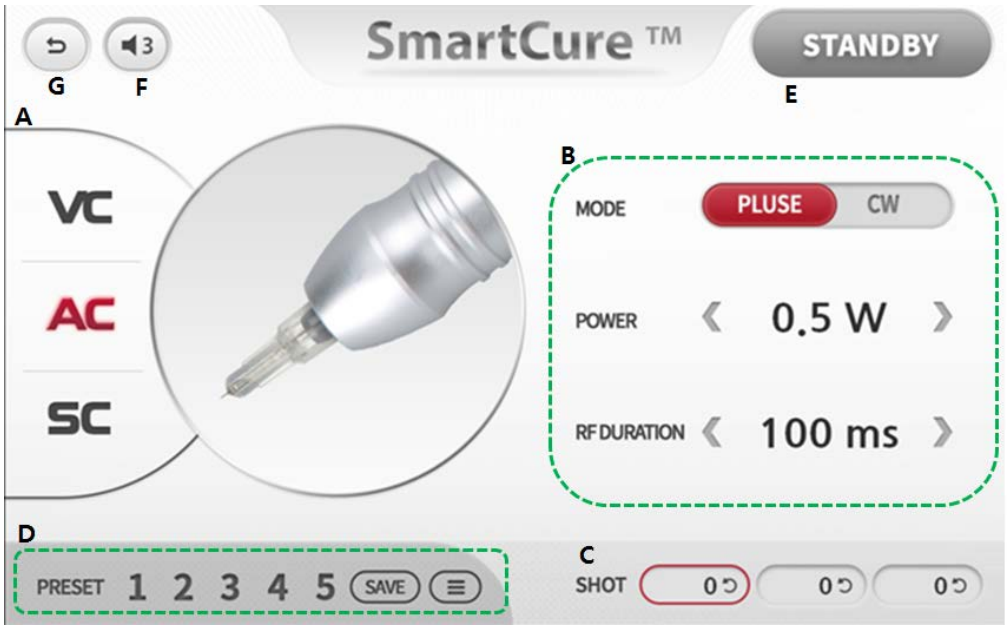
4-1) VC Mode



No	Name	Function
A	Mode conversion	Click the icon to go to each Mode
B	Output setting	RF output setting icon - MODE: Setting Pulse or CW - Intensity: RF output intensity - RF Duration: RF output time
C	Shot Count/Reset	Record the number of SHOT used during the treatment
D	Preset	Storage: Icon to save set value of the patient. Save: Icon to save frequently used values and current output setting. It can store up to 5 setting values.
E	Standby / ready	RF Standby / Ready selection icon
F	Sound	Select SOUND Volume
G	Back	Icon to return to Main screen

4-2) AC Mode

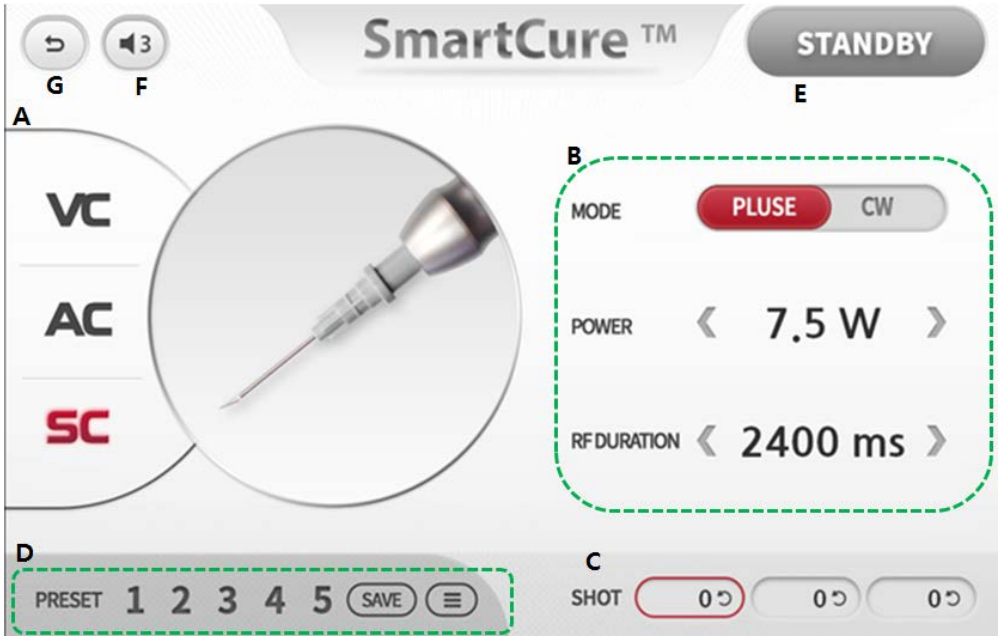
This mode uses micro needle electrodes(MTR-AC-01,04 electrodes)



No	Name	Function
A	Mode conversion	Click the icon to go to each Mode
B	Output setting	RF output setting icon - MODE: Setting Pulse or CW - Intensity: RF output intensity - RF Duration: RF output time
C	Shot Count/Reset	Record the number of SHOT used during the treatment
D	Preset	Storage: Icon to save set value of the patient. Save: Icon to save frequently used values and current output setting. It can store up to 5 setting values.
E	Standby / ready	RF Standby / Ready selection icon
F	Sound	Select SOUND Volume
G	Back	Icon to return to Main screen

4-3) SC Mode

This mode uses micro needle electrodes(MTR-AC-19G, 22G, 27G electrodes)

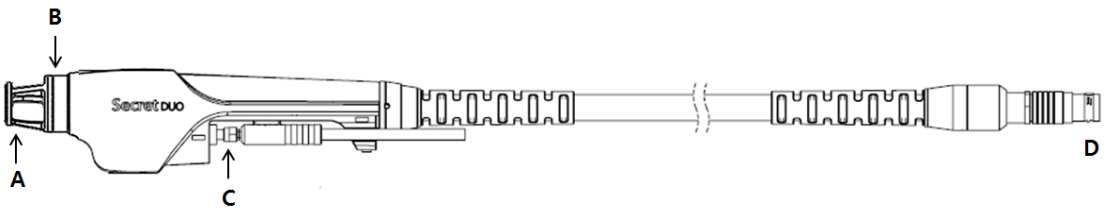


No	Name	Function
A	Mode conversion	Click the icon to go to each Mode
B	Output setting	RF output setting icon - MODE: Setting Pulse or CW - Intensity: RF output intensity - RF Duration: RF output time
C	Shot Count/Reset	Record the number of SHOT used during the treatment
D	Preset	Storage: Icon to save set value of the patient. Save: Icon to save frequently used values and current output setting. It can store up to 5 setting values.
E	Standby / ready	RF Standby / Ready selection icon
F	Sound	Select SOUND Volume
G	Back	Icon to return to Main screen

1.3 Description of the Hand-piece

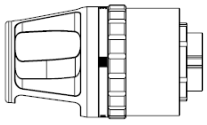
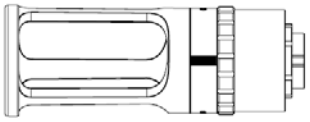
1) Laser hand-piece

(1) Description of Laser hand-piece



No	Name	Function
A	Beam guide	Bar that adjusts laser focus to prevent shaking
B	Laser irradiation part	A part from which the laser irradiates ⚠ **Do not look directly into the laser beam guide**
C	Fiber connector	Terminal to connect Laser hand-piece and fiber (Laser output delivery part) *See caution⚠ on page 49
D	Laser hand-piece socket	Terminal to connect main body and Laser hand-piece

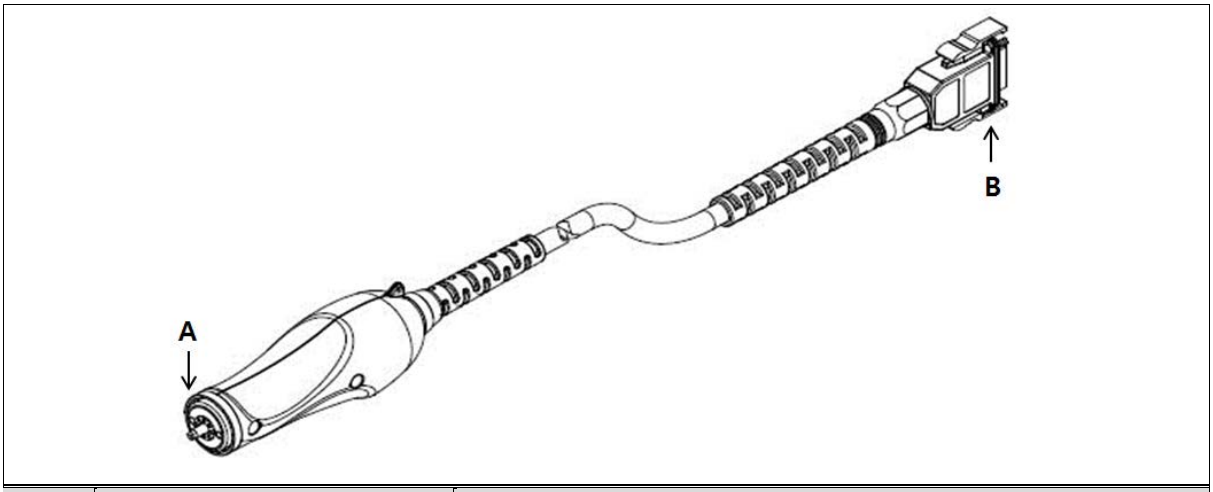
(2) Laser hand-piece beam guide(Patient contact)

Figure	Name	Function
	Laser handpiece beam guide_300㎛	300㎛
	Laser handpiece beam guide_600㎛	600㎛

2) Bigger Hand-piece.

- Connect 64pin electrode, 25pin type electrode depending on the application.

(1) Description of Bigger hand-piece



No	Name	Function
A	Electrode Connector	Part that connects needle electrodes
B	Bigger Handpiece Socket	Connector that connects to the main body

(2) Sterile Micro Needle electrodes (Patient contact)

- Used in the case of Micro coagulation. To be used in connection with a Bigger handpiece

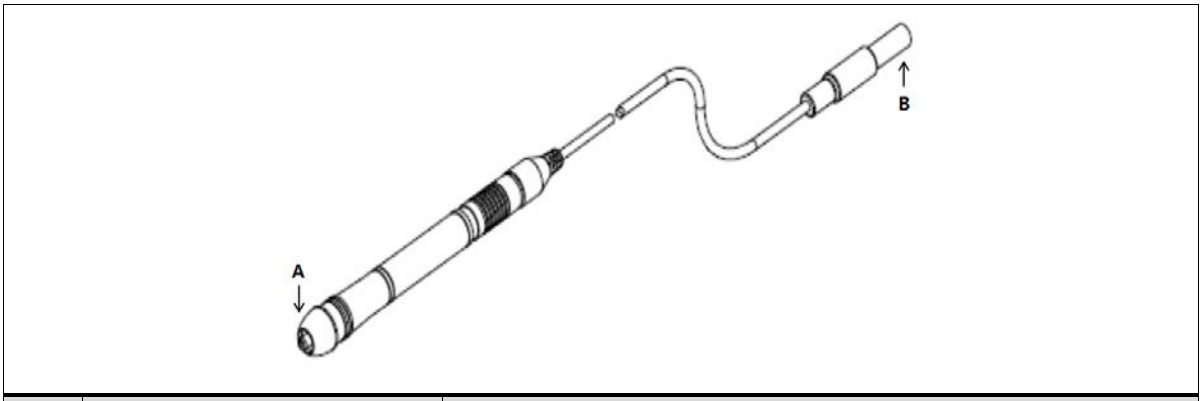
Figure	Name	Function
	MTR-AC-10	Pin unit : 10ea Needle ø0.25
	MTR-AC-C-10	Pin unit : 10ea Needle ø0.25 [Insulated microneedle]
	MTR-AC-16	Pin unit : 16ea Needle ø0.25

	MTR-AC-C-16	Pin unit : 16ea Needle ø0.25 [Insulated microneedle]
	MTR-AC-25	Pin unit : 25ea Needle ø0.25
	MTR-AC-C-25	Pin unit : 25ea Needle ø0.25 [Insulated microneedle]
	MTR-AC-64	Pin unit : 64ea Needle ø0.25
	MTR-AC-C-64	Pin unit : 64ea Needle ø0.25 [Insulated microneedle]

3) SmartCure Hand-piece

- Insert mocro needle electrode to the hand piece.

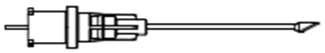
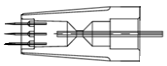
(1) Description of SmartCure hand-piece



No	Name	Function
A	Electrode Connector	Part that connects needle electrodes
B	SmartCure Handpiece Socket	Connector that connects to the main body

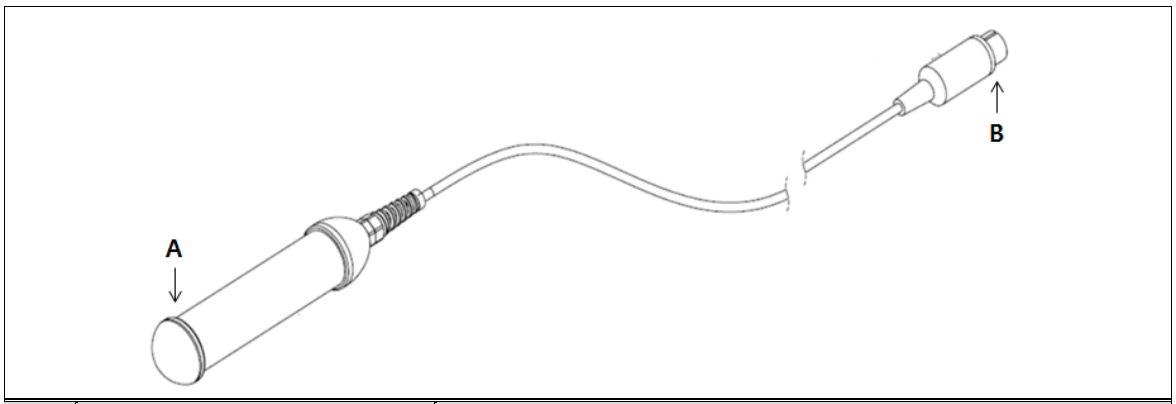
(2) Sterile Micro Needle electrodes (Patient contact)

- Insert Mono polar type Sterile Needle electrodes into SmartCure hand-piece

Figure	Name	Function
	MTR-AC-19G	Pin unit : 1ea Needle ø1.1
	MTR-AC-22G	Pin unit : 1ea Needle ø0.7
	MTR-AC-27G	Pin unit : 1ea Needle ø0.4
	MTR-AC-01	Pin unit : 1ea Needle ø 0.25 mm x 1.5 mm
	MTR-AC-04	Pin unit: 4ea Needle ø 0.25 mmx1.5 mm

4) Neutral Hand-piece

- Electrode for connection to the body of the patient, intended to provide a return path for the High frequency energy(HF energy) current with such a low current density in the body tissue that physical effects such as unwanted burns are avoided..



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

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

<table>
<tr><td rowspan="4">Common</td><td>Power Cable</td><td>Cable Holder</td></tr>
<tr><td>  </td><td>  </td></tr>
<tr><td>Key Swtich</td><td colspan="2">Remote Interlock</td><td>Foot Switch</td></tr>
<tr><td>  </td><td colspan="2">  </td><td>  </td></tr>
<tr><td rowspan="2">Only Laser</td><td>Eye protective goggle for doctor</td><td>Eye protective goggle for patient</td></tr>
<tr><td>  </td><td>  </td></tr>
</table>

NOTE | Use the accessories supplied by the manufacturer.

2. Installation of Equipment

NOTE

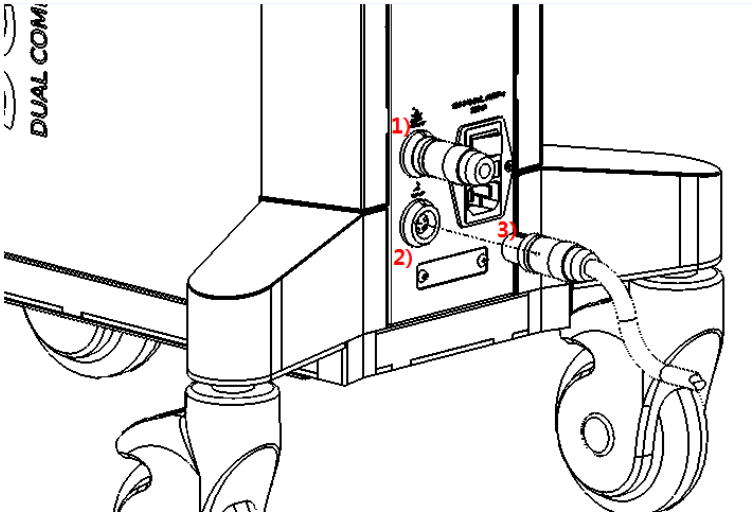
- Install and use the Secret DUO ONLY in a safe treatment room
- Install system at least 100 mm distance from the wall and allow for easy disconnection of the Secret DUO
- Check the power and system specifications when installing the product.

2.1 Installation of the Main body

1) Connect the power cable to the power cord terminal on the back of the main unit.

2) Connect the foot switch to the foot switch terminal on the back of the main unit.

3) Connect the power cable to the power cord terminal on the back of the main unit



NOTE

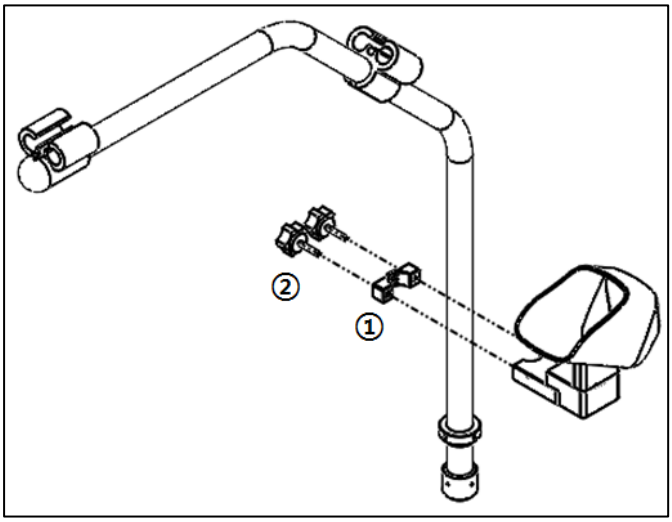
- When connecting the foot switch, set the foot switch in the direction of arrow on the main unit.
- An error message can appear and product may not function if connection is not properly done.
- The foot switch terminal and remote interlock are indicated on the connection terminal to prevent confusion.
- Always plug the unit into a properly grounded outlet. The unit is grounded through the grounding conductor in the power cable. This protective grounding is essential for safe operation.

4) How to install hand piece holder

- Laser hand piece holder

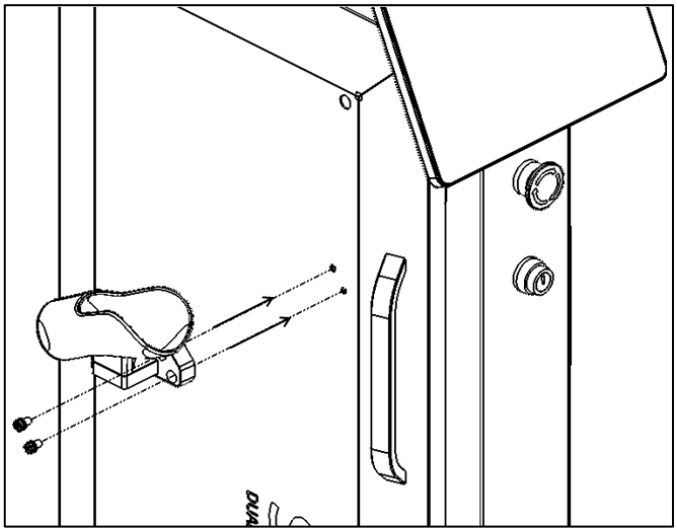
Place the ‘handpiece holder’ and the ‘handpiece holder supporter 'closely to the holder as shown below, and tighten the bolts by aligning the two screw holes inside.

(Screw Standard: SEMS M5*12)



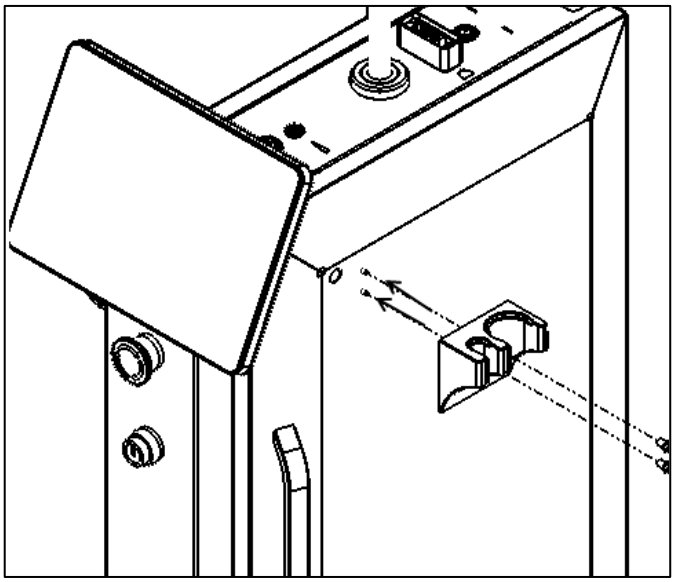
- Bigger hand piece holder

Tighten the bolts by aligning the two screw holes inside the 'handpiece holder supporter' with the two screw holes on the side of the main body (Screw Standard: SEMS M5*12)



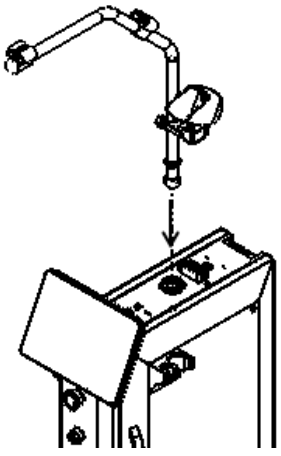
- SmartCure & Neutral hand piece holder

Tighten the bolts by aligning the two screw holes inside the 'handpiece holder supporter' with the two screw holes on the side of the main body (Screw Standard: SEMS M4*12)



- Please tightly screw the hand piece holder to the main body.
- In case of connected improperly, it might be risk to be falling off.

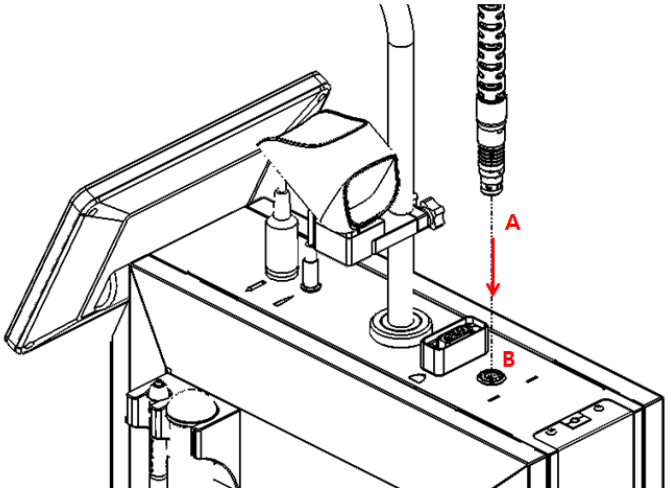
5) Insert the cable holder into the cable holder connector (arrow) on the top of the Main body vertically, and then turn it clockwise to connect tightly.



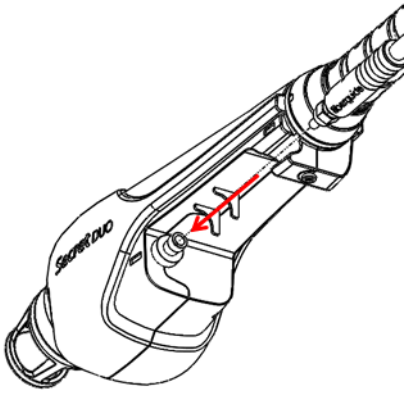
- If it is not connected correctly, it may disrupt a surgical treatment

2.2 Installation of Laser hand-piece & Fiber

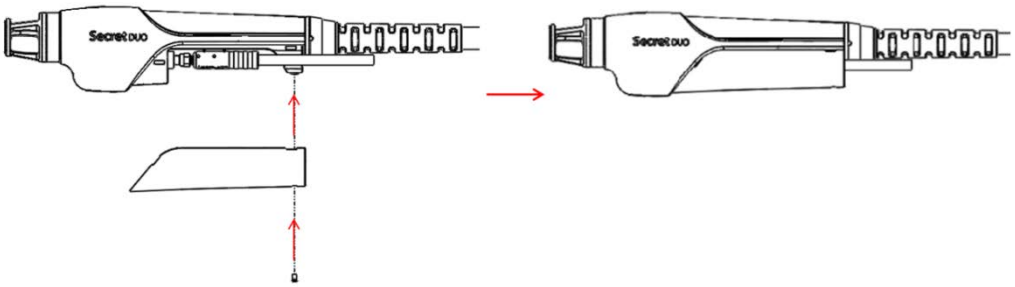
1) Mounting the Laser handpiece socket (A) on the Laser handpiece connector (B) of the top of main body vertically.



2) Carefully connect the laser fiber from the main body to the fiber connector of the handpiece so that the fiber does not bend.



3) After horizontally inserting the fiber into the fiber connector of the laser hand-piece, Close the prevent cover of the handpiece and tighten the bolt to the screw hole.

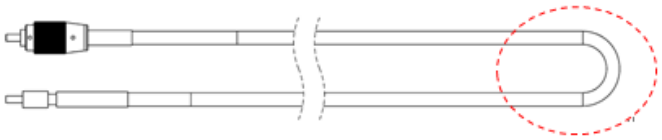


CAUTION!

- Be sure to turn OFF the power when connecting the fiber to the handpiece.
- When connecting the fiber, insert it horizontally and strongly rotate the ring clockwise. Laser output can become unstable during operation if the fiber is not connected properly.
- Be careful not to disconnect the fiber from the handpiece as the laser may come out of the fiber end terminal.
- Be sure to close the prevent cover of the handpiece after the laser fiber is connected.
- Be careful when moving or installing the fiber.

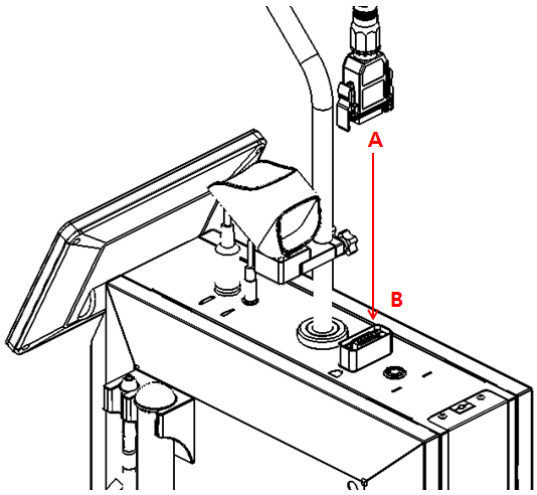
  The following situations can damage the fiber.

  1) If the fiber is bent



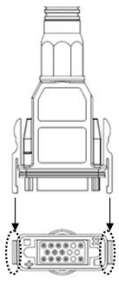
  2) If shock is applied to the fiber connection part

2.3 Installation of Bigger handpiece



1) For connecting Bigger handpiece to the main body, connect Bigger handpiece socket to the key hole of Bigger handpiece connector vertically.

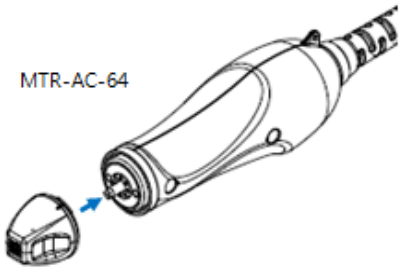
NOTE



- When connecting bipolar hand piece, attach to the key hole between Bigger handpiece connector and Bigger handpiece socket.
- Vertically insert until clicking sound is created by the fixing holders on both sides of Bigger handpiece 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 electrode connector of hand piece and turn clockwise for connection.



NOTE

Not connected/ improper connection

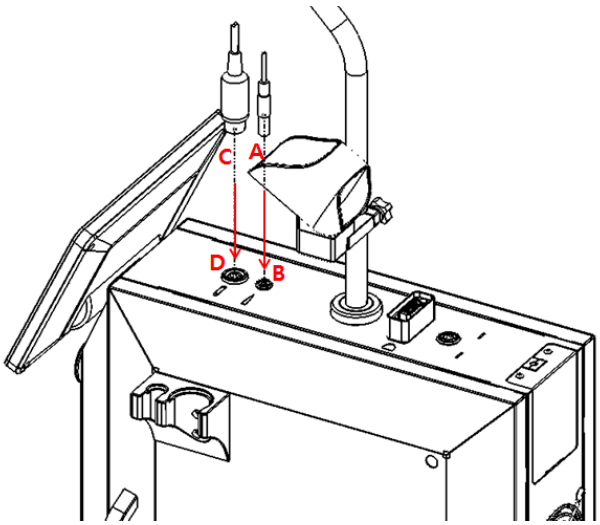
- The connection state is displayed as follows.
- In case of no connection or improper connection: red lamp is lighted

Normal connection

- In case of proper connection: blue lamp is lighted
- In case an error message occurs and the connection is not surely made, the product does not operate.

2.4 Installation of Smartcure handpiece and Neutral handpiece

1) Mounting the SmartCure handpiece socket(A) on the Smartcure handpice connector(B) of the top of main body vertically.
2) Mounting the Neutral handpiece socket(C) on the neutral handpice connector(D) of thetop of main body vertically.



NOTE

- Insert the SmartCure hand-piece into the connecting hole for SmartCure on the top of the main body until you hear the clicking sound.
- Insert the Neutral 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

NOTE

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

Chapter 5. Use of Equipment

Refer to "Chapter 4. Installation of equipment" for installation of this product.

All control modules and display screen appear on the front LCD monitor of the main unit. Since it is touch screen, the screen can be controlled by touch.

NOTE

Refer to “1.2 of Chapter 4. Installation of Equipment “for detailed explanation on display

CAUTION!

Fit the tip perfectly to the skin during the treatment. If not, unexpected burns may occur to the patient.

Turning on the power by using the main unit key switch leads to the following main screen.

In order to move to the screen of the corresponding mode, select each menu.

1540: The enters the Laser treatment mode.

RF: As a High frequency treatment mode, It consists of Auto and Manual Mode.

SMARTCURE: As a High frequency treatment mode, It consists of VC. AC and SC Mode.

! : Information menu

NOTE

- Turn the power on after completing installation. If the power is turned on or each mode is entered without completing installation, an error message appears and the product does not function properly.
- You cannot enter two modes at the same time, Finish a mode before entering another mode.
- If you want to power off equipment, please make sure to turn key-switch off in the **‘main screen’**. If you power off in the ‘mode screen’, this can cause malfunction.

1. 1540 Mode

1) Select 1540 Mode at the main screen and then following Mode is coming.
2) Set the individual output value at the left setting Mode.
3) Select the parameter and adjust output value with UP/DOWN ICONS on both side.
   - Energy: Laser output energy(8.4mJ ~ 60mJ)
   - Distance: Dot distance(0.1mm ~ 2.0mm)
   - i-stack: Output repetition(1^{st}~10^{th})
   - MODE: Output repetition time(Single, 0.2, 0.5, 0.7, 1.0, 1.5, 2.0s)
4) Use icons on the right side of the screen to set irradiation area.
5) Set the Shape type and Scanning below it
6) After setting the value, if you touch the right above STANDBY, the icon is changed to READY. If you push the foot switch, the Laser is coming out.
7) Use storage to save current output value. Press number button on storage and press SAVE to save the current value in the designated number.
   ex) Select 1 on storage and press SAVE to save the current value in 1.
   When 1 is pressed later on, the saved value is automatically entered.
8) 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.

NOTE

An audible tone occurs during laser emission, and the laser emission indicator 

is indicated on the screen. The indicators continue the duration of laser emission.

2. RF Mode

2.1 AUTO Mode

1) Select “RF” Mode at the main screen.
2) Select the "AUTO" mode at the top and then following Mode is coming.
3) 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.
4) Select the treatment area first and then choose below auto1~3 depending on application
5) Select the treatment area and choose below auto 1~3, and then standard parameter is automatically set.

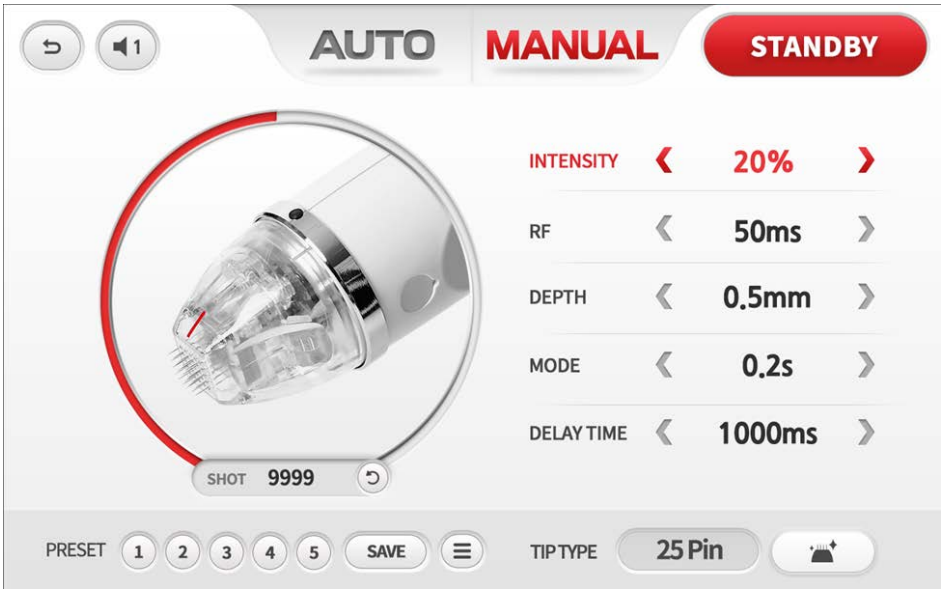
Terminology (Parameter)	INTENSITY: RF Energy RF: RF output time DEPTH: Needle penetration depth MODE: Interval time between Needle coming out (Repeat Time) DELAY TIME: Needle out time

6) After setting the value, if you touch the right above STANDBY, the icon is changed to READY.
If you push the foot switch, the RF Needle is coming out.
7) 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

8) 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.

2.2 MANUAL Mode



1) Select “RF” Mode at the main screen
2) Select the "MANUAL" mode at the top and then following Mode is coming.
3) Set the individual output value at the right setting Mode.
4) Select the parameter and adjust output value with UP/DOWN ICONS on both side.
   - Intensity: RF Energy (0 ~ 100%)
   - RF: RF output time (50 ~ 950ms)
   - Depth: Needle Penetration Depth (0.5 ~ 3.5 mm)
   - Mode: Interval time between Needle coming out (Repeat Time) _Single, 0.2s, 0.5s, 1s, 2s
   - Delay Time: Needle out time (100ms ~ 1000ms)
5) After setting the value, if you touch the right above STANDBY, the icon is changed to READY. If you
   push the foot switch, the RF Needle is coming out.
6) 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

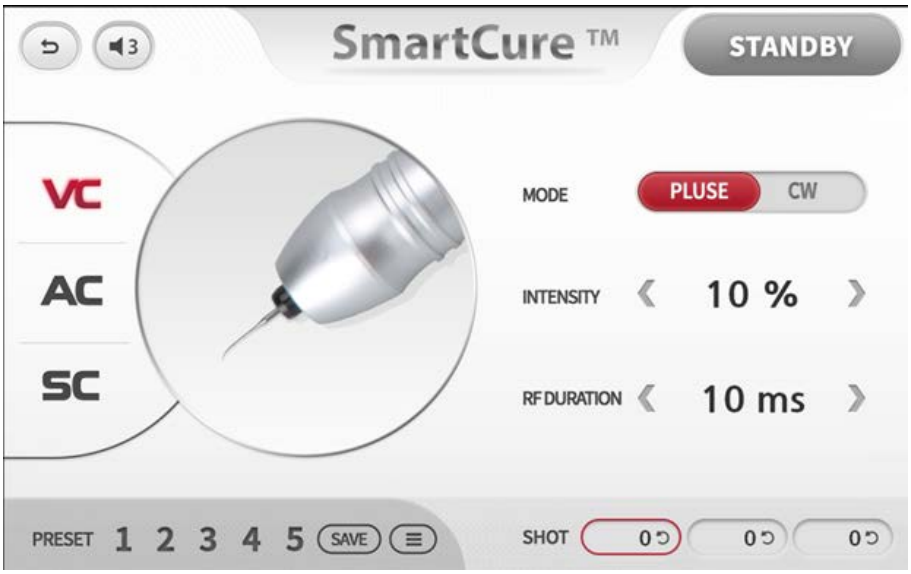
7) After finishing the treatment, you touch the right above READY and change to STANDBY, and place the hand piece in the hand piece holder of main body.
8) After finishing the equipment, turn off the Power Button.

NOTE

- Refer to 5 of chapter 2 for recommended parameters.

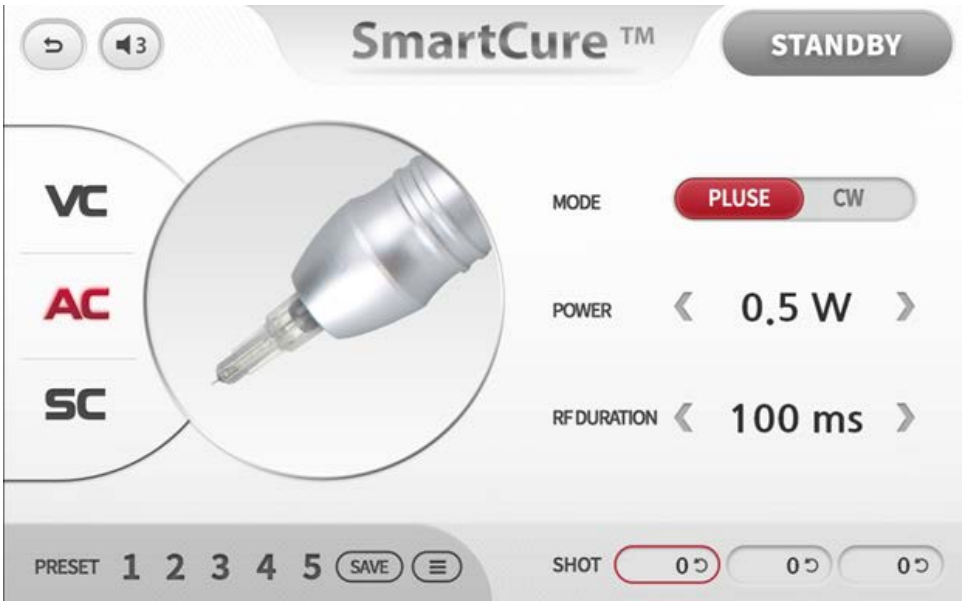
3. SmartCure Mode

3.1 VC Mode



1) Select “SmartCure” Mode at the main screen,
2) Select the "VC" mode on the left side and then following Mode is coming.
3) Set the individual output value at the right setting Mode.
4) Select the parameter and adjust output value with UP/DOWN ICONS on both side.
   - MODE: PULSE or CW
   - INTENSITY: RF Energy (10~ 100%)
   - TIME: RF output time (10 ~ 900ms)
5) After setting the value, if you touch the right above STANDBY, the icon is changed to READY. If you push the foot switch, the RF needle is coming out.
6) Use storage to save current output value. Press number button on storage and press SAVE to save the current value in the designated number.
   ex) Select 1 on storage and press SAVE to save the current value in 1.
   When 1 is pressed later on, the saved value is automatically entered.
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.

3.2 AC Mode



1) Select “SmartCure” Mode at the main screen,
2) Select the "AC" mode on the left side and then following Mode is coming.
3) Set the individual output value at the right setting Mode.
4) Select the parameter and adjust output value with UP/DOWN ICONS on both side.
   - MODE: PULSE or CW
   - INTENSITY: RF Energy (0.1 ~ 45W)
   - TIME: RF output time (100 ~ 3000ms)
5) After setting the value, if you touch the right above STANDBY, the icon is changed to READY.
   If you push the foot switch, the RF needle is coming out.
6) Use storage to save current output value. Press number button on storage and press SAVE to save the current value in the designated number.
   ex) Select 1 on storage and press SAVE to save the current value in 1.
   When 1 is pressed later on, the saved value is automatically entered.
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.

CAUTION!

- It is recommended not to use the AC mode higher than 15W maximum. (The maximum output power of AC mode is 45W.)

3.3 SC Mode

1) Select “SmartCure” Mode at the main screen,
2) Select the "SC" mode on the left side and then following Mode is coming.
3) Set the individual output value at the right setting Mode.
4) Select the parameter and adjust output value with UP/DOWN ICONS on both side.
   - MODE: PULSE or CW
   - INTENSITY: RF Energy (0.1 ~ 45W)
   - TIME: RF output time (100 ~ 3000ms)
5) After setting the value, if you touch the right above STANDBY, the icon is changed to READY.
   If you push the foot switch, the RF needle is coming out.
6) Use storage to save current output value. Press number button on storage and press SAVE to save the current value in the designated number.
   ex) Select 1 on storage and press SAVE to save the current value in 1.
   When 1 is pressed later on, the saved value is automatically entered.
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.

CAUTION!

- It is recommended not to use the SC mode higher than 15W maximum. (The maximum output power of SC mode is 45W.)

WARNING!

If you take off the hand piece while not to change to STANDBY, it might cause electric shot and get the burn.

4. General Option

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

4.1 SOUND Function

If you touch Above **"1. Sound"** 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)

4.2 Aiming Beam Function (Applies only Laser Mode)

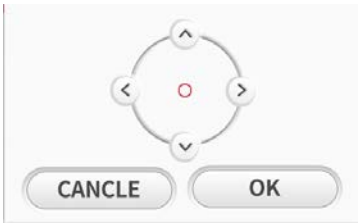
If you touch Above **"2. Aiming Beam"** icon, you can control the Aiming beam brightness.

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)

4.3 Beam Guide Function (Applies only Laser Mode)

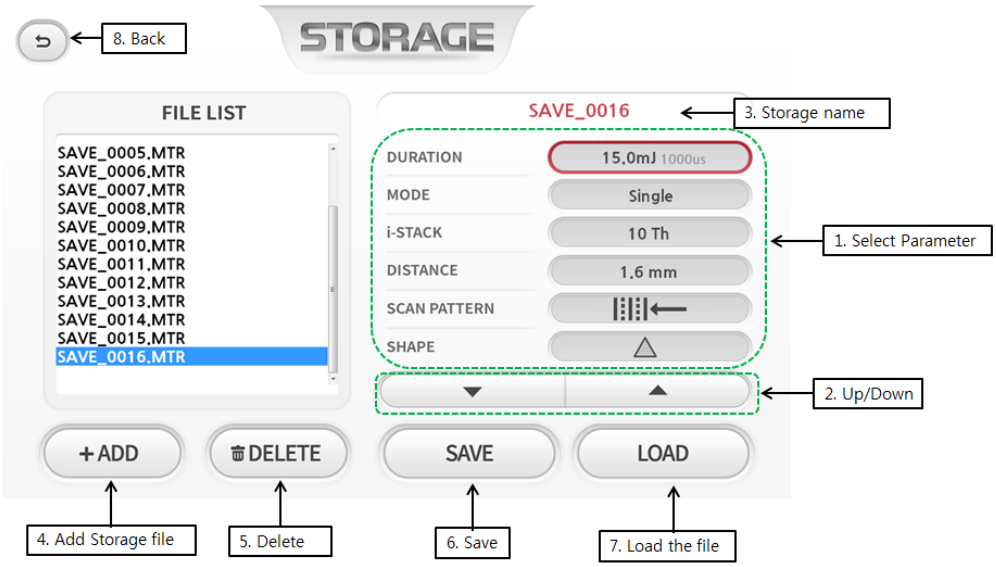
If you touch Above **"3. Beam Guide"** icon, you can adjust the position of the beam.



The beam is adjusted in the direction of each arrow.

4.4 STORAGE (except for AUTO mode)

Press the STORAGE button at the bottom of Mode. If you choose STORAGE, below screen is coming.



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) If you want to add a list to the new File List, press the 'Add' button and then set the parameters.

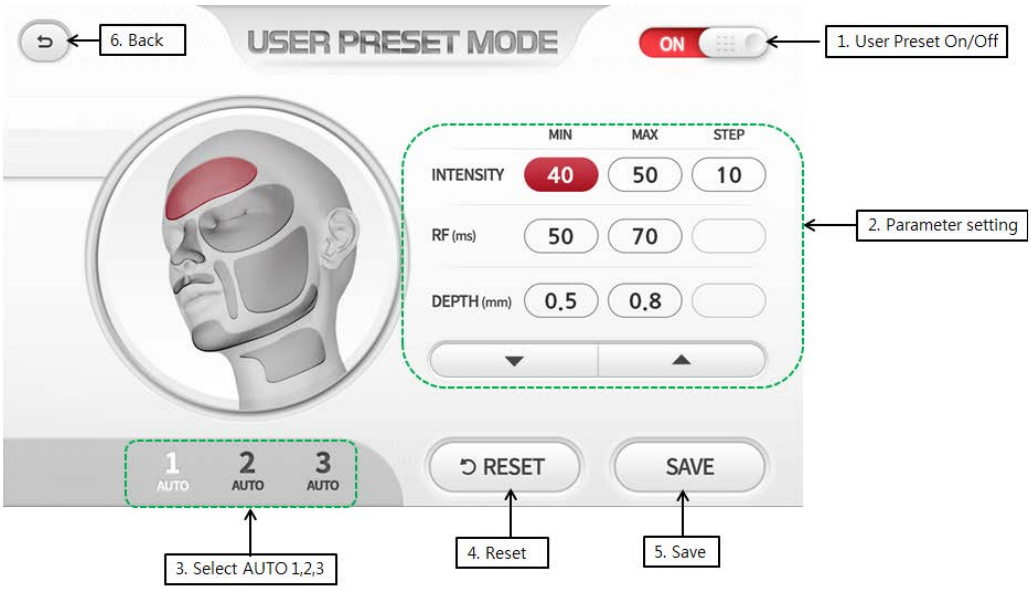
5) Choose a name among File List select LOAD and then the screen is changed to each Mode, and the saved parameter comes.

6) 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.

7) 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 pervious Mode.

4.5 User Preset Mode (Applies only to AUTO mode)

Touch the "**5. Setting"** icon at the bottom of the screen to switch to User Preset mode as shown below



1) Use the "1. User preset ON/OFF" icon to choose the area where you would like to change the initial setting value.
   - ON: By pressing "User Preset Mode, ON" the initial setting value can be changed.
   - OFF: Cannot change initial setting value when "User Preset Mode, OFF" (use default value)

2) 2. Parameter setting" icon to set the auto parameter range of the selected area.
   * Please refer to the range of operable parameters in User preset mode.

3) "Use the "2. AUTO 1, 2, and 3 Select" icon to select the indications to change the parameter range of the selected area.

4) By using a button "4. Reset" to reset the current setting value to the default setting value, and press the SAVE button in order to reflect the default setting value in AUTO mode.

5) After completing parameter range setting, click the button, "5. Save" to save the setting value.
   * Please refer to "5. Adjusting treatment parameters" of Chapter 2 for basic setting value.

6) When the setting is completed, press a button "6. Back" to switch to the AUTO mode screen.

** Operable parameter range in User preset mode*

	Min	Max	Step
Intensity	0 ~ 90	10 ~100	2, 5, 10
RF	50 ~ 900	60 ~ 950	-
Depth	0.5 ~ 3.4	0.6 ~ 3.5	-

NOTE

The Min value of each parameter cannot be set to a larger value than the Max value.

4.6 CLEANING / INSPECTION Function

Choose right below **"Cleaning/Inspection"** 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.

CAUTION!

CLEANING / INSPECTION function is only for checking dirt (skin particle and blood) and the needle status and purposed to better efficacy with less pain.

The CLEANING function is not sterilization mode. Never reuse the needle after cleaning and must be single use only for one patient.

** Common precautions for modes **

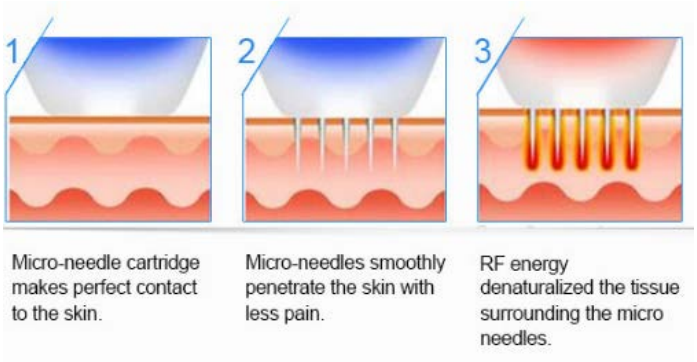
NOTE

- Turn the power on after completing installation. When the power is turned on or each mode is attempted without completing installation, an error message appears and the product will not function properly.
- Configure output values in STANDBY state and convert to READY state when setting is done.
- Before operation, check the configured parameters and convert to READY state.
- Since energy is irradiated by pressing the foot switch in READY state, aim the hand piece at the body part of the patient being treated.

  Convert to READY state and operate the foot switch or volume switch.
- Two or more handpieces cannot be used at the same time. Finish a mode before entering another mode.

NOTE

- Method of usages



NOTE

To report an accident or serious incident, please contact the manufacturer

Manufacturer : ILOODA sales@ilooda.com

Authority : Obelis S.A mail@obelis.net

Chapter 6. Technical Specification

1. Specification Sheet

Rated input		100-240VAC, 50/60Hz, 3.0~1.1A	
Operation Mode		1540Laser Mode, RF Mode, SmartCure Mode	
Spec.	1540 Laser	Wavelength	1540nm ±10%
		Laser Power	12W ±20%
		Pulse Duration	700㎲~ 5000㎲
		Energy	8.4mJ ~ 60.0mJ
		Aiming beam	635nm, 1mW peak
		Distance	0.1mm ~ 2.0mm
		i-Stack	1st~ 10th
		MODE (Output repetition time)	Single, 0.2, 0.5, 0.7, 1.0, 1.5, 2.0s
		Scanning	
		Shape	
	RF	Output Power (at 500Ω load)	Max 25W ±10% (with 25pin) Max 70W ±10% (with 64pin)
		Frequency	2MHz± 10%
		RF Output Time	50ms ~ 950ms
		Delay time	100ms ~ 1000ms
		Depth	0.5mm ~ 3.5mm (0.1 step)
		Mode(Repeat Time)	Single, 0.2s, 0.5s,0.8s, 1s, 2s (Repeat time)
		Intensity(%)	0 ~ 100(%) (10 step)
		Electrode	Micro Needle electrode
	SmartCure Mode (VC mode)	Output Power (at 500Ω load)	Max 18W ±10%
		MODE	Pulse/CW
		Intensity(%)	2~ 100(%) (2 step)
		Frequency	4MHz ±10%
		RF Duration	10ms~900ms

		Electrode	Micro needle electrode
	SmartCure Mode (AC/SC mode)	Output Power (at 500Ω load)	Max 45W ±10%
		MODE	Pulse/CW
		Intensity(W)	0.1~45W - Output Power step: 0.1W ~ 1w(0.1W step) 1W ~ 10w(0.5W step) 10W ~ 45W(1W step)
		Frequency	2MHz
		RF Duration	CW, 100-3000ms (100 step)
		Electrode	Micro needle 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(Manual) Mode (Bipolar hand-piece mode)

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

Intensity(%)	Volt (rms)	25Pin(W)	Volt (rms)	64Pin(W)
10	7.17	0.16	15.7	0.5
20	19.6	0.7	32.8	2.1
30	30.7	1.8	50.8	5.1
40	42	3.5	69.8	9.7
50	53.7	5.7	90	16.2
60	65.5	8.5	109	23.7
70	77.1	11.8	129	33.2
80	88.7	15.7	149	44.4
90	101	20.4	168	56.4
100	112	25.0	188	70.6

2) SmartCure Mode

: Choose the VS mode, AC mode or SC mode in SmartCure Mode.

① VC Mode

- Frequency: 4MHz ± 10%
- Intensity: 2% ~ 100% (2step)
- Output value per Intensity (at 500Ω load)

② AC Mode

- Frequency: 2MHz ± 10%
- Intensity: 0.1W ~ 1W (0.1W step)
  1W ~ 10W (0.5W step)
  10W ~ 45W (1W step)
- Output value : Max 45W (at 500Ω load)

③ SC Mode

- Frequency: 2MHz ± 10%
- Intensity: 0.1W ~ 1W (0.1W step)
  1W ~ 10W (0.5W step)
  10W ~ 45W (1W step)
- Output value : Max 45W (at 500Ω load)

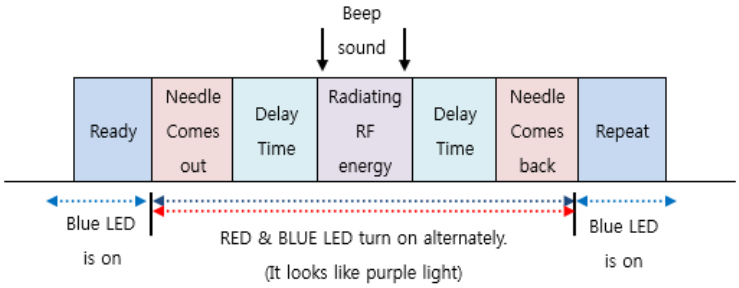
3. Frequency of use (treatment interval)

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

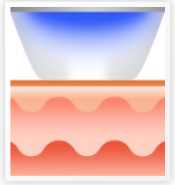
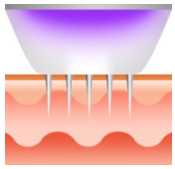
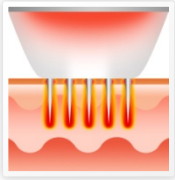
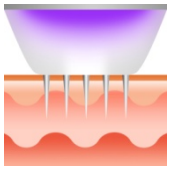
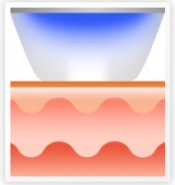
4. Description of the micro-needle electrode movement

: 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.

Chapter 7. RF Output power characteristics

NOTE

- Use only accessories that have been approved for use with the Secret DUO.
- Any associated equipment and active electrodes must be rated to with stand the combination of output voltage, Vp-p and crest factor as stated in the table (Refer to below)

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

MODE (Connected accessories)	Output Power	Output frequency	Vp-p max	Vrms	Crest Factor
Manual (25 pin)	25W@500Ω	2MHz	175	112	1.5
Manual (64 pin)	70W@500Ω	2MHz	281	186	1.5
VC Mode (Smartcure H/P)	18W@500Ω	4MHz	112	96	1.2
AC Mode (Smartcure H/P)	45W@500Ω	2MHz	246	152	1.6
SC Mode (Smartcure H/P)	45W@500Ω	2MHz	246	152	1.6

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

1.1 Output setting energy value per mode

- Output value per Intensity (at 500Ω load)

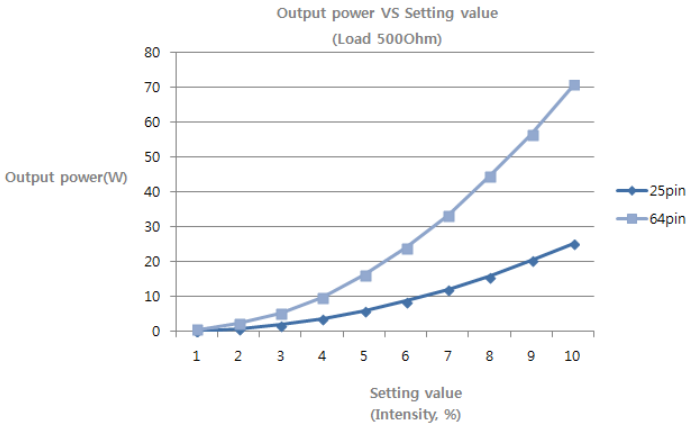
Intensity(%)	Voltage(RMS)	W
10	7.17	0.1
20	19.6	0.7
30	30.7	1.8
40	42	3.5
50	53.7	5.7
60	65.5	8.5
70	77.1	11.8
80	88.7	15.7
90	101	20.4
100	112	25.0

[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

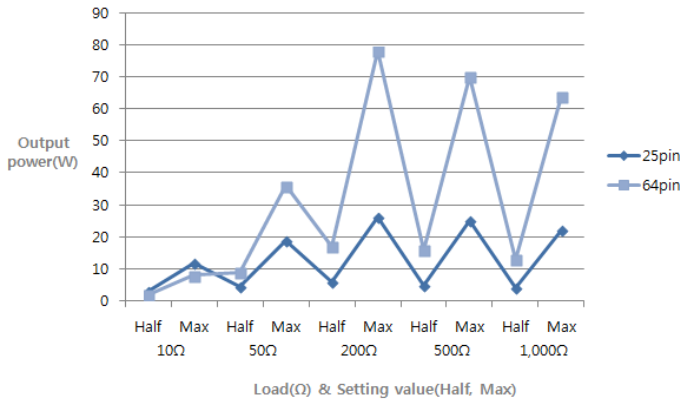


1.2 Load resistance diagram

- Output data

Intensity(%)	Load(Ω	W(Connected 25pin)	W(Connected 64pin)
50(Half)	10Ω	0.3	1.5
100(Max)		1.4	2
50(Half)	50Ω	1.3	6
100(Max)		6	10
50(Half)	200Ω	3.5	15
100(Max)		16	35
50(Half)	500Ω	5	16
100(Max)		25	70
50(Half)	1000Ω	4	13
100(Max)		22	64

- Output diagram



2. SmartCure Mode (Smartcure handpice)

: Choose the VC mode, AC mode or SC mode in SmartCure Mode.

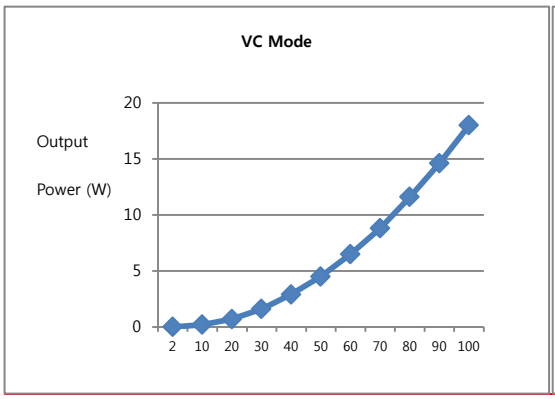
2.1 Output setting energy value per mode

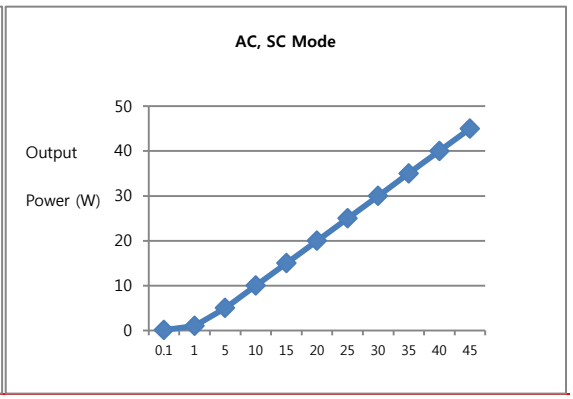
Intensity(%)	Voltage (RMS)	W
2	20	1
10	32	2
20	39	3
30	46	4
40	54	6
50	60	7
60	68	9
70	75	11
80	82	13
90	88	15
100	95	18

[VC Mode]

Power (W)	Voltage (RMS)	W
0.1	7.2	0.1
1	22	1
5	50	5
10	71	10
15	87	15
20	100	20
25	112	25
30	122	30
35	132	35
40	141	40
45	150	45

[AC,SC Mode]



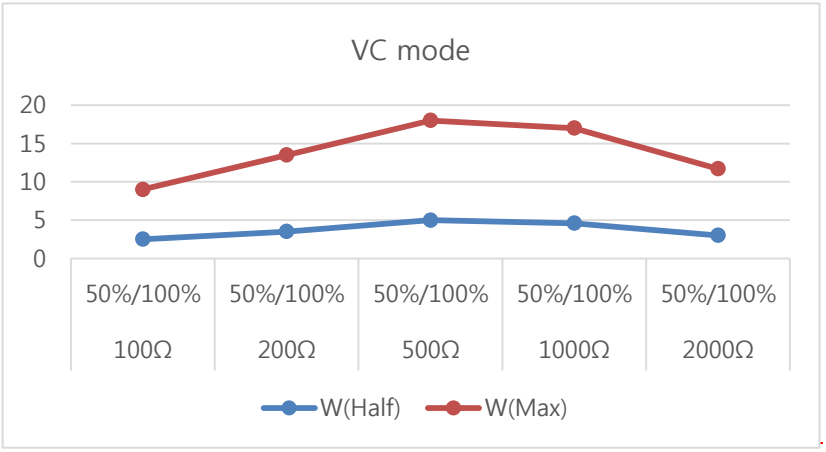


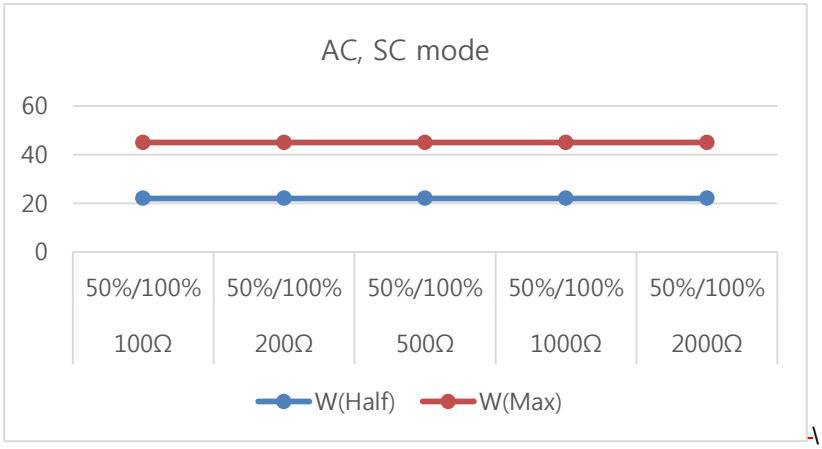
2.2 Load resistance diagram

- Output data

Intensity(%)	Load(Ω	W(VC Mode)	W(AC,SC Mode)
50(Half)	100Ω	2.5	22.0
100(Max)		9.0	45.0
50(Half)	200Ω	3.5	22.0
100(Max)		13.5	45.0
50(Half)	500Ω	5.0	22.0
100(Max)		18.0	45.0
50(Half)	1000Ω	7.0	22.0
100(Max)		17.0	45.0
50(Half)	2000Ω	6.0	22.0
100(Max)		13.0	45.0

- Output diagram

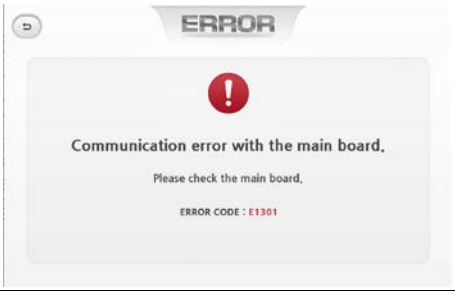




Chapter 8. Explanation on Pop-up Messages

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

1. Error Messages



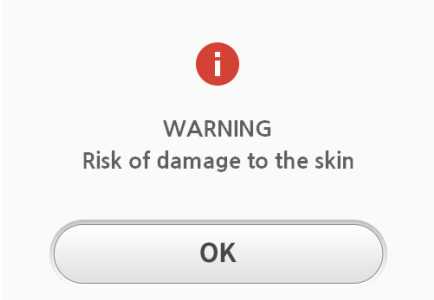
Screen indicating an error message.

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
INTERFACE COMMUNICATION ERROR	**Communication error with the main board. Please check the main board. ERROR CODE : 1301**	If there is no communication between systems, an error message occurs. Ask the agency.
FOOT SWITCH NOT CONNECT ERROR	**Footswitch not detected. Please check the footswitch connection. ERROR CODE : 501**	If the footswitch is not connected, an error message occurs. Please check your Footswitch connection and try again.
INTERLOCK NOT CONNECT ERROR	**Interlock switch error. Please check the interlock switch connection. ERROR CODE : 401**	If the Interlock switch is not connected, an error message occurs. Check the Interlock switch connection and try again.
FIBER NOT CONNECT ERROR	**Error: Fiber not detected Please check the Fiber connection. ERROR CODE : 2601**	If the Fiber is not connected, an error message occurs. Check the Fiber connection and try again.
IGBT TEMPERATURE ERROR	**Error: IGBT Over Temperature Please check the IGBT Module. ERROR CODE : 702**	If the IGBT temperature exceeds the standard range (0 to 65 degrees), an error message occurs. Ask the agency.
LASER TEMPERATURE ERROR	**Error: Laser Over Temperature Please check the Laser Module. ERROR CODE : 305**	If the Laser temperature exceeds the standard range (15 to 32 degrees), an error message occurs. Ask the agency.

LASER OVER CURRENT ERROR	**Error: Laser Over Current Please check the Laser Module Circuit. ERROR CODE : 301**	If the Laser Current exceeds 20% of the standard range, an error message occurs. Ask the agency.
LASER NOT CONNECT ERROR	**Error: Laser Module not detected Please check the Laser Module connection. ERROR CODE : 302**	If the Laser is not connected, an error message occurs. Ask the agency.

2. Warning/Notice Message



Screen indicating a warning/notice message.

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

CONTENTS	SOLUTION
NOTICE Please check the Needle Cartridge.	A message occurs when Needle Cartridge is not connected.
NOTICE Needle Cartridge Error (EEPROM)	A message occurs when reading error of Needle Cartridge EEPROM.
WARNING Defective Needle Cartridge. Please replace the Cartridge.	A message occurs when Needle Cartridge is error (storing shot count error)
WARNING Exceeded maximum usage count of the Needle Cartridge. Please use a new one.	A message occurs when Needle Cartridge maximum usage is exceeded
WARNING Risk of damage to the skin	A message occurs when RF output duration is set to 400ms or more

NOTICE **Please make sure to use a needle for VC mode.**	A message occurs when entering SmartCure VC Mode.
NOTICE **Please make sure to use a needle for AC mode.**	A message occurs when entering SmartCure AC Mode.
NOTICE **Please make sure to use a needle for SC mode.**	A message occurs when entering SmartCure SC Mode

3. Information Message

The screen of pop-up message.

The window pops up, the description in the box is different from depending on the sort of pops-up. Refer to table below

CONTENTS	SOLUTION
Would like to restore the preset parameters?	A message occurs when pressing Reset button in Auto mode Setting screen
Would you like to save the customized parameters?	A message occurs when pressing Save button in Auto mode Setting screen
Please check the footswitch connection.	A message occurs when you press the Ready button while holding press the Foot Switch.
Would you like to save?	A message occurs when Save button is pressed after Preset Number(1 ~ 5) is selected.
Select a number and click SAVE button.	A message occurs when Save button is pressed without Preset Number (1 ~ 5) selected.
Would you like to install the new SW?	A message occurs during SW UPDATE in Information Mode.
The file size of 'interface.bin' is zero(0 byte)	A message occurs when F/W update file size is error during SW UPDATE in Information Mode.
Please check the update file	A message occurs when there is no update file during SW UPDATE in Information Mode.
Please Check the USB connection	A message occurs during SW UPDATE without USB.

Chapter 9. Electromagnetic Compatibility Guidance and manufacturer's declaration

Guidance and manufacturer’s declaration - electromagnetic emissions		
This equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment -guidance
RF Emissions CISPR 11	Group 1	This equipment 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
RF Emissions CISPR 11	Class A	This equipment 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 61000-3-2	Complies	

Guidance and manufacturer’s declaration - electromagnetic immunity			
This equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the This equipment 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	±8 kV Contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV Contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV (for power supply lines) ±1 kV (for input/output lines)	±2 kV (for power supply lines) ±1 kV (for input/output lines)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	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	• UT= 0%, 0.5 cycle (0, 45, 90, 135, 180, 225, 270 and 315°) • UT = 0 %; 1 cycle UT = 70%; 25/30 cycles (0 degrees) • UT = 0%; 250/300 cycle	• UT= 0%, 0.5 cycle (0, 45, 90, 135, 180, 225, 270 and 315°) • UT = 0 %; 1 cycle UT = 70%; 25/30 cycles (0 degrees) • UT = 0%; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Secret DUO image intensifier requires continued operation during power mains interruptions, it is recommended that the Secret DUO image intensifier be powered from an uninterruptible power supply or a battery.

Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 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			
This equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the equipment , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	6 Vrms 150 kHz to 80 MHz In ISM bands 3 V/m 80 MHz to 2.7 GHz	6 Vrms 3 V/m	IEC 60601-1-2:2014 $d = 2.0\sqrt{P}$ 80 MHz to 2.7 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 equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the equipment [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 equipment and the equipment		
This equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the equipment as recommended below, according to the maximum output power of the communications equipment.		
Rated maximum output power of Transmitter(W)	Separation distance according to frequency of transmitter(m)	
	IEC 60601-1-2:2014	
	150 kHz～80 MHz $d = 1.2\sqrt{P}$	80 MHz～2.7 GHz $d = 2.0\sqrt{P}$
0.01	0.12	0.20
0.1	0.38	0.63
1	1.2	2.0
10	3.8	6.3
100	12	20
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.		


CAUTION!

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


CAUTION!

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 generate, 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

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

This equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Portable RF communications equipment's should be used no closer than 30 cm (12 inches) to any parts of the product. Otherwise, the performance of this equipment could be degraded.

Immunity Test	Band [a] (MHz)	Service [a]	Modulation [b]	IEC 60601 Test Level(V/m)	Compliance Level(V/m)
Proximity fields from RF wireless communications equipment IEC 61000-4-3	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	27	27
	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	28	28
	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	9	9
	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	28	28
	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	28	28
	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	28	28
	5100 – 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	9	9

NOTE. If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

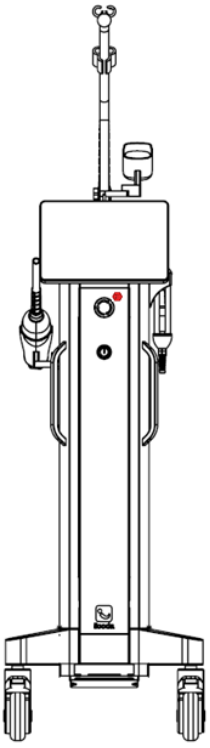
c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Appendix 1. Label and Symbols

1.1 Labels

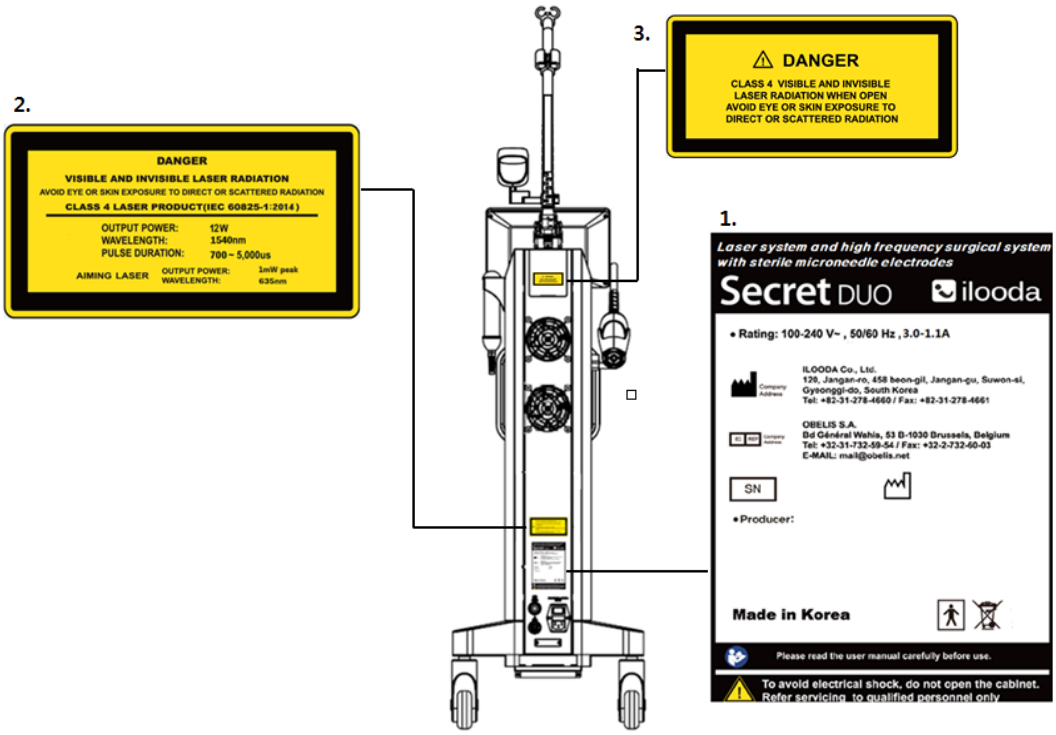
1) Main unit

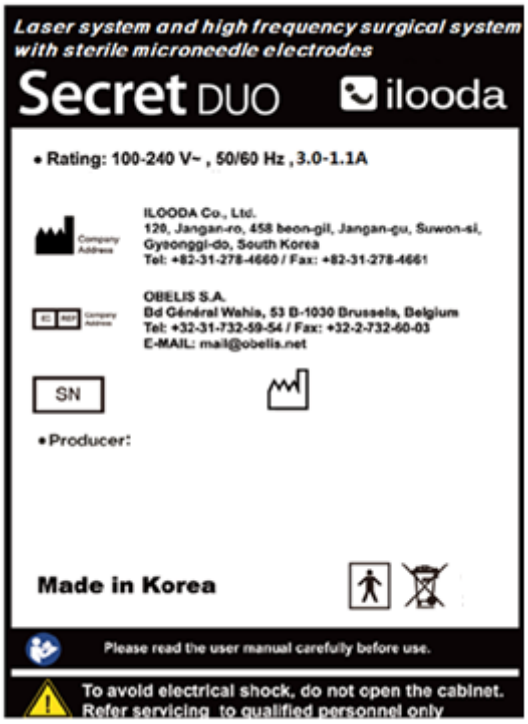
- Front

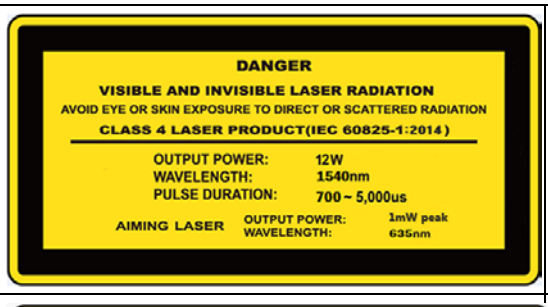


No	Indication	Type	Description
1		LABEL	The emergency stop device is a manual control device. It is the method of initiating the emergency stop function.
2		Symbol	Power on/off

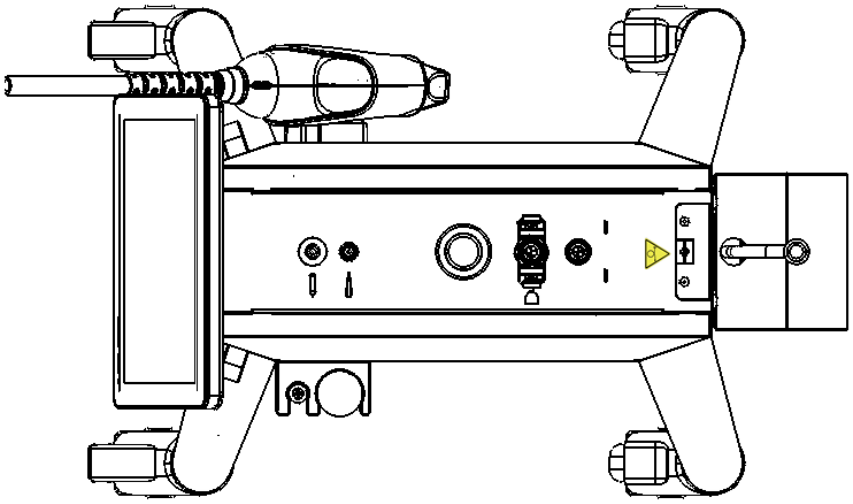
- Back



No	Indication	Type	Description	
1		LABEL		User Manual Reference
				Serial No
				Manufacture Date
				Manufacturer
				Applied part(BF type)
				Waste Electrical and Electronic Equipment
				Warning marking

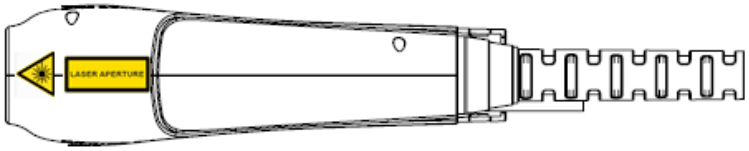
2		LABEL	Indicates the equipment is categorized as Class 4 laser product (According to the IEC60825-1:2014)
3		LABEL	Laser emitting a warning

- Upper



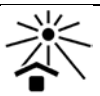
No	Indication	Type	Description
1		LABEL	Fiber Applicator

2) Laser Handpiece



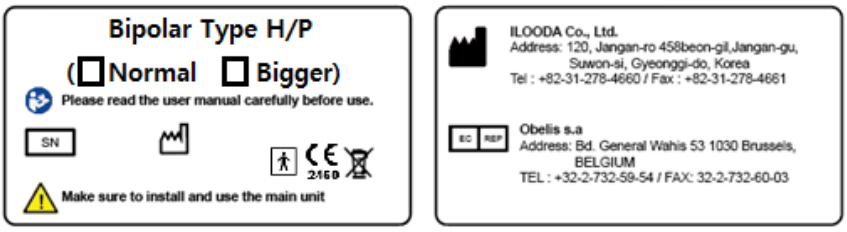
No	Indication	Type	Description
1		Symbol	It indicates the part emitting the laser.
2		LABEL	It indicates the part emitting the laser

3) Electrodes Labels

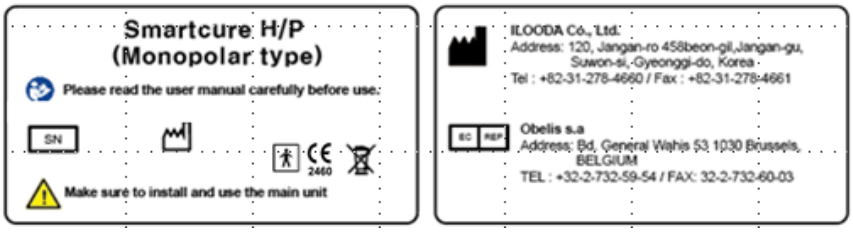
No	Label	Symbol	Label
1	**- Bipolar type needle electrode**  **- Monopolar type needle electrode** 		Manufacturing date
		LOT	Lot number
			Use by date (Expiration date)
		STERILE EO	Sterile using EO gas
			Consult User manual
			Single use
			Don’t use when packing damaged
			Keep away from sunlight
			Storage temperature limitation
			Manufacturer
		EC REP	Authorized EC representative

4) RF Hand-pieces Labels

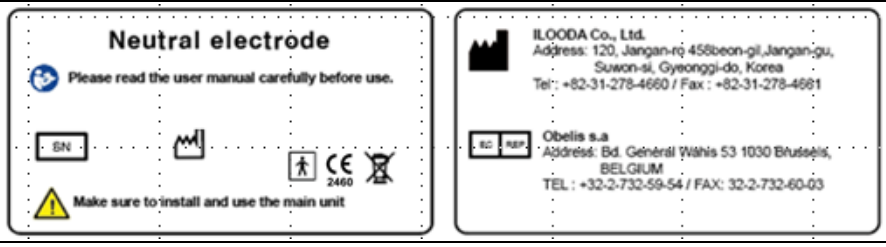
Bipolar Hand-pieces



SmartCure Hand-pieces (Monopolar type)



Neutral Electrode



Appendix 2. Regular Safety Inspection

Secret DUO 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 problems on it, Refer to “Table. Daily equipment inspection log"

Object of Inspection	Matters to be Inspected	Result of Inspection YES / NO	Inspector	Remarks
Laser enclosure	Check whether or not laser, main power cable and plug are worn out or damaged.			
Laser labeling	Check whether or not the laser label is properly attached without damage.			
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.			
Key switch	The equipment is operated only the key switch is on. Turn off key switch and check whether or not energy is emitted.			
Foot switch	1. Check if there is any damage on the machine or cable. 2. The energy(laser or HF) is emitted when you press the Foot switch only at READY. When you press foot switch at the STANDBY, check the laser emission or HF output. 3. The error sign is coming and the equipment is not operating when the foot switch is not connected.			
Emergency Stop button	Press emergency stop button in the treatment mode. It is normal only if treatment is discontinued immediately.			
Remote interlock	Check whether or not the equipment properly stops when taking out the remote interlock while in operation. Check if there is any error message when operating equipment without remote interlock. It is normal only if the equipment does not operate with error message.			

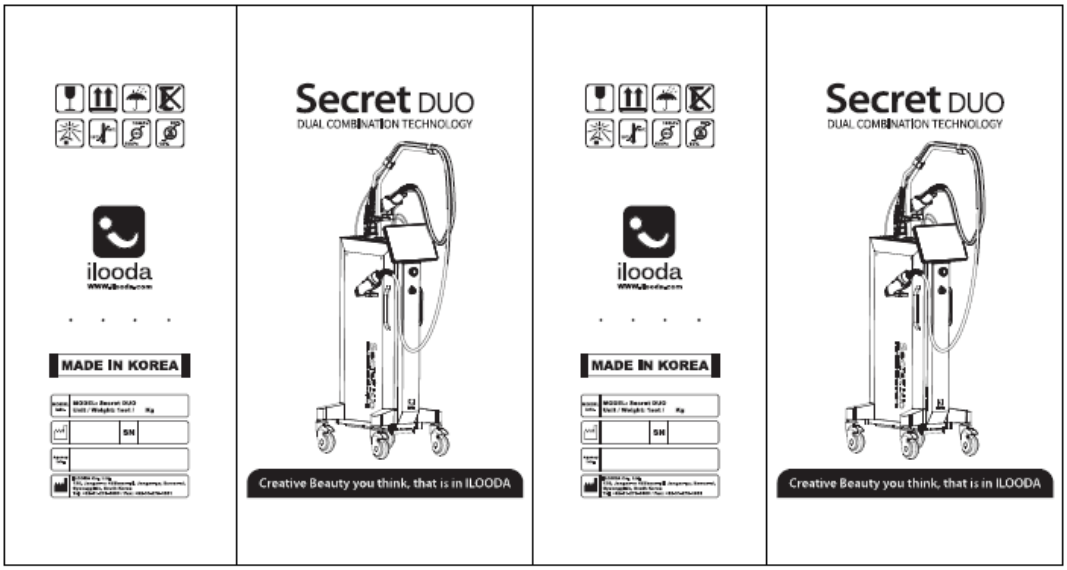
Warning of Laser or HF radiation	Visual warning on display and audial warning is installed together. This Warning sign is expressed on LCD and “beep” sound at the same time.			

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

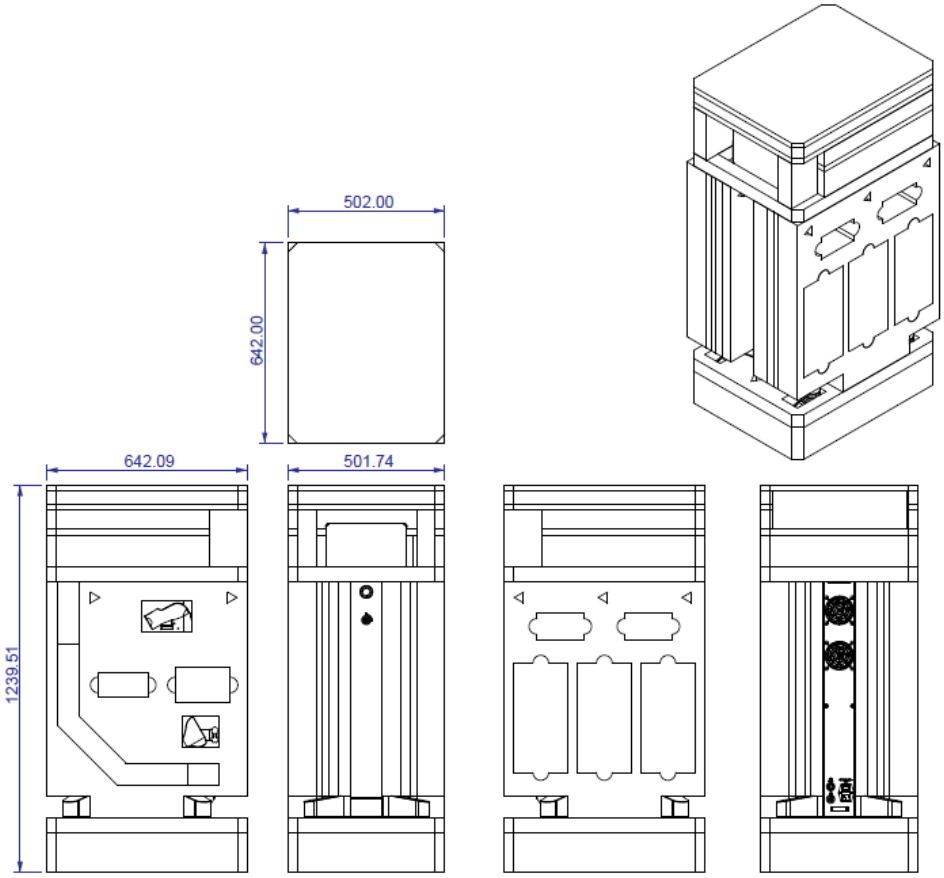
Appendix 3. Packaging Information

To protect the device from the shock during transportation, Secret DUO shall be packaged as below.

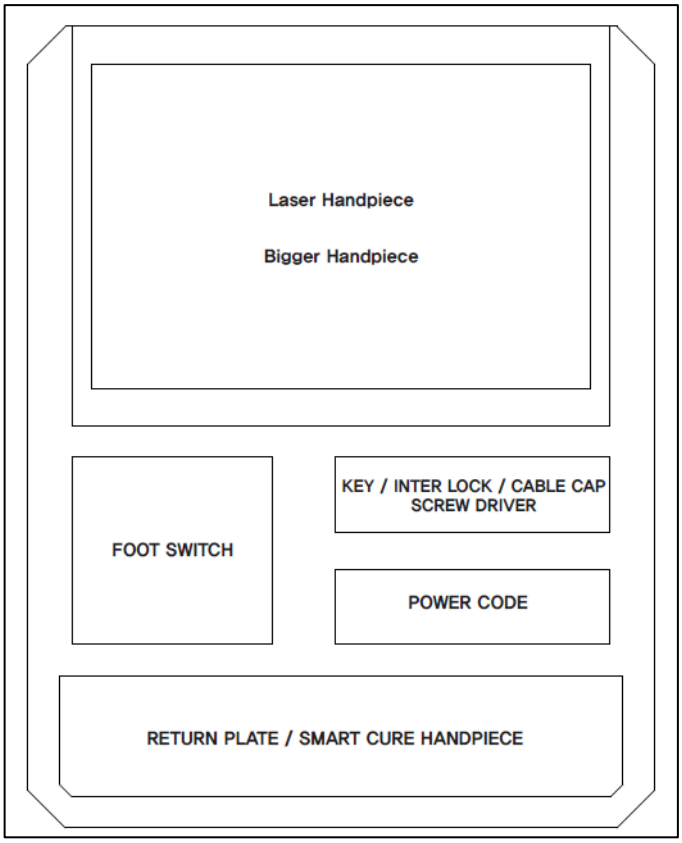
1) Main Unit



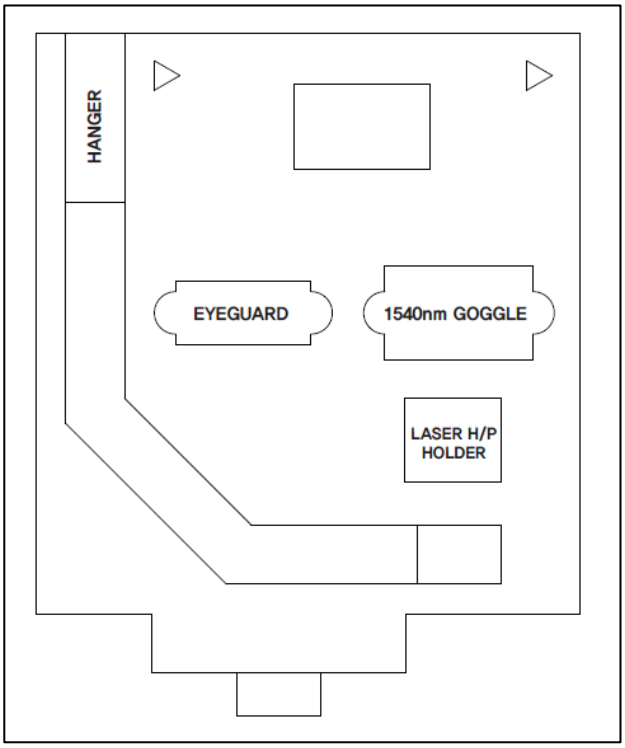
2) Main Unit and Accessories packing



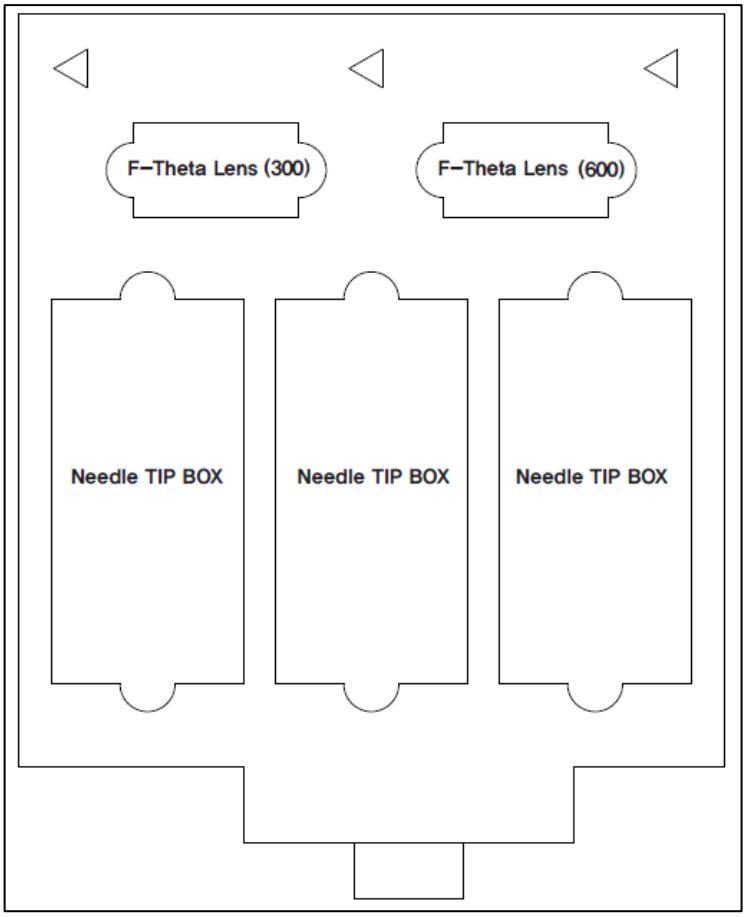
- Top side



- Left side



- Right side


F-Theta Lens (300)
F-Theta Lens (600)
Needle TIP BOX
Needle TIP BOX
Needle TIP BOX

Appendix 4. The revision of User manual

REV	Revisions	Date
IFU-E-SecretDUO(REV.0)	First Edition of Secret DUO User Manual	25th.September. 2019