Edge ONE™

Operation Manual

V 1.2

Table of Contents

1 Edge ONE™ Manual ..... - 3 -

2 Medical Safety ..... - 3 -

2.1. Treatment Restrictions ..... - 3 -

2.2. Eye protection ..... - 3 -

2.3 Temporary symptom after treatment ..... - 4 -

2.4 Possible side effects ..... - 4 -

3 System Safety ..... - 5 -

3.1 Safety Guide ..... - 5 -

3.2 Emergency Stop Button ..... - 7 -

3.3 Safety Label ..... - 7 -

4 Arrangement before use ..... - 8 -

4.1 Unwrapping ..... - 8 -

4.2 Security of space ..... - 8 -

4.3 Electrical Requirements ..... - 8 -

4.4 Components Assembling ..... - 8 -

5 System Description ..... - 9 -

5.1 Components and Features ..... - 9 -

5.1.1 Key Components ..... - 9 -

5.1.2 List of Components ..... - 11 -

5.1.3 Touch LCD Screen ..... - 11 -

5.2 Description of Components ..... - 11 -

5.2.1 Surgical Handpiece ..... - 11 -

5.2.2 Fractional Handpiece ..... - 12 -

5.2.3 Types of Fractional Handpiece Tip ..... - 12 -

5.2.4 Arm ..... - 13 -
5.2.5 Footswitch ..... - 13 -

6 Installation ..... - 14 -
6.1 Device Installation ..... - 14 -
6.1.1 Connection of Foot switch / Power cord ..... - 14 -
6.1.2 Connection of Fractional Handpiece ..... - 14 -
6.1.3 Connection of Fractional Handpiece Tip ..... - 14 -
6.1.3 Connection of Surgical Handpiece ..... - 15 -
6.1.4 Fixation of device ..... - 16 -
6.2 Device Movement ..... - 16 -
6.2.1 Movement in operation room ..... - 16 -
6.2.2 Movement to distant place ..... - 16 -

7 Device Operation ..... - 17 -
7.1 Turning On ..... - 17 -
7.2 Modes of treatment ..... - 19 -
7.2.1 Fractional mode ..... - 19 -
7.2.2 Surgical Mode ..... - 23 -
7.3 Turning Off ..... - 26 -

8 Cleaning ..... - 26 -
8.1 Cleaning of Touch Screen / Exterior of device ..... - 26 -
8.2 Handpiece Maintenance ..... - 26 -
8.2.1 Maintenance of Fractional Handpiece ..... - 26 -
8.2.2 Maintenance of Surgical Handpiece ..... - 27 -
8.2.3 Maintenance of Fractional Handpiece Tip ..... - 28 -
8.3 Storage ..... - 28 -

9 System Messages ..... - 29 -

1 Edge ONE™ Manual

This manual includes the description of system components and display, and how to operate the device with touch screen.

Warning: Do not operate the system before you read this manual completely.

2 Medical Safety

2.1 Treatment Restrictions

It is not allowed to treat the patients if the following is checked;

- Allergic skin to topical anesthesia and/or antibiotics
- Open fresh wound on the area of treatment
- Herpes simplex infection during recent months before treatment
- Photo-sensitive skin
- Psychoneurosis as alcoholic or drug poisoning
- Diabetes Mellitus and/or any of connective tissue diseases
- Cardiac pacemaker or defibrillator implanted
- Cancer or any of malignant diseases
- High blood pressure and/or any of acute diseases
- Pregnant woman, infant, child

2.2 Eye protection

- Both of patient and operator should wear the eye protecting goggles during the entire treatment process.
- Operator should wear the protective goggles against to the laser beams of 10600nm and 637nm or the one which its sides are protected according to the ANSI (American National Standards Institute) standards.
- Cover patient's eyes by gauze and use a standard goggles for face treatment.

2.3 Temporary symptoms after treatment

The following responses are possible minor and temporary symptoms and it should be advised to the patients before the treatment to avoid causing unnecessary fear or anxiety of it.

- Redness and Edema

  : There could be redness and edema for 1 to 3 days after treatment. It is normal response that the treated area is rather uneven and looks brown temporarily caused by corneous tissue of epidermis. This dead skin cell's exfoliation time may differ from each patient's skin type or treated area, but generally it takes 3 to 7 days after treatment.

- Microhemorrhage

  : Slight bleeding could happen right after treatment. However, it stops within 1 hour in most cases.

- Pain

  : There is no special awareness of pain since it is endurable with topical anesthesia on the area of treatment.

2.4 Possible side effects

The patients who have the following symptoms should be treated carefully.

- PIH(Post Inflammatory Hyper-pigmentation)

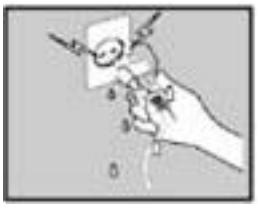
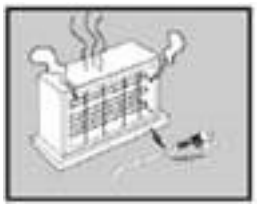
  : It is better to use total density less than 200 dots/cm^2 and must apply sun blocking product on the area to prevent from PIH

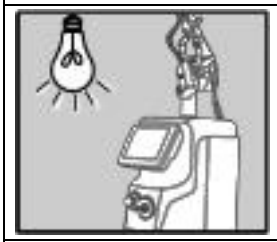
- Herpes Simplex

  : Herpes simplex can be formed more likely at the corner of mouth. Therefore, patient should be aware of it and operator could prescribe some oral antiviral agent for 3 days from the day of treatment if total density or pulse energy were high relatively.

3 System Safety

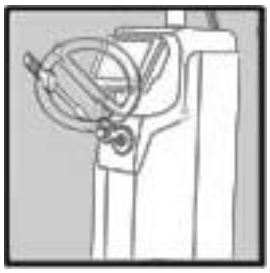
3.1 Safety Guide

Power Supply	
	Confirm if a power cord is plugged in socket properly.
	Never use a damaged wire. It may cause fire by a short circuit.
	Do not plug in by wet hand. It may cause an electrical shock.
	It may cause fire when several power cords are plugged in one socket.
Installation	
	Do not install the device close to inflammable materials.
	Do not leave a power cord or cable close to heating apparatus. It may cause melting of wire or a short circuit.

	Keep the device apart from oil box to secure from the risk of fire.
	Keeps the device in an airy place avoiding humidity, high temperature, dust, salinity, and direct sun light.
	Make the lighting of the room brighter, and it may reduce the amount of penetrating rays to eyes in case of emergency.

Transportation

	Be careful to do not drop handpiece. It may cause to break the built-in lens.
	Do not tilt the device.
	Do not pour water or put a heavy thing on the device.
	Turn off the switch and plug out when the device is not used.

Handling	
	Do not use the device close to inflammable materials.
	When there is any trouble, contact to the after-sales service team of the manufacturer promptly, never trying to repair or disassemble the device arbitrarily. Any service related to the troubles should be done by an appointed professional technician and standard parts should be used only.
	Do not plug out too hard.

3.2 Emergency Stop Button

- Stop the system by pressing Emergency Stop button at the time of emergency.
- To re-start the treatment, turn it clockwise until the button pops up. The system reboots automatically.

3.3 Safety Label

Symbol / Label	Description
	[Warning for exposure to laser radiation]
	[Warning for exposure to laser radiation] Avoid eye or skin exposure to direct or scattered radiation

4 Arrangement before use

4.1 Unwrapping

- Unwrap the package and remove transparent film on screen. If the film is not removed, touch screen may not work properly.

4.2 Security of space

Secure enough space before setting.

When the system is turned on for a long time, it can be warm.

[Figure 1] Size of Edge ONE™

4.3 Electrical Requirements

Edge ONE™ system requires 100-240V and 50-60Hz power.

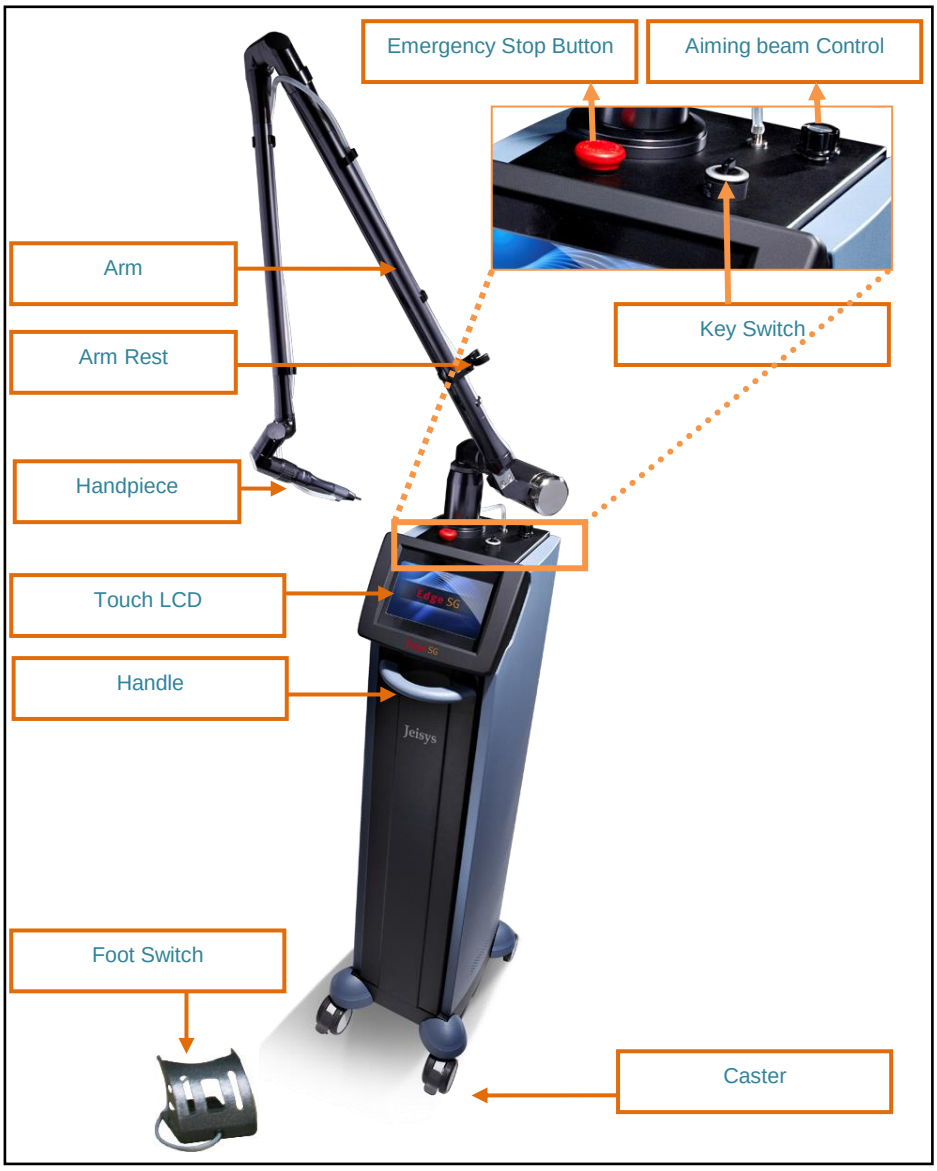
4.4 Components Assembling

Please refer the 6.1 Device installation (page 14).

5 System Description

5.1 Components and Features

5.1.1 Key Components



5.1.2 List of Components

No.	Item	Qty
1	Edge One System	1unit
2	Handpieces (Fractional HP, Surgical HP)	3unit
3	Scanner Handpiece Tip	5unit
4	Foot Switch	1unit
5	Power Cord	1unit
6	Operation Manual	1vol.
7	Protective Goggles – For Operator	1unit

5.1.3 Touch LCD Screen

<Surgical Mode>

<Fractional Mode>

- It is easy to control parameters for operator by using 8.4 inch touch screen.
- Please refer to 7.2 Modes of Treatment (page 21) for each function of the buttons.

CAUTION

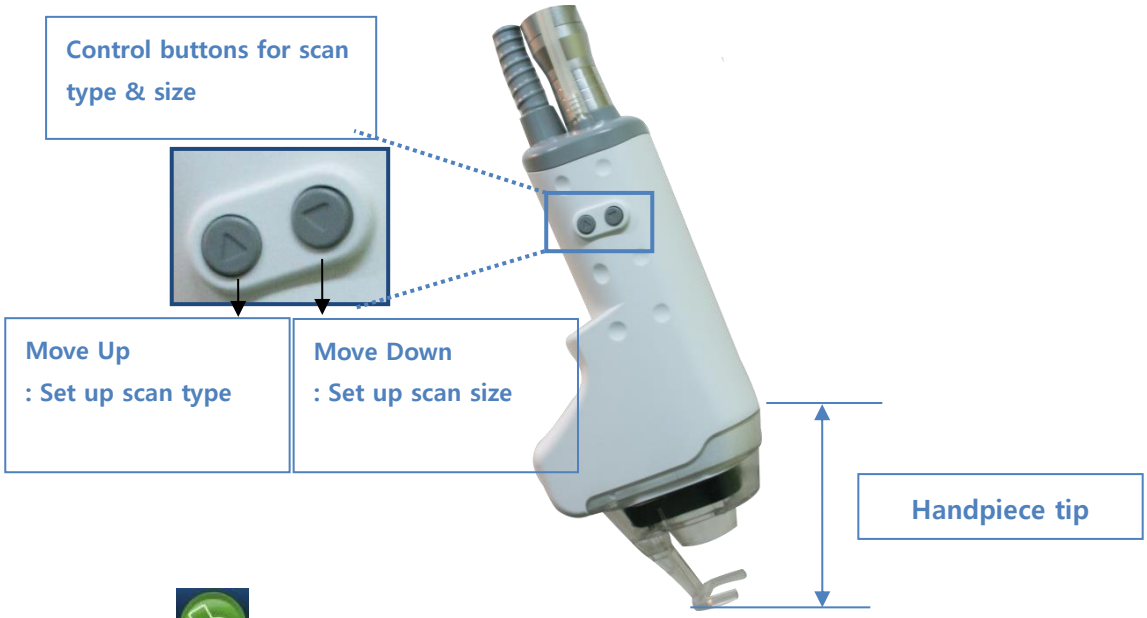
Do not hold Touch LCD Screen by hands when transferring device to avoid any damage on it. Instead, hold the handle and move the device slowly for safety.

5.2 Description of Components

5.2.1 Surgical Handpiece

- Types of Surgical HP - f:50mm, f:100mm

5.2.2 Fractional Handpiece



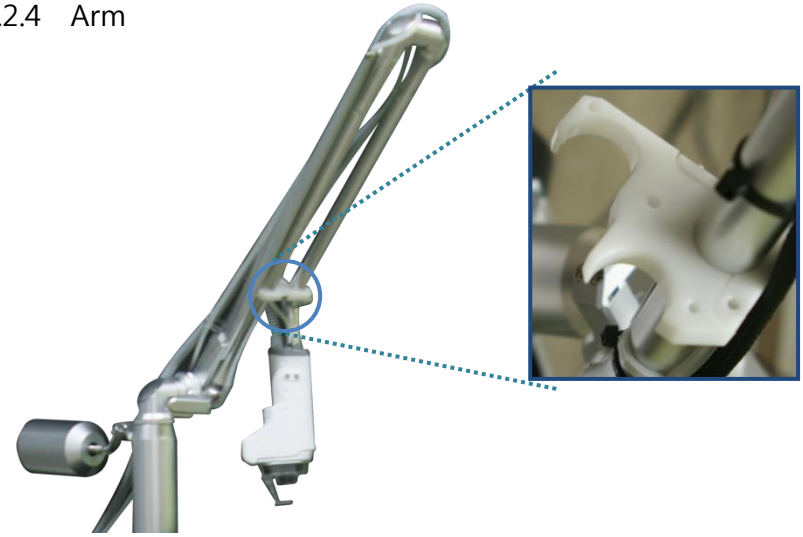
- Button on the screen of treatment should be active to use the control buttons for scan type and size.
- The system should be

to use the control buttons for scan type and size.

5.2.3 Types of Fractional Handpiece Tip

	120S Tip	120 Tip	350 Tip	800 Tip	Surgical Tip
Types					
Size of beam	120μm	120μm	350μm	800μm	120μm
Range of scan	2 X 2mm - 10X10mm	2 X 2mm - 15X15mm			Single beam
Size of scan	Even though the range of scan is same, the size of scan for 120μm is smaller than the one of 350μm and 800μm				.
Description	Density setting range:0.3-28.3% (49-2500 dots/cm²), 1~2500Total Dots	Density setting range:0.3-28.3% (49-2500 dots/cm²), 1~5625Total Dots	Density setting range:0-42.4% (16-441 dots/cm²), 0~961Total Dots	Density setting range:0-24.6% (16-49 dots/cm²), 0~100 Total Dots	Attach when using Surgical mode

5.2.4 Arm



- Arm is a part of components to deliver laser beam light. The 10,600nm laser radiation goes through seven mirrors and is delivered to the scanner handpiece.
- Arm delivers guide beam for visualizing the area of treatment.
- It is possible to rotate 360° to make treatment easier.
- It is designed to prevent from swaying by fixing the arm to the arm rest.

CAUTION

Be careful to do not damage Touch LCD Screen by handpiece when turning arm.

5.2.5 Foot switch

- To radiate laser beam, press the button 'Standby' to be 'Ready' on treatment screen and then press the foot switch.

6 Installation

6.1 Device Installation

6.1.1 Connection of Foot switch / Power cord

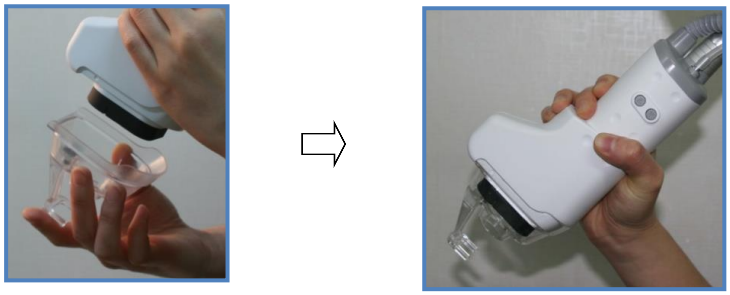
Foot Switch Socket Power Cord Socket

- Attach a foot switch connector to the foot switch socket located on the lower side of back. Check out the connector's direction for the 5 holes of socket before attachment.

6.1.2 Connection of Fractional Handpiece

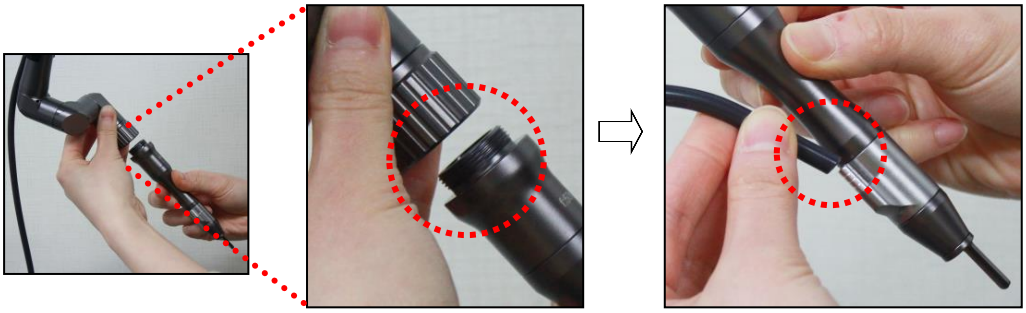
Connect the end of articulated arm to a handpiece. Then connect an air hose to a handpiece. When disassembling handpiece, do the same procedure adversely.

6.1.3 Connection of Fractional Handpiece Tip



- Attach a tip to the bottom of fractional handpiece. It is magnet type and so makes easy to attach and detach.
- All the 5 tips can be attached as the same way above.

6.1.4 Connection of Surgical Handpiece



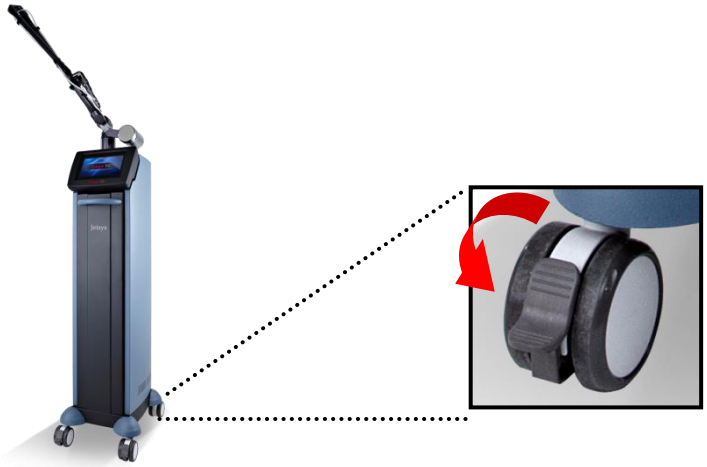
- Connect the end of articulated arm to a handpiece. Then connect an air hose to a handpiece. When disassembling handpiece, do the same procedure adversely.
- When using surgical handpiece, please attach the surgical tip onto the fractional handpiece (Refer to 5.2.3 Types of Fractional Handpiece Tip (page 12)).
- If the surgical tip is not attached, a pop-up message will appear on the screen as below. When touching 'OK' button, you can start the treatment on surgical mode without attaching a surgical tip onto the fractional handpiece.

CAUTION

It is recommended to hold handpiece making air hose locating in the middle it as the left picture.

It is recommended to turn down the fixture of handpiece end for security of sight.

6.1.5 Fixation of device



- There are locking latches on the casters of device fixation.
- Confirm if the device is installed like the above picture.

6.2 Device Movement

6.2.1 Movement in operation room

- When moving device, do the whole procedure adversely referring to '6.1 Device Installation (page 14)' menu for safety.

CAUTION

Use the handle only for transferring the device and move slowly for safety.

6.2.2 Movement to distant place

- If it is necessary to move the device to a place far away from the original place, please contact to the manufacturer for efficiency and safety.

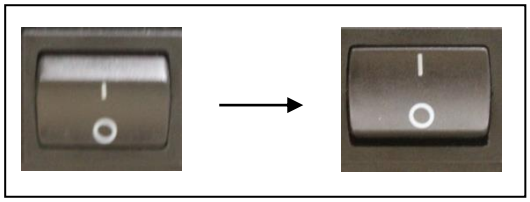
CAUTION

When moving the device to a distant place, it should be done by a person who completed the technical course about CO2 laser device or contact the manufacturer.

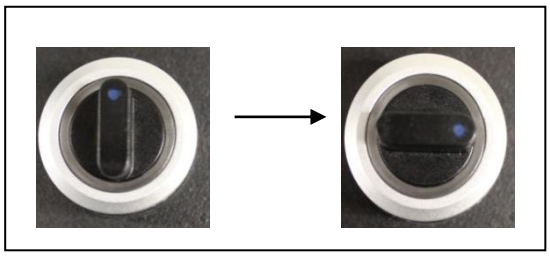
7 Device Operation

7.1 Turning On

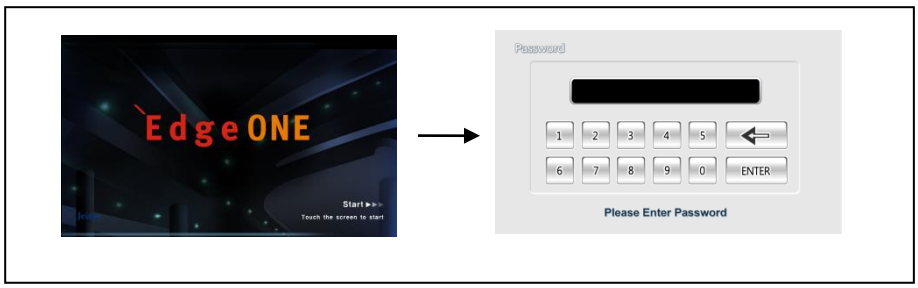
① Turn on the main power switch on the back of device.



② Turn the key switch to 'ON'



③ Once Edge ONE logo is shown, touch anywhere of screen. It turns to system checking and then changes to treatment mode screen.



④ Treatment Mode Screen

- Surgical Mode
- Fractional Mode

● Surgical Mode

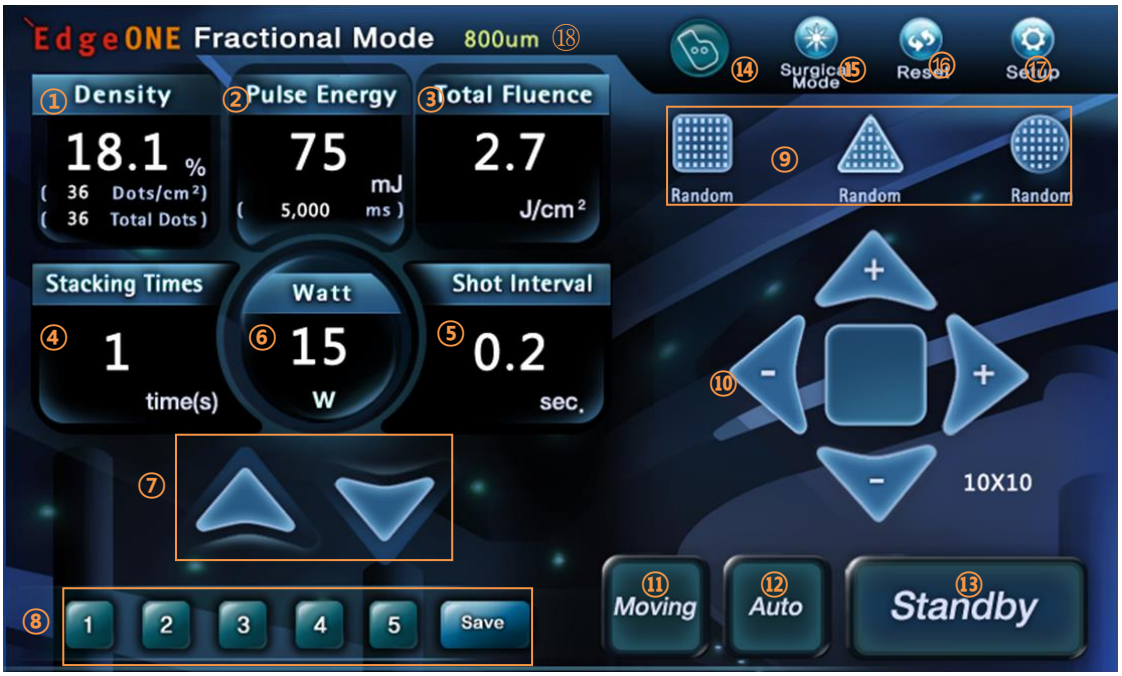
- Click the 'Surgical Mode'. ▶ Treatment Screen

● Fractional Mode

- Click the 'Fractional Mode'. ▶ Treatment Screen

7.2 Modes of treatment

7.2.1 Fractional mode



① **Density:** It displays the coverage (%) of selected scan type (⑨).
Its value can be set up by the up/down buttons (⑦).
Dots/cm^2: display number of dots per unit (1cm^2)
Total Dots: display actual number of dots irradiated through
(Range of setting: 120(s)um▶0.3-28.3%, 120um▶0.3-28.3%,
350um▶0.0~42.4%, 800um▶0.0~24.6%)

② **Pulse Energy:** It displays the amount of pulse energy. (Watt x Time)
Its value can be set up by the up/down buttons (⑦).
ms in the brackets means the time of pulse emitting.
(Range of setting: increase by 1mJ in the range of 1-300mJ
but if Watt is used for Edge pulse, it is increased by 18mJ
in the range of 1.80-18mJ)

③ **Total Fluence:** It displays the total calculated energy delivered to a patient.

④ **Stacking Times:** It displays number of continuous irradiation per dot.
Its value can be set up by the up/down buttons (⑦).
E.g. if it sets as '2', two shots of irradiation is done continuously in one dot.
(Range of setting: 1 ~ 10)

⑤ **Shot Interval:** It means the time between shot and shot.

Its value can be set up by the up/down buttons (⑦).

(Range of setting: increase by 0.2s in the range of 0.2-3.0s)

⑥ **Watt:** It displays the selected value of Watt.

Its value can be set up by the up/down buttons (⑦).

(Range of setting: can be controlled by 1watt in the range of 1 ~ 30Watt, Edge pulse)

✓ *Edge pulse: High peak power super pulse*

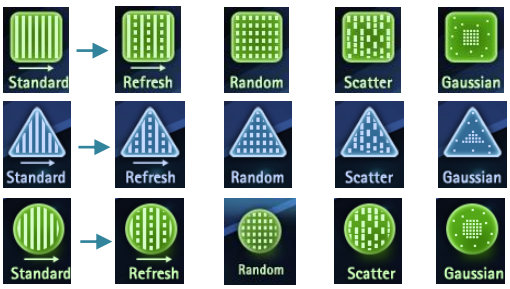
⑦ **Parameter change button:** It is for changing the values of Density, Pulse Energy, Stacking Times, Watt and Shot Interval as you want using up/down buttons.

⑧ **Memory:** .It saves and displays the most frequently used setting.

Set the value of parameter after selecting the buttons from memory 1 to 5, and then press the Save button for more than 3 seconds for saving a new parameter. And click the 'OK' button when the following pop up message is appeared. Now you can retrieve the saved setting by touching the buttons from 1 to 5.

If you want to cancel the selection, click one more time the selected memory button.

⑨ **Scan type and pattern:**



Select the type and pattern as you want.

⑩ **Size of scan:**

Types of tip	Size of minimum scan	Size of maximum scan	Default setting
120um Focusing tip(S)	2X2	10X10	10X10
120um Focusing tip	2X2	15X15	
350um Defocusing tip	2X2	15X15	
800um Defocusing tip	2X2	15X15	

⑪ **Moving:** when selecting

→

button, it makes continuous irradiation during the time foot switch is pressed on.

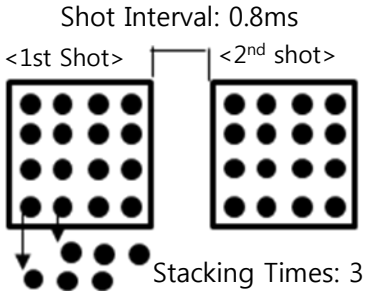
⑫ **Auto:** when selecting

→

button, it makes irradiation applying stacking times and shot interval during the time the foot switch is pressed on.

E.g.> 16 dots/cm^2, Stacking Times : 3, Shot Interval : 0.8ms

Assume the treatment parameter as the above.



- It gives 3 shots per dot continuously, 16 dots in the area of 1cm x 1cm, and the 2nd shot is irradiated 0.8ms after the 1st one.
- During the time foot switch is on, it irradiates continuously.

⑬ **Stand by/Ready:** It displays system status. Touch this button for being system Ready to start treatment.

Ready: Ready state to irradiate laser beam

Stand by: Standby state to irradiate laser beam

⑭ **Handpiece:** when selecting button, it is possible to change type and size of scan during treatment at will using the buttons located on the side of handpiece. Please refer 5.2.2 Fractional Handpiece(page 12).

⑮ **Surgical mode:** It changes screen to 'Surgical mode'.

⑯ **Reset:** It displays the screen as default by resetting current one.

⑰ **Set up:** It changes screen to Set up.

ⓐ Touch Calibration: For Engineer only.

ⓑ Service: For Engineer only.

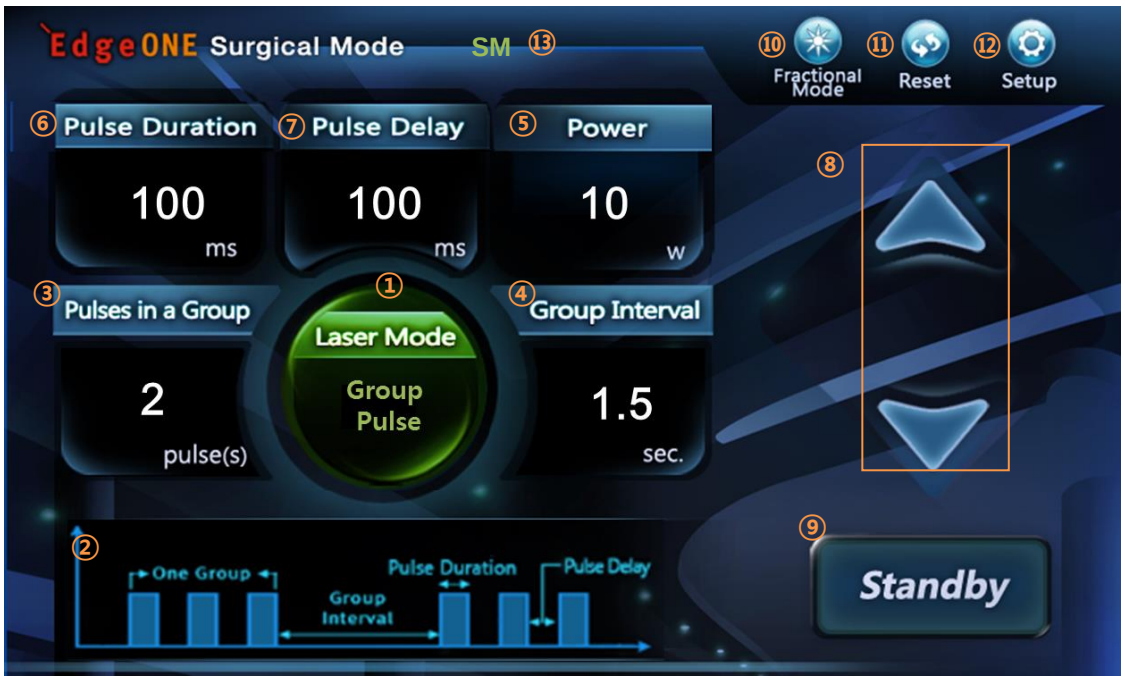
ⓒ Back: Back to the before stage.

⑱ **Tips:** It displays all kinds of tip attached to scanner handpiece.

(Tips: 120Sμm, 120μm, 350μm, 800μm)

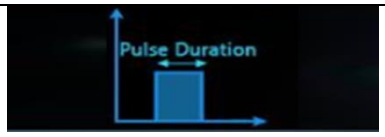
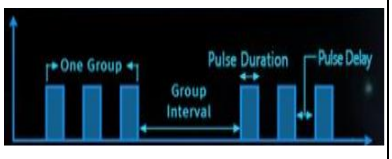
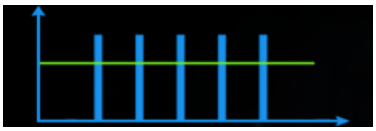
Surgical Tip (SM) works in the Surgical Mode only

7.2.2 Surgical Mode



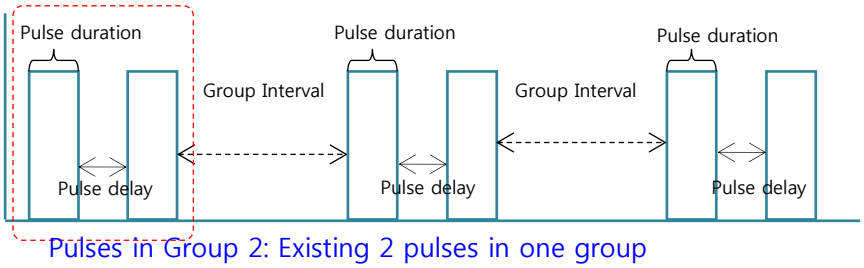
① **Laser Mode:** It displays all kinds of Laser. When selecting Laser Mode button, it can be changed as one's purpose.

(Range of setting: CW, Single, Repeat, Group Pulse, ULTRA)

CW		Continuous irradiation during the time foot switch is on
Single		1 shot irradiation during Pulse duration
Repeat		Irradiation by Pulse duration and Pulse delay alternately during the time foot switch is on
Pulses in a Group		Irradiation applying Pulse duration, Pulse delay, Pulses in a Group, and Group Interval during the time foot switch is on
ULTRA		Irradiation of High Peak Power in the selected Hz during the time foot switch is on

② **Figure:** It displays the figures of pulse for each laser mode selected.

③ **Pulses in a Group:** It displays the number of pulse belong to a group applying Pulse duration, Pulse delay, Group Interval during the time foot switch is pressed on. For instance, if it sets as 'Pulse duration-100ms, Pulse delay-100ms, Group Interval-2sec, Pulses in Group-2', laser irradiation is done as the following picture.



Pulses in Group 2: Existing 2 pulses in one group

④ **Group Interval:** It displays the interval between set continuous irradiation time and pulse group.

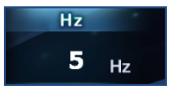
It can be controlled only when Laser mode(①) is 'Group Pulse' mode. It can be changed by the up/down buttons (⑧).

(Range of setting: increase by 0.1 sec in the range of 0.1-9.9sec)

⑤ **Power / Hz:**

It displays the selected value of Watt in the cases of that Laser mode is 'CW' / 'Single' / 'Repeat' / 'Group Pulse' each.

(Range of setting: increase by 1 in the range of 1-30W)



It displays the selected value of Hz when Laser mode is 'ULTRA'.

(Range of setting: increase by 10 in the range of 10-500Hz)

It can be changed by the up/down buttons (⑧).

⑥ **Pulse duration:** It displays Pulse duration.

(Range of setting: increase by 1 in the range of 1-1000msec. When Laser mode is 'ULTRA', it can be increase by 10usec in the range of 80usec-1000usec)

It can be changed by the up/down buttons (⑧).

⑦ **Pulse delay:** It can be controlled when Laser mode is selected as 'Repeat' and 'Group Pulse' modes only.

It can be changed by the up/down buttons (⑧).

(Range of setting: increase by 1 in the range of 1-1000msec)

⑧ **Parameter change button:** It is possible to change Pulses in a Group, Group Interval, Power, Pulse duration, pulse delay as one's purpose by the up/down buttons.

⑨ **Stand by:** It displays system status. Touch this button for being system Ready to start treatment.

Ready: Ready state to irradiate laser beam

Stand by: Standby state to irradiate laser beam

⑩ **Fractional Mode:** It changes screen to 'Fractional mode'.

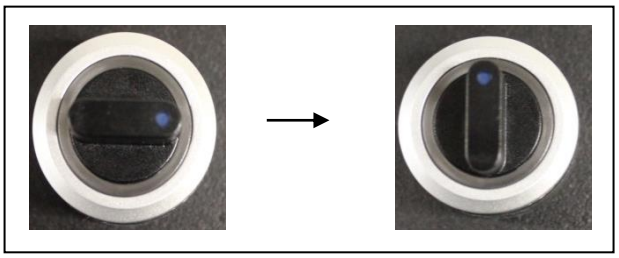
⑪ **Reset:** It displays the screen as default by resetting current one.

⑫ **Set up:** Refer to 7.2.1 Fractional mode Set up part(page 23)

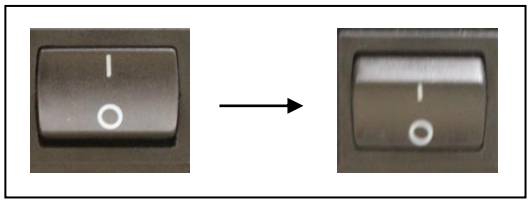
⑬ **Tips:** It displays all kinds of tip attached to scanner handpiece.

7.3 Turning Off

① Turn the key switch to 'OFF'.



② Once the device is turned off, make the main switch OFF on the back of system.



8 Cleaning

8.1 Cleaning of Touch Screen / Exterior of device

To transfer the device to a storage place, clean it first since it could be contaminated by patients and medicinal substances during treatment.

- Soak a soft pad in the noncorrosive detergent such as the fluids of 99% ethanol or isopropyl alcohol, and wipe the screen and exterior of device smoothly with it.
- Wipe out whole body once more by a clean dry cloth or pad.

CAUTION

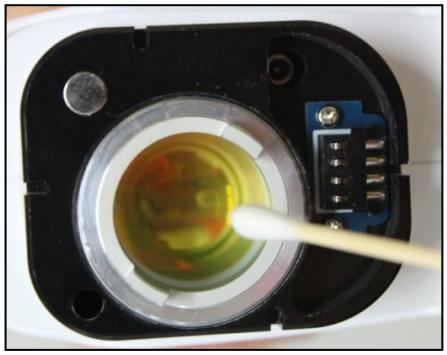
Do not pour detergent fluid directly on touch screen or device.

It may cause failure of device.

8.2 Handpiece Maintenance

8.2.1 Maintenance of Fractional Handpiece

- Fractional handpiece should be kept clean at all the time.
- Lens should be cleaned by a wet cotton swab soaked by ethanol 90% fluid as the below picture.



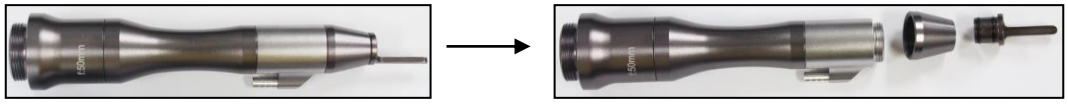
- If it is not cleaned thoroughly by the above method, instill ethanol one or two drop on the surface of lens and wait for 3 to 5 seconds to make dust or foreign substances soaked.
- Once the dust or foreign substances are wet enough, wipe them by a cotton swab.

8.2.2 Maintenance of Fractional Handpiece Tip

- Clean the whole body of tip by a soft cloth and use a wet cotton swab with ethanol for the part where touches skin directly.

8.2.3 Maintenance of Surgical Handpiece

- Separate tip from handpiece by turning right by one hand and pulling the supporting end of handpiece at the same time by another hand.



- Wipe out the surface of handpiece by a soft cloth.
- Lens should be cleaned by a wet cotton swab soaked by ethanol 90% fluid as the below picture. It should be done carefully to do not damage on coating of lens, not giving too much pressure on the cotton swab.

8.3 Storage

- When store the device, it should be done by the person in charge or skilled personnel only.
- Please avoid the following places for storage.
    ① Watery
    ② Being exposed to direct sunlight
    ③ Dusty
    ④ Highly humid
    ⑤ Having chemicals or gas
    ⑥ Salty
    ⑦ Having bad ventillation

9 System Message

Edge One™ System checks system in real time and notices its states at every time when it is changed by the pop-up message like the below.

Codes	Messages	Possible Causes	Recommendations
M-40	"Can not find the USB drive!!"	Thumbdrive is not properly attached to the USB port when updating system	Attach thumbdrive to the port of device properly.
M-41	"Can not find the Update File!!"	There is no file in the drive at the time of USB update	Contact to the manufacturer
P-41	"Out of the FootSwitch."	Ready button is pressed in the state of no footswitch attached	Check if footswitch is properly attached on the device.
P-42	"Out of the Handpeice Tip."	Handpiece tip is not attached to the handpiece	Check if tip is attached on the handpiece
P-43	"The door is opened."	The door of operation room is opened	Close the door.