HIRONIC

doublo · gold™

USER MANUAL

PRODUCT	Focused Ultrasound Stimulator System
MODEL	DOUBLO-GOLD™

TABLE OF CONTENTS

Copyright

Intellectual Property Rights

DOUBLE-GOLD™-related intellectual property rights referred to herein include all of the patent, trademark and design rights applied for or registered in Korea and other countries. All of the rights related to this product are protected by the relevant intellectual property rights.

The product referred to herein is protected by Hironic Co., Ltd.'s intellectual property rights, including the patent rights and their patent family, as well as the trademark rights and design rights. Unauthorized use of this product is an infringement of Hironic Co., Ltd.'s intellectual property rights and may be subject to civil and/or criminal penalties.

Intended of Use

DOUBLO-GOLD™ is intended for lifting of various parts such as upper face includes eyebrows, lower face, neck, etc and sculpting of skin by way of the deposition of micro-focused ultrasound(MFU) energy at depths between 1.5 mm and 13.0 mm beneath the skin. Deposition of MFU energy results in a change to the physiology, resulting in stimulation of new collagen and elastin as part of the healing process.

DOUBLO-GOLD™ is also intended for use for the treatment of Axillary Hyperhidrosis.

Patient population: Male and female patients who were 18 to 75 years of age.

The diagnosis of hyperhidrosis: Hyperhidrosis Disease Severity Scale (HDSS) score of 3 or 4.

Contraindications

DOUBLO-GOLD™ must not be used on patients with the following symptoms.

* Patients with open wounds on the treatment area
* Patients with metal stents/implants in the treatment area
* Patients with bio absorbable mechanical implants
* Patients with implantable electrical devices
* Patients with an active systemic or local skin disease that may alter wound healing
* Patients with treatment with botulinum toxin;
* Patients with a known allergy to starch powder or iodine
* Patients with secondary hyperhidrosis due to an underlying disease, such as hyperthyroidism, lymphoma, or malaria
* Patients with prior surgical treatment of hyperhidrosis, including sympathectomy, surgical debulking of the sweat glands, subcutaneous tissue curettage, or ultrasonic surgery
* Patients with a history of chronic drug or alcohol abuse or autoimmune disease

Warning

As the procedure outcome has not been studied yet, please exercise caution if the patient has the following symptoms.

* Herpes Simplex
* Autoimmune Disease
* Diabetes
* Epileptic
* Pregnant or Breastfeeding
* Infants
* The consequences of directly operating DOUBLO-GOLD™ on patients with an implanted medical device, such as a defibrillator or pacemaker, have not yet been studied.

⚠Caution

* When the operator notices a potential safety problem or abnormal symptom, he or she must immediately stop the procedure and inform the DOUBLO-GOLD™ customer service center.
* Use of the DOUBLO-GOLD™ system together with other devices has not yet been tested, and could result in unexpected consequences.
* Ultrasonic gel is only available from manufacturers or CE certified products.
* Do not immerse or expose the device and handpiece to water. Exposure to water will cause equipment failure.
* If DOUBLO-GOLD™ is used without the Ultrasonic gel, the treatment area may be burned. Be sure to use the Ultrasonic gel.
* DOUBLO-GOLD™ can only be used by qualified doctors.
* To avoid misuse of the cartridge, please read the manual carefully.
* DOUBLO-GOLD™ has a 5 year life cycle.
* DOUBLO-GOLD™ is a medical device. Since the product has been tested and manufactured in accordance with international standards (IEC), the parts supplied by Hironic Co., Ltd must be used. The use of unauthorized products may cause serious harm to the patient. Use only products approved by Hironic Co., Ltd.
* This product is between 18 and 75 years of age, with a Hyperhidrosis Disease Severity Scale (HDSS) score of 3 or 4.
* If the product is used differently than the intended use, it may cause unknown side effects and may be dangerous to the patient.

Possible Side Effects

Temporary and very limited side effects reported in clinical applications are as follows:

* **Redness**: After treatment of the treated area, flushing generally persists for 48 hours.
* **Mild discomfort, Tenderness, Soreness, Pain, Palpitation, Paresthesia**: Some discomfort during the procedure, which may be momentary.
* **Bruising**: Between 48 to 72 hours of treatment in rare cases may form a few bruises.
* **Folliculitis, Insomnia, Ulcer**: May occur rarely after the procedure, but disappear within 2 weeks after the procedure.
* **Numbness, Chills / URI**: After treatment, the treatment area may become cold or numb for a while. It disappears within two weeks after the procedure.2 months).

Information for Patients after Operation

* Avoid exfoliation for at least a week because the skin is sensitive after treatment
* It is recommended to avoid intensive exercise or visiting a sauna for about a week after operation.
* Avoid drinking alcohol.
* Use a mild cream or moisturizer.
* When operating on the same area as the previous procedure, consult with a doctor in advance.

Interaction

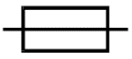
* Do not use this device together with other equipment because there are no study results assessing co-usage.

DOUBLO-GOLD™ System Information

The components of the device include the Main body, Cart(Optional), Cartridge(Optional), Controller, Power Cable, Foot Switch (Optional), Hose Handler etc.
Cartridge should be inserted into the handpiece after turning the device on. Ultrasound gel has to be applied onto the Cartridge. Place the Handpiece on treated areas and push the Switch Button.
Then, the ultrasonic energy will be delivered.
There are five types of cartridges: S7(7.0MHz), D7(7.0MHz), M7(7.0MHz), D4(4.0MHz), L4(4.0MHz)

Signs

The signs that can be found on the components, accessories, or the packaging that come with the product are as follows:

Symbol / Label	Description
	Indicates a potential threat that may result in injury or property damages if the instruction is neglected.
	Provides important information on using the device.
	On medical equipment: identifies a type B applied part complying with IEC 60601-1. (IEC 60878-5840)
	Indicates power ON mode; this is in accordance with the regulation for protection against electric shocks (IEC 60878-5007).
	Indicates power OFF mode; this is in accordance with the regulation for protection against electric shocks (IEC 60878-5008).
	Indicates the medical device manufacturer.
	Indicates the date on which the medical device was manufactured.
	Indicates that this product cannot be disposed of as general wastes, according to the Directive on Waste Electrical and Electronic Equipment (Directive 2002/96/EC and EN50419). The product should be collected separately and recycled. For more information on disposal, contact Hironic Co., Ltd.
	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Indicates where the fuse box or fuses are located on the product; this is in accordance with the regulation for protection against electric shocks (IEC 60417-5016).
	Consult instruction for use (ISO 7010)

※ **Please familiarize yourself with the system signs before use.**

User Documents

DOUBLO-GOLD™ System User Manual
Detailed information regarding DOUBLO-GOLD™ system composition, DOUBLO-GOLD™ operating method, equipment problem solving, cleaning and maintenance are included in the DOUBLO-GOLD™ system user manual.

DOUBLO-GOLD™ Instruction Manual
The instruction manual provides instructions on the use of each type of cartridge, and the latest information regarding safety and usage.
Hironic Co., Ltd has the right to edit the content of the user documentation.
Prior to using the system, the user should be fully acquainted with latest documentation at all times.

DOUBLO-GOLD™ Customer Service
Customer Service Center Homepage : **www.hironic.com**
Local agency or Hironic Co., Ltd. C/S center : **ocs@hironic.com**

NOTE

All images in the DOUBLO-GOLD™ user documents are examples.
The appearance and specifications of the actual system hardware may differ from what is shown in the user documents.

1. Product Overview and Components

1.1 Product Overview

1.1.1 Overview

This device uses focused ultrasound to produce localized, mechanical motion within tissues and cells for the purpose of producing either localized heating for tissue coagulation or for mechanical cellular membrane disruption intended for treating Axillary Hyperhidrosis.

1.1.2 Intended use

Indications for Use: DOUBLO-GOLD™ is indicated for use as a treating Axillary Hyperhidrosis.

1.1.3 Intended user

Medical Doctor

1.1.4 Specifications of DOUBLO- GOLD™

1.1.4.1 Electrical specifications

A) Class and type of protection against electric shock : Class I , type B
B) Rated voltage and power consumption : AC 100~240V, 50/60Hz, 3.15A, 160VA
C) Technical Specifications
   * Energy type : HIFU (High Intensity Focused Ultrasound)
   * Fluence : Max 2.0 J
   * Cartridge : S7, D7, M7, D4, L4
   * Spacing : Max 10 mm
   * Length : Max 25.0 mm
D) Display
   * LCD (15 Inch Color Screen)
   * HIFU Control (7 Inch Color Touch Screen)
E) Sysyem Safety
   * DSP Watchdog : Power will be completely turned off when DSP or Firmware malfunctions
   * If the excessive voltage rating is applied, protection circuit will be operated.

1.1.4.2 Physical specifications and weight

A) Main Body (W X D X H) : 400 X 425 X 460 mm
B) Hand piece (W X D X H) : 42 X 85 X 228 mm
C) Weight : 15.5 Kg (Main Body), 25 Kg (Cart)

1.2 Components and Features

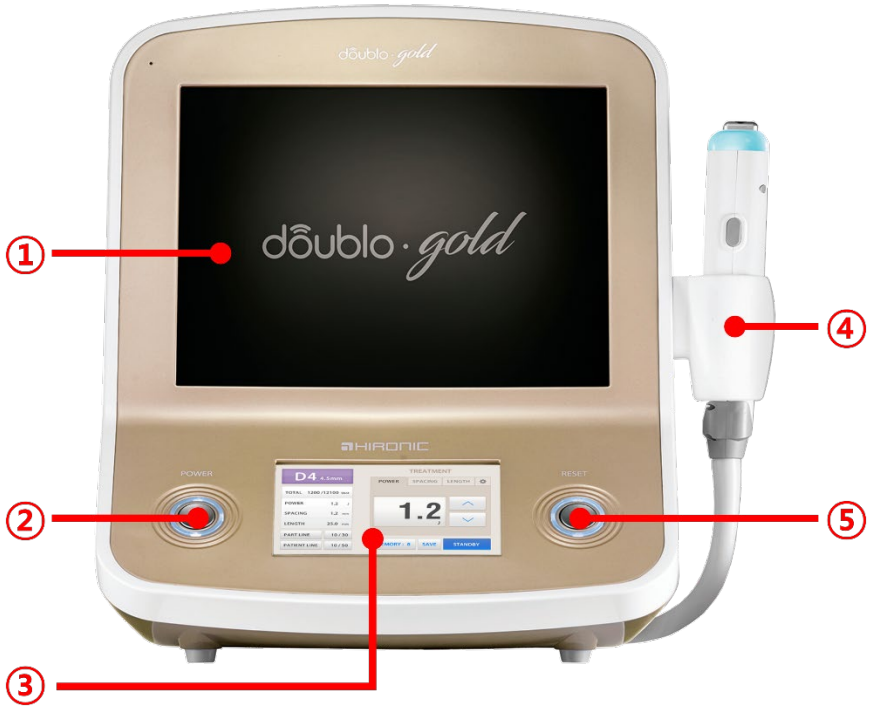
1.2.1 Components

DOUBLO-GOLD™ consists of the following components:

NO	Item	Unit	Remark	
1	Main Body	1 EA	Main Unit	-
2	Cart	1 EA	Accessories	Optional
3	Hand piece	1 EA	Main Unit	-
4	Controller	1 EA	Accessories	-
5	Power Cable	1 EA		-
6	Foot Switch	1 EA		Optional
7	Cartridge (M7, D4, D7, S7, L4)	1 SET		Optional
8	Hose Handler	1 EA		-
9	Cartridge Film & Magnetic protective Cap	1 SET		Optional
10	Ultrasound Transmission Gel	1 EA		Optional

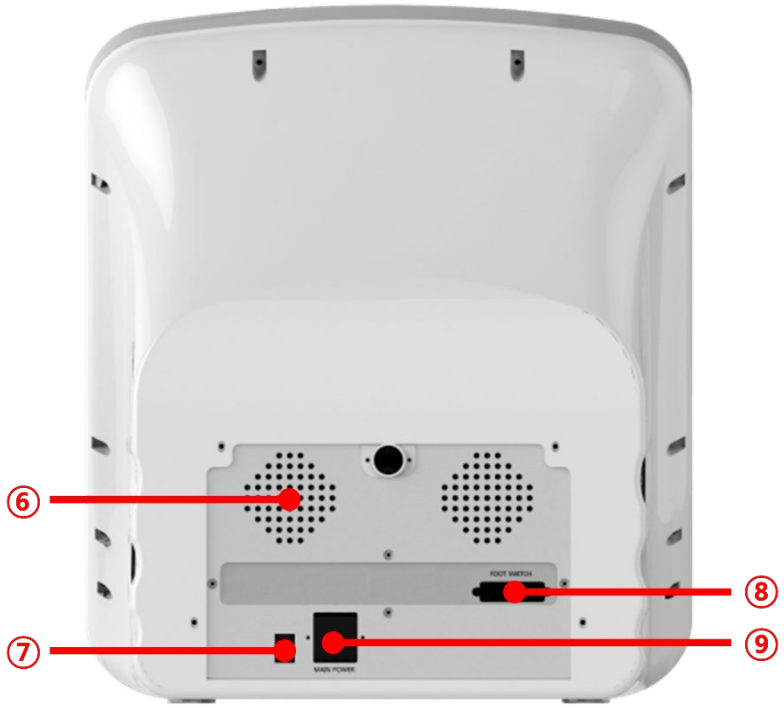
1.2.2 Component names & functions

1.2.2.1 Main body - front view



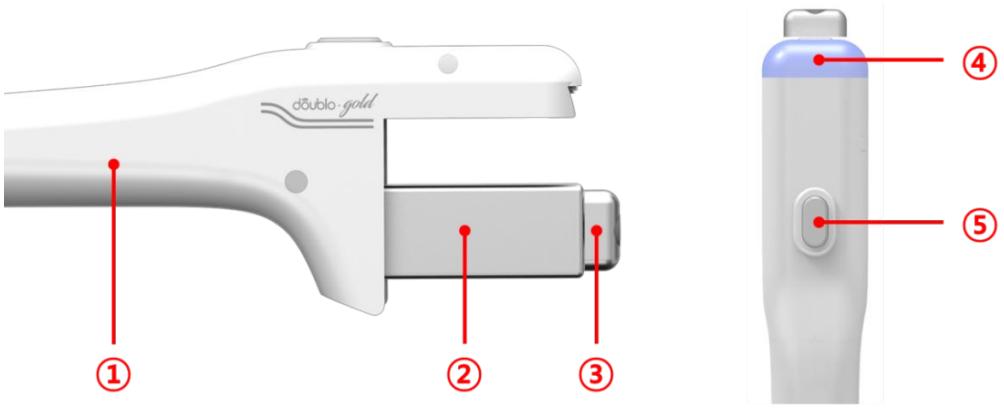
No.	Product	Description
①	**LCD Screen**	Displays Image or video
②	**[Power] Switch**	ON/OFF switch for the LCD Screen and HIFU Control System
③	**HIFU Control System**	A touch screen that adjusts the HIFU operational condition such as Power, Spacing, Length and Check the cartridge information
④	**Handpiece Stand**	Holder for holding handpiece.
⑤	**[Reset] Switch**	Resets the display when a malfunction occurs

1.2.2.2 Main body - rear view



No.	Component	Note
⑥	**Ventilation Hole**	Discharges heat from inside to outside
⑦	**[Main Power] Switch**	ON/OFF Switch of main power input to device
⑧	**Foot Switch Connection Port**	Foot Switch Connection Port
⑨	**AC Inlet**	Connects with the power cable

1.2.2.3 Handpiece



No.	Item name	Description
①	**Knob**	Knob of the handpiece
②	**Fixing brocket**	Cartridge fixing bracket
③	**Lock of cartridge**	Lock of cartridge
④	**Operation indicator lamp**	A device that displays the operation of ultrasound transducers by using a LED light
⑤	**Hand switch**	A switch that generates High Intensity Focused Ultrasound

1.2.2.4 Cartridge

No.	Item name	Description
①	**Display of Cartridge type**	Displays the type of cartridge, depth and frequency depending on each cartridge
②	**Display of therapeutic area**	Displays treatment areas; the energy is radiated from the right of the cartridge
③	**Cartridge board connector**	Connects Board which electrically controls the ultrasound transducer with the handpiece in the cartridge
④	**Cartridge connecting rod**	Moves the transducer placed inside to be automatically connected with the handpiece
⑤	**Cartridge connecting passage**	Passage for connecting the fixing brackets
⑥	**Display center**	Displays the center of coagulation zone during the treatment, and is used to forecast the therapeutic areas through displaying the therapeutic area

1.2.2.5 Cart

Holds up the Main body; includes 2 drawers for storing the user's goods

1.2.2.6 Foot switch

This is pushed to generate the High Intensity Focused Ultrasound.

1.2.2.7 Ultrasound transmission gel (ECOSONIC)

Ultrasound Gel used to deliver ultrasound to the skin

Manufacturer : Sanipia In.
#129, Sundongsandangil, Gimje-si, Jeonbuk. Korea

2. General Safety

2.1 Items to Be Confirmed before Use

2.1.1 When you locate the product, please check the following.

* It is recommended to locate the device in an area with good ventilation, as the device heats up slightly when operating.
* Locate the device on a flat surface where there is no slope.
* Check the grounding condition.
* Never touch the plug with a wet hand (this could cause electric shock).
* Do not use the cables if they have been immersed in liquid or broken.
* To avoid the risk of electric shock, do not locate the device right next to other electrical machines. If you connect it to an extension cord with other devices, there is the risk of fire or explosion.
* Use a power outlet which has a ground terminal. Failure to ground the device properly may cause a malfunction due to electric shock.
* If possible, avoid places that are exposed to direct sunlight.

2.1.2 When moving the product to another location, please follow this sequence.

* Turn off the power and disconnect the power cable before moving.
* The handpiece should be firmly fixed to the supporter to prevent it from falling down.
* Put the caster brakes up to move the device.
* Move slowly while holding the handle of Cart.
* After moving, put the caster brakes down to fix its position.
* Connect the power cable.

2.2 Power Connection

2.2.1 Checklist prior to turning on

* Operate after inserting at least one cartridge.
* Make sure the plug is properly inserted. Do not connect the product with wet hands because of the risk of electric shock.
* Confirm that the power switch on the back of the body is ON.

2.2.2 Checklist before turning on the power

* Make sure that the power plug is inserted correctly. Do not handle cables with wet hands. This creates the risk of electric shock.
* Do not use a damaged cable. There is a risk of electric shock.
* Confirm that the [Main Power] switch on the back of the Main Body is ON.

Checking the grounding for the power cable

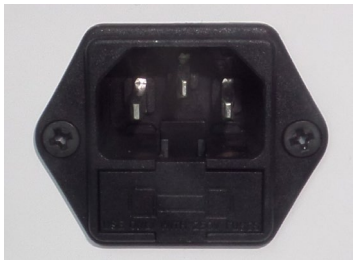
[Cable grounding position]

[Electrical outlet grounding position]

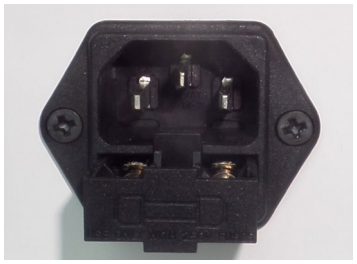
[Correctly connected]

* Plug the power cable all the way into the power outlet to ensure proper grounding. An incomplete connection may cause the device to malfunction during operation, particularly when using the front touch panel.

Replacing the power cable fuses



[Step 1]



[Step 2]

[Step 3]

* Turn off the device before replacing the fuses. Always be careful to avoid electric shock.
* To replace the fuses, use a screwdriver to pull out the fuse holder on the power supply unit on the back of the device until the holder is visible.
* Remove the fuses from the holder, insert new fuses, and then close the holder.
- Fuse capacity: 250V, 3.15A (x2). Push the holder to ensure that it slides all the way in; then, connect the power cable to the AC socket.

NOTE

If the power cable is not fully plugged in, the device may not turn on.

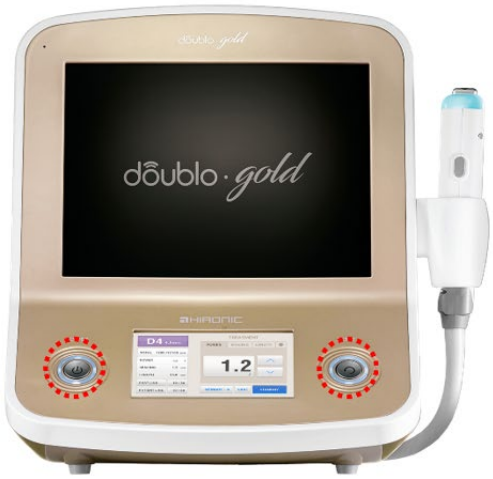
2.3 Turn on/off

2.3.1 Turn on the power

* Push the main power ON after checking whether the power cable is fully connected at the bottom of the rear body.
* Push the power switch at the left of the front body.
* The device will be turned ON when there is a blue light in both the power and reset button.

2.3.2 Turn off the power

* Push the power button lightly at the left of the front body. The upper imaging software and windows will automatically proceed to shut down. This takes approximately 1 minute.
* The HIFU system at the bottom of the body is immediately ready to quit, and will be automatically turned off.
* At this point, the color of the LED in the Power and Reset switch will turn pink.
* Do not push the main [Power] switch at the rear of the body, the front [Reset] switch or the front [Power] switch.
* Frequent forced shutdowns can cause system errors and slow the boot time.



[Power] Switch [Reset] Switch

[Main Power] Switch

3. How to Use

3.1 Safety Checks before Use

* Set up proper parameters based on the treatment guideline and the patient's condition.
* If contaminants are found at the handpiece, remove using gauze and alcohol.

3.2 Precautions before Use

* Use under the guidance and prescription of a specialist.
* Do not use on pregnant women and children.
* Do not use on patients with dermatitis.
* Avoid direct exposure to sunlight that can damage the skin.
* Do not use products containing isotretinoin such as glycolic acid, salicylic acid, Retin-A® which may be irritate the skin.
* Clean the treatment area with a gentle cleanser, and do not apply creams, lotions, foundation, powder, etc., before treatment.
* Check the switch contact situation, polarity and device settings and make sure that the equipment is working correctly.
* Use in combination with other devices can interfere with the correct procedures and cause danger.
* Ultrasonic gel is only available from manufacturers or CE certified products.
* DOUBLO-GOLD™ is designed so that settings cannot be changed while the machine is in "READY" Mode. Do not change the setting while the ultrasound is in operation.

3.3 Precautions during Use

* Set the energy level considering the thickness of skin.
  - Areas with thin skin such as the forehead, intra orbital and lateral orbital should be treated with low energy.
  - During treatment, an anatomical understanding of facial blood vessels and nerves is required.
  - If the operator moves the handpiece during the procedure or if the patient moves the handpiece due to pain, the handpiece may not touch the treated area, and may cause burns.
  - Do not overlap the treatment in the same line. Duplicate heat results in burns.
  - If the practitioners move the handpiece or the patient moves due to the pain, it may result in excess energy on a certain area, which may cause burns.
  - Before using in close proximity to the eyes, first determine the energy level which does not affect the eyes.
  - Check the type and depth of the cartridge. During ultrasonic radiation, be careful not to exceed the amount of time and radiation level required.
  - Check device and patient status continuously to monitor for problems.
* If problems with the device or the patient are found, keep the patient safe and hold the device to work.
* If a failure is found in the equipment, stop using the device and turn off the power.
* In a power outage, turn off the power immediately and return the switch to its original position.

3.4 Precaution after Use

* After treatment, remove the gel and then check for edema, erythema, or blisters at the treatment area.
  - It is recommended to perform appropriate post-treatment where strong energy has passed.
  - Clean with cold water and a gentle cleanser.
* If the treatment area turns red (which usually disappears within a few hours), avoid washing or showering with hot water.
* Avoid exfoliation for at least a week, as the skin can be sensitive after treatment.
* Makeup is available immediately after the procedure.
* Use a gentle cream or moisturizer.
* When you go out, avoid direct sun exposure., and use a sunblock above SPF 30.
* Avoid saunas.
* Do not perform any exercise that makes you sweat profusely.
* Return Operation switches and accessories to their original state based on the specific order.
* After the procedure, remove stained gel on/in the equipment and cartridges immediately.

Caution

* **When the device breaks down, the operator must confirm whether or not the socket or fuse has any problem based on their own judgment, but must not disassemble or operate the device arbitrarily.**
* **Set an appropriate mark for a breakdown, and notify the Hironic Co., Ltd. customer service center.**

※ Local agency or Hironic Co., Ltd. C/S center : ocs@hironic.com.

4. Operation

4.1 How to Operate the Device

4.1.1 HIFU control system

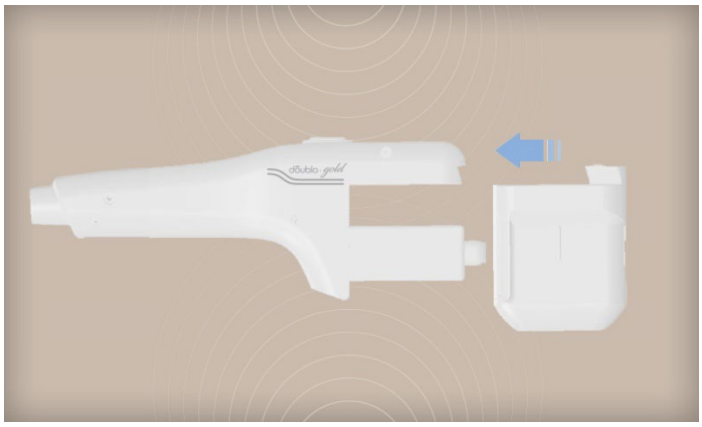
* This is located in the bottom of the front body, and controlled through the 7-inch touch screen.
* This equipment can display HIFU energy, spacing, length and settings as a main operating unit to control the device. You can adjust each menu by touching the screen.
* Use only the original Cartridge supplied by manufacturer.
* Use the appropriate Cartridge for the Treatment area.
* Locate the DOUBLO-GOLD™ in a well ventilated place.

⚠ Caution

Hironic Co., Ltd. will not be responsible for damage or malfunction related to the use of consumable products that are not original cartridges provided by Hironic Co., Ltd. Furthermore, if equipment failure occurs following any arbitrary disassembling, remodeling or reuse of our cartridges, warranty services will not be provided.

* Loading Screen: When you turn the power switch on, a loading screen appears on the touch screen and displays the process of loading software. After loading, the screen changes to the area selection.

* Connection between Handpiece & Cartridge: After the Cartridge Connection screen is displayed, insert the cartridge into the handpiece. The system checks the information of the inserted cartridge and then moves to next screen to adjust ultrasound power (power, spacing, length etc.).

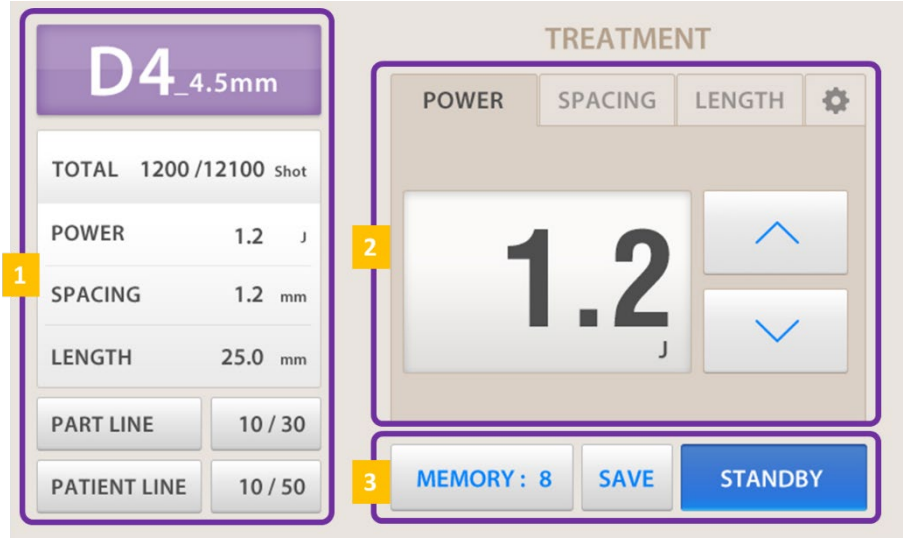


< Before Connection >

< After Connection >

* Memory Selection: Select the memory area to store the parameters for the part to be treated. You can save the parameter value (Power, Spacing, Length) to the memory for the procedure.

* Parameter Setting: On this screen, you can check the parameters of energy. You can also set the parameters of the ultrasound such as Power, Spacing, and Length.

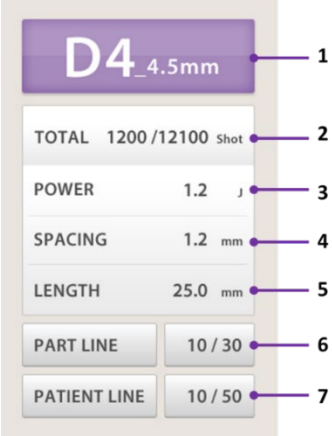


No.	Explanation
1. Left Menu	1. Information of cartridges 2. Displays the current energy (Power / Spacing / Length) 3. Information about the number of treatments
2. Right Menu	1. Control Power 2. Control Spacing 3. Control Length 4. Environment Setting
3. Bottom Menu	1. Memory Selection 2. Data Saving 3. Ready / Standby

Caution

* **Setting values are to be used within a safe range, and side effects etc. fully considered in treatment.**
* **The pre-set reference setting uses arbitrary parameters set by the manufacturer, and is not guaranteed to be safe for every patient. We recommend its use only as a reference.**
* **During the treatment, setting values should be safely controlled after the operator checks the patient's skin conditions, thickness, and adverse reactions.**

* LEFT MENU



1) Cartridge Information

Cartridge	Max Power	Frequency	Depth	Spacing	Length
M7	0.20 ~ 0.75 J	7.0 MHz	3.0 mm	1.0 ~ 10.0 mm	5 ~ 25 mm
D7	0.20 ~ 2.00 J	7.0 MHz	4.5 mm	1.0 ~ 10.0 mm	5 ~ 25 mm
S7	0.20 ~ 0.75 J	7.0 MHz	1.5 mm	1.0 ~ 10.0 mm	5 ~ 25 mm
D4	0.20 ~ 2.00 J	4.0 MHz	4.5 mm	1.0 ~ 10.0 mm	5 ~ 25 mm
L4	0.20 ~ 2.00 J	4.0 MHz	13.0 mm	1.0 ~ 10.0 mm	5 ~ 25 mm

2) TOTAL
- Count used by the cartridge.
- Check the remaining amount of cartridge shot counts.

3) POWER
- A button controlling the gap between the two dots.

4) SPACING
- A button controlling the gap between the two dots.

5) LENGTH
- The total length of a treatment line.

6) PART TIME
- The actual number of lines treated to the area/ Recommended treatment lines pre-set (Even if the actual line exceeds the preset line, ultrasound continues to occur.e.g. 120/80)

7) PATIENT LINE
- The total number of lines per patient who underwent treatment.

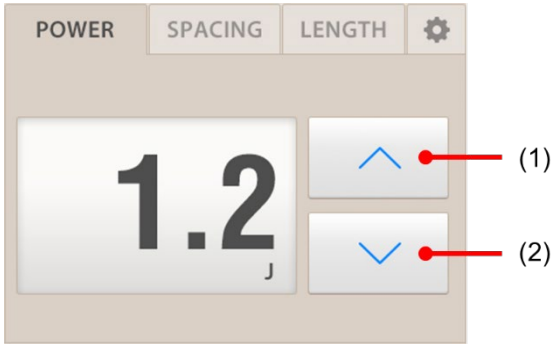
* RIGHT MENU

1. POWER adjustment

(1) Increase Power
- Adjustable

(2) Decrease Power
- Adjustable

※ Max or Min Value is dependent on the type of Cartridge



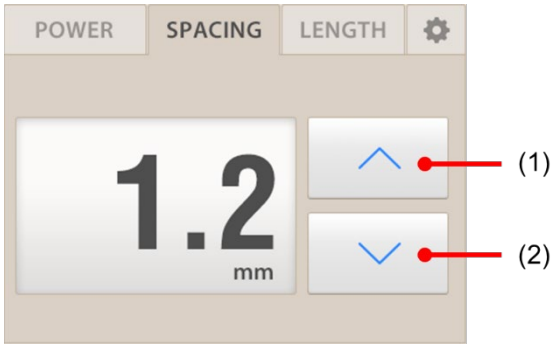
2. SPACING adjustment

The spacing between any two consecutive points

(1) Increase Spacing
- Adjustable

(2) Decrease Spacing
- Adjustable

※ Max or Min Value is dependent on the type of Cartridge



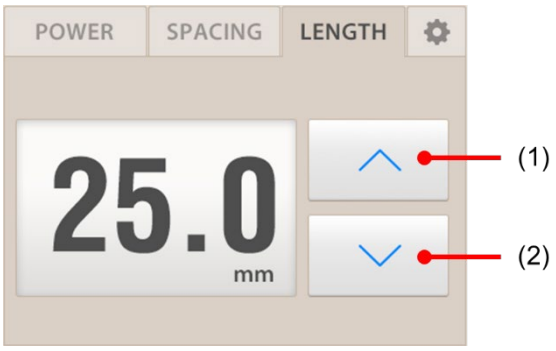
3. LENGTH adjustment

The total length of consecutive points

(1) Increase LENGTH
- Adjustable

(2) Decrease LENGTH
- Adjustable

※ Max or Min Value is dependent on the type of Cartridge



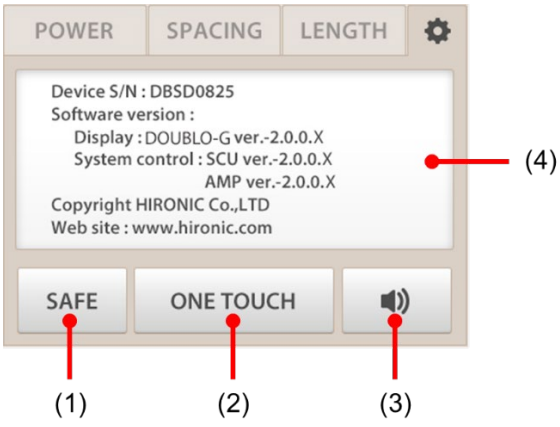
4. Environment Setting

(1) Safe mode
- Ultrasonic energy is emitted at the setting value only while the switch is pressed

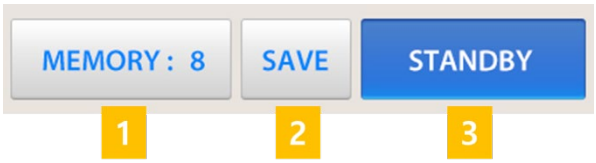
(2) One Touch mode
- When the switch is pressed, ultrasonic energy is emitted at the setting value

(3) Mute Function

(4) Display information of Software version



* BOTTOM MENU



MEMORY : 8	You can select the memory to store the parameter values used in the treatment (Memory 1 ~ Memory 8)
SAVE	After Adjusting any or all of the ultrasonic energy (Power, Spacing, Length), and pressing the SAVE button, Final data is stored in the memory.
STANDBY	Initially started as a standby state. If you press the standby button after setting the ultrasonic energy, this button will change to Ready status, and Ultrasonic energy emission becomes available.
READY	When in Ready state, the Indicator lamp on the handpiece turns blue. During emission, the Indicator lamp on the handpiece turns purple.

4.1.2 LCD Screen

At the top of the Main body, the LCD screen can play images or video. Images or video can be played via the supplied remote control.
Through the USB port on the rear panel, images or video can be stored in the main body.

4.1.3 How to insert cartridge to the hand piece

* Select the appropriate cartridge for the treatment area and then insert cartridges into the hand piece.

---

* Place the cartridge into the inside to fully connect with the hand piece.

---

* Fix the hand piece locking screws by rotating it counter-clockwise

※ If the hand piece lamp turns red, the cartridge is not inserted correctly or has a problem.

---

* After applying ultrasound gel to the surface of the cartridge, start the ultrasonic radiation close to the treatment area.

4.1.4 How to apply the cartridge to the patient's skin

* Put the cartridge in contact with the skin after applying an appropriate amount of gel to the skin. **[Picture 1]**
* Confirm that cartridge is in good contact with the skin. Otherwise, there is the risk of burns. **[Picture 2]**
* Using a lot of gel can cause burns and errors in treatment, as the focus will be on the skin's surface. **[Picture 3]**
* If the operator moves the handpiece or the patient moves due to the pain, there will be an excess of energy, which may cause burns.
* After ultrasonic emissions, detach the cartridge from the treatment area and then remove the ultrasound gel applied.

[Picture 1] (Correct)

[Picture 2] (Incorrect)

[Picture 3] (Incorrect)

4.1.5 How to check the energy emission

* After applying the gel on the membrane of cartridge, please push the button by the upright position of handpiece. Then, you can see the sequence of energy emission.
* Before applying to the patient's treatment area, the practitioner should try it on his or her arms to check for the feeling of pain.
* Hot or prickling pain sensation indicates proper energy emission.
* Try once on the patient's treatment area and check the response of pain and redness. Then, operate the treatment as per the instructions in the manual.
* After performing 300 shots or more with DOUBLO-GOLDTM, redness and erythema may occur on the treatment area.

Caution

* **The pre-set reference is not absolutely safe for every patient, and is recommended as a reference only. During the treatment, the decision of setting values should be safely controlled after the operator checks the patient's skin conditions, thickness, and adverse reactions.**
* **We are not responsible for problems caused by applying the preset reference in treatment.**

5. Maintenance & Storage

5.1 Notes on Management

* After the procedure, it is best to remove the gel immediately.
* Do not fold or bend any connection hose linked to the handpiece.
* Inspect the device and its components on a regular basis.
* The device is intended for indoor use in a dry location.
* Push the main power switch at the rear to the [I] position to turn OFF if the device will be out of use for one day or more.
* If storing the device for a longer period, disconnect the power cord and reseal it in the pouch.
* If the device has not been in use for an extended period of time, be sure to perform a safety inspection before use to secure safety for the operator.
* Avoid use in a location where the temperature can increase because of direct sunlight.
* Take care not to drop the handpiece on the floor.
  (In particular, the cartridge is vulnerable to shock and may leak fluid if dropped).

5.2 Cautions for Storage

* Disconnect the power cord from the socket and store.
* The device is intended for indoor use in a dry location.
* Keep the device a safe environment, away from sun exposure, severe humidity, strong wind, dust and salt which might harm the device.
* Avoid storing on a sloped surface, or in a location where it will be subject to vibration or excessive impact (including when transporting).
* Do not keep in place where chemicals or gas are stored.
* Inspect the device and its components on the regular basis.
* If the device has not been in use for an extended period of time, be sure to perform a safety inspection before use to secure safety for the operator.
* Keep at room temperature, as the liquid inside the cartridge may damage the device if frozen.
* Store while maintaining sterile conditions. If reusing, it is recommended to disinfect the skin contact area. Storing the equipment for a long time without using the equipment, check the amount of distilled water. if it is insufficient, replenish distilled water before using.
* Reusing after long-term storage at a temperature of 3℃ or lower, use it after checking with our customer support team and agency(overseas).
* In case of leakage distilled water of the equipment or cartridge, stop using it and check it at our customer support team and agency (overseas) before using.
*

NOTE

	Usage	Transportation / Storage
Temperature	10℃ ~ 30℃	10℃ ~ 40℃
Humidity	30% ~ 70%	30% ~ 70%
Air Pressure	80 ~ 106 kPa	80 ~ 106 kPa

5.3 Preparations for Transportation

* Please note the following when moving the product to another location or region.
  - To prevent damage during transportation, you should disconnect the power cable.
  - Wrap up carefully in order to prevent shock or scratch.
  - Stand the device up when transporting – do not lay it down.

5.4 Methods for Cleaning

* Clean the hand piece and CARTRIDGE with an alcohol wipe.
* Wipe with a smooth fabric when cleaning the LCD monitor.
* Wipe with a smooth fabric that has been wet with distilled water when cleaning the surface of the device.
* Store after removing moisture from the cartridge after usage.
* Do not immerse the handpiece in water when cleaning the device. Electrical hazards may occur.

6. Troubleshooting

6.1 Emergency Measures

Symptom	Measure
The product emits a burning smell An abnormal noise can be heard when the product is used	* Turn off the power by pressing the emergency stop switch or turning off the key switch. * Disconnect the power cord from the socket. * Contact a local agency or Hironic Co., Ltd. C/S center. ⚠ **Caution** **If you use the device continuously, this might cause damage to module inside. This may cause the risk of fire and other safety threats.**
When noise is generated by the handpiece	* This occurs when the cartridge is not properly recognized. Please replace with a new cartridge. * Occasionally, a magnet breakaway from the cartridge can lead to poor recognition. Check the magnet in the cartridge. * Reactivate it after turning off the power at the rear and replacing the cartridge.
When glass of the LCD touch screen is broken	* Stop product use and treatment immediately. * Turn off the power and disconnect the power cord from the socket. * Contact a local agency or Hironic Co., Ltd. C/S center. ⚠ **Caution** **If you use the device continuously, this might cause a malfunction of the device.**
When burns and blisters occur	* Apply immediate cooling to the treatment area. Prescribe steroids like dexa depending on the situation, and apply ointment to a wound to promote skin rejuvenation.

6.2 Dealing with Breakdowns

Symptom	Measure
The device will not turn on	* Confirm that the electrical outlet is working properly and the power cable is connected properly. * Confirm that the power cable is firmly connected to the device. * Confirm that the fuses are in the fuse holder. Replace the fuses if there is a problem with them. * If the problem persists after checking the above, please contact the dealer or the after-sales service center.
Heat is not passed to the skin during the treatment	* Test again after changing the cartridge. * There may be a temporary problem with SMPS. Test by turning the power off and back on after 2-3 minutes. * If you can't feel any heat after doing the above, please contact a local agency or Hironic Co., Ltd. C/S center.
When the power switch in the front of device does not turn OFF	* Push the main power switch at the rear body to [I] state for power off. * After checking the power cable connections, check the ON/OFF status. * If this continues even after toggling the power switch ON/OFF 2~3 times, please contact a local agency or the Hironic Co., Ltd. C/S center.
The device is turned off when User control handpiece is activated	* Shut down may occur because of water inflow to transducers inside the cartridge. If this occurs, it is recommended to use a different cartridge.
Cartridge Problem	* If a cartridge film problem, operation error, or recognition error occurs, please contact the dealer or the after-sales service center.

6.3 Messages Code

Code	Message	No. of H/P LED blinks		Description
		Red	Blue	
1	"Cartridge is not connected. Please connect a cartridge."	LED ON	-	Cartridge is not mounted.
2	"Initialize motor fail."	3 Times	1 Time	Hand piece (motor) is not initialized. - H/P motor initialization error when authorizing power. - Failed attempt to identify initial location when mounting cartridge.
3	"TCN75 Over heat"	4 Times	1 Time	Cartridge is overheating. (above 60℃).
4	"Cartridge end of lifespan. Please change cartridge."	5 Times	1 Time	All cartridge counters consumed.
5	"Write to cartridge fail"	5 Times	1 Time	Information not saved in cartridge. - No response in cartridge memory device.
6	Invalid Device	-	-	Country Code Error - please contact the dealer or the after-sales service center
7	"This Cartridge is not registered. Please contact the retailer."	2 Times	1 Time	Problems entering serial number.
	"This Cartridge is not registered. Please contact the retailer."	LED OFF		Unregistered cartridge.

7. Warranty

7.1 Overview

This section describes the warranty coverage for normal use of the product, and exceptions to the warranty.

7.2 Warranty Coverage

* When you use DOUBLO-GOLD™ properly and accept the after-service, Hironic Co., Ltd. will guarantee the device for 14 months from the date of invoice or 12 months from the date of delivery, whichever comes earlier, as free from defects in material and workmanship under normal use and service conditions.
* The warranty covers the main body and components (handpiece, foot switch), and excludes expendable components.
* When guarantee service is requested, we will respond promptly. Either repair, maintenance or replacement will be performed at Hironic Co., Ltd. or at the designated place where the device is located.
* When requesting warranty service, the user must provide data, video or picture information to Hironic Co., Ltd. in order to identify the problem with the product.
* To maintain the warranty coverage, any modification or alteration of the product must be performed by a service agent officially designated by Hironic Co., Ltd. You should be well informed of the content of the manual, as unintended use or usage that does not comply with the manual will be excluded from guarantee.
* In any case, Hironic Co., Ltd. has the ultimate responsibility in judging the cause and nature of a product breakdown.

NOTE

* **This warranty shall become void if anyone other than service technicians authorized by Hironic Co., Ltd. attempts to repair and/or alter the product.**
  Damage caused by user negligence will not be covered by the warranty. Please carefully read and understand this User Manual.
* **Hironic Co., Ltd. assumes the responsibility and the right to make decisions regarding warranty coverage based on the details and causes of the product damage; such decision will be final, and is not subject to change.**

NOTE

Any device issue caused by the user's disassembly or modification of the device is not covered by the warranty.

7.3 Exceptions to the Warranty

Problems caused by failure to follow the instructions and safety precautions suggested in this manual will not be covered by the warranty. The following instructions must be observed with extra caution when using the product.

* Damage to the connector or product due to movement by pulling the handpiece hose, warranty service will not be provided.
* If the user utilizes, modify or removes the product for purposes other than its intended purpose, warranty service will not be provided.
* Expendable components are excluded from guarantee coverage.
* When the product is damaged or lost due to user's carelessness, warranty service will not be provided.
  - Damage due to disassembling or shock to handpiece
  - Damage caused by excessive force to both ends of the hose that is connected to the handpiece
  - Use of a Cartridge which is not supplied by Hironic Co., Ltd.
* If the device is disassembled or repaired independently by a person other than a service agent certified by Hironic Co., Ltd., warranty service will not be provided.
* If the sealed sticker at the back of the panel is damaged without the consent of Hironic Co., Ltd., warranty service will not be provided.

NOTE

DOUBLO-GOLD™ is designed according to the international standard. Use only genuine components and consumables supplied by the manufacturer. Do not modify or alter the product. Damage caused by unauthorized tampering is not covered by the warranty

Electromagnetic Compatibility (EMC)

* Medical electrical equipment requires special precautions related toe, and needs to be located and put into service according to the EMC information provided in the documents accompanying the equipment.
* It is possible that radiated or conducted radio-frequency (RF) electromagnetic interference from portable and mobile RF communications equipment or other strong or nearby RF sources can affect medical electrical equipment, which could result in performance disruption of the DOUBLO-GOLD™ system. Evidence of disruption may include erratic readings, equipment ceasing to operate, or other incorrect functioning.
* The DOUBLO-GOLD™ system should not be used near other equipment or stacked with other equipment. If adjacent or stacked use is necessary, the system should be observed to make sure it works in the configuration you are using.
* Use of accessories, cartridges, and cables other than those specified and supplied by Hironic Co., Ltd. may result in increased emissions or decreased immunity of the system, or improper performance.

Guidance and manufacturer's declaration – electromagnetic emissions

The DOUBLO-GOLD™ is intended for use in the electromagnetic environment specified below. The customer or the user of the DOUBLO-GOLD™ should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The DOUBLO-GOLD™ 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	The DOUBLO-GOLD™ is suitable for use in all 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	A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Compatibility (EMC)

Guidance and manufacturer's declaration – electromagnetic immunity

The DOUBLO-GOLD™ is intended for use in the electromagnetic environment specified below. The customer or the user of the DOUBLO-GOLD™ should ensure that it is used in such an environment.

Immunity Test	IEC 60601-1-2 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± 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 100 kHz repetition frequency	± 2 kV 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge Line-to-line IEC 61000-4-5	± 0,5 kV, ± 1 Kv	± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge Line-to-ground IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV	± 2 kV	
Voltage dips IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the DOUBLO-GOLD™ image intensifier requires continued operation during power mains interruptions, it is recommended that the DOUBLO-GOLD™ image intensifier be powered from an uninterruptible power supply or a battery.
	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	
Voltage interruptions IEC 61000-4-11	0 % UT; 250/300 cycle	0 % UT; 250/300 cycle	
RATED power frequency magnetic fields (50/60Hz) 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.

Electromagnetic Compatibility (EMC)

Guidance and manufacturer's declaration – electromagnetic immunity

The DOUBLO-GOLD™ is intended for use in the electromagnetic environment specified below.
The customer or the user of the DOUBLO-GOLD™ should ensure that it is used in such an environment.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted Disturbances induced by RF fields IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the DOUBLO-GOLD™, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF EM fields IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	Recommended separation distance: $\mathbf{d} = \left\lfloor \frac{\mathbf{3.5}}{\boldsymbol{V_1}} \right\rfloor \sqrt{\boldsymbol{P}}$ $\mathbf{d} = \left\lfloor \frac{\mathbf{3.5}}{\boldsymbol{E_1}} \right\rfloor \sqrt{\boldsymbol{P}}$ 80 MHz to 800 MHz $\mathbf{d} = \left\lfloor \frac{\mathbf{7}}{\boldsymbol{E_1}} \right\rfloor \sqrt{\boldsymbol{P}}$ 800 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, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

Electromagnetic Compatibility (EMC)

Recommended separation distances between portable and mobile RF communications equipment and the DOUBLO-GOLDTM

The DOUBLO-GOLD™ is intended for use in the electromagnetic environment specified below.

The customer or the user of the DOUBLO-GOLD™ should ensure that it is used in such an environment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz to 2,7 GHz $d = 2{,}3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters 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's manufacturer.

NOTE 1 At 80 MHz and 800 MHz, 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.

Warranty Certificate

This warranty certificate replaced any explicit or implied warranties. The seller cannot guarantee the conditions or marketability of the product for any purposes.

Hospital name	
Name	
Address	
Contact info.	
Mobile phone	
Email	
Product name	**DOUBLO-GOLD™**
Serial No.	
Delivery date	
Warranty expiration date	
Seller/Company	
Seller contact information	
Others	

Important!

To take full advantage of your warranty, please send the details above via email.
You can send the details via fax, but you will need to notify a contact person at Hironic Co., Ltd. in advance.

HIRONIC

Hironic Co., Ltd.
19F, U-TOWER, 767, Sinsu-ro, Suji-gu,
Yongin-si,
Gyeonggi-do, 16872, Republic of Korea
Tel. +82-31-525-7000
Fax. +82-31-525-7010
www.hironic.com

Customer Support Center
Tel. +82-31-525-7600
E-mail: ocs@hironic.com

MEMO

doublo · gold™

User Manual

Hironic Co., Ltd.
19F, U-TOWER, 767, Sinsu-ro, Suji-gu,
Yongin-si, Gyeonggi-do, 16872,
Republic of Korea
Tel. +82-31-525-7000
Fax. +82-31-525-7010
www.hironic.com

Customer Service Center
Tel. +82-31-525-7600
E-Mail: ocs@hironic.com

HIRONIC