

doubleTM

new 2.0

USER MANUAL

PRODUCT	Focused Ultrasound Stimulator System
MODEL	NEW DOUBLO 2.0 TM



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Copyright

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Indications for Use

1. Focused ultrasound stimulator system (Handpiece - FL, SD)
 - Eyebrow lifting due to tissue coagulation by focused ultrasound.
2. Electrosurgical device, general-purpose (Handpiece - RM, RM(B))
 - Tissue coagulation by high-frequency energy.
3. High frequency stimulator (Handpiece - SD)
 - Pain relief by high-frequency energy.



Caution

Manipulation, control, and procedural implementation of the equipment in a way that is inconsistent with the instructions for normal use stated in the manual can cause a serious danger.

Caution

- * Using this system for other purposes than the intended use is prohibited. Ensure that the system is not used by someone that is not a permitted user (doctor).
- * Make sure the system is neither pointed at nor used on a body part of the patient that may cause damage to their eye or body tissues.
- * In the event of a device breakdown, do not disassemble or manipulate the device, attach a breakdown indication to the device and contact the manufacturer.
- * If the handpiece is dropped, impacted or bumped, serious damage may occur. When not in use, the applicator should be stored safely. Hironic Co., Ltd. is not responsible for damage to the applicator caused by negligence in use, such as dropping, abuse, misapplication, etc.
- * Be careful not to submerge the applicator or cartridge in any liquid as this may damage it.
- * Be sure to familiarize yourself with how to use the device, and always check whether it works properly before use.
- * Do not use this product and other devices at the same time as the research results on the use of the interior of the body embedded medical electronic devices and life support electronic devices have not been disclosed.
- * Do not arbitrarily disassemble or modify this system.
- * Since devices generally generate high-frequency voltage and current, do not locate devices sensitive to electric or magnetic fields around them.
- * Do not use it for children or where it is easy to get hurt.
- * Do not use with anesthetic gases or flammable substances.
- * Note that the sound output is irradiated in the "Ready" mode.
- * Apply after applying ultrasonic gel closely to the skin before use.
- * Do not stare directly at the ultrasound output area.
- * Do not move the device excessively during the treatment.
- * If any abnormality is found in the device or patient during use, immediately put the patient in a safe state, stop the device, and take appropriate measures.
- * If heat area is not accurately identified, stop treatment.
- * Those who are undergoing skin treatment should consult a doctor before using.
- * If there is a burn on the skin surface during treatment, stop treatment immediately and proceed with burn treatment first.
- * In case of severe swelling of skin, stop treatment immediately.
- * Avoid direct sunlight and do not locate in a place that generates a lot of heat.
- * Excessive humidity can lead to blistering on device parts and surfaces. And this may cause damage to important parts, so keep the humidity appropriately.
- * Use in a place where air can circulate to prevent damage from overheating, dust, mechanical vibration, etc.
- * Do not locate this device outdoors where temperature fluctuates.
- * Locate this device indoors and place it in a well-ventilated place, away from patients and people. Always keep the hand Piece clean by wiping it with alcohol.
- * The handpiece cable must not be twisted, rolled or bent unnecessarily or excessively.
- * Be especially careful when moving the device as it may cause serious damage to the device.

Precautions for Treatment

- * Continuously monitor the system and patient to make sure that there is no problem during the treatment process.
- * If a problem is found with the system or patient, stop operation of the system and take other adequate measures while keeping the patient safe.
- * Since electric sparks may cause ignition on a flammable liquid or gas, be sure that there is no flammable gas nearby prior to using the system.
- * Be careful while using the electrodes. Be sure that the patient is not in contact with the electrodes while they are not used.
- * In the case of a patient with a pacemaker or electrode implanted, attention must be paid since the device may involve a functional error and ventricular fibrillation. In general, do not use this device along with any other system that is involved in life-sustaining such as a pacemaker.
- * Since liquids (such as saline solution or blood) are conductive, be sure that there is no liquid nearby during the treatment in order to prevent an accidental skin burn.
- * Be sure to use it in a well-ventilated area. Avoid certain areas such as sharp corners or shelves.
- * Removing the electrode from the skin while electricity flows through the device may cause a risk of skin burn. Be sure to cut off the power output before removing the electrode from the skin.
- * Do not stare directly at the ultrasound output part of the device.
- * Do not irradiate the air without applying the gel for ultrasound delivery to the cartridge film.
- * Please check if the cartridge film needs gel for ultrasound delivery in the middle of the procedure.
- * Under conditions (for example, high ambient temperature and long operating period without pausing or stopping) as below, the surface temperature of skin contact part may exceed 41°C then allow the cartridges and tips to cool down or use another.
 - FL Cartridge: After 50 shots operation, allow the cartridge to cool down for 30 minutes or use another cartridge.
 - SD Cartridge: After 15 minutes operation, allow the cartridge to cool down for 30 minutes or use another cartridge.
 - RM Tip: After 10 minutes operation, allow the tip to cool down for 15 seconds or use another tip.
- * Pay attention to the procedure on the curved areas of the skin.
- * After the treatment, in order to prevent infection between patients, the disposable tip used for the handpiece must be replaced and used for each patient treatment, and must be discarded after use.
- * Do not use it toward the eyes during the treatment. If there is a wound inside the eye, stop the device immediately and first aid should be given.
- * Do not irradiate the shot on the overlapped area.
- * In case of complaining of severe redness or pain at the energy irradiation area, energy control or appropriate measures should be taken after checking for abnormalities.
- * The handpieces of SD, RM/RM(B) are all bi-polar which are used without a neutral electrode.

Restrictions for Use

- * Although there is no age or gender restriction on use of the system, it is necessary to check the health condition of the patient to decide whether to use the system on them and the output level before using the system.

Side Effects

The temporary side effects specified below may occur.

- * Redness, pressure pain, swelling, pain, bruises, numbness, blister, skin burn, itching, hyperpigmentation, hypopigmentation, irregular skin contour, indentation, necrosis (cell loss), skin hardening, tubercle, skin relaxation, asymmetry (resulting from an imbalanced operation or an anatomic imbalance)
- * Although the treatment may cause swelling, redness, or discomfort, such phenomena are temporary and do not last longer than a week.
- * Although it is rare, small papules shaped like a white head may remain for weeks (1 or 2 months). During the treatment, you may feel slight pain and itching in the treatment area.
- * During the treatment, there may be a dull sensation in the treatment area.
- * During the treatment, you may feel stiffness in the treatment area.
- * During the treatment, you may feel nerve paralysis at the treatment site.
- * The affected part may temporarily have rubefaction, redness, itchiness, or swelling.
- * There may be temporary pain, bruising, inflammation, water blister, and ulcers at the treatment site.
- * There may be temporary loss of pigmentation at the treatment site. This is a phenomenon that may appear when a general laser or high-intensity ultrasound device is used to treat the skin.

General Precautions

- * Before operating the device, make sure to become familiar with the user manual and receive professional training related to the product.
- * The user must thoroughly read and understand the instructions specified in the user manual and take adequate safety measures. The user should also be aware of potential hazards all the time.
- * Do not disassemble or modify this system arbitrarily.
- * Only the manufacturer or service technicians authorized by the manufacturer can handle/repair the system.
- * Before using the system, make sure you thoroughly read and understand the safety instructions (in the user manual) provided by the manufacturer and receive relevant training on using the system.
- * Do NOT use any components other than the ones supplied.
- * Do NOT subject the main unit to excessive shocks.
- * Never touch the power socket of the system with wet hands.
- * Make sure the power cable is connected correctly and the system components are attached or mounted correctly and properly.
- * Before using a system that has not been used for an extended period of time, first check that the system is functioning properly.
- * Use this system in a location with good ventilation.
- * Be sure to check the grounding of the system prior to use. While not using the system, be sure to turn it off.
- * Avoid direct sunlight and do not locate near a device that generates intense heat.
- * In order to prevent the system from being damaged by overheating, dust, or air pressure, use it in a well-ventilated place.
- * Check the status of grounding and do not touch the power socket with wet hands.
- * Upon a breakdown, take emergency measures and ask a professional technician for repair.
- * RF Micro Needle TIP is supplied EO gas sterile. Do not use a product that has been opened or its packaging damaged.

Precautions for Prevention of Safety Accidents

- * The heat generated when using electrodes in electrosurgical devices can be a source of ignition if flammable materials are present, so these materials must be completely evaporated before use.
- * Do not place any combustible materials near the device.
- * Do not use the system in a place where adverse effects can be expected due to atmospheric pressure, temperature, humidity, ventilation, dust, salt, air containing sulfur, or liquid such as water.
- * Avoid using the system in a location where chemicals are stored or gas is generated. Avoid using the system around inflammable material.
- * Use standard power frequency, voltage and permitted electric current (or power consumption).
- * Perform inspection and maintenance regularly.
- * Make sure a fire extinguisher is located in the location where the system is used.
- * Do not place the system near inflammable materials, such as anesthetics or solvents.
- * Locate at least 10cm away from the wall to allow ventilation.
- * Do not irradiate the shot on the overlapped area.
- * This device should not be Located outdoors where temperature fluctuates.
- * In case of complaining of severe redness or pain at the energy irradiation area, energy control or appropriate measures should be taken after checking for abnormalities.

Interactions












- * Do not use the system together with other devices. There is no study proving the system's effect when used together with other devices.
- * During treatment, do not use a cell phone or other mobile communication devices which may affect electric medical systems.

Precautions for Infection and Side Effects




- * RF MICRO NEEDLE TIP for RM, RM(B) handpiece is disposable. Be sure to discard it after use, DO NOT re-use.

Definitions of Symbols and Labels

Symbols that can be found on the components, accessories, or the packaging that come with the system are as follows:

Symbol / Label	Description
	Indicates a potential threat that may result in death or serious injuries to the practitioner if the instruction is neglected.
 NOTE	Provides important information on using the system.
	Manufacturer.
	Date of manufacture.
	Indicates a type B applied part; this is in accordance with the regulation for protection against electric shocks (IEC 60417-5840).
	Indicates a type BF applied part; this is in accordance with the regulation for protection against electric shocks (IEC 60417-5333).
	This mark indicates that the product cannot be disposed of as general waste, 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.
ON / OFF	Indicates turning the product power on/off switch.
	Serial number.
	Indicates the possibility of electromagnetic interference.
	Indicates that instructions in the user manual must be followed.
	Do not re-use.

Introduction

Symbol / Label	Description
	Sterilized using ethylene oxide.
	Batch code.
	No pushing

- ※ It is recommended that the descriptions of signs and indications displayed on the screen be thoroughly read and understood before using the system.

1. Product Overview and Components

1.1 Overview of NEW DOUBLO 2.0™

This equipment is a medical combination device, and the focused ultrasound stimulation system handpiece (FL Handpiece) built into the body uses focused ultrasound, and is used to coagulate tissues or mechanically destroy cell membranes by using local thermal effects. General-purpose electrosurgical device handpiece (RM, RM(B) Handpiece) is used for coagulation using high-frequency current. The high frequency function of the handpiece (SD Handpiece) in which the functions of the focused ultrasound stimulation system and the high frequency stimulator work together is used to relieve pain by applying high frequency energy to the human body, and the electric surgical device is used to coagulate skin tissue using high frequency. It is composed of foot switch, other accessories and power cable.

1.1.1 Electric specifications

- A) Rated voltage / frequency: 100-240 V~, 50/60 Hz
- B) Power consumption: 250 VA
- C) Display part: 12.1 TFT LCD

1.1.2 Form and degree of protection for rating

- A) Form and degree of protection against electric shock: Class 1 device, Type B device

1.1.3. Safety devices

No.	Device	Description
1	Power Protection for inputs	Since the circuit protective fuse is attached to the power input, power is cut off when power exceeding the rated power is applied. (Fuse capacity: 250V, 3.15A)
2	Automatic restoration functional device	The system is programmed to return to the default state if a power failure or a temporary power cut off occurs.
3	RF Micro Needle Tip Sensing device	This automatically detects whether the RF Micro Needle TIP is attached. The output is not initiated without a RF Micro Needle TIP attached. An alarm message will pop up instead.

1.1.4. Mechanical specifications

- A) Main unit [W × D × H]: 700 x 605 x 1315 mm
- B) FL Handpiece [H × Φ]: 55 mm x 50 Φ / Length: 2.2 m
- C) SD Handpiece [H × Φ]: 110 mm x 50 Φ / Length: 2.2 m
- D) RM Handpiece [H × Φ]: 110 mm x 45 Φ / Length: 2 m
- E) RM(B) Handpiece [H × Φ]: 170 mm x 45 Φ / Length: 2 m
- F) Foothold Switch Case [W × D × H]: 148 x 160 x 140 mm
- G) Foot switch [W × D × H]: 68 x 120 x 37 mm
- H) Power cable: 3 m

1.2 Product Performance

NEW DOUBLO 2.0™ specifications are as below :

NO	Handpiece	Item	Details
Focused Ultrasound			
1	FL Handpiece	Outer Power	0.1 ~ 3.0 J
		Operating Frequency	2 MHz, 4 MHz, 7 MHz
2	SD Handpiece	Outer Power	0.1 ~ 3.0 J
		Operating Frequency	2 MHz, 4 MHz, 7 MHz
Radio Frequency			
3	SD Handpiece	Outer Power	25.54 W @ 500Ω
		Operating Frequency	2 MHz
4	RM/RM(B) Handpiece	Needle Type	0.1 ~ 3.5 mm (0.1 mm step)
		Output Power	19.88 W @ 500Ω
		Operating Frequency	0.5, 1, 2 MHz

FL handpiece cartridge specifications are as below :

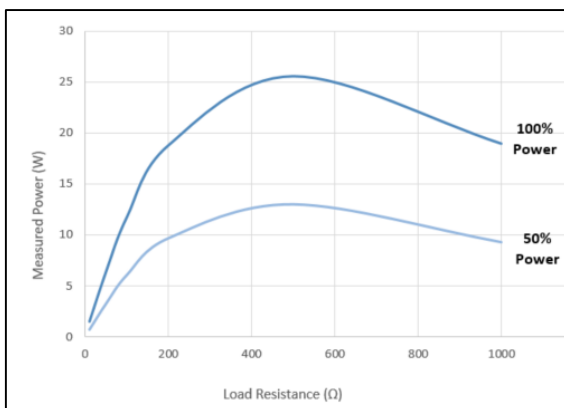
NO	Cartridge	Mode	Energy	Frequency	Depth	Spacing (1mm Step)	Length
1	S1.5/A1.5	DOT	0.5 J	7 MHz	1.5 mm	1.0 ~ 5.0 mm	5.0 ~ 25 mm (DOT: 1 mm step) (LINE: 1 mm step)
		LINE	0.5 J			N/A	
2	S2/A2	DOT	1.0 J	7 MHz	2.0 mm	1.0 ~ 5.0 mm	
		LINE	0.8 J			N/A	
3	N3/A3	DOT	1.0 J	7 MHz	3.0 mm	1.0 ~ 5.0 mm	
		LINE	1.0 J			N/A	
4	N4.5/A4.5	DOT	1.5 J	4 MHz	4.5 mm	1.0 ~ 5.0 mm	
		LINE	1.0 J			N/A	
5	W6/A6	DOT	3.0 J	2 MHz	6.0 mm	1.0 ~ 5.0 mm	
		LINE	2.0 J			N/A	
6	W9/A9	DOT	3.0 J	2 MHz	9.0 mm	1.0 ~ 5.0 mm	
		LINE	2.0 J			N/A	

SD handpiece cartridge specifications are as below :

NO	Cartridge	Energy	Frequency	Depth	Spacing	Length
1	P1.5/L1.5	0.5 J	7 MHz	1.5 mm	N/A	N/A
2	P3/L3	1.0 J	7 MHz	3.0 mm		
3	P4.5/L4.5	1.5 J	4 MHz	4.5 mm		
4	P9/L9	3.0 J	2 MHz	9.0 mm		

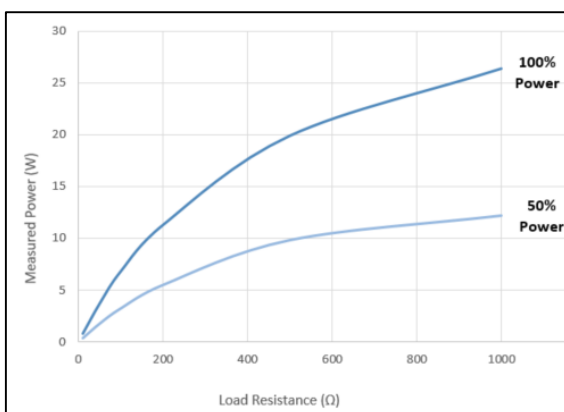
Handpiece Output Diagram

SD Handpiece



Load Resistance(Ω)	100% Power (W)	50% Power (W)
10	1.48	0.72
50	6.39	3.27
100	11.73	6.08
200	18.77	9.68
500	25.54	13.00
1000	18.93	9.29

RM/RM(B) Handpiece



Load Resistance(Ω)	100% Power (W)	50% Power (W)
10	0.8	0.38
50	3.71	1.79
100	6.82	3.26
200	11.29	5.53
500	19.88	9.86
1000	26.35	12.23

SD Handpiece RF output power @ 500 Ω

Handpiece Type	Load [Ω]	RF [LV]	RF [W]
SD	500	1	2.62
		2	5.11
		3	7.48
		4	10.06
		5	13.00
		6	15.38
		7	17.96
		8	20.56
		9	23.03
		10	25.54

RM/RM(B) Handpiece RF output power @ 500 Ω

Handpiece Type	Load [Ω]	RF [W]
RM/RM(B)	500	0.98
		1.97
		2.91
		3.94
		5.01
		5.94
		6.97
		7.85
		8.92
		9.86
		10.95
		11.80
		12.97
		13.91
		15.00
		16.02
		17.15
		17.93
		18.88
		19.88

1.3 Product Components and Functions

1.3.1 Product configuration

NEW DOUBLO 2.0™ consists of the following :

NO	Components	Quantity	Note
1	Main Body	1 EA	-
2	FL Handpiece	2 EA	-
3	SD Handpiece	2 EA	Option
4	RM Handpiece	1 EA	Option
5	RM(B) Handpiece	1 EA	Option
6	Power Cable	1 EA	-
7	Foot Switch	1 EA	-

1) Main Body



2) FL Handpiece



3) SD Handpiece



4) RM Handpiece



5) RM(B) Handpiece



6) Power Cable



7) Foot Switch



1.3.2 Additional components

NO	Components	Quantity	Note
1	FL Handpiece Cartridge S1.5, S2, N3, N4.5, W6, W9 A1.5, A2, A3, A4.5, A6, A9	1 EA	Option
2	SD Handpiece Cartridge P1.5, P3, P4.5, P9, L1.5, L3, L4, L9	1 EA	Option
3	RF Micro Needle Tip RMT-I25, RMT-I49, RMT-N25, RMT-N49	1 EA	Option
4	User Manual	1 EA	-

1) FL Handpiece Cartridge



2) SD Handpiece Cartridge



3) RF Micro Needle Tip



4) User Manual



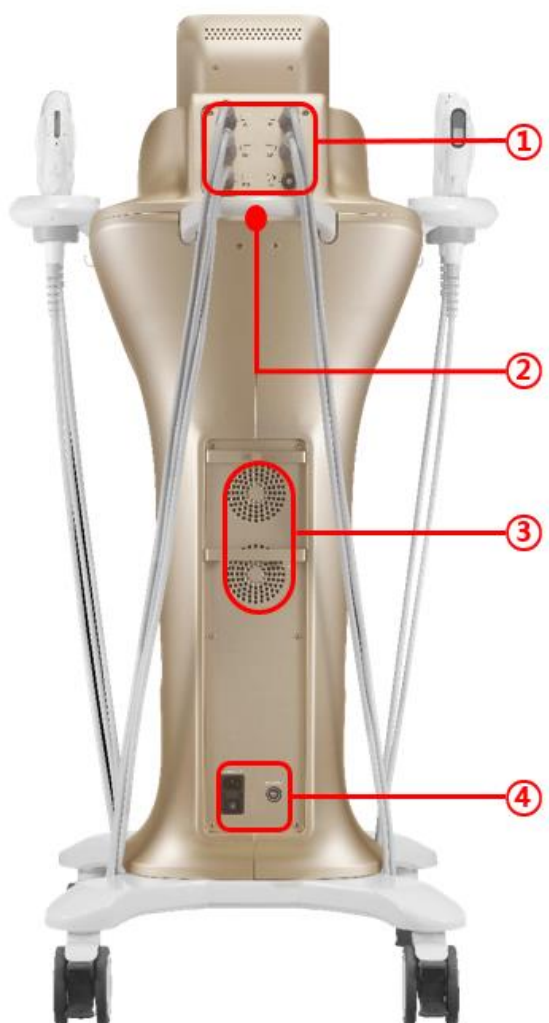
1.3.3 Names and functions of components

1.3.3.1 Main body—front view



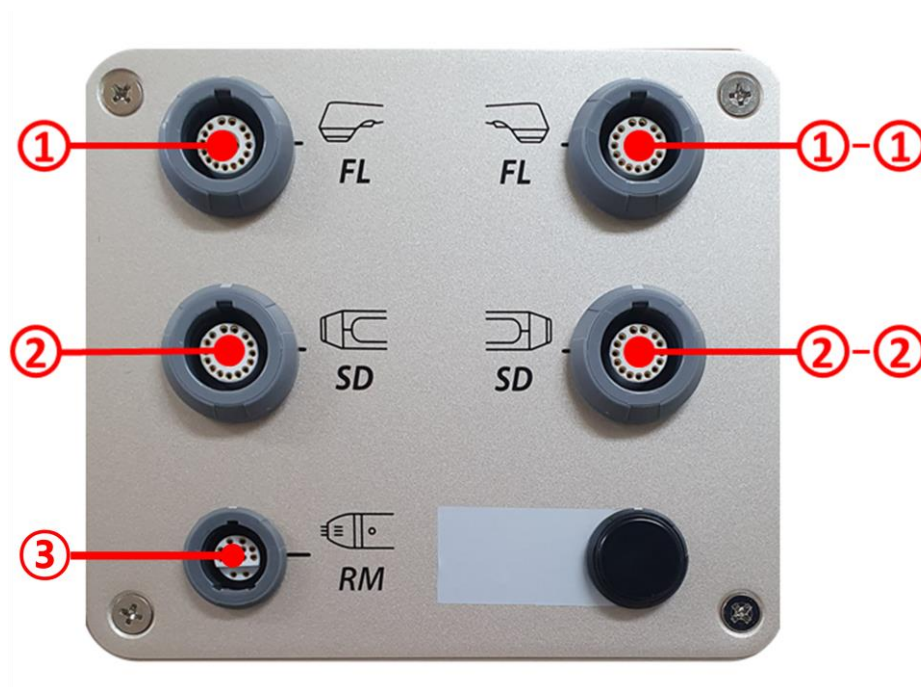
No.	Item name	Description
1	Touch Display	A touch display shows the device status so that a user can set up energy values, etc.
2	Power switch	A switch used to control equipment operation
3	Handle(Front)	Front handle for carrying the device.
4	LED	This indicates the product's operation status in LED color.
5	Handpiece holder	This holder is exclusively for a handpiece. When a handpiece is attached, the main unit sensor recognizes it automatically.
6	Caster	There are 4 casters used to transport the device. As each has a locking unit, these can be fixed while the device is used.

1.3.3.2 Main body-rear view



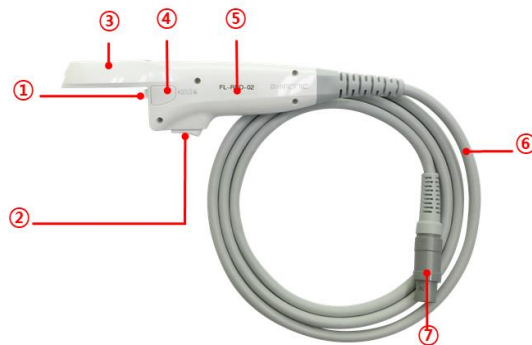
No.	Item name	Description
1	Handpiece connector	Port to connect the handpiece to the main unit
2	Handle for transportation	Handle for carrying the device
3	Ventilation hole	Heat inside the system is discharged through this hole to the outside.
4	Power switch	Use this switch to connect/disconnect the external power supply.
	Foot switch socket	A port to connect the foot switch to the main unit for system operation

1.3.3.3 Handpiece connector

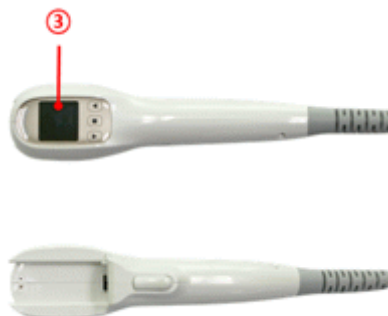


No.	Item name	Description
1 / 1-1	FL Handpiece Connector	Connector of the FL Handpiece
2 / 2-2	SD Handpiece Connector	Connector of the SD Handpiece
3	RM, RM(B) Handpiece Connector	Connector of the RM, RM(B) Handpiece

1.3.3.4 FL Handpiece



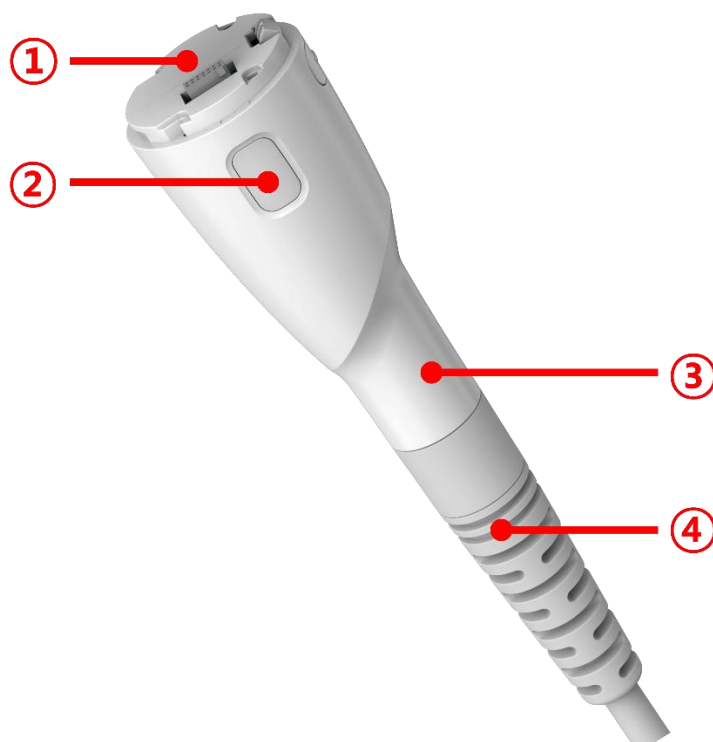
Handpiece LOGO



Handpiece Socket

No.	Item name	Description
1	FL Cartridge Connection Unit	Unit where the FL Cartridge is mounted
2	Output button	When the button is clicked in the standby state, the Shot is irradiated.
3-1	LCD information	Display device to check cartridge information - Type of cartridge - Spacing (mm) - Number of remaining shots (shot) - Power (J) - Length (mm) - Lock/Unlock
3-2	Power control button	Cartridge Power Control button
	READY/STANDBY button	READY/STANDBY select button
3-3	LCD Status	Display device status by colors as below; - Standby: blue / Ready: green - Energy emission: orange - Unconnected cartridge: red
4	Cartridge release button	Button used to lock and release cartridge connection
5	Handle	Used as a handle during treatment
6	Cable	Electric cable to deliver the HIFU output to the handpiece and Cartridge.
7	Connector	The part connected to the handpiece connection terminal on the back of the device.

1.3.3.5 SD Handpiece



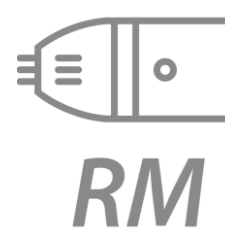
Handpiece LOGO



Handpiece Socket

No.	Item name	Description
1	SD Cartridge Connection Unit	Unit where SD Cartridge is mounted
2	LED	Display device to check cartridge status - Standby: blue / Ready: green - Energy emission: orange - Unconnected cartridge: red
3	Handle	Used as a handle during treatment
4	Cable	Electric cable to deliver the output to the handpiece and Cartridge.

1.3.3.6 RM Handpiece (RF Micro Needle Handpiece)



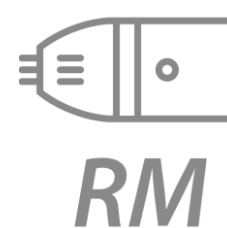
Handpiece LOGO



Handpiece Socket

No.	Item name	Description
1	RF Micro Needle TIP Connection Unit	Unit where RF Micro Needle TIP is mounted
2	Handle	Used as a handle during treatment
3	Cable	Electric cable to deliver the RF output to the handpiece and RF Micro Needle.

1.3.3.7 RM(B) Handpiece (RF Micro Needle Big Handpiece)



Handpiece LOGO



Handpiece Socket

No.	Item name	Description
1	RF Micro Needle TIP Connection Unit	Unit where RF Micro Needle TIP is mounted
2	Handle	Used as a handle during treatment
3	Hand Switch	Clicking the button initiates the handpiece's operation
4	Cable	Electric cable to deliver the RF output to the handpiece and RF Micro Needle.

1.3.3.8 FL Cartridge



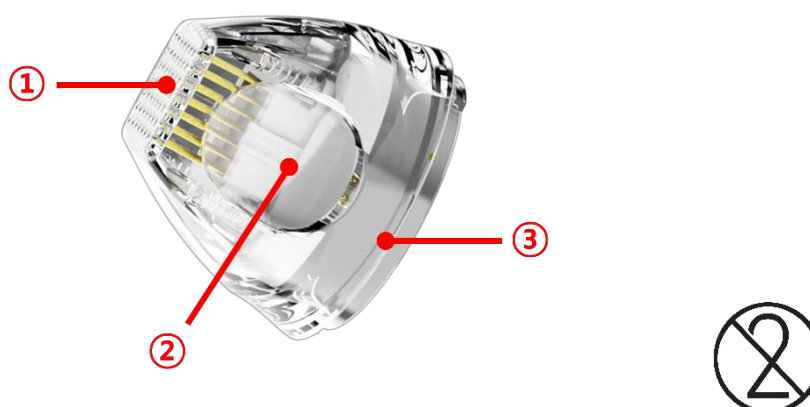
No.	Item name	Description
1	Transducer moving shift	Device to move the transducer
2	Cartridge type mark	Indicates the type of cartridge
3	SHOT Radiating range	Unit where SHOT is radiated
4	Treatment area mark	Indicates the treatment area of the cartridge

1.3.3.9 SD Cartridge



No.	Item name	Description
1	Board Connector	The part that connects the cartridge to the handpiece and allows the mechanical devices in the cartridge to be electrically controlled.
2	Cartridge type mark	Indicates the type of cartridge
3	Ultrasonic waves radiating part	Unit where ultrasonic waves are radiated
4	RF radiating part	Part where RF is radiated

1.3.3.10 RF Micro Needle TIP (RF Micro Needle TIP is disposable.)



No.	Item name	Description
1	Skin contact	The part where RF Micro Needle comes into contact with the skin
2	Knob	Knob for protecting the RF Micro Needle TIP when it is connected to the handpiece
3	Handpiece connector	Part where the RF Micro needle TIP is connected to the handpiece

1.3.3.11 Foot switch



No.	Item name	Description
1	Exterior cover	This cover/guide prevents the foot switch from being pressed when it has overturned.
2	Foot switch	This switch is equipped with an embedded contact switch, which causes energy irradiation when the foot switch is pressed.
3	Connection cable	This cable transmits foot switch position signals to the main unit.
4	Foot switch connector	This connector connects to the foot switch port in the bottom rear of the system.

1.3.3.12 Power cable



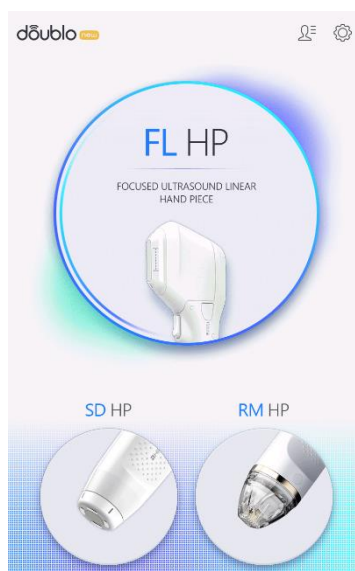
No.	Item name	Description
1	Power cable	This cable is fixed onto the rear bottom of the main unit to supply external power to the main unit.

1.3.3.13 User manual



No.	Item name	Description
1	User manual	Product user's manual

1.3.3.14 Software



No.	Item name	Description
1	NEW DOUBLO 2.0™ Operation Software	Function: The software is used to configure/manipulate functions and view the system status and settings.

2. General Safety

2.1 Precautions before Use

2.1.1. Check the following before initial locating the product.

- Avoid a location that is humid or exposed to water.
- Locate the device where the device will not be damaged by excessive air pressure, temperature extremes, humidity, lack of ventilation, direct sunlight, dust, salt, or air containing ions.
- Locate the product in a safe location with no slope, vibration and impact.
- Avoid a location where chemicals are stored or gases are generated.
- Pay attention to the power frequency, voltage and allowable current (or power consumption).
- Use a power socket with a grounding terminal. Failing to do so may result in malfunction as this product is affected electrically.

2.1.2. To move the product to another place, follow the steps below.

- First turn off the system and remove the power cable socket.
- In order to ensure that the handpiece does not fall off while being transported, mount it on the rack securely or hold it separately while carrying it.
- Unlock the brakes on the wheels so that the wheels can roll.
- Hold the handle on the main unit and move the product slowly.
- Be careful so that the handpiece cable does not bump into other objects during transportation.
- After the moving is finished, lock the brakes on the wheels to anchor the product.
- For a long-distance transportation, separate the handpiece from the main unit and pack it securely. Pack it securely in order to prevent the main unit from being hit or damaged during the transportation.



Caution

Use caution to minimize impact applied to the product when moving it.

2.2 Power Connection

2.2.1 Checking the grounding status

- Make sure that the power plug is correctly connected. Do not attempt to connect the power cord to the product with wet hands as there is a risk of electric shock.

Checking the power cable grounding status



[Cable grounding position]



[Electrical outlet grounding position]



[Correctly connected]

- Plug the power cable all the way into the electrical outlet to ensure proper grounding. Incorrect connection may cause incorrect grounding on the connector, so the LCD touch panel input may not work properly or the product may malfunction.

How to replace the fuse of the main power switch at the back of the device



[Click the fuse box]



[Separate the fuse box]



[Replace the fuse]

- The NEW DOUBLO 2.0™ system is equipped with 2 fuses that automatically cut off current if the allowable current is exceeded.
- To replace the fuse, check the fuse box and press with a finger the indicated part. The fuse box will then be separated. As the fuse box is separated, replace the fuse.



NOTE

The system may not turn on if the power cable is not fully plugged in.
The system may malfunction if it is used in an environment where grounding is not possible

3. How to Use

3.1 Preparations before Use

- To use the system, first secure an Location space.
 - Avoid locations where strong electricity or a magnetic field is running, as well as locations that can be exposed to heat or moisture. The system may malfunction or break down.
 - Locate the system in a location where proper temperature and humidity can be maintained. Ensure that the interior temperature and humidity of the place where the system is Located are maintained between 10°C and 30°C and between 30% and 70%.
 - Ensure that the ventilation hole is at least 30 cm away from the walls.
 - Locate the system on a stable and flat surface.
- Be sure that the handpiece has properly been cleaned using an antiseptic solution (use dedicated cleaning tools) before use.
 - Be sure that the outside of the handpiece is not damaged.
(If there is a damaged part, please consult with Hironic Co., Ltd..)
- Check all components necessary for treatment are properly connected to the main unit before use.
 - Connect every component of the system.
 - Connect the power cable to a grounded outlet.

3.2 Treatment

- Apply a layer of ultrasonic delivery gel thinly to the cartridge film. If applying too much or too little, contact with the skin may be difficult.
 - Moisture-based gels should be used, and other lotions or lubricants may damage the cartridge and handpiece.
- When performing the next line on the same treatment area, move the cartridge 2~3mm apart and press the ultrasound output button.
- After 5 lines of treatment, check if more ultrasonic delivery gel is needed in the cartridge film.
 - When the components including the handpiece are normally connected and power is applied, the device will initialize and check the device's component connection status.
- Under conditions(for example, high ambient temperature and long operating period without pausing or stopping) as below, the surface temperature of skin contact part may exceed 41°C then allow the cartridges and tips to cool down or use another.
 - FL Cartridge: After 50 shots operation, allow the cartridge to cool down for 30 minutes or use another cartridge.
 - SD Cartridge: After 15 minutes operation, allow the cartridge to cool down for 30 minutes or use another cartridge.
 - RM Tip: After 10 minutes operation, allow the tip to cool down for 15 seconds or use another tip.

3. How to Use

3.3 Instructions for Use and Handling

- After all the components are connected, use the following steps to apply power to the system.
 - Turn the power switch on the rear side of the device to ON.
 - Position the switch in the front of the device to ON.
- Checking for system failure
 - Turn on and off the switch at the front side of the device and check if it operates properly.
 - Put each handpiece on the main unit's handpiece holder and check that they are recognized properly.
- Device booting and initialization
 - If all components, including the handpiece, are properly connected and power is applied, the system performs initialization and checks the connection of the components.



Caution

This product is very sensitive. Please read the user manual thoroughly before using the product. Be careful while using the product and handpiece in order to prevent any problems on them.

Power ON / OFF & Operation

The power switch is located on the back side of the main unit.

For proper operation of NEW DOUBLO 2.0™, turn on the power switch on the back side and use the On/Off switch on the front.



[Power Switch]

The Device On / Off switch is located on the front side.

For proper operation of NEW DOUBLO 2.0™, press the Device On / Off Switch button and turn it on. While the device is operated, keep the Device On / Off Switch button pressed for 5 seconds to turn off NEW DOUBLO 2.0™.

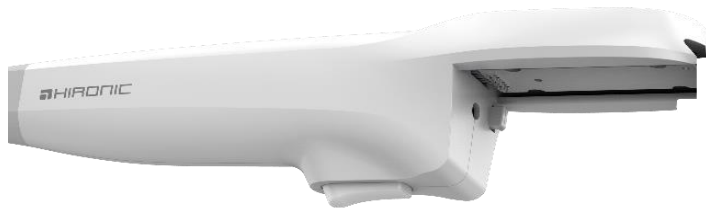
Device On: White LED Color On
Device Off: White LED Color Off



[Device On / Off Switch]

[FL Handpiece Cartridge] How to Connect and Disconnect

1. To connect the cartridge, prepare the FL Handpiece.



2. Connect the cartridge in the direction of the arrow.



3. How to disconnect the cartridge
: Press the PUSH TO RELEASE button.

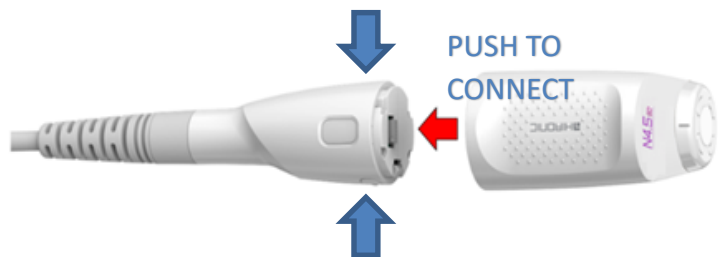


[SD Handpiece Cartridge] How to Connect and Disconnect

1. To connect the cartridge, prepare the SD handpiece.



2. How to connect the cartridge : press the cartridge connection buttons on both sides of the handpiece.



- 3 How to disconnect the cartridge : press the cartridge disconnection buttons on both sides of the handpiece

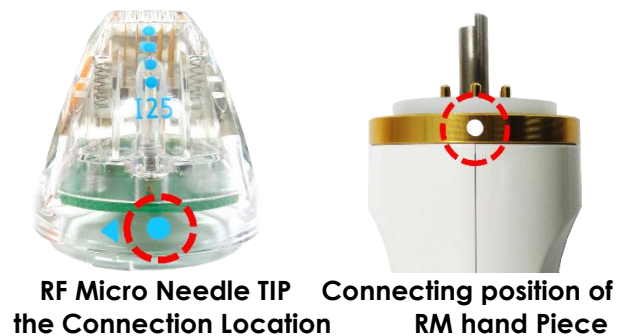


[RF Micro Needle TIP] How to connect

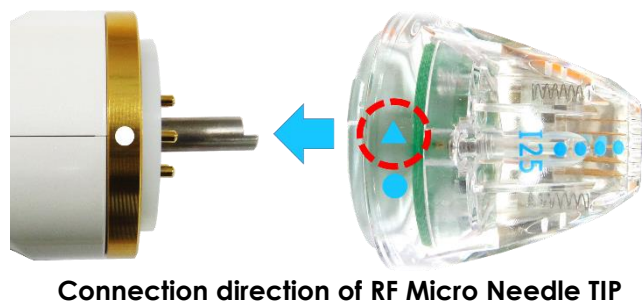
1. To connect the device, prepare the RF Micro Needle TIP and RM/RM(B) handpiece.



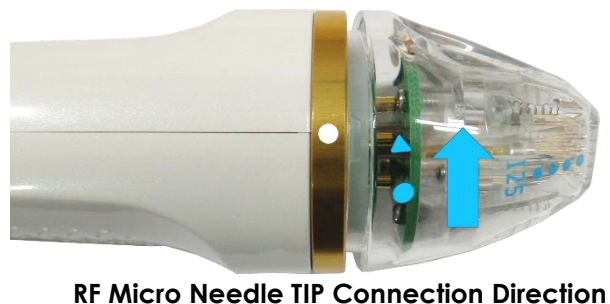
2. Check the connection position of the RF Micro Needle TIP and the connection position of the RM handpiece.



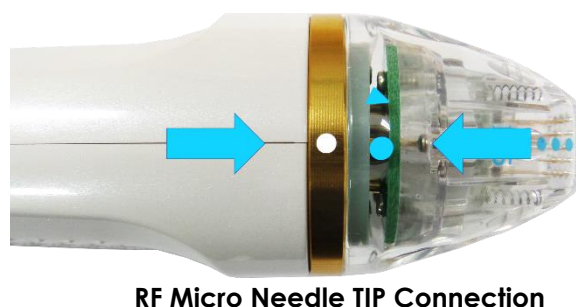
3. Center the triangle icon on the RF Micro Needle TIP as shown in the figure on the right, and connect it to the RM handpiece.



4. Connect the RF Micro Needle TIP to the RM handpiece as shown on the right and rotate the RF Micro Needle TIP in the direction of the arrow.



5. As shown in the figure on the right, the RF Micro Needle TIP is connected by aligning the connection position of the RF Micro Needle TIP with the connection position of the RM handpiece.



Locking/unlocking the wheels

The main unit of NEW DOUBLO 2.0™ is equipped with four wheels that have locks.

These wheels are designed to stop rolling if the locks are engaged.

Make sure to engage the wheel locks before using the system to prevent the system from moving during radiation treatment.

[Engaging locks]

Step on each lock. The lock lever will descend to lock and prevent the wheel from rolling.

[Disengaging locks]

Raise each lock lever. The wheel will be unlocked, and can roll.



Caution

Make sure you lock the wheels before using the system to prevent the system from moving during treatment.



Caution

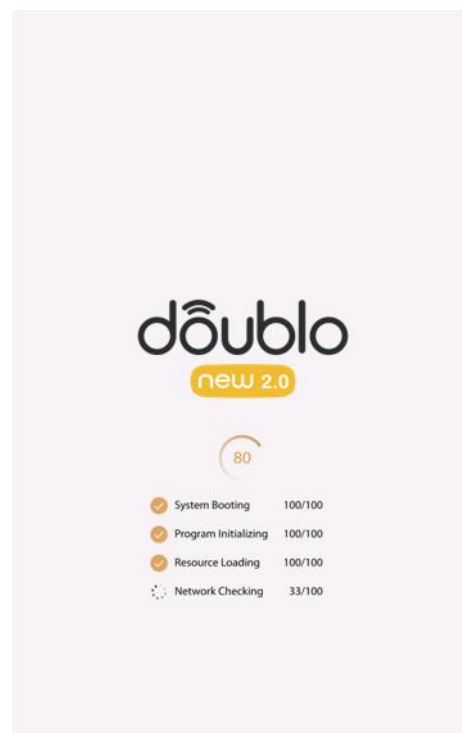
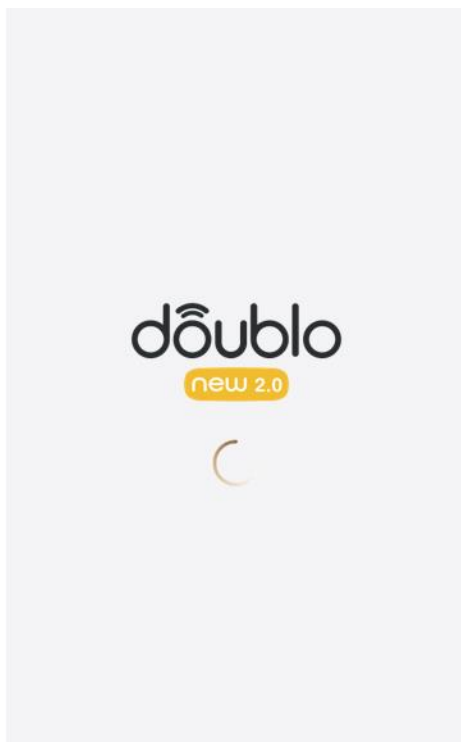
If wheel locks are engaged with excessive force or engaged in an incorrect direction, the locks may become damaged.

3.4 Instructions for User Interface

- Initialization screen
 - As soon as power is supplied to the system, the system automatically starts initialization.
 - The initial screen displays the manufacturer's logo and the product's model name.
 - SW booting time of 1~2 minutes is required to check the equipment.

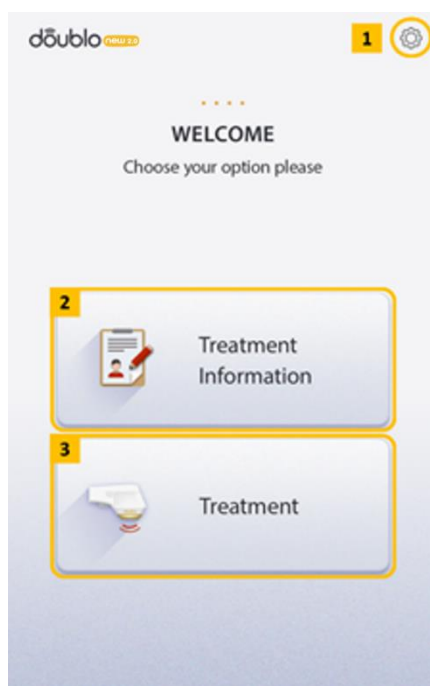


[Initialization screen - 1]




[Initialization screen - 2]

- Main Screen
 - Patient Information / Treatment can be selected.



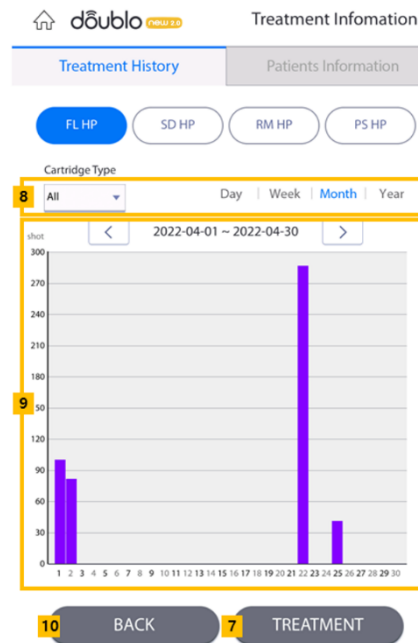
[Main Screen]

No.	Symptom	Function
1		This takes the user to the settings screen.
2	Treatment Information	This takes the user to the treatment information screen.
3	Treatment	This takes the user to the handpiece selection screen.

- Treatment History
 - You can check the TREATMENT HISTORY records used on the device.



[Treatment History]



[Screen of Treatment history (Statistics)]

No.	Symptom	Function
1	Treatment History	The treatment history is displayed.
2	Patients Information	Patients information is displayed.
3	Handpiece Selection	User can check the treatment history by type of handpiece.
4	Information Sorting	User can sorting the treatment history by type of Tip type, Period, Part, Feedback
5	Treatment History	User can check and select the treatment history by category.
6	STATISTICS	This takes the user to the usage statistics screen by type.
7	TREATMENT	This takes the user to the handpiece selection screen.
8	Statics Information Sorting (Cartridge Type, Period)	User can set the cartridge type and period.
9	Statistic Graph	The result graph value selected from Statics Information Sorting is displayed on the screen.
10	BACK	Move to the previous page.

- Patient Information
 - Upon completion of device initializing, you can save patient information by using the window below. Even if the entry is not completed yet, pressing the "SAVE" button will lead to the next page.

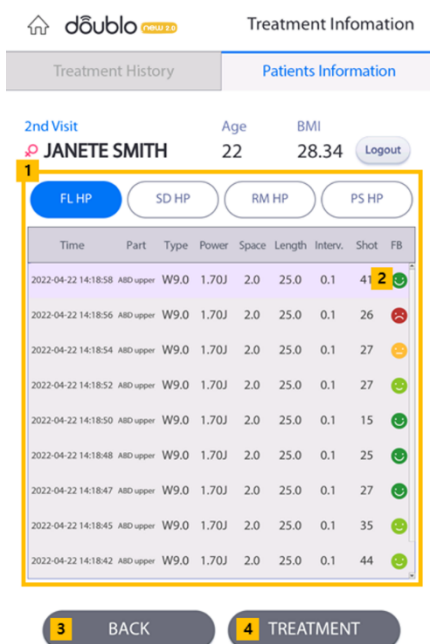
[Patient Information]

[SEARCH PATIENT]

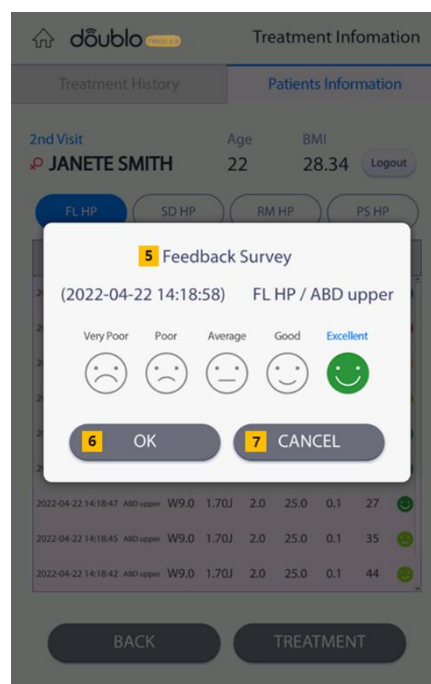
No.	Symptom	Function
1		This takes the user to the handpiece select page.
2	Patient Information	User can enter and search patient information.
3		Used to search for a patient's name. (When selected, it moves to the Patient Search pop-up screen)
4		It is used to reset the input value.
5	PATIENT CODE	Patient codes are automatically set in the order of enrollment.
6	Name	This is to enter a patient's name.
7	Gender	This is to enter a patient's sex.
8	Birthday	This is to enter a patient's date of birth.
9	Height / Weight	This is to enter a patient's height and weight.
10	BMI	This shows the BMI. (When the height and weight are entered, the value is calculated automatically and displayed) *BMI: (weight (kg) ÷ (height (m) x height (m)))
11	BACK	Cancels input of patient information and returns to the previous screen.
12	SAVE	Save the input value and move to the next screen.
13	Search	This is used to search patients.
14	BACK	Move to the previous page.
15	SELECT	Move to the selected Patient information screen.




- Selected Patient Information
 - When Patient Information is selected, a popup window will appear and show patient Information and Feedback Survey.



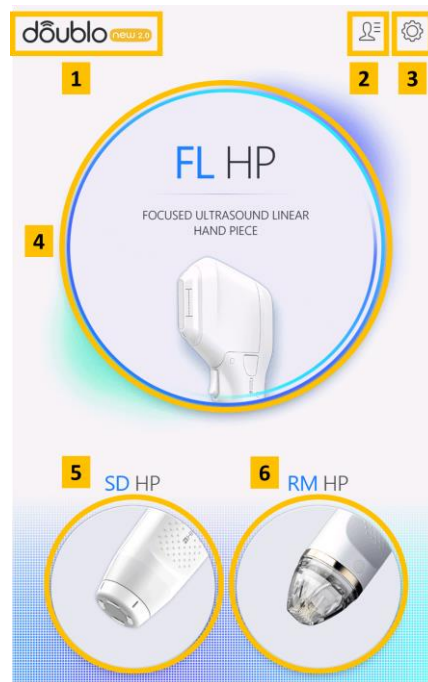
Patient information








Feedback Srvey

No.	Symptom	Function
1	Treatment History	User can check and select the treatment history of the selected patient. User can check the treatment history for each handpiece..
2	FB	Shows patient treatment satisfaction.
3	BACK	Move to the previous page.
4	Treatment	Move to the handpiece selection screen for treatment.
5	Feedback Survey	If user press one selected procedure history for 1 second, the patient's procedure satisfaction pop-up is displayed, and user can select and save in 5 steps. <div> Very Poor Poor Average Good Excellent </div> 
6	OK	Satisfaction with the selection is saved in the treatment history.
7	CANCEL	Cancel the treatment satisfaction.

- Treatment – Handpiece Selection
 - The GUI screen appears differently depending on connected handpiece.



FL / SD / RM / RM(B) Connection GUI

No.	Symptom	Function
1	Model Logo	Logo of the model name.
2		Move to the Treatment Information screen.
3		Move to the Settings screen.
4		Select FL HP icon, leads to the FL Handpiece settings page.
5		Select SD HP icon, leads to the SD Handpiece settings page.
6		Select RM/RM(B) HP icon, leads to the RM/RM(B) Handpiece settings page.

No.	Symptom	Function
1	LINE / DOT	Set the energy irradiation mode. - LINE mode: Irradiation in the form of a line - DOT mode: Irradiation in the form of a dotted line
2	MODE 1 / 2 / 3	If user press the mode button for 3 seconds, the current treatment setting value is saved. (User can save frequently used values for convenient use.)
3	Treatment area	The treatment area for each cartridge is displayed. - Face: S1.5 / S2 / N3 / N4.5 / A1.5 / A2 / A3 / A4.5 - Body: W6 / W9 / A6 / A9
4-1	Interval (sec)	Set the interval (time) for shot irradiation in LINE mode. - 0.1 ~ 1.0 sec (0.1 sec increments) - 1.0 ~ 3.0 sec (0.5 sec increments)
4-2	Spacing (mm)	Set the interval (length) between dots in DOT mode. - 1.0 ~ 2.0 (in 0.1 mm increments) - 2.0 ~ 5.0 (0.5 mm increments)
5	Length (mm)	Set the irradiation length. - 5.0 ~ 25.0 mm (1.0 mm increments)
6	Line (shot)	Set the number of shots for the selected area. - 5 ~ 1000 shots (in units of 5 shots)
7	CARTRIDGE TYPE	Displays the type of cartridge located. - Face: S1.5 / S2 / N3 / N4.5 / A1.5 / A2 / A3 / A4.5 - Body: W6 / W9 / A6 / A9
8	HIFU POWER (J)	Set the HIFU power value. - HIFU: 0.1 ~ 3.0 J (For HIFU power values by mode and cartridge, see Performance.)
9	TOTAL SHOT	Displays the total number of shots performed. (You can set the number of shots when you click the alarm button.)
10	AUTO / MANUAL	Set auto/manual mode. - AUTO (automatic): Stores and uses frequently used values for each part - MANUAL: Set the desired value and use it
11	STANDBY	Indicates the standby state before energy irradiation. Click STANDBY to switch to READY.
	READY	When the hand switch/foot switch is pressed with energy irradiation enabled, the shot is irradiated. Click READY to switch to STANDBY.

- FL Handpiece (Manual Mode)
 - This screen is displayed when the Manual button is clicked. You can select a specific setting for treatment.



LINE Mode



DOT Mode

No.	Symptom	Function
1	LINE / DOT	Set the energy irradiation mode. - LINE mode: Irradiation in the form of a line - DOT mode: Irradiation in the form of a dotted line
2-1	INTERVAL (sec)	Set the interval (time) for shot irradiation in LINE mode. - 0.1 ~ 1.0 sec (0.1 sec increments) - 1.0 ~ 3.0 sec (0.5 sec increments)
2-2	SPACING (mm)	Set the interval (length) between dots in DOT mode. - 1.0 ~ 2.0 (in 0.1 mm increments) - 2.0 ~ 5.0 (0.5 mm increments)
3	Length (mm)	Set the irradiation length. - 5.0 ~ 25.0 mm (1.0 mm increments)
4	HIFU POWER (J)	Set the HIFU power value. - Face: 0.1 ~ 1.5 J - Body: 0.1 ~ 3.0 J
5	M1 / M2 / M3	If user press the mode button for 3 seconds, the current treatment setting value is saved. (User can save frequently used values for convenient use.)
6	TOTAL SHOT	Displays the total number of shots performed. (You can set the number of shots when you click the alarm button.)
7	AUTO / MANUAL	Set auto/manual mode. - AUTO (automatic): Stores and uses frequently used values for each part - MANUAL: Set the desired value and use it
8	STANDBY	Indicates the standby state before energy irradiation. Click STANDBY to switch to READY.
	READY	When the hand switch/foot switch is pressed with energy irradiation enabled, the shot is irradiated. Click READY to switch to STANDBY.

- FL Handpiece Treatment Screen



LINE Mode



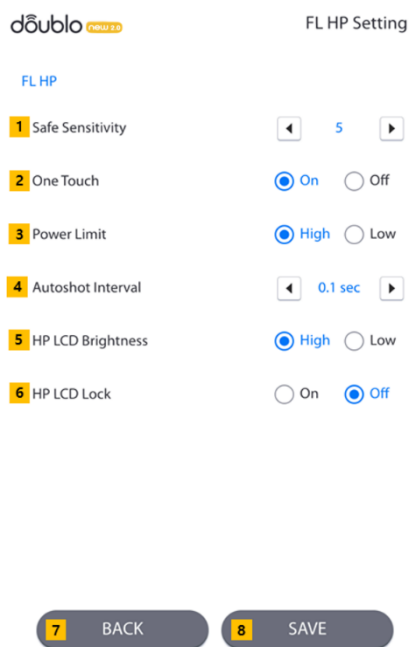
DOT Mode

No.	Symptom	Function
1	FL Handpiece treatment progress animation	<p>During FL handpiece treatment, the animation shown above screen is displayed. (If user press the hand switch/foot switch in the READY state, the animation operation is activated.)</p> <ul style="list-style-type: none"> - LINE Mode: Display in line form - DOT Mode: Displayed in dotted line form

※ Precautions for treatment

- 1) The cartridge film should not be irradiated in the air without applying the ultrasonic delivery gel.
- 2) Before irradiating, check whether the cartridge film is in close contact with the skin before irradiating.
- 3) In the middle of the treatment, it should be checked whether the cartridge film requires more ultrasound delivery gel.
- 4) When irradiating multiple shots, it is necessary to irradiate the cartridge by moving the cartridge at intervals of 2-3 mm for each shot.
(Never do multiple irradiations in the same spot.)
- 5) FL cartridge contact sensor: The contact sensor detects whether or not the cartridge is in close contact with the skin surface to prevent burns during shot irradiation.
- 6) FL cartridge movement sensor: It detects the movement of the transducer in the cartridge through the movement sensor to prevent continuous irradiation in one place.

- FL Handpiece Settings
 - This is a screen that appears when you click the SETTING button. You can set whether to operate ONE TOUCH, HP DISPLAY BRIGHTNESS, and AUTOSHOT INTERVAL.



FL Handpiece Settings Menu

No.	Symptom	Function
1	Safe Sensitivity	Set the sensitivity of the skin contact sensor from 1 (low) to 5 (high).
2	One Touch	Set the irradiation type of SHOT. - On: Press the hand switch/foot switch once to irradiate 1 shot - Off: irradiate shot while hand switch/foot switch is pressed
3	Power Limit	Set cartridge output value limits for patient safety. - High: Generates Max output value of cartridge - Low: Generates Mid output value of cartridge (For output values by mode and cartridge, see Performance.)
4	Autoshot Interval	Set the interval (time) of consecutive shots. - 0.1 ~ 1.0 sec (0.1 sec increments) - 1.5, 2.0, 2.5, 3.0 sec
5	HP LCD Brightness	Set the LCD brightness of the handpiece. - High: bright - Low: Dark
6	HP LCD Lock	Set the handpiece LCD touch function to On/Off.
7	BACK	Move to the Treatment screen.
8	SAVE	Save the edited information.

- SD Handpiece (Auto Mode)
 - After selecting the appropriate part for the treatment area, set the desired value.



SD Handpiece Auto Mode (Face)



SD Handpiece Auto Mode (Body)

No.	Symptom	Function
1	MODE 1 / 2 / 3	If user press the mode button for 3 seconds, the current treatment setting value is saved. (User can save frequently used values for convenient use.)
2	Treatment area (Face / Body)	The treatment area for each cartridge is displayed. - Face: P1.5 / P3 / P4.5 / L1.5 / L3 / L4.5 - Body: P9 / L9
3	Shot speed (Hz)	Sets the HIFU shot speed. - RF Only Mode: Face - 7 Hz / Body - 8 Hz - HIFU Only Mode: 1 ~ 10 Hz - RF/HIFU cross mode: 1 ~ 7 Hz
4	Dot (shot)	Set recommended shots for each part. - 50 ~ 9950 shot (50 shot increments)
5	CARTRIDGE TYPE	Displays the located cartridge type. - Face: P1.5 / P3 / P4.5 / L1.5 / L3 / L4.5 - Body: P9 / L9
6	Power	Set the power of RF and HIFU. - RF: 1 ~ 10 Lv - HIFU: 0.1 ~ 3.0 J
7	TOTAL DOT	Displays the total number of DOT COUNT performed. (You can set the number of shots when you click the alarm button.)
8	AUTO / MANUAL	Set auto/manual mode. - AUTO (automatic): Stores and uses frequently used values for each part - MANUAL: Set the desired value and use it
9	STANDBY	Indicates the standby state before energy irradiation. Touch STANDBY to switch to READY.
	READY	If user press the footswitch with energy irradiation enabled, The shot will be irradiated. Touch READY to switch to STANDBY.

- SD Handpiece Treatment screen (AUTO)
 - Choose the spot to be treated depending on the patient's condition, and select the part corresponding to the selected treatment.



SD Handpiece AUTO Mode
(When cartridge is located)



SD Handpiece AUTO Mode
(When energy irradiation)

No.	Symptom	Function
1	SD Handpiece Ready Mode	Touch STANDBY to switch to the handpiece operation screen in READY state and display the same image as the screen.
2	SD handpiece treatment progress animation	When performing SD handpiece treatment, an image like the screen is displayed. (If user press the footswitch in the READY state, the animation operation is activated.)

※ Precautions for treatment

- 1) The cartridge film must not be irradiated in the air without applying the ultrasonic delivery gel.
- 2) Before irradiating, check whether the cartridge film is in close contact with the skin before irradiating.
- 3) In the middle of the procedure, it should be checked whether the cartridge film requires more ultrasound delivery gel.
- 4) When irradiating next shot on the same treatment area, the 2 ~ 3 mm cartridge must be moved to irradiate.
- 5) Under conditions (for example, high ambient temperature and long operating period without pausing or stopping) as below, the surface temperature of skin contact part may exceed 41°C then allow the cartridges and tips to cool down or use another.
 - FL Cartridge: After 50 shots operation, allow the cartridge to cool down for 30 minutes or use another cartridge.
 - SD Cartridge: After 15 minutes operation, allow the cartridge to cool down for 30 minutes or use another cartridge.
 - RM Tip: After 10 minutes operation, allow the tip to cool down for 15 seconds or use another tip.

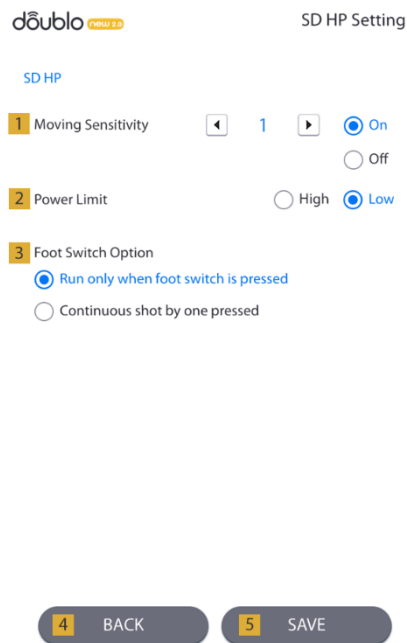
- SD Handpiece Treatment (MANUAL Mode)



SD Handpiece Manual Mode

No.	Symptom	Function
1	RF	Set the RF POWER (Lv), RF ON TIME (ms/shot), RF OFF TIME (ms/shot) values. - RF POWER: 1 ~ 10 Lv - RF ON TIME: 50 ~ 450 ms/shot - RF OFF TIME: 50 ~ 450 ms/shot
2	HIFU	Set the values of HIFU POWER (J) and SHOT SPEED (Hz). - HIFU POWER: 0.1 ~ 3.0 J - SHOT SPEED: 1 ~ 10 Hz
3	M1 / M2 / M3	If user press the mode button for 3 seconds, the current treatment setting value is saved. (User can save frequently used values for convenient use.)
4	TOTAL DOT	Displays the total number of DOT COUNT performed. (You can set the number of shots when you click the alarm button.)
5	AUTO / MANUAL	Set auto/manual mode. - AUTO (automatic): Stores and uses frequently used values for each part - MANUAL: Set the desired value and use it
6	STANDBY	Indicates the standby state before energy irradiation. Touch STANDBY to switch to READY.
	READY	If user press the footswitch with energy irradiation enabled, The shot will be irradiated. Touch READY to switch to STANDBY.

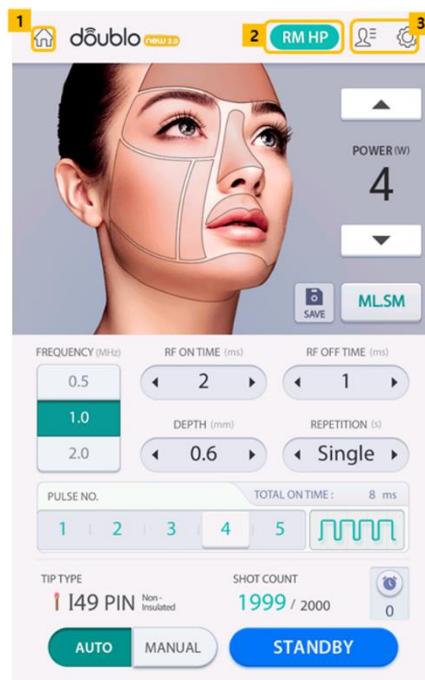
- SD Handpiece Setting
 - This screen is displayed when the setting button is clicked. You can select a specific setting for treatment.







SD Handpiece Setting Screen

No.	Symptom	Function
1	Moving Sensor	Set the Moving sensor function to On/Off.
2	Power Limit	Cartridge output value limit can be set for patient safety. - High: Generates Max output value of cartridge - Low: Generates Mid output value of cartridge (For output values by mode and cartridge, see Performance.)
3	Foot Switch Option	Select whether continuous irradiation or single irradiation occurs when the footswitch is actuated once.
4	BACK	Move to the Treatment screen.
5	SAVE	Save the edited information.

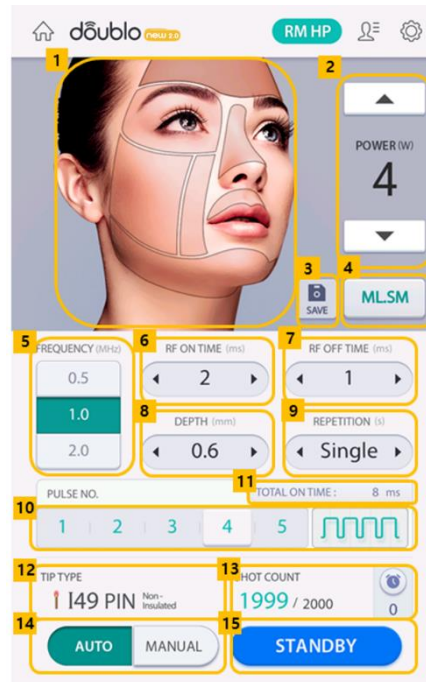
- RM Handpiece (Auto Mode)



RM Handpiece Auto Mode

No.	Symptom	Function	
1		Move to the hand Piece selection page.	
2	Selected Handpiece	Selected handpiece is displayed. (RM)	
3	Patient information display		This icon is displayed on the screen when patient information is loaded from the patient's information entry page.
			This icon is displayed on the screen when patient information is skipped in the patient information entry page.
			Clicking on the SETUP leads to the settings page.

- RM Handpiece (Auto Mode)
 - You can set detailed values for the area to be treated directly.
 - Choose the spot to be treated depending on the patient's condition, and select the part corresponding to the selected treatment.



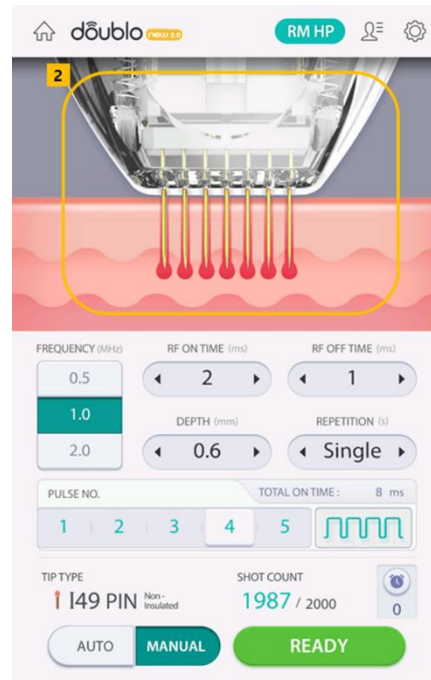
RM Hand Piece Auto Mode

No.	Name	Function
1	Treatment area Select	User can select from 7 parts including forehead / eyes / cheeks / nasolabial folds / nose / chin line + pharynx / neck. User can select and use 3 treatment modes.
2	POWER (W)	Set the power. - 1 to 20 W (Unit: 1 W)
3	SAVE	Save setting information.
4	EASY GUIDE	Easy guide set up.
5	FREQUENCY (Mhz)	Set the frequency. - 0.5 / 1.0 / 2.0 Mhz
6	RF ON TIME (ms)	Set the RF irradiation time. - 1 to 30 ms (Unit: 1 ms) - 30 ~ 100 ms (Unit: 5 ms) - 100 ~ 950 ms (Unit: 10 ms) (Display warning pop-up for more than 400 ms)
7	RF OFF TIME (ms)	Set the RF non-irradiation time. - 1 to 30 ms (Unit: 1 ms) - 30 ~ 100 ms (Unit: 5 ms) - 100 ~ 950 ms (Unit: 10 ms)
8	DEPTH (mm)	Set the depth of needle penetration. - 0.1 ~ 3.5mm (Unit: 0.1mm)
9	REPETITION	Set the RF irradiation repeat interval (hours). - Single / 0.2 ~ 1.0 s / 2.0 s
10	PULSE NO.	Set the number of pulses. - PULSE NO.: 1 ~ 5
11	TOTAL ON TIME	Displays the total RF irradiation time. - 1 to 4,750 ms
12	TIP TYPE	Displays the mounted tip TYPE. - 25PIN (insulated / non-insulated) - 49PIN (insulated / non-insulated)
13	SHOT COUNT	Displays the number of shots used and the total number of shots for the RF Micro Needle tip. (User can set the number of shots when User click the alarm button.)
14	AUTO / MANUAL	Set auto/manual mode. - AUTO (automatic): Stores and uses frequently used values for each part - MANUAL: Set the desired value and use it
15	STANDBY	Indicates the standby state before energy irradiation. Click STANDBY to switch to READY.
	READY	If user press the footswitch with energy irradiation enabled, the shot will be irradiated. Click READY to switch to STANDBY.

- RM Handpiece Treatment (MANUAL Mode)
 - The treatment is performed by setting the setting value of MODE or the operation value



RM Handpiece MANUAL Mode
(With RM tip located)



RM Handpiece MANUAL Mode
(When energy irradiation)

No.	Symptom	Function
1	RM Handpiece Ready Mode	Click STANDBY to switch to the READY handpiece treatment screen and display the same image as the screen.
2	RM Handpiece Operation Animation	During RM hanpiece treatment, the image on the screen is displayed. (Pressing the footswitch in the Ready state activates the animation.)

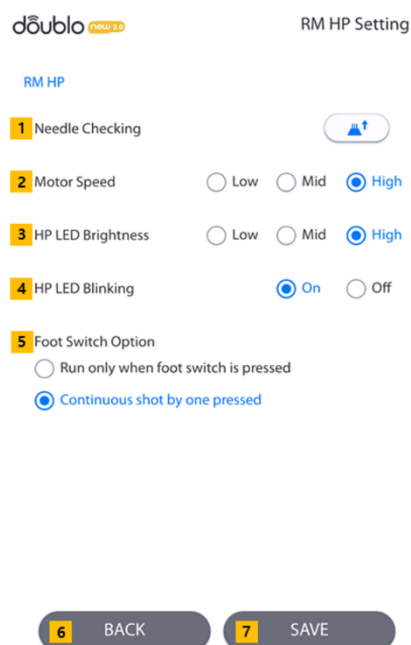
- RM Handpiece (Manual Mode)
 - This screen is displayed when the Manual button is clicked. You can select a specific setting for treatment.





RM Handpiece Manual Mode

No.	Symptom	Function
1	POWER (W)	High-frequency power settings - 1 ~ 20 W (unit: 1 W)
2	FREQUENCY (Mhz)	Set the frequency. - 0.5 / 1.0 / 2.0 Mhz
3	RF ON TIME (ms)	The needle radiation (repetition interval) is set up.
4	RF OFF TIME (ms)	The needle radiation (repetition interval) time is set up.
5	DEPTH (ms)	The time of needle exposure is set up.
6	REPETITION	Set the RF irradiation time. - 1 to 30 ms (Unit: 1 ms) - 30 ~ 100 ms (Unit: 5 ms) - 100 ~ 950 ms (Unit: 10 ms) (Display warning pop-up for more than 400 ms)
7	PULSE NO.	Set the RF non-irradiation time. - 1 to 30 ms (Unit: 1 ms) - 30 ~ 100 ms (Unit: 5 ms) - 100 ~ 950 ms (Unit: 10 ms)
8	TOTAL ON TIME	Displays the total RF irradiation time. - 1 to 4,750 ms
9	TIP TYPE	Displays the mounted tip TYPE. - 25PIN (insulated / non-insulated) - 49PIN (insulated / non-insulated)
10	SHOT COUNT	Displays the number of shots used and the total number of shots for the RF Micro Needle tip. (User can set the number of shots when User click the alarm button.)
11	AUTO / MANUAL	Set auto/manual mode. - AUTO (automatic): Stores and uses frequently used values for each part - MANUAL: Set the desired value and use it
12	STANDBY	Indicates the standby state before energy irradiation. Click STANDBY to switch to READY.
	READY	If user press the footswitch with energy irradiation enabled, the shot will be irradiated. Click READY to switch to STANDBY.

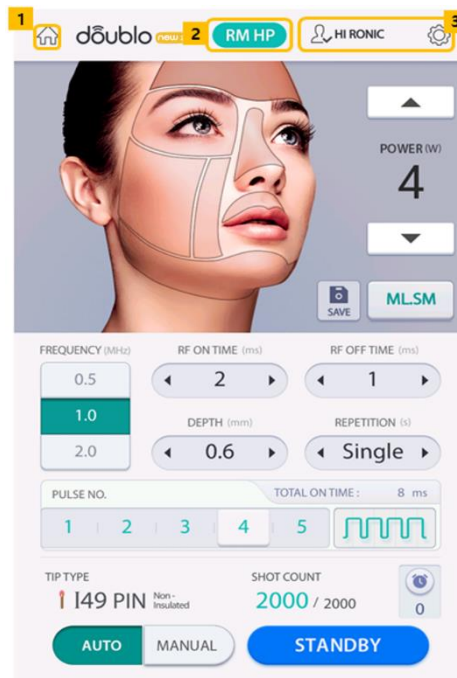
- RM Handpiece Settings information
- This screen appears when the SETTING button is clicked. You can set up RF Micro Needle actions and the motor speed.







RM Handpiece Settings Screen

No.	Symptom	Function
1	Needle Checking	 When selected, the needle protrudes out of the tip.
		 When selected, the needle is inserted into the tip.
2	MOTOR SPEED	User can set the motor speed that moves the RF Micro Needle tip. - Low: 1666 Hz - Mid: 2222 Hz - High: 3333 Hz
3	HP LED Brightness	Set the LED brightness of the handpiece. - Low, Mid, High
4	HP LED Blinking	User can select whether the LED on the handpiece blinks or not.
5	Foot Switch Option	Single or continuous irradiation can be selected for footswitch operation.
6	BACK	Move to the Treatment Menu screen.
7	SAVE	Save modified information.

- RM(B) Handpiece (Auto Mode)
 - Stored treatment values for each part can be conveniently used by recalling information during the next treatment.

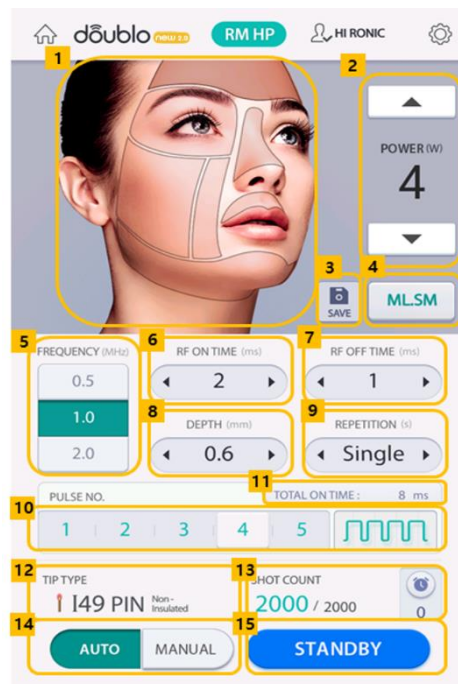


RM(B) Handpiece Auto Mode

No.	Symptom	Function	
1		Move to the hand Piece selection page.	
2	RM Handpiece	The RM handpiece is displayed.	
3	Patient information display		This icon is displayed on the screen when patient information is loaded from the patient's information entry page.
			This icon is displayed on the screen when patient information is skipped in the patient information entry page.
			Clicking on the SETUP leads to the settings page.

- RM(B) Handpiece (Auto Mode)
 - You can set detailed values for the area to be treated directly.
 - Choose the spot to be treated depending on the patient's condition, and select the part corresponding to the selected treatment.

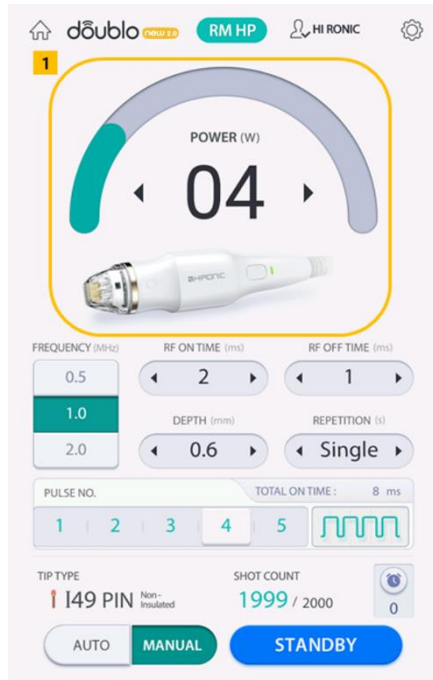
RM(B) Handpiece Auto Mode



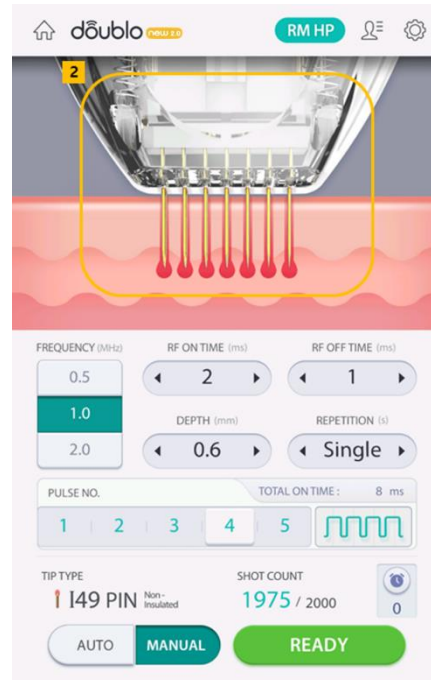
RM(B) Handpiece Auto Mode

No.	Name	Function
1	Treatment area Select	User can select from 7 parts including forehead / eyes / cheeks / nasolabial folds / nose / chin line + pharynx / neck. User can select and use 3 treatment modes.
2	POWER (W)	Set the power. - 1 to 20 W (Unit: 1 W)
3	SAVE	Save setting information.
4	EASY GUIDE	Easy guide set up.
5	FREQUENCY (Mhz)	Set the frequency. - 0.5 / 1.0 / 2.0 Mhz
6	RF ON TIME (ms)	Set the RF irradiation time. - 1 to 30 ms (Unit: 1 ms) - 30 ~ 100 ms (Unit: 5 ms) - 100 ~ 950 ms (Unit: 10 ms) (Display warning pop-up for more than 400 ms)
7	RF OFF TIME (ms)	Set the RF non-irradiation time. - 1 to 30 ms (Unit: 1 ms) - 30 ~ 100 ms (Unit: 5 ms) - 100 ~ 950 ms (Unit: 10 ms)
8	DEPTH (mm)	Set the depth of needle penetration. - 0.1 ~ 3.5mm (Unit: 0.1mm)
9	REPETITION	Set the RF irradiation repeat interval (hours). - Single / 0.2 ~ 1.0 s / 2.0 s
10	PULSE NO.	Set the number of pulses. - PULSE NO.: 1 ~ 5
11	TOTAL ON TIME	Displays the total RF irradiation time. - 1 to 4,750 ms
12	TIP TYPE	Displays the mounted tip TYPE. - 25PIN (insulated / non-insulated) - 49PIN (insulated / non-insulated)
13	SHOT COUNT	Displays the number of shots used and the total number of shots for the RF Micro Needle tip. (User can set the number of shots when User click the alarm button.)
14	AUTO / MANUAL	Set auto/manual mode. - AUTO (automatic): Stores and uses frequently used values for each part - MANUAL: Set the desired value and use it
15	STANDBY	Indicates the standby state before energy irradiation. Click STANDBY to switch to READY.
	READY	If user press the footswitch with energy irradiation enabled, the shot will be irradiated. Click READY to switch to STANDBY.

- RM(B) Handpiece Treatment (MANUAL Mode)
 - The treatment is performed by setting the setting value of MODE or the operation value



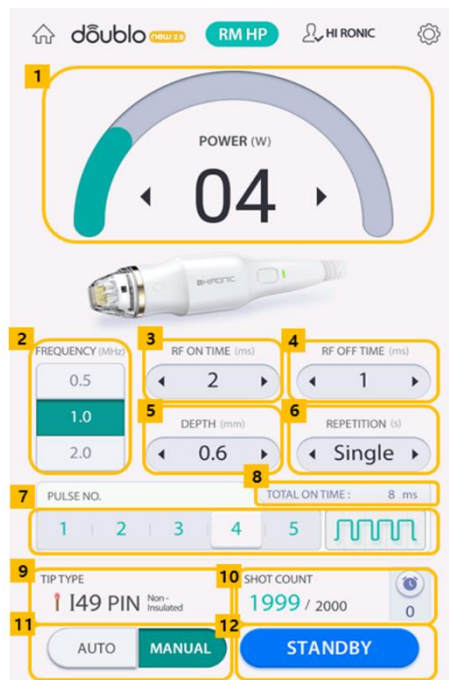
RM(B) Handpiece MANUAL Mode
(With RM tip located)



RM(B) Handpiece MANUAL Mode
(When energy irradiation)

No.	Symptom	Function
1	RM(B) Handpiece Ready Mode	Click STANDBY to switch to the READY handpiece treatment screen and display the same image as the screen.
2	RM(B) Handpiece Operation Animation	During RM hanpiece treatment, the image on the screen is displayed. (Pressing the footswitch in the Ready state activates the animation.)

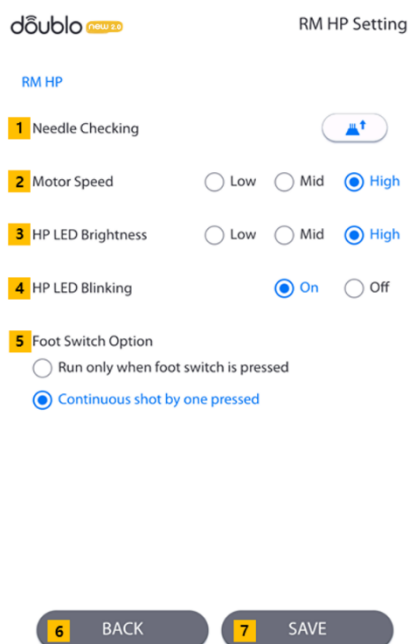
- RM Handpiece (Manual Mode)
 - This screen is displayed when the Manual button is clicked. You can select a specific setting for treatment.



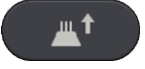

RM(B) Handpiece Manual Mode

No.	Symptom	Function
1	POWER (W)	High-frequency power settings - 1 ~ 20 W (unit: 1 W)
2	FREQUENCY (Mhz)	Set the frequency. - 0.5 / 1.0 / 2.0 Mhz
3	RF ON TIME (ms)	Set the RF irradiation time. - 1 to 30 ms (Unit: 1 ms) - 30 ~ 100 ms (Unit: 5 ms) - 100 ~ 950 ms (Unit: 10 ms) (Display warning pop-up for more than 400 ms) The needle radiation (repetition interval) is set up.
4	RF OFF TIME (ms)	Set the RF non-irradiation time. - 1 to 30 ms (Unit: 1 ms) - 30 ~ 100 ms (Unit: 5 ms) - 100 ~ 950 ms (Unit: 10 ms) The needle radiation (repetition interval) time is set up.
5	DEPTH (ms)	The time of needle exposure is set up.
6	REPETITION	The needle radiation (repetition interval) is set up.
7	PULSE NO.	Set the number of pulses. - PULSE NO.: 1 ~ 5
8	TOTAL ON TIME	Displays the total RF irradiation time. - 1 to 4,750 ms
9	TIP TYPE	Displays the mounted tip TYPE. - 25PIN (insulated / non-insulated) - 49PIN (insulated / non-insulated)
10	SHOT COUNT	Displays the number of shots used and the total number of shots for the RF Micro Needle tip. (User can set the number of shots when User click the alarm button.)
11	AUTO / MANUAL	Set auto/manual mode. - AUTO (automatic): Stores and uses frequently used values for each part - MANUAL: Set the desired value and use it
12	STANDBY	Indicates the standby state before energy irradiation. Click STANDBY to switch to READY.
	READY	If user press the footswitch with energy irradiation enabled, the shot will be irradiated. Click READY to switch to STANDBY.

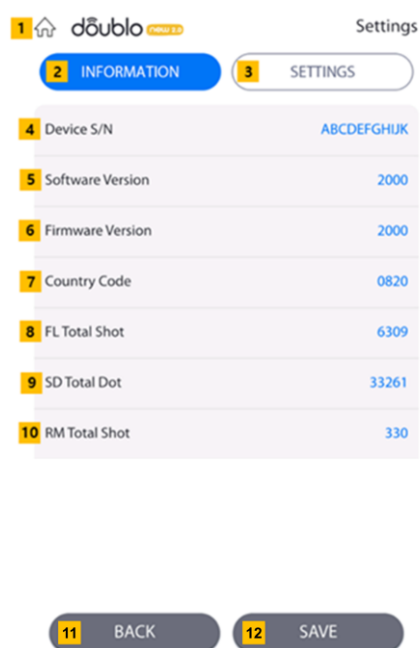
- RM(B) Handpiece Settings information
 - This screen appears when the SETTING button is clicked. You can set up RF Micro Needle actions and the motor speed.



RM(B) Handpiece Settings Screen

No.	Symptom	Function
1	Needle Checking	 When selected, the needle protrudes out of the tip.
		 When selected, the needle is inserted into the tip.
2	MOTOR SPEED	User can set the motor speed that moves the RF Micro Needle tip. - Low: 1666 Hz - Mid: 2222 Hz - High: 3333 Hz
3	HP LED Brightness	Set the LED brightness of the handpiece. - Low, Mid, High
4	HP LED Blinking	User can select whether the LED on the handpiece blinks or not.
5	Foot Switch Option	Single or continuous irradiation can be selected for footswitch operation.
6	BACK	Move to the Treatment Menu screen.
7	SAVE	Save modified information.

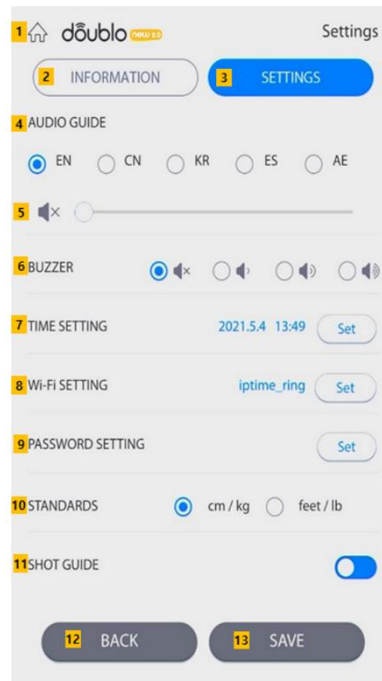
- Settings INFORMATION
 - Displays the device' s version information



INFORMATION MENU

No.	Symptom	Steps to take
1		Move to the handpiece selection screen.
2	INFORMATION	Display the product information.
3	SETTINGS	Display the settings.
4	Device S/N	Display the device's serial number.
5	Software Version	Display NEW DOUBLO 2.0™ software version.
6	Firmware Version	Display NEW DOUBLO 2.0™ firmware version.
7	Country Code	Display the country code of the device.
8	FL HP Total Shot	Display the total number of shots used for the FL handpiece.
9	SD HP Total Shot	Display the total number of shots used for the SD handpiece.
10	RM HP Total Shot	Display the total number of shots used for the RM handpiece.
11	BACK	Return to the previous page.
12	SAVE	Save the settings.

- **SETTING Information**
- Used to show the device's version and usage tips, adjust the volume, and confirm / select audio guides.



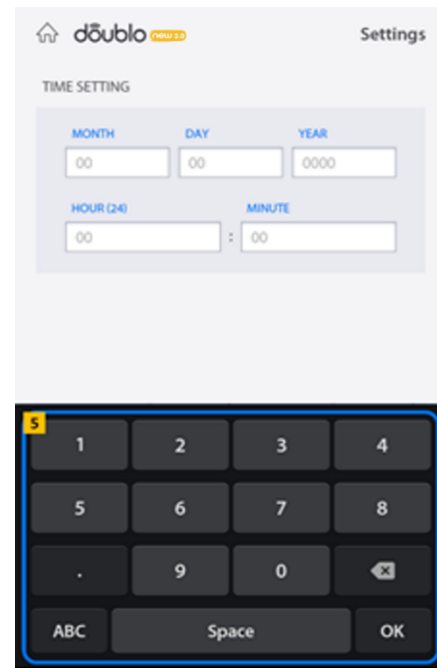
Settings Menu

No.	Symptom	Function
1		Move to Handpiece Selection Screen.
2	INFORMATION	Display the product information.
3	SETTINGS	Display the settings.
4	AUDIO GUIDE	Select the voice language for the initial guide. - EN (English), CN (Chinese), KR (Korean), ES (Spanish), AE (Arabic)
5	AUDIO CONTROL	Adjust the volume of the initial guide.
6	BUZZER	Set the buzzer volume to 4 levels. - Mute, Min, Medium, Max
7	TIME SETTING	Show the set time Time can be set when selecting Set.
8	Wi-Fi SETTING	Show the set WIFI WI-FI can be set when selecting Set.
9	PASSWORD SETTING	Set the password for the product.
10	STANDARDS	User selects to set the weight and height units.
11	SHOT GUIDE	Provide a guide by marking lines for each treatment area
12	BACK	Move to the Treatment Menu screen
13	SAVE	Save modified information


- TIME SETTING
- Set up the device time.



TIME SETTINGS



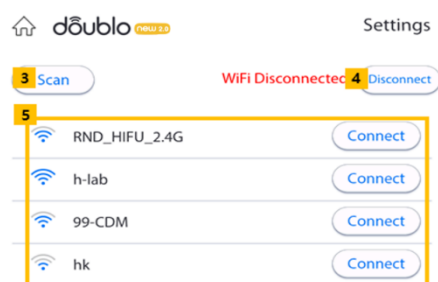
TIME SETTINGS (KEY PAD)

No.	Symptom	Function
1		Move to the Handpiece selection page.
2	TIME SETTING	Set the device's time.
3	BACK	Move to the SETTINGS screen.
4	SAVE	Save the modified information.
5	KEY PAD	Select the number to be entered.


- Wi-Fi SETTING screen
- This menu is used to select the Wi-Fi connection of the device.



Wi-Fi SCAN screen



Wi-Fi Connect screen

No.	Symptom	Function
1		Move to the handpiece selection page.
2	Model / Logo	Indicates the model name and logo. * Model name: NEW DOUBLO 2.0™, V-RO 2.0™ 2 types, the product logo is displayed according to the model name.
3	Scan	Scan for accessible Wi-Fi signals.
4	Disconnect	Disconnect the Wi-Fi connection.
5	Connect	Show the connected Wi-Fi.
6	BACK	Move to the treatment menu screen.
7	CLEAR	Reset the information.

- **PASSWORD SETTING Screen**
- This menu is used to setting the password of the device.

1 dōublo NEW 2.0 Settings

PASSWORD SETTING

2 **CURRENT PASSWORD** (Initial password: 123456789A)
Password

3 **NEW PASSWORD**
New Password
Confirm New Password


4 **BOOT LOCK** ☐ On ☒ Off

5 **BACK** 6 **SAVE**

PASSWORD SETTING Screen

No.	Symptom	Function
1		Move to the handpiece selection page.
2	CURRENT PASSWORD	Enter the currently set password.
3	NEW PASSWORD	Enter the new password to be set and confirm again.
4	BOOT LOCK	Enter the password at boot time and move to the home screen.
5	BACK	Move to the treatment menu screen.
6	SAVE	Save the modified information.

[Pop-up messages]

Symptom	Description
	 <p>"Alarm Count Setting"</p> <p>This message will appear when the Alarm button is clicked.</p> <ul style="list-style-type: none"> ※ Select the desired number of shots and save the setting. The alarm will then be set up. ※ This is to turn the alarm on or off.
<p>WARNING</p> <p>It might cause damage to the Skin</p>	<p>WARNING - It might cause damage to the Skin</p> <p>This warning is generated when the RF ON TIME setting of the RM handpiece is over 400.</p> <ul style="list-style-type: none"> ※ When the value is set under 400, this popup menu will disappear.
<p>"Tip is not connected. Please connect a Tip."</p>	<p>"Tip is not connected. Please connect a Tip."</p> <p>This message will appear when no Tip has been connected.</p> <p>If no Tip has been connected to the handpiece, connect a Tip.</p> <ul style="list-style-type: none"> ※ If there is a Tip that has been connected but this message is displayed, it indicates that a PCB error of the Tip. Replace the Tip with a new one.
<p>"Initialize motor fail."</p>	<p>"Initialize motor fail."</p> <p>This message appears when the handpiece (motor) is not initialized.</p> <ul style="list-style-type: none"> - Check if the Tip motor moves smoothly. ※ If the same symptom remains even after you connect another Tip, contact and the manufacturer for assistance.
<p>"Tip is end of lifespan. Please change Tip."</p>	<p>"Tip is end of lifespan. Please change Tip."</p> <p>This will appear when the maximum Tip shot counter has been reached.</p> <ul style="list-style-type: none"> - Replace the Tip with a new one. - When the Tip memory has been deformed. (When the number of shots used has changed)
<p>"Write to Tip fail"</p>	<p>"Write to Tip fail"</p> <p>This will appear when no information has been saved in the Tip and the memory device inside the Tip fails to respond.</p> <ul style="list-style-type: none"> - The Tip memory is not usable. If this message appears again even after disconnecting and relocating it, the Tip may be out of order. Contact and consult the manufacturer.

4. Maintenance and Storage

4.1 Storage and Maintaining the Product

- The system and components should be inspected on a regular basis.
- If an impact is applied to the main unit and components, the device may come to be damaged.
- If it is deemed that the system does not operate properly or has broken down, please contact the manufacturer for assistance. Do not arbitrarily disassemble the system.
- To use the system after it has been unused for an extended period of time, first check that the system is clean, safe and working properly.
- Since the cartridge comes in contact with the patient's original skin, keep it clean through standard procedures, and wipe lightly with a soft cloth moistened with 70% isopropyl alcohol. Use another clean cloth to wipe the handpiece and hand Piece cables as well. Never immerse the cartridge or handpiece in liquid.
- Store the system in a place that is not affected by direct sunlight, moisture, atmospheric pressure, temperature, humidity, ventilation, sun rays, dust, or air containing salt.
- Do not store the system in a bathroom or other places that are highly humid.
- If it is deemed that there is a problem with this product during storage, please contact the manufacturer for assistance. Do not arbitrarily disassemble the system.
- Ensure that the system is maintained in a safe state under any conditions, including when the system is transported, to ensure protection against slopes, vibration or excessive force.
- The handpiece should be located where the physical impact does not close.
- Keep the LCD screen clean so that no foreign matter remains on the touch screen and handpiece.
- Avoid using the system in a location where chemicals are stored or gas is generated.

4.2 General Maintenance and Management

- Do not twist or pull the handpiece cable. It may break the inner wire or damage the connector.
- Use only water-soluble ultrasonic gels. Other lubricants or lotions, especially mineral oil, can damage the cartridge or handpiece.
- Do not use ultrasonic protection pads. Also, do not place anything between the cartridge and the patient.
- Use only ultrasonic delivery gel on the cartridge film and wipe it off after the treatment. Be careful not to get the gel on the hand Piece or body unit.
- 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 10°C 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

	Operating conditions	Storage condition
Temperature	10°C ~ 30°C	10°C ~ 40°C
Relative humidity	30% ~ 70%	30% ~ 70%
Atmospheric pressure	80 ~ 106 kPa	80 ~ 106 kPa

4.3 Preparations for Transportation

Follow these procedures before transporting the device:

- Detach the handpiece, foot switch, and other components.
- Seal the hand Piece and accessories safely before transport so that they are not damaged.
- Put the system in a dedicated transport box. Exercise caution to ensure that the system does not collide with other objects during transportation.
- If a dedicated storage box is not available, pack the system with other material that can prevent excessive force or scratches.

4.4 Cleaning

- Use a soft brush to remove dust and other foreign materials off the electrical outlet.
- Always check that there is no foreign material found in or on the electrical outlet before connecting the power cable.
- Use a soft cloth to wipe the main unit.
- Do not use water or oils such as benzene or thinner, to clean the system.
- Use exclusive cleaning tools (lens cleaning tissue, proper cleaning tools, etc.) to clean the handpiece and dry thoroughly for storage.
- After using the system, make sure you turn it off and use a dry cloth or soft brush to wipe the system.
- Do not touch the power part of the system with wet hands.



Caution

Never dip a handpiece into solution since it can be damaged. After each use, clean the handpiece.



Caution

If you use a forged or falsified cartridge, you should not use it as it may cause side effects and you cannot receive after-sales service and other services provided by us.





NOTE

If it is deemed that the system does not operate properly or has broken down, please contact the manufacturer for assistance. Do not arbitrarily disassemble the system. If the product has been disassembled arbitrarily and the product malfunctions, the issue will not be covered by our paid or free-of-charge repair service. We hereby notify that we will not and shall not be held accountable for any and all legal problems caused by disassembly at your discretion.

5. Troubleshooting

5.1 Steps to Take in Emergency Situations

Symptom	Steps to take
Burning smell is coming from the product Abnormal noise is coming from the product	<ul style="list-style-type: none">• Use the power button on the rear side of the system to turn it off.• Unplug the power cable from the electrical outlet.• Contact the original distributor or our after-sales service center. <div> Caution If the product is used continuously, internal modules may become damaged one after another and fire or safety accidents may occur.</div>
The display screen is broken or damaged	<ul style="list-style-type: none">• Immediately stop the treatment and use of the product.• Turn off the system and unplug the power cable from the electrical outlet.• Contact the original distributor or our after-sales service center. <div> Caution If the touch screen is broken and the system is used continuously, energy will not be irradiated uniformly and the patient's skin may become damaged.</div>
Blisters or burns are present in the treated area	<ul style="list-style-type: none">• Immediately cool the affected area. Apply burn ointment to the area to hasten skin regeneration, if necessary.• Contact the original distributor or our after-sales service center.

5.2 Troubleshooting by Symptom

Symptom	Steps to take
The system cannot be turned on	<ul style="list-style-type: none">• Check if power is applied to the electrical outlet and the plug is inserted properly.• Confirm that the power cable is firmly connected to the system.• Confirm that the power switch (circuit breaker) on the rear of the system works properly. (If over current enters the system, the circuit breaker may not work properly.)• If the main unit still does not operate properly after checking the above, contact the original distributor or our after-sales service center.
The main power switch (circuit breaker) on the rear of the system does not work properly	<ul style="list-style-type: none">• Turn off the power switch (circuit breaker) on the rear of the main unit.• Check the power cable connection and confirm that the system can be turned on/off. Turn the Device On / Off switch on the front of the system on and off 2 or 3 times repeatedly. If the main unit does not respond, contact the original distributor or our after-sales service center.
Loud noise is audible	<ul style="list-style-type: none">• Check if the product is placed on a flat and stable surface.• Check if the product is located at least 30 cm away from the wall.• Contact the service center if the device makes a loud or irregular noise.

5.3 Cybersecurity Response Method

Symptom	Steps to take
When the RMS server does not work	<ul style="list-style-type: none">• If an error occurs when updating S/W after turning on the RMS server while connected to WIFI, contact the service center.• If an error occurs when updating F/W after turning on the RMS server while connected to WIFI, contact the service center.
If an error occurs after RMS update	<ul style="list-style-type: none">• If an error occurs or the device is stopped after RMS update, it is caused by failure to verify the sterility of the file. Please contact the service center.

6. Warranty

6.1 Overview

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

6.2 Warranty Coverage

- If the product has been used for intended purposes, Hironic Co., Ltd. provides a warranty for one year after delivered.
- Free-of-charge warranty covers the main unit and applicator. Consumable components are excluded.
- If you request repairs that fall within the required conditions for the warranty coverage, repair or replacement will be performed at either the head office of Hironic Co., Ltd. or the location where the product is delivered, depending on the target component for repair and the period of time required for the repair.
- When making a warranty claim, the user should provide Hironic Co., Ltd. with materials, video or photos that show details of the problem.



NOTE

- **To maintain free-of-charge warranty, repair or modification shall be performed by service personnel officially appointed by Hironic Co., Ltd. If the product was not used for the intended purpose or the instructions herein were not followed and the product malfunctions, the issue will not be covered by the warranty. Make sure you thoroughly read and understand the user manual. Hironic Co., Ltd. shall be responsible and entitled to make a decision regarding details and the cause of a damage in the product; the decision is final and subject to no change.**



NOTE

- **If the system has been disassembled or modified arbitrarily and the system malfunctions, the issue will not be covered by the warranty.**

6.3 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 need to be followed with extra caution when using the product.

- Damage to the main unit or handpiece, caused due to the user's negligence when using or moving the product, is not covered by the warranty.
- The warranty is void if the product has been used for unintended purposes or it has been altered or disassembled.
- Consumables are not covered by the warranty.
- Damage or loss due to the user's carelessness is not covered by the warranty.
- The warranty is void if a damage has occurred due to disassembly of or shock to the system or applicator (including the cables), the applicator has been removed from the main unit with an excessive force and damaged, or the system has been disassembled or repaired by someone that is not a service technician authorized by Hironic Co., Ltd.
- The warranty is void if a seal on the product has been damaged without permission by Hironic Co., Ltd.



NOTE

Use only genuine components and consumable parts supplied by the manufacturer. Do not modify or alter the product. Damage caused by unauthorized tampering is not covered by the warranty.

Warranty Certificate

This warranty certificate supersedes any explicit or implied warranties. The seller cannot guarantee the warranty or the conditions of the product.

Hospital name	
Name	
Address	
Contact info.	
Mobile	
Email	
Product name	NEW DOUBLO 2.0™
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 Co., Ltd.

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E-mail: ocs@hironic.com

M E M O



User Manual



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